Critical Assessment of Pelvic Floor Surgical Reconstruction Outcome

Giacomo Novara a, Antonio Galfano a, Mariangela Mancini a, Vincenzo Ficarra b, Walter Artibani a,*

a Department of Oncological and Surgical Sciences, Urology Clinic, University of Padua, Padua, Italy
b Department of Urology, University of Verona, Verona, Italy

1. Introduction

Pelvic organ prolapse (POP) is a major healthcare problem. It was reported as present in 50% of parous women [1], with aggregated rates of prolapse surgery which were estimated at between 15 and 49 per 10,000 women/years [2]. A landmark study from North America showed that the lifetime risk of surgery for prolapse or stress urinary incontinence (SUI) was 11%, with 29% of the patients experiencing...
surgical failure and requiring repeated surgical procedure [3]. Moreover, the economic burden for POP surgery is considerable, with costs estimated to be as high as $1,012 million in 1997 in the USA [4] and recent estimates suggest that demand for prolapse surgery will increase by 45% in the next 30 years [5].

The etiology of POP is multifactorial, with several well-recognized risk factors, such as pregnancy, vaginal childbirth, menopause, chronic rise in intra-abdominal pressure (obesity, cough), and pelvic floor muscle weakness, the pelvic floor musculature being the most important determinant for the maintenance of pelvic organ support [6–8].

POP can occur in the anterior vaginal wall (cystocele, urethrocele, cystourethrocele), the apical vagina (prolapse of uterus or vaginal vault after hysterectomy), the posterior vaginal wall (enterocele, rectocele), or a combination of these sites. According to the terminology recommended by the International Continence Society for prolapse grading [9], the terms anterior vaginal wall prolapse, posterior vaginal wall prolapse, and vaginal vault prolapse should be preferred, because the information obtained at the physical examination may not allow exact identification of the prolapsing structures [10].

POPs can produce a variety of symptoms, including pelvic floor complaints (sensation of vaginal bulging or protrusion, seeing or feeling a vaginal or perineal bulge; pelvic or vaginal pressure); lower urinary tract symptoms (frequency, urgency, urinary incontinence; hesitancy, weak stream, dribbling; feeling of incomplete emptying; needs of manual reduction of prolapse or position changing to void); bowel symptoms (flatus or stool incontinence; feeling of incomplete emptying; hard straining to defecate; urgency to defecate; digital evacuation, splinting vagina or perineum to defecate); and sexual dysfunction (dyspareunia; decreased lubrication) [11]. Because of all these symptoms, POP can definitely affect patients’ quality of life.

The choice of therapeutic options depends on several issues, such as prolapse grade, symptoms, quality of life impairment, patient’s general health status, patient’s expectations, and desire to maintain normal sexual life. Conservative management, mechanical devices, and surgery are the main options available.

Surgery aims at restoring the physiological anatomy of the vagina, as well as at resolving symptoms and preserving lower urinary tract, bowel, and sexual functions.

Several surgical options have been used in POP surgery, involving either vaginal, abdominal or laparoscopic approaches, but certain clinical problems (e.g., indications for prophylactic anti-incontinence surgery or use of mesh-graft) still lack methodologically consistent studies providing high-quality evidence. The present review aims at summarizing the most important evidence available in the field, as well as at indicating the proper methodology for subsequent studies.

2. Methods

The review of the literature was performed using MEDLINE through a complex search strategy including both “free text” and “MeSH” (Medical Subject Heading) protocols. Specifically, the MeSH search was conducted by means of the following terms retrieved from the MeSH browser provided by PubMed: “prolapse”, “uterine prolapse”, “rectal prolapse”. Multiple “free text” searches were performed applying singularly the following terms through “Title” and “Abstract” all the fields of the records: “pelvic organ prolapse”, “rectocele”, “cystocele”, “anterior vaginal wall prolapse”, “posterior vaginal wall prolapse”, “vaginal vault prolapse” and “colpocele”. Subsequently, the following search limits were employed: language (English), Humans, gender (Female), ages (“Adult: 19-44 years”, “Middle Aged: 45-64 years”, “Middle Aged + Aged: 45 + years”, “Aged: 65 + years”, “80 and over: 80 + years”) and publication types (“Clinical Trial”, “Meta-Analysis”, “Practice Guideline”, “Randomized Controlled Trial”, “Review”, “Clinical Trial, Phase I”, “Clinical Trial, Phase II”, “Clinical Trial, Phase III”, “Clinical Trial, Phase IV”, “Consensus Development Conference”, “Consensus Development Conference, NIH”, “Controlled Clinical Trial”).

Two hundred sixty-two records were identified and the authors reviewed their abstracts, selecting papers concerning the review topic. Moreover, the Cochrane database of systematic review was browsed for records regarding surgical treatment of POP, and other significant studies cited in the reference lists of the selected papers were considered.

