

# Abdominal hysterectomy for benign indications: evidence-based guidance for surgical decisions

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Received: 11 June 2012 / Accepted: 28 July 2012 / Published online: 15 August 2012  
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**Abstract** The purpose of this review is to provide evidence-based guidance for surgical decisions during abdominal hysterectomy performed for benign indications. Using combinations of terms “abdominal,” “hysterectomy,” and “randomized clinical trials (RCT),” we performed Ovid, PubMed, and Cochrane searches for publications between 1988 and 2008. After reviewing over 3,000 abstracts, 19 RCT were identified. There are no grade A recommendations. The only grade B suggestion is use of a bipolar vessel sealing device (LigaSure) for vascular pedicles rather than sutures. Routine closure of peritoneum should be avoided. Evidence behind 71 % (15/21) of surgical steps is insufficient (grade I). Despite its common performance, there are no grade A recommendations that can be made for the technical aspects of abdominal hysterectomy. Since almost 70 % of the surgical steps during abdominal hysterectomy

lack randomized clinical trials, adequately designed studies are needed to decrease perioperative morbidity.

**Keywords** Abdominal hysterectomy · Benign indication · Randomized controlled trials · Evidence-based medicine

## Background

Hysterectomy, or removal of the uterus, is the most common major gynecologic procedure in the USA. Approximately, 600,000 hysterectomies were performed in the USA in the early 2000s [1] and 20 million US women have had their uterus removed [2]. From 1994–1999, the overall hysterectomy rate for US female was 5.5 per 1,000 women who are at least 15 years old [2]. Though the uterus can be removed vaginally, or with laparoscopy, the most common route is with open abdominal hysterectomy (AH). In 2003, there were 538,722 hysterectomies for benign disease, and about two thirds (66 %) of them were performed by abdominal laparotomy [3].

While the mortality with AH for benign indications is 0.25 per 1,000 procedures, morbidity occurs in 3–5 %. The potential complications include infection, blood transfusion, ureteral, bladder or intestinal injury, deep venous thrombosis, and pulmonary embolism [4–6]. One possible way to decrease the surgical complication rate is to ascertain what aspects of the surgery are evidence-based and have been linked with lower morbidity. Additionally, a review of the literature would identify the surgical decisions that are not based on randomized clinical trials (RCT) and potentially encourage properly designed trials.

The purpose of the review article is to provide gynecologists with evidence-based guidance during planned AH regarding operative technique and to identify the steps that need a properly conducted RCT.

This study was presented as an oral presentation at the “CAOG Annual Meeting, Maui, Hawaii, October 25–28, 2009.”

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## Material and methods

Since this is a literature search, an approval from the Institutional Review Board was not obtained. From TeLinde's *Operative Gynecology*, tenth edition [7], a standard textbook for gynecological surgeons, we identified 21 surgical steps for abdominal hysterectomy and sought RCTs for each one. Using combinations of terms "abdominal," "hysterectomy," "randomized clinical trials (RCT)," and each surgical aspect (e.g., minilaparotomy, open vaginal cuff), we performed Ovid, Cochrane, and PubMed searches for articles published between 1988 and 2008. Each publication and Cochrane review was examined, and the pertinent references were obtained. Articles were excluded if they were in foreign language, focused on antibiotics, pain management, cancer, cost-or-decision analysis, laparoscopy, vaginal hysterectomy, or did not discuss technical aspects of abdominal hysterectomy. Additionally, we excluded studies done on cadavers.

All RCTs that focused on a surgical aspect of abdominal hysterectomy were included. If there were no RCTs, non-randomized reports with comparison groups were included in our analysis. Each step of the surgery was reviewed separately, and the evidence levels and recommendations were categorized according to the US Preventive Services Task Force (Tables 1 and 2) [8].

We excluded randomized trials that concurrently compared several steps of surgery because, with such a design, it is not feasible to directly compare the effects of each individual step [9]. We did not specifically review preoperative

consideration like prophylactic oophorectomy and perioperative aspects such as prophylactic antibiotics and prevention of venous thromboembolic events for there are ACOG guidelines to inform clinicians [10–12]. Chi-square test for trend was done, and  $P < 0.05$  was considered significant.

