

Shear wave elastography as a new, non-invasive diagnostic modality for the diagnosis of penile elasticity: a prospective multicenter study

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Abstract

Objective: Shear wave elastosonography (SWE) could be used to evaluate the elasticity of penile tissue. Few studies in the literature, however, have investigated its use in patients with erectile dysfunction (ED) or have attempted to correlate findings with International Index of Erectile Function (IIEF-5) scores. The primary aim of this study was to evaluate the characteristics of erectile tissue using SWE and to determine possible relationships with IIEF-5 and Erection Hardness Scale (EHS) scores. The secondary aim was to establish a cut-off SWE examination value over which cavernous tissue stiffness could contribute to a subsequent organic alteration.

Methods: This prospective study included male patients 18–80 years of age who attended two general andrology clinics and underwent SWE. Subjects were divided into groups according to IIEF-5 score, and correlations between SWE and IIEF-5 and EHS questionnaire scores were explored.

Results: A total of 270 subjects (mean age 46.7 ± 16.9 years) were included. ED was reflected by low IIEF-5 and EHS scores and a decrease in the mean elasticity of the corpora cavernosa according to SWE, although the difference between the left and right corpora cavernosa was not statistically significant. No statistically significant correlation was found between measurements of the corpora cavernosa (in kPa) and age. The optimal cut-off identified was 24.75 kPa.

Conclusion: Results demonstrated that the mean elasticity of the corpora cavernosa according to SWE was correlated with IIEF-5 score and EHS score.

Keywords: erectile dysfunction, erection, shear wave elastosonography, stiffness

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Introduction

Erectile dysfunction (ED) is defined as the temporary or permanent inability to obtain an erection or to maintain an erection for as long as necessary for satisfactory sexual performance.¹ ED has a negative impact on the life of affected patients and their partners, often manifesting as relationship problems and personal low self-esteem in everyday life.²

The Massachusetts Male Aging study reported that approximately 52% of men >40 years of age exhibit some degree of ED.³ In addition, the same study reported an increase in ED rates, ranging from 22% to 49%, in men between 40 and 70 years of age.³ The prevalence of ED is similar among different ethnic groups, with an estimated prevalence of 22% in Caucasians, 24% in African Americans, and 20% in Hispanics.⁴

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Evidence suggests that ED should be distinguished as non-organic/psychogenic ED or organic ED. Organic etiologies include vascular, neurogenic, Peyronie's disease (PD), medication side effects, and endocrinological sources.¹ History, clinical examination, and laboratory testing play key roles in understanding the etiopathogenesis of ED.⁵

Standardized questionnaires, such as the short form International Index of Erectile Function (IIEF-5) and the Erection Hardness Scale (EHS) are useful for a subjective evaluation of quality of deficit and the evaluation of its impact on patient quality of sexual life.^{6,7} Although nocturnal penile tumescence is used as an objective diagnostic method, it may be influenced by many factors including anxiety, depression, and sleep apnea.^{8,9}

Nevertheless, diagnostic evaluation of ED has evolved significantly in recent years.¹⁰ Recently, ultrasound Doppler, after pharmacological stimulation of erection, has been used to evaluate the presence and/or intensity of a caverno-venous leak in patients with ED.¹¹ Another technique, dynamic penile echo color Doppler, is widely used; however, it is an invasive method that may be painful for some patients.¹² Furthermore, low-frequency drug-induced erection may evolve into priapism.¹³

In 2003, an elastosonographic method was introduced as a new ultrasound technique that provides information regarding the rigidity of tissues rather than their morphology. There are two types of elastosonographic methods: strain elastosonography and shear wave elastosonography (SWE).

Although there have been some studies in the literature investigating the use of SWE in patients with ED or attempting to correlate results with IIEF-5 scores, the conclusions are not fully conclusive when considering subjective assessment.^{14–16}

Accordingly, the primary aim of the present study was to evaluate the characteristics of erectile tissue using SWE in a male population, and to explore possible correlations with IIEF-5 and EHS scores. The secondary aim was to establish a cut-off SWE examination value, over which cavernous tissue stiffness is pathological and can predict the onset/presence of penile elasticity alteration.

Materials and methods

This prospective, observational, multicenter study included male patients sexually active (1–3 sexual intercourse per week at least 6 months) 18–80 years of age who attended two general andrology clinics between January 2019 and January 2020. Individuals >80 or <18 years of age, those with diabetes, hypercholesterolemia, hypertriglyceridemia, smokers, spinal trauma, treatment with continuous phosphodiesterase-5 inhibitors, ischemic heart disease <6 months, pelvic surgery within 1 year, hypotestosteronemia (<8 nmol/L), PD, non-organic ED, and penile trauma were excluded.

