

# THE ACCEPTANCE AND SATISFACTION OF SAUDI MALES TO VASOACTIVE AUTOINJECTION INTRACAVERNOUS THERAPY, EXTERNAL NEGATIVE PRESSURE DEVICE AND PENILE PROSTHESIS IN THE TREATMENT OF ERECTILE DYSFUNCTION

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**Background:** The aim of the study was to determine the acceptance and satisfaction of Saudi impotent male patients to intracavernous vasoactive autoinjection therapy, external negative pressure device and penile prosthesis insertion in the treatment of their impotence.

**Subjects and Methods:** The medical records of 210 Saudi patients who presented with erectile dysfunction and were offered intracavernous vasoactive autoinjection therapy, external negative pressure device or penile prostheses for the treatment of their erectile dysfunction were retrospectively analyzed to determine the acceptance and satisfaction of their selected treatment modalities.

**Results:** Intracavernous vasoactive autoinjection therapy was the most acceptable treatment option, followed by negative pressure device, and then insertion of penile prosthesis. About 11.9% of patients refused all treatment options. Only 40% and 12% of patients who were treated with intracavernous vasoactive autoinjection therapy and external negative pressure device, respectively, were satisfied with their treatment modality. After one year of follow-up, insertion of penile prosthesis had the highest satisfaction rate among the treatment modalities, with 92% and 87% of patients being satisfied at 3 and 12 months' follow-up, respectively.

**Conclusion:** Intracorporeal vasoactive autoinjection therapy had the highest acceptance rate compared with external negative pressure devices and penile prosthesis, however, it had low satisfaction rate and the dropout rate was high. External negative pressure devices are generally poorly accepted and are rarely satisfactory in our patient population. Penile prosthesis insertion is poorly accepted, however, it has the highest satisfaction rate. Such information will allow patients under treatment for impotence and their treating physicians to make better, educated choices on the mode of treatment.

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**Key Words:** Erectile dysfunction, intracavernous vasoactive autoinjection therapy; external negative pressure device, penile prosthesis.

Since the introduction of Sildenafil as an effective oral treatment for impotent patients, it has become the first choice of therapy by both patients and treating physicians. About 30% -50% of patients, however, do not respond favourably to Sildenafil.<sup>1,2</sup> Others have had to discontinue medication because of side effects, such as severe hypotension, dizziness and severe headaches.<sup>2</sup> Also, a large group of impotent patients with unstable coronary artery diseases, nitrate intake and severe hepatic dysfunction are not allowed to receive Sildenafil because of potentially fatal side effects. These patients are confronted with less attractive treatment options, such as intracorporeal injection with vasoactive agents, external negative pressure devices, or insertion of penile prosthesis.

Information on acceptance of and satisfaction from these treatment modalities in the Saudi population is not available. Such information is very helpful when discussing different therapeutic options with this group of patients in the hope that it will help guide them and their treating physicians in the selection of an appropriate treatment option. We present a retrospective analysis of the acceptance and satisfaction among 210 consecutive impotent Saudi patients who were offered either intracorporeal therapy with vasoactive agents, external negative pressure device, or insertion of penile prosthesis for the treatment of their erectile dysfunction.

## Subjects and Methods

A total of 540 patients presented for evaluation of impotence between 1990 and 1999. In all patients, detailed medical and sexual history was taken and a complete physical examination was performed. No interview of sexual partners was performed because of social constraints. All patients underwent determination of serum

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fasting blood sugar, serum testosterone and prolactin. Patients with hypogonadism and/or hyperprolactemia were treated medically. Routine office testing with intracorporeal vasoactive agent (prostaglandin E<sub>1</sub>, or remix of papaverine, prostaglandin E<sub>1</sub> and phentolamine) was performed in the majority of patients. Other more invasive testing, such as penile Doppler ultrasonography, dynamic cavernosometry and cavernosography, nocturnal penile tumescence monitoring and pudendal angiography were used frequently in our early patient population, however, later as patient goal directed approach was adopted, these diagnostic modalities were used in a highly selective group of patients. Patients who presented to the hospital after the introduction of Sildenafil were offered the drug, except those with existing contraindications. Our study included Saudi patients presenting before the introduction of Sildenafil to Saudi Arabia and patients who were contraindicated, failed to respond or developed intolerable side effects to Sildenafil. Non-Saudi patients, and patients who we believed would benefit from penile venous ligation or penile revascularization, and patients who responded to correction of hypogonadism and or hyperprolactinemia were excluded from the study.

