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New methods in the diagnosis of impotence: RigiScan® penile tumescence and rigidity monitoring and diagnostic papaverine hydrochloride injection

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Summary. In 26 patients with erectile impotence and 8 healthy volunteers the value of continuous monitoring of penile tumescence and rigidity by means of the RigiScan was tested. Based on history and routine screening tests the patients were divided into 3 groups of preliminary diagnosis: psychogenic (5 patients), organic (10 patients), mixed (11 patients). Real-time measurements of tumescence and rigidity were performed during direct visual stimulation and after intracorporeal injection of 80 mg papaverine hydrochloride according to a specific protocol. A total of 21 patients were monitored during sleep studies for 2 or 3 consecutive nights. The rigidity figures of the volunteers correlated well with their subjective interpretation of the erection. Evaluation of the recordings of the impotent patients enabled reclassification of the mixed group into 3 patients with mainly organic and 8 patients with mainly psychogenic impotence. RigiScan recording of penile tumescence and rigidity appears to be of great value in the diagnosis of impotent patients. Real-time monitoring during direct visual stimulation and after papaverine injection can generally replace nocturnal measurements. If the patient shows a positive response on visual sexual stimulation (VSS) alone, then his impotence is of psychogenic origin. Failing rigidity during VSS after injection indicates vascular impotence. In patients who show negative results during VSS alone, and positive response after injection or during subsequent VSS, nocturnal monitoring will differentiate between psychogenic and neurogenic impotence.

Erectile impotence is the inability to obtain or sustain a penile erection that enables intercourse. Penile erection involves the coordinated interaction of the vascular, peripheral and central nervous system, but its mechanism has not been fully elucidated to date. In patients complaining of erectile impotence, each of these functions should be carefully evaluated before treatment is started. The primary goal of the evaluation of impotence is to characterize patients into two therapeutic categories [9], one consisting of those patients for whom psychological counselling should be tried first and the second of patients without psychological abnormality in whom the sexual dysfunction is of organic origin.

Nocturnal penile tumescence measurement is a widely used technique for the differential diagnosis of impotence [3, 12]. A normal pattern of nocturnal penile tumescence indicates that neural and vascular supply, as well as penile structures, are intact. A normal nocturnal recording in a man with impotence complaints might indicate psychogenic impotence, while abnormal nocturnal penile tumescence is indicative of organic impotence. The key problem in erectile dysfunction, however, is not the lack of increasing volume during erection but the lack of stiffness, therefore penile rigidity seems a more crucial variable than circumferential expansion [6, 13, 14, 19, 21]. Nocturnal penile tumescence monitoring alone is therefore of limited value in the diagnosis of impotence.

Various methods of documentation of penile rigidity have been developed, among which are the recording of buckling force [12], penile application of stamps [2], Erectiometer bands [10] or snap-gauge cuffs [8], and finally, photography of the penis [20]. These techniques, however, do not give sufficient information on frequency, quality or duration of penile rigidity and of possible difference in the rigidity between penile base and shaft [20]. A new device, the RigiScan, has been developed, that measures tumescence and rigidity more accurately in patients with impotence [4, 11, 16].

The intracavernous drug-induced erection with papaverine hydrochloride is a new method in the management of impotence [17]. In normal men, the smooth muscle around the sinusoidal channels in the corpora cavernosa relaxes, the arterial inflow increases and the venous outflow decreases [1]. Virag [18] and Abber [1] found statistical differences in response to injection between nonorganic impotence and impotence caused by vascular lesions. This might qualify intracavernous papaverine injection as a screening test in the differential diagnosis of erectile dysfunction.

The aim of this study was threefold:

- to test the value of continuous monitoring of tumescence and rigidity in the evaluation of patients with impotence,

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Fig. 1. RigiScan: computer-controlled, battery-powered system for recording of penile tumescence and rigidity

- to clarify the value of intracavernous injection of papaverine hydrochloride as a screening test for impotence,
- to test the possibility of replacing nocturnal RigiScan recording by real-time measurement after papaverine injection and during visual sexual stimulation.

