Original article

Safe and effective intervention surgery for pelvic organ prolapse with CR-Mesh® kit: a comparative study from United Kingdom and Italy

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Abstract: Background: Surgical approach for the treatment of genital prolapse remains subject of controversy. The aim of pelvic surgery is to relieve symptoms, to correct the prolapse and to improve the quality of life. Objective: To compare success rates, intraoperative and postoperative complications, safety, functional outcome and satisfaction rate in a UK and an Italy group in a retrospective case series using CR Mesh® kit[19] for the management of vaginal prolapse over the first year. Materials and Method: This is a prospective, observational study of 40 women in each arm and 80 patients in total, operated in the period from October 2008 to December 2010. In this study, we compared data from our audit (UK Group) with data from our Italian colleague (Italy Group). All the surgeons received their surgical training for this repair from the same trainers. This comparative study is undertaken as all the surgeons received similar surgical training. The results were collected and checked compliance against NICE interventional procedure guidelines No.267 audit support. Results: The preliminary audit confirms the intra-operative safety and efficacy of the procedure with no intra-operative and post-operative complications. Anatomical restoration was successfully achieved in 95-100% of patients. Re-operation rate was 2.5% in UK group. There were no mesh erosions noted in both the groups after one year. 90% of the patients were satisfied with improvement in functional outcome concerning urinary, bowel symptoms and sexual function and improvement in quality of life whilst the dissatisfaction rate was 10%. Conclusion: Pelvic floor reconstruction with CR Mesh procedure safely addresses repair of POP and is compliant with standards defined by NICE.[25] It is one of the first case series of its kind with medium term follow-up for this procedure.

Key words: CR Mesh; Pelvic Organ Prolapse, Pelvic floor reconstruction.

INTRODUCTION

POP occurs in up to 50% of parous woman. Up to 30% of all females suffer from pelvic floor relaxation to a degree that has negative impact upon their quality of life. Olsen et al.[1] estimated that the lifetime risk (up to age 80 years) of undergoing surgery for vaginal prolapse was 11%. 29% to 40% of the prolapse surgery is for recurrence[1,2] and the prolapse is at the site of the original procedure in 60% of re-operations.[3]

Pelvic organ prolapse (POP) is nothing but herniation of viscera through the weakened pelvic floor and vaginal walls. Cystocele and urethrocele are herniation due to a defect in the anterior compartment. Cervical, uterine and vault prolapse are herniation due to a defect in the central compartment. Enterocele, rectocele and perineal body deficiency are herniation due to a defect in the posterior compartment (Figure 1).

It is important to understand the supports of the pelvis before embarking on the prolapse repair. There are three levels of supports in the pelvis. Main function of Level I is suspension, Level II is attachment and Level III is fusion (Figure 2).

Table 1 describes the structures in detail. Identifying the defect and offering a side-specific and site-specific repair is a prerequisite for a successful and long lasting effect. The aim of any pelvic surgery is to restore the anatomical and functional defect, relieve symptoms and improve the patient's quality of life with minimum morbidity from the surgery.

Nevertheless, what is "cure" and how are we to define it? A woman presenting with a prolapse seldom asks for an "anatomical cure". What she wants is a resolution of her symptoms of a vaginal lump as well as a resolution of any associated bowel and bladder dysfunction. [6] Therefore, the choice of surgery depends on the patient's symptoms, associated pelvic defects and underlying medical conditions. The choice of course, is heavily dependent on the training, expertise and experience of the individual surgeon.[7,8] Abdominal sacro-colpopexy has remained the gold standard for the repair of vaginal apical suspension defects.[9] Vaginal approach is less invasive with lesser patient morbidity and has fewer side-effects/complications.

