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CLASSIFICATION OF SEXUAL DYSFUNCTION FOR MANAGEMENT OF INTRACAVERNOUS MEDICATION-INDUCED ERECTIONS

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ABSTRACT

A total of 75 patients was placed into 1 of 3 classes of sexual dysfunction based on nocturnal penile tumescence tracings rather than on etiology of the sexual dysfunction. The patients then were given an intracavernous injection with incremental dosages of 0.2 to 1.0 ml. of a combination of papaverine hydrochloride and phentolamine mesylate vasoactive intracavernous therapy. The results of the study were categorized as class 1—mild sexual dysfunction (100% successful with low dosages of medication), class 2—moderate sexual dysfunction (95% successful but larger dosages of medication were required) and class 3—severe sexual dysfunction (a 50:50 chance of a successful treatment and even higher dosages of medication were required).

A portable home nocturnal tumescence monitor classification of severity of sexual dysfunction provided a guideline for the intracavernous pharmacological injection initial dosage and the probability of success or failure in patients who desire this form of therapy for male sexual dysfunction. (*J. Urol., 143: 298–301, 1990*)

Male impotence usually is classified according to the origin of the problem, for example psychological, diabetes mellitus, after a radical operation, vascular problems, medication and so forth.[1] Since the introduction of intracavernous drug-induced erection with vasoactive agents[2] there have been studies with these drugs to differentiate vascular from nonvasculogenic impotence.[3] The vasoactive drugs also have been compared to other forms of impotence evaluation, such as the penile-brachial index, penile Doppler blood flow and nocturnal tumescence monitoring.[4–6] The vasoactive drugs also have been used to treat impotence and much has been written on the pharmacological self-injection erection program.[7–9] A simple, meaningful guide has not been available for the urological clinician who uses intracavernous medication to treat male sexual dysfunction, whether due to organic and/or psychological causes.

A classification of male sexual dysfunction based on the severity of the problem as indicated by the nocturnal penile tumescence tracing rather than origin may be more functional for the treatment of sexual dysfunction with intracavernous medication. I describe a classification system of male sexual dysfunction based on the severity of sexual dysfunction as determined by nocturnal penile tumescence and rigidity monitoring with a portable nocturnal tumescence monitor.† I also show that once the patient has been placed in a sexual dysfunction class based on severity of sexual dysfunction and nocturnal penile tumescence tracings, the initial dosage of medication can be determined along with the incremental increase in dosage, and the per cent of success or failure that one can expect to achieve in each class can be predicted with reasonable certainty.

MATERIALS AND METHODS

I studied 75 patients with erectile dysfunction in the pharmacological self-injection erection program from January 1987 through April 1988. The 75 patients were selected from a larger group of 147 who presented for treatment of impotence by self-injection of pharmacological agents. The impotence evaluation included a history, physical and neurological examinations, determination of serum testosterone and prolactin levels, a biochemical profile, penile-brachial index and penile blood flow. Patients were excluded from the study if they did not use the portable nocturnal penile tumescence monitor or used it incorrectly, had an obvious neurological disease or spinal cord injury, or responded to testosterone hormone replacement and a combination of 5 mg. yohimbine and 10 mg. isoxuprine hydrochloride 3 times a day.

After nocturnal penile tumescence evaluation the patients were classified into 1 of 3 categories of increasing sexual dysfunction based upon the penile tumescence and rigidity tracings. Patients in class 1 (mild sexual dysfunction) had a normal penile tumescence tracing (fig. 1) consisting of 3 to 6 erections per 8-hour night with a 10 to 15-minute duration per erection, a 3 cm. increase over resting tumescence at the penile base lead, a 2 cm. increase at the penile tip lead, and rigidity of more than 75% at the base and tip of the penis.[10, 11] Patients with a tracing showing normal tumescence and rigidity, and who had more than 1 erection per night for 1 to 10 minutes also were placed in class 1 (fig. 2). Men in class 2 (moderate sexual dysfunction) had a nocturnal penile tumescence tracing that showed no more than 1 normal erection lasting less than 10 minutes during 2 nights of testing. Class 2 also included men whose penile tumescence increased 2 to 3 cm. over resting tumescence at the penile base lead and 1 to 2 cm. at the penile tip, with penile rigidity 50 to 75% of normal at the penile base and tip (figs. 3 and 4). Patients in class 3 (severe sexual dysfunction) had a penile tumescence increase of 0 to 2 cm. over resting tumescence at the penile base lead and 0 to 1 cm. at the penile tip, with the penile rigidity being less than 50% of normal (fig. 5).

