World Journal of Urology (2019) 37:2189–2197
https://doi.org/10.1007/s00345-019-02639-4

ORIGINAL ARTICLE

Patient satisfaction with adjustable transobturator male system in the Iberian multicenter study

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Received: 25 November 2018 / Accepted: 10 January 2019 / Published online: 16 January 2019

Abstract

Backgrounds Patient-reported outcome measurements are important for urinary incontinence. We analyze self-assessed patient satisfaction and define the clinical profile of patient with highest satisfaction with the adjustable transobturator male system (ATOMS).

Methods Patient perception of results was evaluated in a series of 181 patients after ATOMS adjustment. Baseline incontinence severity was defined in pads-per-day (PPD) as mild (2), moderate (3–5) or severe (≥ 6), and dryness as use of none or one security PPD. Post-operative pain at discharge was evaluated by 0–10 visual analogue scale and complications by Clavien–Dindo classification. Multivariate analysis was performed to anticipate "very much better" than baseline perception on patient global impression of improvement and a predictive nomogram was developed.

Results Dryness was achieved in 80.7% (94.9% mild, 80.8% moderate and 65.8% severe groups). Mean pad-test and pad-count decrease with respect to baseline was 458 ± 330 ml and 3.2 ± 1.9 PPD, respectively (both $p < .0001$). Complications presented in 25 (13.8%). The proportion of patients that self-declared satisfied with the procedure was 87.1%; 90.6% perceived their situation "better" and 48.1% "very much better" than before. Multivariate analysis revealed best perception is defined by dryness after adjustment ($p < .0001$), baseline severity of incontinence ($p = .007$), low post-operative pain at discharge ($p = .0018$) and lack of complications ($p = .007$).

Conclusions Self-assessed satisfaction with ATOMS is very high. Factors that predict best perception of improvement include dryness, baseline SUI severity, presence of complications and pain level during admission. Radiotherapy and device generation were not independent predictors. A nomogram to predict patients that are completely satisfied with ATOMS after adjustment is proposed.

Keywords Adjustable transobturator male system · Male stress urinary incontinence · Patient-reported outcome measurement · Satisfaction

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Introduction

Male stress urinary incontinence (SUI) after prostatectomy severely impacts quality of life in prostate cancer survivors as it affects both physical activity and well-being [1]. Prevalence of male SUI is very variable, mainly depending on the definition used, but severe incontinence with frequent or total urinary leak occurs in less than 10% of patients [2]. The EAU guidelines recommend the use of artificial urinary sphincters (AUS), available since the 70s, to manage the cases with severe incontinence, while slings can be an option for patients with mild-to-moderate urine loss. However, surgical patterns from certifying American urologists showed AUS implantation represented only 12% of anti-incontinence procedures performed in men with SUI [3]. That maybe due in part to patient's preference and also to the risks associated with AUS procedure, including a high revision rate [4]. On the other hand, male slings have evolved in the last decades with the introduction of fixed and adjustable which may tackle urinary incontinence with different modes of action [5]. Comparative studies between all these options are unfortunately lacking.

The adjustable transobturator male system (ATOMS) is a self-anchoring device that compresses bulbar urethra ventrally and can be adjusted post-operatively without surgical re-intervention [6]. This device opens, therefore, a new perspective for the treatment of patients with mild-to-moderate SUI and can be the best option in patients with limited dexterity or cognitive impairment regardless of incontinence severity [7]. In fact, accumulated experience regarding the efficacy of ATOMS in severe male stress incontinence suggests that AUS is not the only gold standard in such scenario [8–10]. There, however, are still uncertainties concerning optimal patient selection.

The need for a better qualitative assessment of health care delivery from the patient's perspective has led to increased interest in patient-reported outcome measurements (PROMs) to give priority to medical decisions and benchmark quality, and to compare outcomes between institutions. A few reports indicate 85–92% global satisfaction rate with the ATOMS device when patients are asked in a yes–no fashion [10, 11], proportion that appears equivalent to that reported by patients treated with AUS [12, 13]. Further research is needed to investigate determinants of satisfaction and to better understand the patient experiences and expectations. We evaluated the data from the Iberian ATOMS study [10] with the intention to define the clinical profile of patients that are completely satisfied after the placement of an ATOMS device.

