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" *Role of Trans-vaginal Strain Elastography in The Assessment of Cervical Incompetence in Early Pregnancy* "

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Abstract

Background: Cervical incompetence, affecting 1 in 100 to 1 in 2000 pregnancies, causes second-trimester loss, preterm labor, and neonatal complications. It involves painless cervical dilation from structural or functional weakness and is diagnosed by obstetric history and ultrasound or physical exam findings.

Aim: To investigate the role of transvaginal strain elastography in evaluating cervical incompetence in early pregnancy.

Patients and methods: Prospective case-control research has been carried out at outpatient clinics of El-Salhya El-Gededa Central Hospital. The study included two groups: a study group of 25 pregnant females with a history of cervical incompetence, and a control group of 25 healthy pregnant females with no known risk factors, serving as a reference.

Results: At a cutoff value of 0.16%, the anterior cervical lip strain showed 88% sensitivity and 84% specificity for diagnosing cervical incompetence, outperforming cervical length (cutoff 36.1 mm; sensitivity 76%, specificity 84%) and endocervical canal width (cutoff 5.87 mm; sensitivity 44%, specificity 76%), all with statistically significant differences. In univariate analysis, body mass index (BMI), gravidity, parity, anterior cervical lip strain ratio, cervical length, and endocervical canal width were significant predictors. However, multivariate analysis identified gravidity, anterior cervical lip strain ratio, and endocervical canal width as independent predictors of cervical incompetence.

Conclusion: Transvaginal strain elastography is an efficient tool for early diagnosis of cervical incompetence, showing a softer anterior lip and higher sensitivity and specificity than cervical length or canal width.

Key words: Cervical incompetence ,Transvaginal strain elastography, Early pregnancy, Diagnostic accuracy

Introduction:

With a prevalence of 1:100 to 1:2000, cervical incompetence is a serious obstetrical concern that causes premature labor and associated newborn morbidity and death. For lack of uterine contractions, it is described as the inability to sustain a full-term pregnancy in the second trimester due to a structural or functional impairment of the cervix**. (1)**

Cervical incompetence is diagnosed based on a patient's obstetric history and other criteria, such as a dilated cervix on speculum examination or a short length of the cervical canal as assessed through transvaginal ultrasound**. (2)**

Elastography is a non-invasive imaging method utilized to determine the stiffness of soft tissue patches. It consists of two primary forms: shear-wave elastography and strain elastography. Shear wave elastography uses a time-relatable force to visualize tissue elasticity, while strain elastography measures tissue deformation in response to an applied force, often an ultrasonic probe. Greater strain rates indicate softer tissues**. (3)**

Strain elastography is able to provide an objective estimate of tissue stiffness because softer tissues deform more readily than tougher tissues when subjected to external pressure. Lesions in the liver, breast, thyroid, and prostate are just a few examples of the many soft tissues that elastography has been used to study.

Recent studies have demonstrated elastography's potential use in obstetrics and gynecology, for example, in determining the severity of uterine adenomyosis and fibroids, gauging the efficacy of inducing labor, and expecting premature birth**. (4)**

Preterm birth or cervical incompetence are known to be associated with short cervical canal length in the 2nd trimester of pregnancy. Recent studies have shown that a short cervical length in the first trimester may be used as an indicator of preterm delivery, and that there is a positive link between a short cervical length in the 1st and 2nd trimesters. Just a small number of studies, however, have looked at how long the endocervical canal is in the 1st trimester of pregnancy and how often that predicts cervical incompetence**. (5)**

Several studies have also found that cervical incompetence in the first trimester is linked to a wider endocervical canal. Preterm birth is a common complication of cervical incompetence, and the condition is commonly detected after the fact, when the mother has already gone through the trauma of an unplanned delivery in the second trimester**. (6)**

The goal of this work was to investigate the role of transvaginal strain elastography in assessment of cervical incompetence in early pregnancy.

Patients and methods

This was prospective case-control research carried out at the outpatient clinic of the Radiology Departments located in El-Salhya El-Gededa Central Hospital in the period between 01/10/2023 and 01/05/2025.

The research was in line with the Declaration of Helsinki and permitted by the research ethics committee of faculty of medicine Port-said university ((ERN: MED (04/07/2023s.no (98) RAD822_003).

The study population was subdivided into two groups as the 1st group is (study group) that included 25 pregnant women of prior history of cervical incompetence and the 2nd group is (control group) that included 25 normal healthy pregnant women with no known risk for cervical incompetence and was considered as a reference group.

Inclusion criteria: Pregnant women aged between 20 to 45 years, singleton pregnancy and gestational age between 11to 13 weeks.

Exclusion criteria: Multiple pregnancies, first trimester vaginal bleeding and previous pregnancies complicated by scar tissue following a cerclage, previous cervical conization, loop electrosurgical excision procedure and patients' refusal to participate.

