Diagnosis and Therapy of Female Pelvic Organ Prolapse. Guideline of the DGGG, SGGG and OEGGG (S2e-Level, AWMF Registry Number 015/006, April 2016)

Diagnostik und Therapie des weiblichen Descensus genitalis. Leitlinie der DGGG, SGGG und OEGGG (S2e-Level, AWMF-Registernummer 015/006, April 2016)

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Key words
- pelvic organ prolapse
- stress urinary incontinence
- pelvic floor
- surgical therapy
- physiotherapy
- pessary treatment

Schlüsselwörter
- genitaler Deszensus
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- Beckenboden
- operative Therapie
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Abstract

Aims: The aim was to establish an official interdisciplinary guideline, published and coordinated by the German Society of Gynecology and Obstetrics (DGGG). The guideline was developed for use in German-speaking countries. In addition to the Germany Society of Gynecology and Obstetrics, the guideline has also been approved by the Swiss Society of Gynecology and Obstetrics (SGGG) and the Austrian Society of Gynecology and Obstetrics (OEGGG). This is a guideline published and coordinated by the DGGG. The aim is to provide evidence-based recommendations obtained by evaluating the relevant literature for the diagnostic, conservative and surgical treatment of women with female pelvic organ prolapse with or without stress incontinence.

Methods: We conducted a systematic review together with a synthesis of data and meta-analyses, where feasible. MEDLINE, Embase, Cinahl, Pedro and the Cochrane Register were searched for relevant articles. Reference lists were handsearched, as were the abstracts of the Annual Meetings of the International Continence Society and the International Urogynecological Association. We included only abstracts of randomized controlled trials that were presented and discussed in podium sessions. We assessed original data on surgical procedures published since 2008 with a minimum follow-up time of at least 12 months. If the studies included descriptions of perioperative complications, this minimum follow-up period did not apply.

Recommendations: The guideline encompasses recommendations for the diagnosis and treatment of female pelvic organ prolapse. Recommendations for anterior, posterior and apical pelvic organ prolapse with or without concomitant stress urinary incontinence, uterine preservation options, and the pros and cons of mesh placements during surgery for pelvic organ pro-

Zusammenfassung

Ziel: Erstellung einer offiziellen, internationalen, interdisziplinären Leitlinie, publiziert und koordiniert von der Deutschen Gesellschaft für Gynäkologie und Geburtshilfe (DGGG). Die Leitlinie wurde für den deutschsprachigen Raum entwickelt und wird neben der DGGG auch von der Schweizerischen Gesellschaft für Gynäkologie und Geburtshilfe (SGGG) und der Österreichischen Gesellschaft für Gynäkologie und Geburtshilfe (OEGGG) mitgetragen. Das Ziel dieser Leitlinie, die von der DGGG publiziert und koordiniert wurde, ist es, durch die Evaluation der relevanten Literatur einen evidenzbasierten Überblick über die Diagnostik sowie konservative und operative Therapie des Descensus genitalis der Frau mit oder ohne Belastungsinkontinenz zu geben.

Methoden: Es erfolgte ein systematischer Review sowie Synthese von Daten, anteilig mit Metaanalyse (S2e). Es wurde eine umfassende Literatursuche in MEDLINE, Embase, Cinahl, Pedro und im Cochrane-Register, in Referenzlisten und in den Abstracts der Annual Meetings der International Continence Society und der International Urogynecological Association durchgeführt. Abstracts wurden eingeschlossen, wenn es sich um randomisierte Studien handelte, die als Podiumpräsentation vorgestellt und diskutiert wurden. Es wurden Originalarbeiten seit 2008 eingeschlossen, deren Nachkontrollzeitraum bei mindestens 12 Monaten lag. Für die Beschreibung von perioperativen Komplikationen wurden jegliche Daten herangezogen.

Empfehlungen: Es werden Empfehlungen zur Diagnostik, konservativen und operativen Therapie des Genitaldeszensus gegeben, wobei die 3 urogynäkologischen Kompartimente, Prävention oder Behandlung von Belastungsinkontinenz, Vor- und Nachteile von Netzaugmentationen sowie uteruserhaltende Optionen, berücksichtigt

lapse are presented. The recommendations are based on an extensive and systematic review and evaluation of the current literature and include the experiences and specific conditions in Germany, Austria and Switzerland.

wurden. Sie beruhen auf einer umfassenden, systematischen und aktuellen Literaturbetrachtung und -auswertung unter Berücksichtigung von Erfahrungen und spezifischen Bedingungen in Deutschland, Österreich und der Schweiz.

I Information on the Guideline

Guidelines program of the DGGG, OEGGG and SGGG

Information on the guidelines program is available at the end of the guideline.

Citation format

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Guideline documents

The complete long version together with a list of the conflicts of interest of all authors, a guideline report and a PDF slide version for PowerPoint presentations are available in German on the homepage of the AWMF:
http://www.awmf.org/leitlinien/detail/ll/015-006.html

Authors

Cf. **Table 1**.

Abbreviations

CI	Confidence interval
ICI	International Consultation on Incontinence
ICS	International Continence Society
IUGA	International Urogynecological Association
OAB	Overactive bladder
OR	Odds ratio
POPQ	Pelvic organ prolapse quantification system
QOL	Quality of life
RCT	Randomized controlled trial
RR	Relative risk
TVT	Tension-free vaginal tape

II Application of the Guideline

Purpose and objectives

The aim of this guideline is to provide an evidence-based overview of the diagnosis and the conservative and surgical therapy of female pelvic organ prolapse and to offer support for targeted decision-making as part of individual patient care.
The recommendations are based on an extensive, systematic review and evaluation of the current literature and also take the experiences and specific conditions in Germany, Austria and Switzerland into account. This represents an update of the guidelines of 2008 and also includes the warnings issued by the American Food and Drug Administration (FDA) in its recent notification of 2011 (http://www.fda.gov/medicaldevices/safety/alertsandnotices/publichealthnotifications/ucm061976.htm), which resulted in considerable changes to pelvic surgery and the placement of surgical meshes. But of course, this guideline does not absolve physicians from the necessity of keeping up-to-date with the most recent literature and *does not replace decision-making with the patient*.

