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KEY WORDS

prostate ◗ benign prostatic hyperplasia ◗ lower urinary tract symptoms ◗ prostatic stents ◗ sexual function

ABSTRACT

Introduction. This study was conducted to explore the effects of the bell-shaped Horizon prostatic stent on sexual function in the treatment of patients with LUTS/BPH.

Materials and methods. 108 Patients with LUTS/BPH were prospectively enrolled in the study. All stents were inserted in an outpatient setting under local anesthesia. To assess sexual function, the 15 item International Index of Erectile Function (IIEF) questionnaire was used. A comparison was made between the total score of the IIEF and the different domains (erectile function (EF), orgasmic function (OF), sexual desire (SD), intercourse satisfaction (IS), and overall satisfaction (OS)) at baseline, one month, and three months after placement of stents. In addition, patients were given the general assessment question "have you experienced any retrograde or painful ejaculations?".

Results. At baseline, one patient complained of painful ejaculations (1%). After one month, four (4%) patients complained of painful and two (2%) complained of retrograde ejaculations. A statistically significant decline in the mean OF and IS scores was found. After three months, the IS score significantly improved and the decrease in the OF was smaller than after one month. However, the number of patients reporting painful and retrograde ejaculation was again higher than at baseline (three (4%) and five (7%) percent respectively).

There was no change in the total IIEF score or the other subscores of the IIEF at one and three month(s).

Conclusion. The bell-shaped Horizon prostatic stent had a negative influence on OF, which did not improve with time. The first month after stent placement, IS was lower than at baseline. After three months however, IS significantly improved compared to baseline. The stent did not negatively affect the total IIEF score or the other domains of the IIEF.

INTRODUCTION

Patients with lower urinary tract symptoms suggestive of benign prostatic hyperplasia (LUTS/BPH) often experience sexual dysfunction. This co-existence of LUTS and sexual dysfunction in elderly men is not only due to the fact that the incidences of both conditions increase with age. The results of several community-based surveys indicate that the association of LUTS and sexual dysfunction is independent of age and various co-morbidities [1-10].

In the majority of patients with LUTS/BPH, the main incentive for any kind of treatment is improvement of quality of life by alleviation of symptoms. Sexual function is generally acknowledged as an important determinant of quality of life and therefore, the treatment of LUTS/BPH should not impair sexual function. Both pharmaceutical and instrumental treatments for LUTS/BPH are known to have several possible harmful effects on sexual function.

The use of prostatic stents in patients with LUTS/BPH has been studied since 1980. Prostatic stents aim at immediate improvement of symptoms by relieving obstruction. Over the past decades, the use of prostatic stents has been studied for various indications and different stent designs have been developed. Numerous papers describe the clinical results of studies to the efficacy and safety of the various stents, but few of these papers address the effect of prostatic stents on sexual function.

We performed a prospective study on the efficacy and safety of the bell-shaped Horizon prostatic stent in a group of patients with LUTS/BPH. In a previous paper, we described the results of the voiding parameters and symptom scores [11]. In this paper, we explore the effect of the bell-shaped Horizon prostatic stent on sexual function.

MATERIALS AND METHODS

Stents

An extensive description of the bell-shaped Horizon prostatic stent (Endocare incorporated, USA) and of the insertion and removal procedure was published previously [11]. Here, we will give a concise summary. The bell-shaped Horizon prostatic stent is a circular coil made of nitinol, a material with a temperature based shape memory. The predecessor of this stent was designed with an increasing diameter towards both ends of the stent (hourglass-shaped). Because of a high migration rate, adjustments in stent design were necessary. It was thought that the proximal wide end might have caused the stent to be pulled into the bladder instead of anchoring it in the prostatic fossa. Therefore, the successor of the hourglass-shaped Horizon prostatic stent was designed with a larger diameter of the distal end of the stents only (Fig. 1). This bell-shaped design was comparable to that of the Memokath prostatic stent [12, 13], another thermo-expandable prostatic stent known to migrate less often than the hourglass-shaped stent. The bell-shaped Horizon prostatic stent was available in six different lengths, ranging from 3.5 to 6 cm. In our study, the stent length was chosen to be 0.5 cm longer than the length of the prostatic urethra. All stents were inserted and removed by the same urologist (JdlR).