The men were given a simple, informational question and answer sheet (available on request) about vasoactive intracavernous pharmacotherapy on the initial visit to acquaint them with the program and medication. Many patients also attended Impotents Anonymous sessions for further education and to talk with patients who already were being treated with intracavernous medication for the sexual dysfunction problem. Before the first trial of intracavernous medication-induced erection a detailed consent form was reviewed and signed by the patient.

A mixture of 30 mg./ml. papaverine hydrochloride and 1 mg./ml. phentolamine mesylate was used. The initial dosage was 0.20 ml. and it was increased by 0.05 ml. increments in subsequent injections. The initial intracavernous injection was ex-

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plained and demonstrated to the patient while injecting unilaterally into the base of the cavernous body with a 27-gauge needle. The patient was instructed to lie down and compress the injection site for 5 minutes. He then was observed for 20 minutes, a blood pressure reading was taken and observation was made of penile tumescence and rigidity. The patient then was sent home and encouraged to engage in sexual intercourse. Based upon the patient observations regarding quality and duration of erection, the subsequent dosage was adjusted if necessary. After the initial injection the patient was observed while performing the subsequent injection in the office. He then was sent home with a 10 ml. multidose vial of the mixture in a labeled box, several 1 ml. diabetic 27-gauge syringes, a drawing of the injection technique and detailed injection instructions.

Responses were monitored at home and this process was repeated by telephone reports with increasing dosages until a dosage was determined with which the patient was satisfied or until a maximum volume of 1.0 ml. medication was reached. If the treatment was successful the patient continued the program and was followed every 2 months at an office visit, at which time he returned the unused medication, was questioned and examined, underwent a biochemical profile and received new supplies. If the treatment was not successful other forms of therapy, such as the use of external devices or penile prostheses, were discussed. Success was defined objectively by the patient as a rigid sustained erection for satisfactory intercourse and the desire to continue the intracavernous medication program.

RESULTS

Patients were placed into 1 of 3 classes of sexual dysfunction based upon the nocturnal penile tumescence tracings. Of the patients 35% (26) 32 to 76 years old (average age 56 years) were placed in class 1 (mild sexual dysfunction), 43% (32) 31 to 76 years old (average age 56 years) were placed in class 2 (moderate sexual dysfunction) and 22% (17) 34 to 76 years old (average age 69 years) were placed in class 3 (severe sexual dysfunction). Table 1 summarizes the number of responders for each dosage of medication in each class.

All 26 patients in class 1 had 100% success with the intracavernous drug-induced erection program. Although some patients require physical stimulation after injection all class 1 patients achieved a full erection within 10 to 20 minutes, which

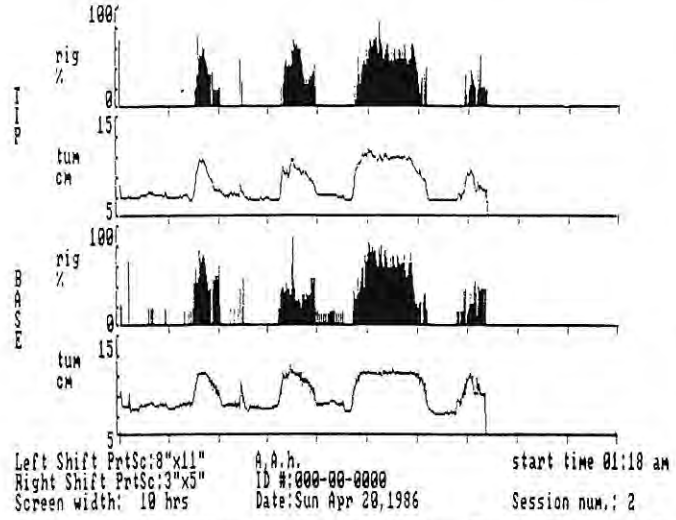

FIG. 1. Class 1. Normal nocturnal erections. Each mark on x-axis indicates 1 hour. There were 3 erections per 8-hour night 10 to 60 minutes in duration, 3 to 5 cm. increase in tumescence (*tum cm*) at penile base lead (*BASE*), 2 to 5 cm. increase at penile tip lead (*TIP*), and rigidity (*rig %*) of more than 75% at base and tip of penis.

