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Pelvic organ prolapse treated by vaginal native tissue repair: 5 years follow up.

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ABSTRACT

Pelvic organ prolapse is a common condition, with a worldwide prevalence of 30- 50% in women over 50 years of age. We evaluated the efficacy of native tissue repair in 108 patients affected by genital prolapse, enrolled from September 2011 to June 2017, who underwent vaginal hysterectomy eventually associated with anterior and/or posterior vaginal plastic. A clinical multidisciplinary examination with Pelvic Organ Prolapse Quantification System and administration of questionnaire concerning quality of life, urinary symptoms and sexual problems were performed the day before and 1, 3, 6, 12, 48 and 60 months after surgery. After 12 months, 5.9% of patients showed recurrent vaginal prolapse, while 8.6% at 5 years follow up. 90% of patients declared to have a satisfying quality of life at 5 years follow up and only 3 patients had persistent dyspareunia. Our technique involves the suspension of the vaginal vault to the middle third of the uterosacral and the cardinal ligaments together, according with the De Lancey theory. In our experience vaginal native tissue repair is effective, safe and improves pelvic organ prolapse- related symptoms, sexual function and quality of life.

Keywords: Pelvic organ prolapse; Quality of life; Sexual function ; Vaginal native tissue repair.

SOMMARIO

Il prolasso genitale è una condizione comune, con una prevalenza del 30-50% tra le donne di età superiore ai 50 anni. Abbiamo valutato l'efficacia della chirurgia fasciale in 108 pazienti portatrici di prolasso genitale, reclutate da Settembre 2011 a Giugno 2017, sottoposte a colpoisterectomia talvolta associata a plastica vaginale anteriore e/o posteriore. Le pazienti sono state sottoposte, il giorno prima dell'intervento e 1, 3, 6, 12, 48 e 60 mesi dopo l'intervento, ad una valutazione basata sul Pelvic Organ Prolapse Quantification System ed alla somministrazione di un questionario riguardante qualità di vita, sintomi urinari, disturbi della sessualità. Una recidiva di prolasso si è presentata nel 5,9% delle pazienti dopo 12 mesi e nel 8,6% dopo 5 anni di follow up. Solo 3 pazienti hanno avuto una dispareunia persistente, di queste il 90% ha dichiarato tuttavia una soddisfacente qualità di vita a 5 anni di follow up. La nostra tecnica chirurgica prevede la sospensione della volta vaginale al terzo medio dei legamenti uterosacrali e cardinali insieme, seguendo la teoria di De Lancey. Nella nostra esperienza la chirurgia fasciale è risultata efficace, sicura ed in grado di migliorare la sintomatologia correlata ai prolapsi, la vita sessuale e la qualità di vita.

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INTRODUCTION

Pelvic organ prolapse (POP) is defined as the herniation of the pelvic organs to or beyond the vaginal walls.

It is a common condition, indeed population based studies report a worldwide prevalence of about 30-50% of symptomatic POP in women over 50 years of age, with a lifetime risk to undergo surgery for prolapse or incontinence of 11- 19%^(1, 2). The health care impact of prolapse is likely to expand and its prevalence is going to increase, according with the fact that the medium age of population is rising, since it is more common in elderly women. POP impairs quality of life (QoL) of women affected because of vaginal bulge symptoms and changes in sexual function. Many studies about this topic have underlined that POP can seriously compromise QoL and limit physical, psychological, and sexual functions⁽³⁾. These women frequently report disorders of sexual desire, arousal, orgasm, and pain and these problems can decrease the QoL and affect the relationship between partners⁽⁴⁾.

The etiology of POP is multifactorial, however two are its main risk factors: vaginal delivery and conditions associated with increased abdominal strain⁽⁵⁾.

The surgery for POP is based on two main procedures: native tissue repair or surgery with mesh graft materials.