Material and methods

The RigiScan (Fig. 1) features a self-contained microprocessor with clock, calender and data storage, and two loop strings connected to two dc motors. The system is battery-powered and weighs 2.3 kg. For measurement, the loop strings are placed near the base and tip of the penis, respectively. During measurement, the loops are tautened every 15 s with a force of 1.7 N to measure penile circumference. The loop length is read from potentiometers. Between tautenings, no force is exerted on the loop strings. When tumescence occurs, the loops increase in circumference, thus pulling the strings out of the instrument and adjusting the potentiometers to the increased length readings. When, after tautening, tumescence increase over 1 cm is noted, the loops are tautened once every 30 s with a somewhat higher force (2.8 N). The resultant extra-shortening of the loop is a measure of penile rigidity. Penile circumference is measured in the range 5–15 cm. Rigidity is given in percentage, 100% rigidity meaning that no extra shortening is measured under the higher force. Each 0.05 cm of extra shortening diminishes the rigidity figure by 2.3%. It must be understood that this rigidity measurement reads the circumferential rigidity of the penis and not the axial rigidity, or buckling force, which is the clinically important parameter. Bradley et al. [4], however, showed that circumferential rigidity is linearly related to the buckling force. After the recording, the RigiScans memory retains the identification and measurement data. It can store the data of up to three 10-h monitoring sessions. The instrument's memory contents can be dumped into a microcomputer memory and stored permanently.

Monitoring can be performed either with the instrument alone or with the instrument connected to the microcomputer (real-time measurement). The first method is practiced especially in nocturnal (sleep) monitoring in patients. Real-time studies are monitored directly on the graphic video terminal and both real-time and off-line studies can be displayed from floppy disk storage on the terminal. The system software gives a representation of the data in 4 graphs: base and tip circumferences and rigidities, in cm and %, respectively. All terminal screens can be hard-copied onto the computer printer. For reliable nocturnal recordings, at least 2–3 night sessions are necessary. This corroborates findings of Bradley et al. [4] and those in classical nocturnal penile tumescence recordings [5, 6].

Based on RigiScan data of over 500 patients in the Uro-Center of San Diego, Johnson summarized the guidelines of normal data as given in Table 1 [7].

The 8 healthy volunteers were monitored while watching a visual sexual stimulation (VSS) video tape. Their recordings were performed on the off-line system. Afterwards they gave a subjective grading of erectile performance. A total of 26 impotent males were studied. All patients underwent routine screening tests consisting of detailed history and physical (including neurological) examination, determination of serum hormone levels, calculation of the penile brachial index, and psychological screening. Angiography, cavernometry and cavernography were not performed in this preliminary study.

Of the 26 patients, 21 performed measurements with the RigiScan during 2 or 3 consecutive nights, mostly at home. The results were evaluated according to Johnson's guidelines (see Table 1) with the exception of the number of erections: the occurrence of a single event was judged as positive.

Tumescence and rigidity were recorded in all patients during direct VSS at the outpatient department. The procedure was as follows: The loops were fixed to the penis and monitoring was started. A period of 5 min was allowed during which the subject could relax after penile manipulation and accustom himself to the regular tautening of the loops. A VSS video tape was then run for 25 min. After a resting period of 5 min, 80 mg papaverine hydrochloride was injected intracorporeally and the effect recording during 35 min. During the last 10 min of this period another VSS video tape was run. The whole session was recorded using the RigiScan system in the real-time mode.

Table 1. Normal findings with RigiScan monitoring [7]

Number of erections	3–6 per 8-h night
Duration of erections	10–15 min per event
Tumescence base	> +3 cm
Tumescence tip	> +2 cm
Rigidity insufficient	<40%
Rigidity partially sufficient	40%–70%
Rigidity sufficient	>70%

Abnormalities:
Dissociation: normal base readings with abnormal tip rigidity (with or without normal tip tumescence)
Uncoupling: normal tumescence with abnormal rigidity (base and tip)

Results

All volunteers showed good tumescence increase. Rigidity correlated well with their subjective interpretation. The results also corroborated Johnson's data in that rigidity of less than 40% was judged as insufficient, from 40% to 70% as partly sufficient and over 70% as sufficient for coitus. For the patient recordings, therefore, rigidity of at least 40% is regarded as adequate.