## Findings

Our literature search yielded 3,509 abstracts and of these, 3,392 (97 %) were excluded. The two most common reasons for excluding the articles were that the focus of the study was not a surgical aspect of hysterectomy or that it involved patients with cancer. We reviewed 117 articles that met the inclusion criteria (Fig. 1).

*Patient position* for AH is usually dorsal supine; however, some surgeons prefer lithotomy position so that a second assistant can be placed between the legs [7]. Patient position has not been studied separately in any trial (recommendation I; level of certainty, low).

*Skin cleansing* is done for the purpose to minimize wound complications and infectious morbidity. This can be performed using a variety of solutions (e.g., povidone-iodine, chlorhexidine gluconate, hexachlorophene). We did not identify any RCT evaluating the efficacy of any of these skin preparations in reducing the infectious wound morbidity (recommendation I; level of certainty, low).

*Vaginal preparation* involving preoperative cleansing has been advocated to reduce postoperative infectious morbidity. A variety of preparations are available (e.g., povidone-

**Table 1** Recommendations according to US Preventive Services Task Force (USPSTF)

Grade	Definition	Suggestions for practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service
C	The USPSTF recommends against routine providing of this service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small.	Offer or provide this service only if other considerations support the offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

**Table 2** Level of certainty regarding the net benefit

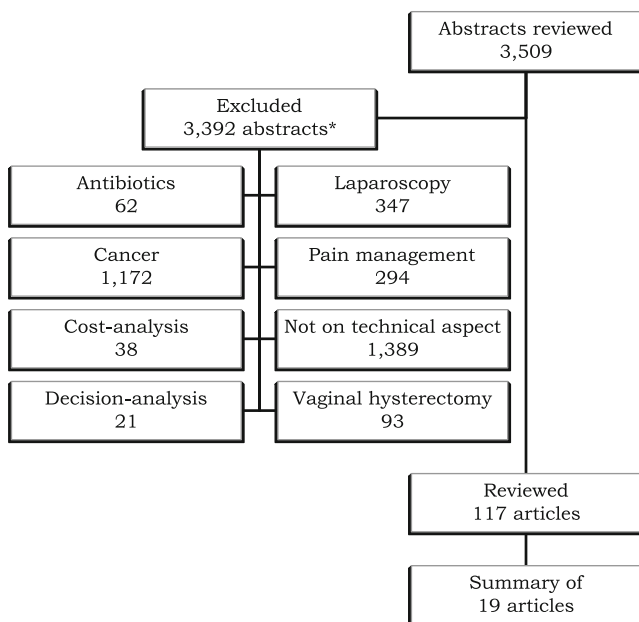
Level of certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects on the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effect of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as: <ul style="list-style-type: none"> <li>• The number, size or quality of individual studies.</li> <li>• Inconsistency of findings across individual studies</li> <li>• Limited generalizability of findings to routine primary care practice</li> <li>• Lack of coherence in the chain of evidence</li> </ul> As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion
Low	The available evidence is insufficient to assess effect on health outcome. Evidence is insufficient because of: <ul style="list-style-type: none"> <li>• The number or size of studies</li> <li>• Important flaws in study design or methods</li> <li>• Inconsistency of findings across individual studies</li> <li>• Gaps in the chain of evidence</li> <li>• Finding not generalizable to routine primary care practice</li> <li>• Lack of information on important health outcomes</li> </ul> More information may allow estimation of effects on health outcomes.

iodine solution or gel, chlorhexidine). Three randomized trials, involving 1,889 patients, studied the preoperative vaginal cleansing using either povidone-iodine solution or gel. While two RCT [13, 14] did not show a decrease in infectious morbidity, Buppasiri et al. [15] noted a significant decrease with febrile morbidity. Specifically, they noted that the relative risk of infectious morbidity was 8 vs. 19 %, with

a risk difference of  $-10$ , and 95 % confidence intervals (CI) of  $-17.8$  to  $-2.2$  % (adjusted odds ratio of 0.4; 95 % CI of 0.2–0.9 %). Thus, preoperative vaginal preparation using 1 % povidone-iodine solution may decrease postoperative infectious morbidity. Compliance with the study's protocol (1,000 cc night before and day of surgery) may not be feasible in clinical practice (recommendation C; level of certainty, moderate).

