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Invited Editorial

Hysterectomy for benign disease: clinical practice guidelines from the French College of Obstetrics and Gynecology

Xavier Deffieux^{a,*}, Bertrand de Rochambeau^b, Gautier Chene^c, Tristan Gauthier^d, S. Huet^d, Géry Lamblin^c, Aubert Agostni^e, Maxime Marcelli^e, François Golfier^f

^aService de Gynécologie Obstétrique, Hôpital Antoine Béchère (APHP), 92140 Clamart, France

^bService de Gynécologie Obstétrique, Hôpital Privé Marne Chantierne, 77177 Brou-sur-Chantierne, France

^cCHU Lyon Est, hôpital femme mère enfant, département de gynécologie-obstétrique, université Claude-Bernard Lyon 1, 69000 Lyon, France

^dService de gynécologie-obstétrique, hôpital Mère-Enfant, CHU de Limoges, 87000 Limoges, France

^eService de Gynécologie Obstétrique, Hôpital la Conception (APHM), 13005 Marseille, France

^fService de gynécologie-obstétrique, hospices civils de Lyon, université Claude-Bernard Lyon 1, centre hospitalier Lyon Sud, 69495 Pierre-Bénite cedex, France

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ABSTRACT

Objective: The objective of the study was to draw up French College of Obstetrics and Gynecology (CNGOF) clinical practice guidelines based on the best available evidence concerning hysterectomy for benign disease.

Methods: Each recommendation for practice was allocated a grade, which depends on the level of evidence (clinical practice guidelines).

Results: Hysterectomy should be performed by a high-volume surgeon (>10 hysterectomy procedures per year) (grade C). Stimulant laxatives taken as a rectal enema are not recommended prior to hysterectomy (grade C). It is recommended to carry out vaginal disinfection using povidone-iodine solution prior to hysterectomy (grade B). Antibiotic prophylaxis is recommended during hysterectomy, regardless of the surgical approach (grade B). The vaginal or laparoscopic approach is recommended for hysterectomy for benign disease (grade B), even if the uterus is large and/or the patient is obese (grade C). The choice between these two surgical approaches depends on other parameters, such as the surgeon's experience, the mode of anesthesia, and organizational constraints (duration of surgery and medical economic factors). Vaginal hysterectomy is not contraindicated in nulliparous women (grade C) or in women with previous cesarean section (grade C). No specific hemostatic technique is recommended with a view to avoiding urinary tract injury (grade C). In the absence of ovarian disease and a personal or family history of breast/ovarian carcinoma, the ovaries should be preserved in premenopausal women (grade B). Subtotal hysterectomy is not recommended with a view to reducing the risk of peri- or postoperative complications (grade B).

Conclusion: The application of these recommendations should minimize risks associated with hysterectomy.

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Introduction

In drawing up these clinical practice recommendations, the French College of Obstetrics and Gynecology (CNGOF) conducted an exhaustive review of the literature concerning complications of hysterectomy for benign disease, with a view to reducing their prevalence.

* Corresponding author at: Service de Gynécologie Obstétrique et Médecine de la Reproduction, Hôpital Antoine Béchère, 157 rue de la Porte de Trivaux, F-92140 Clamart, France. Tel.: +33 1 45 37 44 87; fax: +33 1 45 37 49 63.

E-mail address: xavier.deffieux@aphp.fr (X. Deffieux).

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Methods

This study is based on an exhaustive review of literature meta-analyses, randomized trials, controlled studies, and large uncontrolled studies, published on the subject up until December 2015. French- and English-language articles from Medline, PubMed, EMBASE, and the Cochrane Database were searched, using key words (MeSH and no MeSH) (*hysterectomy; laparoscopy; laparotomy; supracervical; total; subtotal; vaginal; robotic; laparoscopy-assisted; vaginal cuff closure; barbed suture; ligasure; thermofusion; vaginal cuff dehiscence*). The expert editors summarized the literature for each of the questions addressed and the recommendations were established

by a “working group” (5 experts), following which these recommendations were proofread and amended by a group of expert proofreaders. Each recommendation for practice was allocated a grade, which not only depends on the level of evidence (LE1: Very powerful randomized comparative trials, meta-analysis of randomized comparative trials; LE2: Not very powerful randomized trials, well-run non-randomized comparative studies, cohort studies; LE3: case-control studies; LE4: non-randomized comparative studies with large biases, retrospective studies, transversal studies, series of cases), but also on feasibility and ethical factors. Grade A represents the scientifically established evidence; grade B represents a scientific presumption; grade C is based on a low level of evidence, generally founded on LE3 or LE4. In the absence of any conclusive scientific evidence, some practices have nevertheless been recommended on the basis of agreement between all the members of the working group (‘expert opinion’).

