# Shedding light on erectile dysfunction: unveiling perspectives and pioneering new erectile assessments

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# Part III

## Patients' perception

# Chapter 3

## Patients' perception on nocturnal erectile function assessment with the RigiScan

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## Introduction

Erectile dysfunction (ED) is a prevalent condition affecting many men, and its incidence rate increases with age [1,2]. ED has emerged as an important sentinel marker of cardiovascular and overall health among men [3,4]. Timely and accurate diagnosis of ED not only facilitates treatment but also offers a valuable opportunity to identify comorbid conditions and potentially life-threatening conditions [5].

The RigiScan® (GoTop Medical, Minneapolis, MN, USA) [6] is a diagnostic tool used to assess erectile function during sleep and is traditionally regarded as the most validated diagnostic procedure for differentiating between psychological and organic causes of ED [5,7]. The utilization of the RigiScan® has significantly propelled research in the field of ED.

The RigiScan® examination involves wearing a device with two rings around the penis, which is connected to a recording unit. During the night, the device measures changes in penile circumference, rigidity and the duration and frequency of these events, providing healthcare professionals with objective data on nocturnal erections [8,9]. The data obtained from the RigiScan® examination can assist in the diagnosis and management of ED [9,10].

While these data have diagnostic value, the use of the RigiScan® has certain disadvantages. Patients may experience discomfort or a sense of awareness while wearing the RigiScan® device while sleeping. The large size of the device and its location on the leg hinders the ability to assume a comfortable lying position. Patients may experience interruptions or awakening due to the device, which can cause an inaccurate representation of nocturnal erections [8,9,11]. This discomfort and the potential need for multi-night measurements can impact the accuracy of the data. Furthermore, the RigiScan® is delicate and easily damaged, requiring careful handling and detailed instructions for proper attachment. There is also an issue regarding software compatibility with modern computer operating systems [12].

The clinical utility of the RigiScan® examination has been declining due to these limitations. As a result, there is a growing demand for the development of a new measurement method [13]. Understanding patient experiences with the RigiScan® can provide valuable insight for developing new diagnostic tools that are more comfortable, reliable, and user-friendly.

## Aim

The primary aim of this study was to evaluate Dutch patients' perceptions of the RigiScan® and to explore what patients indicate as advantages and disadvantages of the RigiScan®. The secondary aim was to determine whether there is a need for a new device and what conditions a new device must meet for patient satisfaction.

## Materials and methods

From March 2022 until February 2023, a nonvalidated questionnaire with 12 items was mailed to all patients who had a RigiScan® measurement at St. Antonius Hospital and the Leiden University Medical Center (LUMC) between 2016 and February 2023. To obtain a higher response rate, a reminder was sent two weeks later.

The questionnaire was designed by two Dutch sexologists from St. Antonius Hospital in collaboration with two urologists from LUMC involved in andrology and sexual health. There was no validated questionnaire for our research question. The survey questions were pretested through an online survey in seven individuals whose characteristics were similar to those of the sampling frame to ensure relevance and consistency in interpretation, this was done in September 2021. After making changes, with the use of feedback, the questionnaire was pilot tested.



The questionnaire consisted of four parts: 1) age, 2) medical history, 3) user-friendliness, 4) experiences with the RigiScan®, 5) sleep quality, 6) patient-experienced (dis)comfort, and 7) wishes for a new sensor. Some answers could be given on a scale from 0 to 10. The translated questionnaire is available in the Appendix.

Study data were collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools hosted at St. Antonius Hospital. REDCap is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trials for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources [14].

The statistical outcomes were analyzed with IBM SPSS statistics 25 (SPSS Inc., Chicago, IL, USA). The data were analyzed with the use of descriptive statistics. To analyze the relationship between age and the outcomes of difficulty in attaching the device, sleep quality, and pain or discomfort, we used both categorical and continuous representations of age. Age was categorized into three groups: 19-40 years, 40-60 years, and over 60 years. For categorical age groups, we used the Kruskal-Wallis test to assess overall differences between groups. If the Kruskal-Wallis test indicated significant differences, we performed post-hoc pairwise comparisons using the Mann-Whitney U test to identify which specific groups differed.

