

Original Article

Comparing the Effects of Vacuum Constrictive Devices and Intra-Cavernosal Injection of Papaverine for Erectile Dysfunction

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HIGHLIGHTS

- Evaluation of vacuum constrictive device (VCD) and intracavernosal injection (ICI) of papaverine for the treatment of ED.
- For treatment protocol of the ED, the patient's wife should be considered in addition to the patient's condition.
- The study showed that in unconsummated couple's vasoactive drugs injection in corpus cavernosum as first-choice of second-line therapy will be more successful.

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ABSTRACT

Introduction

For erectile dysfunction (ED) treatment, Vacuum therapy (VT) utilizes negative pressure to distend the corporal sinusoids and to increase the blood inflow to the penis. In the current study, we evaluated the vacuum constrictive device (VCD) and intracavernosal injection (ICI) of papaverine for the treatment of ED.

Methods

A total number of 80 ED were divided into 4 groups of 20 couples. The first group was treated with Papaverine who had a virgin wife (a). The second group was unconsummated marriage couples who were treated with vacuums (b). The third group was and the couples with experience of sexual intercourse who had been treated with Papaverine injection (c). The fourth group was the couples with experience of sexual intercourse that were treated with a vacuum device (d).

Results

After 4 months of treatment, all patients were able to have sex. In the unconsummated couples group treated with papaverine and consummated couples treated with papaverine, all of the indicators of the erectile function were significantly increased compared to pre-treatment (p -value <0.05). There were no significant differences between the two methods in terms of other complications such as ecchymosis, blisters, headache, cutaneous rash, and vaso-vascular shock (p -value >0.05).

Conclusions

This study showed that in patients with erectile dysfunction who are having virgin spouses and who are not responding to the first line of oral medication that 5-inhibitors phosphodiesterase can be the excellent candidate for ICI of vasoactive drugs therapy.

Keywords: Erectile Dysfunction; Papaverine; Vacuum Constrictive Device; Intra-Cavernosal Injection

Introduction

Erectile dysfunction (ED) is defined as an inability to create or maintain an erection that is necessary for satisfactory sexual activity (1). Although erectile dysfunction is a

benign disorder, it has a significant effect on physical, mental health and changes the patient's quality of life (2). In the past, erectile dysfunction was considered, in most cases, to be a purely psychogenic disorder, but current

evidence suggests that more than 80% of cases have an organic etiology (3). Erection is a neurovascular tissue phenomenon that is controlled by hormones. This action includes vascular dilation, smooth muscle relaxation, and corpus cavernosum activation mechanism of the trabecular blockage which leads to entrapment of blood in the penis which will lead to erection (4, 5). Epidemiological studies indicate the worldwide prevalence of ED and estimated to be 3-76.5% of people worldwide prevalence and this number increase with aging (6). Age is the strongest predictor of erectile dysfunction (7). Risk factors for erectile dysfunction include lack of sufficient physical activity, obesity, smoking, high blood cholesterol, and metabolic syndrome (8, 9). The most important pathophysiological mechanisms of erectile dysfunction are microvascular angiopathy. So, atherosclerosis of the pelvic artery arises as a background process (10).

As a rule, erectile dysfunction can be modified successfully with existing methods, but cannot be cured completely and definitively. Only certain types of erectile dysfunction, including psychogenic ED, arterial ED caused by trauma in young patients, and hormonal ED can be treated completely (11, 12). Treatment that is used for erectile dysfunction includes Lifestyle changes, 5-phosphodiesterase inhibitors, injected of vasoactive drugs into the corpus cavernosum intracavernosal injection of vasoactive substances (ICI), vacuum constriction devices (VCD) (13-15). VCD leads to passive congestion of the corpus cavernosum and creating an erection which could be maintained by placing a constrictive ring at the base of the penis, preventing the outflow of blood from the corpus cavernosum, so the erection with this device is not natural (16). The most common side effects of using vacuum devices include Pain, inability to ejaculate, petechiae, tingling, and numbness in less than 30% of patients. Vacuum therapy is considered one of the basic treatment modalities for ED (17). VCD could be an effective treatment modality.