Materials and methods

Patient population

We retrospectively analyzed data of 181 men with SUI treated with ATOMS in different institutions from Spain and Portugal between November 2012 and March 2017. This cohort of patients was selected from a larger series of 215 consecutive treated patients that were studied to define efficacy, safety and durability of the device in a multicenter setting. Selection criteria for this post hoc study was based exclusively on availability of self-assessment patient satisfaction data; in other words, patients without Patient Global Impression of Improvement (PGI-I) evaluation after adjustment of the device were excluded. Ethics committee approval and patient consent were obtained. Three generations of ATOMS device (A.M.I., Feldkirch, Austria) were used with changes limited to the design of the port: inguinal port (IP), simple scrotal port (SP) and pre-attached silicone-covered scrotal port (SSP).

The criteria to implant the device was bothering and persistent SUI for > 12-months after prostate surgery refractory to conservative options. SUI severity was classified based on 24-h pad-count (pads/day, PPD) as mild (2 PPD), moderate (3–5 PPD) and severe (≥ 6 PPD). Pre-operatively cystourethroscopy ruled out urethral or bladder neck stricture in all cases. Patients with a clinical suspicion of severe detrusor overactivity or detrusor underactivity were further investigated by urodynamic testing and if confirmed were not included.

The procedure was performed with the patient in the lithotomy position, with a 14-Fr Foley catheter inserted for bladder drainage (Fig. 1). Thrombosis prophylaxis was used. Urine culture was negative before surgery and implantation was performed under dual antibiotic prophylaxis (i.v. gentamicin 2 h before induction and oral amoxicillin–clavulanic acid continuing for 1 week post-operatively). Intraoperative irrigation with an antibiotic solution was used. If needed, the initial post-operative adjustment was performed in the office 2 weeks after the implantation by direct percutaneous injection of physiological sodium chloride solution or sterile water and thereafter when required at intervals of 4 weeks until either dryness or maximum filling capacity of the system was reached. We considered dry patients those who did not use pads or wear one safety PPD or had a negative 24-h pad-test with occasional urine losses not exceeding 10 ml/day. Patients were evaluated thereafter every 3–6 months. Data regarding patient perceived outcomes and continence were obtained after device adjustment.

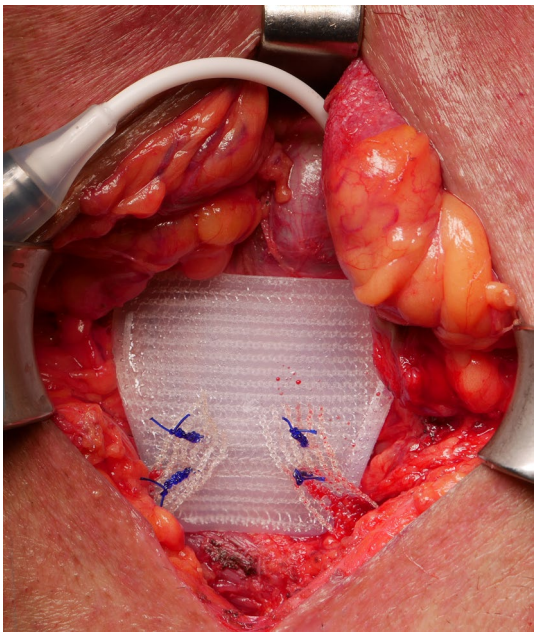

Fig. 1 ATOMS with pre-attached silicone-covered scrotal port. The device ventrally compresses bulbar urethra and cushion filling can be adjusted post-operatively through the port

Variables evaluated

Data were included into an institutional review board-approved database regarding demographics, previous radiotherapy, characteristics of SUI, operative parameters, complications, continence outcomes and follow-up. Operative parameters included generation of device used, surgical time, length of admission and visual analogue scale (VAS) for pain on a 0–10 scale. Post-operative complications were defined following Clavien–Dindo classification within 3 months after surgery. Number of adjustments was registered for each individual case. Continence outcomes were evaluated at the time of the final adjustment including dryness rate, pad-count, pad-test and post-void residual volume. PROMS were investigated by physicians in the office as direct questioning regarding satisfaction with the implant (evaluated in a yes/no fashion) and PGI-I, and self-assessed questionnaire classifying patients according to different degree of satisfaction after device adjustment compared to baseline (evaluated as 1 "very much better", 2 "much better", 3 "slightly better", 4 "without change", 5 "a bit worse", 6 "much worse" and 7 "very much worse").