Fig. 1. The bell-shaped Horizon prostatic stent with a length of 5.5 cm.

Patients

The study was conducted in accordance with the regulations of the local ethical committee. An informed consent was obtained from all patients prior to any study-related proceeding. The inclusion criteria were moderate to severe LUTS (defined as an International Prostate Symptom Score (IPSS) >7) suggestive of BPH. The exclusion criteria were a history of malignancies of the urinary tract, previous pelvic irradiation or surgery, prior pharmaceutical, minimally invasive or surgical treatment for LUTS/BPH, urolithiasis, insufficient detrusor contractions, and urinary tract infections. Similar to the study with the hourglass-shaped Horizon prostatic stent, this study was performed in a group of LUTS/BPH patients without significant co-morbidities.

Main outcome measures

To assess sexual function, the 15 item International Index of Erectile Function (IIEF) questionnaire was used. The IIEF is a validated, self-administered questionnaire that addresses five domains of sexual function: erectile function (EF), orgasmic function (OF), sexual desire (SD), intercourse satisfaction (IS), and overall satisfaction (OS). The questionnaire adds up to a total of 75 points; a higher score indicates better sexual function [14, 15]. In addition, patients received the general assessment question: "have you experienced any retrograde or painful ejaculations?". To explore the effect of prostatic stents on sexual function, the results of the IIEF at baseline were compared to the results after one month and three months, the moment that most stents were still *in situ*. Other assessments included transrectal ultrasonography to determine prostate volume at baseline, uroflowmetry to measure maximum urinary flow (Qmax), transabdominal ultrasonography of the bladder to assess post-void residual urine volume, and the IPSS questionnaire including the Quality of Life (QoL) item [11].

Insertion

Insertions were performed in an outpatient setting under local anesthesia. The stents were placed under cystoscopic guidance, using a specially designed insertion device. The stents were flushed with a heated solution, which allowed full expansion.

Removal

Stents were removed in case of migration, severe complications, or when considerable worsening of symptoms occurred. Removal was performed under local anesthesia and antibiotic prophylaxis in the outpatient department. The stent was irrigated with cooled solution, which caused it to become flexible. It was then pulled outside with a grasper through the sheath of the cystoscope.

Statistics

To assess the number of sexually inactive patients at baseline, the percentage of patients answering the first question of the IIEF with "no sexual activity" was counted. In the calculation of the total IIEF score, only patients who completely filled out the questionnaire were taken into account. For the calculation of the scores of the different domains of IIEF, the patients that completed all the questions of a specific domain were considered. Not all patients filled out each questionnaire completely. Because of these missing data, the number of patients used for the calculation of means vary between the different domains and the total score of IIEF.

Assessment of sexual function was performed only on patients with the stent still *in situ*. The number of patients with the stent still *in situ* was counted at the scheduled follow-up visits. Since not all patients were seen exactly one or three months after stent insertion, the number of patients with the stent still *in situ* does not correspond to the number of patients with a stent *in situ* at 30 and 90 days as derived from the Kaplan-Meier survival analysis that was reported on in the previous paper on the bell-shaped Horizon prostatic stent[11].

The significance of changes in the different domains of the IIEF between baseline and one month and three months follow-up was assessed by paired-samples *T*-tests. Spearman's test was used to assess the correlation between IIEF and IPSS as well as QoL and Qmax. The correlation between the changes in IIEF and the changes in IPSS as well as QoL and Qmax was also assessed by Spearman's test. All inferential statistical tests were considered significant at $p < 0.05$. Statistical analyses were executed with the statistical software SPSS for Windows (version 14, SPSS Inc. Chicago, IL, USA) and Microsoft Office Excel (2003).