All the papers were ranked according to the grade of evidence as stated by Phillips and Sackett [12]. Meta-analyses of randomized clinical trials (RCTs) constitutes the highest evidence (level 1a), followed by an adequately sampled, single RCT (level 1b); low-quality RCTs, prospective cohort studies, and high-quality case-control studies give level 2 of evidence. Lower grade of evidence was provided by retrospective case-control studies or good quality case series (level 3), while poor quality case series or expert opinion provide level 4 of evidence [12].

Among the selected papers, there were two meta-analyses [13,14] and 19 RCTs [15–33]. All the other studies were prospective or retrospective surgical series or reviews.

3. Results

3.1. Anterior vaginal wall prolapse surgery

The support of the anterior vaginal wall depends on the connective tissue which lays transversely from
the pelvic side walls and longitudinally from the pelvic bone to the apical uterosacral ligament complex. Four primary types of defects determining anterior vaginal wall prolapse can occur: a central defect is due to a defect in the vaginal muscolaris or pubo-cervical fascia in the midline; detachment of the vagina from the arcus tendineus fascia pelvis causes the paravaginal or lateral defect; detachment of the vaginal muscolaris from the pericervical ring of connective tissue results in a transversal defect. Finally, apical vaginal prolapse such as prolapse of the uterine or vaginal cuff can concur in anterior wall descent [34].

Correct identification of the specific defect may sometimes be difficult at physical examination but anterior colporrhaphy is the traditional therapeutic choice for anterior vaginal wall prolapse due to a central defect. Although long-term trials are not available in the literature, surgical series reported prolapse recurrence rates as high as 30–40% at follow-up longer than 2 years (level 3 of evidence) [35–40].

3.1.1. Which is the optimal surgical treatment?
No randomized study investigated the roles of paravaginal defect repair in the treatment of anterior vaginal wall prolapse and no prospective study compared anterior colporrhaphy and paravaginal defect repairs in patients with anterior vaginal wall. However, several surgical series reported very high success rates following either abdominal or vaginal procedures of paravaginal repairs (67–100%), performed for anterior vaginal wall prolapse due to lateral defects (level 3 of evidence) [41–44]. In one of the most recent series, Bruce et al. reported a prolapse cure rate of 92%, although the mean follow-up was only 17 months (level 3 of evidence) [45]. However, significant complication rates have been reported for paravaginal repair, including ureteric obstructions, bleeding, and pelvic haematoma [39].

A few trials were present in literature comparing other surgical options. Colombo et al. studied 71 patients with grade 2–3 cystocele, urethral hypermobility, and SUI [22]. The patients were randomized to undergo total abdominal hysterectomy, suspension of the vaginal vault to uterosacral ligament, and Burch colposuspension Vs. vaginal hysterectomy, obliteration of Douglas pouch, anchoring of the vaginal vault to uterosacral ligament and anterior colporrhaphy. After a follow-up time slightly longer than 12 months, the patients in the anterior colporrhaphy arm turned out to have significantly better prolapse cure rates (97% Vs. 66%) but higher rates of SUI persistence (48% Vs. 14%) (level 2 of evidence) [22].

Table 1 summarizes the reported studies.

<table>
<thead>
<tr>
<th>Author</th>
<th>Cases</th>
<th>Indication</th>
<th>Procedure</th>
<th>Success rate</th>
<th>Follow-up (months)</th>
<th>Level of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior vaginal wall prolapse</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colombo [22]</td>
<td>71</td>
<td>Cystocele (stage 2–3) + stress urinary incontinence</td>
<td>Abdominal hysterectomy + Burch colposuspension Vs. Vaginal hysterectomy, colporrhaphy</td>
<td>97% Vs. 66% (p &lt; 0.05)</td>
<td>12</td>
<td>1b</td>
</tr>
<tr>
<td>Maher [26]</td>
<td>95</td>
<td>Vaginal vault prolapse</td>
<td>Sacral colpexy Vs. Sacropsinov colpopexy</td>
<td>76% Vs. 69%</td>
<td>24</td>
<td>1b</td>
</tr>
<tr>
<td>Shull [41]</td>
<td>149</td>
<td>Lateral defect</td>
<td>Paravaginal repair</td>
<td>84%</td>
<td>N.R.</td>
<td>3</td>
</tr>
<tr>
<td>Vaginal vault prolapse</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benson [15]</td>
<td>80</td>
<td>Uterine or vaginal vault prolapse</td>
<td>Abdominal Vs. vaginal approach</td>
<td>58% Vs. 29% (p &lt; 0.05)</td>
<td>30</td>
<td>1b</td>
</tr>
<tr>
<td>Roovers [29]</td>
<td>82</td>
<td>Uterine prolapse</td>
<td>Vaginal hysterectomy Vs. Abdominal hysterectomy/colposacopexy</td>
<td>95% Vs. 95%</td>
<td>12</td>
<td>1b</td>
</tr>
<tr>
<td>Maher [53]</td>
<td>43</td>
<td>Uterine prolapse</td>
<td>Laparoscopic hysteropexy</td>
<td>79%</td>
<td>12</td>
<td>3</td>
</tr>
<tr>
<td>Barranger [54]</td>
<td>30</td>
<td>Uterine prolapse</td>
<td>Abdominal sacrohysteropexy + Burch + posterior colporrhaphy</td>
<td>93%</td>
<td>44</td>
<td>3</td>
</tr>
<tr>
<td>Posterior vaginal wall prolapse</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kahn [21]</td>
<td>63</td>
<td>Rectocele</td>
<td>Transanal repair Vs. Posterior colporrhaphy</td>
<td>70% Vs. 87.5%</td>
<td>25</td>
<td>2</td>
</tr>
<tr>
<td>Nieminem [28]</td>
<td>30</td>
<td>Rectocele</td>
<td>Rectovaginal fascia plication</td>
<td>60% Vs. 91% (p &lt; 0.05)</td>
<td>12</td>
<td>2</td>
</tr>
<tr>
<td>Abramov [60]</td>
<td>307</td>
<td>Rectocele</td>
<td>Midline fascial plication Vs. Discrete fascial repair</td>
<td>96% Vs. 60%</td>
<td>&gt;12</td>
<td>2</td>
</tr>
</tbody>
</table>

