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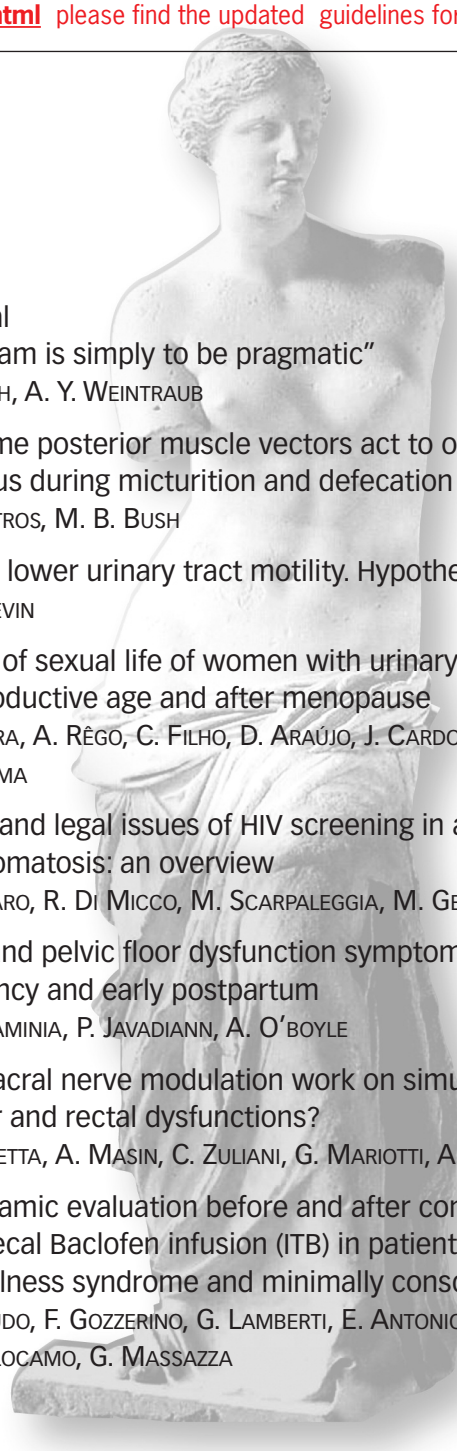

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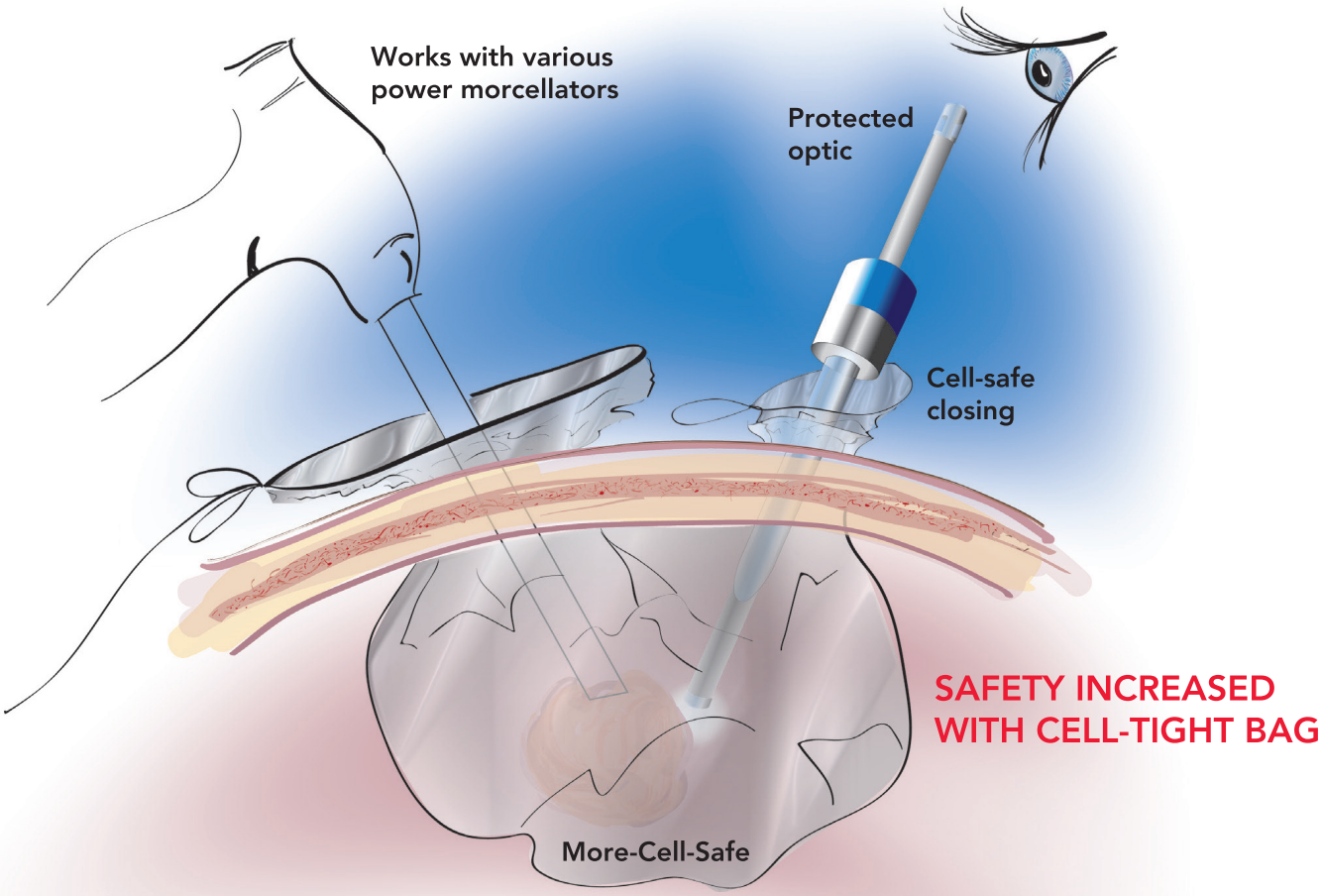

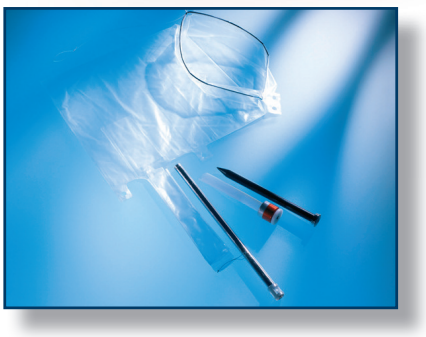

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Editorial

"To dream is simply to be pragmatic"

Mr. Shimon Peres the former president and prime minister of Israel

The Israeli Society Of Urogynecology and Pelvic Floor

The ISPP (International Society of Pelviperineology) 2016 annual meeting took place at the Peres House for Peace on the Mediterranean Sea shore, in Tel-Aviv-Jaffa, 21-24th September 2016. This took place around the time Shimon Peres, one of the greatest leaders in Israeli history had passed away at the age of 93. The event was held in collaboration with The Israeli Society for Urogynecology and Pelvic Floor Medicine (ISUG), the Israeli Society of Urology and the Israeli Society of Colorectal Surgery. This was one of the biggest and most successful urogynecology conferences being held in Israel with involvement of more than 250 participants, in which more than 50 were guests from around the world (including: Austria, Australia, Belgium, Brazil, the Czech Republic, France, Germany, Italy, Japan, Palestine, Slovenia, Reunion Island, Russia and Turkey). Preceding the meeting four workshops were held, focusing on the Integral Theory System, chronic pelvic pain, pelvic floor ultrasound and intractable OAB. Thereafter, eight plenary sessions and four original research sessions were conducted lasting for a full and very busy two days. Out of dozens of abstracts submitted, 40 were selected for oral presentation. The third day of the conference was dedicated for live surgeries for incontinence and pelvic floor prolapse reconstruction, vaginal and laparoscopic repairs, performed by masters and transmitted to the venue auditorium in an interactive mode.

The former president and Prime Minister, Mr. Shimon Peres, was known for always looking for new solutions – whether fighting for peace or pushing for scientific research and new technological innovations.

The ISUG is the official pelvic floor society in Israel. It brings together, urogynecologysts, gynecologists, physiotherapists, nurses, and all medical professionals with an interest in pelvic floor disorders. The aims of ISUG are to bring together all medical professionals in the field in order to establish national clinical guidelines, promote health and disseminate information to patients, to share knowledge and provide a forum for research through scientific meetings, conferences and lectures and to academically and clinically stimulate the society's members.

The ISUG has decided to declare Pelviperineology Journal (PPJ) as an official journal of the society. We believe that the PPJ has an essential role in achieving the society's goals. Israeli researchers and authors are encouraged to submit their work to the PPJ and a link to the journals website is available on the society's website.

The ISUG is an active academic society on several levels:

- It holds annual conferences with a broad scientific program including sessions to present research abstracts of original studies especially emphasizing studies conducted by residents and young researchers.
- Discussions regarding issues with multidisciplinary aspects are organized and encouraged on "Friday morning" quarterly meetings, with the participation of physicians from different disciplines, such as gynecological endoscopists, physiotherapists, urologists and other professionals.
- Provides sponsorship and support for scientific meetings held in various medical centers throughout the country, in which experts from around the world discuss a subject or demonstrating live surgery.

Historically, ISUG was established in 2002 and in 2010, the ISUG organized the first IUGA Regional Symposium in Israel. This too was a very successful event with many participants from around the world including physicians from the Palestinian Authority. During this meeting the obstetrical anal sphincter injuries (OASIS) hands-on Workshop was first conveyed in Israel by Sultan and Tucker. This workshop was a milestone in the ISUG decision to adopt the program and implement it in Israel. Since then in the past six years, starting February 2011, the ISUG has worked vigorously to advance and substantiate the diagnosis and management OASIS and to raise the awareness and knowledge in this field, by delivering voluntarily the workshop at most of the hospitals in Israel.

Among the many activities of ISUG, one of the most important missions lays with the education and training of the younger generation. The ISUG conducts a unique final exam preparatory course for residents.

The society is in the process of establishing a formal urogynecology fellowship in Israel that would be recognized by the Scientific Council of the Israeli Medical Association.

ISUG is dedicated to advances in knowledge of urogynecological diseases, urinary or fecal incontinence, and vaginal prolapse and the dissemination of this knowledge to patients. For this reason the society is involved in the translation of international patient leaflets to Hebrew that are soon to be published. In addition, one of the ISUG's goals is to write and publish clinical guidelines and position statements in accordance with internationally accepted guidelines, but adapted to Israel. The society has already published position statements on management od overactive bladder syndrome and the diagnosis and management of obstetrical anal sphincter injuries.

One of ISUG's main goals for the future is to establish a formal school for urogynecology in order to better educate medical students, residents, nurses and physiotherapists in the field.

Finally, Mr. Shimon Peres had said "All my life I have worked to ensure that Israel's future is based on science and technology as well as on an unwavering moral commitment… They called me a dreamer. But today, when I look at Israel, we all can see clearly that the greater the dream, the more spectacular the results." These visionary ideas are held by many in Israel and are an inspiration for the ISUG in the field of urogynecology and pelvic floor medicine.

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Focus

The same posterior muscle vectors act to open urethra and anus during micturition and defecation

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Abstract: The generally accepted mechanism for micturition and defecation is that the pelvic floor muscles relax, detrusor contracts, urine and feces are expelled. To our knowledge, no EMG or imaging proof has ever been offered to validate this mechanism. X-ray and EMG evidence presented here confirms an alternative hypothesis, that only the forward acting pelvic muscles relax prior to micturition, m.pubococcygeus for micturition and m.puborectalis for defecation; prior to detrusor contraction, the same backward acting muscle vectors contract against competent uterosacral ligaments (USL) to open out the posterior urethral wall and anorectal angle. This exponentially decreases the internal resistance to fecal and urine flow. If USLs are loose, this mechanism weakens and the patient may complain of evacuation difficulties for bladder, bowel or both. Shortening and reinforcing the USLs has been demonstrated to reverse this cascade of events to cure the evacuation dysfunctions.

Key words: Micturition; Defecation; Pelvic muscle contraction; Frictional resistance.

BACKGROUND

The generally accepted mechanism for micturition is that the pelvic floor relaxes, detrusor contracts, urine is expelled. To our knowledge, no EMG or imaging proof has ever been offered to validate this mechanism. In their Standardization of terminology report in 2005, The International Continence Society[1] stated that the pelvic floor muscles must relax in order to remove the passive continence mechanisms, thereby favouring normal micturition.

The mechanics of defecation and fecal continence are similarly poorly understood. Valvular theories for continence[2] rely on raised intra-abdominal pressure to force the anterior wall of the rectum downwards to close off the anorectal junction.

An understanding of the mechanisms of normal micturition and defecation is a pre-requisite for understanding organ evacuation dysfunction. One case in point is voiding dysfunction following the Burch colposuspension[3]. Unlike a sling, there is no discrete point of obstruction with the Burch. Using Hegar dilators, urethral stricture is rarely found in surgery naive patients with "outflow obstruction". We believe that the answer to these questions is the exponentially determined urethral resistance which is instantaneously modified by an external striated muscle mechanism first described in 1990[4]. Neither is there any obvious mechanical obstruction in patients with obstructive defecation syndrome (ODS).

MECHANISM OF MICTURITION AND DEFECATION

This external opening mechanism, since validated with EMG and video x-ray studies[5-7] stretches open the posterior urethral and anal walls (Figs. 1,3) and is in turn dependent on competent suspensory ligaments[4]. The external opening mechanism for the urethra was described as follows: *"immediately prior to commencement of voiding, the forward closure vector (m.pubococcygeus) relaxes; relaxation of m.pubococcygeus releases the closure pressure of the hammock on the posterior urethral wall, thereby freeing the posterior vectors (levator plate and the conjoint longitudinal muscle of the anus) to actively open the urethra prior to detrusor contraction, exponentially lowering the resistance to flow immediately prior to the expulsive action of the detrusor*"[4].

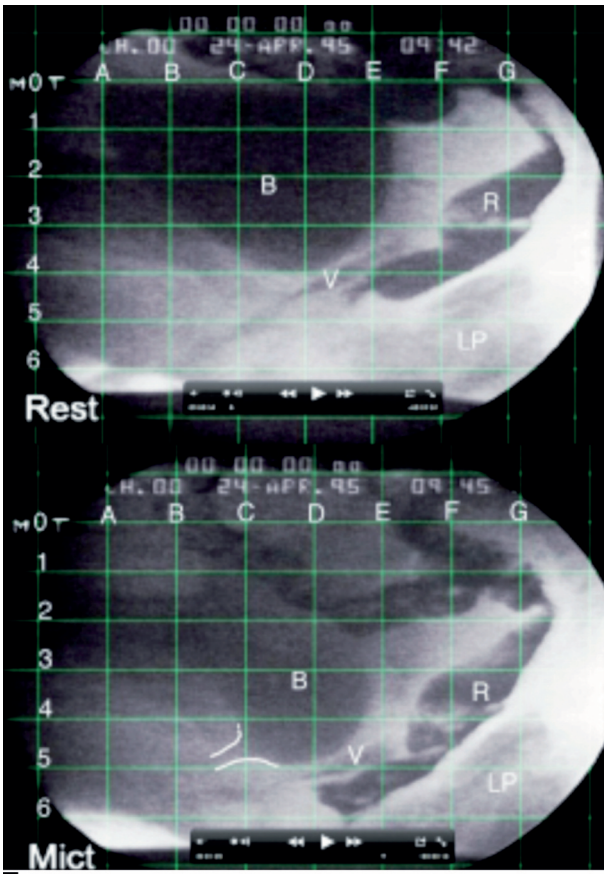

Figure 1. –Active opening of the urethra.
The upper X-ray is at rest. The lower X-ray was taken during micturition. Dye has been injected into bladder 'B', vagina 'V', rectum 'R', levator plate 'LP'. The grid allows direct comparison of organ movement during micturition. LP is seen to insert in to the posterior wall of rectum. *Micturition:* The bladder base, vagina and rectum have been pulled down from level 4 to level 5, apparently by contraction and downward angulation of the levator plate.

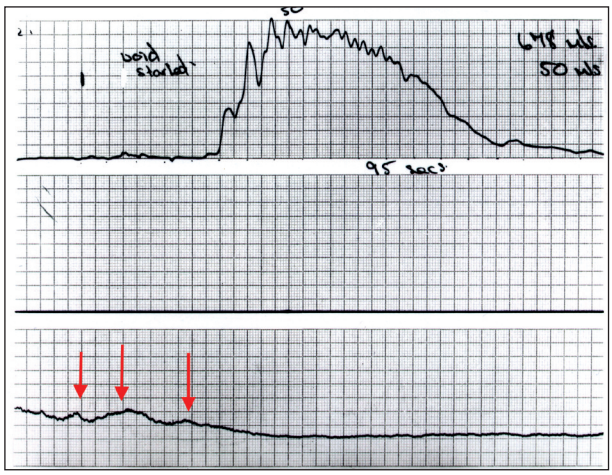

Figure 2. –Active opening of the urethra-normal patient.
The EMG probe was placed in the posterior fornix of the vagina. The arrows indicate commencement of muscle contraction in the region of the posterior fornix of vagina well before micturition commences, indicating active opening of the urethra. Note disappearance of muscle activity once flow commences. The reason for this is that urine is incompressible, so while there is urine flow, the urethra remains open.

