

Review Paper

Adaptation of Pelvic Organ Prolapse Guideline in Iranian Adult Women

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ABSTRACT

Introduction: Pelvic organ prolapse (POP) is a common disease which presents as symptomatic descent of the anterior or posterior vaginal wall prolapse, uterus or apical prolapse subsequent to hysterectomy, and enterocele. Since, social and cultural factors have impact on interval between symptoms incidence and seek for medical care, diagnosis method and treatment process, it was important to prepare a guideline for management of the Iranian women with POP. **Methods and Materials:** This guideline has drawn on the evidence based search strategy developed for study goals to provide a native guideline. Therefore, during a systematic search, all clinical guidelines relevant to the subject extracted. Of 85 study, 35 study with evidences grades, systematic reviews or high quality clinical trials selected and further grading performed. Current recommendations presented with due attention to best data available in the literature or based on a mixture of clinical experience and experts' panels decisions. **Summary of Recommendations:** Pelvic floor muscle training recommended as the first line treatment in patients with urinary incontinence or POP (Grade A). Physicians should recommend pessaries to all women seeking treatment for their prolapse (Grade A). Subtotal hysterectomy is not recommended to prevent further prolapse (Grade A). In terms of recurrence, dyspareunia and stress urine incontinency (SUI), abdominal sacropexy is better than vaginal sacropexy, however, these results cannot be extended to reoperation rate and patients' satisfaction (Grade: A). Since graft using fascia increases rate of recurrence, it should not be used ruling abdominal sacrocolpopexy (Grade: A). Round ligament suspension does not provide any effect on uterus or vaginal prolapse treatment (Grade: B). In patients who underwent first time anterior colporaphy, local tissue should be repaired instead of mesh usage (Grade: B). Anatomic outcomes of the polypropylene mesh are much better than anterior colporaphy, however, enough data is not provided on its functional outcomes (Grade A). Levator ani muscle fixation should be prevented in sexually active women (Grade C). In women who suffer concurrent POP and SUI, both should be repaired in the same time (Grade A).

BACKGROUND

Pelvic organ prolapses (POP) is a common condition whereas approximately 50% of adult women suffer from during their life (4). POP is classified to, prolapse of the apical segment of the vagina (such as hystera or vaginal cuff), prolapse of the anterior wall of the vagina (including cystocele, urethrocele, and paravaginal defects) and prolapse of the posterior wall of the vagina (including enterocele, rectocele) (6). However, POP is not always limited to one of these segments and can present in one or more compartments. Of all women experiencing POP, only 10-20% of the victims' experience its symptoms and 11% of them undergo surgical intervention to prolapse correction at least once (6). In addition, it is estimated that elder patients will develop more symptoms than young patients. In a recent study, POP prevalence reported to be 53% among Iranian women, which was same as developed countries (3). Since, very few studies have been carried on etiological features of the POP, epi-

demiological and observational studies have been taken into consideration to evaluate POP risk factors. Several risk factors have been introduced to play role in POP, including pregnancy, childbirth, connective tissue abnormalities, ageing, menopause, pelvic floor muscle weakness, obesity and chronically raised intra-abdominal pressure. There have been lack of symptoms complex for POP patients that leads to various problems in diagnosis. However, majority of the patients commonly present with pelvic floor symptoms such as lump or protrusion bulging down to the vagina, pelvic heaviness, and backache. In addition, most of the patients suffer sexual dysfunction (dyspareunia and vagina dryness), symptoms (stress urine incontinency (SUI)) and bowel symptoms, frequently (1-4).

Several treatment options have been described to be effective in POP treatment, however certain indications of each treatment is unclear, therefore choice of the treatment should be made with due attention to the severity of prolapse and

associated symptoms, as well. Treatments available for POP can be categorized as conservative, mechanical and surgical interventions. Conservative treatments are dedicated to mild degrees of the POP and include pelvic floor muscle training and lifestyle interventions. Despite controversial opinions on using mechanical treatment due to lack of the randomized trials comparing pessary with other treatment options considering their complications, in some patients, pessaries are more appropriate option in comparison to surgery.