Table 1 – Literature data concerning comparisons of different surgical techniques for anterior vaginal wall, vaginal vault, and posterior vaginal wall prolapses
3.1.2. Should a prophylactic anti-incontinence procedure be performed at the time of anterior prolapse repair?

A few trials investigated the relationship between anterior vaginal wall prolapse and SUI. Regarding “de novo” SUI, Colombo et al. randomized 102 continent patients with grade ≥2 cystocele to cystopexy alone or in combination with Hurt’s pubourethral ligament plication [17]. At a follow-up slightly shorter than 3 years, the two procedures turned out to have similar success rates both in terms of prolapse cure and SUI prevention, but the patients in the second arm showed a higher incidence of dyspareunia (56%) (level 2 of evidence) [17].

As far as occult SUI is concerned, the same group compared the outcome of 109 incontinent patients with grade ≥2 cystocele randomized to undergo cystopexy and posterior pubourethral ligament plication Vs. cystopexy and Pereyra bladder neck suspension, demonstrating overlapping rates both of prolapse recurrence and “de novo” SUI (level 2 of evidence) [19]. Similar data was found by Bump et al. (level 2 of evidence) [16]. Clustering the data of these two similar studies as reported by Maher [14], prolapse repair and needle colposuspension showed a trend towards a lower incidence of “de novo” SUI which did not achieve statistical significance (level 1a of evidence) [14]. In 2004 Meschia and colleagues published an RCT comparing the role of TVT Vs. Hurt’s endopelvic fascia plication in patients undergoing cystocele repair for severe POP and concomitant occult SUI [27]. The patients in the two arms turned out to have similar prolapse recurrence rates (about 30%) but the incidence of “de novo” SUI was significantly lower in those treated with TVT (4% Vs. 36%; p = 0.01), which might be preferred despite longer operative times (level 2 of evidence) [27].

Table 2 shows the most important studies concerning prophylactic anti-incontinence procedure.

On the whole, the quality of the evidence emerging from those studies concerning anterior vaginal wall repair was quite poor. The significance of the studies was limited by the inadequate size of patient samples, the heterogeneity of the different RCTs which prevented high-quality meta-analysis, the absence of blinding procedures as well as the presence of several biases, and short follow-up time.

3.1.3. To mesh or not to mesh?

The use of mesh still remains a point of concern in the surgery of pelvic organ prolapse. There is a number of prosthetic materials available for use in pelvic reconstructive surgery and polypropylene is currently the most commonly used product.

The ideal prosthetic material should be biocompatible, inert, have minimal allergic or inflammatory reaction, be sterile, non-carcinogenic, resistant to infection, and should avoid shrinkage and mechanical stress while being easy to handle and.
readily available at a reasonable cost [46]. According to the physical properties of prosthesis, Amid suggested a classification for prosthesis, based mainly on the porosity and filament type. Type 1 meshes (Atrium, Marlex, Prolene and Trelex) have pore size >75 nm, which allows the infiltration by macrophages, fibroblasts, collagen fibres and angiogenesis, reducing the risk of infection, extrusion or erosion of the prosthetic material. Moreover, materials with large pores have lower stiffness, reducing tissue trauma and erosive risk. Type II meshes (Gore-Tex), indeed, are microporous, with pore size is <10 nm which presents a barrier to new tissue formation. Type III meshes (Teflon, Mersilene, SurgiPro) are macroporous materials with multifilamentous or microporous components, while type IV grafts (Silastic, Cellgard) had submicronic pores [47].

