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PELVIPERINEOLOGY

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2022
Volume: 41
Issue: 2
August

ISSN: 1973-4905 E-ISSN: 1973-4913

PELVIPERINEOLOGY
Rivista Italiana di Colon-Proctologia Founded in 1982

EDITORIAL BOARD

Editorial Office: International Society for Pelviperineology
e-mail: editorinchief@pelviperineology.org
Quarterly journal of scientific information registered at the Tribunale di Padova, Italy n. 741 dated 23-10-1982 and 26-05-2004
The journal is property of the International Society for Pelviperineology

Publisher Contact
Address: Molla Gürani Mah. Kaçamak Sk. No: 21/1 34093 İstanbul, Turkey
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Web: www.galenos.com.tr
Publisher Certificate Number: 14521

Printer: La Grafica Faggian, Via F. Severi 2/4 Campodarsego (Padova) IT
E-mail: comm@lagraficafaggian.it
Printing Date: August 2022
ISSN: 1973-4905 E-ISSN: 1973-4913

International scientific journal published quarterly.

Official Journal of the: International Society for Pelviperineology (www.pelviperineology.com)
Associaciòn LatinoAmericana de Piso Pelvico
Perhimpunan Disfungsi Dasar Panggul Wanita Indonesia
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EDITORIAL

Dear Colleagues;

We have been experiencing a massive submission of articles to the Journal of Pelviperineology. I would kindly like to thank to the authors who have been willing their studies to be published in the journal. In a very short while; our journal has become one of the most read journal on pelvic floor dysfunctions. Protecting and sustaining this trust is my primary goal.

I wish you a pleasant reading...

Prof. Dr. A. Akın SİVASLIOĞLU

Editor-in-chief

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DOI: 10.34057/PPj.2022.41.02.2022-3-1
Pelviperineology 2022;41(2):73-80

The analysis of the prevalence, importance and reporting rates of incidental lung lesions in non-contrast abdominal CTs performing for the evaluation of the urinary system

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Citation: Doğan E, Alaşan F. The analysis of the prevalence, importance and reporting rates of incidental lung lesions in non-contrast abdominal CTs performing for the evaluation of the urinary system. Pelviperineology 2022;41(2):73-80

ABSTRACT

Objectives: We aim to find the rate of incidentally detected lung lesions in non-contrast abdominal computed tomography (CTs) performed to evaluate the urinary system (urinary CT), to determine their reporting rate, and to draw attention to the importance of evaluating in an appropriate window the visualized parts of the lung.

Materials and Methods: In total, 152 patients [50.99±18.23; 6-89 years (age ± standard deviation; age range)] were included in the study. Lung segments in the cross-section area were evaluated in patients admitted to the hospital with urinary problems without known lung disease. The findings were classified according to gender, age group, and location of pathology.

Results: Three hundred thirty-four reportable lung pathologies and changes were detected. Of these pathologies, 48 (14.4%) were lesions that could be observed in the urinary CT window while 286 (85.6%) were the lesions that could only be detected by evaluation in the lung CT window. The reporting rate of lesions detected in the lung window was statistically significantly lower than the lesions detected in the urinary CT window [Lesions that could be detected in the main evaluation window were reported at a rate of 83.3%, while the reporting rate of lesions evaluated in the lung window was 20.62% (p=0.007)]. The frequency of encountered lesions increased over 50 years of age. In 67.76% of the patients, there was a pathology that required treatment, follow-up or further radiological evaluation.

Conclusion: The rate of lung lesions seen in urinary CTs is quite high, and the reporting rate is low. Urinary CTs should be evaluated in lung window.

Keywords: Computed tomography; urinary system; pelvic CT

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Received: 02 March 2022 **Accepted:** 02 April 2022

INTRODUCTION

Non-contrast abdominal computed tomography (CTs) performed to evaluate the urinary system (urinary CTs) are one of the examinations that have an important place in daily routine. It is taken without contrast, especially for better visualization of the calculi.[1] In CT scans focused on one region, the evaluation for the preliminary diagnosis is at the forefront. CT examinations are done in various CT windows with different settings of Hounsfield unit (HU). The most commonly used CT windows are abdomen and bone in abdominal examinations, and mediastinum, lung and bone windows examinations in chest.[2,3] While scanning a non-contrast urinary CT, field of view starts from a little bit upper from the diaphragmatic dome. Therefore, the graph also includes images belonging to the lung basales.[1]

Urinary CT scans usually are not evaluated in the lung window unless there is a suspicious lesion in the main windows from our point of view. Therefore, the evaluation of findings related to lung parenchyma remains incomplete. Because of the same reasons, pulmonary findings may be omitted. In our study, we examined urinary CTs in the lung window. We aim to find the rate of incidentally detected lung lesions in urinary CT, to determine their reporting rate, and to draw attention to the importance of evaluating in an appropriate window the visualized parts of the lung. As far as we know, there is no previous study on this subject in the literature.

MATERIALS AND METHODS

Study Design and Patient Population

Our retrospective study was approved by Muğla Sıtkı Koçman University Human Research Ethics Committee with the number of 210185/2021. The design and conduct of the study were in accordance with the general principles outlined in the Declaration of Helsinki.

The patients with previously known pulmonary pathology, CTs with artefacts, and the patient with urinary system pathology that will be reflected the chest images (34 patients had known lung pathology, two patients had a CT with screening artefacts, 8 patients had malignancy, two patients had autoimmune diseases) were excluded from the study. Urinary CT radiographs of the patients between January 2020 and December 2021 were evaluated retrospectively. In total, 152 patients with the mean age of [50.99±18.23; 6-89 years (age ± standard deviation (SD); age range)] were included in our study. Out of these patients, 87 were males and 65 were females. The mean age of the males was 52.78±17.54; 6-89 years while mean age of females was 48.60±18.99; 8-85 years.

A pre-analysis minimal sample size power analysis had been conducted using G-power 3 software, (https://www.psychologie.hhu.de/arbeitsgruppen/allgemeine-psychologie-und-arbeitspsychologie/gpower) indicating that a total analytic sample of 111 would provide the authors with 0.95 1-β power to detect meaningful results. Our sample size was enough for the study.

CT Technique

All urinary CT images were obtained without contrast agent injection in the supine position and performed with a 256-slice multi-detector CT scanner (Somatom, Siemens Healthcare, Erlangen, Germany) or 4 slices of Toshiba-TCT-60 AX (Toshiba Medical system Corporation, Yokohama, Japan) devices.

The following technical parameters were used; tube voltage, 100-120 kV; tube current-exposure time product, 200-300 mAs; pitch, 0.9125-1.375 and; and section thickness after reconstruction, 1-1.25 mm.

CT Image Analysis

A radiologists who have thoracic imaging experience more than 10 years retrospectively evaluated CT images. Every CT were evaluated in lung window settings as width, 1000 to 1600 HU; level, 700 to -550 HU. Detected elementary lesions were stored in excel files.

Clinical Data Analysis

The clinical significance of the lesions and necessity of follow-up and treatment were evaluated by a pulmonologist who have 11 years of experience.

Statistical Analysis

All continuous variables were expressed as medians, intervals, counts and percentages. The data were recorded (Excel 2010, Microsoft) and analysed using statistical software (SPSS, version 22.0, IBM). Continuous variables were expressed as mean ± SD values. CT findings were analysed with chi-square (χ^2) t and Student's t-tests. $P<0.05$ values were considered statistically significant.

RESULTS

Out of 152 patients, 78 of them were requested from the urology outpatient clinic, 62 were requested by the emergency service whereas only 12 examinations were requested by a department except for these two departments.

Twenty-one patients had completely normal lung appearance. Out of these patients, 12 were males and 9 were females. Out of other 131 patients with reportable pathologies and changes,

56 patients were males whereas 75 were females. There was no statistically significant difference between pathological and non-pathological groups according to genders (p=0.71). The mean age of the normal patients was 28.00±14.08 (8-71) while the mean age of the pathological group was 53.39±16.91 (6-89). There was statistically significant difference between normal reported and abnormal groups in terms of the age distribution (p=0.04) (Figure 1).

In total, 61 patients were <50 years old (younger group) while 91 patients were >50 years old (older group). The number of reportable pathologies and changes was significantly higher in older group than younger group (p=0.032). Thirty-nine different pathology and changes were found in the CT images of lung sections.

Three hundred thirty-four different pathology and changes were detected. Most frequent findings in lung images were paracardial fibrotic changes (PFC) with the rate of 40.13%, hiatal hernia with the rate of 21.71% and the pleural thickening with the rate of 19.74%. Fourty-eight of them were the pathologies can be seen in standard CT windows. 40/48 of them were reported (83.3%). Out of the all pathologies, 286 of them can be seen only lung windows. Only 59/286 of them were reported (20.62%). There was statistically significant difference between two groups (p=0.007) (Table 1).

In 103/152 (67.76%) patients, there was a pathology that required treatment, follow-up or further radiological examination.

DISCUSSION

Non-contrast thin section abdominal CT is the standard CT method used for urinary system evaluation. In the literature, this technique is called in different names, especially like non-contrast abdominal CT. However, this name is general and does not completely equal the technique that we mentioned. For this reason, this method will be called urinary system CT or urinary CT throughout our article.[4,5]

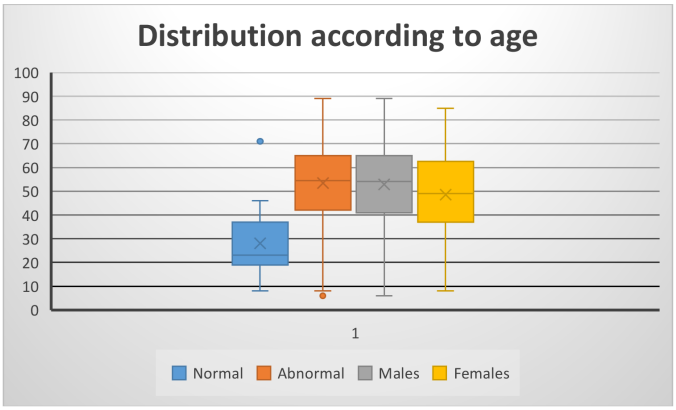

Figure 1. The figure shows the age distribution of normal reported and abnormal groups as well as male and female gender groups. There was significant difference between normal and abnormal groups.

We detected 334 pathologies as 39 different subheadings in 152 patients. In other words, there was an average of 2.2 reportable findings per patient. One hundred twenty-six different appearances related to were detected. Out of them, 61 were PFC, 16 were inferior lingular fibrosis, 23 were basal fibroatelectatic changes, 18 were focal pulmonary intertitial fibrosis (FPIF). There were some solid evidences of ILD compatible with usual interstitial pneumonia (UIP) in two patients. The ground glass opacity (GGO) was detected in the dependent lung region in six patients. In the presence of these findings, there are many reasons that require further examination of the patient in terms of lung findings. Patients with PFC, inferior lingular fibrosis, and basal fibro atelectatic changes should be questioned in terms of infection history, asbestosis, previous diseases and drug use. After anamnesis, an advanced radiological examination should be applied, if necessary, in order to examine the presence of fibrosis in other regions.[6] FPIF occurs especially around osteophytes and a tortoise aorta. It is a very common pathology that manifests itself in a spectrum ranging from GGO and reticulation to coarse fibrosis. Does not require further examination.[7] Six patients had GGO in the dependent lung areas. This finding is usually due to gravity and is innocent. However, in case of the presence of this finding, the patient should be clinically evaluated by a pulmonologist and it should be confirmed by prone position. If it remains fixed in the prone position, it is suspicious for ILD.[8] An UIP pattern was present in two of our patients. In patients with ILD findings, drug history, rheumatological diseases, asbestosis and rare etiological factors should be questioned and idiopathic pulmonary fibrosis (IPF) should be considered in case of exclusion. As it is known, IPF is a serious pathology with a poor five-years survey compared to most of the malignancies.[9-11]

Bronchiectasis was detected in eleven of our patients. In one patient, bronchiectasis is in plugged form. Although bronchiectasis is most commonly idiopathic, it may be secondary to primary ciliary dyskinesia, cystic fibrosis, post-infective pathologies, central obstructions and many rare factors.[12,13] It can be seen in tubular, varicose and cystic forms. Radiologically, the signet ring sign is diagnostic. It can be mutually the result or cause of infective processes. It is associated with numerous pathologies. In the diagnosis of diseases associated with bronchiectasis, it is necessary to evaluate the lung as a whole.[14] Since this pathology is detected only at baseline in urinary CT, the diagnosis cannot be made from a small part of the lung. It requires further radiological examination and clinical evaluation to rule out the above-mentioned pathologies.[15]

Table 1. Lung lesion and reportable changes can be seen in urinary CT, their percentage and reporting rates

Pathology or reportable changes	Males	Females	Age <50	Age >50	Total	Per	Reporting rate	Per
PFC	36	25	12	49	61	40.13%	11	18.03%
Inferior lingular fibrosis	9	7	4	12	16	10.52%	4	25%
Basal fibro atelectatic changes	12	11	6	17	23	15.13%	4	17.39%
FPIF	13	5	1	17	18	11.84%	1	5.56%
Dependant GGO	3	3	2	4	6	3.95%	1	16.67%
ILD-honey comb changes	2		-	2	2	1.32%	1	50%
Bronchiectasis	7	3	3	7	10	6.58%	3	30%
Plugged bronchiectasis	1		1	-	1	0.66%	-	0%
Nodule <6 mm single	6	8	7	7	14	9.21%	2	14.29%
Nodules <6 mm multiple	8	9	5	12	17	11.18%	4	23.5%
Nodule >6 mm single	6	6	2	10	12	7.89%	3	25%
Nodules >6 mm multiple	2	2	2	2	4	2.63%	2	50%
Subsolid GGO nodule multiple >6 mm	1	-	-	1	1	0.66%	-	0%
Subsolid single nodule >6 mm	-	1	-	1	1	0.66%	-	0%
Infection (COVID-19)	2	2	1	3	4	2.63%	1	25%
Air cyst	11	3	4	10	14	9.21%	1	7.14%
Mosaic attenuation	5	1	4	1	6	3.95%	-	0%
Hiatal hernia	19	14	9	24	33	21.71%	27	81.82%
Lymph node	2	-	1	1	2	1.32%	2	100%
Curvilinear bant unilateral	4	1	1	4	5	3.39%	1	20%
Curvilinear bant bilateral	1	-	-	1	1	0.66%	-	0%
Atelectasis	-	1	-	1	1	0.66%	1	100%
Tree-in-bud	-	2	1	1	2	1.32%	-	0%
Eventration	8	6	6	8	14	9.21%	4	28.57%
Bochdalek hernia	4	6	2	8	10	6.57%	3	30%
Multicystic disease	1	-	1	-	1	0.66%	-	0%
Focal pleural thickening	17	13	11	19	30	19.74%	11	36.67%
Mitral calcification	-	1	-	1	1	0.66%	1	100%
Cardiomegaly	-	1	1	-	1	0.66%	1	100%
Rib fracture	1	-	1	-	1	0.66%	1	100%
Aorta aneurism	1	-	-	1	1	0.66%	1	100%
Emphysema	5	-	2	3	5	3.39%	1	20%
Focal GGO	-	2	2	-	2	1.32%	-	0%
Pericardial fluid	-	3	1	2	3	1.97%	2	66.67%
Dependant atelectasis	3	1	2	1	4	2.63%	1	25%
Pleural plaques and calcifications	2	2	-	2	4	2.63%	3	75%
Interlobular septal thickenings	1	-	-	1	1	0.66%	-	0%
Vascular malformation	-	1	-	1	1	0.66%	-	0%
Paracardial fat hypertrophy	-	1	1	-	1	0.66%	1	100%

Per: percentage; PFC: paracardial fibrotic changes; GGO: ground glass opacity; FPIF: focal pulmonary interstitial fibrosis; ILD: interstitial lung disease; COVID-19: coronavirus disease-2019; CT: computed tomography

Nodules were detected in 49 patients in different forms. Nodules were smaller than 6 mm in 31 of these patients. According to Fleischner staging, if the nodule is smaller than 6 mm and carries risk factors (genetic malignancy history, smoking, etc.), albeit nodule is single, a 12-month follow-up is necessary. In the case of multiple nodules, short-term follow-up CT examinations of up to 3 months may be required. In nodules larger than 8 mm, (PET-CT) is required in the high-risk group, even if there is only one nodule. Since a part of the lung is seen on urinary CT, it cannot be determined whether the nodule is single or multiple. Perhaps larger nodules and additional findings will be detected in the remaining part of the lung. Therefore, chest CT is required as further examination. Multiple nodules larger than 6 mm were detected in 4 of our patients. According to Fleischner staging, these patients should be followed. In addition, it was detected in a single subsolid nodule larger than 6 mm in our patient. In this patient, even if the nodule is seen alone in the chest CT scan, followed up for at least five years is recommended (Figure 2).[16,17]

The time-period in which we conducted our study overlapped with the Coronavirus disease-2019 (COVID-19) pandemics. Bilateral peripheral GGO and consolidation areas being solid evidence of the diagnosis of COVID-19 that requires the isolation of the patient and the treatment process (azithromycin, doxycycline, favipiravir, prednisolone, etc.) were detected incidentally in 4 patients.[18] In the retrospective inquiry, these patients stated that they did not apply to the hospital due to COVID-19 and that they had not been diagnosed with COVID-19 before. In 75% of these patients, the lesions were not noticed in proper time because only the urinary system was evaluated.

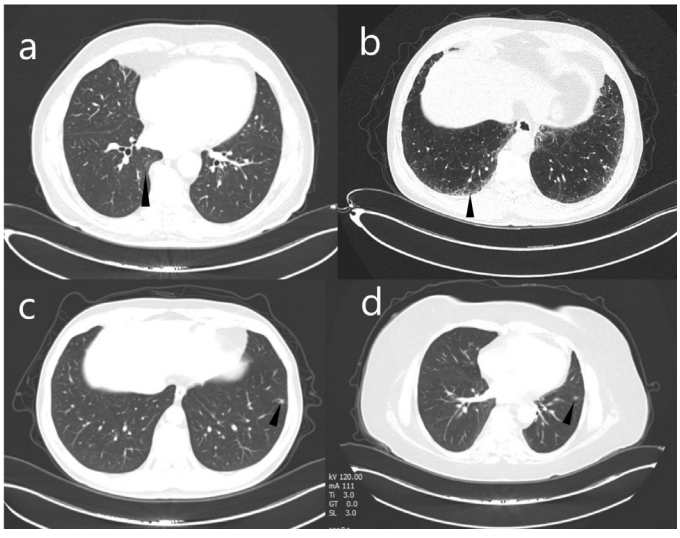

Figure 2. a) FPIF (arrowhead), b) UIP pattern with peripheral reticulations and millimetric honey comb appearances (arrowhead), c) Nodule located in antero-basal segment, d) Nodule with peripheric halo in the same location.

FPIF: focal pulmonary interstitial fibrosis; UIP: usual interstitial pneumonia

In addition, two of our patients had tree-in-bud findings that can be associated with infection. This finding is the reflection of plugged bronchioles on the radiological image. It is primarily associated with bronchiolitis or tuberculosis and need treatment according to primary diagnosis.[19,20]

Fourteen patients had air cysts. The air cyst is distinguished from emphysema by the presence of a wall.[21] These cysts were multiple in four of our patients. Two of them were female in the reproductive age group. As it is known, although the incidence of idiopathic cysts is a high rate, multiple cystic lung diseases should be excluded.[22] Lymphangiomyomatosis should be ruled out in women of reproductive age.[23] Langerhans cell histiocytosis is considered in cysts with irregular borders.[24] Requires further investigation. Our patient has findings evidence of the multicystic disease (Figure 3).[25]

Mosaic attenuation findings were detected in 6 of our patients. It is a pattern that can be seen in small airway diseases, especially in hypersensitivity pneumonia and obstructive vascular diseases. Requires further investigation if the appearance is evident.[25,26] Prominence in the expiration CT is valuable in radiological diagnosis.[27]

Curvilinear parenchymal band alone is not a diagnostic finding but it is valuable along with other findings. Pleural thickening with plaque or calcifications suggests ILD when accompanied by asbestosis, honeycomb or reticulation. More often, it may be due to parenchymal compression or compressive atelectasis.[28] In our study, there were unilateral curvilinear bands in five patients and

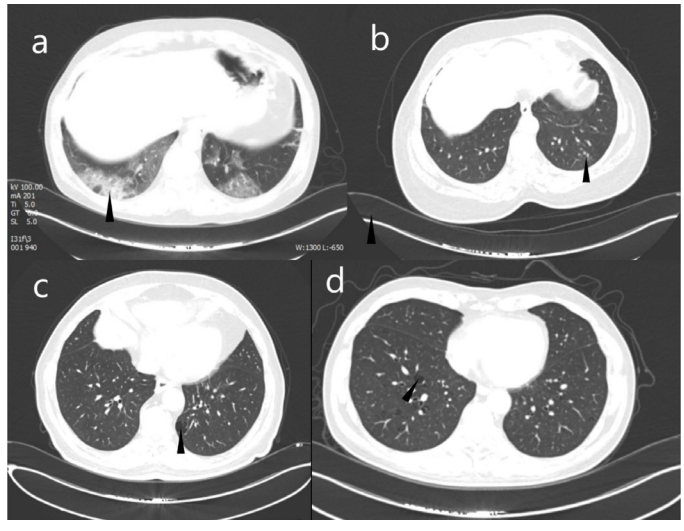

Figure 3. a) Bilateral GGOs and consolidations are compatible with COVID-19 pneumonia (arrowhead), b) Multiple millimetric nodules with halo in a patient with local infection (arrowhead), c) An air cyst located in the medial basal segment of the left lung (arrow head), d) Multiple air cyst. The big one is marked with an arrowhead.

GGO: ground glass opacity; COVID-19: coronavirus disease-2019

bilateral curvilinear bands in one patient. In addition, similarly, curvilinear GGO or band-like appearances of gravity-dependent atelectasis can be detected in the posterior. These are usually innocent findings. No follow-up is required. Our tree patients had evidence of dependant atelectasis.[29]

Focal pleural thickenings in 30 patients, pleural plaque and calcifications in four patients, and interlobular septal thickenings in one patient were seen without other findings. Although pleural calcifications and plaques are mostly attributed to asbestosis, sequels of previous infection, pneumothorax, haemothorax, empyema, mechanical irritation but may rarely be secondary to mesothelioma and pleural lymphoma. This finding may require detailed anamnesis as well as sometimes further clinical and radiological examination.[30,31]

Pathologies related to the diaphragm were also frequently encountered incidentally. Bochdalek hernia was present in 10 patients and partial eventration of diaphragm in 14 patients. Although Bochdalek hernia is the most common congenital hernia, it is more common, especially acquired due to increased intra-abdominal pressure. It rarely requires surgical treatment.[32]

Two of our patients had focal GGO. This entity can be associated with infection, carcinoma *in situ*, alveolar haemorrhage and etc. It is linked to mentioned diseases at a high rate and definitely requires further evaluation.[33,34]

Vascular malformation was detected in one patient. In the cases of the presence vascular malformation, the patient should be examined for the presence of accompanying vascular malformations.[35]

Emphysema is usually seen in the forms of centrilobular and paraseptal emphysema in the elderly patients, in relation to smoking, in localizations close to the apex of the lungs. Emphysema of the basal lungs is known as panlobular emphysema and is attributed to alpha-1 antitrypsin deficiency. However, this is a rare pathology. Emphysema, which usually enters the imaging field on urinary CT, is emphysema associated with air trapping areas or paraseptal emphysema areas that extend inferiorly. When combined with UIP, it is called combined pulmonary fibrosis. It often accompanies chronic obstructive pulmonary disease. It is a pathology that requires further evaluation.[36,37]

The pathologies that can be seen in mediastinal window are also evaluated in our paper. Hiatal hernia in 33 patients, lymph node in two patients, mitral calcification in one patient, aortic aneurysm in one patient, cardiomegaly in one patient were found (Figure 4).

Ultimately, in 103/152 (67.76%) patients, there was a pathology that required treatment, follow-up or further radiological examination. Seventy-eight of them were requested from the urology outpatient clinic, 62 were requested by the emergency service whereas only 12 examinations were requested by a department other than these two departments. Therefore, there was no detailed pulmonary examination and anamnesis when they referred to the radiologist. Given reporting rates, 83.3% of thoracic lesions observed in the mediastinal window were reported, while this rate decreased to 20.63% in the finding that can be seen in only lung windows. It follows from this that the evaluation in the lung window is rarely performed on urinary system CTs. Because of all these reasons, many pathologies remain untreated.

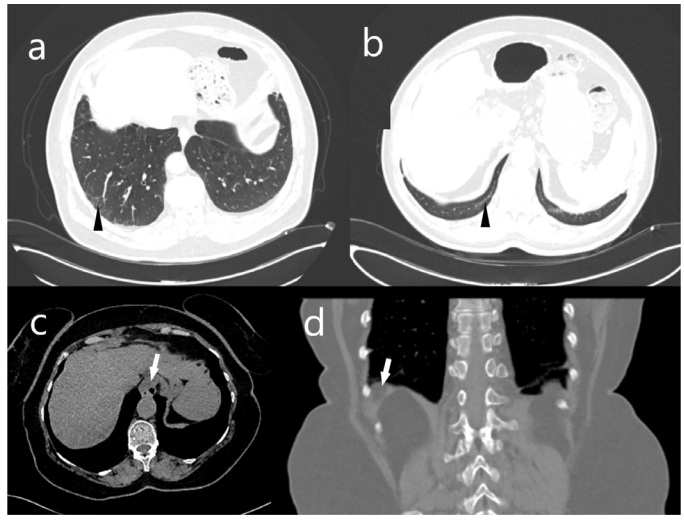

Figure 4. a) Peripheral pleural irregularity (arrow head) and mosaic attenuation, b) Dependant atelectasis (arrow head), c) Hiatal hernia (white arrow), d) Bochdalek hernia in the right diaphragm (white arrow).

Study Limitations

Our study is a single-centre study. The number of our patients is sufficient but limited. Turkey is one of the countries with a high workload. Diagnosis rates may vary according to workload and experience.

CONCLUSION

Urinary CT's is an inevitable tool for physicians, especially for urology and emergency departments. However, this valuable technique includes many clues for accompanying pulmonary diseases especially in elderly patients. According to our study 67.8% of our patients had an accompanying pulmonary pathology which required further examination or consultation of pulmonologist. The frequency of lesion was dramatically increased with ageing. The patients belonging completely normal lung appearances in CT were young age group.

ETHICS

Ethics Committee Approval: Our retrospective study was approved by Muğla Sıtkı Koçman University Human Research Ethics Committee with the number of 210185/2021. The design and conduct of the study were in accordance with the general principles outlined in the Declaration of Helsinki.

Informed Consent: Retrospective study.

Peer-review: Externally peer-reviewed.

Contributions

Concept: E.D.; Design: E.D.; Data Collection or Processing: E.D., F.A.; Analysis or Interpretation: E.D.; Literature Search: E.D., F.A.; Writing: E.D.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study received no financial support.

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DOI: 10.34057/PPj.2022.41.02.2022-4-3
Pelviperineology 2022;41(2):81-90

Management of complex pelvic floor dysfunctions: Combined versus single surgical procedure in a multidisciplinary approach. A prospective study

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Citation: Ascanelli S, Chimisso L, Montori S, Martinello R, Ippolito C, Carcoforo P. Management of complex pelvic floor dysfunctions: Combined versus single surgical procedure in a multidisciplinary approach. A prospective study. Pelviperineology 2022;41(2):81-90

ABSTRACT

Objectives: The management of pelvic floor dysfunction (PFD) is challenging because of high failure rates after surgery. The objective of this study was to compare the combined surgical treatment for complex PFD versus single procedures to improve the outcome.

Materials and Methods: A prospective series of consecutive patients (n=30) undergoing single pelvic procedure (SP group) was compared to patients (n=30) operated with combined procedure (CP group) over a 24-month period in a tertiary referral university center in Italy. The primary outcome was the overall rate of PFD recurrence and "*de novo*" PFD at 24-months after surgery. Secondary outcomes included postoperative complications, functional outcomes, quality of life, and patient satisfaction.

Results: At 24-months after surgery, we observed more recurrences in the SP group compared to CP group (6.7% vs 3.3%). *De novo* defects occurred more frequently in the SP group than in CP group (30% vs 6.7%; p=0.022). Ten percent of women of SP group underwent further surgery, compared to 3% in the CP group. Minor complications occurred in 33.3% of women in SP group and 43.3% in CP group. Postoperative improvement of pelvic prolapse was better in CP group (p=0.009). PFDI and PFQI questionnaires revealed significant postoperative clinical and quality-of-life improvement (p<0.0001) in both groups. Defecatory symptoms improved significantly in CP group (p=0.049). Minor fecal incontinence worsened in CP group while urinary symptomatology resulted improved in both groups. Patient satisfaction was very good in both groups.

Conclusion: The combined surgical approach to PFD is effective and safe.

Keywords: Pelvic floor dysfunction; pelvic organ prolapse; obstructed defecation; laparoscopic rectopexy; combined pelvic surgery; multidisciplinary pelvic floor

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Received: 25 April 2022 **Accepted:** 31 May 2022

INTRODUCTION

Pelvic floor disorders (PFD) are an increasing global health problem involving millions of women throughout the world, especially in the elderly population. Approximately one in five women undergoes surgery for genital prolapse [prolapse of the pelvic organs (POP)] or urinary incontinence (UI) by the age of 85 years, and it has been estimated that the demand for pelvic reconstructive surgery will increase of 45% over the next years.[1] However, the management of these patients is still difficult with incomplete resolution of symptoms and high failure rates after surgery requiring further procedures. Re-operation rates for POP and UI in parous women are unacceptably high and vary widely in the literature, ranging from 10% to 56%.[2,3] Most of the factors that influence reoperation have not yet been identified. The suboptimal results obtained after surgery for PFD may be attributable to the incomplete study of pelvic function: UI rarely presents as an isolated symptom, but it is more often associated with other pelvic disorders, such as POP or fecal incontinence (FI); 80% of patients with POP have UI; one-third of women with POP have symptoms of obstructed defecation syndrome (ODS).[4] Moreover, surgical interventions aimed at treating an isolated pelvic dysfunction may unmask or exacerbate pre-existing symptoms in other compartments or even lead to the development of new symptoms, undoing previously implemented compensation strategies (*de novo* UI, coping strategies).[5] The diffusion of the unifying concept of viewing the pelvic floor as an integral system,[6] overcoming the traditional compartmentalized single-specialty approach to PFD, and the spread of the multidisciplinary outpatient clinic (MOC) has contributed to improved outcomes.[7] Combined surgical treatment of multiple PFD in the same surgical operation has been performed to reduce the risk of reoperation for recurrence or "*de novo*" dysfunctions. It appears that suspension techniques performed by either open or laparoscopic approach allow for the correction of more pelvic compartments, adjusting the pelvic anatomy and preserving bowel, bladder, and sexual function.[8-11] Similarly, trans-perineal techniques allow the correction of defects of multiple pelvic compartments.[12,13] It is also possible to combine a suspension technique with a trans-perineal technique.[14] At present, there are very few published data on the impact of combined surgical approach to complex PFD on clinical outcome and patient satisfaction,[15] (Table 1). A comparison of the different surgical procedures is difficult, because of data lacking and difficult standardization of the multiple surgical procedures; furthermore, evidence-based guidelines do not exist. The objective of this study was to compare the outcome of combined surgical treatment of PFD versus single procedures within a multidisciplinary pelvic floor pathway, to try to clarify what is the most correct surgical approach to complex PFD. The primary aim was to evaluate effectiveness of single procedure surgery versus combined surgical treatment. Secondary aims were to evaluate safety, functional outcomes, quality of life, and patient satisfaction in the two approaches.