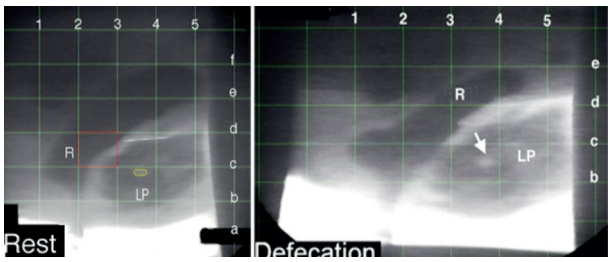

Figure 3. –Proctogram taken from a video of defecation.
Radioopaque dye has been injected into the rectum 'R' and levator plate 'LP'.
At rest: The rectum "R" is resting on LP with a well-defined anorectal angle (about 110 degrees) situated just above horizontal line 'c'. Yellow circle is a defect in LP .
Defecation: The rectum and anorectal angle have descended to lie just above the horizontal line 'b'; the anorectal angle has opened to almost 180 degrees; the anterior rectal wall has been pulled forwards beyond the vertical line '1'; The anorectum has been opened out very significantly, at least to twice its resting diameter. In the video, the feces appear to run down the posterior wall of rectum. The circular defect in LP, has moved down and back (arrow), consistent with backward/downward opening muscle vector forces actively opening out the anorectum.

The pattern of defecation (Figures 3a,3b) was described as follows[7]*:*

"backward movement of the upper part of the anorectum and forward movement of its lower part effectively opened and straightened the anorectal tube to at least double its resting diameter. The rectum emptied in one bowel movement, and feces can be seen moving downwards along the posterior wall of the rectum." Fundamental to this mechanism is the prior relaxation of the forward vector, m.puborectalis[7].

The mechanisms of micturition and defecation are remarkably similar. Both are opened out by the posterior vector forces which act backwards and downwards, levator plate (LP) and longitudinal muscle of the anus (LMA) (Figures 1,3). Both mechanisms require relaxation of a forward retaining vector, m.pubococcygeus for micturition and m.puborectalis for defecation.

An essential consequence of this mechanism is the cascade of events dependent upon the keystone of this mechanism, the uterosacral ligament: the downward opening vector contracts against the uterosacral ligament (USL); in the USL, if the insertion of the downward vector force is loose, the vector forces weaken[8]; the vectors cannot open out the posterior urethral wall or posterior anal wall; the detrusor contracts against an unopened urethra/anus and therefore, a high internal resistance to flow is encountered for both urine and feces; the patient will have bladder/bowel emptying difficulties because of greatly increased resistance to flow[9-10].

It follows that the cascade of events which leads to these voiding dysfunctions is potentially reversible by surgical strengthening of the uterosacral/cardinal ligament complex by insertion of polypropylene tapes[11]. Studies showed a marked improvement in bladder and bowel evacuation problems following reconstruction of the uterosacral ligaments[11].

An active mechanism explains the inability of spinal cord patients to micturate spontaneously, and the almost invariable finding of a normal urethra and anus in patients with 'obstructive evacuation'. The 'obstruction' is functional not anatomical, contraction of the detrusor against an anatomically normal, but insufficiently opened urethra/anus.

DISCLOSURES

No conflicts either author.

Contributions: Figures, Peter Petros. Both authors contributed to analysis of the figures, to their interpretation and the writing of the manuscript.

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Hypothesis

Normal lower urinary tract motility. Hypothesis

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Abstract. The objective: To clarify the mechanisms of urinary continence and micturition. *State of the problem:* Based on the assumption that all peristaltic organs obey the same laws we offer a hypothesis of motor function of the lower urinary tract. *Hypothesis*: The pressure on the wall of the empty bladder is equal to intra-abdominal pressure (IAP). During the intake of urine, the pressure in the bladder rises to a threshold level of the first order (TP-1) and remains unchanged to volume 300-400 ml (main volume). In the volume of the more basic the pressure in the bladder is increased to the threshold pressure of the 2nd order (TP-2), which causes relaxation of the internal urethral sphincter (IUS). Urine, penetrating to the neck of bladder, stimulates the urge to urinate. At this moment, retention of urine is provided by the contraction of the external urethral sphincter (EUS) and puborectal muscle (PRM). If the implementation of urination is not possible, detrusor relaxes adapting to the new volume and intravesical pressure decreases from TP-2 to TP-1, which leads to a reflex contraction of IUS and passive relaxation EUS and PRM. Inflow to the bladder of an additional urine volume causes again an increase in pressure to TP-2, followed by relaxation of IUS and contraction of the EUS and PRM. While the EUS and PRM contract, the IUS relaxes to recover its contractile capacity and vice versa. This ensures continued retention of urine. Urination begins with tension of the abdominal wall, which causes an increase in intra-abdominal pressure and the pressure increase in the bladder from TP-2 to TP-3. All sphincters (IUS, EUS, and PRM) relax, and the urine under the same pressure flows through the urethra opening as the result of coordinated contraction of the bladder micromodules. The maximum volume of urine after a long delay can be up to 1 liter (main and reserve volume, which entered to the bladder as result of the forced delay). In men, when a large amount of urine is accumulated in the bladder, the prostate contraction squeezes the urethral lumen at the level of IUS for supporting of a prolonged urinary retention.

Keywords: External urethral sphincter; Detrusor; Internal urethral sphincter; Hypothesis; Physiology of urination; Prostate.

Abbreviations: IAP – intra-abdominal pressure; TP-1 - threshold pressure-1 (filling); TP-2 - threshold pressure-2 (urge); TP-3 - threshold pressure-3 (urgency); IUS – internal urethral sphincter; EUS – external urethral sphincter; PRM – puborectalis muscle, LAM – levator ani muscle.

STATE OF THE PROBLEM

Paired ureters, urinary bladder, and urethra constitute the lower urinary tract. Oblique passage of ureters through the bladder wall results in compression of the distal ureter to preclude urine reflux. Ureters are anchored by longitudinal ureteral musculature that outlines the bladder trigone and extends into dorsal submucosa of the urethra as urethral crest. The male urethra has penile and pelvic components, the latter is divisible into preprostatic, prostatic, and postprostatic regions. The muscle coat of the bladder-urethra forms three functional entities in craniocaudal series. These are the detrusor muscle (to effect voiding), the smooth muscle of the internal urethral sphincter (IUS) for generating tonic resistance, and the striated urethralis muscle of the external urethral sphincter (EUS) for phasic and voluntary continence. The vesical neck is a transition region. It is part of the IUS by virtue of its histology and innervation, but it contains detrusor fascicles that pull it open during micturition. Viscous accommodation plus sympathetic reflex inhibition of the vesical wall allows the urinary bladder to greatly expand in volume with minimal increase of intravesical pressure, within limits. At low volumes continence can be maintained by passive resistive elements of the urethral outlet. As volume increases, sympathetic reflex activity is necessary for continence. The striated external urethral sphincter is reflexly contracted to counter abrupt elevations of intravesical pressure and to maintain continence voluntarily[1].

The bladder is a large organ, generally serving as a reservoir for urine, but with intermittent expulsion of urine as perceived timely be the individuals; this alternation between storage and voiding phases is known as the "micturition cycle". Functionally, the bladder structure may comprise modules with variable linkage, which supports presence of localized micromotions, propagating contractions and the shifting of micromotions over time. Conceptually, such activity could facilitate the ability to transition to voiding at any bladder volume. Thus, the urination takes place at constant intravesical pressure, and it is possible for any urinary bladder volume[2]. Urine constantly arrives to the bladder after its emptying. Small-volume vesical distension effected no significant urethral or vesical pressure changes while distension with 350 and 400 mL of saline produced vesical pressure elevation ($P < 0.01$) and urethral pressure decrease ($P < 0.01$). Vesical distension after individual vesical and urethral anesthetization effected no change in the urethral pressure[3]. The rise in intravesical pressure leads to the disclosure of the vesical neck, i.e, IUS, and the emergence of the urge[1]. During urination the vesical pressure rises, and the tonus of the IUS reduced[4]. Hence the perfectly obvious fact, indicating that there is a certain threshold volume of urine, below which the pressure in the bladder remains unchanged. This gradual uninterrupted relaxation of the bladder is the result of coordination of muscle relaxation of different micro modules. In the research of Shafik et al has been shown that external urethral sphincter (EUS) contraction effected the inhibition of vesical contraction and suppression of the desire to micturate[5]. The pressure rise in the bladder increases the tone in the ureterovesical junctions and renal pelvis[4]. Shafik et al determined the reaction of the bladder and urethral sphincters to the distention of the adjacent parts of urinary system as specific reflexes. For example: vesicoureteral inhibitory reflex, vagino-urethrovesical reflex, meato-vesico-urethral reflex and others. When analyzing reflexes described above, it is clear that they obey the law of Bayliss-Starling, which explains the mechanics of peristaltic movement. In accordance with this law, the distention of the lumen in any part of the gut leads to the increased pressure cranial and decreased tone caudal to the extension zone[6]. Analysis of the reactions to distension of the different parts of the urinary tract lumen is fully consistent with this law. For example, "…the vesical pressure drop on renal pelvis distension postulates a reflex relationship that we call the "reno-vesico-sphincteric reflex"[7]. Considering the same laws for both the urinary tract and anorectal area, which is responsible

for fecal retention and defecation, we can extrapolate with the high reliability the normal and pathological reactions of the anorectal zone to the reactions of different parts of the urinary system.

The EUS does not connect directly with the bones. In women, its lower part is tightly connected to the levator ani muscle (LAM) through the tendon ligament. Contraction of the EUS pulls the urethra back and down. Contraction of the LAM compresses the rectum and moves the rectovaginal complex forward and upward. The simultaneous contraction of the EUS and LAM results in bending the middle urethra forward and closing its lumen. In men, there is no connection between the EUS and LAM[8]. Many authors called the LAM all the muscles of the pelvic floor. However, despite the fact that all the muscles of the pelvic floor are difficult to be separated from each other they have different function. Consolidating all the muscles in a single name causes much confusion. For example, it is known that puborectalis muscle (PRM) relaxes during defecation. Since the PRM is considered to be part of the LAM, for a long time it has been thought that all parts of the LAM, including iliococcygeus and coccygeus, during defecation also relax[9,10]. If the LAM during defecation relaxes, it means that in the other times it is in a contracted state. This is contrary to common sense, because striated muscle cannot be in the contracted state for a long time. Secondly, there is a question about its role in long-term contraction. It is known that this massive muscle is not involved in the retention of feces. Recently, there were reports that the LAM during defecation does not relax, but contracts, creating a channel for the passage of stool[11,12]. Thus, from the pelvic floor muscles only the PRM participates in the retention of urine and feces. Different parts of the LAM surround the urethra, vagina and rectum, it allows to some authors call them, respectively: pubourethralis, pubovaginalis, puboperinealis and puboanalis[10].

Modern representations about the normal anatomy and physiology of the lower urinary tract are fragmented, i.e. not systematized. The role of the prostata in urodynamics of the healthy men has not been clear yet. It is found that its contraction during ejaculation prevents the release of sperm into the bladder[13]. Therefore, at this time the prostata contraction overlaps the urethral lumen. In prostatic hypertrophy, the contraction of muscle fibers of the prostata plays an essential role in the violation of urodynamics until the development of the urethral obstruction[14].

Based on published data, and general laws for the peristaltic organs, we propose the hypothesis of the normal urodynamics (physiology of storage, retention and urination).

HYPOTHESIS OF THE NORMAL MOTILITY OF THE LOWER URINARY TRACT

The accumulation and retention of urine.

The view that the urethral sphincters beyond the urination are in the constantly contracted state, raises some questions. Have the urethral sphincters a constant tonus? Second, how to explain the ability of smooth muscle sphincter to be in the contracted state for a long time, if it is known that every muscle fiber during contraction expends its contractile capacity and then inevitably comes relaxation, during which the muscle restores its ability to contract. This equally applies to the muscle of bladder - to the detrusor[15,16]. We hypothesize that many groups of the muscle bundles are in the various stages of recovery of the contractile capacity. At any moment an electrical stimulus that excited by the Cajal cells[17], leads to the contraction of the groups, which are ready to contraction. During the next electric wave, other groups of muscle bundles are contracted, while the previous muscle fibers relaxed for recovery of their contractile ability. All groups of the muscle bundles are contracted at different times in a vicious circle. This is manifested in the form of slow regular waves of electrical activity[18]. This can explain the ability of the IUS to provide the continuous continence. If there is a need to enhance the tone of the IUS, the extra-bladder center sends the more intense electrical stimulus that causes contraction of an additional number of the groups “almost ready to contraction”. In this case, the tone of each muscle fiber is not changed, but the tone of the IUS rises[11,18]. The functional structure of bladder can be represented as muscle modules[19], each of which consists of the number of muscle bundles. After complete emptying of the bladder, all or almost all of the modules are in the contracted state, while muscle bundles make a circular cycle from contraction to relaxation and vice versa.

In an empty bladder the pressure on its wall is equal to intra-abdominal pressure (IAP). There is a continuous portioned flow of urine from kidneys to bladder. Each urine portion slightly increases the total volume of urine and the intraluminal bladder pressure. In response, the internal computer, the role of which performs the intramural nervous system, increases the number of the relaxed muscle modules. As a result, of such continuous correction the pressure inside the bladder is maintained at the same level. We call this pressure the threshold pressure of the 1st order (TP-1), which slightly higher than IAP. At this time, the IUS is in the closed state, but its tone is changed in accordance with the minimal necessity. When the pressure within the bladder rises, the tone of the IUS increases, and when the pressure in the bladder decreases the tone of the IUS decreases. This reflex reaction provides retention at the required level without excessive overload of the muscle fibers. And it manifests, as was shown by Shafik et al as an undulating electric activity of the IUS[18].

When the volume of urine in the bladder increases up to a certain level (main volume ≈ 300-400 ml), the further increase in volume causes an increase in pressure inside the bladder - the threshold pressure of the 2nd order (TP-2). It causes the reflex disclosure of the IUS (the neck of bladder) in the form of a cone, the tip of which directed to the urethra. At this time, the urethra closed by the contracted EUS and PRM. In this case there is a complete analogy with the rectoanal inhibitory reflex[11]. Disclosure of the IUS leads to the penetration of urine into the neck of bladder, which causes a feeling the urge to urinate. Thus, at a time when the IUS ceases to perform urine retention function, this role is performed by the contraction of the EUS and PRM. Striated muscle of the EUS and PRM is not capable to the long-term contraction and relaxes. If urination is not possible, the bladder pressure is reduced from TP-2 to TP-1, as the result of relaxation of a certain amount of muscle modules. The IUS again contracts and the urge to urinate disappears[5]. The newly arrived urine portion causes the pressure rise in the bladder, resulting in relaxation of the IUS and contraction of the EUS and PRM. After a few seconds, the bladder relaxes, the IUS contracts again, and the EUS and PRM relax. During contraction of the IUS the muscles of the EUS and PRM restore the ability to contraction. The EUS and PRM compress the urethra when the IUS relaxes and restores its ability to contraction. Such periodicity of the different muscles contraction, preventing leakage of urine, lasts as long as there will be an opportunity to empty the bladder. The bladder can take additionally to the main

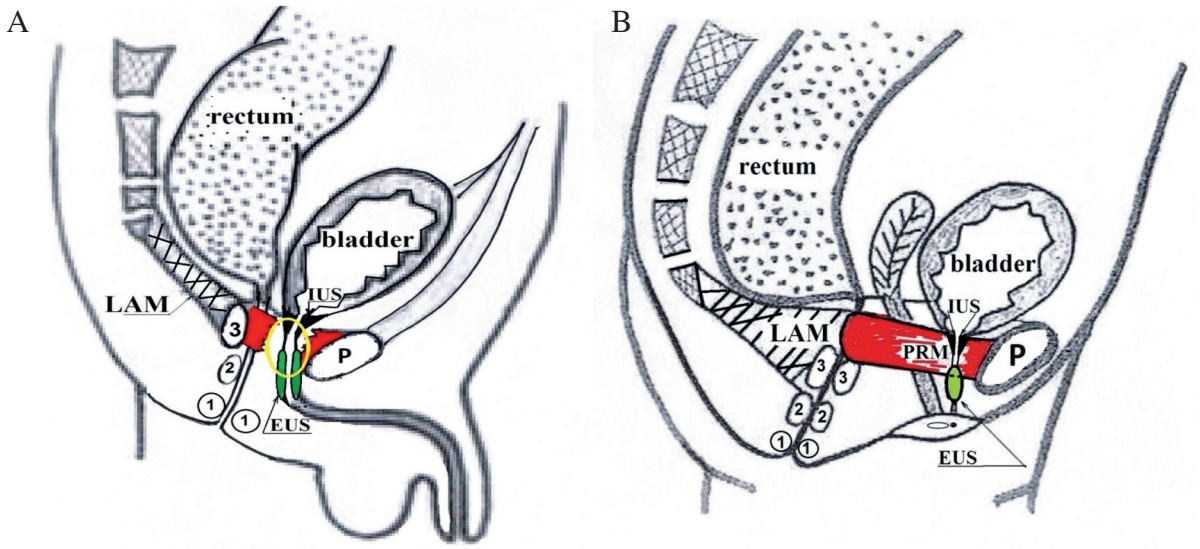

Figure 1. – Schemes of the lower urinary tract in male (A) and female (B).
LAM – levator ani muscle; P- pubis; 1-2-3 – tree parts of the external anal sphincter; IUS – internal urethral sphincter (black); EUS – external urethral sphincter (green); PRM – puborectalis muscle (red); Yellow circle - it is a projection of the prostate location.

volume about 300-500 ml of urine, which we call the reserve volume. In the process of the bladder filling its wall progressively becomes thinner.