Patient evaluation included history, clinical examination and SWE. Patients were divided into groups according to IIEF-5 score, and data from the new ultrasound method were compared with IIEF-5 and EHS questionnaire scores.

Ultrasound examination was performed using an ultrasound machine (EleLogiq S8, GE Healthcare, Waukesha, WI, USA) equipped with a linear probe (7.5–13 MHz). The study was conducted in accordance with the Privacy Act and the principles of the Declaration of Helsinki. The study was approved by the local ethics committee (No. 36366, University of Perugia, Perugia, Italy). Each patient was informed about the purpose of the investigation and was formally enrolled after providing written informed consent to participate.

Diagnostic technique

The examination was performed by a single operator in a dedicated room; a single operator performed the diagnostic examination in both centers. The operator performed at least 30 h of dedicated training with this ultrasound method.

The penis was investigated as follows. The two corpora cavernosa (CC, left and right) were investigated separately. The linear probe was affixed laterally to each of the CC. Each cavernous body was divided into three sections longitudinally: proximal, middle, and distal. Each section (proximal, medial and distal) had a length of 2 cm starting from the base of the penile crura.

Within the selected area, a region of interest (ROI, a circular area with a radius of 1 cm) was identified from the albuginea tunic to the intracavernous septum on both CC, and tissue stiffness was calculated using dedicated software.

All patients were examined while supine with the glans facing the pubic symphysis. The penis was examined in a flaccid state. Initially, a B-mode scan was obtained to exclude possible penile plaques or cavernous fibrosis that could indicate the presence of PD. Subsequently, scan data were acquired using the SWE method. At the time of measurement, patients were asked to hold their breath.

SWE

Elastosonography incorporates a particular technique in which an acoustic radiation force pulse generated on a fabric induces a transversal wave that propagates in the direction of the ultrasonic beam. Starting from the speed of the transversal wave, it is possible to estimate the modulus of elastic deformation (i.e. Young's modulus). The speed of the shear wave is proportional to the stiffness of the tissues. From this, the stiffness of the tissues can be expressed in kPa according to Young's modulus. Therefore, the higher the stiffness, the higher the absolute value in kPa. This technique is useful because it enables operators to record quantitative measurements of tissue stiffness within the ROI. To obtain accurate results, the operator performed a minimum pre-compression on the tissue and also maintained the same position during detection by the software.

Two questionnaires were administered to all patients. First, the IIEF-5 reflects erectile quality reported by patients. A score of 22–25 was considered to indicate normal sexual activity, 17–21 indicated mild ED; 12–16 indicated mild to moderate ED; 8–11 indicated moderate ED; and 5–7 indicated severe ED.⁶ Second, the EHS score, for which responses were assessed as follows: 0 = penis does not enlarge; 1 = penis is larger, but not hard; 2 = penis is hard, but not sufficient for penetration; 3 = penis is sufficiently hard for penetration, but not completely hard; and 4 = penis is completely hard and fully rigid.¹⁷

We identified non-organic ED patients by EHS questionnaire. In the literature there are studies showing that the EHS is correlated with the maximal penile circumferential change, and it represents the objective erectile function, showing this by the measurement of nocturnal penile tumescence and rigidity.¹⁸ However, monitoring of nocturnal penile tumescence and rigidity with the RigiScan is still considered a useful diagnostic tool for psychogenic ED at the present stage.¹⁹ Consequently EHS can be used to differentiate a psychogenic form from an organic one.

Statistical analysis

Statistical analysis was performed using the paired *t*-test for continuous parametric variables, and the Pearson's correlation test was used for quantitative variables. All calculations were performed using SPSS version 22.0 (IBM Corporation, Armonk, NY, USA). Differences with $p < 0.05$ were considered to be statistically significant.

Results

A total of 322 patients were assessed for eligibility according to the inclusion and exclusion criteria; however, 52 refused to participate. Therefore, 270 patients (mean \pm SD age, 46.7 \pm 16.9 years) were ultimately included in the final analysis.

The IIEF-5 questionnaire was administered to all patients. Subsequently, patients were divided into five groups [A–E ($n = 54$ each)] according to IIEF-5 score (Table 1). Group A had no ED, while groups B, C, D, and E had mild, mild to moderate, moderate, and severe ED, respectively. With worsening IIEF-5 score, the ability to obtain satisfactory rigidity and penetration decreased according to EHS questionnaire scores (Table 2).

