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Prostaglandin E_1 versus sex therapy in the management of psychogenic erectile dysfunction

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The treatment for psychogenic erectile dysfunction has been previously managed by non-medical methods consisting of counseling with a psychiatrist, psychologist or sex therapist. The success rate for treatment with counseling has not been uniformly successful. This paper compares the treatment of psychogenic erectile dysfunction using standard sex therapy and self-injection therapy using low-dose PGE1. Fifty men with psychogenic impotence were divided into two groups: standard sex therapy for twelve weeks or treatment using low-dose (2.5 – 5.0 μg) of PGE1. The results showed that men treated with low-dose PGE1 had a 47% improvement of obtaining an unaided erection compared to 58% improvement rate with sex therapy. 69% of patients in the PGE1 group were satisfied with their treatment compared to 75% receiving sex therapy. The frequency of intercourse reported in patient diaries for the two groups was similar (20.5 per month for PGE1 *vs* 20.0 per month for sex therapy. The reported duration of erection by patients receiving PGE1 therapy was longer than that reported by those receiving sex therapy (35 min *vs* 10 min). The comparison of the cost of treatment of the two treatment groups reveals that the sex therapy is approximately 25% more expensive than the PGE1 treatment. This pilot study demonstrates that the efficacy of PGE1 was numerically, though not statistically, less than sex therapy in the treatment of psychogenic impotence. The cost per positive outcome with PGE1 treatment is lower than that of sex therapy treatment making PGE1 more cost-effective. *International Journal of Impotence Research* (2000) **12,** 191–194.

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Introduction

It was only a few years ago that most textbooks on sexual dysfunction suggested that the etiology of erectile dysfunction was psychogenic in 90% of patients.[1] Today, it is *felt* that organic causes, mostly vasculogenic, are responsible for erectile dysfunction (ED) in most men over age 50 y. However, in men less than 50 y of age, psychogenic erectile dysfunction remains the source of many men's erectile failure.[2,3]

The treatment for psychogenic impotence has consisted of referral to a psychiatrist, psychologist, or sex therapist who provided counseling. Although Masters and Johnson described a treatment program involving a combination of behavioral and psychotherapeutic elements with a 70% success rate after 5 y,[4] few others have been able to repeat their outcomes using the same techniques.[5] Other treatments for psychogenic impotence have included intracavernosal injection of prostaglandin E_1 (PGE1), and more recently oral sildenafil, have been reported to be effective for psychogenic erectile dysfunction.

This study will report our experience using low-dose PGE1 (CAVERJECT™, Pharmacia & Upjohn, Bridgewater, NJ, USA) for the management of psychogenic impotence and compare the results to standard sex therapy by a qualified sex therapist. The study investigated the impact of these treatments along the dimensions of efficacy, sexual quality of life and cost of care.

Materials and methods

Fifty men presenting with ED were screened for psychogenic impotence. The diagnosis of psychogenic ED was based on the history of preservation of full, rigid morning or nocturnal erections, and rigid erections with self-stimulation or masturbation. The diagnosis of psychogenic ED was confirmed with measurement of nocturnal erections in the home environment. Confirmation was based on Rigi-Scan™ (Osbon Medical Systems, Augusta, GA, USA) device measurements demonstrating a 70%

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or greater erection recorded at the base and tip of the penis sustained for more than five minutes during at least one of two nights of testing, or the breaking of three bands on the Snap Gauge™ test on at least one of three nights of testing. The men also received an injection of PGE1 in the clinic to assess the integrity of the blood supply to the penis. Serum testosterone, prolactin, free thyroxine (T4) and glucose levels were obtained to rule out an endocrinologic etiology of ED. The testosterone and prolactin levels were obtained in the early morning hours.

Twenty-five men were randomized to each of the two treatment arms, standard sex therapy or to treatment using low-dose (ie, 2.5–5.0 μg) of PGE1. Patients assigned to sex therapy were scheduled to weekly visits to the therapist for a maximum of twelve weeks. Patients assigned to PGE1 were given a trial injection of 2.5 μg in the office and asked to evaluate the quality of their erection for vaginal penetration. If the erection was judged to be less than 75% of the patient's normal erection, a second injection of 2.5 μg was administrated after 60 minutes had lapsed since the first injection. The optimum dose was defined as a dose producing an erection lasting up to 60 minutes and with rigidity adequate for intercourse. The patients received information and observed a video regarding the use of sterile injection technique. The drug for self-injection was to be used at a frequency at the patient's discretion, but was limited to three times a week with at least 24 hours between each dose. The patients returned to the clinic at the end of weeks 4, 8 and 12 of therapy for evaluation of therapeutic progress, safety and effectiveness. The treatment continued for up to a maximum of 12 weeks but could be stopped at the point that the physician in the injection arm, or sex therapist in the sex therapy arm, and the patient felt the treatment had eliminated the sexual dysfunction.

