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Evidence-based Guidelines for Vaginal Hysterectomy of the International Society for Gynecologic Endoscopy (ISGE)

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ABSTRACT

Objective: This project was established by the International Society for Gynecologic Endoscopy (ISGE) to provide evidence-based recommendations on the selection of women in whom vaginal hysterectomy can be safely performed.

Study design: The ISGE Task Force for vaginal hysterectomy for non-prolapsed uterus defined key clinical questions that led the literature search and formulation of recommendations. The search included Medline/PubMed and Cochrane Database. English language articles were reviewed from January 2003 to January 2018, in conjunction with reviews published by the American College of Obstetricians and Gynecologists (ACOG) and the American Association of Gynecologic Laparoscopists (AAGL). The bibliographies of selected works were also checked to acquire additional data where relevant. The available information was graded by the level of evidence using the approach developed by the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Working Group. For each clinical question, the ISGE recommendations were defined in accordance with the evidence quality.

Results: Six recommendations on patient selection for vaginal hysterectomy, including two grade 1B and four grade 2B recommendations were established.

Conclusion: Vaginal hysterectomy for non-prolapsed uterus is the treatment of choice for many gynaecological patients in whom hysterectomy is indicated. It may be safely executed, and thus, should be offered to a large group of appropriately selected women, who today are operated in the main by the abdominal or laparoscopic approach. All efforts should be directed towards teaching the technique of vaginal hysterectomy during residency.

Key words/phrases: guidelines, hysterectomy, planning hysterectomy, route of hysterectomy, vaginal hysterectomy.

INTRODUCTION:

Hysterectomy is one of the most common operative procedures for benign uterine diseases (1). It can be performed abdominally, vaginally, or laparoscopically, with or without robotic assistance. The advantages provided by vaginal hysterectomy (VH), laparoscopic-assisted vaginal hysterectomy (LAVH), and laparoscopic hysterectomy (LH) over abdominal hysterectomy (AH) include less postoperative pain, less need of analgesia, shorter hospital stay, and more rapid recovery and return to daily activities (2-6). Additionally, there are fewer intra-operative and postoperative complications reported with vaginal hysterectomy as compared with abdominal hysterectomy (AH) or laparoscopic hysterectomy (LH) (7-9). AH for benign uterine conditions remains the chosen route worldwide. This preference is largely due to a lack of experience in VH, resulting in the surgeon's reluctance to perform VH, especially in patients without uterine prolapse, with uterine fibroids, previous caesarean sections, previous laparotomies, as well as in nulliparous women. Correctly challenging these contraindications may lay the foundation for implementing different approaches towards an increased number of VHs (10-13).

Globally, the rate of LH has been shown to be increasing, without a significant reduction in AHs. Seventy to 80% of hysterectomies have been shown to be carried out via the abdominal approach, according to all large-scale surveys, except when treating uterovaginal prolapse, for which the vaginal route is generally preferred. This latter indication accounts for about 10% of all hysterectomies conducted worldwide (14). This increase in LH has thus been incurred at the expense of VH while, ideally,

it is the VH rate that should increase at the expense of the AH rate. This decrease in the rate of VH is demonstrated clearly in Australia, where the rates of VH have dropped between 2001 and 2015 by 53% in younger patients and 29% in the older age group (15). Nigeria demonstrated a further decrease in VH, where the vaginal route was utilised in approximately 12% of hysterectomies performed in a teaching university hospital. In Norway, the preferred route of hysterectomy has changed in favour of LH, where the number of VHs have decreased to below 10%, mainly performed for utero-vaginal prolapse (16). It is a common perception that the decreasing VH rate, which came about as a consequence of the dependence on LH, may be at least partially attributed to the impact of the industry that manufactures and promotes the laparoscopic equipment.