Tissue elasticity according to SWE was correlated with IIEF-5 and EHS scores (Table 3). In fact, the elasticity of the CC decreased with worsening IIEF-5 and EHS scores, although the difference between the two CCs was not statistically significant (Table 4). No statistically significant correlation was found between kPa measurements of CC and subject age (Table 5).

Based on the positive correlation between CC measurement values and the extent of ED, a cut-off value for CC measurement was calculated.

The cut-off was calculated considering the SWE values of both CC. The ROC curve was then generated to determine which is the best cut-off for the variable in determining the presence of penile elasticity (Figure 1). The AUC of 0.94 is also statistically significant ($p < 0.001$). The optimal cut-off identified by Youden Index was identified as the value 24.75 kPa, which guarantees a sensitivity = 0.862 and a specificity = 0.811.

Discussion

Results of the present study demonstrated that SWE values measured for the CC of the penis were correlated with erectile function and

Table 1. Total patients divided by groups according to IIEF-5 score.

	IIEF-5 score	Patients, n (%)	Mean age (\pm SD)
Group A	25/25	9 (16.6)	29.7 (\pm 7.7)
	24/25	11 (20.3)	
	23/25	14 (25.9)	
	22/25	20 (37)	
Group B	21/25	8 (14.8)	34.6 (\pm 10.2)
	20/25	12 (22.2)	
	19/25	6 (11.1)	
	18/25	14 (25.9)	
	17/25	13 (24)	
Group C	16/25	8 (14.8)	45.5 (\pm 8.4)
	15/25	6 (11.1)	
	14/25	8 (14.8)	
	13/25	7 (12.9)	
	12/25	22 (40.7)	
Group D	11/25	11 (20.3)	57 (\pm 13)
	10/25	17 (31.4)	
	9/25	14 (25.9)	
	8/25	8 (14.8)	
Group E	7/25	19 (35.8)	67 (\pm 7.2)
	6/25	16 (29.6)	
	5/25	19 (35.8)	

IIEF-5, International Index of Erectile Function short form; SD, standard deviation.

penile rigidity. In particular, the increase in stiffness within the structure of the CC of the penis correlated with a reduction in erectile function; more specifically, a decrease in stiffness of the penis during erection that enables sexual intercourse.

The erectile tissue consists of large amounts of sinusoidal space, which are covered with endothelium and delimited by pear-shape partitions known

Table 2. Results of the Erectile Hardness Scale (EHS) questionnaire according to the groups previously carried out.

	EHGS	Patients n (%)
Group A	0 – Penis does not enlarge	0 (0)
	1 – Penis enlarged but not rigid	0 (0)
	2 – Rigid penis but no penetration	4 (7.4)
	3 – Rigid but not full penetration	29 (53.7)
Group B	4 – Fully rigid penis	21 (38.9)
	0 – Penis does not enlarge	0 (0)
	1 – Penis enlarged but not rigid	22 (40.7)
	2 – Rigid penis but no penetration	10 (18.5)
Group C	3 – Rigid but not full penetration	22 (40.7)
	4 – Fully rigid penis	0 (0)
	0 – Penis does not enlarge	0 (0)
	1 – Penis enlarged but not rigid	7 (13)
Group D	2 – Rigid penis but no penetration	21 (38.9)
	3 – Rigid but not full penetration	26 (48.1)
	4 – Fully rigid penis	0 (0)
	0 – Penis does not enlarge	0 (0)
Group E	1 – Penis enlarged but not rigid	20 (37)
	2 – Rigid penis but no penetration	27 (50)
	3 – Rigid but not full penetration	4 (7.4)
	4 – Fully rigid penis	3 (5.6)
	0 – Penis does not enlarge	11 (20.4)
Group E	1 – Penis enlarged but not rigid	18 (33.3)
	2 – Rigid penis but no penetration	19 (35.2)
	3 – Rigid but not full penetration	5 (9.3)
	4 – Fully rigid penis	1 (1.9)

Table 3. Results of SWE in the left and right corpora cavernosa according to IIEF-5 result.

	Left corpus cavernosum (mean \pm SD) kPa	Right corpus cavernosum (mean \pm SD) kPa	p-value
Group A	20.03 \pm 7.77	19.95 \pm 6.58	0.948
Group B	23.09 \pm 3.67	25.25 \pm 4.29	0.8
Group C	46.46 \pm 6.50	47.69 \pm 4.74	0.199
Group D	50.15 \pm 8.93	51.16 \pm 7.69	0.522
Group E	74.74 \pm 22.78	76.29 \pm 15.87	0.687

Table 4. Pearson's correlation between the IIEF-5 and EHS questionnaires and the mean (kPa) of the left and right corpora cavernosa.