Mesh graft materials have been introduced in gynecology in 1962 with the first sacral colpopexy. In the last decades of twentieth century, several different surgical procedures have been developed basing on the utilization of mesh graft materials, since, in 2011, Food and Drug Administration (FDA) warned about mesh related complications, as bleeding, mesh erosion, dyspareunia, pelvic pain and lower urinary symptoms⁽⁶⁾. This 2011 FDA update explains the reduction of this kind of surgery and the consequent greater importance given to native tissue repair. The endopelvic fascia plays an essential role in the statics and dynamics of the pelvic visceral support⁽⁷⁾, so native tissue surgery appears to be the best way to obtain the anatomic and functional cure of POP⁽⁸⁾, with the great advantage of avoiding mesh graft materials. However, only few trials on the long-term efficacy and complications of native tissue repair are described in literature^(9, 10).

The aim of this study is to evaluate the efficacy of native tissue repair in women with hysterocele, eventually associated

with cystocele and/or posterior vaginal wall prolapse. We have examined not only the complications and recurrence rate after surgery, but also the improvement in patients' quality of life considering physical, psychical and sexual aspects.

MATERIALS AND METHODS

From September 2011 to June 2017, 108 patients affected by genital prolapse (hysterocele +/- cystocele and/or posterior vaginal wall prolapse) who underwent vaginal hysterectomy, eventually associated with anterior and/or posterior vaginal plastic and/or urethrocolpopexy, were considered for our study. All 108 women agreed to take part to the study after a written consensus. Patients who underwent anterior/posterior vaginal plastic or urethrocolpopexy alone, prosthetic surgery or previous hysterectomy were not included in the study, such as patients who refused to take part to the study.

Our aim was to investigate the long term efficacy of native tissue repair in this group of patients, starting from their situation before surgery and arriving to five years follow up, so the sample size calculator was not evaluated.

All data have been collected using an internal urogynecological database.

The preoperative visit consisted of a clinical evaluation made by a multidisciplinary team composed of colorectal surgeons, gynecologists and urologists. Vaginal prolapse was staged by the gynecologists according to the Pelvic Organ Prolapse Quantification System (POP-Q) with the patient in lithotomy position. During the visit, patients answered also to an urogynecological interview about their quality of life, focusing on urinary, sexual and bowel disorders. The International Consultation on Incontinence Questionnaire Short form (ICIQ-SF) was used to subjectively quantify the patient's perception of stress and urge urinary incontinence, while the Kings Health Questionnaire (KHQ) was important to evaluate the impact of prolapse on their quality of life.

Before surgery, all patients were given low-molecular weight heparin to prevent venous thromboembolism. A short-term antibiotic prophylaxis with endovenous 2g cephazoline (Dalacin 900 mg in intolerant patients) was

performed 30 minutes before surgery. The surgery used was vaginal hysterectomy with intrafascial technique and vaginal vault suspension.

The surgical technique included an anterior colpotomy, starting with finding the right plane between cervix and bladder; a V-shaped incision was then made at the back of the cervix, extending into the posterior vaginal fornix. The posterior peritoneum was cut open and the posterior cul-de-sac was explored with the surgeon's finger to identify any adhesion or other pathologies. A retractor was placed anteriorly on the midline to retract the bladder upwards, the anterior peritoneum was then cut open to accommodate the retractor and a stitch of Vycril 2-0 used as peritoneum finder. Upward traction on the retractor was used during the rest of vaginal hysterectomy to retract the bladder. The uterus was removed through sequential clamping, cutting, and suture-ligating pedicles bilaterally from the uterosacral ligaments, cardinal ligaments, the utero-ovarian ligaments (if the adnexa were not removed), to the uterine and cervicovaginal vessels. The apical support of the vaginal vault was provided by its attachments to the middle third of uterosacral ligaments and cardinal ligaments. In case of anterior defect, an anterior median longitudinal colpotomy was performed and the pubocervical fascia was reached, detaching the vaginal wall from the vesico-vaginal septum. McCall culdoplasty was performed in all cases. The stitch of Vycril 2-0 used to identify the anterior peritoneum was used to suspend vaginal vault. In case of posterior defect, a vertical incision in the posterior vaginal mucosa was performed and the rectovaginal fascia was dissected from the posterior vaginal mucosa.