POP non-mesh reconstruction entails unacceptably high recurrence rate, thus mesh augmentation is indicated for long lasting prolapse cure. This also avoids hysterectomy of the prolapsed uterus.[10] Having said that, surgical approach for the treatment of genital prolapse with large mesh remains controversial and the outcomes, major complications and improvement in quality of life remain at its infancy.[11] Currently, most of the information on the outcomes of vaginal surgery with synthetic mesh implants comes from short-term follow-up[12,13,14] or exists in non-peer review publications such as conference abstracts.[15, 16]

Pelvic floor mesh reconstruction involves extensive deep pelvic dissection. Hence, it is mandatory that surgeons are thoroughly familiar with the anatomy, accurate surgical technique, potential hazards, preventive measures and management of complications before embarking on the implantation of such meshes. It is suggested that surgeons undergo a meticulous training program with an expert prior to undertaking the procedure[17] and maintain skills with frequent operation performance.[17, 18]

OBJECTIVE

To compare success rates, intraoperative and postoperative complications, safety, functional outcome and satisfaction rate in a UK and an Italy group in a prospective, observational case series using CR Mesh® kit[19] for the management of vaginal prolapse over the first year.

MATERIALS AND METHODS

CR Mesh[20]

CR Mesh (Figure 3) is designed to restore fascial support to either the anterior or the posterior vaginal compartment. It has a number of features, which are designed to make it

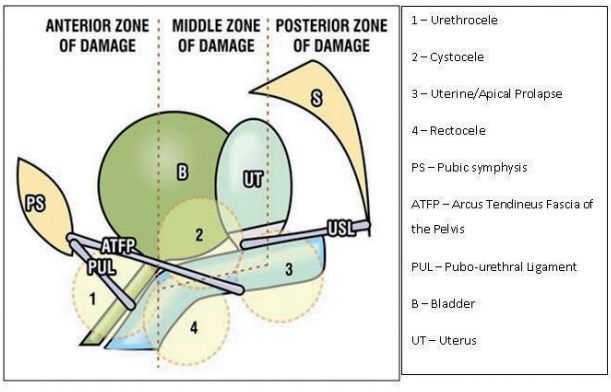

Figure 1. – (The Integral Theory System[4]) – Zones of damage and anatomical changes.

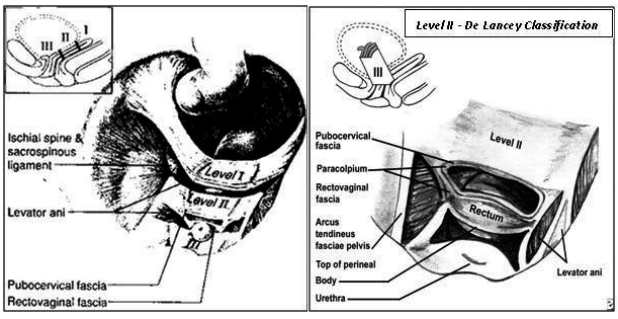

Figure 2. – Three Levels of Pelvic Support[5].

less likely to cause mesh related complications after surgery. These features are advances from previous techniques that have proven to be successful in reducing the risk of mesh related complications. The features include:

- Lightweight low-density monofilament mesh structure- The main body of the mesh is composed of a very low-density wide weave macroporous monofilament polypropylene.
- Strong non-distensible upper vaginal slings for firm lateral attachment.
- Independent attachment of mesh components - No glue, sutures or rivets left within the patient.
- Complete flexibility and adjustability to customise mesh for each patient – Adjustable length of the mesh.
- The mesh is tailored to fit the patient rather than the patient is made to fit the mesh.

There are several mesh kits available in the market to restore pelvic anatomy. However, most of them do not address Level I pelvic organ prolapse similar to CR Mesh. CR Mesh® kit[20] is now available in Europe and Australia for advanced pelvic floor surgeons who complete a training program. The technique is more complex and difficult than standard techniques using available meshes. However, this results in a superior anatomical restoration due to the accurate recreation of the pelvic anatomy.

