CLINICAL PRACTICE GUIDELINE

Hysterectomy for Benign Uterine Disease

Klaus J. Neis, Wolfgang Zubke, Mathias Fehr, Thomas Römer,
Karl Tamussino, Monika Nothacker

SUMMARY

Background: Hysterectomy is the second most common operation in obstetrics and gynecology after Cesarean section. Until now, there has not been any German clinical guideline with recommendations concerning the indications for hysterectomy for benign uterine conditions, in consideration of the available uterus-preserving alternative treatments.

Methods: We systematically searched the Medline database in 2013, in 2014, and in December 2015, focusing on aggregate evidence, and assessed the retrieved literature. The guideline recommendations were developed by a consensus process with structured independent moderation.

Results: 30 systematic reviews and 8 randomized controlled trials were analyzed. Among the study patients treated with either hysterectomy (by any technique) or an organ-preserving alternative, at least 75–94% were satisfied with their treatment. Vaginal hysterectomy was associated with lower complication rates, shorter procedure duration, and more rapid recovery than abdominal hysterectomy and is therefore the preferred technique. If vaginal hysterectomy is not possible, a laparoscopic approach should be considered. Abdominal hysterectomy should be reserved for special indications. In 2012, the frequency of abdominal hysterectomy in Germany, Austria, and Switzerland was lower than elsewhere in the world, at 15.7%, 28.0%, and 23.9%, respectively. Uterus-preserving techniques were associated with higher re-intervention rates compared to hysterectomy (11–36% vs 4–10%).

Conclusion: The main objective is to reduce the frequency of abdominal hysterectomy. Patients should be counseled and made aware of uterus-sparing alternatives to hysterectomy so that they are able to make informed decisions.

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Hysterectomy is the second most common surgical procedure in gynecology, second only to Cesarean section. In Germany, the hysterectomy rates range between 2.13/1000 and 3.62/1000 person-years (PY), while in the United States it is 5.4/1000 PY (1, 2). Over the last 10 to 20 years, the number of hysterectomies performed has consistently declined worldwide (3).

Uterine fibroids, endometriosis as well as functional disorders can cause abnormal uterine bleeding which may lead to anemia. Anemia may, in turn, impair work capacity and quality of life. In addition, sexual health may be significantly affected.

Until 1989, the only surgical approaches for hysterectomy were vaginal and abdominal hysterectomy; then in the early 1990s, three laparoscopic techniques were developed:

- Total laparoscopic hysterectomy (TLH) (4)
- Laparoscopically assisted vaginal hysterectomy (LAVH) (5)
- Laparoscopic supracervical hysterectomy (LASH) (6, 7).

The aim of laparoscopic approaches was to avoid the morbidity associated with abdominal incision. While this goal was generally achieved in most countries, Germany, Austria and Switzerland performed well, with abdominal hysterectomy rates in 2012 of 15.7% (3), 28.0% (8) and 23.9% (9), respectively. In comparison, the rate of abdominal hysterectomy in the United States in 2012 was 56% (2). Within 15 to 20 years of their introduction, laparoscopic hysterectomy procedures had found worldwide acceptance and the first Cochrane review comparing the various surgical approaches to hysterectomy was performed (10).

In an attempt to clearly define and distinguish the areas of indication for each method and to optimize indications, the German Society of Obstetrics and Gynecology (DGGG, Deutsche Gesellschaft für Gynäkologie und Geburtshilfe) initiated the preparation of the guideline “Indications and Methods of Hysterectomy for Benign Gynecological Disease”.

At the same time, uterus-preserving techniques to treat benign uterine disease were developed, most of them based on minimally invasive surgery. These were also included in the guideline.