Methods

All cases have been subjected to complete history taking, followed by a general examination and an obstetric examination, which included abdominal inspection.

Trans-vaginal Strain Elastography

All individuals included in the study subjected to trans-abdominal and trans-vaginal ultrasound using ultrasound machine (SonoScape model S50 ELITE 2021) by two radiologist of 20 and 6 years' experience.

A trans-abdominal ultrasound technique was initially used by 3-5 MHz trans-abdominal probe, where an abdominal scan of the pelvis was conducted to assess the uterus and both ovaries to rule out any pathological conditions. Gestational age was measured using Crown Rump Length (CRL) and femur length (FL). Images were acquired of both ovaries and adnexal regions, noting any cystic or solid lesions, and the pouch of Douglas was assessed for any free or loculated fluid.

Subsequently, a transvaginal ultrasound technique was employed using a 4–9-megahertz transvaginal probe, repeating the same steps as in the abdominal scan for better visualization of the gestational sac and fetal scan. The cervical length was defined as the linear distance between the two ends of the glandular region surrounding the endocervical canal, and the cervical internal os width has been determined from inner-to-inner edges.

Following the measurement of cervical length and width, elastographic analysis was performed. A real-time elastogram of the complete posterior and anterior cervical lips was produced when the entire green quality bar was reached with the proper amount of manual compression. In the corresponding color map, high strain results were represented by the color red, indicating that the tissues were softer, low strain results were represented by the color blue, indicating stiffer tissues, and moderate strain results were represented by the color yellow (medium soft) and green (medium hard), indicating moderate tissue stiffness.

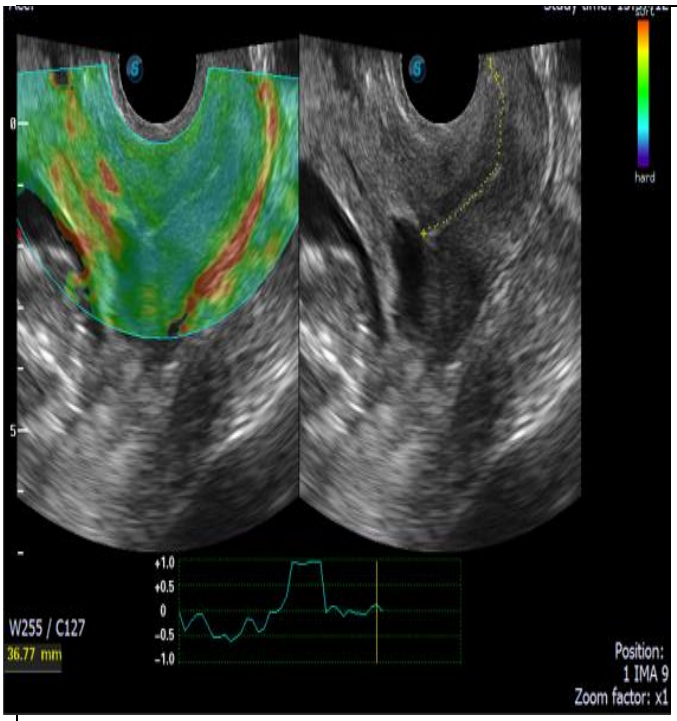
Strain ratios (estimated through the machine software) of the posterior and anterior cervical lips have been calculated and displayed as a percentage, with lower strain ratios suggesting firmer tissues and higher strain ratios indicating softer tissues. All women were followed up until delivery, and neonates were classified according to their gestational age into preterm babies with a gestational age under thirty-seven weeks and full-term babies with a gestational age of 39–40 weeks (Figure 1).

Ethical considerations: All participants were fully informed about the research's benefits and purpose, and written consent was attained, ensuring their right to refuse without affecting their care. Confidentiality of data was strictly maintained and used solely for scientific purposes. No harmful procedures were performed, and proper medical treatment was provided to all. Participants were informed of the results, had access to the researcher for clarification, and retained the right to withdraw from the research at any time without justification.

Statistical analysis

SPSS (Version 25 for Windows) has been utilized for information coding, processing, and analysis. Descriptive statistics consisted of standard deviations, means, ranges, medians, and percentages.

Independent t-tests have been utilized for normally distributed continuous variables, Mann-Whitney U tests for non-normally distributed information, and chi-square tests for categorical variables. A p-value less than 0.05 was deemed statistically significant.



