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KEYWORDS :

Role of Elastography in Evaluation of Erectile Dysfunction and its Comparison with Colour Doppler - a Pilot Study.

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INTRODUCTION : Erectile Dysfunction (ED) is defined as the inability to achieve and maintain an erection adequate for satisfactory sexual intercourse[1] Erection is a complex hemodynamic process that has four basic elements, namely- cavernosal sinusoid relaxation, arterial inflow, venous occlusion and neural control [2, 3].Any disease affecting one or more of the above element could be a potential cause of erectile dysfunction. ED can be distinguished as a pure psychogenic, organic and mixed disorder [4]. Potency is the ability to attain and maintain a functional /rigid erection and is best characterized by axial rigidity rather than hemodynamic parameter [5-7]. Some clinical studies have shown that potency is not always associated with normal hemodynamics or vice-versa Therefore other factors may also be responsible for rigid erection. This disparity between penile rigidity and hemodynamic erectile response is because of expandability of erectile tissue as described by Udelson et al.[6-8] Thus Impotence may occur in some patient solely on the basis of abnormal penile tissue property despite normal hemodynamics.

Since long time colour, doppler has been used to evaluate hemodynamic integrity and to classify patient as having arteriogenic or venogenic impotence based on Peak Systolic Velocity (PSV), End Diastolic Velocity (EDV) and Resistive Index (RI) but this technique fails to characterize the elasticity of penile tissue which is of equal importance for normal potency.

Elastography is currently being used for other tissues like prostate, breast, muscle etc for ,characterization and quantification of tissue mechanical properties [9]. To the best of our knowledge, this technique never been used with penile tissue. Considering the above facts we planned to carry out a study with following aims:

(1) To evaluate the independent role of elastography in evaluation of ED.
(2) To compare elastography and colour doppler in the evaluation of ED.

MATERIALS AND METHOD: This comparative observational study was conducted in teritiary care hospital of Rajasthan during Jan-Aug 2015, after getting ethical clearance from the college's ethics committee.Total 120 patient underwent study after Informed consent. Patients between 20 to 60 years of age who had complaint of poor erection (moderate to severe ED by International index of erectile function score) were enrolled as cases and equal number of age matched patients who presented with complaints of infertility or urological problems other than ED were enrolled as controls. Both cases and controls were grouped by age. Cases were grouped into 2 categories - group A (patient aged 20-40 years with ED positive) and group B (patient aged 40-60 years ED positive); and controls were grouped into two categories - group a (patient aged 20-40 years ED negative) and group b(patient aged 40-60 years ED negative). All patients were asked detailed medical history and underwent physical examination, blood investigations (random blood sugar, serum lipid profile and thyroid function tests). Serum testosterone and prolactin level were also assessed. Patient with history of pelvic surgery/trauma, diagnosed case of stricture urethra, lower urinary tract symptoms (LUTS), presence of neurological disease, peyronies disease, diabetes and hypogonadism were excluded from this study. Patients on antipsychotics and antihypertensive medications were also excluded from the study.

All individuals of case and control groups underwent flaccid penile elastography by (HITACHI HI-VISION PREIRUS) sonography machine with a linear (L-74M) 5-13 MHz transducer and determinations obtained on a transverse scan at the ventral surface of the proximal portion of the penis. Elasticity of lesion was displayed from red (soft) to green (intermediate) and blue (hard) (IMAGE-1&2); strain ratio (SR) was automatically calculated calculated by elastography software (strain of reference area to strain of lesion area) and expressed through semiquantitative three point scale (<1= more elastic, 1-2=intermediate elastic,>2 = less elastic). (IMAGES 3, 4). Strain Ratio <1 was considered as normal cavernosal tissue elasticity and Ratio >1 was suspicious of increased cavernosal tissue stiffness.

