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ORIGINAL CLINICAL ARTICLE

# Do voiding urodynamic parameters predict the success of adjustable transobturator male system (ATOMS) to treat postprostatectomy urinary incontinence?

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**Abstract**

**Objective:** To evaluate whether urodynamic voiding risk factors can be predictive of failure of postprostatectomy urinary incontinence (PPI) treatment with adjustable transobturator male system (ATOMS).

**Materials and Methods:** We carried out a longitudinal study on 77 males treated for PPI with ATOMS. Patients were submitted preoperatively to a urodynamic study. The postoperative outcome was checked by pad-test. Treatment success was defined as daily pad-test below 10 mL. Statistical analysis used were Fisher exact test, $\chi^2$ lineal by lineal test, Student *t* test, and logistic regression analysis. The signification level was set at 95% bilateral.

**Results:** Treatment was successful in 54 patients (70%) achieving continence. The urodynamic parameters that related to postoperative continence outcome were the cystometric bladder capacity (direct relationship with continence ($P = .019$), type of voiding (more probability to achieve continence in patients who voided voluntarily followed by patients with involuntary voiding and abdominal straining voiding) ($P = .034$), Bladder Outlet Obstruction Index (BOOI) (inversely related with continence) ($P = .025$), and maximum voiding abdominal pressure (inversely related with continence) ($P = .049$). Multivariate analysis showed that cystometric bladder capacity (odds ratio [OR], 1.01; confidence interval [CI], 1.02-1.00), BOOI (OR, 0.97; CI, 0.99-0.94), and maximum abdominal bladder pressure (OR, 0.97; CI, 0.98-0.94) were independent risk factors to predict treatment success after ATOMS implant.

**Conclusions:** The study of functional voiding parameters is useful to know the risk factors that influence postoperative outcome of PPI with ATOMS device. These findings could be of primary importance to facilitate optimum patient selection for this implant and therefore improve operative results.

**KEYWORDS**
adjustable transobturator male system, postprostatectomy incontinence, predictive factors, urodynamics

  

## 1 | INTRODUCTION

Postprostatectomy urinary incontinence (PPI) causes a major impact on patients' quality of life (QoL) and may affect different daily activities although this tends to improve with time.[1,2] This complication has been attributed mainly to intrinsic sphincter deficiency, a kind of stress urinary incontinence (SUI), either for direct sphincter muscular wall lesion or nerve damage.[3,4]

Repair of refractory incontinence could greatly improve QoL.[5] Surgical treatment of this type of incontinence is based on returning urethral sphincter function by artificial urinary sphincter (AUS) or male slings (adjustable or nonadjustable) that increase urethral rest pressure.[6] Adjustable transobturator male system (ATOMS®, A.M.I., Feldkirch, Austria) has demonstrated its effectiveness for the treatment of PPI both in multicentre studies performed in Europe and Canada and meta-analysis.[7-11] Interestingly, patient-reported outcomes (PROs) with the device confirm a high level of satisfaction can be expected, but not all patients achieve continence after the implant.[12,13]

Several clinical and urodynamic risk factors can be responsible for urinary incontinence persistence after surgical treatment of PPI but, due to their different mode of action, they may differ between surgical devices used. For AUS, persistence of urethral sphincter dysfunction and urodynamic filling phase disorders, like diminished bladder compliance and higher detrusor overactivity (DO) pressure, have been proposed as determinants for failure of surgical treatment of PPI and persistent incontinence.[14] Regarding retrourethral sling, low bladder compliance or DO have also been defined as adverse urodynamics.[15]

Voiding urodynamic risk factors have not been considered as determinants for failure, possibly because PPI is mainly conceived as a filling phase dysfunction. However, there is a known relationship between both urinary phases; for instance, SUI is related to lower urethral resistance during voiding phase.[16] Therefore, the study of urodynamic voiding factors can inform us about the urethral conditions and whether these conditions can influence postoperative results.

ATOMS device exerts a compressive effect on ventral bulbar urethra that reinforces sphincteric function. Our hypothesis is that there are also some voiding dysfunctions related to continence status after ATOMS implantation. Consequently, our purpose is to study the urodynamic risk factors related to persistence of PPI in patients submitted to ATOMS implantation.

## 2 | MATERIAL AND METHODS

A longitudinal study with consecutive patients that gave consent to be included in the study was carried out between December 2015 and December 2019 on 77 males aged 69 ± 5.5 years, submitted to primary ATOMS implant for treating PPI. The main features of medical history, including comorbidities and previous treatments, is presented in Table 1. Patients underwent a urodynamic study 19 ± 19.1 months before surgery (mean ± SD). The indications for ATOMS implantation were clinical, that is, bothersome and persistent SUI for more than 12 months after prostate surgery refractory to conservative options. Severity of baseline incontinence was based both on 24 hours pad-count and 24 hours pad-test.

