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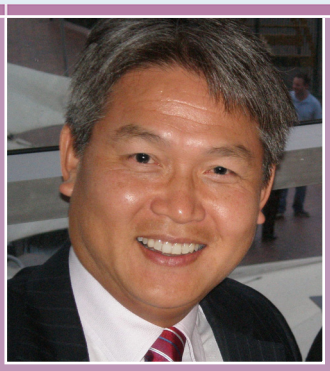

Advances and Controversies in Pelvic Organ Prolapse Surgery

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Pelvic organ prolapse, a term referring to the herniation of one or more of the pelvic organs (bladder, uterus, small bowels, rectum) through the vaginal walls and eventual protrusion outside the vagina, is seen in up to 50% of parous women, of whom 20% may develop symptoms and 11% may require surgery (Olsen 1997).

Apart from a bulge protruding outside the vaginal opening, women with prolapse may experience a range of bladder (such as difficulty voiding, incomplete bladder emptying, urge or stress incontinence), bowel (difficulty evacuating, incomplete emptying, needing to strain or apply perineal pressure) or sexual symptoms (discomfort, looseness). As prolapse symptoms often develop gradually over years, many women may make gradual changes to their lifestyles to deal with the prolapse symptoms such as reducing physical activities, avoiding coitus or wearing incontinence pads before seeking help. Some women may feel too embarrassed to talk about their problems and suffer in silence, while others may become frustrated or not sure what to do if they happen to have experienced suboptimal outcomes (prolapse recurrence, persistent incontinence, pain) following previous repair surgeries.

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Women with asymptomatic or mildly symptomatic prolapse can be appropriately reassured that no specific treatment is warranted other than pelvic muscle exercises with the help of a physiotherapist interested in pelvic floor and periodic check to monitor progress. While the use of topical oestrogen has not been shown to prevent progression of prolapse, it may help symptoms of vaginal atrophy, urinary frequency and urgency in postmenopausal women.

For symptomatic women, vaginal pessary is an appropriate first-line non-surgical management to consider, particularly for those who have not completed childbearing, the elderly who may be medically/surgically unfit or high-risk, or those who prefer to avoid surgery.

While vaginal hysterectomy plus anterior and posterior colporrhaphy have been the traditional surgeries performed in 90% of women with uterine and vaginal prolapse, it is now clear that these procedures may not be adequate as they not only rely on patient's own damaged tissues but also fail to adequately address the vaginal vault support. Attempts to compensate for these deficiencies by overzealous suture-plication have resulted in up to 30% incidence of complications such as prolapse recurrence, vaginal stenosis, bowel or sexual dysfunction after in traditional vaginal repairs (Hasse 1998, Kahn 1997).

In recent years, there have been many developments and changes in prolapse and incontinence surgery aiming to improve functional and anatomical outcomes and reduce complications, catalysed by promising outcomes from the use of surgical mesh slings for stress incontinence. Numerous surgical mesh products and mesh kits with tools to aid the delivery and insertion of mesh transvaginally have been introduced into surgical practice. The rapid turnover of grafts/meshes and new surgical techniques have made it difficult to properly evaluate the efficacy and safety of products, devices or actual surgeries. Maher et al in the 2010 Cochrane Review into surgical management of pelvic organ prolapse concluded that:

- The use of mesh or graft inlays during anterior vaginal repair reduces the risk of recurrent vaginal prolapse.
- Abdominal sacral colpopexy has a lower rate of recurrent vault prolapse and dyspareunia than vaginal sacrospinous colpopexy.
- There is no data exist on the effectiveness of polypropylene mesh in the posterior vaginal compartment.
- More adequately powered randomised clinical trials are needed

In 2008, the FDA released a Public Health Notification to inform clinicians and patients of adverse events related to the use of surgical mesh in pelvic organ prolapse. In July 2011, the FDA issued an Update on the Safety and Effectiveness of Transvaginal Placement of Urogynecologic Mesh for Pelvic Organ Prolapse. This document has raised alarm and stirred up debate and controversies about the use of mesh in pelvic organ surgery.

In Australia, following the ABC 7.30 report running a story on 'Medical giant faces history-making class action' in October 2012, various media outlets produced related news segments which have caused panic, confusion and fear among the public.

Subsequently, statements from the company mentioned in the 7.30 report, from the Therapeutic Good Administration (TGA), the RANZCOG, and elsewhere joint statements from the American College of Obstetricians and Gynecologists (ACOG) and American Urogynecologic Society (AUGS), Medicine and Healthcare Products Regulatory Agency (MHRA) in the UK, have been made to reassure clinicians and patients that:

- For the vast majority of women, mesh and tape implants are a safe and effective operation, but as with all surgery, there is an element of risk
- There are different types of mesh for different purposes that have different outcomes
- There is not enough supporting evidence to justify taking mesh off the market.
- Pelvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals
- Surgeons placing vaginal mesh should undergo training specific to each device and have experience with reconstructive surgical procedures and a thorough understanding of pelvic anatomy
- Patients should be informed about all treatment options, including the pluses and minuses of each option for pelvic organ prolapse

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The large number of surgical options and the numerous grafts/meshes currently available in clinical practice can be broadly categorised according to:

- The route of surgery:
  - transvaginal
  - transabdominal: laparoscopic or open surgery
- The materials for repair:
  - patient's own natural tissues
  - biologic grafts (cadaveric, porcine or bovine)
  - meshes (absorbable, permanent)
- The types of surgical procedures:
  - anterior and posterior colporrhaphy
  - vaginal hysterectomy
  - vaginal sacrospinous or uterosacral ligament colpopexy
  - laparoscopic or abdominal sacrocolpopexy
  - laparoscopic or abdominal sacrohysteropexy

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Ultimately, the choice of surgery for different individuals should take into consideration the severity and sites of prolapse, the quality of native tissues, risk factors for recurrence (past repair surgery, certain medical conditions such as chronic constipation/coughing, connective tissue deficiencies), patient's preferences and doctor's surgical training.

With thorough preoperative evaluation, appropriate counselling, careful consideration of individual differences and patient preferences, appropriate surgeon's training and experience, women should be able to select the 'optimal' procedure aimed at delivering the 'best' chance of anatomical success while minimising associated risks/complications from surgery.

Salient points:

- Traditional prolapse repair surgery carries up to 30% risk of recurrence or complications
- Recent advances in pelvic organ prolapse surgery offer a myriad of choice from which appropriate procedures may suit individual differences
- There is no one-size fit-all solution
- No operation will guarantee long-term success
- All surgeries carry some risks
- The use of grafts or meshes may improve the durability of the repairs but the potential benefits must be weighed against potential risks of mesh complications
- Addition of grafts/meshes mean potential additional risks which should be weighed against benefits
- Mesh repairs in well-trained and experienced hands have shown promising results with low risk of complications
- Ensure adequate patient information and involvement in decision making process
- Long-term data regarding safety and efficacy is required