Quality Requirements for gynecological ultrasound examinations of DEGUM level II

Recommendations of the Sections/Working Groups Gynecology and Obstetrics of DEGUM, ÖGUM and SGUM

Qualitätsanforderungen an die gynäkologischen Ultraschalluntersuchungen der DEGUM Stufe II

Empfehlungen der Sektionen/Arbeitskreise Gynäkologie und Geburtshilfe der DEGUM, ÖGUM und SGUM

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ABSTRACT
Gynecological sonography is the central and most frequently used technical examination method used by gynecologists. Its focus is on the clarification of masses of the uterus and the adnexa, fertility diagnosis, clarification of bleeding disorders and chronic and acute pelvic problems, pelvic floor and incontinence diagnosis as well as the differential diagnosis of disturbed early pregnancy. The indication for diagnostic and therapeutic interventions, preoperative planning and postoperative controls are largely based on the findings of gynecological sonography. These examinations are particularly dependent on the experience of the examiner.

Based on the proven multi-stage concept of obstetric diagnostics, gynecological sonography should primarily be performed by an experienced and specialized examiner in patients for whom the initial gynecological examinations have not yet led to a sufficient assessment of the findings. So that the expert status required for this has an objective basis, the Gynecology and Obstetrics Section of DEGUM in coopera-
ition with ÖGUM and SGUM implemented the option of acquiring DEGUM Level II for gynecological sonography. The effectiveness of the care in the multi-level concept depends on the quality of the ultrasound examination at level I. Quality requirements for the basic examination and the differentiation between the basic and further examination have therefore already been defined by DEGUM/ÖGUM. The present work is intended to set out quality requirements for gynecological sonography of DEGUM level II and for the correspondingly certified gynecologists.

Common pathologies from gynecological sonography and requirements for imaging and documentation are described.

ZUSAMMENFASSUNG


Häufige Pathologien aus der gynäkologischen Sonografie und Anforderungen an die Bildgebung und Dokumentation werden beschrieben.

Objective
Gynecological sonography is the primary and most frequently used examination method used by gynecologists. It focuses on the clarification of uterine and adnexal masses, fertility diagnostics, clarification of bleeding disorders and chronic as well as acute lower abdominal complaints, pelvic floor and incontinence diagnostics as well as differential diagnostics of early pregnancy disturbances. The indication for diagnostic and therapeutic interventions, preoperative planning, and postoperative controls are largely based on findings of gynecologic sonography. These examinations are particularly dependent on the experience of the examiner [1–5].

The potential of MRI, CT, and PET as second-line diagnostics is undisputed, but unfortunately, gynecological issues are currently still being addressed in an unfocused manner by cost-intensive, partly radiation-intensive, and non-specialized techniques. This lack of confidence in gynecologic diagnostics is not evidence- or guideline-based [6]. Other radiological methods are not superior with respect to most issues; radiological cross-sectional imaging techniques can provide relevant information in only a few selected specific issues [7–15]. Such unnecessary use can cause treatment delays, suboptimal treatment rates, and primary over- and undertreatment if the therapeutic and care pathways of gynecological patients do not remain under the direction of gynecologists [16–18].

Imaging diagnostics are of central importance and are the focus of this study. However, it should not be forgotten that patient history as well as clinical and laboratory parameters are also of crucial importance for diagnosis.

Following the proven multistage concept of obstetric diagnostics, gynecologic sonography by an experienced specialized examiner should therefore be performed primarily on patients in whom the initial gynecologic examinations have not yet led to an adequate assessment of the findings. In order to provide an objective basis for the expert status required for this purpose, the Gynecology and Obstetrics section of the German Society for Ultrasound in Medicine (DEGUM), in cooperation with the its Austrian and Swiss counterparts (ÖGUM/SGUM), has implemented the possibility of acquiring DEGUM Level II for gynecologic sonography. However, the effectiveness of care in the multilevel concept is based on the quality of the ultrasound examination at Level I. Quality requirements for the baseline examination and the differentiation between baseline and follow-up examinations have therefore already been defined by DEGUM/ÖGUM [19]. The purpose of this paper is to present quality requirements for DEGUM Level II gynecologic sonography and as well as appropriate certification of for gynecologists.