Table 1. Change in the mean International Index of Erectile Function (IIEF) one month and three months after placement.

Variable	Score (baseline)		Change in score (one month – baseline)				Change in score (three months – baseline)			
	Mean	SD	Mean	SD	p-value	No. of patients	Mean	SD	p-value	No. of patients
EF	17.95	6.15	-0.37	6.15	0.590	81	-0.51	7.73	0.621	57
OF	6.44	4.32	-0.83	2.96	0.012*	82	-0.53	2.94	0.166	60
SD	6.07	2.04	-0.21	1.51	0.197	84	-0.31	1.53	0.120	62
IS	6.77	4.33	-0.96	3.57	0.020*	78	1.06	2.84	0.011*	50
OS	6.49	2.60	-0.27	2.11	0.249	81	-0.10	2.42	0.746	58
IIEFtot	44.21	22.50	-2.62	13.18	0.087	76	0.28	12.35	0.877	46

* denotes statistical significance at the 5% level (2-tailed test)

Abbreviation: EF: Erectile function, OF: orgasmic function, SD: sexual desire, IS: intercourse satisfaction, OS: overall satisfaction, IIEFtot: total score of International Index of Erectile Function, SD: standard deviation

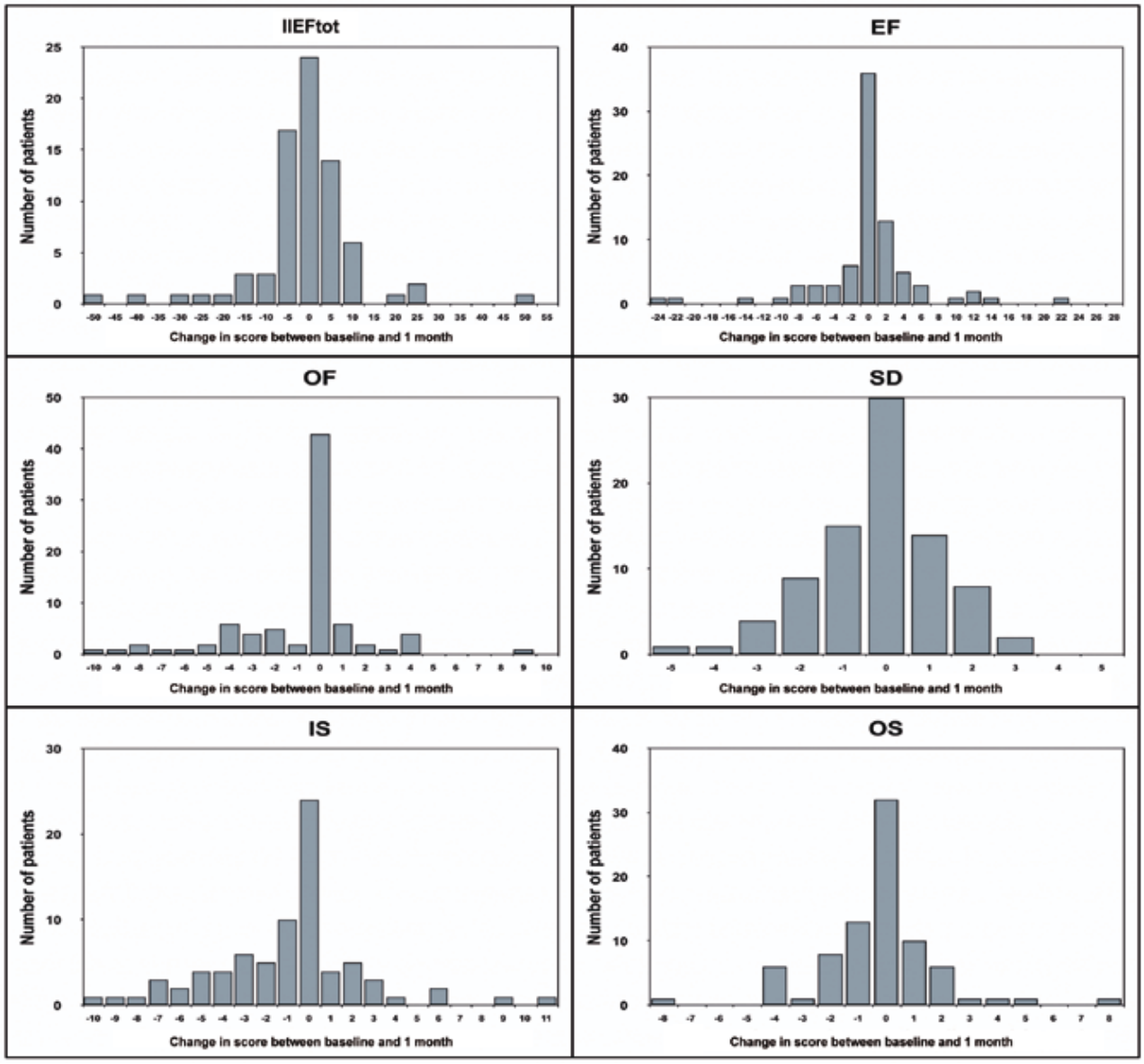

Fig. 2. Histogram of the change in sexual function between baseline and one month. Abbreviations: IIEFtot: total score of International Index of Erectile Function. EF: Erectile function, OF: orgasmic function, SD: sexual desire, IS: intercourse satisfaction, OS: overall satisfaction. Note: the column above 0 reflects the number o patients with a change in score between -4 and 0 (including) for IIEFtot and between -1 and 0 (including) for EF.

RESULTS

Patients

