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Association of clinical outcome with elastographic changes following pelvic floor muscle training (kegels exercises) in patients with pelvic organ prolapse- stage 1/stage 2

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Abstract: Introduction: Elastography has emerged as a valuable diagnostic method for assessing the integrity of the pelvic floor muscles. It measures tissue stiffness and deformation in response to compression, providing a non-invasive and objective assessment of tissue stiffness using gray-scale ultrasonography. In this study, we aim to evaluate the clinical outcomes and elastographic changes following Pelvic Floor Muscle Training (Kegel Exercises) among patients with Pelvic Organ Prolapse in Stage 1 and Stage 2.
Materials & Methods: Patients eligible for the study were enrolled after obtaining written informed consent, ensuring the confidentiality of their details. Detailed history, general examination, systemic examination, and local examination were performed following standard protocols. Per speculum examination was conducted to determine the degree of prolapse based on POP-Q staging. Transperineal Elastography was performed on women diagnosed with Stage 1 or Stage 2 POP to evaluate Pelvic floor dysfunction. Study participants were instructed on how to perform Kegel exercises and were followed up. Clinical and elastography scores were recorded and analyzed.
Results: Out of 120 subjects, 56 had a clinical score of 3 (46.7%) and 52 had a clinical score of 4 (43.3%) at the 1st month evaluation. For elastography scores, 60 subjects had an ES2 score (50%) and 60 had an ES3 score (50%). After 6 months of performing Kegel exercises as prescribed, 44 subjects had a clinical score of 1 (36.7%), 32 had a clinical score of 2 (26.7%), and 44 had a clinical score of 3 (36.7%). In terms of elastography scores, 48 subjects had an ES4 score (40%), 48 had an ES3 score (40%), and 24 had an ES2 score (20%). There was a statistically significant difference between the baseline clinical and elastography scores and the scores at 6 months ($p<0.05$).
Conclusion: The results of this study indicated that pelvic organ prolapse stage and levator ani distension in women were correlated with the elasticity properties measured by elastography. Further research is required to explore the relationship between pelvic floor elasticity characteristics and clinical data.

Keywords: Elastography; Prolapse; Levator ani; Pelvic floor.

1. Introduction

Pelvic organ prolapses (POP) is defined as an abnormal descent of one or more of the anterior vaginal wall, posterior vaginal wall, uterus (cervix) or the apex of the vagina (vaginal vault or a cervical stump if a hysterectomy had been performed earlier) [1]. Depends on what organ is prolapsed, POP can manifests as uterine prolapse, vaginal vault prolapse, cystocele or anterior vaginal prolapse, and rectocele or posterior vaginal prolapse.

In recent years, elastography has developed into a useful diagnostic method for recognizing the pelvic floor muscle. Elastography is a relatively recent method for measuring how stiff and deformed tissues are in reaction to compression. Gray-scale ultrasonography offers an easy, non-invasive, objective, and useful technique to assess tissue stiffness [2].

Pelvic Organ Prolapse is known to occur when the pelvic floor muscles as well as ligaments stretch, weaken and are no longer capable of providing support to the uterus [3]. Taking into consideration high incidence of POP among women of North India (7.6%),[4] prevention of prolapse of pelvic organs in order to preserve pelvic floor function as well as to improve symptoms such as urinary incontinence and improve sexual function, is of utmost importance.

Pelvic organ prolapse can be a burden to the patients, whether it is psychological, social and/or economic. This burden is higher if it is not properly treated. In the developed countries, 11 to 19% of women had undergone repair surgery for POP [5].

Pelvic floor muscle training, often known as Kegel's exercises, can help strengthen the pelvic floor muscles, preventing progression and to some extent treating Pelvic Organ Prolapse.

Although numerous investigations on the pelvic floor's appearance on ultrasound and magnetic resonance imaging have been carried out, making it feasible to specifically assess the morphology of the muscle, these modalities are costly, leading to limited patient compliance.Recent research has described the use of ultrasound elastography, a new dynamic method, to close the gap between ultrasound imaging and tissue structure and/or pathology. It is regarded as a revolutionary technology that enables non-invasive tissue elasticity testing.

2. Material and methods

This Prospective Interventional Study was conducted in Department of Obstetrics and Gynecology, Teerthanker Mahaveer Medical College & Research Centre. We included women with Stage 1/2 Pelvic Organ Prolapse as per POP-Q staging. IEC Approval was taken from institutional ethical committee. All patients with Stage 1/ Stage 2 Pelvic Organ Prolapse, according to POP-Q staging, were included [6] presenting in the Department of Obstetrics and Gynaecology of TMMC & RC.

