ORIGINAL ARTICLE

Genital prolapse repair with Avaulta Plus® mesh: Functional results and quality of life

Cure de prolapsus par voie basse avec prothèse Avaulta Plus®: résultats fonctionnels et qualité de vie

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Summary
Purpose. — Evaluate anatomic and functional outcomes of genital prolapse repair by vaginal route using a mixed polypropylene and porcine skin mesh.

Patients and methods. — Prospective pilot study from January 2009 to January 2011 in the gynecologic department of a tertiary university hospital. Twenty patients with stage II-III genital prolapse underwent anterior wall prolapse repair with anterior Avaulta Plus® mesh. Functional results were evaluated using the Pelvic Floor Distress Inventory-short form (PFDI-20), the Pelvic Floor Impact Questionnaire-7 (PFIQ-7) and the Pelvic Organ Prolapse/Urinary Incontinence Sexual questionnaires (PISQ-12).

Results. — No per-operative complications occurred. One postoperative hematoma (5%) occurred requiring a second surgery. At a mean follow-up of 19.7 months, three patients had vaginal mesh exposure (15%) requiring a second surgery for two of them. Of the 20 women, 17 (85%) had optimal anatomic results and three (15%) had residual genital prolapse (Ba = −2 in two cases and Bp = −2 in the one). No recurrence was observed during the study period. A significant improvement in the PFDI-20 (P < 0.001) and PFIQ-7 scores (P < 0.001) was observed but no improvement in the PISQ-12 score.

Conclusion. — In this series, we reported that genital prolapse repair using Avaulta Plus® mesh resulted in a high success rate and improved quality of life but with an important prevalence of vaginal mesh exposure.

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Introduction

Pelvic organ prolapse is a major public health issue in an aging population: the prevalence varies between 2.9 and 97.7% according to studies. It varies respectively between 2.9 and 11.4% with detection by questionnaire or between 31.8 and 97.7% practicing clinical examination and classification of Baden Walker or POP-Q classification [1,2]. The lifetime risk of these women undergoing pelvic organ prolapse surgery is estimated between 11.8 and 19.6% [3].

Pelvic reconstructive surgery can be performed by laparotomy, laparoscopy or the vaginal approach depending on the patient’s comorbidities, the surgeon’s choice and the patient’s preference. In a recent meta-analysis including 40 trials, abdominal sacral colpopexy was demonstrated to be more effective than vaginal sacrospinous colpopexy with a lower rate of recurrent vault prolapse [4]. On the other hand, vaginal sacrospinous colpopexy was quicker and cheaper to perform and associated with an earlier return to daily activities [4]. To reduce the risk of recurrence after vaginal surgery, synthetic meshes using polypropylene have been developed [5] and their efficacy confirmed compared to standard anterior repair [4]. However, the use of synthetic meshes is associated with a risk of 11.9% of vaginal mesh exposure [6] thus questioning the legitimacy of its use. Conversely, the use of porcine skin implant is well tolerated with a low rate of exposure (0.9%), but it is associated with a high recurrence rate [7]. To reduce the rate of vaginal mesh exposure while improving long-term results, a mixed mesh composed of both porcine skin and polypropylene (Avaulta Plus®, Bard, France) has been developed. Avaulta plus® is a four arm synthetic mesh inserted through the obturator oramen used for the surgical cystocele repair by vaginal approach. However, few data regarding the use of Avaulta Plus® is available [8].

Therefore, the aim of this study was to evaluate per- and postoperative complications, anatomic and functional outcomes and quality of life in patients after grade II-III genital prolapse repair using the Avaulta Plus® mesh.

Patients and methods

From January 2009 to January 2011, 99 patients with stage II-III genital prolapse were referred to the Department of Gynaecology of Tenon Hospital for pelvic reconstructive surgery. Among them, 68 patients underwent a laparoscopic sacrocolpopexy, 11 underwent native tissue repair by vaginal route and 20 patients underwent anterior wall prolapse repair using anterior Avaulta Plus® (Bard, France) by the transobturator route. Patients eligible for vaginal sacrocolpopexy had a contraindication to laparoscopy due to multiple laparotomies or comorbidities. These 20 patients composed the study population. Ethics Committee approval was obtained for this prospective study by the Collège National des Gynécologues et Obstétriciens Français (CNESOF CEROG-2010-011).

