Review Article

Current Treatments for Female Pelvic Floor Dysfunctions

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Abstract

As global population aging, the issue of pelvic floor dysfunctions becomes increasingly. Millions of women were affected every year. The treatment of pelvic floor dysfunction has evolved in the past decade. This review aims to provide the current information on the treatment for female pelvic floor dysfunction, including pelvic organ prolapse (POP), urinary, fecal incontinence (FI), and myofascial pelvic pain among women. We used PubMed, Embase, and Web of Science to search for studies that were related to pelvic floor dysfunction regarding the POP, urinary, FI, and treatments. The development of laparoscopic surgery and synthetic and biological materials for pelvic floor reconstructive surgery were summarized. The surgical outcomes and complications of different pelvic floor reconstructive surgeries were compared. New devices for FI and the potential modified pelvic floor reconstructive surgery were also discussed here. Female pelvic medicine will continue to evolve for better treatment in the future. The pelvic floor reconstructive surgery tends to be minimally invasive approach with synthetic graft use.

Keywords: Fecal incontinence, myofascial pelvic pain, pelvic floor reconstructive surgery, pelvic organ prolapse, urinary incontinence

Introduction

Female pelvic floor dysfunction including pelvic organ prolapse (POP), myofascial pelvic pain (MFPP), urinary or anal incontinence, etc. Pelvic floor dysfunction has been negatively affecting the quality of life (QOL) of millions of women. Women approximately have a 50% chance of developing POP in their lifetime, and 11%–19% lifetime risk of undergoing surgery for prolapse or incontinence.[1,2] In the US, approximately 200,000 surgical procedures for prolapse are performed every year.[3,4] These data are likely underestimated the number of women with symptomatic POP since many women do not undergo surgery. This issue has been more and more important as the global population increasingly becomes aging and had a lower birth rate.

MFPP syndrome is an underdiagnosed syndrome and untreated component of chronic pelvic pain. The estimated prevalence of MFPP varied from as low as 14%–23% among women with chronic pelvic pain,[5] but to as high as 78% among women with interstitial cystitis (IC).[6] Researchers even question the pathophysiology of IC and thought that IC is a result or comorbidity of MFPP but not a disease.

The treatment of pelvic floor dysfunction has evolved in the past decade. This review aims to provide current treatments in female pelvic medicine and reconstructive surgery.

Overactive Bladder

The initial management of overactive bladder (OAB) includes urinary diary, modifying contributory factors, topical vaginal estrogen use, Kegel's exercises, and bladder training. If this management is ineffective, then start a trial of pharmacologic therapy. Antimuscarinics which blocks the

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basal release of acetylcholine during bladder filling is the most commonly used medication in OAB.[7] Antimuscarinics are contraindicated in patients with angle-closure glaucoma and gastric retention. Fesoterodine is superior to tolterodine on diary endpoints, including urgency urinary incontinence, symptom bothers and health-related QOL in women.[8]

A new medication for OAB is beta 3 agonist – mirabegron is a beta 3-adrenoceptor agonist, an option for patients who do not tolerate antimuscarinic medications or have contraindications to antimuscarinic medications. In a meta-analysis of Phase III trials, mirabegron decreased the mean number of incontinence episodes per 24-h period with placebo (standardized mean difference –0.44, 95% confidence interval –0.59 to −0.29).[9] A subsequent systematic review by the British National Institute for Health and Care Excellence concluded that the clinical effectiveness of mirabegron was similar to that of the antimuscarinics but had a different side effect profile, specifically less dry mouth and constipation.

Patients who are drug refractory can try invasive treatments including sacral neuromodulation (InterStim) and cystoscopically intravesical on a botulinum toxin A (Botox) injections.

Synthetic and Biological Graft Materials for Pelvic Floor Reconstructive Surgery

The Food and Drug Administration cleared the first surgical mesh product specifically for stress urinary incontinence (SUI) in 1996, and then for POP in 2002. Since then, there has been a trend to enforce or reinforce repairs with synthetic and also biological materials. Most surgical mesh devices cleared for urogynecologic procedures are composed of nonabsorbable synthetic polypropylene. The surgical mesh has been developed from a thick, heavy, small hole, to thin, light, and macrohole. Transvaginal mesh implantation for POP is no longer suggested because researches have shown that mesh erosion is considerable high (10%–19%), and the related complications are not rare,[10] such as pain, infection, bleeding, dyspareunia, organ perforation, and urinary problems.[11-13]

