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Transvaginal Mesh Procedures for Pelvic Organ Prolapse

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Abstract

Objective: To provide an update on transvaginal mesh procedures, newly available minimally invasive surgical techniques for pelvic floor repair.

Options: The discussion is limited to minimally invasive transvaginal mesh procedures.

Evidence: PubMed and Medline were searched for articles published in English, using the key words "pelvic organ prolapse," transvaginal mesh," and "minimally invasive surgery." Results were restricted to systematic reviews, randomized control trials/controlled clinical trials, and observational studies. Searches were updated on a regular basis, and articles were incorporated in the guideline to May 2010. Grey (unpublished) literature was identified through searching the websites of health technology assessment and health technology assessment-related agencies, clinical practice guideline collections, clinical trial registries, and national and international medical specialty societies.

Values: The quality of evidence was rated using the criteria described in the Report of the Canadian Task Force on the Preventive Health Care. Recommendations for practice were ranked according to the method described in that report (Table 1).

Benefits, harms, and costs: Counselling for the surgical treatment of pelvic organ prolapse should consider all benefits, harms, and costs of the surgical procedure, with particular emphasis on the use of mesh.

Recommendations

1. Patients should be counselled that transvaginal mesh procedures are considered novel techniques for pelvic floor repair that demonstrate high rates of anatomical cure in uncontrolled short-term case series. (II-2B)
2. Patients should be informed of the range of success rates until stronger evidence of superiority is published. (II-2B)
3. Training specific to transvaginal mesh procedures should be undertaken before procedures are performed. (III-C)
4. Patients should undergo thorough preoperative counselling regarding (a) the potential serious adverse sequelae of transvaginal mesh repairs, including mesh exposure, pain, and dyspareunia; and (b) the limited data available comparing transvaginal mesh systems with traditional vaginal prolapse repairs or with traditional use of graft material in the form of augmented colporrhaphy and sacral colpopexy. (III-C)
5. Until appropriate supportive data are available, new trocarless kits should be considered investigative. (III-C)

Table 1. Key to evidence statements and grading of recommendations, using the ranking of the Canadian Task Force on Preventive Health Care

Quality of evidence assessment*	Classification of recommendations†
I: Evidence obtained from at least one properly randomized controlled trial	A. There is good evidence to recommend the clinical preventive action
II-1: Evidence from well-designed controlled trials without randomization	B. There is fair evidence to recommend the clinical preventive action
II-2: Evidence from well–designed cohort (prospective or retrospective) or case–control studies, preferably from more than one centre or research group	C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making
II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category	D. There is fair evidence to recommend against the clinical preventive action
	E. There is good evidence to recommend against the clinical preventive action
III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees	L. There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making

*The quality of evidence reported in these guidelines has been adapted from The Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.[36]
†Recommendations included in these guidelines have been adapted from the Classification of Recommendations criteria described in the The Canadian Task Force on Preventive Health Care.[36]

INTRODUCTION

The prevalence of pelvic organ prolapse increases with age and is approximately 31% across all age groups.[1] The likelihood of requiring surgical repair by age 80 is approximately 11%,[2] and 29% to 40% undergo reoperation within 3 years following traditional surgery.[2,3] Traditional non-augmented vaginal techniques include, but are not limited to, anterior and posterior colporrhaphy, McCall culdoplasty, and sacrospinous and uterosacral ligament apical vault suspensions. Persistently high failure rates have led to graft use,[4] but non-standardized techniques have resulted in varied outcomes and complication rates.[5] Graft use for pelvic floor surgery is commonly accepted, mainly in the form of sacral colpopexy and tension-free vaginal tape, both of which demonstrate longevity of successful repair.[6,7] However, sacral colpopexy can carry significant morbidity that may be increased if performed by laparotomy.[6] Its laparoscopic counterpart may provide comparable success rates and expedite convalescence.[8]

This technical update does not focus on the specific issue of graft use, because its use in sacral colpopexy is already accepted in general practice and because grafts may be of various types: synthetic (polypropylene), xenografts (porcine dermis or porcine small intestinal submucosa), or allografts (cadaveric). This update focuses on the rapidly expanding area of transvaginal mesh (TVM) systems that employ graft material, usually polypropylene mesh, placed vaginally, using trocars.