All women underwent pelvic examination to grade genital prolapse using the International Continence Society terminology for female Pelvic Organ Prolapse-Quantitation (POP-Q) scale. The maximal extent of prolapse was measured during a Valsalva manoeuvre or coughing and was confirmed by the patient as being the most severe protrusion.

Surgery

Avaulta Plus® is a monofilament, four arm polypropylene mesh coated in the central part with a porous, cellular crosslinked collagen barrier, used for anterior wall prolapse.
The polypropylene mesh is made of small fibers, which provide a thin cross section of the mesh without loss of strength and may also contribute to decreasing the size of encapsulation. The central part of the polypropylene mesh, but not the outer limit, is covered with a layer of porcine collagen.

Surgery was performed under general or spinal anesthesia. Prophylactic anticoagulant therapy (low-molecular-weight heparin) was given the evening before the operation, and prophylactic antibiotic therapy (cefazolin, 2 g intravenously) at the beginning of the operation. The patients were placed in the dorsal lithotomy position. Genital prolapse repair was preceded by routine vaginal hysterectomy by performing a transversal colpotomy 2 cm from the uterine cervix according to the modified Heaney technique [9]. If the latter had already been performed, a transversal incision was made at the apex of the vagina. Cystocele was dissected centrally and laterally while keeping the Halban pubocervical fascia lying on the vaginal wall. After accessing the paravesical space, finger palpation identified the Arcus Tendinous Fascia Pelvis (ATFP), which extends from the posterior aspect of the pubic arch to the ischial spine. Four skin incisions were made on the genitocrural crease to insert cannula-equipped guides. The mesh was placed with the porcine skin facing the vaginal skin between the bladder and the anterior vaginal wall and secured bilaterally by four arms across the obturator foramen according to the technique previously described [10]. Traction on the lateral arms of the mesh allowed for "tension free" adjustment under the bladder. No colpectomy was performed. Colporrhaphy was achieved by a non-locking continuous absorbable suture. A Foley catheter was left in place for 24 h. The operating time and intra- and postoperative complications were recorded.

Anatomic and functional results analysis

All patients were evaluated by clinical examination at 1 and 6 months postoperatively and then every year using the International Continence Society terminology of female pelvic organ prolapse. They completed three questionnaires. The Pelvic Floor Distress Inventory- short form (PFDI-20) [11] is composed of the Pelvic Organ Prolapse Distress Inventory-6 (POPDI-6), the Colorectal Anal Distress Inventory-8 (CRADI-8), and the Urogenital Distress Inventory-6 (UDI-6). The POPDI-6, CRADI-8, and UDI-6 questionnaires are scored from 0 to 100, with 0 indicating no discomfort and 100, major discomfort. Therefore, the PFDI-20 is scored from 0 to 300. They also completed the Pelvic Floor Impact Questionnaire-7 (PFIQ-7) for each pelvic compartment Urinary Impact Questionnaire-7 (UIQ-7), Pelvic Organ Prolapse Impact Questionnaire-7 (POPQ-7), and Colo-Rectal-Anal Impact Questionnaire-7 (CRAIQ-7), with a score from 0 to 300 (0 indicating no discomfort and 300, major discomfort). Finally, they completed the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12 (PISQ-12), scored from 0 to 48, with 0 indicating high satisfaction and 48, major discomfort [12].

Statistical analysis

Parametric continuous variables were compared with Student’s t-test. The scores were categorized according to quartiles, and the probability of improvement was evaluated for the quartiles. Potential predictive factors of improvement were evaluated. P value < 0.05 was considered statistically significant. All tests were two-sided. Statistical analyses were performed using R software.

