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

Background

Hysterectomy is the most commonly performed gynecological surgical procedure. In 2005, over 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 \([2]\), but evidence suggests that hysterectomy may also be a cause of future prolapse \([3-6]\).

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 \([7]\). Personal and health care related costs for prolapse are high, with the annual cost of ambulatory care of pelvic floor disorders in the United States from 2005 to 2006 being almost $300 million \([8]\). Annual direct costs for prolapse surgery in the United States are estimated to exceed 1 billion dollars \([9]\).

Approximately 200,000 women undergo inpatient procedures for prolapse in the United States each year \([10]\), with regional and racial differences in rates of surgery 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 total
The number of women who will have surgery for 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 11 to 19% of women undergo surgery for prolapse or incontinence during their lifetime [16-17].

Hysterectomy is associated with a risk of subsequent surgery for pelvic organ prolapse [3-4], particularly when performed on women with existing prolapse [5-6]. While some studies suggest that post hysterectomy prolapse is more common following vaginal hysterectomy, than after the abdominal approach [4-5] it is unclear if 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 the development of post-hysterectomy prolapse are compounded by the fact that there are low institutional compliance rates with evidence-based guidelines to perform a concurrent suspension procedure at the time of hysterectomy for existing prolapse treatment [18].

Randomized trials suggest that, over the short term, cervical preservation or removal does not affect the rate of subsequent pelvic organ prolapse [19-20]. However, no studies have addressed the risk of pelvic organ prolapse many years after surgery, which may differ after total versus 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 following hysterectomy for benign disorders.

**Identification and Assessment of Evidence**

This AAGL practice guideline was produced with the following search methodology; electronic resources including Medline, PubMed, EMBASE, EBM/Systematic Reviews, and ISI were searched for all English publications from 1945 to 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 hand 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, with 58 publications identified, including 6 RCTs. All studies were assessed for methodological rigor and graded according to the classification system outlined at the end of this document.

**Clinical Presentation of Post-Hysterectomy Prolapse**

As for any form of vaginal prolapse, post-hysterectomy vaginal vault prolapse may be associated with a variety of symptoms or complaints, 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, as well as bowel complaints such as obstructed defecation, fecal urgency or fecal incontinence. Symptoms of prolapse correspond poorly to compartment of defect and stage of prolapse [21].

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 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. Level III consists of the perineal body and includes interlacing muscle fibers of the bulbospongiousus, transverse perinei, and external anal sphincter. Studies suggest it is the paracolpium's vertical fibers at Level I that prevent prolapse of the vaginal apex [22]. Since 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 a significant apical component [23-24]. Even in cases where 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 woman’s symptoms and lead to new complaints related to
vaginal stricture, foreshortening, or scar tissue.

**Diagnosis of Post-Hysterectomy Prolapse**

Assessment of women with symptoms of prolapse following hysterectomy
should include the fundamental targeted history and physical examination. The
current recommendations for objective assessment of vaginal support included 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 maximal valsalva and/or traction
during examination. Staging, by 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 above, apical prolapse is frequently
associated with more severe anterior or posterior compartment prolapse, but is
essential to identify in order 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 [25].

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 in fact 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 a herniation of peritoneum is tempting, but has not been supported
histologically [26]. Strict adherence to the POP-Q terminology avoids the
presumptive diagnosis of which organs are affected by the lack of vaginal support,
and focuses rather on the vaginal supports themselves. Vaginal topography has
been shown to correlate poorly with the location of surrounding visceral structures
[27]. As such, researchers and clinicians may be well served to use “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.
Ultrasound, MRI and fluoroscopy with contrast are among these modalities, which
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 help to identify disorders that may not be readily demonstrated during a
vaginal exam, such as sigmoidocele or rectal intussusception. Consequently, many
providers obtain some form of imaging when the symptoms often associated with
prolapse are not supported by, or are disproportionate to the examination findings.