POP Repair With CR Mesh[20]

The procedure for implanting the CR Mesh is as described by Dr. B. Farnsworth[21] and it is not within the context of this paper to discuss the procedure in detail. The important steps in the procedure are:

1. **Level I - Apical support -** Provided by a suture suspended between the top of the mesh and the medial end of the sacrospinous ligament. The origin of the uterosacral ligaments is recreated by attaching the apical support to a point at the medial end of the sacrospinous ligament within a few millimetres of the sacrum on each side. High apical suspension accurately recreates the uterosacral ligaments.
2. **Level II - Lateral support -** Provided by the sling arms for either the anterior vaginal walls (cystocele) or the posterior vaginal wall (rectocele), depending on their placement. Firm lateral attachments with permanent muscle fixation - lateral fixation to the obturator foramen anteriorly and the levator complex posteriorly ensures that upper vaginal support is restored.
3. **Level III - Distal support -** Provided by 2 distal mesh extensions, tunnelled at the level of the obturator foramen anteriorly and around the perineal body posteriorly. This results in independent bladder neck and perineal reconstruction respectively- both the bladder neck and perineal body are directly reattached to the sacrum.

This is a prospective, observational study of 40 women in each arm and 80 patients in total, operated in the period from October 2008 to December 2010. In this study, we compared data from our audit (UK Group) with data from our Italian colleague (Italy Group). All the surgeons received their surgical training for this repair from the same trainers.[21,22] This comparative study is undertaken as all the surgeons received similar surgical training.

Case selection: patients experiencing stage 3 or 4 vaginal apical supportive defects, (Table 2) diagnosed clinically in accordance with the International Continence Society (ICS) Pelvic Organ Prolapse Quantification (POP-Q) (Figure 4) standard scoring system, were offered CR Mesh repair.

Standards: We benchmarked our performance against The National Institute for Health and Clinical Excellence (NICE), UK guidelines[11]. NICE is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health. NICE makes recommendations on the safety and efficacy of a procedure and presents recommendations in a suitable

TABLE 1. – Three Levels of Pelvic Support[5].

Levels	Function	Area/Tissue	Attachments	POP
Level I	Suspension	Parametrium Upper paracolpium	Cardinal L Uterosacral L	Uterine P Vault P
Level II	Attachment	Paracolpium Upper 2/3 of vagina	Pubocervical Rectovaginal Fascia (ATFP)	Cystocele Enterocele Rectocele
Level III	Fusion	Levator plate Perineal body Lower 1/3 of vagina	Pubococcygeus Ileococcygeus	Urethrocele Low rectocele Deficient Perineal body

TABLE 2. – POP-Q system[24].

Stage 0	No descent of pelvic structures during straining
Stage I	Leading edge of the prolapse is < 1 cm above the hymenal ring
Stage II	Leading edge of the prolapse extends from 1 cm above the hymen to 1 cm below the hymen.
Stage III	Leading edge of the prolapse is > 1 cm below the hymen, but there is no complete vaginal eversion.
Stage IV	The vagina is completely everted

Table 3.

Demographics	UK Group
Age – Range (Mean)	47-81 years (67.4)
Body Mass Index - Range (Mean)	23-43 (29.5)
Parity - Range (Mean)	1-7 (3.03)
Associated medical disorders: Diabetes, asthma, hypertension etc	90%
Sexually active	10% sexually active

Table 4.

Previous Surgery	UK Group (%)
None	55%
Abdominal hysterectomy	17.5%
Vaginal Repair	12.5%
Vaginal hysterectomy	5%
Burch Colposuspension	5%
Laparoscopic hystero/colpopexy	5%
Sacrospinous Fixation	2.5%
Prolift Repair	2.5%

Table 5.

Vaginal Mass/Bulge	UK Group (%)
Bulge/Lump in the vagina	90%

Table 6.

Bowel Symptoms	UK Group (%)
Need for digital evacuation	2.5%
Constipation – Difficulty in emptying bowels	25%

format for health professionals. NICE Guidance[11] was used as gold standard to assess our study. The outcome measures were checked for compliance against NICE audit support[25].

Outpatient consultation: patients were referred by their general practitioners with a history of pelvic organ prolapse that had recurred or occurred for the first time. Patients were assessed gynaecologically for the associated signs and symptoms and a POP-Q was performed on each patient at the first visit. Demographics, sexual activity, previous vaginal repair, vaginal mass, bladder and bowel specific symptoms were collected.