From July 2002 to November 2002, 108 men meeting the inclusion criteria at the initial screening were included in the study. The mean (standard deviation, SD) age of the patients was 66 (8 patients) years and mean (SD) prostate volume amounted to 66 (26) cm^3. At the follow-up visits, one and three months after baseline, 16% and 35% of the stents, respectively, had been removed. In none of these cases deterioration of sexual function was mentioned as the reason for stent removal.

Voiding function and symptom scores

The results of the safety and efficacy of the bell-shaped Horizon prostatic stent were discussed in detail in a previous paper [11]. Insertion of stents resulted in statistically significant improvements of voiding parameters and symptom scores. Substantial improvements were only temporarily maintained, which might have been attributable to tilting of the stents within the prostatic urethra. The bell-shaped Horizon prostatic stent was concluded not to be suitable for clinical practice. At present, the Horizon prostatic stent is no longer available.

Sexual function

The first question of the IIEF was answered with "no sexual activity" by 23 (22%) patients. After one and three months, 19 (22%) and 16 (26%) patients, respectively, answered this question with "no sexual activity". At baseline, 62 (60%) patients suffered from erectile dysfunction (EF score less than or equal to 25[16]). The corresponding numbers after one and three months were 47 (57%) and 33 (57%) patients respectively. At baseline, the total score of IIEF (IIEFtot) was not related to the IPSS score, the QoL question of the IPSS or Qmax (Pearson's correlation coefficients of 0.047, -0.102, and 0.029).

IIEF

Table 1 gives an overview of the results of the IIEF questionnaire at baseline and the changes one and three months after insertion relative to baseline. Figure 2 (Fig. 3) shows the distribution

