

Title

Clinical Practice Guidelines: Synthesis of the guidelines for the surgical treatment of primary pelvic organ prolapse in women by the AFU, CNGOF, SIFUD-PP, SNFCP, and SCGP.

Authors

Loïc Le Normand, CHU de Nantes, Nantes
Michel Cosson, CHRU de Lille, Lille
Florence Cour, Hôpital Foch, Suresnes
Xavier Deffieux, Hôpital Antoine Béchère, Clamart
Laurence Donon, Polyclinique Côte Basque Sud, Saint-Jean-de-Luz
Philippe Ferry, CH de La Rochelle, La Rochelle
Brigitte Fatton, CHU Carémeau, Nîmes
Jean-François Hermieu, Hôpital Bichat, Paris
Henri Marret, CHU de Tours, Tours
Guillaume Meurette, CHU de Nantes, Nantes
Ariane Cortesse, Hôpital Saint-Louis, Paris
Laurent Wagner, CHU Carémeau, Nîmes
Xavier Fritel, CHU de Poitiers, Poitiers

Correspondence

Xavier Fritel, CHU de Poitiers, 2 rue de la Milètrie, 86000 Poitiers, xavier.fritel@univ-poitiers.fr

Résumé

Objectif : Élaborer des recommandations pour la chirurgie du prolapsus génital non récidivé de la femme.

Méthode :

Revue de la littérature, établissement des niveaux de preuve, relecture externe, et gradation des recommandations par l'Association française d'urologie, le Collège national des gynécologues et obstétriciens français, la Société interdisciplinaire d'urodynamique et de pelvi-périnéologie, la Société nationale française de coloproctologie, et la Société de chirurgie gynécologique et pelvienne.

Résultat :

Il est utile d'évaluer les symptômes, le retentissement, les attentes de la femme, et de décrire le prolapsus avant une chirurgie (grade C). En l'absence de signe urinaire spontané ou masqué, il n'y a aucun argument pour recommander un bilan urodynamique (grade C). Lorsqu'une promontofixation est indiquée, la cœlioscopie est recommandée (grade B). Une préparation digestive avant chirurgie vaginale (grade B) ou abdominale (grade C) n'est pas recommandée. Il n'y a pas d'argument pour une prothèse recto-vaginale systématique en prévention de la rectocèle (grade C). La prothèse vésico-vaginale par voie vaginale doit être discutée compte tenu d'un rapport bénéfice-risque incertain à long terme (grade B). La myorrhaphie des élévateurs ne paraît pas recommandée en première intention pour la cure des rectocèles (grade C). Il n'y a pas d'indication à une prothèse par voie vaginale pour la cure de rectocèle en première intention (grade C). Il n'y a pas de raison de réaliser systématiquement une hystérectomie au cours de la chirurgie (grade C). On peut ne pas traiter l'incontinence d'effort dans le même temps, si la femme est avertie de l'éventualité d'une chirurgie en 2 temps (grade C).

Mots clés : prolapsus génital, traitement chirurgical, recommandations, femme.

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Abstract

Objective:

Develop guidelines for surgery for primary pelvic organ prolapse (POP).

Method:

Literature review, establishment of levels of evidence, external review, and grading of recommendations by 5 French academic societies: Association française d'urologie, Collège national des gynécologues et obstétriciens français, Société interdisciplinaire d'urodynamique et de pelvi-périnéologie, Société nationale française de coloproctologie, and Société de chirurgie gynécologique et pelvienne.

Results:

It is useful to assess woman's symptoms and expectations and to describe the prolapse and its effects before any surgery (Grade C). Without spontaneous or occult urinary signs, no evidence supports performance of a urodynamic assessment (Grade C). When sacropexy is indicated, laparoscopy is recommended (Grade B). Bowel preparation before vaginal (Grade B) or abdominal (grade C) surgery is not recommended. No evidence supports the routine use of rectovaginal mesh to prevent rectocele (Grade C). Vaginal placement of vesicovaginal mesh should be discussed in view of its uncertain long-term benefit-risk ratio (Grade B). Levator myorrhaphy does not appear to be recommended for first-line treatment of rectocele (Grade C). Similarly, vaginal mesh for first-line treatment of rectocele is not indicated (Grade C). There is no reason for routine hysterectomy during surgery for POP (Grade C). It is not necessary to treat stress

incontinence at the same time, as long as the woman is warned that subsequent surgery may be necessary (Grade C).