Biographic materials were mostly used in suburethral sling surgery for SUI. Fascia from patient's rectus muscle or lateral thigh were two commonly used autologous materials. A pilot study of sling surgery with patient's rectus fascia showed that three out of five patients experienced persistent voiding difficulty at 3, 5, and 8 weeks after initial implantation. One patient with persistent genuine SUI at 17 weeks and a final patient with persistent SUI at 4 years after implantation.[14] In addition, increased operation time, postoperative suprapubic pain, fluid collections in the suprapubic wound, and incisional hernias are reported.[15] A higher than expected intermediate-term failure rate using fresh frozen cadaveric fascia lata for suburethral sling surgery was reported.[16] Although the QOL was generally improved after sling surgery with the porcine dermis, 75% recurred <1 year after surgery,[17] and the cure rate of porcine dermis sling is inferior to rectus fascia sling (84.4% vs. 54%).[18] A long-term study of pubourethral sling operation with porcine small intestinal submucosa reported a cure rate of 69%, 12% were improved while 19% were failed or unchanged. No urinary retention or dyspareunia was reported, and no vaginal erosion or adverse tissue reaction was detected.[19]

Pelvic Organ Prolapse Reconstructive Surgery

Apical prolapse (uterine or vaginal vault prolapse)

Fixation site

The round ligaments and the ventral abdominal wall are not suggested to be used because of the high risk of recurrent prolapse. Sacral promontory is a good and secured fixation site in apical prolapse reconstructive surgery, no matter attach with anterior and posterior vaginal wall (sacrocolpopexy [SCP]) or attach with lower uterus (sacrohysteropexy [SHP]) or attach with the cervix after subtotal hysterectomy (sacrocervicopexy); all result in success rates from 76% to 100% with a 4% (range 0%–18%) reoperation rate for prolapse.[20] Furthermore, hysterectomy plus uterosacral suspension is not recommended because it had a six-fold increase in POP recurrence compared to hysterectomy plus SCP or SHP.[21]

Mesh

The best type of mesh and suture material remains controversial. In a systemic review of 65 studies, the average rate of synthetic mesh erosion was 3.4%; the polypropylene had the lowest rate (0.5%) followed by polyethylene and polytetrafluoroethylene (3.1%–5.0%).[20]

Route–Transvaginal

Transvaginal mesh repair (TVMR) for vaginal apical prolapse is associated with a higher rate of a complication requiring reoperation for any reason compared to traditional vaginal surgery or SCP.[22] Abdominal or laparoscopic SCP appears to result in lower rates of mesh complications compared to TVMR, with the vaginal mesh erosion or revision rate reported at 4.0%–5.6%.[23,24] TVMR is associated with a higher rate of overall failure and apical prolapse compared to abdominal or laparoscopic SCP.[10,24]

Colpocleisis remains a good surgical option for elderly patients because of short surgical time and recovery time. However, postoperation urinary frequency (63%) and urgency urinary incontinence (56%) and bowel symptoms

such as constipation and fecal incontinence (FI) (44%) were reported.[25]

Laparoscopic approach for sacrocolpopexy

Laparoscopic SCP harbor a good efficacy like open SCP. However, it needs for extensive dissection and advanced suturing skills.[26] There is a randomized trial which compared laparoscopic SCP with open SCP and revealed less blood loss and shorter hospital stay in laparoscopic group.[27] Functional and anatomical outcome were also comparable. Another retrospective analysis also suggested laparoscopic SCP should be considered the first-line therapy for POP.[28] Perioperative complication and short-term outcome of laparoscopic SCP was also comparable with abdominal SCP.[29]

A new approach of SCP by laparoscopically supracervical hysterectomy, cervical coring, and transcervical morcellation of the specimen was reported.[30] Remove the endocervical canal during hysterectomy using either the 15-mm or 20-mm classic intrafascial supracervical hysterectomy instrument, adequate removal of endocervical glands and endometrial glands was reported. Therefore, this approach may have the advantages of eliminating the cyclic bleeding and cervical neoplasia that may happen after supracervical hysterectomy in the premenopausal patient.