The urodynamic study included filling cystometry and pressure flow study. The polygraph used was Uro 2000 (MMS, Enschede, The Netherlands). The study was made according to the specifications of the International Continence Society (ICS)[17] and the protocols of Good Urodynamic Practices (GUP).[18] Patients were placed in a sitting or standing position and proceeded to bladder filling through an 8-Fr two-way transurethral catheter, with saline solution at room temperature at a rate of 50 mL/s. Abdominal pressure was recorded by a transrectal balloon catheter and abdominal and bladder pressures were measured with reference to the atmospheric pressure. The filling phase was over when the patient

**TABLE 1** Medical history, comorbidities, and previous treatments (n = 77)

| | Number | Percentage |
|---|---|---|
| Without comorbidity | 26 | 33.8 |
| High blood pressure | 37 | 48.1 |
| Diabetes | 19 | 24.7 |
| Cardiac disease | 9 | 11.7 |
| Renal insufficiency | 1 | 1.3 |
| Asthma | 1 | 1.3 |
| Multiple sclerosis | 1 | 1.3 |
| Ictus | 1 | 1.3 |
| Urethroplasty | 6 | 7.8 |
| Cervicotomy | 2 | 2.6 |
| Laparoscopic radical prostatectomy | 75 | 97.4 |
| Transurethral resection of the prostate | 2 | 2.6 |
| Concomitant overactive bladder syndrome | 22 | 28.6 |
| Radiotherapy | 10 | 13 |

reported a strong desire to void or registered a terminal involuntary detrusor contraction. Bladder outlet obstruction was calculated according to Bladder Outlet Obstruction Index (BOOI) and detrusor contractility according to Bladder Contractility Index (BCI). We defined voluntary detrusor contraction as voiding voluntarily initiated by detrusor contraction and abdominal straining as voiding by Valsalva without detrusor contraction.

All ATOMS devices were with silicone-covered scrotal port design. The surgical technique of transobturator passage and establishment of four-point suburethral fixation by knotting the mesh arms to the silicone cushion followed the initial clinical description and so did perioperative management measurements.[19] The procedure was performed with the patients in the lithotomy position under spinal anesthesia, with a 14-Fr Foley catheter inserted for bladder drainage. Postoperative adjustment of cushion reservoir was performed by direct percutaneous injection of physiological sodium chloride into the scrotal port 1 month later and periodically if needed until either dryness was achieved or maximum filling capacity of the system was reached. Patients were evaluated thereafter every 3 to 6 months with 24 hours pad-count and 24 hours pad-test. Definition of treatment success was use of no pad or one security pad per day with less than 10 mL of leakage. All patients had a minimum 6 months follow-up. Information regarding continence was retrieved at the time of adjustment and regularly on follow-up visits. Data were included into an institutional review board approved database regarding urodynamic findings and continence outcomes. Tabulation of urodynamic data (MV and SR) was totally independent from that of baseline clinical data and operative results (IA and JCA).

Statistical analysis was performed using SPSS V22.0 with Fisher's exact test for dichotomous variables, $\chi^2$ lineal by lineal association test for categorical variables, mean comparison test for independent groups (Student *t* test) and Pearson regression coefficient for parametric variables. Parametric distribution of variables was tested by the Kolmogorov-Smirnoff test. Stepwise multivariate logistic analysis was also developed to evaluate what variables independently influenced on continence result. All tests were two-sided with a level of $P < .05$ considered statistically significant. Quantitative variables are expressed as mean ± SD and qualitative variables by absolute number (percentage). The study was approved by the Ethics and Research Committees of Getafe University Hospital (Madrid, Spain).

## 3 | RESULTS

Table 2 summarizes the preoperative urodynamic data of the patients included in the study. Baseline 24 hours pad-count was 5 ± 1.2 pads/day, and pad-test was 606 ± 358.6 mL. Postoperatively adjustment of cushion reservoir was performed 7 ± 7.4 times. The final cushion volume was 17 ± 6.3 mL. Fifty-four patients (70.1%) were dry, that is, achieved continence or treatment success (pad-test under 10 mL). Forty-eight patients (62.3%) had "zero" leakage. Postoperatively the number of daily pad-count was 1 ± 1 pads/day, and the incontinence leakage volume was 52 ± 105.3 mL. Comparison of SUI severity between baseline and after adjustment was statistically significant, both regarding pad-count and pad-test ($P < .0001$ each).