Key words: Pelvic organ prolapse, surgical treatment, guidelines, women.

Sponsors: French Urology Association (Association française d'urologie, AFU), French National College of Obstetricians and Gynecologists (Collège national des gynécologues et obstétriciens français, CNGOF), the Interdisciplinary Urodynamics and Pelvic Perineology Society (Société interdisciplinaire d'urodynamique et de pelvi-périnéologie, SIFUD-PP), the French National Society of Coloproctology (Société nationale française de colo-proctologie (SNFCP), and the Gynecologic and Pelvic Surgery Society (Société de chirurgie gynécologique et pelvienne, SCGP).

Organizing committee: M. Cosson (gynecologist, Lille, CNGOF, SCGP, SIFUD-PP), P. Ferry (gynecologist, La Rochelle, SCGP), X. Fritel (gynecologist, Poitiers, CNGOF, SIFUD-PP), J-F. Hermieu (urologist, Paris, AFU, SIFUD-PP), L. Le Normand (urologist, Nantes, AFU, SIFUD-PP), H. Marret (gynecologist, Tours, CNGOF), G. Meurette (colorectal surgeon, Nantes, SNFCP).

Working group of expert-authors: V. Basset (urologist, Paris), N. Berrogain (urologist, Toulouse), Dr V. Cardot (urologist, Paris), Dr M. Cayrac (gynecologist, Montpellier), Dr A. Cortesse (urologist, Paris), Dr F. Cour (Urologue, Suresnes), Pr X. Deffieux (gynecologist, Clamart), Dr L. Donon (urologist, Bordeaux), Dr B. Fatton (gynecologist, Nîmes), Dr M. Géraud (urologist, Versailles), Dr J-F. Hermieu (urologist, Paris), Dr J-F. Lapray (radiologist, Lyon), Dr L. Le Normand (urologist, Nantes), Dr G. Meurette (colorectal surgeon, Nantes), E. Ragni (urologist, Marseille), Dr J-B. Terassa (urologist, Paris), T.

Thubert (gynecologist, Clamart), Dr A. Vidart (urologist, Suresnes), Dr L. Wagner (urologist, Nîmes), S. Warembourg (gynecologist, Nîmes).

Reviewers: G. Amarenco (physical medicine and rehabilitation, Paris), P. Ballanger (urologist, Bordeaux), M.-L. Barussaud (colorectal surgeon, Poitiers), M. Boukerrou (gynecologist, La Réunion), L. Bresler (colorectal surgeon, Nancy), C. Carlier-Guérin (gynecologist, Châtelleraut), S. Conquy (urologist, Paris), M. Cosson (gynecologist, Lille), R. de Tayrac (gynecologist, Nîmes), H. Fernandez (gynecologist, Paris), A. Fauconnier (gynecologist, Poissy-Saint-Germain), G. Giraudet (gynecologist, Lille), Jacquet (gynecologist, Tours), B. Jacquetin (gynecologist, Clermont-Ferrand), Jourdain (gynecologist, Bordeaux), G. Legendre (gynecologist, Angers), V. Letouzey (gynecologist, Nîmes), J-P. Lucot (gynecologist, Lille), G. Mellier (gynecologist, Lyon), L. Panel (gynecologist, Montpellier), G. Robain (physical medicine and rehabilitation, Paris), C. Saussine (urologist, Strasbourg), D. Savary (gynecologist, Arcachon), R. Yiou (urologist, Créteil).

