

Patient acceptability and quality of self-administered intravaginal gel for pelvic MRI

Noemi J Hughes^{1*}, Sanjaya Kalkur¹, Jufen Zhang², Sidath H Liyanage³

¹Department of Obstetrics and Gynaecology, Southend University Hospital NHS Foundation Trust, Prittlewell Chase, Southend-on-Sea, SS0 0RY, United Kingdom.

²Anglia Ruskin University, East Road, Cambridge, Cambridgeshire, CB1 1PT.

³Department of Radiology, Southend University Hospital NHS Foundation Trust.

***Corresponding author:** noemihughes@doctors.org.uk

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Corresponding author:

Noemi J Hughes, Department of Obstetrics and Gynaecology,
Southend University Hospital NHS Foundation Trust, Prittlewell
Chase, Southend-on-Sea SS0 0RY, UK.

Email: noemihughes@doctors.org.uk

Abstract

Background: MRI of the pelvis can be limited for infiltrating lesions or those of same signal intensity as surrounding structures. Vaginal distension using aqueous gel counters this by defining the fornices, cervix and anterior rectal wall. This increases the accuracy of diagnosis and staging of various pelvic pathology, however, there is currently neither a universally accepted protocol for using gel nor focus on patient self-administration.

Aims: To improve patient expectations regarding pelvic MRI with intravaginal gel, as well as the service we provide should they prefer self-administration and this produces vaginal distension of radiological quality equivalent to doctor-administration. **Methods:** Illustrated information explaining the benefits of gel and the technique of self-administration was sent to patients scheduled for pelvic MRI between March 2020 and April 2021 at our study centre. This included a questionnaire to assess understanding and preference for self-administration. Vaginal distension achieved on imaging was analysed using TeraRecon and compared between self and doctor-administered cases.

Results: 38 of 45 patients opted for self-administration of gel. Those who identified as White British were more likely to self-administer. There was comparable quality of vaginal distension between self and doctor administered cases, with no significant difference between orthogonal measurements and retained gel volume.

Conclusion: Self-administration of intravaginal gel for pelvic MRI is acceptable to patients and frees a doctor of this duty. It is a well tolerated technique which produces high quality vaginal distention on imaging. We recommend wider use of intravaginal and even rectal gel in the investigation of complex endometriosis and pelvic tumours.

Introduction

There are several challenges involved in imaging the female pelvic organs, largely relating to the small area of anatomy concerned. The pelvis contains several thin, closely opposed structures and the vaginal walls are normally collapsed. At present, MRI is regarded to have superior sensitivity and resolution for the diagnosis and staging of various gynaecological conditions.¹⁻³ Such imaging has become a significant prerequisite for adequately counselling patients and planning their management such as surgery. MRI can, however, be limited by lesions which have the same signal intensity as the surrounding structures and intravenous contrast agents cannot delineate infiltrating lesions from the parametrium.^{4,5} Vaginal distension and opacification with gel is a technique developed to counter this.

The vagina is a potential space which has capacity for expansion between its superior and lateral walls. This can be achieved using solid^{6,7} or liquid materials such as aqueous gel⁸. Following gel insertion, the vagina appears as a clear structure of high signal intensity on T2-weighted images, with increased definition of the cervix, fornices and anterior rectal wall^{9,10}. By doing so, gel has increased the utility of MRI in diagnosis of Mullerian abnormalities⁷, pelvic cysts^{11,12} and endometriosis¹³⁻¹⁵ with adhesions¹⁶. It has also improved the diagnosis of vaginal, cervical^{3,9} and non-gynaecological such as urethral malignancies². Since inflammation, oedema and tumour compression can resemble parametrial infiltration on MRI¹⁷, better visualisation of the vagina using gel has been shown to reduce the risk of over-staging and can have significant implications for patient management¹⁸.

There is currently no universally accepted protocol for vaginal distension using gel for pelvic MRI¹⁹. Insertion using a syringe is an inexpensive and quick technique that is usually well-tolerated by patients^{9,18}. The gel can occupy the entire anatomical space of the vagina and exhibits less backflow compared to non-viscous liquids such as saline¹⁴. It has also been found to cause less artefact than solid alternatives^{3,6}. The protocol adopted at our centre was for a junior gynaecologist to insert aqueous ultrasound gel into a patient's vagina prior to scan using a bladder syringe. Unfortunately, patients were often neither informed about the use of gel, nor offered the option of self-administration. This led to a lack of patient preparedness regarding their expectations of the procedure, as well as having sanitary products to absorb subsequently expelled gel. Explaining the purpose of and consenting a

patient for gel insertion during their scan appointment was also time-consuming and required a doctor to leave their ward duties.

