ABSTRACT

Objectives. To evaluate, using a long-term, prospective study, the satisfaction rate, attrition rate, and follow-up treatment of well-trained patients using an external vacuum erection device, the Osbon ErecAid System, in the treatment of mild, moderate, and severe organic erectile dysfunction.

Methods. One hundred twenty-nine patients were assessed to determine the severity and cause of their erectile dysfunction. Patients with organic erectile dysfunction who were interested in the Osbon ErecAid received the device after thorough training. Patients received a follow-up questionnaire regarding satisfaction, months of use, reasons for discontinuing, and further treatment.

Results. Our attrition rate was 65% overall and was lowest among patients with moderate erectile dysfunction (55%). All patients with mild dysfunction discontinued use, and a large number (70%) of patients with complete dysfunction also discontinued use. Of the patients who discontinued, most stopped treatment early (median 1 month, mean 4 months) and 63% did not seek further treatment. Thirty-five percent of patients were satisfied with the device and have continued to use it long term (mean 37 months).

Conclusions. Our study showed a lower success rate than previous reports. Patients who were satisfied with the Osbon ErecAid continued to use it for long periods. Patients who were not satisfied dropped out very quickly, and many did not seek further treatment. Patients with moderate erectile dysfunction had a higher rate of success than patients with mild or severe erectile dysfunction.

Erection-inducing vacuum constricting devices (VCDs) were described as early as 1917, but did not become widely used until the 1970s.¹ By promoting penile blood engorgement with a suction chamber and maintaining tumescence with a constricting band, VCDs assist in achieving an erection. The potential strengths of this therapy are its nonmedical, noninvasive nature and its cost-effectiveness. The potential weaknesses include the learning required to use it, complaints of lack of full rigidity of the penis and lack of rigidity proximal to the constricting band, and a sense of lack of spontaneity because of the mechanical nature of the device. Numerous published reports exist that describe this treatment as very effective.²–⁷ As newer treatments for erectile dysfunction emerge, it is important to better determine for which patients VCDs are appropriate, what outcomes to expect from their use, and, for patients who fail, what alternatives to choose. We conducted a long-term, prospective study of patients who were well trained in the use of the Osbon ErecAid VCD (Osbon Medical Systems, Augusta, Ga). By stratifying patients by severity of erectile dysfunction, it was our intent to display any differences in success rates among these groups. Furthermore, with excellent and consistent training of all patients by an Osbon representative, we believe that the patients in our study had the best opportunity for success with the VCD. With long-term follow-up, we proposed to determine when patients would stop using the VCD and for how long those who were satisfied with it would continue its use.
MATERIAL AND METHODS

PATIENT EVALUATION

Between 1990 and 1996, 146 patients were enrolled in our Osbon study. These patients all presented to our clinic with a complaint of erectile dysfunction. All patients completed a detailed sexual function questionnaire at their initial office visit. From this survey, the duration and severity of the erectile dysfunction were determined.

The erectile dysfunction of patients whose penis had atrophy with degenerative changes of the penile tissue and whose penis was completely limp or became full but without hardness was classified as complete. The erectile dysfunction of patients who achieved sufficient hardness for intromission but were unable to maintain their erection was classified as moderate. The erectile dysfunction of those patients who could penetrate and achieve orgasm was classified as mild.

Each patient was seen and evaluated by one of us (J.F.E.), who took a detailed medical and sexual history. A complete physical examination was conducted, as were studies of serum testosterone and duplex Doppler ultrasound of the penile arteries combined with intracavernous administration of prostaglandin E1. In this manner, all patients were diagnosed with vascular, cavernosal, neurogenic, or hormonal erectile dysfunction. Only patients with these organic diagnoses were included in the study.

INSTRUCTION

Patients with a diagnosis of organic erectile dysfunction were presented, in a nonbiased manner, with choices of no treatment, VCD, injection, or implantation. All patients included in the study chose the VCD as the first line treatment. The Osbon VCD was the only device prescribed to limit variability. Only patients with these organic diagnoses were included in the study.

FOLLOW-UP

In late 1996, patients received a follow-up questionnaire by mail. Those who did not respond or did not complete the questionnaire entirely were followed up by telephone. Patients who could not be reached were considered to have dropped out of the study.

RESULTS

Of the 146 patients originally enrolled in the study, 129 completed the patient questionnaire and were included the analysis. The mean time of follow-up was 37 months after receiving the Osbon prescription. All but 11 patients included in the study had filled their prescription more than 12 months before completing the follow-up questionnaire. At the conclusion of the study, 84 patients (66%) were no longer using the device (inactive), and 45 patients (35%) were still using it (active). Patient age and diagnosis were comparable between the two groups. The mean age of active patients was 66 years (range 52 to 78), compared with 64 years (range 39 to 80) for inactive users.

