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Original research

Transvaginal Ultrasound (TVUS) Shear Wave Elastography (SWE) for the Evaluation of Benign Uterine Pathologies: A Prospective Pilot Study

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Running title: Shear Wave Elastography of Benign Uterine Diseases

Transvaginal Ultrasound (TVUS) Shear Wave Elastography (SWE) for the Evaluation of Uterine Adenomyosis and Leiomyomas: A Prospective Pilot Study

Abstract

Objectives: This study evaluated diagnostic performance of transvaginal ultrasound (TVUS) shear wave elastography (SWE) for evaluating benign uterine adenomyosis and leiomyomas. **Methods:** IRB approval was obtained for prospective enrollment of 34 premenopausal women with pelvic pain and/or bleeding between January 2015-June 2016. TVUS SWE was performed with regions of interest in multiple uterine segments and shear wave velocities (SWVs) were recorded. Reference pelvic MR exams were performed and reviewed without access to the US results. **Results:** Continuous variables were analyzed using means, t-tests and ANOVA. MR revealed adenomyosis in 6 women (12 uterine segments), and leiomyomas in 12 women (28 segments). On a per patient basis, mean SWV in 16 women with no adenomyosis or leiomyoma was 4.3 ± 1.7 m/s, compared with 5.7 ± 2.3 m/s in 18 women with MR diagnosis of myometrial pathology ($p < 0.0002$, 95% CI -2.2, -0.6). On a per segment basis, SWV in normal myometrium was 4.8 ± 1.9 m/s, compared with 4.9 ± 2.5 m/s in adenomyosis and 5.6 ± 2.5 m/s in leiomyoma ($p=0.34$ by one-way ANOVA). In pairwise comparison, SWV for adenomyosis and leiomyoma did not differ significantly ($p=0.40$). **Conclusions:** TVUS SWE did not distinguish adenomyosis from leiomyoma. However, our pilot study demonstrated that myometrial SWVs were higher in uteri with adenomyosis and leiomyomas than in uteri with normal myometrium ($p < 0.0002$), indicating increased tissue stiffness in women with myometrial diseases and suggesting a potential role for SWE in treatment response assessment.

Key words: uterine leiomyoma; adenomyosis; shear wave elastography; transvaginal ultrasound

Introduction

Uterine adenomyosis, abnormal growth of endometrial tissue into the myometrium, is a common incidental finding in hysterectomy specimens. Estimates of true prevalence range from 18-66% in hysterectomy and biopsy specimens in the recent literature.[1] The primary symptoms of adenomyosis are chronic pelvic pain and abnormal uterine bleeding, but there is also an association with subfertility.[2] Adenomyosis is under-diagnosed: in one recent study, fewer than a quarter of patients had a correct preoperative diagnosis, with a frequent misdiagnosis as leiomyoma by ultrasound.[3] The prospective diagnosis of adenomyosis is clinically significant because it may alter treatment decisions.

B-mode transvaginal ultrasound (TVUS) and pelvic MR have been evaluated for detection of adenomyosis, with sensitivity of approximately 74% and positive predictive value (PPV) of 68% for TVUS and sensitivity of 81% and PPV 76% for MR in reader studies with attention to this diagnosis.[4] However, in everyday practice the prospective diagnosis of adenomyosis by conventional ultrasound remains uncommon.

Sonoelastography, including static strain elastography and dynamic shear wave elastography (SWE), has been extensively studied in liver fibrosis [5, 6 7] thyroid [8] and breast neoplasms [9, 10] in the past decade; in all instances the pathological condition tends to be firmer than normal visceral parenchyma. In contrast, obstetric and gynecologic implementations are underexplored with most of the studies using strain elastography, a subjective method [11]. SWE is an objective quantitative ultrasound elastography technique, which can depict the stiffness of anatomic structures, to aid in their detection and characterization. SWE uses a push pulse, often referred to as acoustic radiation force, from the imaging transducer to generate shear waves in soft tissues. Shear waves propagate perpendicular to the direction of the push pulse and their velocity can be tracked by ultrasound, directly assessing tissue stiffness. As smooth muscle tumors, leiomyomas tend to be firm and rubbery on gross examination. Adenomyosis is glandular tissue, more similar to soft endometrium than firm myometrium.

The application of elastography to the uterus has been tested in vitro in a study of unfixed hysterectomy specimens [12], distinguishing between leiomyomas (firmer than myometrium) and endometrial polyps (softer than myometrium) and illustrating a single case of adenomyosis (similar to endometrium, softer than myometrium). TVUS elastography probes enable in vivo evaluation of this concept. Early reports have focused on endometrium [13, 14] with distinction between normal and hypertrophic endometrium (relatively soft) versus polyps (slightly firmer). Assessment of cervical ripening in labor [15], which is critical to predict the likelihood of success in labor induction, has also been explored. Sonoelastographic characterization of benign myometrial conditions is ongoing. Several recent studies use strain elastography to diagnose adenomyosis and uterine leiomyomas [16-18]. Only one study in the literature investigates SWE of adenomyosis [19]. Thus, the use of in vivo SWE for myometrial assessment is truly a novel application of an emerging technology. Therefore, we propose to assess the test performance of TVUS with SWE to evaluate the marginal diagnostic utility of ultrasound elastography for benign uterine pathologies, using pelvic MR as the reference standard.