The novel TVM procedures have been part of a surgical evolution attempting to maintain durability of repair, minimize morbidity and invasiveness, allow regional anaesthesia, and address appropriate anatomical defects of pelvic floor dysfunction.[9] They are intended to be minimally invasive surgical techniques for pelvic organ prolapse repair that facilitate a tension-free placement of a broad coverage polypropylene implant without trimming of the vagina or suturing of the mesh to the vagina. The involved "systems" allow selective application of anterior, posterior, or total vaginal implants, and the need for hysterectomy is potentially eliminated. The mesh implants have arms that are delivered with trocars through anatomical landmarks via the obturator membrane or the ischiorectal fossa. The currently available commercial kits are listed in Table 2.

Early literature with short-term follow-up has shown the TVM systems to be relatively effective, but there is limited long-term follow-up to demonstrate their potential longevity or safety profile.[9-17] The issues of mesh erosion, dyspareunia, pelvic pain, mesh shrinkage, and de novo stress incontinence have been introduced in early studies. Modifications of the TVM procedure were carried out (elimination of hysterectomy and creating only longitudinal incisions) upon review of initial case series in attempts to reduce rates of vaginal mesh exposure.[15]

Even newer technology has allowed the development of single-incision trocarless TVM systems. These include the

Elevate system from AMS and the Pinnaclesystem from Boston Scientific (both approved by the FDA). Their intent is to lower rates of nerve and vascular injury associated with trocar placement, expedite operating time, and potentially reduce rates of pelvic pain and dyspareunia. As no literature yet exists on their risks and effectiveness, they are not discussed in this update.

TVM PROCEDURE

The TVM procedure addresses midline, paravaginal, and apical defects through placement of a macroporous monofilament polypropylene implant. Characteristics of the available TVM systems are listed in Table 3. Typically hydrodissection guides creation of a full-thickness longitudinal vaginal incision through which the paravesical and/or pararectal spaces are then accessed. Arms of the mesh implant are delivered through the obturator membrane and/or ischiorectal fossa via trocars. Positioning of the mesh is performed, and the vaginal epithelium is closed without trimming. A mid-urethral sling can then be carried out through a separate incision. There are variations of this procedural technique.

TVM OUTCOMES

Currently the vast majority of the published studies are limited to short-term follow-up (typically 3 to 12 months) through either observational or retrospective studies.[11-15,17-25] Initial rates of anatomical cure (typically defined as less than POP-Q stage II) in all compartments combined range from 79% to 100%.[11-15,17-23,26] These results are comparable to subjective satisfaction rates from the procedure.

The only published randomized clinical trial in this area compared the Perigee system from AMS with traditional anterior colporrhaphy for anterior compartmental prolapse.[27] Seventy-five patients were randomized to either traditional anterior colporrhaphy (n = 38) or a Perigee procedure (n = 37). Anatomic failure was defined as recurrent POP-Q stage II prolapse or greater. Optimal repair was achieved in 55% of the colporrhaphy group and 87% of the Perigee group ($P = 0.005$). Rates of dyspareunia and voiding symptoms were not different. Mesh exposure rate was 5% in the Perigee group, and all were managed as outpatients. Number needed to treat analysis was carried out and determined that 9 anterior colporrhaphy patients would have recurrent anterior vaginal wall prolapse to prevent 1 mesh erosion. A summary of outcomes is shown in Table 4.

Table 2. Commercial TVM kits available

Company	Device	Implant material
American Medical Systems Inc., Minnetonka, MN	Apogee/ Perigee	Intepro polypropylene InteXen porcine dermis
Gynecare/Ethicon, Johnson & Johnson, Somerville, NJ	Prolift	Gynemesh-PS polypropylene
CR Bard Inc., Murray Hill, NJ	Avaulta-Plus	Polypropylene +Porcine collagen

*Trocarless not included: see Recommendation 5.

