

ORIGINAL RESEARCH

Validation of two dimensional transperineal ultrasound and & dynamic magnetic resonance imaging in pelvic floor dysfunction using Passing Bablock Regression and Bland Altman plot

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ABSTRACT

Background: Pelvic floor dysfunctions are complex conditions which commonly affects the elderly women. The pelvic floor dysfunction includes defect of anterior, middle and posterior compartment which includes cystocele, uterine descent and rectocele. MRI has been used for imaging female pelvic floor in preoperative planning of complicated cases. Recently perineal ultrasonography is gaining importance in imaging of pelvic floor. **Aims and Objectives:** To compare the measurements of pelvic floor during rest and valsalva in patients with pelvic floor dysfunction, measured using transperineal two-dimensional(2D) ultrasound and magnetic resonance imaging.

Results and Conclusion: The Cystocele, Uterine Prolapse and Posterior Vaginal Prolapse parameters were analyzed using Passing and Bablok Regression and Bland Altman plot. The above tables and diagrams clearly indicates there is a minimal systematic differences. Proportional differences, Random differences (Residual Standard Deviation), Good Positive Spearman Rank correlation and No linearity in all the three studied parameters.

Hence, Transperineal ultrasound has significant positive Spearman rank correlation and minimal Systematic, Proportional and Random differences with above three parameters in comparison with gold standard dynamic Magnetic resonance imaging in measuring pelvic floor dysfunction, Transperineal ultrasound can be used as screening tool to evaluate women with pelvic floor dysfunction.

Key words: USG, MRI, pelvic dysfunction & passing bablock regression

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INTRODUCTION

Pelvic floor dysfunctions are complex conditions which commonly affects the elderly women. The pelvic floor dysfunction includes defect of anterior, middle and posterior compartment which includes cystocele, uterine descent and rectocele. MRI has been used for imaging female pelvic floor in preoperative planning of complicated cases. Recently perineal ultrasonography is gaining importance in imaging of pelvic floor.

There are many shared advantages of the two imaging modalities namely

No ionizing radiation

Non invasive

Superior soft tissue contrast

Apart from the above-mentioned combined advantages, transperineal ultrasound scores over in the aspect of cost effectiveness and repeatability as well as reproducibility of the examination which can be performed in an outpatient clinic. However, MRI is superior in imaging large volume of pelvis.

STRESS URINA INCONTINENCE

Urinary incontinence may indicate a symptom, a sign or a condition.

The patient complaints of involuntary leakage of urine which she finds socially and hygienically unacceptable. The sign is the objective demonstration of urine loss, and the condition is the underlying pathophysiologic mechanism responsible for the urine leak. The symptom of involuntary urine loss may be associated with stressful activity like coughing, sneezing, straining or other physical activity. This is called as stress urinary incontinence. Involuntary urine loss may follow a strong desire and need to void this is called as urge incontinence.

NORMAL ANATOMY OF THE ANAL CANAL

The anal canal is 3-4 cm in length and is surrounded by the internal sphincter above and the external sphincter below. The internal sphincter represents the expanded distal portion of the circular smooth muscle of the rectum and is innervated by autonomic nerves. The external sphincter is a striated muscle and is innervated by the pudendal nerve (sacral 2, 3, 4). The anal pressure remains above the rectal pressure and internal sphincter remains contracted in a continent woman and internal sphincter opens only when the rectum distends aided by intra-abdominal pressure. The external sphincter muscle is supplemented by the puborectalis muscle of the levator ani and this prevents or defers defecation when the suitable situation does not prevail. In addition the rectum forms an angle of 60-130° with the anal canal and this also helps to keep the internal anal sphincter closed, and prevents stool entering into the anal canal. During defecation, the angle straightens up and allows the faecal matter to enter the anal canal. The levator ani muscle relax, so also the external sphincter.

Fecal incontinence is defined as loss of normal control leading to involuntary leakage of faecal contents. Depending upon the degree of incontinence, flatus, loose motion or solid stools leaks out. Fecal incontinence is reported in 0.5-2% women following vaginal delivery. Women are more prone to fecal incontinence than men and elderly women suffer more than younger women.

Fecal incontinence may follow some years after delivery, but many develop it within 6 months of delivery. The occult damage to the internal sphincter occurs in 35% women following vaginal delivery, though perineum appears intact.