At the start and end of therapy, patients completed a questionnaire that asked the patients to assess their ability to obtain spontaneous erections satisfactory for intercourse. This is one of the two primary outcome measures used within the trial. The second is an additional item within the end of therapy questionnaire that asked the respondents to predict their ability to perform at six months in the future. In patients suffering from psychogenic impotence, expectations can be causally linked to experience. For that reason, this latter measure is viewed as a potential indicator of long-term outcome.

All of the patients completed sexual diaries during their treatment and completed the Sexual Life Quality Questionnaire (SLQQ)[6] at the start and end of treatment. The instrument contains ten questions regarding aspects of sexual quality of life such as anxiety about sexual performance and feelings during lovemaking. In the post-treatment version, it contains an additional six questions asking the respondent to indicate their degree of satisfaction with aspects of the treatment itself, such as ease of use and effectiveness. The responses recorded on the Likert scales of the SLQQ are transformed to a 0 to 100 scale where higher scores indicate better quality of life or patient satisfaction.

Clinical and quality of life outcomes were tested for statistical significance using chi square and independent *t*-tests. These tests were conducted using SPSS for Windows, Version 8.0.0.

The cost of each treatment arm was estimated on the basis of survey results from five sex therapists and five pharmacies in the New Orleans area. The quantity of services (urologic workup, sex therapy visits, PGE1 doses, PGE1 treatment monitoring) were based on the patterns of care and follow-up used by our practices (NHB and ER). The costs of treating all patients, including those later lost to follow-up, were added to the treatment group to which they were assigned, ie, sex therapy or low-dose PGE1.

Results

The patients randomized to each of the treatment arms were similar in the demographic characteristics of age, ethnicity, previous treatment for ED and baseline sexual quality of life (Table 1). Those assigned to PGE1 reported a shorter average duration of ED and a lower proportion of sexual situations producing an erection, but neither of these reached statistical significance. Thirteen (52%) of the PGE1 patients and 16 (64%) of the sex therapy patients completed therapy. The reasons for drop out included lack of efficacy, pain at the injection site, loss to follow-up, and the desire to switch to sildenafil which became commercially available during the study and was receiving significant media coverage. None of the patients experienced priapism during the study. One patient reported a single event of penile pain and bleeding at the injection site, another reported episodic ecchymosis associated with the use of PGE1.

At the end of treatment, patients in the low-dose PGE1 group reported that they were able to obtain an unaided erection in 62.9% of sexual situations, a net 47% increase or 294% improvement over baseline (Table 2). Patients assigned to sex therapy reported an ability to obtain an unaided erection in 82.0% of sexual situations, a net improvement of 58% or 264% over baseline. The majority of the patients (69% of the PGE1 arm and 75% of the sex therapy arm) were extremely satisfied with their treatments. When asked to predict their performance six months after treatment, 69% of PGE1 treated patients and 81% of sex therapy treated patients believed they would be able to achieve an unaided erection adequate to engage in sexual intimacy.

Change from baseline on the sexual quality of life scale and patient evaluations of the treatment

Table 1 Characteristics of the study subjects

Characteristic	*PGE1 (n = 25)*	*ST (n = 25)*	*P value*
Age (y)	49.6	50.1	0.86
Ethnicity (No.)			
White	17	15	
Black	8	8	
Hispanic	0	1	
Oriental	0	1	
Previous treatment (No.)			
None	22	24	
Oral medications	2	1	
Vacuum or other device	1	0	
Duration of ED (y)	3.5	4.4	0.42
% Sex situations producing erection	16.0%	22.5%	0.11
SLQQ QoL Subscale at baseline	7.1	5.8	0.54

Table 2 Efficacy of PGE1 and sex therapy

Endpoint	*PGE1 (n = 13)*	*ST (n = 16)*	*P value*
% Sex situations producing erection	63%	82%	0.30
% Extremely satisfied with treatment	69%	75%	0.42
% Confidence in performance in 6 months	69%	81%	0.45

domains on the SLQQ for each of the therapies are reported in Table 3. Similar improvements in sexual quality of life as measured by the SLQQ were seen for both treatment arms (74 point improvement with PGE1 versus 71 for sex therapy). The patient ratings of two of the six treatment domains were nearly identical (disruption to lovemaking, efficacy of treatment). Three of the items in which a 7 point or greater difference was observed favored PGE1 therapy (ease of use, affect on lovemaking pleasure, naturalness of erection) while the remaining item (closeness to ideal treatment) favored sex therapy.

The frequency of intercourse reported in patient diaries for the two groups was similar (20.5 per month for PGE1 versus 20.0 for sex therapy), as was the proportion of erections adequate for intercourse (62% versus 58%). The reported duration of erection by patients receiving PGE1 therapy was longer than that reported by those receiving sex therapy (35 minutes versus 10 minutes, $P = 0.02$).