Another way to treat erectile dysfunction injection of vasoactive drugs into the corpus cavernosum of the penis. ICI of vasoactive drugs continues to be a highly effective and safe treatment tool for men with wide varieties of ED etiologies (18). three drugs often used for injection: alprostadil, papaverine, and phentolamine. These drugs can be used alone or in various combinations with each other. Taking this drug in patients with mood instability - psychological, history of priapism, history of severe coagulation disorders, cardiovascular disease, or use of monoamine oxidase inhibitors is contraindicated. One of the most important side effects of injection in the penis is the occurrence of priapism (19-21). Unconsummated marriage is said to be that married couples are not able to have successful sexual intercourse at the beginning of the marriage, and therefore the wife will remain a virgin (22).

One of the most important physical, psychological, and cultural-social factors involved in the unconsummated marriage are Premature Ejaculation, erectile dysfunction, vaginismus, hypersexual desire, sexual anxiety, Social-cultural factors, lack of privacy, Former abnormal sexual relations (23).

Sexual function is one of the most important needs of marital life. According to studies, the cause of more than half of the differences leading to divorce in traditional societies is the lack of proper sexual intercourse (24-26). Since the first line of therapy for patients is phosphodiesterase inhibitors and it is not effective in 30% of patients and duration of effectiveness vanishes in 6% of patients on a yearly basis so many patients require other treatments (27). According to the latest Urology guideline, a VCD and ICI are the next treatment line, but in none of the references and studies, there is no comparative study on the effect of these two methods. In European Urology guidelines, the use of vacuum devices as the first line of treatment for erectile dysfunction is expressed and in the American Journal of Urology, the VCD and ICI of vasoactive drugs are both considered at the same level as the second line of treatment. Since there are controversial information about the effects of vacuums on unconsummated marriage, comparative study is necessary.

Methods

This study is a randomized clinical trial (IRCT2016013126298N1). Our target community is the unconsummated marriage and the couples with experience of sexual intercourse who referred to the Shahed University Family Health Clinic due to their impotence and has been screened for the diagnosis of erectile dysfunction. The sample size is at 80 cases that refer to the family health clinic of Shaheed University for fifteen years due to erectile dysfunction. For establishing the basis of the study patients were divided into 4 groups of 20 couples. The clinical entry criteria for patients where all patients should have organic erectile dysfunction.

All Patients should attain complete erection with a vacuum device or ICI of Papaverine at the training session designed for the study. Oral medicines were not effective in any of the patients, or have a contraindicated or patient developed side effect during the use of these drugs.

The wife of all unconsummated couples was evaluated by a gynecologist for vaginismus and virginity and if they were not virgins, they were excluded from the group of couples which include unconsummated couples. In consummated couples group the last date of intercourse with full rigid penis penetration was also asked and if it was more than six months patient was advised to have more regular intercourse and also dilate the vagina by a finger before sex to ease better penetration. In each of the four groups after the complete description, complete

explanation, and acceptance, the treatment is given to the patient and his wife (7, 28, 29). Required information about possible complications and effective measures to be taken were given to all couples.

The exclusion criteria are:

1- Psychological problem inpatient or his wife such as nonsexual erection, sexual anxiety, patient with good nocturnal or morning erection, 2- Vaginismus, 3- Patients with no secondary sexual characteristics or hormonal impairment, 4- Premature ejaculation (PE), 5- Patients who tended to change their treatment, 6- Patients whose wife are not willing to continue treatment, 7- Patients who have developed side effect, not willing to continue using Papaverine injection or vacuum device therapy (28, 29), 8- Patients with hypertension, 9- Unstable status regarding the continuation of living together, 10- Homosexual, 11- Patient in whom full rigid erection was not attained by either of treatment modalities. After examining the criteria for entering and leaving, patients are divided into 4 groups.