A lack of adequate training offered in VH is also of relevance in new generations of gynaecologists performing total laparoscopic hysterectomy (TLH) in patients who may have otherwise undergone an uncomplicated VH. In a study performed in the USA in 2011, by Antosh *et al.*, only 41.7% of residents reported VH as their preferred route of hysterectomy, as compared to 47.1% who preferred laparoscopic approaches (17). Lee and King, considering the difficulties in teaching both LH and VH during residency, have suggested that TLH represent the new gold standard in minimally invasive approaches for hysterectomy, while the professional societies, such as the American College of Obstetricians and Gynaecologists (ACOG) and the American Association of Gynecologic Laparoscopists (AAGL), have been encouraged to direct more resources to promote education in and practice of LH if a substantial decrease in AH is truly our primary goal (<http://www.contemporaryobgyn.net/modern-medicine-feature-articles/vaginal-versus-laparoscopic-hysterectomy>). However, this highlights a fundamental problem currently facing clinical gynaecology, namely insufficient VH training/practice due to

the inadequate experience of junior trainers in VH, and the consequent lack of appreciation of the benefits afforded by VH.

VH for the non-prolapsed uterus is an appropriate alternative for a large group of women who are predominantly operated upon via LH or AH today. The International Society for Gynaecologic Endoscopy (ISGE) was motivated to carry out this endeavour to establish evidence-based recommendations on the selection of women for VH.

MATERIALS AND METHODS:

The ISGE Task Force for vaginal hysterectomy for the non-prolapsed uterus defined key clinical questions (Panel 1), which led to the literature search from Medline/PubMed and the Cochrane Database. English language articles, both original works and previous reviews (published from January 2003 to January 2018, with the bibliographies of selected works checked to identify additional references and relevant data), were analysed in conjunction with reviews/guidelines published by the ACOG and AAGL. The available information was graded by the level of evidence, using the GRADE approach, proposed and developed by the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Working Group (<http://www.gradeworkinggroup.org>) (Table 1). In accordance with the evidence quality, the recommendations were established for each clinical question. No Ethical Committee approval was required for this work.

PANEL 1. Vaginal hysterectomy – key clinical questions

Question 1: Which route of hysterectomy should be considered as the first choice in women undergoing hysterectomy for benign indications?

Question 2: Should nulliparity, absence of utero-vaginal prolapse, uterine fibroid/(s), previous caesarean section, premalignant cervical and/or premalignant endometrial disease be considered as contraindications to vaginal hysterectomy?

Question 3: Which factors should be considered prerequisites for a successful vaginal hysterectomy?

Question 4: In women without adnexal disease and who are not at an increased risk for cancer, should routine removal of the ovaries and fallopian tubes be recommended during vaginal hysterectomy

LITERATURE REVIEW AND RECOMMENDATIONS:

Most hysterectomies are performed for benign indications such as symptomatic uterine fibroids, abnormal uterine bleeding, endometriosis, and prolapse. The hysterectomy rates differ considerably among countries (18). Almost 30% of women in the USA are submitted to the procedure by the age of 60 years, while the hysterectomy rates in developing countries are lower (<https://www.medscape.com/viewarticle/712569>). In the USA, almost 600.000 hysterectomies are performed yearly for benign disease. In 2007, Wu *et al.* reported on hysterectomy rates in the USA for the year 2003, and found that the abdominal route was the most common (66.1%), followed by vaginal (21.8%) and laparoscopic (11.8%) routes (19).

The introduction of robotics has changed the rates in favour of robotic hysterectomy (RH) with a further decline not only in VH but also in conventional LH (15, 20). Recent findings in the USA hospitals, where robotics have been introduced, have indicated that the use of abdominal hysterectomy has declined from 66,1% in 2003 to 54,2% by 2010. The use of VH declined throughout, from 24.8% in 1998 to 16,7% in 2010. Use of LH increased to a peak of 15.5% of cases in 2006, and then

declined to 8.6% of procedures in 2010, whereas use of RH increased from 0,9% in 2008 to 8,2% in 2010 (20). Robotics do not truly make a difference in increasing the ratio of VH and conventional LH in favour of AH, as evidenced by the fact that the latter remained at a constant 64% nationwide in the USA in 2009 (21).