Role of the prostate in urine retention in male

It is known that the prostate surrounds the prostatic urethra. It contains smooth muscle fibers, the role of which is extremely simple: its length becomes shorter during contraction.

Since the muscle fibers are arranged circularly, during their contraction the urethral lumen becomes narrow. Professor Shafik et al clearly demonstrated that the contraction of the prostate during ejaculation squeezes the urethra, preventing the sperm to get into the bladder[13]. It is also known that the erection makes it impossible to urinate, thus helping to avoid nocturnal enuresis. This phenomenon is also known as the effect of Bonfield [Wikipedia]. In benign hyperplasia of the prostate, α1- adrenoblockers are used to improve the urodynamics. They causes relaxation of smooth muscles of the prostate and thus increase the urethral lumen[20]. After removal of the urinary catheter, the three-time use of α1-adrenoblocker Xatral 10 mg is recommended for the prevention of prostatic spasm. All these data indicate that the contraction of prostate closes the lumen of the prostatic urethra, i.e., participate in the retention of urine.

The prostate plays the role of the urine retention in the case of bladder overflow. When the volume of bladder exceeds the main plus reserve volume, the arrival of a new portion of urine does not cause relaxation of the bladder, the bladder pressure rises to TP-3, what leads to the reflect contraction of the prostate.

Voiding

Urination is a reflex process that coordinates the relaxation of the IUS, EUS and PRM with continuous detrusor contraction. This process takes place under the control of the CNS and under the constant threshold pressure (TP-3), which as a result of contraction of the anterolateral abdominal wall muscle simultaneously with vesical contraction[21].

Internal computer leads to the contraction of such number of micro-modules as is necessary to maintain the constant pressure in the bladder throughout the urination process, with the exception of the last portion which coming out under low pressure. Since TP-1 is not change, regardless of the amount of urine (up to 400 ml), urination can be triggered with any amount of urine by the rise of the intra-abdominal pressure. When it reaches the level of the TP-2, the IUS opens. The urine enters the neck of bladder, causing the urge to urinate. Continuing tension of the anterior abdominal wall leads to an increase in pressure to TP-3, and the voluntary EUS and PRM are instructed to relax. Urination occurs to the complete emptying of bladder. Thus, the wall of bladder has the surprising elasticity since the bladder can be stretched to a volume of 1 liter and reduced to a complete evacuation.

CONCLUSION

Based on the assumption that all peristaltic organs obey the same laws we have offered the hypothesis of motor function of the lower urinary tract. In an empty bladder the pressure on its wall is equal to intra-abdominal pressure (IAP). The accumulation of urine in the bladder occurs at the constant pressure - threshold pressure of the 1st order (TP-1), which slightly higher than IAP. When urine volume reaches 300-400 ml (the main volume), the pressure in the bladder is increased to the threshold pressure of the 2nd order (TP-2), which causes relaxation of the IUS. The urine, penetrating to the neck of bladder, stimulates the urge to urinate. At this moment, retention of urine is provided by the contraction of the EUS and PRM. If the implementation of urination is not possible, detrusor relaxes adapting to the new volume and intravesical pressure decreases from TP-2 to TP-1, which leads to a reflex contraction of IUS and passive relaxation EUS and PRM. Inflow to the bladder of an additional urine volume causes again an increase in pressure to TP-2, following by relaxation of the IUS and contraction of the EUS and PRM. While the EUS and PRM contract, the IUS relaxes to recover its contractile capacity and vice versa. This ensures continued retention of urine. Urination begins with tension of the abdominal wall, which causes the increase in intra-abdominal pressure and the pressure increase in the bladder from TP-2 to TP-3. All sphincters (IUS, EUS, and PRM) relax, and the urine under

the pressure flows through the opened urethra as the result of coordinated contraction of the bladder micromodules. The maximum volume of urine after a long delay can be up to 1 liter (main and reserve volume, which entered to bladder as the result of forced delay). There is a possibility that the prostate contraction can induce urethral compression for supporting of a prolonged urinary retention.

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Disclosures

The proposed hypothesis opens up new possibilities in the diagnosis and treatment of diseases of the urinary system. The article was not sent to another journal and its materials were not previously published. I am the only author of the new hypothesis. I did not get financial support.

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Commentary

I warmly welcome this original contribution to the journal. The PPJ mission statement right from its origin has always been to encourage original thought in any research concerning the pelvic floor, male and female, pediatric to geriatric, investigative and management, conservative or interventional.

This contribution occupies another special category, conceptual. Without hypotheses there is no innovation, no new treatment, no Cochrane, nothing.

For the most part, it is a review. The review is wide ranging in its background information. The references in the review set a basis for the formulation of a hypothesis of normal bladder function which is based on the assumption that all peristaltic organs obey the same motility laws. This is an original concept and it will hopefully lead to a vigorous debate within the pages of the journal.

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Original article

Quality of sexual life of women with urinary complaints in reproductive age and after menopause

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Abstract: *Aim*: To compare the quality of sexual life of women with urinary incontinence during reproductive age and menopause, and to analyze epidemiological data, including gynecological and obstetric characteristics. *Methods*: Cross-sectional, descriptive, and quantitative studies that evaluated women with urinary symptoms who sought assistance at the female urology services of Women's Hospital and received gynecological care and assessment according to the Golombok Rust Inventory of Sexual Satisfaction (GRISS)-Female version in Macapa City, from February to June 2013. *Results*: Stress urinary incontinence was the predominant symptom, with a prevalence of 94.1% in postmenopausal women and 87.8% in non-menopausal women. Vaginal deliveries were more predominant than cesarean deliveries (median: 3 > 1) in both groups. Statistical significance was observed in the frequency of sexual intercourse (p = 0,0217), sexual satisfaction (p = 0,0105), expression of feminine sensuality (p = 0,0293), dyspareunia (p = 0.0022), and anorgasmy (p = 0.0002). *Conclusions*: Urinary incontinence had a negative effect on female sexuality, especially when associated with advanced age, which resulted in a decline in the quality of life of the women in this study.

Keywords: Quality of Life; Sexuality; Urinary Incontinence; Women's Health.

INTRODUCTION

Urinary incontinence (UI), according to the International Continence Society, is defined as a complaint of any involuntary urine leakage[1]. Stress UI (SUI) is defined as an involuntary urine leakage during activities that require efforts, in combination with increased intra-abdominal pressure, but without simultaneous contractions of the detrusor muscle. Urgency UI (UUI) is characterized by the presence of urgency with a consequent urine leakage. Finally, mixed UI (MUI) is defined as the simultaneous occurrence of UI and UUI[2].

An estimated one-third of women experience involuntary urine leakage or excessive urgency within their lifetimes. The real prevalence mainly depends on age and peaks in the postmenopausal period, singly or in the form of MUI[3].

According to Tinelli[4], estrogens increase the tone and vascularization of pelvic floor muscles, which explains the relationship between estrogen deficit in menopause and the increasing prevalence of urogenital problems.

Nilsson et al.[5] found that half of women with UI reported a concern about urinary leakage during intercourse, and nearly two-thirds declared they fear the odor and reported feeling unattractive. Cohen et al.[6], in a qualitative study involving patients with UUI, found that partners of patients complained mainly of interruption of intercourse by urinary leakage during intercourse.

UI is a condition that affects women's personal, social, professional, and sexual well-being. Women with SUI present significantly more tendency to have decreased libido, decreased vaginal lubrication, and dyspareunia, regardless of age, educational level, and ethnicity[7].

Female sexuality is influenced by biological factors such as puberty, pregnancy, and menopause, and by individual aspects, including social and cultural variables, making it a complex and striking phenomenon in women's quality of life[8,9].

Thus, this study aims to compare the quality of sexual life of women with UI complaints in the reproductive age and menopausal period, and to analyze the associated epidemiological profile, and gynecological and obstetric characteristics.

METHODS

This was a cross-sectional, descriptive, and quantitative study in women with urinary symptoms who sought urogynecological service at Women's Hospital Mãe Luzia, Macapá City, between February and June 2013. The study was conducted in accordance with the recommendations of the Declaration of Helsinki, revised in 2008,[10] regarding the guidelines for research involving human subjects. The project was approved by the research ethics committee of the Federal University of Amapá. All the participants signed the Free and Informed Consent Term form.

Inclusion criteria were as follows: the presence of urinary symptoms as the chief complaint, no confirmation by urodynamic examination, and no history of corrective surgery via vaginal access, retropubic access, or both. The exclusion criteria were as follows: communication failure or difficulty in answering the questionnaire, pregnant women, postpartum women, infants, children aged <18 years, and women with disease and/or neurological sequelae.

The patients were divided into two groups, the menopausal group (women who had their last menstrual cycle within >12 months) and reproductive age group (women who had their reproductive capacity preserved), and gynecologically evaluated and assessed by using the Golombok Rust Inventory of Sexual Satisfaction (GRISS)–Female version.

The GRISS[11] questionnaire is used internationally and consists of 28 questions that evaluate seven areas of female sexual function (frequency of sexual activity, sexual communication, sexual satisfaction, sexual avoidance, expression of sensuality, vaginismus, and anorgasmia). Each evaluation received a score of 0-9, distributed between the frequency of the mentioned events (never, rarely, sometimes, often, and always). The total GRISS score indicates the degree of sexual satisfaction, and the cutoff point in each domain is 5 points.

In addition to the GRISS, a questionnaire was used to assess socioeconomic aspects, the presentation of urinary complaints, and gynecological history. The questionnaire application was made by the same researcher, and responses to the questionnaire were self-reported.

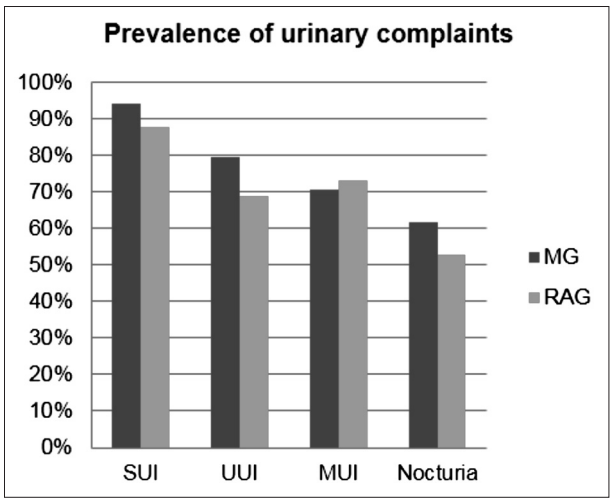

Figure 1. – Prevalence of urinary complaints in the reproductive age group (RAG) and menopause group (MG) of patients treated at the urogynecology clinic of a reference hospital in Macapá City, AP, between February and June 2013 (n = 108). MG: Menopause Group; RAG: Reproductive Age Group; SUI: Stress Urinary Incontinence; UUI: Urgency Urinary Incontinence; MUI: Mixed Urinary Incontinence.

To evaluate the GRISS, the domains were presented through measures of central tendency and variation, and analyzed by using the Mann-Whitney *U* test. The evaluation according to age group was performed by using the Kruskal-Wallis test with Dunn's posttest. Quantitative variables were analyzed by using the c^2 test (chi-square). A p value of <0.05 indicated a significant difference. All statistical analyses were performed in the BioEstat version 5.3 software.

RESULTS

The total patient sample (108 women) was divided into groups as follows: reproductive age group (RAG) with 74 patients and the menopause group (MG) with 34 patients. The MG presented a mean age of 58 ± 13 years; and the RAG, 40 ± 16 years. Most of the women were married (47.1% and 43.2%, respectively), with 11 years of education (41.2% and 48.6%, respectively; Table 1).

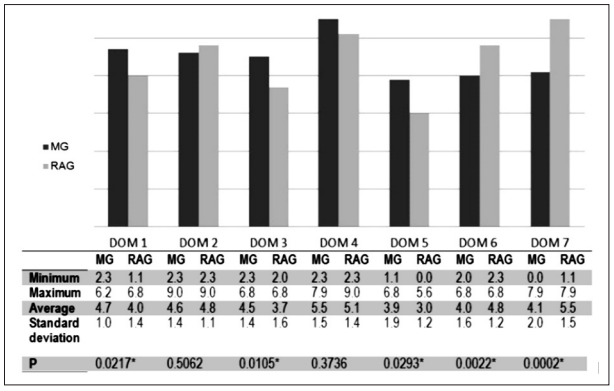

Figure 2. – Evaluation of assessments related to sexual satisfaction (GRISS questionnaire) in the menopause group (MG) and reproductive age group (RAG) of patients treated at the urogynecology clinic of a reference hospital in Macapá City, AP, between February and June 2013 (n = 108). MG: Menopause Group; RAG: Reproductive Age Group; DOM 1: Frequency of Sexual Activity; DOM 2: Sexual Communication; DOM 3: Sexual Satisfaction; DOM 4: Sexual Avoidance; DOM 5: Lack of Sensuality Expression; DOM 6: Vaginismus; DOM 7: Anorgasmia.

Table 1. Distribution of socioeconomic data in the reproductive age group (RAG) and menopause group (MG) of patients treated at the urogynecology clinic of a reference hospital in Macapa City, AP, between February and June 2013 (n = 108).

	RAG (n)	%	MG (n)	%
AGE				
20-30	7	9.5	0	0.0
31-40	30	40.5	0	0.0
41-50	34	45.9	4	11.8
51-60	3	4.1	16	47.1
61-70	0	0.0	12	35.3
71-80	0	0.0	2	5.9
EDUCATIONAL LEVEL				
Illiterate	0	0.0	3	8.8
Elementary School	22	29.7	13	38.2
High School	36	48.6	14	41.2
College	16	21.6	4	11.8
MARITAL STATUS				
Married	49	66.2	22	64.7
Single	19	25.7	5	14.7
Divorced	6	8.1	7	20.6

Among the urinary complaints, the most prevalent was SUI in both groups (94.1% in the MG and 87.8% in the RAG). Nocturia was the less prevalent complaint (61.8% and 52.7%, respectively Figure 1). In the MG the beginning of menopause was more prevalent in two age groups, the 45- to 47-year (29.4%) and 51- to 53-year age groups (32.4%) (Figure 2; Table 2).

With respect to obstetrical history, we observed that the mean number of vaginal deliveries was 3.76 in the MG and 2.83 in the RAG. Meanwhile, the mean numbers of cesarean births were 0.14 and 0.22, respectively. Home births occurred at a higher frequency in the MG (1.35 births per woman) than in the RAG (0.48).

Among the seven areas assessed in the GRISS, five were statistically significantly related to the lower sexual quality of life in the MG than in the RAG (frequency of sexual intercourse, p = 0.0217; sexual satisfaction, p = 0.0105; women sensuality expression, p = 0.0293; dispaurenia, p = 0.0022, and anorgasmia, p = 0.0002).

DISCUSSION

The sexual quality of life, especially in women, is not adequately evaluated by using physical or clinical methods, as in other areas of individuals' health[2,12,13,14]. Therefore, evaluation questionnaires are useful to translate subjective aspects of women's sexuality into quantitative variants of sexual satisfaction[2,12].

Table 2. Distribution of gynecological and obstetrical history in the reproductive age group (RAG) and menopause group (MG) of patients treated at the urogynecology clinic of a reference hospital in Macapá City, AP, between February and June 2013 (n = 108).

	RAG (n)	%	MG (n)	%
MENOPAUSAL AGE, YEARS				
45-47			10	29.4
48-50			9	26.5
51-53			11	32.4
54-56			4	11.8
Mean number of natural deliveries	2.83		3.76	
Mean number of cesarian deliveries	0.22		0.14	
Mean number of forceps deliveries	0.02		0	
Mean number of homebirths	0.48		1.35	
Mean number of abortions	0.37		0.47	

The mean age observed in the MG was compatible with the period when menopause installation often occurs, which is from 45 years of age[15,16]. Nevertheless, the presence of urinary complaints in younger women (20-45 years) suggests that this age group can also report UI, which demonstrates that UI is not an exclusive condition of advanced age. However, symptom severity and its impact are greater in the postmenopausal population, as evidenced by the low scores in the GRISS components evaluated in this study.

The following sociodemographic findings were similar between the two groups, being predominant: civil status "married/common-law marriage," educational level "completed high school," and the origin of the urban area. The study of Bomfim et al.[17], which evaluated the profile of incontinent women who were attending public and private services in Maceio City, Alagoas, obtained similar sociodemographic results, suggesting that this profile has greater motivation to seek health service[3,15], despite the great personal and social stigma that UI generates in these women's lives[18,19].

In order of frequency, the most prevalent urinary complaints in urogynecology clinics are stress incontinence, UUI, and to a lesser extent, nocturia[2]. This same pattern was observed in this study and in the studies of Riss et al[2] and Liebergall-Wischnitzer et al[13].

