

Changing trends in pelvic organ prolapse surgery

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Abstract

In many regards female pelvic organ prolapse (POP) remains an enigma to patients and clinicians alike. The uncertainty is contributed to by the wide variety of symptoms being attributed to POP and significant variation in the rate, timing and types of interventions performed. As a result of and contributing to the lack of clarity, there are no published guidelines available to guide women and their clinicians on the surgical management of POP. This article will review and discuss some of the recent changes and trends in the surgical management of prolapse.

Keywords hysterectomy; rectopexy; sacral colpopexy; uterine prolapse

The extent of the problem

For many years, and perhaps the most cited reference in the POP literature was the 11% lifetime risk of women undergoing POP and or continence surgery by the age of eighty. Approximately two thirds of the risk or 6.8% related to prolapse interventions. This estimated lifetime risk was calculated from a sample of 384 women undergoing surgery in 1995 from a North-western health region in the United States of America. More recent American work estimated the lifetime risk of pelvic floor surgery by the age of 80 was 20% with data calculated from 95,000 women with health insurance undergoing surgery between 2007 and 2011. Continence and prolapse interventions were equally represented with the lifetime risk of prolapse surgery being 12.6%. As the cohort's insurance status insures that women would be readily able to access healthcare, this estimation may be higher than expected for the general American population. Alternatively, the data may also underestimate the true rate as elderly women (>65 years), who are at increased risk of POP interventions, may have transitioned to government funded insurance.

In Western Australia, the lifetime risk of POP surgery by the age of 85 years was significantly higher than previous reports at 19% in a general female population. The cohort captured 51,000 women undergoing prolapse surgery between 1981 and 2005 in any Western Australian hospital irrespective of provider, facility or insurance status. We recently completed an international comparison of rates of prolapse and continence interventions in 16 developed OECD countries throughout the world and found the median rate of prolapse procedures was 1.38 per 1000 women. We also confirmed significant variation with the

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estimated rate in United States of 2.2/1000 women being more than 4 times higher than the 0.5/1000 women reported in Switzerland. Notwithstanding the limitations of these studies it is likely that significant variation exists in the rate of POP interventions around the world. Standardisation of data collection and reporting of prolapse surgery would be a valuable first step to aid in defining the current and future demands on health systems around the world.

The changes in POP surgery

During the last decade we have witnessed an unheralded time of change in POP surgery. Traditionally prolapse surgery was performed vaginally, however the 2004 Cochrane systematic review on the surgical management of prolapse review determined the sacral colpopexy was the procedure of choice for apical prolapse after a meta-analysis of data from three randomised controlled trials (RCT) found the sacral colpopexy had lower rates of prolapse, reoperation for prolapse, urinary incontinence and dyspareunia as compared with the vaginal sacrospinous colpopexy. During the same time period transvaginal mesh procedures also gained in popularity for the surgical management of prolapse to the extent that the Food and Drug Administration (FDA) of America estimated that mesh was utilised in one third of the 300,000 prolapse operations in 2010 with transvaginal mesh representing 75% and sacral colpopexy 25%. The absolute number of surgical interventions for prolapse are difficult to determine in America however in a group of 270,000 women who underwent POP surgery between 2000 and 2010 mesh was utilised in 7.9% of repairs in 2000 and usage peaked at 32.1% in 2006 and decreased to 27.5% by 2010. The distribution of mesh utilisation between the vaginal and abdominal surgeries was not clarified.

Alternatively, another group reported in 2013 that transvaginal mesh procedures increased from 36.7 to 60.8 per 100,000 women-years between 2005 and 2010. During the same time sacral colpopexy increased from 19.2 to 25.8 per 100,000 women-years with a five-fold increase in minimally invasive sacral colpopexy and a decrease in the open approach. Following the 2011 American FDA update on safety and efficacy of transvaginal mesh that raised concerns regarding the mesh erosion, contraction and vaginal pain and subsequent litigation many have predicted a dramatic reduction in transvaginal mesh utilisation and an increase in minimally invasive sacral colpopexy. In the first available snapshot of change in POP surgeries following the 2011 FDA safety update at the University of Pittsburgh medical centre, transvaginal mesh as a proportion of all POP cases decreased from 30% in 2008 to 2% in 2011 with minimally invasive sacral colpopexy increasing from only 5% of cases to nearly 33% during the same time period.

The evidence for sacral colpopexy

Clearly we are seeing increasing utilisation of the sacral colpopexy following the reduced utilisation of the transvaginal mesh. The term minimally invasive sacral colpopexy has been coined to include both the laparoscopic and robotic approaches with the implied assumption that both procedures are equivalent and as effective as abdominal sacral colpopexy (ASC). Five RCTs compared sacral colpopexy (four ASC and one Laparoscopic sacral colpopexy LSC) to a variety of transvaginal apical

suspending procedures including sacrospinous and uterosacral colpopexy and transvaginal mesh and formed the basis of the 2013 Cochrane review finding that the sacral colpopexy is the procedure of choice for apical vagina prolapse. On meta-analysis of three papers comparing ASC and vaginal sacrospinous colpopexy, the ASC was associated with a lower risk of subjective failure and of recurrent vault prolapse, and less stress urinary incontinence and dyspareunia compared to the vaginal sacrospinous colpopexy. However, the ASC had greater morbidity including greater operating and recovery time and higher cost than vaginal sacrospinous colpopexy. A single RCT available only as an abstract compared ASC (n = 54) and vaginal uterosacral colpopexy (n = 56) and found a reduced rate of recurrent prolapse (6% versus 34%) and a lower rate of reoperation (5% versus 18%) at two years in the ASC group. While the operating time and hospital stay were significantly less after the ASC, both the rate of intraoperative and postoperative complications was greater following the ASC as compared to uterosacral colpopexy. These findings for the uterosacral colpopexy closely mimic that found for the sacrospinous colpopexy above.