MATERIALS AND METHODS

This prospective trial was designed to evaluate the efficacy and safety of combined surgery for treatment of complex PFD. From April 2018 to April 2019, we recruited all consecutive patients with complex PFD with indication for surgical treatment referring at the MOC for PFD at the University Hospital of Ferrara, Italy. Complex PFD were managed by multi-compartmental pelvic surgical procedure in the experimental group [group "combined procedure", (CP)]. In the control group patients were surgically treated with single-compartmental pelvic surgical procedure [group "single procedure", (SP)]. The inclusion criteria were age over 18 years, diagnosis of complex PFD by joint assessment at the MOC for PFD with indication for surgery. The diagnosis of complex PFD was attributed by the joint assessment of the multidisciplinary team (MDT) consisting of a gynecologist, a urologist, and a colorectal surgeon if more than one symptom (vaginal bulging/prolapse, stress UI, urge UI, bladder voiding symptoms, dyspareunia, FI, constipation, and obstructed defecation), and more than one pelvic floor defect (cystocele, uterine or apical prolapse, enterocele, rectocele, internal rectal prolapse, and descending perineum) were present. The type of surgical procedure (single or combined) was decided by the MDT after the joint evaluation based on symptoms and pelvic defects. The exclusion criteria were neoplastic diseases treated during the 12 months prior to the first PFD visit, previous pelvic radiotherapy, pregnancy, chronic inflammatory diseases (endometriosis, inflammatory bowel diseases, diverticulitis), neurological diseases, external full-thickness rectal prolapse, follow-up performed at another hospital, explicit refusal to complete the questionnaires. During preoperative PFD MDT visit and at the 24-months visit after surgery, patients underwent pelvic organ prolapse quantification system (POP-Q)[16] measurement of the prolapse and they were administered the following self-filling questionnaires about PFD, constipation, ODS, FI, and patient satisfaction:

-Pelvic floor distress inventory (PFDI-20 score, short form) and pelvic floor impact questionnaire (PFIQ-7 score, short form) which are valid and reliable short forms of 2 condition-specific quality-of-life questionnaires for women with PFD, investigating urinary, pelvic organ prolapse, and colorectal-anal distress.[17] In both PFDI-20 and PFIQ-7, patients reported whether they experienced symptoms of pelvic floor dysfunction, and how

Table 1. Review table on combined surgical approach for POP

Combined surgical approach	Surgery for SUI	Abdominal surgery	Combined transvaginal and transrectal	Combined abdominal and transvaginal	Combined abdominal, transvaginal, and transrectal	Reference
Multi compartmental POP	Concurrent Sub urethral sling 5	LRCS 38 LH 2				Martín del Olmo JC et al, Surg Endosc 2019
Multi compartmental POP		ORCS 29				Lim M et al, DCR 2007
Multi compartmental POP		LRCS 10				Sagar PM et al, DCR 2008
Multi compartmental POP		RASC and RR 16				Park H et al. J Minimally Invasive Gyn 2014
Multi compartmental POP	Concurrent TVT-O 24		VARE 23 VAHY 21 STARR 68			Boccasanta P, Am J Surg. 2010
Multi compartmental POP			Posterior VWR 15 anterior, posterior VWR and VAHY 3 STARR 18			Ascanelli S et al, Minerva Chirurgica 2018
Multi compartmental POP		Concurrent resection rectopexy 7			LVR, posterior VWR and VCS 74	Slawik S et al, Colorectal Dis 2008
Multi compartmental POP	Concurrent burch procedure 7 marshall-marchetti-krantz bladder suspension 1 bladder neck suspension 1	Concurrent LSR 1 LMR 3 OMR 2 ORR 8 OSR 9 Abdominal sacral colpopexy 11 uterine suspension 1 transabdominal hysterectomy 3		Cystocele repair 5 paravaginal repair 9 McCall culdoplasty 2 uterosacral plication 2 anterior repair 2 perineoplasty 4 transvaginal hysterectomy 2 vaginal sling 1	Transvaginal rectus fascial sling 1 posterior repair 4 enterocele repair 3	Riansuwan W et al, Colorectal Disease 2010

POP: pelvic organ prolapse; SUI: stress urinary incontinence; LRCS: laparoscopic ventral mesh recto/colpo/sacropexy; LH: laparoscopic hysterectomy; ORCS: open mesh sacrocolporectopexy surgery; RASC: robotic assisted laparoscopic mesh sacrocolpopexy; RR: robotic mesh rectopexy; VARE: vaginal repair of enterocele; VAHY: vaginal hysterectomy; STARR: stapled transanal rectal resection; TVT-O: transobturator tape; VWR: vaginal wall repair; LVR: laparoscopic ventral rectopexy; VCS: vaginal sacrocolpopexy; LRR: laparoscopic resection rectopexy; LSR: laparoscopic sutured rectopexy; LMR: laparoscopic mesh rectopexy; ORR: open resection rectopexy; OSR: open-sutured rectopexy; OMR: open mesh rectopexy

much these symptoms bothered them. The PFDI-20 has three scales: Pelvic organ prolapse distress inventory, colorectal-anal distress inventory, and urinary distress inventory. Response options for rating distress associated with each symptom range from 0 to 4. Higher scores indicate more symptom distress. The PFIQ-7 measures impact of bladder, bowel, and vaginal symptoms on daily physical activity, travel, social/relationships, and emotional health. The PFIQ-7 has three scales: The urinary impact questionnaire, the colorectal-anal impact questionnaire, and the pelvic organ prolapse impact questionnaire. Response options range from 0 to 3. Higher scores indicate more impact on daily activity.

-Wexner cleveland clinic constipation scoring system (CSS), the most widely adopted instrument for evaluation of constipation, easy to understand and administer. It consists of 8 items scored from 0 to 4 for a maximum score of 30,[18]

-Altomare score for ODS, a validated instrument specifically designed for ODS. It consists of 7 items scored from 0 to 4 with a maximum score of 27,[19]

-Cleveland clinic Florida fecal incontinence questionnaire (CCF-FI), a frequently used instrument containing five questions on solid and liquid fecal soiling, flatus control, pad wearing and adjustments to daily living made necessary by FI,[20]

-Visual analogue scale (VAS) for patient satisfaction, the well-known horizontal line of 100-mm long with at the beginning and at the end, two descriptors representing extremes of satisfaction (no satisfaction and extreme satisfaction). The patient rated his satisfaction by making a vertical mark on the 100-mm line. The measurement in millimeters was converted to the same number of points ranging from 0 to 100 points. The question was "Are you satisfied with your surgical treatment?".[21]

All patients complaining UI or urinary voiding symptoms underwent urodynamic tests. All patients complaining constipation and ODS, with Wexner Constipation and ODS score more than 10 at the first MDT visit, underwent pre-operative defecography and rectal manometry. The obtained scores, as well as the presence of pelvic floor defects and symptoms were compared before and 24 months after surgery. All patients were visited by the MDT at 7 days, 1 month, 6, 12, and 24 months after surgery. All data concerning pre- and post-operative clinical data, diagnostic tests, and questionnaires scores, produced by the MDT were collected prospectively and stored in the electronic reports in the hospital information system systems applications products. Data were collected by two researchers (LC and SM) who were not member of the MDT. Written informed consent was obtained from all patients. The study was conducted in accordance with the principles of Helsinki Declaration, with approval of the Regional Medical Ethics Review Board (identification code: 160597). The primary outcome was the overall rate of PFD recurrence, "*de novo*" pelvic floor defects, and re-operation rate at 24 months after surgery in CP group vs SP group to evaluate effectiveness of combined surgical treatment versus single procedure surgery. Secondary outcomes included postoperative complications according to Clavien-Dindo Classification[22] to evaluate safety. To compare functional outcomes, quality of life, and patient satisfaction we measured the variations of POP-Q score, PFDI-20 and PFQI-7 scores, Wexner CSS score, ODS score, CCF-FI score, and VAS scoring in the two groups, before and 24 months after surgery.

Surgical Technique

Patients underwent single or combined surgery. All surgical procedures in both study groups were performed by staff surgeons trained in pelvic surgery and advanced laparoscopy: The procedures were performed by the same gynecologist (RM), and/or the same urologist (CI), and/or the same colorectal surgeon (SA) individually or in combination. The techniques performed were:

1)Trans-perineal techniques:

a) Colpo-hysterectomy (CH) for the correction of uterine prolapse, always associated with anterior colporrhaphy (AC), or vaginal cystopexy according to Kelly, and with posterior colporrhaphy (PC)[23]

b) Anterior colporrhaphy (AC) or vaginal cystopexy[24]

c) Posterior colporrhaphy (PC)[25]

d) Correction of stress UI with urethral suspension by placement of a polypropylene tape [trans-obturator tape (TOT)][26]

e) transanal prolassectomy with stapler [stapled trans anal rectal resection (STARR)] for the correction of rectal prolapse associated with ODS according to technique codified by Longo[27]

2) Abdominal suspension techniques:

a) Laparoscopic correction of uterine prolapse with the use of polypropylene prosthesis: Lateral uterine suspension (LUS)[28]

b) Laparoscopic sacrocolpopexy (LSCP) for vaginal vault prolapse using polypropylene prosthesis anchored to the sacral promontory[29]

c) Laparoscopic correction of the rectal prolapse by ventral rectopexy (LVR) with biological prosthesis according to D' Hoore technique.[30]

These procedures were variably associated in the combined approach.

Statistical Analysis

The sample size of this trial was based on expected indication to surgery for complex PFD of 10-20%[5] and a two-sided 95% confidence interval for a single proportion extended to 10% on either side, with an assumed dropout rate of 5% at 6 months. Given that about 400 women are visited each year at the MOC for PFD of the University Hospital of Ferrara, the final sample size was determined to be 60 patients in a period of 12 months: Thirty patients treated with single pelvic procedure and 30 patients treated with multiple combined procedures in one surgical operation. Data were expressed as median (interquartile

range- 25-75) and mean ± standard deviation according to distribution assessed by Shapiro-Wilk test. Categorical data were presented as numbers. Data were analyzed using chi-square, Student's t-test, and Mann-Whitney U tests as appropriate. Cox regression analysis was used to assess independent predictors of improvement of POP-Q.[9] Significance was considered for values of $p<0.05$. Statistical analysis was performed with IBM SPSS Statistics for Windows, Version 24.0 (IBM Corp. Armonk, NY: IBM Corp.). This report complies with strengthening the reporting of observational studies.

RESULTS

From April 2018 to April 2019, 389 patients suffering from complex PFD were visited at the MOC of the University Hospital of Ferrara, Italy. Of these, 66 women (17%) were candidates for surgical treatment: Thirty-four women underwent SP, while 32 women underwent CP. Of these, 6 patients were lost during follow-up: Four patients in the SP group, and 2 patients in the CP group for a final count of 30 patients analyzed per group (Figure 1). The baseline characteristics of the patients are reported in Table 2. The two groups were homogeneous, except for childbirth modes: The vaginal delivery was significantly more frequent in the CP group, while the percentage of caesarean section was significantly higher in SP group. The most frequent pre-operative symptoms were urinary symptoms, recurrent urinary infections, constipation, vaginal bulge, and ODS in both groups (Figure 2). After surgery, there was a general improvement of all symptoms: In particular, bulging, urinary symptoms, and ODS decreased significantly in the CP group (Figure 2). Regarding the pelvic floor defects before surgery, the two groups were homogeneous. Rectocele, cystocele, rectal prolapse, and descending perineum were the most frequent defects. We observed postoperative improvement of defects with no significant differences between the two groups (Figure 2). Surgical procedures performed in the two groups are listed in Table 3. The most frequently SP performed were LVR, LUS, and STARR. The most frequently CP performed were trans-perineal procedures such as STARR in combination with CH, AC, PC, or TOT. Among mixed (suspension and trans-perineal) procedures, the most frequently procedure performed was LUS in association with STARR. The median duration of operation was longer in CP group (145 minutes vs 125 minutes; $p=0.022$). Mesh was used in suspension procedures: In particular, the cross-linked Permacol mesh (Medtronic) was always used in LVR, while synthetic polypropylene mesh was always used for LUS and LSCP. The median length of stay was longer in CP group (4 days vs 3 days), without statistical significance (Table 4). We observed 33.3% of minor complications in SP group and 43.3% in CP group, but this difference was not statistically significant (Table 4). Grade I and grade II complications are listed in Table 4. One case of intestinal obstruction (grade III complication) occurred in CP group after LSCP with STARR due to the adhesion of ileus to the polypropylene mesh. The patient underwent reoperation with ileal resection. All patients underwent pelvic floor rehabilitation within 6 months after surgery. At 24 months after surgery, we observed more PFD recurrences (ODS and rectocele) in the SP group compared to CP group (6.7% vs 3.3%), but the difference was not statistically significant (Table 4). *De novo* defects occurred more frequently in the SP group than in CP group (30% vs 6.7%; $p=0.022$), especially affecting the posterior compartment (Table 4). Ten percent of women of SP group underwent further surgery, in comparison with 3% in the CP group, but this difference was not statistically significant. MOC evaluation at 24 months after

Table 2. Baseline characteristics of patients

Baseline characteristics of patients	SP group (n=30)	CP group (n=30)	*p*
Age (years) (mean ± SD)	65.1±8.63	67.1±9.18	0.393
BMI (kg/m^2) (mean ± SD)	25.63±3.75	27.45±4.18	0.081
ASA [n (%)] I II III	 4 (13.3) 21 (70) 5 (16.7)	 2 (6.7) 16 (53.3) 12 (40)	0.121
COPD [n (%)]	6 (20)	7 (23.3)	0.756
Smoke [n (%)]	14 (46.7)	15 (50)	0.797
Diabetes [n (%)]	7 (23.3)	8 (26.7)	0.767
Depression [n (%)]	8 (26.7)	7 (23.3)	0.767
Age at menopause (mean ± SD)	50.2±3.98	50.6±2.89	0.631
Hormone replacement therapy [n (%)]	17 (56.7)	14 (46.7)	0.442
Fibromyalgia [n (%)]	11 (36.7)	11 (36.7)	0.999
Anticoagulant drugs [n (%)]	8 (26.7)	6 (20)	0.544
Previous hysterectomy [n (%)]	2 (6.7)	7 (23.3)	0.073
Parity >1 [n (%)]	16 (53.3)	23 (76.7)	0.060
Vaginal delivery	21 (70)	29 (96.7)	0.010
Episiotomy	6 (20)	9 (30)	0.411
Dystocic delivery	2 (6.7)	1 (3.3)	0.536
Perineal tears (grade III/IV)	9 (30)	4 (13.3)	0.103
Caesarean section	9 (30)	1 (3.3)	0.010

BMI: body mass index; ASA: American society of anesthesia score; COPD: chronic obstructive pulmonary diseases; SD: standard deviation

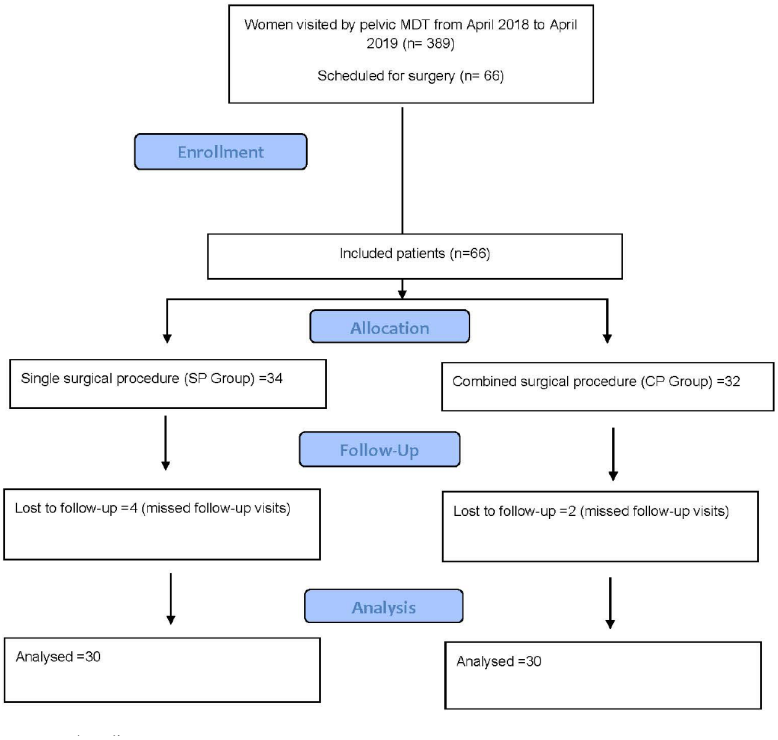

Figure 1. Flow diagram

MDT: multidisciplinary team

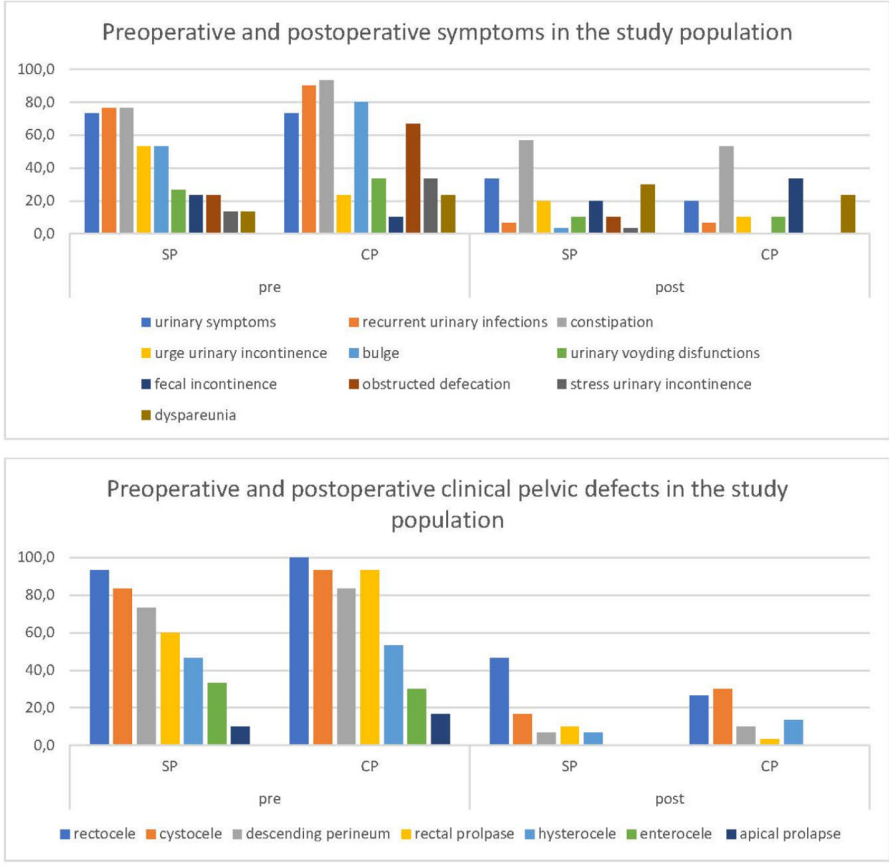

Figure 2. Preoperative and postoperative symptoms and clinical pelvic defects in the study population

SP: single procedure; CP: combined procedure

Table 3. Surgical procedures

	SP (n=30)	CP (n=30)	
1a (n, %) CH	3		
1b (n, %) AC	3		
1c (n, %) PC	0		
1d (n, %) TOT	2		
1e (n, %) STARR	6		
2a (n, %) LUS	6		
2b (n, %) LSCP	1		
2c (n, %) LVR	9		
1a + 1b + 1c + 1d (n, %)		2	
1a + 1b + 1c + 1e (n, %)		6	
1b + 1e (n, %)		1	
1b + 2c (n, %)		1	
1b + 1c + 1e (n, %)		1	
1c + 1e (n, %)		1	
1c + 1e + 2a (n, %)		1	
1c + 2a (n, %)		2	
1c + 1d + 1e (n, %)		1	
1d + 1e (n, %)		1	
1d + 2b (n, %)		1	
1d + 2c (n, %)		4	
1d + 1e + 2a (n, %)		1	
1e + 2a (n, %)		4	
1e + 2b (n, %)		1	
2a + 2c (n, %)		2	
Duration of operation (min), median (1Q 3Q)	125 (50 160)	145 (110 185)	p=0.022

CH: colpo-hysterectomy; AC: anterior colporrhaphy or vaginal cystopexy; PC: posterior colporrhaphy; TOT: trans obturator tape; STARR: stapled trans anal rectal resection; LSCP: laparoscopic sacrocolpopexy; LVR: laparoscopic ventral rectopexy

surgery showed significant postoperative improvement of pelvic prolapse (reduction in POP-Q) compared to preoperative grade in both groups (p<0.0001), with better result in CP group compared to SP group (p=0.009) (Table 5). PFDI and PFQI questionnaires revealed significant clinical and quality-of-life improvement (p<0.0001) in both groups after surgery, regardless of the single or combined procedure (Table 5). Defecatory symptoms such as constipation and ODS improved significantly after surgery especially in CP group (p=0.049) where patients had higher initial scores (Table 5). Minor FI expressed with CCF-FI score worsened in CP group after surgery, without significant difference (Table 5). Urinary symptomatology resulted improved in both groups after surgery with a significant better improvement of urge UI after combined surgery Figure 2. Patient satisfaction was very good in the two groups without significant differences (Table 5).

DISCUSSION

The surgical correction of multiple pelvic compartments at the same time seems to be associated with better outcome in comparison to surgical treatment of single pelvic defect. Combined surgery consents to prevent the manifestation of *de novo* pelvic symptoms which may occur after single pelvic defect approach or the worsening of a pre-existing symptom.[5,6,15,20] Symptoms such as UI may occur or become more severe after the first surgical correction of prolapse and, therefore, the simultaneous correction seems to prevent the appearance of UI.[2,3,23,26] In the presented series *de novo* defects occurred more frequently in SP group than in CP group (30% vs 6.7%; p=0.022), especially affecting the posterior compartment (16% in SP group; 6.7% in CP group) and anterior one (10% in SP group; 0 in CP group) (Table 4). In addition to the lower rate of *de novo* symptoms, patients undergone combined surgery presented lower rate of PFD recurrence after 2 years (3.3% in CP group vs 6.7% in SP group), and lower need for subsequent surgery (3% in CP group vs 10% in SP group) (Table 4). These results indicate good quality of treatment within the multidisciplinary pelvic flow pathway being in line with the literature in which the need to re-interventions for PFD recurrences ranges between 10% to 30%.[3] However, very few studies have been carried out comparing single compartment surgery to multi-compartmental surgery, especially in terms of functional outcome.[2] In the current study the significant postoperative improvement of prolapse, measured with POP-Q, in both groups, but with a statistically significant better result in the CP group (p=0.009) (Table 5) suggests that the simultaneous correction of multiple prolapse is the optimal way to correct the pelvic floor defects with better results in terms of objective correction. On the other hand, when several surgical procedures are combined there could be an increased risk for complications. Our data showed a slight, not statistically significant increase of grade II postoperative complications in CP group (Table 4). We observed one case of intestinal obstruction (grade III complication) occurred in CP group after LSCP with STARR due to the adhesion of ileus to the polypropylene mesh. The patient underwent reoperation with ileal resection. In this case the complication was due to the synthetic mesh rather than the combination of the two procedures. Other studies have confirmed the lack of statistically significant differences in terms of overall morbidity between combined and single procedures.[2] FI is a major concern after pelvic surgery involving the posterior compartment.[15,27,30] In the present study minor FI expressed with CCF-FI score worsened in CP group after surgery, without significant difference (Table 5).

Table 4. Short- and long-term (24 months) outcome results

Outcome results	SP (n=30)	CP (n=30)	*p*
Lenght of stay, median (1Q 3Q)	3 (3 3)	4 (3 4)	0.999
Early complication (Clavien-Dindo) (n, %)	10 (33.3)	13 (43.3)	0.591
I	0 (-)	1 (3.3)	0.999
II	10 (33.3)	11 (36.6)	0.999
Urinary tract infections	4 (13.3)	4 (13.3)	
Bladder retention	2 (6.7)	2 (6.7)	
Ileus	1 (3.3)	1 (3.3)	
Thrombosis in external hemorrhoids	1 (3.3)	1 (3.3)	
Anal fissure	1 (3.3)	0 (-)	
Fecal impaction	0 (-)	1 (3-3)	
Wound infection	1 (3.3)	2 (6.7)	
III	0 (-)	1 (3.3)	0.999
Ileal obstruction	0 (-)	1 (3.3)	
PFD recurrence at 24 months (n, %)	2 (6.7)	1 (3.3)	0.999
ODS	1	1	
Rectocele	1	-	
***De novo* PFD at 24 months (n, %)**	9 (30)	2 (6.7)	0.022
SUI	2 (6.7)	0 (-)	
UUI	1 (3.3)	0 (-)	
ODS	2 (6.7)	1 (3.3)	
FI	1 (3.3)	0 (-)	
Rectocele	2 (6.7)	1 (3.3)	
Apical prolapse	1 (3.3)	0 (-)	
Re-operation at 24 months (n, %)	3 (10)	1 (3.3)	0.614
LVR	1 (3.3)	1 (3.3)	
TOT	1 (3.3)	0 (-)	
LSCP	1 (3.3)	0 (-)	
Length of follow-up (months), median (1Q 3Q)	33 (29 36)	31.5 (30 73)	0.958

PFD: pelvic floor dysfunction, ODS: obstructed defecation syndrome; SUI: stress urinary incontinence; UUI: urge urinary incontinence; FI: fecal incontinence; LVR: laproscopic ventral rectopexy; TOT: trans-obturator tape; LSCP: laparoscopic sacrocolpopexy

In contrast, major FI (CCF-FI >10) improved in both groups after surgery. The improvement of PFD-related symptoms and quality of life in both groups after surgery, as showed by significant reduction in PFDI and PFQI scores despite single or combined procedure (Figure 2, Table 5) suggests considerations about the role of surgical approach in improving women symptoms because perceived symptomatology and objective pelvic defect do not always match. Other studies have shown that, after surgery for prolapse, there is persistent improvement in quality of life despite recurrences, and that surgical correction of the objective pelvic defect is only weakly correlated with an improvement in quality of life even when comparing surgical versus conservative treatments.[17] Overall patient satisfaction was high in both groups after surgery, demonstrating the correct surgical approach chosen by the MDT. Multidisciplinary approach is the cornerstone for a correct approach to complex PFD.[7] MDT meetings consent to standardizing care, agreeing on the management plan and type of combined or staged surgery according to the patient's real needs, balancing the pros and cons of strategies, and improving quality of the service received by patients.

Study Limitations

The limits of the present study are represented by the small sample size, the lack of randomization, and the short follow-up time. We thought it was non-ethical to randomizing patients to one treatment rather than another because the treatment was tailored to the patients' symptoms and defects. We are continuing to enroll patients to increase the sample size, trying to better standardize the procedures to allow for comparison.

CONCLUSION

The combined treatment of pelvic defects and prolapses in multiple compartments in multidisciplinary approach is feasible and safe because it consents a better restoration of the pelvic floor anatomy, it reduces recurrences, *de novo* defects, and the need for further surgical correction, without increasing postoperative complications. Other studies comparing the outcome of single and combined pelvic procedures are necessary to achieve evidence-based guidelines supporting surgeons' choices.

Acknowledgements

Authors acknowledge Elena FORINI of the Statistic Office, University Hospital Ferrara, Italy for the statistical analysis.

ETHICS

Ethics Committee Approval: The study was conducted in accordance with the principles of Helsinki Declaration, with approval of the Regional Medical Ethics Review Board (identification code: 160597).

Informed Consent: Written informed consent was obtained from all patients.

Peer-review: Internally peer-reviewed.

Contributions

Surgical and Medical Practices: S.A., L.C., S.M., R.M., C.I., P.C.; Concept: S.A.; Design: S.A., R.M., C.I., P.C.; Data Collection or

Table 5. Clinical, functional, and quality of life results

Outcome results	Single procedure (SP) n=30	Combined procedure (CP) n=30	*p*
pre POP-Q, median (1Q 3Q)	3 (2 3)	3 (3 3)	0.042
post POP-Q, median (1Q 3Q)	1 (0 1)	0 (0 1)	0.009
p	<0.0001	<0.0001	
pre PFDI (mean ± SD)	105.04±64.68	135.14±56.96	0.061
post PFDI (mean ± SD)	55.35±39.22	51.36±50.52	0.733
p	<0.0001	<0.0001	
pre PFQI (mean ± SD)	89.59±89.28	130.106±74.37	0.061
post PFQI (mean ± SD)	43.92±55.47	31.74±36.68	0.320
p	0.0014	<0.0001	
pre ODS, median (1Q 3Q)	9 (0 14)	16 (14 18)	0.0005
post ODS, median (1Q 3Q)	0 (0 8)	0 (0 4)	0.216
p	0.012	<0.0001	
pre Wexner CSS, median (1Q 3Q)	9.5 (0 12)	12.5 (10 16)	0.002
post Wexner CSS, median (1Q 3Q)	5 (0 10)	2.5 (0 5)	0.049
P	0.026	<0.0001	
pre CCF-FI score, median (1Q 3Q)	0 (0 0)	0 (0 0)	0.210
post CCF-FI score, median (1Q 3Q)	0 (0 0)	0 (0 4)	0.258
p	0.528	0.386	
VAS satisfaction, median (1Q 3Q)	8 (7 9)	9 (8 9)	0.067

POP-Q: pelvic organ prolapse quantification system; PFDI: pelvic floor distress inventory; PFQI: pelvic floor impact questionnaire; ODS: altomare score for obstructed defecation syndrome; Wexner CSS: constipation scoring system; CCF-FI: cleveland clinic score for fecal incontinence; VAS: patient satisfaction visual analogue scale; SD: standard deviation

Processing: L.C., S.M.; Analysis or Interpretation: S.A., L.C., S.M., R.M., C.I., P.C.; Literature Search: S.A., L.C., S.M.; Writing: S.A., L.C.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study received no financial support.

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DOI: 10.34057/PPj.2022.41.02.2022-3-3
Pelviperineology 2022;41(2):91-97

The effect of apical tensioning and suburethral support on stress and urgency urinary incontinence

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Citation: Jäger W, Paeffgen A, Hagemeier A, Neumann E, Ludwig S, Mallmann P. The effect of apical tensioning and suburethral support on stress and urgency urinary incontinence. Pelviperineology 2022;41(2):91-97

ABSTRACT

Objectives: In the present study, we evaluated the effect of apical suspension of the vagina on urinary incontinence by replacing both uterosacral ligaments with polyvinylidene-fluoride (PVDF) structures.

Materials and Methods: All patients had stress and urgency urinary incontinence (mixed urinary incontinence). These PVDF-structures were sutured to the cervical stump (after supracervical hysterectomy) or to the vaginal vault according to the standardized cervicosacropexy (CESA) or vaginosacropexy (VASA) technique. The length of PVDF-structures in patients who underwent CESA and VASA was 8.8 cm and 9.3 cm, respectively.

Results: In total 39% and 33% of the patients who underwent CESA or VASA became continent, respectively. Stress-related and urgency symptoms disappeared in all patients. The number of patients who became continent with these suspensions decreased with the increasing age, particularly in those aged >60 years. The age-dependent decrease in continence rates was significant among patients who underwent CESA. The percentage of patients in the <60-years and >60-years-of-age groups who became continent after CESA was 50% and 26%, respectively (p=0.002). In patients who underwent VASA, the respective continence rates were 41.5% (<60-years-of-age group) and 28.9% (>60-years-of-age group) (p=0.100).

Conclusion: Patients who still exhibited mixed urinary incontinent were then offered a transobturator tape (TOT) procedure, following which the continence rates ranged between 40.4% and 43.3%.

Patients with mixed urinary incontinence are usually treated with different medical methods, which provide a limited success rate. The results of our study demonstrated that a bilateral apical fixation of the vaginal apex either alone or in combination with a suburethral TOT procedure was effective in treating and restoring urinary continence in 56% and 87% of patients aged >60 and <60 years, respectively.

Keywords: Urinary incontinence; urgency; cervicosacropexy; vaginosacropexy; transobturator tape; bilateral apical fixation

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Received: 28 March 2022 **Accepted:** 09 Jun 2022

INTRODUCTION

Urinary incontinence is a chronic disorder associated with a progressive increase in symptoms of uncontrolled urine leakage over the lifetime of an individual (X). In the early stage, the leakage of urine occurs only with a sudden increase in the pressure on the bladder outlet, for example, in case of coughing or sneezing. This phase is called "stress-urinary incontinence".[1]

In the later stage of the disease, urinary leakage occurs with even a low pressure on the bladder. Eventually, patients lose bladder control while rising from a chair or walking. This later stage of urinary incontinence is accompanied by a sudden feeling of urgency; hence, it has been termed "urgency urinary incontinence".[2]

The treatment of urinary incontinence depends on the symptoms. Incontinence caused by coughing or sneezing can be cured with a suburethral tape that compresses the urethra when the vertical pressure on the bladder increases.[3] The association between urgency and incontinence led to the formulation of a hypothesis, which suggests that this form of urinary incontinence is the consequence of a neurological dysfunction in the closing musculature.[2] Based on this hypothesis different neurological treatment modalities were developed that led to a reduction in symptoms.[4] However, these treatments are not effective in the long run because the patients often exhibit urinary incontinence upon discontinuation of the treatment.