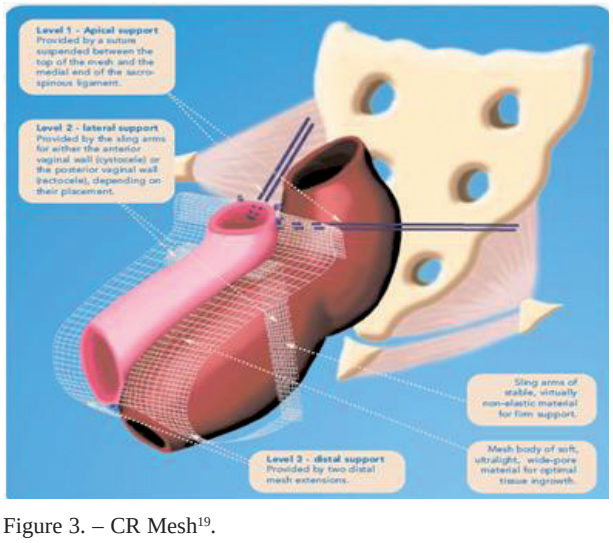

Figure 3. – CR Mesh[19].

Table 7.

Bladder Symptoms	UK Group (%)
Urge Incontinence	27.5%
Urgency	17.5%
Hesitancy	2.5%
Weak stream	2.5%
Incomplete emptying	7.5%
Stress Incontinence	50%

Table 8.

POP - Q measurements	UK Group - Range (Median)
Anterior	
Aa	2.5 (–3 to 3)
Ba	2.0 (–2 to 4)
Stage	3 (2 to 3)
Posterior	
Ap	–2.5 (–3 to 2)
Bp	–2 (–3 to 1)
Stage	2 (1 to 3)
Middle	
C	–5 (–9 to 5)
D	–6 (–8 to –4)
Stage	2 (0 to 3)
gh (genital hiatus)	5 (2 to 6)
Pb (perineal body)	2.5 (2 to 5)
tvl (total vaginal length)	8.5 (7 to 10)

Once stage 3 or 4 vaginal apical supportive defect was confirmed, the procedure, risks and complications including mesh erosion were explained and informed consent was obtained. Patients received explanation that the technique is recent and long-term data is not available.

There is a slight difference in the selections of patients. In The UK group, this was offered to women who were not sexually active. However, the procedure was offered to 10% of sexually active women as these women had several other surgical procedures that had failed. In the Italy group, the procedure was offered to patients regardless of their sexual activity.

Demographic features and previous surgical history in UK group are summarized in Tables 3 and 4. In Italy group, age range was 38-74 years, with mean of 55.5 years. 75% of this group were sexually active.

Tables 5, 6, and 7 demonstrate symptoms in the UK group while Table 8 reports POP-Q measurements. In Italy group, 50% women complained of bulge/lump in the vagina, 7.5% complained of bowel dysfunction, 12.5% had symptoms of overactive bladder and 15% had stress incontinence.

Investigations: apart from routine pre-operative investigations, in the UK group, urodynamic assessment were performed on patients with urinary symptoms, whereas in the Italy group, urodynamics and proctograms were performed on patients with urinary or bowel dysfunction respectively.

Operation: all patients received 1.2 gram Co-amoxiclav intravenously at the induction of anaesthesia and continued on oral co-amoxiclav for seven days post-operatively. Surgical area was prepared by iodine antiseptic vaginal wash prior to commencement of surgery. Adhesive plastic sheet was attached below the level of vaginal fourchette to prevent any contamination from perianal region. Vaginal tissues were liberally infiltrated with a 0.25% solution of bupivacaine with adrenaline 1:200,000 prior to dissection. (Up to 40 ml of solution was diluted in 100 ml of normal saline). An indwelling catheter and lubricated vaginal pack