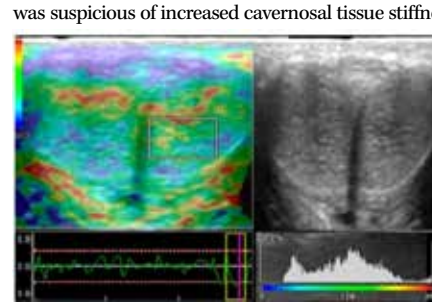

Image 1 : Predominently green pattern in elastogram Of ED (-) patient

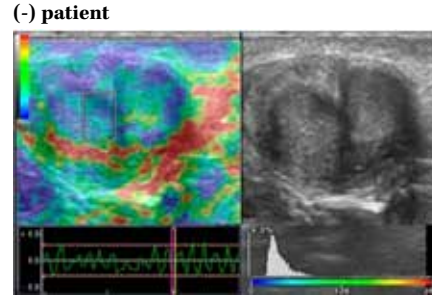

Image 2 : Predominently blue pattern in elastogram Of ED(+) patient

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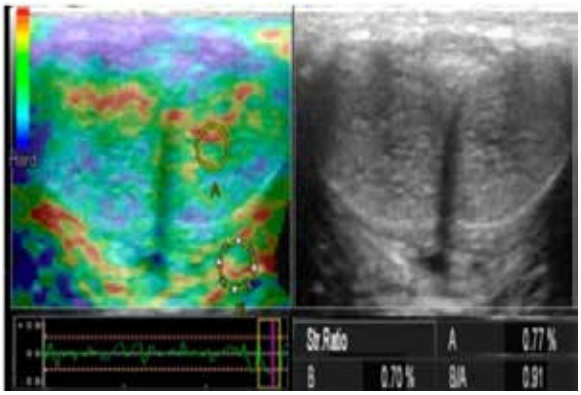

Image 3 : Elastographic image of ED (-) patient with Strain ratio 0.91

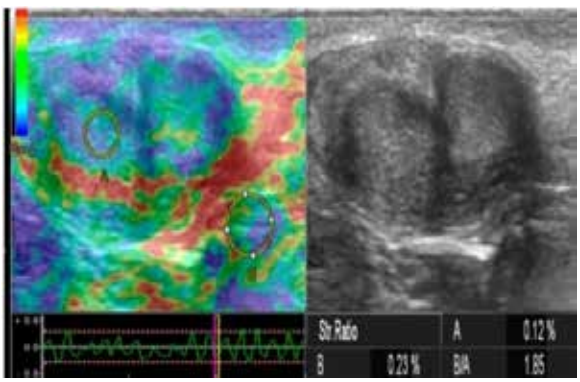

Image 4: Elastographic image of ED(+) patient with Strain ratio 1.85

Erectile response was induced in case groups by Intracavernosal PGE-1 (20 mcg) injection whereas control groups were asked to masturbate to have a good erection. If they failed to achieve a good erection, they were asked to come the next day and masturbate 1 hour after taking 20 mg tadalafil. After this, colour doppler was done for all patient and their PSV,EDV and RI were recorded (IMAGES-5- 6). Doppler criteria for normal vascular integrity was PSV >35 cm/sec, EDV< 3cm/sec or RI >0.9 or reversal of blood flow on spectral window [10]. However in our study,we considered PSV<35 cm/sec as criteria for arteriogenic ED and RI< or = 0.9 as abnormal doppler parameter for venogenic ED. After full erection, hardness was assessed and graded according to EHS by Goldstein et al [11]. Erection hardness was graded from 0 TO 4 - flaccid (0), mild tumescence (1), moderate tumescence but inadequate rigidity (2), full tumescence with moderate rigidity (3), full tumescence and full rigidity (4). In our study , elastography was not performed in erect state in our study in view of change in the property of cavernosal tissue due to pooling of blood.

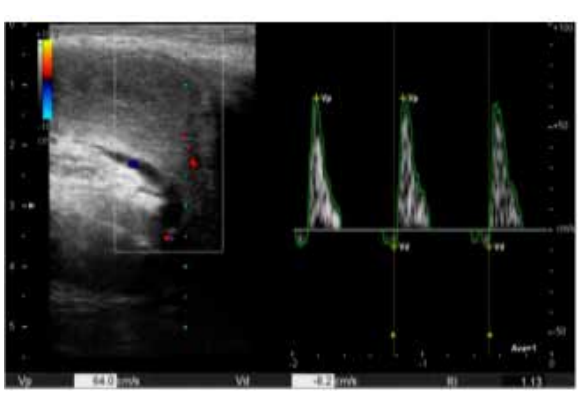

Image5: Colour doppler showing PSV ,EDV and RI Of ED(-) patient.