Patients presenting with Rectal Prolapse, pre-existing uncontrolled Chronic Debilitating Disorders like Diabetes, Chronic Obstructive Pulmonary Disease, Chronic Cough, Bronchial Asthma were excluded in this study. Patients who have undergone Pelvic floor surgeries, Nulliparous Prolapse were also excluded.

The patients eligible for the study enrolled after obtaining a written informed consent. Confidentiality of the patient details was maintained in the study. After eliciting detailed history from the patient, thorough general, systemic and local examination will be done as per standard protocol. Per speculum examination of the patients was done to assess degree of prolapsed according to POP-Q staging. Per vaginal examination of patients was performed in lithotomy position. After emptying the bladder, two distal phalanges of index as well as middle finger were inserted into the introitus and the patient was asked to squeeze as well as lift their pelvic floor muscle.

Clinical evaluation of muscles of pelvic floor, their strength and resting tone was done by per vaginal examination by using a proposed scale for grading the Levator Ani resting tone [7]. Evaluation of dysfunction of Pelvic floor was done and women who were diagnosed with Stage 1/ 2 POP underwent Transperineal Elastography. All the patients were examined using Siemen's Accuson S3000 or Siemen's Juniper US Elastography scanners. For each subject levator ani was located as well as evaluated in a resting state. The patients were then counselled about how to perform Kegel's exercises. The Kegel exercise programme consisted of 10 sets of contractions in a day where each set included 10 repetitions [8].

Patient was then called upon for a follow up every month for a period of 6 months where they were clinically evaluated and graded using a proposed scale for grading the Levator Ani resting tone [7]. The patients were also evaluated radiologically at 12 weeks and 24 weeks via Transperineal and Transvaginal Elastography. Elastography grading was done using a four-point scale scoring system [8].

Table 1. A proposed scale for grading the levator ani resting tone [7]

0	Muscle cannot be palpated
1	Muscle palpated but flaccidity present with a wide hiatus and resistant to distension minimally
2	Hiatus was wide but resistant to distension
3	Hiatus was fairly narrow with fair resistance to palpation but it can be easily distended
4	Hiatus narrow and muscle distensible but highly resistant to distension or pain
5	Hiatus narrow, no distension possible, "woody" feel, possibly with pain: 'vaginismus'

Table 2. Elastographic four-point scale scoring system [8]

Elastographic score	Overall impression	Elastographic appearance
ES1	Soft	Less than 10% displaying red, the predominant colours being purple, green, or yellow. The node cannot be distinguished from the surrounding tissues.
ES2	Moderately soft	Areas that are mostly yellow or green, with between 10% and 50% of them being red. The node is only partially separated from the tissues around it.
ES3	Moderately stiff	Predominantly red, with between 10% and 50% of the region being yellow or green. The node is only partially separated from the tissues around it.
ES4	Stiff	Predominantly red in colour, with less than 10% of the sample showing green or yellow. The node can be distinguished from the tissue around it.

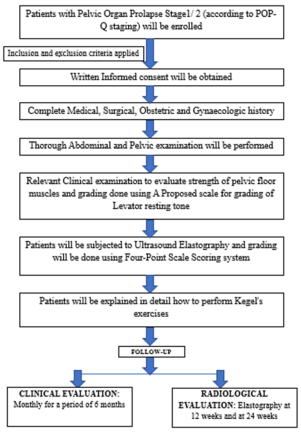

Figure 1

3. Results

Table 3. Mean value of demographic characteristic of study participants

Characteristic	**Mean**	**SD**
Age (years)	38.86	7.69
BMI (Kg/m2)	23.18	2.81
Duration of Symptoms (months)	6.66	2.90

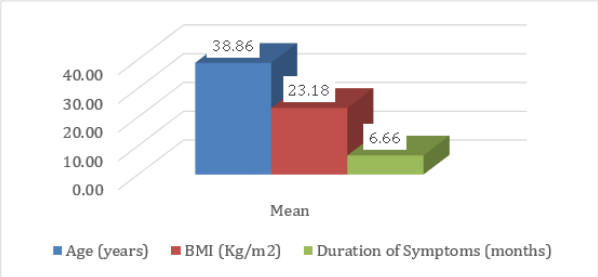

Figure 2. Graphical representation of Mean value of demographic characteristic of study participants

Table 4. Mean value of parameters related to Obstetric History of study participants

Obstetric History	**Mean**	**SD**
Married life (in years)	17.49	8.51
Parity	3.45	1.20
Living	3.35	1.21
Abortion	0.84	0.78
Last childbirth/ abortion (in years)	9.21	6.65

Table 5. Distribution of study participants according to POP-Q Grade

POP-Q Grade	Frequency (n=120)	Percentage (%)
1	33	27.5
2	87	72.5

Out of 120 study subjects, 72.5% were in POP-Q Grade 2 and 27.5% were in POP-Q Grade 1.