Recently a large multicentre “Optimal” RCT comparing uterosacral (n = 188) and sacrospinous colpopexy (n = 186) in women with apical prolapse and stress urinary incontinence was completed. The authors found that at two years the rate of awareness of prolapse, prolapse on examination and reoperation rate for prolapse were similar in both groups. In an interesting secondary analysis the authors evaluated the impact of perioperative behavioural therapy and demonstrated no detectable reduction in urinary symptoms, prolapse symptoms or anatomic findings with the addition of five sessions of peri-operative behavioural change and pelvic floor muscle training as compared to no intervention.

To minimise the morbidity and cost associated with the ASC the laparoscopic sacral colpopexy was popularised and in 2011 we reported two-year outcomes of a RCT comparing the LSC (n = 53) to transvaginal mesh (n = 54). We demonstrated that the LSC had a longer operating time than the transvaginal mesh (97 minutes versus 55 minutes), however the LSC had less blood loss, a lower rate of recurrent prolapse, reoperation and cost, quicker return to activities of daily living and higher patient satisfaction as compared transvaginal mesh surgery.

Route of sacral colpopexy

Four RCTs addressed the issue of approach to sacral colpopexy with two comparing the abdominal and laparoscopic approach. Freeman et al. 2013 demonstrated that the LSC and ASC had similar anatomical outcomes at one year with reduced blood loss, length of stay and morphine use postoperatively after the LSC. Similarly Di Biase et al. 2013 compared laparoscopic (n = 36) and open (37) approach to sacral colpopexy and demonstrated similar anatomical outcomes in the two groups at two years. The LSC had longer operating time with reduced blood loss, postoperative pain and admission time as compared to open sacral colpopexy. The LSC has also been compared to robotic sacral colpopexy (RSC) in two small RCTs with both demonstrating that laparoscopic and robotic approaches to sacral colpopexy were equally effective in the short-term in correcting prolapse. However, both also demonstrated the LSC

had reduced operating time, post-operative pain and cost as compared to RSC.

The early data from these RCTs suggest the laparoscopic approach is the preferred route of performing sacral colpopexy. However due to both the LSC and RSC being coded as minimally invasive sacral colpopexy we are unable to determine if the findings from RCTs are being reflected in clinical practice. A possible barrier to uptake of the laparoscopic approach has been the lengthy learning curve. Multiple authors have reviewed the learning curve and based upon decreasing operating time, determined competency was achieved after 30–40 cases. Importantly, the complication rate was similar during and after the learning phase. It remains to be determined if our health economists, policy makers and community would prefer to see surgeons invest time to establish their laparoscopic skills set or pay greater cost to have a robotically assisted procedure.

Sacral colpopexy and uterine prolapse

While sacral colpopexy is a preferred surgical option for apical vaginal prolapse, the efficacy of this procedure for post-hysterectomy vault versus uterine prolapse is unclear. In the five RCTs that compared sacral colpopexy with alternative procedures and contributed to level one evidence of superiority of sacral colpopexy as compared to vaginal based interventions, both women with uterine prolapse and post-hysterectomy vaginal prolapse were included in three trials and only post-hysterectomy prolapse in the remaining two. Of the 192 undergoing sacral colpopexy in these five trials, 41 (21%) underwent a concomitant hysterectomy. Unfortunately, a comparison of outcomes between those having sacral colpopexy with and without hysterectomy was not able to be performed and we cannot reliably extrapolate the results of sacral colpopexy in women with vault prolapse to those with uterine prolapse. There are some theoretical concerns regarding the use of sacral colpopexy in those with uterine prolapse mainly related to increased risk of mesh exposure associated with concomitant hysterectomy and sacral colpopexy. Limited data is available on this topic, with many papers not reporting the rate of mesh exposure in those with and without concomitant hysterectomy. In a recent meta-analysis on this topic, Gutman and Maher (2013) evaluated nine comparative studies that reported the rate of mesh exposure in those undergoing sacral colpopexy with (n = 592) and without hysterectomy (n = 1125) and found the mesh exposure rate was increased nearly four-fold in the concomitant hysterectomy group (8.6% versus 2.2%). Despite this data in a recent RCT comparing laparoscopic and robotic sacral colpopexy more than half underwent a concomitant hysterectomy at the time of sacral colpopexy without adverse outcomes. Given the paucity of comparative data on sacral colpopexy and hysterectomy for uterine prolapse and the increased rate of mesh complications when sacral colpopexy mesh is placed in contact with hysterectomy incisions this surgery requires significant further evaluation.

In recognition of the increased risk mesh exposures when performing hysterectomy at time of sacral colpopexy, some have advocated supracerical hysterectomy (Figure 1) as an alternative to hysterectomy and sacral colpopexy in those with uterine prolapse. Two authors have reported on the feasibility of

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