These urinary symptoms increase with age[2,15] and have significant effects on the quality of sexual life[19,20], confirmed in this study by the reduced scores in the GRISS domains in the MG. This assertion is supported by the study of Ratner et al[14], which identified improvement in sexual quality of life of incontinent women after treatment of UI.

The higher frequency of vaginal deliveries in the MG than in the RAG suggests that women in this group had obstetrical risk profile for UI[12,15], especially for SUI[21] (>90% in the MG).

Prado[22] affirms, however, that the mode of delivery does not alter the risk of developing UI. As compared with nulliparity, pregnancy in itself constitutes a risk. Regardless of the mode of delivery, UI is caused by damage to the pelvic floor during pregnancy[3].

Nevertheless, the probability of injury to the pelvic floor increased with the highest number vaginal deliveries[15]. In addition, advancing age and menopause itself constitute triggering factors such as the findings of Ratner et al[14], Bomfim et al[17], and Cetinkaya et al[21].

The analysis of GRISS score in the "Frequency of Sexual Intercourse" domain confirmed the reduction in the frequency of sexual intercourse in the MG, similarly to the results reported by Ratner et al[14] and Topatan, Yildiz[16]. Climacteric or postmenopausal women have reduced frequency of sexual relations[16], triggered by the reduction of libido[13], discomfort during intercourse due to atrophy of the vaginal mucosa, lubrication reduction[8,20], weight gain, onset of comorbidades[14,20], the absence of a partner, or reduced sexual interest by both parties in a stable union[8,20,23].

The MG also showed higher scores in the domain "Dyspareunia" and "Anorgasmia." These conditions trigger a reduction in sexual satisfaction and frequency of sexual relations[15,24] and commonly increase owing to changes in the genitourinary tract during menopause[14]. These domains affect the third domain, "Women Sensuality Expression," the results of which suggest less satisfaction with their own bodies and reduction in strategies to improve the sexual life in the MG. This population may lose interest in sex due to urinary symptoms and the many physical changes previously cited[14,16].

Sexual interest is determined based on intrinsic hormonal and psychological factors such as self-image and self-esteem. Both decreased hormonal levels and dissatisfaction caused by the body[15,25] are determining factors for the reduction of sexual interest[18,24]. Women who feel unable to express their sensuality possibly feel retracted to continue their sex life appropriately[23]. Thus, the "Sexual Satisfaction" domain (domain 3) score was also reduced in the MG[14,16].

Exuberant symptoms of UI[19] that are associated with inadequate support offered by the partner[19,20] and insufficient medical care directed to sexuality have significant impact on women's quality of life[13,14,19,22] and make the development of coping strategies to maintain quality of sexual life difficult[20], especially when they occur during the climacteric or menopausal period[20,21].

The absence of a urodynamic study is explained by the focus in the clinical finding of UI, its perception, and the impact of these symptoms on the quality of life of this population, as these factors are the real modifiers of the quality of life in this group. As limitations, we noted the absence of data about comorbidities (obesity, diabetes mellitus, and hypertension), factors known to be related to sexuality.

In conclusion, UI has a negative impact on female sexuality, which is aggravated in the presence of menopause. However, to determine whether menopause, gynecological-obstetrical profile, or both are the predominant factors for the deterioration of sexual quality of life, further studies are needed to define the degree of influence of each of these changes on women's sexuality.

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Review

Ethical and legal issues of HIV screening in anal condylomatosis: an overview

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Abstract: Although the strong evidence of the prevalence of condylomata in the HIV-positive population, literature on HIV prevalence and regulation of HIV screening in HIV-unscreened population which is diagnosed with condylomata is unconclusive. Our aim is to review literature about HIV screening and diagnosis of anal condylomata in order to evaluate medical aspects, ethical and legal issues concerning the management of this disease. We undertook an online search on Pubmed for the keywords "HIV", "screening" and "anal condylomata" and 21 papers were analysed, 2 being randomized controlled trial, 9 comparative studies and 10 reviews. A total of 1211 patients were reviewed. All authors strongly recommend HIV testing in patients with clinical evidence of anal condylomata. In undeveloped countries with high prevalence of HIV, a proctological evaluation could be a good opportunity to have a "targeted" screening in a high risk population. In conclusion, two HPV vaccines now available could represent an unexpected therapeutic option for HIV infected male patients to prevent anal cancer. Clinical trials and prospective studies are necessary to validate this interesting hypothesis.

Keywords: Anal condylomatosis; HIV screening; Papilloma virus.

INTRODUCTION

HIV infection is a true plague and a major health concern worldwide. It is estimated that 33.4 millions people globally have been infected to date. HIV transmission is by sexual contact, intravenous drug abuse, maternal to fetal route or rarely through transfusion of infected blood or blood products. HIV infection is a dynamic process with pathological features that vary with the chronology of the disease[1]. Nowadays, though most countries have ready access to screening centers and retroviral treatment, factors such as extreme poverty, social stigma and lack of education can be obstacles to proper management of the disease. Despite tremendous efforts by organizations worldwide, personal, political, social and economic barriers compromise treatment and prevention. Chronic immunosuppression for various reasons is an important risk factor for persistent infections with human papillomavirus (HPV) and, consequently, HPV-associated disease[2]. Most genital warts (condylomata lesions) will spontaneously resolve in the immunocompetent population[3], but immunocompromised patients with condylomata (especially HIV-infected patients) generally require an expensive therapy, carrying a high risk of recurrence. There seems to be a complex interaction between HIV, HPV and local mucosal immune mechanisms[4]. HIV enhances the HPV transcription and upregulates HPV E7 which influences the cellular differentiation leading to the higher amounts of HPV DNA in the tissue[5]. Furthermore, HPV causes a decrease in the number of the local macrophages, Langerhans and CD4 cells and the impairment of the local cytokine production resulting in impaired local immune control of HPV infection[6]. Many studies have now documented that people living with human immunodeficiency virus (HIV)/AIDS, mainly men who have sex with men (MSM), but also heterosexual men and women, have an increased risk for anal cancer[7,8]. In HIV-infected women, the risk for anal cancer is approximately 14 times higher than among HIV-positive women diagnosed with AIDS, with the anal cancer rate estimated at 30-36 per 100 000 person-years[9]. Although there is strong evidence of the prevalence of condylomata in the HIV-positive population, literature on HIV prevalence and regulation of HIV screening in HIV-unscreened population who is diagnosed with condylomata is unconclusive[10,11]. Because of the intimate nature of questions on sexual behaviors and sexually-transmitted infection risks, detailed and accurate data to assess HIV risk are challenging to collect. Anogenital warts can be considered a visible marker of HIV risk and could help clinicians treating non-gay-identified MSM who may be reluctant to disclose some sex behaviors. Particularly for these non-gay-identified MSM (but for all MSM as well as transgenders), failure to screen for HIV during any health-related encounter represents a missed opportunity to detect incidental infections. Our aim is to review the literature about HIV screening and diagnosis of anal condylomata in order to evaluate medical aspects, ethical and legal issues concerning the management of this disease.

MATERIALS AND METHODS

We undertook an online search on Pubmed for the keywords "HIV", "screening" and "anal condylomata" and we found 83 papers, which have been published during the last 30 years. We included in our review all the original articles and reviews in order to evaluate the state of art in terms of HIV screening and diagnosis of anal condylomatosis. We excluded papers which were not written in English and single case report. Our analysis considered several clinical characteristics, HPV genotypes, coexisting HIV infection and related therapeutic options.

RESULTS

21 papers were analysed, 2 being randomized controlled trials, 9 comparative studies and 10 reviews. A total of 1211 patients were reviewed. Some studies investigated HPV genotypes , others compared results after surgical treatment versus no surgery but topical cream, in several papers authors evaluated the efficacy of several HPV detection tests. 2 studies did not include HIV patients.

8 papers reported ethical and legal issues about the management of HPV-HIV coexisting disease and HIV screen-

ing in patients affected by anogenital warts. All authors strongly recommend HIV testing in patients with clinical evidence of anal condylomata. Prior to testing, the patient should be consented with a thorough explanation of the rationale, risks, and benefits of testing[12]. Consequently, the discussion of ethical and legal issues about HIV testing is the key to obtain a voluntary informed consent[13]. In case of positive result, the patient must be directly sent to the proper treatment. Taking care of the positive patients as soon as possible is an ethically fundamental step to ensure patients to benefit from knowing their HIV condition. An unconsented HIV testing is forbidden. As regard as HIV-tested patients, all standard measures to ensure strict confidentiality should be applied, consistently with applicable law. These include storing HIV test results in a secure medical record, protection of the legal proceeding if applicable, and establishing security protections to prevent unauthorized disclosure of test results to third parties[14,15]. The incidence of anal cancer in HIV-positive MSM is comparable with that of cervical cancer before the introduction of screening programme[16] and the question is whether such a screening would also be an effective strategy to decrease the incidence of anal malignancy. According to cost-benefit model, anal cytological screening in HIV-positive MSM should be cost-effective for preventing anal cancer.

DISCUSSION

HIV has become a more and more frequent condition all over the world, nevertheless many questions about screening guidelines remain unanswered. Anal condylomatosis is a disease which is frequently associated to HIV sero-positivity and could be a marker of concomitant infection. However the intimate nature of the disease and the common patient reticence about sexual habits together with the strict policy regulating HIV diagnosis make the management of this condition very difficult form the medical, ethical and legal views. To date, literature about this topic provides unclair results[17,18].

Youngs and Hooper[19] found no strong ethical objections to self-testing being made widely available in the UK. Pretest counselling for an HIV test is not an ethical necessity, and self-testing has the potential to increase early diagnosis of HIV infection, thus improving prognosis and reducing ongoing transmission. Self-testing kits might also empower people and promote autonomy by allowing people to dictate the terms on which they test their HIV status. Admittedly, there are some potential areas of concern. These include the possibility of user error with the tests, and the concern that individuals may not present to health services after a positive result. False negatives have the potential to cause harm if the 'window period' is not understood, and false positives might produce psychological distress. There is, however, little evidence to suggest that self-testing kits will cause widespread harm, and we argue that the only way to properly evaluate whether they might cause significant harm is to carefully evaluate their use, now that they are available on the market.

Maybe it can be a good solution in undeveloped countries with high prevalence of HIV, where a proctological evaluation could be a good opportunity to have a "targeted" screening in a high risk population.

Limitations of the study are poor quality data and the fact that the majority of included studies are retrospective analyses, but in our opinion it represents a pragmatic overview about an interesting and overdiscussed aspect of a diffuse pathological condition.

CONCLUSION

Improved medical therapy of HIV infection have made individuals with advanced immunosuppression live longer, so the incidence of HPV-associated tumors and other cancers within this population shows an increasing trend[20,21]. Although it is clear that HIV patients have higher incidence of anal intraepithelial neoplasia, the correct approach to the treatment of this pre-carcinogenic condition is not well established[22]. For this reason, HIV screening in patients affected by HPV genotype 16 and 18 might be a valid tool to study the histological and immunohistochemical features of the interaction between these viruses and lesions deriving from their co-infection[23]. Moreover, two HPV vaccines now available[24] could represent an unexpected therapeutic option for HIV infected male patients to prevent anal cancer. Clinical trials and prospective studies are necessary to validate this interesting hypothesis.

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Original article

Parity and pelvic floor dysfunction symptoms during pregnancy and early postpartum

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Abstract: We studied the pelvic floor dysfunction symptoms in pregnancy and early postpartum and its association with parity and gestational age. Women who had been referred to low risk obstetric clinic for prenatal and early postpartum care, between January 2005 and August 2006 were recruited to the study. Women were invited to complete an anonymous, self-report questionnaire regarding pelvic floor symptoms (PFDI-20). Dataset of 733 women were available for analysis. Only in nulliparous women, urinary frequency (58.8% vs 80.8%, P 0.005) and stress incontinence (20.5% vs 50.6%, P 0.001) were significantly more prevalent in second half of pregnancy in contrast to first half. All symptoms except painful defecation and urge urinary incontinence were significantly more prevalent in antepartum period than early postpartum. Logistic regression analyses revealed that increase in number of previous vaginal delivery was independently associated with presence of painful void, urge urinary incontinence and urinary frequency in early postpartum period. Pelvic floor dysfunction symptoms are significantly more frequent during pregnancy in comparison with early postpartum period. Additionally, prevalence of most symptoms was the same during first and second half of pregnancy. Parity and history of prior vaginal delivery did not affect the frequency of most symptoms during pregnancy.

Keywords: Pelvic floor dysfunction symptoms; Pregnancy; Parity; PFDI- 20.

INTRODUCTION

The pelvic floor has a fundamental role in supporting the pelvic organs and in the mechanism of urinary continence and anal continence. Some factors may interfere in the mechanism of support, causing a prolonged increase of intra-abdominal pressure, overloading the pelvic floor muscle and its neural, fascial and fibromuscular structures. Among the main factors are obesity, constipation, senility, parity, chronic cough and pregnancy[1,2]. In the case of pregnancy, the supporting structures are believed to be overloaded due to the fetus weight and the progressive growth of the uterus, both in weight and size. Additionally, the pregnant uterus increases the angle between the vesical neck and urethra, which can contribute to urinary symptoms[3]. Hormonal changes due to pregnancy can also cause changes in tissue, in the support, and in the continence mechanism. The increased production of steroidal hormones such as estrogen and progesterone may contribute. Estrogen is known to potentiate α-adrenergic stimulation of the smooth muscle of the urethra in animals, thus probably having a continence-maintaining effect[4,5]. Progesterone dominance during pregnancy potentiates beta-adrenergic stimulation and antagonizes the estrogen effect[4].

Parity is believed to be an important risk factor in the development of pelvic floor trauma with predisposing women to pelvic floor dysfunction symptoms including urinary incontinence, anorectal symptoms and pelvic organ prolapse[1,3,6-8]. Given the role of prior birth-related trauma in multiparous women with history of vaginal delivery, and role of pregnant uterus and pregnancy related hormones during pregnancy, do multiparous pregnant women experience a more symptomatic pregnancy for PFD symptoms than nulliparous women?

To remedy this, we sought to investigate the pelvic floor dysfunction symptoms frequency and severity during pregnancy and early postpartum and the association of symptoms with parity, and number of prior vaginal delivery.

METHODS

This was an observational cross-sectional study. The institutional review board at Naval Medical Center, Portsmouth, VA (NMCP) reviewed and approved this study. Women who had been referred to our low risk obstetric clinic for prenatal and early postpartum care during January 2005 - August 2006 were recruited to the study. After arriving for scheduled appointments, women were invited to complete an anonymous, self-report questionnaire regarding pelvic floor symptoms, along with a brief survey of demographic and obstetrical characteristics after signing the informed consent. Pelvic Floor Distress Inventory- 20 (PFDI-20) was used as validated questionnaire. Participants were instructed to complete the survey only once during their outpatient experience for the current pregnancy. Study materials were regularly collected and returned to the primary author in large mailers at regular intervals. Our exclusion criteria were history of CNS diseases, pelvic floor reconstructive surgeries and severe medical disease including diabetes, cardiovascular disease, and pulmonary and renal diseases.

PFDI-20 questionnaire;

The questionnaire utilize was the Pelvic Floor Distress PFDI-Twenty (PFDI-20), the short version of the Pelvic Floor Distress Inventory developed by Barber et al. This concise, user-friendly, tool was chosen due to its comprehensive nature and the efficiency in which it is administered in a busy practice. The PFDI-20 consists of three subscales with a total of 20 questions, which address urinary, prolapse and anorectal symptoms, the Urogential Distress Inventory (UDI-6), the Pelvic Organ Prolapse Distress Inventory (POPDI-6), and the Colorectal-Anal Distress Inventory (CRADI-8). Each question asked if a specific symptom is present (yes or no), and if the answer is 'yes,' whether this symptom bothers the individual, 'not at all,' 'somewhat,' 'moderately,' or 'quite a bit.' Higher scores for each subscale and individual questions are indicative of greater bother by the symptom.

To create a clinical picture, symptoms were categorized into 11 groups by combining questions on questionnaire that refer to similar clinical situation.

Additionally, to evaluate role of parity and number of prior vaginal deliveries on frequency of symptoms during pregnancy, pregnant women were categorized to four groups of first pregnancy, second pregnancy with one prior vaginal de-

TABLE 1. Demographic summary.

All Cases(733)	
Age, years (Mean ±SD)	25.69±4.8
BMI (Mean ±SD)	28.81±5.8
Parity (Median, Min-Max)	2 (0-9)
Number of prior vaginal delivery (Median, Min-Max)	1(0-9)
Antepartum (436)	
Age, years (Mean ±SD)	25.75±0.2
BMI (Mean ±SD)	29.26±0.3
Parity (Median, Min-Max)	1(0-5)
Number of prior vaginal delivery (Median, Min-Max)	1(0-5)
Gestational Age<=24 (n)	82
Gestational Age >24 (n)	354
Postpartum (297)	
Age, years (Mean ±SD)	25.89±0.36
BMI (Mean ±SD)	27.7±0.4
Parity (Median, Min-Max)	2(1-9)
Number of prior vaginal delivery (Median, Min-Max)	2(0-9)
Vaginal delivery (n)	215
Unplanned C-Section(n)	37
Forceps assisted delivery(n)	12
Scheduled C-Section(n)	33
Push, min (Median, Min-Max)	20(1-240)
Tear (n)	35
Birth weight (gram) (Mean ±SD)	3402±533

livery, multiparous with prior CS deliveries, multiparous (more than 2 pregnancy) with prior vagina deliveries.