Common pathologies seen in gynecological sonography and imaging and documentation requirements are described. This compilation is based on frequency, clinical relevance, evidence, and anchoring in current guidelines and does not claim to be exhaustive.
Pathologies of the Uterus

Pathologies of the myometrium

The main requirement for advanced sonography of the myometrium is the description of masses, especially the differentiation between fibroids and adenomyosis (Fig. 1d–f).

The reporting and documentation of a normal finding or pathological findings should include the items listed in Table 1 [20, 21] (Fig. 2, 3).

Fibroids represent the most common benign tumors of the uterus. Depending on their location, a distinction is made among subserosal, intramural and submucosal fibroids. A round shape and hypoechogenic structure are typical. In regresively altered fibroids, calcifications are also found as anechoic foci within the resistance. Color Doppler typically reveals vessels predominantly in the marginal area of the fibroids.

3D sonography is a suitable additive method for the evaluation of the myometrium and the endo-myo-metrial junction.

Despite the rarity of the pathology (0.3–0.4/100 000), the distinction between myoma and sarcoma is a common issue faced by sonographic as well as radiological imaging. In most cases, a sufficiently preoperative diagnosis is not possible [22]. If a patient presents with a question of sarcoma risk, the risk stratification criteria summarized in Table 2 should be reviewed [23, 24].

Cervical cancer

In addition to gynecological palpation and speculum examination, transvaginal sonography is a component of the primary gynecologic diagnosis of cervical cancer. In adenocarcinoma, cervical carcinoma is usually a hyper- or isoechogenic mass, whereas squamous cell carcinoma is usually hypoechogenic (Fig. 1m1). The task of advanced sonography is to supplement preoperative staging [26, 26]. The sonographic criteria have been summarized in Table 3.

Optional methods not proven by larger studies include 3D (power) Doppler sonography (Fig. 1m2), tomographic 3D sonography and elastography [27, 28]. 3D ultrasonography can spatially visualize abnormal perfusion within the cervix.

Uterine malformations

An accurate description of findings and classification of congenital uterine anomalies is essential for prognostic assessment and treatment planning. The diagnostic tool of choice is 3D sonography performed by an experienced examiner. Unfortunately, clinical practice often shows incorrect nomenclature.

Correct description of findings according to classifications and guidelines is decisive, but none of these guidelines are universally accepted [29].

- Classification according to the American Fertility Society/ASRM [30]
- VCUAM classification [31]
- Classification according to ESHRE/ESGE [11, 32]

In principle, diagnostic procedures in childhood and adolescence should be limited to as few invasive measures as possible, and radiation exposure should be kept to a minimum.

The clinically rare uterus didelphys can usually be diagnosed by two-dimensional imaging of 2 completely separated (hemi-) uteri. Particular attention should also be paid to the detection of 2 cervices. The two (hemi-) uteri are usually displaced towards the pelvic walls.

Conspicuous width of the uterus is an initial sonographic criterion for most uterine malformations. In cross section, two lateraled endometrial sections are still visible close to the fundus (Fig. 1g). The cavum shape is more recognizable by the endometrium, which is thicker and more echogenic during the secretory phase of the cycle.

After orientation by 2D ultrasonography, the use of 3D ultrasonography in specification is the method of choice, as it is the only one that allows accurate assessment of the cavum shape and the external fundal contour.

Most studies show a sensitivity of 3D ultrasound of more than 92 % for the correct detection of uterine malformation and at least an equivalence to MRI [11, 33–35].

