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Research Article

SILDENAFIL CITRATE: A NON-INVASIVE SUBSTITUTE IN PENILE DUPLEX ULTRASOUND EVALUATION OF ERECTILE DYSFUNCTION

Monga BR^{1*}, Ramteke AA¹, Autkar GM¹ and Juvekar RL²

¹Department of Radiology, Wockhardt Hospital, 1877, Dr Anand Rao Nair Marg, Mumbai Central, Mumbai-400011, India

²Department of Urology, Wockhardt Hospital, 1877, Dr Anand Rao Nair Marg, Mumbai Central, Mumbai-400011, India

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ABSTRACT

Aims: Penile Doppler Ultrasound (PDU) combined with intracavernosal injection (ICI) of vasoactive agent papaverine is an established diagnostic test for evaluation of penile hemodynamics in patients with erectile dysfunction (ED). The present study investigated the clinical utility of oral sildenafil citrate (a safer vasoactive agent) along with audiovisual sexual stimulation (AVSS) for non-invasive duplex Doppler ultrasound evaluation of vasculogenic ED.

Methods and Material: This Institutional Ethics Committee approved observational study included 36 patients with complaints of ED, referred from the department of urology for pharmacologic PDU investigation, between April 2017 and May 2018. All these patients with International Index of Erectile Function-5 (IIEF-5) score < 25, underwent grey scale and Doppler ultrasound examination of the penis in flaccid as well as erection phase. Oral sildenafil citrate (50-100 mg) was administered and audiovisual sexual stimulation (AVSS) was provided for pharmacologic erection. Pre and post-medication cavernosal arterial diameters, peak systolic velocities (PSVs), end-diastolic velocities (EDVs), and resistance indices (RIs) were recorded.

Pre and post sildenafil cavernosal artery diameters, PSVs and EDVs were compared using paired t test.

Results: The differences in the pre and post-medication cavernosal arterial diameters, PSVs and EDVs were statistically significant ($P < 0.05$). On PDU examination, 23 patients showed arterial insufficiency, three had venous insufficiency, one patient recorded combined arterial and venous insufficiency and nine patients were considered normal.

Conclusions: Penile duplex Ultrasound using oral sildenafil citrate combined with AVSS is a safe, non-invasive and effective, first-line screening test for assessing vasculogenic ED.

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INTRODUCTION

Erectile dysfunction (ED) or impotence is defined as the inability to reach or maintain penile stiffness/ erection that is sufficient for satisfactory sexual intercourse.¹ Its incidence and prevalence are expected to increase significantly in the Indian population along with the increase in various lifestyle diseases.^{2,3}

ED occurs mainly due to psychogenic and/ or organic aetiologies.⁴ Organic causes of ED include vasculogenic, neurologic, pharmacologic, endocrinologic, urologic and mechanical factors such as Peyronie's disease.^{4,6} Vascular insufficiency due to either arterial or venous or both arterial and venous insufficiencies is a common cause of organic ED.^{4,5}

Accurate diagnosis of vasculogenic ED is imperative as aetiology specific, targeted- treatment options are now available.^{5,7} Arteriography with selective internal iliac angiography and dynamic infusion cavernosometry with cavernosography (DICC) are considered the gold standards for evaluation of arteriogenic and venous impotence; respectively.^{6,8,9} However, these invasive techniques cannot be recommended as screening tools for evaluation of ED.