Comparison of different approaches to hysterectomy

Currently available evidence indicates that minimally invasive procedures, including VH and LAVH/LH/RH, should be the preferred route of hysterectomy, as they offer the same benefits, and avoid large and painful abdominal incisions that are needed for AH. Additionally, longer hospital stay and a delay in returning to daily activities are also avoided (2, 5, 22, 23). Specifically, the 2009 Cochrane review found that VH, as compared to AH, is associated with a shorter hospital stay, the ability of the patient to resume normal daily activities more quickly, and fewer infections and episodes of raised temperature after surgery (2). LH, as compared to AH, has the same advantages as VH. While there was less blood loss and fewer wound infections in LH, as compared to AH, LH took longer and was associated with a greater risk of damaging the ureter or the bladder (2). No differences were found between LH and VH with regards to their benefits. However, when compared to VH, LH takes 39.3 minutes longer than VH, on average, and is associated with a higher rate of complications (2). Fewer complications have been associated with VH, when comparing this method of hysterectomy to all other routes. In 2015, a further Cochrane review by Aarts *et al.* confirmed the findings of Nieboer *et al.* regarding the advantages of VH over the other routes of hysterectomy, including RH (2, 22). He found that RH presented no difference in outcomes when compared to conventional LH, beneficial or otherwise. Thus, both Cochrane reviews concluded that VH should

be considered the first choice for hysterectomy in the treatment of benign conditions (Grade: 1B).

The 2009 ACOG guidelines on choosing the route of hysterectomy for benign disease state that, when feasible, VH is the safest and most cost-effective route by which to remove the uterus (23). LH is an alternative to AH for those women in whom a VH is not indicated or possible (23). The AAGL adopted the statement advising that surgeons without requisite training and skills required for the safe performance of VH or LH should enlist the aid of colleagues who do, or should refer patients requiring hysterectomy to such individuals for their surgical care (24).

In June 2017, the ACOG confirmed their 2009 statement defending VH as the route of choice wherever feasible. This statement was based upon data collected over the course of almost a decade, which indicated that VH was associated with better postoperative outcomes when compared with other approaches to hysterectomy (<https://www.acog.org/-/media/Committee-Opinions/Committee-on-Gynecologic-Practice/co701.pdf?dmc=1&ts=20170702T0930167819>). It was concluded that LH serves as a preferable alternative to open AH for patients in whom VH is contraindicated or not feasible (Grade2B). Through their analysis of the data captured, the ACOG found that the introduction of RH lead to a decrease in both LH and a VH. VH in particular had decreased from 25% in 1998 to 17% in 2010.

The evidence-based formal guidelines for the preferred route of hysterectomy have been largely neglected by surgeons, and as such, the choice for hysterectomy is usually based on subjective preferences rather than standardised selection criteria for the route of hysterectomy. When formal guidelines were used to determine the route of hysterectomy, VH was performed in 90% of the patients treated, and in 100% of the patients in whom the pathology was confined to the uterus (25). In comparison, when formal guidelines were not incorporated in the decision-making process, VH was reported in 42% of the patients treated, and in 64% of the patients

in whom the pathology was confined to the uterus. Should guidelines be used to assist clinical decision-making, potential savings of \$1.2 million (USA) could be attained for every 1000 hysterectomies performed vaginally, as well as a reduction of 20% in complications associated with the procedure (25). A cost effectiveness analysis undertaken with the eVALuate study revealed that the vaginal approach was more cost-effective compared to the laparoscopic route, primarily due to the use of disposable instruments in laparoscopy (3). Sculpher *et al.* found that LH cost an average of \$780 (USA) more than VH, per patient. With more than 500.000 hysterectomies performed annually in the United States, and more than 100.000 in the United Kingdom, the vaginal approach seems even more relevant in this time of economic strain (26).

To sum up, it is evident from the literature that the vaginal route should be considered the preferred choice. VH skill should not be sacrificed in favour of LH. Academic institutions worldwide are urged to review a strategy in order to retain the skill of VH, via appropriate training programs.

Factors influencing the route of hysterectomy

Surgeon training and experience have often been deemed particularly influential leading factor for the selection of the most appropriate approach to hysterectomy . The lack of training in VH has been raised by several authors as being an important factor, with lack of experience in vaginal surgery leading to gynaecologists having a dependence on the abdominal and/or laparoscopic routes when contemplating hysterectomy (27-29). Training in vaginal surgery during residency is important in order to challenge supposed contraindications to VH. It has been shown that VH can be safely performed in women without uterine prolapse, in those with an enlarged fibroid uterus up to 12 weeks gestation, in patients with a

history of one or more previous caesarean sections, previous laparotomies, premalignant cervical or endometrial pathology, as well as in nulliparous women. Correctly challenging these contraindications may lead to an increased number of VHs (10-13) (Grade: 2B).