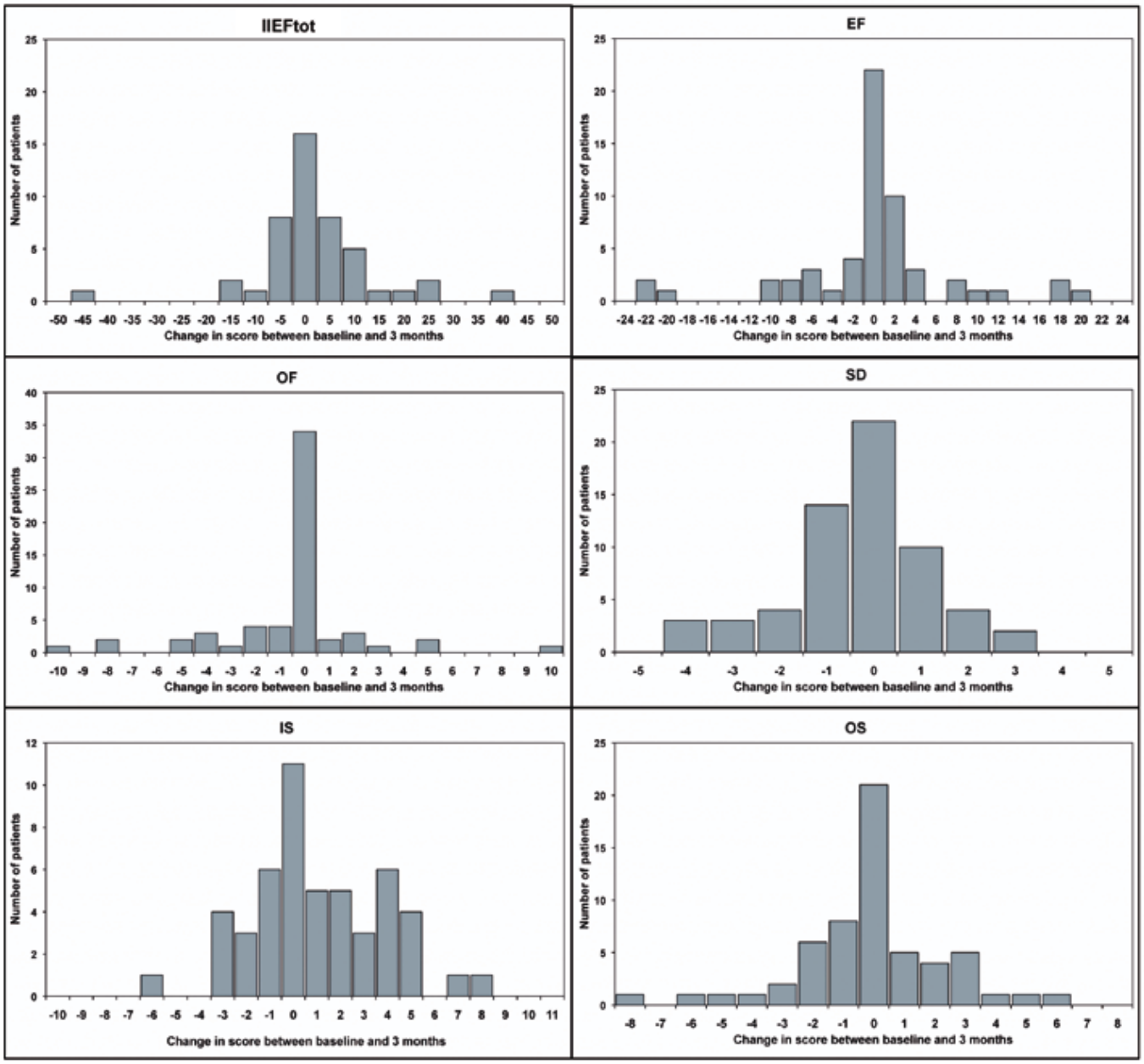

Fig. 3. Histogram of the change in sexual function between baseline and three months. Abbreviations: IIEFtot: total score of International Index of Erectile Function. EF: Erectile function, OF: orgasmic function, SD: sexual desire, IS: intercourse satisfaction, OS: overall satisfaction. Note: the column above 0 reflects the number of patients with a change in score between -4 and 0 (including) for IIEFtot and between -1 and 0 (including) for EF.

of changes in the total IIEF score and of the different domains of the IIEF from baseline to one month (three months). From these figures, it can be derived that a large majority of patients experienced only minor changes in the total IIEF score and in the different domains. On average, there was a slight deterioration in the total IIEF score after one month and a very small improvement after three months, neither of which was statistically significant. There was no apparent association between the change in mean total IIEF score, and the changes in the total IPSS score, the QoL question of the IPSS, nor Qmax (Pearson's correlation coefficients of 0.05, -0.06, and -0.04 at one month, and -0.15, -0.25, and -0.02 at three months respectively).

