Cardiovasc Intervent Radiol (2008) 31:260–268
DOI 10.1007/s00270-007-9209-0

CLINICAL INVESTIGATION

MR Reproducibility in the Assessment of Uterine Fibroids for Patients Scheduled for Uterine Artery Embolization

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Received: 21 February 2007 / Accepted: 21 May 2007 / Published online: 4 December 2007

Abstract Magnetic resonance imaging (MRI) is increasingly applied in the evaluation of uterine fibroids. However, little is known about the reproducibility of MRI in the assessment of uterine fibroids. This study evaluates the inter- and intraobserver variation in the assessment of the uterine fibroids and concomitant adenomyosis in women scheduled for uterine artery embolization (UAE). Forty patients (mean age: 44.5 years) with symptomatic uterine fibroids who were scheduled for UAE underwent T_1- and T_2-weighted MRI. To study inter- and intraobserver agreement 40 MR images were evaluated independently by two observers and reevaluated by both observers 4 months later. Inter- and intraobserver agreement was calculated using Cohen's κ statistic and intraclass correlation coefficient for categorical and continuous variables, respectively. Inter-observer agreement for uterine volumes ($\kappa = 0.99$, $p < 0.0001$), dominant fibroid volumes ($\kappa = 0.98$, $p \leq 0.0001$), and number of fibroids ($\kappa = 0.88$; CI, 0.77–0.93; $p < 0.0001$) was excellent. For the T_1- and T_2-weighted signal intensity of the dominant fibroid there was good agreement between the observers (87%; 95% CI, 71.9%–95.6%) and the intraobserver agreement was good for observer A (95%; 95% CI, 83.1%–99.4%) and moderate for observer B ($\kappa = 0.47$). The interobserver agreement with respect to the presence of adenomyosis was good ($\kappa = 0.73$, $p < 0.0001$), while both intraobserver agreements were fair to moderate (observer A, $\kappa = 0.55$, $p = 0.0003$; and observer B, $\kappa = 0.66$, $p < 0.0001$). In conclusion, MRI criteria used for the selection of suitable UAE patients show good inter- and intraobserver reproducibility.

Keywords Uterine artery embolization · Fibroids · Leiomyoma · Menorrhagia · Uterus · Magnetic resonance imaging · Adenomyosis

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Introduction

Magnetic resonance imaging (MRI) is increasingly applied for the evaluation of uterine fibroids before and treatment effectiveness after uterine artery embolization (UAE). MRI is thought to be very useful in assessing the eligibility of UAE patients, especially in comparison to ultrasound (US) imaging, which may be hampered by the mere size of the fibroid uterus [1]. A previous study indicated that MRI should be considered in all patients with presumed fibroids, because it would significantly alter the diagnosis and treatment plans of interventional radiologists [2]. Various findings on MRI are thought to be of special interest in determining the suitability of patients for UAE treatment, i.e., size of the uterus and fibroids, number and location of fibroids, presence of pedunculated fibroids, signal intensity on T_1- and T_2-weighted images, and presence of any

concomitant adenomyosis. Until now only one study has investigated some of these items in an interobserver study [3].

This study aimed to evaluate inter- and intraobserver agreement for MRI parameters which may be of clinical importance in planning UAE in women with uterine fibroid disease.

Materials and Methods

Patients

Forty patients were recruited from 9 of the 34 participating hospitals in the multicenter, randomized trial (EMMY trial) which compares UAE with hysterectomy in women with fibroid disease [4, 5]. Patients were included if (i) the clinical diagnosis of uterine fibroids had been confirmed by US; (ii) menorrhagia was the predominant complaint among other probably fibroid-related signs and symptoms; (iii) hysterectomy was thought to be the ultimate solution and other treatment options were unsuitable or had failed to provide symptomatic relief; (iv) they were premenopausal; (v) preservation of the uterus was not warranted for future pregnancy; and (vi) the following disorders were absent—renal failure (creatinine > 150 mmol/L), active pelvic infection, clotting disorders, allergy to contrast fluid, (suspected) uterine malignancy, submucosal fibroids protruding by >50% within the uterine cavity, and pedunculated abdominal fibroids.

Of the 81 patients who underwent MRI as part of the diagnostic work-up prior to the UAE procedure, 40 had available digital images. Because patients subsequently underwent UAE and consequently did not receive a hysterectomy, no histopathological reports were obtained to validate the measurements. Written informed consent was obtained in all patients. The study was approved by the Central Committee Involving Human Subjects (www.ccmo.nl) and by the local ethics committees of all participating hospitals.