Qualitative variables were compared using Fisher’s exact test or the Chi² test, and quantitative variables by the Wilcoxon rank-sum test. UDI and UIQ scores were compared using the Wilcoxon signed-rank paired test. Multivariate analysis was performed using the generalized linear logistic model. A value of P < 0.05 was considered to denote a significant difference.

Results

Epidemiological and surgical characteristics

This retrospective cohort study is about all women with stage III or II genital prolapse who underwent pelvic reconstructive surgery and placement of a vaginal mesh Avaulta plus®.

Epidemiological characteristics of the 20 patients are shown in Table 1. In mean, women had 75 years old. All the women were menopausal. Mean body mass index BMI (kg/m²) was 26. Four women had a BMI above 30. Eleven patients (55%) had significant medical comorbidities and 7 (35%) had a history of abdominal surgery including four (20%) hysterectomies: one for cervical epidermoid carcinoma, two for myoma and one for genital prolapse. This last patient underwent 5 years ago surgical prolapse repair including hysterectomy associated with porcine skin implant cystocele repair and saccropinous fixation.

Among the 20 patients, three (15%) had a stage II genital prolapse and 17 (85%) patients had a stage III genital prolapse. Anterior wall prolapse (Ba) of grade 2 or 3 was

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y) Mean ± SD</td>
<td>74.8 ± 6.7</td>
</tr>
<tr>
<td>Weight (kg) Mean ± SD</td>
<td>65.4 ± 11.3</td>
</tr>
<tr>
<td>Body mass index (kg/m²) Mean ± SD</td>
<td>25.9 ± 3.9</td>
</tr>
<tr>
<td>Parity (n) Mean ± SD</td>
<td>3.1 ± 2.7</td>
</tr>
<tr>
<td>Patients with diabetes, n (%)</td>
<td>3 (15)</td>
</tr>
<tr>
<td>Patients with high blood pressure, n (%)</td>
<td>11 (55)</td>
</tr>
<tr>
<td>Prior hysterectomy, n (%)</td>
<td>4 (20)</td>
</tr>
<tr>
<td>Prior surgery for gynaecological cancer, n (%)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Prior surgery for genital prolapse, n (%)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Prior abdominal surgery, n (%)</td>
<td>7 (35)</td>
</tr>
<tr>
<td>Genital prolapse stage, n (%)</td>
<td></td>
</tr>
<tr>
<td>Stage II</td>
<td>3 (15)</td>
</tr>
<tr>
<td>Stage III</td>
<td>17 (85)</td>
</tr>
<tr>
<td>Urinary incontinence, n (%)</td>
<td></td>
</tr>
<tr>
<td>Stress incontinence</td>
<td>9 (45)</td>
</tr>
<tr>
<td>Urgency</td>
<td>6 (30)</td>
</tr>
</tbody>
</table>

n: number; Y: years; SD: standard deviation.
observed in three and 17 patients, respectively. Posterior wall prolapse (Bp) of grade 2, or 3-4 was observed in three and six patients, respectively. Superior vaginal prolapse (C) of grade 2, or 3 was observed in four and seven patients, respectively, and posterior fornix prolapse (D) of grade 2, or 3 was observed in one and two patients, respectively.

Preoperative stress urinary incontinence was present in nine (45%) patients, associated with urgency in six (30%) patients. Placement of Avaulta Plus® mesh was feasible in all the patients. Genital prolapse repair was associated with hysterectomy in 13 patients (65%), with transobturator midurethral tape in nine patients (45%), and with sacrospinous fixation in six patients (30%). Two senior surgeons performed the surgery of the study group.

No per-operative complications were observed. One immediate postoperative complication occurred in a 75-year-old patient consisting of a retroperitoneal haematoma a few hours after surgery that included, in addition to mesh placement, a hysterectomy, a sacrospinous fixation and stress urinary incontinence treatment using a transobturator midurethral tape. She required a laparotomy with packing and blood transfusion. The origin of bleeding was related to the hysterectomy but not to mesh placement. The median hospital stay was 4 days (range 2–15).