The most common issue is the differentiation between the common septate or subseptate uterus and the comparatively rare bicorne uterus, which due to different therapeutic approaches, is of significant relevance. The separate assessment of the external and internal fundus contours in relation to the uterine cavity in an exact coronary plane is crucial. Here, the connecting line between the two ostia is considered the reference plane. In the case of subseptate uterus, there is an intracavitary indentation greater than 50 % of the myometrial fundus thickness or > 1 cm (Fig. 1h) [11, 36, 36].

In a bicornate uterus, the fundus is externally retracted more than 50 % of the myometrial fundus thickness or > 1 cm [11, 36]. 3D (transvaginal) sonography is essential for biometrically-anchored classification according to ESHRE/ESGE [37].

The cervix must also be evaluated in addition to assessment of the shape of the fundus. If there are two broad cervical parts which diverge in the lower section, a double cervix rather than a septated cervix must be assumed.

Intracavitary pathologies/endometrial assessment

Deviations from the normal endometrial structure can be caused by

- endometrial hyperplasia (Fig. 1k)
- endometrial carcinoma (Fig. 1l1, l2)
- endometrial polyps (Fig. 1i, j)
- intracavitary myomas
- synechiae

Findings and documentation of intracavitary pathologies in advanced sonography should be based on the criteria compiled in Table 4 [38–41].

3D sonography as well as sonohysterography can also provide additional information for the evaluation of the uterine cavity. In particular, coronary imaging of the uterine cavity makes it possible to obtain additional information using the 2D mode [42].
Endometrial carcinoma

Postmenopausal bleeding is the leading clinical symptom of endometrial carcinoma. The sonographic criteria of endometrial carcinoma are [41, 43]:

- increased endometrial thickness (at least > 4 mm, average between 11–26 mm)
- heterogeneous endometrium structure
- indistinct center line
- evidence of multiple, partially bundled vessels sprouting into the endometrium

Infiltration of the cervix as well as myometrial infiltration depth are easily assessable by transvaginal sonography; it supports preoperative staging and should be integrated into the description of findings [44].

Fallopian Tube Pathologies

Hydrosalpinx/saktosalpinx

Hydrosalpinx or saktosalpinx results from a functional obstruction of the tubes and accumulation of secretions in their lumen, often initially due to inflammation. Detection is particularly important when diagnosing infertility. The differentiation from ovarian cystic lesions is a challenge to differential diagnosis.

Typical manifestation in sonography includes:
- tubular, tortuous cystic mass
- evidence of pseudo septa (Fig. 4)
- echogenic, roundish wall deposits (beads-on-a-string) and "cogwheel" sign in cross-section due to deposits (Fig. 5)
- possibly a demarcation to a normal adjacent ovary can be shown

3D sonography can be helpful to demonstrate the tortuous cannular shape of the cystic distention of the tube [45].

Tubo-ovarian abscess

The sonographic evaluation of a tubo-ovarian abscess can be difficult in terms of differential diagnosis, since the picture can be heterogeneous and resembles malignant adnexal findings due to the formation of a conglomerate as well as strong vasculization (Fig. 6, 7). Pain is the dominant clinical symptom which can usually be specifically provoked by careful use of a transvaginal probe, together with inflammation.
Sonographically, the cystic parts are never anechoic, but are usually hypoechoic with a ground glass-like part (pus), which can be sharply separated by sludge [46].

**Ectopic pregnancy/tubal pregnancy**

Preoperative diagnosis of ectopic pregnancy relies primarily on combined serologic assessment of HCG progression and transvaginal sonography [47, 48].

Since this should already be mastered in the daily basic diagnostics, the criteria are presented in the soon to be published requirements of DEGUM Level I and at this point are only referred to [49, 50].

Ectopic pregnancies outside the fallopian tube are much rarer and diagnostically and therapeutically challenging; in which case specialized management is required. In particular, interstitial pregnancies, cesarean scar pregnancies, and cervical pregnancies should be considered.

