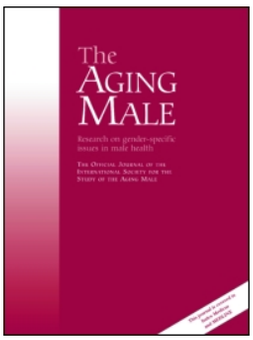

The Aging Male

ISSN: 1368-5538 (Print) 1473-0790 (Online) Journal homepage: https://www.tandfonline.com/loi/itam20

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To cite this article: Bogdan Pajovic, Antonio Dimitrovski, Nikola Fatic, Milos Malidzan & Marko Vukovic (2017) Vacuum erection device in treatment of organic erectile dysfunction and penile vascular differences between patients with DM type I and DM type II, The Aging Male, 20:1, 49-53, DOI: 10.1080/13685538.2016.1230601

To link to this article: https://doi.org/10.1080/13685538.2016.1230601

Published online: 01 Oct 2016.

The Aging Male

http://informahealthcare.com/tam
ISSN: 1368-5538 (print), 1473-0790 (electronic)

Aging Male, 2017; 20(1): 49–53
 DOI: 10.1080/13685538.2016.1230601

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ORIGINAL ARTICLE

Vacuum erection device in treatment of organic erectile dysfunction and penile vascular differences between patients with DM type I and DM type II

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Abstract

The aim of this study is to investigate changes in the vascular system and hemodynamics between patients with organic erectile dysfunction (ED) (DM type I and II), as well as to compare the quality of sexual life between those two groups after the treatment with vacuum erection device (VED). Study enrolled 50 males with DM, aged from 35 to 67 years, who have attended the urologic clinic due to inability to attain and maintain an erection of the penis sufficient to permit satisfactory sexual intercourse. Patients were using VED and six months later were assessed for therapy results. The International Index of Erectile Function (IIEF) was used to quantify erectile dysfunction. Alprostadil injection test was also used, with Doppler color flow imaging system, to evaluate the peak systolic velocity (PSV) and diameter of cavernosal artery (DCA). Significantly higher values of PSV were obtained in patients with DM type II. Also, DCA showed significant difference between two groups of patients. There was significant improvement in three items of IIEF after six months of treatment among both groups of examinees. Patients with DM type I had more serious risk for development of arteriogenic ED. VED could be a good alternative therapy for patients who denied peroral therapy.

Keywords

Erectile dysfunction, vacuum erection device, diabetes mellitus

History

Received 14 August 2016
Revised 25 August 2016
Accepted 26 August 2016
Published online 14 September 2016

Introduction

Erectile dysfunction (ED) is defined as the consistent or recurrent inability to attain and maintain a penile erection sufficient for sexual intercourse [1]. It should not be regarded only as a quality of life (QoL) issue, but also as a potential warning sign of cardiovascular disease [2]. It is already known that diabetes mellitus (DM) is a well-established risk factor for ED and that ED affects 50% overall and 30% of treated diabetics [3]. The primary mechanism that links increased risk of ED to diabetes is suggested to be vascular and neural. It is clear that microangiopathy of the cavernosal artery, corporal veno-occlusive dysfunction and autonomic neuropathy are the primary pathophysiological pathways for ED [4]. There is no special protocol for treatment of ED in diabetic patients other than in the treatment of ED in general population. When first line therapy with phosphodiesterase type 5 (PDE5) inhibitors is ineffective or contraindicated, patients should be offered other non-surgical treatment choices such as intracavernous injection therapy, intraurethral alprostadil and vacuum constriction devices [5].

The vacuum erectile device (VED) uses negative pressure to increase blood inflow into the corpora cavernosum, with a ring at the base of the penis to maintain erection for intercourse or without a ring for penile rehabilitation [6]. It is used when pharmacotherapies have failed and in patients with stable relationship [2]. It is widely believed that VED therapy is more acceptable among elderly patients with occasional sexual intimacy, as younger patients may show limited acceptance because of its perceived ''unnatural'' erection [7]. As the population continues to age, acquiring the comorbidities commonly associated with ED, such as hypertension, diabetes mellitus and atherosclerotic vascular disease, the demand for VED should persist or even increase [8]. Despite the high prevalence of this condition in patients with diabetes, little is known regarding differences in QoL between ED patients with DM type I and II. Thus, the aim of our research was to investigate changes in the vascular system (cavernosal artery) and hemodynamics between patients with organic ED (DM type I and II), as well as to compare the quality of sexual life between those two groups after the treatment with VED.