With regard to the mesh in anterior vaginal wall prolapse repair, Julian and colleagues published an interesting RCT in which the use of Marlex mesh was assessed in a cohort of 24 patients with recurrent anterior vaginal wall [18]. The authors demonstrated significantly better outcome in patients where mesh grafts were used (recurrence rate 0% Vs. 34%), but mesh erosion occurred in 25% of the patients, needing surgical excision (level 2 of evidence) [18]. In 2001, Sand et al. analyzed 143 women with cystoceles, comparing anterior endopelvic fascia plication with and without using a folded Vicryl mesh [23]. The authors reported significantly higher objective success rates in cystocele repair with the use of the mesh (75% Vs. 57%, p = 0.02), without any mesh-related complication (level 1b of evidence) [23]. In the same year, Weber et al. compared classical anterior repair, ultralateral repair (with a larger lateral dissection towards pubic rami), and the use of a vicryl mesh. At a mean follow-up of 24 months, the three techniques yielded statistically overlapping cure and complication rates (level 1b of evidence) [24]. A nice RCT was recently published by Gandhi et al., assessing the efficacy of a patch of cadaveric fascia lata in an adequately-powered cohort of patients with recurrent anterior vaginal wall prolapse [31]. At a median follow-up of 13 months, the authors showed similar rates of prolapse recurrence (21% in the patch group and 29% in the control group, p = 0.229), failing to show any statistically significant benefit for biological graft in anterior vaginal repair (level 1b of evidence) [31]. However, the short follow-up time and the lack of reliable data regarding reoperation and complication rates limited the quality of the evidence. A few large retrospective surgical series, in fact, reported very high cure rates (75–100%) associated with variable incidence of

<table>
<thead>
<tr>
<th>Author</th>
<th>Cases</th>
<th>Indication</th>
<th>Procedure</th>
<th>Success rate</th>
<th>Follow-up (months)</th>
<th>Mesh-related complications</th>
<th>Level of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anterior vaginal wall prolapse</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Julian [18]</td>
<td>24</td>
<td>Recurrent cystocele</td>
<td>Colporrhaphy + mesh Vs. Colporrhaphy alone</td>
<td>100% Vs. 66%</td>
<td>24</td>
<td>25%</td>
<td>1b</td>
</tr>
<tr>
<td>Sand [23]</td>
<td>143</td>
<td>Cystocele</td>
<td>Colporrhaphy + mesh Vs. Colporrhaphy alone</td>
<td>75% Vs. 57%</td>
<td>12</td>
<td>0%</td>
<td>1b</td>
</tr>
<tr>
<td>Weber [24]</td>
<td>83</td>
<td>Cystocele</td>
<td>Colporrhaphy + mesh Vs. Colporrhaphy alone</td>
<td>42% Vs. 37 Vs. 46%</td>
<td>24</td>
<td>4%</td>
<td>1b</td>
</tr>
<tr>
<td>Gandhi [31]</td>
<td>153</td>
<td>Cystocele</td>
<td>Colporrhaphy + fascia lata Vs. Colporrhaphy</td>
<td>21% Vs. 29%</td>
<td>13</td>
<td>0%</td>
<td>1b</td>
</tr>
<tr>
<td><strong>Vaginal vault prolapse</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Culligan [30]</td>
<td>100</td>
<td>Vaginal vault prolapse</td>
<td>Abdominal colposacropexy with polypropylene mesh Vs Abdominal colposacropexy with fascia lata</td>
<td>91% Vs. 68%</td>
<td>12</td>
<td>N.R.</td>
<td>1b</td>
</tr>
<tr>
<td>Fitzgerald [56]</td>
<td>67</td>
<td>Vaginal vault prolapse</td>
<td>Colposacropexy + cadaveric fascia</td>
<td>17%</td>
<td>12</td>
<td>N.R.</td>
<td>3</td>
</tr>
<tr>
<td><strong>Posterior vaginal wall prolapse</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gandhi [61]</td>
<td>N.A.</td>
<td>Rectocele</td>
<td>Colporrhaphy + fascia lata Vs. Colporrhaphy</td>
<td>76% Vs. 89%</td>
<td>12</td>
<td>N.R.</td>
<td>1b</td>
</tr>
<tr>
<td>Sand [23]</td>
<td>132</td>
<td>Rectocele</td>
<td>Colporrhaphy + mesh Vs. Colporrhaphy</td>
<td>92% Vs. 9%</td>
<td>12</td>
<td>N.R.</td>
<td>2</td>
</tr>
</tbody>
</table>

N.A.: Not available; N.R.: Not reported.
infections, erosion, fistula formation, and other mesh related complications (0–16%) (level 3 of evidence) [10,48–50].

Although limited by several methodological issues, the available data seems to show a reduction in the surgical failure rate by the use of synthetic meshes. The best available studies are detailed in Table 3.

### 3.2. Apical vaginal prolapse surgery

The support of the vaginal vault depends on the function of endopelvic fascia and ligaments. The endopelvic fascia consists of the fibromuscular tissue layer underlying the vaginal epithelium, which envelops the entire vaginal canal, extending from apex to perineum and within the arcus tendineus. Tears in this layer as well as detachment from vaginal apex can determine prolapse. The vaginal apex, moreover, is supported by uterosacral ligaments, extending from the apex to the sacrum, and cardinal ligaments, extending laterally from the apex to the pelvic sidewall [51].

