Special Article

AAGL Practice Report: Practice Guidelines on the Prevention of Apical Prolapse at the Time of Benign Hysterectomy

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ABSTRACT   Pelvic organ prolapse may adversely impact physical, sexual and emotional health. Women with symptomatic prolapse often experience altered bladder and bowel function, increased pelvic pressure, diminution of sexual satisfaction, and altered body image. With increasing vaginal descent, various bladder, bowel, and prolapse symptoms are increased. Approximately 200,000 women undergo inpatient procedures for prolapse in the United States each year, with regional and racial differences in rates of surgery reported. The demand for health care services related to pelvic floor disorders will increase at twice the rate of the population itself. Journal of Minimally Invasive Gynecology (2014) 21, 715–722 © 2014 AAGL. All rights reserved.

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Hysterectomy is the most commonly performed gynecologic surgical procedure. In 2005, >500 000 hysterectomies were performed in the United States [1]: 64% abdominally, 22% vaginally, and 14% laparoscopically [1]. Pelvic organ prolapse is one of the most common reasons that hysterectomy is performed [2]; however, evidence suggests that hysterectomy may also be a cause of future prolapse [3–6].

Pelvic organ prolapse may adversely affect physical, sexual, and emotional health. Women with symptomatic prolapse often experience altered bladder and bowel function, increased pelvic pressure, diminution of sexual satisfaction, and altered body image. With increasing vaginal descent, various bladder, bowel, and prolapse symptoms increase [7]. Personal and health care–related costs of prolapse are high, with the annual cost of ambulatory care of pelvic floor disorders in the United States from 2005 to 2006 almost $300 million [8]. Annual direct costs for prolapse surgery in the United States are estimated to exceed $1 billion [9].

In the United States, approximately 200 000 women each year undergo inpatient procedures to treat prolapse [10], and regional and racial differences in rates of surgery have been reported [11]. The demand for health care services related to pelvic floor disorders will increase at twice the rate of the population itself [12]. The number of women who will undergo surgery to treat prolapse is projected to increase from 166 000 in 2010 to 245 970 in 2050 [13].

The true prevalence of pelvic organ prolapse is difficult to ascertain because many women with prolapse do not seek medical care. Various studies report the prevalence of symptomatic prolapse to be between 6% and 8% among adult women [14,15]. Population-based studies report that during their lifetime, 11% to 19% of women will undergo surgery to treat prolapse or incontinence [16,17].

The role of hysterectomy in the development of prolapse has been debated. Some studies have associated hysterectomy with a risk of subsequent surgery to treat pelvic organ prolapse [3,4], in particular when performed in women with existing prolapse [5,6]. Other studies have not found a correlation between hysterectomy and subsequent prolapse. Baseline data from the Women's Health Initiative of 10 727 women who underwent hysterectomy, for any reason, compared with 16 616 women with a uterus showed similar rates of cystocele (33% vs 34%) and rectocele (18% vs 19%) [18,19]. Only parity and obesity affected prolapse in that large observational comparison.

Although some studies have suggested that post-hysterectomy prolapse is more common after vaginal hysterectomy than after the abdominal approach [4,5] it is unclear whether this association is due to selection bias or whether

the technique of vaginal hysterectomy is more prone to cause surgical trauma to the vaginal support tissues. Rates of development of post-hysterectomy prolapse are compounded in that there are low institutional compliance rates with evidence-based guidelines to perform a concurrent suspension procedure during hysterectomy to treat existing prolapse [20].

Randomized trials suggest that, over the short term, cervical preservation or removal does not affect the rate of subsequent pelvic organ prolapse [21,22]. However, no studies have addressed the risk of pelvic organ prolapse many years after surgery, which may differ after total vs supracervical hysterectomy.

The purpose of this Practice Guideline is to critically review the literature and provide recommendations designed to reduce the incidence of de novo apical vaginal prolapse after hysterectomy performed to treat benign disorders.