Primary endpoint of the study was to determine the characteristics of the patients who reported themselves as "very much better" with the implant (PGI-I 1), and to analyze factors determinant of such maximal satisfaction. Global Response Assessment (GRA) scale (evaluated as 1 "worse", 2 "without change", 3 "slightly improved", 4 "moderately improved", 5 "greatly improved" and 6 "totally cured") was also assessed in a subset of patients to evaluate correlation between PGI-I and GRA questionnaires, and thereof consistency to use PGI-I scale as the primary endpoint of this study.

Statistical analysis

The median values and interquartile range (IQR) were calculated for quantitative variables and qualitative variables were described using absolute and relative frequencies. Paired *t* test was used to compare pre-operative and post-operative continuous variables. Cochran–Armitage trend and chi-square contingency tests were performed to compare variables affecting dryness and satisfaction after adjustment. Factor determinants of a "very much better" response on PGI-I were evaluated by univariate analysis using odds ratio estimates and 95% Wald confidence limits for the variables investigated. All the variables with significant impact in univariate analyses were then evaluated in a multivariate logistic regression model (stepwise selection .20 in and .15 out). The association of predicted probabilities and observed responses was evaluated and area under ROC curve for the selected model was calculated. The apparent and expected optimism-corrected performances of the model were calculated with internal (bootstrap iterations, 1000) validation. Finally, a nomogram predicting highest satisfaction with ATOMS is proposed. The statistical analysis was developed using Statistical Analysis System 9.3 (SAS Institute Inc, Cary, NY, USA).

Results

Table 1 summarizes baseline situation, severity of incontinence, and operative and post-operative data of 181 patients included in this study. Mean follow-up for this series was 24.3 ± 14.2 (range 8–60) months. Mean patient age was 69.7 ± 7 (range 34–83). SUI was mainly due to radical prostatectomy. Thirty-six patients (19.9%) had received radiotherapy. The type of port used was IP in 30 (16.6%), SP in 26 (14.4%) and SSP in 125 (69%).

Pre-operative SUI severity was mild in 36 (19.9%), moderate in 90 (49.7%) and severe in 55 (30.4%) patients. Mean 24-h pad-count was 4.1 ± 1.9 (1–12) PPD and 24-h pad-test was 492 ± 373.8 (40–1650) ml. Mean operative time was 65.4 ± 25.5 (30–140) min and median hospital admission 1.9 days. No intraoperative complications occurred. Complications within first 90 days after surgery occurred in 25 (13.8%), classified as grade I in 16 (8.8%), grade II in 3 (1.7%) and grade 3 in 6 (3.3%). The list of complications is detailed in Table 2. No transfusion was needed. Mean visual analogue scale (VAS) for pain on first post-operative week was 2.8 ± 2.6 (0–7), 6 ± 5 for devices with IP and 1.5 ± 5 for SP and SPP combined ($p = .0015$). No patient needed

Table 1 Patient characteristics of the series evaluated ($n = 181$)

Baseline data	
Age, years, mean ± SD (range)	69.7 ± 7 (34–83)
Radical prostatectomy, *n* (%)	165 (91.2)
Transurethral resection, *n* (%)	11 (6)
Simple prostatectomy, *n* (%)	5 (2.8)
Irradiated patients, *n* (%)	36 (19.9)
24-h pad count, *n*, mean ± SD (range)	4.1 ± 1.9 (1–12)
24-h pad-test, ml, mean ± SD (range)	492 ± 373.8 (40–1650)
Mild stress incontinence, *n* (%)[a]	36 (19.9)
Moderate stress incontinence, *n* (%)[a]	90 (49.7)
Severe stress incontinence, *n* (%)[a]	55 (30.4)
Operative data	
Inguinal port, *n* (%)	30 (16.6)
Simple scrotal port, *n* (%)	26 (14.4)
Silicone-covered scrotal port, *n* (%)125 (69)	
Surgical time, min, mean ± SD (range)	65.4 ± 25.5 (30–140)
Admission length, days, median (IQR)	1.9 (1)
Total filling, ml, mean ± SD (range)	13.4 ± 8.2 (2–32)
Number of adjustments, *n*, mean ± SD (range)	1.4 ± 1.9 (0–6)
Post-operative data	
VAS of pain week 1 (0–10), mean ± SD (range)[b]	2.8 ± 2.6 (0–7)
Post-operative complications, *n* (%)[c]	25 (13.8)
Post-operative complications grade I, *n* (%)	15 (8.3)
Post-operative complications grade II, *n* (%)	4 (2.2)
Post-operative complications grade III, *n* (%)	6 (3.3)
Removal rate at follow-up, *n* (%)	6 (3.3)
Follow-up after implant, mo, mean ± SD (range)	24.3 ± 14.2 (8–60)
24-h pad count after adjustment, *n*, mean ± SD (range)	0.9 ± 1.4 (0–7)
24-h pad-test after adjustment, ml, mean ± SD (range)	63.5 ± 201 (0–1225)
PGI-I after adjustment, mean ± SD (range)	1.9 ± 1.1 (1–6)
GRA after adjustment, mean ± SD (range)[d]	4.85 ± 1.3 (1-6)
No stress incontinence, *n* (%)[a]	146 (80.7)
Mild stress incontinence, *n* (%)[a]	16 (8.8)
Moderate stress incontinence, *n* (%)[a]	15 (8.3)
Severe stress incontinence, *n* (%)[a]	4 (2.2)