*Skin incision types* for abdominal hysterectomy have not been studied separately in a trial. The skin incision can be longitudinal or transverse. Many gynecologists choose a Pfannenstiel incision for its cosmetic appeal, which is a low transverse incision (recommendation I; level of certainty, low).

*Skin incision length* during abdominal hysterectomy can be  $<6$  cm (minilaparotomy) vs.  $>6$  cm (laparotomy). There have been no RCT trials comparing the minilaparotomy vs. laparotomy with transverse or longitudinal skin incision. There is one observational study [32] with 199 patients, comparing the outcome in  $\leq 6$  vs  $>6$  cm transverse incision. The investigators conclude that minilaparotomy is an option during AH for benign indications. The study was hampered not only by a nonrandomized design but also by having significantly different uterine sizes in the two groups. Thus, while minilaparotomy may be the clinicians' and patient's preference in certain clinical situations, it cannot be recommended to improve perioperative outcomes (recommendation, I; certainty low)

**Fig. 1** Results of the literature search

*Subcutaneous incision* can be made either by a scalpel or electrocautery. One randomized clinical trial [16] with 380 patients was identified which compared electrocautery vs. scalpel in a subcutaneous incision during abdominal hysterectomy. Postoperative wound complications like seroma, hematoma, infection, or dehiscence were not significantly different in the two groups ( $P=0.4$ ). Thus, the subcutaneous tissue can safely be incised by either electrocautery or scalpel (recommendation, C; certainty, moderate).

*Fascial incision* has not been studied separately in a trial. In a low transverse Pfannenstiel incision, the fascia is usually incised transversely with the scalpel and then extended with scissors. Some clinicians advocate the use of electrocautery in the cutting mode for the fascial incision [33]. We did not identify any study ascertaining the optimum method to incise the fascia during AH (recommendations, I; certainty, poor).

*Rectus fascia dissection of the rectus muscles* with transverse fascial incision has not been studied separately during AH (recommendations, I; certainty, poor).

*Opening of the peritoneum* is achieved with either blunt or sharp dissection. During this surgical step, injury to the underlying organs and bladder inferiorly should be avoided. RCTs have not addressed what is the optimum manner to avoid these potential complications (recommendations, I; certainty, poor).

*Retractors* are used to improve the exposure during the surgery. The options include self-retaining (Balfour, Kerschner, Bookwalter, Omni-Tract, O’Conner-O’Sullivan, Mobius) or hand-held retractors (Heaney, Deaver, or Richardson). A potential complication with retractor usage is femoral nerve injury [34]. We were unable to identify any study that showed a significant decrease in the rate of this complication. Thus, the selection of the retractor should be based on surgeon’s preference (recommendations, I; certainty, poor).

*Ureter identification* during AH is advocated to avoid injury that tends to occur at the infundibulopelvic ligament where the ovarian vessels are ligated, area of the uterine artery ligation, and the bladder base. The identification may be done by direct visualization of the ureter in the retroperitoneal space on the medial leaf of the broad ligament, palpation, or prophylactic placement of ureteral catheterization. No RCT has addressed the effect and/or optimum method of identification of the ureter to reduce its injury during AH alone (recommendations, I; certainty, low).

*Vascular pedicles* (involving, uteroovarian/infundibulopelvic ligaments, uterine vessels, and cardinal and uterosacral ligament) can be ligated by suture ligature, staples, or by electrocoagulation. Though an RCT [35] compared staples with suture ligature, we excluded this trial because the investigators did not mention if they used the stapling device for all vascular pedicles, and they used the stapling technique for the closure of vaginal vault. Thus, it is difficult

to discern what aspect of surgical technique improved the operative outcome.

We identified two RCTs ( $n=87$ ) comparing suture ligature vs. bipolar vessel sealing device (LigaSure, Boulder CO) [17, 18]. Compared to suture ligature, use of bipolar vessel sealing device (LigaSure) for vascular pedicles significantly decreased ( $P<0.01$ ) the postoperative pain during the first three postoperative days [17]. There was no significant reduction in the operating time, blood loss, perioperative complications, and hospital stay [17, 18]. Thus, we recommend use of bipolar vessel sealing device (LigaSure) for vascular pedicles (recommendations, B; certainty, moderate).