Results

Preoperative medication

In one study preoperative anemia was associated with increased prevalence of postoperative morbidity and mortality in major noncardiac surgery, but the study included no finding specific to hysterectomy [1]. There are various ways to correct anemia before hysterectomy or to attempt to reduce uterine volume (to avoid laparotomy or to reduce the risk of complications): iron therapy and/or induction of amenorrhea using progestins, gonadotropin-releasing hormone (GnRH) agonists, selective progesterone receptor modulators (SPRMs), estrogen/progestin combinations, etc. No study has compared these different options.

As the data concerning its use before hysterectomy are discordant, misoprostol is not recommended (expert opinion) [2–4]. The literature data are insufficiently robust to make recommendations concerning other pre- or perioperative medications (tranexamic acid, mefenamic acid, etc.).

There are data showing that SPRMs reduce abnormal preoperative bleeding in the case of fibroma, but there are no robust data on their impact on the choice of surgical approach in hysterectomy [5,6]. One trial indicated that SPRMs reduce uterine volume 50% less than GnRH agonists, but this was only a secondary end point [5].

Preoperative prescription of GnRH agonists for 3 months is associated with a decrease in uterine volume (LE1) and in perioperative blood loss (LE2), but without a decrease in the prevalence of transfusion (LE2) [7–22]. There are no robust data showing whether the prescription of GnRH agonists increases the frequency of vaginal hysterectomy. The potentially beneficial effects of GnRH agonists should be weighed against their side effects and high cost. There are no robust data on the value of associated estrogen therapy (add-back therapy) [23,24] or of the combined prescription of tibolone in hysterectomy [25–28]. Preoperative treatment with GnRH agonists is recommended in the case of hysterectomy for benign disease, for which median laparotomy is considered, bearing in mind the volume of the uterus (grade B). Uterine volume should be reevaluated after this treatment to see whether another surgical approach is possible.

Embolization and occlusion of the uterine arteries were evaluated in isolated treatment or treatment prior to myomectomy, but there is no study on their benefits in hysterectomy [29–32].

No comparative study has evaluated autotransfusion in hysterectomy, and so it is not recommended (expert opinion).

Preoperative urine and vaginal culture

No study has examined the value of urine culture before hysterectomy. As for vaginal bacterial ecology and the risk of

infection after hysterectomy, the prevalence of postoperative infection of the vaginal vault is higher when there is bacterial vaginosis before hysterectomy (LE3) [33–35]. Preoperative treatment of bacterial vaginosis reduces the risk of infection of the vaginal vault after total abdominal hysterectomy (LE3) [36]. As there is no study in the general French population of the prevalence of these vaginal infections before hysterectomy, routine vaginal sampling prior to hysterectomy is not recommended (expert opinion). If there are suggestive symptoms and vaginal sampling leads to diagnosis of vaginosis before hysterectomy, preoperative treatment of the vaginosis is recommended (grade B).

Preoperative vaginal disinfection

Preoperative vaginal disinfection with povidone-iodine solution reduces the risk of postoperative pelvic abscess (LE2) [33–36] and is recommended before hysterectomy (grade B).

Antibiotic prophylaxis

The prevalence of infections after hysterectomy is approximately 10% (LE2) [37]. Perioperative antibiotic prophylaxis with cephalosporin is associated with an approximately 50% decrease in the prevalence of infections after hysterectomy (LE3) [37–39] and is therefore recommended for hysterectomy, whatever the surgical approach (grade B).

Risk factors for laparoscopic conversion

A history of pelvic surgery (LE3) and uterine weight (LE3) are risk factors for laparoscopic conversion in the case of laparoscopic or vaginal hysterectomy [40–42].

Bladder and ureteral injury

During hysterectomy for benign disease the prevalence of bladder injury is 0.6% to 1% (LE3) and that of ureteral injury 0.04% to 0.5% (LE3) [43–45]. A history of cesarean section and a large uterus are the two identified risk factors for bladder injury (LE3) [43–45]. Associated endometriosis is an identified risk factor for ureteral injury (LE3) [43–45].

Normal findings on cystoscopy during hysterectomy do not discount the diagnosis of bladder lesion (LE3) [46–48] and therefore cystoscopy cannot be recommended (grade C). There are limited data concerning the intravenous injection of indigo carmine [49], intravesical instillation of methylene blue, and gas insufflation [50], which cannot therefore be recommended.