With due attention to higher prevalence of the POP among Iranian women and lack of clear evidence on approach to patients with POP and choosing the most appropriate treatment option, we aimed to compile a native guideline to manage POP in Iranian women.

METHOD

In current study, in order to achieve trials and studies, research strategy designed according to the “PIPOH” question. Further, a systematic search performed to acquire all evidence based guidelines related to study topic, with assistance of a clinical librarian who was familiar with searching principles on clinical guidelines. Despite, two phase database search for this study, included a primary search on 2014 and an additional up dating search on 2016, no specific guideline obtained for current topic. Therefore, in order to acquire required information to answer questions, individual search performed on previous guidelines considering each part topic including evaluation, diagnosis, conservative treatments, and surgical interventions. In case, guidelines did not provide enough evidences, systematic reviews and randomized controlled trials (RCTs) perused and grading completed for evidences, subsequently. Furthermore, two reviewers (SH, PB) evaluated each study relevancy and association with aimed subjects. To obtain current study recommendations, data acquired from best clinical evidences in literature used, in addition, if there were lack of evidences on specific topics in literature or there was a need for further evaluations, a multidisciplinary committee formatted by expert gynecologists, urologists, physiotherapists, obstetricians, nurses tasked to define the exact questions on POP treatment and draft out recommendations from their researches and discussion.

In order to answer each questions, validated scientific data extracted from literature with due attention to their level of evidence based on framework provided by University of Oxford Center evidence based medicine as follows:

- Le1a: randomized comparative trials or meta- analysis of randomized comparative trials
- Le1b: not very powerful randomized trials
- Le2a: well-designed non-randomized study
- Le2b: well-designed semi-observational or cohort studies
- Le3: non-randomized comparative studies with large biases, retrospective studies, transversal studies, series of cases, and case reports
- Le4: based on committees’ reports, conclusion and experts’ opinion

Afterward, recommendations made based on the decisions of the experts’ committee by allocating evidence grade

with due attention to level of the evidence, feasibility and ethical factors. In addition, some specific evidences without scientific bases, enrolled according to professional consensus in case of all panel members’ agreement.

- Grade A: based on high quality clinical studies such as at least one randomized comparative trials
- Grade B: based on well-run clinical studies without any randomized comparative trial
- Grade C: based on cohort studies and case series
- Grade D: based on researcher or panel suggestions

Searches performed by key words of the “pelvic organ prolapse” and “vaginal prolapse” or “uterine prolapse” from MeSH, PubMed, TRIP (www.tripdatabase.com), National Guideline clearinghouse, NICE (www.nice.org.uk), SIGN (www.sign.ac.uk), NZ Guideline Group, G-I-N, Best Practice, RCOG (Royal college of obstetricians and gynecologists) and Google Scholar.

RESULTS

Searches from MeSH, PubMed (www.pubmed.gov), TRIP (www.tripdatabase.com), national guideline clearinghouse (www.guideline.gov), NICE (www.nice.org.uk), SIGN (www.sign.ac.uk), NZ guideline group (www.nzgg.org.nz), G-I-N (www.g-i-n.net), Best Practice (www.bestpractice.bmj.com), RCOG (royal college of obstetricians and gynecologists) and Google Scholar, performed by key words of the “Pelvic organ prolapse”, “vaginal prolapse” and “uterine prolapse”.

During search on PubMed, sixteen guidelines explored using key word of “pelvis organ prolapse”, and 12 guidelines gained by key word of “vaginal prolapse”. While, TRIP search, 34 guidelines from different countries founded using “pelvis organ prolapse” key word, however, searching by “vaginal or uterine prolapse” provided 18 guidelines.

Search performed on National Guideline Clearinghouse with “vaginal prolapse” or “uterine prolapse” and “pelvic organ prolapse” key words, provided 7 and 11 guidelines, respectively. However, the guidelines acquired during NICE search with same key words, provided 13 and 14 guidelines, respectively. Finally, searching RCOG website, 3 guidelines founded using mentioned key words. Searches on other databases provided no more results.

Primary search indicated that no clinical guideline was available to be completely relevant to the subject, and only a single clinical guideline is under compilation in China. A total of 85 guidelines, found by the literature search from 2002, and after screening to evaluate their relevancy with current study goals, 25 study selected.