Surgical treatment of upper vagina prolapse presents several points of concern, both in cases of uterine prolapse and post-hysterectomy vaginal vault prolapse.

#### 3.2.1. Which is the optimal surgical treatment?

The most controversial point in the treatment of apical vaginal prolapse is the choice of the surgical approach, with, theoretically, the low morbidity favoring the vaginal route and durability the abdominal way, respectively [52].

A Cochrane meta-analysis of 27 randomized trials collected data from 3,643 patients undergoing vaginal, abdominal or laparoscopic hysterectomy for benign gynecological disease [13]. Although functional data are largely insufficient, data on perioperative morbidity, complications, hospitalization, and convalescence showed that vaginal surgery outperformed abdominal hysterectomy. On the other hand, there was no evidence of benefits regarding laparoscopic versus vaginal hysterectomy, despite a longer operating time (level 1 of evidence) [13].

With regard to post-hysterectomy vaginal vault prolapse, Maher et al. [26] enrolled 95 patients to be randomized to abdominal sacrocolpopexy or vaginal sacrospinous colpopexy, in order to investigate prolapse recurrence rates, lower urinary tract, bowel and sexual functions, quality of life (by means of validated questionnaires such as the Short Urinary Distress Inventory, the Incontinence Impact Questionnaire, and the RAND SF-36 Health Survey). After a mean follow-up of 2 years, both subjective (94% in the abdominal arm Vs. 91% in the vaginal arm) and objective cure rates (76% Vs. 69%, respectively) were similar for both procedures. With regard of LUTS, storage symptoms were cured in 27% of the patients who underwent abdominal surgery and in 37% of those where vaginal surgery was carried out (p = 1.00), while “de novo” frequency-urgency syndrome occurred in 34% and 22% of the patients, respectively. Preoperative voiding dysfunction was cured in about 80% of the patients in both arms, while “de novo” voiding symptoms were shown only in a couple of patients. Bowel function, evaluated in terms of postoperative constipation (36% Vs. 27%), obstructed defecation (9% Vs. 6%), and fecal incontinence (4% Vs. 8%) turned out to be similar in both arms. Preoperative dyspareunia resolved in 56% of the patients randomized to the abdominal surgery arm and in 43% randomized to vaginal surgery, being present postoperatively in about 20% of cases. In both arms, the scores of the Short Urinary Distress Inventory and the Short Incontinence Impact Questionnaire were similarly and significantly improved after surgery. Vaginal sacrospinous colpopexy, however, was followed by significantly higher risks of anterior vaginal wall and vault prolapse (45% Vs. 13% in the abdominal surgery group), while abdominal sacrocolpopexy was associated with a longer mean operating time, slower return to activity of everyday life, and greater costs (level 1b of evidence) [26]. Two RCTs with a similar design but lower methodological quality were published by Benson et al. [15] and Lo et al. [20] (level 2 of evidence). Combining the data of the three studies as proposed in Maher’s meta-analysis, abdominal sacrocolpopexy out-performed vaginal sacrospinous colpopexy for recurrence of vaginal vault prolapse (3% Vs. 16%), postoperative SUI (19% Vs. 34%), and dyspareunia (15% Vs. 36%). However, the two techniques yielded similar rates of surgery-related adverse events, hospital stay duration, and the need for repeated surgery for prolapse and/or SUI (level 1a of evidence) [14]. As stated, no randomized studies have been published assessing the role of laparoscopic surgery in this setting, although several series suggested the feasibility and efficacy at intermediate-term follow-up of laparoscopic pelvic floor reconstructive surgery (level 3 of evidence) [39].

Another point of debate is uterus preservation in the treatment of uterine prolapse. Roovers et al. randomized 82 women with stages II to IV uterine prolapse to uterus preservation and abdominal sacrocolpopexy Vs. vaginal hysterectomy and uterosacral ligament plication [29]. In both arms of the
trial, prophylactic anti-incontinence procedures were performed. A validated questionnaire, the Urogenital Distress Inventory (UDI) was used to assess prolapse-related symptoms. The UDI scores regarding emptying and voiding symptoms turned out to be statistically significantly better in patients who underwent vaginal hysterectomy. Uterus preservation resulted in significantly higher failure rates, both in terms of prolapse recurrence and need for further surgical procedures (level 1b of evidence) [29]. Assessing post-operative pain and quality of life in the 6 weeks after surgery, moreover, the authors reconfirmed best scores for the patients undergoing vaginal procedures (level 1b of evidence) [30,55]. Although this might by an option in the case of young women who want to maintain their fertility, the wide variations in the rate of subsequent pregnancy and term deliveries warranted caution when counseling patients regarding uterine preservation.

Although impaired by several drawbacks, the available evidence supports the choice of the vaginal route for hysterectomy, while abdominal sacrocolpopexy out-performed vaginal sacrospinous colpopexy in both anatomic and functional outcomes. Although uterus preservation is the object of increasing interest, hysteropexy exposes patients to higher risks of prolapse recurrence and further surgery (Table 1).