TVM COMPLICATIONS

TVM procedures have introduced postoperative complications that initially received little attention. These include higher rates of mesh exposure than previous procedures (4.7%), mesh shrinkage (≤ 17%), and dyspareunia (≤ 13%).[21,22] The TVM procedures have relatively low rates of intraoperative complication. A summary of perioperative complications is shown in Table 5. The following factors may increase the incidence of mesh exposure: lack of full-thickness dissection, improper mesh placement, estrogen status, patient nutritional status, BMI, age, smoking, inadequate hemostasis, and immunosuppression.[12,28,29] Although visceral mesh erosion is possible, there is little evidence of it to date. Significant complications should be managed by a subspecialist.

In October 2008, the FDA released a statement regarding potential serious complications associated with transvaginal placement of surgical mesh in pelvic floor surgery.[30] On February 4, 2010, Health Canada issued important safety information on surgical mesh for stress urinary incontinence and pelvic organ prolapse.[31] It outlined the serious potential adverse events associated with transvaginal meshes placed for pelvic organ prolapse or incontinence, using minimally invasive procedures information from over 1000 reports from 9 urogynaecologic surgical companies. These included vaginal mesh exposure, infection, pain, voiding dysfunction, pelvic floor dysfunction recurrence, and visceral or vascular perforation. The Health Canada document[31] made recommendations for obtaining specialized training to carry out these procedures, being vigilant for adverse events associated with the trocars and the mesh, obtaining informed consent for surgery by advising the patient of potentially uncorrectable sequelae of mesh placement including pelvic pain and dyspareunia, and reporting complications to appropriate bodies.

Relatively new long-term sequelae of pelvic floor reconstruction—vaginal scarring and mesh exposure—were also addressed in this notification. These may reduce

Table 3. Characteristics of TVM systems

Device	Trocar	Anterior attachment	Posterior attachment	Retrieval device	Mesh material
Prolift	Straight + cannula	Proximal & distal ATFP	Sacrospinous ligament	Y	Type I polypropylene; Anterior/posterior/total
Apogee	Straight		Ileococcygeus muscle	N	Type I polypropylene or porcine dermis
Perigee	Helical	Proximal & distal ATFP		N	Type I polypropylene or porcine dermis
Avaulta-Plus	Straight & helical	Proximal & distal ATFP	Ileococcygeus + perineal body	Y (InSnare)	Type I polypropylene coated with porcine collagen; anterior/posterior

ATFP: arcus tendineus fascia pelvis

Table 4. Outcomes of TVM procedures

Author	Design	N	Device	Follow-up, months	Anatomic cure, %
Gauruder-Burmester et al.[22]	Retrospective	120	AMS	12	93
Fatton et al.[21]	Retrospective	110	Prolift	6	95.3
Altman et al.[10]	Prospective cohort	123	Prolift	2	87 to 91
Abdel-Fattah and Ramsay[14]	Retrospective cohort	289	Prolift/AMS	3	94 to 100
Shek et al.[23]	Retrospective	46	Perigee	10	87
Van Raalte et al.[12]	Observational	350	Prolift	6	90
Hinoul[19]	Observational	48	Prolift		95.2
Lucioni[20]	Observational	12	Prolift	10	92
Gabriel et al.[11]	Case series	73	Avaulta	4	100
Nguyen and Burchette[27]	RCT vs. AR	75	Perigee	12	87 vs. 55
Murphy[18]	Retrospective cohort cf colpocleisis	90	Prolift	24	97.8 vs. 93.3
Elmer et al.[26]	Prospective cohort	261	Prolift	12	79 to 86
Cosson et al.[4]	Retrospective	687	Prolift	3	94
Kdous et al.[16]	Observational	45	Prolift	24	93
Davila[13]	Observational	55	Apogee	3	91
Rane et al.[17]	Observational	70	Perigee	36	95.7
Moore et al.[24]	Observational	42	Perigee	12	93
Davila[25]	Observational	298	AMS	9	96

patients' quality of life through debilitating discomfort and dyspareunia. Several studies have investigated this issue with conflicting results.[12,13,19,27,32-34]

DISCUSSION

While numerous short-term observational and retrospective studies are emerging that demonstrate the potential effectiveness of the TVM systems, there is a need to demonstrate their longevity and safety profiles, particularly in comparison with traditional and established procedures for pelvic floor repair. Appropriately designed and adequately powered prospective and randomized trials with sufficient long-term follow-up comparing TVM with accepted "gold-standard" procedures such as sacral colpopexy would allow accurate assessment of success with appropriate subjective and objective outcome measures and complication rates. TVM procedures must be more thoroughly evaluated before it is assumed they offer benefits over traditional repairs. The ethical issues associated with the introduction of new surgical devices are discussed in a commentary by Ross et al.[35]