*Total vs. supracervical hysterectomy* involves removal of the uterine body and the cervix in the former, while in the latter, the cervix is kept intact. A Cochrane review [36] summarized three RCT ( $n=733$ ) (−19, −21) comparing the perioperative outcomes with these two options. The length of surgery (weighted mean difference [WMD] of 11.4 min, 95 % CI 6.6–16.3 min), the estimated blood loss (WMD 85 ml; 95 % CI 27–142 ml), and febrile morbidity (odds ratio [OR] 4.3; 95 % CI 0.25–0.75) were significantly reduced with supracervical hysterectomy. There was, however, no significant difference in the odds of requiring blood transfusion, duration of hospitalization, and return to normal activity. With supracervical hysterectomy, the likelihood of cyclical vaginal bleeding after 1 year was significantly higher when compared to total hysterectomy (11.9 vs. 0.8 %; OR 11.3, 95 % CI 4.1, 31.2). At 2 years, however, there was no significant difference in ongoing bleeding. With 2 years after the surgery, there is no difference in the rate of urinary incontinence, constipation, and measures of sexual function.

One of the RCTs [22] summarized in the Cochrane review published follow-up (mean 9 years, range 7–11 years) of 65 % (181 of 265) of the cohorts that were randomized. There was no long-term difference with total or supracervical hysterectomy with regards to quality of life, mental health, and pelvic organ function. Urinary and bowel function variables did not change significantly.

Thus, for short-term benefit (operative time, blood loss, and febrile morbidity), there is a role for supracervical abdominal hysterectomy in selected women, though there are no long-term advantages (recommendations, C; certainty, high).

*Vaginal cuff open vs. closed* are the two options once the corpus and the cervix are removed. An open vaginal cuff may provide drainage and potentially prevents infective morbidity. We identified four RCTs ( $n=612$ ) published between 1992 and 1998 [23–26]. Though they differed in how they closed the cuff and the primary outcomes, two of three RCTs noted a significant decrease in the operative time when the cuff was closed, possibly due to the hemostasis at the vaginal cuff obtained during closure with staples or sutures [23, 26]. Using staples to close the cuff [23], there

was significant improvement in intraoperative hemostasis and granulation at 6 weeks postoperative. Compared to when the cuff is open, the amount of fluid in the pelvis with a closed cuff is significantly higher on postoperative day 5 [26]. This, however, was not associated with improved febrile morbidity (recommendations, C; certainty, moderate).

*Vaginal cuff closure* may be achieved with absorbable staples or with sutures. Only one RCT ( $n=60$ ) compared these two options and noted that there was no significant difference in the operative time and febrile morbidity [27]. Thus, there is no clinical advantage of using staples (recommendations, C; certainty, moderate).

*Angle stitch* consists of reattachment of cardinal and uterosacral ligament to the vaginal cuff with the aim of preventing apical prolapse [37]. Though classical teaching advocates this surgical step, we did not identify either RCT or observational studies (recommendations, I; certainty, low).

*Intraabdominal irrigation*, done to decrease perioperative morbidity with normal saline before abdominal wall closure, is advised [7]. We did not find any RCTs evaluating irrigation vs. no irrigation (recommendations, I; certainty, low).

*Peritoneal closure* involves closure of the parietal and visceral peritoneum. We identified three RCTs ( $n=298$ ) comparing closure of the peritoneum with nonclosure in AH. While two trials evaluated either visceral [28] or parietal peritoneal closure [29], one studied the closure of both layers [30]. Nonclosure of the peritoneum, when compared with closure of either single layer or both layers, significantly reduced the operative time in all three trials. The estimated blood loss is also significantly less in the nonclosure group in one trial (45-ml reduction,  $P=0.03$ ). There is no significant difference in the postoperative pain, febrile morbidity, wound infection, and hospital stay between peritoneal closure and nonclosure groups. Thus, routine peritoneal closure is not recommended (recommendations, D; certainty, moderate).