Statistical methods;

Continuous variables were reported as means (±SD) or medians. Groups were compared with the use of the t-test or the Wilcoxon test, accordingly. Categorical variables were analyzed with Fisher's exact test, chi square test. A multivariate logistic model was developed to predict the probability of PFD symptoms, based on obstetrics and demographic factors. A p value less than 0.05 was considered to indicate a statistical significance. Statistical analysis was performed with SPSS version 20.0.

RESULTS

Dataset of 733 women were available for analysis with the mean age and BMI of 25.7 (± SD 4.8) and 28.8 (± SD 5.8), respectively. All demographic data are summarized in table 1.

As described in methods, we categorized women in antepartum (n: 436) period based on their parity and history of prior vaginal delivery to four groups. In each group pregnancy was divided to GA<= 24 weeks and GA >24 weeks.

Antepartum

Group 1. During first pregnancy, the prevalence of pelvic floor dysfunction symptoms ranged from 12%-81%. Urinary frequency (58.8% vs 80.8%, P 0.005) and stress incontinence (20.5% vs 50.6%, P 0.001) were significantly more prevalent in second half of pregnancy. However, Obstructive defecatory symptoms (ODS) and stress incontinence were the most bothersome symptoms in first and second half of pregnancy, respectively.

Group 2. During second pregnancy with history of one prior vaginal delivery, the prevalence of pelvic floor dysfunction symptoms ranged from 9%-70%. There was no significant difference in prevalence of pelvic floor dysfunction symptoms between first and second half of pregnancy. ODS in first half and pelvic pressure and stress incontinence in second half of pregnancy were the most bothersome symptoms (Table 2).

Group 3. During pregnancy in multiparous women with history of 0-1 prior vaginal deliveries, the prevalence of pelvic floor dysfunction symptoms ranged from 0-63%. There was no significant difference in prevalence of pelvic floor dysfunction symptoms between first and second half of pregnancy. ODS and stress incontinence were the most bothersome symptoms in first half and second half of pregnancy, respectively.

Group 4. During pregnancy in multiparous women with history of 2-6 prior vaginal deliveries, the prevalence of pelvic floor dysfunction symptoms ranged from 6%-79%. There was also significant difference between the prevalence of pelvic pressure (44.4% vs 78.6%, P 0.004) in first and second half of pregnancy. While ODS was the most bothersome symptom in first half of pregnancy, this was true for stress incontinence in second half of pregnancy (Table 2).

Comparison of pelvic floor dysfunction prevalence in first and second half of pregnancy among all groups

In comparison between different groups during pregnancy of <= 24, stress incontinence was significantly more prevalent in Group 2 (59%) with the next close prevalence in group 4 (56%) in comparison with group 1 (20.5%) and 3 (25%). In second half of pregnancy, primigravid women were the most symptomatic group for urinary frequency and voiding dysfunction in comparison with multiparous women, and group 2 was the most symptomatic group for painful void (Table 2).

Postpartum

297 women in their early postpartum period entered the study with the mean age of 25.89±0.36 and median parity of 4 (range 1-9). Two hundreds and fourteen patients had

TABLE 2. Comparison of pelvic floor dysfunction prevalence in first and second half of pregnancy among all groups.

	First half of pregnancy (GA<=24)					Second half of pregnancy (GA>24)				
	Group1 N:34 (%)	Group2 N:22 (%)	Group3 N:8 (%)	Group4 N:18 (%)	p	Group1 N:146 (%)	Group2 N:97 (%)	Group3 N:40 (%)	Group 4 N:71 (%)	p
1-Pelvic pressure	19 (55.8%)	10 (45.4%)	1 (12.5%)	8 (44.4%)	0.17	90 (61.6%)	63 (65.9%)	25 (62.5%)	55 (77.4%)	0.11
2-Bulge	11 (32.3%)	8 (36.3%)	1 (12.5%)	8 (44.4%)	0.43	74 (50.6%)	38 (40.2%)	12 (30%)	31 (43.6%)	0.067
3-ODS	14 (41.1%)	9 (40.9%)	2 (25%)	4 (22.2%)	0.76	58 (39%)	36 (38.1%)	14 (35%)	29 (40.8%)	0.88
4-AI	7 (20.5%)	5 (22.7%)	1 (12.5%)	4 (22.2%)	0.64	39 (26.7%)	16 (16.8%)	6 (15%)	14 (19.7%)	0.16
5-Painful defecation	6 (17.6%)	4 (18.1%)	1 (12.5%)	2 (11.1%)	0.8	22 (15%)	14 (15.4%)	2 (5%)	8 (11.3%)	0.35
6-Urge AI	6 (17.6%)	4 (18.1%)	2 (25%)	7 (38.9%)	0.39	19 (12.3%)	18 (18.5%)	6 (15%)	16 (22.5%)	0.34
7-Frequency	20 (58.8%)	14 (63.3%)	3 (37.5%)	9 (50%)	0.38	118 (80.8%)	67 (70.1%)	21 (52.5%)	49 (69%)	0.008
8-Urge incontinence	4 (11.7%)	5 (22.7%)	0	5 (22.2%)	0.23	39 (26.2%)	32 (34%)	12 (30%)	29 (40.8%)	0.54
9-Stress incontinence	7 (20.5%)	13 (59%)	2 (25%)	11 (55.6%)	0.006	74 (50.6%)	58 (60.8%)	19 (47.5%)	46 (64.8%)	0.23
10-Voiding dysfunction	4 (11.7%)	2 (9%)	0	1 (5.6%)	0.74	32 (21.9%)	10 (11.3%)	3 (7.5%)	4 (5.6%)	0.002
11-Painful void	9 (26.4%)	5 (22.7%)	0	2 (22.2%)	0.56	35 (23.2%)	33 (35%)	1 (2.5%)	23 (32.4%)	0.001

TABLE 3. Prevalence of pelvic floor dysfunction symptoms in early postpartum period categorized by model of delivery.

Symptoms	Vaginal delivery (215) (%)	Scheduled CS repeat (33) (%)	Unplanned CS (37) (%)	Forceps assisted delivery (12) (%)	P
1-Pelvic pressure (54)	36 (16.7%)	3 (9.1%)	12 (32.4%)	3 (25%)	0.056
2-Bulge (48)	34 (15.9%)	1 (3.2%)	8 (21.6%)	4 (33.3%)	0.062
3-ODS (74)	55 (25%)	6 (18.2%)	8 (21.6%)	5 (41.7%)	0.4
4-AI (29)	23 (10.5%)	1 (3%)	4 (10.5%)	2 (16.7%)	0.48
5-Painful defecation (55)	43 (19.7%)	4 (12.1%)	5 (13.2%)	3 (25%)	0.53
6-Urge AI (49)	37 (17%)	3 (9.1%)	8 (21.6%)	1 (8.3%)	0.47
7-Frequency (46)	34 (15.6%)	3 (9.1%)	6 (15.8%)	3 (25%)	0.59
8-Urge incontinence (28)	21 (9.6%)	0	5 (13.2%)	2 (16.7%)	0.18
9-Stress incontinence (68)	51 (23.6%)	4 (12.1%)	8 (21.6%)	5 (45.5%)	0.14
10-Voiding dysfunction (7)	5 (2.3%)	0	2 (2.8%)	0	0.47
11-Painful void (40)	26 (11.9%)	3 (9.1%)	7 (18.4%)	3 (25%)	0.30

TABLE 4. Comparison of pelvic floor dysfunction symptoms prevalence between antepartum and early postpartum periods.

Symptoms	Antepartum (436) (%)	Post-Partum (297) (%)	P Value
1-Pelvic pressure (321)	278 (63.2%)	43 (14.4%)	<0.0001
2-Bulge (224)	187 (43.4%)	37 (12.4%)	<0.0001
3-ODS (236)	171 (38.6%)	65 (21.8%)	<0.0001
4-AI (120)	96 (21.5%)	24 (8%)	<0.0001
5-Painful defecation (111)	60 (13.7%)	51 (17.1%)	0.104
6-Urge AI (120)	79 (17.8%)	41 (13.8%)	0.258
7-Frequency (138)	309 (69.8%)	32 (10.7%)	<0.0001
8-Urge incontinence (148)	128 (28.8%)	20 (6.7%)	<0.0001
9-Stress incontinence (293)	238 (54.3%)	55 (18.5%)	<0.0001
10-Voiding dysfunction (64)	58 (13%)	6 (2.1%)	<0.0001
11-Painful void (154)	121 (27.2%)	33 (11.1%)	<0.0001

history of vaginal delivery (Table 1). Categorizing patients based on their mode of delivery showed no significant differences in prevalence of pelvic floor dysfunction symptoms in early postpartum (Table 3).

Comparing pelvic floor dysfunction symptoms prevalence during antepartum period vs. early postpartum, all symptoms except painful defecation and urge urinary incontinence were significantly more prevalent in antepartum ($p<0.0001$) (Table 4).

Logistic regression analysis:

Multivariate logistic regression analysis was used to evaluate the prediction of symptoms in antepartum and postpartum groups, separately. Age, parity, number of prior vaginal delivery, BMI, birth weight, tear, and mode of delivery entered the model as variables. Our logistic regression analyses revealed that increase in number of previous vaginal delivery was independently associated with presence of painful void, urge urinary incontinence and urinary frequency in early postpartum period with odds of 3.5, 4 and 3.5, respectively (P: 0.028, P: 0.036, P: 0.013). No interaction was noted between the remaining other covariates in antepartum and remaining postpartum cases. (Age, Parity, Type of delivery, BMI, History of Tear, Birth weight).

DISCUSSION

Pelvic floor dysfunction symptoms are significantly more frequent during pregnancy than early postpartum. While it seems that hormonal change and enlarged uterus are the main reasons for pelvic support system malfunction, the prevalence of most symptoms did not differ significantly during first and second half of pregnancy; additionally, parity and history of prior vaginal delivery as an indicator of prior pelvic floor trauma did not affect the frequency of symptoms during pregnancy. Increasing number of prior vaginal delivery is associated with presence of urinary urgency during early postpartum period.

In an attempt to identify the role of pregnancy on pelvic floor support apparatus, in a case- control study, O'Boyle et al. compared the pelvic organ support in nulliparous pregnant women with non-pregnant women who were matched for age and BMI[9]. They reported nulliparous pregnancy is associated with increased POP-Q stage compared with non-pregnant control group. In 2004, they further investigated the pelvic support status during each trimester of nulliparous pregnancy and early postpartum period. They revealed that overall POP-Q stage and points Aa, Ap, Ba, and Bp significantly descend relative to the hymen in the third trimester and early postpartum period compared to the first trimester. However, there were no difference between third trimester and postpartum period[10].

Prevalence of pelvic floor dysfunction symptoms with advancing gestational age;

After identifying the pregnancy-induced pelvic support changes throughout pregnancy, the investigation of pelvic floor dysfunction symptoms during pregnancy is required. Urinary symptoms are the most investigated symptoms among all pelvic floor dysfunction symptoms in literature. Van Brummen et al. reported that among 515 nulliparous pregnant women, 74% experienced urinary frequency and 63% experienced urgency by 12 weeks' gestation, increasing to a prevalence of 81% and 68% by 36 weeks, respectively[11]. Similar to the onset of other urinary symptoms, incontinence can begin early and increase significantly during pregnancy in nulliparous women[11,12].

Our study showed that urinary frequency and urinary stress incontinence are significantly more prevalent in second half of pregnancy in nulliparous women; interestingly, this difference did not observed in multiparous women.

Prevalence rates for fecal or flatus incontinence before, during, and after first pregnancy of 0-1%, 0-8%, and 2-26% have been reported[13,14]. A prospective cohort study included 487 nulliparous pregnant women evaluated the anorectal symptoms during pregnancy, 3 months and 12 months postpartum[15]. Obstructive defecatory symptoms (ODS) had been significantly more prevalent at 12 weeks of pregnancy compared to 36 weeks; however, prevalence of fecal incontinence did not differ significantly during pregnancy. It is also has been reported flatus and fecal incontinence, constipation, and painful defecation in early pregnancy, were notable predictor for pelvic floor dysfunction symptoms after delivery, except for fecal incontinence[15].

Our study showed that there was not significant difference in prevalence of obstructive defecatory symptoms and anal incontinence between first vs. second half of pregnancy in nulliparous and multiparous women but ODS was the most bothersome symptoms in first half of pregnancy in all women.

We specifically addressed the pelvic organ prolapse symptoms in our study as well. Only in multiparous women with history of more than 2 vaginal deliveries, pelvic pressure was more prevalent in second half of pregnancy compared to first half of pregnancy.

Role of parity and number of prior vaginal deliveries in prevalence of PFD symptoms during pregnancy

Birth- related pelvic floor trauma due to childbirth is one the proposed etiologies for the development of PFD symp-

toms. There are scarce data in literature regarding the prevalence and severity of PFD symptoms during pregnancy in multiparous women while most studies had been focusing on first pregnancy. Our study signified that parity and number of prior vaginal deliveries does not have a role in almost all PFD symptoms during pregnancy and nulliparous women complain of PFD symptoms during pregnancy in same frequency as multiparous women.

Antepartum versus postpartum

Urinary incontinence is markedly lower in postpartum patients in contrast to antepartum as reported earlier in literature. (44% vs. 9%)[16-19]. According to Fitzgerald and Graziano, the function of the urinary system usually returns to normal soon after childbirth[20]. Tarazi et al. evaluated 343 women in their pregnancy and postpartum period and showed that urinary incontinence is more prevalent during pregnancy vs. postpartum. Moreover, they reported that urinary incontinence is associated with multiparty and reduction in vaginal pressure in postpartum[19]. In agreement with aforementioned studies, our study showed significant decrease in prevalence of all PFD symptoms postpartum. Higher number of prior vaginal deliveries increases the odds for presence of painful void, urge urinary incontinence and urinary frequency in early postpartum period.

Our study is limited by lack of pre-pregnancy screening for PFD symptoms; however, we eliminated the recall bias in that way. Also, women did not undergo pelvic exam with POP-Q measurements, but they have been screened for the symptom of vaginal bulge. Our study has certain strong points. This is the first study using the validated PFDI-20 questionnaire in pregnancy in both nulliparous and multiparous women investigating all PFD symptoms during pregnancy. Large population number and minimal missing data increased the study power.

In conclusion, PFD symptoms are moderately prevalent during pregnancy with ODS being the most bothersome symptom in first half of pregnancies in nulliparous and multiparous women. Despite to role of enlarge uterus with advancing gestational age and history of prior vaginal deliveries as an indicator of preexisting pelvic floor trauma, the prevalence of PFD symptoms mostly did not differ significantly between multiparous and nulliparous women. Delivery brings immediate relief for most symptoms with higher number of prior vaginal deliveries as a risk factor for postpartum painful void, urge urinary incontinence and urinary frequency.

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Multidisciplinary UroGyneProcto Editorial Comment

To improve the integration among the three segments of the pelvic floor, some of the articles published in *Pelviperineology* are commented on by **Urologists, Gynecologists, Proctologists/Colo Rectal Surgeons** or **other Specialists**, with their critical opinion and a teaching purpose. Differences, similarities and possible relationships between the data presented and what is known in the three fields of competence are stressed, or the absence of any analogy is indicated. The discussion is not a peer review, it concerns concepts, ideas, theories, not the methodology of the presentation.

Uro... Reporting the results of an observational study in 733 women on pelvic floor dysfunction symptoms in pregnancy and early postpartum and their association with parity and gestational age, the authors conclude that urinary frequency and urinary stress incontinence are more prevalent in the second half of pregnancy in nulliparous women compared to multiparous women, and that in the latter changes of PFD symptoms during pregnancy are not observed.

We know that different connective tissues are associated with various pelvic floor symptoms[1,2], and periurethral biopsies in nulliparous women with and without urodynamic stress incontinence have shown significantly less collagen in the tissues of those without urinary stress incontinence. Probably in nulliparous women the changes in the connective tissue that occur in the second part of the pregnancy are reversible and they disappear after childbirth. In multiparous women however connective tissue changes are likely to be permanent and this could explain the absence of a significant difference in PFD symptoms during all the stages of pregnancy. From an anatomical point of view this finding justifies the association between pelvic prolapse and multiparity.

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Gyne... I congratulate the authors on an excellent observational study. The purpose of this comment is to expand on their hypothesis of a role for hormones in the causation of these symptoms.

Disappearance of pregnancy induced bladder symptoms immediately after delivery was reported by Francis in 1948[1] and this coincides with removal of the placenta, which of course produces the relaxin hormone.

Connective tissue in the area of the urogenital organs is sensitive to hormones. During pregnancy, collagen is depolymerized by placental hormones, and the ratios of the glycosaminoglycans change[2].

The vaginal membrane becomes more distensible, allowing dilatation of the birth canal during delivery. There is a concomitant loss of structural strength in the vagina and its suspensory ligaments. This was first reported by Zarrow in 1948, and attributed to increased levels of the hormone relaxin[3].