RECOMMENDATIONS

Diagnosis

In primary evaluation, pelvic organ prolapse severity should be obtained (Grade D)(15). Therefore, POP-Q system provides a reliable method for POP grade obtaining (Grade C) (6). Sensation of the vaginal fullness has a strong relationship with higher grades of POP, especially in patients

with grades III and IV of the POP, where provides higher sensitivity and specificity (Le I) (15). It is suggested to evaluate symptoms severity and their effect on patients' quality of life (QoL) and sexual performance using reliable questionnaires (Grade A)(15).

In addition, some tools should be employed in order to evaluate patients' QoL (Grade C) (6). During physical examination patient's positioning may affect POP severity (Le II) (6). While literature review, there were no study discussing physical examination and imaging in POP with due attention to level of evidences and recommendations grade.

Pelvic organ prolapse categorize with due attention to anatomy of the prolapse, including anterior vaginal wall prolapse, posterior vaginal wall prolapse, and apical vaginal prolapse and uterine prolapse. In terms of POP staging, ICS classification (known as POP-Q) system is routinely used by most of the clinicians, which classifies PO as follows:

- Stage 0: no prolapse
- Stage I: define as descent of the most distal portion of the prolapse is at least 1 cm above level of the hymen.
- Stage II: distal portion of the prolapse is between 1 cm above level of hymen and 1 cm below level of hymen.
- Stage III: distal portion of the prolapse descends more than 1 cm below the hymen, however, not more than 2 cm within the total vagina length.
- Stage IV: total eversion of the vagina.

Interventions

POP treatment includes follow up, non-surgical approaches and surgical interventions. Whereas, patients with asymptomatic and mild POP undergo follow up. Non-surgical treatments such as lifestyle changes, pelvic floor muscle training (PFMT), and pessaries. Surgical interventions contain reconstructive surgeries and obstructive surgeries.

Life style

PFMT may lead to improvement of POP symptoms and decrease in its severity (POP grade) (Grade A) (5). Pelvic floor muscle training (PFMT) suggested as the first line treatment in patients with urine incontinency and pelvic organ prolapse (POP), which can decrease POP grade II to grade I. In addition, PFMT has is suggested in patients with stress urine incontinence (SUI), instead of pessaries (Grade C) (17).

Pessaries

Pessaries are intravaginal devices that provide support for vaginal walls and pelvic organs (Le 1) (18). Pessaries are often made of silicon and are available in different sizes and shapes (Le 1) (25), since silicon pessaries do not absorb secretions and have longer durability, despite several autoclaving and washings (Le 1) (15). Physicians should suggest pessaries to all women who are seeking treatment for their POP (Grade B) (19). Pessaries should be taken into consideration in all women with symptomatic POP or stress urine incontinency (Grade A) (18). Pessary is the first choice of treatment in patients with symptomatic POP, patients who

are not willing to undergo surgery, patients with unsuccessful surgery, patients planning to become pregnant or patients in postpartum stage, and elder patients or patients with underlying diseases (Grade D) (15). However, use of pessary should be avoided in patients with acute vaginal infections, inflammatory pelvic diseases, vaginal bleeding of unidentified origin, and probability of fail to receive regular follow up (Grade D) (15). Although, complications due to pessary use are rare, vaginal discharge is the most prevalent complication (Le II) (18). In addition, superficial vaginal wound due to pessary implementation can easily treat by taking out the pessary and topical estrogen administration (Grade B) (18). On the other hand, topical estrogens are useful in preventing mucosal lesion and vaginal infections (Grade A) (15). Pessary is an appropriate substitute in grade II-IV POPs (Le III) (15). Pessary leads to decreased vagina diagonal and probably prevents POP development (Le I) (15).

Ring pessaries are suggested in most of the patients due to its implementation simplicity and possibility of sexual activity (Grade C) (27). It is suggested to use the biggest pessary that patients feel comfortable. Pessaries should be considered in symptomatic patients who refuse surgery, are not able to effort surgery costs, and need more time to perform PFMT (Grade C) (17).