### 3.2.2. To mesh or not to mesh?

As with anterior vaginal wall defects, the use of mesh in the treatment of vaginal vault prolapse is not adequately established. Several materials have been used, either homologous (cadaveric fascia lata, rectus sheath), autologous (dura mater, fascia lata) or synthetic (Prolene, Mersilene, Marlex, Teflon, Gore Tex). A landmark RCT was recently published by Culligan et al., who compared cadaveric fascia lata and polypropylene mesh in a cohort of 100 patients undergoing abdominal colposacropexy. At a median follow-up of 12 months, the authors demonstrated higher success rate in the mesh arm (91% Vs. 68%, \( p = 0.007 \)), defining objective anatomic failure as a Pelvic Organ Prolapse-Quantification (POP-Q) stage of 2 or greater at any post-operative interval (level 1b of evidence) (Table 2) [30]. Data on mesh-related complications were not provided in the report, but a large review on abdominal colposacropexy reported only 70 cases of mesh erosion out of 2,178 procedures (3.4%). In the that review, specifically, cadaveric fascia and Prolene mesh were followed by very low rates of erosion (0 and 0.5%, respectively), while Mersilene (3%), Gore-Tex (3.4%), Marlex (5%), and Teflon (5.5%) performed less well (level 2 of evidence) [55]. Those figures, as well as the failure rates in the surgical series employing fascia in sacrocolpopexy [54], might support the use of polypropylene mesh graft in this setting. However, data at longer follow-up and the ongoing analyses on secondary end-points such as quality of life from Culligan’s trials could further reinforce those statements.

#### 3.2.3. Should a prophylactic anti-incontinence procedure be performed at the time of apex vaginal wall prolapse repair?

After repair of vaginal vault prolapse, a significant percentage of previously continent patients can experience “de novo” SUI. According to the definitions of continence and to various studies, those figures range from 8 to 60% [33,55]. To date, urodynamic testing is often performed with and without prolapse reduction to mimic the effects of prolapse repair but the predictive efficacy of this method is not validated. In such a context, surgeons can elect to offer prophylactic anti-incontinence procedures at the time of pelvic floor reconstruction, being aware that such procedures are an over-treatment, with risks of complications for most of the patients. On the other hand, prolapse repair alone can be performed, but this may result in the need for subsequent surgery for patients who develop SUI. This issue was addressed by a recently published RCT, the Colpopexy and Urinary Reduction Effort (CARE) trial [33]. The authors randomized 322 women without symptoms of SUI, undergoing abdominal sacrocolpopexy for vaginal vault prolapse, to concomitant Burch colposuspension or no prophylactic anti-incontinence procedure. Burch colposuspension was chosen as an anti-incontinence procedure because several studies assessed its long-term efficacy and it can be easily performed through the same incision as colpopexy. Patients were assessed, asked to complete validated questionnaires (Medical Epidemiological and Social Aspects of Aging [MESA] questionnaire, Pelvic Floor Distress Inventory [PFDI], Pelvic Floor Impact Questionnaire [PFIQ], Hunskaar measure for the severity of urinary incontinence), and underwent POP-Q standardized physical examinations and a urodynamic test. The trial, moreover, was well powered and very consistent from the methodological point of view. Postoperative SUI was defined according to one of 3 criteria: symptoms as stated by PFDI; positive stress test or need for anti-incontinence surgery. At a 3-month follow-up, 23.8% of the Burch group and 44.1% in the control group were incontinent (absolute risk reduction 20.3%, \( p < 0.0001 \)).
According to the different definitions of SUI, positive stress test (4.7% in Burch group Vs. 8.6% in the control group, \( p = 0.14 \)) and further anti-incontinence surgical procedures (5.1% in Burch group Vs. 11.5% in the control group, \( p = 0.05 \)) had similar prevalence in the two arms. However, the symptoms of SUI assessed by PFDI were significantly less prevalent (19.0% Vs. 39.7%, \( p < 0.0001 \)) and less bothersome (6.1% Vs. 24.5%, \( p < 0.0001 \)) in the patients randomized to prophylactic Burch colposuspension. No other statistically significant differences in storage or voiding symptoms were recorded between the two arms (level 1b of evidence) [33]. Although the current follow-up is insufficient to assess long-term efficacy and complication rates (such as recurrent POP and lower urinary tract symptoms) and allow health economic analyses, the study is a landmark in the literature, and its results might contribute to a change in clinical practice. To date, tension-free polypropylene tapes, in fact, remain a valid mini-invasive alternative for the treatment of those patients experiencing SUI after colposacropexy alone.

### 3.3. Posterior vaginal wall prolapse surgery

Posterior vaginal wall prolapses are due to the herniation of the pelvic organ (more commonly the rectum) through the recto-vaginal septum, a fascial layer which provides suspensory support of the perineal body from the sacrum with uterosacral ligaments [57].