Use of the Uterosacral Ligaments

Native tissue repairs of apical prolapse incorporate structures such as the
uterosacral ligament to reestablish pelvic supports. In 1929, Richardson described
cuff angle closure incorporating the broad and uterosacral ligaments to support the
vault during abdominal hysterectomy [28]. In 1957, the McCall culdoplasty was
described [29] 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 utilizing different numbers of sutures and different points of fixation [30-
31]. All rely on the uterosacral ligaments for support of the vaginal apex. Similar
procedures have been described for use during abdominal [32-33] and
laparoscopic[34-38] hysterectomy. These approaches have not been studied in
randomized trials for the prevention of post-hysterectomy prolapse.

Richardson angle stitch

The efficacy of this procedure was reported in a study of unembalmed
cadavers using hanging weights attached to the vaginal apex. Following total
hysterectomy, there was equal resistance following hysterectomy with a Richardson
angle stitch and after supracervical hysterectomy where the uterosacral ligament
was left intact [39]. Another cadaveric study assessing vaginal apical descent before
and after tying the Richardson angle stitch found that the distance of apical descent
was significantly reduced (cm difference and p value if mention significance) with
incorporation of the cardinal and uterosacral ligaments. This study suggested that
incorporation of this ligament complex to the vaginal angle at the time of
hysterectomy may prevent apical prolapse [40]. We were unable to identify any
published prospective studies on living patients evaluating the efficacy of this
technique.
Vaginal Procedures

There is currently only one randomized trial comparing techniques to prevent vault prolapse after vaginal hysterectomy performed for non-prolapse related gynecologic disease. This randomized trial [41] compared a vaginal Moschowitz-type operation, peritoneal closure of the cul-de-sac, and McCall’s 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) three years following the McCall’s culdoplasty 2/32 (6%) than with either peritoneal closure 13/33 (39%) or the vaginal Moschowitz procedure 10/33 (30%) (p=.004).

Colombo and Milani performed a retrospective case-control study comparing 62 women with advanced uterovaginal prolapse who underwent sacrospinous fixation or McCall culdoplasty for the prevention of post-hysterectomy vault prolapse. Although the investigators reported fewer recurrences at any vaginal site (27% vs 15%) in the McCall group 4 - 9 years postoperatively, the results did not reach statistical significance [42].

Several case series have evaluated attachment of the vaginal cuff to the uterosacral ligaments for the prevention of vaginal vault prolapse after hysterectomy performed for uterovaginal prolapse (rather than for prolapse prevention at the time of hysterectomy for non-prolapse related gynecologic disease). Inmon 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. While only 46/106 patients were followed to 2 years, the authors reported no recurrences. In a series of 112 patients who had attachment of the cuff to the cardinal and uterosacral ligaments and high obliteration of the cul-de-sac to prevent post-hysterectomy enterocele [43], no cases of post-hysterectomy enterocele developed from 7 to 42 months after the procedure. Chene et al. retrospectively evaluated the outcomes of 185 women who underwent TVH and modified McCall culdoplasty for “mild to moderate hysterocele” at their institution. They reported 89.2% with stage 0 prolapse at the apex 2 years after surgery [44]. Given retrospectively reviewed 68 patients 2 - 22 years (average 7 years) after McCall culdoplasty performed for moderate to severe apical prolapse and noted only 2 “failures” (although this was not defined)[45]. Hoffman 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 [46]. While these case series suggest that the uterosacral ligaments can be successfully utilized to prevent vaginal vault prolapse after hysterectomy done for uterovaginal prolapse, they do not specifically address the issue of preventing prolapse during hysterectomy for non-prolapse indications.

With uterosacral ligament suspension (USLS), 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 USLS to prevent vault prolapse following hysterectomy performed for non-prolapse indications. We therefore reviewed articles that examined the efficacy of uterosacral ligament suspension performed at the time of hysterectomy for prolapse in addition
to those evaluating prophylactic uterosacral ligament suspension performed to prevent post hysterectomy vault prolapse.