Aims and objectives

To our knowledge, there is currently no focus on the potential of patient self-administered intravaginal gel for pelvic MRI in the scientific literature. We therefore wanted to provide patients with the relevant information, assess their acceptance of self-administration and to compare the radiological quality of vaginal distension achieved between self and doctor-administered gel. In doing so, we aim to improve patient expectations regarding their scan, as well as the service we provide should they prefer to self-administer gel, this produces distension of equivalent quality and relieves a doctor of the duty.

Materials and methods

This work was officially registered as a Quality Improvement Project at Southend University Hospital. We produced a patient information sheet explaining the intended benefits of intravaginal gel for pelvic MRI and the protocol for self-administration (supplementary material). This featured images to demonstrate the distension and opacification of the vagina achieved using gel (figure 1) and stepwise instructions for the technique of self-administration (figure 2). A questionnaire was also produced to collect patient demographic data, assess their understanding of the information provided and their acceptance of self-administration (supplementary material). It gave the opportunity for patients to rate the ease and discomfort of the procedure following the scan, as well as to provide signed consent for use of their anonymised responses and scan images for this publication.

The online portal (ICE) used to request MRI at our centre was updated with a prompt for clinicians to specify whether a scan requires intravaginal gel (figure 3). This appears as a yellow banner when the option for MRI pelvis (gynae) is selected and attempts to ensure as many patients as possible whose imaging would benefit from gel undergo the correct protocol. A Request for Patient Identifiable Information was run by the radiology department to generate the list of patients scheduled for MRI pelvis with gel between March 2020 and April 2021. These patients were posted the information sheet and questionnaire to return completed at their scan appointment.

For patients who indicated that they would prefer not to self-administer gel, a doctor was called to attend their scan. During each appointment, 60cm³ of warmed Skintact gel was provided to either the patient or doctor in a pre-filled bladder syringe. This has a narrow beak that approaches or enters the vaginal fornices. Patients were advised to lie in a dorsal recumbent position on the scanner table for insertion and to minimise movement or generating intra-abdominal pressure following this.

Patients were imaged with MRI using the endometriosis scan protocol in place at our hospital (Supplemental Material 3). Subsequent images were reviewed in PACS by a single radiologist with 11 years of experience in gynaecology imaging. Vertical measurements were taken from the anterior and posterior fornices to the centre of the vaginal introitus (in cases of total hysterectomy, one vertical measurement was taken from the apex of the vaginal vault). Axial transverse and anteroposterior dimensions were measured at the level of the fornices (or vault apex) and at the bladder neck (Figure 2). The volume of retained intravaginal gel was calculated in cm³ using Aquarius Intuition advanced visualisation software (Version 4.4.13 P4; TeraRecon, Inc., Durham, NC). T2 Axial MR sequences were loaded into the Volume Browse workflow in Intuition. The threshold of the 3D image was adjusted so that the hyperintense vagina was visible and was isolated from adjacent structures using the Dynamic Region Grow segmentation tool. Mask overlay tool was used to verify the quality of the segmentation. Further manual segmentation was performed where necessary using the FreeROI tool. Smoothing was applied to the 3D image and the volume calculated (Figure 3). Using the same process, the volume of a scanned syringe filled with 60 cm³ gel was calculated to be 63.1 cm³, indicating acceptable validity of the software (Figure 4). The mean or median, depending on the distribution of the data, of the orthogonal measurements and volumes were calculated to assess the quality of vaginal distension achieved by self, compared to doctor-administered cases.

Continuous data are expressed as a mean with standard deviation (SD) or as a median with interquartile range (IQR: 25th to 75th percentiles) if the data was not normally distributed. Categorical data are expressed as a percentage of the total population (%), n). Multiple linear regression models were used to evaluate whether the factors age, BMI, or scan findings were associated with volume. These were presumed logically to be related to patient physical size and were easy to collect using a questionnaire. The analyses were performed using the Stata

statistical computer package (14th Version, StataCorp, TX, USA). A two-tailed p-value of <0.05 was considered significant. Fisher exact tests were used to assess the association between two categorical variables, as expected value in some categories was less than five.

Results

During the study period, 45 patients underwent pelvic MRI with intravaginal gel. The median age was 35 (IQR: 27-42), with a range between 59 and 21 years. Median BMI was 26.9 (IQR:24.5-30.5). All patients were either students or working professionals and 36 (80%) identified as White British. The clinical indication for the scan in all 45 cases was to investigate the cause of either chronic pelvic pain or infertility, with endometriosis as the working diagnosis. 38 (84%) patients indicated preference to self-administer gel, for reasons relating to personal dignity, simplicity of the technique and not wanting to burden a doctor. The (16%) who preferred not to indicated a lack of confidence in themselves to correctly insert the gel despite the information provided, concerns about pain and anxiety surrounding the whole procedure.