IIEF subscores

It is important to distinguish between the different aspects of sexual function (such as erectile function and ejaculatory function) as measured by the IIEF subscores. The number of patients that reported a deterioration in OF and IS after one month is notable. The mean OF score worsened significantly relative to baseline. Similarly, as evaluated by the general assessment question, only one (1%) patient complained of painful ejaculations at baseline, whereas one month after placement of the stent, four (4%) patients complained of painful ejaculations and two (2%) patients experienced retrograde ejaculations. The IS domain also showed a statistically significant decrease one month after stent insertion. For the other domains, there was no statistically significant change after one month relative to baseline.

After three months however, the picture is different. The only IIEF subscore with a significant effect relative to baseline concerns the IS domain. The mean IS score after three months showed a clinically and statistically significant improvement from baseline. The deterioration of the OF subscore was not statistically significant. However, the number of patients reporting painful and retrograde ejaculation was higher than at baseline (three – 4% and five – 7% respectively).

We note that due to stent removal the number of patients after three months is lower than after one month. However, unreported

tests show that the patterns observed in Table 1 and in Figures 2 and 3 cannot be attributed to changes in the sample composition. If we restrict the sample to patients with observations both after one and three months, the significant deterioration in OF and IS after one month and the improvement in IS after three months is still observed.

DISCUSSION

Because of the fact that many problems were encountered with the use of prostatic stents, current clinical guidelines generally advocate the use of prostatic stents in patients unfit for surgery only [17]. Since the first use of prostatic stents, a variety of indications have been the subject of study. Prostatic stents were mostly studied in patients with high operating risks. However, some studies (including our previous study with the hourglass-shaped Horizon prostatic stent) investigated the use of prostatic stents in patients without significant co-morbidities [18-21]. Because the Horizon prostatic stent design was adjusted to solve the problems encountered with the hourglass-shaped stent, the present study was conducted in a comparable group of otherwise healthy patients with LUTS/BPH. Especially in these patients, it is of major importance that treatment of LUTS/BPH does not impair sexual function.

Although a considerable amount of the patients suffered from erectile dysfunction in the present study, in contrast to the current literature, we found no correlation between the severity of LUTS and sexual dysfunction at baseline. This might be explained by the relatively low number of patients. The change in the mean total IIEF score appeared not to depend on the changes in IPSS, QoL, or Qmax.

The total score of the IIEF questionnaire did not show statistically or clinically significant changes one month or three months after stent insertion. The majority of patients also did not experience large changes in the IIEF subscores, but we documented a statistically and clinically significant deterioration in the OF domain one month after stent insertion. We also found that the number of patients reporting painful ejaculation increased. This painful ejaculation might be due to irritation caused by the foreign body in the urethra. Although the decrease in the OF domain after three months was smaller than after one month, the amount of patients reporting painful or retrograde ejaculation was higher. Therefore, the negative effect on ejaculatory function does not seem to wear out after time. Since the stents were designed to be inserted beyond the bladder neck, the rate of retrograde ejaculation was expected to be higher than we found. An explanation for this relatively low rate of retrograde ejaculation might be that, because of a suboptimal visualization during stent placement, the stents were in fact not inserted beyond the bladder neck, but in the prostatic fossa only. Another possible theory might be that elongation of the urethra during erection and ejaculation caused the stents to be temporarily retracted within the prostatic fossa, resulting in antegrade ejaculation.

The IS significantly decreased after one month compared to baseline. This might be explained by the fact that the OF and IS domains of the IIEF are known to be interrelated [14] Remarkably, after three months, IS significantly improved compared to baseline, while all other domains slightly (but not significantly) worsened. We have no straightforward explanation for this improvement in IS.