Surgical Interventions

Surgical procedures in POP includes, anterior colporrhaphy, posterior colporrhaphy, vaginal cuff suspension to sacrospinous or uterosacral ligaments, and McCall colpoplasty, however, in 29-40% of the cases, recurrence or reoperation is needed, during three year follow up (20-21). Although, some of surgical methods such as vaginal cuff suspension to uterosacral ligament or urine incontinence treatment, various biologic grafts and propylene meshes are being used since many years ago, vaginal meshes and grafts, which implement with special trocars depending on their type and provide support for pelvic organs, are recently used in anterior posterior and even apical prolapses treatment (22).

Cystoscopy should be performed during operation, and at the end of the prolapse and incontinence surgeries to evaluate bladder and ureter injuries (Grade C) (19). Bowel preparation provides no additional advantage to prevent contamination in vaginal POP surgeries (Grade B) (23). In order to prevent vaginal cuff prolapses, patients are suggested to undergo McCall colpoplasty (Grade B) (24). Cardinal and uterosacral ligaments suturing to vaginal cuff during vaginal or abdominal hysterectomy is effective to prevent prolapse (Grade B) (24).

Subtotal hysterectomy is not suggested to prevent vaginal cuff prolapse (Grade A) (24). Simple hysterectomy without vaginal cuff suspension is not effective in uterine prolapse treatment (Grade B) (24).

Surgical approach to vaginal cuff prolapse subsequent to hysterectomy (16)

Surgery should be suggested to patients with symptomatic prolapse (Grade D). This surgery can only perform by gynecologists or urologists with urogynecology fellowships who have received required educations and certificates (Grade D).

Patients should be aware that both vaginal and abdominal approaches are effective in vaginal cuff prolapse treatment (Grade A). Abdominal sacropexy provides less recurrence, dyspareunia and postoperative SUI comparing to vaginal approach, however, it is not true in terms of need for reoperation and patients' satisfaction (Le I). Sacrospinous fixation is not suggested in patients with short-length vaginas (Grade D).

Patients who suffer recurrence subsequent to previous surgery or are at higher risk of prolapse, it is better to use synthetic meshes to provide reconstruction (Grade C). In order to prevent higher risk of recurrence, fascia should not be used as graft in abdominal sacrocolpopexy (Grade A). In case of prolapse recurrence, patients should be referred to expert gynecologists (Grade D).

Uterine preserving apical prolapse surgery(25)

In case of patient reluctance to uterine preserve, uterine preserving approaches should take into consideration including, uterosacral or sacrospinous ligaments fixation in vaginal approaches and hysteropexy in abdominal approaches (Grade B). In hysteropexy, uterine should not suspend to anterior abdominal wall to prevent higher risk of recurrence (Grade B).

Anterior compartment prolapse (26)

Several cystocele recurrences subsequent to use of vaginal tissue grafts, it has been suggested to use biologic and synthetic materials to enhance surgery outcomes. In this section, we will discuss three common surgery approaches (normal tissue reconstruction, biologic grafts, and synthetic meshes).

Prior to any surgery, some points should be assured:

- Patients suffers symptomatic cystocele: sense of vaginal heaviness, sense of vaginal wall protrusion, dysuria, sexual dysfunction, urinary symptoms, and solitary SU cannot be defined as cystocele
- Grading should be performed based on standard grading systems such as POP-Q or ICS.
- Symptoms irritation should take in to consideration during history taking.
- Symptomatic Grade I and II cystocele should be treated by non-surgical approaches, unless symptoms persistence despite of conservative methods.

In patients who receive anterior vaginal wall reconstruction, prophylactic antibiotic is suggested (Grade A). In patients who undergo anterior colporrhaphy for the first time, damaged tissue repair should be administrated instead of vaginal mesh (Grade B). Vaginal surgery using meshes should only be performed by educated specialists who received required certificates (Grad C).

All possible postoperative complications including pain, dyspareunia, mesh infection, probability of shortened vaginal length and possible urinary symptoms should demonstrate to patients (Grade C). Propylene meshes are significantly more effective than biologic grafts in anterior compartment prolapse (cystocele), but may lead to higher rate of inflammation (Grade A).