Table 3 Results of the Sexual Life Quality Questionnaire (SLQQ)

Endpoint	*PGE1 (n = 13)*	*ST (n = 16)*	*P value*
Improvement in SLQQ QoL Subscale	74	71	0.53
Treatment satisfaction			
Ease of using treatment	88	80	0.29
Affect on lovemaking pleasure	86	75	0.28
Disruption to lovemaking	77	79	0.88
Naturalness of erection	92	75	0.13
Efficacy of treatment	82	80	0.88
Closeness to ideal treatment	68	80	0.24

Table 4 compares the costs of the two treatments per two outcome measures. In the first, the observed utilization by all patients entering the study and the costs obtained through the provider survey are allocated across those patients completing treatment who were extremely or somewhat satisfied with their treatment. In the second, those costs are allocated across those patients completing treatment who were confident or neutral about their projected ability to perform in a sexual situation six months post-treatment. By these calculations, we are able to derive a total cost per each of the two key outcome variables. In the first calculation, cost per patient reporting being extremely or somewhat satisfied with their treatment, the costs per patient in the sex therapy group were 25% higher than those in the PGE1 group ($1181 *vs* $943). Using the alternative outcome measure, cost per patient confident or neutral about their projected ability to perform in a sexual situation six months post-treatment, the costs per patient in the sex therapy group were 26% higher than those in the PGE1 group ($1453 *vs* $1153).

Table 4 Cost comparison of the two treatment arms

Sex therapy ($n = 25$)			
Cost of baseline urologic exam	25 × $115.00	$2875.00	
Cost of sex therapy visits	157 × $102.00	$16 014.00	
Total cost of sex therapy			$18 889
Cost per patient extremely or somewhat satisfied with treatment ($n = 16$)			$1181
Cost per patient confident or neutral on ability to perform at 6 months ($n = 13$)			$1453
PGE1 therapy ($n = 25$)			
Cost of baseline urologic exam	25 × $115.00	$2875.00	
Cost of titration/follow-up visits	35 × $40.00	$1400.00	
Cost of injection doses	273 × $22.35	$6101.55	
Total cost of PGE1 therapy			$10 377
Cost per patient extremely or somewhat satisfied with treatment ($n = 11$)			$943
Cost per patient confident or neutral on ability to perform at 6 months ($n = 9$)			$1153

Discussion

The treatment of patients with ED with intracavernosal vasoactive agents appears to be well established. It is effective in 70–80% of patients with organic and psychogenic ED and has a good safety profile provided the effective dose is established by careful titration.[7]

There have been several reports in the literature of transient, partial, or complete restoration of spontaneous coital erections in patients using self-injection therapy with PGE1. McMahon[8] assessed the incidence of restored spontaneous erections in 153 men with chronic ED treated with intracavernosal injection of PGE1, and in a control group of 53 untreated men with chronic ED. In a six month follow-up, it was found that in the PGE1 arm, a statistically significant improvement occurred only in patients with psychogenic impotence but not in patients with either arteriogenic or venogenic ED. There was no significant improvement noted in the control group. It was concluded that the treatment with self-injection of PGE1 is associated with restoration of spontaneous erections only in patients with psychogenic ED and rarely in patients with organic ED.

In another trial, French authors[9] studied the effectiveness of intracavernosal PGE1, on spontaneous erections in 35 patients. Patients with erection disorders were treated with six intracavernosal injections of PGE1 at 15-day intervals. Spontaneous erections were compared before and after the treatment. After more than one year, 24 (73%) of the 33 patients who completed the PGE1 treatment reported improvement in spontaneous erections enabling intercourse. The authors concluded that the increase in spontaneous erections is due to an influence on the psychogenic component of ED and possibly due to a local, long-lasting action of PGE1, on the cavernosal tissue.

Ghanem *et al*[10] reported on their experience using short term PGE1 in the treatment of persistent psychogenic ED. Amongst 153 patients with psychogenic ED, 64% used the injections for less than 3 months before spontaneous erections returned, and only 12% needed the injections for up to one year.

Although the goal of this study was to compare the two treatment arms for efficacy in the management of psychogenic ED, the authors are aware PGE1 only addresses the loss of erection and not the broader solution of psychogenic erectile dysfunction which includes resolution of conflict in the relationship, performance anxiety, guilt and other deep rooted causes of psychogenic ED.

Conclusion

In this pilot study, the efficacy of PGE1 was numerically, though not statistically, less than sex therapy in the treatment of psychogenic impotence (net improvement 47% *vs* 58% over baseline respectively). The cost per positive outcome with PGE1 treatment is lower than that of sex therapy treatment making PGE1 more cost-effective. The authors recognize that the small sample size in this study must be taken into account in interpreting these results and that the study only demonstrates short term efficacy of PGE1 compared to conventional sex therapy. Further research will be needed to examine the role of PGE1 therapy as a substitute for, or adjunct therapy to, sex therapy in the treatment of psychogenic ED.

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