The purported intent of the TVM systems is to further reduce the invasiveness and potential morbidity of the

Table 5. Complications of TVM procedures

Author	Device	N	Follow-up, months	Intraoperative, %	Postoperative, %	Exposure rate, %
Cosson et al.[4]	Prolift	687	3	6.7	6.7	6.7
Gauruder-Burmester et al.[22]	AMS	120	12	–	2.8 hematoma	8 to 11
Fatton et al.[21]	Prolift	110	3	1 cystotomy 2 hematoma	6	4.7 2.8 granuloma
Altman et al.[34]	Prolift	248	6	4 viscus injury 0.4 EBL >1L	14.5 total (UTI, retention, fever)	2
Abdel-Fattah and Ramsay[14]	Prolift 76% AMS 24%	289	3	1.6 cystotomy 1.1 rectal injury 0.06 vascular	5.2 buttock pain 0.07 sepsis	10 vaginal 0.06 bladder
Van Raalte et al.[12]	Prolift	350	6	–	6 dyspareunia 2 de novo SUI	1
Davila[13]	Apogee	55	3	–	4 granulation 4 dyspareunia	11
Rane et al.[17]	Perigee	70	36	–	1.4 pain	7.1
Moore et al.[24]	Perigee	42	12	–	11 de novo SUI	7
Davila[25]	AMS	298	9	–	1 pain	12
Hinoul[19]	Prolift	48		–	13 de novo SUI 15 dyspareunia	10.4
Gabriel et al.[11]	Avaulta	73	4	2.7 EBL > 500 mL 1.4 cystotomy	–	3.1
Shek et al.[23]	Perigee	46	10	–	10.9 mesh arm dislodgement	6.5

laparoscopic sacral colpopexy by delivering the mesh vaginally as opposed to using an intraperitoneal approach and to eliminate the need for general anaesthesia and concurrent hysterectomy. Comparison of these procedures with traditional techniques by adequately trained pelvic floor surgeons is the first step towards elucidating the effectiveness and appropriateness of the use of these novel surgical techniques in our common urogynaecologic practices. The evolution of graft materials with interwoven absorbable mesh, such as monocryl, addition of barrier layers, such as bovine collagen, and xenografts, such as porcine dermis or small intestinal submucosa further complicates the challenge of determining the best materials and techniques for pelvic floor surgery. These graft materials mimic to a certain extent the anatomical considerations of the transvaginal mesh systems and warrant further evaluation and comparison with TVM systems as an alternate minimally invasive novel vaginal approach to pelvic floor repair.

The more than 1000 reports of mesh complication referenced in the FDA notification[30] raise concerns about adequacy of training and ability to prevent complications. Traditionally, advanced pelvic floor reconstructive surgery (such as laparoscopic sacral colpopexy, pubovaginal slings, vaginal paravaginal repairs, and to a lesser extent colpocleisis) has been the domain of the trained pelvic floor reconstructive surgeon and, less commonly, the general gynaecologist who feels competent to carry out these procedures from experience or extra training. The role of the subspecialist has included mentoring and training of generalists interested in novel techniques. The TVM systems assume familiarity with pelvic floor anatomy and surgical techniques not typically known to most generalists. Familiarity with these procedures does require surgical expertise, knowledge of pertinent anatomy, and experience with the procedure itself. These elements would facilitate the trained pelvic floor surgeon's dissemination of his or her knowledge and skill to the interested generalist. Adequate training programs would ensure that trainees could perform competently and safely. Until adequate effectiveness and safety evidence is available, the use of new TVM devices for prolapse repair should be considered experimental and restricted to use in investigative trials.

Recommendations

1. Patients should be counselled that transvaginal mesh procedures are considered novel techniques for pelvic floor repair that demonstrate high rates of anatomical cure in uncontrolled short-term case series. (II-2B)
2. Patients should be informed of the range of success rates until stronger evidence of superiority is published. (II-2B)
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5. Until appropriate supportive data are available, new trocarless kits should be considered investigative. (III-C)

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