181 patients with Patient Global Impression of Improvement (PGI-I) evaluation

PVR post-void residual, *IQR* interquartile range, *SD* standard deviation

[a]Incontinence severity was classified as: None, no pads or 1 security pad and < 10 cc/day; Mild, 1–2 pads/day; Moderate, 3–5 pads/day; Severe, 6 or more pads/day

[b]Visual Analogue Scale (VAS) of pain on first post-operative week available in 171 patients

[c]Post-operative complications were evaluated according to Clavien–Dindo classification during first 90 days

[d]Global Response Assessment available in 148 patients

analgesics 3 months after surgery or later. Six devices (3.3%) were retrieved due to infection (three cases), port extrusion (two cases) and ineffectiveness (one case), four of them within 90 first post-operative days and two later during follow-up.

Adjustment was considered complete at a mean 1.4 ± 1.9 (0–6) post-operative fillings and a total filling volume of 13.4 ± 8.2 (2–32) ml was reached. Globally 146 patients (80.7%) were dry. After adjustment, mean 24-h pad-count was 0.9 ± 1.4 (0–7) PPD and mean pad-test 63.5 ± 201 (0–1225) ml, thus revealing mean change from baseline in daily pad-count and pad-test of 3.2 ± 1.9 PPD and 458 ± 330 ml, respectively (both $p < .0001$). Figure 2 shows pad-count change before surgery and after adjustment for every patient. Persistent SUI with ATOMS was mild in 16 (8.8%), moderate in 15 (8.3%) and severe in 4 (2.2%).

Table 2 Post-operative complications within 90 days of surgery according to Clavien–Dindo classification

Complication (grade)	No. patients	No. reoperation
Hematuria (I)	1	
Epididymitis (II)	1	
Scrotal hematoma (I)	4	
Queloid scar (III)	1	1
Inguinal pain (I)	1	
Perineal/scrotal pain (I)	9	
Wound infection (II)	2	
Port erosion (III)	2	2[(a)]
Delirium (I)	1	
Device infection (III)	3	3[(b)]
TOTAL (%)	25 (13.8)	6 (3.3)

[a]1 device retrieved

[b]3 devices retrieved

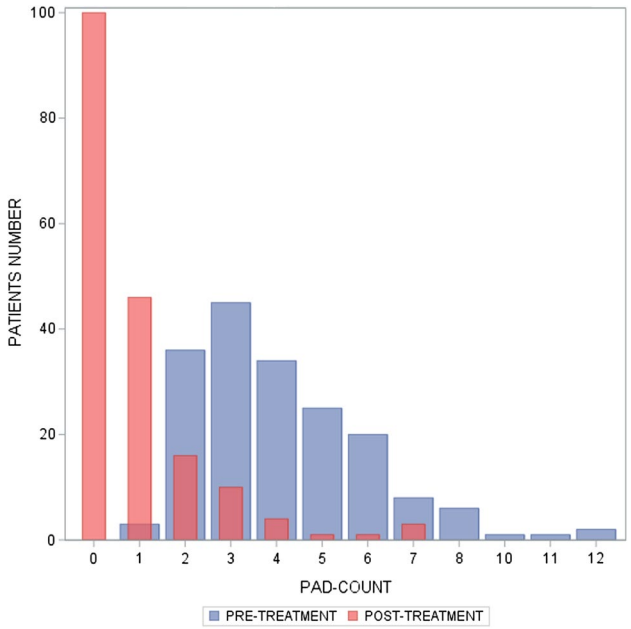

Fig. 2 Pad-count change before surgery and after adjustment for the 181 patients evaluated

Dryness was higher in patients with less baseline severity (p = .005) and in those with non-irradiated field (p = 0.0002). Dry rate was 94.9% (37 of 39) for mild baseline incontinence, 80.8% (84 of 104) moderate and 66.8% (25 of 38) severe. Regarding the influence of previous radiotherapy, dry rate was 86.2% for non-irradiated patients (125 of 145) and 58.3% (21 of 36) for irradiated.