Several studies in the past have investigated the role of penile duplex ultrasound and Doppler spectrum analysis for the diagnosis as well as post-therapy response evaluation of vasculogenic ED.^{5, 6, 8-15} These investigators have used minimally invasive pharmacologic erection technique with intracavernosal injection (ICI) of vasoactive agents such as

*Corresponding author: **Bhagyam R Monga**

Department of Radiology, Wockhardt Hospital, 1877, Dr Anand Rao Nair Marg, Mumbai Central, Mumbai-400011, India

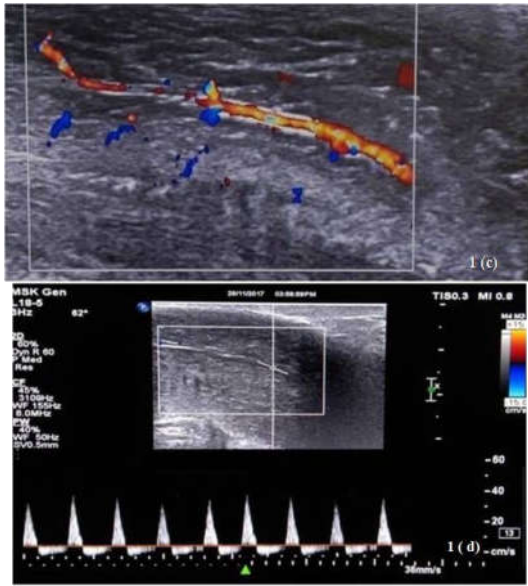


Figure 1 (a- d) Normal response to oral sildenafil and AVSS

Pre-medication PDU images showing normal flow (a) and baseline spectral waveform (b) within the cavernosal artery. Post- sildenafil PDU images demonstrate increased cavernosal arterial diameter (c) and increased PSV with end diastolic flow reversal (d), suggesting normal response to sildenafil.

Statistical Analysis

The results were analysed statistically using SPSS 16.0 (SPSS for Windows, Version 16.0. Chicago, SPSS Inc) software. Quantitative data was presented as means, standard deviation and range. Pre and post Sildenafil cavernosal artery diameters, PSVs and EDVs were compared using paired t test. A p-value <0.05 was considered statistically significant. For cavernosal artery diameter and PSV the post-medication values were greater than the pre-medication values, hence one tailed hypothesis was used. Whereas for EDV the post-medication values were either greater or lesser than pre-medication values, hence two tailed hypothesis was used.

RESULTS

The mean age of the 36 study participants was 53.69 years (age range 38–69 years). Age distribution of the patients is summarized in Table 1. Majority of the patients (44.44%) were in the age group of 50-59 years.

Table 1 Age-wise distribution of Study Participants

Age group in years	Frequency	Percentage (%)
30-39	2	5.56
40-49	9	25.00
50-59	16	44.44
60-69	9	25.00
Total	36	100.00

In this study, the pre-medication IIEF-5 score recorded mild ED in 11(30.56%) patients, mild to moderate ED in 13 (36.11%) patients, moderate ED in 11(30.56%) patients and severe ED in 1 (2.77%) patient.

The post oral sildenafil, clinical erectile response assessment using the EHGS revealed a score of grade 1 in 12 (33.33%) patients and grade 2 in 15 (41.67%) patients. Six (16.67%)

patients achieved a grade 3 response, whereas three (8.33%) patients showed grade 4, fully hard rigid erection. Patients with EHGS scores of grade 3 and grade 4 showed mean PSVs of 42.08 cm/s and 42.67 cm/s, respectively.

In the present study, the pre-medication cavernosal artery 0.50 mm to 1.30 mm with a mean of 0.98 ± 0.24 mm. Post oral sildenafil, cavernosal artery diameters varied from 0.50mm to 1.80 mm with a mean of 1.30 ± 0.29 mm (Figure 2a). There was a statistically significant difference in the pre and post-medication cavernosal artery diameters ($P < 0.00001$) (Table 2).