		IIEF-5 questionnaire	EHS questionnaire	Mean CC left	Mean CC right
Mean CC left	Pearson's correlation	-0.805**	-0.408**	1	0.793**
	N	270	270	270	270
Mean CC right	Pearson's correlation	-0.862**	-0.446**	0.793**	1
	N	270	270	270	270

**The correlation is significant at 0.01 (two rows).
CC, corpus cavernosum; EHS, Erectile Hardness Scale; IIEF, International Index of Erectile Function.

Table 5. Correlation between stiffness (kPa) measurements and age.

	Mean age (\pm SD)	Left CC (mean \pm SD) kPa	Pearson's correlation left CC	p-value	CC right (mean \pm SD) kPa	Pearson's correlation right CC	p-value
Group A	29.7 (\pm 7.7)	20.03 \pm 7.77	0.159	0.251	19.95 \pm 6.58	0.035	0.803
Group B	34.6 (\pm 10.2)	23.09 \pm 3.67	0.208	0.132	25.25 \pm 4.29	0.008	0.954
Group C	45.5 (\pm 8.4)	46.46 \pm 6.50	0.022	0.873	47.69 \pm 4.74	0.115	0.408
Group D	57 (\pm 13)	50.15 \pm 8.93	0.126	0.363	51.16 \pm 7.69	0.214	0.120
Group E	67 (\pm 7.2)	74.74 \pm 22.78	0.065	0.638	76.29 \pm 15.87	-0.022	0.875

CC, corpus cavernosum; kPa, kilopascal; SD, standard deviation.

as “trabeculae” consisting of smooth muscle cells (SMCs), collagen, and elastic fibers.²⁰ The flaccidity or erective state of the penis depends on the amount and tone of the SMCs in the sinusoidal spaces, which, under normal conditions, account for approximately 45% of the trabecular tissue.²¹ Another important component of the penile structure is collagen. Collagen content has been reported to be altered in cases of ED.²²

A quantitative reduction in the SMC component with a relative increase in connective tissue forms the anatomical substrate of organic forms of ED.²⁰ SWE is a new, non-invasive method that has been applied in several other diagnostic areas to measure tissue stiffness. For example, it is used in endocrinology to discriminate benign thyroid nodules from malignant tumors,²³ in senology ultrasonography to differentiate fibroadenomas

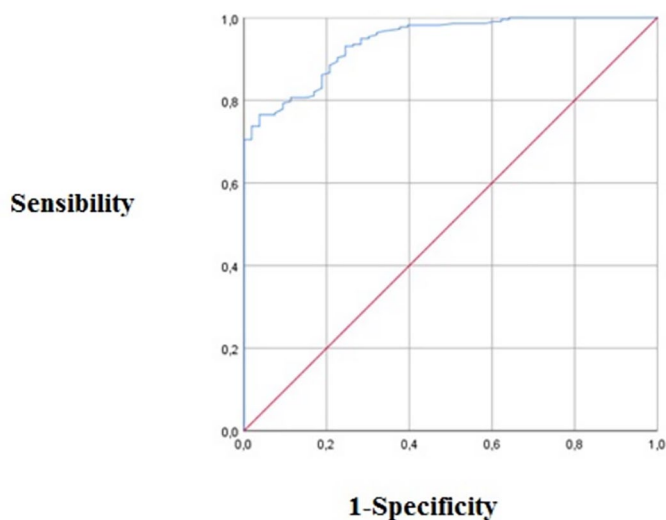


Figure 1. ROC curve.

from invasive ductal carcinomas,²⁴ and in gastroenterology, to diagnose cirrhosis.²⁵

The best method to perform tissue assessment of the CC of the penis is biopsy. In fact, using this method, it is possible to observe tissue composition and quantify SMCs, elastic fibers, and collagen.²⁶ However, this process of histological analysis is complicated and invasive, and can cause serious side effects.

Because the tissue structure of the CC essentially consists of sinusoidal gaps, elastic tissue, and SMCs, tissue stiffness could be considered an index of the structure of the CC of the penis. Moreover, the structure of penile tissue plays a key role in the pathogenesis of ED. In the field of urology, this new elastosonographic ultrasound method was used by Camoglio *et al.*²⁷ in children with hypospadias to assist in choosing one treatment over another. In that study, the authors used a strain method for the determination of tissue stiffness. Richards *et al.*²⁸ demonstrated that this elastosonographic technique could be used to diagnose PD. In fact, this method was able to characterize and localize typical plaques of the disease, especially when they were not visible using the B-mode ultrasound technique.²⁹

Consistent with our findings, which demonstrated that stiffness of the CC decreased with increasing age, previous anatomopathological studies have shown that sinusoidal gaps in the CC gradually decrease with age, and there is a decrease in the number of elastic fibers, with proliferation of

fibrosis and a decrease in SMCs and an increase in tissue atrophy. In addition, we demonstrated that as stiffness of the CC (measured in kPa) increased, a significant correlation was found with IIEF-5 and EHS scores. This demonstrated that decline in erectile function can be caused by worsening of the penile structure as a whole.