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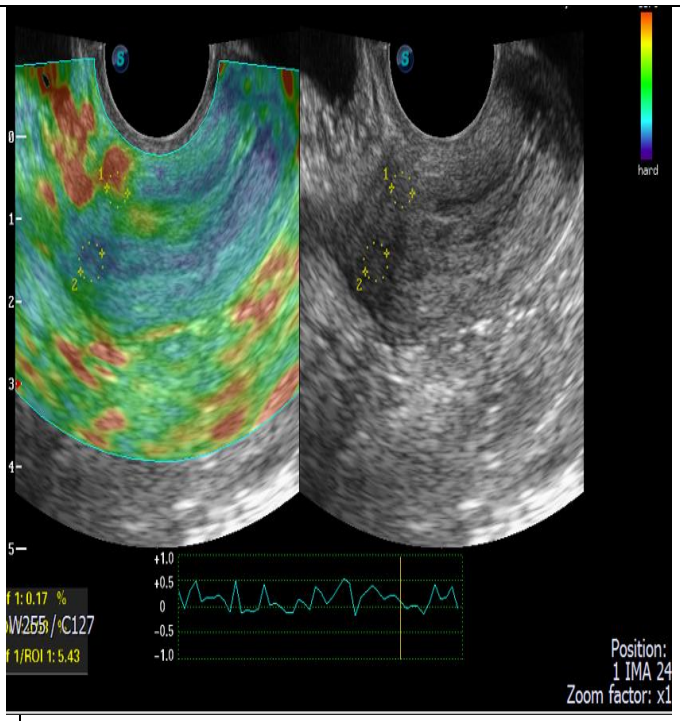

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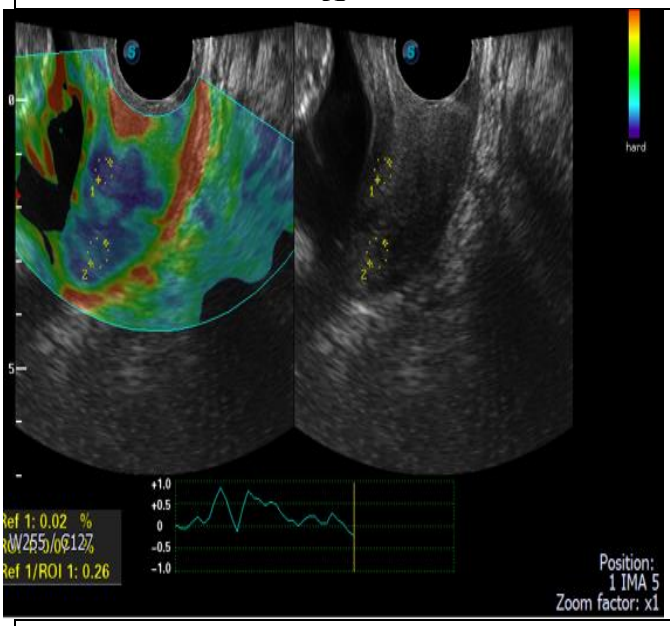