Targeted area of patient care

- Inpatient care, German-speaking countries, cross-sectoral care
- Outpatient care, German-speaking countries, cross-sectoral care

This guideline targets patients aged 18 years and older with symptomatic or asymptomatic female pelvic organ prolapse with or without stress urinary incontinence.

User group/target audience

This guideline is aimed at gynecologists, coloproctologists and physiotherapists. It additionally provides information for urologists and GPs.

Adoption and period of validity

This guideline is valid from May 1st, 2016 through to April 30th, 2019. Because of its specific contents, this period of validity is only an estimation. If important changes in the evidence should occur, amendments to the guideline will be published by the AWMF after a methodological validation even before the period of validity has expired.

III Methodology

The methodology used to compile this guideline was based on a stratified classification system. The rules are prescribed by the AWMF rulebook (version 1.0). Guidelines are differentiated into lowest level (S1), intermediate level (S2e or S2k) and highest level (S3).The lowest level is defined as a collection of recommendations for action compiled by a non-representative group of experts. In 2004 the S2 category was subdivided into 2 sublevels: systematic evidence-based (S2e) and structurally consensus-based (S2k). The highest level (S3) integrates both approaches.
This guideline corresponds to level: S2e

Literature search, inclusion and exclusion criteria

- An extensive literature search in MEDLINE, Embase, Cinahl, Pedro and the Cochrane Register, in reference lists and among the abstracts of the Annual Meetings of the International Continence Society (ICS) and the International Urogynecological Association (IUGA).
- Abstracts were included if they described randomized studies which had been presented to and discussed by a panel of experts.
- Following the 2nd FDA warning in July 2011 on the use of synthetic meshes in vaginal prolapse surgery (http://www.fda.gov/downloads/medicaldevices/safety/alertsandnotices/ucm262760.pdf), the original plan to include literature up until 2011 was expanded. Publications up until 2014 were included.
- Search terms: pelvic organ prolapse, cystocele, rectocele, enterocele, uterine prolapse AND therapy, pessary, pelvic floor exercise, pelvic floor muscle training, surgery, repair, colporrhaphy, sacrocolpopexy, sacral colpopexy, mesh, stress urinary incontinence; ultrasound, ultrasonography, urodynamics; complications
- Inclusion criteria: original research published since 2008; follow-up of at least 12 months to evaluate success rates; no time limits for descriptions of perioperative complications.
- No limitations with respect to language.
- Definition of anatomical success following surgery: no prolapse beyond stage 1 according to the IUGA/ICS prolapse quantification system [1,2]. Stage 2 is considered an anatomical failure. This corresponds approximately to Baden-Walker Grade 2, i.e. “prolapse to the hymen”, while Grade 1 (“prolapse half-way to the hymen”) would still be assessed as a success or as normal, as long as the patient is asymptomatic [3].

Grading of evidence using Oxford

For the purposes of this guideline, evidence was classified (levels 1–5) in accordance with the classification system of the **Oxford** Centre for Evidence-based Medicine in its 2009 version.
While the quality of the evidence (strength of evidence) is intended as an indication of the robustness of the published data and therefore of the degree of certainty/uncertainty associated with the data, the level of recommendation expresses the result of weighing up desired vs. unwanted consequences of alternative approaches. For more information, please refer to the following homepage: http://www.cebm.net/o?=1025.

Recommendation grading

The individual recommendations have been formulated in such a way that they indicate the level of requirement for each recommendation. There are three levels of requirement. The level of requirement depends on the ratio between the benefits and the disadvantages of alternative approaches. The terms "must/must not" indicate a strong recommendation (high level of requirement), "should/should not" indicate a simple recommendation (mid-level requirement), and "can" or "may"/"cannot" or "may not" signify an open recommendation (limited level of requirement); if the recommendation is contraindicated, the physician must make a decision after carefully weighing up the options. This also applies to strong recommendations.

Symbol	Description of grade of recommendation	Wording
A	Strong recommendation, highly binding	must/must not
B	Recommendation, relatively binding	should/should not
0	Open recommendation, not binding	may/may not

Conflicts of interest

The conflict of interest statements of all guideline authors were entered in the AWMF form, and the tabular list is included in the long version of the guideline and in the guideline report (both in German).

IV Guideline

1 Introduction and definitions

Female pelvic organ prolapse or female genital prolapse is a common condition in women; the incidence of pelvic organ prolapse is increasing due to the overall rise in life expectancy. Therapy options consist of a number of conservative or surgical approaches. The aim of this guideline is to provide an evidence-based description of the diagnosis and the conservative and surgical therapy of female pelvic organ prolapse in women aged over 18 years. National and international socio-economic conditions were also taken into consideration.

The recommendations for the diagnosis and treatment of female pelvic organ prolapse are based on an extensive, systematic review and evaluation of the recent literature which also took account of the experiences and specific conditions in Germany, Austria and Switzerland. The guideline is an update of the guideline published in 2008 and has also included the warnings of the American Food and Drug Administration (FDA), including the last notification published in 2011 (http://www.fda.gov/medicaldevices/safety/alertsandnotices/publichealthnotifications/ucm061976.htm) which led to substantive changes in prolapse surgeries using mesh implants. General dissatisfaction with the anatomical outcomes following standard prolapse surgery resulted in a significant increase in the use of various biological and synthetic implants (meshes). Following the second warning by the FDA, some of industrially produced mesh kits which were still available five years ago have since been withdrawn from the market (e.g. Prolift®, Prosima®, Avaulta®, Perigee® in the USA, in the meantime also Elevate®). The material properties (macropores > 75 µm and lightweight ≤ 32 g/m^2 meshes, no multifilament absorbable or non-absorbable materials) of the new generation of meshes have been improved or amended, and the required apical fixation has now also been integrated.

Female pelvic organ prolapse is often associated with stress urinary incontinence. The symptoms of stress urinary incontinence have been defined as a leakage or loss of urine in response to physical activities such as coughing or lifting. If urine leakage during coughing only occurs after repositioning of the prolapse during clinical examination or after insertion of a pessary, it is referred to as *occult stress incontinence*. In addition to repair of the prolapse, the simultaneous protection or recreation of continence is a special aspect which is also discussed in this guideline.