**Tubal carcinoma**

In recent years, the fallopian tube has been discussed as an underestimated starting point of ovarian cancer. As a rule, differentiation from ovarian carcinoma is only successful if the tumor is clearly distinct from the ovary. Typical tubular carcinoma presents as an elongated rigid structure with irregular internal echomorphic pattern and increased perfusion on color Doppler examination.

**Pathologies of the Ovary**

The most important aspects of further examination of the ovary are to differentiate functional from pathologic changes of the ovary, to assess the risk of malignancy, and to attempt histopathologic classification. ▶ Table 5 summarizes the sonographic criteria which, according to current evidence, have proved particularly useful in the assessment of ovarian findings [49–51].

3D ultrasonography and 3D power Doppler imaging can make an additional diagnostic contribution in certain cases [52].

**Common benign ovarian findings**

Pathologies with common pathognomonic sonographic appearance include:
- simple (para-)ovarian cysts (▶ Fig. 8e),
- endometrioma (▶ Fig. 8f)
- mature teratomas/dermoid cysts (▶ Fig. 8g)
- serous or mucinous cystadenomas (▶ Fig. 8h, i) and
- fibromas (▶ Fig. 8k) [51, 53].

Therefore, these benign diagnoses should be evaluated, detected and documented in a targeted manner within the framework of further sonographic diagnostics.
The diagnosis of ovarian torsion is based on the combination of clinical symptoms and sonographic criteria, as summarized in Table 6 [54].

**Ovarian torsion**

Suspected torsion is an emergency diagnosis; consequently, there is no time for multi-level diagnostics in most cases. Therefore, it should be possible to make the diagnosis promptly even using basic diagnostics [10].

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| Table 4 Sonographic criteria for further evaluation of intracavitary pathologies. |
|----------------------------------|---------------------------------|
| **Criterion**                    | **Endometrial thickness**       |
|                                  | • Maximum measured height in sagittal sectional plane |
|                                  | • Includes both halves of endometrium |
|                                  | • Sonic alignment 90° to uterine longitudinal axis |
|                                  | **Echogenicity**                 |
|                                  | • Consistent                     |
|                                  | • Heterogeneous                  |
|                                  | • Hyperechogenic                 |
|                                  | • Isoechogenic                   |
|                                  | • Hypoechogetic                  |
|                                  | • (in relation to myometrium)    |
|                                  | **Endometrium midline**          |
|                                  | • Linear                         |
|                                  | • Non-linear                     |
|                                  | • Irregular                      |
|                                  | • Not delimitable                |
|                                  | **Subendometrial-myometrial junctional zone (EMJ)** |
|                                  | • Regular                        |
|                                  | • Irregular                      |
|                                  | • Discontinuous                  |
|                                  | • Not delimitable                |
|                                  | **Bright edge**                  |
|                                  | • Echogenic border zone between intracavitary lesion and endometrium |
|                                  | **Intracavitary fluid collection** |
|                                  | • Greatest diameter in sagittal plane |
|                                  | **Synechiae**                    |
|                                  | • Tissue strings crossing the cavity of bridging the endometrium |
|                                  | **Color Doppler**                |
|                                  | • Color score 1–4 (Fig. 3)       |
|                                  | **Vascular pattern in power Doppler** |
|                                  | • Dominant vessel                |
|                                  | • Multiple vessels               |
|                                  | • Extending individually         |
|                                  | • Bundled                        |
|                                  | • Branched                       |
|                                  | • Scattered                      |
|                                  | • Ring-shaped                    |

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**Fig. 4** Hydrosalpinx with typical pseudosepta.

**Fig. 5** Hydrosalpinx with small rounded echogenic wall deposits ("beads-on-a-string").
Endometriosis

Manifestation of endometriosis is very heterogeneous. Preoperative diagnosis of propagation is important for surgical planning. According to the guidelines, a multistage diagnosis should be performed according to internationally established assessment criteria [55–57]:

Basic diagnostics should detect endometriomas and adenomyosis.