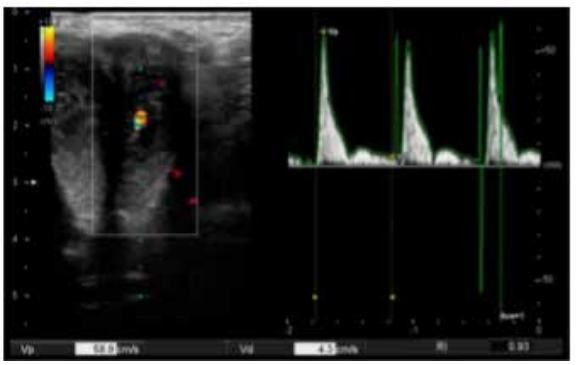

Image 6: Colour doppler showing PSV ,EDV and RI of ED(+) patient.

PSV, RI and SR were compared with EHS which was taken as the final deciding parameter of potency and rigidity for our study. SPSS (19.0) statistical software was used for all statistical analysis. Data were expressed as the mean ± SD. Differences between mean values of the two groups were analyzed by student's t-test. Differences were considered significant at $p<0.05$.

RESULTS: Doppler was abnormal in 3 (10%) patient of younger age group as compared to 5 (16.6%) in older age group whereas elastography was normal in 21 patients (70%) in group A & 15 patients (50%) in group B; and grade 4 EHS was seen in 21 patients (70%) of group A and 16 patients (53.3%) of group B. (Table 1)

In patient belonging to group A , colour doppler was abnormal in 3 out of 30 (10%) patient whereas elastography and EHS was abnormal in 9 out of 30 (30%) patient . In group a patients, none of the individuals had abnormal doppler and EHS and only one (3.33 %) individual had abnormal elastography. On statistical inference,these difference were significant with respect to elastography ($p<0.0001$) and EHS ($P<0.0016$); and insignificant with respect to PSV ($p>0.544$) and RI ($p>0.351$) (TABLE-2 & FIG-1).

In patient belonging to group B , colour doppler was abnormal in 5 out of 30 (16.66%) patients whereas elastography and EHS was abnormal in 15 out of 30 (50%) patients . In patients belonging to group b , 1 out of 30 (3.33%) had abnormal colour doppler, 1out of 30 (3.33%) had abnormal elastography and none of the patients had abnormal EHS. These difference were statistically significant with respect to elastography ($p<0.0004$) and EHS ($p< 0.0001$) but insignificant with respect to PSV ($p>0.332$) and RI ($p>0.242$) (TABLE-2& FIG-1).

In patient belonging to group A, 3 out of 30 (10%) patients were diagnosed as having vasculogenic impotence and 27 out of 30 (90%) patients were diagnosed as psychogenic impotence by colour doppler study alone (Table 3). On comparative study of elastography, EHS and colour doppler, 7 out of 27 (25.92%) patients had abnormal elastography and 6 out of 30 (22.2%) patients had abnormal EHS among colour doppler "diagnosed" psychogenic ED patients. Among vasculogenic ED patients, only 2 patients had abnormal elastography whereas EHS was abnormal in all. In control groups, only one person was found to have abnormal elastography and none of them had poor EHS and colour doppler.

In patients belonging to group B, 25 out of 30 (83.33%) patients were diagnosed as psychogenic impotence by colour doppler and 5 out of 30 (16.66%) patients were labeled as vasculogenic ED. On comparative study of colour doppler, EHS and elastography, 11out of 25 (44.0%) patients had abnormal elastography and 9 out of 25 (30.0%) patients had abnormal EHS among psychogenic ED patients whereas among vasculogenic ED patient 13.33% had abnormal elastography and EHS was abnormal in

all. In control group only one patient had abnormal Doppler and elastography but none of them had poor EHS