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Methods

We have performed a prospective study which enrolled 50 males with DM, aged from 35 to 67 years (average 49.9) who have attended the urologic clinic due to inability to attain and maintain an erection of the penis sufficient to permit satisfactory sexual intercourse. Patients were divided into two groups, according to DM type, where DM type 1 numbered 30 patients and DM type 2 numbered 20 examinees. Patients who attended the Urological department were already diagnosed by family doctors in regard to genesis of DM. After admission to our clinic we took thorough patients' history and examined blood glucose levels and HbA1C, which were used as comparison criteria between groups (Table 2). Patients from the first group had medical history of DM longer than 10 years, whereas examinees in the second group, no longer than five years. Inclusion criteria for patients were: at least three months duration of symptoms [9], low cardiovascular risk category [10], prior unsuccessful usage of PDE5 inhibitors and patients in steady relationship. Exclusion criteria were: patients on anticoagulation therapy, those with penile anomalies, patients with prostate disease, endocrinological disorder despite DM and psychiatric disorders.

History and physical examination

Patients were thoroughly questioned about their sexual life (onset of ED, duration of problem, presence of erections, loss of libido, relationship issues), their medical and surgical history (duration of DM, hypertension, neurological or endocrine disorders, prostate disease and surgery, trauma). Full physical examination was performed: cardiovascular, neurological, abdominal; digital rectal examination (DRE) was obtained as well as external genitalia assessment to exclude foreskin phimosis or penile deformities or lesions [11].

Laboratory tests

Following laboratory tests were performed for every patient: fasting glucose, lipid profile, serum total testosterone [12] and total PSA, the latter one for exclusion of the prostatic pathology. We also measured HbA1C % for every patient, at the beginning of the study. Patients were on regular and standard therapy for diabetes mellitus (insulin and oral medications) and active in life-style changes without therapy. Total testosterone (T) was measured in serum, on two occasions, early in the morning, and was analyzed within 1 h after collection, by using a chemiluminescence immunoassay (Architect i2000SR, Abbott Laboratories, Philippines).

Intracavernosal injection (ICI) test

This was done for all patients using 10 μg of alprostadil, according to current protocol [12]. During the onset of erection, the patient was left alone and asked to stimulate the penis manually. After injection, every patient was evaluated using Doppler color flow imaging system equipment with 7.5 MHz linear-array transducer (Hewlett-Packard-Sonos 1000; Providian Medical Equipment LLC, Willowick, OH). The peak systolic velocity (PSV) and diameter of cavernosal artery (DCA) were recorded sequentially at five minutes interval for up to 20 min [12]. According to instructions, normative values for PSV of the cavernous arteries after pharmacostimulation range from 35 cm/s to 47 cm/s in normal subjects [13].

VED usage

Patients were advised to use VED which comprises standard three components [14]. Instructions on the use of vacuum method followed by audio-visual presentation were given to each patient. We recommended that the constriction ring should not be left on for >30 min to prevent ischemic injury to the penis [7]. Six months later patients were invited for an interview and assessment of therapy results. The device should be used at least four times per month [5]. The International Index of Erectile Function (IIEF) was used to quantify ED and determine its differences in score and degree between two groups of examinees [15], prior the treatment, as well as six months after it.

Statistical analysis

Statistical analysis has been performed by the Statistical Package for Social Sciences (SPSS) version 11 for Windows software package (SPSS Inc., Chicago, IL). Methods of statistical description included the Z test for proportion and Student's t test, in order to determine statistical significance. The difference of the obtained values was considered to be significant when $p<0.05$, and highly significant when $p<0.01$.

Ethics

Each subject signed the acceptance of the study protocol, in which the Ethical Principles for Medical Research Involving Human Subjects (The Helsinki Declaration) were clearly stated. They all signed the written consent form.

Results

Two months after commencing the study, nine patients discontinued examination: three patients came back to therapy with PDE 5 inhibitors and others had problems with dissatisfied partners or suffered conflict in relationship. The examination continued with 41 males. In 35 patients (85%), the obtained blood flow into the penis enabled normal sexual intercourse. Six other patients (15%) did not have satisfying penis rigidity. Two patients were complaining of severe pain while applying the ring on the base of the penis. Coldness of the penis with subsequent inability to have sexual intercourse and partner's dissatisfaction were present in two patients. Complications in the form of petechial bleeding occurred in three patients but these patients did not hold to 30 min duration of sexual intercourse nor constriction of the penis. None of the patients had increased levels of T nor PSA levels >4.

PSV and DCA mean values before and after ICI of Alprostadil are presented in Table 1. We initially compared differences in both groups separately, 5 and 20 min interval after ICI, as well as between groups together. Table 2 reveals the comparison between PSV, blood glucose levels and

HbA1C between two groups of examinees, aiming to estimate the influence of proper blood glucose control on erectile function. Changes in IIEF scores in both groups of patients, prior and six months after the treatment using vacuum devices are presented in Table 3.