The patients were divided into 3 groups of preliminary diagnosis, based on history and clinical investigation. Pure psychogenic impotence was diagnosed in 5

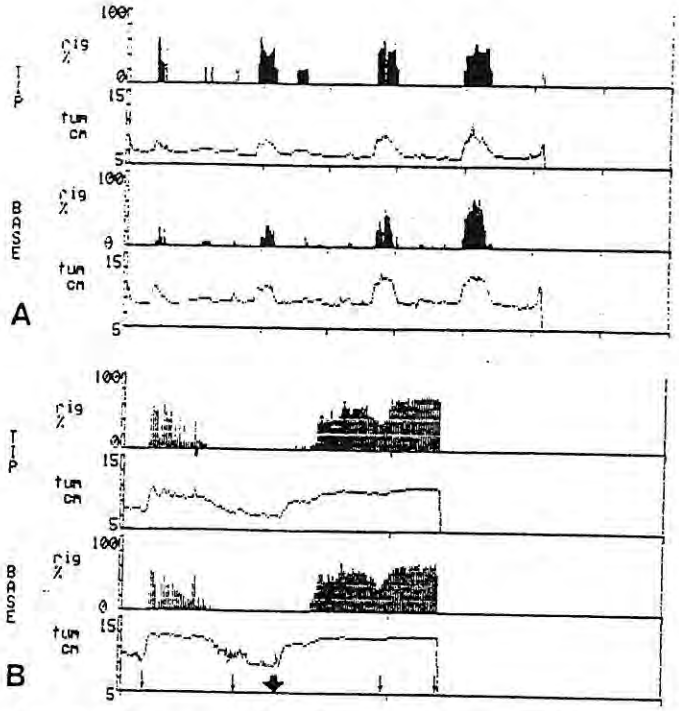


Fig. 2A, B. RigiScan recordings in psychogenic impotence. A Nocturnal monitoring; 8-h screen. B Real-time monitoring; 2-h screen. Small arrows: beginning and end of visual stimulation. Fat arrow: intracorporeal injection of papaverine (80 mg)

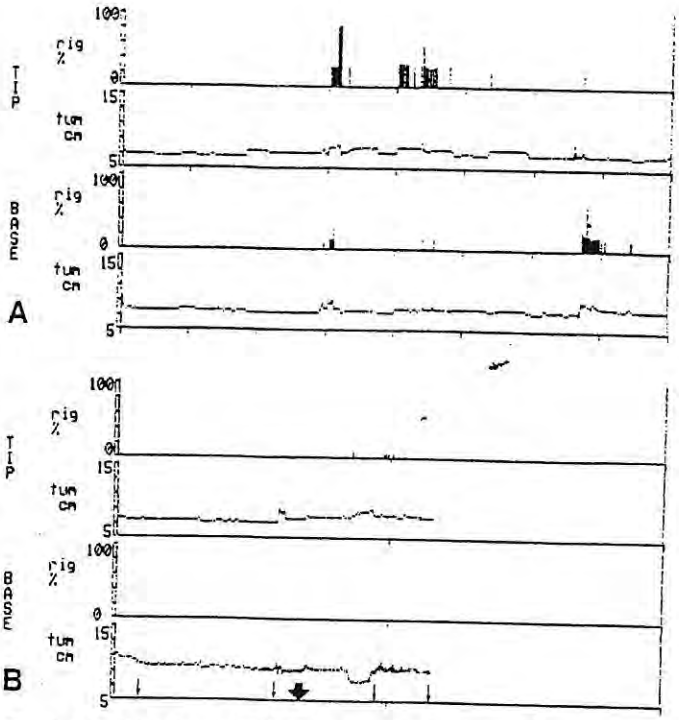


Fig. 3A, B. RigiScan recordings in organic impotence. A Nocturnal monitoring; 8-h screen. B Real-time monitoring; 2-h screen. Small arrows: beginning and end of visual stimulation. Fat arrow: intracorporeal injection of papaverine (80 mg)

men (2 with ejaculatio praecox), pure organic impotence in 10, and mainly psychogenic with co-existence of an organic factor in the remaining 11. Nocturnal recordings were performed in 4 psychogenic, 6 organic and all 11 mixed patients.

Figure 2A shows the nocturnal recording of a psychogenic patient. Three periods of good erection lasting 15–30 min and a short fourth one were found. In an organic patient (Fig. 3A), slight tumescence was found, together with some inadequate rigid periods. This patient was a 55-year-old diabetic after amputation of the rectum. The real-time measurements in the same patients (Figs. 2B, 3B) showed very similar results.