Degradation of the collagen and an increase in the special dermatan sulfate proteoglycans can at least partly explain the pregnancy-associated softening of this connective tissue; relatively high estrogen levels seemed to be an absolute condition for the process even when it is induced pharmacologically[4].

Laxity in the uterosacral ligaments explains the uterovaginal prolapse so often seen during pregnancy[5]. According to the integral theory[5], uterosacral ligament laxity may also cause USI, pelvic pain, urgency, ODS and fecal incontinence, owing to collagen depolymerization induced by relaxin. Loss of vaginal membranous support may cause gravity to stimulate the nerve endings at the bladder base, causing premature activation of the micturition reflex. This is expressed as symptoms of 'bladder instability', perceived by the pregnant patient as frequency, urgency and nocturia[5].

Removal of the placenta restores connective tissue integrity, and the symptoms rapidly disappear in a large percentage of patients[1]. The hypothesis that this group of symptoms (urgency, nocturia and abnormal bladder emptying ODS pelvic pain) is associated with uterosacral ligament laxity was tested prospectively in a group of 67 gynecology patients in a urodynamically controlled study[6]. A substantial cure rate for these symptoms was achieved by reinforcement of the uterosacral ligaments, even in many patients who did not have major uterine/apical prolapse.

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Procto... About half of pregnant women have to deal with constipation, but only few need medical attention, the problem usually beginning at the 11-12th week to become more pronounced after the sixth month and it may be cause and consequence of symptomatic hemorrhoids (prolapse, edema) and anal fissures. These quite annoying conditions often have a triggering moment in the effort required for a difficult evacuation. Among of the numerous factors affecting defecation (and likewise fecal continence) i.e. sphincters' relaxation, pelvic ligaments integrity, peristalsis, stool consistency, anorectal sensitivity, emotions) also the intestinal bacterial flora seems to play a very important role. Furthermore in pregnancy-constipation we must consider several causes of bowel malfunctioning: *progesterone*, that prevents uterus contractions, favors the growth of the myometrium and promotes placental activity, it slows down the intestinal motor activity and the transit, worsening a pre-existing constipation or causing a new problem; the *compression* from the pregnant uterus; an increased *water demand* reducing the amount needed to soften intestinal contents; a frequent intake of *iron supplements* often necessary during pregnancy; a reduced *physical movement*, variations in *diet*. All the above conditions need to be considered and in pregnancy the type of constipation should always be analyzed for an appropriate treatment.

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Original article

Does sacral nerve modulation work on simultaneous bladder and rectal dysfunctions?

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Abstract: Introduction: Our target was to retrospectively examine the results of Sacral Nerve Modulation (SNM) in patients complaining of simultaneous bladder and the rectum dysfunctions, here called double pelvic dysfunction (DPD). *Methods:* In 2009, in six Italian centres, patients treated with SNM were asked to complete a self-assessment questionnaire for DPD. The questionnaire investigated the changes in micturition and rectal symptoms after SNM using specific questions for each dysfunction and symptom - overactive bladder (OAB), urinary retention (UR), faecal incontinence (FI) and constipation (Co). *Results:* Data obtained from forty-four patients with a mean follow-up period of 56.9 months were retrospectively analysed. 73% of patients treated with SNM for DPD reported a significant clinical improvement, and in particular we observed an improvement of 68% for UR+Co, 78% for OAB+Co and 75% for OAB+FI. Among the OAB+Co and UR+Co cases a higher percentage showed a clinical improvement in the vesical alterations (100% and 95% respectively) than in the anorectal ones (79% and 68%). In the OAB+FI group, on the other hand, a higher percentage of cases showed improvements in the anorectal alterations (100%) than in the vescical ones (75%). The improvement was confirmed by a reduction in use of devices and incontinence protection products (pads, self-catheterization and laxatives/enemas). Neurogenic patients had a better outcome than the non-neurogenic ones especially in the OAB+FI group (p=0.021). *Conclusions*: In our survey SNM has been more effective in DPD with FI and OAB, especially in a picture of neurological DPD. Therefore, considering also the economic aspect, SNM seems a viable option in highly selected cases of neurogenic DPD including FI. Retrospectively analysed through a patient self-assessment questionnaire, SNM is effective in simultaneous bladder and rectum dysfunction especially with neurogenic faecal incontinence.

Key words: Sacral nerve modulation; Urinary retention; Overactive bladder; Urinary incontinence; Faecal incontinence; Constipation.

INTRODUCTION

Sacral Nerve Modulation (SNM) is a known treatment for both bladder and rectum dysfunctions. A wide literature supports the use of SNM in unresponsive overactive bladder (OAB), urinary retention (UR), faecal incontinence (FI) and chronic constipation (Co)[1-4]. Only few papers[5,6,7,8,9,10,11,12], though, considered the effects of SNM on simultaneous bladder and rectal dysfunctions, and most of them either have a short-term follow-up or focus only on double incontinence. The aim of this study was to analyze the results of SNM on a population of cases with double pelvic dysfunction (DPD), presenting simultaneous urinary and faecal disorders.

MATERIALS AND METHODS

In 2009 a retrospective survey about the effectiveness of SNM in DPD was proposed to the Clinical Departments performing SNM in north-eastern Italy. A total of 6 centres accepted and were included in the analysis. The retrospective analysis was conducted on all patients affected with DPD treated with SNM. A self-assessment questionnaire for DPD was used to analyse the patient's opinion and satisfaction after the SNM therapy. The questionnaire investigated the general data as well as the perceived changes in micturition and rectal symptoms using specific questions for each disorder and symptom - dry and wet OAB, UR, FI and Co (see attachment).

The score for each question ranged from 0 (unchanged) to 5 or 6 (complete resolution). Each score defined no changes, partial or complete resolution from the pre-SNM status. The answers had then been converted into a total score ranging from 40 to 200 (40=unchanged after SNM, 200=complete resolution of DPD after SNM).

In order to assess the improvement of Quality-of-Life (QoL) a visual analogical scale ranging from 0 (not improved) to 5 (extremely improved) was used.

STATISTICAL ANALYSIS

Statistical analyses were performed using SPSS 12.0 software for Windows (SPSS Inc., Chicago, IL, USA).

Continuous data were showed as average $\pm$ standard deviation (SD) and range, while the categorical ones were shown as absolute and relative frequencies.

Differences between categorical variables were evaluated using the χ^2 test or Fisher's exact test when appropriate. Statistical comparisons of continuous variables between two groups were performed by the Student's t-test or the Mann-Whitney non-parametric test respectively for normal and non-normal distributions.

A one-way analysis of variance (ANOVA) was used to statistically compare the differences between the groups.

Comparisons between the baseline and the last follow-up clinical outcome were performed through the McNemar-Bowker test for categorical data.

The relationship between double disorders improvements were evaluated through the Cramer's V test.

All 2-tailed p value <0.05 results were considered statistically significant.

RESULTS

The six centres involved in the survey were five Departments of Urology and one of General Surgery. Forty-four patients completed the questionnaire. They were 42 females and 2 males, with a mean age of 60 $\pm$ 12 years (range 37-84). The patients' baseline characteristics are shown on Table 1. Mean duration of follow-up was 56.9 months (range 24-108). The evaluation included only those patients who did not interrupt the stimulation during the follow-up period.

The SNM main indication was urological in 40 patients (22 UR, 18 OAB) and proctological in 4 (3 FI, 1 Co). The aetiology was neurogenic in 12 cases (27%), due to multiple sclerosis in 5 patients.

Table 1. Baseline characteristics of patients.

	Total (n=44)	OAB+Co (n=14)	OAB+FI (n=8)	UR+Co (n=22)	*p value*
Age	61 (12)	64 (13)	64 (9)	58 (12)	0.256†
Neurogenic etiology	12 (27%)	3 (21%)	2 (25%)	7 (32%)	0.782°
Multiple sclerosis	5 (11%)	2 (14%)	1 (13%)	2 (9%)	0.108°
Previous surgery	3 (7%)*	2 (14%)	0	1 (5%)	0.369°

† One-way Analysis of Variance (ANOVA); ° Chi-square test.
* 5 operations.
Mean and standard deviation in parenthesis.

A total of 22 patients suffered from UR, 22 from OAB, 36 were Co and 8 had FI.

The DPD were: Co and UR in 22 patients (50%), OAB and Co in 14 cases (32%) and OAB and FI in 8 cases (18%). These 3 groups of DPD patients were similar in age and neurological or other etiology distribution (p>0.1).

Questionnaire results

To the question "After SNM did you detect any significant and lasting change in the anorectal and urinary dysfunction?" 32 patients out of 44 (73%) replied positively on both diseases, 41/44 (93%) answered *yes* considering only the bladder dysfunction, and 34/44 (77%) replied *yes* only for the rectal one (table 2).

Patients were divided into three groups (OAB+Co, UR+Co, OAB+FI), and no statistically significant differences were found in the clinical improvement of the urinary and rectal functions (P>0.05). The improvement of the urinary alterations seemed to have a more positive trend (p=0.068). In the OAB+Co and UR+Co groups a higher percentage of cases showed a clinical improvement on vesical dysfunction (100% and 95% respectively) than in Co (79% and 68% respectively). On the other hand, in the OAB+FI group a higher percentage of cases showed improvements on anorectal (100%) than on vesical alterations (75%).

Considering the single dysfunction, Figure 1 shows the questionnaire scores after SNM. There was not a significant difference in each disease score values in particular regarding urological and faecal disturbances (p>0.05). Single dysfunction did not reveal any statistically significant difference for the DPD scores (Figure 2).

Considering the aetiology, patients were divided between neurogenic and non-neurogenic ones. A statistically significant difference between the two groups was observed in the OAB+FI group score (p=0.021). Neurogenic patients seemed to have a better outcome than the non-neurogenic ones (score 190.0 ± 8.5 vs. 136.0 ± 22.9). A difference between neurogenic versus "non-neurogenic" in the OAB+Co group was detected (score 182.7±8.3 vs. 157.5 ± 24.3), but it was not statistically relevant (p=0.110) (Table 3).

Regarding the Quality of Life (QoL), no statistically significant differences were observed among all groups after the SNM implant (p>0.10) (Table 4). The evaluation was conducted considering both the single and the double dysfunction. Each group of patients was subdivided according to the type of the single dysfunction. The relevance of improvements in QoL was ranged from 3.1 to 4.1 without any statistically important difference (p>0.10). A similar considerable improvement in QoL was found among the 3 groups of DPD, with a mean score ranging from 3.5 to 3.7.

Pads results

After the SNM patients with OAB significantly reduced the use of pads or panty-liners (McNemar-BowkerTest, p=0.002). Only 1 patient (5%) used as many pads as before the implant, 25% reduced the numbers of pads, and 70% of patients were free from any kind of protection (Figure 3). Statistically significant results were also observed among patients with FI (McNemar-Bowker Test, p=0.030). 50% of incontinent patients stopped using pads after SNM, 38% reduced their number and only for one patient (12%) the number of pads remained the same (Figure 4).

Considering the use of pads in patients with OAB and FI, we detected that 63% of patients did not use or have dramatically reduced the number pads in both disturbances, while 37% have reduced their use for one problem but still wear them for the other.

Table 2. Clinical improvements after SNM acquired through the question: "After SNM did you detect any significant and lasting change in the anorectal and urinary dysfunctions?".

Improvement	OAB+Co (n=14)	OAB+FI (n=8)	UR+Co (n=22)	*p-value*
Vescical alteration	14 (100%)	6 (75%)	21 (95%)	0.068°
Ano-rectal	11 (79%)	8 (100%)	15 (68%)	0.183°
Both	11 (79%)	6 (75%)	15 (68%)	0.782°

° Chi-square Test.

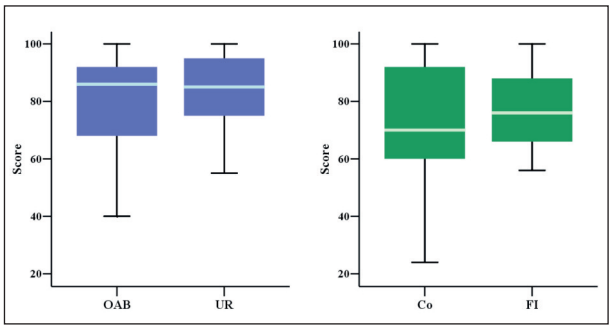

Figure 1. – Questionnaire scores for each disease (average and standard deviation). Differences were not statistically significant (p>0.05).
Values range from 20 to 100 (20=unchanged after SNM, 100=complete resolution of DPD after SNM).

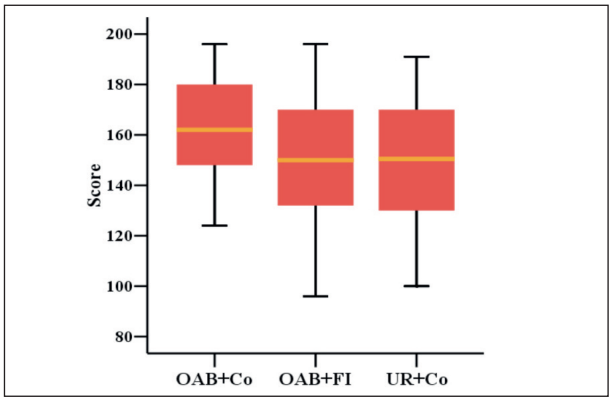

Figure 2. – Questionnaire scores for each DPD group: the differences observed were not statistically significant (p>0.05).
Values range from 40 to 200 (40=unchanged after SNM, 200=complete resolution of DPD after SNM).

Self-catheterization results

After SNM, 89% of patients with UR didn't need self-catheterization anymore, while 11% significantly reduced them to 1-2 per day. The improvement compared with the preoperative situation was statistically significant (McNemar-Bowker Test, p<0.001) (Figure 5).

TABLE 3. Questionnaire scores on the basis of neurogenic or non-neurogenic etiology.

DD	Neurogenic (n=12)	Not Neurogenic (n=32)	*p-value*
OAB + Co	182.7 (8.3)	157.5 (24.3)	0.110
OAB + FI	190.0 (8.5)	136.0 (22.9)	0.021
UR + Co	139.4 (23.5)	154.7 (24.5)	0.183

TABLE 4. Quality of life scores for single dysfunction and for DPD using a visual analogical scale ranging from 0 (not improved) to 5 (extremely improved).

Single Dysfunction	Score Mean (SD)	*p-value*
OAB	3,6 (1,2)	0.147#
Urinary Retention	4,1 (0,8)	
Fecal Incontinence	3,9 (0,8)	0.200#
Constipation	3,1 (1,2)	
Double Dysfunction		
OAB + Constipation	3,7 (0,8)	
OAB + Fecal incontinence	3,6 (1,12)	0.742†
UR + Constipation	3,5 (0,7)	

Mann-Whitney nonparametric Test;
† One-way Analysis of variance (ANOVA)

The post-void residual disappeared in 48% of patients, it was reduced by at least 50% in 48% of patients and only in one case (4%) it remained unchanged.

Laxatives and Enemas results

The use of laxatives and enemas decreased during the follow-up period after SNM, and the difference compared to the baseline evaluation was statistically significant (McNemar-Bowker Test, p<0.001) (Figure 6).

In the DPD group with OAB + Co, considering the use of both laxatives/enemas and pads, we observed that 55% of patients did use neither ones nor the others. 18% stopped using aids and reduced the pad use. 27% of patients still used the same amount of laxatives/enemas but had reduced/eliminated pads.

A statistically significant correlation was found between the reduction of self-catheterizations and the reduction of laxatives/enemas used in the DPD group UR+Co (V Cramer test p=0.570, p=0.05). In particular 67% of patients eliminated all aids, 28% reduced both, and 5% was unchanged for laxatives/enemas but reduced self-catheterization.

Other specific symptoms: changes after SNM

Urinary urgency: 82% of patients reported it decreased by at least of 50% and in 27% of patients the symptom completely disappeared.

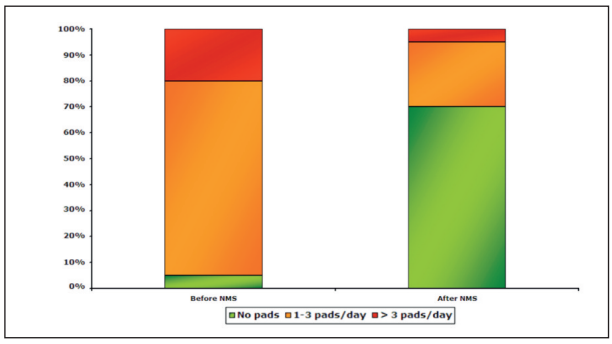

Figure 3. – Change in pad usage in OAB patients before and after SNM (McNemar-Bowker Test, p=0.002).

Faecal urgency: 63% of patients did not complain of it after the implant, and in 13% it rarely happened.

Difficult evacuation: 72% had at least a 50% improvement; in particular 61% of patients declare that the evacuation was always/almost always easy. The feeling of bowel emptying occurred after every evacuation in 39% of cases, and in 38% it improved to 50% or more.

Abdominal pain: 83% of patients rarely complained of pain, and 22% stated that this symptom completely disappeared.