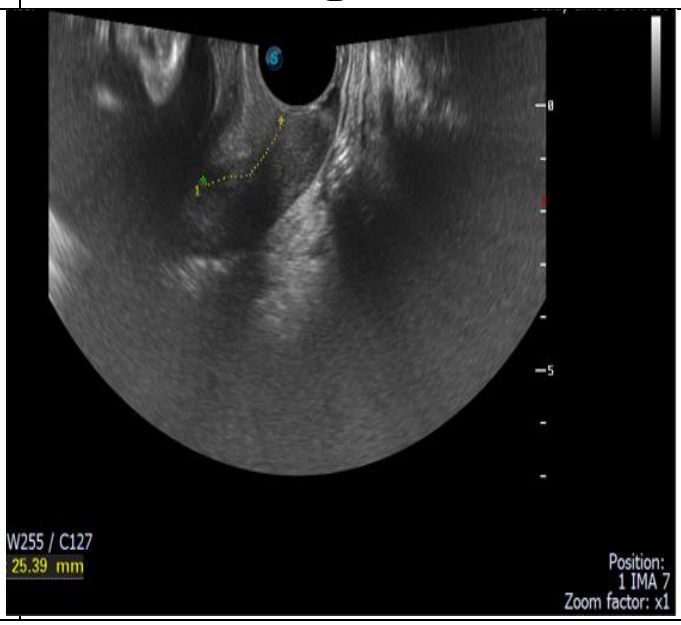

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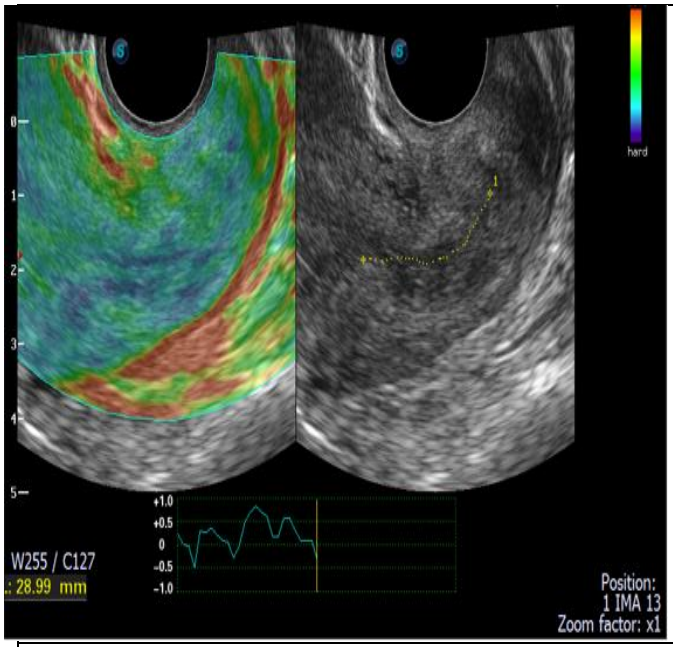
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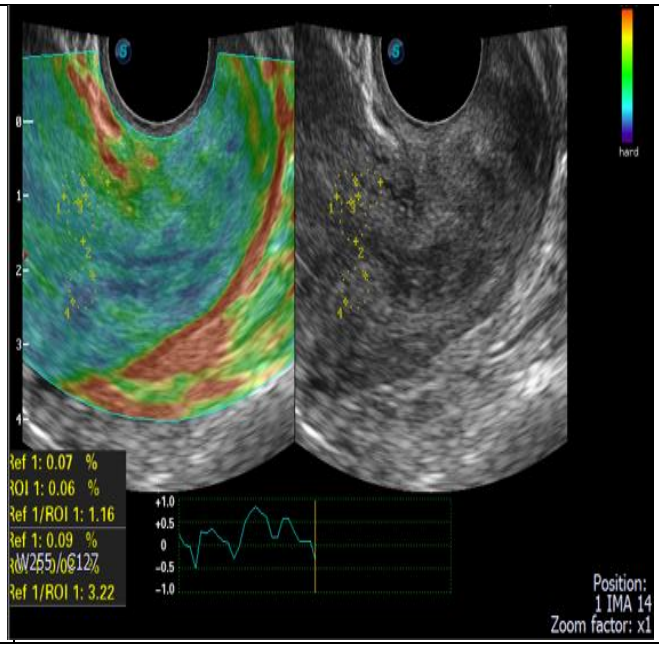