2 Diagnosis

2.1 Medical history

A standardized questionnaire should be used to record the patient's specific medical history of pelvic floor symptoms. It is recommended that validated questionnaires which also include an assessment of the patient's quality of life should be used to assess quality control and in all studies [1]. Validated pelvic floor questionnaires available in German include the questionnaire of the International Consultation on Incontinence (ICI; www.iciq.net), the German version of the King's Health Questionnaire [2], the German version of the "urinary incontinence-specific measure of quality of life" (I-QOL) [3] and the German Pelvic Floor Questionnaire (German version of the Australian Pelvic Floor Questionnaire) [4], for which a validated post-therapeutic follow-up module is also available [5].

2.2 Clinical examination

In addition to standard inspection of the external genitalia, assessment of the prolapse is done using a split speculum, and the evaluation must include coughing or pushing. The extent of prolapse must be documented separately for the anterior (bladder, anterior vaginal walls), middle (cervix or uterine stump) and posterior compartment. Quantification of the pelvic organ prolapse using the ICS/IUGA standard terminology is internationally recommended [6, 7]. This should then be followed by a cough stress test carried out both without repositioning and after repositioning of the prolapse, e.g. with a speculum, pessary, swab or digitally, to detect clinical or occult stress urinary incontinence.

Further examination must consist of vaginal palpation of the pelvic floor and must include an assessment of pelvic floor contractility as well as rectal examination of patients with defecation disorders and fecal incontinence.

Quick urine tests (dipstick test) are not sufficiently sensitive for proper urine analysis; women with dysuria and a negative urine dipstick test should be assessed using a urine culture test with an antibiogram [8, 9].

2.3 Imaging

2.3.1 Sonography

For an in-depth discussion, please refer to the detailed AWMF guideline on the use of ultrasonography in urogynecology (only available in German: Sonographie im Rahmen der urogynäkologischen Diagnostik, 015-055).

Assessment of residual urine with ultrasonography is part of the standard examination for prolapse and bladder voiding disorders.

Evidence-based recommendation 2.E1

Level of evidence 3 **Grade of recommendation 0**

Renal sonography to exclude urinary retention is particularly recommended in patients with high-grade prolapse. The prevalence of hydronephrosis is reported to be 5–17%, although this usually decreases following surgical treatment [52–55].

Evidence-based recommendation 2.E2

Level of evidence 3 **Grade of recommendation 0**

Pelvic floor sonography can be a useful diagnostic tool in addition to vaginal and rectal examination.
Biological meshes are not detectable sonographically [10]. The position, mobility, folding and even tearing of the proximal anchor fixation of synthetic meshes can be detected sonographically using a perineal, introital or endovaginal approach [10–13].

Evidence-based recommendation 2.E3

Level of evidence 3 **Grade of recommendation 0**

Perineal sonography can also be used as visual biofeedback to explain findings to patients and show how pelvic floor contractions affect the bladder neck, e.g. prior to coughing to reduce the prolapse [14–16].

Evidence-based recommendation 2.E4

Level of evidence 4 **Grade of recommendation 0**

Vaginal sonography can be used to shed light on a number of different aspects:

- For a depiction of the uterus and the adnexa prior to surgery
- To exclude uterine pathologies prior to carrying out uterus-preserving surgery
- To assess cervical length or the relationship between the uterine body and the cervix: cervical elongation after uterus-preserving surgery can result in persisting symptoms.
- To exclude extrauterine pelvic pathologies

2.3.2 MRI

As with defecography, dynamic MRI can be used to obtain images of all three compartments at rest, during pressing, and during contractions of the pelvic floor [17]. Dynamic MRI can be used to visualize complex and/or recurrent prolapse conditions [18, 19] and is particularly suitable to assess internal rectal prolapse/intussusception and rectal emptying or stool retention [20–22].

Evidence-based recommendation 2.E5

Level of evidence 3 **Grade of recommendation 0**

Dynamic MRI can be useful to visualize complex conditions and symptoms.

2.4 Urodynamic examination

Evidence-based recommendation 2.E6

Level of evidence 3 **Grade of recommendation 0**

A systematic review of diagnostic tests showed that the patient's medical history and a clinical stress test are good predictors of stress urinary incontinence in urodynamic studies [23, 24]. There are no data which confirm the necessity of carrying out urodynamic studies prior to planned prolapse surgery. Occult stress incontinence can also be detected by carrying out stress test with a sufficiently full bladder after prolapse repositioning.

2.5 Cystourethroscopy

Evidence-based recommendation 2.E7

Level of evidence 4 **Grade of recommendation 0**

If diffuse symptoms and findings such as bladder pain and hematuria are also present, particularly if the patient has had a previous operation, cystourethroscopy can help to exclude morphological causes such as bladder tumors or stones, urethral stenosis, intravesical mesh erosion, or chronic urothelial changes caused by interstitial cystitis [25–27].

Evidence-based recommendation 2.E8

Level of evidence 3 **Grade of recommendation B**

Cystourethroscopy is recommended at the end of prolapse surgery to exclude intraoperative bladder and urethral injury and to establish ureter function.

3 Patient Information

To enable patients to make an informed decision, the information given to patients should be well structured and should include, where possible, the physician's own data on the successes and complications of interventions. The discussion with the patient should include information about the patient's medical condition; observant, conservative and surgical treatment options along with their anatomical and functional success rates; the advantages and disadvantages of mesh implants; complications and their treatment options; the impact of therapy on the patient's sexuality, bladder and bowel functions, and further surgical interventions which could potentially be necessary (e.g. two-stage stress urinary incontinence surgery).

4 Conservative Therapy

As many women are not aware of their pelvic organ prolapse, surgery should only be carried out in symptomatic patients and in patients who are bothered by the prolapse [28]. Conservative options include pelvic floor rehabilitation, pessary therapy, clinical observation, reduction of known risk factors such as obesity, smoking and chronic constipation, digital support during defecation (pressure placed on the posterior vaginal wall or the perineum).

Evidence-based recommendation 4.E1

Level of evidence 3 **Grade of recommendation C**

As prolapse regression without therapy has also been reported [28, 29], observation alone should also be listed as an option during the discussion with the patient.