DISCUSSION

Only few papers[5,6,7,8,9,10,11,12] considered the SNM effects with simultaneous bladder and rectal dysfunctions. Furthermore, the most of these articles mainly focus on the double incontinence and include only few patients. The relevance of the present study is the analysis of the SNM re-

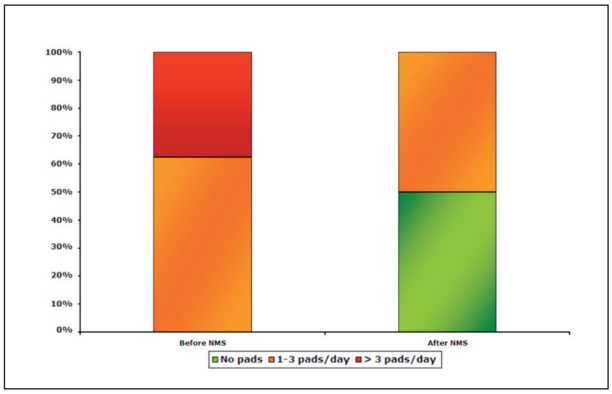

Figure 4. – Change in pad usage in FI patients before and after SNM (McNemar-Bowker Test, p=0.030).

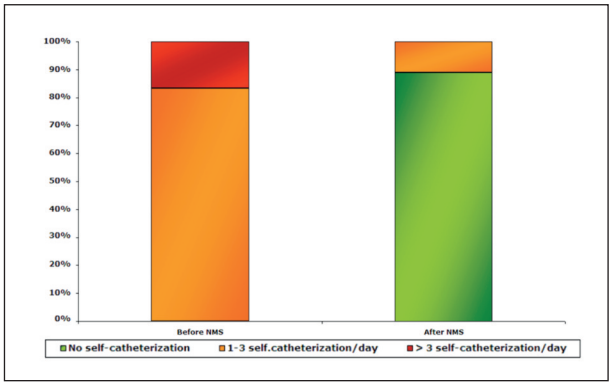

Figure 5. – Changes in self-catheterization per day in UR patients before and after SNM (McNemar-Bowker Test, p<0.001).

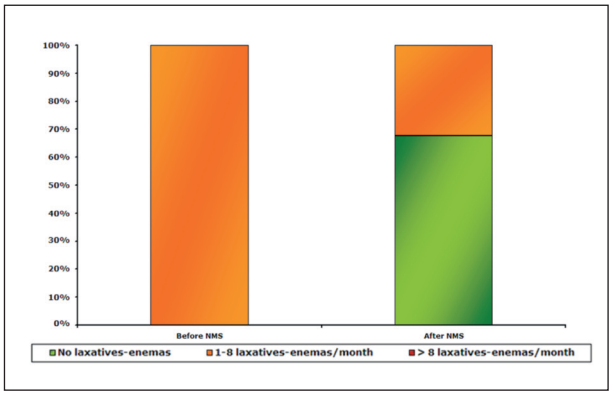

Figure 6. – Changes in laxatives /enemas usage in Co patients before and after SNM (McNemar-Bowker Test, p<0.001).

sults in a heterogeneous population of cases with DPD, presenting simultaneous urinary and faecal disorders.

Rectal and bladder dysfunctions are debilitating conditions, sometimes associated, and that often share the same pathophysiological factors[13,14]. Few epidemiological data are available in the literature and, in the few articles analysing DPD, symptoms of OAB, FI or Co overlap significantly with utero-vaginal prolapse as the main risk factor for women.

Prevalence of double incontinence, which affects mainly women, ranges from 9% to 26%, and the Odd Ratio to develop FI in patients with urinary dysfunction was calculated as 4.6[15-16].

Epidemiologic data about the correlation between Co and urological dysfunctions are particularly rare. Gordon et al[17] reported Co in 46% of 283 women with double incontinence, and in 38% of patients with one urinary disturb. In a survey Cameron et al[18] found that women experiencing difficult defecation have an increased rate of OAB. Coyne observed the same correlation among men and in his survey OAB resulted to be a very strong predictor of Co in both genders[19].

The influence of SNM on the nervous system cannot yet be explained[20], but when conservatory measures fail, SNM is a known option to treat patients with urinary and rectal dysfunctions. In 2009 a Cochrane Collaboration review[4] concluded that SNM offers benefits for carefully selected people with OAB and UR. Similarly Mowatt et al[2], in a review analysing 3 cross-over studies, concluded that SNM leads to a significant improvement of defecation disorders only in carefully selected patients.

Therefore, in theory, SNM should have a dual benefit on simultaneous bladder and rectal dysfunctions in DPD, considering the positive results of SNM on both areas and the common origin of the bladder and rectum innervation.

The data available in literature about SNM on DPD are mainly related to the colorectal cases and the details about the bladder functioning are sometimes not accurate.

In the first report from the SNM Italian Group, 10 out of 16 patients with FI also complained of urinary symptoms (4 stress incontinence, 4 urge incontinence and 2 UR). All patients improved FI to more than 50%. Patients with UR and urge incontinence resolved completely the urinary disturbance and those complaining of stress urinary incontinence improved as well[3].

In another paper observing 6 patients implanted for FI with simultaneous urinary symptoms, the SNM was effective on all the FI cases but ineffective on the urinary disturbances except for one OAB[5].

In the article by Altomare he observed 14 patients with FI, mainly cause by neurological factors, who fully did benefit from SNM. After a mean 14-months follow-up, 4 out of 6 patients with associated urinary symptoms report an improvement (1 out of 2 urge-incontinence, 1 out of 2 UR and again 2 out of 2 stress incontinences)[7].

El-Gazzaz et al[8] reported his experience with 22 patients implanted for double incontinence (the type of urinary incontinence was not defined). In 31,8% of cases both symptoms improved, in 13.6% only FI did, in 18.2% only urinary incontinence did, and in 4 cases nothing changes.

Faucheron et al used a questionnaire to evaluate 57 patients complaining of FI and urinary dysfunctions, treated with SNM and with a mean follow-up period of 62.8 months. Specific scores improved significantly for FI and, to a lower degree, for urge urinary incontinence, but not in stress urinary incontinence and UR. Overall 73% of patients were satisfied with the results obtained on their double incontinence, 17.6% were unchanged and 8.7% were disappointed with SNM. Besides, a revision surgery was necessary in 16 cases (28%), and 4 device explantations were performed. The best results were observed in FI due to a neurological cause and, secondarily, in urge urinary incontinence[9].

In a multicenter, open label, randomized crossover study of 33 children complaining of incontinence (mixed in 19 cases, urinary in 9 and faecal in 5), mainly caused by neurological factors, it was observed an overall positive response rate of respectively 81% for urinary function and 78% for bowel function[10].

In brief, between 30% and 100% of patients with double incontinence experienced improvements in both dysfunctions[11], while there are no data available in literature about the other types of DPD.

Our research suffers from two limitations. Firstly, it is a retrospective study, as it commonly happens when evaluating SNM effects. Secondly, the questionnaire we used to show the different course of sintomathology after the SNM was not validated. However we specifically focused our analysis on DPD cases treated with SNM and many patients, in addition to the good clinical results, reported a major decrease in the use of pads and the medical supplies for DPD. Overall 73% of implanted patients answered *yes* to the question "have you had a significant and lasting change in bladder and rectal function?" A higher rate of improvement was reported for urinary symptoms than for anorectal ones (93% vs. 77%), maybe because most patients were selected by urologists. Considering the score obtained from the self-administered questionnaire, no statistically significant differences were observed among the different dysfunctions and the positive results were equally distributed.

Three groups of DPD were detected: OAB and FI, UR and Co, and OAB + Co. There were no cases of UR and FI. In the three groups of DPD the percentages of clinical improvement after SNM ranged from 68% to 100%. The questionnaire scores, ranging from 149.5±31.8 to 162.9±24.1, suggested a considerable improvement in comparison with the baseline with no statistically significant differences among the groups. In general, FI seems to respond more and with better results than Co to SNM. On the other hand Co, especially when examined by an urologist instead of a proctologist, might be caused by incorrect lifestyle habits instead of a real dysfunction. Inadequate water intake, for example, is a common habit in patients complaining of OAB who willingly avoid drinking since they are scared of urinary incontinence.

It is important to assess risk of bias in studies about the response to SNM with questionnaires, for example the effects of the "taking care of a chronic patient" as well as the placebo-like effect. For these reasons we investigated objective data too, such as the change in pads usage, self-catheterizations, laxatives/enemas and post-voiding residuals. We observed that after SNM there was a significant improvement in all of them. This also means that both social and personal costs were reduced especially with FI where there is no other therapy available.

We analysed the data dividing the patients according to their etiology, neurogenic vs. non-neurogenic ones. The neurogenic group was reported to have a better outcome after SNM, particularly in the OAB+FI and OAB+Co groups. These results are similar to those of other authors and confirm that SNM can be effective in both single and DPD due to incomplete neurogenic lesion[7,9,10,21,22].

It is now appropriate to make a brief costs analysis too. Watanabe estimated that SNM is the most expensive therapy for idiopathic OAB at a base rate of $26,269 for a 3 years therapy considering initial implantation plus revisions and management of adverse events[23]. On the other hand, others authors estimated that SNM in FI could be economically advantageous or represents a relatively low additional cost for the national health system[24,25].

CONCLUSION

In our analysis 68% of cases with retentive DPD (UR and Co) had an improvement in both dysfunctions after SNM, while 27% of patients were unchanged for Co and 5% for both alterations.

Moreover, 79% of OAB and Co cases improved their urinary and faecal dysfunctions while 21% remained constipated.

In the group OAB+FI 75% of patients resolved both problems, and 25% still complained of urinary symptoms. Regarding the total score, a statistically relevant difference among the groups was found in this particular group (p=0.021).

Neurogenic patients seem to have a better outcome than the non-neurogenic ones (score 190.0 ± 8.5 vs. 136.0 ± 22.9).

This analysis reports two main limits: the retrospective evaluation performed with a non-validated patient self-assessment questionnaire and the small sample observed. However, we reported a significant clinical improvement specifically expressed by the reduction in use of all the devices and protections related to DPD and these clinical data were correlated to the improvement reported by the self-administered questionnaire.

In our survey – like in literature – the best outcome of SNM in DPD was observed with neurogenic FI and OAB. But while there is a wide range of support tools to treat OAB which are recognized to be effective and cheaper – such as antimuscarinic drugs and Beta3-adregenic agonists, intra-vesical botulinum toxin, tibial nerve stimulation - for FI there is no other therapy but SNM.

DISCLOSURES

In Italy this kind of studies does not require the IRB approval. Conflict of Interest for all authors – None.

CONTRIBUTORS

Andretta Elena: study concept, manuscript draft and design, data acquisition; Masin Alessandra: data analysis and interpretation, and data acquisition; Zuliani Cristina: supervision; Mariotti Gianna: statistical analysis; Sciarra Alessandro: critical revision.

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QUESTIONNAIRE

This questionnaire investigates the perceived changes in micturition and rectal symptoms post-SNM. As physiological functions are commonly susceptible to variations, we ask you please to answer the following questions reporting your average vesical and faecal functions.

Patient's initials ..... Age ..... Centre ..... Procedure date .....

You have undergone implantation of SNM for:
- Constipation
- Faecal incontinence
- Urinary retention
- Overactive bladder

Not-neurogenic Neurogenic (indicate the condition)
.....

Have you observed significant and persistent changes in the anorectal function after SNM? Yes No

If yes, to what degree has your Quality-of-Life improved?

Not at all					Extremely
0	1	2	3	4	5

Have you observed significant and persistent changes in the vesical function after SNM? Yes No

If yes, to what degree has your Quality-of-Life improved?

Not at all					Extremely
0	1	2	3	4	5

OVERACTIVE BLADDER

Has the urinary urgency improved?
1 YES, it has disappeared
2 YES, it has decreased by at least 2/3
3 YES, it has decreased by 50%
4 YES, it has decreased by 1/3
5 NO, it has not improved

To what degree has your urinary frequency decreased?
1 Extremely
2 Quite a bit
3 Moderately
4 A very little bit
5 Not at all

What is your present urinary frequency?
1 4-6 times per day
2 7-8 times per day
3 9-10 times per day
4 10-15 times per day
5 > 15 times per day

Has the urge incontinence improved?
1. YES, it has disappeared
2. YES, it rarely happens
3. YES, but it happens at least once a day
4. YES, but it happens many times a day
5. NO, it has not improved

Did you use incontinence protection products before SNM?
1 NO
2 YES, 1-2 liners per day
3 YES, more than 3 liners per day
4 YES, 1-2 pads per day
5 YES, more than 3 pads per day
6 YES, Incontinence diapers

Are you using incontinence protection products after SNM?
1 NO
2 YES, 1-2 liners per day
3 YES, more than 3 liners per day
4 YES, 1-2 pads per day
5 YES, more than 3 pads per day
6 YES, Incontinence diapers

URINARY RETENTION

Has SNM made urination easier?
1. YES always
2. YES almost every time
3. YES in 50% of cases
4. YES, but only sometimes
5. NO, it has not improved

To what degree has the urinary stream force increased?
1. Extremely
2. Quite a lot
3. Moderately
4. Yes but a little bit
5. Not at all

Did you catheterize yourself before SNM?
1. NO
2. YES once a day
3. YES twice a day
4. YES 3-4 times a day
5. I necessarily required catheterizations to void

How many catheterizations a day do you need after SNM?
1 None
2 1
3 2
4 3-4
5 I need catheterisations to void

If you catheterize yourself, has the post-void residual decreased after SNM?
1. YES it disappeared
2. YES, it decreased by at least 2/3
3. YES, it decreased by 50%
4. YES, it decreased by 1/3
5. NO, it has not decreased

FAECAL INCONTINENCE

Has your faecal incontinence improved?
1. YES, it disappeared
2. YES, it happens once a month
3. YES, it happens once a week
4. YES, it happens once a day
5. NO, it has not improved

Has the form of leakage changed?
1. YES, I have no more leakage
2. YES, I loose gas only
3. YES, I soil only
4. YES, I loose liquid stools only
5. NO, I loose faeces as before

Is the faecal leakage preceded by urgency?
1. NO
2. Rarely
3. Sometimes
4. Often
5. Always

Does the faeces leakage happen without your awareness?
1. NO
2. Rarely
3. Sometimes
4. Often
5. Always

Did you use faecal incontinence protection products before SNM?
1 NO
2 YES, one liner per day
3 YES, more than 3 liners per day
4 YES, 1-2 pads per day
5 YES, more than 3 pads per day
6 YES, incontinence diapers

Are you using faecal incontinence protection products after SNM?
1 NO
2 YES, one liner per day
3 YES, more than 3 liners per day
4 YES, 1-2 pads per day
5 YES, more than 3 pads per day
6 YES, incontinence diapers

CONSTIPATION

Have the spontaneous defecations increased?
1. YES, I defecate 1- more times a day
2. YES, I defecate 4-6 times a week
3. YES, I defecate 2-3 times a week
4. YES, I defecate once a week
5. NO, they have not

Is it easier to evacuate?
1. YES, always
2. YES, almost every time
3. YES, in 50% of cases
4. YES, but only sometimes
5. NO it is not easier

Has the abdominal pain/bloating improved?
1. YES, it disappeared
2. YES, I rarely experience it
3. YES, I sometimes experience it
4. YES, but I experience it quite often
5. NO it has not improved

Has the feeling of bowl emptying improved?
6. YES, always
7. YES, almost every time
8. YES, in 50% of cases
9. YES, but only sometimes
10. NO it has not improved

Did you use laxatives/enemas before SNM?
1 Never
2 YES, 1-3 times a month
3 YES, 1-2 times a week
4 YES, more than 3 times a week
5 I could not evacuate without them

Are you using laxatives/enemas after SNM?
1 Never
2 YES, 1-3 times a month
3 YES, 1-2 times a week
4 YES, more than 3 times a week
5 I cannot evacuate without them

Multidisciplinary UroGyneProcto Editorial Comment

To improve the integration among the three segments of the pelvic floor, some of the articles published in *Pelviperineology* are commented on by **Urologists, Gynecologists, Proctologists/Colo Rectal Surgeons** or **other Specialists**, with their critical opinion and a teaching purpose. Differences, similarities and possible relationships between the data presented and what is known in the three fields of competence are stressed, or the absence of any analogy is indicated. The discussion is not a peer review, it concerns concepts, ideas, theories, not the methodology of the presentation.

Uro... Sacral Nerve Stimulation (SNM) has become a well-established therapy for refractory non-neurogenic lower urinary tract dysfunction (LUTD), and it has been used extensively in the management of fecal incontinence (FI) over the past 20 years. SNM represents also a promising option for the managing of refractory neurogenic LUTD (NLUTD). It remains to be seen which types of NLUTD and which underlying neurological disorders best respond to SNM. There is evidence indicating that SNM may be effective and safe for the treatment of patients with NLUTD. However, the number of investigated patients is low with high between-study heterogeneity, and there is a lack of randomized, controlled trials 1.

Despite the poor quality of studies published, SNM appears to be clinically efficacious in treating FI with up to 42% achieving full fecal continence and the majority experiencing improvement in symptoms. Another common indication for SNM is constipation. Beneficial outcomes occur in approximately half the patients 2, with poor results at a medium-term follow-up and high rates of adverse effects mostly related to electrode displacement 3. Optimizing patient selection is critical to the use of SNM in treating constipation, although there is evidence of efficacy in both slow transit and rectal evacuation difficulty.