1. Introduction

Pelvic organ prolapse (POP) in women can be defined as a hernia in the vaginal cavity involving one or several components of the pelvis. It can involve any combination of these three compartments: anterior (bladder), apical (uterus or vagina), and posterior (rectum, rectouterine pouch and its contents). This condition is frequent, with a prevalence that ranges from 2.9 to 11.4% when assessed by questionnaire and from 31.8 to 97.7% when evaluated by a clinical examination applying the Pelvic Organ Prolapse Quantification (POP-Q) classification. The cumulative incidence of surgery reaches 11% in women older than 70 years [1]. A wide range of symptoms — urinary, genital, sexual, or anorectal — can lead to consultation [2]. This diversity of symptoms explains that of the management, which may involve all of the specialists involved in functional pelvipерineal disorders: urologists, gynecologists, coloproctologists, and colorectal surgeons. This approach to disorders of pelvic floor function calls for multidisciplinary cooperation in complex or risky situations, such as desire for pregnancy, simultaneous rectal prolapse, or fecal incontinence.

It was therefore decided that all of the French professional societies involved in the management of this condition should participate in the validation of these guidelines: Association française d'urologie (AFU), Collège national des gynécologues et obstétriciens français (CNGOF), Société interdisciplinaire d'urodynamique et de pelvipérinéologie (SIFUD-PP), Société nationale française de colo-proctologie (SNFCP), and Société de chirurgie gynécologique et pelvienne (SCGP).

2. Methods

The writing of these clinical guidelines follows the methods recommended by the French national health authority (Haute Autorité de Santé) [3].

A multidisciplinary group represented by the committee for women's urology and perineology of the French urology association (CUROPF), including urologists, gynecologists, and a colorectal surgeon, chose and formulated questions about the treatment of primary (that is, not previously surgically treated) pelvic organ prolapse in women. The drafting of these different sections was assigned to a group of expert authors under the aegis of CUROPF. These guidelines are based on a systematic review of the meta-analyses and randomized trials that provide a high level of evidence, when these exist, and of the recent and/or relevant literature. These draft guidelines were then discussed by the entire group. A group of external reviewers who had not participated in the drafting of the section was selected among each of the professional societies listed above. Their comments were taken into account in the final version of the text and in this short version of these guidelines. The guidelines are graded according to the levels of the evidence provided by the supporting literature. When there is no formal evidence, but the group considers it important that a recommendation be made, it is reported as professional consensus (PC).

3. Assessment before surgical treatment of a primary pelvic organ prolapse

The most specific symptom of pelvic organ prolapse is the patient's perception of a vaginal bulge that is more or less exteriorized during stress [4,5]. The symptoms associated with prolapse, whether urinary (incontinence, overactive bladder, obstructed micturition), gastrointestinal (dyschezia, anal incontinence), gynecologic and sexual (dyspareunia, vaginal bleeding), or pelvic or perineal pain, are not specific to any grade or type of prolapse (LE3). It is useful to verify that the discomfort described by the woman is related to the prolapse observed by the physician (PC). Similarly, it is helpful to assess the symptoms and the functional effects of the prolapse (the discomfort reported by the woman), as well as her expectations and wishes, before reaching a decision about surgery (Grade C).

Only symptomatic pelvic organ prolapse should be treated (PC). Surgery is indicated only in women with both overt symptoms and significant prolapse.

Because the appropriate surgical technique depends, among other things, on the severity of the prolapse and on its anatomical type (LE3) [6], it is useful to describe the prolapse observed before surgery (Grade C). The objectives of the clinical examination are to describe the prolapse (anatomical structure involved, severity, or grade); assess its effects on the woman's quality of life or the functional disorders associated with it to guide assessment and treatment; and look for risk factors for recurrence, surgical difficulties, or postoperative complications (PC).

The risk factors for postoperative complications or surgical difficulties are: obesity and smoking, which are risk factors for mesh exposure (LE3) [7]; surgical history, which may cause problems in the surgical approach; and pelvic pain syndrome with

hypersensitization, which is a probable risk factor for postoperative pain and mandates great precautions in determining that surgery is indicated.