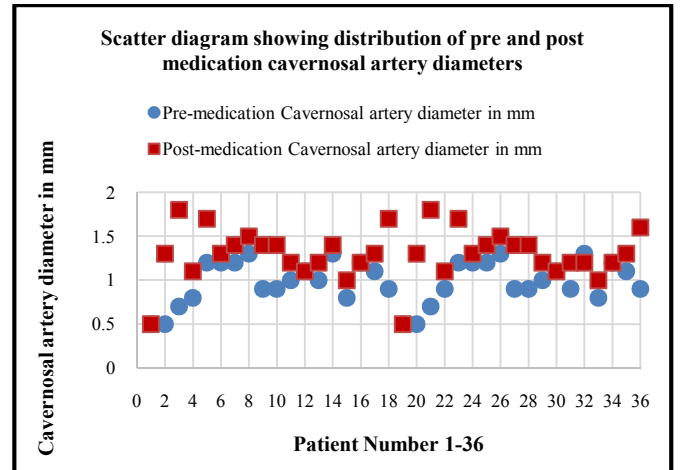


Fig 2a Scatter diagram showing the distribution of the pre and post- medication cavernosal artery diameters.

Table 2 Results and statistical analysis of the pre and post oral Sildenafil penile Doppler ultrasound parameters

Variables	Pre-medication baseline Mean values	Post oral sildenafil medication Mean values	Difference	t-value	P value
Cavernosal artery diameter in mm	0.98 ± 0.24	1.30 ± 0.29	0.32	6.1893	< 0.00001
PSV in cm/s	14.45 ± 8.4	22.47 ± 14.3	8.02	4.8646	< 0.00001
EDV in cm/s	2.85 ± 1.32	3.36 ± 1.37	0.51	2.0343	0.04954

The pre-medication PSV varied from 6.0cm/s to 39.0 cm/s and the mean PSV was 14.45 ± 8.41 cm/s. Post sildenafil PSV ranged from 6.7cm/s to 55.0 cm/s with a mean of 22.47 ± 14.32 cm/s. A t-value of 4.86 and P-value 0.00001 ($P < 0.05$) indicated that the difference in these results was statistically significant (Figure 2b, Table 2).

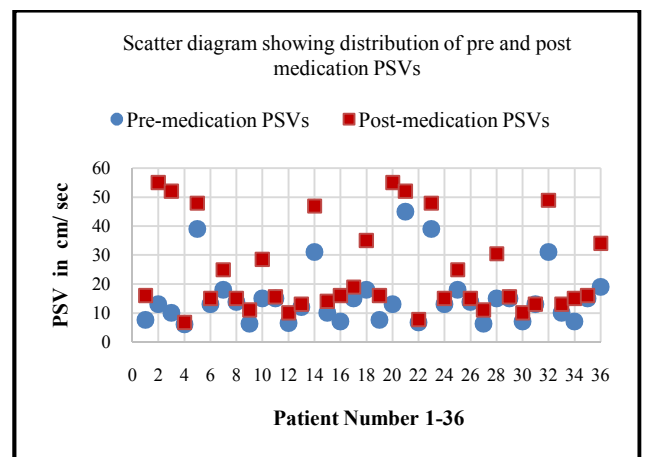


Fig 2b Scatter diagram showing the distribution of the pre and post- medication peak systolic velocities (PSVs).

Range of the pre-medication EDV recorded was 1.0 cm/s - 6.0cm/s with a mean EDV of 2.85 ± 1.32 cm/s. The post-sildenafil EDV ranged from 0.0cm/s to 6.20 cm/s with a mean of 3.36 ± 1.37 cm/s (Figure 2c). As depicted in Table 2. The difference in the pre and post- medication EDV measurements was found to be statistically significant.

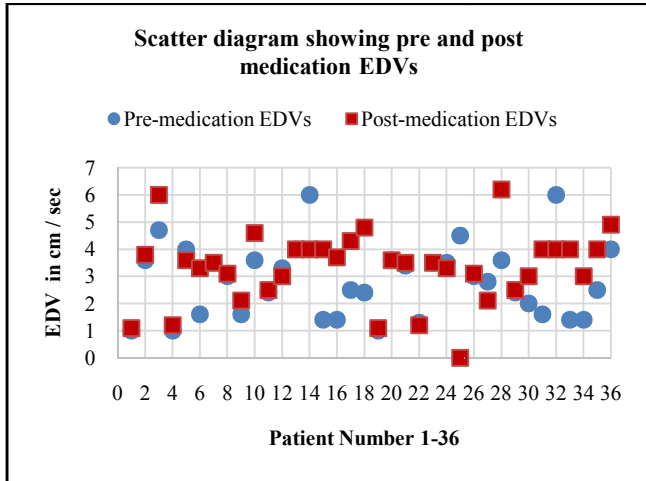


Fig 2c Scatter diagram showing the distribution of the pre and post- medication end diastolic velocities (EDVs).