Identification and Assessment of Evidence

This AAGL practice guideline was produced with the following search method: electronic resources including Medline, PubMed, EMBASE, EBM/Systematic Reviews, and ISI were searched for all English-language publications from 1945 to the present related to reduction of the risk of post-hysterectomy vaginal vault prolapse. The MeSH terms included all subheadings, where keywords apical prolapse, uterine prolapse, pelvic organ prolapse, vaginal vault prolapse, or hysterectomy adverse effects occurred, with colpocleisis, colpopexy, vaginal suspension repair, culdoplasty, culdeplasty, or culdosuspension, and vaginal prolapse prevention or gynecologic surgical procedures. Additional publications were identified from a manual search of the references in the identified publications, yielding 262 articles. The full text of all publications was retrieved, abstracted, tabulated, and added to a data table. Articles were reviewed for relevance to the topic, and 58 publications were identified including 6 randomized controlled trials. All studies were assessed for methodologic rigor and graded according to the classification system outlined in the Appendix at the end of this article.

Clinical Presentation of Post-Hysterectomy Prolapse

As with any form of vaginal prolapse, post-hysterectomy vaginal vault prolapse may be associated with a variety of signs and symptoms, including vaginal bulging, palpable or visible tissue protrusion, pressure, discomfort with ambulation or activity, pelvic or back pain, dyspareunia, or obstructed intercourse. Alterations in the support mechanisms may be associated with lower urinary tract symptoms including irritative or obstructed voiding, urinary retention and/or various forms of urinary incontinence, and bowel symptoms such as obstructed defecation, fecal urgency, or fecal incontinence. Symptoms of prolapse correspond poorly to compartment of defect and stage of prolapse [23].

Some of the potential mechanisms for post-hysterectomy prolapse include surgical injury to the innervation and vascularization of the pelvic floor muscles or alterations in the connective tissues. DeLancey [24] has described a system of 3 integrated levels of vaginal support. Level I consists of the cardinal and uterosacral ligaments, and suspends the vaginal apex. Level II consists of the endopelvic fascia connections to the arcus tendineus fascia pelvis, which attaches the vagina to the aponeurosis of the levator ani muscle. Level III consists of the perineal body and includes interlacing muscle fibers of the bulbospongiosus, transverse perinei, and external anal sphincter. Studies have suggested that it is the paracolpium vertical fibers at Level I that prevent prolapse of the vaginal apex [24]. Because the uterosacral–cardinal ligament complex must be divided during hysterectomy, loss of Level I support contributes to subsequent prolapse of the vaginal apex.

There is increasing recognition that anterior or posterior vaginal prolapse may have an important apical component [25,26]. Even in cases in which the leading edge of the prolapse represents the anterior or posterior vaginal compartment, failure to recognize or address apical prolapse is likely to lead to suboptimal treatment outcomes for prolapse procedures and perhaps to iatrogenic problems. Midline colporrhaphy when undertaken for an apical support defect may inadequately address the symptoms and lead to new symptoms related to vaginal stricture, foreshortening, or scar tissue.

Diagnosis of Post-Hysterectomy Prolapse

Assessment of women with symptoms of prolapse after hysterectomy should include the fundamental targeted history and physical examination. The current recommendations for objective assessment of vaginal support include use of the Pelvic Organ Prolapse Quantification (POP-Q) system. The determination of apical prolapse is made by measuring the location, relative to the vaginal hymen, of the cuff or hysterectomy scar (point C) during a maximal Valsalva maneuver and/or traction during examination. Staging using the POP-Q system is an overall assessment according to the compartment of most severe prolapse and does not call for staging of individual compartments. As described, apical prolapse is frequently associated with more severe anterior or posterior compartment prolapse but is essential to identify to formulate appropriate reparative strategies. Apical support during the POP-Q examination may help to identify how much of the observed prolapse is attributable to the apical component [27].