Evidence-based recommendation 4.E2

Level of evidence 2 **Grade of recommendation B**

Systemic hormone replacement therapy is not beneficial for pelvic floor function and should not be explicitly prescribed to treat prolapse or incontinence [30, 31].

Evidence-based recommendation 4.E3

Level of evidence 2 **Grade of recommendation B**

The application of topical estrogen in the vagina is an established treatment for vaginal dryness and irritation of the vagina (e.g., to treat symptoms of atrophic vaginitis) [32, 33] and is essential in pessary therapy to prevent local lesions, bleeding, and necrosis [34, 35].

4.1 Pelvic floor muscle training

Several randomized studies have shown that targeted pelvic floor muscle training can reduce the symptoms of prolapse, lower the grade of prolapse, and prevent progression [36–41]. Studies have also demonstrated an improvement in associated stress urinary incontinence following pelvic floor muscle training [37,39,42]. It should be noted, however, that in these studies the correct pelvic floor contraction was determined by the physiotherapist by means of palpation. This was then followed by individual and targeted training of the pelvic floor musculature, which should not be equated with the unspecific pelvic floor exercises often done in Germany [43].

Five controlled randomized studies reported conflicting results in response to the question whether perioperative pelvic floor muscle training could improve functional outcome after prolapse and/or incontinence surgery [44–47]: two of the studies [44,46] reported improved incontinence and prolapse symptoms; however, three other studies [45,47,48] found no difference in outcomes.

4.2 Pessary therapy

Pessaries can be successfully fitted in most women [49], with observational studies reporting success in around 50–100% of cases; however, successful continuation of pessary therapy is much lower, with a reported rate of 14–67% [50–59]. In addition to prolapse symptoms, stress incontinence has been reported to improve in 23–45% of cases; studies have also reported improvements for overactive bladder, defecation disorders, sexual function and body image [52,60–63]. A prospective study found no significant differences in terms of symptom scores between the functional results for pessary therapy and those for surgical therapy [64].

Indications for pessary therapy can include patient preference for conservative treatment, temporary family planning when the patient intends to have more children, and an increased risk of perioperative complications due to co-morbidities [65].

4.3 Recommendations for conservative therapy

Evidence-based recommendation 4.E4

Level of evidence 1 **Grade of recommendation B**

Targeted pelvic floor muscle training (note: not gymnastical exercises) should at least be offered to patients who have lower stages of prolapse (Stages I and II) to reduce prolapse symptoms and concomitant stress urinary incontinence.

Evidence-based recommendation 4.E5

Level of evidence 3 **Grade of recommendation 0**

Accompanying perioperative pelvic floor rehabilitation may be considered; however, the results reported in studies differ considerably.

Evidence-based recommendation 4.E6

Level of evidence 2 **Grade of recommendation B**

Pessary therapy is a good conservative option which should be offered to patients. It is still not clear which pessary is most suitable for which type of prolapse.

5 Surgical Therapy of Anterior Compartment Prolapse

5.1 Anterior colporrhapy or anterior vaginal wall repair

Evidence-based recommendation 5.E1

Level of evidence 3 **Grade of recommendation B**

Simultaneous apical fixation appears to significantly reduce the risk of recurrence. The patient should be examined to determine whether concomitant anterior and middle compartment prolapse is present, as anterior vaginal wall repair could be performed concomitantly with apical fixation.

Evidence-based recommendation 5.E2

Level of evidence 3 **Grade of recommendation 0**

The risk of cystocele recurrence appears to be higher following anterior vaginal wall repair in patients with levator defects (avulsions). Anterior mesh placement can be considered in these patients [74].

Prolapse of the anterior vaginal wall is commonly associated with an apical defect, so that surgical repair of the middle compartment should be considered in these patients [66].

Success rates for anterior vaginal wall repair were reported in 22 randomized studies; they varied strongly and also depended on the additional surgical procedures carried out concomitantly. Because of the different surgical techniques used in the studies, the calculated cumulative success rate of 63% for more than 1000 women who underwent surgery should be interpreted with caution.

If surgery is performed concomitantly to support the apical (middle) compartment, the risk of recurrence decreases significantly (OR: 0.68; 95% CI: 0.54–0.85).

The risk of recurrence appears to increase almost twofold in patients with levator defects (avulsion of the pubococcygeus muscle from the pubic rami) [67–70].

5.2 Surgery using synthetic or biological implants

Evidence-based recommendation 5.E3

Level of evidence 1 a **Grade of recommendation A**

The use of synthetic meshes in the anterior compartment further reduces the anatomical and subjective risk of prolapse recurrence but has no positive impact on patients' quality-of-life. However, de novo dyspareunia and re-operation for mesh complications and urinary stress incontinence are more common compared to anterior vaginal wall repair. The decision making process has to include information on rates of re-operation, chronic pain syndrome and dyspareunia.

Evidence-based recommendation 5.E4

Level of evidence 3 **Grade of recommendation 0**

When placing a synthetic mesh in the anterior compartment, concomitant apical mesh fixation or surgery to stabilize the middle compartment can be considered.

Evidence-based recommendation 5.E5

Level of evidence 1 b **Grade of recommendation B**

Because the success rates for biological implants are not higher than the success rates for anterior vaginal wall repair, biological implants should not be used.

Evidence-based recommendation 5.E6

Level of evidence 3 **Grade of recommendation 0**

Women with levator defects (avulsion of the pubococcygeus muscle from the lower pubic rami) generally appear to have an increased risk of recurrence, although the risk is lower following anterior synthetic mesh augmentation. Anterior synthetic mesh augmentation can or may therefore be considered in these patients.

In studies with apical fixation or concomitant apical surgery [71–79], anterior repair using a synthetic mesh (excluding Prolift® and Perigee®) had a cumulative success rate of 93%; the cumulative success rate of studies without apical fixation or without standard apical surgery [80–89] was 83%. The cumulative rate of mesh erosion was 8% (137/1740); the cumulative rate for chronic pain and de novo dyspareunia was 7% (59/846).

In a retrospective analysis, women with levator avulsion had a higher risk of cystocele recurrence even after placement of a synthetic mesh [90].

