Early-stage cervical cancer: Tumor delineation by magnetic resonance imaging and ultrasound — A European multicenter trial☆,☆☆

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HIGHLIGHTS
► US and MRI are both highly accurate for the preoperative assessment of early-stage cervical cancer.
► US may be more accurate than MRI in detecting residual tumors and assessing parametrial invasion.

ARTICLE INFO
Available online 28 September 2012

Keywords:
Ultrasound
Magnetic resonance tomography
Cervical cancer
Imaging
Staging

ABSTRACT

Objective. To compare the diagnostic accuracy of ultrasound (US) and magnetic resonance imaging (MRI) in the preoperative assessment of early-stage cervical cancer using pathologic findings as the reference standard.

Patients and methods. Prospective multi-center trial enrolling 209 consecutive women with early-stage cervical cancer (FIGO IA2-IIA) scheduled for surgery. The following parameters were assessed on US and MRI and compared to pathology: remaining tumor, size, tumor stromal invasion ≥2/3 (superficial) or ≥2/3 (deep), and parametrial invasion.

Results. Complete data were available for 182 patients. The agreement between US and pathology was excellent for detecting tumors, correctly classifying bulky tumors (>4 cm), and detecting deep stromal invasion (kappa values 0.84, 0.82, and 0.81 respectively); and good for classifying small tumors (<2 cm) and detecting parametrial invasion (kappa values 0.78 and 0.75, respectively). The agreement between MRI and histology was good for classifying tumors as <2 cm, or >4 cm, and detecting deep stromal invasion (kappa values 0.71, 0.76, and 0.77, respectively). It was moderately accurate in tumor detection, and in assessing parametrial invasion (kappa values 0.52 and 0.45, respectively). The agreement between histology and US was significantly better in assessing residual tumor (p<0.001) and parametrial invasion (p<0.001) than the results obtained by MRI. Imaging methods were not significantly influenced by previous cone biopsy.
Introduction

Cervical cancer ranks second world-wide among female malignancies [1]. One peak in incidence is in the third and fourth decades of life, indicating that it often affects young women who wish to retain their childbearing prospects. Assessment of the extent of the disease is crucial in planning optimal treatment strategy that offers fertility-sparing surgery to women who have small tumors with no lymph node metastasis [2]. Precise knowledge of tumor size and location within the cervix allows the surgeon to tailor the radicality of surgery for each individual (e.g., nerve-sparing procedure) in order to minimize postoperative morbidity.

The International Federation of Gynecology and Obstetrics (FIGO) recommends a clinical staging system for cervical cancer, although it is well-known that the accuracy of such a system is suboptimal when compared with surgical and pathological data. The extent of the disease is underestimated in 17% to 32% of those cases in stage IB, and in up to 67% of cases in stages II to IV [3,4]. The FIGO system also produces over-staging of approximately 64% in stage IIB [3,4]. Although the revised system did not previously include imaging, FIGO now encourages its use in the staging of cervical cancer for assessing prognostic factors such as tumor size, parametrial and pelvic side wall invasion, adjacent organ invasion, and lymph node metastases [5]. Imaging is thus complementary to clinical assessment, with magnetic resonance imaging (MRI) considered the optimal modality for staging cervical carcinoma FIGO stage IB1 or greater [2]. Computer tomography (CT) has not proven accurate for assessing parametrium or tumor size because of the low contrast of soft tissue [6,7].

In recent years ultrasound (US) has gained increased attention in preoperative staging of cervical cancer [8–11]. As compared to MRI, US is faster, cheaper, more widely available, and requires no preparation of the patient. Some prospective studies have shown that the accuracy of transrectal or transvaginal US is comparable to MRI in this regard [8,9]. One of the aforementioned studies demonstrated that transrectal US was even superior to MRI at detecting small tumors [8]. However, the encouraging experiences reported by single institutions have never been tested in a multicenter design.

The aim of this prospective multicenter study was to compare the diagnostic accuracy of US and MRI for the preoperative assessment of women with early-stage cervical cancer.