But there is a way to help these patients!

Urgency urinary incontinence is often seen in patients with pelvic organ prolapse.[5,6] Petros and Ulmsten[7] hypothesized in their "integral theory" that both stress and urgency urinary incontinence are commonly caused by laxity of the anterior vaginal wall. This hypothesis was supported by observations that the surgical repair of pelvic organ prolapse led to permanent continence, as well as complete disappearance of the feeling of urgency in 14-45% of patients.[8-11]

For visualization purpose, the vagina is separated into three levels.[12] An apical fixation is usually performed at the apical end of the vaginal stump (level 1) or at the bladder-urethral junction (level 2) according to the Burch procedure. Colporrhaphy involves repair of the lax anterior vaginal wall at level 2.[13] These procedures employed to increase tension on the anterior vaginal wall can lead to urinary continence and the disappearance of urgency; however, the reasons for large differences observed in continence rates following these procedures are unknown.

Sacrocolpopexy (apical fixation) involves tensioning of the vagina on the longitudinal axis. The stump of the apical vagina (colpo) is anchored at the sacral bone.[14] Surgical textbooks do not mention the most appropriate degree of tensioning of the vagina, that is, the optimal length of the anchor chain,[15] and this parameter is determined by surgeons. To evaluate whether the extent of tensioning could be responsible for different continence rates, the apical suspension of the vagina was standardized in the present study.

Because the dimensions of the bony pelvis are nearly identical in women of different ethnicities standardization of colposuspension (apical fixation) was possible.[16] Apical prolapse is caused by a defect of the holding apparatus, especially of the uterosacral (USL) and laterally (cardinal) ligaments. As a first step in surgical standardization the author decided to replace both USL as a repair of level 1.[10,17]

The fixation sides of the USL were known; however, the length of the ligaments was unknown. Based on literature of pelvic anatomy, the physiological length of the USL was calculated to be approximately 9 cm, which is in accordance to anatomical studies.[18] In patients with uterine prolapse, the USLs were replaced with polyvinylidene-fluoride (PVDF) structures of defined length.[10,17,19-21] The tapes were fixed at the promontory, placed retroperitoneally in the peritoneal folds of the USLs, and sutured to the implantation sides of the USLs at the cervix. This standardized method of cervicosacropexy performed using an 8.8 cm long PVDF structure in every patient was termed CESA. In vaginosacropexy, these PVDF structures used were 9.3 cm long and were sutured to the lateral ends of the vaginal vault. This standardized method for placement of the PVDF structures was referred to as VASA.[22] Thus, every patient was operated on in the same way. We deliberately decided to replace the USL with an 8.8 cm long PVDF structure in CESA, and because of the length of the resected cervix, a 9.3 cm long structure was used in VASA (Figure 1).[10,17,20-22]

CESA and VASA procedures were originally developed as surgical treatments for patients with uterine or vaginal (apical) prolapse; however, we observed that several patients with either stress urinary incontinence or urgency urinary incontinence became continent after undergoing CESA or VASA.[10,17] Therefore, in the URGE 1 study, patients with urgency urinary incontinence were randomized to receive either medical treatment with solifenacin or surgical treatment with CESA/VASA. In the solifenacin treatment group 10% of patients experienced a relief from their symptoms, whereas in the CESA/VASA surgical treatment group, 42% of the patients became continent.[19] However, upon completion of the treatment, the patients in the solifenacin treatment group became incontinent, whereas those in the CESA/VASA surgical treatment group remained continent.

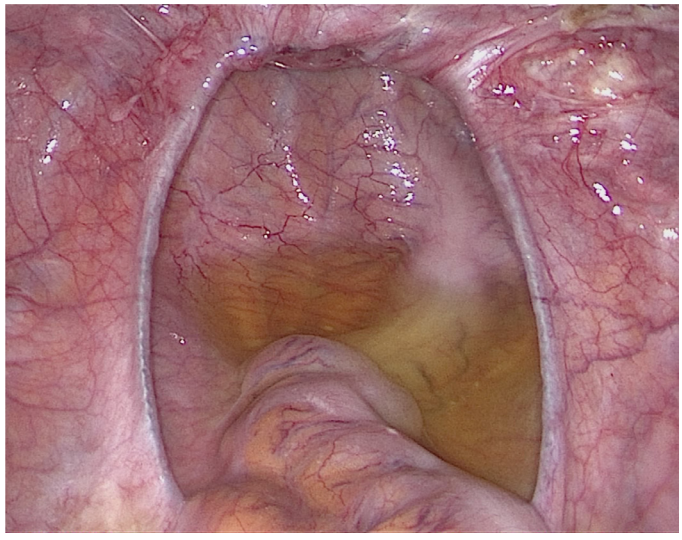

Figure 1. The small pelvis with a cervicosacropexy structure (DynaMesh CESA® FEG Textiltechnik Aachen, Germany) placed between the cut surface of the cervix and promontory in the run of both uterosacral ligaments.

According to the integral theory, patients who remained incontinent after replacement of the USL would require support of the urethra.[7,13,23] Therefore, these patients received an additional suburethral tape. This led to continence in 76% of the patients with urgency urinary incontinence.[10,11]

However, the reason for incontinence among some patients even after the treatment remained unclear. After standardization of the CESA/VASA procedure and placement of the suburethral tape (TOT 8/4), addressing this question was feasible.

MATERIALS AND METHODS

Patients with urinary incontinence who presented to the Department of Gynecology at the University of Cologne between 2012 and 2020 were included in this study. The study was approved by the Ethical Committee of the University of Cologne (approval no: 20-176).

Mixed urinary incontinence (MUI) was defined as a combination of stress urinary incontinence and urgency urinary incontinence. Continence was defined as no loss of urine on any occasion and the absence of a feeling of urgency. Patients with symptoms of both urgency and stress urinary incontinence were included in the study. Patients who had undergone colporrhaphy or colposuspension or a transvaginal tape (TVT) or transobturator tape (TOT) procedure were excluded from the study. Patients with a clinical prolapse of the uterus or vaginal stump (> stage 1) and those with a clinical cystocele or rectocele who required an additional colporrhaphy were also excluded from the study.

The patients underwent either CESA or VASA, which was performed as described previously.[17] For suspension, specially designed PVDF structures were used (DynaMesh CESA®, DynaMesh VASA®, FEG, Aachen, Germany). In CESA, the cervix was dissected below the side where the uterine vessels reach the uterus, and the bladder attachment at the cervix remained untouched. In VASA, the sutures were secured to the furthest lateral edges of the vaginal vault. Since 2016, CESA and VASA have been performed laparoscopically.[20,24]

Patients who became continent after CESA or VASA did not receive further treatment. Patients who remained incontinent were offered a TOT procedure. The placement of the TOT had also previously been standardized. Before tensioning the tape, a Hegar pin 8 was placed in the urethra, and a Hegar pin 4 was placed between the tape and the urethra (TOT 8/4).[25]

The CESA, VASA and TOT 8/4 procedures were performed by the same surgeons (WJ and SL).

The patients provided information about their symptoms of urinary incontinence by completing a modified LUTS questionnaire of the ICS before surgery and again between 4 and 6 weeks after surgery. Patients experiencing continence were asked to contact the department, in case of incontinence relapse.

Statistical Analysis

Patient data were registered in a computer databank on the day of surgery. Statistical analysis was performed in collaboration with the Institute of Medical Statistics at the University of Cologne.

RESULTS

In total, 1033 women with urinary incontinence were treated at our institution during the study period. Two hundred-fifteen patients underwent a CESA or VASA plus a TOT procedure simultaneously. In addition, 135 patients underwent a colporrhaphy at the time of CESA or VASA. These patients, as well as 43 patients with incomplete data were excluded. In addition, 45 patients were operated on for different indications. After identifying the patients with only urgency urinary incontinence or stress urinary incontinence, 326 patients with MUI were included in the study to evaluate the effects of the surgical treatment (Figure 2).

Of the total, 159 patients underwent CESA, and 167 patients underwent VASA. Sixty-two of 159 patients (39%) and 55 of 167 patients (32.9%) who underwent CESA and VASA, respectively, became continent; however, the difference in the continence rates was not significant (p=0.300).

The enrolled patients were further subdivided into two groups based on their age: One group comprised patients aged <60 years, and the other group comprised patients aged >60 years.

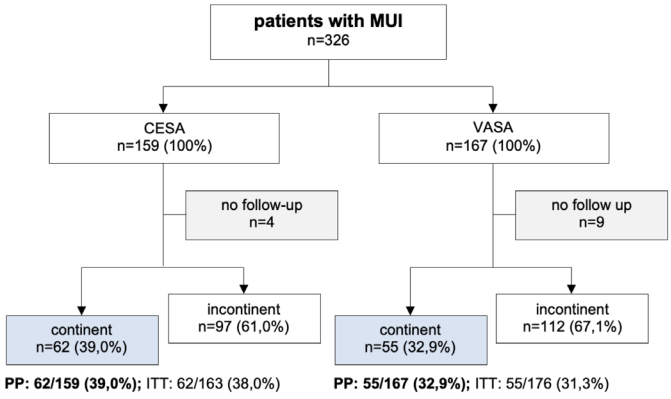

Figure 2. Distribution of evaluable patients with mixed urinary incontinence (MUI) according to the type of operation.

Pp: per protocol treated patient; ITT: intention to treat; CESA: cervicosacropexy; VASA: vaginosacropexy

In the <60-years-of-age group, 46.8% patients became continent after undergoing CESA or VASA compared with 27.8% in the >60-years-of-age group (p=0.001).

The difference in the continence rates (the number of patients who became continent after surgery per 100 patients) of the patients who underwent CESA or VASA was statistically significant between the two age groups. The number of patients who became continent was higher in the <60-years-of-age group than in the >60-years-of-age group.

Among the patients who underwent CESA, the continence rates were 43/85 (50%) in the <60-years-of-age group and 19/73 (26%) in the >60-years-of-age group (p=0.002) (Figure 3).

The respective continence rates for patients who underwent VASA in the two age groups were 22/53 (41.5%) and 33/114 (28.9%); however, this difference was not significant (p=0.100) (Figure 4).

The patients who remained incontinent after CESA or VASA were offered a TOT procedure. The observed continence rates among patients who underwent CESA or VASA after the TOT procedure were comparable (i.e., 40.4% after CESA and 43.3% after VASA; p=0.700).

However, the effects of the TOT procedure after CESA or VASA varied between the two age groups (Figure 5).

The continence rates (pp) for patients who underwent CESA were 55/63 (87%) and 26/46 (56%) in the <60- and >60- years-of-age groups, respectively. Among patients who underwent VASA, the continence rates in the <60- and >60- years-of-age groups (pp) were 29/38 (76%) and 52/77 (67%), respectively.

The continence rate after the TOT procedure in patients who underwent VASA was 43% irrespective of the age. However, the continence rate after TOT in patients who underwent CESA varied depending on the age, with the rates in the <60-years and >60-years-of-age groups being 60% and 25.9%, respectively (p=0.02).

1) Materials and Methods

The merit of this study is the homogeneity of patients' symptoms and the treatment administered to them. All the patients exhibited MUI, and none of them had previously received a colposuspension (apical suspension), colporrhaphy, TVT, or TOT.

All patients underwent standardized CESA/VASA with or without a subsequent TOT 8/4 operation, and these operations were performed by the same surgeons using identical surgical techniques in every patient.[10,20,24,26-28]

2) The Effect of Apical Suspension

The results of this study confirmed that apical suspension of the vagina can lead to restoration of urinary continence. Presence of continence or incontinence is confirmed at the uterovesical junction (UVJ) (level 2). The CESA and VASA structures are placed at level 1. Therefore, when patients became continent, the effect

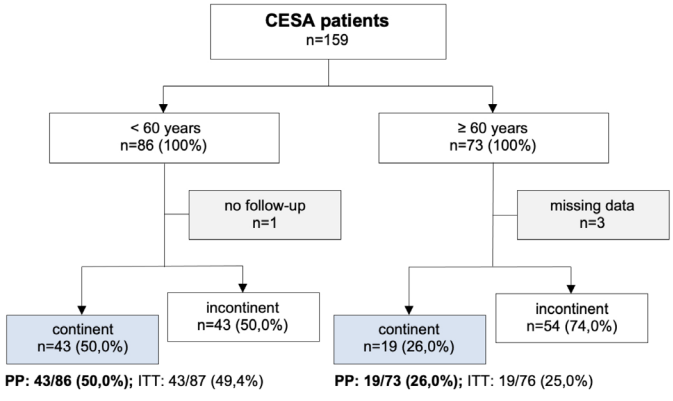

Figure 3. Distribution of evaluable patients who underwent cervicosacropexy (CESA) according to the age at surgery.

Pp: per protocol treated patient; ITT: intention to treat

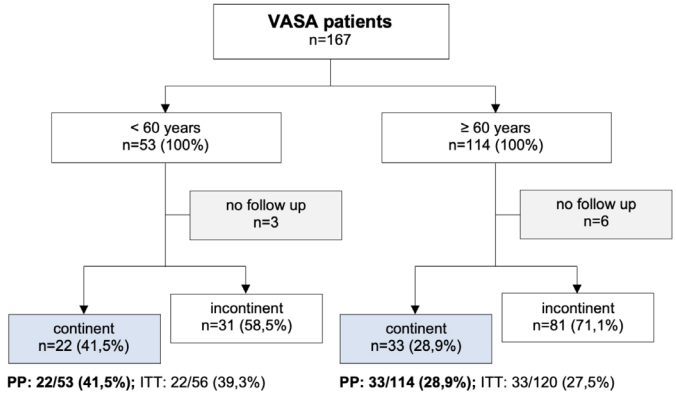

Figure 4. Distribution of evaluable patients who underwent vaginosacropexy (VASA) according to age at surgery.

Pp: per protocol treated patient; ITT: intention to treat

of the apical suspension must have extended to the UVJ region. Tensioning of the vagina probably supports the bladder base. Therefore, when a slight pressure is applied on the bladder, such as when a patient stands up, the UVJ will not open. With the re-establishment of continence, the feeling of urgency also disappears. The causal relation between the anatomical suspension of the UVJ and continence is demonstrated by the observation that patients with incontinence do not lose urine in the sitting position.[10,11,21] Continence or incontinence is a result of pressure and counterpressure on the UVJ, respectively.[29]

The symptom of urgency is independent of incontinence. Patients with continence also experience urgency when the bladder is filled to a particular level. Urgency can even be experienced by patients while sitting when the UVJ is closed by compression. The reason for the disappearance of the feeling of urgency after surgery irrespective of whether the patient undergoes CESA, VASA, or TOT cannot be explained. Urgency is definitively a neurological sensation that originates in the brain; however, it is not the cause of rather a symptom associated with incontinence.[10]

3) Aging

In this study, the clinical results of CESA and VASA in terms of urinary incontinence were found to be critically dependent on patients' age. In the <60-years-of-age group, 50% and 41% of all patients became continent after CESA and VASA, respectively. In the >60-years-of-age group, the continence rates after surgery were 26% for patients who underwent CESA and 28% for those who underwent VASA.

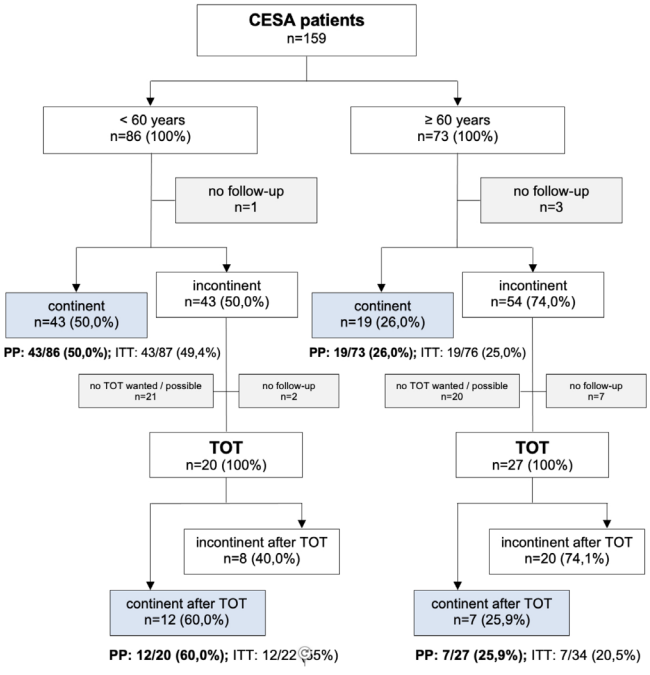

Figure 5. Continence rates after cervicosacropexy (CESA) and vaginosacropexy (VASA) and a transobturator tape (TOT) procedure according to patients' age at surgery.

Pp: per protocol treated patient; ITT: intention to treat

The cut-off of 60 years of age was chosen and implemented in the present study protocol based on the results of previous studies.[30] However, the final results suggest that patients who were most adversely affected in terms of their continence rates after surgery were aged ≥70 years. In this group of patients >70 years, the continence rates for those who underwent CESA and VASA were 16% and 20%, respectively.

The age of patient plays a critical role in urinary incontinence, which follows a consistent pattern. Urinary incontinence often starts around the age of 40 years with leakage of urine on coughing or sneezing.[31] The urgency phase begins at approximately 60 years of age with urine loss while standing or walking. Initially, the patients remain continent until they go to the toilet immediately upon experiencing the sensation of urgency; however, within a few years, the patients begin losing bladder control while on their way to the toilet. In our series, this phase developed between the ages of 60 and 65 years.

The etiology of urinary incontinence remains unknown. The course of symptoms is identical in all patients, which is an indication that urinary incontinence is a single disorder that intensifies over time. Considering that urinary incontinence is caused by the events associated with aging, the reason for incontinence only in some but not in all patients with increasing age remains to be investigated.

In our study, we asked the patients whether their mother was also incontinent. Approximately 90% of the patients reported that their mother was also incontinent. However, we abstained from interpretating these data because of the lack of a control group (i.e., mother incontinent-daughter continent). Therefore, the suspected genomic relation remains to be studied further.

4) Caveat

The effects of patients' age on treatment results in the present study can explain the heterogeneity of the results reported in previous studies. Treatment was significantly less effective in patients aged more than 60 years. Therefore, future studies on patients with urinary incontinence should consider patients' stratification based on the age.

5) Suburethral Suspension

For the interpretation of the effects of the TOT procedure, clinicians should consider that only 51% of the patients who remained incontinent after CESA or VASA were willing to undergo a TOT procedure. The reasons for patients' refusal to undergo a

TOT procedure remain unknown. Therefore, the clinical results in the present study must be interpreted while considering this aspect.

The TOT procedure led to continence in approximately 53% of the patients who were experiencing incontinence and urgency even after undergoing CESA or VASA. This effect was not dependent on patients' age.

The effects on continence can be explained by the compression of the urethra by the TOT. However, the reason for the disappearance of the feeling of urgency in these patients remains to be explored.

We could not identify the reason for the presence of incontinence among 47% of the patients who underwent a TOT procedure. We also attempted to eliminate inter-patient differences in the placement of the tape by standardizing the TOT procedure.

One interpretation could be that the placement of the TOT was not correct in relation to the UVJ. A study reported that incontinence after the placement of a suburethral tape was caused by a displacement of the tape over time.[32] However, all the patients in our study reported that they were incontinent immediately after the first spontaneous micturition following surgery, and the placement of the tape did not show any signs of displacement.

It can be assumed that the persistent incontinence among these patients was contributed by another factor.

6) Considerations

The etiology of urinary incontinence is unknown. In the present study, its symptoms were effectively treated through CESA or VASA and TOT 8/4. CESA or VASA cured the symptoms of incontinence in approximately 45% of our patients, while the TOT procedure cured nearly 50% of the remaining patients having incontinence. Overall, these treatments could cure urinary incontinence in nearly 75% of patients.

In our study the continence rate following surgery was dependent on patients' age. The overall continence rates for patients who were treated according to the treatment protocol (pp-rates) were between 87% (in patients aged <60 years) and 56% (in patients aged >60 years).

CONCLUSION

The anatomical effects of CESA/VASA and TOT on the anterior vaginal wall vary. CESA and VASA exert a longitudinal tension not only at level 1 but also, in part, at level 2. The suburethral tapes have no effect in that respect; they do not exert tension on any part of the vagina but support the urethra in the area in front of the UVJ. This effect is evident when the patient is in the upright position. Therefore, the surgical treatment must be targeted at level two-the level of the UVJ. In the future, the additional lateral suspension of the vagina at level 2 must also be standardized to better evaluate the effect on urinary incontinence.

The scientific principle of monocausality states that each individual effect is based on an individual cause. Therefore, incontinence as an effect must have an individual cause, which remains unknown. It can be hypothesized that aging is accompanied by changes at the DNA level that leads to the decreased production of specific enzymes or proteins. In some patients, this may lead to a laxity of the anterior vaginal wall at the level of the UVJ. Additionally, considering a neurological reason for incontinence seems unreasonable.

So far, no causative treatment for urgency urinary incontinence or MUI has been found. Medical treatment does not help these patients effectively. However, surgery can be used as the mainstay treatment to re-establish continence in about 70% of these patients who otherwise have no chance for continence. By the standardization of CESA, VASA and the TOT 8/4 every surgeon can reproduce our findings.

ETHICS

Ethics Committee Approval: Patients with urinary incontinence who presented to the Department of Gynecology at the University of Cologne between 2012 and 2020 were included in this study. The study was approved by the Ethical Committee of the University of Cologne.

Informed Consent: Retrospective study.

Peer-review: Internally and externally peer-reviewed.

Contributions

Surgical and Medical Practices: W.J., S.L., Concept: W.J., E.N., P.M., S.L., Design: W.J., A.P., E.N., P.M., S.L., Data Collection or Processing: W.J., A.P., A.H., S.L., Analysis or Interpretation: W.J., A.P., A.H., S.L., Literature Search: A.P., E.N., S.L., Writing: W.J., A.P., S.L.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: FEG Textiltechnik mbH, Aachen Germany Wolfram Jäger, Sebastian Ludwig.

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DOI: 10.34057/PPj.2022.41.02.2022-2-3
Pelviperineology 2022;41(2):98-103

Prevalence of urinary incontinence and associated factors in crossfit practitioners: A cross-section study in Brazil

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Citation: Coelho KC, Zacarin ER, Otavio RV, Antunes MD, Araújo CGA, Wittig DS, Branco BHM, Seleme M, Berghmans B. Prevalence of urinary incontinence and associated factors in crossfit practitioners: A cross-section study in Brazil. Pelviperineology 2022;41(2):98-103

ABSTRACT

Objectives: The objective was to identify the prevalence of urinary incontinence and the associated factors in CrossFit practitioners.

Materials and Methods: A cross-sectional study with 235 CrossFit practitioners from Brazil. Urinary incontinence was investigated using an instrument created by the authors based on the 3IQ questionnaire. Data were analyzed using the chi-square test.

Results: The prevalence of urinary incontinence in CrossFit practitioners was 9.7%. However, it was observed that the female sex is associated with factors present in the practice of CrossFit.

Conclusion: The prevalence of urinary incontinence among CrossFit practitioners is low, yet it is essential to create strategies and actions that promote pelvic health and prevent urinary incontinence in CrossFit practitioners in Brazil. High-intensity interval training such as CrossFit promotes the improvement of physical fitness, but some movements can lead to urinary incontinence. The objective was to identify the prevalence of urinary incontinence and the associated factors in CrossFit practitioners. A cross-sectional study with 235 CrossFit practitioners from Brazil. Urinary incontinence was investigated using an instrument created by the authors based on the 3IQ questionnaire. Data were analyzed using the chi-square test. The prevalence of urinary incontinence in CrossFit practitioners was 9.7%. However, it was observed that the female sex is associated with factors present in the practice of CrossFit. The prevalence of urinary incontinence among CrossFit practitioners is low, yet it is essential to create strategies and actions that promote pelvic health and prevent urinary incontinence in CrossFit practitioners in Brazil.

Keywords: Exercise; pelvic floor; rehabilitation; sports; urinary stress incontinence

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Received: 01 March 2022 **Accepted:** 15 June 2022

INTRODUCTION

CrossFit is a high-intensity functional training model.[1] It is characterized by a sports modality with high energy and high-intensity interval training (HIIT)[2] and which aims to develop the physical fitness of practitioners and athletes especially in the components related to cardiovascular, respiratory, and muscle resistance, strength, flexibility, power, speed, coordination, balance, and precision.[1-3] This modality is composed of cyclical and acyclic movements, weightlifting exercises, as well as gymnastic exercises.[4]

This HIIT gained prominence for having motivational and challenging features, which is why it gets more and more practitioners.[5] This optimization occurs through the execution of functional exercises, in high intensity and constantly varied, such as the deadlift, shot put, bicycle, swim, run, squat, jump, overhead medicine ball, and jump ropes. Exercises are systematically organized through workout of the day (WOD).[6,7]

CrossFit practice requires the athlete to reach the limit of their physical conditioning. In cases where there is no correct and specific physical preparation, there may be injuries, and can be followed by pain, discomfort, and even the inability to continue training.[8] In some circumstances, depending on the chosen WOD, repetitive weightlifting besides other exercises that cause axial overload, can generate several musculoskeletal injuries. Some repetitive jumping exercises and maximum abdominal contraction, such as skipping rope and the burpee, which increase the support exercised by the pelvic floor and intra-abdominal pressure can lead to urinary incontinence (UI).[9,10]

According to the International Continence Society, UI is characterized by involuntary urine loss, being considered a multifactorial condition. It is a condition that affects women, men, and children, negatively impacting the quality of life of individuals.[11] The prevalence rates of UI vary from 0% to 80% in different sports and with higher prevalence in those involving HIIT.[12,13]

The pathophysiology of UI with high-impact exercises is possibly related to explosive in intra-abdominal pressure, which can lead to an elastic change and neuromuscular fatigue over time, thus causing an imbalance between the support offered by the pelvic floor and sudden pressure variations during exercise.[2] Some authors also report on the cause of UI, such as paralysis or weakness of the pelvic floor muscles.[13-15]

Individuals who have a diagnosis of UI, feel embarrassed by the odor and feeling of being dirty, due to the uncontrolled leakage of urine. Thus, the negative impact on the quality of life is very frequent.[16-18] Currently, there are few good quality studies that performed this type of association, making this investigation necessary. In this sense, the objective of the study was to identify the prevalence of UI and the associated factors in CrossFit practitioners in Brazil.

MATERIALS AND METHODS

This is a cross-sectional and observational research, carried out following the recommendations of strengthening the reporting of observational studies in epidemiology.[19]

The study was approved by the Ethics and Research Committee (CEP) of Universidade Cesumar, under opinion no: 2,919,167/2018. We fully attended the Resolution 466/2012 of the Ministry of Health of Brazil, as well as the Declaration of Helsinki. All participants signed the informed consent form.

Inclusion criteria were individuals of both sexes aged between 18 and 60 years, literate, without neurological and physical impairment and who practiced CrossFit residing in Brazil. Pregnant women and individuals with disabilities were excluded.

We evaluated socio-demographic data, health status, as well as characteristics of CrossFit practice. To assess the prevalence of UI and a HIIT such as CrossFit considering its practice at a recreational and high-performance level, information was collected through a structured questionnaire prepared by the authors, with questions involving UI were based on the 3IQ questionnaire, which is a useful and quick validated instrument for establishing the presence of UI and classifies the type of UI.[20,21]

Statistical Analysis

Descriptive analysis was performed with the results expressed in absolute and relative frequency. To assess any association between characteristics related to the practice of HIIT, CrossFit, and UI with the sex of the individuals, we used simple logistic regression, estimating the odds ratio, with interval 95% confidence.

Subsequently, using the methodology proposed by Hosmer and Lemeshow,[22] variables that showed at least a moderate association ($p<0.25$) were selected with the variable that indicates adherence to treatment by the chi-square test of association.[23]

RESULTS

A total of 235 CrossFit practitioners participated in the study in the city of Maringá-PR, most (55.7%) being female. Table 1 shows the frequencies of responses to the questions according to sex and the results of the association test. It could be observed, at 5% significance, that the number of hours of CrossFit practice

Table 1. Profile of Brazilian CrossFit practitioners (n=235)			
Variables	**Men**	**Women**	***p***
Time practicing			
Less than 6 months	27 (26.0%)	49 (37.4%)	0.063
6 months to 1 year	23 (22.1%)	21 (16.0%)	
More than 1 year	19 (18.3%)	32 (24.4%)	
More than 2 years	35 (33.7%)	29 (22.1%)	
Times a week			
4 times	23 (22.1%)	26 (19.8%)	0.312
5 times	46 (44.2%)	61 (46.6%)	
6 times	25 (24.0%)	22 (16.8%)	
Time per day			
30 to 60 minutes	58 (55.8%)	93 (71.0%)	0.018*
60 to 90 minutes	42 (40.4%)	31 (23.7%)	
Time of the day			
Evening	33 (31.7%)	41 (31.3%)	0.333
Night	57 (54.8%)	64 (48.9%)	
The practice of other sport			
No	62 (59.6%)	109 (83.2%)	0.0004*
Yes	42 (40.4%)	22 (16.8%)	
Concern to perform the exercises correctly			
No	1 (1.0%)	1 (0.8%)	0.999
Yes	103 (99.0%)	130 (99.2%)	
Priority			
Quality	97 (93.3%)	127 (96.9%)	0.222
Advancing without thinking about quality	7 (6.7%)	4 (3.1%)	
CrossFit athlete (competition level)			
No	79 (76.0%)	105 (80.2%)	0.524
Yes	25 (24.0%)	26 (19.8%)	
TOTAL	**104 (100%)**	**131 (100%)**	

*: *p*-value <0.05

(*p*=0.0182) was one of the variables that proved to be significantly associated with the sex of the individuals, with most women training from 30 to 60 minutes (71%) and 23.7% from 60 to 90 minutes, while 55.8% of men practice from 30 to 60 minutes and 40.4% from 60 to 90 minutes.

It is also observed that 40.4% of men practice another sport besides CrossFit, while only 16.8% only practice CrossFit, indicating an association of this factor with sex (*p*=0.004). On the other hand, when observing the leakage of urine factor (Table 2) before starting the CrossFit, a proportion of 12% of affirmative responses is observed among women, while no men reported this problem, thus characterizing an association between these variables (*p*=0.0014).

Similarly, when compared to women, a higher percentage of men did not experience the loss of urine doing CrossFit (95.2% *versus* 80.9%), while all males did not report having urine leakage practicing another sport and 5.3% of women said they had this problem. Thus, there is evidence of an association with sex in these two cases, with *p*-values equal to 0.0049 and 0.0185, respectively.

The other factors did not show a significant association between these variables and the respondents' sex, with no significant divergence between frequencies according to sex.

DISCUSSION

The prevalence of UI is low among CrossFit practitioners. In this study, the prevalence of UI in both sexes was 9.7% during HIIT (CrossFit); most people do not seek to be high-performance athletes and try to perform movements correctly. Based on the aspects, the hypothesis of this study has not been proven.

The pelvis is divided into the greater pelvis (abdominal cavity, also considered false pelvis) and lesser pelvis (pelvis cavity, also considered true pelvis). This structure has reduced mobility, except when it comes to pregnancy.

However, some particularities can be observed when we talk about male pelvis and female pelvis, namely: The female pelvis presents greater anterior inclination; opening of the male pelvis is characterized by the oval shape; opening of the female pelvis is characterized by its rounded shape; the male pelvic cavity is funneled, while the female pelvic cavity has a cylindrical shape; and the subpubic angle, where the ischial ramus and bilateral pubis join, show differences between males (60º) and females (90º).

In both sexes, most practice this activity for 30 to 60 minutes a day. In this sense, a significant difference was observed between the hours of its practice per week in the study, corroborating with some studies that also observed that the longest time was 30 to 60 minutes.[4,24,25]

For women, it was found that most practice only CrossFit as a regular exercise. On the other hand, when testing the relative frequency for the practice of other physical activity combined with HIIT such as CrossFit by men, it was observed that the results were higher than that of women (40.4%). This suggests that men are more willing to perform physical activities when compared to women. This can be justified because women are more involved with family issues and double the workday.