Globally, 155 patients (87.1%) self-declared satisfied after adjustment. This proportion was variable for different degrees of baseline severity of incontinence (94.9% (37 of 39) mild, 83.6% (87 of 104) moderate and 81.6% (31 of 38) severe), without reaching statistical significance ($p = 0.17$). Satisfaction was higher in non-irradiated patients than in irradiated (89% vs. 72.2%, $p = .01$). Median PGI-I and GRA scores at adjustment were 1.9 ± 1.1 (1–6) and 4.85 ± 1.3 (1–6), respectively. A correlation between scores was demonstrated (Spearman − 0.855). Regarding PGI-I 87 (48.1%) self-assessed "very much better" (PGI-I 1), 46 (25.4%)"much better" (PGI-I 2), 31 (17.1%) "slightly better" (PGI-I 3), 12 (6.6%) "without change" (PGI-I 4), 3 (1.7%) "a bit worse" (PGI-I 5), 2 (1.1%) "much worse" (PGI-I 6) and none (0%) "very much worse" (PGI-I 7) (Fig. 3).

Univariate analysis to predict factors associated with "very much better" self-assessment in PGI-I revealed baseline severity of incontinence ($p = .07$), no irradiation ($p = .05$), SSP device generation ($p = .01$), absence of post-operative complications according to Clavien–Dindo classification ($p = .0086$), absence of post-operative pain ($p = .0036$) and dryness after adjustment ($p < .0001$). Multivariate analysis showed that severity of baseline SUI ($p = .007$), presence of complications ($p = .007$), post-operative pain ($p = .0018$) and dryness after device adjustment (0 or 1 security PPD) ($p < .0001$) were independent predictors (Table 3). In multivariate analysis, irradiation and device generation were not independent predictors of satisfaction. Accuracy for prediction of ROC-curve model was 82.2% (Fig. 4). This model was internally validated by bootstrapping with 84 (95% CI 83–84) % apparent performance and 5.1 (95% CI 4.9–5.2) % expected optimism. With the aforementioned variables, a nomogram is proposed to predict optimal reported satisfaction in the outcomes as defined by "very much better" assessment on PGI-I (Fig. 5).

Discussion

The definition of success after surgical correction of male stress urinary incontinence is not totally standardized. For some success needs complete cure of incontinence or total dryness (i.e. no urine leakage under any circumstance). For others continence is better defined as social continence (i.e. patients without incontinence but including the possibility of wearing a security PPD), as a small or thin pad may not impact leading a regular life condition. These tend to be the most widely accepted definitions of success but other outcome measures used are 50% or greater improvement over baseline, 24-h pad-test under a certain limit such as 10–20 mL, perception of quality of life on impact questionnaires (e.g. UCLA/RAND Prostate Cancer Index) and also patient satisfaction rates [13–15].

Patient perception of the effect of surgery on the condition must also be considered as self-assessment instruments could limit or even eliminate confounding factors of