Vaginal anterior and/or posterior compartment reconstruction surgery

Traditional vaginal wall repair with native tissue had a high recurrence rate of 16%–70%,[31] most recurred at the same site, some at a new site that indicates the need of simultaneous prophylactic pelvic floor enforcement during POP reconstructive surgery. A comparative study of cystocele repair with the porcine dermis, traditional anterior colporrhaphy, and polypropylene mesh showed that the recurrence rates were 57%, 25%, and 18%, respectively.[32]

However, a randomized control trial reported that vaginal mesh exposure occurred in 13.3% of women and dyspareunia occurred in 2.7% in the synthetic grafts treatment group at the 12-month follow-up.[33]

In general, synthetic grafts treatment gives higher anatomical success rate and fewer recurrence, whereas biologic materials appear to be better tolerated while traditional anterior repair has fewer complications.[34] Again, transvaginal mesh implantation for anterior and/or posterior compartment prolapse is no longer suggested because researches have shown that mesh erosion is considerable high (10%–19%), and the related complications are not rare, such as pain, infection, bleeding, dyspareunia, organ perforation, and urinary problems.[11-13] Abdominal or laparoscopic SCP appears to result in lower rates of mesh complications compared to transvaginal POP surgery with mesh, with the median vaginal mesh erosion rate reported at 4% within 23 months of surgery.[23] No mesh should be used in posterior vaginal wall repair because it can cause rectum to freeze up and affect normal colon peristalsis.

Stress Urinary Incontinence Surgery

Treatment options for SUI may consist of weight loss interventions, topical estrogen therapy,[35] pelvic floor muscle physical training, and anti-incontinence surgery, while colposuspension is the ultimate treatment for SUI.[19,23]

The anti-incontinence surgery began with anterior colporrhaphy in 1914 with a poor cure rate of 20%–30% and patients have to receive a second anti-incontinence surgery. Although colporrhaphy with Kelly application reported a higher success rate,[36] this procedure is not popular now may be related to inadequate durable native fascia can be found for repair in old age women and the complicated and time-consuming procedure.

Afterward, the approach way or sling anchoring site in anti-incontinence surgery have been evoluted from abdominal or laparoscopic Burch urethropexy[37] to needle-assisted bladder neck suspension,[38] and colposuspension such as suprapubic mid-urethra slings (e.g. Gynecare TVT, SPARC, IVS, Align, Advantage, Lynx etc.), transobturator mid-urethra slings (Altis, TVT-O, MiniArc. MONARC, Align TO etc.).

As a treatment of SUI, laparoscopic burch colposuspension is equally effective as open burch colposuspension.[39,40] Surgeon experience and surgical technique are the most important for successful suspension. Subjective cure rates of laparoscopic burch colposuspension are no difference when compared with tension-free slings.[41] However, objective cure rates are more successful in tension-free slings. Both operative methods improved sexual function.[42] Finally, laparoscopic burch colposuspension is still an option for SUI in order to prevent mesh-caused complications.[39]

Among these surgical procedures, the tension-free suburethral sling placement has been shown to be simpler, less costly, and shorter in duration than the other procedures. Most of the commercially available tension-free suburethral slings use Type I mesh.[43]

It remains controversial that which sling kit has better treatment outcomes compared to others because data on several kits are lacking, differential measures of outcomes, and disproportionate sample sizes in the related studies. The Gynecare TVT was the most cited sling kit with low complication rate: bladder perforation (27–38/1000), reoperation (24–34/1000) that related to the tape, hematoma (0.1–0.7/1000), major vessel injury (0.7/1000), of nerve injury (0.7/1000), and urethral lesion (0.7/1000) were reported.[44,45]

Absorbable sling with small intestine submucosa (SIS) was also used in colposuspension. A 1-year study of sling with SIS reported that although no erosion but anterior repair had a higher recurrence rate of 40%.[46]

For some cases of intrinsic sphincter deficiency, suburethral sling surgery followed by Coaptite injection is needed; 50% of these patients may need a second injection 6 weeks later.

Fecal Incontinence Surgery

Overlapping anal sphincteroplasty[47]

A 10-year period anterior and posterior overlapping anal sphincteroplasty study showed that 85% (17/23) declared themselves satisfied by the repair; 60% (12/23) showed good fecal continence.[48] A systematic review of 16 studies with a total of 900 sphincter repairs evaluating long-term outcomes after sphincteroplasty reported that patients' QOL remained high after surgical repair despite the deterioration in continence over time.[49] Anal sphincteroplasty may be a first-line attitude, especially in young female although functional deteriorate with time.