Patients and methods

A prospective, multicenter, interdisciplinary clinical trial was conducted at: Lund University Hospital, Lund, Sweden; Catholic University of the Sacred Heart, Rome, Italy; Charles University, Prague, Czech Republic; and the Lithuanian University of Health Sciences Hospital, Kaunas, Lithuania. The participating institutions were required to have a high-tech US system, at least a 1.5 T MRI system, a dedicated radiologist, a US examiner, and a pathologist familiar with the study’s protocol and goals. Approval was obtained from the ethics committee of Lund University (LU-412-07) and local institutional boards of the other centers. The study was conducted from September 2007 to April 2010.

Patients

We enrolled consecutive patients whose biopsies confirmed cervical cancer of all histological types and who were scheduled for radical surgery with cervical cancer of FIGO stages IA2 to IIA1 [5]. All patients were staged according to FIGO criteria using vaginal and rectal examination, standard chest radiographs, and transabdominal US examination to look for ureteral obstruction. Patients also underwent gynecological US and MRI examinations of the pelvis and lower abdomen within two weeks prior to surgery. The MRI and US examiner had access to patient history but were blinded to the FIGO staging and the results of the other imaging technique. The US study protocols were filled out directly after the examination by the US expert. The MRI examination was assessed and reviewed locally according to golden standard at each department. Most often the MRI assessment was done directly by the study radiologists, or reviewed by the two study radiologists, with all protocols being filled out prior to surgery.

In Lund and in Prague, the sentinel node (SLN) technique was routinely used to preoperatively detect lymph node metastasis. If a positive sentinel lymph node was detected in a frozen section, paraaortic lymphadenectomy was performed and radical surgery was aborted.

Data acquisition

The following parameters were prospectively evaluated by US, MRI, and pathology: presence of tumor, tumor size in three perpendicular diameters (anteroposterior, craniocaudal, and transversal), depth of stromal invasion (≤2/3 or >2/3), and parametrial involvement. To classify the tumors as ≤2 or >2 cm and ≤4 cm or >4 cm, we used the maximal tumor diameter obtained from measuring the tumor in three dimensions. A study protocol was completed at the time of the examination by the US examiner, radiologist, and pathologist. In addition to the SLN biopsies carried out in two institutions, the surgical procedure included systematic pelvic lymphadenectomy in combination with radical hysterectomy (164/182) or radical trachelectomy (18/182).

US examination technique

Sonographic examination was performed at each center by one or two US experts with more than ten years’ experience in US gynecological scanning. High-end US systems were used: GE Voluson E8 US system with a 5–9 MHz transducer or a Philips IU22 US system with a 3–9 MHz transducer in Lund; an Esaote Technos MPX with a 5–9 MHz transducer (until January 2008) and a GE Voluson E8 with a 5–9 MHz transducer (after January 2008) in Rome; a Logic 9 with a 5–9 MHz transducer (until December 2009) and a Voluson E8 with a 5–9 MHz transducer (after December 2009) in Prague; and a Toshiba Aplio XG with a 3.6–8.8 MHz transducer in Kaunas. Patients were examined with their bladder empty either transvaginally or transrectally in the lithotomy position. Standardized US examination technique was used. The methodology of cervical cancer assessment has been described in a recently published review [12].

MRI examination

MRI was performed using a Philips 3 T magnet Intera with a phased-array cardiac coil wrapped around the pelvis in Lund; a Philips 1.5 T magnet Achieva with a phased-array pelvic coil in Prague; a GE 1.5 T magnet Vectra with a multichannel body coil in Rome; and a Siemens 1.5 T magnet Magnetom Avanto with a pelvic coil in Kaunas.