The use of imaging is reserved for complex situations: inadequate data from the clinical examination; discordance between the functional signs and the clinical abnormalities observed; or doubt about any related organ pathology (PC). Imaging examinations that might usefully complete the description of prolapse in complex situations are essentially colpocystodefecography, dynamic MR defecography, and relevant ultrasound.

Factors that might guide the treatment choice should be sought (PC): high-grade prolapse (POPQ stage 3 or 4); large genital hiatus (gaping introitus); factors promoting high abdominal pressure (associated with occupation, physical activity, constipation, and chronic bronchopulmonary disease).

Functional urinary disorders associated with prolapse should be sought by questioning (using aided by symptom questionnaires and a voiding diary as appropriate) and by clinical examination to identify manifest or occult urinary incontinence (PC). Clinical evaluation of bladder emptying is difficult; it can be better assessed by uroflowmetry (with qualitative and quantitative analysis) and measurement of post-voiding residues (PC).

Ultrasound to look for dilatation of the ureter and renal pelvis can be useful in cases of permanently exteriorized prolapse, which may affect the upper urinary system (PC).

Anorectal symptoms should be sought and evaluated by questioning and clinical examination (PC). It can be useful to consult with a coloproctologist in cases involving functional anorectal disorders (PC).

Careful questioning and a clinical gynecological examination (digital and by speculum) are desirable before any prolapse surgery to avoid overlooking any reproductive organ disorders (PC). A specialist's opinion is indicated for postmenopausal vaginal bleeding

or clinical gynecological abnormalities (Grade C). Looking for risk factors for endometrial cancer is mandatory, a preoperative pelvic ultrasound and an endometrial biopsy may be useful when a subtotal hysterectomy or uterine morcellation are planned (PC), (PC). To avoid overlooking a cervical disorder, a clinical examination is necessary, completed as appropriate by a PAP smear or verification that a recent Pap test was normal (PC).

In the absence of spontaneous or occult urinary signs, no evidence supports the recommendation of a urodynamic assessment (Grade C).

4. Surgical treatment of primary pelvic organ prolapse by laparoscopic sacropexy

There is no advantage to bowel preparation before colon surgery (LE2) [8,9].

Analogously we can assume that it provides no such benefits in sacropexy procedures.

Bowel preparation before surgical sacropexy is not recommended (Grade C).

In the absence of a posterior colpocele, the utility of a posterior mesh graft has not been established (LE3) [10]. There is no evidence to support the routine use of a posterior mesh graft in the rectovaginal space to prevent secondary rectocele during sacropexy (that is, any of sacrocolpopexy or sacrohysteropexy, or sacrocolpohysteropexy) for genitourinary prolapse (Grade C).

The consensual indication for laparoscopic ventral rectopexy remains symptomatic rectal prolapse (Grade C), and its anatomical and functional results have been assessed best (LE3) [11]. The treatment of rectocele and enterocele by placement of a posterior sling has been evaluated less well (LE3); it is therefore not possible to reach a conclusion about the results of posterior mesh for these indications (PC).

There are no high-quality comparative data that make it possible to reach a conclusion about the type and material for the fixation. We can only report the most common practices without drawing any conclusions. Most often, anterior mesh is fixed to the uterine isthmus and the anterior wall with sutures; for sacropexy, non-absorbable sutures are used most often. Almost all authors recommend peritonization of the mesh used for sacropexy to limit the risk of postoperative occlusion.

High rates of mesh erosion have been observed with PTFE (9%) or silicone (19%) (LE3) [12]. Use of non-absorbable mesh, either type I (macroporous polypropylene) or type III

(polyester) is recommended; type II mesh (PTFE, silicone) should no longer be used (Grade C). Because of their inferior anatomical results in the short and medium terms (LE2 [13]), the use of biological mesh is not recommended (Grade B).

Anatomical and functional results do not differ between laparotomy and laparoscopy (LE1) [14]. Postoperative complications are more severe in laparotomy. Laparoscopy is associated with less blood loss, shorter hospitalization, and shorter convalescence (LE1). The long-term results between these two surgical approaches have not been compared. When sacropexy is indicated, laparoscopy is recommended (Grade B).