Discussion

Our study clearly showed significantly higher values of PSV in patients with DM type II, over the examinees with DM type I, initially (34.1 cm/s vs. 19.7 cm/s), as well as 20 min after ICI (38.2 cm/s vs. 26.1 cm/s). Also, DCA showed significant difference between two groups of patients, initially (0.12 cm vs. 0.47 cm), as well as five (0.16 cm vs. 0.52 cm) and 20 min (0.19 cm vs. 0.60 cm) after ICI of alprostadil. Cavernous arterial insufficiency is suggested when PSV is less than 25 cm/s and PSV consistently greater than 35 cm/s defines normal cavernous inflow [12]. Secondary diagnostic criteria for arteriogenic ED include an increase in the diameter of the cavernosal artery of less than 75% after ICI [16]. According to those standards, our study clearly revealed arterial insufficiency in patients with DM type I, whereas patients with DM type II had almost normal cavernous inflow prior to the therapy. This could impose on importance of duration and type of DM as significant influential factor in prognosis and treatment of diabetic patients with ED. Also, blood glucose levels and HbA1C values were significantly higher among first group of patients, which confirmed positive correlation between poor glucose regulation and vascular insufficiency. Study made by Almehmadi et al. [17] showed positive correlation between the prevalence of DM (both types) and ED. They also claimed that severe ED is prognostic indicator of co-morbidities in men with hypogonadism, which was not discussed in our study. Prior study has already shown that duplex ultrasonography after intracavernous injection could reveal a high prevalence (>75%) of penile arterial insufficiency among diabetic men with ED [18]. Nevertheless, the study did not compare two forms of DM, and thus made it obscure, which form predominates in provoking arterial insufficiency. Lue et al. [19] claimed that PSV of the cavernous arteries, when exceeding 25 cm/s within five minutes of vasodilator injection, imply a nonarteriogenic cause of ED, which would suggest, according to our results, that DM type I could have arterial insufficiency as the primary cause of ED, whereas DM type II had some other, nonarteriogenic cause of ED.

For patients who cannot take PDE5 inhibitors, or are proven non-responders, the vacuum constriction device continues to serve as a major treatment option [20]. The effectiveness of VED has been established for different causes of ED [7]. For diabetic ED, Arauz–Pacheco et al. [21] and Bodansky et al. [5] reported successful rates of 75% and 58%, respectively. Our results of 85% successful rate indicated correlation with this, as well as with other studies [22,23] which showed that 83.5% and 81% of patients continue to use the device for intercourse as desired. According to our study, VED could be a good alternative therapy for patients who denied peroral therapy. Study from Nunez Mora et al. [24] showed, like our study, that males with a stable partner and impotence arising from venous leakage or mild cavernous artery insufficiency are the ideal candidate.

There are no contemporary data regarding QoL of DM patients, after treatment with VED as monotherapy. We found VED as very effective, safe and promising treatment modality in DM patients, especially in DM type II. According to our

Table 1. Peak systolic velocity (PSV) and diameter of cavernous artery (DCA) before and after intracavernous injection (ICI) of alprostadil.

	PSV (cm/s)	DCA (cm)
Mean		
Group IDM type I	PSV (cm/s)	DCA (cm)
Initial	19.7 (2.4)	0.12 (0.03)
After ICI (5 min)	24.3 (3.4)*	0.16 (0.04)*
After ICI (20 min)	26.1 (3.1)*	0.19 (0.02)*
Group II DM type II		
Initial	34.1 (4.3)†	0.47 (0.07)†
After ICI (5 min)	36.7 (6.2)*	0.52 (0.13)†
After ICI (20 min)	38.2 (5.4)*,†	0.60 (0.09)*,†

*Statistically significant difference compared with initial values among corresponding groups.
†Statistically significant difference between Group I and Group II.

Table 2. Peak systolic blood flow (PSV) estimation using color-duplex ultrasonography. Blood glucoses levels and HbA1C are evaluated too.

	Peak systolic velocity (cm/s)	Blood glucose levels	HbA1C (%)
Mean (SD)			
Group IDM type I			
	19.7 (2.7)	14.1 (3.7)	11.2 (3.1)
Group IIDM type II			
	34.1 (3.3)	9.15 (2.5)	8.3 (2.6)
p values	<0.01	<0.01	<0.05

Table 3. Changes in IIEF scores in both groups of patients, prior and six months after the treatment using vacuum devices.