Table 6. Distribution of study participants according to Clinical Score

Clinical Score at 1 month	**Frequency (n=120)**	**Percentage (%)**
2	8	6.7
3	56	46.7
4	52	43.3
5	4	3.3
Clinical Score at 2 months	**Frequency (n=120)**	**Percentage (%)**
1	4	3.3
2	28	23.3
3	44	36.7
4	44	36.7
Clinical Score at 3 months	**Frequency (n=120)**	**Percentage (%)**
1	4	3.3
2	36	30.0
3	44	36.7
4	36	30.0
Clinical Score at 4 months	**Frequency (n=120)**	**Percentage (%)**
1	8	6.7
2	40	33.3
3	48	40.0
4	24	20.0
Clinical Score at 5 months	**Frequency (n=120)**	**Percentage (%)**
1	8	6.7
2	68	56.7
3	27	22.5
4	17	14.2
Clinical Score at 6 months	**Frequency (n=120)**	**Percentage (%)**
1	44	36.7
2	32	26.7
3	44	36.7

Table 6 shows distribution of study participants according to clinical score. Majority of study subjects had score 3 (36.7%) and score 4 (36.7%) in distribution of study participants according to clinical score at 2 months. Majority of study subjects had score 3 (36.7%), score 4 (30%) and score 2 (30%) with distribution of study participants according to clinical score at 3 months. Majority of study subjects had score 3 (40%), score 2 (33.3%) and score 4 (20%) in distribution of study participants according to clinical score at 3 months. Majority of study subjects had score 2 (56.7%), score 3 (22.5%) and score 4 (14.2%) In distribution of study participants

according to clinical score at 5 months. Majority of study subjects had score 3 (36.7%), score 1 (36.7%) and score 2 (26.7%) in distribution of study participants according to clinical score at 6 months.

Table 7. Distribution of study participants according to Elastography Score with Baseline & 12 and 24 weeks

Elastography Score	Baseline	12 weeks	24 weeks	p-value
ES2	60	44	24	
ES3	60	60	48	<0.001
ES4	0	16	48	

Table 7 shows distribution of study participants according to Elastography Score with Baseline & 12 and 24 weeks. There was statistically significant difference seen with respect to elastography score at Baseline & 12 and 24 weeks. ($p<0.05$)

Table 8. Distribution of study participants according to Clinical Score (Baseline) with Elastography (Baseline)

Clinical Score (Baseline)	Elastography (Baseline)		Total	p-value
	ES2	ES3		
2	0	8	8	
3	12	40	52	
4	44	12	56	<0.001
5	4	0	4	
Total	60	60	120	

Table 8 shows distribution of study participants according to elastography score and clinical score at baseline. There was statistically significant difference seen with respect to elastography score and clinical score at baseline. ($p<0.05$)

Table 9. Distribution of study participants according to Clinical Score (3rd month) with Elastography (12 weeks)

Clinical Score (3rd month)	Elastography (12 weeks)			Total	p-value
	ES2	ES3	ES4		
2	0	0	4	4	
3	0	32	4	36	
4	16	20	8	44	<0.001
5	28	8	0	36	
Total	44	60	16	120	

Table 9 shows distribution of study participants according to elastography score at 12 weeks and clinical score at 3 months. There was statistically significant difference seen with respect to elastography score at 12 weeks and clinical score at 3 months. ($p<0.05$)

Table 10. Distribution of study participants according to Clinical Score (6th month) with Elastography (24 weeks)

Clinical Score (6th month)	Elastography (24 weeks)			Total	p-value
	ES2	ES3	ES4		
1	0	8	36	44	
2	0	20	12	32	
3	24	20	0	44	<0.001
Total	24	48	48	120	

Table 10 shows distribution of study participants according to elastography score at 24 weeks and clinical score at 6 months. There was statistically significant difference seen with respect to elastography score at 24 weeks and clinical score at 6 months. ($p<0.05$)

Table 11. Distribution of study participants according to Clinical Score (1st month) with Clinical Score (6th month)

Clinical Score (1st month)	Clinical Score (6th month)			Total	p-value
	1	2	3		
2	8	0	0	8	
3	36	20	0	56	
4	0	12	40	52	<0.001
5	0	0	4	4	
Total	44	32	44	120	

Tabele 11 shows distribution of study participants according to clinical score at 1 month and 6 months. There was statistically significant difference seen with respect to clinical score at 1 month and 6 months. ($p<0.05$)

Table 12. Distribution of study participants according to Elastography (Baseline) with Elastography (12 weeks)

Elastography (Baseline)	Elastography (12 weeks)			Total	p-value
	ES2	ES3	ES4		
ES2	44	16	0	60	
ES3	0	44	16	60	<0.001
Total	44	60	16	120	

