Voiding Function and Dysfunction, Bladder Physiology and Pharmacology, and Female Urology

The Aetiology of Prolapse

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Female pelvic organ prolapse is a common condition that is said to be multifactorial in aetiology. While a number of risk factors such as vaginal childbirth, obesity and ageing are commonly accepted, it is not clear as to how these risk factors affect the development of prolapse—that is, which pathophysiologic mechanisms are responsible for disease manifestation. Measures used in epidemiological studies, such as presentation for surgical treatment, are generally confounded by other conditions, and evidence is lacking for some of the most frequently quoted aetiologic factors. In this paper, I will try to summarise the available evidence in order to separate hearsay and hypothesis from available research findings and to suggest a way forward for diagnosis and treatment.

Editorial Comment: An interesting compilation of opinion from a single author regarding the subject expressed in the title. References are cited indicating that in the United States pelvic organ prolapse is responsible for more than 200,000 surgical procedures per year, with about 30% of these being reoperations. The author concludes that “it is now highly likely that delivery-related major levator trauma (‘avulsion injury’) represents a significant part of the ‘missing link’ between vaginal childbirth and prolapse.” The author goes on to say that, if validated, the potential positive consequence of this is “while presumptive risk factors such as age and abnormalities in connective tissue composition, biomechanics or metabolism are non-modifiable and therefore largely useless in clinical practice, this is not the case for levator trauma. It constitutes a modifiable risk factor which opens up opportunities for prevention . . . .”

Alan J. Wein, M.D., Ph.D. (Hon.)

Incidence of Recurrent Pelvic Organ Prolapse 10 Years Following Primary Surgical Management: A Retrospective Cohort Study

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We conducted this study to estimate the rate of, and identify risk factors for, recurrent pelvic organ prolapse (POP) following primary surgical repair. The study consisted of a retrospective cohort study of 142 women who underwent primary surgical management of POP in 1993 and were followed up to 10 years. Prolapse severity was graded using an established classification system of clinical descriptors. Hazard ratios (HR) for recurrent POP were determined using Cox regression. 36 recurrent cases were identified (recurrence rate: 3.7 per 100 woman-years). A cystocele was the most frequent element of primary (87%) and recurrent (72%) prolapse. No predictors of the likelihood of recurrence were
identified, though recurrence was somewhat more common among women with a history of two or fewer vaginal deliveries vs three or more (HR = 1.6; 95% confidence interval = 0.81–3.3). Recurrent POP following surgical management is common. Our ability to predict recurrence is limited.

**Editorial Comment:** I doubt the recurrence rate is any different for urologists than for gynecologists. These authors review some of the relevant literature in their discussion section, citing recurrence rates as high as 35% to 58%. There is no further subdivision as to whether the recurrences are simply anatomical observations or symptomatic problems. It would be interesting to see whether, as with at least some other surgeries, more experience means better results. It is hard to argue with the conclusion of the authors that the literature, including their observations, “should help set more realistic expectations of the long-term impact of surgical interventions for pelvic organ prolapse, particularly for certain types of prolapse.” They cite recent historical literature describing 200,000 such surgeries in the United States annually.

Alan J. Wein, M.D., Ph.D. (Hon.)

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**Long-Term Patient Satisfaction With Prolapse Surgery in General Gynecology**

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This retrospective cohort study aimed to explore the factors associated with long-term success of prolapse surgery in a general gynecology setting. A chart review was performed of 528 women who had had a total of 535 operations for prolapse at least 4 years earlier. Those who had not had further pelvic floor surgery were sent a questionnaire exploring their satisfaction with surgery. The outcome could be determined for 406 (75%) of the women, of whom 238 (59%) were improved. In multivariate analyses, women were more likely to be satisfied with surgery if they were older, did not have a prior or concurrent colposuspension, if the prolapse operation included a hysterectomy and if they were operated on by one particular team. Selection of the right operation for the correct patient by the correct surgeon could improve the success of prolapse surgery.