All the patients included in the study were offered three treatment modalities that included intracorporeal treatment with vasoactive agent, external negative pressure device, or insertion of penile prosthesis. The success rate, side effects, cost and complications of each modality was thoroughly discussed. Printed materials, and occasionally videotapes, were presented to the patients.

Patients who elected intracorporeal treatment had at least two further visits for dose determination and teaching of the technique of intracorporeal injections. They came to the clinic every two months for evaluation of response, potential complications, dose adjustment and to receive a new drug supply.

Patients who elected external negative pressure device (Osbon Medical Systems, Georgia, USA) as the first treatment option were taught the technique of its use and were given a videotape provided by the manufacturing company on usage instruction and were evaluated in one month and then every three months afterwards.

All patients who selected a penile prosthesis (American Medical Systems, Minnesota, USA), were offered an inflatable penile prosthesis, except those above the age of 80 or those with significant limitations to their manual dexterity, who were treated with semi rigid penile prosthesis.

All patients were followed for 3-60 months (mean, 18.5 months). Patients who had unfavourable response to the intracorporeal therapy or vacuum device were offered the two remaining options. Patients in whom the penile prosthesis was removed due to infection or malfunction were offered a second penile prosthesis.

## Results

Two hundred and ten patients were included in the study. A total 165 and 45 patients presented before and after the introduction of Sildenafil, respectively. All patients had poor tumescence alone or in conjunction with other aspects of erectile dysfunction, such as a lack of libido or premature ejaculation. Their ages ranged from 27 to 85 years (mean, 56.3). Seventy-five percent had one sexual partner while 15% and 7% had two or more than two partners, respectively. Three percent were single. The main etiological factor for impotence in these patients is outlined in Table 1, with arterial insufficiency being the leading cause. The degree of impotence was graded according to our previous study<sup>3</sup> where 21%, 47% and 32% had grade I, II, and III of impotence, respectively.

The choice of treatment options is outlined in Table 2, with vasoactive intracorporeal agent treatment being the most chosen therapy. About 50% of the 25 patients who refused therapy had grade I impotence, while the rest had grade II or III impotence.

One hundred and thirty-four patients chose intracorporeal therapy, 27 patients (20%) required more than one session for the teaching of the technique either at the commencement of treatment or in their initial follow-up visit. Nine patients (6.7%) refused to self inject, four of them brought their spouses for teaching exercise, and the rest brought along a male companion.

Ninety patients (67%) were treated with intracorporeal prostaglandin E<sub>1</sub> and 44 patients received intracorporeal Trimix of three medication that included prostaglandin E<sub>1</sub>, papaverine and phentolamine. Twenty-three patients (37%) who were receiving intracorporeal treatment for their erectile dysfunction did not inform their spouses.

At 3 and 12 months of treatment, 91 patients (68%) and 54 patients (40%), respectively, were satisfied and continued to use the medication. All satisfied patients reported good spousal satisfaction. The reasons given by those who were dissatisfied are as outlined in Table 3. Complications occurred in 19 patients (14%), and included rupture of subcutaneous blood vessel (5.9%), priapism (4.4%) and dizziness (3.7%). Thirty-one patients of the unsatisfied population (38.7%) elected to insert penile prosthesis while the remaining refused further treatment.