**TABLE 2** Preoperative urodynamic data (n = 77)

| | |
|---|---|
| Cystometric bladder capacity, mL[a] | 279 ± 95.9 |
| Bladder compliance, mL/cm$H_2O$[a] | 112 ± 116.1 |
| Detrusor overactivity[b] | 44 (57%) |
| Bladder capacity at first involuntary contraction, mL[a] | 210 ± 75.6 |
| Maximum involuntary contraction pressure, cm$H_2O$[a] | 40 ± 19.2 |
| Type of voiding[b] | |
| Voluntary detrusor contraction | 13 (17%) |
| Terminal voiding overactivity | 43 (56%) |
| Abdominal straining | 21 (27%) |
| Maximum voiding detrusor pressure, cm$H_2O$[a] | 28 ± 22.8 |
| Maximum voiding abdominal pressure, cm$H_2O$[a] | 45 ± 36.5 |
| BOOI, cm$H_2O$[a] | −0.1 ± 26.0 |
| BCI, cm$H_2O$[a] | 101 ± 38.7 |
| Postvoid residual urine, mL[a] | 6 ± 22.6 |

[a]Mean ± standard deviation.
[b]Number (percentage).

Type of voiding could be classified as by involuntary detrusor contraction (terminal voiding overactivity) in 43 (56%), abdominal straining in 21 (27%) and voluntary detrusor contraction in 13 (17%). We observed a relationship between the type of voiding and the cure of incontinence. Patients who voided with voluntary urinary contraction had higher probability to reach continence than the other voiding types (Table 3).

The relationship between urodynamic finding and continence status is shown in Table 4. We observed a significant relationship between continence and cystometric bladder capacity, maximum abdominal voiding pressure and BOOI (Figure 1). Multivariate analysis showed cystometric bladder capacity (odds ratio [OR], 1.01; confidence interval [CI], 1.02-1.00), BOOI (OR, 0.97; CI, 0.99-0.94), and maximum abdominal bladder pressure (OR, 0.97; CI, 0.98-0.94) were independent predictive variables (Table 5).

**TABLE 3** Relationship between type of voiding and urinary continence

| Type of voiding | Urinary continence (n = 54) |
|---|---|
| Voluntary detrusor contraction | 12 (93%) |
| Terminal voiding overactivity | 30 (70%) |
| Abdominal straining | 12 (57%) |

$\chi^2$ lineal by lineal association $P = .034$.

A strong correlation between postoperative incontinence severity, reduced cystometric capacity, and maximum abdominal voiding pressure was evidenced. Additionally, voluntary voiding pattern of micturition was associated with reduced residual incontinence severity and reduced number of postoperative adjustments (Table 6). Conversely, higher number of adjustments needed were in correlation with BOOI and maximum abdominal voiding pressure. There was also a correlation between BOOI and final filling-cushion of the ATOMS system (Table 6).

## 4 | DISCUSSION

The body of evidence to treat PPI with ATOMS device has grown since its original concept design in 2005[20] and first clinical report in 2012.[19] The device has evolved with changes regarding the design and pre-attachment of the port to allow fast and easy implant through a single perineal incision.[21] Unfortunately, as with any other incontinence prostheses, not all patients achieve urinary continence after device adjustment, and approximately 20% of the patients treated with last generation silicone-covered scrotal port ATOMS will remain incontinent to some degree.[8-10] Patients not achieving dryness can be very satisfied with their device but dryness after adjustment is a major factor to define PROs.[13] Baseline severity of SUI incontinence, former radiation, and secondary treatment have been identified by several authors as clinical determinants of treatment failure.[7-9] However, a more accurate definition of the optimal candidates for ATOMS implant remains a matter of current investigation.

Our study found three independent urodynamic parameters that influenced postoperative continence of patients submitted to ATOMS implantation. One of these was related to filling phase, cystometric bladder capacity, and the other two were related to voiding phase: maximum abdominal voiding pressure and BOOI. We also observed that patients who voided with voluntary detrusor contraction had higher probability to become continent than those who urinated differently.