Importantly, the EF domain of the IIEF did not significantly change after the insertion of the stents. So apparently, the introduction of a foreign body into the prostatic urethra does not hinder the ability to obtain or maintain an erection.

Only a few studies on prostatic stents addressed their effect on sexual function. Nordling et al. assessed the Prostakath (a spiral prostatic stent) in 45 patients with urinary retention. Erectile function was unchanged after insertion of the spiral, but retrograde ejaculation occurred in all sexually active patients [22]. The Urolume wallstent, a permanent prostatic stent, also did not have a negative impact on erectile function [19, 20, 23]. Retrograde ejaculation was reported more often than in the Horizon prostatic stent: in 24-38% of patients [19, 20, 23].

Direct comparative studies between prostatic stents and other treatment modalities of LUTS/BPH have – to the best of our knowledge – not been performed. In addition, the available data in literature on the effect of different LUTS/BPH therapies, are sometimes inconsistent. As a consequence, comparisons of possible effects on sexual function between the various therapies should be interpreted with care. However, it appears that other therapies for LUTS/BPH impair erectile function more often than prostatic stents. After transurethral resection of the prostate (TURP), the rate of impotence in the literature varies from 3.4 to 32%. However, there are also reports of improved erections after TURP [24]. Most clinical studies with α_1-adrenergic receptor antagonists (α-blockers) have, if anything, reported adverse rather than beneficial effects on erectile function [25]. The incidence of impotence with α-blockers ranges from 0 to 12.5% of the patients in literature, without any indication that impotence occurs more frequently with one rather than the other α-blockers [25]. On the other hand, the US package inserts for tamsulosin, alfuzosin, doxazosin, and terazosin describe priapism as a rare but possible adverse effect. In addition, some recent studies also reported a beneficial effect of α-blockers on erectile function [26, 27]. The incidence of erectile dysfunction with the 5α-reductase inhibitors (5ARI's), finasteride and dutasteride is six to 11% [28]. After transurethral microwave therapy (TUMT), the reported incidence of erectile dysfunction equals 0 to 8% [28].

Since prostatic stents are often placed beyond the bladder neck, many patients with prostatic stents experience retrograde ejaculation. After TURP, the rate of retrograde ejaculation equals 53-75% [24]. In patients using the α-blocker tamsulosin, abnormal ejaculation is reported in 0-30% of patients, whereas studies with alfuzosin, doxazosin, and terazosin generally report lower rates of abnormal ejaculation (0-1.4%) [25]. The reported incidence of ejaculatory dysfunction with the 5α-reductase inhibitors (5ARI's), finasteride and dutasteride is 3 to 5% [28]. After TUMT, the reported median rate of ejaculatory dysfunction is 2 to 49% [28].

In our previous paper on the efficacy and safety of the bell-shaped Horizon prostatic stent we concluded that this stent was not suitable for clinical practice [11]. Nevertheless, we do think that the findings presented in this paper are a valuable contribution to the current knowledge on prostatic stents. Prostatic stents have not received much attention in recent literature. However, new developments still take place illustrated by the fact that only recently a new stent was launched (the Allium triangular prostatic stent) in Europe [29, 30]. Furthermore, although the various available stent designs differ both in shape and material, the results of this study into the effect of the Horizon prostatic stent on sexual function might to some extent be translated to the effect prostatic stents have on sexual function in general. To assess the effect on sexual function of the different stent designs still available on the market (the Allium triangular prostatic stent, the Memokath, and the Spanner) a comparative study should be considered.

CONCLUSIONS

The bell-shaped Horizon prostatic stent had a negative influence on orgasmic function. In the first month after stent placement, intercourse satisfaction (IS) was lower than at baseline. At three months after stent placement however, IS significantly

improved relative to baseline. Erectile function did not worsen after stent placement. The total IIEF score was not negatively affected by the bell-shaped Horizon prostatic stent. Overall, the results of our study suggest that the possible adverse effects on sexual function of prostatic stents mostly correlate to orgasmic function.

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