Imaging Technique

MRI was performed using different brands of 1.0-T (n = 7) or 1.5-T (n = 33) MRI scanners, all equipped with a phased-array body coil. Most scans were performed on a 1.5-T MR unit (Horizon Echospeed; General Electric, Milwaukee, WI, USA). Sagittal T_1-weighted TSE images were performed, as well as T_2-weighted images in the sagittal, axial, and coronal directions, with slice orientation perpendicular and parallel to the long axis of the uterine cavity.

Pelvic MRI was performed using the following T_2-weighted TSE sequences: TR, 6000 ms; TE, 96 ms; field of view, 300 × 300 cm; imaging matrix, 224 × 512 (sagittal and transversal/oblique); slice thickness, 7 mm; and interslice gap, 0.7 mm. The use of contrast was optional in this trial and administered in 10 of the 40 patients. This number was too small to allow further analysis.

Image Analysis

One radiologist and one senior resident in radiology (observer A [A.S.] and B [A.M.]), both with ample experience in abdominal MRI, working in different hospitals, read the MR images. Both observers had a training session where instructions on the evaluation of the MR images were provided. Both observers independently evaluated all 40 MR images. On a second occasion, 4 months after the first reading, both observers independently evaluated all MR images once again in random order to avoid recall bias. Both observers were blinded to their own and each other's results. They were aware, however, that patients were participants in the EMMY trial and that, obviously, uterine fibroids were to be expected.

MR images were examined on a workstation with viewing software (IMPAX SP4 SU4 DS3000; AGFA, Mortsel, Belgium). Both observers evaluated and recorded the overall quality of the images as good, moderate, or poor. The position of the uterus was classified as either anteflexed, in a straight position, or retroflexed. The total number of fibroids was recorded. The largest fibroid was indicated as the dominant fibroid. The homogeneity of the dominant fibroid was graded as homogenous or inhomogeneous. The location of the dominant fibroid was defined as being either submucosal (the epicenter of the fibroid is closer to the uterine cavity than to the myometrium), intramural, or subserosal (the epicenter of the fibroid is closer to the abdominal cavity than to the myometrium). The presence (yes/no), number (total), and location (submucosal, subserosal or both) of pedunculated fibroids (diameter of the stalk of the fibroid was <50% of the largest diameter of the fibroid), which were not regarded as the dominant fibroid, were recorded. Uterine and dominant fibroid volumes were determined by measuring the maximum linear dimension in three planes (i.e., longitudinal [D1], anterior-posterior [D2], and transverse [D3]) and applying the ellipsoid formula (volume = D1 × D2 × D3 × 0.5233) [6]. The longitudinal and anterior-posterior distances were measured in the sagittal plane (Fig. 1), while the transverse diameter was measured in the transverse or coronal plane (Fig. 2). The cervix was excluded in the measurement of the uterine volume. The signal intensity of the dominant fibroid was recorded on the T_1- and T_2-

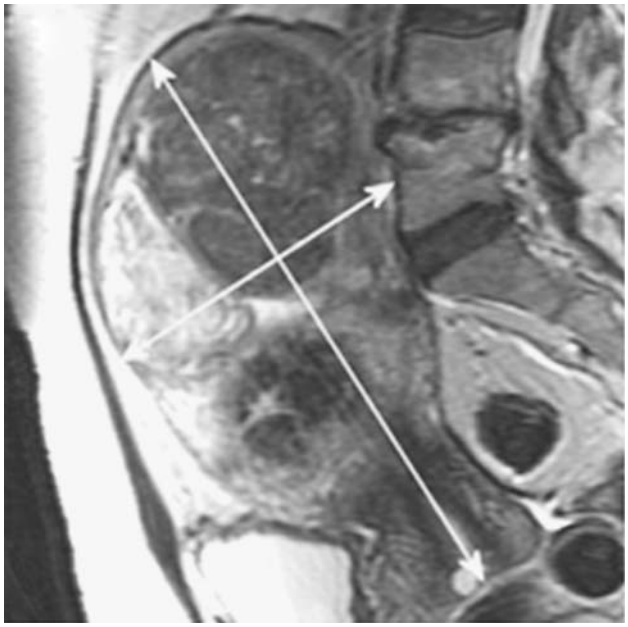

Fig. 1 Sagittal T2-weighted MR image: uterus with three intramural fibroids. Measurement of the largest longitudinal and anterior-posterior distance of the uterus