In addition to categorical analysis, we treated age as a continuous variable to explore its linear relationship with the outcomes. Simple linear regression was conducted to determine whether

age could predict the difficulty in attaching the device, sleep quality, and pain or discomfort. Statistical significance was set at a p-value of less than 0.05 for all tests.

The Dutch Medical Ethics Committee was consulted, an application was submitted, and approval was obtained for this study (registered as W19.122 on July 1, 2019). Local approval was received from St. Antonius Hospital (registered as Z19.092 on March 5, 2020) and LUMC (registered as N20.162 on January 4, 2021).

## Results

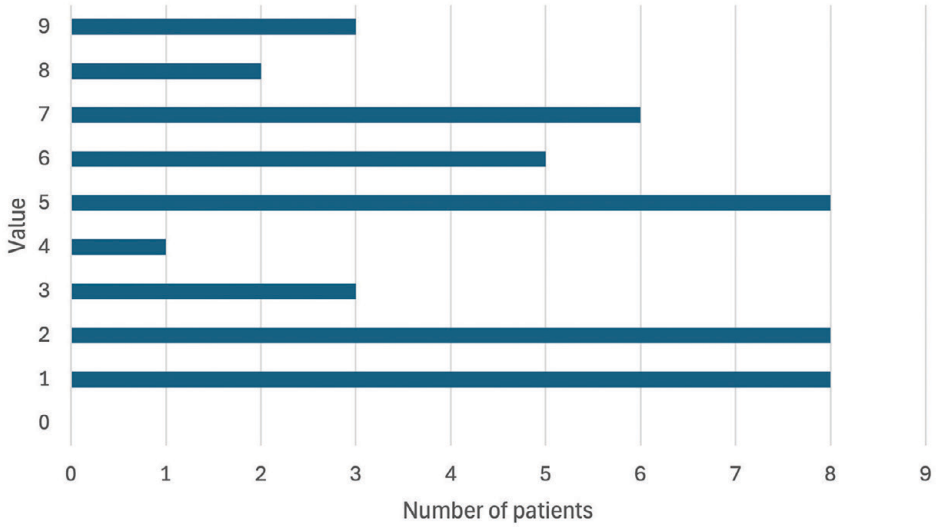
Between the first of January 2016 and February 2023, 120 patients underwent a RigiScan® examination for nocturnal erection detection. The questionnaire was sent to all 120 patients. Of these patients, 47 (39.2%) returned completed questionnaires. Three respondents (6.4%) did not answer one of the questions.

The mean age of the respondents (at the time of completing the questionnaire) was 39 years with a standard deviation of 16 years (range: 19-73 years). A total of 32 patients (68.1%) reported an absence of comorbidities. Heart and/or vascular disease was reported by six (12.8%), Peyronie's disease by four (8.5%), diabetes by two (4.3%) and prostate cancer by one (2.1%). None of the respondents reported hypogonadism. Human immunodeficiency virus, granulomatosis with polyangiitis, sleep apnea, depression and muscle stiffness were each reported once as explanations for selecting the answer "other".

For 45 patients (95.7%), this was the first time that the RigiScan® was used. Two patients had this examination once before. All of the subjects underwent the RigiScan® measurement at home. The majority of patients underwent the RigiScan® examination for one night (n= 20, 42.6%), while 17 patients (36.2%) underwent two nights of examination and 10 patients (21.3%) underwent three nights of examination.

The answers to the question of how complicated it was to attach the RigiScan® to the penis ranged from zero (easy) to ten (very difficult). The average score was 4.6±2.5 (range: 1-9) points. Figure 1 shows a bar chart for the question, "How complicated was it to put the measuring device on the penis?"