Aside from personal training, factors that are considered prerequisites for a successful VH are vaginal accessibility, together with the size and mobility of the uterus. The confirmation of pathology confined or not confined to the uterus also influences the route of hysterectomy selected (25). The use of a set of guidelines on the route of hysterectomy – incorporating vaginal accessibility, uterine size and mobility, and pathology confined to the uterus – has been proposed (25). In a randomised trial where residents followed these guidelines for selection of hysterectomy, the percentage of VHs performed for benign conditions was found to be more than 90% (<https://www.omicsonline.org/open-access/28-years-of-using-hysterectomy-guidelines-to-determine-the-feasibility-of-vaginal-hysterectomy-2161-0932-1000375.php?aid=72317>). When pathology is not confined to the uterus (adnexal pathology, known or suspected, adhesions, and endometriosis), thereby precluding VH, it is advisable to perform LAVH to restore anatomy or to free the adnexal before proceeding to VH (5) (Grade: 2B). LAVH has its place where there is uncertainty of a successful VH, or in order to perform adhesiolysis, treat endometriosis, and restore pelvic anatomy. LAVH is especially needed when prophylactic oophorectomy is required, as it is not always possible for the ovaries to be removed vaginally. In a study by Chrysostomou, it was demonstrated that by performing laparoscopies in patients who were considered unsuitable for VH, all the subjects were able to proceed to an uncomplicated VH (www.sajog.org.za/index.php/SAJOG/article/download/18/93). The author reached the conclusion that the laparoscopic approach should be converted to a vaginal procedure as soon as possible (e.g. after adhesiolysis, treatment of endometriosis,

adnexectomy, location of the fibroids). Nothing is gained by continuing laparoscopic dissection, as this unnecessarily prolongs the surgery and increases the risk of visceral damage. As the surgeon's confidence increases, ultimately more cases will be achieved by VH alone, and the overall operative risks may thus be decreased.

Vaginal accessibility: Vaginal accessibility is determined by assessing 3 key components: the angle of the pubic arch, the shape of the vagina, and the uterine descent. A pubic arch that is wide, or more than 90 degrees, allows for easier access to the uterus and placement of instruments, facilitating the vaginal approach. However, with a small 1 – 2 cm posterior midline episiotomy, vaginal accessibility may be obtained even when the pubic arch is less than 90 degrees (13, 23, 30).

The shape of the vagina, especially the breadth of the vaginal apex, is best assessed during vaginal examination. A vaginal apex 3 cm wide facilitates a vaginal approach, as it provides ample space for anterior and posterior entry, and improves lateral visualization of the vasculature (13, 30).

The ACOG has stated that VH is indicated for patients with a mobile uterus of less than 12 weeks gestational size (Grade: 1B) (23). It is a common belief that uteri up to 12 weeks gestation can be delivered vaginally without any additional reduction procedures.

Pathology not confined to the uterus: When pathology is not confined to the uterus, and if the surgeon is uncertain of successful vaginal removal of the uterus, then it is advisable to perform laparoscopy to restore anatomy before undertaking VH. The decision to perform elective salpingoophorectomy is not dependent on the route of hysterectomy, and is not a contraindication to the performance of VH (31). This removal of the ovaries and Fallopian tubes during VH is recommended in women who are at high risk of developing ovarian cancer. Mandatory salpingectomy

is recommended in those who are carriers of the germ line mutation BRCA1 and BRCA2 genes, in which the occurrence of serous tubal intraepithelial carcinoma (STIC) has been established (Grade: 2B) (31). However, removing the fallopian tubes and ovaries in women with non-proven genetic or familial risk of ovarian cancer cannot be justified in 40-80% of case (31). It is important to consider that prophylactic salpingo-oophorectomy in premenopausal women at low risk for ovarian cancer is associated with a higher risk of developing osteoporosis and cardiovascular disease, and has thus been linked to reduced survival rates (32-35). Bearing this in mind, in the absence of ovarian disease and personal/family history of breast/ovarian carcinoma, routine removal of the ovaries during VH for benign uterine disease is not recommended, as the risks outweigh the benefits (Grade: 2B). The performance of prophylactic bilateral salpingectomy with ovarian conservation during vaginal hysterectomy, as suggested by ACOG in 2015 (<https://www.acog.org/-/media/Committee-Opinions/Committee-on-Gynecologic-Practice/co620.pdf?dmc=1>), has been found to prevent a diagnosis of ovarian cancer in 1 of every 225 patients undergoing surgery. Furthermore, the implementation of salpingectomy helps prevent death from ovarian cancer in 1 in every 450 women having surgery (36). Prophylactic bilateral salpingectomy with ovarian conservation during VH should therefore be undertaken routinely (Grade 2B) (36).