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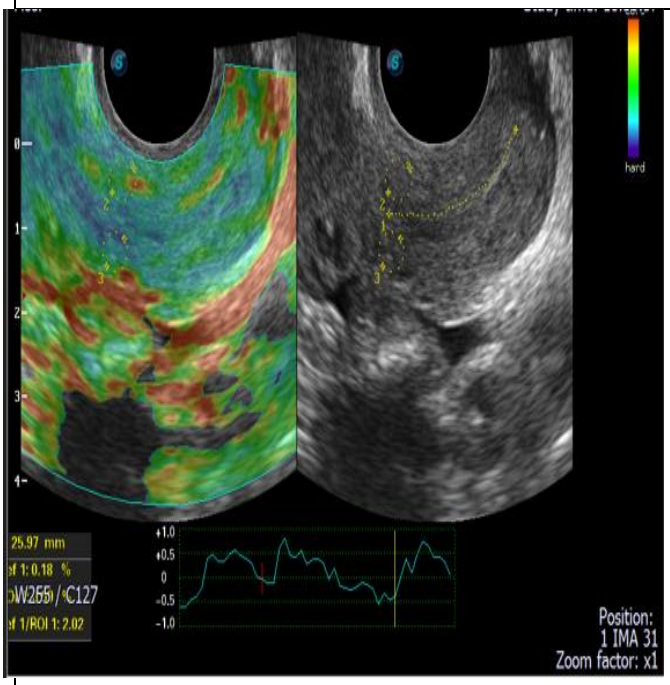
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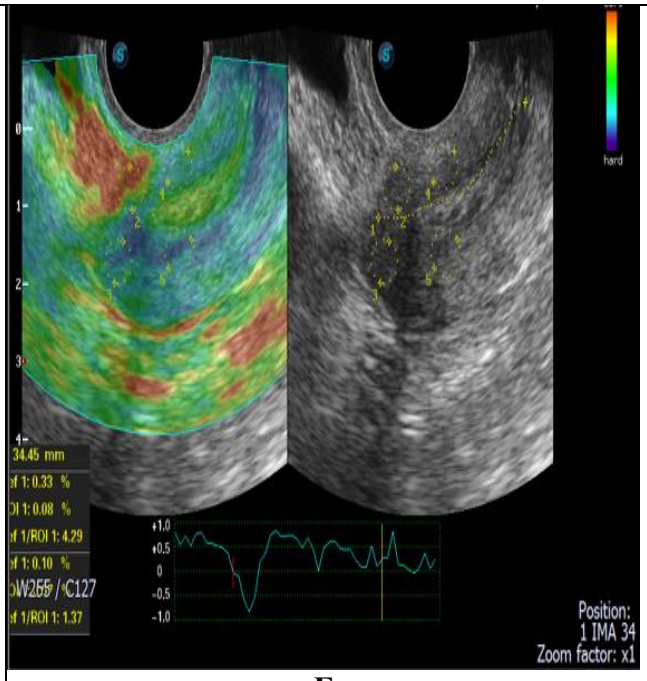
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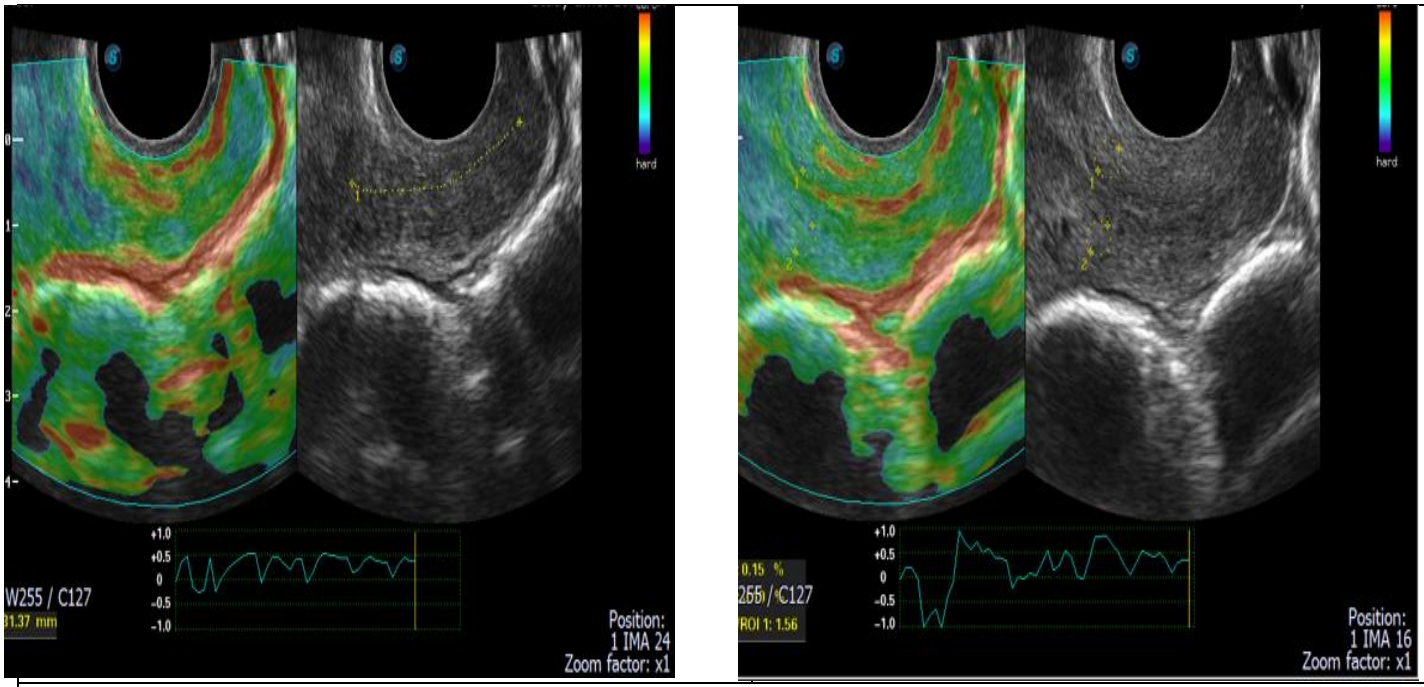