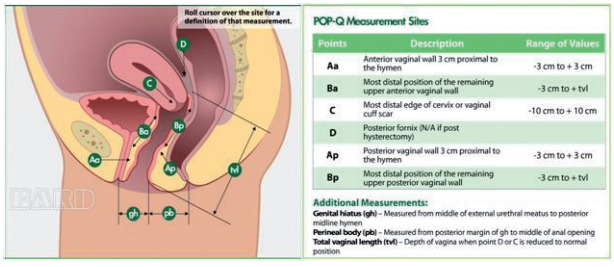

Figure 4 - Pelvic Organ Prolapse Quantification (POP-Q) Standard scoring system[23].

were inserted after the procedure, which were removed 24 hours later. In cases of suspected retention of urine, residual urine was measured by in and out catheter following emptying of the bladder by the patient. Patients who had posterior CR Mesh almost inevitably showed marked perineal bruising because of the very nature of the procedure. Full blood count was performed on second post-operative day unless indicated otherwise. Women were discharged on second post-operative day. Operative details, intra-operative and post-operative complications of all the patients were collected.

Post-operative follow-up: postoperatively, patients in the UK arm were reviewed at 4 weeks where mesh erosion, urinary, bowel symptoms, pain, vaginal discharges were assessed. In the Italian arm, patients were reviewed clinically at three monthly intervals for one year and with urodynamics and proctogram at their six-month visit. In both the groups, quality of life assessment questionnaires were sent to patients between six months to one year following surgery.

The numbers and types of procedure performed are shown in Table 9. In the UK group, 19 patients had anterior CR mesh, 11 had posterior CR mesh and 10 patients had total CR mesh (anterior and posterior mesh) whilst in the Italian Group, 15 patients had anterior CR mesh, 15 patients had posterior CR mesh and 10 patients had total CR mesh procedure.

TABLE 9.

Types of procedure performed	UK Group n (%)	Italy Group n (%)
Anterior CR Mesh procedure	19 (47.5%)	15 (37.5%)
Posterior CR Mesh	11 (27.5%)	15 (37.5%)
Total CR Mesh (Anterior and Posterior Mesh)	10 (25%)	10 (25%)

RESULTS

Assessed against NICE Criteria[25]

When analysing the results of the criteria 3, 5, 6, 7 and 8, NICE recommends that consideration be given to the type of prolapse, whether it is a first or recurrent prolapse, whether there have been previous repairs and any underlying medical conditions or comorbidities. Results should also be analysed by type of mesh used and approach. Patients who lost follow-up should be excluded from the study. However, no patients were lost for follow-up in both UK and Italy group.

Criterion 1: The % of patients receiving surgical repair of vaginal wall prolapse using mesh within a given period who have (A) Received written information on the procedure and any possible complications (B) Had a discussion with the clinician about the procedure which is documented in the notes and (C) Given written consent to treatment.

Definition: Specific information regarding the treatment should be provided including reference to complications of sexual dysfunction and erosion into the vagina, which would require additional procedures. Success rates should also be provided.

TABLE 10. – Summary - Outcome compared with NICE Guidelines[25].

Criteria	NICE Standard	UK Group	Italy Group
Criterion 1			
% of patients receiving (A) received written information on the procedure and any possible complications, (B) had a discussion with the clinician about the procedure which is documented in the notes and (C) given written consent to treatment	(A)100% (B) 100% (C) 100%	(A) 0% (B) 100% (C) 100%	(A) 0% (B) 100% (C) 100%
Criterion 2			
% of patients whose surgery is undertaken by a gynaecologist with special expertise in the surgical management of pelvic organ prolapse	100%	100%	100%
Criterion 3			
% of patients with clinical or symptomatic improvement compared to baseline at 6 and 12 months – Objective failure rate	9%-23%	10%	0%
Criterion 5			
% of patients who require further re-operation for recurrent or de novo prolapse due to failure of repair within 1 year of the procedure	1%-9%	2.5%	0%
Criterion 6			
% of patients who have an assessment of their quality of life at t 1 year	100%	100%	100%
Criterion 7			
% of patients who suffer intraoperative and complications within 30 days post procedure (Reported complications include bladder injury, urethral or rectal perforation and damage to other surrounding organs)	Insufficient evidence to set a standard	0%	0%
Criterion 8			
% of patients who suffer any of the following complications within 12 months post procedure			
• Mesh erosion	<10%	0%	0%
• Urinary or faecal incontinence	<15%	2.5%	2.5%
• De novo dyspareunia	<10%	0%	0%
• Vaginal narrowing secondary to mesh	–	0%	0%
• Vaginal pain	–	2.5%	0%
• Chronic sepsis, discharge	–	0%	0%
• Fistula	–	0%	0%