Once reported, 21 (47%) patients had radiological findings suggestive of adenomyosis or endometriosis and 24 (53%) had a normal scan. 32 patients had an anteverted uterus and there were 2 cases of an anteverted cervix following subtotal hysterectomy. 9 patients had a retroverted uterus and there were 2 cases of total hysterectomy. In all 45 cases, good vaginal distension and opacification was reported on imaging with some overspill present at the introitus. Mean orthogonal measurements and retained intravaginal gel volumes are presented for comparison in table 1. The mean volumes of 59.1cm^3 (self-administered) and 59.2cm^3 (doctor-administered) were compared using the Mann-Whitney U test, which found no significant difference at the 0.05 significance level ($z=-0.799$, $p=0.42$).

Regarding the protocol itself, 60cm^3 appears to be appropriate for insertion given the mean volumes calculated. A caveat to using volume to compare quality of distension, however, is the variation which can occur secondary to vaginal size and pelvic pathology rather than the technique of administration. We therefore looked for a relationship between retained intravaginal gel volume and the patient factors of age, BMI and positive scan findings in an attempt to standardise volume for comparison. Using multiple linear regression models, however, no statistically significant correlations were found. We also analysed the

association between preference to self-administer gel and patient age, ethnicity and occupation. This was having noted that 16 of 17 healthcare professionals and 33 of 36 White British patients chose self-administration. Using Fisher's exact tests, a significant association was found between only ethnicity and preference to self-administer gel ($p=0.02$).

Assessed following the scans, the modal rating given for both ease and comfort of the procedure was 1/5 (where 5 corresponded to extreme difficulty or discomfort). This was the case in both patients who self-administered the gel and those for whom a doctor attended. When patients gave a rating higher than 1, it was largely attributed to pain already present and caused by their underlying condition. All 45 patients indicated that the information sheet provided was easy to understand, though would benefit from the addition of details regarding the syringe and whether active menstruation affects the procedure. Several patients were surprised and intimidated by the physical appearance of 60cm³ gel and for those who did not use tampons, the parallel drawn to insertion of a tampon applicator was not helpful.

Discussion

MRI is regarded as the superior imaging modality for the diagnosis and staging of various gynaecological conditions.¹⁻³ Vaginal distension and opacification with gel is a technique developed to facilitate MRI delineation of closely opposed organs in the pelvis and lesions which may have the same signal intensity as surrounding structures.^{4,5} Gel insertion produces a high T2-weighted signal intensity, which increases the definition of the cervix, vaginal fornices, and anterior rectal wall.^{9,10} This has increased the utility of MRI in the diagnosis of pelvic pathology such as endometriosis, defined as the presence of ectopic endometrial tissue outside of the uterus.¹³⁻¹⁶ This has the potential to be complicated by deep infiltration or adhesions, which can be challenging to distinguish from normal anatomy on imaging.¹³

Chassang et al.²⁰ were one of the first groups to report a significant increase in the sensitivity of MRI (from 63.1% to 81.7%) in diagnosing deeply infiltrating endometriosis following the administration of vaginal and rectal gel. This was, however, based on the interpretation of images from several radiologists with differing levels of experience who did not separately evaluate the different anatomical locations with potential for endometriotic disease. In a subsequent prospective study of 63 patients, Fiaschetti et al.¹⁵ compared MRI findings to

those of ensuing laparoscopic surgery and concluded that intravaginal gel significantly increased the diagnostic value of pre-operative imaging of the rectovaginal septum, uterosacral ligaments, and posterior vaginal fornix. They found the overall sensitivity, specificity, positive, and negative predictive values of imaging with gel were 90.8%, 94.6%, 90.8%, and 94.6% respectively, compared to 67.8%, 95.3%, 89.4%, and 83.5% without it. On the other hand, Uyttenhove et al.²¹ conducted a similar study of 67 patients and found that opacification with gel did not significantly improve the evaluation of vaginal or rectosigmoid endometriosis. Only four patients in this study, however, underwent surgery and so they used a senior radiologist review for comparison rather than the gold standard of diagnostic laparoscopy.