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Figure (1): (A): Cervical length trace measurement of the cervical length (free hand method). **(B):** Cervical length is 36mm (Considered normal), yet high anterior lip strain rate measurement (0.17) suggesting incompetence. **(C)**: Low strain rate 0.26 and low strain of anterior lip 0.02 suggesting hard tissue predicting competence despite short cervical length 25mm.**(D):** Border-line cervical length of about 28mm, however strain rate is normal (1.1) (anterior lip 0.07 and posterior lip 0.06), keeping with competent cervical canal proven at full term delivery. **(E):** Short cervical length 25.9mm and corresponding high strain rate of anterior lip of inner os (0.18%) suggesting soft cervix (incompetent), proven at PTD 35 weeks **(F):** Normal cervical length 34mm and high strain rate (4.29) of the inner os (anterior lip 0.33 and posterior lip 0.08) suggesting incompetence**. (G):** Normal length 31mm and normal strain rate (anterior lip 0.15, posterior lip 0.10 and strain rate 1.56).

Results

According to **table 1** there was highly statistically significant variance among the studied groups with regard to color of elastography.

Table (1): color of elastography between studied groups.

	Cervical incompetence group N=25		**Non-Cervical incompetence group N=25**		**P-value**
	N	%	N	%	
Warm group					**0.007**
Soft (Red)	8	32%	9	36%	
Medium soft (Yellow)	11	44%	2	8%	
Cold group					
Medium hard (green)	3	12%	12	48%	
Hard (Purple)	3	12%	2	8%	

According to **table 2** there was a statistically insignificant variance among the examined groups with regard to Age, body mass index (BMI) and cesarean delivery, whereas there was statistically significant increase with regard to gravidity and parity in cervical incompetence group when compared to non-cervical incompetence group.

Table (2): Distribution of general characteristics amid the examined groups.

	Cervical incompetence group Number =25		**Non-Cervical incompetence group Number =25**		**P-value**
	Mean	SD	Mean	SD	
Age	31.4	3.93	30.48	3.029	0.3
BMI	28.2	4.5	24.47	2.22	**0.001**
Gravidity	2.84	0.89	1.8	0.7	≤0.001
Parity	1.4	0.8	0.64	0.56	≤0.001
	N	%	N	%	
Cesarean Delivery	8	32%	7	28%	0.75

According **to table 3**, there was a statistically insignificant variance among the examined groups with regard to APGAR score at 1 minutes and 5 minutes, while a statistically significant variance has been observed among the examined groups with regard to delivery age, birth weight, and preterm birth

Table (3): Distribution of neonatal outcome among the studied groups.

	Cervical incompetence group Number =25		**Non-Cervical incompetence group Number =25**		**P-value**
	Mean	SD	Mean	SD	
Delivery age (weeks)	35.92	5.2	39.08	4	**0.02**
Birth weight (g)	2554.44	722.3	2906.16	375.1	**0.03**
APGAR score					
1 min	7.64	1.86	8.52	1.5	0.07
5 min	8.68	1.7	9	1.08	0.43
	N	**%**	**N**	**%**	
Preterm birth	8	32%	2	8%	**0.03**

According to **table 4**, there was a statistically insignificant variance among the examined groups with regard to GA at scan, crown Rump length and posterior cervical lip strain rate, whereas a statistically significant variance has been observed among the examined groups with regard to cervical length, endocervical canal width, and anterior cervical lip strain rate.

Table (4): Distribution of Cervical elastography data between the studied groups.

	Cervical incompetence group Number=25		**Non-Cervical incompetence group Number =25**		**P-value**
	Mean	**SD**	**Mean**	**SD**	
GA at scan (wks)	**12.4**	**0.9**	**12.8**	**0.6**	**0.07**
Crown Rump length (mm)	**68.7**	**7.3**	**67.8**	**6.7**	**0.642**
Strain rate (%)					
Anterior cervical lip strain rate %	**0.21**	**0.06**	**0.12**	**0.05**	**<0.001**
Posterior cervical lip strain rate %	**0.1**	**0.06**	**0.09**	**0.08**	**0.61**
Cervical length (mm)	**34.7**	**5.4**	**39.5**	**4.0**	**<0.001**
Endocervical canal width (mm)	**5.9**	**0.9**	**5.2**	**0.9**	**0.007**

P value above 0.05: Not significant, P value under 0.05 is statistically significant, p-value under 0.001 is highly significant., SD: standard deviation

Table 5 showed that ,at cut off value 0.16% anterior cervical lip strain had sensitivity of 88% and specificity of 84% for the diagnoses of cervical incompetence with statistically significant difference, at cut off value 36.1 cervical length had sensitivity of 76% and specificity of 84% for the diagnoses of cervical incompetence with statistically significant difference, and at cut off value 5.87 endocervical canal width had sensitivity of 44% and specificity of 76% for the diagnoses of cervical incompetence with statistically significant difference (Figure 2).

	Cut off Value	AUC	Sensitivity	Specificity	Sig.	Lower	Upper
Anterior cervical lip strain rate	0.16%	.860	88%	84%	<.001	.748	.972
Cervical length (mm)	36.1	.640	76%	52%	0.03	.485	.795
Endocervical canal width (mm)	5.87	.600	44%	76%	0.01	.442	.758