Standard: NICE recommends 100% compliance.

Results: Compliance was 100% in UK group for points (B) and (C). Detailed patient information leaflets were not available regarding the procedure. Compliance was 100% in all areas in Italy group.

Criterion 2: The % of patients receiving surgical repair of vaginal wall prolapse using mesh within a given period whose surgery is undertaken by a gynaecologist with special expertise in the surgical management of pelvic organ prolapse.

Definition: The British Society of Urogynaecologists define a urogynaecologist as having a surgical workload of at least one major urogynaecology procedure associated with pelvic floor dysfunction (i.e. incontinence and/or prolapse) per working week per year.

Standard: NICE recommends 100% compliance.

Results: Compliance was 100% in both UK and Italy groups. The operators had performed more than 80 procedures per year for vaginal prolapse and/or incontinence procedure annually.

Criterion 3: The % of patients receiving surgical repair of vaginal wall prolapse using mesh for which there was a clinical and symptomatic improvement compared to baseline at 6 months and 1 year

Definitions: The POP-Q is recommended as an objective measure for clinical outcome. It reports outcome as four stages and clinical improvement is defined as a transition to at least one stage lower than baseline.

Standard: NICE recommends objective failure rates between 9% and 23%; insufficient evidence to set a standard

Results: In the UK Group, the dissatisfaction rate with the operation or outcome was 10% whilst in the Italy group; all patients were satisfied with the outcome. Thus, our results from both the groups were within the objective failure rate. Studies with CR Mesh showed that 90% of the patients were satisfied with the results and had an improvement of quality of life[26].

Criterion 5: (There are no Criteria 4 in NICE standards) The % of patients receiving surgical repair of vaginal wall prolapse using mesh who require further re-operation for recurrent or de novo prolapse due to failure of repair within 1 year of the procedure.

Definition/Standard: Re-operation rates between 1% and 9% were reported across different types of mesh at a mean follow-up of 1.5 years; insufficient evidence to set a standard.

Results: In the UK group, 5% of the patients required a further procedure. However, only 2.5% were for the recurrence of Level 1 prolapse and 2.5% was due to a prolapse in a different compartment. There were no re-operations in the Italian group within 18 months.

Criterion 6: The % of patients receiving surgical repair of vaginal wall prolapse using mesh who have an assessment of their quality of life at 1 year.

Definitions: Assessment of quality of life provides some indication as to the success of the treatment from the patient perspective.

Standard: NICE recommends 100% compliance.

Results: Compliance was 100% in both UK and Italy groups.

Criterion 7: The % of patients receiving surgical repair of vaginal wall prolapse using mesh who suffer: Intraoperative complications and complications within 30 days post procedure.

Definitions: Complications include bladder injury, urethral or rectal perforation, and damage to other surrounding organs.

Standard: NICE had insufficient evidence to set a standard.

Results: Compliance was 100% in both UK and Italy groups. There were no intraoperative complications or complications within 30 days of the surgery in both the groups.