Urodynamic filling phase risk factors for postoperative incontinence have been described by other authors. Solomon et al[14] suggest that DO and bladder compliance influenced on the probability to achieve urinary continence after AUS implantation. They attributed

**TABLE 4** Relationship between urodynamic data and continence status

| Urodynamic data | Continent (n = 54) | Incontinent (n = 23) | *P*-value |
|---|---|---|---|
| Cystometric bladder capacity, mL[a] | 296 ± 88.6 | 240 ± 103.1 | .019* |
| Bladder compliance, mL/cm$H_2O$[a] | 121 ± 119.8 | 91 ± 106.2 | .298 |
| Detrusor overactivity [b] | 31 (57%) | 13 (56%) | 1.000 |
| Maximum involuntary contraction pressure, cm$H_2O$[a] | 39 ± 15.3 | 42 ± 25.8 | .676 |
| Maximum voiding detrusor pressure, cm$H_2O$[a] | 28 ± 20.2 | 27 ± 28.4 | .877 |
| Maximum voiding abdominal pressure, cm$H_2O$[a] | 39 ± 31.2 | 59 ± 44.0 | .049* |
| BOOI, cm$H_2O$[a] | −5 ± 23.8 | 12 ± 28.0 | .025* |
| BCI, cm$H_2O$[a] | 105 ± 39.0 | 90 ± 36.9 | .806 |
| Postvoid residual urine, mL[a] | 3 ± 9.8 | 14 ± 38.0 | .206 |

[a]Mean ± standard deviation.
[b]Number (percentage).
*Significative.

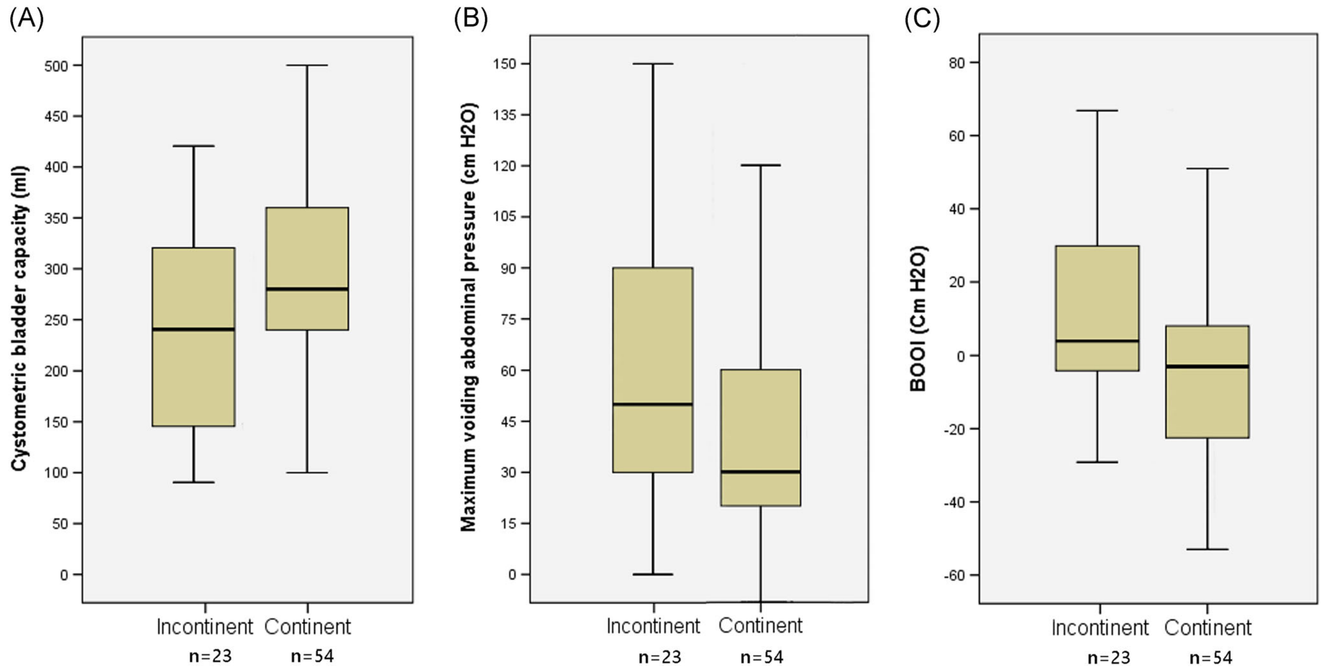


**FIGURE 1** Relationship between postoperative continence status and cystometric bladder capacity ($P = .019$), maximum voiding abdominal pressure ($P = .049$), and BOOI ($P = .025$). BOOI, Bladder Outlet Obstruction Index

this because both conditions increase bladder pressure, thus exceeding AUS pressure to occlude the urethra. Our study did not observe this relationship, possibly for the different mode of action of the devices. However, we observed that patients with terminal voiding overactivity had less probability of achieving continence than those with voluntary voiding patterns.