AIMS AND OBJECTIVES

To compare the measurements of pelvic floor during rest and valsalva in patients with pelvic floor dysfunction, measured using transperineal two-dimensional (2D) ultrasound and magnetic resonance imaging.

MATERIAL AND METHODS

STUDY DESIGN: Prospective study.

STUDY DURATION: 2 year.

STUDY PLACE: Barnard Institute of Radiology, Madras Medical College.

SUBJECTS

The study population consisted of 50 parous women with various pelvic floor dysfunction, attending the urogynecology department in Government Kasturba Gandhi Hospital for Women and Children. The study period includes two years from June 2010 to May 2012.

The physical examination including the patients age, BMI, parity, mode of delivery were recorded. The urogynecologist scored the various defects of the three compartments separately at rest and with maximum strain. The clinical findings were noted along with the patient's symptoms.

PATIENT PREPARATION

1. Partially filled bladder.
2. No fasting.
3. Coach the patient to do valsalva.

The study was performed on a 1.5 Tesla super conductive whole-body MRI scanner MAGNETOM VISION (SIEMENS MAGNETIC VISION).

During the study the patient is placed on the strong homogenous magnetic field. The hydrogen nuclei, protons, distributed through the entire body tissue generate signals when stimulated by a radio frequency pulse. These signals are processed into images by a computer.

RESULTS & STATISTICAL ANALYSIS

The study was conducted on 50 women with pelvic floor dysfunction who attended Urogynecology clinic and the following observations were made.

All the 50 patients were categorized according to their symptoms as those with stress incontinence, urge incontinence and fecal incontinence and they were subjected to both two dimensional transperineal ultrasound and dynamic magnetic resonance imaging at the same time.

STATISTICAL ANALYSIS

The data was entered in a MS excel database and later imported to MedCalc (MedCalc Software, 12.6.0 version, Belgium) for the analyses. Imprecision was reported in terms of coefficient of variation. For method comparison study initially correlation plots were used. Since correlation coefficient only measures the strength and direction of a relation between two methods, not the agreement between them, we employed Bland and Altman analysis [06] supplemented by Passing and Bablok regression analysis [07] to know the agreement between the two methods. They are used to identify if any systematic difference exists between the methods.

Passing-Bablok regression is a linear regression procedure with no special assumptions regarding the distribution of the samples and the measurement errors (Passing & Bablok, 1983). The result does not depend on the assignment of the methods (or instruments) to X and Y. The slope B and intercept A are calculated with their 95% confidence interval. These confidence

intervals are used to determine whether there is only a chance difference between B and 1 and between A and 0.

The Bland-Altman plot, or difference plot, is a graphical method to compare two measurements techniques (Bland & Altman, 1986 and 1999). In this graphical method the differences (or alternatively the ratios) between the two techniques are plotted against

the averages of the two techniques. Alternatively (Krouwer, 2008) the differences can be plotted against one of the two methods, if this method is a reference or "gold standard" method.

Horizontal lines are drawn at the mean difference, and at the limits of agreement, which are defined as the mean difference plus and minus 1.96 times the standard deviation of the differences.

RESULTS

Table 1: Cystocele USG findings vs. MRI-Passing and Bablok Regression

Passing and Bablok regression

Variable X	Cystocele_USG_ Cystocele USG_
Variable Y	Cystocele_MRI_cm_ Cystocele MRI_cm_

Sample size	50
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	Variable X	Variable Y
Lowest value	4.3000	4.5000
Highest value	7.2000	7.4000
Arithmetic mean	5.5320	5.6600
Median	5.5000	5.6000
Standard deviation	0.6870	0.6887
Standard error of the mean	0.09716	0.09739

REGRESSION EQUATION

$y = 0.200000 + 1.000000 x$	
Systematic differences	
Intercept A	0.2000
95% CI	0.2000 to 0.2000
Proportional differences	
Slope B	1.0000
95% CI	1.0000 to 1.0000
Random differences	
Residual Standard Deviation (RSD)	0.1164
± 1.96 RSD Interval	-0.2281 to 0.2281
Linear model validity	
Cusum test for linearity	No significant deviation from linearity (P=0.63)