a) Unconsummated marriage who are treated with Papaverine, b) Unconsummated marriage who have treated with vacuum constrictive device, c) Couples with experience of sexual intercourse who have been treated with Papaverine, d) Couples with experience of sexual intercourse who have been treated with vacuum constrictive device

Patients treated with papaverine will be trained in the first session of the Papaverine injection. They will be treated appropriately if they developed priapism. In this study, Papaverine is used in a various dose ranging from 20 to 80 mg, till patient achieve a fully rigid erection sufficient for penetration. In the other groups of patients who are being treated with vacuum devices, the correct use of vacuums is also taught. At the beginning of the study, patients are taken to be written consent, including information on the treatment and complication.

A week after starting treatment, all patients are called to ensure the effectiveness of the treatment. Patients are contacted every month to evaluate the progression of treatment, and each patient visit is completed with a patient-designed questionnaire. All patients are recruited 4 months after the start of the therapy and at least 15 times sex and the effects of treatment and complications were also investigated. In this study, an international index of erectile function was used to assess the quality of treatment. This test examines the quality of sexual intercourse in the five areas of erectile function, sexual intercourse, orgasm performance, sexual desire, and ultimately overall satisfaction (30).

Descriptive statistics were used for estimating mean, standard deviation, frequency. For statistical analysis and comparison of the two groups, the Chi-square test and nonparametric tests such as Wilcoxon and Mann-Whitney were used. The Chi-square test was used to measure the

normal distribution of data.

Results

In this study, 80 men with pure organic sexual dysfunction as inclusion criteria enrolled in the study. The average age of patients was 30 ± 5.8 years (21-70 years).

These patients are divided into 4 groups: (a)The first group unconsummated marriage couples who had been treated with Papaverine. This age group was 28 ± 4.3 years old and the average duration of marriage was 59 days (14-170 days). All of these patients had a virgin wives. (b)The second group was unconsummated marriage couples who were treated with vacuums. The mean age of these patients was 26.4 ± 4.8 with an average duration of marriage was 81 days (10-192 days). The wives of all of these patients were also virgins. All of these patients had an erection in the first session of the treatment; all of them were trained by the therapist expert in applying the vacuum device. After 4 months of use of the vacuum device, only 1 out of 20 patients were able to proximity successfully, and 19 patients had no had been able to maintain sufficient erection for penetration. (c) The third group was and the couples with experience of sexual intercourse who had been treated with Papaverine injection. The average age of this group was 35 ± 6.3 years and the average age of marriage was 3.7 ± 4.05 years (2-15 years). After 4 months of papaverine injection, all 20 patients were able to sex successfully. (d) The fourth group was the couples with experience of sexual intercourse that were treated with a vacuum device. The average age of the group was $31/2 \pm 5/1$ years and the average duration of the marriage was $8 \pm 3/2$ years (1-16 years). In seven patients the time past from last intercourse was more than six months of whom five required vaginal dilatations by their husband to facilitate successful intercourse. After 4 months of treatment, all patients were able to have sex (Table 1-4). The severity of the complications of the two target methods VCD and ICI is given in Table 5.

Data were analyzed using Wilcoxon, Kolmogorov-Smirnov, and Mann-Whitney tests. The results of a questionnaire that was presented to the patients according to the International Standard for the Erection of Erection showed that the vacuum device can provide an adequate erection in all patients (Figure 1).

According to the results obtained in the unconsummated couples group treated with papaverine and consummated couples treated with papaverine, all of the indicators of the erectile function were significantly increased compared to pre-treatment (p -value <0.05). In the group of the couples with the virgin wife that was treated with vacuum only in the field of erectile function, there was a significant difference compared to before treatment. (p -value <0.05) But in other areas and the total amount of erectile function, the information before treatment was almost identical and sometimes even scores decreased

Table 1. Frequency of distribution of variables before and after treatment in the couples with experience of sexual intercourse treated with ICI of papaverine