A standardized MRI examination technique was used in each center, in accordance with the recommendations of the European Society of Urogenital Radiology, including T2-weighted sequences in sagittal and axial oblique planes (perpendicular to the long axis of the cervix) and axial T1-weighted sequences. To assess tumor size, location and its
extension to the parametria T2-weighted images on two orthogonal planes, sagittal and axial oblique sequences (perpendicular to the long axis of the cervix) or axial sequences were primarily used. The axial T1-weighted images from the symphysis to the left renal vein were required to detect pelvic and abdominal lymph nodes. Slice thickness varied from 3 mm to 5 mm, with interstice gaps ranging between 0.0 mm and 2.1 mm. Matrices used were 512×512, 512×256, 256×256, 192×256, 240×320, and 256×320. Additionally, some centers used T2-weighted oblique sequences parallel to the long axis of the cervix (coronal oblique plane), T2- and T1-weighted sequences in the coronal plane, T1-weighted sequences in the sagittal plane, or T2-weighted images with fat suppression in the sagittal and axial planes. The intravenous administration of gadolinium-chelates was optional. Centers in Lund and Kaunas performed sequences using an intravenous contrast medium. In Lund, intravenous gadolinium contrast was administered at a dosage of 1 mmol/kg (Omniscan, GE Medical). In Kaunas, a contrast medium was injected intravenously at a dosage of 1 ml/5 kg body weight, or 15 ml/75 kg (Omniscan®, GE; Gadovist® or Magnevist®, Bayer Schering). Moreover, centers in Lund and Rome used an intramuscular injection of 1 mg of butyl scopolamine (Buscopan®, Schering) before examination to reduce intestinal peristalsis. The center in Lund also used superparamagnetic ferrisene-based contrast material (Lumirem®, Guerbet) administered rectally in order to reduce artifacts from the bowel (maximum volume 300 ml) and a tampon saturated with ferrisene contrast inserted into the vagina.

Pathological examination

At each center a dedicated pathologist with substantial experience in gynecological oncology assessed the pathological specimens and completed a study protocol specifying the presence, size and extent of any tumor. The handling of the surgical specimen differed slightly between the institutions, the common features of the procedure were as follows: the surgical specimen was sent fresh directly to the pathology institution. Each tumor was described at macroscopic examination including size and location of lesion, distance from margins and gross depth of invasion. These findings were compared with those gained from microscopic examination. 4-colored ink staining was applied — left, right, posterior and anterior. The specimen was then sectioned transversally at approximately 3 mm intervals. Cranio-caudal (C-C) tumor diameter was measured as a sum of C-C tumor size in the amputated part of the cervix and a number of involved transverse sections. The other two diameters (antero-posterior and latero-lateral) were measured directly from transversal sections. Other parameters assessed microscopically were depth of stromal invasion and parametrial involvement.

Statistics

Cohen’s Kappa was used to determine the agreement between either US or MRI and histology for assessment of tumor extension. Kappa values of 0.81 to 1.0 were taken to indicate excellent agreement, 0.61 to 0.80 good agreement, 0.41 to 0.60 moderate agreement, and ≤0.40 poor agreement [13,14]. McNemar’s test and Fisher’s exact test were used to compare the diagnostic performance of US and MRI. The Breslow-Day test for homogeneity of odds ratios was used to test significant differences between sites. All calculations were performed using SPSS software (Statistical Package for Social Sciences, Version 19.0.1) and p-values <0.05 were considered significant.

Results

A total of 209 women with early stage cervical cancer were prospectively included in the study (41 from Lund, 29 from Rome, 110 from Prague, and 29 from Kaunas). However, 16 women (8%) were subsequently deemed ineligible because of enrolment disqualifications (radical hysterectomy not being performed due to positive lymph nodes), and 11 women (5%) because of missing or incomplete data. Thus, data on 182 women obtained by clinical assessment, MRI, US, and pathology were considered in the final analysis. Age, cone biopsy prior to imaging assessment, FIGO stage, histological type, surgical procedure, and presence of any residual tumor on final histological report are shown in Table 1.

The maximal tumor diameter was not significantly different if measured by US (27.6 mm [SD±16.0]), MRI (28.6 mm [SD±15.6]), or histology (26.6 mm [SD±16.9]). (p = 0.54).