**Functional and anatomical results**

The mean follow-up was 19.7 ± 7.5 months. A significant improvement in general digestive and urinary symptoms was observed after genital prolapse repair using Avaulta Plus® mesh (Table 2). At the first postoperative visit, 17 (85%) patients had optimal anatomical results and three (15%) sub-optimal anatomical results with residual genital prolapse: two cases of Ba = −2 and one case of Bp = −2. No recurrence of genital prolapse was observed during the study period.

Four patients (20%) had postoperative complications. Three patients had a mesh exposure. One occurred in the patient experiencing a retroperitoneal haematoma diagnosed 8 months after surgery for a prolapse of the three compartments but did not require additional surgery. The two other mesh exposures occurred in a 78- and 61-year-old patients with only anterior wall prolapse repair without hysterectomy, and required a partial mesh resection at 18 and 6 weeks, respectively. Overall, a second surgical procedure was performed in three patients. The fourth complication occurred in a 80-year-old patient who had iterative urinary infection with de novo stress urinary incontinence: the cystoscopy was normal, she didn’t required additional surgery.

**Changes in quality of life after genital prolapse repair**

Changes in PFDI-20, PFIQ-7 and PISQ-12 scores are given in Table 3. An improvement in PFDI-20 (89.2 vs 30.5, P < 0.001) was observed, also in subgroups POPDI-6 (43.1 vs 9.7, P < 0.001), UID-6 (34.4 vs 13.7, P < 0.02) and CRADI-8 (11.6 vs 7.1, ns).

An improvement in PFIQ-7 (63.5 vs 8.7, P < 0.001) was observed, also in subgroups POPIQ-7 (30.9 vs 2.1, P < 0.001), UIQ-7 (20.9 vs 6.9, ns) and CRAI-7 (11.9 vs 0, P < 0.01).

Only woman with de novo urinary symptoms had a decreasing quality of life.

No changes in the PISQ-12 score was noted in the two patients who were sexually active.

**Discussion**

The current study demonstrates that genital prolapse repair using the Avaulta Plus® mesh, a mixed polypropylene and porcine skin mesh, was associated with a significant improvement in symptoms and quality of life with good anatomical results. However, despite the use of a porcine skin component, mesh exposure remains a risk.

Two endpoints are crucial to evaluate the safety and the efficacy of genital prolapse repair using a mesh; the rate of complications, particularly of mesh exposure, and the rate of second surgery for recurrence. A recent review in genital prolapse repair procedures including eight randomized trials comparing standard anterior repair to polypropylene mesh augmentation and three randomized trials comparing standard anterior repair to porcine skin augmentation, showed that the rate of mesh exposure was 11.9% in the polypropylene group and 0.9% in the porcine skin group underlining the protective role of biological mesh [4,13]. In the present study, three of the 20 patients (15%) had mesh exposure despite the use of a mixed mesh. At one year of follow-up, Cervigni et al. [14] observed the development of vaginal mesh exposure in 21 patients (21.6%). Moreover, two of our three patients experiencing mesh exposure required a second surgery. These results are in agreement with those of randomized trials using armed transobturator polypropylene mesh by the vaginal route with an incidence of second surgical procedures for mesh exposure varying between 3% and 16% [4,15]. No study has compared the risk between polypropylene mesh alone and mixed mesh using polypropylene and porcine skin. Our results suggest that the addition of porcine skin does not seem to impact the rate of mesh exposure. These results are in keeping with those published by Achtari et al. [16] comparing polypropylene mesh to polypropylene + polyglactine with a rate of mesh exposure of...
Moreover, studies have shown that obese patients with BMI greater than 30 had an odds ratio of 10.1 for mesh exposure but the authors did not report the confidence intervals. Moreover, in the present study, 13 of the 20 patients underwent hysterectomy associated with genital prolapse repair. No consensus exists about the role of concomitant hysterectomy and genital prolapse repair on the risk of mesh exposure [16, 18]. The only randomized trial, which involved only 15 patients, did not find a negative effect on mesh exposure in patients who had undergone concomitant hysterectomy and genital prolapse repair by the vaginal route [19]. Moreover, because of the risk of complications and the lack of data, the Food and Drug Administration (FDA) sent letters out to all manufacturers of the vaginal mesh product including Avaulta®, issuing a requirement that manufacturers conduct post-market studies in the United States.