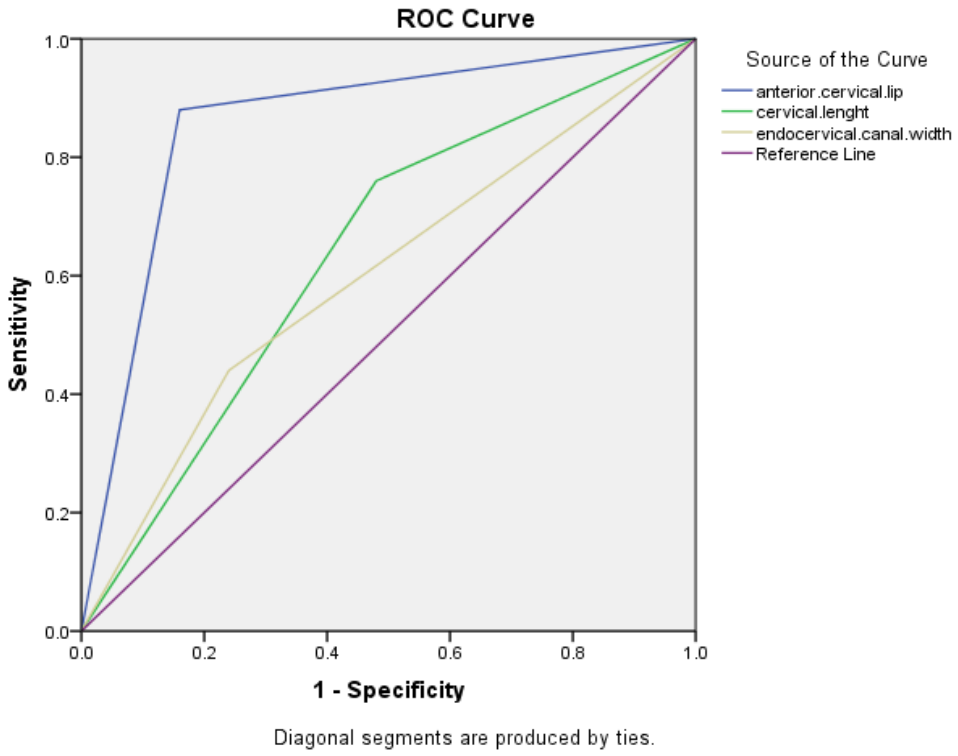

Figure (2): ROC curve of Anterior cervical lip strain rate, Cervical length, Endocervical canal width for the diagnoses of cervical incompetence.

Table 6 showed that, according to the univariate analysis, BMI, gravidity, parity, anterior cervical lip strain ratio, endocervical canal width, and cervical length were significant predictors of cervical incompetence. However, in the multivariate analysis, only gravidity, anterior cervical lip strain ratio, and endocervical canal width remained as independent significant predictors.

Table (6): Univariate and Multivariate Logistic Regression Analysis of Parameters aoosciated with Cervical Incompetence

Univariate Logistic Regression			**95% CI**	
	OR	**Sig.**	**Lower**	**Upper**
BMI	1.21	**.001**	1.231	1.753
Gravidity	3.61	**.001**	1.9	3.9
Parity	2.76	**.003**	1.7	4.12
CRL	1.2	.636	0.9	1.06
Anterior cervical lip strain rate	33.21	**.001**	15	132
Posterior cervical lip strain rate	3.1	.567	1.6	7.8
Cervical length	2.5	**.005**	1.9	7.6
Endocervical canal width	2.75	**.01**	1.9	7.3
Multivariate Logistic Regression				
BMI	1.12	0.569	0.96	1.7
Gravidity	2.7	**0.005**	1.5	4.6
Parity	1.7	0.41	0.9	3.6
Anterior cervical lip strain rate	51.8	**0.002**	17	256
Cervical length	3.6	0.22	1	15.6
Endocervical canal width	5.79	**0.041**	1.5	25.6

Discussion

This prospective cross-sectional research was conducted at outpatient clinics of ultrasound unit of radiology department of El-Salhya El-Gededa Central Hospital and Port-Said university hospital in in Egypt.

In our study illustrated that, there was a statistically insignificant variance among the examined groups with regard to age, BMI and cesarean delivery, while there was statistically significant increase regarding gravidity and parity in cervical incompetence group when compared to non-cervical incompetence group. Additionally, a highly statistically significant variance has been observed among the examined groups with regard to color of elastography.

Also, our findings were in line with **Chen et al., (2)** who estimated and compared the accuracy of 1st trimester endocervical canal width, cervical length, and cervical elastography in pregnant females with and without a history of cervical insufficiency. They revealed that the cervical insufficiency group had significantly greater parity and gravidity than non-cervical insufficiency group. While there was a statistically insignificant variance among the examined groups with regard to age and cesarean delivery.

Our findings illustrated that there was a statistically insignificant variance among the examined groups with regard to APGAR score at one minute and five minutes, while a statistically significant variance has been observed among the examined groups with regard to delivery age, birth weight, and preterm birth.

Similarly, our results were in accordance with **Jiang et al., (7)** who revealed that CI group had a significantly earlier average gestational age at birth (p <-value under .001). Infants in the CI group additionally demonstrated significantly lower average birth weights as in comparison with those in the control group.

The current research stated a statistically insignificant variance has been observed among the examined groups with regard to GA at scan, crown rump length and posterior cervical lip strain rate, whereas a statistically significant variance has been observed among the examined groups with regard to cervical length, anterior cervical lip strain rate, and endocervical canal width.