After surgery, a vaginal pack and a bladder catheter were positioned in all cases. The first one was removed after 24 h, the second one after 48 h. If, after catheter removal, patients suffered of a voiding dysfunction, the bladder catheter was re-positioned and patients were discharged with the catheter in place and re-evaluated after 1 week.

A clinical examination with POP-Q evaluation and administration of ICIQ-SF and KHQ were then performed 1, 3, 6, 12, 48 and 60 months after surgery. The outcome of prolapse surgical treatment was evaluated both subjectively, by ICIQ-SF and KHQ, and objectively, by POP-Q evaluation. Objective

cure for prolapse was defined when the vaginal defects were stage 0-I, evaluated by POP-Q classification. Recurrence of prolapse was defined as a prolapse of stage II or higher according with POP-Q classification.

POP-Q has been performed all times by the same gynecologists.

RESULTS

108 patients with pelvic organ prolapse were enrolled in this study. Among these, 108 women had a pre-operative and 1 month post-operative follow up, 80 had a 3 months follow up, 71 a 6 months follow up, 51 a 12 months follow up and only 35 a 48 and 60 months follow up.

The mean age of enrolled patients was 66.14 years (range 41-86 y.o.). Patients' characteristics are shown in **Table 1**.

Table 1
Population characteristics

Population characteristics	Mean
Age (years)	66.14
Body mass index	29.3
Number of vaginal deliveries	2.5
Birth weight of largest baby (gr)	3480

The surgery performed in all cases was native tissue repair through uterosacral and cardinal ligaments suspension. The mean operative time was 97.5 minutes (range 75-120 minutes), and the same expert surgeon performed surgery in all cases. The median postoperative hospital stay was 3 days.

48 hours after surgery, the bladder catheter was removed and spontaneous normal voiding was present in 90.5%, while in 9.5% the bladder catheter was re-positioned and removed after one week, with normal spontaneous voiding.

Neither severe intraoperative complication occurred nor blood transfusions were necessary. Early postoperative complications happened in 2 women on 108 (1.8%).

There was a case (0.9%) of vault abscess with fever, treated with vaginal evacuation and intravenous antibiotics; and one case of

hematoma (0.9%), evacuated on the fourth post-operative day.

24 patients (22.2%) had a preoperative diagnosis of stress urinary incontinence, 45 (41.7%) of urge incontinence (**Table 2**).

Table 2
Study population

Study population	108
Stress incontinence	24 (22.2%)
Urge incontinence	45 (41.6 %)
Urgency	63 (49.2 %)
Frequency	67 (62 %)
Nocturia	53 (49 %)
Dysuria	13 (12 %)
Hesitancy	11 (10.2 %)
Incomplete emptying	44 (40.7 %)
Dyspareunia	23 (21.3 %)
Bulging symptoms	74 (68.5 %)

At 1-month follow-up, subjectively, 20 out of 24 (83.3%) stress incontinent patients were cured. After 12 months, only 2 (8.3%) patients remained incontinent, but they reported that the incontinence had no longer an important impact on their quality of life; these 2 patients improved at 5 years follow up.

About urge incontinence 35 out of 45 (77.7%) incontinent patients were cured at one month, while only one (2.8%) remained incontinent also at the 5 years follow up.

Some patients experienced de novo stress incontinence with the following incidence: 3.8% after 1 month, 6.3% after 3 months, 5.6% after 6 months, 5.9% after 12 months, 5.7% after 5 years.

Others complained de novo urge incontinence with an incidence of 2.8% after 1 month, 5% after 3 months, 7% after 6 months, 0% after 12 months, 5.7% after 5 years. It is important to underline that all these patients had a history of recurrent urinary tract infections.