Materials and Methods

From January 2015 to June 2016, premenopausal women with pelvic pain and/or bleeding and no history of gynecologic malignancy, who provided informed consents, were enrolled in this IRB approved prospective study. Medical records were reviewed for demographic and clinical information. TVUS was performed on a SuperSonic Aixplorer (SuperSonic, Aix en Provence, France) US machine by a registered diagnostic medical sonographer with 2 years of SWE experience. A 6-8 MHz transvaginal probe was used to image the uterus, and representative still and cine greyscale and color Doppler images were stored. In SWE mode, 2 or 3 regions of interest (ROIs) ($\geq$ 0.5 cm in diameter) were placed in each of the following segments, depending on the anatomical location and target tissue thickness, to obtain shear wave velocities (SWVs): anterior and posterior cervix, anterior and posterior myometrium,

fundus, and within endometrial stripe, as well as centered within any visualized myometrial or endometrial mass. The size of the ROI was carefully chosen in order to measure adequate soft tissue/lesion yet within the confined uterus/lesion. The SWV was measured by the SWE software on the US machine and shown on the image. The reliability of the measurements was based on the quality of elasticity color map overlaid on the gray scale image and the standard deviation of each measurement. The measurement was considered invalid if the color pixels in the ROI were scant or the standard deviation was greater than 30%.

Ultrasound images were stored and reviewed using Syngo Dynamics workstations (Siemens Healthineers, Mountain View, CA). US images were reviewed in consensus by a board certified abdominal radiologist with 10 years' experience and a current abdominal imaging fellow. Mean values at each uterine anatomic site were calculated when two or more ROIs returned technically adequate velocities. The SWVs were tabulated.

As the reference standard, contrast enhanced pelvic MR exams were performed on a 1.5T GE Signa Excite (GE Healthcare, Waukesha, WI) or Philips Ingenia (Philips Healthcare, Andover, MA) scanner using an anterior body surface coil including the following sequences: three plane localizers, sagittal and short axis T2-weighted FSE with fat saturation, and pre and post contrast T1-weighted axial SPGR through pelvis. Patients received 1 mg glucagon IM and 0.2mL/kg body weight intravenous gadobenate dimeglumine (MultiHance, Bracco Diagnostics, Monroe Twp, NJ). MRI images were stored and reviewed using McKesson PACS (McKesson Radiology, San Francisco, CA).

MR exams were reviewed in consensus by two board certified radiologists with 1 and 7 years' experience after abdominal fellowship training, who were blinded to the ultrasound and clinical findings. The presence, type and location of any uterine pathology were recorded. Adenomyosis was diagnosed when the uterine junctional zone thickness exceeded 12 mm on T2WI and/or subendometrial cysts were identified in an area of junctional zone irregularity [20]. Uterine leiomyomas were diagnosed when focal,

well circumscribed masses with low signal on T2WI were identified within or arising from the myometrium[21].

SWVs were analyzed on a per patient and a per anatomic site basis, recognizing that the multiple measurements within a single uterus are not independent observations. Continuous variables were analyzed using means, t-tests and ANOVA, and categorical variables were analyzed using counts, frequencies, and percentages. All statistical tests were performed using Microsoft Excel (Microsoft Inc, Redmond WA) or SAS 9.4 (SAS Institute, Cary NC), assuming $p < 0.05$ for statistical significance.

Results

34 premenopausal women (mean age 36.8 years, range 22-52) were enrolled, with mean time between US and MR exams 11 days (±27, range 0-118). The studies were performed on the same day for 25 women, US was performed prior to MR for 4 women, and MR preceded US for 5 women.

MR revealed adenomyosis in 6 women involving 12 uterine segments, leiomyoma in 12 women involving 28 segments, and no cervical pathology in any of the 34 women. One woman had both adenomyosis and leiomyomas at MR imaging. On a per patient basis, mean SWV in combined segments of 16 women with no adenomyosis or leiomyoma was 4.3 ± 1.7 m/s (, range 1.8-9.4), compared with 5.7 ± 2.3 m/s (, range 1.7-9.9) in 18 women with MR diagnosis of myometrial pathology ($p < 0.0002$, 95% CI of difference -2.2, -0.6) (Figure 1). Treating each myometrial segment as an independent observation, SWV in normal segments was 4.8 ± 1.9 m/s, compared with 4.9 ± 2.5 m/s in adenomyosis and 5.6 ± 2.5 m/s in leiomyoma ($p=0.34$ by one-way ANOVA) (Figure 2). In pairwise comparison, SWV for adenomyosis and leiomyoma did not differ significantly ($p=0.40$).

Mean cervical stromal SWV was 5.26 m/s (±1.99, range 2.3-10.0), higher than that of normal myometrium ($p=0.04$). Only one patient had endometrial pathology, diagnosed as a polyp on MR,

demonstrating SWV of 3.6 m/s. Representative images in a normal uterine segment, adenomyosis, and leiomyoma are shown in Figures 3-5.