Table 2 presents the sensitivity, specificity, agreement, and kappa values for US and MRI in the evaluation of residual tumors; tumors<2 cm; tumors>4 cm; stromal invasion>2/3; and parametrial invasion. The agreement between US and pathology was excellent for detecting tumors, correctly classifying bulky tumors (>4 cm), and detecting deep stromal invasion (kappa values 0.84, 0.82, and 0.81 respectively); and good for classifying small tumors (<2 cm) and detecting parametrial invasion (kappa values 0.78 and 0.75, respectively) (Table 2). The agreement between MRI and histology was good for classifying tumors as <2 cm, or >4 cm, and detecting deep stromal invasion (kappa values 0.71, 0.76, and 0.77, respectively) (Table 2). It was moderately accurate in tumor detection and in assessing parametrial invasion (kappa values 0.52 and 0.45, respectively) (Table 2).

When comparing the accuracy of the two imaging methods, US was significantly better than MRI in the detection of residual tumors, and in the assessment of parametrial invasion in women with early-stage cervical cancer. We found no significant differences among the four centers in the study with regard to tumor detection and parametrial invasion for US and MRI.

Table 3 shows the accuracy of US and MRI in identifying residual tumors in patients who underwent cone biopsy prior to examination. The accuracy of the imaging method was not affected by such biopsies.

Women with bulky nodes detected by US or MRI were excluded from the study. Among the included women lymph node metastases were later detected at histology in 20% (38/188) of the women. Most of the women with lymph node metastasis had micrometastasis and seemingly normally sized lymph nodes. In Lund where the sentinel node technique was systematically employed only one positive lymph node (1/27, 4%) was later detected at histology. Among the 38 women with positive lymph nodes at histology 3 had been suspected on ultrasound and 4 on MRI.

Discussion

Our prospective multicenter study of women triaged for surgery with early-stage cervical cancer showed that US and MRI have high

Table 1

<table>
<thead>
<tr>
<th>Variable</th>
<th>n = 182</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean±SD)</td>
<td>46.3 (± 13.5)</td>
</tr>
<tr>
<td>Cone biopsy prior to assessment</td>
<td>64 (35%)</td>
</tr>
<tr>
<td>FIGO stage</td>
<td></td>
</tr>
<tr>
<td>IA2</td>
<td>9 (5%)</td>
</tr>
<tr>
<td>IB1</td>
<td>135 (74%)</td>
</tr>
<tr>
<td>IB2</td>
<td>24 (13%)</td>
</tr>
<tr>
<td>IIA</td>
<td>14 (8%)</td>
</tr>
<tr>
<td>Histological type</td>
<td></td>
</tr>
<tr>
<td>Squamous cell carcinoma</td>
<td>132 (72%)</td>
</tr>
<tr>
<td>Adenocarcinoma</td>
<td>45 (25%)</td>
</tr>
<tr>
<td>Adenosquamous carcinoma</td>
<td>5 (3%)</td>
</tr>
<tr>
<td>Surgery</td>
<td></td>
</tr>
<tr>
<td>Radical hysterectomy</td>
<td>164 (90%)</td>
</tr>
<tr>
<td>Radical trachelectomy</td>
<td>18 (10%)</td>
</tr>
<tr>
<td>Residual tumor at final histology</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>152 (84%)</td>
</tr>
<tr>
<td>No</td>
<td>30 (16%)</td>
</tr>
</tbody>
</table>
diagnostic accuracy in the preoperative detection of residual tumors and in the assessment of local tumor extension. US was more accurate in detecting residual tumors and in assessing parametrical invasion. Cone biopsy did not influence the ability of US or MRI to detect residual tumors.

The detection of tumors and the delineation of their margins are crucial for planning individualized treatment of cervical cancer patients. The tumor detection rate for US was 97% at a specificity of 96%, while for MRI it was 90% at a specificity of 67%. The greater accuracy of US in assessing the presence of residual cancer may be due to current technical improvements, including high-frequency endoluminal probes enabling detailed visualization of the cervix. Other features that are unique to US are the direct visualization of tumor vascularization and the dynamic aspects of the examination. Although isoechic tumors may be difficult to detect, by the use of power Doppler imaging the vast majority of tumors will be revealed by the abundant neovascularization that stands out against the sparsely vascularized normal cervical tissue[10]. A cervical tumor is also more rigid than its surrounding tissue, enabling the detection of tumor tissue when using a dynamic examination technique [15]. Although intravenous contrast administration was not routinely employed during MRI in our study, it may improve the detection rate of lesions <2 cm.