In the current study, optimal and suboptimal anatomical results were observed in 85% and 15% of patients, respectively. None of the patients with suboptimal results needed further surgery linked to residual discomfort. Moreover, no recurrence was observed during the study period but the mean follow-up was only of 19.7 months. A recent meta-analysis has demonstrated that standard anterior vaginal repair is associated with more recurrences than when supplemented with resorbable mesh (RR 1.39, 95% CI 1.02 to 1.90) or porcine skin mesh (RR 2.72, 95% CI 1.20 to 6.14) [4]. Moreover, standard anterior repair was associated with more recurrences on examination than when using polypropylene mesh (RR 2.14, 95% CI 1.23 to 3.74), armed transobturator mesh (RR 3.55, 95% CI 2.29 to 5.51) [20, 21] or commercial kits [15]. However, data on morbidity and long-term anatomical, functional and quality-of-life criteria were lacking. In a review including eight randomized trials comparing standard anterior vaginal repair to the use of polypropylene mesh by the transobturator route with four arms, the rate of second surgery for recurrence was significantly lower in the mesh group (4.2% vs 7.8%, P = 0.01) confirming the effectiveness of this technique [15, 21, 22].

Despite the small sample size, the current study demonstrates the positive impact of genital prolapse cure by vaginal route on symptoms and quality of life evaluated by validated questionnaires. Except for urgency, all symptoms reported by the patients preoperatively were improved. These results are in agreement with those of a previous study showing that most preoperative urinary symptoms decreased after genital prolapse surgery with equivalent proportions of de novo symptoms between patients in the laparoscopic and vaginal route groups [23]. Using multivariate analysis, these authors found that only the improvement in the impact of urinary symptoms on daily living was independently associated to the vaginal route (OR = 5.45 [95% confidence interval 2.20–13.44], P = 0.01). In addition to improvement in the symptoms, all parameters of PFDI-20 and PFIQ-7 quality-of-life questionnaires were improved. These results are in agreement with those of using Avaulta® mesh without the porcine skin component [8]. Little is known about the risk of dyspareunia and change in sexuality after repair of genital prolapse by the vaginal route. In a prospective series using the PISQ-12 questionnaire, Sentilhes et al. [24] reported an improvement in sexual quality of life in 60% of women while 40% were worse. Similarly, in a multicentre study using a polypropylene mesh by the transobturator route, Altman et al. [12] found a significant decrease in the PISQ-12 score. This high risk of altered sexual quality of life suggests that the use of mesh by vaginal route should be restricted to sexually active patients.

The limitations of this pilot study should be highlighted. First, the low number of patients may be a potential source of bias. Second, our population was mainly composed of elderly patients with prior morbidity heightening the risk of mesh exposure. However, no data are available to support the impact of diabetes, immunosuppressor treatment or the absence of preoperative hormonal treatment on the risk of mesh exposure [18]. Finally, the low experience of surgeons
with Avaulta Plus® mesh could also be a potential source of bias. However, our teams had considerable experience in genital prolapse cure by the vaginal transobturator route [23].

**Conclusion**

Despite the limits of the present pilot study, our results suggest that the use of Avaulta Plus® mesh offers a high success rate with a significant improvement in quality-of-life but with an important prevalence of vaginal mesh exposure. Further studies are required to evaluate the benefit of adding a porcine component to classic polypropylene mesh in the cure of genital prolapse by the vaginal route.

**Disclosure of interest**

The authors declare that they have no conflicts of interest concerning this article.

**Appendix A. Supplementary data**

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.purol.2013.01.016.

**References**