GROUP / MODALITY	20-40 YRS ED(+) A group N= 30	40-60 YRS ED(+) B group N= 30
NORMAL DOPPLER	27/30 **(90%)**	25/30 **(83.33%)**
ABNORMAL DOPPLER	3/30 **(10%)**	5/30 **(16.66%)**
NORMAL ELASTOGRAPHY	21/30 **(70%)**	15/30 **(50%)**
ABNORMAL ELASTOGRAPHY	9/30 **(30%)**	15/30 **(50%)**
NORMAL EHS	21/30 **(70%)**	16/30 **(53.33%)**
ABNORMAL EHS	9/30 **(30%)**	14/30 **(46.66%)**
NORMAL DOPPLER & ELASTOGRAPHY	20/27 **(74%)**	14/25 **(56%)**
NORMAL DOPPLER&ABNORMAL ELASTOGRAPHY	7/27 **(26%)**	11/25 **(44%)**
ABNORMAL DOPPLER&NORMAL ELASTOGRAPHY	1/30 **(3.33%)**	1/30 **(3.33%)**
ABNORMAL DOPPLER &ELASTOGRAPHY	2/30 **(6.66%)**	4/30 **(13.33%)**

TABLE-1 DISTRIBUTION OF ABNORMAL AND NORMAL DOPPLER, ELASTOGRAPHY AND EHS IN ED PATIENT BY AGE.

TABLE-2 MEAN AND SD OF VARIABLES AMONG ED (+) AND ED (-) PATIENTS

GROUPS	20-40 YRS AGE (N=60)			40-60 YRS AGE (N=60)		
VARIABLE (MEAN)	ED(+)	ED(-)	P	ED(+)	ED(-)	P
PSV	82.11+8.4	83.61+2.6	0.544	68.1+13.0	73.61+7.1	0.332
RI	1.0 +0.1	1.1+0.0	0.351	0.99+0.1	1.0+0.1	0.242
STRAIN RATIO	1.3±0.5	0.7±0.1	0.0001	1.5±0.3	1.0±0.2	0.0004
EHS	3.5±0.5	4.0±0.0	0.0016	3.3±0.5	4.0±0.0	0.0001

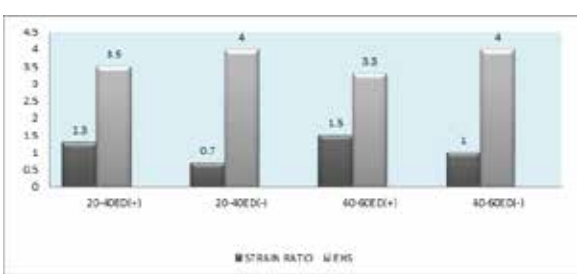

FIG-1. EHS AND STRAIN RATIO OF ED (+) AND ED(-) PATIENTS BY AGE. (p<0.05)

TABLE-3 COMPARISON OF COLOUR DOPPLER, ELASTOGRAPHY AND EHS IN GROUP A PATIENTS (N=30).

DOPPLER	ELASTOGRAPHY	ERECTION HARDNESS SCORE
NORMALOR PSYCHOGENIC **27/30 (90%)**	NORMAL **20/27 (74%)**	NORMAL **21/27 (77.7%)**
	ABNORMAL **7/27 (25.92%)**	ABNORMAL **6/27 (22.2%)**
VENOGENIC- ED **2/30 (6.66%)**	NORMAL **1/30 (3.33%)**	NORMAL **0/30 (0%)**
	ABNORMAL **1/30 (3.33%)**	ABNORMAL 2/30 (6.66%)
ARTTERIOGENIC-ED **1/30 (3.33%)**	NORMAL **0/30 (0%)**	NORMAL 0/30 (0%)
	ABNORMAL 1/30 (3.33%)	ABNORMAL **1/30(3.33%)**

TABLE-4. COMPARISON OF DOPPLER, ELASTOGRAPHY AND EHS IN GROUP B PATIENTS (N=30).