Posterior vaginal wall surgery(27)

Various surgical approaches have been introduced for posterior vaginal wall repair including: plication or posterior

vaginal wall fascia collection, levatoroplasty, propylene meshes, and modified sacropex .

Level I and II evidences suggest that posterior plication without levatoroplasty may lead to better outcomes (Grade B). In women suffering posterior vaginal wall prolapse, defect side or standard colporaphy is suggested to perform instead of biografts (Grade A). In patients who are sexually active, levator ani muscle fixation should not be performed (Grade C). Totally, fascial plication without levatoroplasty is the most preferred approach for posterior vaginal wall prolapse. In addition, evidences do not support biologic and propylene meshes use in posterior wall prolapses.

POP surgery effects on bladder function(28)

Patients without SUI who have positive stress test are at higher risk of incontinence subsequent to anterior vaginal wall prolapse (Le I). In women with occult urinary incontinence, concomitant prolapse and incontinence surgery leads to decreased postoperative incontinence (Grade A). Women suffering POP symptoms with SUI, concomitant repair of incontinence and prolapse is suggested (Grade A). In patients with grade II prolapse or higher candidate for abdominal sacrocolpopexy, breach surgery should be performed without considering stress test results (Grade A). Voidal dysfunction rate subsequent to cystocele repair with or without mesh has been reported to be 0-44%. Whereas, voidal dysfunction with postvoidal residue more than 150 cc is defined as CIC. In summary, it seems obvious or occult urine incontinence should concomitantly repair during surgery.

Obliterative approaches(29)

Colpocolysis is suggested in elderly patients who are not sexually active and are in higher risk of surgical intervention (Grade C). Spongy monofilament polypropylene meshes are suggested to use in vaginal cuff prolapse treatment. In case of poly propylene mesh use, it should not be sutured to vaginal wall or pass through vagina (Grade B). Polyester mesh, pig skin, fascia lata, and polytetrafluoroethylen are not recommended to use (Grade B). Total hysterectomy is not suggested (Grade B).

In the presence of rectum lesion or injury synthetic meshes are not suggested to use in rectovaginal wall (Grade D). In bladder injury, synthetic meshes should only be administrated in vesicovaginal wall, in case of bladder injury reparation is assured.

REFRENSSES

1. Bastani P,HajebrahimiS,Hamedani R,Oskuei AP,Female Sexual Function afterModified Pelvic Floor Organ Prolapse Repair. Medical Journal of Tabriz University of Medical Sciences & Health Services. 2012;34(1).
2. Mousavi A, Mostafaei P. Assessment of the frequency of pelvic organ prolapse and its risk factors in menopausal women referred to the hospitals of Iran University of Medical Sciences in 2004. Razi Journal of Medical Sciences. 2007;14(54):167-77.
3. Simorgh L, Khalkhali-Zavieh M, Sohrabi N, Kouhpayeh-Zadeh J, Eftekhari T, Ghanbari Z. The Correlation of Kyphosis, Lordosis and Pelvic Tilt with Pelvic Organ Prolapses. Journal of Rehabilitation. 2009;10(3):0-.