Discussions

Our pilot study demonstrated that myometrial SWVs were higher in the setting of uterine pathologies including adenomyosis and leiomyomas than in normal myometrium (5.7 vs 4.3 m/s, $p<0.0002$), indicating increased tissue stiffness in women with myometrial diseases. This observation is clinically relevant in several regards. Abnormal contractility and hyperperistalsis, particularly in the inner myometrium or junctional zone, are thought to cause pain and cramping as well as subfertility due to altered sperm transport in adenomyosis [21, 22]. It seems likely that muscular stiffness, contractility, and propagation of peristaltic waves are related, suggesting an avenue for further research into the utility of SWE for treatment response assessment. Systemic and intrauterine pharmacologic therapies as well as ablative treatments — such as high frequency ultrasound ablation and uterine artery embolization — for both adenomyosis and leiomyomas are of increasing interest to women who wish to avoid surgery, and in some cases to maintain fertility. Current methods for assessment of disease severity and treatment response, such as measurements of uterine size and junctional zone thickness, are purely morphologic. Results of clinical trials have been difficult to interpret given the poor performance of these imaging endpoints, with some investigators reporting decreased uterine size as a marker of success [23, 24], while others reported unchanged uterine size in patients with symptomatic improvement [25]. Decreased junctional zone thickness is a marker of response in some trials [25, 26], though others noted no difference in the junctional zone: myometrial ratio, suggesting that decreased junctional zone thickness may simply reflect overall volume loss [23]. As such, the field is ripe for a functional imaging endpoint, and with further standardization of the technique and large scale validation, we suggest that TVUS SWE has tremendous potential in this regard.

In contrast to the assumption that tissues with pathological differences may have measurable elasticity difference, TVUS SWE did not successfully distinguish adenomyosis from leiomyoma, which may relate to a few factors. First, adenomyosis is abnormal growth of glandular tissue into the myometrium. Although glandular tissue itself is soft, local congestion and reactive muscular hypertrophy may be present within the confined myometrium in vivo, resulting in increased stiffness. Second, although we documented diagnostic SWVs in all uterine segments, larger and more globular uteri posed subjective technical challenges, with multiple attempts required, particularly in the more deeply positioned posterior myometrium. Besides, the generally accepted assumption is that SWV measurements are most reliable when they are made in infinite, homogeneous media. In other words, boundary effects will influence the measured speeds, especially within focal masses. However, clinical applications of SWE in confined tissues have been carried out over the last decade [27-29]. Third, leiomyomas are often well marginated, whereas adenomyosis is by its nature infiltrative. As such, it is much easier to place a discrete ROI on a sonographically evident leiomyoma than on an ill-defined region of adenomyosis. In further research, it may be valuable to "work backwards" from known areas of abnormality on MRI in order to more readily isolate the SWV in adenomyosis and leiomyomas. Finally, adenomyosis and leiomyomas coexist in up to 57% of women with adenomyosis on pathologic specimens [30], and in one woman based on MR diagnosis in our study population, and it is possible that some ROIs sampled both conditions at once.

This is an emerging area of research and results from recent publications regarding sonoelastographic characterization of adenomyosis and uterine leiomyomas are inconsistent thus far. In several strain elastography-based studies [16-18], transvaginal compression was applied on the targeted uterine segments to obtain strain ratios among leiomyoma, normal myometrium and adenomyosis. Their results supported the capability of strain elastography to differentiate adenomyosis from leiomyomas, although one study showed suboptimal agreement between strain elastography diagnosis

of adenomyosis and histology [18]. Only one study in the literature used SWE to evaluate adenomyosis [19], with results similar to ours: significantly increased myometrial stiffness in patients with adenomyosis. The abovementioned inconsistency might reflect underlying technical differences in measuring tissue stiffness within a confined organ, which warrants further investigation.

This study has several limitations. First, the sample size is relatively small in this pilot investigation. Larger studies with controlled acquisition methods including number and interquartile range (IQR) of SWV measurements will be needed to establish the reliability of this approach and to establish whether any quantitative threshold separates normal from abnormal uteri. Second, there is lack of pathologic correlation, given the absence of any direct indication for surgery in this population. We formalized MRI interpretation and strengthened our standard of reference by using published criteria, defined anatomic segments, and two experienced readers working in consensus. Third, the phase of menses was not controlled during the examination, and hormonal effects on the myometrium, particularly the junctional zone, may have contributed to unrecognized SWV variation.

In conclusion, this pilot study demonstrated globally increased myometrial stiffness using shear wave elastography in women with myometrial disorders including adenomyosis and leiomyomas. Our result suggests additional directions for inquiry into fibrosis and/or altered muscular contractility as a contributor to chronic symptoms in women with these disorders, and a potential role for elastography in treatment response evaluation.

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Figure legends:

Figure 1: Shear wave velocities in normal vs. abnormal myometrium on a per patient basis.

Figure 2: Shear wave velocities classified by pathology type when treating each myometrial segment as an independent observation.

Figure 3: 39-year-old woman with normal uterus. (a) Sagittal T2WI shows non enlarged uterus with normal junctional anatomy and no myometrial masses. (b) Sagittal SWE shows intermediate SWV of 3.7 m/s in an anterior region of interest.