Department of Obstetrics, Gynecology and Reproductive Medicine, Saarland University Medical Center, Germany: Prof. Dr. med. Neis

Department of Obstetrics and Gynecology, Tübingen University Hospital, Germany: PD Dr. med. Zubke
Cantonal Hospital, Frauenfeld, Switzerland: PD Dr. med. Fehr

Evangelisches Krankenhaus, Köln-Weyertal, Germany: Prof. Dr. med. Römer

Department of Obstetrics and Gynecology, Medical University of Graz, Austria: Prof. Dr. med. Tamussino

AWMF Institute of Medical Knowledge Management, c/o Philipps University Marburg, Germany:
Dr. med. Monika Nothacker MPH

Methods

Guideline development

The guideline was developed by a representative group of 26 clinical researchers as a consensus-based S2k guideline, initially (*eBox*). All members of the guideline consensus group declared potential conflicts of interest in writing; the procedure is documented in the guideline report. In three consensus conferences hosted by Prof. K. Schwerdtfeger as an independent AWMF guideline advisor (AWMF, Association of Scientific Medical Societies in Germany), recommendations were formulated and agreed upon (consensus if >75% of participants agreed) after careful consideration of the potential risks and benefits of the various treatment options. Three grades of recommendation were distinguished which can be identified by the use of the words “shall”, “should” and “can”. After an updated systematic literature search and evaluation had become available (11), these recommendations were verified and confirmed, with only few, unanimously approved, changes. The final guideline was a Level 3 (clinical practice) guideline (*Tables 1, 2*).

Literature search and evidence rating

Pertinent randomized controlled trials and systematic reviews/meta-analyses published between 1990 and 11/2011 were retrieved by an initial systematic literature search in the databases Medline, Cochrane Menstrual Disorders and Subfertility Group Specialized Register, and Cochrane Central Register of Controlled Trials (CENTRAL). A systematic literature search in the PubMed database was conducted for the period 2013/2014 to retrieve updated information on the following topics:

- Comparison of surgical approaches to hysterectomy
- Comparisons of hysterectomy versus uterine artery embolization or fibroid enucleation in patients with symptomatic uterine fibroids.
- Comparisons of hysterectomy versus pharmacotherapy or endometrial ablation in patients with fibroids, abnormal uterine bleeding or adenomyosis.

A literature search was performed in December 2015 to update the initially retrieved information, but did not identify any new randomized trials (see *eTable* for search strategies and inclusion criteria; see *eFigure* for flowchart).

Evidence levels were determined using the 2009 *Oxford Centre for Evidence-based Medicine—Levels of Evidence* document (12). All studies finally included based on title, abstract, and full-text screening—preferably systematic reviews and meta-analyses—were rated with regard to their quality.

Results

Hysterectomy for fibroids

According to German external hospital quality assurance data, approximately 60% of hysterectomies were

performed to treat uterine fibroids (3). The decision whether it is possible to perform uterus-preserving surgery has to be made on a case-by-case basis. No absolute threshold values with regard to size or number of fibroids are available to help with decision making (13).

Women with symptoms who do not want to preserve fertility and do not respond to conservative treatment may benefit from hysterectomy. The Maine Women's Health Study (1994) found that in the presence of moderate, non-life-threatening symptoms, 72% of the women who underwent hysterectomy felt much better, 16% better and 3% worse after surgery compared with the preoperative situation (14). All studies comparing hysterectomy with uterus-preserving interventions in patients with symptomatic fibroids, abnormal uterine bleeding, or adenomyosis found statistically significant improvements in symptoms, quality of life, and treatment satisfaction were shown for both treatment groups (15–17). The quality of some of the included randomized studies was limited by lack of blinding of analysis, lack of information about blinded group assignment, heterogeneity of the tools used to measure quality of life, and wide confidence intervals due to small sample sizes.

In 2014, the US Food and Drug Administration (FDA) issued a warning that if morcellators are used to divide tissue into smaller pieces in women with unsuspected uterine sarcoma, there is a risk that the procedure will spread the cancerous tissue (18). In a position paper, the DGGG pointed out that uterine sarcomas are rare. It recommends to make decisions on a case-by-case basis after in-depth discussion of the benefits and risks of minimally invasive hysterectomy, especially if morcellation is required (19). A meta-analysis performed in 2015 found that the prevalence of leiomyosarcoma is only 1 in 2000 procedures, while the FDA believed the prevalence of unsuspected uterine leiomyosarcoma to be 1 in 498 (20). The discussion on uterine artery embolization and fertility outcomes is ongoing.