There is no randomized trial comparing single- and double-layer sutures of bladder injury.

Vesicovaginal fistula

The prevalence of vesicovaginal fistulas after hysterectomy for benign disease is approximately 0.1% (LE3) [38,51,52]. In the event of a perioperative bladder lesion, the risk of vesicovaginal fistulas increases (to 5%), particularly if the injury is close to the trigone (LE3) [53].

Gastrointestinal complications: injury, ileus, occlusion, and constipation

Adhesiolysis is the main risk factor for gastrointestinal complications of laparotomic hysterectomy and laparoscopic hysterectomy (LE3) [38]. Advanced age is not a risk factor for bowel problems after hysterectomy (LE4) [54]. The prevalence of gastrointestinal injury does not seem to correlate with surgical experience (LE3) [55,56].

The prevalence of postoperative reflex ileus is 0.1% to 1.2% in the case of hysterectomy for benign disease [38,57–59]. The duration of postoperative ileus is reduced by about 9 h after vaginal hysterectomy compared with laparoscopic hysterectomy (LE3) [60]. The value of chewing gum after hysterectomy has not been evaluated [61].

The prevalence of occlusion of the small intestine after hysterectomy for benign disease is low (0.5%) (LE3) [62]. Occlusion is more frequent in the case of laparotomic hysterectomy (LE3) [62].

Hysterectomy is not associated with increased prevalence of short- or long-term constipation (LE2) [63–66].

Gastrointestinal preparation before hysterectomy

No study has evaluated the impact of gastrointestinal preparation on the prevalence of gastrointestinal complications after hysterectomy for benign disease. Preoperative gastrointestinal preparation (sodium phosphate lavage) does not improve the visibility of the surgical field during laparoscopic hysterectomy for benign disease (LE2) [67]. Mechanical gastrointestinal preparation is not recommended before hysterectomy for benign disease (grade B).

Associated adnexal procedures (ovariectomy, salpingectomy)

Bilateral ovariectomy during hysterectomy for benign disease is associated with a lower incidence of breast/ovarian carcinoma (LE2) [68–72], but results in excess overall cardiovascular mortality (LE2) [68–72]. In the absence of ovarian disease and/or a personal or family history of breast/ovarian carcinoma, preservation of the ovaries is recommended in nonmenopausal women (grade B).

There are no data that justify routine adnexectomy during hysterectomy for benign disease in a menopausal woman with no risk factor for breast/ovarian carcinoma. Some data seem to show an excess risk of overall mortality in adnexectomy associated with hysterectomy up to 65 years of age (mathematical model) [70]. After the menopause, the patient's informed choice and the surgical approach should be taken into account when deciding whether or not to perform adnexectomy.

Literature reports on the impact of salpingectomy on ovarian reserve are contradictory and provide short-term results only (LE4) [73–78]. No study has evaluated the impact of salpingectomy on the onset of menopause.

The absence of salpingectomy in hysterectomy for benign disease raises a risk of further surgery, in particular for hydrosalpinx (LE4) [79–82].

Routine salpingectomy during hysterectomy for benign disease is associated with low, but not nil, operative morbidity, essentially in vaginal hysterectomy (LE4) [83–85].

Hysterectomy, tubal ligation, and bilateral salpingectomy are all associated with decreased incidence of ovarian carcinoma, but not of borderline tumors of the ovary (LE2) [86–89]. The degree of protection afforded by the combination of hysterectomy and salpingectomy has not been evaluated. In other words, no high-quality study has proven a decrease in the incidence of ovarian carcinoma if bilateral salpingectomy is performed in addition to hysterectomy. Routine bilateral salpingectomy is therefore not recommended (expert opinion). It can though be considered preoperatively together with the patient in view of the risk of further intervention for tubal disease, adnexal carcinoma, and other operative morbidity associated with salpingectomy and the theoretical risk of impact on ovarian function.

Prevention of prolapse after hysterectomy

There is no comparative study of the effect of McCall culdoplasty on a non-prolapsed uterus after hysterectomy.

Richter's sacrospinous ligament fixation has not been studied comparatively after hysterectomy on a non-prolapsed uterus. McCall culdoplasty and Richter's sacrospinous ligament fixation are not recommended during vaginal hysterectomy (expert opinion).