There is debate as to whether previously described entities including vaginal vault prolapse, enterocele, high rectocele or high cystocele are indeed separate entities or are different points along a spectrum of support disorders. The traditional teaching that vault prolapse is a failure of support of an otherwise intact vagina, whereas enterocele represents a failure in the fibromuscularis sheath of the vagina with

herniation of peritoneum, is tempting but has not been supported histologically [28]. Strict adherence to the POP-Q terminology prevents the presumptive diagnosis of which organs are affected by the lack of vaginal support and focuses rather on the vaginal supports themselves. Vaginal topography correlates poorly with the location of surrounding visceral structures [29]. Thus, researchers and clinicians may be well served to use the terms "anterior vaginal prolapse" rather than "cystocele" and "apical prolapse" rather than "vault prolapse" or enterocele.

A variety of imaging studies are available to more specifically and accurately describe the effects of vaginal support defects on the surrounding organ systems. Ultrasonography, magnetic resonance imaging, and fluoroscopy with contrast medium are among these methods that may demonstrate the organs contained within the vaginal prolapse. In some cases, it may be clinically useful to make such determinations; in addition, imaging studies may enable identification of disorders that may not be readily demonstrated during vaginal examination, such as sigmoidocele or rectal intussusception. Consequently, many providers perform some form of imaging when the symptoms often associated with prolapse are not supported by or are disproportionate to the examination findings.

Use of Uterosacral Ligaments

Native tissue repairs of apical prolapse incorporate structures such as the uterosacral ligaments to reestablish pelvic supports. In 1929, Richardson [30] described cuff angle closure incorporating the broad and uterosacral ligaments to support the vault during abdominal hysterectomy. In 1957, the McCall culdoplasty was described [31], in which the uterosacral ligaments are plicated in the midline, incorporating the cul-de-sac peritoneum and posterior vaginal cuff. This obliterates the peritoneum of the posterior cul-de-sac and elevates the vault toward the plicated uterosacral ligaments. Several adaptations of this procedure have been described using different numbers of sutures and different points of fixation [32,33]. All rely on the uterosacral ligaments for support of the vaginal apex. Similar procedures have been described for use during abdominal [34,35] and laparoscopic [36–40] hysterectomy. These approaches have not been studied in randomized trials for prevention of post-hysterectomy prolapse.

Richardson Angle Stitch

The efficacy of the Richardson angle stitch was reported in a study of unembalmed cadavers, using hanging weights attached to the vaginal apex. After total hysterectomy, there was equal resistance after hysterectomy using a Richardson angle stitch and after supracervical hysterectomy in which the uterosacral ligament was left intact [41]. Another cadaveric study that assessed vaginal apical descent before and after tying the Richardson angle stitch found that the distance

of apical descent was substantially reduced with incorporation of the cardinal and uterosacral ligaments. That study suggested that incorporation of this ligament complex to the vaginal angle during hysterectomy may prevent apical prolapse [42]. We were unable to identify any published prospective studies in living patients that evaluated the efficacy of this technique.

Vaginal Procedures

There is currently only a single randomized trial that compares techniques to prevent vault prolapse after vaginal hysterectomy performed to treat non-prolapse–related gynecologic disease. That trial [43] compared a vaginal Moschowitz-type operation, peritoneal closure of the cul-de-sac, and McCall culdoplasty for prevention of post-hysterectomy enterocele in 100 women undergoing vaginal hysterectomy. The authors found significantly fewer cases of posterior-apical vaginal prolapse (stage 2) at 3 years after McCall culdoplasty (2 of 32 [6%]) than with either peritoneal closure (13 of 33 [39%]) or the vaginal Moschowitz procedure (10 of 33 [30%]) (p = .004).