The success of removing ovaries and Fallopian tubes vaginally varies greatly, and is reported to range between 77% and 91,5% (36-39). Once VH is performed, a moistened pack is gently placed in the pelvis to prevent bowel from obscuring visualization. The transected tube and utero-ovarian ligament are pulled medially into the field until the round ligament is visualised. The round ligament is then clamped, cut and ligated. This allows further descent of the tubo-ovarian pedicle into the field, which can be clamped just above the superior tip of the ovary and then ligated (40).

If there is initial uncertainty surrounding the success in removing the ovaries vaginally, laparoscopic-assisted vaginal hysterectomy (LAVH) should be employed first. Similarly, if a problem arises in removing the ovaries and the tubes during a VH, then laparoscopic assistance should be used to complete the surgery (Grade: 2B). In certain circumstance, such laparoscopic skills may not be easily obtained.

An algorithm for women undergoing hysterectomy for benign indications is shown in Figure 1. A summary of ISGE recommendations for VH are presented below, in Panel 2.

PANEL 2. ISGE recommendations for vaginal hysterectomy

ISGE Recommendation 1: The vaginal hysterectomy should be considered as the first choice for benign indications (**Grade 1B**).

ISGE Recommendation 2: The laparoscopic approach should be considered when vaginal hysterectomy is contraindicated or not technically possible (**Grade 2B**).

ISGE Recommendation 3: Nulliparity, absence of utero-vaginal prolapse, uterine fibroid, previous caesarean sections, as well as premalignant cervical and endometrial disease should not be considered as contraindications to vaginal hysterectomy (**Grade 2B**).

ISGE Recommendation 4: The surgeons should pay attention to the clinical factors which facilitate vaginal hysterectomy and optimise patient outcome (**Grade 2B**).

ISGE Recommendation 5: Hysterectomy for benign causes is best performed vaginally if the uterus is less than 12 weeks of gestation or ≤ 280 g (preoperative clinical and ultrasound estimation, respectively), if accessible vaginally and the pathology is confined to the uterus (**Grade 1B**).

ISGE Recommendation 6: In the absence of ovarian disease and personal/family history of breast/ovarian carcinoma, routine removal of the ovaries during vaginal hysterectomy for benign uterine diseases is not recommended as the benefits outweigh the risks (**Grade 2B**); while in women at increased risk of ovarian, breast and bowel cancer, genetic counselling and routine salpingo-oophorectomy during vaginal hysterectomy should be undertaken. LAVH should also be employed in these circumstances (**Grade 2B**).

REFLECTION

Minimally invasive approaches to hysterectomy are preferable options, based on their well-documented advantages over AH. When VH, the first line approach, is not indicated or feasible, the surgeon should choose between LH or open AH. LH is a preferable alternative in these settings. The 2015 Cochrane review concluded that RH demonstrates no significant advantage over conventional LH (7). However, in cases where the uterine pathology precludes minimally invasive approaches, the importance of AH becomes apparent. AH also serves as an important alternative if LH or VH fail intra-operatively. Thus, while these guidelines strongly motivate for the increase in VH training, it does not aim to dismiss the importance of LH and AH, where their use is appropriate.

The clinician should assess cases by a focussed history, physical examination, and pelvic ultrasound with transvaginal probe before deciding which route of hysterectomy will most safely facilitate removal of the uterus and optimize patient outcomes, taking into account also the clinical situation (Figure 1), and surgeon training and experience. As the most highly recommended route of hysterectomy,

VH should be considered a priority among procedures to be learned by residents. Trainee gynaecologists need to be helped by Program Directors to navigate between Senior Gynaecologists with different skill mix, in learning the performance of VH.