Urinary catheterization and hysterectomy

The prevalence of urinary infections increases significantly after 24 h of indwelling urinary catheterization (LE1) [16–18]. The prevalence of urinary retention is significantly increased by immediate ablation of the urinary catheter (LE1) [16–18]. Nonetheless, compared with 24 h, catheterization of 48 h is associated with more urinary infections, with no decrease in the prevalence of retention (LE2) [16–18].

After hysterectomy, postoperative catheterization should not exceed 24 h (grade B). There are no data allowing a recommendation regarding the duration of perioperative catheterization. It is possible to remove the catheter immediately after hysterectomy (grade C), in which case it is recommended to monitor recovery of urination, in view of the increased risk of retention (expert opinion).

Postoperative drainage

There are no data on the value of postoperative drainage after hysterectomy. Even though it is not associated with an increase in infectious complications (LE2) [93–95], intraperitoneal drainage is not recommended in hysterectomy for benign disease (grade B).

Prevalence of complications according to surgical approach

The choice criteria in the surgical approach have been widely assessed in the recent years [96–122].

Compared with the vaginal approach, the laparoscopic approach is not associated with a decrease in the prevalence of complications 6 weeks after hysterectomy for benign disease (LE2) [99].

Compared with the vaginal approach, the laparoscopic vaginal approach is not associated with a decrease in the prevalence of complications after hysterectomy for benign disease (LE2) [97,100].

Literature data comparing the prevalence of complications in vaginal hysterectomy and in robotic hysterectomy are scarce and discordant, and cannot be used to make a recommendation in the case of hysterectomy for benign disease (LE3) [102,104].

Compared with the abdominal approach by laparotomy, the vaginal approach is not associated with a decrease in the prevalence of bowel injury (urinary, gastrointestinal, or vascular) (LE2) [97]. The vaginal approach reduces the time needed for a return to normal activity in the case of hysterectomy for benign disease, compared with laparotomy (LE2) [97].

Compared with the laparoscopic approach, the robotic approach is not associated with a decrease in the prevalence of complications in the case of hysterectomy for benign disease (LE2) [97,103,105].

Compared with the abdominal approach by laparotomy, the laparoscopic approach is associated with a decrease in the prevalence of complications (all types taken together) (LE2) [101], a decrease in the prevalence of minor complications (LE2) [101], and a quicker return to normal activity in the case of hysterectomy for benign disease (LE2) [101].

Compared with the abdominal approach by laparotomy, the laparoscopic vaginal approach is associated with a decrease in the prevalence of complications (all types taken together) (LE2) [96] and of minor complications in the case of hysterectomy for benign disease (LE2) [96]. The laparoscopic vaginal approach is associated with a greater prevalence of major complications (LE2) [96].

In the case of hysterectomy for benign disease, there is an earlier return to normal activity after vaginal hysterectomy and

laparoscopic hysterectomy compared with laparotomic hysterectomy (LE2) [96,97,99,100,102–104].

Which surgical approach for the general case?

In the case of hysterectomy for benign disease, the vaginal or laparoscopic approach should be preferred (grade B). In terms of prevalence of complications, there is no difference between laparoscopic hysterectomy and vaginal hysterectomy (LE2). The choice between the two will depend on other parameters, such as the surgeon's experience, the mode of anesthesia, and organizational constraints (length of surgery and medical economic considerations). Data on the robotic approach are insufficient to recommend its use in the case of hysterectomy for benign disease (expert opinion).

Which surgical approach in the case of a large uterus?

The first difficulty is the preoperative definition of uterine volume. The literature shows that the clinical exam is sufficient to define a large uterus (>200–280 g or 12 weeks of gestation) [106,111,112]. The use of ultrasound is not recommended for measuring uterine volume (expert opinion).

Laparotomic hysterectomy and laparoscopic hysterectomy are not associated with a proven decrease in complications compared with vaginal hysterectomy (LE3) in the case of a large uterus (>12 weeks of gestation or >200–280 g) and benign disease [107–110]. In hysterectomy for benign disease, if the uterus is large, vaginal or laparoscopic hysterectomy is recommended (grade C). However, in an extreme situation (uterus estimated to be >500 g and/or narrow vagina and/or immobile uterus) there is no reliable finding to recommend a surgical approach.

Which surgical approach in the case of nulliparity?

Nulliparity is not associated with increased prevalence of complications in the case of vaginal hysterectomy for benign disease (LE4) [113–115], which is therefore not contraindicated in the case of nulliparity (grade C).

Which surgical approach in the case of a history of cesarean section?