**Editorial Comment:** The main focus of this article was respondent perception of the success of surgery. A purist would take issue with many things about this article, including the methods of subject selection, the use of a nonvalidated questionnaire and the lack of any supporting examination. Nevertheless, the article certainly suggests that, as with many types of surgery, the “long-term success” is less than we would like it to be. The article cites the literature as describing a lifetime risk of repeat surgery for uterovaginal prolapse of 29%, and correctly states that “this may represent only the tip of the iceberg as women who have had one failed procedure may opt for conservative management rather than further surgery.” A 59% improvement rate is certainly nothing to write home about, especially if the failure rate in the nonresponders was higher. Another interesting factoid derived from the data is that, whereas recent literature has noted a higher complication rate and a lower “success” rate with lower volume surgeons up to a certain point, in this study the surgeon with the lowest success rate performed more procedures than the other surgical teams. It would seem that what is needed is a study that evaluates symptomatic and anatomical “success” rates for the surgery of uterovaginal prolapse stratified by the type (or combination types) of prolapse, degree of prolapse and type of repair utilized, including the use of synthetics as a separate category.

Alan J. Wein, M.D., Ph.D. (Hon.)
Sexual Function After Vaginal Surgery for Pelvic Organ Prolapse and Urinary Incontinence

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Objective: The objective of the study was to assess sexual function following vaginal surgery and to determine the impact on postoperative sexual function in women who undergo concurrent antiincontinence procedures, compared with those who do not. Study Design: Sexually active women undergoing vaginal repairs for prolapse or urinary incontinence were prospectively enrolled. Subjects completed the Female Sexual Function Index (FSFI), Urogenital Distress Inventory (UDI-6), Incontinence Impact Questionnaire (IIQ-7), and a standardized questionnaire. Follow-up occurred at 6 months. Results: Forty-nine subjects (96%) returned their postoperative surveys; 48 were sexually active. Improvements were noted in postoperative prolapse stage, UDI-6, and IIQ-7. However, sexual function and frequency were similar. The most bothersome barrier to sexual activity before repair was vaginal bulging; postoperatively it was vaginal pain. Twelve subjects (25%) commented on the negative impact of vaginal pain postoperatively. Finally, FSFI scores were not different based on performance of antiincontinence surgery. Conclusion: Sexual function was unchanged following vaginal reconstructive surgery despite anatomic and functional improvements; lack of benefit may be attributable to postoperative dyspareunia.

Editorial Comment: This is a subject that has not received much clinical attention, but it sounds like it should. The authors comment, “We believe that we did not note overall changes in sexual function because of the exchange of 1 sexual problem for another. Many subjects reported a high degree of bother secondary to prolapse preoperatively. This led to vaginal discomfort and possibly had an impact on other sexual function such as desire, arousal, and orgasm. Following surgery, this barrier was virtually eliminated. However, in some, surgery led to dyspareunia. Although this did not result in statistically significant changes in sexual function scores, we believe it is clinically significant and worthy of our review. Our hopes would have been to improve patients’ sexual function as we restored their vaginal anatomy, not to create new or worse barriers for them. Based on these findings, we must reflect on our practices. Alterations in surgical technique to reduce vaginal tightness, adequate counseling of patients about expectations following surgery, and addressing these topics early in the postoperative period to implement therapies may help reduce these rates.” It is not clear what kind of “therapies” the authors are referring to.

Alan J. Wein, M.D., Ph.D. (Hon.)