Figure 4: 32-year-old woman with adenomyosis and intracavitary adenomyomatous polyp with subsequent hysteroscopic resection. (a) Coronal T2WI shows substantial adenomyosis in the anterior myometrium (the uterus is anteverted), with a markedly thickened junctional zone (arrows) and tiny

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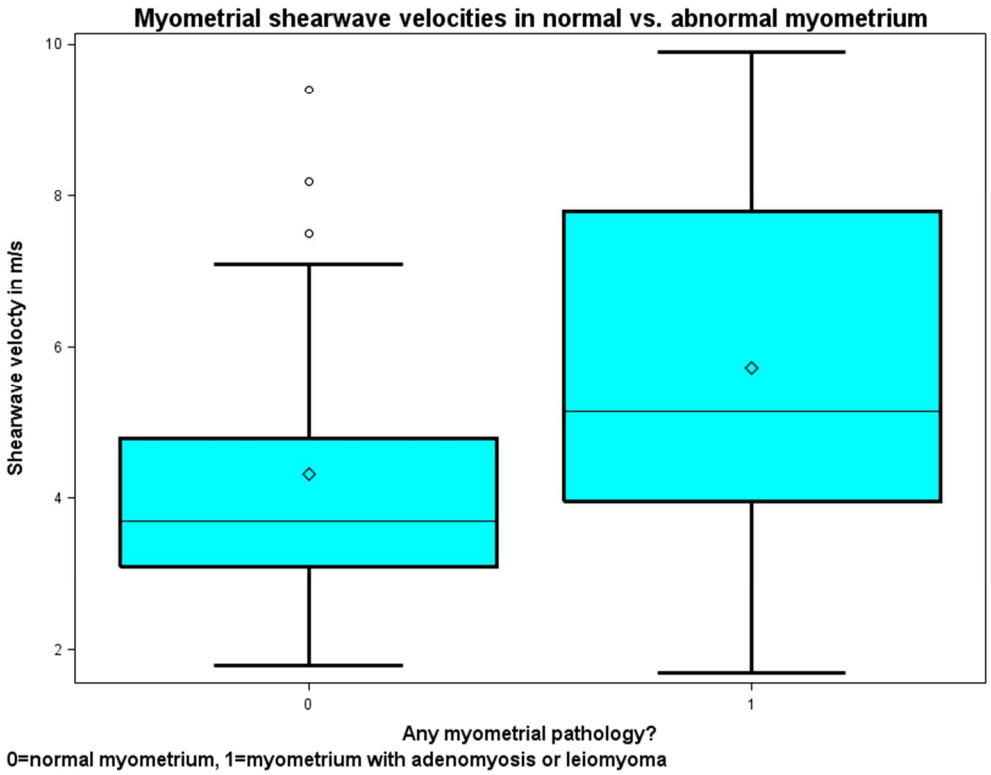
Figure 5: 35-year-old woman with small uterine leiomyomas. (a) Sagittal T2WI shows small low signal masses involving the anterior (arrow) and posterior myometrium. (b) Sagittal SWE with ROI within the anterior leiomyoma shows focally increased tissue stiffness with SWV 8.6 m/s.



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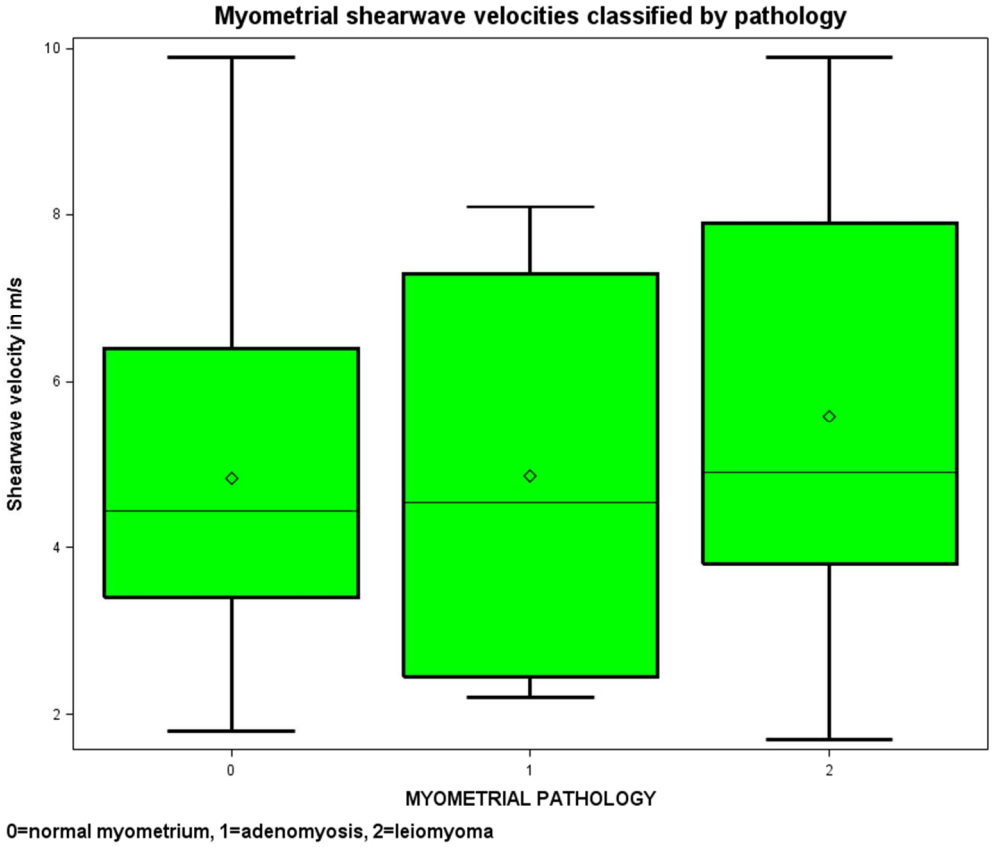

Figure 2: Shear wave velocities classified by pathology type when treating each myometrial segment as an independent observation.