On the PDU evaluation, 23 (63.89%) of the 36 patients, with low PSV values (<25 cm/s) in the cavernosal artery were diagnosed to have arterial insufficiency (Figures 3, 4a-d)).

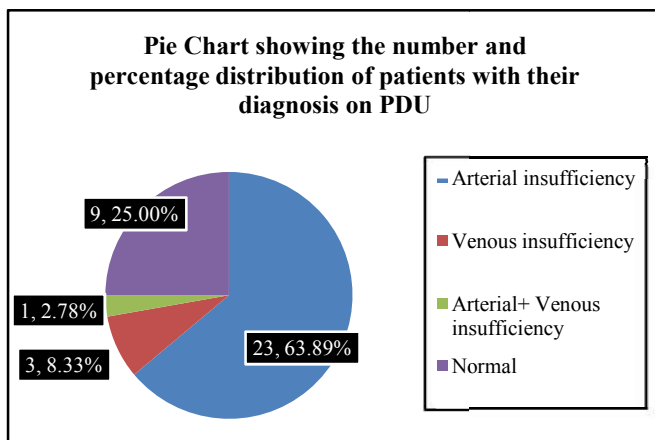


Figure 3 Pie-chart showing number and percentage distribution of patients with their diagnosis on PDU

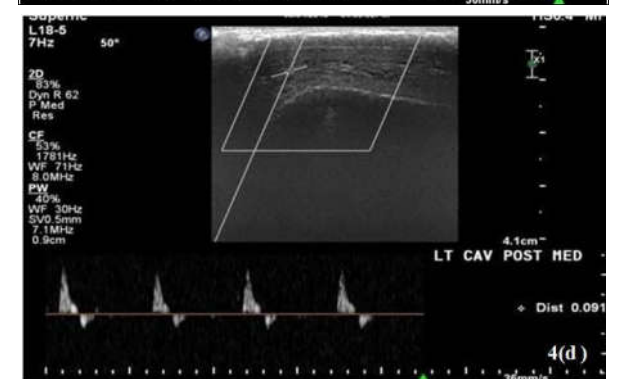
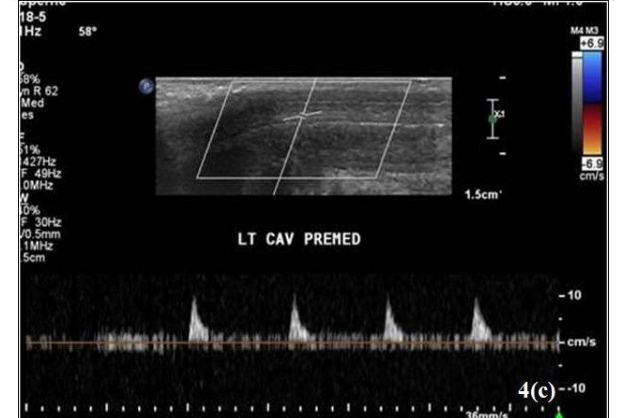
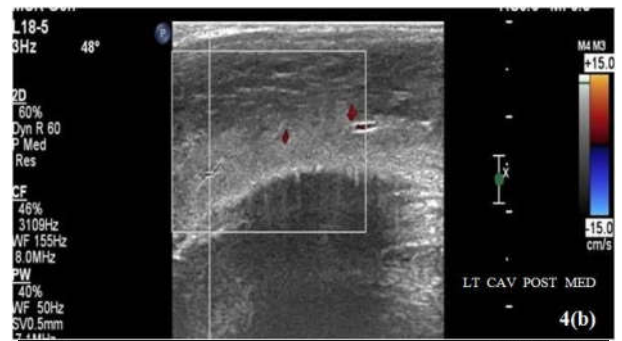


Figure 4(a-d): Arterial Insufficiency. No significant change between the pre-medication (arrow) (a) and post-medication (b) cavernosal arterial diameters. Pre-medication spectral waveform shows dampened PSV with mild diastolic flow(e). Low PSV (10cm/s) with diastolic flow reversal recorded upto 80 min post sildenafil (d).

