



# Analysis of the relationship between sexual satisfaction, erectile dysfunction, and penile vascular parameters in a cohort of patients

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**Background:** Erectile dysfunction (ED) is the second sexual dysfunction affecting men. Penile duplex ultrasound (PDU) with intracavernous injection of a vasoactive agent as alprostadil or papaverine, may play an important role in differentiating psychogenic from vasculogenic ED (arterial or venoocclusive) and may also have an important role in the secondary prevention of cardiovascular events. The aim of this study is to investigate the relationship between the vascular parameters and sexual satisfaction as established by a questionnaire.

**Methods:** Prospective, multicenter analysis of all patients who underwent a PDU between September 2018 and April 2021 in four centers, including patients who were >18 years old and underwent a PDU for ED, Peyronie's disease (PD) or other reasons, signed informed consent and completed an adapted version of the Brief Sexual Symptom Checklist (BSSC). All the patients underwent a standard technique, and from a total of 325 patients, 16 were excluded because of low testosterone levels, and 15 due to missing data,

**Results:** A total of 294 patients were included for the analysis. Significant differences were found between patients with and without ED defined by their score in the Sexual Health Inventory for Men (SHIM) questionnaire in the PSV at 10', adjusted for age (38.07 vs. 44.95 cm/s; P=0.016), and in the PSV and the EHS at 10' for sexually satisfied and non-satisfied patients, and a significant correlation with those parameters and the probability of being sexually satisfied (r=0.147, P=0.011; r=0.132, P=0.023; respectively).

**Conclusions:** In our clinical practice we used the cut-off of >35 cm/s, that seems to be quite low looking at our results. The 10' measurement may be more sensitive in order to establish a diagnosis. BSSC questionnaire is a simple, easy-to perform tool to screen those patients at risk of developing sexual dysfunctions.

**Keywords:** Erectile dysfunction (ED); sexual satisfaction; penile duplex ultrasound (PDU); peak systolic volume (PSV)

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## Introduction

Erectile dysfunction (ED) is the second most prevalent sexual dysfunction affecting men (1) just after premature ejaculation, with incidence ranging from 2% in the 40–49 years old group, to 44.9% in the 70–79 years, according to a real-life, general medicine setting study (2). Psychogenic ED is one of the most challenging types of ED, given that there are men with some grade of organic ED worsened by psychogenic factors (3), which can hinder its proper assessment. Accordingly, a recent systematic review found that as much as 20% (5.1–41.2%) of patients with anxiety disorders suffered some grade of ED (4).

For these reasons, penile duplex ultrasound (PDU) with intracavernous injection of a vasoactive agent as alprostadil or papaverine, may play an important role in differentiating psychogenic from vasculogenic ED (arterial or venoocclusive) (5). Besides, given its ability to accurately assess the vascular parameters of the penis in men with cardiovascular risk factors, PDU may also have an important role in the secondary prevention of cardiovascular events (6). However, the investigation of ED in the general medicine practice can post a huge challenge and create a great demand on available resources (2), so quick tools to screen those patients at risk of having or developing other related comorbidities may be of great importance. The Brief Sexual Symptom Checklist (BSSC) is a simple questionnaire that addresses the presence of sexual problems by an initial single question, and it has been used successfully in general medicine settings to explore overall men's health (7).

The aim of this study is to describe the clinical characteristics of our series of patients who underwent a PDU, and to investigate the relationship between the vascular parameters found, and their comorbidities, the Sexual Health Inventory for Men (SHIM) score (8), and sexual satisfaction as established by a modified version of the BSSC. The hypothesis is that current parameters to define normal status in general population are pretty low, considering SHIM scoring and general sexual satisfaction as defined by the BSSC.

We present the following article in accordance with the STROBE reporting checklist (available at <https://dx.doi.org/10.21037/tau-21-792>).