The final results of the investigations in all patients are presented in Table 2. VSS alone elicited good tumescence increase in all 5 psychogenic patients, with adequate rigidity in 4. One organic and 4 mixed patients also showed tumescence increase, but without rigidity. All other patients showed no or negligible reactions. In all patients who demonstrated tumescence, detumescence occurred during the 5 min rest period. After injection of papaverine hydrochloride, tumescence increased with a 2–15-min delay in all psychogenic patients, in 4 organic patients, and in all but 1 of the mixed patients. In one other mixed patient, a drug-induced collapse occurred. Adequate rigidity after injection was found in the 4 psychogenic patients that had already shown rigidity during VSS alone, and in 4 of the mixed patients (Table 2). VSS after the injection did not change the existing readings of tumescence, whether positive or negative, but the fifth psychogenic patient and another 4 from the mixed group now demonstrated adequate rigidity.

Of the 21 sleep sessions (best of 2 or 3 measurements per patient), neither tumescence increase nor rigidity was observed in 6 patients (see Table 2). Of these, 4 had a preliminary diagnosis of organic, 2 of mixed impotence. In 4 patients (2 organic, 2 mixed), nocturnal tumescence occurred, but without rigidity. The 4 psychogenic and 7 of the mixed patients showed good nocturnal erections.

Of the 20 patients in whom both real-time and nocturnal studies were completed, tumescence and rigidity results were comparable in 18 (see Table 2). One mixed patient (M3) only showed tumescence during the night, whereas sufficient rigidity was found during VSS after papaverine injection. Patient M11, who showed no reactions during the sleep session, also responded well to papaverine injection.

Discussion

From the results on healthy volunteers it was concluded that the RigiScan® monitor is a reliable and objective system to record and measure the quality of erection, also during real-time sessions. Bradley et al. [4, 11] have already described its use in sleep studies.

The patient studies indicate that pure psychogenic impotence can be diagnosed by a positive response to VSS alone. Vascular impotence on the other hand can be

Table 2. Results of real-time and nocturnal RigiScan recordings in 26 impotent patients

Preliminary diagnosis	Visual stimulation		Papaverine injection		+ Visual stimulation	Night recording		Final diagnosis (main cause)
	Tum.	Rig.	Tum.	Rig.	Rig.	Tum.	Rig.	
Psychogenic								
P1	+	+	+	+	+	+	+	psychogenic
P2	+	+	+	+	+	+	+	psychogenic
P3	+	+	+	+	+	+	+	psychogenic
P4	+	+	+	+	+	0	0	psychogenic
P5	+	−	+	−	+	+	+	psychogenic
Organic								
O1	−	−	−	−	−	0	0	vascular
O2	−	−	−	−	−	−	−	vascular
O3	−	−	+	−	−	0	0	vascular
O4	−	−	−	−	−	−	−	vascular
O5	−	−	−	−	−	−	−	vascular
O6	−	−	−	−	−	0	0	vascular
O7	+	−	+	−	−	+	−	vascular
O8	−	−	+	−	−	+	−	vascular
O9	−	−	+	−	−	0	0	vascular
O10	−	−	−	−	−	−	−	vascular
Mixed								
M1	+	−	+	−	+	+	+	psychogenic
M2	+	−	+	−	−	+	−	vascular
M3	−	−	+	−	+	+	−	neurogenic?
M4	−	−	+	−	+	+	+	psychogenic
M5	−	−	★	★	★	+	+	psychogenic
M6	−	−	+	+	+	+	+	psychogenic
M7	−	−	−	−	−	−	−	vascular
M8	−	−	+	+	+	+	+	psychogenic
M9	+	−	+	−	+	+	+	psychogenic
M10	−	−	+	+	+	+	+	psychogenic
M11	+	−	+	+	+	−	−	psychogenic?