A meta-analysis of randomized studies showed that the risk of recurrence increased threefold when no synthetic mesh was placed (RR: 3.5; 95% CI: 2.7–4.4). The success rate for anterior repair was 52%, which increased to 86% ($p < 0.001$) with mesh augmentation. Overall, repeat surgery for mesh complications, stress urinary incontinence or recurrent prolapse was more common following synthetic mesh implantation (RR: 0.58; 95% CI: 0.42–0.81). Anterior repair reduced the risk of a repeat operation. After anterior repair, the risk of de novo dyspareunia, which occurs more frequently after transobturator synthetic mesh placement, was also lower (RR: 0.46; 95% CI: 0.22–0.96). But this was not reflected in the validated sexual questionnaires (PISQ) which were used in some studies.

Meta-analysis of randomized studies showed that Pelvicol® augmentation did not offer better results than anterior repair (RR: 1.3; 95% CI: 0.8–2.2). Only one RCT [91] reported superior results following Pelvicol® augmentation. This did not change, even when the results of all studies which used any type of biological implant were combined; the use of biological graft material did not appear to improve success rates (RR: 1.34; 95% CI: 0.97–1.86).

5.3 Vaginal, abdominal or laparoscopic repair of paravaginal defects

Because studies differed considerably and the concomitant procedures, which mainly affected the middle compartment and often included apical fixation, also varied significantly, the reported success rates of between 70 and 100% (*vaginal repair:* between 90 and 100%, cumulative success rate: 91% [92–97]; *abdominal repair:* between 70 and 95%, cumulative success rate: 94% [92, 98–102]; *laparoscopic repair:* only one study, success rate: 80% [103]) should be interpreted with caution.

5.4 Recommendations for the anterior compartment

Evidence-based recommendation 5.E7

Level of evidence 3 **Grade of recommendation B**

If anterior vaginal wall repair is carried out, concomitant apical fixation appears to significantly decrease the risk of recurrence. Patients should therefore be examined carefully to determine whether they may have both anterior and middle compartment prolapse which would then allow anterior vaginal wall repair to be combined with apical fixation.

Evidence-based recommendation 5.E8

Level of evidence 3 **Grade of recommendation 0**

The presence of a levator defect (avulsion) appears to increase the risk of cystocele recurrence following anterior vaginal wall repair, and anterior mesh placement can be considered in these patients [70].

Evidence-based recommendation 5.E9

Level of evidence 1a **Grade of recommendation A**

The use of synthetic mesh in the anterior compartment reduces the anatomical and subjective rates of prolapse recurrence but without having an additional impact on patients' quality of life. However, rates of de novo dyspareunia and repeat surgery for mesh complications and stress urinary incontinence are higher compared to rates for anterior vaginal wall repair, indicating that discussions with the patient must include information about repeat surgery, chronic pain syndrome, and dyspareunia.

Evidence-based recommendation 5.E10

Level of evidence 3 **Grade of recommendation 0**

When placing a synthetic mesh in the anterior compartment it is worth considering concomitant apical mesh fixation or surgery to stabilize the middle compartment.

Evidence-based recommendation 5.E11

Level of evidence 1b **Grade of recommendation B**

Because the success rates for biological implants are not higher compared to the rates for anterior vaginal wall repair, biological implants are not necessary.

Evidence-based recommendation 5.E12

Level of evidence 3 **Grade of recommendation 0**

Women with levator defects (avulsion of the pubococcygeus muscle from the pubic rami) generally appear to have a higher risk of recurrence, although the risk is lower after anterior synthetic mesh augmentation, which is why this approach should be considered for these patients.

Evidence-based recommendation 5.E13

Level of evidence 3 **Grade of recommendation 0**

A lack of adequate studies makes it impossible to give a clear recommendation in support of paravaginal defect repair, irrespective of whether it is carried out vaginally, abdominally or laparoscopically. This is because apical procedures are usually carried out concomitantly and contribute to high success rates.

6 Surgical Therapy of Posterior Compartment Prolapse

Rectoceles and posterior enteroceles can be the cause of both prolapse symptoms and defecation disorders. Defecation disorders often require manual transvaginal, transanal or perineal assistance. It is important to determine preoperatively whether these disorders are caused by a rectocele, an intussusception or by descending perineum syndrome. Interdisciplinary collaboration with coloproctologists can be useful, particularly if a defecation disorder is present without a visible rectocele.

6.1 Posterior colporrhapy or posterior vaginal wall repair

The cumulative success rate for **posterior vaginal wall repair using midline suturing of vaginal connective tissue (fascia)** is significantly higher at 86% (cumulative success rate: 83/576) than the 70% reported for **defect-specific repair** (cumulative success rate: 82/271). The risk of recurrence is significantly reduced if midline fascial suturing is done (OR: 0.4; 95% CI: 0.28–0.56), which is why this technique should be the method of choice for primary rectocele repair.

The standard approach used to consist of the plication of the levator ani, particularly of the distal levator, but this technique did not reduce the rate of recurrence (45/220, cumulative success rate 80%). Instead, use of an isolated midline fascial suture has been found to yield better results (OR: 0.65; 95% CI: 0.44–0.98) [104–106]. Approximation of the levator ani is not considered

necessary for posterior vaginal wall repair, as the success rates with this method are not higher than those obtained using a midline fascial suture, and high rates of dyspareunia have been reported with this technique.
Two randomized studies reported that transvaginal posterior vaginal wall repair was superior to transanal rectocele repair in terms of anatomical and functional success rates [104,107]. Transvaginal posterior vaginal wall repair is the method of choice to treat symptomatic rectocele and should be used in preference to transanal rectocele repair.

6.2 Surgery using synthetic or biological implants

The use of **biological implants in the posterior compartment** did not show any benefits compared to posterior vaginal wall repair. On the contrary, posterior vaginal wall repair was found to be superior to the augmentation procedure with grafts, and meta-analysis of all comparative randomized and non-randomized studies showed that posterior vaginal wall repair halved the risk of recurrence (RR: 0.58; 95% CI: 0.41–0.84). The use of xenografts (biological implants) in the posterior compartment should be avoided because their use offers no benefits.
There are no randomized studies on the use of non-absorbable **synthetic mesh in the posterior compartment**. Although non-controlled prospective and retrospective studies reported a lower rate of recurrence when synthetic mesh was used, there are currently no comparative studies. There is therefore no reason to use synthetic meshes *routinely* for primary vaginal wall repair of the posterior compartment.