Alternatives to hysterectomy in the treatment of fibroids

Surgical treatment options

Depending on their location, size and number, fibroids can be removed using hysteroscopic, laparoscopic, and laparoscopically assisted or (mini) laparotomy-based procedures. Myomectomy is currently considered to be the only sufficiently studied, organ-preserving treatment option for women who want to preserve fertility. No randomized controlled trial comparing fibroid enucleation techniques with hysterectomy was identified.

Hysteroscopic myomectomy

Intracavitary fibroids can be treated with hysteroscopic myomectomy. According to follow-up data from small cohort studies, hysteroscopic myomectomy improves abnormal uterine bleeding in 70 to 90% of cases (21).

TABLE 1

Guideline recommendations and statements

	Level of evidence	Grade of recommendation	Strength of consensus +++ >95% ++ >75%
Uterine fibroids			
In cases of suspected symptomatic uterine fibroids, the first step is to verify whether the symptoms are actually caused by the fibroids.	Expert consensus	A	+++
If the symptoms are caused by fibroids, the decision about the treatment approach to be taken should be made together with the patient, taking into account her circumstances.	Expert consensus	A	+++
Hysterectomy can be performed in women with symptomatic fibroids who do not want further children, do not respond to treatment alternatives and/or wish to undergo hysterectomy.	Expert consensus	0	+++
Drug therapy with gonadotropin-releasing hormone (GnRH) analogs or ulipristal acetate (UPA) may be indicated in preoperatively anemic patients with uterine fibroids.	1a (GnRH analogs) 1b (ulipristal)	0	+++
Patients should be informed about the individual success and failure rates of the various methods to treat fibroids.	Expert consensus	A	+++
Abnormal uterine bleeding			
In patients with abnormal uterine bleeding, pre-malignant or malignant changes should be excluded prior to initiating further treatment.	Expert consensus	A	+++
In patients who have failed hormone therapy and do not want further children, endometrial ablation and hysterectomy are treatment options.	1a	Statement	+++
If endometrial ablation fails, hysterectomy shall be performed.	Expert consensus	A	+++
Patients should be informed about the individual success and failure rates of the various methods used to treat abnormal uterine bleeding.	1b (LNG-IUS) 1a (endometrial ablation)	A	+++
Endometriosis/adenomyosis			
If primarily the patient requests a hysterectomy, she shall be thoroughly informed about treatment alternatives, their side effects and success rates.	Expert consensus	A	+++
In patients who have failed hormone therapy and do not want further children, hysterectomy should be performed.	Expert consensus	B	+++
Uterine prolapse			
With the surgical treatment of pelvic organ prolapse, the uterus may be spared.	Expert consensus	0	+++
If the uterus is retained, the existence of a malignancy should be excluded.	Expert consensus	B	++
Urinary incontinence			
In patients with incontinence problems, there should be a special indication for hysterectomy.	2–3	A	+++
Chronic pelvic pain			
Prior to hysterectomy for chronic pelvic pain, a laparoscopy should be performed.	Expert consensus	B	++
The indication for hysterectomy to treat chronic pelvic pain should be established together with the patient, taking into account interdisciplinary findings. The patient should be informed about the high failure rate.	2a	A	++
Patient-requested hysterectomy			
Hysterectomy without medical indication should not be performed solely on request of the patient.	Expert consensus	B	+++