SPEARMAN RANK CORRELATION COEFFICIENT

Correlation coefficient	0.926
Significance level	P<0.0001
95% CI	0.873 to 0.958

Table 2: Cystocele USG findings vs. MRI-Bland Altman Plot

Bland-Altman plot

Method A	Cystocele_MRI_cm_ Cystocele MRI_cm_
Method B	Cystocele_USG_ Cystocele USG_

Sample size	50
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Option	Plot differences
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Arithmetic mean	0.1280
95% Confidence interval	0.08658 to 0.1694
P (H ₀ : Mean=0)	<0.0001

Lower limit	-0.1577
95% Confidence interval	-0.2289 to -0.08639
Upper limit	0.4137
95% Confidence interval	0.3424 to 0.4849

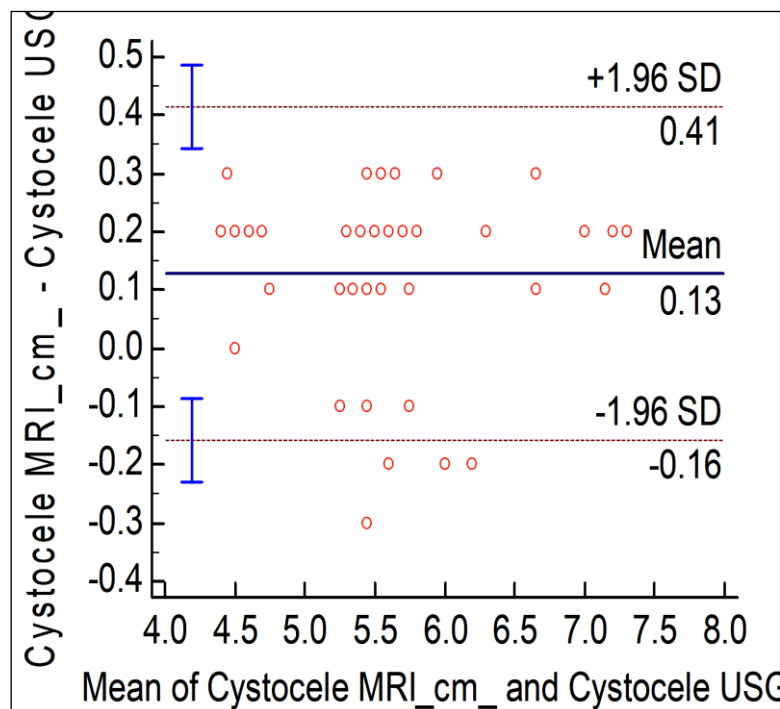


Figure 1: Cystocele USG findings vs. MRI- Bland Altman Plot

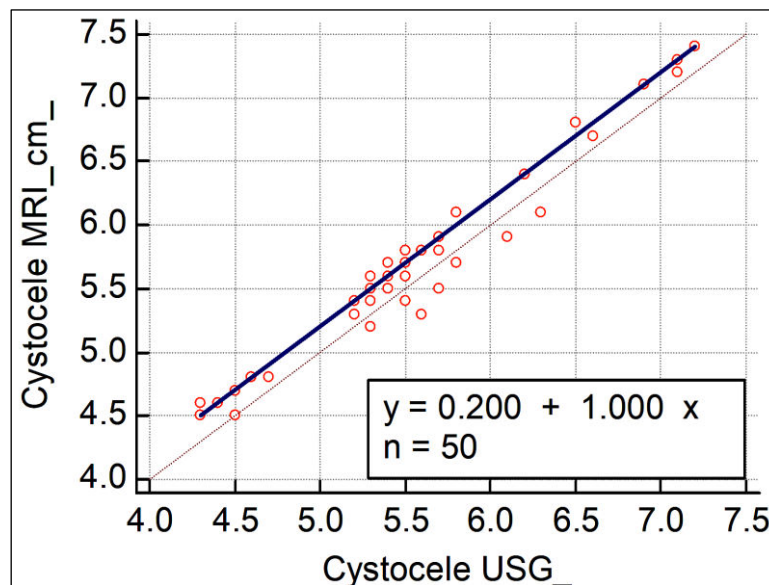


Figure 2: Regression equation Cystocele USG and Cystocele MRI

Table 3: Uterine descent USG findings vs. MRI findings-Passing and Bablok Regression
 Passing and Bablok regression