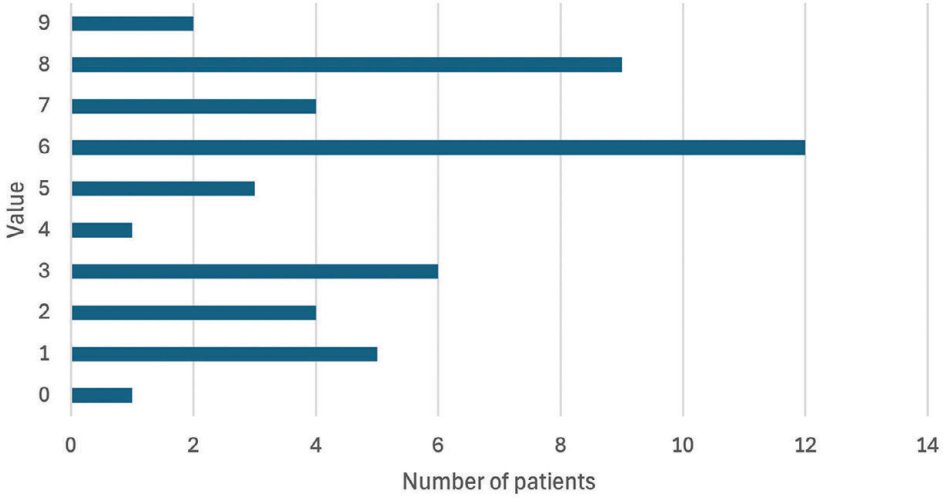
**Figure 1: Bar chart for the question, "How complicated was it to put the measuring device on the penis?"** On a scale from 0 to 10, where 0 was 'very easy', and 10 was 'very difficult' (vertical axis). The number of patients is shown on the horizontal axis.(missing data of three patients)




The majority were able to continue the RigiScan® measurement all night (n=35, 74.5%). Eight patients mentioned that (one of ) the loops slipped off the penis during the night. Two patients removed the RigiScan® loops due to pain or discomfort.

The quality of sleep question was also scaled from zero (no trouble sleeping) to ten (substantial difficulty sleeping). The average response to this question was 5.5±2.6 (range: 0-9) points. (Figure 2) Sixteen people had trouble sleeping. Ten people slept well or experienced little hindrance. Nine people woke up from pain or tightening of the loops of the RigiScan®. Eight people noted waking up more often and that turning was more difficult due to the part of the RigiScan® that was placed on their leg. Eight people lost the leg attachment for the RigiScan® and/or had trouble keeping the device on the leg. Four people mentioned waking up from the sound of the RigiScan®. Three people mentioned that they could not sleep in their normal position due to the large device. In one person, the loops became loose.

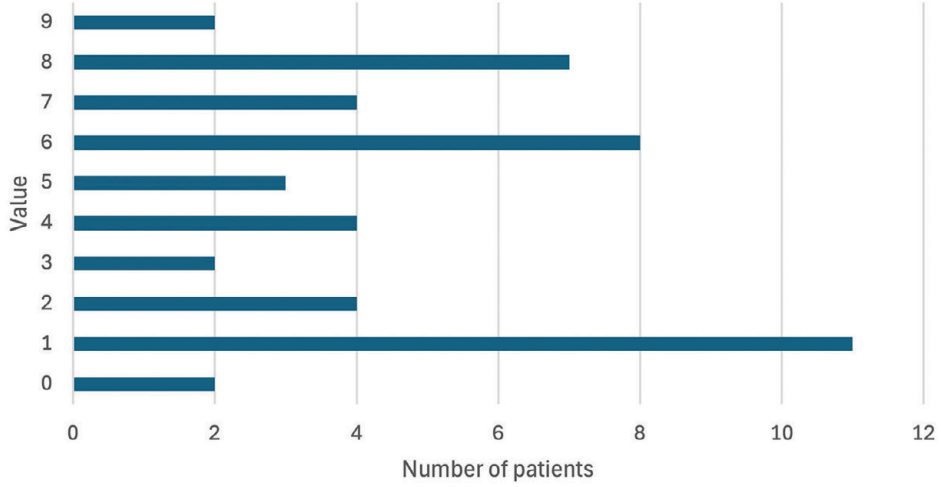
**Figure 2: Bar chart for the question, "How was the quality of sleep during the measurement compared to normal?"** On a scale from 0 to 10, where 0 was 'not bothered by the measurement while sleeping' and 10 was 'very bothered by the measurement while sleeping' (vertical axis). The number of patients is shown on the horizontal axis.