Colombo and Milani [44] performed a retrospective case-control study comparing 62 women with advanced uterovaginal prolapse who underwent sacrospinous fixation or McCall culdoplasty for prevention of post-hysterectomy vault prolapse. Although the investigators reported fewer recurrences at any vaginal site (27% vs 15%) in the McCall group at 4 to 9 years postoperatively, the results did not reach statistical significance [44].

Several case series have evaluated attachment of the vaginal cuff to the uterosacral ligaments for prevention of vaginal vault prolapse after hysterectomy performed to treat uterovaginal prolapse, rather than for prolapse prevention during hysterectomy performed to treat non-prolapse–related gynecologic disease. Inmon [45] described reattaching the apex to plicated shortened cardinal-uterosacral ligaments after vaginal hysterectomy in 106 women with grade 2 (to the introitus) to 4 (complete) prolapse. Although only 46 of 106 patients were followed up to 2 years, the authors reported no recurrences. In a series of 112 patients who underwent attachment of the cuff to the cardinal and uterosacral ligaments and high obliteration of the cul-de-sac to prevent post-hysterectomy enterocele [46], no cases of post-hysterectomy enterocele developed at 7 to 42 months after the procedure. Chene et al [47] retrospectively evaluated the outcomes in 185 women who underwent total vaginal hysterectomy and modified McCall culdoplasty to treat mild to moderate hysterocele at their institution. They reported 89.2% with stage 0 prolapse at the apex 2 years after surgery [47]. Given [48] retrospectively reviewed 68 patients at 2 to 22 years (mean, 7 years) after McCall culdoplasty performed to treat moderate to severe apical prolapse and noted only 2 failures (although this was not defined). Hoffman et al [49] reported a ureteral obstruction rate of 4.5% in a series of 67 patients undergoing high McCall culdoplasty over a

4-year period. All were recognized and resolved intraoperatively [49]. Although these case series suggest that the uterosacral ligaments can be successfully used to prevent vaginal vault prolapse after hysterectomy performed to treat uterovaginal prolapse, they do not specifically address the issue of preventing prolapse during hysterectomy performed for non-prolapse indications.

With uterosacral ligament suspension, the vaginal cuff is reattached to the proximal uterosacral ligaments without plicating the uterosacral ligaments or obliterating the cul-de-sac. There are currently no data on the use of uterosacral ligament suspension to prevent vault prolapse after hysterectomy performed for non-prolapse indications. A recently reported randomized clinical trial compared uterosacral ligament suspension with sacrospinous ligament suspension for the treatment, but not prevention, of uterovaginal prolapse. Two years after vaginal surgery to treat stage 2 to 4 uterovaginal prolapse, women who underwent either uterosacral ligament suspension or sacrospinous ligament suspension had similar surgical cure rates, functional outcomes, and rates of adverse effects [50].

Laparoscopic Procedures

The only study that evaluated laparoscopic uterosacral ligament suspension was a retrospective comparison of 96 patients undergoing vaginal uterosacral ligament suspension with 22 patients undergoing laparoscopic uterosacral ligament suspension and found no substantial difference in recurrent apical prolapse (6% in the vaginal group and 0% in the laparoscopic group) [51]. That study identified a 4% rate of ureteral compromise recognized intraoperatively in the vaginal group and 0% in the laparoscopic group, although this was not statistically significant.

Abdominal Procedures

We identified a retrospective study that evaluated 250 women who underwent prophylactic uterosacral ligament suspension to prevent post-hysterectomy vault prolapse during abdominal hysterectomy [34]. That study reported only a single complication, that is, a rectovaginal hematoma that resolved spontaneously, and no cases of postoperative vaginal vault prolapse. However, the "Results" section is largely qualitative, with no objective measures reported such as POP-Q or Baden-Walker examinations postoperatively.

A case series reported by Lowenstein et al [52] reported outcomes and complications after abdominal uterosacral suspension for treatment of pelvic organ prolapse. At 1-year follow up, they found a 12% rate of subjective symptomatic recurrence of prolapse and a 7% rate of objective anatomic failure. In that series, there was a 9% suture erosion rate with the use of permanent sutures (Gore-Tex; W.L. Gore & Associates, Inc., Newark, DE).