#### 3.3.1. Which is the optimal surgical treatment?

Posterior vaginal wall prolapses are typically approached differently according to the specialist who performs the procedures. Traditionally, colorectal surgeons are more frequently employed for transanal repairs, while gynecologists and urogynecologists have more experience in dealing with vaginal procedures. Two randomized controlled studies prospectively compared transanal and vaginal techniques. Kahn et al. enrolled 63 patients with symptomatic rectocele to undergo either posterior colporrhaphy with levator plication or transanal repair [21]. Gynecologists and colorectal surgeons performed vaginal and transanal procedures, respectively. At a follow-up time slightly longer than 2 years, 87.5% of the patients who underwent vaginal surgery and 70% of those who had transanal repairs were objectively cured. A similar percentage of patients in both arms (about 60%) showed improvement in bowel function (level 2 of evidence) [21]. Similarly, Nieminen et al. randomized 30 patients with symptomatic rectocele to rectovaginal fascia plication Vs. transanal repair [28]. Both procedures provided high rates of symptom resolution (93% Vs. 73%, respectively; \( p = 0.08 \)). However, vaginal procedures allowed better restoration of the anatomy and lower rates of prolapse recurrence (both rectocele and enterocele; 9% Vs. 40%) (level 2 of evidence) [28]. Combining the data of the two studies as proposed by Maher [14], vaginal surgery performed significantly better than the transanal approach in terms of both subjective and objective failure rates. On the other hand, perioperative parameters such as blood loss, narcotic use, and postoperative hospital stay were more favorable in the transanal surgery arm (level 1a of evidence) [14].

While the transvaginal route appears superior to the transanal approach for posterior repair, significant variations exist in the literature on the methods of the vaginal repair. Posterior colporrhaphy with levator ani plication, midline fascia plication, or discrete fascial repair are the main options possible [58,59]. Levator ani plication affords a high rate of anatomical repair of prolapse but is followed by unacceptably high rates of dyspareunia (up to 50%). On the other hand, midline fascia plication and discrete fascial repair seem less likely to correct obstructed defecation [58]. Abramov et al. compared midline fascia plication and discrete fascial repair in a retrospective study involving more than 300 patients. Posterior wall prolapse recurrence turned out to be significantly higher in patients undergoing discrete fascial repair (44% Vs. 18%, \( p = 0.001 \)), with similar rates of constipation, fecal incontinence and dyspareunia in both group (level 3 of evidence) [60]. Although transanal repair of posterior vaginal wall prolapse is inferior to vaginal repair, no clear conclusions can be drawn about the superiority of one of the vaginal techniques for posterior repair and further RCTs are needed in this field as well (Table 1).

#### 3.3.2. To mesh or not to mesh?

Regarding the use of mesh in posterior vaginal wall surgery, at the 28th International Urogynecology Meeting, Gandhi et al. reported preliminary data at a 12-month follow-up of a randomized trial comparing colporrhaphy alone Vs. colporrhaphy with fascia lata graft, showing similar success rates (76% the graft group Vs. 89% in control group, \( p = 0.54 \)) (level 2 of evidence) [61]. Sand et al., in an RCT analyzing the use of mesh in anterior colporrhaphy, performed accessory posterior colporrhaphy with and without mesh in 67 and 65 patients, respectively. Although the rectocele recurrence rate was not the primary end-point of the study, the authors reported overlapping objective failure rates in both arms (10% Vs. 9%) (level 2 of evidence) [23].
The available data discourages the use of homologous, autologous or synthetic meshes in posterior repair (Table 3).

4. Methodology for improved assessment of pelvic floor surgical reconstruction outcome

In the era of evidence-based medicine, meta-analyses of RCTs and good quality RCTs should be performed to collect the highest level of evidence. Only a few clinical situations in urogynecology can be managed in such an evidence-based framework and the available RCTs are often of poor methodological quality, lacking in long-term follow-up or adequate functional data. As stated, pelvic floor disorders are a multidimensional phenomenon, which affect—often at the same time—urinary tract function, bowel function, sexual function as well as patients' quality of life. Success after surgery is complex to define and should be evaluated in multiple domains, including anatomical success and, above all, functional outcomes. Consequently, all those outcomes have to be measured in a standardized, reproducible way, including physical examination through the POP-Q system, multi-domain assessments of symptoms and quality of life through the use of validated questionnaires, frequency-volume charts or bladder diaries and standardized pad-test to quantify the patient's complaints objectively.