Variable X	Uterine_descent_USG_ Uterine descent USG_
Variable Y	Uterine_descentMRI_ Uterine descentMRI_
Sample size	50

	Variable X	Variable Y
Lowest value	0.7000	0.8000
Highest value	3.6000	3.8000
Arithmetic mean	1.8400	2.0400
Median	1.8000	1.9500
Standard deviation	0.6966	0.7097
Standard error of the mean	0.09852	0.1004

Regression Equation

$y = 0.200000 + 1.000000 x$	
Systematic differences	
Intercept A	0.2000
95% CI	0.2000 to 0.2000
Proportional differences	
Slope B	1.0000
95% CI	1.0000 to 1.0000
Random differences	
Residual Standard Deviation (RSD)	0.05401
± 1.96 RSD Interval	-0.1059 to 0.1059
Linear model validity	
Cusum test for linearity	No significant deviation from linearity (P=0.48)

Table 4: Bland Altman plot uterine descent usg Vs MRI

Bland-Altman plot

Method A	Uterine_descentMRI_ Uterine descentMRI_
Method B	Uterine_descent_USG_ Uterine descent USG_
Sample size	50
Option	Plot differences
Arithmetic mean	0.2000
95% Confidence interval	0.1785 to 0.2215
P (H ₀ : Mean=0)	<0.0001
Lower limit	0.05184
95% Confidence interval	0.01488 to 0.08880
Upper limit	0.3482
95% Confidence interval	0.3112 to 0.3851

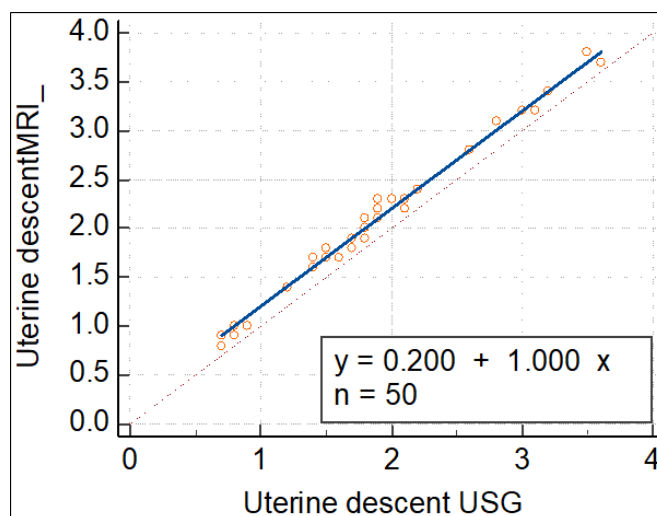


Figure 3: Regression equation Uterine descent USG and Utering descent MRI

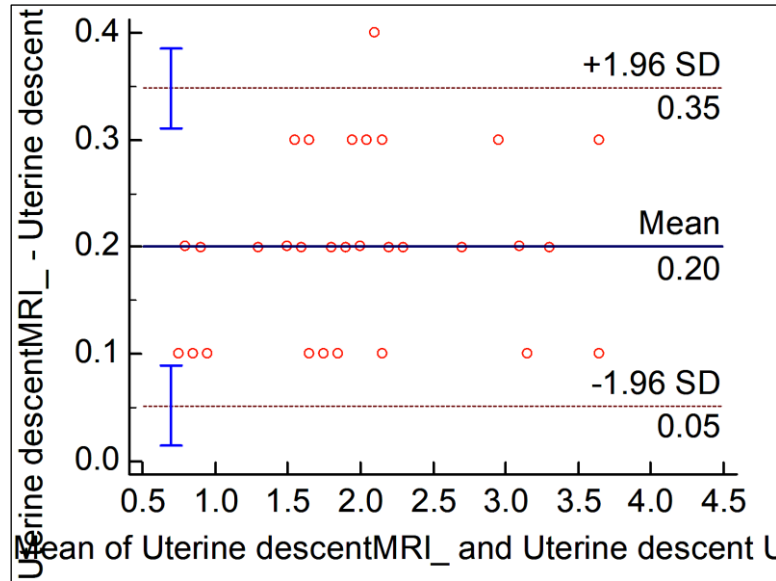


Figure 4: Bland Altman plot Uterine descent USG and Uterine descent MRI

Table 5: Rectocele USG findings vs. MRI-Passing and Bablok Regression.
 Passing and Bablok regression