	Erection ability	Orgasm ability	Sexual desire	Sexual satisfaction	Satisfaction of marital relationship
Before treatment	10.7	3.8	3.7	5.3	3.4
After treatment	24.5	8.05	7.75	11.8	8.52

Table 2. Frequency of distribution of variables before and after treatment in the couples with experience of sexual intercourse treated with VCD

	Erection ability	Orgasm ability	Sexual desire	Sexual satisfaction	Satisfaction of marital relationship
Before treatment	9.3	5.6	1.8	6.7	3.9
After treatment	27.3	6.3	7.5	11.3	8.9

Table 3. Frequency of distribution of variables before and after treatment in the couples with virgin wife treated with injection of Papaverine in corpus cavernous

	Erection ability	Orgasm ability	Sexual desire	Sexual satisfaction	Satisfaction of marital relationship
Before treatment	11.9	4.3	4.05	5.56	3.5
After treatment	26.55	8.35	8.8	11.95	8.95

Table 4. Frequency of distribution of variables before and after treatment in the couples with virgin wives treated with a vacuum device

	Erection ability	Orgasm ability	Sexual desire	Sexual satisfaction	Satisfaction of marital relationship
Before treatment	9.2	5.3	6.4	7.6	4.4
After treatment	13.77	5.2	6.3	7.2	4.1

Table 5. Total complications of therapies

	Pain	Ecchymosis	Blister	Headache	Skin rash	Priapism	Vasovagal shock
ICI	27(67%)	0	0	3(7%)	1(2.5%)	9(22.5%)	0
VCD	7(17.5%)	3(7%)	2(5%)	0	1(2.5%)	0	1(2.5%)

in the areas. In the group of consummated couples who used the vacuum device for their treatment, there was a

significant difference in the percentage of erectile function in all sections and in the total score of comparing with

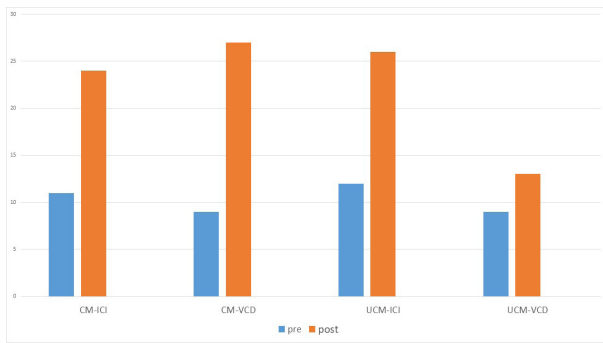


Figure 1. Comparison of erectile function before and after treatment in groups

pre-treatment (p -value <0.05).

Comparison of two treatments of Papaverine cavernous injection and a vacuum device in terms of complications by Chi-square test showed that there was a significant difference between the two methods for pain and priapism, and the incidence of these complications was more in patients treated with cavernous injection (p -value <0.05). There were no significant differences between the two methods in terms of other complications such as ecchymosis, blisters, headache, cutaneous rash, and vaso-vascular shock (p -value >0.05).

Discussion

Erectile dysfunction is defined as the inability to create or maintain the erection for satisfactory sexual activity. This erectile dysfunction is a major and important health problem that can lead to some degree of self-harm or interpersonal disturbance. In this study, 80 men were enrolled with organic sexual dysfunction with the inclusion criteria. These patients were studied in 4 groups. The first group was unconsummated couples who had been treated with an injection of papaverine. The second group was unconsummated couples who were treated with a vacuum device. The third group was the couples with experience of sexual intercourse who had been treated with papaverine injection. The fourth group was the couples with experience of sexual intercourse who had been treated with vacuum devices. In Comparison of two methods of treating Papaverine injection in cavernosum and vacuum device in the couple's experience of sexual intercourse with the help of Mann-Whitney test did not show any significant difference in the total amount of erectile function after treatment (p -value=0.418). While In Comparison of two methods of treating ICI of Papaverine and vacuum device in unconsummated couples with the help of Mann-Whitney test there was a significant difference in the total amount of erectile function after treatment (p -value <0.001).