6.3 Recommendations for the posterior compartment

Evidence-based recommendation 6.E1

Level of evidence 1 **Grade of recommendation A**

Posterior vaginal wall repair to treat a symptomatic rectocele should be chosen in preference to transanal rectocele repair.

Evidence-based recommendation 6.E2

Level of evidence 2 **Grade of recommendation B**

Posterior vaginal wall repair using midline fascial suturing resulted in higher rates of success compared to defect-specific fascial repair and this method should be preferred for primary rectocele repair.

Evidence-based recommendation 6.E3

Level of evidence 3 **Grade of recommendation 0**

Plication of the levator ani is not necessary for posterior vaginal wall repair as it does not result in higher success rates compared to a midline fascial repair and the procedure is associated with high rates of dyspareunia.

Evidence-based recommendation 6.E4

Level of evidence 1b **Grade of recommendation A**

Xenografts (biological implants) should not be used for prolapse repair in the posterior compartment because their use offers no benefits.

Evidence-based recommendation 6.E5

Level of evidence 3 **Grade of recommendation 0**

There are no randomized studies on the use of non-absorbable mesh in the posterior compartment. Although non-controlled prospective and retrospective studies showed that synthetic mesh placement was associated with a lower rate of recurrence, there are no comparative studies on this issue. There is therefore currently no reason to use synthetic meshes *routinely* for primary repair of the posterior compartment.

7 Surgical Therapy of Middle Compartment Prolapse

The surgical repair of suspension defects in the middle compartment (level 1 according to DeLancey [108]) is of special importance as this repair is often carried out in addition to repair of the anterior or posterior compartment and is also as a stand-alone procedure to treat uterine or vaginal vault prolapse.

7.1 Uterosacral ligament fixation/McCall technique/ Shull technique

A systematic review of transvaginal high fixation of the vaginal vault to the uterosacral ligaments showed a cumulative apical success rate of 98% (95% CI: 95.7–100), an anterior success rate of 81% (95% CI: 67.5–94.9) and a posterior success rate of 87% (95% CI: 80–94.9) [109]. Retrospective studies of laparoscopic fixation of the vaginal vault to the uterosacral ligaments after concomitant hysterectomy reported an apical failure rate of 11–13% [110,111].
Vaginal suspension using the uterosacral ligaments is associated with the risk of ureteral injury, ureter ligation and ureteral medial deviation in around 6% (1–11%), and intraoperative cystoscopy is therefore recommended.

7.2 Sacrospinous fixation

In a randomized study published in 2014, Barber et al. [48] reported no significant anatomical or functional differences between vaginal fixation to the uterosacral ligaments or sacrospinous fixation.
Recurrence is most common in the anterior compartment, with reported rates of 5–39% (157/1036, 15%), and occurs less often in the posterior compartment (5–12%, 32/442, 7%). Apical fixation is very effective with a cumulative success rate of 96% (rate of recurrence: 0–14%, 45/1121 [4%]).

7.3 Abdominal, laparoscopic and robot-assisted sacrocolpopexy

A systematic review by Nygaard et al. [112] reported apical success rates of 78–100% for abdominal sacrocolpopexy and a cumulative rate of re-operation for prolapse recurrence of 4.4%. In 23 studies, *laparoscopic sacrocolpopexy* had an equally high cumulative success rate of 91% (number of failures: 215/2341).
In a randomized study, Maher et al. compared laparoscopic sacrocolpopexy including anterior and posterior polypropylene mesh extension with the vaginal Prolift® mesh kit which has since been withdrawn from the market by its manufacturer (Ethicon®) and is no longer available [113]. While laparoscopic sacrocolpopexy took longer (difference: + 52 min [95% CI: 41.5–62.6]), patients were discharged earlier from hospital and were able to resume day-to-day activities more quickly. After two years, recurrence across all compartments was significantly more common in the vaginal mesh group (57 vs. 23%) [113], as was the rate of re-operations (22 vs. 5%, p = 0.006).

7.4 Vaginal high levator myorrhaphy and vaginal fixation of the vaginal vault to the Iliococcygeus fascia

In a randomized study, the apical success rate was 97% after levator myorrhaphy and 98% following uterosacral ligament fixation. The rate of cystocele recurrence was relatively high at 29 and 35%, respectively [114]. There are only a few case series describing vaginal fixation to the fascia of the iliococcygeus muscle, with apical success rates of 53, 83 and 96%.

7.5 Uterus-preserving procedures

If the uterus is healthy with no history of previous disease and no signs of clinical or sonographic uterine pathology, if the patient wishes it, she should be offered a uterus-preserving procedure. Options include vaginal sacrospinous hysteropexy, laparoscopic or open sacrohysteropexy with mesh interposition, and fixation of the uterus to the uterosacral ligaments. Please also refer to the AWMF hysterectomy guideline (015-070).

Five studies directly compared vaginal hysterectomy with vaginal vault fixation to the uterosacral ligaments and sacrospinous hysteropexy but found no significant differences (rates of recurrence: 8 vs. 4%).

7.6 Colpocleisis

Colpocleisis is considered a relatively quick procedure with few complications and is predominantly offered to older women with multiple morbidities who are no longer sexually active and no longer wish to be sexually active. Recurrence following colpocleisis is very rare; studies report an improvement in quality of life and in bladder and bowel function but also that a small number of women (< 5%) regretted the operation [115,116]. Crisp et al. [117] reported in 2013 that 13.8% of 87 women regretted the procedure.

7.7 Recommendations for the middle compartment

Evidence-based recommendation 7.E1

Level of evidence 2 **Grade of recommendation A**

There is good evidence showing that sacrospinous colpopexy, vaginal or laparoscopic fixation to the uterosacral ligaments and open, laparoscopic or robot-assisted sacrocolpopexy can all be used for the repair of middle compartment prolapse, with success rates of more than 90% reported in the literature. The final choice of procedure must be made together with the patient and must weigh up all the findings and symptoms, comorbidities, risk factors, the potential benefit of a planned concomitant hysterectomy procedure, the patient's own wishes, and the department's level of expertise.