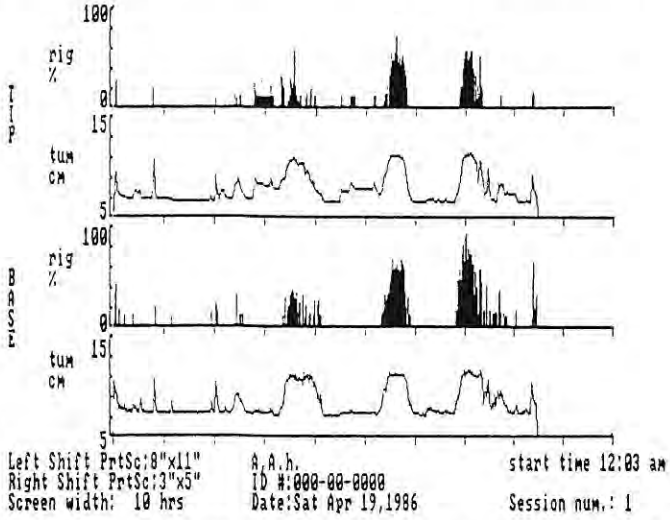

FIG. 3. Class 2. Normal penile tumescence (*tum cm*) response, with penile rigidity (*rig %*) at less than 75% of normal. *BASE* and *TIP*, tracings at base and tip of penis, respectively.

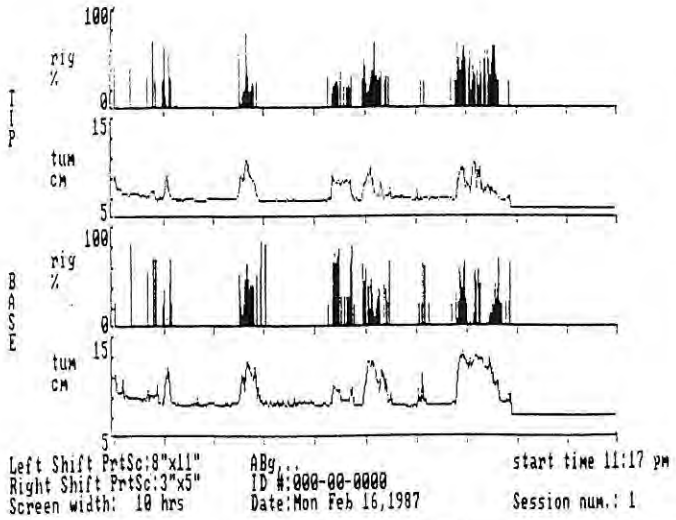

FIG. 2. Class 1. Numerous normal nocturnal erections less than 10 minutes in duration *BASE* and *TIP*, tracings at base and tip of penis, respectively. *tum cm*, tumescence in cm. *rig %*, percentage rigidity.

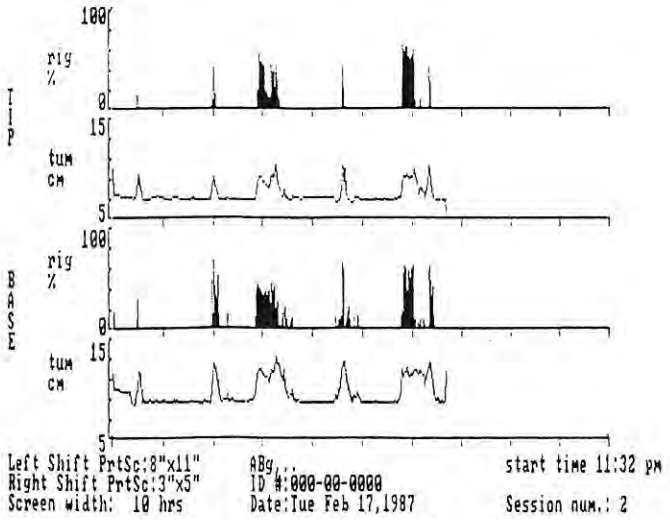

FIG. 4. Class 2. Tumescence (*tum cm*) and rigidity (*rig %*) at 50 to 75% of normal. *BASE* and *TIP*, tracings at base and tip of penis, respectively.