We identified 2 long-term outcome studies that evaluated high uterosacral ligament suspension. The case series of Doumouchtsis et al [53] evaluated the long-term outcomes in 42 women who underwent uterosacral ligament suspension during vaginal hysterectomy to treat prolapse, with a mean follow-up of 59 months. At follow-up, 85% had no prolapse and 15% had grade 1 vault prolapse. Two patients (5%) underwent surgery to treat postoperative vaginal vault prolapse. Silva et al [54] evaluated 5-year anatomic and functional outcomes after high uterosacral ligament suspension. In that study, the rate of symptomatic apical recurrent prolapse was 1%. An additional 4.5% of patients underwent a second surgery to treat anterior and/or posterior compartment prolapse.

Procedures that Attach the Vagina to Pelvic Ligaments

Sacrospinous Ligament Fixation

Sederl [55] first described the technique of attaching the vagina to the sacrospinous ligament in 1958. It was later modified and made popular in the United States by Randall and Nichols [56]. No studies to date have evaluated the efficacy of the sacrospinous ligament suspension technique during hysterectomy, in patients without prolapse, for prevention of future prolapse.

To date, 3 randomized controlled trials have compared sacrospinous ligament suspension with abdominal sacral colpopexy for treatment of apical prolapse [57–60]. The Cochrane Database Review [60] noted that abdominal sacral colpopexy was associated with lower rates of recurrent apical prolapse and dyspareunia than was vaginal sacrospinous colpopexy. These benefits must be balanced against longer operative time, longer time to return to activities of daily living, and increased cost of the abdominal approach. As reported above, a recently reported randomized controlled trial demonstrated similar cure rates for uterovaginal prolapse at 2 years when comparing sacrospinous ligament fixation with uterosacral ligament suspension [51]. Meta-analyses of both prospective and retrospective studies [61–64] report an anatomic or "objective" failure rate of 3% to 37% [65,66]. Failure rates were higher in the anterior compartment than in the posterior and apical compartments and depended on definition of prolapse recurrence, using grade 1 vs grade 2 as criteria [66]. Beer and Kuhn [65] compiled complication events in 1922 women reported in articles indexed in Medline from 1972 to 2002. The most common complications were febrile morbidity (fever or abscess) in 4.1% and hemorrhage and transfusion in 1.9%. Damage to femoral, perineal, and sciatic nerves were reported in 1.8%, and gluteal and bladder pain in 2%.

Procedures that Attach the Vagina to the Anterior Longitudinal Ligament

There are no studies that assess this procedure for the prevention of apical vaginal prolapse. Sacrocolpopexy, a

procedure that attaches the vaginal apex to the anterior longitudinal ligament of the sacrum using permanent mesh, is generally considered the gold standard for treatment of post-hysterectomy prolapse. The success rate is reported to be between 78% and 100% when defined as lack of apical prolapse postoperatively, and between 58% and 100% when defined as no postoperative prolapse [67]. Participants in a study of women with cervical or vaginal vault prolapse were randomized to vaginal repair with bilateral sacrospinous vault suspension and paravaginal repair or to abdominal sacrocolpopexy with paravaginal repair. With a mean follow-up of 2.5 years, the relative risk of unsatisfactory outcome using the vaginal route was 2.11 (95% confidence interval, 0.9–4.9) [57], and the repeat operation rate to treat recurrence of prolapse was greater in the vaginal compared with the abdominal group (33% vs 16%).

In a study of women with vaginal vault prolapse randomized to undergo laparoscopic sacrocolpopexy or total vaginal mesh surgery, the total objective success rate was significantly greater for laparoscopic sacrocolpopexy when evaluated by blinded nonsurgical reviewers at 2 years (77% vs 43%; p < .001.). The repeat operation rate for recurrence of prolapse and/or mesh complications was significantly higher in the vaginal mesh group (22% vs 5%; p = .006) [68].