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Procto... This work highlights the two dysfunctions of the posterior compartment of the pelvic floor, i.e. incontinence and constipation that the gastroenterologist, the proctologist and the colorectal surgeon have often to face with considerable difficulty. In clinical practice, anal and especially fecal incontinence is not an everyday problem, while constipation, whose best definition is unsatisfactory defecation in a retentive sense, is observed with great frequency. It has been estimated that worldwide around 14% of adults suffer from constipation[1]. Dissatisfaction may be due to straining at stool, passing hard stools, sensation of incomplete emptying, sensation of anorectal obstruction, self-digitation and a defaecation frequency of less than three times per week. In order to make the diagnosis two of the above six symptoms must be present for at least 6 months along with abdominal pain, bloating, and frequent laxative and enema use. When significantly impacting on quality of life, constipation imposes controversial therapeutic choices. Conservative current treatment includes diet, laxatives, enemas, suppositories and biofeedback or behavioural treatments. Surgery (colectomy) has been considered having a role in patients with slow-transit constipation, but revealed a high complication rate, reoperation for adhesions in a fourth of the cases and failure in half of the cases. Evacuatory dysfunction may be related to rectal hyposensitivity or sphincters dyssynergia, where rehabilitation is a simple, inexpensive and often short and medium term successful therapy. The so called mechanical outlet obstruction has been in the last decade a popular indication for 'hitching' procedures (such as posterior or ventral rectopexy) or 'excisional' procedures, like stapled transanal rectal resection (STARR). Rectal intussusception and rectocele however are often observed in subjects with normal evacuation, and the relevance of such findings on defecography is uncertain. The reported complication rate of STARR is unacceptably high. There is a close association between severe constipation and emotional disorders, including a past history of physical or sexual abuse. Evaluating these problems is absolutely necessary before indicating any form of surgery or expensive treatment. The role of the uterosacral ligaments in abnormal bowel emptying is stressed by the Integral Theory with the proposal of restoring by TFS its form and function[2,3]. Sacral nerve stimulation (SNM) appears to have a great potential in treating patients with slow-transit constipation, but its use in routine clinical practice is still uncommon, mainly due to the cost of the equipment. Healthcare providers are reluctant to invest into these treatments without a better support from the literature. The emerging data however suggest that SNM has autonomic and central neurological effects that 'normalize' visceral awareness, rectal compliance and colonic motility – features equally beneficial in the treatment of both constipation and incontinence. In conclusion the place of neuromodulation in the management of severe constipation remains to be defined, and the challenge is how to identify those most likely to benefit[1].

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Original paper

Urodynamic evaluation before and after continuous intrathecal Baclofen infusion (ITB) in patients unresponsive wakefulness syndrome and minimally conscious state

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Abstract: Only a few reports have been published on acquired brain injury (ABI), especially on the correlation of urodynamic findings. The aim of this study is to urodinamically assess bladder function in patients on Unresponsive Wakefullness Syndrome (UWS) and Minimally Conscious State (MCS) before and after Intrathecal Baclofen Therapy (IBT) for supraspinal spasticity. After IBT there was a significant increase of Maximum Cystometric Capacity (MCC) and a reduction of Detrusor Leak Point Pressure (DLPP). Accordingly, an increase in Post Void Residual PVR in the first month was identified. While these results may seem a positive consequence of the therapy, they must be related to the type of patient treated, indeed the absence of a detrusor contraction supported by supraspinal centres can create an increase of the post-void residual. However, this discrepancy was filled out six months after implantation and the PVR returns comparable to the baseline.

Keywords: Intrathecal Baclofen therapy; Minimally conscious state; Unresponsive wakefullness syndrome; Urodynamics.

INTRODUCTION

Spasticity of either spinal or supraspinal origin may compromise patients severely and is associated with the development of pain, limb contractures and immobility.

Spasticity of supraspinal origin is much more common than spinal spasticity, but treatment with Intrathecal Baclofen Therapy (IBT) has been evaluated far less frequently in this condition[1].

Baclofen is a structural GABA analogue substance acting on the GABA-B receptor subtype. It is assumed to act at the spinal level attenuating mono and polysynaptic conduction, primarily by inhibiting the release of excitatory transmitters. Baclofen hardly penetrates the blood-brain barrier; therefore, penetration into the cerebrospinal fluid is poor with oral administration.

Only a few reports have been published on acquired brain injury (ABI), especially on the correlation of urodynamic findings. The most commonly expected urodynamic abnormality after ABI is involuntary detrusor contraction, which can be induced by the loss of cortical inhibition caused by suprapontine lesions. Very little is known about changes in urodynamic pattern in patients in Unresponsive Wakefullness Syndrome (UWS) and Minimally Conscious State (MCS). UWS and MCS are chronic disorders of consciousness that can follow ABI. UWS is defined by four criteria[2]: 1) no evidence of awareness of the self or the environment 2) no evidence of purposeful or voluntary response to external stimuli 3) no evidence of language expression or comprehension and 4) preserved EEG sleep-wake cycles. MCS occurs when reproducible, even if minimal, evidence of awareness is observed[3].

The aim of this study is to urodinamically assess bladder function in patients on UWS or MCS before and after IBT.

MATERIALS AND METHODS

We enrolled for this study 16 patients (13 males and 3 females, with an average age of 41.3±13.5 years), admitted to the Neurorehabilitation-Vegetative State Unit of the ASLCN1 in Cuneo ; all patients were in UWS or MCS for CVA (6 extensive brain hemorrhage), TBI (7 patients) and anoxic (3 patients). Patients did not presented associated spinal cord injury and were all having a value ≤ 3 on the Level of Cognitive Functioning (LCF) Scale[4]. The LCF, including the modified LCF-R version, is a "process scale", that is, it evaluates patient behaviour and thus the patient's cognitive level from the moment he or she goes into coma until recovery. It can functions as the instrument for patient evaluation across different units, e.g. it can also be used in the intensive care unit.

The Neurorehabilitation Unit accepts clinically stabilised patients with a diagnosis of traumatic brain injury or non-traumatic brain injury. The only criterion precluding access to the Unit is mechanical ventilation. Patients with a tracheotomy tube or percutaneous endoscopy gastrostomy (PEG) tube are accepted and there are no time limits with respect to the acute event, although the earliest possible access is guaranteed.

A detailed medical history was collected for all patients. A physical medicine examination and neurological examination were carried out every week to evaluate spasticity and, where necessary, radiological and neuroradiological investigations were carried out every month.

The rehabilitation programme for these patients includes the provision of optimal nutrition, control of infections, management of bladder, bowel and autonomic disorders, provision of specialist seating and control of posture and tone problems. Patients underwent one hour of physical therapy treatment and one hour of speech therapy every day, to prevent tertiary injury. Rehabilitative treatment involved passive joint mobilisation and helping/placing patients into an upright sitting position on a tilt table.

All the patients were evaluated upon entry as to their bladder and bowel voiding, combining clinical observations with items specific to related activities contained within the Functional Independence Measure (FIM).

IBT was proposed when severe spasticity became interfering with passive function, positioning or caregiving[5].

All patients were urodinamically evaluated before and one month after Baclofen pump implantation. During urodynamic study were evaluated the presence of Detrusor

Overactivity (DO), Maximum Cystometric Capacity (MCC), detrusor pressure at opening bladder neck (detrusor leak point pressure, DLPP) that coincide to detrusor pressure required to void.

In all patients were applied the Modified Ashworth Scale (MAS), separately for upper and lower limbs, and the Spasm Score, before and after implant, to evaluate changes in spasticity.

In all patients were evaluated Post Void Residual (PVR) pre and post IBT.

In 12 patients we performed a second urodynamic evaluation 6 months after implant, evaluating the same urodynamic findings (DO, MCC, DLPP).

Statistical analysis were performed using paired t-test and/or paired Wilcoxon test when appropriated to evaluate the difference in Ashworth and spasm scale, and to evaluate the urodynamic results at baseline and 1 and 6 months after IBT. We used Fisher's exact test to evaluate the number of patients in Clean Intermittent Catheterization (CIC), and the conscious state at baseline and after IBT. We considered statistical significant when p≤0,05.

RESULTS

Mean age of patients included in the study was 41.3±13.5 years, mean duration of UWS or MCS were 16.7±9.1 months, elapsed time between cerebral injury and our centre's admission was 149.5±41.5 days. At admission 3 patients were in MCS and 13 in a UWS. Time of catheterization was 117,9±98.4 days. At baseline all patients were in spontaneous micturition (reflex urinary incontinence); in 4 out of 16 patients CIC was necessary because high PVR.

Criteria for the implant were: MAS score 2 for three or more joints even if on the same body side; no signs of infection detected by a negative hemoculture, number of white globules in the normal range and absence of fever in the week before the implant.

In all patients we observed an improvement of spasticity, especially of lower limbs after IBT. The mean MAS preimplantation was 2.8±0.4 for upper limbs and 3.5±0.5 for lower limbs, spasm score was 1.8±0.7. After IBT MAS was reduced, 2.4±0.5 for upper limbs and 2.2±0.4 for lower limbs with a statistical significant difference (p≤0.01). Also Spasm Score was improved, after ITB measuring 1.5±0.5 with a significant statistical difference respect baseline (p≤0.03).

One month after IBT in 8 out of 16 patients was necessary CIC for high PVR (Fisher's exact test p≤0.27). Six months after implantation CIC was necessary in 3 out of 12 patients (Fisher's exact test p≤0.3).

At urodynamic evaluation mean baseline MCC was 364,6±150.1 ml., one month after IBT was 391.9±40.8 ml. (p≤0.03). Mean MCC six months after implant (12 patients) was 368.1±146.2 ml (p≤0.11). DLPP was 98.3±7.4 cmH_2O at baseline and 83.8±11.5 cmH_2O one month after IBT, with a significant statistical difference (p=0.04). in the 12 patients evaluated 6 months after IBT mean DLPP was 85,7±12.8 cmH_2O (p≤0.05 respect baseline).

Mean PVR at baseline was 57.5±21.7 ml., and 100.4±50.9 ml. one month after IBT (p≤0.01), although 6 months after IBT mean PVR was 56.8±24.5 (p≤0.58 respect baseline). At baseline in 10 out of 16 patients a DO was identified, after IBT DO was present in 3 out of 16 patients (p≤0.02), and in two patients 6 months after implant.

We observed an improvement in conscious state, at hospital admission 13 out of 16 patients were in VS and 3 out of 16 in MCS, at discharge 7 out 16 were in SV and 9 in MCS (Fisher's exact test p≤0.14).

TABLE 1. Demographics and clinical variables of the enrolled patients (n=16).

	n.	%
male	13	81.3%
female	3	18.7%
age (years±SD)	41.3±13.5	
Duration of DOC (UWS/MCS) prior to ITB (months±SD)	16.7±9.1	
Type of brain injury		
Traumatic	7	43.8%
Hemorragic	6	37.5%
Anoxic	3	18.7%
Indications for ITB treatment		
Severe Spastic Hypertonia	8	50%
Spastic Hypertonia and spasms	4	25%
Spastic Hypertonia and Dysautonomia	4	25%

TABLE 2. Urodynamic data before and after ITB.

	1-3 weeks after implant (T1) (n=16)			4-5 months after implant (T2) (n=12)		
	baseline	T1	p	baseline	T2	p
Detrusor Leak Point Pressure (cm H_2O)	98.3±7.4	73.8±11.5	0.043	98.3±7.4	83.8±14.9	0.152
Maximum Cystometric Capacity (ml.)	364.6±150.1	391.9±40.8	0.031	364.6±150.1	378.1±146.2	0.118
Detrusor Overactivity (yes)	7 (58.3%)	3 (25.0%)	0.045	7 (58.3%)	2 (16.7%)	0.025
Post-voiding Residual Urine Volume (ml.)	57.5 ± 21.7	100.4 ± 50.9	0.01	57.5 ± 21.7	56.8 ± 24.5	0.58

DISCUSSION

Penn and Kroin were the first to report good results with continuous IBT in patients with severe spinal spasticity. A dramatic clinical improvement was reported[6].

Spasticity of supraspinal origin is much more common than spinal spasticity, but treatment with ITB has been evaluated far less frequently in this condition[7]. Reports of successful treatment of patients with supraspinal spasticity are limited[8,9]. Especially patients with severe traumatic and/or hypoxic brain injury often suffer from severe tetraspasticity that is unresponsive to oral medication, physiotherapy or other antispastic therapies.

In the oral pharmacological approach to spasticity, baclofen, a γ-aminobutiryc acid (GABA) agonist, is often used, although in certain cases a lack of response, a ceiling effect or significant side effects as disorientation, dizziness, asthenia and ataxia are revealed when the useful dosage is reached.

The intrathecal administration through a programmable infusion pump system allows an effective control of spasticity after a serious brain lesion with fewer side effects than the oral treatment and with an important global functional improvement.

More limited are the reports on IBT use in patients in UWS or MCS.

Moreover IBT has been demonstrated to be effective to improve bladder capacity or to decrease sphincter dyssynergia in patients affected by spinal cord spasticity. Only a few reports have been published on ABI, especially on the

correlation of urodynamic findings, because injured patients commonly have behavioral, cognitive, or communication problems[10]. The injury to the brain itself, impairment of cognitive and behavioral function, may induce lower urinary tract symptoms (LUTS), as detrusor hyperactivity, only rarely associated with bladder-sphincter dyssynergia, and emptying phase disorders[11,12].

The most commonly expected urodynamic abnormality after ABI is involuntary detrusor contraction, which can be induced by the loss of cortical inhibition caused by suprapontine lesions. Coordinated relaxation of the distal sphincter during detrusor contraction is usually maintained. The incidence of urinary retention after ABI is lower than that after cerebrovascular accident (CVA). Very little is known about changes in urodynamic pattern in patients in UWS or MCS after ABI or CVA treated with ITB[13,14].

The use of baclofen is recommended in the treatment of LUTS thanks to two main modes of action:

– The inhibition of the hypertone which involves the external urethral sphincter

– The increase of detrusor compliance with subsequent increase of the bladder's filling capacity

The use of intrathecal baclofen in the patients suffering from disorder of consciousness is spreading more and more, and not only for the treatment of spasticity and neurovegetative crisis but also for the possibility to induce a change in positive of the state of consciousness, many are today reporting in this sense[15]. Another element to be reckoned with in clinical practice is the indication, suggested by some authors, to use early implant in order to prevent the impairment linked with spasticity before it is structured, thus making almost vain the only pharmacological or rehabilitative intervention.

In people affected by DOC as UWS or MCS, the good clinical practice suggests the weaning from an indwelling catheter because – except for prior problems or coexisting bladder issues – it is a case of overactive bladder emptying without bladder-sphincter dyssynergia. Therefore, it is important to know the potential risk of bladder overdistention due to urinary retention in patients implanted with a baclofen intrathecal release system.

This study, even considering the modest numerosity of the sample, allowed to verify that after the implantation of IBT a significant increase of MCC and a reduction of DLPP. Also the presence of DO is detected with a significantly reduced frequency respect baseline. Accordingly an increase in PVR in the first month was identified. While this data may seem a positive result of the therapy must be related to the type of patient treated, indeed the reduction of a detrusor contraction that it is not supported bysupraspinal centers can create an increase of the PVR. However, this discrepancy was filled out six months after implantation, and the PVR returns comparable to the baseline. Instead, positive results on the reduction of DO were maintained in the long term. The data therefore indicate the need to monitor PVR closely, in the first weeks after implantation, to avoid the risk of bladder supra-distension in these patients with disturbance of consciousness.

CONCLUSIONS

After IBT there was a significant increase of MCC and a reduction of DLPP. Accordingly, an increase in PVR in the first month was identified. While these results may seem a positive consequence of the therapy, they must be related to the type of patient treated, indeed the absence of a detrusor contraction supported by supraspinal centres can create an increase of the post-void residual. However, this discrepancy was filled out six months after implantation and the PVR returns comparable to the baseline.

The data observed would confirm the necessity of carefully monitoring, during the first weeks after the implantation, the likelihood of bladder overdistention in subjects with DOC whose bladder indwelling catheters have been removed and with an "automatic" micturition without bladder-sphincter dyssynergia. The monitoring (if possible with the use of bladder scans) should be prolonged for at least six months, when it seems conceivable the return to cystomanometric values which could be overlapped to the preimplantation ones.

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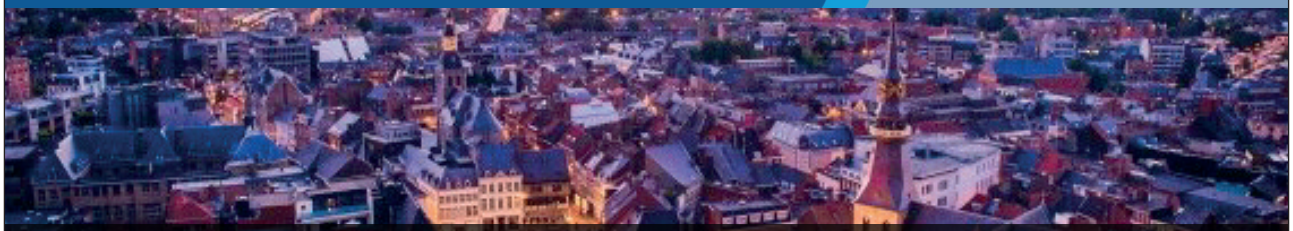

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