1 year after surgery, 5.9% of patients showed recurrent vaginal prolapse (defined as a POP-Q classification equal or higher than II stage), but

no surgical procedure was performed because in all cases it was an asymptomatic recurrence. 3 out of 35 patients (8.6%) with 5 years follow up had prolapse recurrence and surgery has been performed in 2 cases because patients complaint prolapse symptoms.

In our study anterior compartment was the most frequent site of recurrence despite adequate apical suspension. This could also be an expression of the preoperative situation, in which apical compartment prolapse was less severe compared with anterior one.

Before surgery, 64 patients (59.3%) referred to have regular sexual intercourse and 31 (48.4%) of these had dyspareunia; 44 patients (40.7%) did not have sexual activity.

3 months after surgery, 45 patients (56.3%) reported having regular sexual intercourse and only 15 (18.8%) had dyspareunia, while 20 patients (25%) continued not having sexual activity. After 3 months, 2 patients (2.5%) with preoperative regular sexual intercourse declared not having had sexual activity anymore after surgery. On the other side, 10 patients (12.5%) who did not have sex before surgery, claimed they had begun to have sex after surgery, but in this group 2 (20%) referred dyspareunia. 16 patients (20%) with preoperative dyspareunia resolved it at 3 months follow up.

Out of the 35 women that we have followed for 5 years after surgery, 21 (60%) have regular sexual intercourse, 4 of this (19%) complained dyspareunia. 3 patients had persistent dyspareunia at 5 years follow up, and only one developed it after surgery.

Another important result reached with this follow up concerns data on quality of life, obtained thanks to KHQ. Preoperatively, only 6% of patients declared to have a satisfying quality of life, while 76% of patients complaints an important impact of prolapse on their social, sexual and psychical life. Just one month after surgery, patients who declared to have a poor quality of life were only 1%, while 71% were totally satisfied. At 5 years follow up, 90% of patients declared that urogynecological problems had no longer impact on their all-day-life.

DISCUSSION

In our hospital, we routinely perform native tissue repair through uterosacral

ligaments suspension. Our technique involves the endopelvic fascia reconstruction following the De Lancey theory⁽⁷⁾: in normal anatomy, the interaction between De Lancey level I and level II is responsible for correct vaginal orientation and physiological visceral function. In this system, the cardinal ligament is a level I support suspending the uterus and vagina and uterosacral ligament suspension techniques have the crucial role of restoring level I in pelvic support mechanisms. We suspended the vaginal vault to the middle third of the uterosacral ligaments and the cardinal ligaments together, called by some authors “uterosacral-cardinal ligament complex” (UCLC)⁽¹¹⁾. UCLC is considered suitable anchoring element in prolapse surgery because it is more rigid and less deformable than round and broad pelvic ligaments⁽¹²⁾. This suspension is probably the reason of our low recurrence rate.

In case of anterior defects, an anterior median longitudinal colpotomy was performed and the pubocervical fascia was reached, detaching gently the vaginal wall from the vesico-vaginal septum, using finger dissection to identify the proper plane and to retrieve fascial tissue. The vaginal vault was suspended higher to the stitch of Vycril 2-0 used to identify the anterior peritoneum, reducing the recurrence rate of anterior compartment descent.

As told before, the prolapse of anterior compartment could be treated also by prosthetic surgery. A recent literature review⁽¹³⁾ states that the choice between native tissue and mesh repair has to be personalized basing on the prolapse grade and women tissues, underlining how the results obtained until now are not sufficient to establish which one is the best technique related to lowest complication rate. Indeed, according to literature^(13, 14), prosthetic treatment is linked to higher complications rate, such as erosion, infection, retraction, pelvic pain, vaginal bleeding and discharge, dyspareunia and bladder outlet obstruction. On the other side, native tissue repair has fewer complications but gives lower anatomical success rate and higher recurrence comparing to prosthetic surgery, because of the use of women’s weak or damaged tissue, which can become more easily under tension. According to literature⁽¹⁴⁾, the placement of a permanent mesh implant may be particularly useful in women whose native vaginal tissues are of “poor quality” (women with recurrent or advanced stages of prolapse).