LNG-IUS; levonorgestrel intrauterine system

TABLE 2

Guideline recommendations and statements

	Evidence level	Recommendation grade	Strength of consensus
Comparison of surgical techniques			
Vaginal hysterectomy shall be preferred over abdominal hysterectomy, if possible.	1a	A	+++
If vaginal hysterectomy is not possible, the option of laparoscopic hysterectomy should be assessed.	1a	B	+++
Laparoscopically assisted vaginal hysterectomy can be performed as an alternative to abdominal hysterectomy and vaginal hysterectomy.	1a	0	+++
At present, however, the available data do not allow to precisely distinguish between the various laparoscopic techniques.	Expert consensus	Statement	+++
Abdominal hysterectomy should only be performed if there is a special indication.	Expert consensus	B	+++
The available randomized trials have not shown a reliable patient-relevant benefit for the use of the robot-assisted technique.	1b	Statement	+++
Perioperative management			
Antibiotic prophylaxis shall be used in patients undergoing hysterectomy.	1a	A	+++
Perioperatively, a risk-adapted thromboprophylaxis should be administered.	1a	A	+++
Quality of life			
Patients should be informed that they can generally expect their quality of life and sexuality to improve after an indicated hysterectomy compared with the preoperative situation.	1a	B	+++
Prophylactic bilateral salpingo-oophorectomy (adnexectomy) may be associated with adverse long-term effects. Thus, it requires a special consent discussion.	1a	Statement	++

Abdominal myomectomy

A large uterus with numerous fibroids and/or very large deep intramural or transmural fibroids may require an abdominal incision to provide adequate access.

Even though most of the clinically relevant fibroids are usually removed during an open procedure, ultrasonographic follow-up over a period of up to 5 years found that fibroids recurred in 23 to 50% of patients (22).

Laparoscopic myomectomy

Advantages of minimally invasive procedures over open abdominal surgery have been clinically demonstrated. In a small randomized controlled trial of moderate quality, 85% of patients (17/20) did not require pain medication 72 hours after laparoscopic surgery compared with 15% (3/20) of patients after abdominal myomectomy (relative risk reduction [RR] 5.7; 95% confidence interval [95% CI] 2.0; 16.4). Another randomized controlled trial of moderate quality found lower pain levels at 24, 48 and 72 hours postoperatively in patients after laparoscopic surgery compared with abdominal surgery (2.28 versus 4.03 units on a visual scale). The mean length of hospital stay was 76 hours after laparoscopic myomectomy compared with 142 hours after abdominal myomectomy (95% CI not

stated; $p < 0.001$; level of evidence [LoE] 1b). Meta-analyses are not available (23).

In a multicenter study, 52.9% of patients experienced fibroid recurrence 5 years and 84.4% 8 years after laparoscopic myomectomy (LoE 1b) (13).

Uterine artery embolization (UAE) as an alternative to hysterectomy

Uterine artery embolization (UAE) is an alternative to surgical treatment options in women wishing to preserve their uterus (24). The discussion whether uterine artery embolization is an option for women desiring future fertility is ongoing (15).

Five smaller randomized controlled trials of moderate quality compared uterine artery embolization with hysterectomy (LoE 1a) (15). Patient satisfaction was high for both interventions (after 2 years, 79% in patients with uterine artery embolization and 81% in patients with hysterectomy; both $p > 0.1$). Symptom improvement after 2 and 5 years was 82% and 76%, respectively, for uterine artery embolization and after 2 years 93% for hysterectomy; the difference was not statistically significant. Five years after the initial intervention, the reintervention rate was significantly higher (28–32%) after UAE than after hysterectomy (4–10%). No significant differences were found with regard to

FIGURE

Indications for hysterectomy

complication rates. Complications reported after uterine artery embolization were usually “mild” in nature, while complications after hysterectomy were mainly classed as “severe”; heterogeneous definitions with regard to complications were used in the various studies (15).

Acupuncture

A Cochrane analysis of acupuncture in patients with symptomatic fibroids did not find any controlled trial evaluating symptom improvement (25).