Sacral neuromodulation (InterStim)

InterStim should be considered the first-line surgical approach for medically refractory FI with minimal risk and more durable long-term improvement in continence. The mean number of bowel accidents/2-week bowel diary before implant decrease from 19 (9–52) to 3 (0–12) after implantation.[50]

New devices

Solesta is a sterile gel (naturally made materials dextranomer and sodium hyaluronate) that is injected into a layer of tissue beneath the lining of the anus for narrowing the opening through which stool will pass and thereby helping to retain it within the rectum. Injections can be done via the anal canal or via a transsphincteric route, with or without ultrasound guidance. More than half of patients (52%) who received Solesta had a half or more reduction in incontinence episode.[51] The most common adverse events after treatment are mild to moderate pain or discomfort in the rectum or anus (27.4%), minor to moderate bleeding or spotting from the rectum (19.8%), and fever (7.1%). The FI QOL scales (Wexner scores) were significantly better at 6 weeks and 6 months but improvements were not significant at 12 months. There was no significant improvement for either injectable from baseline in mean SF-36 scores at any follow-up point. Little difference was noted between the two bulking agents (PTQ vs. Durasphere). Both agents to be safe and effective, but noted long-term improvement is limited.[52]

Fenix is a small, flexible ring of magnetic cores designed to support a weak sphincter muscle, keeping the anal canal closed to prevent FI. The magnetic beads will separate temporarily to allow the intentional passage of stool. Clinical study with a small number of patients showed that Cleveland Clinic Incontinence Score decreased from a mean of 17.5 (range, 14.0–20.0) to 7.3 (range, 0–12.0), QOL improved, and 76% of the patients with implants experienced a ≥50% reduction in the number of FI episodes per week.[51,53]

TOPAS, the only mesh implant system with minimally invasive delivery to treat FI, is coming soon. In the preliminary study, the TOPAS system substantially reduced FI episodes 3 months after implantation with the benefit being durable through 36 months of follow-up. Patients with reduced FI episodes had sustained improvement in FI symptom severity, QOL, and pelvic floor distress and impact. There were no cases of device migration, revision, erosion.[54]

Myofascial Pelvic Pain

Etiology and clinical symptoms

Myofascial trigger points (MTrPs), tender nodules, or bands within the pelvic floor musculature are a distinctive diagnostic indicator of MFPP. These trigger points can be explained by a variety of mechanical, metabolic factors that affect muscular strain, circulation, and pain. The common mechanical factors including chronic poor posture or body mechanics, birthing or direct trauma, and joint hypermobility lead to future myofascial dysfunction. Muscular strain causes pain and decreased pelvic myofascial circulation, also causes localized hypoxia and ischemia.[55] Once MTrPs was developed, it can be a continuous source of peripheral pain contributing to central sensitization, making it more sensitive to painful stimuli.[56] Therefore, a patient with MFPP describes symptoms in the pelvis, pelvic floor, and distally in the abdomen, back, and legs, share the same symptoms as urinary infection, IC, etc.

Screening standard

Physical examination methods for MFPP are highly variable and poorly defined. Recently, Dr. Meister *et al*. had developed a standardized, reproducible screening examination for assessment of MFPP[57] which is a complete pelvic floor myofascial examination including assessment of external side (bilateral sacroiliac joints, medial edge of the anterior superior iliac spine, and cephalad edge of the symphysis) and internal muscle groups (bilateral obturator internus, levator ani).

Treatments

MFPP can be effectively treated with a variety of physical therapy techniques, including manual therapy, biofeedback, relaxation training, electrical stimulation, and medication. In contrast, Kegel's exercise may exacerbate the pain. Suppository medication with a muscle relaxant (valium 5 mg),

nonsteroid anti-inflammatory drugs (e.g., baclofen 10 mg), and painkiller (lidocaine 5 mg) HS for 1–2 week is helpful for most patients in initial management. Subsequently, physical therapy carried by a well-trained physical therapist is also critical. During physical therapy, the prior suppository use can also reduce the uncomfortable of pelvic floor massage. However, no standardized or superior physical therapy protocol was reported.

For refractory MFPP, intralevator muscle botulinum toxin type A (Botox) injections with a standard pudendal block kit can be considered. A range of 100–300 Units Botox diluted to 10 units per milliliter with normal saline and a depth of 1 cm needle penetration through vaginal mucosa into the muscle fibers was used for injection. The syringe is withdrawn before each injection to avoid intravascular injection. A total of 79.3% of patients reported improvement in pain; the median time to the second injection was 4.0 months (3.0–7.0 months). Although *de novo* urinary retention (10.3%), FI (6.9%), constipation, and/or rectal pain (10.3%) were reported, all the side effects resolved spontaneously.[58,59]

In addition, a vitamin supplement may be helpful because deficiencies of Vitamins B1, B6, and B12, folic acid, Vitamin C and D, iron, magnesium, and zinc have all been associated with chronic MTrPs.[60]

Conclusion

Female pelvic medicine will continue to evolve for better treatment in the future. The pelvic floor reconstructive surgery trends to be synthetic graft use with the minimally invasive approach. Although some show promise in success rate and improving QOL, both the surgeon and patient have to be aware of the related risk profile.

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Conflicts of interest

There are no conflicts of interest.

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