Of the 36 patients who chose external negative pressure device as their first choice, only 13 (35%) and four patients (12%) were satisfied and continued its use at 3 and 12 months of follow-up, respectively. The main reason for their dissatisfaction are as shown in Table 4. Sixty-six percent of patients who were dissatisfied selected intracorporeal injection as their second choice of treatment, 19% requested penile prosthesis and 15% refused further treatment. No side effects were noticed in this group.

Only 15 patients accepted penile prosthesis as the first

TABLE 1. *Etiology of impotence.*

Etiology	No. of patients	Percentage
Diabetes	72	34.2
Arterial insufficiency	58	27.6
Psychogenic	27	12.8
Neurogenic	15	7.1
Pelvic surgery	12	5.7
Hypogonadism	11	5.2
Veno occlusive disease	9	4.2
Hyperprolactinaemia	6	2.8

TABLE 2. *First choice of treatment options.*

	No. of patients	Percentage
Intracavernous therapy	134	63.8
Negative pressure device	36	17.1
Refused therapy	25	11.9
Penile prosthesis	15	7.1

TABLE 3. *Reasons for patients dissatisfaction with intracavernous therapy.*

	No. of patients	Percentage
Needle phobia	42	31.3
Pain	35	26.1
Lack of uniform drug supply	35	26.1
Lack of satisfactory erection	29	21.6
Tolerance to medication	21	15.6
Treatment related complications	19	14
Lack of spontaneity	18	13.4
Spouse request	15	11.1

TABLE 4. *Reason for non-satisfaction with external negative pressure device.*

	No. of patients	Percentage
Unsatisfactory erection	22	61.1
Lack of spontaneity	20	55.5
Disclosure of erectile dysfunction	15	41.6
Pain	13	36.1
Loss of ejaculation	12	33.3
Decrease sensation	10	27.7
Spouse refusal	5	13.8

TABLE 5. *Reasons for non-satisfaction with penile prosthesis.*

	No. of patients	Percentage
Difficulty to activate	4	7.6
SST deformity	1	1.9
Unsatisfactory erection	1	1.9
Detumescence during intercourse	1	1.9
Prosthesis malfunction	1	1.9
Prosthesis infection	1	1.9

line of treatment. The median age of this group was 41.2 years. Ten and five patients had grade 2 and grade 3 impotence, respectively. A total of 52 patients underwent insertion of penile prosthesis, 32 patients had AMS 700, 14 patients had Ambicor, three patients had semi-rigid AMS 600 penile prosthesis, and three patients had AMS 650 penile prosthesis. Twelve patients of the group that had AMS 700 had more than one clinic visit to learn the

mechanism of activation and detumescence. In four patients who had AMS 700 penile prosthesis the prosthesis was left inflated at all times because of inability to learn the technique of detumescence despite multiple teaching sessions. Complications that accompanied penile prosthesis insertion included scrotal hematoma in five patients, surgical wound infection in two patients, intraoperative corporeal perforation requiring repair in one patient, prosthesis infection requiring explanation in one patient and SST deformity requiring repair in one patient.

The reasons for dissatisfaction with penile prosthesis is outlined in Table 5. Thirty-one patients (60%) concealed the information about the procedure from their spouses. The satisfaction rate at 3 and 12 months was 92% and 87% , respectively. There was no difference in satisfaction rate between patients who received inflatable or semi-rigid penile prostheses.

## Discussion

The acceptance and satisfaction of impotent patients to different treatment modalities are related to many factors, including patient's age, number and age of spouses, expectation, the degree of invasiveness and cost of therapy. The aim of treating males with impotence is to provide them with adequate erection suitable for intercourse that is satisfactory for both partners. Thirty-seven percent and 60% of the patients who elected to be treated with intracorporeal vasoactive substance or insertion of penile prosthesis, respectively, concealed the information about their treatment from their spouses. This is probably due to the desire of male patients not to injure their masculine image that subsequently may undermine their role of male dominance. The fact that the spouses were not part of the sexual counseling and in many instances were not aware of the treatment option selected by the husband, may have resulted in the dissatisfaction of some patients, as these patients lacked the understanding, participation and compassion of their spouses in the treatment of their erectile dysfunction.