The prevalence of complications when there is a history of cesarean section does not differ significantly between the different surgical approaches (LE3) [98,116,117]. Vaginal hysterectomy for benign disease is not contraindicated in the case of a history of cesarean section (grade C).

Which surgical approach in the case of obesity?

In the case of obesity (body mass index ≥ 30 kg/m²), laparotomic hysterectomy is associated with an increased risk of complications (LE2) [118,119,12–122]. In the case of hysterectomy for benign disease in an obese patient, vaginal or laparoscopic hysterectomy is recommended (grade C).

Impact of the technique for hemostasis on the prevalence of ureteral and bladder complications

Hemostasis is performed using sutures, bipolar forceps with a low-frequency current, heat sealing (bipolar forceps with a high-frequency current and self-regulation depending on tissue impedance), or ultrasonic shears (vibrating blade plus thermal effect with self-regulation).

No randomized trial has used the prevalence of ureteral and bladder injury as the primary end point. To show a difference, it

would be necessary to include several thousand patients. The low prevalence of ureteral injury makes it unlikely that such a trial will be conducted.

Meta-analyses of randomized trials have not shown (as secondary end point) any difference in the prevalence of urinary tract injury between bipolar coagulation (high or low frequency) and conventional sutures (LE3) [123–132]. Nonetheless, no randomized trial has had sufficient power to answer this question, given the low prevalence of this complication.

No technique for hemostasis can therefore be recommended over others with the sole aim of avoiding urinary tract injury (grade C). The choice of technique will depend on several parameters, including the surgeon's experience and medical economic considerations.

There is the question of the usefulness of a change of dissection techniques depending on how hemostasis is achieved. However, in most studies describing the operating technique, the stages of hysterectomy (exposure and dissection) do not seem to differ between techniques for hemostasis (bipolar forceps with low- or high-frequency current, ultrasound, sutures) (LE3). Some authors have described a particular surgical technique by the vaginal approach using ultrasonic shears (vibrating blade plus thermal effect) [125,126,132], but the technical features supposed to prevent ureteral injury have not been evaluated (no comparative study). As things stand no finding suggests that in order to prevent ureteral injury the dissection technique should be modified in hysterectomy using forceps with a thermal effect or ultrasonic shears, whether by the abdominal or vaginal approach.

Dissection of the broad ligament and ureterolysis

Dissection/opening of the broad ligament is defined as follows: creating a “window” over the anterior and posterior broad ligaments [133]. Laparoscopic surgery of the broad ligament and ureterolysis have not been the subject of studies with a control group (LE4) [133–136] and so are not recommended for the purpose of preventing ureteral injury during hysterectomy for benign disease (expert opinion).

Use of a uterine manipulator

The use of a uterine manipulator is not associated with a decrease in the prevalence of bladder and ureteral injury (LE4) [137–142] and so is not recommended for the purpose of preventing urinary tract injury (expert opinion).

Use of JJ ureteral stents

The routine use of JJ ureteral stents is not associated with a decrease in the prevalence of ureteral injury (LE4) [143–145] and so is not recommended in hysterectomy for benign disease (expert opinion).

Learning curve and prevalence of complications

Regardless of the surgical approach, increasing experience of the surgeon is associated with decreasing prevalence of complications (LE3) [146–151]. However, the learning curve threshold is hard to define. For laparoscopic hysterectomy, it is around 30 cases (LE3) [148]. Performing more than 10 hysterectomies a year is associated with decreased prevalence of complications (LE3) [146,150].

At least 30 hysterectomies should be performed during training (grade C). It is recommended that hysterectomy be done by a surgeon who performs at least 10 hysterectomies a year (grade C).

Peritoneal closure

Peritoneal closure in the case of vaginal hysterectomy for benign disease is not associated with a reduction in complications (LE3) [152–154]. There are no data allowing recommendation of peritoneal closure in vaginal cuff closure in vaginal hysterectomy for benign disease.

Technique of vaginal cuff closure

The risk of vaginal cuff dehiscence is below 2% [155–162]. Its prevalence is slightly increased by laparoscopic or robotic closure compared with vaginal cuff closure (LE3) [161]. After training, the difference in prevalence of dehiscence is no longer significant between the different surgical approaches (LE4) [155]. In the absence of data of sufficient level of evidence, no recommendation is therefore possible.

No study has compared the impact of different surgical approaches or different suture methods on the risk of vaginal granuloma.

No specific suture method (continuous suture versus simple stitches, continuous suture versus double continuous suture) is associated with a decrease in the risk of vaginal cuff dehiscence (LE3) [163,164]. No specific method of vaginal cuff closure is recommended in the case of hysterectomy for benign disease (grade C).