Despite the known benefits of physical exercises such as prevention of hypertension, diabetes, cardiovascular diseases, 60% of the population does not exercise regularly.[26] However, actually more women than man train less.[27]

Table 2. Relationship of urinary incontinence with the CrossFit practice (n=235)			
Variables	**Men**	**Women**	**p**
UI before starting CrossFit			
No	104 (100%)	119 (90.8%)	0.001*
Yes	0 (0.0%)	12 (9.2%)	
UI during CrossFit			
No	99 (95.2%)	106 (80.9%)	0.0049*
Yes	4 (3.8%)	19 (14.5%)	
UI during other physical activity			
No	104 (100%)	124 (94.7%)	0.019*
Yes	0 (0.0%)	7 (5.3%)	
Leakage of urine without physical activity and the feeling of urgency			
Evening	103 (99.0%)	131 (100%)	0.443
Night	1 (1.0%)	0 (0.0%)	
Ability to hold urine when you feel like it			
No	8 (7.7%)	5 (3.8%)	0.254
Yes	96 (92.3%)	126 (96.2%)	
TOTAL	**104 (100%)**	**131 (100%)**	

*: *p*-value <0.05; subtitle: UI: urinary incontinence, it was not possible to perform the test due to the low frequency observed. Source: research data

Concerning the leakage of urine, scientific evidence indicates that modalities such as rhythmic gymnastics,[12,13] athletics, weight training,[28] basketball, footbal,[29] volleyball,[30] cross-country skiing, running,[31] amateur soccer,[32] and sports with a sudden change of movement can stimulate or increase the prevalence of UI.

As for the CrossFit participants of this study, there was no significant difference in the prevalence of UI concerning the practice of HIIT. Gram and Bø[12] did not find any statistically significant risk factors to explain the chances of having UI in rhythmic gymnastics. However, they report that the prevalence of UI is generally high in female athletes.

Yang et al.[2] reported that almost half of women who practice CrossFit reported UI episodes during training, and when compared to nulliparous women who do aerobic exercising, women who practice CrossFit tend to have a higher incidence of UI, indicating that CrossFit exercises potentially demand more pelvic floor support.

In our study 14% of the participants reported UI. The effect of sport on the pelvic floor can promote muscle weakness, lack of proprioception, fatigue induced by strenuous activity in the pelvic floor muscles, and damage to collagen tissue due to increased intra-abdominal pressure because of excessive efforts involved in the practice of high impact sports.[33]

To preserve continence, the integrity of intrinsic and extrinsic factors in the filling phase is necessary, which will provide urethral closure, such as the levator ani muscles, the endopelvic fascia, and their fixations to the lateral walls of the pelvis and the urethra.[17]

Failure of the sphincter mechanism in the neuromuscular component can cause UI.[34] Some studies also report the lack of pre-contraction of the pelvic floor muscles,[35] the influence of the underlying genetic factors, such as a low pelvic floor position within the pelvis, alteration of the conjunctiva, and a delayed neurophysiological response to increases in intra-abdominal pressure, during high-impact activities[12,13] and hormonal changes as hypotheses that cause UI in CrossFit athletes due to increased intra-abdominal pressure while exercising.[34]

Gephart et al.[36] calculated the peak intra-abdominal pressure in women who practice CrossFit and reported that. within a HIIT routine, the maximum intra-abdominal pressure peaks, the duration of the increase in the peak intra-abdominal pressure, and the shape of the pressure curve changed greatly by exercise.

Furthermore, CrossFit is a program of functional exercises, carried out in high intensity and in the shortest possible time. Intensity is essential for the result butis also responsible for the prevalence of almost 30% of UI in women of our study population when practicing CrossFit.[37,38]

In another study,[39] the incidence of UI was observed in 72.3% of participants who practice physical activity in gyms, with 52% of these women having moderate UI. Moreover, Berghmans[40] reports that stress on the integrity of extrinsic factors causes pain, muscle tension, altered circulation, nerve compression

causing muscle shortening, which can trigger pelvic pain and musculoskeletal symptoms. It is worth noting that in the present study, adherence of both sexes to CrossFit was observed.

In our study the incidence of UI in practitioners of HIIT like CrossFit is relatively low. However, that is different in other studies. In this sense, preventive measures are suggested to reduce the incidence of UI during training and the creation of strategies and actions that promote health in the context of interdisciplinarity.

Currently, there is a potential great ally to promote the pelvic health of the population. CrossFit practitioners may use the Pelvis application[11], a fully interactive application with exercises to strengthen, relax, and coordinate the muscles of the pelvic floor for individuals of both sexes to do at any time of the day.

Some limitations were observed in this study, the first of which is the non-randomization of study participants, besides the lack of a urodynamic exam to measure bladder filling and emptying, assessing bladder storage capacity. However, the results of the present study have important clinical and practical implications, such as the need for CrossFit centers to carry out tests related to the participants' pelvic health, as well as encouraging the promotion of pelvic health through educational actions.

CONCLUSION

The prevalence of UI is low among CrossFit practitioners, however, it is important to create strategies and actions that promote pelvic health and prevent UI in CrossFit practitioners in Brazil.

ETHICS

Ethics Committee Approval: The study was approved by the Ethics and Research Committee (CEP) of Universidade Cesumar, under opinion no: 2,919,167/2018. We fully attended the Resolution 466/2012 of the Ministry of Health of Brazil, as well as the Declaration of Helsinki.

Informed Consent: All participants signed the informed consent form.

Peer-review: Externally peer-reviewed.

Contributions

Concept: K.C.C., E.R.Z., R.V.O., C.G.A.A., D.S.W.; Design: K.C.C., E.R.Z., R.V.O., C.G.A.A., D.S.W.; Data Collection or Processing: K.C.C., E.R.Z., R.V.O.; Analysis or Interpretation: K.C.C., E.R.Z., R.V.O., M.D.A., C.G.A.A., D.S.W., B.H.M.B., M.S., B.B.; Literature Search: K.C.C., E.R.Z., R.V.O., M.D.A., C.G.A.A., D.S.W., B.H.M.B., M.S., B.B.; Writing: K.C.C., E.R.Z., R.V.O., M.D.A., C.G.A.A., D.S.W., B.H.M.B., M.S., B.B.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study received no financial support.

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DOI: 10.34057/PPj.2022.41.02.2022-5-1
Pelviperineology 2022;41(2):104-111

Repair of pelvic organ prolapse with trocar-less versus trocar systems: Retrospective comparative study

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Citation: Marcus N, Altura Y, Eboue C, von Theobald P. Repair of pelvic organ prolapse with trocar-less versus trocar systems: Retrospective comparative study. Pelviperineology 2022;41(2):104-111

ABSTRACT

Objectives: The advantages of trocar-less over trocar systems for pelvic organ prolapse (POP) repair with vaginal mesh are gained mainly by bypassing the need of blind trocar insertion, thus potentially reducing complications. The aims of the study were to evaluate the safety and efficacy of trocar-less system designed for POP repair.

Materials and Methods: This is a retrospective, comparative study. One hundred-seven women were operated using the EndoFast Reliant™, trocar-less system (study group), and 123 women underwent surgical POP repair with the IVS TUNNELLER™ (tyco healthcare) trocar system (control group). The patients were evaluated pre- and post-operatively including intra and post-operative complications, anatomical results using the POP quantification and questionnaires on functional symptoms.

Results: Anatomical results were similar in both groups and there was significant improvement in all functional symptoms. There were significantly fewer complications in the study group, mainly intra-operative and immediate post-operative including: Significant bleeding (0.0% vs. 2.4%, p=0.1), bladder injury (0.0% vs. 2.4%, p=0.1), UTI and fever (2.8% vs 17.9%, p<0.001), hematomas (0.9% vs. 3.3%, p=0.23) and post-op voiding dysfunction and catheterization for more than 24 hours (0.9% vs. 13.8%, p<0.001). The surgical technique (Trocar-Less vs. Trocar System) was found as the only variable statistically significant with the correlation to early complications.

Conclusion: The EndoFast Reliant™ system is a trocar-less system for treating POP. The operation has the potential for reducing intra- and post-operative complications, with very satisfactory functional and anatomical results. It was proven safer in this study as compared to trocar system.

Keywords: Pelvic organ prolapse; vaginal mesh; trocar-system; trocarless-system; mesh related complications

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Received: 02 May 2022 **Accepted:** 25 July 2022

INTRODUCTION

In pelvic reconstructive surgery, recurrence of pelvic organ prolapse (POP), especially of cystocele is one of the main concerns and can reach up to 58%.[1] The Cochrane review, based on new randomized controlled trials, shows that the use of mesh at the time of anterior vaginal wall repair reduced the risk of recurrent anterior vaginal wall prolapse by up to 1.5 times.[2] However, there are some main concerns regarding complications while using vaginal mesh and the Food and Drug Administration (FDA) in July 2011 has published a safety notification regarding POP repair with mesh.[3]

Until 2008, most of the transvaginal mesh kits available to treat stress urinary incontinence (SUI) and POP required trocars to introduce the mesh. The trocars which pass blindly through the pelvic walls can cause intra and post-operative complications including: Hematomas, infections, injury to the surrounding organs like bladder, urethra or rectum and pain in case of nerve capture or injury.[4-8] When using trocar-less systems, the procedure is performed trans-vaginally without any need of per-cutaneous incisions or blind trocar passages, thus, trocar-less mesh kits may be a safer solution for inserting the mesh, if they can be proved as equally effective. Results of POP repair with one of the trocar-less kits, the Elevate™ (AMS, USA) system have been satisfactory, with similar anatomical results compared to trocar systems, but with less intra- and immediate post-operative complications.[9,10]

The EndoFast Reliant™ system is a minimally invasive system for the treatment of POP using a single-incision, trocar-less technique.[11] The system consists of a light polypropylene monofilament mesh (<40 g/m^2), fixation devices that include soft tissue fasteners and a retrieval device. The fasteners are deployed through small incision in the skin into soft tissue, with a shallow tissue penetration (2 mm). The shallow penetration reduces the possibility for visceral damage, muscle hematomas, nerve injury and post-operative pain. Each fastener can support an initial average weight of 1.0 kg, far more than required in a typical POP repair procedure.[12]

The aims of the study were to evaluate the safety and efficacy of a trocar-less system (EndoFast Reliant™) designed for POP repair by comparing the anatomical and functional results as well as complications between trocar and trocar-less systems.

MATERIALS AND METHODS

Study Design and Subjects

This is a retrospective, comparative study of 2 cohorts of patients. A Local Ethical Committee approval was obtained for the study in both Ziv Hospital, Israel and CHU Hospital Caen, France.

The main outcomes were pre- and post-operative POP-Q (ICS POP quantification and staging system[13], functional results, intra-operative complications, immediate and long-term complications.

The study includes in total 230 patients in 2 groups. The study group includes all patients (107) operated for the treatment of POP with the EndoFast Reliant™ system between December 2010 and January 2013 in the gynecology department at Ziv Medical Center, Israel. All patients were operated by one surgeon (NMB) after training with trocar and trocar-less kits designed for POP repair. Data for the study was collected from the patient's files.

The control group includes all patients (123) that were operated with the IVS TUNNELLER™ (Tyco Healthcare) trocar system by one surgeon (PvT) at the gynecology department of the CHU of Caen, France. Data was collected retrospectively between the years 2008-2010.

Data collection included demographic features, pre and post-operative examination and symptoms. Intra and post-operative complications. Patients were seen at 6 weeks, 6 and 12 months post-operatively and annually since. Pre-operative evaluation included a physical examination and review. Prolapse stage was determined by using the POP-Q and cough stress test for SUI (obvious or occult). In addition, all patients were asked systematically pre- and post-operatively about pain, dyspareunia, urinary, and defecation symptoms. Questions included: Urge symptoms, urge incontinence, nocturia, SUI, constipation and dyschezia. Success was defined as no bulge symptoms and prolapse less or equal to stage 2.

Each woman in the study and control group underwent an anterior and/or posterior repair. Apical repair was always carried out by the posterior kit in both groups either with or without rectocele prolapse correction. In both groups, the uterus was usually preserved and a mid-urethral sling procedure was performed on any woman with SUI (obvious or occult), in addition to the anterior/posterior repair.

Surgical Technique

Trocar-less system, study group

The EndoFast Reliant™ system is a minimally invasive system for the treatment of POP using a single-incision, trocar-less technique.[11] The system consists of a light polypropylene monofilament mesh (<40 g/m^2), fixation devices that include soft tissue fasteners- the Spider fasteners and a retrieval device. The fasteners are deployed through small incision in the skin into soft tissue, with a shallow tissue penetration (2 mm) Spider. The anterior mesh is designed for the treatment of cystocele and

has 4 arms. The posterior mesh is designed for the treatment of apical defect either with or without accompanied rectocele or for the treatment of isolated rectocele, and has 4 arms. The Spider fastener attaches the mesh to the soft tissue guided by direct view and/or palpation. In addition, the system includes a retrieval device, which allows intra-operative reversibility of fixation without causing damage to the tissue or the mesh.

Anterior Repair (Anterior Kit)

Dissection: A midline full thickness incision is performed on the anterior vagina extending up to 3 centimeters from the urethral meatus. The bladder is dissected away from the vaginal wall, leaving the Halban's fascia on the epithelium. The para vesical fossas are opened until the ischial spine and the arcus tendineous of the levator ani are reached posteriorly and the ischiopubic rami anteriorly.

Mesh insertion: The posterior part of the mesh is sutured to the uterine cervix or to the vaginal vault with one or two sutures. Using the Spider fasteners, the posterior arms are fixed through the same incision to the soft tissue which covers the ischial spine, 1 cm laterally on both sides. The anterior arms are fixed through the same incision to the fascia of the internal obturator muscle utilizing the fasteners. An additional one or two sutures under the bladder neck can be added in order to prevent mesh slipping. The attachment of the 4 arms in these anatomical landmarks creates a tension-free, sub-vesical hammock to treat the cystocele.

Apical and Posterior Repair (Posterior Kit)

Dissection: A midline full thickness incision is performed on the posterior vagina extending up to 1 cm from the uterus cervix or vaginal vault. The para rectal fossas are opened until the ischial spine and the sacrospinous ligaments are reached.

Mesh insertion: The posterior part of the mesh is sutured to the uterine cervix or the utero-sacral ligaments or to the vaginal vault with one or two sutures. The posterior arms of the mesh are fixed to the sacrospinous ligaments, 2 cm medial from the ischial spine by using the Spider fasteners which are inserted through the same incision. In case of rectocele, the anterior arms are fixed to the pubo rectalis muscle on both sides after dissection of the rectum.

Trocar System, Control Group

Patients were operated with the IVS TUNNELLER™ (Tyco Healthcare) trocar system. The surgical technique was described in full by Eboue et al.[7]

Statistical Analysis

In order to compare the change in variables pre- and post-operative, the paired t-test was applied for the quantitative variables of the POP-Q score, and the McNemar test was used for the categorical variables of the POP functional symptoms. The association between categorical variables and the group they belong to (study group vs. control group) was assessed using the χ^2 test of independence, or the Fisher's Exact test. The variables which were found to be significantly associated with the dependent variable (intra and immediate post-operative complications) in the univariate analyses were entered into a multivariate logistic regression model to test the effect of surgical technique correcting for confounders. All statistical tests applied were 2-tailed and a *p*-value of 5% or less, was considered statistically significant.

RESULTS

Data was collected from patient's files and included 107 patients in the study group and 123 patients in the control group. One patient in the study group and 3 in the control group were lost for follow-up. Demographic features of both groups are summarized in Table 1. Differences between the groups were noted for parity (Israeli versus French populations) and longer average follow-up for the control group. Twenty three percent had previous hysterectomy in the study group versus 15% in the control group. Overall, 12% in the study group and 18% in the control group had previous native tissue prolapse repair.

The occurrence of complications intra- and post-operative is summarized in Table 2. The total early complications (intra and immediate post-operation), included bladder injury, hematomas, fever, post-operative voiding dysfunction and catheterization more than first 24 hours were significantly higher in the control (trocar) group [39/123 (31.7%) versus 4/107 (3.7%) in the trocar-less group, ($p<0.001$)]. Mesh erosion rate was also higher in the control group. These results explain the higher re-operation rate in the control group. Statistical analysis was preformed

Table 1. Demographics of the trocar-less and trocar groups

Trocar-less group	Age	60.7±8.8 (43-82)*
	Parity	4.4±2.5 (1-13)*
	BMI	27.6±4.2 (19.1-37.8)*
	Follow-up (months)	13.6±8.9 (1-36)*
Trocar group	Age	62.3±11.4 (35-81)*
	Parity	2.6±1.4 (0-7)*
	BMI	25.0±3.5 (16.0-35.2)*
	Follow-up (months)	34 (1.5-52)*

*average, standard deviation and range; BMI: body mass index

Table 2. Surgical complications for both groups				
		Trocar-less (n, %)	**Trocar (n, %)**	**p**
Intra-operative complications	Significant bleeding	0/107 (0.0%)	3/123 (2.4%)	0.1*
	Bladder injury	0/107 (0.0%)	3/123 (2.4%)	0.1*
Immediate post-operative complications	UTI/fever	3/107 (2.8%)	22/123 (17.9%)	<0.001*
	Urinary retention and need for short period[#] catheterization	1/107 (0.9%)	17/123 (13.8%)	<0.001*
	Hematoma	1/107 (0.9%)	4/123 (3.3%)	0.23*
Long term post-operative complications	Mesh erosion	2/107 (1.9%)	10/123 (8.1%)	0.03*
	de novo SUI	3/50*** (6.0%)	9/65*** (13.8%)	0.29*
	de novo urgency	8/51**** (15.7%)	12/83**** (14.5%)	0.85*
	Recurrent prolapse-non-mesh repaired site	6/107 (5.6%)	1/123 (0.8%)	0.05**
	Recurrent prolapse-procedure failure	5/107 (4.7%)	7/123 (5.7%)	0.73*
	Recurrent prolapse-due to elongation of cervix	1/107 (0.9%)	1/123 (0.8%)	1**
	Recurrent operation due to complications or *de novo* SUI	5/107 (4.7%)	19/123 (15.4%)	0.01*

*calculated by pearson's χ^2 test; **calculated by fisher's exact test; *** the denominator represents women without SUI post-operatively; **** the denominator represents women without urgency post-operatively; [#] short perid-until 4 weeks; SUI: stress urinary incontinence

to detect potential confounders which might be associated with the early complications. Variables of demographics, prior gynecological operations, type of surgical repair performed (anteior/posterior) and pre-operative symptoms were evaluated as potential confounder variables. Parity, anterior repair, as well as pre-operative voiding difficulty were found to be significantly associated with early complications. In order to test the significance of the surgical technique (trocar-less vs. trocar systems) controlling for the above confounders, a multivariate logistic regression model was applied. In this model, only the surgical technique (trocar versus trovcar-less) remained statistically significant (p=0.001), odds ratio=13.9, as seen in Table 3.

Anatomical results for the study group are presented in Table 4. The anatomical results at last visit were very good with almost 94% success rate. Six patients (5.6%) were considered as failure, all were in the apical compartment, but only four (3.7%) were symptomatic. Data regarding the POP-Q examination of the control group was available only for 6 months post-operatively. The anatomical results were compared between the 2 groups. There were no differences between the groups at 6 months, as

Table 3. Potential confounders which might be associated with the early complications, logistic regression				
	p*	**Adjusted OR**	**95% CI for OR**	
			Lower	**Upper**
Procedure method	**0.001**	13.986	2.979	65.668
Parity	0.990	0.998	0.791	1.261
Voiding difficulty	0.502	1.302	0.603	2.814
Anterior repair	0.478	0.482	0.064	3.613
Constant	0.001	0.058		

*calculated by the wald test; CI: confidence interval; OR: odds ratio

Table 4. POP-Q pre- and post-operation, study group			
	Pre-operation [average ± SD, (range)]	**Post-operation [average ± SD, (range)]**	***p***
Ba	0.5±2.3 [(-3)-6]	-2.3±1.1 [(-3)-2]	<0.001
Bp	-1.2±2.0 [(-3)-7]	-2.8±0.5 [(-3)-(-1)]	<0.001
C	-1.3±4.2 [(-8)-7]	-6.9±2.9 [(-9)-5]	<0.001
D	-2.1±3.8 [(-9)-6]	-8.0±2.5 [(-10)-5]	<0.001

POP-Q: pelvic organ prolapse-quantification; SD: standard deviation

Table 5. Six months post-operatively anatomical results in both groups		
	Trocar-less group (n, %)	**Trocar group (n, %)**
Stage 0-1	103/106 (97.2%)	119/120 (99.2%)
Stage 2	3/106 (2.8%)	1/120 (0.8%)

shown in Table 5. In both groups, anatomical success was 97 and 99 percent.

Functional symptoms of the study group were analyzed before and after surgical intervention and are shown in Table 6. There was improvement in all categories. *De novo* dyspareunia was found only in 2 patients (1.9%), one because of tension on one of the arms and the second due to traction at one of the fixation points. Both had re-operation to release the arm and improved.

DISCUSSION

Vaginal wall reinforcement surgeries with transvaginal mesh for the treatment of POP are well established in the literature with large series and randomized trials proving safety, high cure rates and patient's satisfaction.[2,4,8,14-17] Since the FDA warning in 2011,[3] there is a big debate regarding the use of vaginal meshes and guidelines have been published in order to limit the mesh-related complications rate, mainly advising to limit the use for patients with high risk for recurrence, to have a good inform consent and that the surgeon has an adequate training in the field and keeps high volume practicing.

Many of the commercial kits used for POP repair were trocar-guided for the insertion of the mesh into the pelvic floor. Insertion of the mesh with trocars can cause intra and immediate post-operative complications including: Hematomas, infections, injury to the surrounding organs like bladder, urethra or rectum and pain.[4-8] The use of those kits, can explain many of the mesh-procedure related complication rate and not necessarily the mesh itself. The advantages of the trocar-less systems are gained mainly by bypassing the need of blind trocar insertion. While reducing the probability for complications, the trocar-less system also provides a quicker and less invasive operation with reduced morbidity.

Results of the Elevate™ System (AMS USA), a trocar-less system, have been satisfactory, with long term evaluation with similar anatomical results compared to trocar systems, but with less mesh erosion and extrusion incidence, and with less bladder and urinary injuries.[9,10] First results with the EndoFast Reliant™ system were recently published.[11] The EndoFast Reliant™ system can be easily and directly deployed trans-vaginally in narrow spaces through the soft tissue via a single vaginal incision and support substantially more weight than other available trocar-guided techniques.[12] The fasteners' penetration into the tissue is very superficial (2 mm), thus can reduce the possibility for visceral damage, muscle hematomas, nerve injury and post-operative pain.

When testing a new technique like the trocar-less way for introducing the mesh, few aspects should be considered: Efficacy and safety. Efficacy means that the anatomical and functional results are as good as for the trocar kits. Safety can be compared by the rate of complications.

In this study, actually, the trocar versus trocar-less passage was compared. Both groups were operated in the same way, as the surgeon of the trocar-less group has trained for two years with the surgeon of the trocar group. The operation technique was identical with only the different method for the insertion of the mesh; with or without trocar.

Regarding efficacy, the anatomical results with the EndoFast Reliant™ system were very satisfactory. The pre- and post-operative difference in the POP-Q score is statistically significant, $p<0.001$ in all categories of the POP-Q (Ba, Bp, C, D) (Table 4), and long-term results are promising. When comparing the anatomical results to the control group, it is similar in both groups with the same rate of failure at the long term.

As for safety, comparing surgical complications between the two groups in this study (Table 2), there were significantly fewer complications in the less group. The trocar group complications mainly include intra-operative and immediate post-operative complications such as UTI, bladder injury, fever, hematoma and voiding dysfunction (which resulted in catheterization for more than 24 hours). Those complications can be associated with

Table 6. Functional symptoms pre and post-operation			
	Pre-operation (n %)	**Post-operation (n, %)**	***p****
Dyspareunia	13/48** (27.1%)	7/48** (14.6%)	0.07
SUI	57/107 (53.3%)	8/107 (7.5%)	<0.001
Urgency	56/107 (52.3%)	25/107 (23.4%)	<0.001
Voiding difficulty	63/107 (58.9%)	0/107 (0.0%)	<0.001
Constipation	30/107 (28.0%)	26/107 (24.3%)	0.54
*calculated by mcnemar's test; ** 48 women were sexually active; SUI: stress urinary incontinence			

the use of the trocars which can cause more hematomas and bladder injury. The trocar system can also cause some pressure on the bladder neck due to tension and as a result, cause voiding dysfunction and catheterization.

In regards to the number of patients in each group that suffered early complications (intra and immediate post-operative), there were 4 (3.7%) and 39 (31.7%) in the trocar-less and trocar groups, respectively. This difference in the early complication rate between the groups is statistically significant with $p<0.001$. In a multivariate logistic regression, only the surgical technique remained statistically significant as a cause for the different between the groups ($p=0.001$), odds ratio=13.9 (Table 4).

Regarding the long-term complications, the erosion rate was higher in the trocar group (8.1% in the trocar group vs. 1.9% in the trocar-less group). This finding can be explained by the type of mesh that was used in the IVS system and not necessarily due to the use of the trocars. Ultimately, the overall complication rate and re-operation was higher in the trocar group.

Functional symptoms in the study group were improved as can be seen in Table 6. The difference and improvement pre- and post-operatively in 3 of the symptom variables, SUI, urgency and voiding difficulty was statistically significant.

SUI (obvious or occult) was diagnosed in 57 patients in the trocar-less group and they all had an additional mid-urethral sling inserted during the prolapse repair. Only 3/50 patients (6%) suffered from *de novo* SUI after the surgical procedure. A recent systemic review has shown that combination surgery of prolapse repair and prophylactic SUI intervention reduces the risk of SUI *de novo*.[18] In this cohort of women, only symptomatic or occult SUI patients were treated with mid-urethral sling. Still, the rate of *de novo* SUI was low.

Out of 56 patients that had urgency symptoms pre-operatively in the study group, 39 (69.6%) were cured by the repair of the prolapse and 8 patients developed *de novo* urgency.

All of the patients (100%) in the trocar-less group who suffered from incomplete voiding pre-operatively were cured by the repair of the prolapse and there were no *de novo* cases. In comparison, in the trocar group, 17 patients (13.8%) suffered from *de novo* urinary retention, and out of these patients, 4 needed a surgical intervention to release the tension of the mesh to solve the problem. The insertion of the mesh with trocars can cause excessive tension on the bladder neck and therefore voiding difficulties, although normally transient. The trocar-less system may permit a better adjustment of the tension, thus less post-operative voiding difficulties are likely to occur.

In the study group, pre-operative dyspareunia due to the prolapse disappeared for 7 patients. *De novo* pain and dyspareunia was found in 2 patients (2/107, 1.9%), one due to tension on one of the arms and the second due to traction at one of the fixation points. Both had re-operation for releasing the arm and improved. No case of lasting pain was described. Dyspareunia and perineal pain are major complications after mesh operations with great influence on women's quality of life. The dyspareunia rates are varying and in certain series reach 16.7%.[19-22] Dyspareunia post transvaginal mesh surgery is mainly related to over tension or mesh shrinkage; both are responsible for deformation of the vagina and thereby causing dyspareunia. The use of two separated incisions with two separated meshes when repairing anterior and posterior defects can be the reason for better vaginal results without any deformation and therefore no signs of dyspareunia. Perineal pain which is a rare complication,[4-6] can be caused by post-operative hematoma, nerve captured or nerve injury. The trocar-less systems can decrease the rate of the muscles hematomas and therefore decreased this kind of post-operative pain. The spider fasteners hold the mesh while capturing the fascia very superficially, thus reducing the risk of nerve capture or injury.

Complications related to the adjuvant materials and risk factors are well described in the literature[5,23,24] and infections have nearly disappeared since the generalized use of knitted polypropylene monofilaments implants.[6,25,26] The EndoFast Reliant™ system consists of a monofilament polypropylene mesh of <40 g/m^2. There were two cases of small erosions (1.9%), which improved under estrogen therapy and there was no need for surgical intervention. There were no cases of mesh infections in the trocar-less group.

This study, aimed to prove that mesh-related complications can be reduced, and it is pity that many surgeons abandon the vaginal mesh completely.[27]

Study Limitations

This study has a few limitations due to its retrospective and comparative nature and is therefore susceptible to recall and interpretation biases: Firstly, comparing different groups from two separate countries can be problematic and not all data was available for all patients. In addition, each group was operated in a different hospital with a different surgeon. However, the surgeon operating in Ziv did her training in Caen, France so the surgical methods and techniques were the same. It should also be mentioned that both kits are no more in the market now days. There are strengths to the study: All data was collected by an independent student (as part of his MD thesis) which reduces the chance for bias. In addition, both groups were operated in the same way and surgical technique which truly permit the comparison between the ways of inserting the mesh, with or

without trocars. Finally, up to date, there have been very few publications on the EndoFast Reliant™ system, with small groups and short follow-up, hence the importance of this study.

CONCLUSION

EndoFast Reliant™ is a minimally invasive system for treating POP using a single vaginal incision, trocar-Less technique. The operation has the potential for reducing intra- and post-operative complications, with very satisfactory functional and anatomical results. The surgical technique (trocar-less system vs. trocar system) was found as the only variable statistically significant with the colorations to early complications. It was proven safer in this study as compared to trocar system. Further, larger comparative studies and long-term results are required.

ETHICS

Ethics Committee Approval: A Local Ethical Committee approval was obtained for the study in both Ziv Hospital, Israel and CHU Hospital Caen, France (number: 0076/13, 2013).

Informed Consent: Retrospective study.

Peer-review: Externally peer-reviewed.

Contributions

Surgical and Medical Practices: N.M., P.V.T.; Design: N.M., P.V.T.; Data Collection or Processing: Y.A., C.E.; Analysis or Interpretation: N.M., Y.A.; Writing: N.M., Y.A., C.E., P.V.T.

DISCLOSURES

Conflict of Interest: Prof. Peter von Theobald was consultant for Tyco Healthcare between the years 2004-2010. Dr. Naama Marcus is was consultant for IBI medical 2012-2018.

Financial Disclosure: The authors declared that this study received no financial support.

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DOI: 10.34057/PPj.2022.41.02.2022-6-1
Pelviperineology 2022;41(2):112-117

The association between mesh-to-urethra distance and lower urinary tract symptoms in stress urinary incontinence patients surgically treated with an intra-operatively trimmed single incision mini-sling

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Citation: Karakaş Paskal E, Akbaba E, Sivaslıoğlu AA. The association between mesh-to-urethra distance and lower urinary tract symptoms in stress urinary incontinence patients surgically treated with an intra-operatively trimmed single incision mini-sling. Pelviperineology 2022;41(2):112-117

ABSTRACT

Objectives: We aimed to explore the association between mesh-to-urethra distance (MUD) and lower urinary tract symptoms (LUTS) in stress urinary incontinence (SUI) patients implanted with a single incision mini-sling (SIMS).

Materials and Methods: This study included the patients who visited Urogynecology Outpatient Department of Muğla Sıtkı Koçman University Training and Research Hospital from November 2018 to November 2019 complaining of urinary incontinence and were diagnosed as having SUI. The patients were preoperatively questioned for their demographic characteristics, LUTS and any additional complaints. All patients underwent SIMS surgery with mesh trimmed during the operation. During the follow-ups carried out 48 hours, one month, and four months after the surgery, ultrasound to measure the distance from MUD was performed and patients were re-inquired about LUTS.

Results: When MUD was postoperatively evaluated with regards to SUI, most successful outcomes were achieved when MUD was 2.69±1.25 mm (p<0.001), 2.68±1.30 mm (p<0.001) and 2.42±0.96 mm (p<0.001) at 48 hours, one month, and four months after the surgery, respectively. In terms of urination frequency, SUI surgery was successful when MUD was 2.93±1.36 mm (p=0.012) and 2.85±1.34 mm (p=0.001) at month one and month four, respectively. For nocturia, MUD was statistically significant at postoperative month four and nocturia of patients regressed when MUD was 2.78±1.21 mm (p=0.001).

Conclusion: MUD seems to be a good predictor of treatment success in SUI treatment. There is a linear correlation between LUTS and MUD. To the present date, there is no study on association of LUTS and MUD in patients treated with mini slings.