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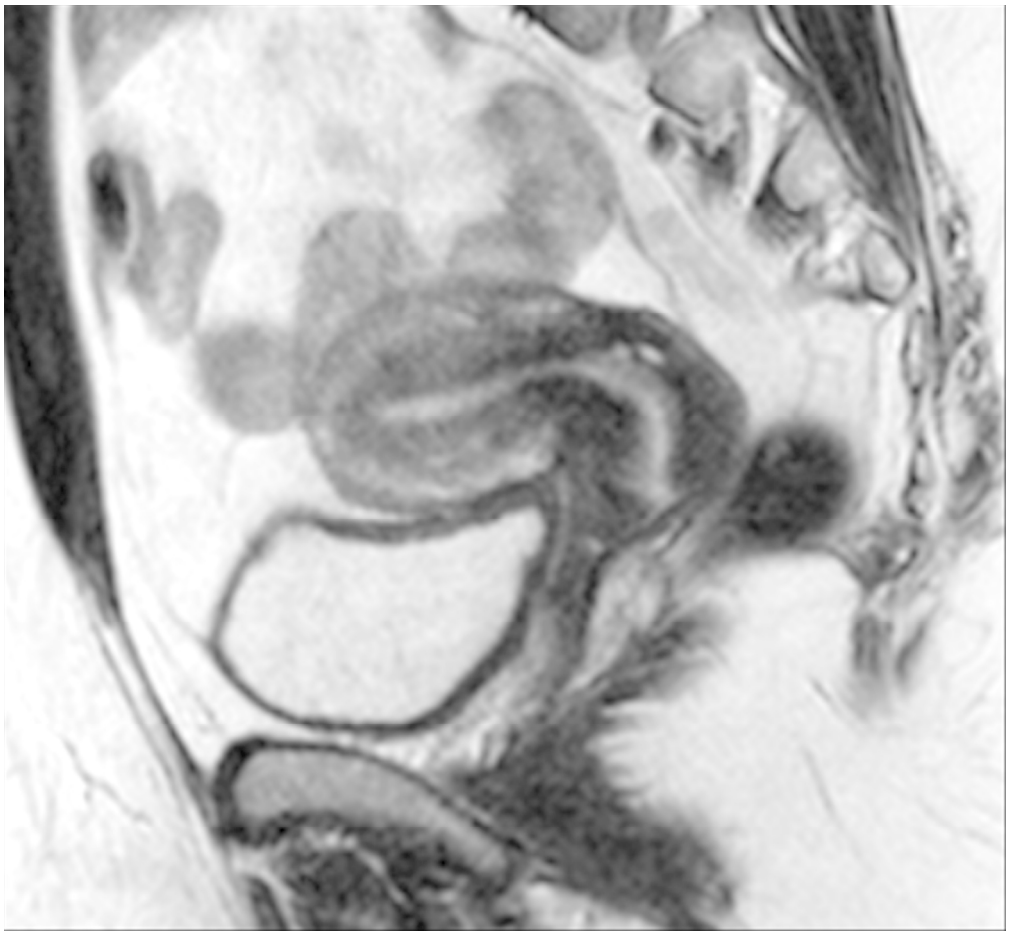

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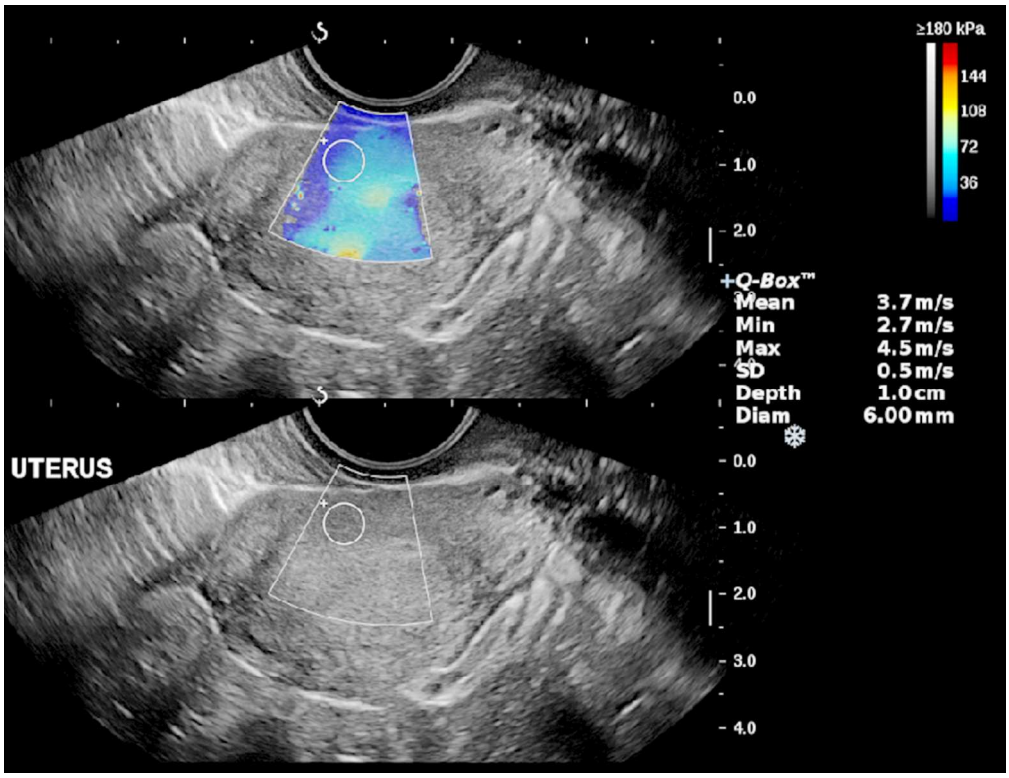