Surgical Management of Pelvic Organ Prolapse in Women

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Background: Pelvic organ prolapse may occur in up to 50% of parous women. A variety of urinary, bowel and sexual symptoms may be associated with prolapse. Objectives: To determine the effects of the many different surgeries in the management of pelvic organ prolapse. Search Strategy: We searched the Cochrane Incontinence Group Specialised Trials Register (searched 3 May 2006) and reference lists of relevant articles. We also contacted researchers in the field. Selection Criteria: Randomised or quasi-randomised controlled trials that included surgical operations for pelvic organ prolapse. Data Collection and Analysis: Trials were assessed and data extracted independently by two reviewers. Six investigators were contacted for additional information with five
responding. Main Results: Twenty two randomised controlled trials were identified evaluating 2368 women. Abdominal sacral colpopexy was better than vaginal sacrospinous colpopexy in terms of a lower rate of recurrent vault prolapse (RR 0.23, 95% CI 0.07 to 0.77) and less dyspareunia (RR 0.39, 95% CI 0.18 to 0.86), but the trend towards a lower re-operation rate for prolapse following abdominal sacrocolpopexy was not statistically significant (RR 0.46, 95% CI 0.19 to 1.11). However, the vaginal sacrospinous colpopexy was quicker and cheaper to perform and women had an earlier return to activities of daily living. The data were too few to evaluate other clinical outcomes and adverse events. The three trials contributing to this comparison were clinically heterogeneous. For the anterior vaginal wall prolapse, standard anterior repair was associated with more recurrent cystoceles than when supplemented by polyglactin mesh inlay (RR 1.39, 95% CI 1.02 to 1.90) or porcine dermis mesh inlay (RR 2.72, 95% CI 1.20 to 6.14), but data on morbidity, other clinical outcomes and for other mesh or graft materials were too few for reliable comparisons. For posterior vaginal wall prolapse, the vaginal approach was associated with a lower rate of recurrent rectocele and/or enterocele than the transanal approach (RR 0.24, 95% CI 0.09 to 0.64), although there was a higher blood loss and postoperative narcotic use. However, data on the effect of surgery on bowel symptoms and the use of polyglactin mesh inlay or porcine small intestine graft inlay on the risk of recurrent rectocele were insufficient for meta-analysis. Meta-analysis on the impact of pelvic organ prolapse surgery on continence issues was limited and inconclusive, although about 10% of women developed new urinary symptoms after surgery. Although the addition of tension-free vaginal tape to endopelvic fascia plication (RR 5.5, 95% CI 1.36 to 22.32) and Burch colposuspension to abdominal sacrocolpopexy (RR 2.13, 95% CI 1.39 to 3.24) were followed by a lower risk of women developing new postoperative stress incontinence, but other outcomes, particularly economic, remain to be evaluated. Authors’ Conclusions: Abdominal sacrocolpopexy is associated with a lower rate of recurrent vault prolapse and dyspareunia than the vaginal sacrospinous colpopexy. These benefits must be balanced against a longer operating time, longer time to return to activities of daily living and increased cost of the abdominal approach. The use of mesh or graft inlays at the time of anterior vaginal wall repair may reduce the risk of recurrent cystocele. Posterior vaginal wall repair may be better than transanal repair in the management of rectoceles in terms of recurrence of prolapse. The addition of a continence procedure to a prolapse repair operation may reduce the incidence of postoperative urinary incontinence but this benefit needs to be balanced against possible differences in costs and adverse effects. Adequately powered randomised controlled clinical trials are urgently needed.