DOPPLER	ELASTOGRAPHY	ERECTION HARDNESS SCORE
NORMALOR PSYCHOGENIC **25/30 (83.33%)**	NORMAL **14/25 (56%)**	NORMAL **16/25 (64%)**
	ABNORMAL **11/25 (44%)**	ABNORMAL **9/25 (30%)**
VENOGENIC- ED **3/30 (10%)**	NORMAL **1/30 (3.33%)**	NORMAL 0/30 (0%)
	ABNORMAL **2/30 (6.66%)**	ABNORMAL 3/30 (10%)
ARTTERIOGENIC-ED **2/30 (6.66%)**	NORMAL **0/30 (0%)**	NORMAL 0/30 (0%)
	ABNORMAL 2/30 (6.66%)	ABNORMAL **2/30(6.66%)**

DISCUSSION: Normal integrity of penile smooth muscle, collagen and elastic fibers with adequate blood flow (incoming and outgoing) with appropriate neurological control are required for functional/rigid erection. Defect in any of these systems may result in erectile dysfunction [12]. The sonographic evaluation of erectile dysfunction was pioneered by Lue et al[13]. Many colour doppler parameters are being used to evaluate the vascular status of men with erectile dysfunction but mainly PSV, EDV and RI are the only clinically accepted one [14, 15]. Colour doppler shows penile blood flow (inflow and outflow) but it does not give idea about penile tissue properties, especially in those patients who are having persistent poor erection despite normal doppler parameters. Elastography is a non invasive modality being used to characterize and quantify different tissues but has not been used with penile tissue. To the best of our knowledge, no study on penile elastography and its comparison with colour Doppler has been done till date.

Colour doppler studies by various authors had different incidence of various type of ED. In a study by Vaqar Bari et al [16], 64% of patients had psychogenic ED,12% had arteriogenic ED and 11% had venogenic ED whereas in a study by saxena et al [17], 40% had venous leak, 34% patient had psychogenic, none had arterial disorder, 14.1% patients had cavernosal muscular asthenia and 2.4% had mixed impotence in younger age group while 29.6% had venous leak, 3.7% had psychogenic impotence, 22.2% had arterial disorder, 3.7% had cavernous muscular asthenia and 11.1% had mixed impotence in the older age group.

In our study, on the basis of colour Doppler, 3.33% patients were found to have arteriogenic ED, 6.66% had venogenic ED and 90% patients were labeled as psychogenic ED in younger age group but in older age group patients, 6.66% had arteriogenic ED, 10% patient were found to have venogenic ED and 83.33% were labeled as psychogenic ED. Majority of patients in our study were labeled as psychogenic ED by colour doppler. However, in pharmacologic colour doppler study, erection is non physiologic because of high intracavernosal blood flow, so minor venous leak can be missed by Doppler study [18]. By applying elastography, majority of ED patients who were labeled as psychogenic were found to have abnormal cavernosal tissue. Thus by elastography, we were able to categorize patient with good and poor elastic cavernosal tissue.

However , elastography has its own limitations, and in its present form it cannot indicate about extent of stretchability of cavernosal tissue. On comparison of elastography and colour Doppler, nearly all individuals had normal colour doppler, elastography and EHS in control group but this was not true for ED cases, particularly for those who were diagnosed as psychogenic impotence on colour doppler. As per our study, all doppler diagnosed vasculogenic ED patient had abnormal elastography and EHS but among doppler diagnosed psychogenic ED patients,

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significant number of patients had abnormal elastography and EHS. Elastography and EHS were found to be abnormal in 18 and 15 patient, respectively, among 52 doppler diagnosed psychogenic ED Cases. Thus, all patients with diagnosis of psychogenic ED on colour Doppler should be considered for elastography to look for cavernosal tissue abnormality before treating them as psychogenic ED.

So, in our opinion, along with colour doppler, elastography is of equal importance for evaluation of erectile dysfunction and to categorize them as arteriogenic, venogenic, cavernous, psychogenic and mixed ED and to treat them accordingly. However limitations of our study were that elastography findings regarding tissue stiffness could not be confirmed by biopsy and strain ratio varied with position of selected reference area.

CONCLUSIONS: Penile elastography is an non invasive modality that can not only identify cavernosal tissue stiffness, but also compliment colour doppler in the evaluation of ED. It also help to identify , ED patient who are worthless subjected to psychogenic treatment on Doppler study alone.

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