4. Kariman NS, Tarverdi M, Azar M, Majd HA. Evaluating the effects of colporrhaphy on the sexual satisfaction of women. *Journal of Reproduction & Infertility*. 2005;6(3).
5. Bo K. Pelvic floor muscle training in treatment of female stress urinary incontinence, pelvic organ prolapse and sexual dysfunction. *World J Urol*. 2012;30(4):437-43.
6. Brubaker L, Bump R, Jacquetin B, Schuessler B, Weidn Pelvic organ prolapse. *Incontinence 2nd International Consultation on Incontinence 2nd ed* Plymouth (UK): Plymouth Distributors. 2002:243-65.
7. Hagen S, Stark D, Glazener C, Sinclair L, Ramsay I. A randomized controlled trial of pelvic floor muscle training for stages I and II pelvic organ prolapse. *International Urogynecology Journal*. 2009;20(1):45-51.
8. Direkvand-Moghadam A, Ghazanfari Z, Montazeri A, Delpisheh A, Direkvand-Moghadam A. Risk factors of pelvic organ prolapse in Iranian women: a cross-sectional study. *International Journal of Epidemiologic Research*. 2014;1(1):29-34.
9. Doaee M, Moradi-Lakeh M, Nourmohammadi A, Razavi-Ratki SK, Nojomi M. Management of pelvic organ prolapse and quality of life: a systematic review and meta-analysis. *International urogynecology journal*. 2014;25(2):153-63.
10. Mant J, Painter R, Vessey M. Epidemiology of genital prolapse: observations from the Oxford Family Planning Association Study. *British journal of obstetrics and gynaecology*. 1997;104(5):579-85.
11. Risk factors for genital prolapse in non-hysterectomized women around menopause. Results from a large cross-sectional study in menopausal clinics in Italy. Progetto Menopausa Italia Study Group. *European journal of obstetrics, gynecology, and reproductive biology*. 2000;93(2):135-40.
12. Klein MC, Gauthier RJ, Robbins JM, Kaczorowski J, Jorgensen SH, Franco ED, et al. Relationship of episiotomy to perineal trauma and morbidity, sexual dysfunction, and pelvic floor relaxation. *Am J Obstet Gynecol*. 1994;171(3):591-8.
13. Smith AR, Hosker GL, Warrell DW. The role of partial denervation of the pelvic floor in the aetiology of genitourinary prolapse and stress incontinence of urine. A neurophysiological study. *British journal of obstetrics and gynaecology*. 1989;96(1):24-8.
14. Snooks SJ, Swash M, Henry MM, Setchell M. Risk factors in childbirth causing damage to the pelvic floor innervation. *International journal of colorectal disease*. 1986;1(1):20-4.
15. Guidelines for the Use of Support Pessaries in the Management of Pelvic Organ Prolapse. *Australian Clinical Practice Guidelines*. 2012.
16. Post-Hysterectomy Vaginal Vault Prolapse. *Royal College of Obstetricians and Gynaecologists*. 2015.
17. Clemons J. Vaginal pessary treatment of prolapse and incontinence. *Up-To-Date version*. 2014;16.
18. Robert M, Schulz JA, Harvey M-A, Lovatsis D, Walter J-E, Chou Q, et al. Technical update on pessary use. *Journal of Obstetrics and Gynaecology Canada*. 2013;35(7):664-74.
19. ACOG Practice Bulletin No. 79: Pelvic organ prolapse. *Obstetrics and gynecology*. 2007;109(2 Pt 1):461-73.
20. Olsen AL, Smith VJ, Bergstrom JO, Colling JC, Clark AL. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. *Obstetrics & Gynecology*. 1997;89(4):501-6.
21. Clark AL, Gregory T, Smith VJ, Edwards R. Epidemiologic evaluation of reoperation for surgically treated pelvic organ prolapse and urinary incontinence. *American journal of obstetrics and gynecology*. 2003;189(5):1261-7.
22. Altman D, Falconer C, Group NTM. Perioperative morbidity using transvaginal mesh in pelvic organ prolapse repair. *Obstetrics & Gynecology*. 2007;109(2, Part 1):303-8.
23. Ballard AC, Parker-Autry CY, Markland AD, Varner RE, Huisingh C, Richter HE. Bowel preparation before vaginal prolapse surgery: a randomized controlled trial. *Obstetrics and gynecology*. 2014;123(2 0 1):232.
24. Barber MD, Maher C.
25. Gutman R, Maher C. Uterine-preserving POP surgery. *Int Urogynecol J*. 2013;24(11):1803-13.
26. Maher C. Anterior vaginal compartment surgery. *Int Urogynecol J*. 2013;24(11):1791-802.
27. Apical prolapse
27. Karram M, Maher C. Surgery for posterior vaginal wall prolapse. *Int Urogynecol J*. 2013;24(11):1835-41.
28. Baessler K, Maher C. Pelvic organ prolapse surgery and bladder function. *Int Urogynecol J*. 2013;24(11):1843-52.
29. Kenton K. Pelvic organ prolapse in women: Obliterative procedures (colpocleisis). *UpToDate*. 2016.

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