Treatment of abnormal uterine bleeding

Provided focal abnormalities have been ruled out as cause of bleeding, hysterectomy is a therapeutic option for the definitive treatment of abnormal (dysfunctional) uterine bleeding. In Germany, 25% of benign hysterectomies were performed in 2012 for abnormal uterine bleeding (3).

Hysterectomy competes with medical approaches and interventions for endometrial destruction and resection. Systematic reviews identified eight randomized controlled trials comparing endometrial ab-

lation with hysterectomy, with a total of 1280 patients (LoE 1a) (16).

Endometrial ablation does not achieve the same definitive reduction in bleeding as hysterectomy (RR 0.89; 95% CI [0.85; 0.93]; 4 studies, n = 650).

At several points in time, reintervention rates were found increased by 11 to 36% (after 1 to 4 years) for endometrial ablation versus hysterectomy. Complications are rare and limited to perforation of the uterine wall and absorption of the distention medium into the bloodstream. The rate of short-term complications is significantly higher for hysterectomy. No differences were found with regard to quality of life for any of the results, obtained with various instruments (16). Treatment satisfaction after one year was high for both interventions: 82% after hysterectomy and 77% after endometrial resection (odds ratio [OR] 0.94; 95% CI: [0.88; 1.0]; data from 4 studies, n = 739).

Drug therapy

In some studies, bleeding severity was reduced by about 40% using oral contraceptives (OCs) (26). For progesterone administration over 21 days, from day 5

to day 26 of the menstrual cycle, a significant reduction in menstrual blood loss was shown. The Practice Bulletin no. 110 of the American Congress of Obstetricians and Gynecologists (ACOG) highlights that within a period of 10 years 46% of the patients in the medical treatment arms of the studies underwent surgery (26). Hysterectomy is the most effective method to end abnormal uterine bleeding.

Comparisons of the satisfaction rates and quality of life achieved with the levonorgestrel intrauterine system (LNG-IUS), organ-preserving surgery, and hysterectomy found no significant differences between the three treatment approaches after one year (27).

Levonorgestrel intrauterine system (LNG-IUS)

Studies have shown that LNG-IUS is more effective than cyclical norethisterone for 21 days. Furthermore, compliance was significantly better with LNG-IUS treatment (28). In the only randomized comparative study with 5-year follow-up, Hurskainen et al. (29) found no differences between primary hysterectomy and LNG-IUS with regard to quality-of-life scores and psychological scores, even though 42% of the patients treated with LNG-IUS later underwent hysterectomy. Treatment satisfaction was 94% in the group with primary hysterectomy (30).

Uterine adenomyosis

Alternatives to hysterectomy for the treatment of symptomatic adenomyosis include systemic treatment with gestagens or oral contraceptives in a long-cycle or long-term regimen (31). With regard to the comparison of LNG-IUS versus hysterectomy, a small randomized controlled trial was identified. After one year, the amenorrhea or oligomenorrhea rate in patients treated with LNG-IUS was 87% (17) (LoE 1b–). In women who do not want to preserve fertility, hysterectomy is the most effective treatment of symptomatic adenomyosis. Adenomyosis is suspected based on presenting symptoms, imaging findings and pregnancy history. The definite diagnosis is ultimately established by histopathological examination of the hysterectomy specimen.

Uterine prolapse and hysterectomy

For decades, hysterectomy was part of the surgical treatment of pelvic organ prolapse. A French working group found in the multivariate analysis of data from two retrospective multicenter trials with 684 and 277 patients, respectively, (32) that simultaneously performed hysterectomy significantly increased the rate of mesh-related local erosions at the vaginal vault (OR 5.17). Uterus preservation is a protective factor in this respect (OR 0.263; 95% CI: [0.112; 0.621]). So far, no convincing evidence exists that hysterectomy lowers the recurrence risk after pelvic organ prolapse surgery. However, it has also not been proven that uterus preservation has no negative impact on recurrence risk in the long term (33).

Urinary incontinence and hysterectomy

Hysterectomy is not a surgical procedure to treat incontinence. It may be beneficial in patients with large fibroids and overactive bladder (34), but, as yet, this has not been proven by well-designed studies.