Three (8.33%) patients were considered to have venous insufficiency (Figure 5a-b), 1 (2.78%) patient was diagnosed to have combined arterial and venous insufficiency and 9 (25%) patients were considered normal (Figures 1, 3).



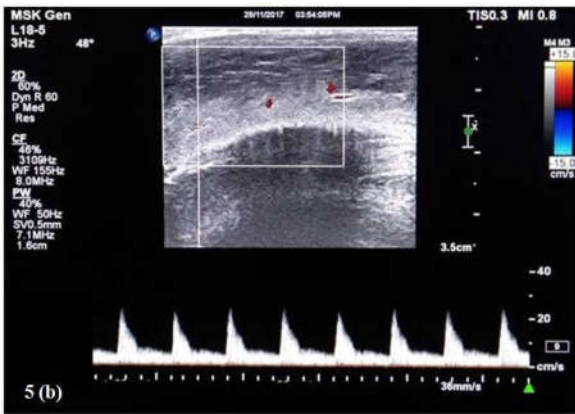


Figure 5 (a,b): Venous insufficiency. Pre-medication, PDU of the cavernosal artery shows normal flow and spectral waveform (a). PDU recorded upto 80 minutes post oral Sildenafil, demonstrates sharp rise in the cavernosal arterial PSV (25 cm/s) with increased EDV of 8 cm/s (b).

Eleven of the 23 patients diagnosed to have arterial insufficiency on PDU, showed post sildenafil EHGS score of grade 1 and 12 patients recorded EHGS score of grade 2 (Figure 6). Out of the three patients with imaging diagnosis of venous insufficiency one patient showed grade 1 response and two patients' recorded grade 2 responses on EHGS. Nine study participants with no evidence of either arterial or venous insufficiency on PDU recorded either grade 4 or grade 3 erectile response using EHGS (Figure 6).

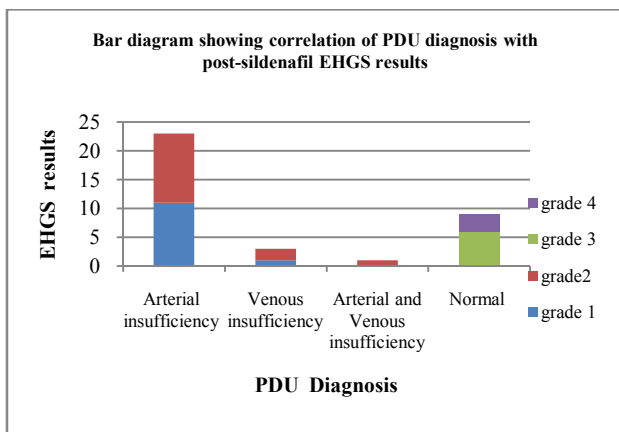


Figure 6 Bar diagram showing correlation of PDU diagnosis with post-sildenafil EHGS results

Figure 7 demonstrates the correlation of PDU diagnosis with the pre-medication IIEF-scores of the patients. All the nine patients considered as normal on PDU, demonstrated mild ED on pre-medication IIEF-5 scoring.