**Laparoscopic Procedures**

The only study evaluating laparoscopic uterosacral ligament suspension is a retrospective comparison of 96 patients undergoing vaginal uterosacral ligament suspension to 22 undergoing laparoscopic uterosacral ligament suspension found no significant difference in recurrent apical prolapse (6% in the vaginal group and 0% in the laparoscopic group) [47]. This study identified a 4% rate of ureteral compromise recognized intraoperatively in the vaginal group, with 0% in the laparoscopic group, although this was not statistically significant.

**Abdominal Procedures**

We identified one retrospective study evaluating 250 women having prophylactic uterosacral ligament suspension to prevent post-hysterectomy vault prolapse at the time of abdominal hysterectomy [32]. This study reports only a single complication (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 exams postoperatively).

Lowenstein et al.’s case series [48] reported outcomes and complications following abdominal uterosacral suspension (AUSS) for the 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
this series, there was a 9% suture erosion rate with the use of permanent (GoreTex) sutures. We identified two long-term outcome studies evaluating high uterosacral ligament suspension. Doumouchtsis’ case series [49] evaluated the long-term outcomes in 42 women who had uterosacral ligament suspension performed at the time of vaginal hysterectomy for prolapse, with a mean follow-up time of 59 months. At follow-up, 85% had no prolapse; 15% had grade 1 vault prolapse. Two patients (5%) underwent surgery to treat postoperative vaginal vault prolapse. Silva et al. [50] evaluated 5-year anatomic and functional outcomes following high uterosacral ligament suspension. In this study, the rate of symptomatic apical recurrent prolapse was 1%. An additional 4.5% of these patients underwent a second surgery to treat anterior and/or posterior compartment prolapse.

Procedures that attach the vagina to pelvic ligaments

Sacrospinous ligament fixation

Soderl 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 [51]. There are no studies to date evaluating the efficacy of the sacrospinous ligament suspension technique at the time of hysterectomy (in those without prolapse) for prevention of future prolapse. There are no RCTs assessing the efficacy of the sacrospinous ligament fixation for the treatment of uterovaginal and/or vaginal vault prolapse [52-55]. Meta-analyses of prospective (from 52-55) and retrospective (from 52-55) studies
report an anatomic or ‘objective’ failure rate from 3-37% [56-57]. Failure rates were higher in the anterior compartment than in the posterior and apical compartments and dependent on definition of prolapse recurrence (using Grade 1 vs Grade 2 as criteria) (Morgan ref). Beer and Kuhn compiled complication events of 1922 women reported in articles indexed in Medline from 1972 to 2002. It showed that most common complications were that of 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 78-100% when defined as lack of apical prolapse postoperatively, and between 58-100% when defined as no postoperative prolapse [58]. In a study of women with cervical or vaginal vault prolapse participants were randomized to a vaginal repair (with bilateral sacrospinous vault suspension and paravaginal repair) or an abdominal sacrocolpopexy (with paravaginal repair). With a mean follow up period of 2.5 years, the relative risk of unsatisfactory outcome with the vaginal route was 2.11 (95%, CI 0.9-4.9) [59] and reoperation rate
for recurrence of prolapse was greater in the vaginal compared to the abdominal
group (33% vs 16%).

A study of women with vaginal vault prolapse randomized to laparoscopic
sacrocolpopexy or total vaginal mesh surgery, the total objective success rate was
significantly greater for laparoscopic sacrocolpopexy compared to vaginal mesh
when evaluated by blinded nonsurgical reviewers at 2-years (77% vs 43%, p< .001.)
Reoperation rate for recurrence of prolapse and/or mesh complications was
significantly higher in the vaginal mesh group compared to those randomized to
laparoscopic sacrocolpopexy (22% vs 5%, p=.006) [60].