Comparison of hysterectomy techniques

Surgical approaches for hysterectomy have been compared in numerous publications, including two systematic reviews, one review based on recommendations of the National Institute for Health and Clinical Excellence (NICE) (35), and one Cochrane review, last updated in 2015 (36) (LoE 1a). Nieboer et al. analyzed 34 randomized controlled trials with a total of 4495 patients (10). In the NICE publication, the analysis additionally included controlled studies involving 37 049 women.

These analyses consistently found the lowest costs and the lowest complication rate for vaginal hysterectomy, followed by laparoscopic procedures. Therefore, abdominal hysterectomy should only be performed if there is a special indication for it. The American College of Obstetricians and Gynecologists has issued similar recommendations (37).

Hysterectomy and the subsequent resolution of symptoms frequently leads to improvements in sexual health, in the form of an increase in the frequency of sexual intercourse and a patient-experienced global improvement of sexual health (38, 39). In this respect, short-term advantages for vaginal and laparoscopic hysterectomy techniques can also be identified; however, after 12 months these can no longer be demonstrated.

Complication data for Germany

In Germany, the 2012 national analysis of external hospital care quality assurance data, *15/I—Gynecological Operations*, is available for approximately 103 000 hysterectomies performed for benign indications (3). The rates of intraoperative and postoperative complications were 1.4% and 4.0%, respectively; consequently, the total complication rate was 5.4%. In 2012, the conversion rate for vaginal or laparoscopic hysterectomies in Germany (2.0%) was markedly below the 7% found in the aggregated evidence (10, 36).

Discussion and conclusions

Both hysterectomy and uterus-preserving methods are available to treat benign uterine conditions. Women differ with regard to the distress they experience, their life situation, and their plans for the future. Frequently, women have already decided which treatment they want. They expect that the gynecologist evaluates the underlying condition and informs them about the various options available. For this end, the evidence base supporting the benefits and risks of the various methods should be explained and patients should be asked about their views. Ideally, these women can then

decide for themselves which therapeutic option suits them best. This approach is commonly referred to as shared decision making (40). As an aid to physicians and patients, algorithms have been developed for the main indication groups, presenting the various treatment options at a glance (*Figure*). In our experience, these are worthwhile and appreciated by patients. Further research is required to enhance our understanding of adequate communication and individualized advice.

In 2013, hysterectomy was removed from the German quality assurance program. In view of the fact that hysterectomy and corresponding treatment alternatives are frequently performed interventions, it is desirable to reintegrate hysterectomy in a continuous monitoring program; in many European countries and in the United States this is the case. Such a monitoring program should also be developed for alternative treatment approaches. Since many of the interventions are performed on an outpatient basis, a cross-sectoral survey will be required which should also cover the aspects of quality of information and communication. In addition, data collected in this setting could show whether and how the algorithms developed in this guideline are applied in clinical practice.

Conflict of interest statement

Prof. Neis is Scientific Director of a research center (ETC) for operative, especially endoscopic surgery which is supported by Storz and Erbe.

Dr. Zubke has received reimbursement of travel and accommodation expenses and fees for the preparation of continuing medical education events from Erbe.

Prof. Römer has received consultancy fees from Bayer and Gedeon Richter. He has also received reimbursement of participation fees, travel and accommodation expenses as well as fees for the preparation of continuing medical education events from Bayer, Hologic and Gedeon Richter.

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Dr. Fehr declares that no conflict of interests exists.