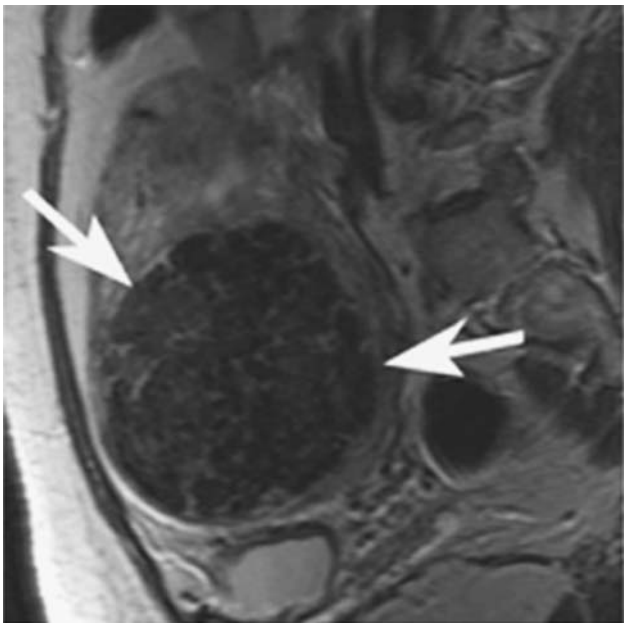

Fig. 3 Sagittal T2-weighted MR image: uterus with a hypointense intramural uterine fibroid (two arrows)

weighted MR images and was classified as predominantly hypointense (Fig. 3), isointense (Fig. 4), or hyperintense (no example could be provided) compared to normal myometrial tissue.

Since adenomyosis is a well-recognized differential diagnosis in women with enlarged uteri and/or menstrual disorders which may cause clinical failures of UAE for fibroid disease, we also assessed inter- and intraobserver agreement regarding the presence of any concomitant adenomyosis.

Adenomyosis was considered present by the observers whenever a diffuse or focal widening of the junctional zone with a maximal thickness of >12 mm was present [7, 8].

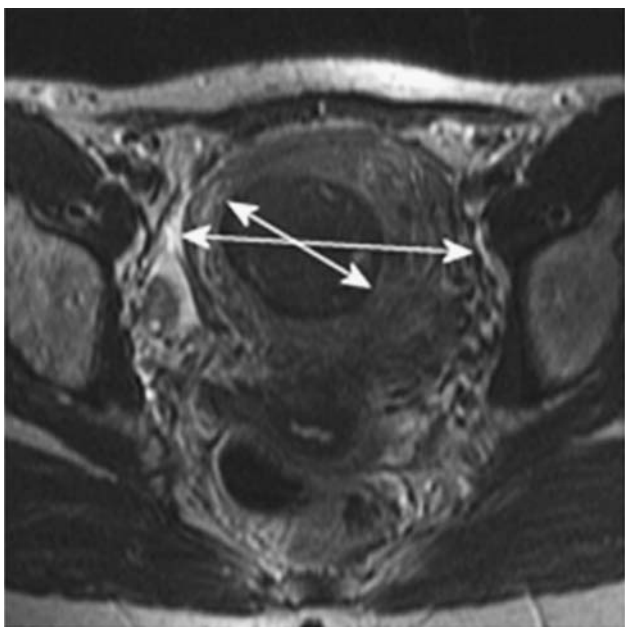

Fig. 2 Transversal T2-weighted MR image: uterus with one intramural fibroid. Measurement of the largest transverse distance of the uterus (long arrow) and the dominant uterine fibroid (short arrow)

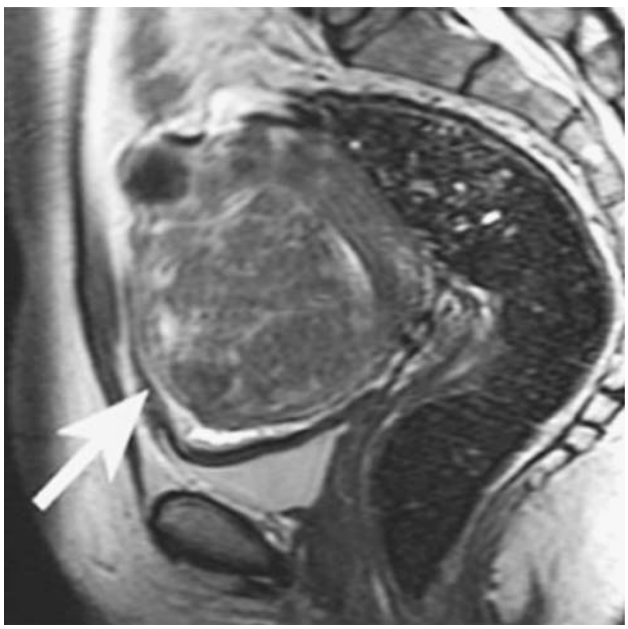

Fig. 4 Sagittal T2-weighted MR image: uterus with an isointense intramural uterine fibroid (arrow)

The presence of myometrial high-signal foci was considered ancillary evidence of adenomyosis (Fig. 5).