Then dynamic transvaginal sonography should be used to check the mobility of the adnexa, uterus, and surrounding structures. Markers of endometriosis and adhesions triggered by it may include fixation of the ovaries to each other so that they appear adjacent and on one image, or as an adherence to the uterus. Fixed retroflexion of the uterus is a sign of uterine adhesions (question mark sign).

The Douglas space is examined in the next examination step by gentle pressure of a vaginal probe against the cervix and simultaneous manual pressure on the lower abdomen. Normally, it should be possible to move the posterior wall of the cervix against the rectum (sliding sign). If this displaceability is missing, obliteration of the Douglas space must be assumed.

The final examination step involves the specific search for nodular foci of deep infiltrating endometriosis in the anterior or posterior segment of the lesser pelvis. This transvaginal examination has significant diagnostic value, but also requires a high degree of accuracy. The following criteria are used to guide the examination:

- **Sonographic criteria for ovary torsion (according to IOTA).**

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Documentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total size</td>
<td>Measurement in 3 orthogonal planes</td>
</tr>
<tr>
<td>Solid portions/papillary stratification</td>
<td>Largest solid portion in 3 planes. Number of papillary stratifications (0–3 or ≥4).</td>
</tr>
<tr>
<td>Tumor complexity</td>
<td>Specific classification as: Unilocular-cystic, Multilocular-cystic, Unilocular-solid, Multilocular-solid, Solid</td>
</tr>
<tr>
<td>Cyst content</td>
<td>Distinction: Anechoic, Hypoechoic, Ground glass, Mixed, Hemorrhagic</td>
</tr>
<tr>
<td>Number of cysts</td>
<td>n = ? &gt; 10?</td>
</tr>
<tr>
<td>Wall structure</td>
<td>Smooth, Irregular</td>
</tr>
<tr>
<td>Acoustic shadows</td>
<td>Present, Absent</td>
</tr>
<tr>
<td>Ascites</td>
<td>Present, Absent</td>
</tr>
<tr>
<td>Doppler sonography</td>
<td>Color score 1–4 (Fig. 3)</td>
</tr>
</tbody>
</table>

**Sonographic torsion criteria**

- Edema of ovary and fallopian tube
- Increased echogenicity
- Ovary enlargement > 4 cm
- Reduced/absent perfusion (cavity: in early-stage hyperemia venous congestion)
- "Whirl-pool" sign in Doppler
- Presence of cysts
- Free fluid

**Fig. 6** Tubo-ovarian abscess: multilocular solid conglomerate tumor, echoic cyst contents with sludge.

**Fig. 7** Color Doppler image of tubo-ovarian abscess: marked increased perfusion, color score 4.
specialization and special experience of the examiner. The targeted diagnosis of deep infiltrating endometriosis should therefore be performed by investigators who have extensive experience in (or in close) cooperation with an endometriosis center beyond the Level II qualification.

Other Areas of Gynecological Sonography

The areas of application listed above cover frequent occasions for more advanced gynecological sonography, but, as explained in the introduction, cannot reproduce the entire spectrum. Sonographic diagnostics can also cover the internal genitals, such as bowel and bladder assessment, as well as upper abdominal sonography, and provide important additional information. Furthermore, important gynecological special areas such as urogynecology or reproductive medicine with differentiated sonographic examination techniques have developed and established, the scope and requirements of which are not part of this overview.

Summary and Outlook

The present compilation of quality requirements for gynecological sonography shows current criteria in the sonographic diagnosis of the most common gynecological pathologies. The DEGUM concept for success is based on the recognized standards of quality assurance, further training and scientific examination of the method. The introduction of DEGUM Level II for gynecological sonography completes the spectrum of gynecological diagnostics with obstetric prenatal sonography and breast sonography. This is an important step for the optimization of diagnostic processes, but also for the conscious perception and recognition of these important diagnostics and their position in the profession.

Conflict of Interest

The authors declare that they have no conflict of interest.

References