## Methods

### *Study design and patients*

Prospective, multicenter analysis of all patients who

underwent a PDU between September 2018 and April 2021 in four centers of Madrid, Spain. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Due to the observational nature of the study, with no interference in common clinical practice, no ethics committee approval was obtained, but all patients signed an informed consent to enter the study. Patients were selected according to the following criteria:

- ❖ Inclusion criteria: male patients who:
  - ◆ Were >18 years old and underwent a PDU for ED, Peyronie's disease (PD) or other reasons.
  - ◆ Signed informed consent.
  - ◆ Completed an adapted version of the BSSC.
- ❖ Exclusion criteria:
  - ◆ Low testosterone levels in the previous analysis.
  - ◆ As long as there is no follow-up period for the purpose of this study, patients with incomplete or missing data were excluded for the analysis.

### *Description of the procedure*

All patients completed the modified version of the BSSC previously. The PDU was performed in all cases by three experienced andrologist, in four clinical settings, with a linear probe with a range of 8–12 MHz. After an initial ultrasound of the flaccid penis, a standard dose of 10 mcg of alprostadil was administered in the proximal shaft of the right corpus cavernosum, with the patient in supine position. The room was always comfortable, with low light and no external noises. The peak systolic volume (PSV) and end diastolic volume (EDV) was measured at 10' and 20' in both proximal cavernous arteries. After getting the measurements, patients were instructed in the maneuvers to do if the erection maintained after 2 hours, including returning to the emergency room if lasting over 3 hours.

### *Variables collected*

For all patients, the following variables were collected: affiliation data, age at the time of the PDU, date of the test, comorbidities as smoking (current, former, never), hypertension (yes/no), dyslipidemia (yes/no), diabetes mellitus (yes/no); sexual satisfaction (yes/no), time not being satisfied (months), reason(s) of dissatisfaction (low sexual desire, erection issues, premature or delayed ejaculation, pain during erection, penile curvature or others), most important problem; score of the different items of the SHIM; reason of performing the test (ED, PD or others);

**Table 1** Baseline characteristics of the cohort

Item	Value
ED according to SHIM score	
No	40 (13.6%)
Mild	60 (20.4%)
Mild to moderate	100 (34%)
Moderate	47 (16%)
Severe	47 (16%)
Comorbidities	
Hypertension	76 (25.9%)
Dyslipidemia	85 (28.9%)
Diabetes mellitus	32 (10.9%)
Smoking history (current or former)	143 (48.6%)
Sexual satisfied according to BSSC	
Yes	42 (14.3%)
No	252 (85.7%)
Reason for sexual dissatisfaction according to BSSC	
Erection issues	241 (82%)
Low sexual desire	70 (23.8%)
Premature ejaculation	62 (21.1%)
Penile curvature	56 (19%)
Pain during erection	27 (9.2%)
Delayed ejaculation	26 (8.8%)
Other reasons	10 (3.4%)

ED, erectile dysfunction; SHIM, Sexual Health Inventory for Men; BSSC, Brief Sexual Symptom Checklist.

PSV left and right at 10' and 20' (cm/s), EDV left and right at 10' and 20' (cm/s); the erection hardness score (EHS) (9) at 10' and 20', and the vascular diagnosis given by the andrologist following other studies' parameters: normal status (PSV >35 and EDV <5), arterial insufficiency (PSV <35 and EDV <5), venous leak (PSV >35 and EDV >5) (10). For statistical analysis, the mean PSV and EDV from left and right arteries were calculated.

### Statistical analysis

Differences of vascular parameters in relation with patients' satisfaction were determined by conducting a Mann-Whitney U test the data as not normally distributed.

Normal data distribution was assessed by Shapiro-Wilk's test or/and Kolmogorov-Smirnov test. Due to not normally distributed data a Spearman's rank-order correlation was run to assess the relationship between age and vascular parameters. An analysis of covariance (ANCOVA) test was run to determine the differences of vascular parameters between patients with comorbidities, after controlling for age which is a variable selected as a potential confounder. Post hoc analysis was performed with a Bonferroni adjustment for multiple comparisons. All statistical analyses were performed using SPSS (IBM Corp. V 24.0, New York, NY, USA).