In a recent metanalysis²² of four studies with a combined total of 120 patients, the pooled sensitivity of MRI in the diagnosis of pelvic pathology following vaginal opacification was 89% compared to 63% without it. Though one of the studies used a mixture of saline and barium as a medium rather than gel, the metanalysis concluded that opacification overall increased the sensitivity of MRI in detecting disease by 54%. Notably, whilst one of the studies included was the aforementioned work by Fiaschetti et al.,¹⁵ the remainder focused on the utility of this technique in the diagnosis of cervical cancer.²² MRI has revolutionised the diagnosis of gynaecological malignancies such that of the vagina and cervix^{3,9} since enhancement using intravaginal gel can improve the distinction of inflammation, oedema, and tumour compression affecting these structures.⁹ In particular, it betters the visualisation of the contours of cervical tumours and can increase the accuracy with which this disease is staged.¹⁸

We set out to improve the service provided at our hospital for patients undergoing pelvic MRI with intravaginal gel. Through distribution of an information sheet and questionnaire over a 13-month period, we found that self-administration of gel is acceptable and even preferable to patients compared to insertion by a doctor. The patients involved described this option as preserving of their dignity, privacy, and personal comfort. From the information sheet provided, the majority gauged that self-administration was a straightforward technique that did not necessitate a doctor to prioritise over their other clinical duties. Further validation was present in the patient feedback following the scans, which indicated having intravaginal gel was easy and comfortable regardless of how it was administered.

Based on orthogonal measures as well as a calculated volume, we found that the radiological quality of vaginal distension achieved by self-administration of gel is comparable to cases for which a doctor attended. We are therefore confident in reforming our MRI protocol to encourage patient self-administration in the first instance, with the option of opting out of this. In doing so, we hope to better the service we provide with regard to patient expectations and experience of their scan, whilst reducing the burden of duties for our doctors.

As part of the reformed protocol, we will continue to distribute an updated version of the information sheet to those scheduled for MRI pelvis with intravaginal gel (Supplemental Material 4). In light of the patient feedback, we have included a more detailed description and a photograph of the bladder syringe to demonstrate its size and shape. We have also removed the comparison made to a tampon applicator and provided reassurance that menstruation, though it may affect patient comfort, does not interfere with gel insertion. Whilst pain is a subjective experience, we believe it valuable to assure patients that the majority of those who have undergone the procedure tolerated it without the need for sedation or analgesia. Future directions for the development of the information we provide could include the production of a short, educational video to demonstrate the technique of gel self-administration and the equipment involved.

Given the effect conveyed by vaginal size and pelvic pathology on the volume of retained intravaginal gel, we acknowledge that it is not entirely reliable to use as a marker for quality of distension. We therefore looked for a potential relationship between volume and patient factors such as their size, in an attempt to standardise volume and find a factor reliable for comparison between patients. Unfortunately, no significant correlation was found between volume and patient age, BMI, or the presence of positive scan findings. This may, however, be due to the small patient population of 45 as a non-significant negative correlation was observed between volume and BMI (Figure 5). Should this prove to be significant in a larger population, it introduces possibility of estimating the volume of gel required by individual patients using an established relationship between BMI and volume. In the meantime, to reduce the extent of gel overspill, we are considering incorporating into the protocol use of a gauze pack between the labia during the scan. This will become especially important following our recent acquisition of an ultrasound gel bottle warmer, which will ensure a constant supply of homogeneously warmed pre-filled syringes. In addition to increasing patient comfort, warming the gel thins its consistency and facilitates the removal of air

bubbles. These can accumulate in the vagina and lead to image artefact,^{9,12} however, thinning will increase the tendency for leakage. An alternative method for assessing the quality of gel distension includes counting the number of air bubbles introduced by doctor compared to self-administration. Though this is an arduous task and artefact from air bubbles was noted to be minimal across the images produced regardless of method of insertion.

For the procedure of gel insertion, we anticipate a minority of patients will continue to ask for a doctor despite the provision of an improved information sheet. Following analysis, we found that there was an association between preference and ethnicity as patients who were not White British were less likely to opt for self administration. The reasoning behind this requires further investigation, however, may be related to prior patient education, healthcare experience, cultural, or religious beliefs. To increase uptake, it may be an option to contact and provide further information and support specifically to patients of minority backgrounds. We accept, however, that this may not be feasible for larger populations in which the majority of patients are not White British. A further option exists in training the MRI radiographers to insert the gel, as they are already present to operate the scanner. Though it was not definitively recorded in this project, the time taken for doctor-administration was longer than cases of selfinsertion given the process of calling a doctor to attend the scan. In situations where they had other more clinically urgent duties, this delay was not necessarily negligible. Radiographers present also have more opportunity to build rapport with the patient and so this provides an efficient and dignified alternative to administration by a doctor, which has already been implemented successfully at other centres.