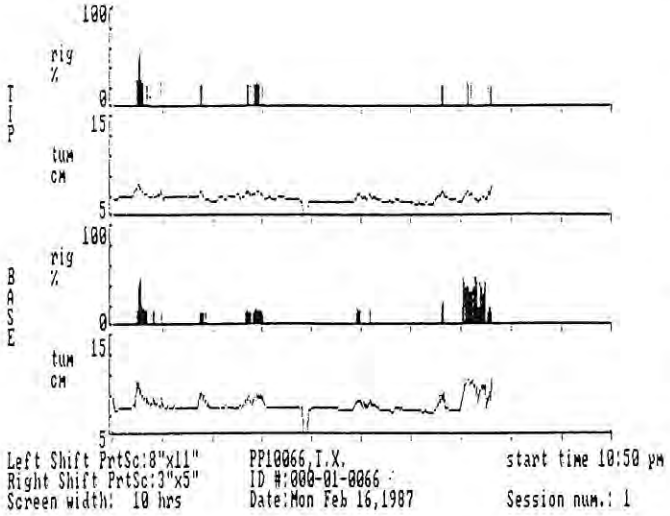

FIG. 5. Class 3. Tumescence (*tum cm*) and rigidity (*rig %*) at 25 to 50% of normal. *BASE* and *TIP*, tracings at base and tip of penis, respectively.

TABLE 1. *Number of responders per class*

Dosage (ml.)	Class		
	1	2	3
0.20	3		
0.25	6	2	
0.30	8	5	
0.35	4	2	
0.40	1	5	2
0.45–0.65	4	12	
0.70–1.00	0	5	6
Nonresponders	0	1	9

Mixture of 30 mg./ml. papaverine hydrochloride and 1 mg./ml. phentolamine mesylate.

lasted 30 minutes to 2½ hours. Many patients maintained an erection even after ejaculation. Of the patients 12% stayed with the initial dosage of 0.20 ml., 80% required 0.20 to 0.35 ml. for a good result, only 8% required a dosage of greater than 0.5 ml. and the highest dosage was only 0.65 ml. in 2 patients.

Of the 32 patients in class 2, 31 (97%) were successful with the intracavernous drug-induced erection program. The study showed that class 2 patients could respond with an initial dosage of 0.25 ml., while 25 patients required a dosage of 0.30 to 0.65 ml., 2 required 0.80 ml. and 3 required 0.90 ml. Only 1 patient failed to respond successfully to pharmacological treatment. There is a statistically significant difference in the dosages between classes 1 and 2. The Mann-Whitney analysis showed a chi-square of 14.5211 and a p value of 0.0001.

Of the 17 patients in class 3, 8 (48%) were successful with the intracavernous drug-induced erection program. Class 3 patients required a minimum dosage of 0.40 ml. for a successful response. Therefore, 0.40 ml. is the recommended initial dosage for this class. Nine patients (52%) reached the maximum dosage of 1.0 ml. without a successful erection and were considered to be treated unsuccessfully by this program.

DISCUSSION

A population of men presented with a desire to improve the sexual dysfunction problem by means of pharmacological agents. These patients were knowledgeable about penile prostheses and revascularization procedures but they did not want to undergo an operation and, therefore, they did not present for treatment until the pharmacological home injection form of treatment became popular. The urologist who uses intracavernous medication for treatment of male sexual dysfunction has not had available a simple, noninvasive method to evaluate the patient and determine an initial dosage of intracavernous medication.

Our results indicate that the portable nocturnal penile tumescence monitor can serve as a useful guide to provide a classification of sexual dysfunction based on severity of the nocturnal erection pattern to assist the urologist in initiating discussion of the intracavernous medication treatment program with the patient. The urologist then is freed of making the distinction between organic and/or psychogenic impotence. The urologist then only must classify the degree of sexual dysfunction as determined by the nocturnal tumescence monitor pattern. The tracing can be shown to the patient to explain graphically the nocturnal erection pattern. Many patients are amazed at the nocturnal tumescence monitor graph. Class 1 impotence patients wondered how the penile performance could be so good at night and so poor when they wanted a good erectile response.

The findings in class 1 patients led to use of the term mild sexual dysfunction instead of organic versus psychogenic or simply impotent. All of the men complained of impotence. Obviously, they were not impotent according to either penile tumescence monitor tracings or the response to intracavernous medication. These men wanted treatment; many had already seen psychiatrists without resolution of the problem. They did not respond to testosterone, yohimbine or isoxuprine hydrochloride but they responded 100% to intracavernous medication, which is the reason for associating class 1 as mild sexual dysfunction.