The anatomical or functional results do not differ according to whether or not the laparoscopic sacropexy was robot-assisted (LE2). Robot assistance did not improve postoperative course or reduce the complication rate compared with laparoscopy (LE3). Robot-assisted surgery cannot currently be recommended over standard laparoscopy for sacropexy (Grade B).

5. Surgical treatment of primary pelvic organ prolapse by a vaginal approach

5.1. Treatment of cystocele

While the use of synthetic mesh in the vesicovaginal space improves the anatomical results of cystocele treatment compared with autologous surgery (LE1), the lack of difference for functional results and the increased number of reoperations associated with specific complications, especially vaginal erosion, do not support the routine use of mesh in the repair of primary cystocele [15,16]. It must be discussed on a case-by-case basis, given the uncertain long-term risk-benefit ratio (Grade B). Its use should be supported with complementary studies focused on the specific populations at risk of recurrence.

5.2. Bowel preparation before vaginal surgery

Bowel preparation by an enema is associated with reduced satisfaction among women and a high prevalence of side effects; at the same time, it does not improve operating conditions for the surgeon (LE2) [17]. Bowel preparation is not recommended before prolapse surgery by a vaginal approach (Grade B).

5.3. Treatment of rectocele by plication or repair of the rectovaginal septum

Repair and plication of the rectovaginal septum are the techniques used to treat mid-rectoceles (level 2 according to DeLancey). In the current state of the literature, no high-grade recommendation can be made about whether plication or elective repair should be preferred. Plication appears to provide better anatomical results than site-specific

repair does in the available studies (LE2), but the functional results appear similar (LE3). Granulomas and vaginal erosion have been reported after the use of non-absorbable sutures (LE4) [18]. Slowly absorbable sutures appear preferable to non-absorbable ones (PC).

5.4. Treatment of mid-rectocele by levator myorrhaphy

Levator myorrhaphy is associated with a high rate of dyspareunia, estimated around 50% (LE3). This technique does not appear to be recommended as a first-line treatment for the treatment of mid-rectocele, according to the data in the literature, which come from series of low-level evidence (grade C).

5.5. Treatment of rectocele by vaginal placement of biologic mesh

The use of biologic mesh does not improve either the anatomical and functional result compared with simple rectovaginal fascial plication (LE1) [19,20]. The use of biologic mesh for the vaginal treatment of rectocele is not recommended (Grade B). Synthetic mesh for the treatment of posterior compartment prolapse has not been specifically assessed in randomized trials for the treatment of rectocele and its potential interest therefore cannot be determined. Nonetheless, mesh erosion rates are reported to range from 5.6% to 12%, and dyspareunia rates to reach 63% (LE3) [21]. Vaginal placement of mesh is not indicated for first-line treatment of rectocele (Grade C).

5.6. Superficial perineorrhaphy

It is performed in the case of symptomatic low rectocele, especially in the case of discomfort during sexual relations (feeling of gap). It is not routinely recommended (PC).

5.7. Repair of high posterior colpoceles (apical rectocele or enterocele) and of the vaginal fundus (level 1)

No difference has been shown between McCall's culdoplasty and Richter's sacrospinous fixation in terms of the anatomical result or complication rate (LE1) [22]. For treatment of prolapse of the vaginal cuff or of the uterus, laparotomic sacropexy is superior in terms of anatomical recovery to sacrospinous fixation, with a lower rate of dyspareunia. Nonetheless the operative time and convalescence are longer, and the cost is higher (LE1) [23].

5.8. Transanal treatment of rectocele or dyschezia

Transanal treatment of rectocele is inferior to vaginal treatment, whether assessed by recurrence of functional symptoms or anatomical, clinical, or defecographic results (LE1) [23]. For the treatment of mid or low rectocele, the vaginal approach must be preferred to the transanal route (Grade B).