Keywords: Mini-sling; mesh; stress urinary incontinence; urethra

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Received: 07 June 2022 **Accepted:** 27 July 2022

INTRODUCTION

Urinary incontinence (UI) has a remarkable negative impact on female quality of life (QoL).[1,2] There has been a number of therapeutic modalities for UI, the most effective of which is surgical intervention relying on the use of mid-urethral slings at the first place. The single-incision mini slings (SIMS) have hattained a widespread use since 2006 owing to its minimal invasive fashion, resulting in fewer complications as retro-pubic or obturator path is not involved in procedure, and short-term post-operative outcomes comparable with conventional methods.[3-5]

The distance between the deployed mesh and urethra (MUD) plays a role on the success of surgery.[6] The mesh can be conveniently displayed through transperineal ultrasound (TPUS) and thus the MUD can be measured.

In this study, our aim is to search for the association of MUD and lower urinary tract symptoms (LUTS) in stress UI (SUI) patients who have undergone SIMS surgery with mesh trimmed during the operation.

MATERIALS AND METHODS

This is a prospective, cross sectional, case-control study which has been approved by Local Clinical Research Ethics Committee (date: 22 Dec 2018 no: 22/VII) of Muğla Sıtkı Koçman University Faculty of Medicine and recruited patients who presented to the hospital's urogynecology outpatient department between November 2018 and November 2019. The patients with any of the following criteria were excluded from the study: A systemic disease (chronic obstructive pulmonary disease, uncontrolled diabetes mellitus, and rheumatoid diseases), history of medication use effecting the urinary tract, urinary tract obstruction, ongoing urinary tract infection, >stage II pelvic organ prolapse (POP) according to POP quantification system, diagnosis of mixed UI, and past pelvic surgery. Among the patients meeting the inclusion criteria, 50 women diagnosed with SUI were included in our study. Verbal and written information was provided to all patients and their informed consents were obtained.

Patient demographics were recorded on admission. Complete urinalysis, urine culture, and blood glucose levels were evaluated.

During the preoperative workup, patients were placed in lithotomy position and thus cough stress test (CST) was applied. In cases with a negative CST result at lithotomy position, the test was repeated while patient was standing. Test was considered positive in the event of urine leakage observed upon coughing or straining. Preoperative query also included LUTS (such as urine leakage, intermittent stream, urinary frequency, urgency, nocturia, pelvic pain, coital incontinence, hesitancy, dysuria, and presence of additional complaints). Voiding >8 times during waking hours was accepted as urinary frequency and >2 times during night was accepted as nocturia.

In order to avoid surgeon-related bias, only the surgeries performed by the same surgeon were included into this study. All surgeries were performed under spinal anesthesia. The patients were placed into lithotomy position. Bladder catheterization was performed using a 18F Foley catheter. A full-thickness incision was performed through the vaginal mucosa at the level of mid-urethral area, that is, 1 cm below the external urethral meatus. Bilateral paraurethral pouches were formed on both sides of urethra making dissections underneath the pubocervical fascia (PCF) toward the retro-pubic space. Monofilament polypropylene mesh was trimmed down to a size of 6 cm of length and 8 mm of width. The mesh was grasped with Péan forceps and inserted through each of the tunnels dissected in paraurethral pouches allowing a rim around the urethra. A space of the thickness of a Metzenbaum scissors was left between the mesh and urethra. PCF was plicated over the mesh. The incision line was closed with separate sutures. Foley catheter was retracted at 8 to 16 hours postoperatively. Patients were discharged to home 24 hours after surgery provided that micturition occured, on average. The patients were instructed to return for a follow-up check at postoperative 48th hour, month 1, and month 4. During the follow-ups, TPUS was repeated and LUTS were re-questioned.

TPUS was performed by the same single investigator while patient bladder was full and once patients were placed into lithotomy position using a GE, Voluson E6 system, vaginal probe. Vaginal probe was taken at vertical position and placed into perineal region. The probe was advanced 2-3 cm along vaginal introitus to pinpoint the location of bladder, urethra, and positional relationship between mesh and urethra. Then, probe was moved to the horizontal axis allowing visualization of pubic bone, bladder neck, urethra, and mesh. In US exam, mesh and pubic bone had a hyperechoic appearance whereas urethra and bladder had hypoechoic appearance. The distance from mesh to urethra was measured from the mesh edge which is closer to urethra in a perpendicular manner to the urethral lumen including the urethral wall (Figure 1, 2).

Statistical Analysis

Statistical analysis was done using SPSS (Statistical Package for Social Sciences) for Windows 17.0. Kolmogorov-Smirnov test was used to verify normal distribution of data. Quantitative (numeric) data were presented as mean ± standard deviation if they have a normal distribution and as median (minimum-maximum) if they have non-normal distribution. Groups with

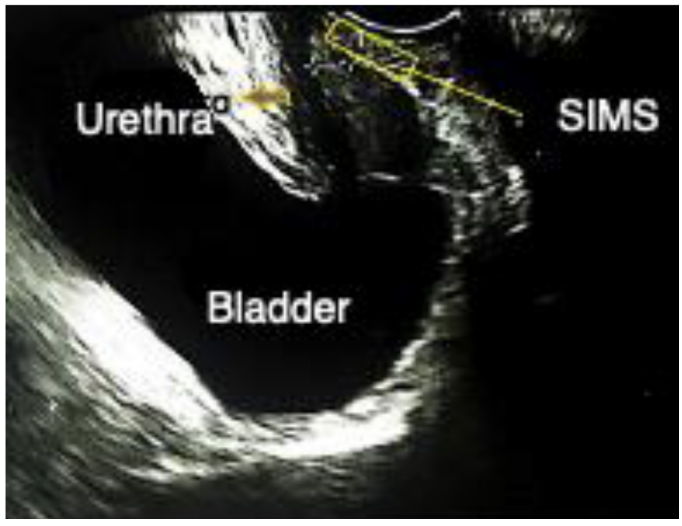

Figure 1. Mesh visualized by TPUS mesh-to-urethra distance: The area between the (+) signs

TPUS: transperineal ultrasound

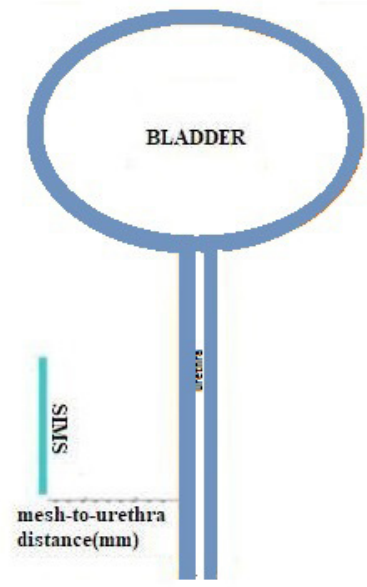

Figure 2. Mesh localization, measurement of the mesh-to-urethra distance

normally distributed variables were compared using Student's t-test. The *p*-value was set at <0.05 for statistical significance.

RESULTS

In total, 50 women were included in this study. Demographic features of patients are given in Table 1.

Data from preoperative inquiry about LUTS are shown at Table 2.

Table 3 tabulates the correlation between MUD and LUTS of patients as determined at follow-ups conducted 48 hours, one month and 4 months after surgery. In patients with persistent postoperative SUI and hesitancy, MUD measurements were significantly different ($p<0.001$) (Table 3). Accordingly, the longer the MUD, the more frequent SUI was. On the other hand, as MUD got smaller, an increased rate of patients was inflicted with hesitancy. Other LUTS did not have any significant correlation with MUD as determined 48 hours after the surgery.

During the evaluations carried out 48 hours after the surgery, the patients no longer complaining of SUI had a mean MUD of 2.69±1.25 mm in comparison to 4.26±1.28 mm in those with ongoing SUI ($p=<0.001$). In addition, MUD had a significant correlation with hesitancy. Patients with hesitancy had a mean MUD of 1.55±0.07 mm, whereas those without hesitancy had a mean MUD of 3.16±1.42 mm ($p<0.001$).

When patients were examined one month after the surgery, MUD was significantly correlated with SUI and frequency. Such that, MUD, on average, was 4.39±0.76 mm in patients with persistent SUI while measured as 2.68±1.30 mm in patients with regressed SUI ($p<0.001$). Patients with ongoing urinary frequency had a mean MUD of 4.11±1.15 mm, whereas those with decreased frequency had a mean MUD of 2.93±1.36 mm

Table 1. Demographic features of patients

	Mean	Minimum-maximum
Age (years)	54.08±11.96	30-80
Gravidity (n)	2.92±1.29	1-6
Parity (n)	2.24±0.77	1-4
BMI (kg/m^2)	28.42±5.05	16-46.7

BMI: body mass index

Table 2. Preoperative symptoms of patients

Lower urinary tract symptoms		(n=50)	
		n	%
Intermittent stream	No	37	74.0
	Yes	13	26.0
Frequency	No	8	16.0
	Yes	42	84.0
Urgency	No	11	22.0
	Yes	39	78.0
Nocturia	No	4	8.0
	Yes	46	92.0
Pelvic pain	No	21	42.0
	Yes	29	58.0
Coital incontinence	No	39	78.0
	Yes	11	22.0
Hesitancy	No	43	86.0
	Yes	7	14.0
Dysuria	No	46	92.0
	Yes	4	8.0

Table 3. The correlation between MUD and LUTS of patients as determined at 48-hour, 1-month and 4-month follow-ups after surgerys

	48 hours			1 month			4 months		
	n	Mean ± SD (mm)	*p*	n	Mean ± SD (mm)	*p*	n	Mean ± SD (mm)	*p*
SUI	No (n=37)	2.69±1.25	**<0.001**	No (n=35)	2.68±1.30	**<0.001**	No (n=32)	2.42±0.96	**<0.001**
	Yes (n=13)	4.26±1.28		Yes (n=15)	4.39±0.76		Yes (n=18)	4.58±0.95	
Intermittent stream	No (n=48)	3.12±1.43	0.547	No (n=47)	3.16±1.43	0.475	No (n=48)	3.17±1.43	0.548
	Yes (n=2)	2.50±1.41		Yes (n=3)	3.76±0.51		Yes (n=2)	3.80±0.84	
Frequency	No (n=39)	2.95±1.38	0.179	No (n=39)	2.93±1.36	**0.012**	No (n=39)	2.85±1.34	**0.001**
	Yes (n=11)	3.61±1.53		Yes (n=11)	4.11±1.15		Yes (n=11)	4.43±0.90	
Urgency	No (n=46)	3.09±1.43	0.890	No (n=46)	3.17±1.42	0.740	No (n=47)	3.15±1.43	0.340
	Yes (n=4)	3.20±1.52		Yes (n=4)	3.42±1.23		Yes (n=3)	3.96±1.07	
Nocturia	No (n=34)	2.85±1.44	0.073	No (n=35)	3.03±1.43	0.211	No (n=35)	2.78 ± 1.21	**0.001**
	Yes (n=16)	3.63±1.28		Yes (n=15)	3.58±1.29		Yes (n=15)	4.18±1.40	
Pelvic pain	No (n=23)	3.13±1.57	0.890	No (n=39)	3.12±1.50	0.483	No (n=42)	3.11±1.40	0.321
	Yes (n=27)	3.07±1.32		Yes (n=11)	3.46±0.95		Yes (n=8)	3.66±1.50	
Coital incontinence	No (n=50)	3.10±1.42	-	No (n=49)	3.17±1.40	0.476	No (n=48)	3.17±1.43	0.582
	Yes (n=0)	-		Yes (n=1)	4.20±0.00		Yes (n=2)	3.75±0.91	
Hesitancy	No (n=48)	3.16±1.42	**<0.001**	No (n=49)	3.23±1.38	0.174	No (n=50)	3.20±1.41	-
	Yes (n=2)	1.55±0.07		Yes (n=1)	1.30±0.00		Yes (n=0)	-	
Dysuria	No (n=50)	3.10±1.42	-	No (n=50)	3.19±1.40	-	No (n=50)	3.20±1.41	-
	Yes (n=0)	-		Yes (n=0)	-		Yes (n=0)	-	

MUD: mesh-to-urethra distance; LUTS: lower urinary tract symptoms; SD: standard deviation

(p=0.012). According to our results, the greater MUD gets, the more the complaints of SUI and frequency are. Depending on the patient responses to our inquiries about LUTS one month after the surgery, there was no statistically significant association among the results.

When inquiries and evaluations were repeated four months after the surgery, comparing the results of SUI, nocturia, and frequency complaints these found to be in a statistically significant association with MUD. Such that, MUD, on average, was 4.58±0.95 mm in patients with persistent SUI while measured as 2.42±0.96 mm in patients with regressed SUI (p<0.001). Patients with alleviated urinary frequency had a mean MUD of 2.85±1.34 mm, whereas those with ongoing complaint had a mean MUD of 4.43±0.90 mm (p=0.001). Similarly, patients with attenuated nocturia had a mean MUD of 2.78±1.21 mm vs 4.18±1.40 mm in those with ongoing nocturia (p=0.001). Our assessment of MUD with regards to status of SUI, nocturia and frequency complaints demonstrates that as smallest MUD gets, the lowest complaint prevalence and thus the highest surgery success rate can be achieved. We did not find any statistically significant association between MUD and any other LUTS.

DISCUSSION

The main goal of UI surgeries is to maintain continence, to significantly improve QoL, and to ensure the surgery results in minimal morbidity.[7,8]

In a study, patients underwent SIMS and transobturator tape (TOT) surgery and six weeks later CST was negative in 91% of patients in both groups.[9] In the same study, CST was repeated one year after with a negative result in 85% of TOT and in 89% of SIMS receivers. Similarly, in a randomized controlled trial comparing patients implanted with transvaginal tape (TVT) or SIMS, rates of recovery were comparable in both groups (55.8% in SIMS, 66.6% in TVT). In our cohort, 48 hours, one month and four months postoperative CST tests were negative in 74.1%, 70%, and 64% of patients, respectively.

When preoperative evaluations for LUTS were compared to the respective postoperative evaluations, all symptoms regressed upon sling surgery. Our patient cohort was composed of SUI patients, 18 (36%) of whom stated incontinence was ongoing four months after the surgery. Costa et al.[10] investigated a cohort of SUI patients associated with urethral hypermobility whereby 56.3% relieved of urgency and 48.3% relieved of urge

incontinence after TOT insertion. In line with the available literature, symptom of urgency in our cohort declined from a preoperative high level of 78% to postoperative level of 6%.

Among the factors playing a role on the success of sling surgery, the relationship between the inserted synthetic mesh material and the urethra is of paramount importance. Therefore, recent studies have been employing US examination with an attempt to quantify the MUD and the distance from mesh to symphysis pubis (MSD) as well as to elaborate angulation of mesh and the relationship of mesh with mid-urethra.[11]

Chantarasorn et al.[12] have analyzed TOT-inserted patients and concluded success rates were lower in patients with a broader MSD, likewise, the same patient group had persistent or worsened urge UI while patients who suffered voiding dysfunction had narrower distance. The authors have pointed out the mean MSD was 12.29±2.51 mm in patients with ongoing SUI vs 10.81±2.44 mm in patients with alleviated SUI (p=0.032). The same study also reported patients with post-operative persistent or deteriorated urge UI had a mean MSD of 11.9±2.47 mm compared to a 10.46±2.37 mm in improved patients (p=0.006). Further, they measured an average distance of 9.91±1.66 mm in patients who developed voiding dysfunction (p=0.014).

In another study utilizing TPUS, Kociszewski et al.[6] have recruited 72 women with SUI who had underwent TVT surgery and post-operatively evaluated MUD as well as the kinking of the mesh during rest or during Valsalva maneuver. They sought for the correlation of US results and surgery success and have figured out the most successful outcomes were attained when MUD was 3.8 mm. The authors have also specified the distance less than 3 mm was associated to postoperative complications and, on the other hand, if greater than 5 mm, their patients have not benefited from the surgery (p=0.00038).[6] An evaluation in patients treated with TOT identified a mean distance of 24 mm from mesh to internal urethral meatus in whom treatment success was achieved.[13]

In this study, we sought to explore the association of MUD and LUTS in patients who were treated with SIMS. During the first follow-up visit, conducted 48 hours after the surgery, we have identified mean MUD was 4.26±1.28 mm in those with persistent SUI vs. 2.69±1.25 mm in those who gained benefit from sling surgery (p<0.001). In the same follow-up, patients with hesitancy were found to have a mean MUD of 1.55±0.07 mm (p<0.001). There is no other study in the literature evaluating the relationship between MUD and SUI in 48th hour postoperative.

In the second follow-up carried out one month after the surgery, we have found out MUD was statistically significantly positive correlation to SUI and frequency. In our assessment of the association between SUI and MUD, mean MUD in patients with ongoing SUI was 4.39±0.76 mm compared to a mean MUD of 2.68±1.30 mm in those who no longer had SUI (p<0.001). In patients with and without urination frequency, MUD was 4.11±1.15 mm and 2.93±1.36 m on average, respectively (p=0.012).

When our patients returned for the follow-ups on month 4, we have identified a statistically significant association of MUD and each of SUI, frequency, and nocturia. Such that, mean MUD in the group still experiencing SUI was 4.58±0.95 mm, whereas this distance was 2.42±0.96 mm in the group no longer experiencing any SUI (p<0.001). MUD was 4.18±1.40 mm in patients with nocturia compared to 2.78±1.21 mm in patients without nocturia (p=0.001) Likewise, patients with and without frequency complaint had a mean MUD of 4.43±0.90 mm, respectively (p=0.012).

Zhu et al.[14] have demonstrated chronic pelvic pain is a risk factor for UI. Consistently, 58% of our patients were complaining of pelvic pain at preoperative period which declined to 16% in postoperative period.

Abdel-Fattah et al.[15] have stated a higher frequency of *de novo* urge UI in the patients treated with SIMS. The irritation due to the contact of the mesh material to the urethra as a consequence of its position is blamed for the *de novo* urge UI. In our study, on contrary to the literature, no *de novo* urge UI has developed.

In our literature search, we did not encounter any studies to compare MUD and relate it with LUTS in patients who underwent TIMS surgery.

Study Limitations

Limitations of our study are small sample size and restricted time frame of follow-up, which was 4 months.

CONCLUSION

Based on US examination of MUD, LUTS and cut-off values have a linear correlation. In particular, in patients who were treated with SIMS, elimination of the complaints of SUI, frequency and nocturia were observed when MUD was 2.42±0.96 mm, 2.85±1.34 mm and 2.78±1.21 mm, respectively. No correlation was identified between other components of LUTS and MUD. To the best of our knowledge, there has been no previous study on association of LUTS and MUD after implantation of mini slings. Therefore, larger studies with a greater number of patients to be conducted in multiple centers and by different surgeons are needed.

Acknowledgement: This study was originally conducted as a graduation thesis in obstetrics and gynaecology (E.K.P.)

ETHICS

Ethics Committee Approval: This is a prospective, cross sectional, case-control study which has been approved by Local Clinical Research Ethics Committee (date: 22 Dec 2018 no: 22/VII) of Muğla Sıtkı Koçman University Faculty of Medicine and recruited patients who presented to the hospital's urogynecology outpatient department between November 2018 and November 2019.

Informed Consent: Verbal and written information was provided to all patients and their informed consents were obtained.

Peer-review: Internally and externally peer-reviewed.

Contributions

Surgical and Medical Practices: E.K.P., A.A.S.; Concept: E.K.P., E.A., A.A.S.; Design: E.K.P., E.A., A.A.S.; Data Collection or Processing: E.K.P., E.A., A.A.S.; Analysis or Interpretation: E.K.P., E.A., A.A.S.; Literature Search: E.K.P., A.A.S.; Writing: E.K.P., E.A., A.A.S.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study received no financial support.

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ORIGINAL ARTICLE

DOI: 10.34057/PPj.2022.41.02.2022-6-3
Pelviperineology 2022;41(2):118-122

The effect of preoperative briefing on anxiety: A randomized study

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Citation: Altaş ÖF, Kutlucan L. The effect of preoperative briefing on anxiety: A randomized study. Pelviperineology 2022;41(2):118-122

ABSTRACT

Objectives: Contrary to the standard information before the surgery, it was aimed to reveal the effect of detailed verbal information on the anxiety level of the patients.

Materials and Methods: Eighty-four patients included in the study were randomized into 2 groups with 42 patients in each group. While detailed verbal information was given to the patients in group 1 before the surgery, standard information was given to the patients in group 2. Amsterdam Preoperative Anxiety and Knowledge scale (APAIS) questionnaire was applied to all patients for preoperative anesthesia and one hour before the operation, immediately after informing.

Results: There was no significant difference between the two groups in terms of demographic data ($p>0.005$). Before the information, patients in group 1 had higher anxiety and desire for information scores than group 2 ($p<0.001$, $p<0.001$). In the within-group evaluation after the information, there was a significant improvement in each parameter in group 1 ($p<0.001$, $p<0.001$). While a significant increase in anxiety was detected in group 2 ($p=0.02$), there was no statistically significant change in the desire to obtain information ($p=0.21$). In the intergroup evaluation, no significant difference was found in any of the parameters after the information ($p=0.86$, $p=0.40$), while a statistically significant difference was found in the APAIS anxiety and APAIS desire to learn scores when the Δ values were examined ($p<0.001$, $p=0.007$).

Conclusion: In our study, we showed that detailed verbal information before the surgery reduced the patients' anxiety and desire to obtain information.

Keywords: APAIS; preoperative anxiety; preoperative information

INTRODUCTION

Anxiety is a feeling of fear and worry that is perceived as life-threatening and disturbs the person.[1] The feeling of uneasiness and tension, caused by the probability of danger, can cause many physiological and psychological problems by increasing sympathetic, parasympathetic, and endocrine stimuli.[2] While the most important cause of anxiety in the preoperative period

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Received: 15 June 2022 **Accepted:** 10 August 2022

is the feeling of uncertainty, it has been demonstrated in some studies that reducing the patient's anxiety level causes the patient's vital parameters to return to normal levels rapidly, the release of low amounts of corticosteroids to the blood stream with the stress response, and accelerated recovery in the postoperative period.[3,4] In order for the patients to have a worriless period after the surgery and consequently shorten the hospital stay, it is essential that the anxiety level of highly anxious patients is reduced with effective preoperative patient evaluation and information. A high level of preoperative anxiety increases the dose of anesthesia required during surgery and the dose of analgesics needed for postoperative pain management.[5] Patients who will undergo surgery may experience anxiety due to fear related to the type of anesthesia to be applied, not being able to wake up from the surgery, being disabled, experiencing severe pain after the surgery, not being able to work after the surgery, fear of losing control over their own body, and the fear of sexual loss. Studies have reported that 60-80% of the patients who will undergo surgery have anxiety in the preoperative period.[6,7] Preoperative anxiety is important for anesthetists and surgeons. According to the results of an observational study conducted on more than 15,000 patients who had undergone non-obstetric surgical procedures, anxiety was reported to be the most common problem in the perioperative period.[8]

In our study, we aimed to reveal the effects of detailed preoperative briefing on the anxiety level of patients, as opposed to standard briefing, and also to exhibit the relationship of this situation with the type of anesthesia.

MATERIALS AND METHODS

In our prospective, randomized controlled study, 100 patients who were scheduled to undergo surgery between October 2021 and March 2022 at the Department of Anesthesiology and Reanimation of Çiğli Training and Research Hospital of İzmir Bakırçay University were evaluated. Included patients were aged between 18 and 65, had an American Society of Anesthesiologists (ASA) score of 1-2, did not use sedatives, psychiatric drugs, or had chronic alcohol consumption, and were able to communicate. Patients with reading and comprehension problems and hearing impairment were not included in the study. Sixteen patients who did not meet the inclusion criteria were excluded from the study. Eighty-four patients were included in the study. The patients were randomly divided into two groups and each group consisted of 42 participants. In addition to the information given to the patients during preoperative anesthetic assessment in normal practice, patients in group 1 were given detailed information about the procedure to be performed and all their questions were answered by an anesthesiologist one hour before the surgery. Patients in group 2 were briefed as per the standard preoperative anesthetic assessment. The Amsterdam Preoperative Anxiety and Information scale (APAIS) questionnaire was administered to both groups immediately after the preoperative anesthetic assessment and immediately after the briefing given one hour before the surgery.

The study protocol was approved by the Clinical Research Ethics Committee of İzmir Bakırçay University (decision no: 345/06.10.2021). Written informed consent was obtained from all patients, and all stages of the study were performed in accordance with the principles of the Declaration of Helsinki.

Evaluation Parameters

Demographic data such as age, height, weight, marital status, occupation, and the educational level of the patients included in the study were recorded. In addition, the type of anesthesia to be administered (general or regional), the type of the surgical procedure to be performed (low, medium, or high-risk) and ASA scores were noted on the evaluation form. The patients' anxiety and desire to obtain information were evaluated using the APAIS questionnaire.

In 1996, the Moerman et al.[9] group in the Netherlands developed the APAIS to assess preoperative anxiety. In this test, anxiety is categorized as anxiety about surgery and anesthesia and anxiety due to lack of knowledge. APAIS includes six statements to evaluate these subgroups. While questions 1, 2, 4, and 5 indicate the total anxiety score, questions 3 and 6 question the desire to obtain information. A 5-point Likert scale is used to score these statements: 1=none, 2=mild, 3=moderate, 4=severe, 5=extreme. While the lowest score is 6, the highest score is 30.[9] Validity and reliability study of the APAIS in Turkish was performed by Çetinkaya et al.[10]

Statistical Analysis

Statistical analysis was performed using IBM SPSS v.24.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were expressed as mean ± standard deviation, median (minimum-maximum), or number and frequency. Fisher's Exact and Pearson's chi-square tests were used to compare the categorical variables between the groups, while the Mann-Whitney U test was used for continuous variables. Values before and after treatment were compared using the Wilcoxon test. The relationship between the variables was evaluated using Spearman's correlation analysis. The repeated measures of covariance analysis was performed to adjust for the effect of potential confounding factors such as age and gender. A p-value of <0.05 was considered statistically significant.

RESULTS

Eighty-four patients were included in the study. The patients were randomly divided into two groups and each group consisted of 42 participants. In comparison of the demographic data, no statistically significant difference was found between the two groups ($p>0.05$) (Table 1).

Considering the clinical data, a statistically significant difference was found between the groups in terms of APAIS anxiety and APAIS desire to obtain information scores before briefing ($p<0.001$, $p<0.001$). In the evaluation made after the briefing, a statistically significant intragroup improvement was observed in each parameter in group 1 ($p<0.001$, $p<0.001$). While there was a significant difference in the anxiety scores of the patients in group 2 ($p=0.02$), which indicated increased anxiety, no difference was observed in terms of the desire to obtain information scores ($p=0.21$) (Table 2).

The comparison of the groups after the briefing exhibited no statistical difference between the groups ($p=0.86$, $p=0.40$). However, a statistically significant difference was found in the APAIS anxiety and desire to obtain information scores of the groups when the Δ values in all parameters were checked against the baseline values ($p<0.001$, $p=0.007$). The correlation analysis revealed a positive correlation only between the APAIS anxiety and APAIS desire to obtain information scores ($p<0.001$).

Table 1. Demographic data

	Group 1 n=42% (n) mean ± SD	Group 2 n=42% (n) mean ± SD	*p*
Age	48.7±12.6	52.3±13.3	0.15
Gender Woman Man	 54.8% (n=23) 45.2% (n=19)	 45.2% (n=19) 54.8% (n=23)	0.38
Height	165.5±20.0	166.2±7.6	0.48
Weight	82.7±19.6	78.1±15.9	0.18
Marital status Married Single	 71.4% (n=30) 28.6% (n=12)	 71.4% (n=30) 28.6% (n=12)	1.0
Educational status Primary and secondary school High school University	 61.9% (n=26) 14.3% (n=6) 23.8% (n=10)	 47.6% (n=20) 31% (n=13) 21.4% (n=9)	0.38
Job House wife Retired Worker	 33.3% (n=14) 23.8% (n=10) 42.9% (n=18)	 33.3% (n=14) 40.5% (n=17) 26.2% (n=11)	0.44
Cigaret Yes No	 40.5% (n=17) 59.5% (n=25)	 33.3% (n=14) 66.7% (n=28)	0.50
ASA 1 2	 16.7% (n=7) 83.3% (n=35)	 9.5% (n=4) 90.5% (n=38)	0.12
Type of anesthesia General anesthesia Regional anesthesia	 52.4% (n=22) 47.6% (20)	 59.5% (n=25) 40.5% (n=17)	0.51
Type of surgery Low risk Medium risk High risk	 16.7% (n=7) 78.6% (n=33) 4.8% (n=2)	 26.2% (n=11) 69% (n=29) 4.8% (n=2)	0.35

ASA: American society of anesthesiologists; SD: standard deviation

DISCUSSION

An ideal anxiety assessment questionnaire should be easy and fast to use in the perioperative setting. We used the APAIS since it is a validated questionnaire-based tool that produces better results than the physician's rough suppositions regarding the patient's anxiety.[2]

In the analysis of the demographic data, no difference was observed between the two groups. However, since we included the patients in our study by randomization, the levels of anxiety and desire to obtain information before briefing were higher in group 1 than in group 2.

After a detailed briefing was given to the patients in group 1, the improvement in the anxiety and desire for information scores was higher in group 1. Similar to our study, in Lin et al.'s[11] study on 100 patients, the authors made 50 patients watch an educational video and reported that the anxiety level of the group that watched the video decreased more. Jlala et al.[5] randomized 110 patients who were planned to undergo upper or lower extremity surgery into two groups. The researchers provided verbal information to one group and made the other group watch a video with detailed information. As a result, they reported that the level of anxiety decreased significantly in the group that watched the video.[5]

Anxiety levels generally tend to decrease after a preoperative anesthetic assessment visit. This emphasizes the effectiveness of the interaction with the anesthesiologist and the information received.[12] As seen in the study by Jlala et al.,[5] anxiety levels usually reach their peak just before surgery. In our study, in the evaluation before the surgery we saw that the level of anxiety increased in group 2, which was provided standard briefing. However, a significant decrease in the anxiety levels was observed in group 1 patients who received detailed verbal information from the anesthesiologist. In these patients, whose anxiety decreased, there was also a decrease in the desire to obtain information. Contrary to these findings, Pokharel et al.[13] reported that anxiety peaked at different times in different patients.

Table 2. APAIS score comparison within and between groups before and after briefing			
	Group 1 (mean ± SD)	**Group 2 (mean ± SD)**	***p*#**
APAIS anxiety scale (BB)	12.59±5.17	8.59±3.85	0.001
APAIS anxiety scale (AB)	9.09±3.92	9.45±4.30	0.86
p*	0.001	0.02	-
APAIS information request (BB)	6.78±2.56	4.90±2.59	0.001
APAIS information request (AB)	5.02±2.24	4.59±2.03	0.40
p*	0.001	0.21	-
p#: comparison between groups; *p**: comparison within groups; BB: before briefing; AB: after briefing; APAIS: Amsterdam preoperative anxiety and information scale; SD: standard deviation			

In our study, we detected a positive correlation between anxiety and the requirement for additional information. Similar to the APAIS study, patients with high anxiety scores needed additional or more information than patients with low anxiety scores.[9] In Matthias and Samarasekera's[2] study, the authors found that the fear of anesthesia was the most important cause of anxiety and demonstrated a high positive correlation between high-level information seekers and anxiety scores.

Sigdel et al.[14] analyzed 140 patients who were to undergo cardiovascular surgery and reported that most of the patients had anxiety. In addition, the authors found that those with higher anxiety levels had a higher level of desire to obtain information.[14] In accordance with this finding, a detailed preanesthetic assessment and briefing of patients should be considered. Preoperative assessment is a stage during which additional information can be provided to patients before surgery and their problems can be addressed. It has also been reported that fear of complications during surgery is associated with preoperative anxiety.[15]

During the preanesthetic assessment, information about the type of anesthesia is generally given to patients by the anesthetist who performs the examination. However, due to time constraints, complexity of the disease process, or language barrier, there may be a lack of disclosure of anesthetic and surgical information. Similar to our study, it was found in some studies that patients who were better briefed before anesthesia showed lower scores on the anxiety scale than those who did not receive any explanation.[16] However, in our study, a correlation was observed between the anxiety of the patient and the requirement for more information. In our study, no significant relationship was found between the level of anxiety and educational status or profession. No correlation with other factors such as age, gender, socio-economic status, marital status, previous surgery experience, or the type of anesthesia was noted. Contrary to our data, the literature shows that the level of anxiety is high among women.[14]

The APAIS is a tool capable of assessing the patients' anxiety and their desire to obtain information. Anesthesiologists can improve the anesthesia experience of patients by emphasizing the management of perioperative time, giving patients much more detailed information about the surgery to be performed, and depending on the answers of the patients.[17] Therefore, we believe that APAIS may be a useful tool for routine use in preoperative visits.