In comparing minimally invasive approaches vs sacrocolpopexy, a randomized trial reported that although both robotic and laparoscopic groups demonstrated similar vaginal support and functional outcomes at 1 year, the robotic approach was associated with longer operative time (67-minute difference; p < .001) and greater postoperative pain at rest and activity, compared with the laparoscopic group [69]. Sacrocolpopexy is not performed for prolapse prevention, and there are no current studies evaluating its use for prophylaxis.

Summary of Recommendations

1. McCall culdoplasty may be performed during vaginal hysterectomy to treat non-prolapse–related disease to reduce the risk of postoperative apical prolapse for up to 3 years (Level B).
2. Uterosacral ligament suspension may be performed during abdominal (Level B) and laparoscopic (Level C) hysterectomy to reduce the risk of post-hysterectomy vaginal vault prolapse.
3. Sacrospinous ligament fixation and abdominal sacrocolpopexy are not recommended for prevention of prolapse during hysterectomy to treat non-prolapse–related disease (Level C).

Recommendations for Future Research

Available data guiding gynecologic surgeons about management of the vaginal vault for prevention of post-hysterectomy prolapse are limited. Randomized trials comparing apical support procedures performed during hysterectomy to treat non-prolapse–related disease are urgently needed because both hysterectomy and vaginal vault prolapse are common. Specifically, a randomized trial comparing McCall culdoplasty with uterosacral ligament plication with uterosacral ligament suspension without plication is important because both procedures are accessible to the non-urogynecologic surgeon.

Acknowledgment

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Appendix

This report was developed under the direction of the Practice Committee of the AAGL as a service to its members and other practicing clinicians. The members of the AAGL Practice Committee have reported the following financial interest or affiliation with corporations: Jason A. Abbott, PhD, FRANZCOG—Consultant, Speakers Bureau: Hologic; Krisztina I. Bajzak, MD, FRCSC, MSc—nothing to disclose; Isabel C. Green, MD—nothing to disclose; Volker R. Jacobs, MD, PhD, MBA—nothing to disclose; Neil P. Johnson, MD, CREI, FRANZCOG, FRCOG, MRCGP—nothing to disclose; Marit Lieng, MD, PhD—nothing to disclose; Malcolm G. Munro, MD—Consultant: Abbott Laboratories, Aegea Medical, Bayer Healthcare Corp., Boston Scientific Corp., Channel Medical, CooperSurgical, EndoSee Corp., Ethicon Women's Health & Urology, Femasys, Gynesonics; Stock ownership: Baxter, Conceptus Inc, Halt Medical, Hologic, Idoman Teoranta, Karl Storz Endoscopy, Sony; Sukhbir Singh, BSc, MD, FRCSC—Consultant: Abbott Laboratories, Ethicon Endo-Surgery; Grants/Research: Bayer Healthcare Corp., Covidien; Speakers Bureau:, Ethicon Endo-Surgery, Minerva Surgical; Eric R. Sokol, MD—Consultant: American Medical Systems; Stock ownership: Pelvalon; Grants/Research: Contura.

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Appendix	
Quality of Evidence and Strength of Recommendations: US Preventive Services Task Force [36]	
I	Evidence obtained from at least one properly designed randomized controlled trial
II	Evidence obtained from non-randomized clinical evaluation
II-1	Evidence obtained from well-designed, controlled trials without randomization.
II-2	Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research center.
II-3	Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
III	Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Recommendations, based on the highest level of evidence found in the data, are provided and graded according to the following categories:

Level A-Recommendations are based on good and consistent scientific evidence.

Level B-Recommendations are based on limited or inconsistent scientific evidence.

Level C-Recommendations are based primarily on consensus and expert opinion.