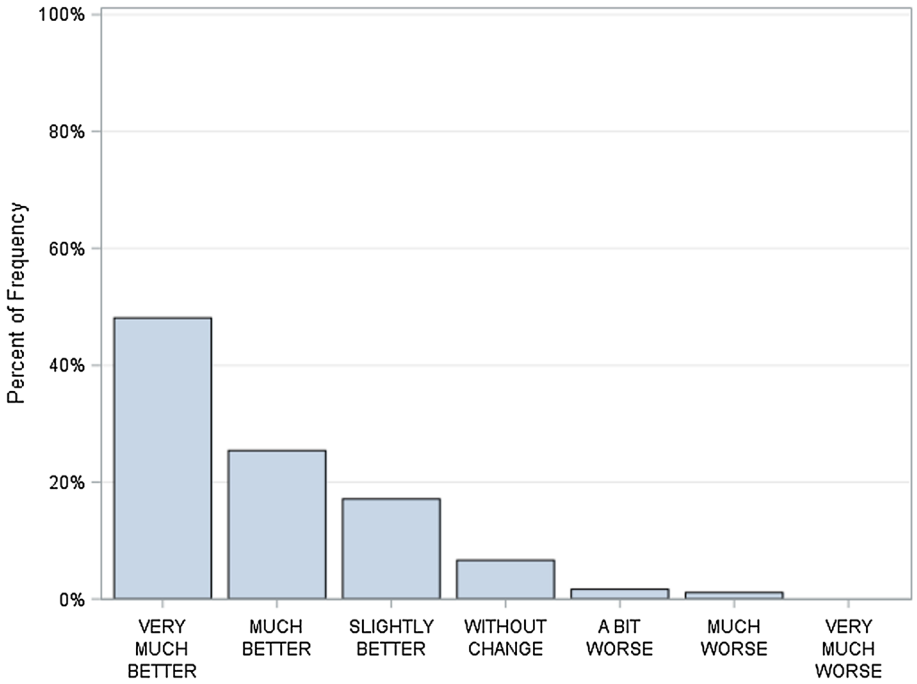

Fig. 3 Percent distribution according to PGI-I categories: "very much better" (PGI-I = 1),"much better" (PGI-I = 2), "slightly better" (PGI-I = 3), "without change" (PGI-I = 4), "a bit worse" (PGI-I = 5), "much worse" (PGI-I = 6) and "very much worse" (PGI-I = 7)

Table 3 Logistic regression model to predict best perception self-assessed as "very much better than before" on PGI-I after adjustment

	Odds ratio estimates			
	Point estimate	95% Wald confidence limits		*p* value
Univariate variable				
Patient age 65–75 versus > 75 years	1.58	0.75	3.32	0.14
Patient age < 65 versus > 75 years	2.64	1	6.93	
Device with SP versus device with IP	1.72	0.55	5.33	0.01
Device with SSP versus device with IP	3.39	1.4	8.19	
Non-irradiated versus irradiated	2.14	0.996	4.61	0.05
Mild versus severe SIU	0.36	0.15	0.86	0.07
Moderate versus severe SUI	0.66	0.33	1.29	
VAS for pain 0 versus ≥ 4 (0–10)	3.46	1.67	7.15	0.0036
VAS for pain 1–3 versus ≥ 4 (0–10)	2.26	0.97	5.27	
No complications versus complications	3.65	1.39	9.58	0.0086
Dry versus non-dry after adjustment	10.21	3.43	30.42	< 0.0001
Multivariate variable				
Non-irradiated versus irradiated	2.22	0.83	5.97	0.11
Mild versus severe SIU	3.45	1.34	8.87	0.007
Moderate versus severe SUI	5.07	1.73	14.86	
VAS for pain 0 versus ≥ 4 (0–10)	5.33	2.1	13.51	0.0018
VAS for pain 1–3 versus ≥ 4 (0–10)	2.18	0.8	5.92	
No complications versus complications	4.44	1.5	13.15	0.007
Dry versus non-dry after adjustment	15.86	4.74	53.09	< 0.0001

PGI-I patient global impression of improvement, *SP* simple scrotal port, *IP* inguinal port, *SSP* silicone-covered scrotal port, *SUI* stress urinary incontinence, *VAS* visual analogue scale

physician perception bias [16], and for that reason validated self-addressed instruments are recommended [17]. Lengthy instruments lead to poor compliance and thereof brevity and simplicity are preferred for a patient self-assessed instrument. In this sense International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) and PGI-I scale

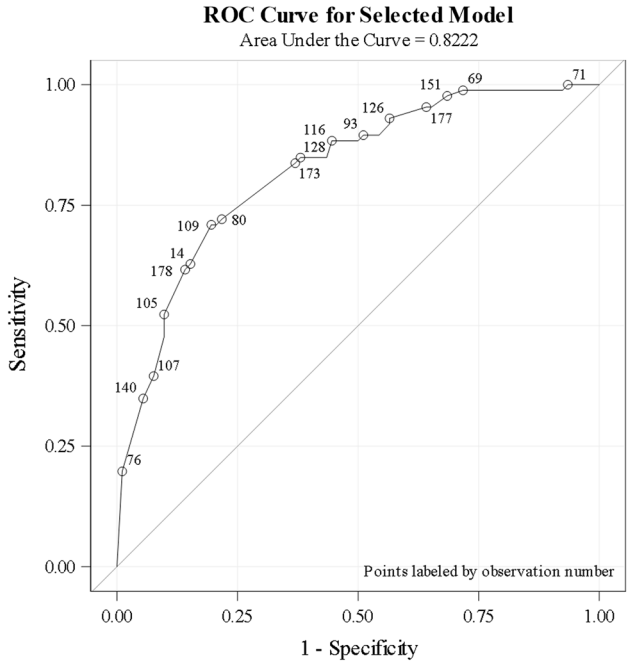

Fig. 4 ROC curve for selected model to predict optimal satisfaction defined by "very much better" assessment on PGI-I