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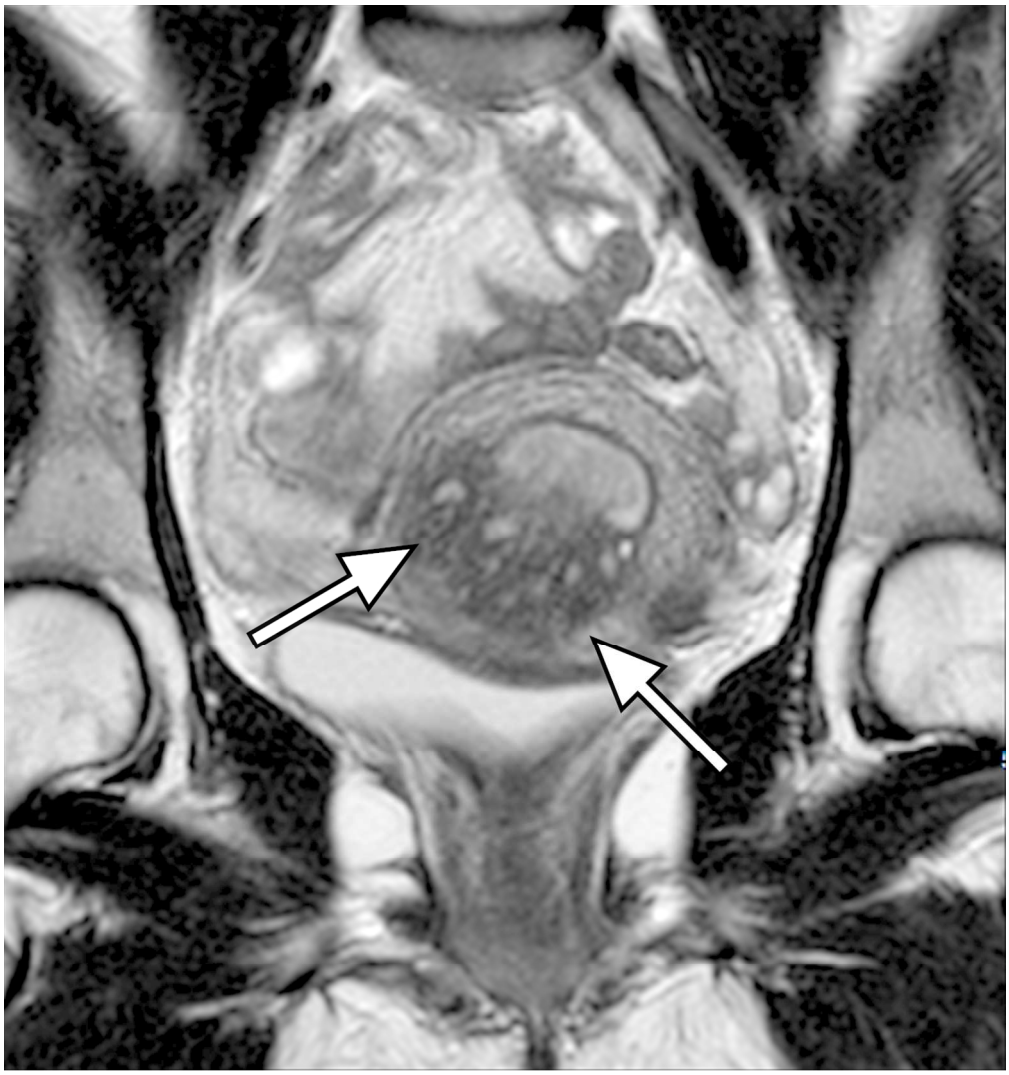