5.9. Techniques of vaginal obliteration (colpocleisis)

In the short term, colpocleisis is associated with an objective efficacy of 98% (LE3) and a subjective efficacy of 93% (LE3) [24]. Improvement of (genital, urinary and anorectal) symptoms is observed, together with improvement of quality of life (LE4) and body image (LE3) for a large majority of women. In the medium term (1 to 3 years), 85 to 100% of women report that they are satisfied or very satisfied (LE3). Over the medium and long term, 5% regret having undergone this procedure (LE4). Colpocleisis is associated with fewer complications than the other vaginal techniques for women older than 80 years (LE2).

This closure of the vagina is a potential option when other techniques do not appear to be indicated for the treatment of prolapse among older women who no longer wish to have vaginal sexual relations (Grade C).

Because uterine exploration is impossible after colpocleisis, the risk of endometrial disease should be assessed first (Grade C).

6. Does hysterectomy modify the anatomical or functional results of prolapse repair?

Hysteropexy by sacrospinous fixation is as effective as hysterectomy with apical suspension in retrospective series and in a randomized prospective study (LE2) [25,26]; it reduces operative time, duration of hospitalization, convalescence time, and time to return to full activities (LE2).

The only prospective study found a recurrence rate after uterine preservation significantly higher than that for hysterectomy with apical suspension [27].

A long cervix is a risk factor for recurrence (LE3) [28]. Women with hypertrophic prolongation of the cervix may undergo cervical resection if uterine preservation is considered (Grade C).

Hysterectomy performed during vaginal repair with mesh intended to treat the anterior compartment, does not appear to improve anatomical results (LE2) [29].

In the case of sacropexy, hysterectomy increases the operative time (LE3), and blood loss (LE3). Uterine preservation does not increase the risk of recurrence for the apical compartment nor does it appear to reduce the rate of secondary cystocele (LE3) [30].

The performance of a hysterectomy during surgery for pelvic organ prolapse does not appear to modify sexual function (LE3).

Uterine preservation does not appear to modify the risk of vaginal erosion during the transvaginal placement of mesh (LE3) [29]. There is not sufficient evidence that uterine preservation has any protective effect against mesh erosion (Grade C).

A total hysterectomy concomitant with sacropexy increases the risk of mesh erosion (LE3) [31]. If a hysterectomy is indicated, a subtotal hysterectomy is preferred to a total hysterectomy (grade C), as long as no cervical pathology is present.

In conclusion, in the absence of a specific indication, there is no reason to perform a hysterectomy routinely during surgical treatment for pelvic organ prolapse (Grade C).

7. Concomitant treatment for urinary incontinence

No randomized trial has assessed the result of a suburethral sling associated with sacropexy for women with stress urinary incontinence (SUI); Only a Burch colposuspension has been assessed in a randomized trial, and no improvement was observed (LE2) [4,32]. Isolated vaginal repair of prolapse (without any specific continence procedure) with transobturator mesh is successful in around 60% of women with evident preoperative SUI (LE3). Concomitant treatment of SUI creates a specific risk of dysuria and of an overactive bladder (LE3). Women may be offered the choice of not treating evident SUI at the same time as prolapse surgery, as long as they are warned that a second intervention may be required later (Grade C).

Concomitant treatment of prolapse and occult SUI reduces the risk of postoperative SUI (LE1). Nonetheless, isolated treatment of prolapse by sacropexy [33] or by a vaginal approach [34] alone treats only 50 to 60% of occult SUI (LE1). Concomitant treatment of SUI results in a risk of overtreatment and specific morbidity (dysuria and/or overactive bladder). Women may be offered the choice of not treating occult SUI at the same time as prolapse surgery, as long as they are warned of the risk of postoperative SUI and of the possibility that a second intervention may be required later (PC).

L. Normand: over the last 5 years, the author has received fees or funding for participation in conferences, training, or expert groups, from the laboratories Allergan, Astellas, Boston Scientific, Laborie, and Medtronic.

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F. Court: in the last three years, the author has received fees or funding for consulting (on the part of Boston Scientific and Lilly laboratories) and communications (from the Lilly laboratories and Menarini). It was investigator for Astellas, Boston Scientific, and Cousin.

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