In laparoscopic or robot-assisted hysterectomy for benign disease, the use of barbed sutures for vaginal cuff closure is not associated with decrease or increase in the prevalence of complications (LE3) [165–168]. There are no data allowing recommendation of the use of barbed sutures in vaginal cuff closure after hysterectomy for benign disease (grade C).

Subtotal hysterectomy

Subtotal hysterectomy is not associated with a decrease in the prevalence of perioperative hemorrhagic or bowel complications (LE3) or with a decrease in transfusion (LE2), although blood loss is reduced (by 50–150 mL) (LE2) [169–180]. Nor is subtotal hysterectomy associated with significant improvement in the sex life of patients (LE1) [169–180]. Subtotal laparotomic hysterectomy is associated with an approximately 10-min decrease in the duration of surgery compared with total laparotomic hysterectomy (LE2) [169–182]. Subtotal laparoscopic hysterectomy is not associated with a significant decrease in the duration of surgery compared with total hysterectomy (LE2) [169–182].

Subtotal hysterectomy involves a risk of postoperative cyclical bleeding (5–20%) (LE4) and of carcinoma of the remaining neck of the cervix (0.2%) (LE4) [183–187].

Overall, subtotal hysterectomy is not recommended for attempts to reduce the risk of peri- or postoperative complications (grade B).

Morcellation of excised tissue

In many cases, morcellation of resected tissue enables hysterectomy by the vaginal or laparoscopic approach and so reduces the use of laparotomy, which is associated with more complications. A uterus can be morcellated by the vaginal or laparoscopic approach. There are no data comparing these two approaches.

Apart from the risk of bowel injury, morcellation of a uterus in the abdominal cavity also involves a risk of dissemination of an unknown malignant tumor and a risk of parasitic myomas [188–200].

There are no comparative data on the different types of morcellator (electric, mechanical, bipolar, etc.). Morcellation in a

bag could theoretically limit the risk of intraperitoneal dissemination, but no study has shown that “in bag” morcellation is associated with a decrease in the risk of complications of morcellation.

Overall, it is recommended to evaluate the neoplastic risk before hysterectomy (using histological sampling and/or imaging) when morcellation is anticipated (expert opinion). This evaluation will take into account any personal and family history predisposing to carcinoma, the patient's age, and the presence of menometrorrhagia. In the case of menometrorrhagia, endometrial biopsy should be performed when the patient presents with a risk factor for endometrial carcinoma, and in all patients over 45 years of age (grade C).

Prevention of thromboembolism

The estimated prevalence of thromboembolic complications after hysterectomy for benign disease is 0.1% when low-molecular-weight heparin prophylaxis is used (LE3) [201–207]. There are no reliable data on thromboembolic risk in the absence of any prophylaxis. Low-molecular-weight heparin prophylaxis after hysterectomy is associated with an increased prevalence of bleeding or of postoperative hematoma (odds ratio: 2.00, 95% confidence interval: 1.34–3.00) (LE3) [207]. There is no randomized trial specific to the prevention of thromboembolic risk related to hysterectomy for benign disease. It is advisable to follow the general recommendations of the *American College of Chest Physicians* (ACCP) [208] or the *French Society of Anesthesia and Intensive Care Medicine* (SFAR) [209] concerning prevention of postoperative thromboembolic risk.

Resumption of activity after hysterectomy

The aim of fast-track surgery or enhanced recovery after surgery is that patients should rapidly recover and regain complete independence. This is a multimodal strategy for which it is difficult to assess each component (mode of anesthesia, surgical approach, treatment to reduce nausea, etc.). Very few studies have considered hysterectomy for benign disease, in particular by the vaginal or laparoscopic approach.

Eating soon after abdominal gynecologic surgery is associated with a decrease in hospital stay of about one day (LE2), without increase or decrease in the prevalence of postoperative complications. No study has compared early with delayed eating in the case of hysterectomy for benign disease.

Routine renal ultrasound after hysterectomy

The prevalence of asymptomatic hydronephrosis after uncomplicated hysterectomy is anecdotal (LE4). Routine postoperative renal ultrasound is not recommended after hysterectomy (expert opinion).

Discussion

These recommendations are not intended to cover all clinical situations, but as many as possible. Various special situations could not be addressed, notably those in the setting of cancer. These recommendations will evolve because many trials in this field are ongoing, in particular studies of hemostatic devices.

Conclusion

The application of these recommendations should minimize risks associated with hysterectomy.

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