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Corresponding author

Prof. Dr. med. Klaus J. Neis
Klinik für Frauenheilkunde, Geburtshilfe
und Reproduktionsmedizin der Universitätskliniken des Saarlandes
Kirrbergerstr. 100
66424 Homburg, Germany
kjneis@gyn-saar.de

Supplementary material
eTable, eFigure, eBox:
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Supplementary material to:

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by Klaus J. Neis, Wolfgang Zubke, Mathias Fehr, Thomas Römer, Karl Tamussino, and Monika Nothacker

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eBOX

Guideline group

● Lead and coordination

Authors

- Prof. Dr. med. K. J. Neis, German Society of Obstetrics and Gynecology (DGGG, Deutsche Gesellschaft für Gynäkologie und Geburtshilfe)
- Prof. Dr. med. K. Schwerdtfeger, AWMF guideline advisor

Steering committee

- PD Dr. med. W. Zubke, German Society of Obstetrics and Gynecology (DGGG)
- Prof. Dr. med. T. Römer, Gynecological Endoscopy Working Group (AGE, Arbeitsgemeinschaft Gynäkologische Endoskopie)
- Prof. Dr. med. K. Tamussino, Austrian Society of Obstetrics and Gynecology (OEGGG, Österreichische Gesellschaft für Gynäkologie und Geburtshilfe)
- PD Dr. med. M. Fehr, Swiss Society of Obstetrics and Gynecology (SGGG, Schweizer Gesellschaft für Gynäkologie und Geburtshilfe)

● Other guideline authors

- Prof. Dr. med. A. Kuhn, Swiss Society of Obstetrics and Gynecology (SGGG)
- Prof. Dr. med. M. Müller, Swiss Society of Obstetrics and Gynecology (SGGG)
- Prof. Dr. med. B. Bojahr, Gynecological Endoscopy Working Group (AGE)
- PD Dr. med. S. Rimbach, Gynecological Endoscopy Working Group (AGE)
- Prim. Dr. med. W. Stummvoll (†), Austrian Society of Obstetrics and Gynecology (ÖGGG)
- Prof. Dr. med. E. Solomayer, Gynecological Endoscopy Working Group (AGE)
- Dr. med. T. Schollmeyer (†), Gynecological Endoscopy Working Group (AGE)
- Dr. med. B. Holthaus, Gynecological Endoscopy Working Group (AGE)
- Dr. med. F. Neis, Gynecological Endoscopy Working Group (AGE)
- Prof. Dr. med. B. Gabriel, Working Group on Urogynecology and Pelvic Floor Reconstruction (AGUB, Arbeitsgemeinschaft Urogynäkologie und Beckenbodenrekonstruktion)
- Prof. Dr. med. C. Reisenauer, Working Group on Urogynecology and Pelvic Floor Reconstruction (AGUB)
- Dr. med. H. Dieterich, Working Group on Aesthetic, Plastic and Reconstructive Surgical Techniques in Gynecology (AWOGyn, Arbeitsgemeinschaft für ästhetische, plastische und wiederherstellende Operationsverfahren in der Gynäkologie)
- Prof. Dr. med. I. B. Runnenbaum, Working Group on Gynecological Oncology (AGO, Arbeitsgemeinschaft Gynäkologische Onkologie)
- Prof. Dr. med. W. Kleine, Working Group on Gynecological Oncology (AGO)
- Prof. Dr. med. A. Strauss, Working Group on Ultrasound Diagnosis in Obstetrics and Gynecology (ARGUS, Arbeitsgemeinschaft für Ultraschall-diagnostik in Gynäkologie und Geburtshilfe)
- Prof. Dr. med. M. Menton, Working Group on Cytopathology and Colposcopy (AG CPC, Arbeitsgemeinschaft Zytopathologie und Kolposkopie)
- Prof. Dr. med. I. Mylonas, Working Group on Infections and Infection Immunology (AGII, Arbeitsgemeinschaft Infektiologie und Infektionsimmunologie)
- Prof. Dr. M. David, German Society of Psychosomatic Obstetrics and Gynecology (DGPFG, Deutsche Gesellschaft für Psychosomatische Frauenheilkunde und Geburtshilfe)
- Prof. Dr. med. L-C. Horn, German Society of Pathology (DGP, Deutsche Gesellschaft für Pathologie), Professional Association of German Pathologists (BDP, Berufsverband Deutsche Pathologen)
- Prof. Dr. med. D. Schmidt, German Society of Pathology (DGP), Professional Association of German Pathologists (BDP)
- Prof. Dr. med. A. T. Teichmann, Federal Association of Leading Physicians in Gynecology and Obstetrics (BLFG e. V., Bundesarbeitsgemeinschaft Leitender Ärztinnen und Ärzte in der Frauenheilkunde und Geburtshilfe)
- Dr. med. P. Brandner, Professional Association of Gynecologists (BVF, Berufsverband der Frauenärzte)
- Dr. M. Nothacker, AWMF guideline advisor/preparation of the evidence report