In response to the query assessing the level of pain or discomfort on a scale ranging from zero (indicating no pain or discomfort) to ten (representing significant discomfort or pain), participants reported an average rating of 4.7±2.8 (range: 0-9) points. (Figure 3) Among the respondents, 29.8% (14 individuals) expressed dissatisfaction with the RigiScan®, stating that it did not fulfill their expectations.

The differences was calculated in the difficulty of attaching the device, quality of sleep, and pain or discomfort with age both as categorical (20-40; 40-60; >60) and linear variables (performing a linear regression analysis). The average scores for difficulty in attaching the device, quality of sleep, and pain or discomfort were 3.4, 5.6, and 4.6 for the 19-40 age group (27 patients); 5.1, 4.3, and 3.1 for the 40-60 age group (15 patients); and 6.2, 6.6, and 4.4 for the >60 age group (5 patients). A Kruskal-Wallis test indicated that age, when divided into groups, was a significant predictor of the difficulty in attaching the device ($p = 0.049$). Subsequent Mann-Whitney tests, however, did not identify significant differences between the specific age groups. Additionally, age was not a significant predictor of sleep quality ($p = 0.2$) or pain/discomfort ($p = 0.4$). A simple linear regression analysis indicated that age was a significant predictor of the difficulty in attaching the device ($R^2 = 0.208$, $p = 0.002$), but not a significant predictor of sleep quality ($R^2 = 0.002$, $p = 0.762$) or pain/discomfort ($R^2 = 0.017$, $p = 0.388$).

**Figure 3: Bar chart for the question, "Can you rate how much pain/discomfort the measurement gave you on a scale of 0 to 10?"**, where 0 was 'not bothered by pain or discomfort' and 10 was 'substantial difficulty with the measurement' (vertical axis). The number of patients is shown on the horizontal axis.




The most important improvements for a successor of the RigiScan® should concern size (n=33, 33.6%), user-friendliness (n=25, 25.5%), noise (n=9, 9.2%), hygiene (n= 7, 7.1%), pain (n= 6, 6.1%), faster results (n=4, 4.1%), visibility for the environment (n= 2, 2.0%), and other factors (n=12, 12.2%) (Table 1). Other improvements suggested by the patients included an indicator light so you know if it is on and if the measurement is done correctly, an increased battery life, decreased heaviness and/or size of the device (three times), increased reliability, decreased pressure on the penis, no cords around the penis, and decreased impact of the measurement protocol on sleep (two times).

**Table 1:** What are the main conditions that a new sensor to measure nighttime erections must meet? [Patients were able to give 3 answers max.]

| Type of improvement | n (47) | % (of total answers) |
|---|---|---|
| User-friendliness | 25 | 25.5 |
| Hygiene | 7 | 7.1 |
| Decreased sound | 9 | 9.2 |
| Decreased size | 33 | 33.7 |
| Decreased pain | 6 | 6.1 |
| Visibility for the environment | 2 | 2.0 |
| Faster results | 4 | 4.1 |
| Other | 12 | 12.2 |

On the question: If a new small and reliable device were to come into the shop to be able to do this measurement anonymously at home, how much money would you pay for this? Forty-two persons answered a number between 0 and 500 euros, and the average amount for a new device was 74 euros. Seventeen people would not pay any money for this. Two persons answered that they were unsure. Three people mentioned that they would only perform this test if it was covered by health care insurance.