Diagnoses were very similar between the two groups; the most common etiology was vascular, followed by cavernosal, neuronal, and hormonal.

Nine of the patients (7%) had mild erectile dysfunction, 54 (42%) had moderate erectile dysfunction, and 66 (51%) had complete erectile dysfunction, as defined above. All 9 patients with mild erectile dysfunction discontinued use of the VCD. Patients with complete erectile dysfunction also quit at higher rates (70% quit and 30% continued). Patients with moderate erectile dysfunction were the most likely to continue using the device (55% quit and 43% continued). Fisher’s exact test for use status as a function of severity indicated that the percentage of patients who stopped was significantly different across the severity levels ($P = 0.01$).

Among inactive patients, the average number of months before quitting was 4 months (median 1, range 1 to 36) (Fig. 1). The three most common reasons for stopping use were as follows: 48% (n = 57) considered it ineffective, 20% (n = 17) too painful, and 24% (n = 20) too cumbersome (Table I). Additional reasons for drop out were as follows: 5 considered the erection to be artificial, which led to a loss of desire, 2 reported loss of a partner, and 6 reported that their ability to obtain a natural erection had been restored. Follow-up treatments for the 84 patients who dropped out were as follows: 31% (n = 26) received intracavernosal therapy, 6% (n = 5) received a prosthesis, and 63% (n = 53) chose to receive no further treatment (Table I).

COMMENT

Previous studies of VCDs have had varying satisfaction rates. Some studies have shown high satisfaction rates,$^{3,6-9}$ but other studies have shown lower satisfaction rates.$^{1,10}$ Some researchers have
argued that success rates are highly determined by the degree of training. We believe that we studied the most motivated and best trained cohort of patients clinically possible. All patients chose the VCD as the first line therapy and received training by watching a videotape and having an individual demonstration with an Osbon representative. Despite this, our overall failure rate was 65%. Most of these patients quit early; the median time of drop out was only 1 month (Fig. 1). These patients most commonly quit because the device was found to be ineffective, cumbersome, or painful.

The severity of erectile dysfunction was a significant factor in drop-out rates. Patients with moderate erectile dysfunction were the most successful. All patients in our study with mild erectile dysfunction discontinued use of the VCD. Patients with complete erectile dysfunction also had low success rates. Thus, the VCD was most useful to patients with moderate erectile dysfunction (P = 0.01).

Sixty-three percent of patients who were unsuccessful with the VCD sought no further treatment. In another study by our group, of patients receiving intracavernosal injections, only 28% of patients who discontinued injections did not seek further treatment. In the intracavernosal injection study, 52% of those patients who discontinued injections for patients seeking these different treatments. The appeal of the VCD is largely that it is noninvasive. Patients willing to give themselves injections may be more willing to try other, more invasive therapies. This underscores the noninvasive strength of the VCD.

Of the active patients in our study, these patients had long-term success with the VCD. The average duration of use for these patients was 37 months (maximum 84). For these patients, the treatment successfully provided a cost-effective, noninvasive, nonmedical therapy. This clearly shows the importance of the VCD as an option in the treatment of organic erectile dysfunction. Again, the success rates were highest for patients with moderate erectile dysfunction. Moderate erectile dysfunction was defined as achieving sufficient hardness for intromission but being unable to maintain the erection. Nearly half of these patients were satisfied with the VCD.

CONCLUSIONS

The Osbon ErecAid provided successful long-term treatment in 35% of patients overall. Our study was the first report to stratify patients as having mild, moderate, or severe erectile dysfunction. Patients with moderate dysfunction had the highest rates of success, and all patients with mild dysfunction discontinued use of the VCD. Many patients who were unsuccessful with the VCD did not seek alternative treatments. The VCD remains a viable noninvasive treatment for erectile dysfunction, particularly for patients with moderate dysfunction.

TABLE I. Reason for discontinuation and new treatment among inactive patients

<table>
<thead>
<tr>
<th>Reason*</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ineffective</td>
<td>48 (57)</td>
</tr>
<tr>
<td>Cumbersome</td>
<td>20 (24)</td>
</tr>
<tr>
<td>Too painful</td>
<td>17 (20)</td>
</tr>
<tr>
<td>Lack of interest</td>
<td>5 (6.0)</td>
</tr>
<tr>
<td>Loss of partner</td>
<td>2 (2.4)</td>
</tr>
<tr>
<td>Problem resolved</td>
<td>6 (7.1)</td>
</tr>
<tr>
<td>New treatment</td>
<td></td>
</tr>
<tr>
<td>No new treatment</td>
<td>53 (63)</td>
</tr>
<tr>
<td>Injections</td>
<td>26 (31)</td>
</tr>
<tr>
<td>Surgery</td>
<td>5 (6.0)</td>
</tr>
</tbody>
</table>

* Patients were allowed to give two reasons.

REFERENCES