Also a multicenter, randomized, controlled trial⁽¹⁴⁾ stated almost the same, finding that

absence of symptoms, 1 year after surgery, was more common and recurrences were fewer in women treated with mesh repair than in those who underwent colporrhaphy, while adverse event were higher in prosthetic group.

Although several approaches are available for the management of POP, the best strategy in case of recurrence after vaginal vault prolapse (VPP), that we have not investigated in this study, still remain debated.

The two most accepted surgical techniques for primary VPP are laparoscopic sacrocolpopexy (LSC) and sacrospinous fixation (SF). No randomized controlled trials have been published comparing the efficacy of the two treatments, however, LSC seems to be correlated to a lower recurrence rate of VPP and less dyspareunia, but this procedure may be linked to potential intra-abdominal morbidities including sacral hemorrhage, bowel/ureter obstruction, and port site herniation. SF is associated with a shorter operation time, lower costs, and an earlier return to daily activities. The bilateral technique (transvaginal bilateral sacrospinous fixation, TBSF) seems to be effective and safe for the reduction of POP and for the improvement of quality of life and sexual function in menopausal women affected by second recurrence of VPP, previously treated by monolateral SF. These results may be related to the possibility of TBSF in tailoring the individual width of the vaginal apex with bilateral sutures of varying lengths on the sacrospinous ligament⁽¹⁵⁾.

A recent meta-analysis⁽¹⁶⁾ showed that all the surgical techniques were associated with good subjective results without important differences between the compared techniques. However a correct comparison between them was difficult to be done because of heterogeneity of the studies examined, therefore, a standard treatment for VPP could not be given.

Our study shows how native tissue repair improves POP related symptoms, sexual function and quality of life.

A substantial improvement in quality of life was recorded at follow up. The reason for a low preoperative score on the KHQ might be related to mechanical problems and urinary incontinence, but also to poor self-perceived body image. In a study by Lowenstein et al⁽¹⁷⁾ on 235 women with genital prolapse resolution of POP symptoms improved sexual function and self-perception of being more sexually attractive. Concerning sexual dysfunction, in our experience only three women have had persistent dyspareunia at 5 years follow up. We have not investigated dyspareunia 1 month

after surgery, because we suggested women not having sex in the first period after surgery. Concerning de novo dyspareunia after 3 months, it's important to consider that dyspareunia, as mentioned above for quality of life, is not linked only to surgery or to prolapse but to several factors, like psychological state, self-perceived body image, interpersonal relationship and so on.

Women with stress urinary incontinence tend to avoid sexual intercourse because of wetness at night, leakage during intercourse, embarrassment, and depression⁽¹⁸⁾.

De novo urge incontinence, in all patients, was associated with a lifetime history of recurrent urinary tract infections (UTI). These findings may represent the stable effects of chronic urothelial inflammation in the etiology of UTI⁽¹⁹⁾.

The strength of the study was the operative technique characterized by the suspension of the vaginal vault to the middle third of the uterosacral and the cardinal ligaments together, reducing the recurrence rate of apical compartment descent. The surgery has been performed by the same expert surgeon in all cases and 19 patients were lost to follow up. We used a standardized questionnaire concerning quality of life, urinary symptoms and sexual problems.

In conclusion, in our experience vaginal native tissue repair is effective, safe and improves POP-related symptoms, sexual function and quality of life. Moreover, traditionally, these women are managed only by one single specialist, resulting in worsening dysfunction in other compartments, poor quality of life, recurrence of genital prolapse and higher costs for the National Health Care Service⁽²⁰⁾. A point of strength of our study is that patients were selected by a multidisciplinary team included colorectal surgeons, gynecologists and urologists.

We aim to continue this study in order to enroll a larger number of patients and to go on with follow up in order that all patients arrive at 5 years follow up.

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We declare no conflict of interest.

Informed consent has been applied to all patients.

This manuscript is conform to the Quality and Transparency of Health Research (EQUATOR) network guidelines.

This study was not registered. The approval of the Institutional Review Board was received.

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