### Results

From a total of 325 patients, 16 were excluded because of low testosterone levels, and 15 due to missing data, so a total of 294 patients were included for the analysis. Mean age was 51.1 years (range, 18–79 years), and the reason for performing the PDU was ED in 221 patients (75.2%), PD in 66 patients (22.4%), and other reasons in 7 patients (2.4%). Baseline characteristics of the population are summarized in *Table 1*. Median time of non-satisfaction was 18 months (range, 1–360 months; SD =37.7).

When analyzing vascular parameters (median PSV and EDV) by groups of comorbidities, we found that PSV at 20' in patients with hypertension, diabetes and dyslipidemia was lower ( $P<0.001$ ) than in those without these conditions. This difference was also observed in patients with hypertension and diabetes at 10' measurement, but not in patients with a history of smoking, even when adjusting for age (*Table 2*). There is also a trend to find differences in EHS depending on comorbidities status, but again with the exception of smoking status. A clear correlation between age and all vascular parameters at 10' and 20' minutes was observed (*Table 3*), measuring lower PSV values and higher EDV values in those elder patients.

Significant differences were found between patients with and without ED defined by their score in the SHIM questionnaire in the PSV at 10', adjusted for age (38.07 vs. 44.95 cm/s;  $P=0.016$ ), as well as in the mean EHS at 10' (2.10 vs. 2.61;  $P=0.001$ ). Differences in the 20' measurements were observed, but with no significance (*Table 2*).

When comparing patients satisfied and non-satisfied with their sexual life, we found differences of statistical significance in the PSV and the EHS at 10', and a significant correlation with those parameters and the probability of being sexually satisfied ( $r=0.147$ ,  $P=0.011$ ;  $r=0.132$ ,  $P=0.023$ ;

**Table 2** Vascular parameters in relation with patients' comorbidities and ED

Comorbidity	Yes	No	P value
Hypertension	n=76	n=218	
Median PSV 10'	34.60 cm/s	42.30 cm/s	<0.01
Median EDV 10'	5.70 cm/s	5.50 cm/s	0.712
Median EHS 10'	2	2	0.007
Median PSV 20'	35.64 cm/s	45.55 cm/s	<0.01
Median EDV 20'	0 cm/s	0 cm/s	0.546
Median EHS 20'	3	3	0.077
Dyslipidemia	n=85	n=209	
Median PSV 10'	37.16 cm/s	40.65 cm/s	0.056
Median EDV 10'	6.31 cm/s	4.95 cm/s	0.396
Median EHS 10'	2	2	0.025
Median PSV 20'	35.88 cm/s	45.48 cm/s	<0.01
Median EDV 20'	0 cm/s	0 cm/s	0.746
Median EHS 20'	3	3	0.030
Diabetes mellitus	n=32	n=262	
Median PSV 10'	34.17 cm/s	40.57 cm/s	0.046
Median EDV 10'	6.62 cm/s	5.35 cm/s	0.155
Median EHS 10'	2	1	<0.01
Median PSV 20'	33.01 cm/s	45.29 cm/s	<0.01
Median EDV 20'	0 cm/s	0 cm/s	0.468
Median EHS 20'	3	3	0.055
Smoking history	n=143	n=151	
Median PSV 10'	40.78 cm/s	41.47 cm/s	0.700
Median EDV 10'	5.29 cm/s	4.17 cm/s	0.073
Median EHS 10'	2	2	0.360
Median PSV 20'	43.51 cm/s	44.96 cm/s	0.430
Median EDV 20'	3.14 cm/s	2.90 cm/s	0.730
Median EHS 20'	3	3	0.230
ED	n=254	n=40	
Median PSV 10'	38.07 cm/s	46.43 cm/s	0.016
Median EDV 10'	5.50 cm/s	6.50 cm/s	0.532
Median EHS 10'	3	2	0.001
Median PSV 20'	43.07 cm/s	48.32 cm/s	0.052
Median EDV 20'	0 cm/s	0 cm/s	0.085
Median EHS 20'	3	3	0.605

Data were adjusted for age with an ANCOVA test. ED, erectile dysfunction; PSV, peak systolic volume; EDV, end diastolic volume; EHS, erection hardness score; ANCOVA, analysis of covariance.