In light of our results, we highly recommend the use of intravaginal gel in patients undergoing pelvic MRI for indications besides possible endometriosis. The quality of vaginal distension achievable is reflected in the consistency of the orthogonal measurements taken and the proximity of the calculated volumes to 60 cm³. Using TeraRecon, we were able to clearly visualise the contours of the inserted gel and surrounding organs. The cervix and rectum, for example, created extraordinarily clear impressions in the gel. We believe this may be a novel application of the software, which could be used more widely to aid in the diagnosis and staging of pelvic disease such as cervical tumours suitable for trachelectomy. There is also the potential of gel in distending and opacifying the rectum to further delineate pelvic structures. This can provide valuable information in the work up of more complex

cases of endometriosis with deep infiltration (Figure 6) as well as gynaecological malignancies.

Unfortunately, there are unavoidable limitations of this protocol including its contraindication in children and patients who have never been sexually active. It may also be inappropriate to use in those who have been subject to sexual abuse or pelvic irradiation leading to scarring and fibrosis. This, as well as gynaecological pathology such as uterine fibroids or adenomyosis, can impede gel insertion and vaginal distension (Figure 7) limiting the benefits in certain patients regardless of how it is administered. In line with this, not all pelvic MRI scans are performed with intra-vaginal gel at our hospital. Per ESUR guidelines, we consider the use of gel justified in cases where endometriosis is suspected given its high negative predictive value.¹⁵ Since we found the modal rating for comfort of the procedure to be 1/5 (minimal discomfort), imaging with gel appears to be a well-tolerated technique justified in ruling out disease and allowing for investigation of alternative diagnoses in patients with a normal scan.

Conclusion

Self-administration of intravaginal gel for pelvic MRI is acceptable to patients and frees a doctor of this duty. It is an inexpensive, well-tolerated technique which increases the quality of pelvic imaging and may significantly improve patient experience and management. Future direction to increase uptake includes augmenting the information we provide and tailoring it to patients of different backgrounds. Further work is required to investigate the utility of gauze in preventing gel overspill and to train MRI radiographers in its insertion. We recommend wider use of gel and even rectal distension for the workup of complex or malignant pelvic pathology such as cervical tumours.

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completion and collection of patient questionnaires. We are especially grateful to Paige Barratt for guidance on using the TeraRecon software.

Author contributions

The project was conceived by SL and SK. The manuscript and supplementary materials were written by NH, with revision and intellectual input from SL and SK. Radiological images were produced and annotated by SL. Statistical analysis was performed by JZ. Patient consent was obtained by NH. All authors have read and approved the manuscript.

Declaration of conflicting interests

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Informed consent to participate

Signed consent for participation in this research was given by each participating patient. Informed consent to publish Signed consent for the processing and publication of the data and images contained in this report was given by each participating patient.

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Tables and Figures

Table 1. Comparison of orthogonal measurements and calculated volumes (no significant differences found).

Measurement	Patient self-administered gel (mean (SD)/Median (IQR)) N=38	Doctor administered gel (mean SD/Median (IQR)) N=7	p-value
Vertical from anterior fornix/vault (figure 4A)	5.2 ± 1.0cm	5.3 ± 0.9cm	0.74
Vertical from posterior fornix/vault (figure 4A)	6.7 (5.6-7.1)	7.2 (6.4-7.9)	0.11
Axial transverse at fornices/vault (figure 4B)	5.2 ± 0.9cm	5.1 ± 0.8cm	0.86
Axial AP at fornices/vault (figure 4B)	4.1 ± 1.0cm	3.8 ± 0.7cm	0.54
Axial transverse at bladder neck (figure 4C)	3.6 ± 0.8cm	3.9 ± 0.4cm	0.40
Axial AP at bladder neck (figure 4C)	2.0 ± 0.7cm	2.2 ± 0.6cm	0.45
Intravaginal gel volume	59.1 (43.9-65.2)cm ³	63.6 (46.3-72.5)cm ³	0.42

Figures

If intravaginal gel is required please specify in the clinical details

<input type="checkbox"/> MR Orbits	<input type="checkbox"/> MR Neck
<input type="checkbox"/> MR Sinuses	<input type="checkbox"/> MRA Carotids
<input type="checkbox"/> MR Salivary Glands	<input type="checkbox"/> MR Temporo-Mandibular Joints
<input type="checkbox"/> MR Rectum	<input type="checkbox"/> MR Pelvis
<input type="checkbox"/> MR Prostate	<input checked="" type="checkbox"/> MR Pelvis (Gynae)
<input type="checkbox"/> MR Small Bowel	<input type="checkbox"/> MR Urinary Bladder
<input type="checkbox"/> MRI Breast Implants Both	<input type="checkbox"/> MR Chest
<input type="checkbox"/> MR Thoracic Spine	<input type="checkbox"/> MR Lumbar Spine
	<input type="checkbox"/> MR Sacro-Iliac Joints

Figure 1. ICE prompt for requesting clinician to specify whether an MRI pelvis scan requires intravaginal gel.