Statistical Analysis

Data entry was performed using SPSS data entry for Windows 3.0. All data entries were visually double checked by an independent second investigator. Analysis was done using SPSS statistical software (version 11.5.1).

Cohen's unweighted κ statistic with 95% confidence intervals (CI) was used to express interobserver and intraobserver agreement for categorical MRI parameters. Inter- and intraobserver reproducibility for continuous variables (i.e., uterine and dominant volumes, number of [pedunculated] fibroids, thickness of junctional zone), were assessed with the intraclass correlation coefficient (ICC) using two-way mixed analysis of variance (consistency type). The κ values and ICCs were interpreted as follows: <0.20, poor agreement; 0.20–0.40, fair agreement; 0.41–0.60, moderate agreement; 0.61–0.80, good agreement; and 0.81–1.00, excellent agreement [9]. A two-tailed p-value <0.05 was considered statistically significant. Whenever κ values could not be calculated due to the fact that two or more categories of a MRI parameter were never scored by the two observers, percentages of full agreement with 95% CI were calculated.

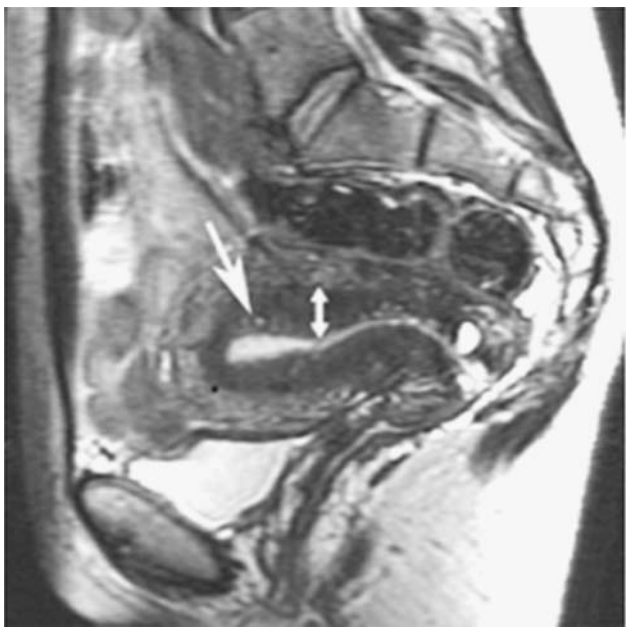

Fig. 5 Sagittal T2-weighted MR image: adenomyosis of the uterus. The thickness of the junctional zone is indicated by the double arrow; the myometrial high signal foci is indicated by the arrow

Results

Patients

Between March 2002 and February 2004, all 40 patients recruited at nine hospitals were included and underwent MRI prior to the UAE procedure. Patients' mean age was 44.5 years (range, 38–54 years). Table 1 reports the results of the first evaluation of both observers. Overall the quality of the images was moderate to good. For both reviewers the position of the uterus was predominately in anteflexion and the location of the dominant fibroid was mostly intramural. The presence of any pedunculated fibroid(s) was reported by observer A as 13 of 40 (32.5%) and by observer B as 12 of 39 (30.8%). Observer A scored the location of the pedunculated fibroids as follows: seven submucous, five subserous, and one both submucal and subserosal (when more than one pedunculated fibroid was found). Observer B scored the location as follows: five submucous, six subserous, and one both submucosal and subserosal. The majority of dominant fibroids had an isointense signal intensity on T_1-weighted images and a hypointense signal intensity on T_2-weighted images. The mean number of fibroids observed was eight and seven for observers A and B, respectively. Adenomyosis was observed in 8 of 40 (20.0%) patients by observer A and 5 of 40 (12.5%) patients by observer B. The median junctional width was 14 mm (range, 12–23 mm) for observer A and 15 mm (range, 13–19 mm) for observer B. In these patients with widening of the junctional zone, observer A recorded 4 of 40 (10.0%) patients with additional myometrial high-signal foci and observer B recorded 3 of 40 (60.0%).