This investigation agreed with **Chen et al., (2)** who found that the anterior cervical lip strain elastography in the cervical insufficiency group (strain rate: 0.19 ± 0.05%) was significantly softer compared to that in the control group (strain rate: 0.11 ± 0.04%) (P-value under .001). The cervical length in the cervical insufficiency group (36.3 ± 4.8 millimeters) was significantly shorter compared to that of the control group (38.3 ± 3.8 millimeters) (P -value equal .014), and the endocervical canal width of the cervical insufficiency group (5.7 ± 1.1 millimeters) was significantly wider in comparison to that of the control group (5.2 ± 0.7 millimeters) (P-value equal .001).

Nevertheless, the elasticity of the posterior cervical lip strain, crown-lump length and GA weren't significantly dissimilar among both groups.

Similarly, our findings were in line with **Jiang et al., (7)** who reported that there was a statistically insignificant variance among the examined groups with regard to GA at scan, crown rump length. On the other hand, the cervical length in the CI group (34.3 ± 2.91 millimeters) was significantly shorter compared to that in the control group (35.2 ± 1.99 millimeters) (*p* -vale equal .036).

Additionally, our findings were similar with earlier research done by **Hee et al., (8) and Molina et al., (9)** indicated that the anterior lip but not the posterior lip of the cervix was significantly softer in the cervical insufficiency group. This might be owing to the anterior cervical lip is closer to the transducer and receives higher compressional force in strain

elastography, leading to in more sensitive alterations compared to in the posterior cervical lip. Additionally, the structural variability of the cervical canal in among the transducer and the posterior cervical lip might distort the distribution of compressional force, thereby confounding the interpretation of stresses in the posterior cervical lip.

This study revealed that at cut off value 0.16% anterior cervical lip strain had sensitivity of 88% and specificity of 84% for the diagnoses of cervical incompetence with statistically significant difference, at cut off value 36.1 cervical length had sensitivity of 76% and specificity of 84% for the diagnoses of cervical incompetence with statistically significant difference, and at cut off value 5.87 endocervical canal width had sensitivity of 44% and specificity of 76% for the diagnoses of cervical incompetence with statistically significant difference.

In a similar manner our results were in accordance with **Chen et al., (2)** who showed ROC curve analyses demonstrated optimum cut-off values of anterior cervical lip strain elastography, endocervical canal width and cervical length to confirm females with a history of cervical insufficiency of 0.15%, 35.5 millimeters and 5.75 millimeters, correspondingly. The sensitivity and specificity of anterior cervical lip strain for females with a history of cervical insufficiency were 0.88 and 0.84, superior compared to those of cervical length (0.78 and 0.50) and endocervical canal width (0.44 and 0.79). Both the sensitivity and specificity of the three parameters taken together were calculated to be 0.83 and 0.90 respectively.

Additionally, our research concurred with **Abdelgaffar et al., (10)** who evaluated the possible benefit of elastographic examination of cervical canal stiffness at twelve to fourteen weeks of gestation in females with cervical incompetence in predicting of spontaneous preterm parturition. Elastography demonstrated good sensitivity and specificity in identifying cervical incompetence.

Regarding univariate analysis, our findings showed that BMI, gravidity, parity, anterior cervical lip, cervical length, and endocervical canal width were significant predictors for cervical incompetence. According to multivariate analysis, gravidity, endocervical canal width, and anterior cervical lip were significant predictors for cervical incompetence.

In a similar vein **Fruscalzo et al., (11)** have observed a significant association among cervical strain and cervical length. Whereas **Öcal et al., (12**) showed that cervical length measurement isn't an effective tool for assessing the females with the history of cervical incompetence. These conflicting outcomes might be related to variances in ultrasonography machines, instrument settings, measuring procedures and gestational durations of the investigations. In addition, many pathophysiologic processes in cervical remodeling may lead to cervical softness and shortening, like progressive alterations in cervical tissue hydration, tissue elasticity and collagen structure **(13).** Consequently, assessments of cervical elasticity might also be able to raise the prediction power beyond that of measurements of cervical length only.

More prospective research including bigger numbers in low-risk females will be necessary to establish elastography as a cost-effective screening tool for predicting of preterm parturition owing to cervical incompetence

Conclusion

The present study evaluated the function of transvaginal strain elastography in evaluation of cervical incompetence in early gestation. This investigation demonstrates that transvaginal strain elastography is a good technique to validate the diagnosis of cervical incompetence. The anterior cervical lip exhibited significant softness in pregnant females with cervical incompetence. The specificity and sensitivity of anterior cervical lip strain for female cervical incompetence surpassed those of cervical length and endocervical canal width.

Recommendations

More researches with larger sample sizes and extended follow-ups are required to validate current outcomes and investigate the role of transvaginal strain elastography in early pregnancy cervical incompetence assessment. Future research should use well-designed randomized controlled trials or large, comparative observational studies, with larger sample sizes to provide meaningful conclusions and longer follow-up periods for accurate long-term outcomes.

Abbreviations

- **CI** cervical insufficiency
- **BMI** body mass index
- **CRL** Crown Rump Length
- **FL** femur length.
- **GA** gestational age.

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