Cui *et al.*¹⁴ analyzed 81 men with ED and 35 healthy volunteers. Both groups underwent SWE in both flaccid and erectile states. The authors found that SWE stiffness values of the CC were significantly higher in those with ED in the flaccid state than in healthy volunteers. Zhang *et al.*³⁰ measured penile viscoelasticity in 10 men with ED or PD using ultrasound vibro-elastography. They performed measurements before and after erectogenic drug injection and reported a significant increase in penile viscoelasticity after drug stimulation, demonstrating that elastosonography can also be used to measure dynamic changes in erection. In a subsequent study, Zhang *et al.*³¹ showed that both the elasticity and the viscosity of the CC of the penis correlated with the peak systolic velocity and also viscosity and elasticity correlated negatively with future cardiovascular risk. Altinbas and Hamidi³² performed real-time strain-type elastography during penile Doppler ultrasound examination in 88 patients with ED, and they were divided in agreement to Doppler ultrasound findings in normal, borderline for arterial insufficiency, arterial insufficiency and venous insufficiency. They found that when compared with the normal group, the arterial failure borderline group and the venous failure group had less stiffness, and the arterial failure group had higher stiffness than the normal group even though a statistically significant difference was recorded in the left CC in the venous failure group. In addition, Hamidi *et al.*³³ investigated the elasticity of the cavernous bodies using real-time elastosonography in patients who had undergone radical prostatectomy with or without preservation of the nerve bundle. The results showed a reduction in the elasticity of the CC (in favor of fibrosis), a reduction in the IIEF-5 score, and a statistically significant shorter penile length in patients who had not preserved the nerve bundle. In 2017, Turkay *et al.*¹⁵ attempted to determine an SWE cut-off value for the diagnosis of ED. They examined 70 men, dividing them into two groups according to the presence or absence of ED. They reported a statistically significant difference between the two groups and determined a cut-off value of 17.1 kPa to differentiate

ED from the absence of ED, with a specificity of 94.2%, a sensitivity of 34.2%, and a negative predictive value of 85%.

Results of our study indicated that the optimal cut-off value to define stiffness according to SWE was 22.1 kPa and 28.8 kPa in the left and right cavernous bodies, respectively. Contrary to our study, the study by Zhang *et al.*,¹⁶ who investigated rat penises in 2015, reported that SWE measurements increased significantly with a decrease in SMCs in the CC. They demonstrated an association between SWE values and histopathological changes in the penis and concluded that SWE could be used for the measurement of SMCs. Furthermore, they found a negative correlation between mean elasticity and age.¹⁶ In 2016, Qiao *et al.*²⁹ reported that increases in collagen fiber density with increasing age contributed to an increase in penile stiffness with a decrease in tissue stiffness. However, here, we did not find statistically significant differences between measurement values in the right and left sides. This led us to conclude that the measurement of cavernous body stiffness is not influenced by factors such as section selection.

Overall, the novelty of the present study was to evaluate the characteristics of erectile tissue using SWE in a male population, and to explore possible correlations with IIEF-5 and EHS scores.

Strengths of the present study consisted of its sample size, and its prospective and multicenter design, although the lack of histological confirmation of our results may be considered a limitation. Furthermore, our data should be confirmed in studies with more extensive sampling to exclude any bias related to sex life habits in a given geographical region. Finally, further studies are needed that correlate SWE of the CC both with standardized questionnaires designed to investigate erectile function, and with diagnostic methods such as Doppler ultrasound.

Conclusions

Our results demonstrated that the elasticity of the CC according to SWE was correlated with IIEF-5 and EHS scores. The optimal cut-off identified by Youden Index was identified as the value 24.75 kPa for defining penile rigidity.

Author Contributions

EI: Writing—original draft and validation, conceptualization and supervision; FT: data curation

and methodology conceptualization and supervision; A.R: formal analysis and validation; G.R: formal analysis and validation; F.R: formal analysis and validation; F.I: formal analysis and supervision; E.C: formal analysis and supervision.

Conflict of interest statement

The authors declare that there is no conflict of interest.

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