Interobserver Reproducibility

Between-observer agreement was excellent for the calculation of uterine (κ = 0.99) and dominant (ICC = 0.98) fibroid volumes, number of fibroid(s) (ICC = 0.88), and presence of pedunculated fibroid(s) (κ = 0.82) (Table 2). Good agreement between the observers was found for the location of the dominant fibroid (κ = 0.80), presence of any concomitant adenomyosis (κ = 0.73), and signal intensity of the dominant fibroid on T_1- and T_2-weighted images (respectively, κ = 0.70 and 33 of 38 [87%]; 95% CI, 71.9%–95.6%). (Percentages of full agreement are reported since the κ values for the T_2 signal intensity could not be calculated.) Interobserver agreement was moderate for the position of the uterus (κ = 0.52) and the location (κ = 0.54) and number (ICC = 0.59) of pedunculated fibroid(s) and fair for the homogeneity of the dominant fibroid (κ = 0.28). Due to small numbers, no definite conclusion could be drawn for the thickness

Table 1 Parameter outcome: first evaluation, observers A and B

	Observer A	Observer B
Quality of MR image, *n*[a]		
Good	27 (67.5%)	26 (66.7%)[a]
Moderate	13 (32.5%)	13 (33.3%)
Poor	0 (0%)	0 (0%)
Position of the uterus, *n*		
Anteflexion	30 (75.0%)	23 (57.5%)
Straight	5 (12.5%)	10 (25.0%)
Retroflexion	5 (12.5%)	7 (17.5%)
Uterine volume[b]		
Mean (SD)	559.4 (630.5)	620.2 (681.9)
Median (range)	360.7 (51–3056)	382.3 (38–3267)
Dominant fibroid volume[c]		
Mean (SD)	170.9 (229.5)	162.6 (213.7)
Median (range)	80.9 (4–1014)	47.8 (3–897)
Location of dominant fibroid, *n*[c]		
Submucosal	10 (25.0%)	13 (34.2%)
Intramural	26 (65.0%)	22 (57.9%)
Subserosal	4 (10.0%)	3 (7.9%)
Signal intensity of dominant fibroid, *n* T1[d,e]		
Hypointense	2 (5.3%)	5 (13.9%)
Isointense	34 (89.5%)	29 (80.6%)
Hyperintense	2 (5.3%)	2 (5.6%)
T2[c]		
Hypointense	40 (100.0%)	33 (86.8%)
Isointense	0 (0%)	5 (13.2%)
Hyperintense	0 (0%)	0 (0%)
Homogeneity of dominant fibroid, *n*		
Homogeneous	15 (37.5%)	5 (13.2%)
Inhomogeneous	25 (62.5%)	33 (86.8%)
No. of fibroids		
Mean (SD)	8.0 (6.5)	7.0 (6.7)
Median (range)	6 (1–27)	4.5 (0–30)
Presence of pedunculated fibroid(s) (nondominant fibroid), *n*[a]		
Yes	13 (32.5%)	12 (30.8%)
No. of pedunculated fibroids (nondominant fibroid)[f]		
Mean (SD)	2.3 (1.4)	1.8 (1.0)
Median (range)	2 (1–5)	1.5 (1–4)
Location of pedunculated fibroid(s) (nondominant fibroid), *n*[f]		
Submucosal	7 (53.8%)	5 (41.7%)
Subserosal	5 (38.5%)	6 (50.0%)
Submucosal & subserosal	1 (7.7%)	1 (8.3%)
Presence of adenomyosis, *n*		
Yes	8 (20.0%)	5 (12.5%)
Thickness of junctional zone, mm[e,g]		
Mean (SD)	15.1 (3.9)	15.6 (2.4)
Median (range)	14 (12–23)	15 (13–19)
Presence of high-signal-intensity foci, *n*		
Yes	4 (10.0%)	3 (7.5%)

[a] Observer B, one missing
[b] Observer A, one missing
[c] Observer B, two missing
[d] Observer A, two missing
[e] Observer B, four missing
[f] If pedunculated fibroid was present
[g] If adenomyosis was present

Table 2 Interobserver agreement of MRI (observer A versus observer B)