Evidence-based recommendation 7.E2

Level of evidence 2 **Grade of recommendation B**

Abdominal sacrocolpopexy is a procedure which has been studied very extensively and for the longest period of time; it is currently the most effective procedure. Laparoscopic sacrocolpopexy can also be considered by departments with the necessary experience in carrying out the procedure.

Evidence-based recommendation 7.E3

Level of evidence 2 **Grade of recommendation B**

Carrying out a hysterectomy concomitantly with sacrocolpopexy should be avoided because of the increased risk of mesh erosion.

Evidence-based recommendation 7.E4

Level of evidence 1b **Grade of recommendation B**

Sacrocolpopexy and sacrospinous fixation procedures are approximately equivalent but offer different benefits and have different disadvantages.
If there are no contraindications, sacrocolpopexy can be carried out in preference to sacrospinous fixation.

Evidence-based recommendation 7.E5

Level of evidence 2 **Grade of recommendation A**

The use of absorbable or biological implants for fixation to the sacrum in sacrocolpopexy is not recommended.

Evidence-based recommendation 7.E6

Level of evidence 2 **Grade of recommendation B**

Intraoperative cystoscopy is recommended for vaginal vault suspension to the uterosacral ligaments because of the increased risk of injury to the ureter.

Evidence-based recommendation 7.E7

Level of evidence 2 **Grade of recommendation B**

Uterine preservation should be considered in patients with the appropriate indications. Vaginal sacrospinous hysteropexy is a good option; there is not yet enough long-term data available on sacrohysteropexy procedures with mesh interposition or fixation to the uterosacral ligaments.

Evidence-based recommendation 7.E8

Level of evidence 3 **Grade of recommendation 0**

Vaginal high levator myorrhaphy and vaginal fixation of the vaginal vault to the fascia of the iliococcygeus muscle have not been studied much and should therefore only be carried out if specifically indicated or if there are no other alternatives.

Evidence-based recommendation 7.E9

Level of evidence 3 **Grade of recommendation 0**

Colpocleisis can be considered in selected patients after carefully discussing the procedure with patients.

8 Genital prolapse and stress urinary incontinence

A risk calculator to weigh up the risk of postoperative stress incontinence was developed based on several models and studies [118]. The risk calculator takes a number of factors into account (www.r-calc.com/ExistingFormulas.aspx?filter=CCQHS).

8.1 Continent women with genital prolapse

A meta-analysis showed that, compared to transobturator mesh procedures, anterior vaginal wall repair protected patients from developing stress incontinence (RR: 0.64; 95% CI: 0.42–0.97) [119]. However, one study evaluated the long-term data after three years and no longer found any significant difference between the two procedures [72,120].

The CARE study [121] compared abdominal sacrocolpopexy in preoperatively continent women with (n = 157) and without (n = 165) concomitant Burch colposuspension. At two years postoperatively, significantly fewer women in the Burch group were incontinent. The study was therefore terminated ahead of schedule and is underpowered.

8.2 Women with symptomatic stress urinary incontinence and genital prolapse

The results of two randomized studies of women with stress incontinence and cystocele who underwent anterior vaginal wall repair showed that 48% (19/40) were continent postoperatively [122,123]. The cumulative continence rate following transobturator mesh was 61% (81/132) [124–126]. However, after the additional insertion of a suburethral tape, 235 out of 237 women (99%) were continent postoperatively [87,127–129].

One randomized study investigated the question whether treatment should be carried out as a one-stage or a two-stage procedure; it was found that the treatment of stress incontinence was equally successful, irrespective of whether the suburethral TVT was inserted at the same time as the anterior vaginal wall repair (83/87, 95%) or three months later (47/53, 89%; based on an on-treatment analysis) [130]. However, 27/94 women (29%) were continent following prolapse surgery alone and refused the planned TVT procedure three months later [130].

8.3 Women with occult stress incontinence and genital prolapse

Three randomized studies reported that suburethral tape insertion concomitantly with prolapse repair (especially anterior vaginal wall repair) significantly reduced stress incontinence rates (21/116, 18% vs. 64/125, 51%) [131–133]. A meta-analysis of these studies showed a decrease by almost 50% (RR: 0.54; 95% CI: 0.41–0.72).

8.4 Recommendations for prolapse and urinary stress incontinence

Evidence-based recommendation 8.E1

Level of evidence 2 **Grade of recommendation B**

In preoperatively continent women with genital prolapse, anterior vaginal wall repair is preferable to transobturator mesh placement to reduce the rate of de novo stress incontinence. The higher rate of recurrence associated with anterior vaginal wall repair compared to transobturator mesh placement should be take into consideration when discussing potential procedures with the patient.

Evidence-based recommendation 8.E2

Level of evidence 2 **Grade of recommendation B**

A concomitant Burch colposuspension can be additionally offered to patients undergoing sacrocolpopexy as a prophylactic measure against postoperative stress incontinence.

Evidence-based recommendation 8.E3

Level of evidence 1 a **Grade of recommendation A**

Patients with occult stress incontinence should be informed about the possibility of undergoing concomitant suburethral tape insertion during vaginal prolapse surgery.

Evidence-based recommendation 8.E4

Level of evidence 2 **Grade of recommendation A**

Suburethral tape insertion can also be performed as a two-stage procedure, e.g. at three months after prolapse surgery.

Evidence-based recommendation 8.E5

Level of evidence 2 **Grade of recommendation B**

Women with symptomatic stress incontinence and prolapse can be offered simultaneous surgery to treat stress incontinence.

Evidence-based recommendation 8.E6

Level of evidence 2 **Grade of recommendation 0**

Suburethral tape insertion can be carried out in preference to Burch colposuspension when treating patients with sacrocolpopexy.

9 Perioperative Management

There is very little evidence-based literature on the perioperative management of gynecological or urogynecological patients. Please refer to the appropriate AWMF guidelines for the perioperative administration of antibiotics, thrombosis prophylaxis and patient positioning (029-022, 003-001, 015-077).