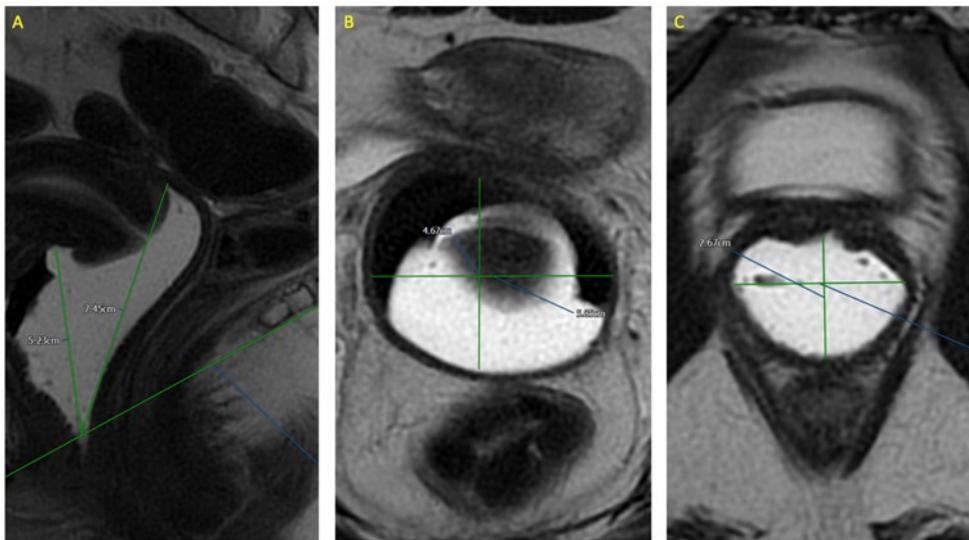


Figure 2. T2-weighted images on a 1.5T GE machine: orthogonal measurements of vaginal distension following self-administered intravaginal gel. Vertical from anterior/posterior fornices to centre of vaginal introitus (a), axial transverse at level of fornices (b), and axial transverse at the level of bladder neck (c).

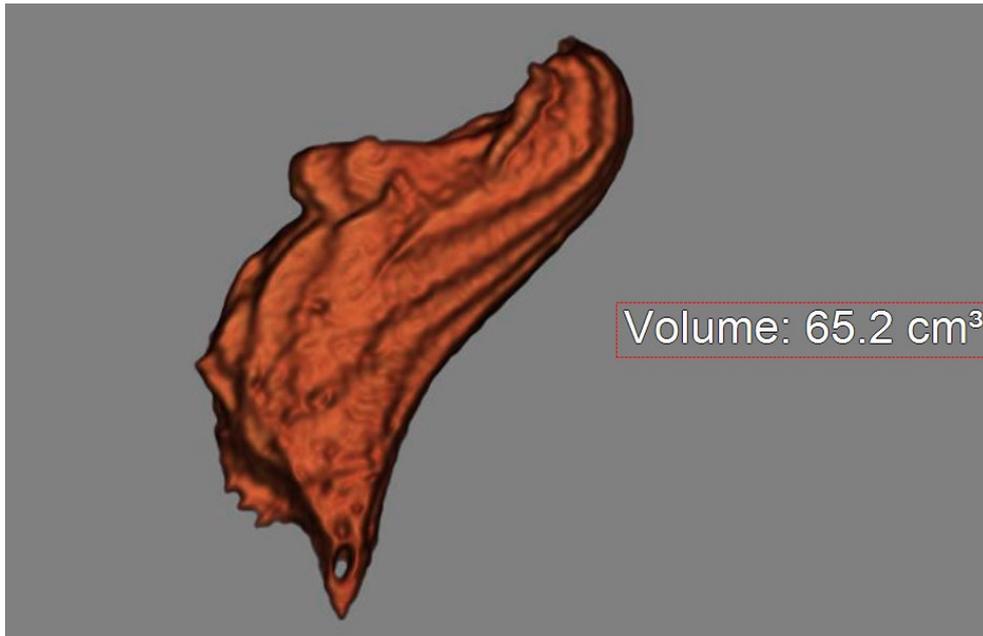


Figure 3. Reconstructed retained intravaginal gel with estimated volume using TeraRecon.