have been validated for male stress urinary incontinence and correlate with decrease in pad weight [18]. PGI-I is a simple scale based on the answer of a single question that reflects different degrees of patient satisfaction. It is a global instrument that does not depend on incontinence-specific questions and that avoids bias toward specific symptomatology not rarely introduced by researchers. However, as incontinence surgery outcomes tend to be reported as cured and improved rates, using the PGI-I, it seems reasonable to consider those who are "very much better" (PGI-I 1) cured and those that are "much better" (PGI-I 2) improved. Other authors considered successful treatment of stress urinary incontinence results perceived as PGI-I responses 1–2 and failures those assessed as PGI-I 3–7 [14].

The main objective of our study is the evaluation of patient perception with their implant and these data could serve for indirect comparison with other anti-incontinence devices currently used. ATOMS is well appreciated by most patients in our study as 87.1% self-declared satisfied with the procedure after device adjustment. Doctor-reported outcomes also confirmed 80.7% dryness rate (defined as patients using no pads or a security PPD with urine loss under 10 mL). Patient-reported outcomes revealed 48.1% graded best perception (PGI-I 1), 73.5% recognized overt

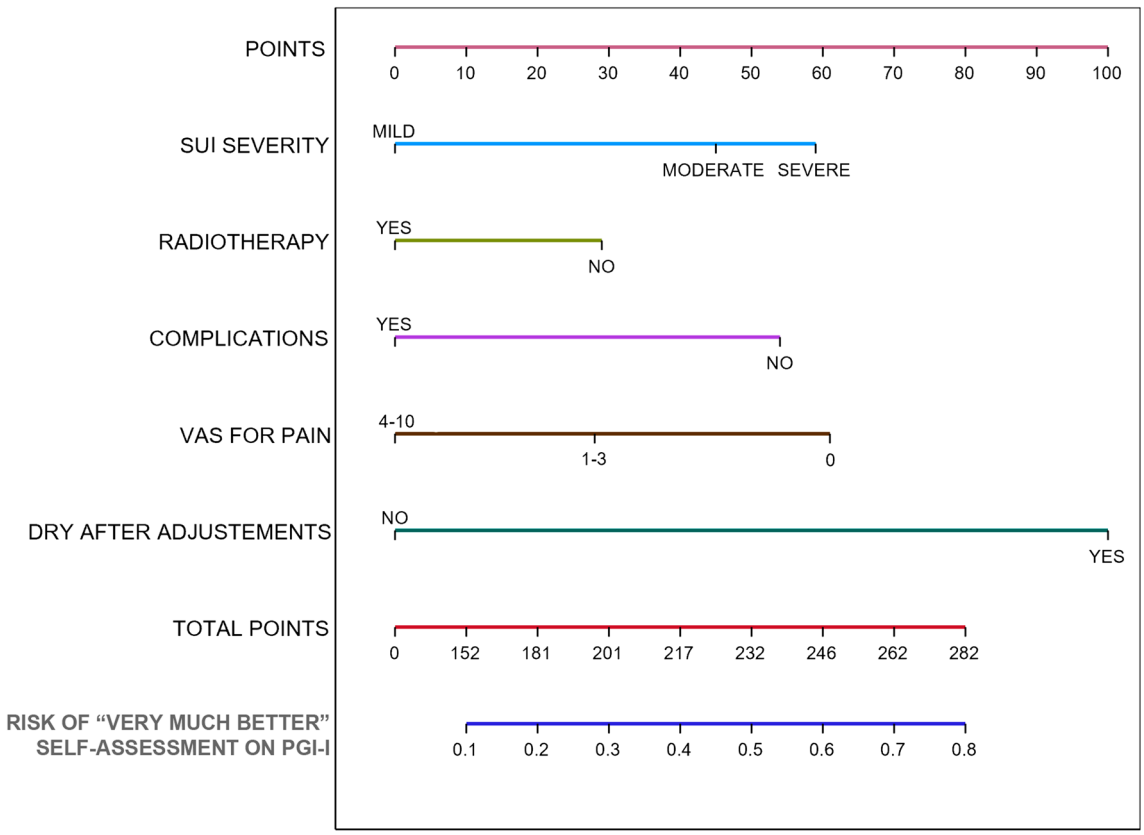

Fig. 5 Nomogram to predict optimal self-assessed patient satisfaction with ATOMS

improvement (PGI-I 1–2) and 90.6% rated a beneficial response (PGI-I 1-3). Other clinical experiences reported on ATOMS implant revealed variable dryness rates ranging from 39 to 92% [7–10, 19–21]. Quality of life issues before and after ATOMS implant have been addressed in multicenter studies [10, 22] but only one small prospective study has addressed PROMs using ICIQ-SF and IIQ-7 confirming that ATOMS system is well appreciated from the patient perspective [9]. A recent report has confirmed ICIQ-SF score is significantly better for SSP and this generation device is also associated to fewer complications [23]. In our series SSP was associated with best perception on PGI-I but only in univariate analysis. Also, VAS for pain on early post-operative was lower for SSP and SP, as only one incision is needed, than for IP that requires two separate incisions.

Patient satisfaction and quality of life after AUS have been evaluated as surrogates of functional outcomes for patient counseling but no clinical variable has been associated with satisfaction [15, 24]. Litwiller et al. [25] reported satisfaction in 90% of patients with AUS, and that 96% would recommend the implant to a friend and 92% would have the device placed again. Haab et al. [26] revealed 3.9 overall satisfaction on a 0–5 scale. Other studies reported 73 and 77% of the patients were satisfied with AUS, with 28% and 58% declaring very satisfied, respectively [27, 28]. Only two studies have used PGI-I scale to report self-impression of improvement with 33 and 51% best perception (PGI-I 1) and overt improvement (PGI-I 1–2) in 66.7 and 85.3%, respectively [14, 29].