The association between high anxiety level of patients during surgery and increased autonomic variations, increased need for anesthesia, and increased postoperative pain has been demonstrated.[13] In their study, Van den Bosh et al.[18] showed that postoperative nausea and vomiting were associated with the level of preoperative anxiety. As a result of these complications, many authors reported that the duration of recovery and hospital stay was prolonged.[13] We believe that this situation will also lead to an increase in health costs. Therefore, it is important to reduce the anxiety of patients with preoperative briefing.[19]

Study Limitations

The first limitation of our study is that it was a single-center study. Had the study been performed with a multicenter design, its efficacy and patient population would have been higher. Not including the patients hospitalized in the clinic but only those who presented to our anesthesia clinic was another limitation.

CONCLUSION

We revealed in our study that detailed briefing before anesthesia reduces anxiety, which also reduces the desire to obtain information. In addition, we found that the anxiety in the group who did not receive verbal information before surgery increased as the time of surgery approached. We believe that the anesthesiologist should identify the patients with a high level of anxiety using applicable scales and utilize audio-visual aids, psychoeducational information, and preoperative nursing services to reduce anxiety.

ETHICS

Ethics Committee Approval: This study was approved by the Clinical Research Ethics Committee of İzmir Bakırçay University (decision number: 345/06.10.2021).

Informed Consent: Informed consent form was obtained from the patients.

Peer-review: Externally peer-reviewed.

Contributions

Medical Practices: Ö.F.A., L.K.; Concept: Ö.F.A.; Design: Ö.F.A., L.K.; Data Collection and/or Processing: Ö.F.A., L.K.; Analysis and/or Interpretation: Ö.F.A., L.K.; Writing: Ö.F.A.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study received no financial support

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REVIEW

DOI: 10.34057/PPj.2022.41.02.2022-1-4
Pelviperineology 2022;41(2):123-139

Surgical reconstruction for apical vaginal prolapse

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Citation: Neuman M. Surgical reconstruction for apical vaginal prolapse. Pelviperineology 2022;41(2):123-139

ABSTRACT

Given that surgical reconstruction for apical vaginal prolapse demands proper training and involve hazards to the pelvic organs, is a challenging issue for pelvic floor surgeons. Patients suffering advance uterine prolapse presents with a variety of debilitating symptoms and significantly impaired quality of life. Proper understanding the herniation nature of the problem and precise pelvic floor anatomy details are essential for being able to design and perform a safe, curative and durable pelvic floor reconstruction. Patients having post hysterectomy vaginal vault prolapse are in a worth situation, as the anatomy is frequently distorted, the supportive tissues are weakened, and the vagina is often shortened. All these makes the efficient reconstruction even more difficult; the following summary was written to shed light on this particular field.

Keywords: Apical vaginal prolapse; gynecology; surgical reconstruction

INTRODUCTION

Post Hysterectomy Vaginal Vault Prolapse (PHVVP) Backgrounds

The accurate occurrence of PHVVP is obscure. It is presumed that the reported rate reflects barley the iceberg tip. Pelvic organ prolapse (POP), entailing many sub groups as vaginal wall relaxation, uterine prolapse, PHVVP and others, occurs with up to 50% of parous women. It was reported to cause a variety of urinary, bowel and sexual symptoms and to necessitate surgical correction in 11% of the female population. Up to 30% of all females suffer from pelvic floor relaxation progressed to a level which has a negative impact upon their quality of life (QoL). The affected women frequently require manual assistance to urinate and report frequency, urgency and urge incontinence as well as sex and bowel function-related symptoms. The lifetime risk of undergoing prolapse surgery is one in eleven, whereas up to 30% of those who underwent surgery eventually will have repeat prolapse surgery, part of them after hysterectomy. Being age-related, it is assumed that the prevalence of POP will further increase with the ageing of the population. Hysterectomy results probably with damages to the integrity and blood supply of the endo-pelvic fascia as well as to the innervation of the pelvic floor musculature. This might potentially contribute to later POP manifestation. As data regarding the causative roll of hysterectomy with POP occurrence is missing, there is a considerable debate whether vaginal hysterectomy is improving or negatively affecting the efficacy the surgical reconstruction

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Received: 19 January 2022 **Accepted:** 08 February 2022

of the POP, thus is essential or contra-indicated for long lasting repair. The natural history of post hysterectomy pelvic floor status was never looked at properly to determine whether should the prolapsed uterus should be removed or preserved in terms of POP cure. Similarly, were not the peri-operative complications and general QoL improvement, including the impact of hysterectomy on the female body image and sexuality looked at properly with vaginal hysterectomy in comparison with preservation of the prolapsed uterus or uterine cervix. Nevertheless, PHVVP challenges commonly the healthcare practitioner, requiring thorough understanding of the pathology and adequate skills for treating it.[1-3]

Vaginal Apex Support Natural Architecture

Based on cadaver dissections, reported were three pelvic levels of support: The first relates to the upper vagina, found to be suspended with paravaginal tissue fibers, connected to the cardinal ligaments. The second one supports the mid vagina by fibers connecting it to the arcus tendineus facia pelvis and the levator muscles. The lower vaginal part is supported with the perineal membrane and the perineal body. These vaginal supporting fibers and ligaments are actually condensations of the endo-pelvic fascia, forming anterior support: The cervico-pubic ligaments, lateral support: The cardinal ligaments and posterior support: The sacro-uterine ligaments. The endo-pelvic fascia attaches the supportive pelvic floor musculature, mainly the levator muscles to the vagina, assembling the supportive effect. The pelvic floor plate consisted of the endo-pelvic fascia and musculature (mainly the levator muscles) forms a supportive trampoline. This pelvic floor anatomical specific unit is ligamentarily stretched both on the antero-posterior and lateral dimensions. Thus, caring the pelvic organs, it enables their proper function.[4,5]

PHVVP Definition

Prolapse is defined as protrusion of an organ or structure beyond the normal anatomical position. Mild prolapse is very common and is generally not associated with QoL impairment, thus it is regarded as a non-pathologic situation. PHVVP, according with Baden classification is defined as: 1st degree: The vaginal vault is slightly descended from the natural level, 2nd degree: The vaginal vault is visible at the introituse, 3rd degree (procidentia): The vaginal vault is protruded out of the introituse, at any extension. Prolapse of the apical segment of the vagina was redefined by the International Continence Society Standardization Committee, on 2002 to be: “any descent of the vaginal cuff scar (after hysterectomy), below a point which is 2 cm or more less than the total vaginal length above the plane of the hymen”, and the prolapse degree is defined according with the ICS Pelvic Organ Prolapse Quantification System (POPQ). According with the POPQ is the normal position of the vaginal apex (C point) level measured 8 cm. above the genital opening, hence defined as (-)8. Total vaginal vault prolapse is measured as 8 cm. below the genital opening, defined as (+)8. The vaginal vault prolapse might be isolated or combined with prolapse of the anterior vaginal wall and anterior pelvic floor compartment, including bladder prolapse (cystocele) and/or urethral prolapse (urethrocele) at various degrees. Smilingly might be the posterior vaginal wall and the posterior compartment of the pelvic floor be affected by the supportive defect and enterocele, rectocele and/or perineal body damage can be associated with the apical prolapse.[6]

PHVVP Incidence

POP is very common, and to some degree normal, especially among older women. Over all POP may occur in up to 50% of parous women. It is reported to significantly impair QoL and necessitate surgical correction in 11% of the female population. Up to 30% of those who underwent surgery will have repeat prolapse surgery for failure within 3 years. The accurate incidence of over all vaginal apex supportive defect and particular PHVVP was not properly evaluated yet. It is probably correct to assume that hysterectomy, vaginal rather than abdominal, aggravates the risk for further vaginal prolapse. This might be due to surgical damage as well as to un-addressed pre-existing weakness of the pelvic floor. The estimated incidence of PHVVP, yet it is widely accepted that the reported rate reflects only the iceberg tip of the problem.[7-9]

PHVVP Risk Factors

Pelvic floor relaxation and POP is related to some well-established risk factors. Among those are parity, obstetrical pelvic floor trauma, obesity, tobacco smoking, aging, chronic bronchial asthma and constipation. All these are regarded as related to increasing with intra abdominal pressure. Then, extra strain is applied to the supportive structure and pelvic nerves, yielding further damage and eventually prolepses at various degrees. Another risk factor is lately identified-the tissue factor. The tissue inherited strength is gaining recognition as a crucially important one, manly the tissue collagen content and structure. Patient having a bio-molecular alternation with the collagen amount, architecture, bio-degradability or production might be subject to POP during life. This condition might be rising out of a genetically inherited predisposition. PHVVP could be related to surgical factors, as failure to suspend the vaginal apex to the sacro-uterine ligaments or further suture break down, both leading to vaginal prolapse.[10-12]

PHVVP Symptoms

Symptoms are not necessarily related to the prolapse level and might be vague only. Yet, especially with extreme prolapse, might the lump immerging out of the hiatal introituse interfere with even simple daily activities as walking and sitting. Associate with significant degree of cystocele, enterocele, rectocele and enlarged vaginal hiatus are specific symptoms. Urinary urge and stress incontinence, urgency and frequency, urinary obstruction-masking stress incontinence might be evident with relaxation of the anterior pelvic floor compartment. Posterior pelvic floor compartment relaxation might be associated with fecal urgency and frequency, urge and stress incontinence. In general, POP might lead to sexual intercourse mechanical impairment; negatively affect the body image and self esteem of the affected patient and cause sever QoL impairment. The POP women frequently require manual assistance for urination and to defecation. The association between the site of anatomical defect, the nature and degree of prolapse and the symptoms is comprehended with the causatively effect of the pelvic floor relaxation on the function and malfunction of the pelvic organs. Those understandings grounds proper goals targeting with pelvic floor reconstruction and ways for regaining the physiological pelvic organs functions, lost as prolapse occurred.[13-16]

PHVVP Diagnosis: Anatomic and Functional Clinical Assessment

Thorough POP diagnosis is crucial for proper design of comprehensive therapeutic plan. Therefore, obtaining patient history is the key for understanding the patient's needs and expectations. Pre-interview filling of pelvic floor impact questioneers might facilitate enlightening the various personal aspects of improvement necessitating debilitation related to the pelvic floor prolapse. Then, a pelvic examination under Valsalva maneuver is mandatory, as PHVVP co-exists frequently together with anterior and posterior vaginal walls prolapse. Thus, differential diagnosis and accurate mapping of the patient's whole pelvic floor is mandatory. It is easy to differentiate as the bladder neck is clearly seen when it is not emptied, as the anterior vaginal wall is normally rich with ruggea, the cervix or the dimpled points marking the sacro-uterine ligaments insertion are visible to define the vaginal apex and the posterior vaginal wall with eventual entero-rectocele is defined-able as well. Prolapse level of each and every site of the pelvic floor is to be properly determined, by any acceptable measurement method, both for therapy planning and for cure assessment. Other issues of importance are the vaginal mucosa status (local estrogen therapy might be consider to reinforce this tissue when atrophy id present prior to surgery), evidence of urinary and fecal incontinence, hiatus dimensions and perineal body integrity. Functional impairments, related to the pelvic floor herniation process, such as urine and fecal storage and emptying problems and sexual intercourse difficulties are to be addressed when clinical pelvic floor assessment is carried out. All these above mentioned anatomical defects and functional deprivations might co-exist with various combinations and deferent prolapse degrees. The pre-operative clinical data collection should be furnished with some laboratory studies. Further to the standard pre-operative ECG, chest X-ray, blood and urine analysis, ultrasound scan might be of benefit to rule out co-existing pelvic organ pathology including urinary obstruction. In the presence of fecal storage or passage abnormality is an ano-rectal work-up indicated. The accurate place of urodynamic studies in terms of pointing the best therapeutic approach and prediction of cure or complication rates is in dispute. Many argue the benefit to be of no clinical value while others claim that the information provided enriches the understanding of the individual pathological backgrounds, hence improves the treatment.[17-19]

PHVVP Diagnosis-QoL Assessment

Given that the main therapeutic goal is recreation the functional capacity of the pelvic organs rather than anatomical reconstruction of the supportive defects and restoration of the original pelvic floor architecture only, one must acknowledge the importance of QoL assessment tools. These tools, namely validated questioneers, are crucial for both, pre-operative as well as post-operative evaluations. Comparison of the two will determine the true treatment value from the patient point of view. The surgeon's judgment was found to differ largely from the self reported patient's perspective, as the physician tends to strongly underestimate the patient's complains this is partially explained with the complains being relatively mild, thus not mentioned at the interview. Another bias leading to the surgeon's-patient's judgment discrepancies emerges out of slight differences with the questions presented to the patient at interview and on the questionnaires: The questionnaires were validated properly, while the frontal interview verbal communication varies profoundly. The use of pelvic floor oriented and validated questioneers is of grate importance for proper pre-operative evaluation and therapeutic plan design. Among the frequently used questioneers are the IIQ-7, the UDI-6 as well as many others.[20]

PHVVP Pathophysiology

The causative process leading to pelvic floor supportive impairment, yielding the PHVVP, is presumed to be multi factorial: Age, genetic connective tissue weakness, previous obstetrical

trauma and poor surgical technique while performing pelvic operations might all contribute to the unfortunate occurrence of this condition. Genetic factors, leading to connective tissue metabolism and biochemistry impairment, are important co-factors responsible to connective tissue weakening and POP formation. This explains the familial occurrence often seen with POP, and was demonstrated to be related to alterations with collagen total content and variants, cross linking, morphology and biodegradability. The female patient age is widely accepted as contributing to POP, especially with true procidentia. This age to POP correlation is mostly significant up to the sixth decade of life. This might be contributed to estrogen deprivation at the menopause. Vaginal delivery is strongly attached to future POP as the pelvic supportive components, mainly the levator ani muscles and endo-pelvic fascial ligaments, might be severely and irreversibly traumatized during the fetal journey through the birth canal. Previous pelvic surgery, especially hysterectomy and retropubic colposuspension, is accepted to be associated to further apical and entero-rectocele formation. This is probably due to endo-pelvic fascial damage attributed to hysterectomy and anterior deviation with the longitudinal vaginal axis as well as to un addressed pre-existing posterior pelvic floor supportive defects occurring with Colposuspension. Previous pelvic floor reconstructive surgery was shown to increase by 12 the incidence of further prolapse reoccurrence necessitating re-operation, and it was un-related to hysterectomy performed for non-prolapse reasons others found that 12 months post POP reconstructive surgery prolapse recurred with 58% of the patients.[21,22]

PHVVP-therapeutic Goals

One should bear in mind the different surgeon's and patient's expectations and desires related to POP therapy. While the practitioner might be satisfied with goon anatomical restoration, the patient looks for the functional recreation mainly. There is a need for a holistic approach towards the patient's anatomical abnormalities and the related functional impairments, including urine and fecal control and sexual intercourse. Patient's un-realistic expectations with the therapeutic process should be identified and adjusted to the known operative curative properties regarding urinary and fecal incontinence, bladder over activity symptoms, sexual functions as well as body image. Co-existing occult urinary female stress incontinence should be diagnosed prior to surgery and dealt with an anti-incontinence concomitant procedure.

PHVVP Herniation Concept

POP is actually bulging of viscera through weakened pelvic floor and vaginal walls. Terms used to describe the POP in general, and particularly PHVVP could be easily replaced by simply stating the specific herniation process. Cystocele and urethrocele are then herniation of the anterior compartment of the pelvic floor. Uterine, uterine cervix and PHVVP prolapse are all central pelvic floor herniation and enterocele, rectocele and perineal body tear are herniation of the posterior compartment of the pelvic floor. Endorsement of this approach improves the understanding of the underlying process and points to the appropriate therapeutic tools elected for cure, based on the knowledge accumulated regarding hernia repair at other regions of the human body.[23]

PHVVP Reconstruction Architectural Design

Correct pelvic floor holistic anatomic-functional approach should be based upon solid long lasting suspension of the vaginal vault apex to well established pelvic sustained structures. Among such are the Arcus Tendineus Fascia Pelvis (ATFP) and the Sacro-Spineous (SS) ligament. The first lays along the lateral border of the levator ani muscles, from the inferior pubic ramus and the obturator membrane anteriorly to the iscial spine posteriorly and the second connects the iscial spine to the sacrum. Another anchoring option is the pre-sacral fascia, which longitudely covers the sacral vertebra and provides a solid structure which might serve as a suspensory point to secure the vaginal apex to. Attaching the vaginal vault to one of these ligaments will yield a long lasting apical support, permitting restoration of the impaired pelvic floor and organs functions. Some advocates the pre-sacral fascia, as it is easily reached it is reached easily via the peritoneal cavity, either by laparotomy or by laparoscopy, while others are against because of relatively high rates of intra and post operative bleeding potential, prolapse recurrence and difficult vaginal access. The ATFP, being relatively easily accessed via vagina is elected by some for vaginal vault support, and others will go for the SS ligament, saying this is the most stable pelvic structure, hence providing the best and longest standing support. Deep pelvic dissection, wider than for the ATFP, is necessary for reaching the SS. The cardinal and the utero-sacral ligaments are other potentially usable supportive pelvic anchoring points, yet not easily identified and often obscure. Unfortunately, there is no comparative data to guide any evidence-based decision making regarding the preferred pelvic supportive connective tissue, rather than experts opinions.

PHVVP Non-mesh Repair

The post hysterectomy prolapsed vaginal vault non-mesh repair operations are mainly done via vaginal approach as the abdominal rout might frequently requires mesh to bridge the gape between the vaginal apex and the anchoring point at the pre-vertebral fascia. For sexually non-active women, whenever

the vaginal sexual functions might be sacrificed, colpectomy or vaginal obliteration (Le Fort operation) is a therapeutic option. These relatively safe and simple operations are carried out vaginally, yet prolapse recurrence rate was not established. The vaginal capacity is significantly and irreversibly reduced with these operations. If sexual intercourse function should be preserved, the vaginal capacity is to be maintained. Then are the commonly performed vaginal vault prolapse non-mesh repair done by apical suspension to the SS ligament. The sacro-spineous fixation operation requires deep para-rectal pelvic dissection and is eventually related to significant intra-operative bleeding. This operation was reported to be complicated by post-operative dispareunia, buttock pain, urinary and fecal incontinence, cystocele and rectocele formation, altered defecation and constipation, bladder injuries, urinary retention and infections. The most troubling disadvantage reported to be attached to this operation is an acceptably high recurrence rate. Neither simple colporrhaphy, with or without plication of the utero-sacral ligaments, nor sacro-spineous and sacral colpopexies, seem to be the preferred procedures for repairing vaginal prolapse. Some authors observed that these surgical modalities are associated with a to up 58% recurrence rate in terms of objective POP scoring and prolapse related subjective symptoms while others reported on a recurrent surgery rate for pelvic floor reconstruction of 30%. True surgery related QoL improvement was never well addressed with these operations.[24-30]

PHVVP Surgical Suspension with Mesh Implants for Recurrence Rate Reduction-justification & Reasonability

Given that recurrence rate following traditional vaginal apex re-suspension it unacceptably high and that underlying causative genetic, traumatic and surgical co-factors contributes to progressive weakening of the endo-pelvic fascia, one would endorse a recurrence reducing surgical method. The mesh implant concept was previously proven as recurrence reduction method with abdominal wall herniorrhaphy and was later implemented for the pelvic floor herniation repair as well.[31]

PHVVP Surgical Suspension with Mesh Implants Special Perspectives

Unlike with abdominal wall hernia vertical mesh repair, the vaginaly horizontal implanted meshes are under relatively high level of physical pressure. This makes the vaginaly implanted meshes prone to further prolapse, unless well secured to solid pelvic structures as the SS, the pre-sacral fascia, the ATFP or the utero-sacral ligaments. The vaginaly implanted meshes are covered by thin and fragile layer of mucosa in comparison with the thick abdominal wall coverage; hence erosion and mesh exposure are possible post operative complication. Anti erosive surgical steps are to be taken in order to minimize mucosal erosion and vaginal mesh protrusion hazard. Among these anti erosive steps are the well respected tension free principles for herniation repair, for both-vaginal wall tissue and mesh. Refrain from excessive vaginal mucosa trimming and dissecting below the sub-mucosal fascia to preserve blood supply and nerve endings might contribute to reduce the post-operative tissue tension as well, avoiding ischemia, mal healing and tissue necrosis, thus reducing the mesh exposure incidence. There is much importance of replacing significant and sufficient parts of the endo-pelvic fascia, beyond the borders of the defected endo-pelvic fascia and pelvic floor herniation process, with the artificial synthetic fascia which is the mesh. This is best done by well spreading the mesh from one pelvic side-wall to the other, from the urethra and bladder neck to the vaginal apex, through the posterior compartment all the way down to the perineal body. Then are the pelvic organs not supported with the defected endo-pelvic fascia any more but rather with the fascia replacing synthetic mesh. Wide dissection is generally required for achieving proper repair and meticulous support ensuring. Ligament through passing with the mesh arms is the preferred anchoring method, as it probably yields long lasting support in comparison with suture mesh fixation methods. The pre-operative surgical field sterilization achieved with abdominal operations could never be gained with vaginal surgery, as this will be never exceed the level of “clean-contaminated” sterilization degree, due to inability to totally disinfect the vagina. Hence, especially anti-infectious designed new mesh types were requested. Macro-porous and mono-filament meshes discourage bacterial growth and nesting and thus are best used for vaginal pelvic floor reconstruction.

PHVVP Surgical Suspension with Mesh Implants for Recurrence Rate Reduction-evolution of the Concept

Though the best approach for restoration of vaginal apical support among the commonly utilized abdominal and vaginal routes remains controversial, the utero-sacral, SS, ATFP and Sacral ligaments vault suspension are the most anatomical among the repairs. Hence, it is most unlikely that these ligament support for the vaginal apical prolapse will create a predisposition to future anterior or posterior vaginal vault defects or compromise vaginal function. Given that vaginal vault herniation is the result of separation of the pubocervical fascia from the recto-vaginal and paracolpion facia, resulting in an apical enterocele, it should be corrected by meticulous herniorraphy including reattachment of the vaginal vault to one of the above mentioned ligaments. Early attempts to apply

the well accepted approach of simple mesh implantation with abdominal wall herniorrhaphy for recurrence rate reduction to the POP repair surgery ended with disappointing results. The failure and mesh exposure rates were extremely high and these attempts were stopped. The reasons for failure were better understood later, as the intra-abdominal forces directed to the pelvic floor implanted mesh and the relatively poor mucosal coverage were acknowledged. These considerations encouraged the design of an innovative procedure for the correction of the apical vaginal support defect, through replacement of the utero-vaginal ligament encoding with a synthetic sling, positioned at the levator plate level space via vaginal approach to the para-rectal area, performed in a daycare setting.[23-25] The novel posterior intra-vaginal sling (PIVS), entailing minimal invasiveness via a vaginal approach together with anatomical restoration of the uterosacral ligament suspension of the vaginal apex, performed in a daycare set-up. Magnetic resonance imaging showed that significant improvements in the restoration of the vaginal configuration were achieved in patients who underwent PIVS. The PIVS operation facilitates uterine conservation, even in the event of advanced uterine prolapse. The restoration of the uterosacral ligaments support enables the surgeon to re-suspend the uterine isthmus, hereby avoiding the necessity to perform vaginal hysterectomy for the treatment of uterine prolapse. Thereafter further developments occurred: The mesh against slings debate rose up; questioning whether the preferred way for POP repair is replacing the specific broken endo-pelvic ligaments with synthetic sling is adequate. Others felt that the whole endo-pelvic fascia should be replaced with large mesh from one side-wall to the other and from the pubic bone towards the sacrum is desired, similar to the way mesh implants are used with abdominal wall herniation repair and ending with large mesh size. The best mesh pelvic fixation points and fixation method are another field of uncertainty with POP vaginal mesh implantation: The SS, ATFP, pre-sacral and the sacro-uterine ligaments were all advocated as suitable for pelvic mesh anchoring with variety of fixation methods. Some feel very strongly that the only long lasting fixation method is passing wide mesh arms through the ligaments, others simply sutured the mesh to ligament and various stapling devices were introduced as well. All the above mentioned influence the needed width of pelvic dissection, hence the needed training and skills as well as the potential operative hazards.[32-37]

Principles of Mesh Reconstruction

The support facilitating and enhancing mesh should be secured to the vaginal apex on one edge and to the elected supportive structure-the SS, utero-sacral, pre-sacral or the ATFP ligaments on the other edge. The mesh should substitute the herniation causing weakened fascia that led to prolapse of the central, anterior and/or posterior pelvic floor compartments. Thus, the PHVVP, as well as the frequently co-existing cystocele and/or entero-rectocele are to be properly corrected simultaneously. In case of co-existing cystocele should the mesh provide support to the whole anterior pelvic floor compartment and be secured also to the anterior end of the ATFP, while with co-existing entero-rectocele should the mesh provide support to the posterior pelvic floor compartment and be secured also to the perineal body. These additive secures will serve to stabilize better the mesh and avoid displacement and recurrent prolapse.

PHVVP-surgical Pearls

Tension free concept for the mesh placement and attachment as well as the mesh covering tissue should be kept in mind at all times when reconstruction of damaged pelvic floor is undertaken. This will reduce tissue ischemia, tissue necrosis, mal healing and later mesh exposure. Preservation of viable blood vessels and nerve endings by deep and full thickness infra-fascial lateral dissection of the vaginal wall will contribute for mesh exposure reduction. This is remarkably facilitated with hydro-dissection which is helpful for getting into the true vesico-vaginal and recto-vaginal spaces leads to lower erosion rates. A non-ischemic colpotomy closing suture knotting and minimization of the vaginal through cut are also valuable anti ischemic measures. Extensive mucosal trimming for tissue tailoring while normal dimensioned vaginal recreation might end with tensioned vagina, thus to further mesh exposure. Important is meticulous mesh flattening before vaginal cut assembling, to avoid post operative infra-mucosal mesh folding and pain, including dysmenorrheal. Mesh position securing, either by ligament passing mesh arms or with suturing, should ensure that the mesh is properly spread to replace the whole herniation causing defected endo-pelvic fascia.

PHVVP Versus "*in situ* uterus" VVP Repair

The uterus un-removed offers the surgeon solid central pelvic encoring points such as the cervical ring or the uterus itself. These organs might then both be attached to various solid structures at the pelvic side-walls, as the SS, sacro-uterine, ATFP or the pre-sacral ligaments. Being connected to the cervico sacral, cardinal and cervico-pubic ligaments provides the spared cervical ring extra sustainability for the pelvic floor, arising out of recruitment these web architecture structures to the pelvic reconstruction. This challenges the widely endorsed common practice of reflective appointment for vaginal hysterectomy with uterine prolapse diagnosis, trained at many centers and performed routinely around the globe. Solid data

regarding the question whether should the prolapsed uterus be removed are not available currently. Yet, some level 2 evidence supports the preservation of the prolapsed uterus or the uterine cervix at least, guiding a potential change with the common attitude of automatic indication towards vaginal hysterectomy whenever POP is present. The direct disadvantages of hysterectomy regarding pelvic floor reconstruction are the damages to the endo-pelvic fascia integrity, vasculature, blood supply and innervation and the deprivation of the advantage of using the cervical rind and the web of connected ligaments for providing extra strength to the pelvic floor architecture. All these are extremely important for maintaining further pelvic floor sustainability and functions. Performing hysterectomy concomitantly with mesh pelvic floor reconstruction increases significantly the risk of post operative mesh vaginal exposure and the need for further operative intervention to cure this complication. Not rare is the occurrence of vaginal shortening after hysterectomy, to such degree that impairment of sexual intercourse. Except of the negative influence on the pelvic floor structure and functions, entails vaginal hysterectomy many operation related complication, some of are health and life threatening, and it might also physiologically mutilate the disregarded hysterectomised patient's body image and self esteem. Minimally invasive novel methods for the treatment of menorrhagia, endometrial polyps and uterine myomas as well as increasing public awareness against preventable hysterectomies lead towards preservation of the prolapsed uterus.[38-47]

PHVVP Repair-vaginal vs. Abdominal Approach

There are two surgical access routes for reconstructive pelvic surgery to correct POP: The abdominal approach (either by laparotomy or via laparoscopy) and the vaginal approach. Though the best approach for restoration of vaginal apical support among the commonly utilized abdominal and vaginal routes remains controversial; the pelvic ligament vault suspension is the most anatomical among the repairs. Hence, it is most likely that the utero-sacral, SS, ATFP and Sacral ligament support for the vaginal apical prolapse will yelled a long lasting vault suspension and restoration of the vaginal functions. For the last decade, various surgical modalities for curing POP through reconstruction of the pelvic floor have been advocated, mainly modification of the colpo-sacral and colpo-sacro-spinal fixations, using vaginal or abdominal approaches, via laparotomy or laparoscopy. These operations where associated with well documented complications such as mesh erosion, dispareunia, buttock pain, urinary and fecal incontinence, altered defecation and constipation, bladder injuries, urinary retention and infections, cystocele and rectocele formation and protrusion, and other disadvantages such as long operative time, slow return to normal living activities and great costs. Given that the vaginal vault herniation is the result of separation of the pubo-cervical fascia from the recto-vaginal and para-colpion fascia, resulting in an apical enterocele, it should be corrected by meticulous herniorrhaphy with reattachment of the vaginal vault to the utero-sacral ligaments. The vaginal approach for POP reconstructive operations is associated with fewer complications and results in a shorter rehabilitation period than the abdominal route, whereas hysterectomy is widely performed concomitantly whenever the uterus is significantly prolapsed. However, there is no clear evidence supporting the role of hysterectomy in improving surgery outcome. The new minimally invasive procedure for apical prolapse suspension, as the PIVS for correction of advanced uterine prolapse, enables uterine preservation. The issue of vaginal hysterectomy within the context of POP was addressed earlier with regard to the potential additive curative effect in terms of reduction of the POP post-operative recurrence rate and the influence of future QoL. No advantage was attached to hysterectomy in the surgical cure of POP.[19-26] Replacement of the broken uterosacral ligaments applying PIVS provides adequate uterine re-suspension, hereby permitting uterine preservation while treating advanced uterine prolapse.[48-52]

PHVVP Repair-laparoscopic Approach

Laparoscopic suspension of prolapsed uterus or prolapsed vaginal vault is feasible and has durable curative results, yet it requires advanced laparoscopic skills and an experienced laparoscopic center as sever damage might occur to the surrounding organs during operation. This is done by suturing mesh to the anterior and posterior aspects of the vaginal vault and securing it to the longitudinal sacral ligament at the level of sacral 2nd or 3rd spine. Post operative dispareunia is claimed to be reduced in comparison with vaginal reconstruction but this was not proved. the advanced laparoscopic surgical skills required for laparoscopic sacro-colpopexy include deep pelvic floor tissue dissection capability as well as familiarity with suturing and knot tying. Thus, this procedure is reserved only for the very well trained end experienced laparoscopists. However, when properly performed is the laparoscopic approach for sacrocolpopexy claimed to be as effective as the abdominal one, while the operative time is significantly longer and hospitalization, blood loss and rehabilitation period are much reduced. Due to the necessitated meticulous and proper prior training remained the laparoscopic sacral colpopexy unpopular at many medical centers.[53-57]

PHVVP-isolated Apical Support Defect Mesh Repair

When the apical vaginal vault is prolapsed while the lower segment of the anterior and posterior vaginal walls are well suspended, apical correction only is needed. This might be

achieved either via the abdominal cavity by laparotomy or by laparoscopy, or vaginaly. The abdominal approach permits exposure of the pre-sacral longitudinal fascia for suspension of the prolapsed vaginal apes, yet frequently implanted mesh is required for bridging over the anatomical gap in-between the two structures. One mesh end is to be fixed to the pre-sacral exposed and bare 4 to 6 square cm of fascia, avoiding the rectal vessels. The other mesh edge is fixed to the exposed vaginal apical wall. Often the bladder and the rectum must be dissected away from the vaginal apex for about 6 to 8 square cm permitting adequate and sufficient mesh appliance in order to provide long standing support. Permanent sutures should be used for the mesh to soft tissue fixation. The suture must not be too tight to reduce the occurrence of tissue ischemia, necrosis and breakdown. Other possible fixation methods are staples, yet safety and durability were not reported. At the end the mesh is to be covered with peritoneum to avoid later intestinal damage. Vaginal apical suspension might also be achieved via vaginal approach, either using the ATFP or to the SS ligaments as anchoring points. The ligaments are reached via colpotomy, para-rectal or para vesical dissection and iscial space development. Displacement of the bladder, rectum and small bowels might be necessary for ligamentary palpation or visualization. Occasionally is the vaginal vault long enough for direct suturing to the suspensory ligament, yet-mesh implants are probably important for avoiding recurrence. Unless done bilaterally, which is a rather complicated operation, vaginal axis lateral deviation is induced, causing further potential dispareunia. The durability of this operation is not well established. Many advocates mesh implantation for sustained correction of vaginal vault prolapse, when performed via vagina. The mesh should be fixed either to the ATFP or to the SS ligaments on both lateral pelvic sides and to the vaginal apex medially.