Evidence-based recommendation 9.E1

Level of evidence 2 **Grade of recommendation 0**

Preoperative and/or postoperative pelvic floor muscle training may be prescribed; however, there is no clear evidence that this will improve incontinence and prolapse compared to pelvic floor surgery without perioperative pelvic floor muscle training.

Evidence-based recommendation 9.E2

Level of evidence 2 **Grade of recommendation B**

The preoperative placement of ureteral stents can be dispensed with as it does not reduce ureteral injuries.

Evidence-based recommendation 9.E3

Level of evidence 3 **Grade of recommendation 0**

Postoperative application of topical estrogen can improve vaginal flora and reduce granulation tissue; there is no evidence that it reduces the rates of mesh erosion.

10 Complications and Their Treatment

10.1 Mesh erosion, extrusion, shrinkage

The rates of vaginal erosion following abdominal sacrocolpopexy are between 0 and 10% after 7 years [134]. The reported rates following vaginal mesh implantation were between 0 and 30% [135, 136]; in the analysis carried out for this guideline the calculated rate was 8% (137/1740). Risk factors for erosion were concomitant hysterectomy procedure, smoking, and the use of polytetrafluoroethylene mesh [134] as well as higher BMI > 30 kg/m^2 (OR: 10) [137]. The colpotomy required for mesh placement should be as short as possible [138]. Smoking increases the risk of vaginal mesh erosion in both vaginal and abdominal mesh implantations (OR: 4.2; 95% CI: 2.5–7.0) [139–142].

Treatment depends on the extent of erosion and the presence or absence of co-infections. Topical application of estrogen is recommended but is often not enough, and partial excision of the mesh is then necessary [143]. The cumulative success rate for topical estrogen application to treat vaginal erosion is 24% (33/139) [142, 144–149].

10.2 Organ injuries

There are few reports in the literature on injuries to the bladder, urethra and ureter. Late visceral mesh erosion is rare, and the only literature to date consists of individual case reports.

Mesh implantation is still possible after intraoperative bladder injury and repair immediately intraoperatively. However, placement of a synthetic mesh should be avoided if there is inadvertent rectotomy intraoperatively.

10.3 Sexual dysfunction

Prolapse surgery can improve dyspareunia but it can also be the cause of dyspareunia arising from scarring, overcorrection, hematoma formation, or nerve irritation or injury. Chronic pain and dyspareunia have been reported in 3–13% of cases, particularly after vaginal mesh placement [135, 136]. If the cause of discomfort is found to be “tension” of the mesh or its fixation arms, treatment options include mobilization of the mesh, incision of the mesh or of its fixation arms, and excision of part of the mesh [144, 150]. Complete excision of the mesh is rarely indicated. Surgical procedures to partially or completely excise the mesh can be difficult; surgery may not always eliminate or reduce patient discomfort and can lead to further complications [150–152]. This is a particular problem of mesh-assisted surgical procedures, and it is therefore particularly important to provide the patient with detailed information on the risks involved.

10.4 Recommendations for the management of complications

Evidence-based recommendation 10.E1

Level of evidence 3 **Grade of recommendation B**

During the discussion with their physician, patients who smoke should be informed about the increased risk of mesh erosion after planned mesh implantation, and the physician should recommend that the patient stops smoking.

Evidence-based recommendation 10.E2

Level of evidence 3 **Grade of recommendation B**

Initial treatment of vaginal mesh erosion can consist of the application of topical estriol or estradiol. If the patient does not respond to treatment, local excision of the exposed mesh should be performed using tension-free vaginal suturing.

Evidence-based recommendation 10.E3

Level of evidence 3 **Grade of recommendation B**

Complete excision of the mesh, particularly of multifilament mesh, should be aimed for in patients with chronic mesh infection or recurrent abscess.

Evidence-based recommendation 10.E4

Level of evidence 3 **Grade of recommendation B**

Because of the high number of associated complications, multifilament mesh should not be used for prolapse repair.

Evidence-based recommendation 10.E5

Level of evidence 3 **Grade of recommendation 0**

If the mesh arms or the synthetic mesh are identified as the cause of chronic pain syndrome, partial or complete mesh excision or division of fixation arms from the central graft can be considered.

Evidence-based recommendation 10.E6

Level of evidence 4 **Grade of recommendation 0**

Planned mesh placement is still possible despite inadvertent injury to the bladder if the bladder is treated immediately intraoperatively; however, mesh placement should be avoided after inadvertent injury to the rectum.

11 Summary

An in-depth discussion with the patient about expectant, conservative and surgical management options to treat prolapse is necessary. Conservative options include targeted pelvic floor muscle training for patients with low grade prolapse, as this can reduce the extent of prolapse and incontinence symptoms, and pessary therapy. A pessary can usually be successfully fitted in most patients and is a low-risk option.

The individual surgical procedure should be chosen in a shared decision making process together with the patient. Current studies and evidence show that there is a wide range of surgical procedures which involve either autologous tissue or synthetic mesh augmentation. Because of the higher rate of complications after vaginal mesh implants, this should only be used when specifically indicated, after the patient has been informed in detail and the benefits and disadvantages carefully weighed up. At present, it is not possible to clearly define the indications. Possible indications include recurrent or total prolapse combined with risk factors such as obesity, chronic obstructive pulmonary disease and indications of generalized connective tissue weakness. Patients with levator defects (levator avulsions) have a higher risk of anterior compartment prolapse recurrence, and placement of a synthetic mesh appears to reduce this risk. Mesh placement should be considered for patients with high grade prolapse, prolapse recurrence, levator avulsions and for patients who are anxious about anatomical correction.

The patient must be informed in detail about the success rates of individual procedures with and without mesh placement, about the treatment alternatives and possible complications. The patient should be informed about the lack of studies on long-term outcomes after vaginal mesh placement.

Regular postoperative documentation of pelvic floor dysfunction and of patients' quality of life is recommended to evaluate the surgical technique and the indications and adapt them where necessary. New surgical procedures with or without implants should only be introduced in the context of clinical trials. In addition to anatomical outcomes, studies should particularly focus on the prospective evaluation of pelvic floor function and on patients' quality of life.

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