The result of the treatment modalities by our patients was comparable to a study in the US by Hanash<sup>4</sup> in which intracorporeal injection was the first choice while penile prosthesis was chosen by a minority after failing oral treatment. The popularity of intracorporeal therapy in patients who failed medical treatment in the previous study and in our patient population is perhaps due to its relative ease, the ability of patients to reverse their therapeutic decision and the desire of most patients to avoid visible external devices or surgery for treatment of their impotence.

Although previous reports have indicated high success rates of intracorporeal pharmacotherapy in achieving satisfactory erection for sexual intercourse in up to 83% of patients,<sup>5,6</sup> a major drawback was the high dropout rate due to complications and non-treatment associated problems. This was true in our patient population and in other

reported series.<sup>7,8</sup> Needle phobia, associated pain, and lack of inexpensive and uniform supply of pharmacological agents were some of the leading causes of dissatisfaction in our patient population. The use of self-injection devices<sup>9</sup> on a routine basis in patients with needle phobias and the combination of sodium bicarbonate<sup>10</sup> or lidocaine<sup>11</sup> with vasoactive substances in patients with pain associated treatment might have increased the satisfaction rate in our patients and helped to reduce the dropout rate. Lue<sup>12</sup> has stated that better satisfaction with intracorporeal therapy depends on detailed attention to patient selection, assessment of their motivation and goals, instruction of injection technique and thorough discussion of side effects, cost and alternatives.

Sidi et al. reported the efficacy of external negative pressure devices in their group of patients with overall satisfaction rates of 68%.<sup>13</sup> This was not the case in our patient population, with only 36 patients accepting it as their first line of therapy and only 12% of them continuing its use after one year of therapy. The majority of our patients were dissatisfied because of poor erection obtained despite repeated teaching sessions. The poor response rate in our small group of patients was in agreement with other Western reports,<sup>14</sup> where the long-term satisfaction rate was only 20%. This may be partly due to patients' over expectation, however, several authors<sup>14,15</sup> have questioned whether erections that were obtained by external negative pressure devices that are characteristically associated with proximal flaccidity, urethral compression, cooling of the penis, could really elicit such a high favorable response rate. Another factor of dissatisfaction may be related to the tendency of our patients to conceal their treatment choice from spouses and as the utilization of external negative pressure devices is obvious and in many instances cumbersome, this may have contributed to the low satisfaction rate.

Although insertion of penile prosthesis had the highest satisfaction rate in our patients and in other reported series,<sup>16</sup> these results were insufficient to convince many patients in our study to accept this as their first line of therapy. This can be explained by the general tendency of men to avoid surgery, especially in a population where comorbid medical conditions such as diabetes and coronary artery disease exist. However, it does seem that since 38.7% of patients who failed intracorporeal therapy elected to proceed with penile prosthesis insertion, failure to respond to nonsurgical treatment seems to encourage some of these patients to accept more invasive treatment.

The acceptance and satisfaction of Saudi impotent patients to vasoactive auto injection therapy, external negative pressure device and penile prosthesis are less than satisfactory. While intracorporeal therapy has high acceptance rates, the dropout rate is rather high. External negative pressure devices are poorly accepted and rarely

satisfactory for our patients. Penile prostheses insertion are not a popular choice despite their excellent satisfaction rate at one year of follow up.

Better patient selection, involvement of the spouse, even indirectly, in the therapeutic decision, frequent teaching sessions, immediate attention to the complications, are factors that are likely to increase the acceptance and satisfaction rate of our patients. Further prospective studies in larger numbers of patients will be needed to further delineate the acceptance and satisfaction of these treatment modalities in our patient population. The introduction of other less invasive treatment modalities, such as the transurethral alprostadil<sup>17</sup> and the newly developed sublingual Apomorphine<sup>18</sup> will be helpful in increasing the available treatment options for this group of patients.

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