Editorial Comment: In the gynecological literature pelvic organ prolapse is cited as existing in 50% of parous women, and the annual aggregate rate of associated surgery is 10 to 30 per 10,000 women. There is an enormous amount of information present in this review, some useful and some not so useful. The RR numbers tell a story but one has to read the actual document to get a sense of what the numbers really are. For instance, for abdominal sacral colpopexy vs vaginal sacrospinous colpopexy the lower rate of recurrent vault prolapse translated to 3 of 84 vs 13 of 85; the number of women failing to improve to stage 2 or better was 3 of 62 vs 13 of 66; those with less postoperative dyspareunia, 7 of 45 vs 22 of 61; those with less postoperative stress incontinence, 14 of 47 vs 28 of 81; and reoperation rates for prolapse, 6 of 84 vs 14 of 85. Overall the main conclusions are 1) “the data from randomized trials are currently insufficient to guide practice” and 2) “there were insufficient data to allow evaluation of the impact of prolapse surgery on continence issues but limited information suggested that concomitant [tension-free vaginal tape] or Burch colposuspension might reduce postoperative incontinence rates: this benefit needs to be balanced against possible differences in cost and adverse effects. There was generally a lack of information on the impact of surgery on quality of life and cost issues.” Regarding implications for research, the authors conclude, “none of the objectives prestated in the protocol ... have been satisfactorily addressed, and all would benefit from testing in further good quality randomized trials... The challenge in prolapse surgery is that while the prolapse itself may cause difficulties with the bladder, bowel and sexual function, surgical correction may also affect these functions in unpredictable ways. Therefore, all trials need to include subjective, objec-
tive and patient determined outcomes, and the direct interaction with bladder, bowel and sexual function must be measured. The impact of intervention should also be assessed by utilizing validated pelvic floor and quality of life questionnaires, morbidity and cost analysis. Ideally, long term outcomes should be reported at least at 2 and 5 years after surgery.”

Alan J. Wein, M.D., Ph.D. (Hon.)

Benign Prostatic Hyperplasia

A Randomised, Placebo-Controlled Study to Assess the Efficacy of Twice-Daily Vardenafil in the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia

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Introduction: Benign prostatic hyperplasia (BPH) is associated with bothersome lower urinary tract symptoms (LUTS) and reduced patient quality of life (QoL). Phosphodiesterase (type) 5 (PDE5) inhibitors such as vardenafil are commonly used for the treatment of erectile dysfunction (ED), but have also been shown to improve the symptoms of BPH. This randomised, double-blind, placebo-controlled study investigated the effects of vardenafil on LUTS and QoL in men with BPH/LUTS, with or without concomitant ED. Methods: Men aged 45–64 yr with BPH/LUTS and an International Prostate Symptom Score (IPSS) > or =12 were randomised to receive either 10mg vardenafil or placebo twice daily. LUTS were assessed with the use of two primary efficacy parameters, IPSS score and maximum urinary flow rate (Qmax), as well as postvoid residual (PVR) urine volume; ED was measured with the use of the erectile function (EF) domain score of the International Index of Erectile Function (IIEF-EF); and QoL was assessed with the Urolife trade mark QoL-9 questionnaire. Results: After 8 wk of treatment, there was a significant improvement in the IPSS total score in the vardenafil group compared with placebo (−5.9 and −3.6, respectively; p=0.0013). Nominally significant improvements in irritative and obstructive IPSS subscores (p=0.0017 and p=0.0081, respectively), EF (p=0.0001), and Urolife QoL-9 (p<0.0001) were also associated with vardenafil treatment. Qmax and PVR urine volume did not change significantly with treatment, although baseline values were already considered close to normal. Vardenafil was generally well tolerated, with most adverse events considered mild or moderate in severity. Conclusions: Vardenafil treatment significantly improved LUTS, EF, and QoL in men with BPH/LUTS. Vardenafil may be considered a promising treatment option for men with symptoms secondary to BPH.

Editorial Comment: The use of phosphodiesterase type 5 inhibitors in the management of LUTS secondary to BPH has now been documented with the 3 currently commercially available agents approved to treat erectile dysfunction—sildenafil, tadalafil and vardenafil. There appears to be consensus that these agents improve LUTS as defined by the IPSS but do not improve objective measures such as Qmax. What is the future of these agents in the treatment of men with LUTS secondary to BPH? In most studies of these agents men with BPH have had normal baseline Qmax, so it is understandable that there would not be a significant change after administration of these agents. Would “objective” improvement increase the likelihood of these agents being used? Is this the burden that needs to be overcome before PDE5 inhibitors become a therapeutic mainstay in BPH? I believe that these agents will have limited shelf life because as a monotherapy they will have to compete with generic tamsulosin and alfuzosin, the proverbial 800-pound gorilla in future BPH management. Moreover, these agents will always be classified as “designer” drugs most appropriate to treat erectile dysfunction and,