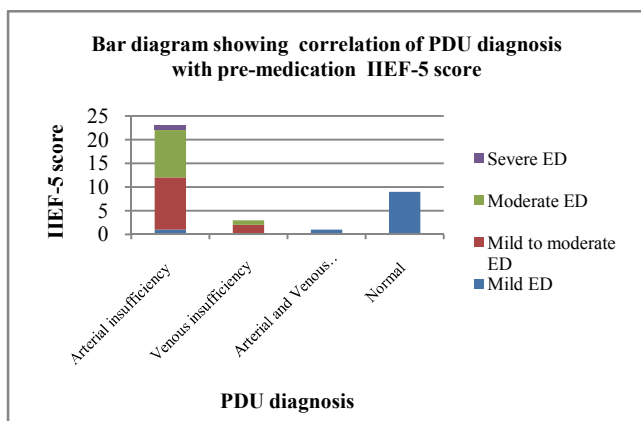


Figure 7 Bar diagram showing correlation of PDU diagnosis with pre-medication IIEF-5 score

DISCUSSION

Normal penile erection is a complex mechanism involving psychological, endocrinologic, neurologic and vascular systems.¹² In erectile dysfunction one or more of these components are either damaged or deficient.

Vasculogenic impotence is a common and potentially curable aetiology of organic ED.^{5, 7, 27} Studies have postulated that isolated ED may be a potential marker of sub-clinical coronary artery disease.²⁸ Accurate diagnosis of vasculogenic ED is thus imperative. Adequate knowledge of the penile hemodynamics leading to normal erection is essential for the evaluation of vasculogenic ED.

Vascular anatomy of the penis is unique with artery of the penis branching into the cavernosal artery and the dorsal artery of the penis. Cavernosal arteries provide blood flow to the corpora cavernosa and are involved in the initiation and maintenance of erection. The corpora cavernosal sinusoids contain the venous sinusoidal occlusion mechanism producing rigid erections.^{11, 27, 29}

Obstruction to penile inflow results in arterial insufficiency; whereas inability to retain the incoming blood in the cavernosa causes veno-occlusive ED. Invasive and non-invasive techniques have been developed to assess vasculogenic impotence. Amongst these, pharmaco penile Doppler ultrasound is an established first-line investigation to evaluate penile arterial and veno-occlusive function.^{22, 27}

Ultrasound evaluation of vasculogenic ED was pioneered by Lue *et al.*¹⁰ Schwartz *et al* evaluated erectile function in normal subjects with color flow Doppler sonography and described a consistent spectral waveform/ intracorporeal pressure pattern characteristic of intact arterial and venous sinusoidal erectile mechanisms.²⁹ They arbitrarily divided spectral waveform variations and intracorporeal pressure changes into phases.^{5, 27, 29}

In 1982, Virag first reported treatment of ED with intra cavernosal injection (ICI) of papaverine.¹⁶ Thereafter, several studies have evaluated the efficacy of PDU in the diagnosis of ED using ICI of papaverine for pharmaco-erection. Papaverine is a nonselective phosphodiesterase (PDE) inhibitor and potent smooth muscle relaxant which acts directly on the penile arteries and cavernosal sinusoids.¹¹

However, ICI of vasoactive agents such as papaverine, PGE1, and phentolamine, is associated with complications including pain, burning sensation, ecchymosis or hematoma formation at the injection site. Fear of injection may cause stress, anxiety, dizziness along with increased sympathetic stimulation resulting in a false-positive interpretation of arterial insufficiency.¹¹ Patients with normal hemodynamic function may have prolonged erections and priapism.¹² Repeated injections may at times result in penile cavernosal tissue fibrosis.¹⁷ Shamloul R demonstrated that the PSV may be falsely lowered in young patients after the first ICI, resulting in a need for repetition of the study.³⁰