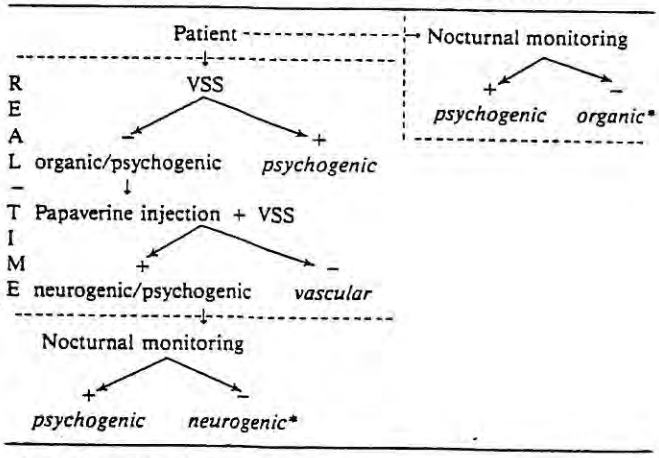
0: no night recording performed
★: patient collapsed after papavarine injection

diagnosed by a negative result on papaverine injection combined with VSS [1, 16, 18]. Tumescence increase can occur, but the erection lacks rigidity. In this manner, 2 patients with combined problems (M2, M7) were classified as having a major vascular problem. Further investigations such as angiography, cavernometry and cavernography are necessary to localize the vascular lesion.

In patients with a negative response to VSS and a positive response after injection or subsequent VSS, either a psychogenic or a neurogenic factor might be the origin of impotence, as pure neurogenic impotence is also sensitive to intracorporeal papaverine injection [1, 16, 18, 22]. Sleep studies with positive results in these patients classify them as mainly psychogenic; negative results on the other hand must be confirmed by first ruling out sleep disturbances [15] before the diagnosis of mainly neurogenic impotence can be made. In the present material it may be expected that patient M3, who showed tumescence without rigidity, probably has neurogenic impotence, whereas in patient M11 – no tumescence and no rigidity – sleeping disturbance is indeed more probable (see Table 2).

The combination of real-time RigiScan monitoring, VSS, intracorporeal papaverine hydrochloride injection, and nocturnal monitoring if necessary, has changed our diagnostic approach in impotent patients, as presented in Table 3. Tumescence increase alone during the investigations is judged as insufficient; rigidity should also be present.

Table 3. Diagnosis by RigiScan and papaverine in impotence



Final diagnosis of main cause are italics.
*Final diagnosis only valid if sleep disturbance is ruled out.

The investigation is started with a VSS session; a positive response then diagnoses psychogenic impotence. In patients with a negative response, a diagnostic injection of papaverine is then administered; a negative response both on this and on subsequent VSS indicates vascular impotence. Nocturnal monitoring of the remaining patients classifies them as psychogenically impotent if the results are positive and as neurogenically impotent if sleep was undisturbed and the results are negative. In patients with combined psychologic and organic disturbances, the major factor contributing to the impotence can be isolated.

Although nocturnal monitoring may also be performed first to separate major organic from major psychogenic disturbances, this is considered too elaborate because of the need for a minimum of two night sessions per patient, and the problems associated with exclusion of sleep disturbances in cases with negative findings.

Conclusion

The final diagnosis after RigiScan monitoring and papaverine injection did not change the preliminary diagnosis of pure organic impotence (see Table 2). All of these 10 patients are now diagnosed as having vascular impotence. In the mixed group, a final diagnosis of mainly vascular impotence was reached if no rigidity was measured, even during VSS after papaverine injection (M2, M7). Four patients from the pure psychogenic group demonstrated rigidity during VSS before injection. This, then, was seen to be sufficient to confirm the diagnosis.

One patient in this group (P5) and the remaining patients in the mixed group showed rigidity only after papaverine injection, or during subsequent VSS. In these patients, nocturnal monitoring separated major psychogenic from major organic (here: neurogenic; M3) impotence. However, controlled sleep studies are necessary before the final diagnosis of mainly neurogenic impotence can be made.

The final conclusions of this study are thus:

- RigiScan monitoring of erections, by continuous recording of penile rigidity and tumescence, increases the quality of the diagnosis in impotent patients.
- Real-time monitoring in combination with intracorporeal injection of papaverine hydrochloride and visual sexual stimulation will separate out the major vascular types of impotence. These patients might show tumescence increase only, without rigidity.
- Real-time monitoring with papaverine injection and visual sexual stimulation obviates the necessity for nocturnal recordings in most cases of impotence.
- In those patients who demonstrate rigidity only after papaverine injection or after papaverine combined with visual stimulation, controlled nocturnal measurements must be performed to differentiate neurogenic from psychogenic impotence.

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