In comparing minimally invasive approaches to sacrocolpopexy, a
randomized trial reported that while 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 min difference; p<.001)
and greater post-operative pain at rest and activity compared to the laparoscopic
group [61]. Sacrocolpopexy is not used for prolapse prevention and there are no
current studies evaluating its use for prophylaxis.

Summary of Recommendations

1. McCall’s culdoplasty may be performed at the time of vaginal hysterectomy
for 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 at the time of abdominal (Level B) and laparoscopic (Level C) hysterectomy to reduce the risk of post-hysterectomy vaginal vault prolapse.

3. Sacrospinous ligament fixation and abdominal sacral colpopexy are not recommended for the prevention of prolapse at the time of hysterectomy for non-prolapse related disease. (Level C).

Recommendations for future research

Available data guiding gynecologic surgeons about management of the vaginal vault for the prevention of post-hysterectomy prolapse are limited. Randomized trials comparing apical support procedures performed at the time of hysterectomy for non-prolapse related disease are urgently needed since both hysterectomy and vaginal vault prolapse are common. Specifically, a randomized trial comparing McCall’s culdoplasty (with uterosacral ligament plication) to uterosacral ligament suspension (without plication) is important, since both procedures are accessible to the non-urogynecologic surgeon.
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Studies were reviewed and evaluated for quality according to the method outlined by the US Preventive Services Task Force.

Class I Evidence obtained from at least 1 properly designed randomized controlled trial.

Class II Evidence obtained from nonrandomized 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 1 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.

Class III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Based on the highest level of evidence found in the data, recommendations 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.

Acknowledgement

This report was developed under the direction of the Practice Committee of the AAGL as a service to their 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, Hologic—Consultant, Speakers Bureau; Krisztina I. Bajzak, MD, FRCSC, MSc, Nothing to disclose; Isabel C. Green, M.D., Nothing to disclose; Volker R. Jacobs, MD, PhD, MBA, Nothing to disclose. Neil P. Johnson, M.D., CREI, FRANZCOG, FRCOG, MRCGP, Nothing to disclose; Marit Lieng, MD, PhD, Nothing to disclose; Malcolm G. Munro, M.D., Abbott Laboratories—Consultant, Aagea Medical—Consultant, Stock Ownership, Baxter—Consultant, Bayer Healthcare Corp.—Consultant, Boston Scientific Corp. Inc.—Consultant, channel Medical—Consultant, Stock Ownership, Conceptus Incorporated—Consultant, CooperSurgical—Consultant, EndoSee Corp.—Consultant, Ethicon Women’s Health & Urology—Consultant, Femasys—Consultant, Gynesonics—Consultant, Stock Ownership, Halt Medical—Consultant, Stock Ownership, Hologic—Consultant, Idoman Teoranta—Consultant, Karl Storz Endoscopy—Consultant; Sony Sukhbir Singh, BSc, M.D., FRCSC, Abbott Laboratories—Consultant, Grants/Research, Speakers Bureau, Bayer Healthcare Corp.—Consultant, Speakers Bureau, Ethicon Endo-Surgery—Speakers Bureau, Minerva Surgical—Grants/Research, Covidien—Speakers Bureau; Eric R. Sokol,
The members of the AAGL Guideline Development Committee for the Prevention of Apical Prolapse at the Time of Benign Hysterectomy have reported the following financial interest or affiliation with corporations: Andrew I. Sokol, M.D.,—Nothing to disclose. Rosanne Kho, M.D.,—Nothing to disclose. Rebecca U. Margulies, M.D.,—Nothing to disclose. Charles R. Rardin, M.D.,—Nothing to disclose. Eric R. Sokol, M.D., American Medical Systems—Consultant, Pelvalon—Stock Ownership, Contura—Grants/Research.

Acknowledgement: We would like to thank Ms. Eliane Purchase, Library Assistant at Mayo Clinic-Arizona for her assistance with the literature search.