**Table 3** Association between vascular parameters and age

Parameter	Rho	P value
Median PSV 10'	-0.229	<0.001
Median EDV 10'	0.134	0.021
Median PSV 20'	-0.327	<0.001
Median EDV 20'	0.178	0.003

Test: Spearman rho. PSV, peak systolic volume; EDV, end diastolic volume.

**Table 4** Vascular parameters in relation with patients' satisfaction

Satisfied	Yes (n=42)	No (n=252)	P value
Median PSV 10'	44.84 cm/s	37.80 cm/s	0.011
Median EDV 10'	0 cm/s	5.74 cm/s	0.246
Median EHS 10'	2	2	0.024
Median PSV 20'	48.18 cm/s	42.20 cm/s	0.053
Median EDV 20'	0 cm/s	0 cm/s	0.436
Median EHS 20'	3	3	0.172
Median SHIM score	21	14	<0.001

Test: Mann-Whitney U. PSV, peak systolic volume; EDV, end diastolic volume; EHS, erection hardness score; SHIM, Sexual Health Inventory for Men.

respectively). Also, differences were found between sexual satisfaction and the SHIM score, with a higher median punctuation in those sexually satisfied (21 *vs.* 14;  $P=0.012$ ). In contrast, no differences were found between the PSV and EHS at 20', or the EDV at any time (*Table 4*). The relation between sexual satisfaction and the PSV and EHS at 10', and SHIM score is summarized in *Figure 1*.

## Discussion

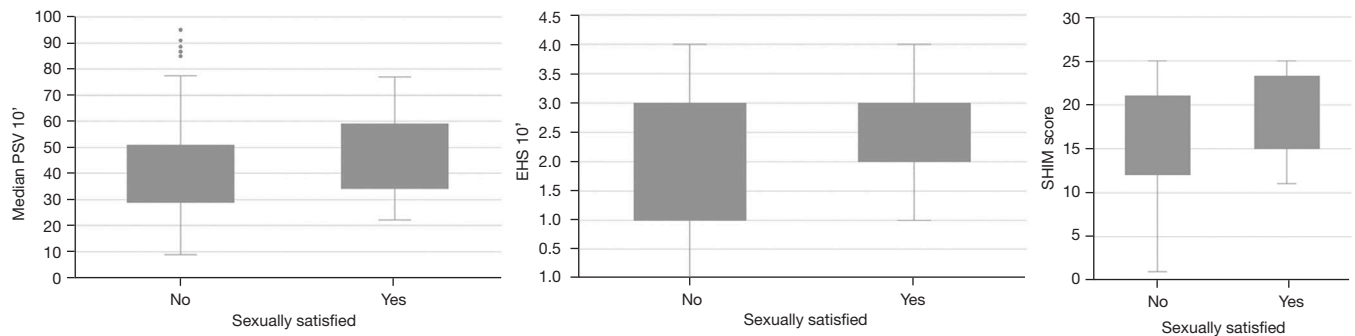
Although the diagnosis of ED in primary medicine practice still involves only clinical evaluation, physical examination and laboratory test (10), it is important to address that it has been established as an independent risk factor for cardiovascular disease. A recent study found that patients with severe ED and lower scoring in validated questionnaires, but with no other vascular risk factors known at the time of diagnosis, have a 30% higher risk of developing hypertension or cardiovascular disease in a period of 10 years (11). More specifically, patients with a

PSV <25 cm/s in the cavernous arteries during an erection, were found to have a hazard ratio (HR) of 1.57 for suffering a major cardiovascular event (6). For this reason, we think that there is an important role in the measurement of the vascular parameters, even though there are studies that conclude that PDU add no important information to a standard intracavernous injection test (12): it is the only way to precisely know the current vascular status of the patient, as long as he could be sexually dissatisfied or complain about ED with PSV of >25 cm/s.