The POP-Q is currently the most objective, site-specific system for quantifying and describing POP [9]. The POP-Q system describes support to the perineal body, complete the evaluation. After its introduction in 1986, POP-Q has been used in clinical research and has demonstrated good reproducibility. The original report, however, did not suggest all the aspects of examination technique, such as position of the patient, use of a standing examination to verify the full extension of the prolapse, type of table or chair used, type of speculum, type and intensity of straining, fullness of the bladder, and contents of the rectum [62]. Although the POP-Q might seem complicated and difficult to learn or apply, there is no doubt that this tool enables us to characterize and report pelvic floor defects accurately, to compare various reported studies, to follow patients over time, and to report outcome measures from study to study [63]. The only valid and reliable symptoms questionnaire designed for specific use with patients with POP is the Pelvic Floor Distress Inventory (PFDI). The FFDI includes 46 items, grouped in 3 scales: Urinary Distress Inventory (UDI), including 28 items regarding lower urinary tract symptoms; Colorectal-anal distress inventory (CRADI), assessing bowel function through 17 questions; and Pelvic Organ Prolapse Distress Inventory (POPIQ), using 16 items to evaluate prolapse-related symptoms [64]. Symptom questionnaires are so important that International Continence Society is developing a set of modular questionnaires (the ICI-Q), which, hopefully, might become the new international standard [65]. The same group who provided PFDI developed the Pelvic Floor Impact Questionnaire (PFIQ), a 92-item condition-specific questionnaire to assess the quality of life of patients with POP [64]. The PFIQ includes 3 scales to assess the impact of lower urinary tract symptoms (Urinary Impact Questionnaire [UIQ]), bowel symptoms (Colorectal-anal Impact Questionnaire [CRAIQ]), and prolapse-related symptoms (Pelvic Organ Prolapse Impact Questionnaire [POPIQ]) on the patient's quality of life [64]. Both questionnaires are the only ones recommended at the 3rd International Consultation on Incontinence to improve the quality of life of patients with POP [65], although short forms of both PFDI (PFDI-20) and PFIQ (PFIQ-7) have been developed recently [66]. To complete the assessment of the quality of life, a generic questionnaire such as RAND SF-36 or Euroquol EQ-5D should be employed [67]. With regard to sexual function, a single questionnaire, the Pelvic Organ Prolapse and Incontinence Sexual Function Questionnaire (PISQ) is recommended by the 3rd International Consultation on Incontinence to evaluate patients with POP. The questionnaire includes 31 items, assessing the impact of POP on 3 domains (behavioral/emotive, physical, and partner-related) [68].

To date, only a few high-quality RCTs have used some of those questionnaires to assess patients with POP [26,29,30,33], but such tools, as well as further research in the field of questionnaires, are strongly recommended by the 3rd ICI to improve the methodological quality of the studies [65].

5. Conclusions

Although few, high-quality randomized controlled trials are available in the field of pelvic floor reconstruction, further RCTs with long term follow-up and special attention to the assessment of functional outcomes through the use of validated questionnaires as well as re-evaluation at longer
follow-up of most of the currently available trials are strongly desired to improve evidence-based management in urogynecology. The high epidemiological burden of those conditions as well as the increasing acknowledgement of the need to perform such kinds of studies will surely bring about an improvement of our current practice in the field of urogynecology.

References

CME questions

Please visit www.eu-acme.org/europeanurology to answer these CME questions on-line. The CME credits will then be attributed automatically.

1. Symptoms of pelvic organ prolapse encompass
   A. Mainly lower urinary tract
   B. Mainly pelvic floor complaints
   C. Mainly bowel symptoms
   D. POPs can produce a variety of symptoms, including pelvic floor complaints lower urinary tract, bowel and sexual complaints

2. POP-Q ICS
   A. Provides objective, site-specific quantification of pelvic organ prolapse and has been shown to have good reproducibility
   B. Does not offer significant advantages compared to the Baden-Walker classification
   C. Is too difficult to be recommended in the every-day clinical practice
   D. Measuring the distance between the most dependent part of each point and the vaginal apex

3. In the treatment of pelvic organ prolapse, surgery
   A. Is the only treatment available
   B. Aims at restoring the physiological anatomy of the vagina, as well as at resolving symptoms and preserving lower urinary tract, bowel, and sexual functions
   C. Is indicated in all the patients
   D. Should be electively performed by the vaginal route

4. The Colpopexy and Urinary Reduction Effort (CARE) study, a randomized controlled trial recently published on the New England Journal of Medicine, showed that
   A. Sacrocolpopexy does not significant improves lower urinary tract symptoms in the patients with apex vaginal vault prolapse
   B. In the patients with apex vaginal vault prolapse treated by abdominal sacrocolpopexy, concomitant Burch colposuspension significantly reduces the risk of post-operative stress urinary incontinence
   C. At the time of any pelvic floor reconstruction, prophylactic anti-incontinence procedures should be done
   D. In the patients with apex vaginal vault prolapse treated by abdominal sacrocolpopexy, concommitant Burch colposuspension significantly increases the risk of postoperative lower urinary tract symptoms

5. Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ)
   A. Should be used in the assessment of patients with pelvic organ prolapse because provide objective measure of prolapse-related symptoms and their impact on patient's quality of life
   B. Do not address the impact of prolapse on bowel function
   C. Do not address the impact of prolapse on lower urinary tract function
   D. Should be used with a further disease-specific quality of life questionnaire

6. According to the Amid classification, Type I meshes
   A. Are macroporous materials with multifilamentous or microporous components
   B. Are not currently used in the clinical practice
   C. Have pores larger than 75 nm, sufficient to allow infiltration by macrophages, fibroblasts, and angiogenesis
   D. Include Gore-Tex and Mersilene