PHVVP-apical and Anterior Vaginal Wall Support Defect Mesh Repair

When the apical vaginal support defect is combined with anterior vaginal wall defect (cystocele), should the apical reconstruction (chapter 22) be followed with anterior vaginal wall reconstruction to complete the pelvic floor repair. This might be done by classical anterior colporrhaphy most of the times, if only the potential supportive characteristics of the vesico-vaginal endo-pelvic fascia are judged to be sufficient for long lasting prolapse correction. There are not any existing objective tools to guide such decision, hence must the surgeon base his preferred approach upon clinical impression related to the tissue nature and personal and family history. Elects the surgeon to perform a classical anterior colporrhaphy, should he make a longitudinal medial anterior wall cut and free the vaginal wall from the bladder Detrusor muscle. Then should he place some transverse sutures to approximate both sides of the vesico-vaginal endo-pelvic fascia to recreate a dissent support for the bladder, trim the un-necessary mucosa to tailor a vaginal at normal capacity and length and close the surgical cut. Should the surgeon decide that the particular pelvic floor might be not appropriate for homologous repair, might a mesh implantation be desired. When such occurs, should the surgeon add to the apical support operation anterior vaginal wall mesh re-enforcement. The mesh should preferably cover the whole anterior wall fascial supportive defect, and be spread from one pelvic side wall to the other, from anterior to posterior, to replace literally the whole anterior compartment pelvic endo-pelvic fascia and prevent recurrent prolapse. Achieving proper mesh placement requires then a rather large para-vesical dissection, along with the bony pelvis up to the iliac spins laterally and posteriorly and to the pubic bone upwards. The mesh should be flattened properly to prevent further lump formation and vaginal pain. The mesh and the overlying whole thickness and well blood supplied vaginal mucosa should be left totally tension free to avoid tissue ischemia, mal-healing and mesh exposure. The mesh should be well attached to solid intra-pelvic ligament to prevent support brake down. The mesh should be also secured to the fascial ring of the uterine cervix or to the vaginal apex at the insertion point of the former sacro-uterine ligaments to recruit the endo-pelvic ligaments for improved supportive results. Mesh fixation to the para-urethral tissue is desired as well to promise latter stabilization of the construction. Normally, mucosal trimming is avoided or limited with mesh implants to reduce the possible tissue tensioning and ischemia.

PHVVP-apical and Posterior Vaginal Wall Support Defect Mesh Repai

When the apical vaginal support defect is combined with posterior vaginal wall defect (recto-enterocele), should the apical reconstruction (chapter 22) be followed with posterior vaginal wall reconstruction to complete the pelvic floor repair. This might be done by classical posterior colporrhaphy, if only the potential supportive characteristics of the recto-vaginal endo-pelvic fascia are judged to be sufficient for long lasting prolapse correction. There are not any existing objective tools to guide such decision, hence must the surgeon base his preferred approach upon clinical impression related to the tissue nature and personal and family history. Elects the surgeon to perform a posterior Colporrhaphy only, should he make a longitudinal medial posterior wall cut and free the vaginal wall from the rectum and enterocele herniation peritoneal sac. Then should he place a tobacco-

pouch round suture to reduce the enterocele herniation and some transverse sutures to approximate both sides of the recto-vaginal endo-pelvic fascia to recreate a dissent support for the rectum. The distant lavator muscles are to be approximated in a similar way to form a functional perineal body. The un-necessary mucosa is trimmed to tailor a vagina at normal capacity and length and then the surgical cut the closed. Should the surgeon decide that the particular pelvic floor might be not appropriate for homologous repair, might a mesh implantation be desired. When such occurs, should the surgeon add to the apical support operation posterior vaginal wall mesh re-enforcement. The mesh should preferably cover the whole posterior wall fascial supportive defect, and be spread from one pelvic side wall to the other, from anterior to posterior, to replace literally the whole posterior compartment pelvic endo-pelvic fascia and prevent recurrent prolapse. Achieving proper mesh placement requires then a rather large para-rectal dissection, along with the bony pelvis up to the iliac spins laterally and posteriorly and to the perineal body anteriorly. The mesh should be flattened properly to prevent further lump formation and vaginal pain. The mesh and the overlying whole thickness and well blood supplied vaginal mucosa should be left totally tension free to avoid tissue ischemia, mal-healing and mesh exposure. The mesh should be well attached to solid intra-pelvic ligament to prevent support brake down. The mesh should be also secured to the fascial ring of the uterine cervix or to the vaginal apex at the insertion point of the former sacro-uterine ligaments to recruit the endo-pelvic ligaments for improved supportive results. Mesh fixation to the perineal body is desired as well to promise latter stabilization of the construction. Normally, mucosal trimming is avoided or limited with mesh implants to reduce the possible tissue tensioning and ischemia.

PHVVP-apical, Posterior and Vaginal Hiatus Support Defect Repair

When the apical vaginal support defect is combined with posterior vaginal wall defect (recto-enterocele) and with widely opened vaginal hiatus should the apical and posterior compartment reconstruction (chapter 24) be followed with reconstruction of the perineal body to complete the pelvic floor repair. This might be done by classical perineorrhphy most of the times, if only the potential supportive characteristics of the recto-vaginal endo-pelvic fascia are judged to be sufficient for long lasting correction of the relaxed tissue. When the ano-vaginal septum is extremely poor, both sides the levator plate recruitment might be necessary for erection of solid perineal body and reducing the vaginal opening dimensions. Was the posterior wall reconstruction made with mesh, could the perineal body reconstruction be use for further covering the mesh, hence reducing the post operative mesh exposure hazard.

PHVVP-apical, Anterior and Posterior Vaginal Wall Support Defect Repair

When the apical vaginal support defect is combined with anterior and posterior vaginal wall defects (cysto-recto-enterocele), should the apical reconstruction (chapter 22) be followed with anterior and posterior vaginal wall reconstruction (chapters 23&24) to complete the pelvic floor repair.

PHVVP-repair of Apical Support Defect Combined with Stress Urinary Incontinence

When the apical vaginal support defect is combined with mid urethral supportive defect (occasionally forming urethrorocele), should the apical reconstruction (chapter 22) be followed with an anti urinary incontinence procedure, usually a mid urethral support reconstruction to complete the pelvic floor repair. One of the trans-obturator or retro-pubic TVT slings might be chosen better than the newly developed “mini slings”, in case that an anterior mesh was implanted, as the required deep para-vesical dissection might impair the tissue ability to harbor these mini-sling’s tips and they might not be well fixed.

PHVVP Mesh Reconstruction-mesh Choice

Accurate diagnosis of all the prolapse features and site specific support requirements identification are mandatory for proper mesh choice. It is the presence of isolated apical supportive defect only at the central pelvic floor compartment or any additional anterior and/or posterior compartments prolapse that determine the requested mesh shape. It is the coexistence of urinary stress incontinence that indicates the need for additional mid-urethral support. The elected mesh or combination of meshes should be providing support for all the prolapsed pelvic floor sites. One must beer in mind that some commercially available anterior compartment meshes are designed for cystocele repair only while others provides the possibility to suspend the prolapsed uterus by cervical ring attachment, thus permitting it to be preserved. Other meshes provide support the mid urethra, concomitantly with anterior compartment reconstruction, hence avoiding the need for additional tape to support the mid-urethra separately. The later ones cure not only the anterior compartment prolapse only but the uterine prolapse and/or stress urinary incontinence simultaneously with the cystocele repair. Other meshes are designed for posterior compartment reinforcement, some of provides the possibility to support the prolapsed uterus or vaginal apex at the same time. Whenever there is a need to treat several sites of pelvic supportive defects more than

one mesh might be needed. There should be a dissent and convincing published body of evidence to prove the safety and efficacy of the specifically chosen mesh. The surgeon must be properly trained with any new mesh by an experienced trainer and familiar with potential hazards' including prevention and management of these. The mesh texture need to be as soft and light as possible, none shrinking, small in dimensions, yet sufficient for complete replacement of all defected parts of the endo-pelvic fascia and pelvic floor herniation. Thorough defected endo-pelvic fascia substitution with the artificial fascia is crucial for insuring long lasting support. Host against graft and graft against host reaction formation should be ruled out according with any particular mesh prior to usage, so should any mesh related bacteria nesting or harboring. This is generally the case with type 1 mono-filament macro-porous knitted meshes, not interfering with macrophages migration. Long lasting anchoring method were reported to involve ligament through passing mesh arms, thus the particular mesh attachments to the pelvic chosen supportive points should be proved before hands for long lasting support, preferably with mesh arms through ATFP or SS ligaments anchoring. Mesh and arm delivery systems for mesh individually prepared or pre-cut kits should be proven to yield the desired correct mesh and arms placement at the pelvic floor. Some pre-cut meshes might be too small to provide the necessary complete coverage of the whole fascial defects, thus easier to place because less dissection is required. Others might provide relatively easy arm placing devices, but at the price of improper arm passage at the deep ligaments of the pelvis for appropriate high support. These meshes might be prone to operative failure and recurrent prolapse. One should not be tempted for these easy to apply kits but rather go for the highly curative ones. Bio meshes where not proven to yield any advantage over the synthetic ones and one should not endanger his patients with bio-hazards. Smilingly, the absorbable meshes where not reported to entail any superiority and one should ask himself is there any potential benefit of a vanishing mesh in herniation repair at all. The list of available commercially manufactured products expends fast and the existing ones are regularly re-shaped, thus there is no point in referring to any particular currently available mesh. With this atmosphere of many newly designed meshes popping up almost monthly, one must be extra couches when choosing his own mesh. Of huge importance is solid clinical data, proving high cure rate and low rate of complications of mild nature. One should seek for proper training before adopting any new operation and maintain his skills with frequent operation performance.[58]

PHVVP Mesh Reconstruction Related Complications

A. Intra-operative complications: Superficial or deep bleeding might occur during operation, related to arterial or venous breakdown. While dissecting or at needle insertion might the neighboring viscera be perforated; this could involve the urethra, the bladder-at the ureteral orifice or remote from there, the small or large intestine.

B. Early post-operative: At the post-operative course might partial or complete bladder outlet obstruction present, field infection could be evident, hematoma formed, vaginal, pelvic or at the thigh pain could appear- with or without neurological deprivation.

C. Late post-operative complications: Chronic vaginal, pelvic or at the thigh pain and dispareunia were reported to complicate prolapse reconstructive surgery, with or without neurological deprivation, so was also vaginal mesh protrusion and bladder or rectal mesh protrusion. There is some unclearness whether the last ones occurred during or after the operation. Sacral abscess formation and vesico and recto-vaginal fistula are severe and health threatening post operative complications related to POP reconstruction. Mesh exposure has been described to complicate the postoperative course of these procedures in about 15% of the patients, other complications are relatively rare, yet important because of their potentially sever consequences. All the above mentioned complications were reported to complicate the abdominal as well as the vaginal operations, with type 1 or non type 1 mesh.

PHVVP Mesh Reconstruction-reducing Operative Complications Rate

Proper training, skill maintaining and good surgical technique keeping are always the golden keys for any operative complication rate reduction.

Avoiding intra-operative bleeding: Hyhdro-dissection first, than dissecting at vessel free anatomical planes will reduce vessel breakage and bleeding. So will sharp dissection and proper needle passing through a-vascular tissues.

Avoiding intra operative urethral, bladder and intestinal injury: Meticulous dissection, according with standardized and pre-designed surgical steps and respecting anatomy alternating adhesion and fibrosis related to prior surgeries, might contribute to avoiding visceral operative damage.

Avoiding early post-operative bleeding: Proper and meticulous intra-operative hemostasis and use of coagulation inducing agent when indicated will definitely reduce post operative bleeding potential. So might the usage of vaginal tampon.

Avoiding post-operative pain: Post-operative vaginal and pelvic pain and dispareunia might be reduced with proper placement and flattening of the mesh and with tension free surgical technique for both-tissue and mesh. Radiated thigh and leg pain are reduced by properly passing the mesh arms within the pelvic structures-away from neighboring situated nerves.

Avoiding post-operative urinary obstruction: Urinary obstruction will be widely avoided by proper non-tension mesh placement at the bladder neck level.

Avoiding post-operative mesh exposure: Choosing the type-1 mesh for bacterial infection avoiding, vessel and innervation sparing full thickness vaginal wall dissection, shortening the vaginal surgical cuts as much as possible, meticulous hemostasis, non-tensile mucosal closing, minimal mucosal trimming-all these will reduce tissue ischemia, necrosis, mal-healing and risk for mesh exposure.

Avoiding post-operative vaginal mesh bladder or rectal mesh protrusion or fistula formation: Meticulous anatomically wise dissection at the proper inter organ planes as well as tension free surgical techniques for both-tissue and mesh and blood vessels preservation will prevent late visceral mesh injury.[59]

PHVVP Mesh Reconstruction-management of Related Complications

Intra-operative bleeding: Apply direct pressure upon bleeding zone, either manually or by packing, if needed - use advanced hemostatic agents, consider selective arterial embolization or pack and finish the procedure. Note: Bleeding might be extra-peritoneal, thus large in volume, be ready for blood transfusion. Intra operative urethral injury: Vaginal repair is possible with 3 different anatomical tissue layers: Urothelium, connective tissue and vaginal mucosa. Visualize urethral patency; keep the bladder drained for a week, continuing the mesh placement is optional.

Intra operative bladder injury: Evaluate damage with cystoscopy whenever bladder injury might be suspected. Unless ureteral orifice is involved-vaginal repair is possible, otherwise repair abdominally. Correction is best performed with 3 different anatomical tissue layers: Urothelium, connective tissue and vaginal mucosa. Consider use of ureteral catheter; visualize ureteral patency, keep the bladder drained for a week. Controversy exists regarding mesh implantation after cystotomy, continuing the mesh placement is optional only if the bladder injury is mild in nature and leakage is not anticipated.

Intra operative small intestine injury: If minor-repair and proceed with operation, otherwise-repair but refrain from mesh placement.

Intra operative large intestine injury: If small-repair, otherwise consider diversion and colostomy. Abort procedure and do not implant mesh to avoid infection and protrusion.

Early post-operative bleeding: If patient is stable hemodynamically-use vaginal tampon and monitor vital signs as well as hematocrit levels and ultrasonic imaging of the hematoma. Consider hematoma evacuation only if clinically significant, provide preventive antibiotics.

Early post-operative pain: To a certain level of post operative pelvic pain is frequent and successfully dealt with by oral analgetics. When excessive or referred pain is evident, suspect nerve involvement or pelvic hematoma, take necessary diagnostic steps and act accordingly by removing the mesh or evacuating the hematoma.

Early post-operative urinary obstruction: Complete post-operative urinary obstruction is rarely improved with expectancy, thus early intervention to relieve increased mesh tension is indicated. This is easily achieved by re-opening the primer surgical cut at the anterior vaginal wall, clamping the mesh on midline sides and gentle down-pulling, avoiding urethral damage as well as exaggerated mesh loosening. If just partial obstruction is diagnosed, and the residual urine volume is only moderately increased, re-catheterization is probably sufficient as spontaneous relief occurs frequently.

Post-operative vaginal mesh protrusion: Small mesh exposures, occurring after abdominal colpo-sacro-pexy or vaginal reconstruction, might it be subject to local estrogens for a month time. There after-surgical removal is indicated if persistent. With large mesh exposures or with non-type 1 mesh surgical removal should be performed as first measure as conservative treatment would be fruitless.

Late post-operative pain: Mesh exposure or retraction and vaginal tissue fibrosis might cause vaginal, pelvic, buttock or thigh pain, with or without neurological deprivation. Local treatment with estrogen and anti inflammatory might reduce pain, otherwise intervention should be considered for exposed mesh removal or mesh tension release. Chronic irradiated pain to lower extremity, especially when combined with neural deprivation, calls for mesh arm removal. This is not easy to perform and entails limit results. Late post-operative discharge: Chronic vaginal discharge might be due to mesh exposure or vaginal granulation tissue formation; thus removal of these is indicated.

Post-operative dispareunia: Mesh exposure or vaginal wall tissue fibrosis should be suspected, especially if the partner is inconvenient during sexual intercourse as well. Thus, removal of these is indicated.

Post-operative vaginal mesh bladder or rectal mesh protrusion and vesico or recto-vaginal fistula: These should be dealt with surgical therapy. The mesh should be removed and injured viscera should be treated. Surgeons should be familiar with and well trained for managing these complications, yet one should seek for proper assistance with decision making as well as with the requested surgical measures.[60-66]

PHVVP Mesh Reconstruction-anatomic and Functional Clinical Outcome Assessment

After completion of the therapy, the accurate outcome is to be properly assessed, especially on research setups and when

adopting new techniques. The post operative anatomical pelvic floor under Valsalva maneuver status should be assessed properly using an accepted prolapse quantification method as the Baden or the ICS POP-Q system. The surgeon's judgment was found to differ largely from the self reported patient's perspective, as the physician tends to strongly underestimate the patient's complains. This is partially explained with complains being relatively mild, thus not mentioned at the interview. Another bias leading to the surgeon's-patient's judgment discrepancies emerges out of slight differences with the questions presented to the patient at interview and on the questionnaires: The questionnaires were validated properly, while the frontal interview verbal communication varies profoundly. The patient is frequently reluctant to report dissatisfaction with the therapeutic results, considering that as impoliteness regarding the surgeon. Hence, the objective and independent patient self assessment validated questionnaires are an essential tool for judgment of the accurate value of POP as for any other medical procedure. Thus, the accurate assessment of the various aspects of the pelvic floor relaxation related QoL is essential. The use of pelvic floor oriented and validated questioners is of grate importance both-for proper pre-operative evaluation and therapeutic plan design and for post operative cure judgment as well. Among the frequently used questioners are the IIQ-7, the UDI-6 and many others.[67]

PHVVP Mesh Reconstruction-reducing Failure Rate

Proper training, skill maintaining and keeping good surgical technique are the keys for failure rate reduction. Proper mesh arms introduction to accurate points at SSL & ATFP on one side and secure anchoring to the vaginal apex or preferably to the cervical ring if not removed earlier on the other one, are crucial for long lasting apical support. Proper mesh flattening and fixation to both lateral pelvic aspects prevent mesh shifting and further lateral supportive defects.

PHVVP Mesh Reconstruction Failure Management

Vaginal vault prolapse re-occurrence might be due to detachment of the mesh arms from the anchoring pints at the supporting pelvic ligaments or to vaginal vault, or to mesh shifting from lateral sidewalls. With either, should the failed surgical technique not be repeated but rather replaced by another technique. Thus, a failed vaginal procedure could be followed with an abdominal one and vice versa. As surgeons are generally familiar mainly with one single surgical method, referring the patient to an experienced college should be considered.

PHVVP Mesh Reconstruction-proper Patient Selection

The only indication for supporting the prolapsed vaginal apex is clear diagnosis of such. Hence, only patients with true PHVVP should be appointed to apical reconstructive surgery. Relative contra-indications might be previous pelvic irradiation, immuno-depresive state, active infection, Systemic steroid use and poorly controlled diabetes. Some of these patients might be subject to other therapeutic and palliative modalities as pessary placement or colpoclesis operation. Adoption of these guidelines will insure success and reduces avoidable failures.[68]

PHVVP Mesh Reconstruction-patient Informed Consent

Prior to enrolling for surgical reconstruction of pelvic floor relaxation must be patient informed consent be obtained. This should particularly focus on the post operative anticipated anatomical and functional prognosis including sexual activity and urine and feces storage and leaking problems. Patient's expectations from therapy, regarding each deferent aspect of physical function as well as QoL improvement and impairment, arising from conditions related to POP and repair should be discussed. The post operative course including sexual and other physical activity restrictions, vaginal bleeding, discharge and pain, pointing the expected level and duration of each detailed feature should be pictured. The raw existing data concerning non-mesh against mesh implantation operations recurrence rate must be presented, as well as other data concerning mesh implantation, complications nature and rate, specific surgeon's training and experience and other commonly performed operations. All these will properly prepare the patient to the operation she is scheduled for, re-adjust her expectations and reduce unrealistic fantasies and improve satisfaction.

PHVVP Mesh Reconstruction-pre-operative Measures

The operation related morbidity was never proved to reduce with prophylactic antibiotics, enema, bowel preparation, lower extremities bandaging, indwelling urethral catheter and even vaginal anti-septic lavage. Nevertheless not supported by any solid data, these measures are widely used for theoretical preventive benefits.

PHVVP Mesh Reconstruction-intra-operative Safety Measures

Bladder drainage with urethral catheter was never proved as beneficial in terms of urethral and bladder injury reduction; some feel though that un-emptied bladder provides better burdens anatomical identification, thus correct dissection and bladder protection might be facilitated with a filled bladder. The mode of anesthesia was shown to have no influence on cure

rates and safety levels; intra operative cough test was not proved to reduce the failure rate of the anti incontinence surgical steps. Some do feel that performing this non-physiological diagnostic measure might contribute to elevation of post operative bladder outlet obstruction rate. No data supports the routine use of anti coagulant medications, neither is performance of routine diagnostic cystoscopy, either prior to surgery or at completion of the operation, unless iatrogenic bladder injury is suspected. Rectal examination was advocated at after posterior compartment mesh implantation, as rectal injury was reported with such. Vaginal routine tampon packing at the end of surgery never proved efficacy with improving cure or with post operative bleeding reduction. On the other hand this is causing significant discomfort and even pain to the patient.

PHVVP Mesh Reconstruction-postoperative Measures

Pain management: The post-operative pain level is usually less that 5 according with a visual analog pain scale ranging 0 to 10. This is frequently dealt with oral analgesic medications repeated every 3 to 5 hours for 1 to 2 days. More effective analgetics are seldom indicated. Stool softeners are beneficial for easing defecation for the first post operative week. Hospital stay varies between 24 and 72 hours after vaginaly conducted operations, depending on successful pain management. This is significantly longer after abdominal operation, as up to 7 post operative hospitalization days are frequently then required. Recommendations regarding post operative activity restrictions refer mainly to refraining from sexual intercourse which is strictly forbidden for 6 weeks, in order to prevent dispareunia, suture brake down and mesh exposure. Heavy lifting is usually advocated to be avoided as well as any other activities leading to increased intra-abdominal pressure and local pressure applied the operative field before compete tissue healing is achieved. Follow-up appointment is to be scheduled for the first and sixth post operative month and yearly thereafter. At these, post operative complications are to be looked for, including mesh exposure, granulation tissue formation, urine and feces storage and passage control impairments, sexual functions difficulties, vaginal or pelvic pain and various prolapse recurrence features.

PHVVP Mesh Reconstruction-further Post-operative Therapy

Patient's QoL after operation might be improved with some simple adjuvant therapeutic measures, as stool bulking and softening agents, easing possible troubling defecation. Bladder over activity symptoms, such as urinary urgency, frequency and urge incontinence, either pre-operatively existing or de novo appearing since, should be considered to be dealt with by anti cholinergic medications. Local or systemic estrogens could nicely reduce vulvo-vaginal inching and dispareunia, be improving surface tissue atrophy. Physiotherapy for pelvic floor muscles reinforcement might often contribute to improving patient's QoL regarding pelvic floor functions re-establishment.

PHVVP Mesh Reconstruction-surgical and Clinical Available Data

Reviewing the English written literature for high level evidence concerning POP surgery reveals some important conclusions: The no-mesh operations anatomical and functional long-term outcomes in terms of cure and complications are not well reported. This is true for vaginal hysterectomy for the cure of procidentia, for paravaginal and site specific prolapse repair, and for abdominal sacral colpopexy as well. Nevertheless, vaginal sacrospinal fixation and abdominal sacrocolpopexy have remained the "gold-standard" for repair of vaginal apical suspension defects. Being less invasive, the vaginal approach is safer and is associated with fewer side effects, yet shorter lasting than the abdominal for the surgical cure of PHVVP repair. Similarly, the use of mesh was found to be justified in terms of post operative prolapse recurrence and surgery related complications only for anterior pelvic floor reconstruction. Questions regarding the preferred mesh type, mesh for central and posterior pelvic floor compartment reinforcement and conservation of the prolapsed uterus remained improperly addressed and unanswered for the time being. As the relevant data referring the various mesh armamentarium is rather poor yet, the decision which mesh is to used- if at all, depends heavily on individual surgeon's training and experience. This is obviously insufficient for properly supporting this decision, which should a clearly evidence based decision making process.[69-79]

PHVVP Mesh Reconstruction-accepted Recommendations

A Cochrane review, analyzing 22 trails, including 2368 patients, show that abdominal sacro-colpopexy (SCP) yields lower rates for POP recurrence and dispareunia when compared with vaginal colpo-sacro-spineous fixation (VCSSF). On the other hand, the VCSSF is shorter in terms of operation time and recovery period. Mesh implants where found to reduce prolapse recurrence at the anterior vaginal wall reconstruction, and the vaginal approach was found to be superior to the trans anal for posterior compartment repair. Many other authors acknowledged the fact that the evidence available is not significant to guide practice and the relative shortage of relevant data needed for proper decision making regarding the operation choice for POP cure, including

PHVVP. At the same time is recognized an unacceptable high rate of recurrence with the non-mesh POP reconstructive surgery. Thus, it is widely agreed that meshes implantation should be further investigated prior to withdrawal of solid recommendations regarding their usage. Simultaneously, despite relative lack of evidence-based information regarding long term efficacy and safety, is the use of grafts for POP vaginal reconstruction growing rapidly. The mesh implantation must be considered carefully for each potential candidate, taking into account that the ultimate goal is QoL improvement, by correcting both, the anatomical and functional derangements. For the time being there are not any data-based guidelines recommendation for proper patient and surgery selection, peri-operative management and surgeon's training. There is a considerable debate regarding the performance of vaginal hysterectomy in association with POP surgery, whether is it beneficial or is it negatively influence the POP management.[80-85]

PHVVP Mesh Reconstruction-surgeon's Proper Training

The preferred potential trainee for acquiring POP surgery skills must be expected to perform more than 20 operations with any specific POP type operation yearly, otherwise skill maintenance would not be feasible. Preliminary requirements are thorough theoretical knowledge regarding general pelvic floor medicine and familiarity with advanced pelvic floor surgery. The candidate training should be done with a very experienced trainer, and should include 20 operations of any type of surgery, to overcome the requested learning curve. Thorough knowledge and awareness concerning complications, including prevention, diagnosis and management is essential.[83,85]

ETHICS

Peer-review: Externally peer-reviewed.

DISCLOSURES

Financial Disclosure: The author declared that this study received no financial support.

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DOI: 10.34057/PPj.2022.41.02.2022-4-1
Pelviperineology 2022;41(2):140-148

Overexpansion of the hiatus causing prolapse and LUTS is a failed concept

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Citation: Petros P. Overexpansion of the Hiatus Causing Prolapse and LUTS is a Failed Concept. Pelviperineology 2022;41(2):140-148

ABSTRACT

Background: A strong association between levator expansion, pelvic organ prolapse (POP) and lower urinary tract symptoms (LUTS).

Aim: To test the hypothesis that anatomical damage at childbirth is the underlying cause for excessive hiatal dilatation, prolapse and LUTS.
Methods: Anatomy and biomechanics of the levator hiatus (LH), pelvic muscles and effects thereof of labour were analysed.

Results: LH is a space between horizontally oriented pubococcygeus muscles containing urethra, vagina, and anorectum. These muscles turn vertically downwards into a "tunnel" surrounded by vertically oriented puborectalis muscle, inserting into anal sphincters and perineum. Hiatal expansion is not necessarily pathogenic. A calculated 45sqcm expansion is required for evacuation of larger stools. Co-occurrence of over-expanded LH, prolapse and LUTS are explained as follows: pre-labour depolymerization of collagen "plasticizes" connective tissues, allowing stretch without rupture. Failure to regain normal length post-delivery may cause nerve damage and extended entheses; both may cause hiatal muscle to sag, resulting in LH expansion; also, causing loose or weakened cardinal/uterosacral ligaments which may cause prolapse and weakened muscle forces which cannot open, close or stretch, leading to bladder/bowel incontinence and evacuation problems. A 79% recurrence of POP after successful surgical confinement of LH by puborectalis mesh sling invalidated the expansion hypothesis. However, data showing 80% cure of OAB, SUI and prolapse by TFS (Tissue Fixation system) minisling ligament repair indicated these ligaments caused the conditions associated with LH expansion, not the expansion per se.

Conclusions: Association is not causation. Muscle, nerve, ligament damage by head descent down the birth canal adequately explains LH/prolapse association. Birth damage simultaneously causes levator hiatus overexpansion, prolapse and LUTS.

Keywords: Cystocele; enterocele; pelvic organ prolapse; rectocele

INTRODUCTION

As its Latin name implies, the levator hiatus (LH) is a space - between the two parts of the pelvic diaphragm. Study after study over the past 10 years has affirmed a strong association between levator expansion, pelvic organ prolapse (POP) and lower urinary tract symptoms (LUTS). In spite of this, such observations remain as hypotheses, as little has been stated about why the hiatus causes LH expansion, and why LH expansion causes POP and LUTS. It is necessary to do so. It is an anatomical incongruity for a space *per se*, to cause POP or LUTS.

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Received: 13 April 2022 **Accepted:** 16 May 2022

Research Questions: This incongruity, POP and LUTS causation by a space, led to our research questions. What is the structure of the hiatus? What is the function of the muscles around the hiatus? Which anatomical structures dilate LH on straining? How can the "strong association" between LH expansion, prolapse and symptoms, be explained anatomically? How can the LH/prolapse hypothesis be proved or disproved?

Principal Hypothesis: Childbirth is the underlying cause for excessive hiatal dilatation, prolapse and LUTS, by damaging ligaments, muscles or their entheses and nerves.