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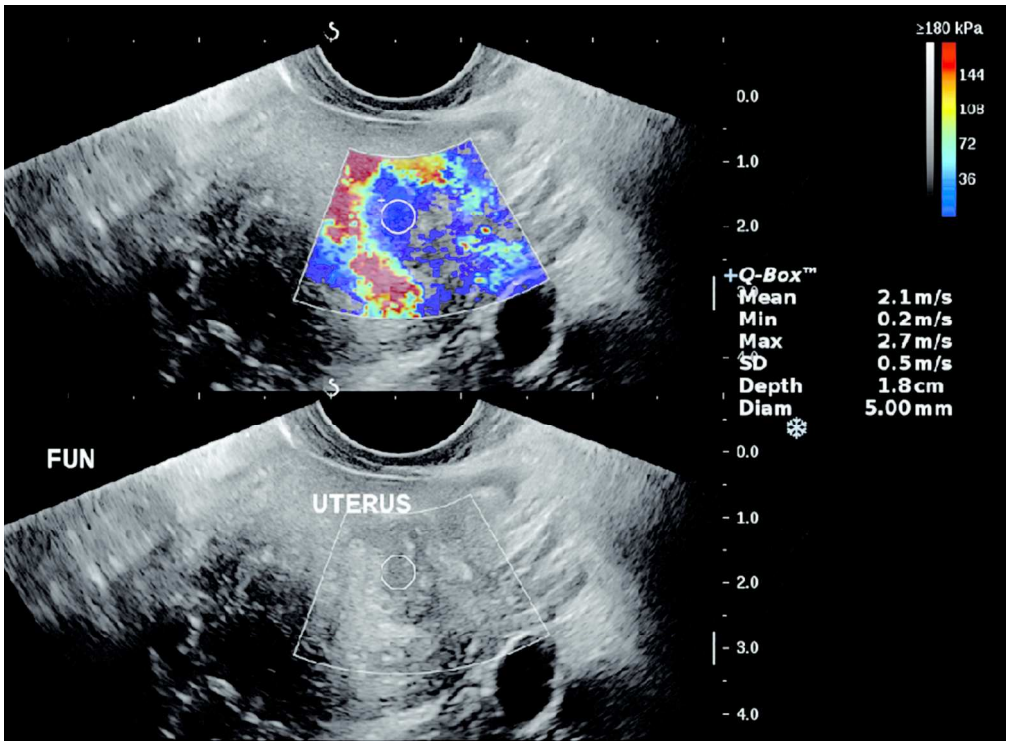

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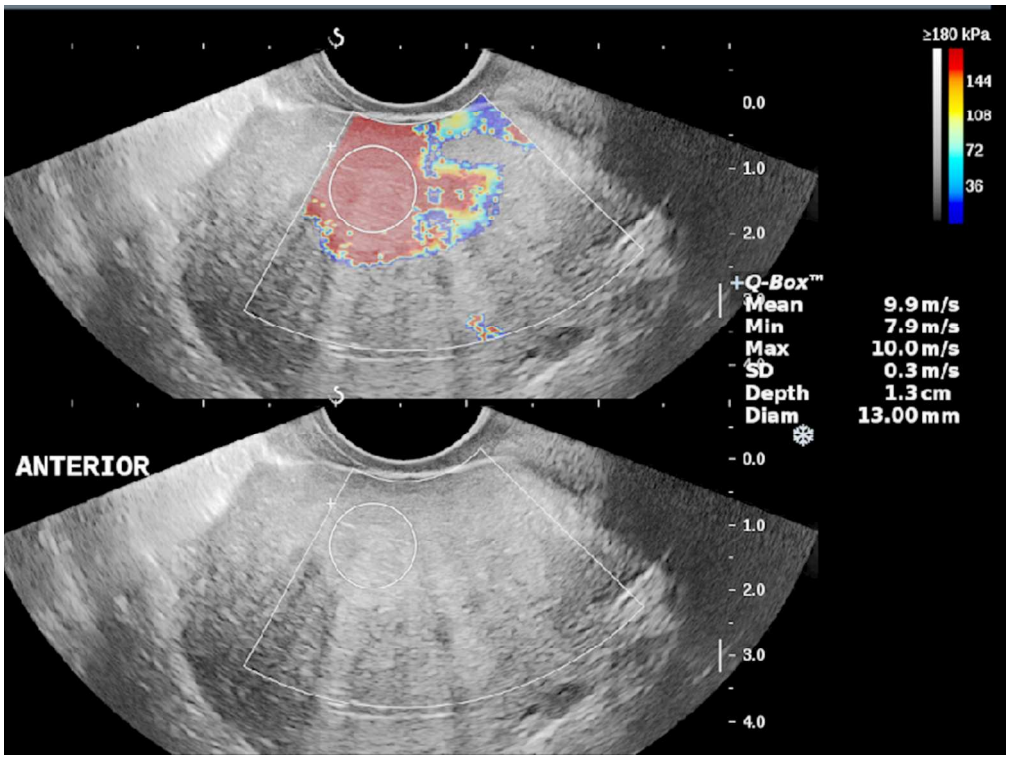