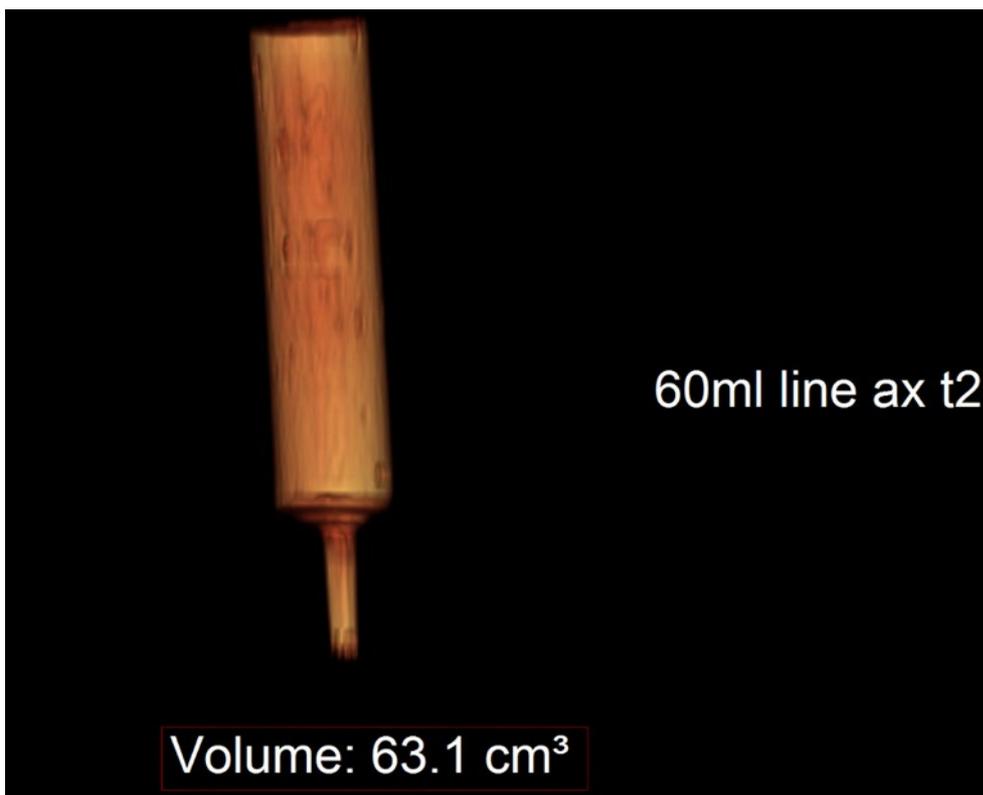


Figure 4. Estimated volume of a scanned syringe (filled to 60cm³) using TeraRecon.

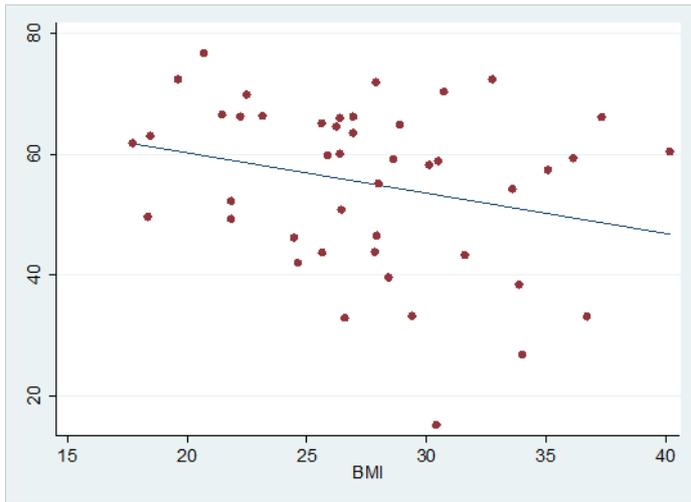


Figure 5. Non-significant negative correlation between patient BMI and intravaginal gel volume, unstandardised coefficient (95% CI): -0.74 (-1.52 , 0.04), $p=0.06$.