Variable	κ	95% CI	p-value
Quality of MR image	0.42	0.12 to 0.72	0.008
Position of the uterus	0.52	0.26 to 0.77	<0.0001
Location of dominant fibroid	0.80	0.63 to 0.97	<0.0001
Homogeneity of dominant Fibroid	0.28	0.0 to 0.67	0.03
Presence of pedunculated fibroid(s)	0.82	0.63 to 1.00	<0.0001
Location of pedunculated fibroid(s)	0.54	0.10 to 0.98	0.02
Signal intensity of dominant fibroid			
T1	0.70	0.36 to 1.00	<0.0001
T2	—[a]		
Presence of adenomyosis	0.73	0.43 to 1.00	<0.0001
Presence of high-signal-intensity foci	0.17	0.0 to 1.00	0.71
	ICC		
Volume of uterus	0.99	0.97 to 0.99	<0.0001
Volume of dominant fibroid	0.98	0.96 to 0.99	<0.0001
No. of fibroids	0.88	0.77 to 0.93	<0.0001
No. of pedunculated fibroids	0.59	0.02 to 0.87	0.02
Thickness of junctional zone	0.14	–0.76 to 0.86	0.39

Note. CI, confidence interval; ICC, intraclass correlation coefficient

[a] Kappa values could not be calculated; percentages are given in text

of the junctional zone (ICC = 0.14, $p = 0.39$) or the presence of high-signal-intensity foci ($\kappa = 0.17$, $p = 0.71$).

Intraobserver Reproducibility

For observer A the intraobserver agreement was excellent for both the uterine (ICC = 0.995) and the dominant (ICC = 0.98) fibroid volumes, the number (ICC = 0.92), presence ($\kappa = 1.0$), and location ($\kappa = 1.0$) of (pedunculated) fibroids, the position of the uterus ($\kappa = 0.94$), and the homogeneity of the dominant fibroid (Table 3). Good agreement between the first and the second reading of observer A was found for signal intensity of the dominant fibroid on the T_1- and T_2-weighted MR images (respectively, $\kappa = 0.73$ and 38 of 40 [95%]; 95% CI, 71.9%–95.6%). (Again, κ values could not be calculated for the T_2 signal intensity; percentages of full agreement are reported instead.) Due to small numbers the agreement between both readings was moderate for the presence of adenomyosis ($\kappa = 0.55$), high-signal-intensity foci ($\kappa = 0.50$), and the junctional zone (ICC = 0.50).

For observer B, intraobserver agreement was excellent for the uterine (ICC = 0.98) and dominant (ICC = 0.97) fibroid volumes and the presence ($\kappa = 0.87$), number (ICC = 0.84), and location ($\kappa = 0.82$) of pedunculated fibroids. The agreement on the presence of high-signal-intensity foci ($\kappa = 1.0$) was excellent. Good agreement between the first and the second reading by observer B was found for the position of the uterus ($\kappa = 0.73$). Agreement between both readings was moderate for the number of fibroids (ICC = 0.58), location ($\kappa = 0.65$) and homogeneity ($\kappa = 0.54$) of the dominant fibroid, signal intensity on T_2-weighted MR images ($\kappa = 0.47$), and presence of adenomyosis ($\kappa = 0.66$). Agreement was fair for observer B for the signal intensity on T_1-weighted images ($\kappa = 0.22$) and the thickness of the junctional zone (ICC = 0.35).

Discussion

We found good to excellent agreement between and within the observers for the uterine and dominant fibroid volumes, number of fibroids (except for observer B), location of the dominant fibroid, position of the uterus (except for the interobserver agreement), signal intensity on T_1- and T_2-weighted MR images (except for observer B), presence of pedunculated fibroids, and presence of adenomyosis (except for observer A). These MRI parameters are of value in the diagnostic workup of patients with uterine fibroids.

Our study has certain limitations. First, MR images were performed on a variety of MR scanners. Given our favorable results, heterogeneity of MR scanners appears not to be a major problem and probably increases the generalizability of our findings. Second, the numbers of patients with adenomyosis were low, therefore it is difficult to draw conclusions for inter- and intraobserver agreement with regard to the thickness of the junctional zone and the presence of high-signal foci.

Various studies found that MRI was superior to US for establishing the number and exact location of fibroids [1, 10–12]. This is important, since these findings play an important role in the identification of eligible patients for undergoing UAE or for planning surgical procedures, especially myomectomy [13]. One study which compared MRI, transvaginal US, and pathological examination reported that the performance of US was significantly poorer for fibroids larger than 375 ml, while the accuracy of MRI was independent of the uterine volume [1]. The location of a fibroid can play a role in the identification of suitable patients for UAE, since an earlier study indicated that submucosal fibroids had a higher chance of volume reduction after UAE [13]. Pedunculated subserosal fibroids are generally recognized as a relative contraindication for the use of UAE [14]. This contraindication stems from the potential hazard for pedunculated subserosal fibroids to separate from the uterus due to stalk necrosis, which may result in serious complications [15, 16].