Variable X	Rectocele_USG_ Rectocele USG_
Variable Y	Rectocele_MRI_ Rectocele MRI_

Sample size	48
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	Variable X	Variable Y
Lowest value	0.8000	0.9000
Highest value	3.5000	3.8000
Arithmetic mean	1.8750	2.0979
Median	1.8500	2.1000
Standard deviation	0.6473	0.7003
Standard error of the mean	0.09342	0.1011

Regression Equation

$y = 0.200000 + 1.000000 x$	
Systematic differences	
Intercept A	0.2000
95% CI	0.08125 to 0.2000
Proportional differences	
Slope B	1.0000
95% CI	1.0000 to 1.0625
Random differences	
Residual Standard Deviation (RSD)	0.1193
± 1.96 RSD Interval	-0.2339 to 0.2339
Linear model validity	
Cusum test for linearity	No significant deviation from linearity (P=0.39)

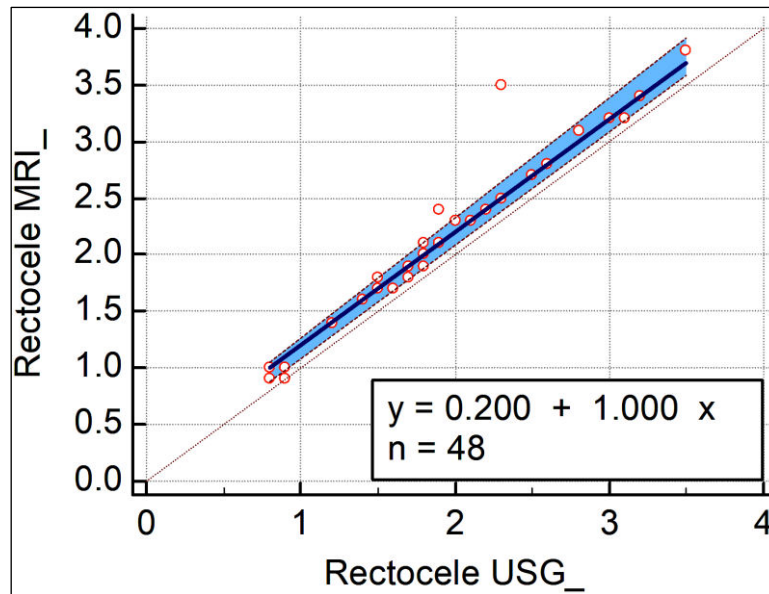


Fig 5: Regression MRI rectocele MRI vs Rectocele USG

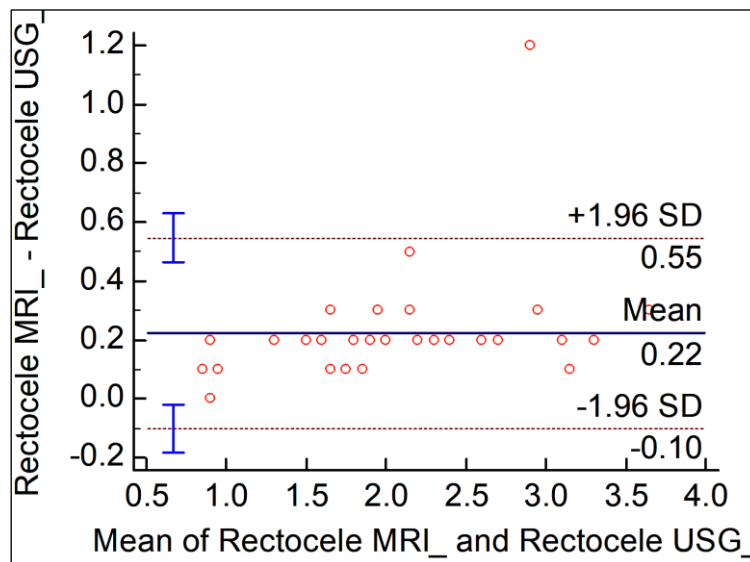


Figure 6: Rectocele USG VS MRI Bland Altman plot.