## Discussion

The focus of this study was on understanding patients' perspectives on the use of the RigiScan®, a diagnostic tool for assessing ED. Our findings indicate that while the RigiScan® has been valuable in identifying the causes of ED, it has significant drawbacks, particularly regarding patient comfort and usability.

The most noticeable and mentioned drawback of the RigiScan® is the placement of straps and the slipping of straps during nocturnal measurements. This issue was mentioned by 25.5% of the respondents. Another critical factor was the impact on sleep quality, an aspect of overall well-being and a necessity in measuring nocturnal erections. The moderate discomfort (5.5±2.6) mentioned by respondents can lead to disrupted sleep patterns, potentially affecting the accuracy of nocturnal erection measurements. Moreover, respondents rated discomfort/pain at an average of 4.7±2.8 points, highlighting the need for a more gentle and less intrusive measurement.

The results indicate that attaching the device becomes more complicated as patients age, with significant differences observed in the average scores across age groups. The linear regression analysis confirmed that age is a significant predictor of the difficulty in attaching the device, explaining approximately 20.8% of the variance. However, age was not a significant predictor of sleep quality or pain/discomfort, suggesting that these factors are influenced by other variables. The small sample sizes within each age group limit the ability to draw definitive conclusions.

Patients mentioned several areas for improvement, including the desire for a smaller and lighter device. A more compact design could be less disruptive during sleep and more comfortable to wear during the night. They also expressed the need for a device that is easier to use, simplifying the process of using the RigiScan®. Patients suggested the desire for a device that produces minimal noise during the measurement, minimizing any potential disruptions to their sleep or discomfort caused by sounds.

The RigiScan® has long been the gold standard for differentiating between psychological and organic causes of ED [7]. It has been instrumental in diagnosing and understanding ED in men [7]. However, its use is decreasing rapidly due to outdated hardware and software and suboptimal patient experience [12]. This decline in usage and our study's insights from the patient's perspective underscore the need to explore alternative diagnostic tools that are more patient-friendly and practical.

In addition to patients, sexologists also acknowledge the issues with the current measurement method. Both groups expressed a shared desire for the improvement of the existing measuring device [13]. A significant proportion of sexologists expressed interest in using a 'simple sensor' for ED diagnosis if available [13]. Now that this has been established, hopefully, a more modern sensor can be developed that meets the requirements of both users and sexologists.



Despite the value of this study, there are limitations to consider. The response rate was relatively low at 39%, which may impact the generalizability of the findings. However, it should be noted that the response rate is higher than the average response rate of 30% for email-based questionnaires [15]. The low response rate may be attributed to the inclusion of a large population of non-Dutch speaking patients from the LUMC population. Additionally, the demographic characteristics of the respondents remain unknown, and this lack of information introduces the possibility that compared to the respondents, the nonrespondents may hold different beliefs regarding the RigiScan®, potentially leading to an untestable bias.

Additionally, the time gap between the RigiScan® examination and the survey distribution may have contributed to a lower response rate and could have led to recall bias, affecting the accuracy of the responses.

Given these limitations, further research is needed to confirm whether a new diagnostic device, designed with the improvements identified by patients, can indeed enhance patient satisfaction and lead to more accurate results. Additionally, it would be valuable to conduct this study with a new device to compare patient experiences, sleep quality, and comfort. This research may serve as a basis for further investigations into improving ED diagnosis and management, ultimately benefiting patients seeking treatment for this common condition.

This study revealed that patients who underwent a nocturnal erectile function assessment with the RigiScan® device preferred a more patient-friendly and less invasive diagnostic device. Their feedback emphasizes the importance of developing a compact, quiet, and user-friendly tool for assessing nocturnal erections. Further research is needed to ascertain whether a new sensor encompassing these suggested improvements can enhance patient satisfaction.

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