Table 3 Intraobserver agreement of MRI

Variable	Observer	κ	95% CI	*p*-value
Quality of MR image	A	0.27	0.0 to 0.64	0.053
	B	0.45	0.14 to 0.76	0.004
Position of uterus	A	0.94	0.83 to 1.00	<0.0001
	B	0.73	0.53 to 0.93	<0.0001
Location of dominant fibroid	A	0.8	0.63 to 0.97	<0.0001
	B	0.65	0.44 to 0.86	<0.0001
Homogeneity of dominant fibroid	A	0.83	0.65 to 1.00	<0.0001
	B	0.54	0.18 to 0.90	0.001
Presence of pedunculated fibroid(s)	A	1	—	<0.0001
	B	0.87	0.70 to 1.00	<0.0001
Location of pedunculated fibroid(s)	A	1	—	<0.0001
	B	0.82	0.51 to 1.00	0.003
Signal intensity of dominant fibroid				
T1	A	0.73	0.37 to 1.00	<0.0001
	B	0.22	0.0 to 0.72	0.02
T2	A	—[a]		
	B	0.47	0.05 to 0.89	<0.0001
Presence of adenomyosis	A	0.55	0.17 to 0.92	0.0003
	B	0.66	0.34 to 0.98	<0.0001
Presence of high-signal-intensity foci	A	0.5	0.0 to 1.00	0.25
	B	1	—	0.03
		ICC		
Volume of uterus	A	0.995	0.99 to 0.997	<0.0001
	B	0.98	0.97 to 0.99	<0.0001
Volume of dominant Fibroid	A	0.98	0.96 to 0.99	<0.0001
	B	0.97	0.94 to 0.98	<0.0001
No. of fibroids	A	0.92	0.85 to 0.96	<0.0001
	B	0.58	0.33 to 0.75	<0.0001
No. of pedunculated fibroids	A	0.84	0.55 to 0.95	0.0001
	B	0.84	0.49 to 0.96	0.0006
Thickness of junctional zone	A	0.5	–0.67 to 0.96	0.2
	B	0.35	–0.64 to 0.90	0.25

Note. CI, confidence interval; ICC, intraclass correlation coefficient

[a] Kappa values could not be calculated; percentages are given in text

Scores for signal intensity of the dominant fibroid in our study were variable: the interobserver agreement was good for signal intensity on T_1- and T_2-weighted images, while the intraobserver agreement varied from good for observer A to fair to moderate for observer B. Signal intensity on MRI may be an indicator for treatment success of UAE. A high T_1-weighted signal intensity at baseline was found to be a predictor for a poor response in terms of reduced fibroid volume and vascularity, as was a large uterus [3, 17], while a high signal intensity on T_2-weighted images was found to be predictive of increased uterine volume reduction compared to those with a low signal intensity at baseline [17–19].

Only one earlier study has investigated the interobserver agreement among three observers for various characteristics on MR images in women with fibroid disease. That study reported excellent κ values for identifying the location of the dominant fibroid, as well as for signal intensity on T_1-weighted images (κ = 0.80–0.95) and T_2-weighted images (κ = 0.92–1.0), T_2-weighted heterogeneity (κ = 0.81–0.92), and gadolinium enhancement (κ = 0.96–1.0) [3]. Our data confirmed these observations for the location of the dominant fibroid, except for the κ values of observer B, which showed less agreement for signal intensity on T_1- and T_2-weighted images.

In the literature, opinions differ widely on the question whether adenomyosis should be treated with UAE. Some studies have reported encouraging short-term clinical results [20–22], while one case report concluded that concomitant adenomyosis was the main reason for clinical failure of UAE in women with fibroid disease [23]. One larger study showed that despite encouraging short-term results of UAE in treating adenomyosis, midterm results

were rather disappointing, with only 55% of patients showing clinical improvement after 2 years [24]. A recent study showed similar results for the treatment of adenomyosis, with a clinical UAE success rate of 57.4% after a mean follow-up period of 4.9 years [25].

Thus, it seems important to distinguish between adenomyosis and fibroid disease, especially in patients scheduled for UAE, but this can be quite challenging, mainly because both uterine abnormalities are assumed to coexist in 20% of patients [26] and cause similar symptoms of abnormal uterine bleeding and dysmenorrhea. Most authors recommend the use of MRI, particularly in patients with associated gynecologic disorders. The sensitivity and specificity of MRI in diagnosing adenomyosis range from 77.5% to 89% and from 67% and 92.5% [7, 27, 28]. One study compared MRI findings with histopathologic findings as a gold standard and concluded that MRI is highly accurate in distinguishing between adenomyosis and fibroids in patients with enlarged uteri [29]. Using a standardized MR definition for adenomyosis, we found inter- and intraobserver agreement to be good to excellent.