Table 6: Rectocele USG findings vs. MRI-Bland Altman plot
Bland-Altman plot

Method A	Rectocele_MRI_ Rectocele MRI_
Method B	Rectocele_USG_ Rectocele USG_
Sample size	48
Option	Plot differences
Arithmetic mean	0.2229
95% Confidence interval	0.1749 to 0.2709
P (H ₀ : Mean=0)	<0.0001
Lower limit	-0.1011
95% Confidence interval	-0.1838 to -0.01852
Upper limit	0.5470
95% Confidence interval	0.4644 to 0.6296

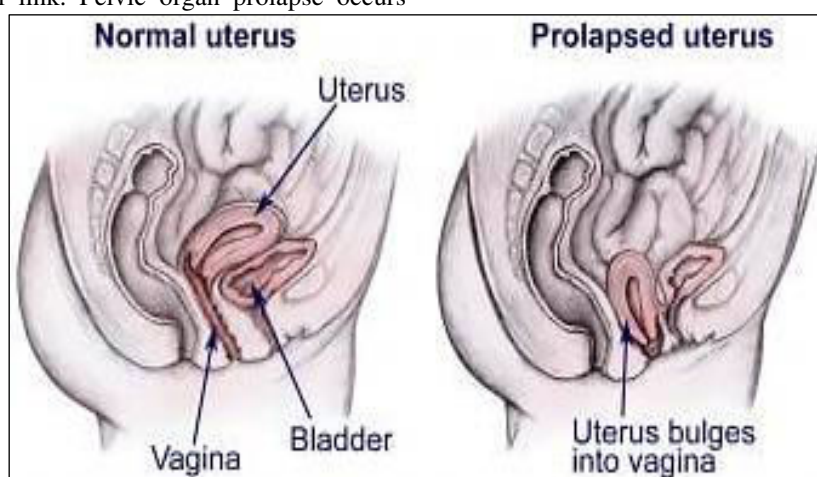
DISCUSSION

A cystocele is a condition in which supportive tissues around the bladder and vaginal wall weaken and stretch, allowing the bladder and vaginal wall to fall into the vaginal canal. Usually, the muscles and connective tissues that support the vaginal wall hold the bladder in place. With a cystocele, the muscles and tissues supporting the vagina weaken and stretch, allowing the bladder to move out of place.

A cystocele is the most common type of pelvic organ prolapse External link. Pelvic organ prolapse occurs

when the vaginal walls, uterus, or both lose their normal support and prolapse, or bulge, into the vaginal canal or through the vaginal opening. Other nearby pelvic organs, such as the bladder or bowel, may be involved and also drop from their normal position in the body.

Uterine prolapse (also called descensus or procidentia) means the uterus has descended from its normal position in the pelvis farther down into the vagina. See image below.



A posterior vaginal prolapse is a bulge of tissue into the vagina. It happens when the tissue between the rectum and the vagina weakens or tears. This causes the rectum to push into the vaginal wall. Posterior vaginal prolapsed is also called a rectocele.

The Cystocele, Uterine Prolapse and Posterior Vaginal Prolapse parameters were analysed using Passing and Bablok Regression and Bland Altman plot. The above tables and diagrams clearly indicates there is a minimal systematic differences. Proportional differences, Random differences (Residual Standard Deviation), Good Positive Spearman Rank correlation and No linearity in all the three studied parameters.

CONCLUSION

Hence, Transperineal ultrasound has significant positive Spearman rank correlation and minimal Systematic, Proportional and Random differences with above three parameters in comparison with gold standard dynamic Magnetic resonance imaging in measuring pelvic floor dysfunction, Transperineal ultrasound can be used as screening tool to evaluate women with pelvic floor dysfunction. Except in the Teritrial care and First referral unit Hospitals other District, Taluk hospitals does not have MRI scan. Private hospitals are having MRI centre, but the cost is very high. As per our study if a Women found to have pelvic floor dysfunction by transperineal ultrasound who needs surgical intervention can be confirmed with gold standard dynamic magnetic resonance imaging by referring the women to nearest teritrial care hospital. Since, our sample size is low, we will do further

research for large number of samples to generalize our Research statement.

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