Class 1 was designated mild sexual dysfunction even though the nocturnal tumescence monitor pattern was normal. The question raised was whether these men who complain of impotence really are normal men with a psychological problem. To evaluate this question more objectively the organic etiologies of the impotent patient for each nocturnal penile tumescence class were compared (table 2). In 11 class 1 patients there was no obvious cause to explain the sexual dysfunction, while 15 had an obvious etiology. Even if the 11 patients had psychological impotence 15 others with a normal nocturnal penile tumescence tracing had an organic condition.

Class 2 was designated as moderate sexual dysfunction because the nocturnal penile tumescence tracings were not normal as in class 1 but they were not less than 50% of the normal tracing as in class 3. In this class the average patient age was 56 years, the same as in class 1. Only 6 of the 32 patients had no obvious cause for the sexual dysfunction (table 2). The nocturnal penile tumescence tracings were sufficient to diagnose moderate sexual dysfunction. In this class one may advise the patient that intracavernous injection should be successful in more than 95% of the cases. The initial dose was 0.25 ml. and many of the men required doses of greater than 0.5 ml. for success.

Class 3 was designated as severe sexual dysfunction because the nocturnal tumescence monitor pattern was less than 50% of normal. Patient age and underlying etiology of impotence were obvious; average patient age was 66 years and most patients had a diabetic and/or vasculogenic etiology (table 2).

TABLE 2. *Etiology of sexual dysfunction*

Diagnosis	Nocturnal Penile Tumescence Class (No. pts.)		
	1	2	3
Vasculogenic	8	10	8
Diabetes	3	12	7
Prostate surgery	1	1	1
Medication	1	1	
Alcohol	1	1	
Obesity	1	1	
No obvious cause	11	6	1
Totals	26	32	17

According to this study the urologist may advise the patient that he has a 50:50 chance of this form of therapy being successful and that he may safely initiate treatment with a dosage of 0.4 ml. medication. Although the dosages of medication overlapped in the 3 classes statistical analysis showed that the dosages were significantly different. Also significant was the initial successful dosage among classes 1 to 3.

The prediction of response to intracorporeal pharmacological medication by means of the nocturnal tumescence monitor has been demonstrated by Allen and Brendler, who concluded that laboratory-conducted nocturnal tumescence monitoring allowed them to predict response to intracorporeal pharmacological erections.[10] However, the classification of impotence also required consideration of a penile-brachial index and a complicated bulbocavernosus-to-ischiocavernosus muscle activity ratio, making it an involved and probably costly laboratory-oriented evaluation. When the tests were normal they concluded that the impotence was psychogenic. They still used vasoactive therapy as the first line of treatment for those impotent men.

A number of patients who used the nocturnal tumescence monitor incorrectly despite good personal instruction were not included in this study. In addition, nothing can be stated regarding use of the portable nocturnal tumescence monitor in patients with spinal cord injury and/or neurogenic impotence, since none was included in the series. I am aware that a portable nocturnal tumescence monitor is not as sophisticated as a sleep laboratory. However, the portable monitor is a noninvasive, fairly easy-to-use device that requires no observer or sophisticated sleep laboratory. A number of studies report the monitor to be acceptable for evaluation of sexual dysfunction.[11, 12] However, the portable nocturnal tumescence monitor is not without critics.[13, 14] The portable monitor was used to classify sexual dysfunction for management via a drug-induced erection program.

One may ask why the maximum total dosage used was 1.00 ml. In my experience before this study higher dosages of medication were used without additional response than that obtained with 1.0 ml. Perhaps, a response occasionallly can be obtained with 1.25 or 1.50 ml. but the risk-to-reward ratio may increase with the dosage of greater than 1.0 ml. There were no complications in this study with the 1.0 ml. maximum dosage. The patient usually agrees with the conclusion that a complication is not worth an erection. He then can be offered alternative choices of treatment if the maximum dosage is reached without success.

More experience will be required with the use of the portable nocturnal tumescence monitor to refine this sexual dysfunction classification and intracavernous dosage selection. However, one may conclude from this study that sexual dysfunction severity for treatment with intracavernous medication can be classified by penile tumescence monitor tracing patterns. One also can conclude that initial and subsequent dosages can be selected, and a gauge of the per cent success and/or failure can be given to the patient. Therefore, the portable nocturnal tumescence monitor may be considered a useful tool in the evaluation and management of the sexual dysfunction patient who desires intracavernous drug-induced erections. It is hoped that this classification will enhance the urological approach to this form of treatment.

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