To avoid these complications, investigators have been evaluating use of non-invasive, oral vasoactive agents such as sildenafil citrate for pharmaco stimulation during the PDU of ED.¹⁸⁻²³ Arslan *et al*, Bacar *et al* and Speel *et al* in their respective studies concluded that oral sildenafil with visual

sexual stimulation (VSS) could achieve arterial response comparable to that after ICI of papaverine.³¹⁻³³ Vishwaroop B *et al* found oral sildenafil to be as effective as injection papaverine in evaluating ED and have recommended its use with genital self-stimulation in the evaluation of ED, especially in young men with psychogenic impotence.¹⁹ Erdogru *et al* and Copel *et al* had a different opinion about the efficacy of Sildenafil.^{18, 20} They recorded a significantly better clinical response to ICI of vasoactive agents as compared to sildenafil in association with VSS. Observations of Yang Y suggest that although PDE5-Is such as sildenafil and papaverine ICI show similar effects on the PDU parameters in detecting arterial ED, more patients achieve better clinical responses to ICI.²²

In this context, present study investigated the potential use of oral vasoactive agent sildenafil citrate as a non-invasive alternative to ICI of papaverine, for the PDU evaluation of ED. Sildenafil citrate is a highly effective oral agent in the treatment of ED.³⁴ It is a Phosphodiesterase type 5 inhibitor (PDE5-I) which maintains erection by inhibiting the catabolism of cyclic guanosine monophosphate and increasing its levels.²²

The action of PDE5-Is on the cavernosal smooth muscles needs to be augmented with AVSS as the nitric oxide-cyclic guanosine monophosphate pathway needs to be activated by sexual stimulation.²¹ So, adhering to the protocol used by similar studies conducted in the past, AVSS was provided in our study along with oral sildenafil to obtain pharmacoection.^{18, 20, 22, 31-33}

In our study, a statistically significant difference was noted in the pre and post-medication cavernosal artery diameters ($P < 0.00001$). However, inconsistent and overlapping differences were recorded in the post oral sildenafil diameters of the cavernosal arteries, across different clinical response categories. Thus in conjunction with the observations of Quam *et al* and Benson *et al*, this study did not consider cavernosal arterial diameter as an indicator of arterial function.^{11, 12}

The differences in the pre and post- medication PSV and EDV measurements were also found to be statistically significant ($P < 0.05$). Using diagnostic criteria of PSV < 25 cm/s, 23 patients were diagnosed with arterial insufficiency.^{5, 11-14} Of the 23 patients diagnosed with arterial insufficiency on PDU, 10 (43.47 %) patients showed moderate ED; 11 (47.82%) patients showed mild to moderate ED; one (4.34%) patient showed severe ED and one (4.34%) patient recorded mild ED on the IIEF-5 analysis (Figure 7).

The three patients diagnosed with venous insufficiency (mean EDV of $> / = 5$ cm/ sec) recorded normal PSV measurements. In the present study, one patient showed PDU parameters indicating mixed arterial and venous insufficiency. However the final PDU interpretation of this case was indeterminate results, as venous competence cannot be assessed on PDU in a patient with arterial insufficiency.^{11, 21}

None of the study participants complained of any significant adverse reactions post sildenafil administration.

The results of this observational study indicate that sildenafil citrate can be used as an effective vasoactive agent for non-invasive PDU evaluation of vasculogenic ED. These observations are in conjunction with earlier existing comparable studies.^{19, 23, 31-33} Sildenafil has the added advantage of being a cost-effective, safer substitute for ICI, with higher

patient compliance and convenience. Moreover, most of the complications associated with ICI are avoided.

A time-consuming stimulation protocol which needs to be supplemented with AVSS to obtain pharmaco-erection is the major disadvantage of oral sildenafil. Hence if sildenafil is to be used as a substitute for ICI of papaverine, its characteristics of erection induction should be considered so as to avoid potential diagnostic pitfalls.²²

Limitations of Study

The limitation of our study is a lack of comparison with intracavernosal or other oral vasoactive agents.

CONCLUSION

The authors of this study conclude that oral sildenafil citrate when combined with AVSS induces a sufficient erectile response for assessing the penile hemodynamic parameters on duplex Doppler ultrasound. It may be used as a non-invasive, safer, first-line screening test along with PDU for the evaluation of vasculogenic ED. More invasive ICI can be reserved for patients with indeterminate PDU results or inadequate erectile response.

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