	Erectile function (items 1–5, 15)	Intercourse satisfaction (items 6–8)	Orgasmic function (items 9 and 10)	Sexual desire (items 11 and 12)	Overall satisfaction (items 13 and 14)
Mean (SD)					
Group I DM type I					
Initial	8.8 (3.64)	5.36 (2.98)	5.4 (2.98)	8.6 (2.09)	3.23 (2.26)
Six months	14.77 (6.77)*	9.87 (2.53)*	5.80 (2.49)	9.22 (2.92)	7.87 (2.12)*
Group IIDM type II					
Initial	10.43 (2.99)	6.06 (3.34)	6.18 (2.99)	9.09 (1.04)	4.09 (2.34)
Six months	19.09 (6.32)*,†	10.61 (2.47)*	6.90 (1.70)	9.3 (0.94)	7.09 (1.92)*

IIEF: international index of erectile function questionnaire.
*Statistically significant difference compared with initial values among corresponding groups.
†Statistically significant difference between Group I and Group II after six months treatment period..

results, there is significant improvement in three items of IIEF (erectile function, intercourse satisfaction and overall satisfaction), after six months of treatment among both groups of examinees. Besides that, after six months of treatment, the second group of patients had significantly better erectile function than the first one, which confirms better prognosis of ED treatment in patients with DM type II. A study carried out by Bodansky et al. [5] showed that the partner's sexual satisfaction and self-esteem significantly increased over six months, after the treatment with VED. In those continuing to use the device, it was considered highly effective, painless in use and not embarrassing. This study, however, included patients with autonomic neuropathy and did not use IIEF as objective symptom scale, thus results could not be completely comparable. Nonetheless, recent data claims that diabetes has been associated with a greater prevalence of decreased desire and orgasmic dysfunction, and that a higher odds ratio is seen with insulin-dependent diabetes mellitus [12].

Our study showed several complications in nine patients after treatment with VED: penile pain, coldness of the penis and petechial bleeding. Despite this, VED treatment indicated a high level of satisfaction and only six patients reported that vacuum device did not lead to adequate level of erection for satisfying sexual intercourse. Still, according to previous studies [22,25,26] the most common reasons for patients' dissatisfaction were penile pain, inconvenience, loss of rigidity, painful ejaculation and sensation of trapped ejaculate. This could be the reason why some studies claim that only 12% of patients choose VED as a preferable treatment modality [27]. However, our study examined patients with DM, who have already tried other treatment modalities and, due to dissatisfaction, chosen to use VED. Lack of our study, however, includes the absence of a control group and failure to determine PSV and DCA after the treatment with VED. Nevertheless, our focus was on determination of QoL in diabetic patients with ED as well as in determining the differences in vascular impairment between the two diabetic groups.

Our study did not include hormonal role in ED nor the influence of endocrine profiles on cardiovascular function. Study made by Condorelli et al. [28] showed that physical activity in association with PDE5 inhibitors could compensate the effects of hypogonadism on erectile function and facilitate the clinical response to these drugs even in the absence of adequate serum concentrations of total testosterone. Nevertheless, study made by Saad et al. [29] suggested that aging and obese men with DM type 1 might have subnormal testosterone levels and that their glycemic control, lipid profiles and erectile function might benefit from testosterone replacement therapy. Besides that, recent data confirm the overall beneficial effect of all testosterone treatment modalities on metabolic and cardiac risk factors [30]. This could be important information for our further research on this topic, where we plan to correlate testosterone levels with endocrine function in patients with DM and its influence on erectile function.

Conclusion

Results showed that patients with DM type I had more serious risk for development of arteriogenic ED than patients with DM type II. The cause is probably longer period of effects of high concentration of glucose on the arterial wall and endothelium. The additional indicator is also a higher level of HbA1c in patients with DM type I and that means a longer period of inadequate control of the disease. Using Color-Duplex ultrasonography, changes in PSV and DCA indicated worse situation in patients with DM type I and this result correlates with higher level of HbA1c and worse control of glucose level. VED is a very effective, safe and promising treatment modality in those patients, especially in DM type II. Aging, level of cholesterol and hypertension could also have implications in our results but during this study we did not investigate these parameters. Future randomized studies should follow up patients' PSV and DCA after the treatment and consider combined therapy (VED and PDE5 inhibitors) as a potential treatment option in patients with DM.

Declaration of interest

No part of this paper has been presented, published, or submitted for publication elsewhere in this or in any other language.

This clinical study was conducted in accordance with the principles laid down in the WMA Declaration of Helsinki along with the strict respect of patient's rights and clinical study protocol. Patient confidentiality and data security are guaranteed.

Authors did not have any support in funding of the paper. The authors of this paper hereby declare that have not received nor shall receive any financial benefits from publishing the paper, neither have they received any financial incentive from a third party. We, the author and co-authors, hereby solemnly declare that we are not in any situation which could give rise to a conflict of interest.

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