In a study by Ghanem and colleagues in 2007 which involve unconsummated couples, Tadalafil was used to treat patients, and eventually, 91% of patients were able to have sex (31). In a study by Ozdemir and coworkers In

2008 on unconsummated couples, it was stated that 67% of cases due to psychological problems, 11% due to erectile dysfunction, and 5% due to premature ejaculation (32). In Zargoshi's study, he also observed ED, PE, performance anxiety, vaginismus, hypo sexual desire disorder, and hypogonadism as a Cause of unconsummated marriage (33, 34). In our study to have a purer conclusion, we have excluded psychological and premature ejaculation from the study, and only patients with organic erectile dysfunction have been included in the study.

In a study by Usta and et al., in 2001, 67 % of the unconsummated couple had a psychological problem, 27 % had Vascular Disorders of the Penis, and 4% neurogenic erectile dysfunction (35). In our study, we focused on the effect of a female factor on the treatment of their male spouses' erectile dysfunction by evaluating the patient's wife's virginity and its effect on the outcome of erectile function treatment.

After treatment with Papaverine injection cavernosum, more than 81% of the patients were able to erect for sexual intercourse (35, 36). we included only patients who respond completely by attaining full rigid erection during the early steps of the study to exclude any male factor interfering with the result of the study. So, all patients entered in the study had attained full rigid erection by VCD or ICI papaverine. In 2004, Abbasi et al. performed a study on 134 patients with organic erectile dysfunction. They used papaverine for the treatment of patients and stated that 46% of patients responded to papaverine therapy. They did not evaluate the last date of intercourse in the female partner which could affect the success rate of treatment, but in our study, five couples had abstained sexual intercourse due to their husband's ED for more than six months which could lead to vaginal narrowing. In Zarghoshi's study, unconsummated marriage also concluded the use of ICI as the first line of treatment as it was observed in our study but he did not perform any comparative study (23, 35, 37).

We had studied the use of VCD in the treatment of male ED with 100% ineffective inducing erection but failed to have successful intercourse in patients with virgin wives and sexual abstinence, and senile vaginal atrophy (30, 38). but in this study patients with more than six months duration of sexual abstain were able to have satisfactory sexual relations after an increasing number of tries for sexual intercourse, finger dilation of the vagina before sex, and use of smaller size constrictive ring or use of two constative rings. In some of the above studies on patients with erectile dysfunction with virgin spouses discussed the effect of psychological factors on the development of the disease and its impact on the treatment of patients. Because according to their studies, the failure of some patients it's due to a lack of awareness of sexual intercourse and sexual misconceptions. Some also had functional anxiety that was improved with psychotherapy. Vaginismus was also improved with psychotherapy.

To omit the impact of psychological outcome we had excluded these couples from the study.

Conclusions

According to our study, to select the treatment protocol for patients with erectile dysfunction, the condition of the patient's wife should be considered in addition to the patient's condition. This is the first study which is considering the importance of female factors which could affect the outcome of male sexual treatment in male ED. This study showed that in patients with erectile dysfunction who are having virgin spouses and who are not responding to the first line of oral medication that 5 inhibitors phosphodiesterase, is better to use the intra-cavernosal injection of vasoactive drugs for their treatment.

Authors' contributions

FKH is the principal surgeon and who suggests this novel method, AGH and SKF are urologists who run the project and provide the data and MV wrote the manuscript. AMKH edited the manuscript as well. All authors reviewed the results and approved the final version of the manuscript.

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Conflict of interest

All authors claim that there is no competing interest.

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There was no founding.

Ethics statement

The study was performed prospectively under the Shahed University ethical committees after receiving the IRCT code (IRCT2016013126298N1). All patients signed informed consent before enrolling.

Data availability

Data will be provided by the corresponding author on request.

Abbreviations

ED	Erectile dysfunction
ICI	Intra-cavernosal injection
PE	Premature ejaculation
VCD	Vacuum constrictive device
VT	Vacuum therapy

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