In conclusion, MRI criteria used for the selection of suitable UAE patients showed a good inter- and intraobserver reproducibility, thereby confirming that commonly used MRI prior to UAE is reliable.

Acknowledgments The EMMY study is funded by ZonMw "Netherlands Organisation for Health Research and Development" (grant application no. 945-01-017) and supported by Boston Scientific Corporation, the Netherlands. We are indebted to all participating patients and EMMY Trial Group members and nurses. We thank M. Nuberg, H. van Welsum, and M. Cornet for their administrative efforts. The members of the EMMY Trial Group were as follows**:** *Initiators*—J. Reekers, W. Ankum, and G. Bonsel; *Steering Committee*—J. Reekers, W. Ankum, M. Burger, G. Bonsel, E. Birnie, G. Veldhuyzen van Zanten, H. van Overhagen, S. de Blok, and H. Vervest; *Safety Committee*—J. Evers, M. Prins, and J. van Engelshoven, Academic Hospital Maastricht, the Netherlands (nonparticipating center); *Data Management and Analysis*—W. Hehenkamp, E. Birnie, and N. Volkers; and *Executive and Writing Committee*—W. Hehenkamp, N. Volkers, E. Birnie, W. Ankum, and J. Reekers. Clinical centers were as follows (number of randomized patients is given in parentheses): *Academic Medical Center, Amsterdam* (32)—J. Reekers, W. Ankum, M. Burger, G. Bonsel, E. Birnie, W. Hehenkamp, and N. Volkers; *Onze Lieve Vrouwe Gasthuis, Amsterdam* (40)—S. de Blok and C. de Vries; *Atrium Medical Centre, Heerlen* (4)—T. Salemans and G. Veldhuyzen van Zanten; *Groningen University Hospital, Groningen* (3)—D. Tinga and T. Prins; *Bosch Medical Centre, Den Bosch* (1)—P. Sluijffers and M. Rutten; *Bronovo Hospital, The Hague* (1)—M. Smeets and N. Aarts; *Medical Centre Rijnmond-Zuid, Rotterdam* (2)—P. van der Moer and D. Vroegindeweij; *St. Elisabeth Hospital, Tilburg* (6)—F. Boekkooi and L. Lampmann; *Flevo Hospital , Almere*—G. Kleiverda; *Gooi-Noord Hospital, Laren*—R. Dik and J. Marsman; *Kennemer Gasthuis, Haarlem* (4)—C. de Nooijer , I. Hendriks, and G. Guit; *Leyenburg Hospital, The Hague* (4)—H. Ottervanger and H. van Overhagen; *St. Lucas/Andreas Hospital, Amsterdam* (4)—A. Thurkow; *Martini Hospital, Groningen* (10)—P. Donderwinkel, J. Wijma, and C. Holt; *Medical Centre Alkmaar, Alkmaar* (4)—A. Adriaanse and J. Wallis; *Medical Centre Leeuwarden, Leeuwarden* (9)—J. Hirdes, J. Schutte, and W. de Rhoter; *Hospital Midden-Twente, Hengelo* (6)—P. Paaymans and R. Schepers-Bok; *Medisch Spectrum Twente, Enschede* (5)—G. van Doorn, J. Krabbe, and A. Huisman; *Reinier de Graaf Gasthuis, Delft* (2)—M. Hermans and R. Dallinga; *Slingeland Hospital, Doetichem* (4)—F. Reijnders and J. Spithoven; *St. Jans Gasthuis, Weert* (1)—W. de Jager and P. Veekmans; *Twenteborg Hospital, Almelo* (6)—P. van der Heijden, M. Veereschild, and J. van den Hout; *University Medical Centre Utrecht*, *Utrecht* (4)—I. van Seumeren, A. Heintz, R. Lo, and W. Mali; *Westeinde Hospital, The Hague* (2)—J. Lind and Th. de Rooy; *Diakonessenhuis Utrecht, Utrecht* (5)—M. Bulstra and F. Sanders; *De Heel Hospital, Zaandam* (1)—J. Doornbos; *Rijnstate Hospital, Arnhem* (3)—P. Dijkhuizen and M. van Kints; *Slotervaart Hospital, Amsterdam* (4)—Ph. Engelen and R. Heijboer; and *BovenIJ Hospital, Amsterdam* (5)—A. Dijkman.

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