Noticeably, the PROMS we report for ATOMS are not worse than those reported for AUS, and that could be in part due to patient expectations unfulfilled for AUS and re-intervention due to mechanical failures, infection, urethral atrophy and erosion arising from the decreased perfusion of the compressed urethral segment [15]. Satisfaction with ATOMS has been evaluated in a cohort of patients with previous failed AUS or sling for SUI and 76.6% of these patients self-reported totally cured or greatly improved with ATOMS [30]. However, despite the fact that durability of the ATOMS device is robust in the short-medium term [10, 22, 31], we could not exclude that satisfaction with the device, here investigate at a single time point, may worsen at follow-up periods.

The main of the study is its retrospective nature. The Iberian ATOMS study was designed to evaluate efficacy and safety in a consecutive series of patients treated in real practice [10]. This post hoc study conducted in the subset of patients with self-assessed evaluation of satisfaction could have some added bias as they were not necessarily consecutive patients and the self-assessed questionnaires were administered by physicians in the office. Also, evaluation was performed only after adjustment and not later during follow-up. Thereof changes in the patterns of perception cannot be evaluated. As far as we know, no previous study has been aimed to identify the population of patients that perceive maximal satisfaction with ATOMS, and that could give some light on the decision to better use this device. Best satisfaction with ATOMS depends on several factors. Baseline severity of incontinence is the only pre-operative variable. The rest are post-operative and include magnitude of pain in the early post-operative period assessed by VAS, presence of post-operative complications (any degree) defined by Clavien–Dindo classification and getting dry after adjustment. This last factor is possibly the most determinant of best patient satisfaction. Radiotherapy and device generation are not independent factors to influence such perception. The nomogram we propose can be a helpful tool for clinicians dealing male incontinence.

Acknowledgements The authors acknowledge Mr. Juan Dorado (PerTICA S.L.) for statistical analysis.

Authors' contribution The contribution to each author is as follows: protocol/project development: JCA. Data collection or management: JCA, IA, AO, MC, AR, JP, MR, AT, GE, FT, BM, FEM, FC. Data analysis: JCA, IA, AO, MC, AR, JP, MR, AT, GE, FT, BM, FEM, FC. Manuscript writing/editing: JCA, FC.

Compliance with ethical standards

Conflict of interest The authors have no conflict of interest or specific disclosure regarding the publication of this article.

Ethical standards The protocol was approved by local ethics committee in Hospital Universitario de Getafe (A08/17). All subject received informed consent to undergo surgery and all procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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