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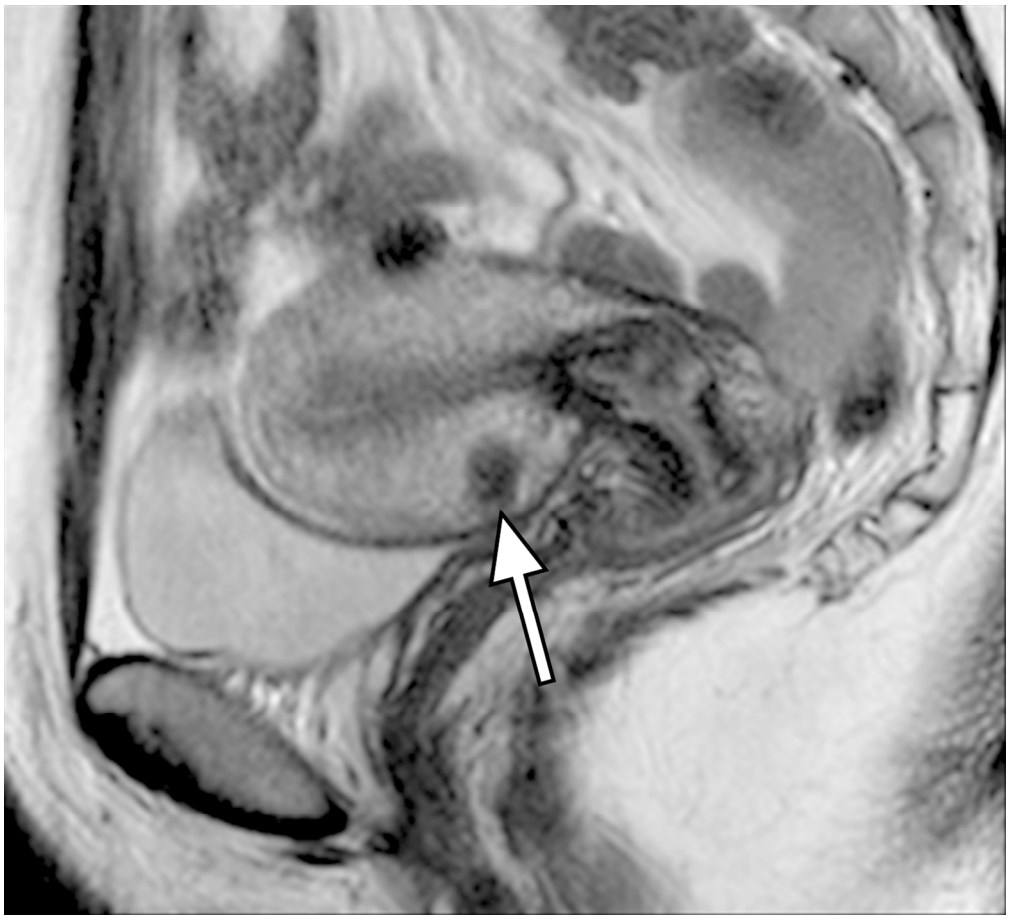

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127x115mm (300 x 300 DPI)

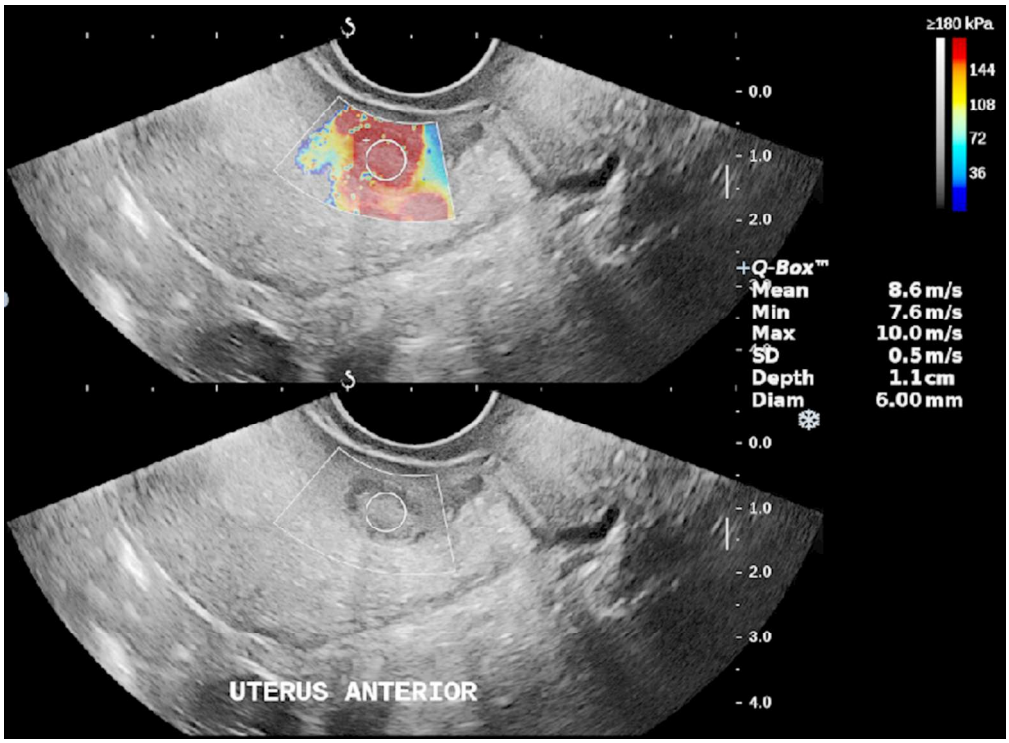

Figure 5: 35 year old woman with small uterine leiomyomas. (a) Sagittal T2WI shows small low signal masses involving the anterior (arrow) and posterior myometrium. (b) Sagittal SWE with ROI within the anterior leiomyoma shows focally increased tissue stiffness with SWV 8.6 m/s.

127x93mm (300 x 300 DPI)