Criterion 8: The % of patients who suffer any of the following complications within 12 months post procedure which include mesh erosion, urinary or faecal incontinence. de novo dyspareunia, vaginal narrowing secondary to mesh, vaginal pain, chronic sepsis, discharge and fistula

Definitions: Mesh erosion occurred in 6% regardless of the mesh type, de novo urinary incontinence in 10% of women, de novo dyspareunia in 7% following surgery using combined mesh and 12.8% following surgery using non-absorbable synthetic mesh. **Standard:** NICE recommends mesh erosion <10%, urinary incontinence <15% and dyspareunia <10%

Results: Mesh erosion: In the UK group, two (5%) patients had mesh erosion at the 4-week visit and they were asymptomatic. Mesh erosion was noted on the incision line on the posterior vaginal wall, which was not healed completely. Further follow-up at 8 weeks visit revealed well-healed scar and there was no erosion noted. There were no mesh erosions detected in both groups after 1 year and this is comparable against NICE standards. Refraining from excessive vaginal mucosa trimming and dissecting below the sub-mucosal fascia preserves blood supply and nerve endings. Thus, ischaemia, poor healing and tissue necrosis are avoided and likelihood of mesh exposure is reduced[27].

Urinary incontinence: We reported one (2.5%) case of residual urinary incontinence in both the groups 12 months following surgery. Once again, this was comparable with NICE standard and compliance was 100% in both UK and Italy groups. Nonetheless, 6 (15%) patients in both groups complained of urge incontinence and frequency immediately after surgery, which resolved with anticholinergics and/or antibiotic therapy within 4 weeks. In 1 (2.5%) patient in UK group, the obturator arms of the anterior CR mesh were divided at level III after six months following initial repair, as excessive compression of the urethra resulted in difficulty in micturition and recurrent urinary tract infections.

Dyspareunia: In sexually active patients, there were no complaints of de novo dyspareunia. Indeed, in the UK group, 8 (20%) of sexually inactive patients due to disrupted pelvic anatomy resumed sexual function after their surgery. 75% of patients in Italy group said there was an improvement in their sexual function following surgery due to absence of bulge or fear of incontinence.

Other complications: To date we did not have any complications of chronic sepsis, discharge or fistula. 25% patients complained of constipation initially after surgery but resolved following use of laxatives.

Other findings: although there are no standards provided by NICE guidelines regarding vaginal pain, 1 (2.5%) woman in the UK group complained of protracted vaginal pain resulting from mesh contracture, which was at the point of anchoring of the mesh to the sacrospinous ligament. Pain resolved on division of that part of the mesh. No such complications were noted in the Italy group.

DISCUSSION

We are well aware of some of the deficiencies in our paper. The numbers of patients in both groups were small be-

cause of selectivity of patients for this type of surgery with stage 3 or 4 vaginal apical supportive defects. Gynaecologists who perform a large number of prolapse and incontinence surgeries operated the patients; hence, it contributes to the low rate of major complications. As the study is small, further follow-up studies are required to demonstrate the safety of this procedure. Long-term follow-up studies are required to assess these findings further. Detailed patient information leaflets were developed following the audit in the UK group to achieve 100% compliance with Criteria 1.

CONCLUSION

Pelvic floor reconstruction with CR Mesh procedure safely addresses repair of POP and is compliant with standards defined by NICE.[25] It is one of the first case series of its kind with medium term follow-up for this procedure. The preliminary audit confirms the intra-operative safety and efficacy of the procedure with no intra-operative complications and there were no major complications resulting from surgery within 30 days. Anatomical restoration was successfully achieved in 95-100% of patients. Re-operation rate was 2.5% for recurrent prolapse in the UK group. There were no mesh erosions noted in both the groups after one year.

The procedure is associated with minimal morbidity with good improvement in the quality of life for the patients. 90% of the patients were satisfied with improvement in functional outcome concerning urinary, bowel symptoms and sexual function and improvement in quality of life whilst the dissatisfaction rate was 10%. We did not have any patients with chronic sepsis, discharge and fistula or de novo dyspareunia. Table 10 summarizes outcomes compared with NICE Guidance[25].

Surgical expertise, proper training before adopting new operation and maintaining skills with regular operations are essential to improve success rate and decreases complication and failure rates.

CONFLICT OF INTEREST: The authors declare that have not received any grants or financial support for the study and there is no conflict of interest.

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