Table 12 shows distribution of study participants according to elastography score at baseline and 12 weeks. There was statistically significant difference seen with respect to elastography score at baseline and 12 weeks. ($p<0.05$)

Table 13. Distribution of study participants according to Elastography (Baseline) with Elastography (24 weeks)

Elastography (Baseline)	Elastography (24 weeks)			Total	p-value
	ES2	ES3	ES4		
ES2	24	36	0	60	
ES3	0	12	48	60	<0.001
Total	24	48	48	120	

Table 13 shows distribution of study participants according to elastography score at 12 and 24 weeks. There was statistically significant difference seen with respect to elastography score at 12 and 24 weeks. ($p<0.05$)

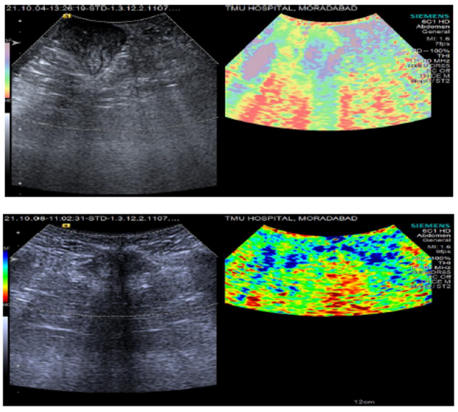

Figure 3. Conventional Transperineal Ultrasound and Elastography image of: A- 49 Years old Patient Predominantly Green or Yellow, Scored as ES1 on 1st OPD Visit (Baseline Scan) B- Same patient after performing Kegel exercises for 3 months, predominantly green with areas of red, scored as ES2

4. Discussion

The present study involved 120 subjects with Stage 1/ 2 POP, according to POP-Q staging system. In this prospective study, we used transperineal elastography in POP-Q stage I/II patients before as well as after Kegel exercises. This is the first instance in the study region that we are aware of transperineal elastography being used to assess levator ani in patients receiving Kegel exercises. In our study, majority of subjects (85.8%) were above 30 years of age. 16.7% of subjects presented with SUI while 13.3% complained of something coming out per vagina and 12.5% complained of pain in lower abdomen.

In response to raised abdominal pressure, PFMT strengthens PFM and enhance support for pelvic organs. By demonstrating a reduction in symptoms and severity, several studies including our study have demonstrated the treatment's effectiveness [7]. Cavkaytar came to the conclusion that women who have SUI and MUI have found home-oriented Kegel exercises to be effective. Subjects with urinary stress incontinence showed a greater improvement [7]. Magnetic resonance imaging (MRI), which was the only available imaging technique for evaluating LAM at the time, found LAM trauma in 25–30% of pregnant females who gave vaginal birth [9]. But recently, ultrasound has made it possible for us to examine the levator ani muscle with little pain and at a lower cost. The development of 3D pelvic floor ultrasound has enhanced feasibility in assessing axial planes, much like MRI. Using 3D perineal ultrasound assessment, Valsky and Albrich found that prevalence of LAM avulsion was 18.8 and 39.5%, respectively, within 48 hours of delivery [10,11]. Serdar proposed that 3D transperineal ultrasonography could be used to identify even the slightest of abnormalities in puborectalis muscle even within a span of 36 hours of pregnancy termination [12]. According to 3D ultrasonography measurements, one found that subjects in the PFMT group have thicker muscles, a smaller hiatal area, shorter muscles, and high-up bladder as well as rectum compared to those in the control group. Transperineal ultrasound, according to Dietz [13] could offer beneficial visual biofeedback while instructing patients to perform kegel exercises. Delft found a significant correlation between transperineal ultrasound and the Modified Oxford Scale for hiatal area and the hiatal anteroposterior diameter.

Several papers from past few years have advocated using elastography to assess the pelvic floor muscle. We have seen in our study that in POP patients, the change in the levator ani's function occurred earlier than its structural abnormality [14]. Chen showed that ultrasonic elastography can be used to estimate the perineal body tissue qualities [15]. Rafeef also noted that transperineal elastography showed calculable responses to changes in intensity of contraction in anatomical region of the SUS rigidity at time of voluntary pelvic floor muscular contractions.

5. Conclusion

In this study, for quantitative evaluation of women's LAM elasticity, elastography was used as a novel technology, and its correlation was high. The results of this research also revealed that, as determined by elastography, the prolapse stage and levator ani distension in women were correlated with the LAM elasticity properties. Although the findings were positive, further future research is required to fully explore the relationship among elasticity of pelvic floor characteristics and clinical data.

Transperineal elastography, in POP-Q stage I/II patients, demonstrated to be a reliable and useful tool for evaluating the levator ani both before and after performing kegel exercises. Therefore, it should be utilized to assess the pelvic floor integrity.

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Conflicts of Interest: Authors declare no conflict of interests.

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