*Techniques of fascial closure* include use of running or interrupted delayed absorbable sutures. We did not identify any RCT studying fascial closure technique in AH for benign pathology (recommendations, I; certainty, low).

*Irrigation of the subcutaneous tissue* to decrease wound complications in AH has not been evaluated separately by RCT (recommendations, I; certainty, low).

*Subcutaneous tissue closure vs. no closure* are two options before skin approximation to minimize wound-related morbidity. We identified one RCT ( $n=60$ ) comparing closure with 2-0 polyglycolic acid (Dexon) vs. nonclosure in patients undergoing AH with  $\geq 2.5$ -cm thickness of the subcutaneous tissue [31]. Mid-line vertical incision was used in 47 %, while the remaining patients had a Pfannenstiel incision. There were fewer seromas, infections, and wound disruptions in the suture group, but statistical significance was not reached. The RCT lacked sample size

calculations and did not perform any statistical analysis (recommendations, C; certainty, low).

*Closure of the skin* techniques include use of staples, subcuticular suture reinforced with surgical tape (e.g., Steri-Strips), or 2-octyl-cyanoacrylate skin adhesive (Dermabond, distributed by Ethicon, Inc). We did not find any RCTs that address the optimum method of skin closure in AH (recommendations, I; certainty, low).

## Comments

In the USA [3], there are 69 hysterectomies performed per hour, and for benign disease, 41 abdominal hysterectomies are done every hour. While the likelihood of postoperative morbidity is about 4 % [4], this rate may decrease further if RCTs with AH demonstrate a clinically significant decline in perioperative complications. A summary of published RCTs would not only allow us to identify the surgical steps that should be performed because of the existing evidence but also encourage investigators to design additional randomized studies.

There are three findings of this review. First, after reviewing over 3,000 abstracts, we identified only 19 RCTs [13–31] that met the inclusion criteria. These trials included 4,129 patients (Table 3). The surgical step with the largest number of cohorts ( $n=1,899$ ) examined the use of vaginal irrigation before AH, and the one with the fewest patients ( $n=60$ ) focused on closing the vaginal cuff with sutures vs. staples [33]. Interestingly, of these 19 studies, only three [16, 20, 27] or 16 % of RCTs were done in the USA. Thus, our evidence-based knowledge of AH is derived from a limited number of studies, with small sample size, done in foreign countries. There is, therefore, an urgent need for additional randomized trials, including in the USA.

The second finding is that 71 % (15/21) of the surgical decisions gynecologists make during AH have insufficient (grade I) evidence. This is understandable considering the limited number of RCTs. About 24 % (5/21) of surgical steps are based on grade C evidence, indicating that these steps should not be done routinely but on an individual basis. We identified only one (5 %) grade D recommendations and that is the peritoneum should not be closed. Using similar analysis, Berghella et al. [9] concluded that with cesarean delivery, neither parietal nor visceral peritoneal layer should be closed (grade D). Though there were no grade A recommendations for AH, there was one grade B suggestion: compared to suture ligation, use of a bipolar vessel sealing device (LigaSure) for vascular pedicles significantly decreases postoperative pain during the first three postoperative days (Table 3). However, this study involved a small sample size of only 57 patients. Thus, if this surgical step is advocated to be done routinely, then an RCT that is compliant with Consolidated Standards of Reporting Trials (CONSORT) guidelines [38] should be conducted.