We were surprised to find that cone biopsy prior to imaging did not affect the accuracy of US or MRI in detecting residual tumors. Still, it is our clinical impression that the delineation of small tumors can be more difficult in cases where cone biopsy has recently been performed, since it is difficult to differentiate inflammatory or reparative changes from tumor tissue.

A significant limitation in the clinical evaluation of patients with cervical cancer is the inability to appropriately assess tumor size, especially if the tumor is located in the endocervical region. It has been shown that tumor size has prognostic implications, as it correlates with local tumor extension and the risk of nodal metastases. Correct tumor size assessment may have clinical implications in patients with bulky stage IB cervical cancer. They may benefit from neoadjuvant chemotherapy followed by less radical hysterectomy. Moreover, assessment of tumor size and its cranial extension towards the internal cervical os is crucial in the planning of fertility-sparing procedures. For these reasons, the precise size and location of the tumor are the most important criteria in tailoring the management of the patient. US and MRI allow direct measurement of tumor size in three dimensions. We found the accuracy of both imaging techniques in the size assessment of small and large tumors to be comparable.

The other major prognostic factor is the depth of stromal tumor infiltration because it is also associated with the risk of nodal involvement. The pre-treatment evaluation of tumor-free cervical stroma is important for planning the extent of surgery, especially if nerve-sparing or more extensive parametrical resection is being planned. Based on our findings, US and MRI are highly accurate in the assessment of deep (i.e., >2/3) invasion.

The most important patient recruitment factor for radical surgery is the absence of parametrical extension. However, clinical examination underestimates parametrical invasion in up to one-third of all patients [3,4]. The overall false negative rate of US (3/169) and MRI (4/159) was very low in women triaged for surgery. The false positive rate was also low, although it was significantly higher for MRI (8%) than for US (2%); p<0.001. The slightly better performance of US may be due not only to the detailed visualization of the intact or disrupted echogenic pericervical fascia on US, but also to the use of color Doppler to differentiate infiltrated lateral ligaments from cervical vessels, and to a dynamic examination technique. Our results are in agreement with the data of the two single-unit studies available in the literature [8,9] that report the comparison between US and MRI in the assessment of cervical cancer. The two earlier studies

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Table 2

<table>
<thead>
<tr>
<th>Histology</th>
<th>US</th>
<th>Histology</th>
<th>MRI</th>
<th>Comparing US to MRI*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumor &gt;4 cm</td>
<td>No 148 7</td>
<td>Kappa = 0.82 (95% CI, 0.70–0.93)</td>
<td>No 143 6</td>
<td>Kappa = 0.76 (95% CI, 0.63–0.88)</td>
</tr>
<tr>
<td>Yes 2 25</td>
<td>Sens = 90% Spec = 99% Agreement = 95%</td>
<td>Yes 7 26</td>
<td>Sens = 81% Spec = 95% Agreement = 93%</td>
<td></td>
</tr>
</tbody>
</table>

Table 3

<table>
<thead>
<tr>
<th>Tumor detected at US</th>
<th>Tumor detected at MRI</th>
<th>Agreement</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Tumor detected at US</td>
<td>Yes 143 6</td>
<td>Kappa = 0.76 (95% CI, 0.63–0.88)</td>
<td></td>
</tr>
<tr>
<td>Yes 2 25</td>
<td>Sens = 90% Spec = 99% Agreement = 95%</td>
<td>Yes 7 26</td>
<td>Sens = 81% Spec = 95% Agreement = 93%</td>
<td></td>
</tr>
</tbody>
</table>

Comparison of accuracy of imaging methods in women with or without previous cone biopsy.