● Under the auspices of

- Prof. Dr. med. D. Wallwiener, German Society of Obstetrics and Gynecology (DGGG)
- Prof. Dr. med. U. Lang, Austrian Society of Obstetrics and Gynecology (ÖGGG)
- Dr. med. D. Ehm, Swiss Society of Obstetrics and Gynecology (SGGG)
- Prof. Dr. med. M. Beckmann, DGGG guideline representative

eTABLE

Search strategies used for hysterectomy guideline (database: Medline via Pubmed)

Question	Date/period	Search terms and limits
Patients with symptomatic fibroids: hysterectomy vs. fibroid enucleation and hysterectomy vs. uterine artery embolization	27 Oct 2013 from 1990	(Hysterectomy [MeSH] OR hysterectomy OR hysterectomies) AND (Myoma [MeSH: NoExp] OR myoma OR myomas OR leiomyoma OR leiomyomas OR fibromyoma OR fibromyomas OR fibroma OR fibromas OR fibroid OR fibroids) Filters: Clinical Trial, Randomized Controlled Trial, Systematic Review, Review, Meta-Analysis; publication dates from 1990/01/01 to 2013/10/27
Patients with symptomatic fibroids: drug therapy	30 June 2014 from 1990	(gnrh OR progesterone OR estrogen OR progestin OR aromatase) AND (Myoma [MeSH: NoExp] OR myoma OR myomas OR leiomyoma OR leiomyomas OR fibromyoma OR fibromyomas OR fibroma OR fibromas OR fibroid OR fibroids) Filters: Clinical Trial, Randomized Controlled Trial, Systematic Review, Meta-Analysis; publication dates from 1990/01/01 to 2014/06/30
Patients with abnormal uterine bleeding: hysterectomy vs. endometrial resection vs. drug therapy	5 May 2014 from 1990	(Menorrhagia [MeSH] OR menorrhagia [tw] OR polymenorrhoea [tw] OR heavy bleeding [tw] OR DUB [tw] OR AUB [tw] OR (abnormal AND bleeding) [tw] AND hysterectomy [tw] Filters: Clinical Trial, Randomized Controlled Trial, Systematic Review, Meta-Analysis; publication dates from 1990/01/01 to 2014/05/05
Patients with uterine adenomyosis: hysterectomy vs. treatment alternatives	5 May 2014 from 1990	(Adenomyosis [MeSH] OR adenomyosis OR adenomyos*) AND hysterectomy Filters: Meta-Analysis, Systematic Review, Randomized Controlled Trial; publication dates from 1990/01/01 to 2014/05/05
Hysterectomy technique comparison	5 May 2014 from 2008 (end of search: Nijboer et al., 2009)	„hysterectomy“ Limits: Review, Systematic Review, Meta-Analysis

AUB, abnormal uterine bleeding; DUB, dysfunctional uterine bleeding; MeSH, major subject heading; tw, text word; vs, versus

eFIGURE

Method of the literature search

Check whether the included studies are up-to-date as of 12/2015 by means of update search; 2 more recent Cochrane Reviews identified: (15) and (36). No new randomized controlled trial included; results unchanged

n = number; Pat., patients; RCT, randomized controlled trial(s); SR, systematic review(s)

* Publications in the following languages were included: German, English, French, Spanish