There is still a need to standardize the technique for performing a PDU, considering that in the available literature many variations are described regarding the vasoactive agent used, its dose, the need of additional injections, the timing of the measurements and, most importantly, the cut-off levels of the PSV and EDV (13). A threshold of PSV >30 cm/s has been traditionally considered to be normal (14), but in our clinical practice we preferred to use the cut-off of >35 cm/s, given that it is the proposed in recent, well-conducted study (10), and there is still some margin to the cut-off proposed to be at high-risk of developing a major cardiovascular event (<25 cm/s) (6). The median values observed in our series support this choice, as long as PSV at 10' time was 38.07 cm/s for those patients with any grade of ED as defined by the SHIM, in contrast to the value of 44.95 cm/s observed in those without ED. No differences were observed at the 20' time.

Regarding sexual satisfaction, 85.7% of the patients of our series reported to be non-satisfied in the BSSC, a rate that is consistent with a cohort that underwent evaluation with a PDU for different reasons, but mainly ED. This fact also can explain the high rates observed in comorbidities as hypertension, dyslipidemia, diabetes or smoking history (*Table 2*), along with the age. Differences observed in the PSV for those patients satisfied and non-satisfied with their sexual life (44.84 *vs.* 37.80 cm/s;  $P=0.011$ ) resulted to be significative at the 10' time, but not in the 20', and similar results are observed with the EHS (*Table 3*). The similarity of the values obtained in sexually and non-sexually satisfied patients with those without and with ED, as defined by the SHIM, backs up the BSSC as a valid questionnaire to select those men at risk of developing sexual dysfunctions, in the line with previous studies (7).

All the significative differences in PSV were found at the 10' evaluation (*Table 4*) for both ED and sexual satisfaction (*Tables 2,4*). This could be a consequence of an insufficient size of the sample, as long as a trend was observed in the 20' figures, or show that the 10' evaluation is more sensitive



**Figure 1** Box plots comparing median PSV and EHS at 10', and SHIM score with sexual satisfaction. PSV, peak systolic volume; EHS, erection hardness score; SHIM, Sexual Health Inventory for Men.

than the 20'. This finding is very important in order to achieve the objective of standardization of the technique. We think that, as long as the 10' measurement is the most important to make the diagnosis, the 20' should be performed to confirm the findings, always putting together the PSV, EDV and EHS values.

This study has been conducted in four experienced centers, all the tests performed by three experienced andrologists, with strict, homogeneous criteria, and all the authors consider this its main strength. However, it has limitations. The main is the lack of a "normal" cohort to compare all the measurements and, consequently, define a new cut-off level of PSV for ED and for sexual satisfaction, in line with the thoughts of the team that the current of 35 cm/s is too low. Although the sample is not small, the search for these small differences requires a higher number of patients involved. Another limitation is the lack of proper assessment of depression or anxiety with specific questionnaires in the sample, as long as it could a reason of sexual dissatisfaction.

## Conclusions

Differences in systolic parameters between patients with ED and sexual satisfaction seem to be similar, but the current cut-off levels of PSV may be quite low. The 10' measurement may be more sensitive in order to establish a diagnosis. BSSC questionnaire is a simple, easy-to perform tool to screen those patients at risk of developing sexual dysfunctions. There is a need of more, well-performed and with a higher number of patients in order to continue the standardization of the technique.

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## Footnote

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*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Due to the observational nature of the study, with no interference in common clinical practice, no ethics committee approval was obtained, but all patients signed an informed consent to enter the study.

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