METHODS

This was a limited review which was confined to anatomical or surgical papers relevant to the hypothesis. Anatomy and biomechanics of the levator hiatus (LH), pelvic muscles and effects thereof of labour were analysed. Particular emphasis was given past major anatomical cadaveric studies of the hiatal muscles.[1-5] More recent studies were also examined [6-12] as were functional anatomical and surgical studies based on the Integral Theory System.[13-22] Traditional nomenclature was used.[1,2]

RESULTS

Levator Hiatus and its Muscles

Shafik[1] Levator Hiatus and its Muscles: Based on 25 cadavers, Shafik[1] described LH, Figure 1, as, "*The levator hiatus occupies the anterior part of the levator plate. It is bounded on either side by the medial portion of the levator plate, which I call the "levator crura" posteriorly by the anococcygeal raphe, and anteriorly by the back of symphysis pubis. It is covered by a fascial membrane which is the continuation of the fascia on the pelvic surface of the levator plate. The membrane is pierced by the intrahiatal structures: Rectal neck and prostate in males, and rectal neck, vagina and urethra in females. Its fibers are condensed at the periphery of the hiatus to form the hiatal ligament.*"

The pubococcygeus muscles originated from the lower end of symphysis, ran horizontally backwards as two crura, became tendinous as they passed behind the rectum, decussated in a crisscross pattern behind the rectum to form the anococcygeal raphe. Laterally, each crus blended with the corresponding iliococcygeus to form the "levator plate" which turned downwards to enclose the intrahiatal structures as a muscular tube descending down to the perineum, "levator tunnel". The "tunnel" was separated from the organs by a fascial membrane, a continuation of fascia from levator plate. The outer surface of the tunnel was formed by puborectalis muscle. At the rectal neck inlet, the levator plate bent sharply downward to form what is now known as the conjoint longitudinal muscle of the anus (Shafik's[1] "levator anal sling"), extending along rectal neck and anal canal proper, to penetrate external anal sphincter and insert into the perianal skin. In adults, anteroposterior diameter of LH ranged from 3 to 4 cm, and transverse LH diameter from

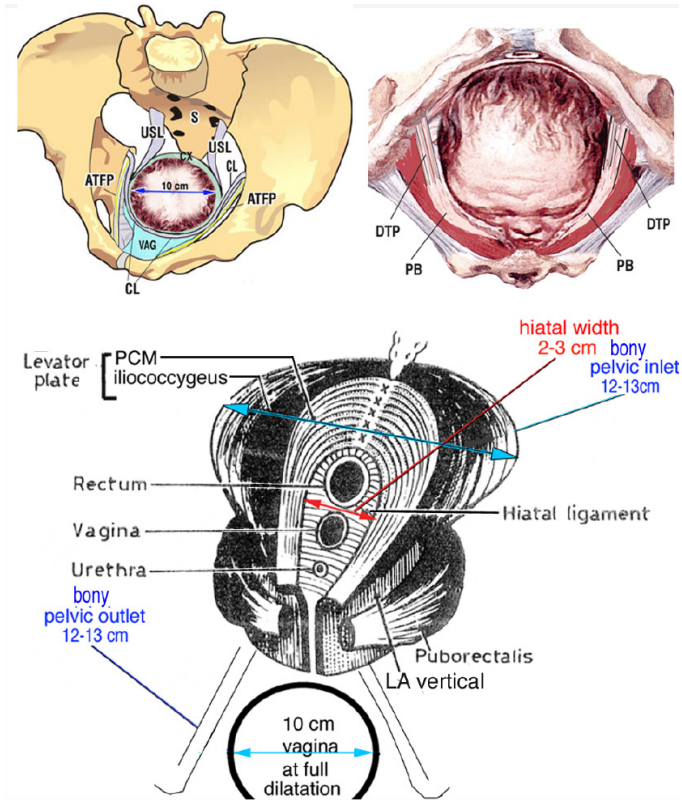

Figure 1. Lower Figure. 3D Schematic view of the levator hiatus, non-pregnant state, behind pubic symphysis, from Shafik[1], by permission. It shows the horizontal pubococcygeus muscles (PCM) bordering the hiatus ("crura") joining with iliococcygeus to form the levator plate and with each other to form the anococcygeal raphe. PCM muscles turn vertically downwards to form a "tunnel" which surrounds the organs. Puborectalis muscle (PRM) forms the outer wall of the tunnel. Below, bounded by the descending rami is the vagina at full dilatation.
Left upper figure: Cervix at full dilatation, 10cm, head entering birth canal. Cardinal (CL) and uterosacral USL) ligaments are severely stretched, as is ATFP attachment to ischial spine. Vaginal attachment to CL and cervix is stretched and often tears to cause a cystocele.
Right upper figure: Vagina at full dilatation, 10 cm. Perineal body (PB) is stretched and displaced downwards and laterally. Deep transversus perinei ligament attachments (DTP) of PB to descending ramus are also stretched. Levator/puborectalis muscle attachments to symphysis may be torn or stretched and dislocated.

2 to 3 cm.[1] Hiatal ligament composition of collagen and elastin[1] explains its ability to expand.

Courtney Conjoint Muscle

Allowing for differences in nomenclature, Courtney's descriptions[2] of pubococcygeus, puborectalis, the surrounding levator muscle tube essentially accord with Shafik's.[1] He described the conjoint muscle (now "LMA") extending inferiorly from the level of the levator fascia to the perianal skin below. The "LMA" was composed of the longitudinal muscle layer of the rectum, fibers from the levator fascia and muscle fibers from both the superior and inferior layers of all three portions of the levator muscle (puborectalis, pubococcygeus and iliococcygeus).[2] This combined layer completely encircled the rectum below the level of the levator fascia, much as described by Shafik.[1]

Zacharin Hiatal Attachments[3]

Figure 2 shows that, at the level of the hiatal ligament, the vagina "V", urethra "U", rectum "R" are tightly bound to each other and to the levator crus "LC" by connective tissue. The uterus "UT" and cervix "CX" are well above the levator crus (LC). Zacharin saw the levators as a contracted floor to retain abdominal contents. He accepted the concept of a widened hiatus causing POP and devised an operation to suture the crura. He reported post-operative urinary retention from this procedure.

Pathogenesis of Cystocele and Uterine Prolapse

Figure 2 (right), shows LH in red circles, and a round fetal head moving down the birth canal. Note the level 1 supports of the uterus, USL and cardinal and their fascial supports are well above LH. So it is impossible, no matter how widely LH is expanded, for LH to cause POP, unless the head has also damaged CL and USL at the same time as it has caused the structural damage leading to pathological LH expansion.

The Biomechanics of Labour Impact All Collagenous Structures to Cause LH Expansion and Prolapse[23,24]

Prior to labour commencing, connective tissue collagen in the birth canal depolymerizes and loses 95% of its strength.[23] Collagen repolymerization "snaps back" by 24 hours.[14] Depolymerization plasticizes all connective tissues, so they can stretch without rupturing. Inability of the collagen to regain its prebirth length and strength is, according to,[13,14] a major causation of pelvic organ prolapse and LUTS. With reference to Figure 2, at 10 cm dilatation of the cervix, Figure 1, USLs may stretch to cause uterine prolapse, the cardinal (CL) ligaments to cause a cystocele, further down, damage to the hiatal ligament, muscles or their insertions to bone, perineal body, a recto-perineocele. The required expansion of LH from 2-3 cm to 10 cm during birth grossly stretches the LH muscles laterally and may place extreme pressure on the entheses at the symphysis or sacrum, extending them to cause widened LH at rest and on straining, as

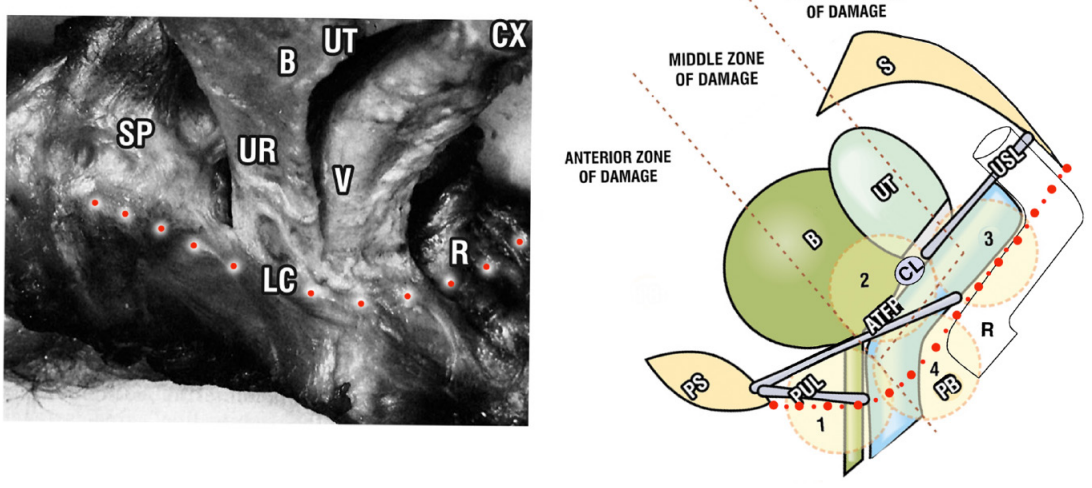

Figure 2. Sites of damage of the head to the levator hiatus and muscles and ligaments as it descends down the birth canal. The red circles represent the pubococcygeus muscle, "levator crus (LC)" which forms the lateral border of the hiatus.
Left figure: Zacharin's[3] dissection showing the attachments of the hiatal ligament. At this level, urethra "U", vagina "V" and rectum "R" are tightly bound to each other and to "LC" by connective tissue. UT: uterus; CX: cervix; SP: symphysis pubis. From Zacharin[3] 1985, by permission.
Right figure: Head descending down birth canal to damage. The red circles represent the levator crura extending from symphysis to cocccyx. "3" USL-uterosacral ligament; "3" CL, cardinal ligament and ATFP attachment to ischial spine; "4" PB, perineal body. "1" PUL pubourethral ligament and pubovisceral muscles.

reported.[6,7] Pathogenesis of rectal prolapse was described,[24] "*The USLs are attached to the lateral wall of the rectum by filamentous ligament-like structures. When the uterus descends, USLs lengthen and invariably splay laterally, to create an enterocele. Lateral USL displacements carry the lateral rectal wall with them; the anterior rectal wall stretches laterally, widening it, so it prolapses inwards to cause intussusception.*"

Integral System[13-22,24-27] a Holistic "Monocoque" Support System, Figure 3

The Integral Theory's concept of a holistic "monocoque" pelvic structure follows the same structural principle of a wire suspension bridge, Figure 3: Every pelvic part supports every other part, with the final structure greater than the sum of the parts. All elements of the pelvis, muscles, ligaments, fascias, organs, are integrated to create a strong, holistic light efficient structure.[25-27] With reference to Figure 3, like a suspension bridge, the ligamentous attachments of USL to rectum, cervix, sacrum, PUL, PVL to symphysis, urethra, bladder are all structural components. However, pelvic anatomy differs suspension bridge analogies because reflex muscle stretching of tissues and smooth muscles (arrows, Figure 4), creates tensile strength VIDEO1 https://www.youtube.com/watch?v=3vJx2OvUYe0. A 4th muscle, puborectalis (PRM), is part reflex (during anorectal closure and evacuation), and part voluntary, during "squeezing" or interrupting the urinary stream ("Kegel muscle"). PRM does not tension pelvic ligaments/fascias. It contracts only against the pubic bone anteriorly. At the level of the pubococcygeus muscle, Figure 2, rectum, vagina, and urethra are densely connected by dense collagenous tissue. The anterior part of the hiatus, is stabilized by insertion of PUL (pubourethral ligaments) into PCM, symphysis, midurethra and vaginal skin.[27] The pubovesical ligament (PVL) stabilizes the bladder by its attachment to the arc of Gil-Vernet et al[5].[14] The forward vector (VIDEO1), constitutes

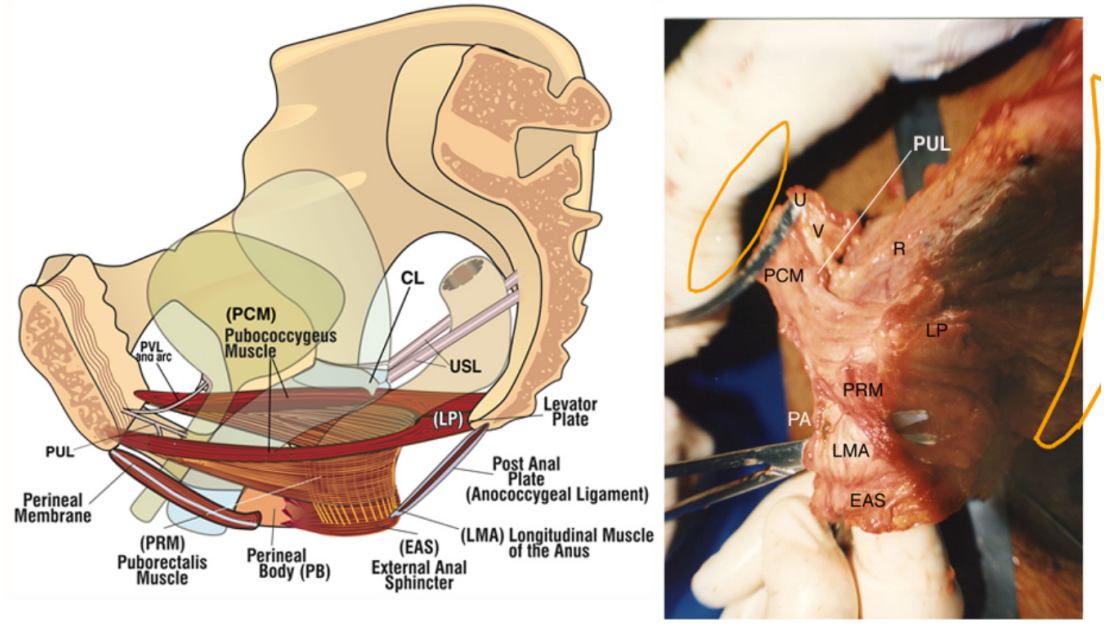

Figure 3. A "monocoque" support system

Right figure: The pelvic muscles. A large knife cut away all pelvic supports and muscles from the pelvic side wall. Vagina and bladder removed at bladder neck level. The horizontal pubococcygeus muscles (PCM) sweep behind the rectum (R) and merge with the contralateral side to form part of the levator plate (LP). The vertical remnant of muscle forward, above and below the label "LP" is the severed iliococcygeus muscle. Below PCM and LP is the vertical puborectalis muscle (PRM) which becomes medial to PCM and attaches directly to the symphysis. The vagina (V) is seen attached to rectum (R) at the level of the hiatus. The conjoint longitudinal muscle of the anus (LMA) is internal to PRM and PCM, but outside the rectum as indicated by the dissecting scissors. LMA inserts into the external anal sphincter (EAS). Puboperinealis (PA) was necessarily cut away along with the perineal body attachments to the descending rami. PUL is the pubourethral attachment to the inner wall of PCM (PP PUL paper).

Left figure: The hiatal muscles, PCM, LP, LMA, PRM are the central point of the "monococque" support system. However, the bladder, uterus and rectum by means of their ligamentous attachments, *well above the hiatus*, are important stabilizers, laterally, cardinal ligaments (CL); posteriorly, USLs; anteriorly PUL (pubourethral ligamenst), PVL (pubovesical ligaments) and insertions of PVL to the anterior bladder wall (arc of Gilvernet). The inferior attachments of rectum and vagina to PB and its attachments to the descending ramus by the transverse perinei ligaments (see Figure 1), bulbo and ischio cavernosus, stabilize the organs inferiorly. From Petros PE.[17,18]

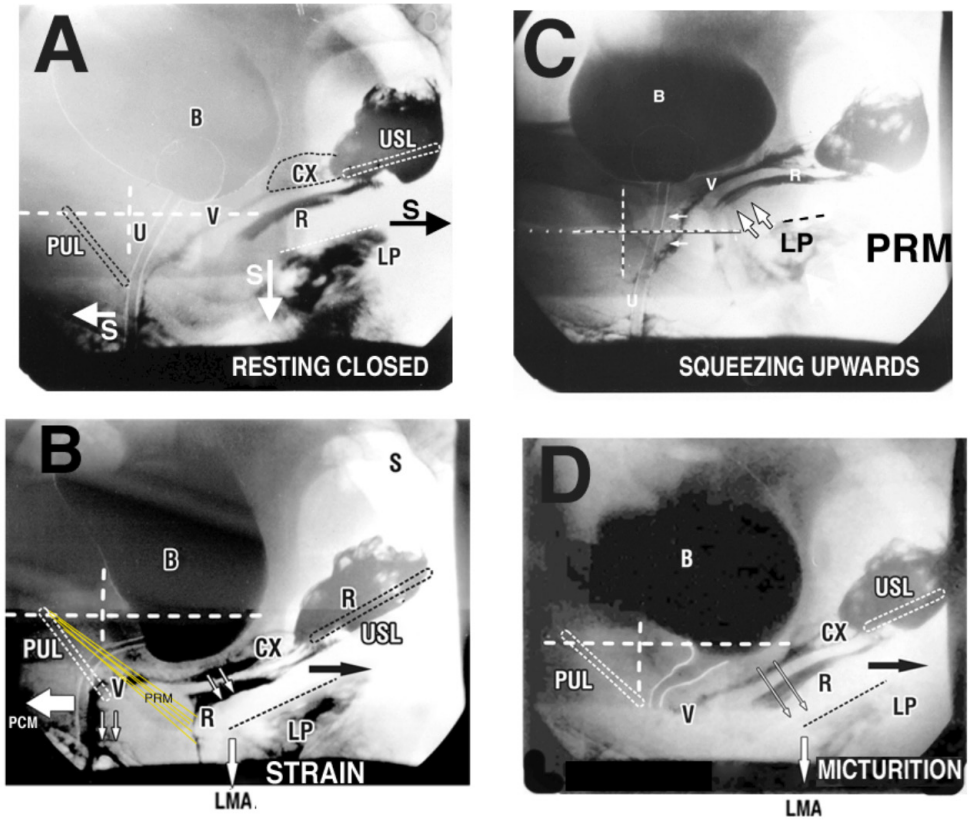

Figure 4. Role of the levator plate in bladder/anorectal closure and micturition. Sitting X-rays Vertical and horizontal lines are bony co-ordinates; A: RESTING CLOSED note S= directional slow twitch muscles as in B. radio-opaque dye inserted into bladder (B), rectum (R), vagina (V) and levator plate (LP). B: STRAIN; note 3 fast-twitch opposite directional forces (arrows) activated by strain; indentation of rectum by PRM; downward angulation of LP by LMA rotates bladder "B" around PUL and rectum "R" around PRM for closure; D: MICTURITION note 2 directional forces for micturition (forward force relaxed), angulation of LP by LMA pulls open posterior urethral wall; C: SQUEEZING UPWARDS: Note LP lifted upwards and forwards from below (by puborectalis PRM). PCM=pubococcygeus; LMA: conjoint longitudinal muscle of the anus. PCM: pubococcygeus muscle; PUL: pubourethral ligaments; USL: uterosacral ligaments. CX: cervix.
From Petros PE [ref].

the medial part of PCM.[25] Its forward action against PUL further stabilizes the anterior part of LH, while the lateral part of PCM, also acting against PUL, Figure 3, sweeps backwards to join with liococcygeus muscle (ICM) to form levator plate (LP), insert into posterior wall of rectum to stabilize the posterior part of LH and the rectum itself. The bladder is attached to the lower end of the anterior cervical ring by the vesicovaginal ligament[14] which must be severed prior to any hysterectomy. Posterior stabilization is by insertion of levator plate (LP), to the lower end of sacrum and coccyx, and by USLs from sacrum, into lateral walls of rectum and cervix, Figure 3. Important lateral stabilization of the monococque system is provided by cardinal ligament (CL), liococcygeus muscle and ATFP into the side wall of the pelvis.

The 4 main pelvic muscles, pubococcygeus (PCM), levator plate (LP), conjoint longitudinal muscle of the anus (LMA) and puborectalis (PRM), Figures 1&3, act together in different combinations in bladder/bowel closure and evacuation.[13,16-18]

Figure 4A RESTING CLOSED X-ray myograms show the opposite directional movements of the 3 reflex muscle forces, slow-twitch at rest "S". Figure 4B STRAIN, fast-twitch movements during coughing/straining: PCM contracts forwards against pubourethral (PUL) ligament to close distal urethra; LP contracts backwards to tension vagina and rectum in preparation for the downward vector LMA to contract against uterosacral ligaments (USL) to rotate bladder around PUL for urethral closure, and around a contracted PRM for anorectal closure. Figure 4C SQUEEZING UPWARDS. It is clear from Figures 1 and 3, that PRM is sited below LP and is lifting it upwards above the horizontal co-ordinate during squeezing (See "squeezing segment VIDEO3, defecation). Figure 4D MICTURITION PCM relaxes, LP/LMA unrestrictedly pull open the posterior urethral wall to exponentially lower resistance to urine expulsion the 4th power of radius (Poiseuille's Law)[21], micturition VIDEO2 https://www.youtube.com/watch?v=eiF4G1mk6EA&feature=youtu.be

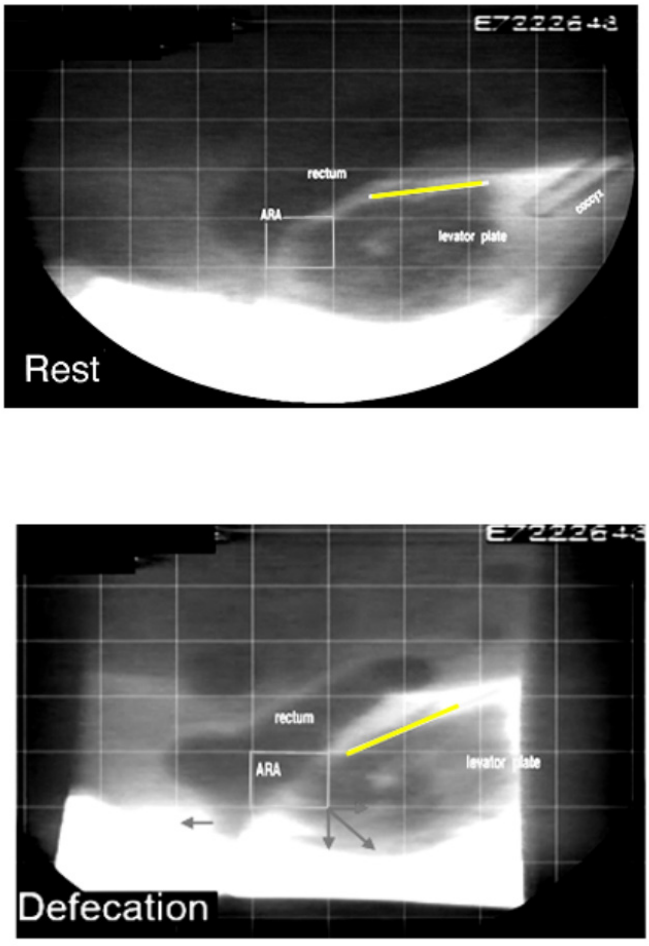

Figure 5. Rest: ARA is the anorectal angle at rest. The yellow line marks the superior border of levator plate.
Defecation: Note attachment of levator plate (backward vector) to rectum just above ARA as in the anatomical dissection, Figure 3. Note angulation downwards of the anterior part of levator plate (yellow line) by the downward vector LMA (conjoint longitudinal muscle of the anus, Figure 3), to open out the posterior wall of the rectum, effectively doubling outlet tube diameter.

VIDEO4. Note lateral expansion of the rectum. By permission Dr Ilario Froehner Jnr.

Defecation

Figure 5 Puborectalis muscle (PRM) relaxes. This allows the backward/downward vectors LP/LMA to pull open the posterior rectal wall. External opening of the anorectum exponentially lowers the resistance to expulsion of feces by the 3rd power of the radius.[22] See defecation VIDEO3 https://youtu.be/MS82AZoWn7U

Anatomical Perspective-some Explanatory Comments

There are many difficulties in reporting any anatomical studies. Anatomical dissections give highly variable, complex findings, very different for every dissection. In the hiatus alone, Shafik[1] noted three distinct pubococcygeus crural patterns, direct insertion,[18] crossover and "scissors.[3] In spite of attempts to "standardize" nomenclature, major differences remain. Purported functions are at best hypotheses. Some traditional names are admittedly inaccurate, e.g., "anococcygeal raphe"[1] or insufficient, "puboccygeus" as it should include iliococcygeus.[2,7] Shafik[1] hypothesized bladder/bowel function.[1] Petros implicated ligaments in normal function and damaged ligaments in causation of dysfunction.[13-19] Shafik[1] defined the levator hiatus as a 3D structure, which he called "levator tunnel", enclosed by levator muscles, which he called "levator sling", both surrounded by puborectalis muscle Figure 1. Courtney also described these structures, but named them differently. Shafik's[1] "anal sling", a conjoint striated/smooth was described by Courtney[2] as the posterior "longitudinal muscle of the rectum" and by Petros as the "longitudinal muscle of the anus (LMA)" to distinguish it from the longitudinal smooth muscle of the rectum which joins the LMA as the conjoint muscle. Shafik[1] and Courtney[2], described structures equivalent to puboperineus and puboanalis, as offshoots from PCM or PRM. They described in detail, the complex insertions of PCM, PRM, LMA into the 3 anal sphincters, coccyx, lower sacrum and intermuscular connections, fibres extending to the urethral rhabdosphincter and bulbocavernosus. Whether extensions or actual muscles, all must have an important role in function, as the pelvic floor functions holistically. For example, MRI observations of anterior wall of the anorectum being pulled forwards to open out the anus during defecation,[20] were attributed wholly to forward contraction of PCM. Specific prolongations as described to the anal fascia and inter-sphincteric fascial structures ("puboanalis") would more directly assist this action. A direct insertion into the perineal tendon, as described by Courtney[2] (now "puboperineus") would play an important role in stabilizing the pelvic structures and may further explain the downward movement of the distal urethra seen on straining.[17,18] Cadaveric dissections, dynamic ultrasound, Berglas and Rubin's[4] X-ray myogram methods, Figures 4, 5, (VIDEOS 1-3) were used to correlate organ displacements during bladder/bowel closure and evacuation, with pelvic muscle actions.[13-22] More recent innovative anatomical studies, using high definition 3D/4D ultrasound and MRI studies, many linked to cadaveric or mathematical models,[6-12] promise to take interpretations of pelvic muscle anatomy to yet another, higher, level of understanding.

DISCUSSION

The research questions are discussed seriatim.

Research Question 1: "What is the structure of the hiatus?" LH is a variable space 2-3 cm in diameter[1], bound by a collagenous hiatal ligament, Figure 2. LH is usually in a contracted state,[4] as it is important to minimize its diameter to support the abdominal contents. A fine collagen/elastin connective tissue layer across the LH,[1] confirmed by live dissection of the anterior part of LH by the author,[27] prevents abdominal contents slipping through.

Research Questions 2-4: "What is the function of the muscles around the hiatus? Which anatomical structures dilate LH on straining?" Expansion of the LH laterally is necessary for childbirth and to open out the anorectum prior to defecation, Figure 5, VIDEOS 3&4. LH expansion is not pathogenic as implied by many authors. Figure 1 shows the magnitude of distension required for childbirth, 10 cm. As regards defecation, an LH diameter as little as 2 cm,[1] has to expand considerably to allow evacuation of large Bristol type 2 stools.[28] The horizontal attachments of iliococcygeus muscle to levator crura, and crisscross pattern of the "anococcygeal raphe" behind the rectum Figure 1, allow the hiatus to expand LH laterally to enable expulsion of large fecal stools. Using an LH area at rest of approximately 12 sq cm and observations of the rectal diameter doubling during defecation, fig5, a "normal" woman with no prolapse would need to dilate her LH to a minimal 45 sq cm to allow expulsion of feces. This is far beyond the arbitrary 25 sq cm cut-off limit for pathogenic expansion suggested by some experts. Rectal expansion exponentially decreases resistance to fecal evacuation[20,22] enabling defecation without obstruction.

A Hypothesis for a Resting Expanded LH by a Sagging Hiatus:

In 1956, Berglas and Rubin[4] explained that, as a pelvic floor sags, the crura lengthen, and the hiatus enlarges. Sagging of levator muscles may be caused by nerve damage, as demonstrated with EMG studies[29] and by computer simulation,[30] muscle damage[31] elongated entheses.[32] Figure 2 graphically shows how a head moving down the birth canal can damage the ligamentous parts of the holistic "monocoque" organ support system.

Is it Anatomically Possible for a Widening Levator Hiatus to Cause POP?

In both the cadaveric and schematic images, Figure 2, the uterus, and therefore, its level 1 ligament supports (CL and USL), are well above LH, so it is impossible for an LH to cause POP, *unless the head has also damaged CL and USL at the same time*.

Research Question 5: How can the "strong association" between clinical signs of prolapse and symptoms, be explained anatomically?

Proof that POP and symptoms were related was surgically demonstrated by Inoue et al.[33] with 5 year and 10 year[34] data. Inoue used the TFS tensioned minisling for holistic ligament repair (mean 3.2 per patient).[33,34] Sixty-eight women had multiple POP defects cystocele (n=61), uterine prolapse (n=59), rectocele (n=35), plus SUI (n=28), with at least one stage 3 or 4 defect per patient.[33] The change in cure rates of symptoms and prolapse is summarized in Table 1.[33]

Research Question 6: How can the LH/prolapse hypothesis be proved or disproved? The acid test for this question was provided by some of its most passionate proponents for causation,[35-37] who directly tested the hypothesis with a 3x25 cm mesh sling around the puborectalis muscle to limit PRM expansion. The sling was performed as a 2nd operation on women immediately after they had undergone a primary operation for prolapse. A pilot study, 115 women between 2010-2,[36] and an RCT, 221 women, reported in 2021[37] demonstrated convincing decrease in LH expansion, but it did not prevent POP recurrence: 66% at 2 years for the pilot study[36] and 79% for the RCT.[37] Despite the two operations performed for prolapse, the improvement in POP and LUTS recorded was low,[36,37] far inferior to the ligament repair method.[33,34] Five year data,[33] Table 1, and 10 year data for 960 patients, 3100 TFS implants,[34] using TFS ligament repair methods based on the 3 level pelvic organ ligament support system,[34] validate the hypothesis that POP and LUTS were caused by ligaments, not hiatal distension.

CONCLUSIONS

Association is not causation. Overexpansion of the hiatus causing prolapse and LUTS is a failed concept. This was irrefutably demonstrated surgically: A confining 3 cm by 25 cm mesh placed around the puborectalis muscles prevented hiatal expansion on straining, but registered a 79% prolapse recurrence at two years with a level one RCT study.[37]

The relationship between hiatal expansion, prolapse and LUTS causation was anatomically explained by a holistic ligament-based "monocoque" structural system tensioned by reflex muscle forces. Immediately prior to birth, the collagen of the hiatal and pelvic ligaments depolymerizes to lose 95% of its strength; the head stretches the intrahiatal organs and structures as it descends down the birth canal. Failure to regain their original length and strength explains expanded LH, prolapse and LUTS.

Table 1. Lower und upper 95%-confidence intervals for the observed relative frequencies of Prolapse, Urgency, Nocturia, Day time frequency, Dragging pain and Fecal incontinence after certain time intervals with the tests results by testing Ho: $p \leq p_0$ vs. H1: $p > p_0$.
"*", "#" and "/" means significant p-values when p_0 is setting equal to 0.80, 0.75 and 0.60, respectively. With other words these symbols depict that the observed cure rates are significantly higher than 0.80, 0.75 and 0.60 respectively ($p<0.05$; Binomial tests)

Time after TFS	Cure of prolapse		Cure of urgency		Cure of nocturia		Cure of day time frequency		Cure of dragging pain		Cure of dysuria		Cure of fecal incontinence	
12 mths	62/68		30/31		17/18		30/32		13/14		35/38		16/18	
Observed cure rate (in %)	91.2%		96.8%		94.4%		93.8%		92.9%		92.1%		88.9%	
95% (lower CI; upper CI)	0.877	0.946	0.936	0.999	0.890	0.998	0.895	0.980	0.860	0.997	0.877	0.965	0.815	0.963
Test results of Ho: p≤0.80 vs. H1: p>0.80	*		*		#		*		§		*		§	
24 mths	57/65		25/30		11/17		26/29		14/15		26/28		12/15	
Observed cure rate (in %)	87.7%		82.3%		64.7%		89.7%		93.3%		92.9%		80%	
95% (lower CI; upper CI)	0.836	0.918	0.765	0.901	0.531	0.763	0.840	0.953	0.869	0.998	0.880	0.977	0.697	0.903
Test results of Ho: p≤0.80 vs. H1: p>0.80	*		§		ns		§		§		#		ns	
36 mths	48/58		23/24		14/23		27/30		9/10		25/26		6/7	
Observed cure rate (in %)	82.7%		95.8%		60.9%		0,900		0,900		96.2%		85.7%	
95% (lower CI; upper CI)	0.778	0.877	0.918	0.999	0.507	0.710	0.845	0.955	0.805	0.995	0.924	0.999	0.725	0.989
Test results of Ho: p≤0.80 vs. H1: p>0.80	§		*		ns		#		§		*		ns (?)	
48 mths	42/50		18/20		8/17		13/19		6/6		22/23		5/5	
Observed cure rate (in %)	0.84		90.0%		47.1%		68.4%		1,000		95/6%		100%	
95% (lower CI; upper CI)	0.788	0.892	0.833	0.967	0.350	0.592	0.578	0.791	1.000	1.000	0.914	0.999	1.000	1.000
Test results of Ho: p≤0.80 vs. H1: p>0.80	§		§		ns		ns		§ (?)		*		ns (?)	

Yellow marked fields in table 2 means, that we have to pay attention in the interpretation of significances, because for these fields the corresponding sample sizes are too small. From Inoue[32] by permission. CI: confidence interval

ETHICS

Peer-review: Internally peer-reviewed.

DISCLOSURES

Financial Disclosure: The author declared that this study received no financial support.

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