It is essential to revive the use of VH as it is safer, more economical, and has rapid recovery rates and fewer complications among all the routes of hysterectomy. It can be expected that reducing the prevalence of LAVH will prompt the surgeon to become more proficient in VH, and to recognise that laparoscopic assistance is only necessary in specific cases.

CONCLUSION:

VH should be considered the ideal surgical approach when hysterectomy for benign uterine disease is undertaken. The guidelines proposed here provide suggestions that the majority of patients and clinicians would consider following. Their implementation can lead to a decrease of hysterectomies performed abdominally and a significant increase in hysterectomies performed vaginally, which may be achieved without an inappropriate increase in laparoscopic hysterectomy. Clinical judgement is needed for these suggestions, as physicians must evaluate the particular needs and expectations of each patient to arrive at the best management decision for each individual case.

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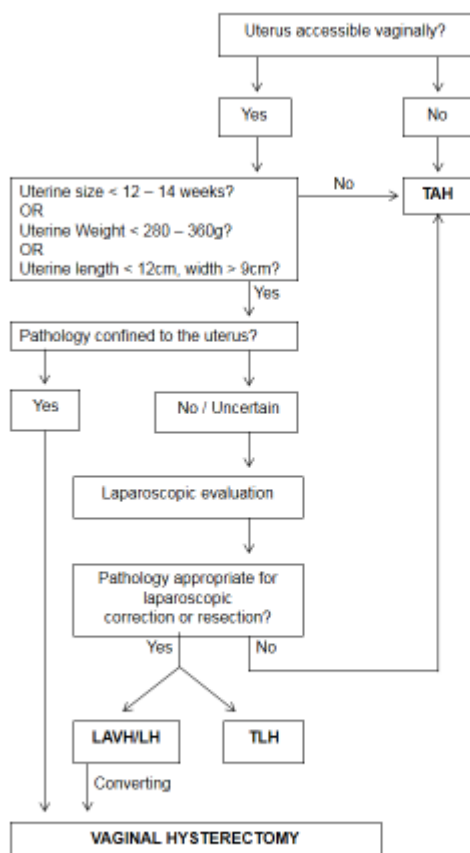
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Determining the route of hysterectomy for benign disease (clinical examination and pelvic ultrasonography-based approach). Abbreviations: **LAVH**, laparoscopic-assisted vaginal hysterectomy; **LH**, laparoscopic hysterectomy; **TAH**, total abdominal hysterectomy; **TLH**, total laparoscopic hysterectomy.

FIGURE 1. Determining the route of hysterectomy for benign disease (clinical examination and pelvic ultrasonography-based approach). *Abbreviations:* **LAVH**, laparoscopic-assisted vaginal hysterectomy; **LH**, laparoscopic hysterectomy; **TAH**, total abdominal hysterectomy; **TLH**, total laparoscopic hysterectomy.

TABLE 1. Grading of recommendations and quality of supporting evidence

Grade of recommendation	Risk/benefit	Quality of supporting evidence
1A. Strong recommendation, high quality evidence	Benefits clearly outweigh risk and burdens, or vice versa.	Consistent evidence from well performed randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk.
1B. Strong recommendation, moderate quality evidence	Benefits clearly outweigh risk and burdens, or vice versa.	Evidence from randomized, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate.
1C. Strong recommendation, low quality evidence	Benefits appear to outweigh risk and burdens, or vice versa.	Evidence from observational studies, unsystematic clinical experience, or from randomized, controlled trials with serious flaws. Any estimate of effect is uncertain.
2A. Weak recommendation, high quality evidence	Benefits closely balanced with risks and burdens.	Consistent evidence from well performed randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk.
2B. Weak recommendation, moderate quality evidence	Benefits closely balanced with risks and burdens, some uncertainty in the estimates of benefits, risks and burdens.	Evidence from randomized, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate.
2C. Weak recommendation, low quality evidence	Uncertainty in the estimates of benefits, risks, and burdens; benefits may be closely balanced with risks and burdens.	Evidence from observational studies, unsystematic clinical experience, or from randomized, controlled trials with serious flaws. Any estimate of effect is uncertain.