**Table 3** Evidence-based recommendations for abdominal hysterectomy

Technical aspect	RCT	Number	Rec	Certainty	Comment
Patient position	0		I	Low	
Skin cleaning	0		I	Low	
Vaginal preparation	3	1,899	C	Mod	Povidone-iodine vaginal antiseptics may reduce the overall infection morbidity after abdominal hysterectomy. Compliance with protocol (1,000 cc night before and day of surgery) may not be feasible.
Skin incision type			I	Low	
Skin incision length (minilaparotomy)	0		I	Low	
Subcutaneous incision	1	380	C	Mod	Incision of subcutaneous tissue by electrocautery or scalpel does not influence the rate of wound complications.
Fascial incision	0		I	Low	
Rectus fascia dissection	0		I	Low	
Opening peritoneum	0		I	Low	
Retractors	0		I	Low	
Ureter identification	0		I	Low	
Vascular pedicles: suture ligature vs. bipolar vessel sealing device ligature	2	87	B	Mod	Compared to suture ligature, use of bipolar vessel sealing device (LigaSure) for vascular pedicles significantly decreases postoperative pain during first 3 postoperative days.
Total vs. supracervical hysterectomy	4	733	C	High	Compared to total, supracervical hysterectomy is associated with a significant decrease in the duration of surgery, intraoperative blood loss and fever. Postoperative cyclical bleeding up to a year is significantly more common with supracervical than total hysterectomy.
Vaginal cuff open vs. closed (sutures or staples)	4	612	C	Mod	With staples intraoperative time is significantly reduced. Granulation at 6 weeks is significantly less with staples than open.
Vaginal cuff closed suture vs. staples	1	60	C	Mod	No clinical advantage of closing the vaginal cuff with suture or staple.
Angle stitch	0		I	Low	
Intraabdominal Irrigation	0		I	Low	
Peritoneal closure	3	298	D	Mod	Not recommended because peritoneal closure provides no postoperative benefits while unnecessarily increasing surgical time and anesthesia exposure.
Techniques of fascial closure	0		C	Low	
Subcutaneous tissue closure vs. nonclosure	1	60	I	Low	No significant difference in closure vs no closure but the trial design was poor.
Closure of skin with staples vs. subcuticular suture	0		I	Low	
Total	19 <sup>a</sup>	4,129			

RCT randomized clinical trial, Rec recommendation

<sup>a</sup> The Cochrane review [36] is a summary of three RCTs [19–21]

The third finding of the study focuses on the comparison of evidence for cesarean delivery (CD) vs. AH. The reasons for comparing the two surgeries are that they are the two most common major procedures done by an obstetrician-gynecologist, and it allows us to determine to what extent

RCTs have been done to minimize postoperative morbidity. Previously, Berghella et al. [9] reported that, of 44 surgical decisions during CD, 16 % had grade A recommendations compared to none for AH. Overall, the distribution of the recommendations for the two common surgical procedures

is significantly different ( $P=0.029$ ). For CD, 43 % of the recommendations were grade I and for AH, 71 %. Thus, it seems more RCTs have been done for CD than AH. Another difference noted between the different surgical steps of CD and AH is that, in CD, the suture closure and drainage of >2-cm subcutaneous tissue has been recommended as level A [9, 39], whereas in AH, the same recommendation was not observed. This may, again, be due to lack of adequately powered and designed trials.

There are several limitations of this study that should be acknowledged. We used the tenth edition of TeLinde's *Operative Gynecology* to ascertain the technique involved with AH, and there may be surgical steps that were mentioned in earlier editions but are omitted in the latest. Edition 8 [40, 41] for example, described extra- vs. intrafascial AH, and this is not described in the newest version. Though there is an RCT comparing extra- and intrafascial AH [42], we did not include this study in our summary because this step is not mentioned in the tenth edition. We acknowledge that though RCT may show clinical benefit, the recommendation may be difficult to implement in routine practice. Perioperative vaginal irrigation, for example, with 1,000 ml of povidone-iodine vaginal antiseptics on the night before and prior to start of surgery decreased infectious morbidity [15] but seems difficult to implement routinely. While we excluded RCTs that combined AH with other major gynecological surgeries, there may be some useful information from these reports. We excluded manuscripts that focused on other surgeries in conjunction with AH and hysterectomy for cancer because the postoperative outcomes may be different when the surgery is done alone or without underlying cancer. Chou et al. [43] for example, randomized over 3,000 patients to either have or not have bilateral prophylactic ureteral catheter and reported that the likelihood of ureteral injury was similar. This conclusion may be valid with AH but needs confirmation. We did not determine if the RCT trials we included were compliant with the CONSORT statements or not [38]. Compliance with the statements improves the quality of the RCT, and noncompliance with them is associated with an overestimate of the effectiveness of intervention [44].

## Conclusion

In summary, though abdominal hysterectomy is the most common major gynecologic surgery, there is a paucity of RCTs that minimize perioperative morbidity. Additionally, evidence with vaginal and laparoscopic hysterectomy needs to be reviewed.

**Conflict of interest** The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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