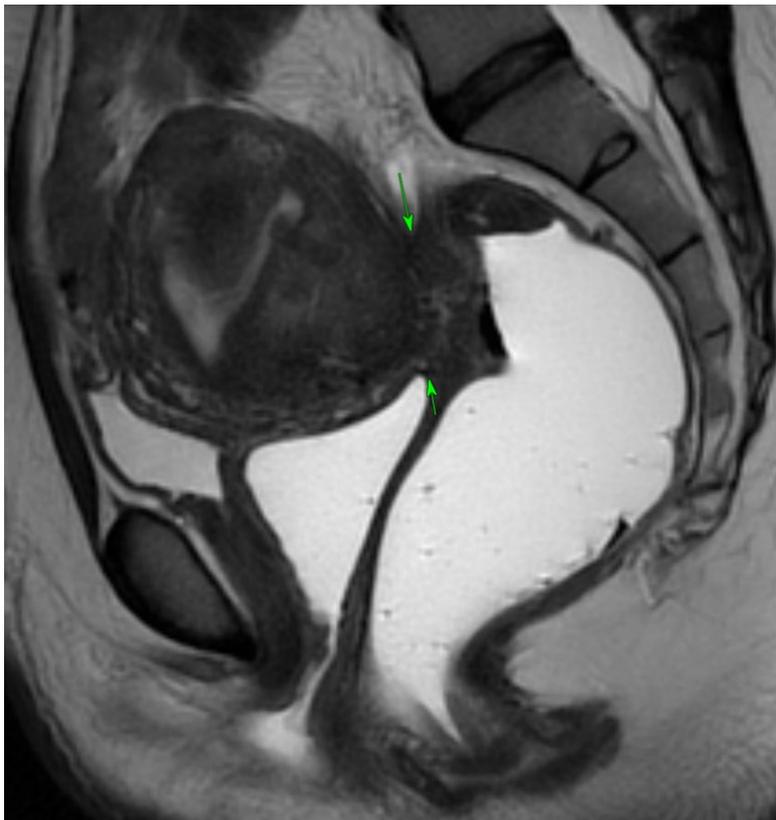


Figure 6. T2-weighted image on a 1.5T GE machine: concurrent vaginal and rectal distension with gel revealing endometriotic plaque tethering the uterus (arrows). Selfadministered intravaginal gel, doctor assisted with rectal insertion.

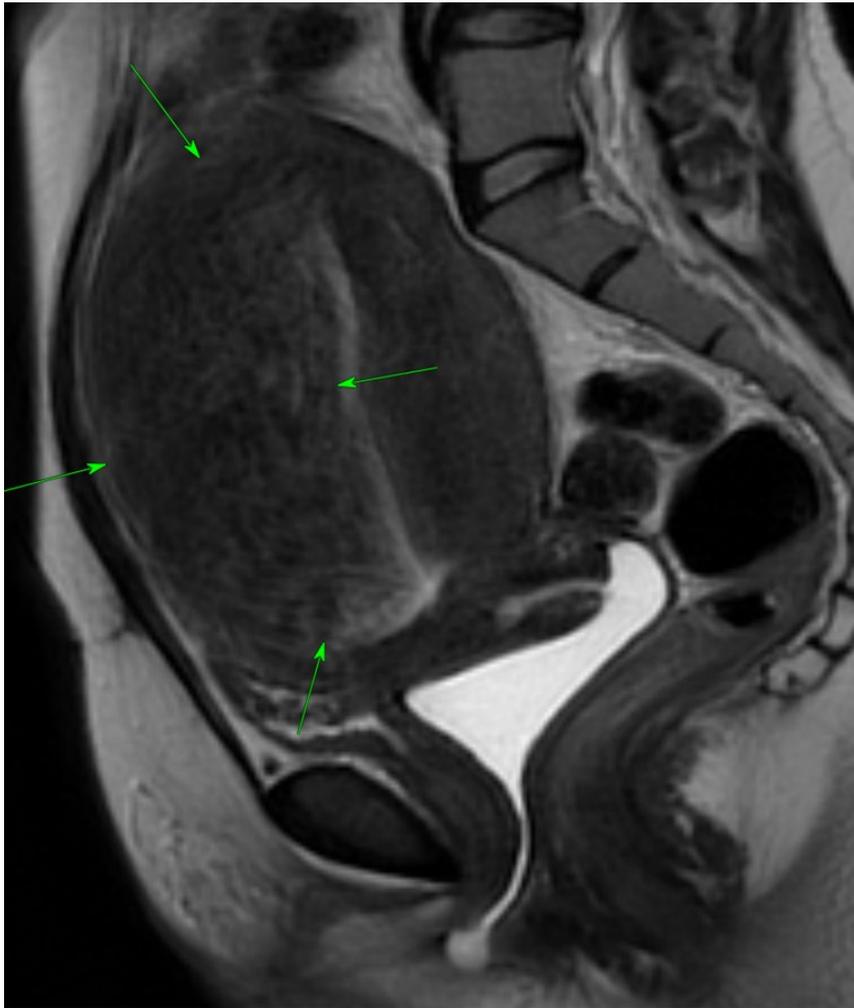


Figure 7. T2-weighted images on a 1.5T GE machine: marked adenomyosis in the anterior myometrium (arrows) impeding gel insertion and vaginal distension. Doctor-administered gel.