For US: sensitivity p = 1.0, specificity p = 0.23; for MRI: sensitivity p = 0.78, specificity p = 0.25.
found no significant differences between US and MRI in evaluating parametrial invasion [8,9], even though no definitive conclusions could be drawn because of the smaller sample size and the low prevalence of parametrial invasion in early-stage cervical cancer. The first of these studies employed a transrectal examination [8], while the second used a transvaginal approach [9]. In agreement with our findings, previous studies using MRI found that negative predictive value is high (96% to 100%) if the stromal ring (i.e., pericervical fascia) is found to be intact [16,17]. Nevertheless, any imaging methods may be limited in their ability to identify minimal tumor invasion into the parametria.

Single unit MRI studies with dynamic contrast technique or the use of diffusion-weighted imaging (DWI) sequences might enable more accurate determination of cervical stromal and parametria invasion. Our results reflect current clinical practice in multicenter settings. They correspond with published data showing the lower spatial resolution and artifact limitations of MRI for diagnosing a minimal parametrical extension of cervical tumors [6].

Excluding women with obviously bulky nodes, 20% (38/188) of the included women were found to have lymph node metastasis. Most women had microscopic metastasis in seemingly normally sized lymph nodes. Both US and MRI failed to detect the vast majority of these positive lymph nodes. The sentinel node technique seems to outperform imaging when it comes to detecting positive lymph nodes in women with early cervical cancer [18,19]. In Lund where the sentinel node technique was routinely used only one positive lymph node (1/27, 4%) was missed. It appears that the sentinel node technique is particularly reliable in women with small (<2 cm) tumors [19].

The strengths of our study are its prospective design; the multicenter setting; and the dedicated US examiners, radiologists, and pathologists using standardized study protocol on a large number of patients. One of the major limitations of the study was the restricted number of women with parametrial invasion (as to be expected in women triaged for surgery), despite the study size. We encourage further large scale prospective studies comparing the efficacy of US and MRI in the assessment of parametrial invasion, since it is rare in women with early-stage cervical cancer who have undergone surgery. We choose not to include women with more advanced disease, since these women will not undergo surgery and thus we would have no golden standard. It is important to stress that the findings in our study apply to women with early-stage disease, and that generalization of the results to women with more advanced disease cannot be made.

Inter-observer reproducibility is essential when assessing the validity of an imaging method. The ideal would be to present the results of such an evaluation as part of this study, because it is not until such a comparison is made that we truly know which method works best in a clinical setting over several institutions. To perform an optimal reproducibility study using ultrasound the women should preferentially be examined by several operators. This study was however not designed for multiobserver assessment of the women. Instead we choose a multi-center design to assess the accuracy over several centers. We found no significant diagnostic differences between the participating centers.

Another weakness was the variety of US and MRI equipment employed at different institutions. MRI was performed using 1.5 T or 3 T magnets, slice thickness and the inter-slice gap were not uniform, and contrast medium injections were given in 70/209 cases. The latter may have resulted in an overestimation of parametrial invasion, since pericervical reactive changes will show enhancement, as will neoplasms. All of the above factors might have influenced the accuracy of the MRI results. Nevertheless, as previously mentioned we did not find any significant diagnostic differences for either US or MRI among the different centers conducting the study.

US is a widely-available and affordable imaging technique that does not require a contrast medium. The extra costs of MRI (including more expensive equipment, longer examination time, and use of contrast agents) must be considered along with its potential as a diagnostic tool in any comparison with US. The proven benefits of US in precise tumor delineation, including assessment of tumor stroma infiltration and parametrium, in the hands of a specially trained examiner, justify its use for individual treatment planning. In the future, the diagnostic accuracy of transrectal versus transvaginal approaches should be compared, the role of 3D ultrasound and contrast be explored, and the reproducibility of US and MRI be compared in women with cervical cancer.

Our analysis of prospectively retrieved data showed US to be superior to MRI for residual tumor detection and parametrial extension assessment, and comparable to MRI for size and stromal invasion determination. We conclude that US is an accurate preoperative staging imaging technique complementary to MRI in women with early-stage cervical cancer.

Conflict of interest statement

The authors declare that there are no conflicts of interest.

References