Our study found an inverse relationship between cystometric capacity and postoperative continence. Utomo et al[22] using adjustable continence therapy (proACT), another compressive device also showed that a small cystometric capacity is associated with unsuccessful clinical outcome. Soljanik et al[23] using a retrourethral transobturator sling reported a cystometric capacity under 200 mL was an adverse parameter. It is possible that despite having DO most patients do not experience urinary incontinence because they modify their behavior voiding pre-emptively up to a certain value of functional bladder capacity. In this case patients may change incontinence by frequency.

Voiding functional parameters have been rarely studied as risk factor for postoperative persistence of PPI. Kim et al studied the influence of bladder contractility on postoperative outcome in a population of patients treated with AUS and male sling Argus T® (Promedon, Cordoba, Argentina) and, as our study, they did not find any influence.[24] To our knowledge this is the first time that urethral functional parameters are studied as risk factor for postoperative incontinence of PPI. We show that BOOI correlated inversely with the probability to become continent postoperatively, despite increased number of adjustments and filling volume. One cause of increment of urethral resistance is fibrosis as it is seen in urethral stricture.[25] Some degree of fibrosis around and at the external sphincter is frequently seen in PPI.[26] Radiotherapy, another cause of urethral fibrosis, is a well-known risk factor for postoperative incontinence with different anti-incontinence devices including ATOMS.[8,10,14] Méndez Rubio et al[27] found 41% of reduction of urethral diameter while voiding in videourodynamic studies of patients submitted to radiotherapy. Fibrosis increases the elastic coefficient of the urethra which reduces the compressive effect of ATOMS cushion on the urethra. This compression is believed to be the mechanism that promotes urinary continence after

**TABLE 5** Multivariate analysis

| Variable | Multivariate coefficient | *P*-value |
|---|---|---|
| Cystometric bladder capacity | 0.010 | .026* |
| Maximum abdominal voiding pressure | −0.029 | .038* |
| BOOI | −0.032 | .036* |
| Constant | −0.583 | .586 |

*Significative.

**TABLE 6** Urodynamic predictors and type of voiding determine ATOMS filling volume, number of adjustments, and postoperative incontinence severity (pad-count and pad-test after adjustment)

| | Number of adjustments | Final cushion volume, mL | 24 h pad-test | 24 h pad-count |
|---|---|---|---|---|
| Cystometric bladder capacity, mL | $r = -.170$<br>$P = .139$ | $r = -.138$<br>$P = .233$ | $r = -.346$<br>$P = .002$* | $r = -.344$<br>$P = .002$* |
| Maximum abdominal voiding pressure | $r = .286$<br>$P = .012$* | $r = .214$<br>$P = .064$ | $r = .240$<br>$P = .037$* | $r = .280$<br>$P = .014$* |
| BOOI | $r = .217$<br>$P = .048$* | $r = -.322$<br>$P = .018$* | $r = .131$<br>$P = .345$ | $r = -.200$<br>$P = .147$ |
| Type of voiding | | | | |
| Voluntary voiding | 0.46 ± 0.78 | 14.5 ± 5.24 | 1.15 ± 2.99 | 0.08 ± 0.28 |
| Other patterns [a] | 1.86 ± 1.74 | 18.23 ± 6.42 | 62.27 ± 112.85 | 0.69 ± 1.11 |
| | $P = .000$* | $P = .054$* | $P = .000$* | $P = .000$* |

[a]Other patterns include terminal voiding overactivity and abdominal straining.
*Significative.

ATOMS implant; consequently, its annulment would prevent, at least in part, the resolution of incontinence.

The other independent voiding risk factor is increased abdominal voiding pressure. This parameter is related to abdominal straining which has been proved in our study to lower the probability of postoperative continence and increase postoperative urine loss despite higher number of adjustments. There are some classical observations suggesting that this factor can be harmful for continence. For instance, abdominal straining leads to the relaxation of pelvic floor muscle which favors urinary incontinence in women.[28] The observation of Plevnick[29] that the increase of abdominal pressure acts opening the bladder neck is another argument in favor. Additionally, Hasegawa et al[30] suggested that the patients who urinate with straining sometimes suffered from SUI. Finally, Brune and Obrink[31] confirmed that repeated straining leads to a significant loss of urethral smooth muscle tone. Based on these observations, strain voiding appears a condition that weakens the intrinsic urethral sphincter mechanism. Therefore, an explanation why strain voiding worsens the ATOMS results is possibly based on the finding that these patients have a higher grade of incontinence, as can be seen in Table 6.

The main limitations of our study are the relatively small number of patients and the long interval between the urodynamic preoperative study and the implantation of ATOMS, caused by a long surgical waiting list. However, reproducibility studies have shown the stability of urodynamic findings over time.[32] The main strengths are the novel description of some voiding dysfunctions as risk factors for incontinence persistence after ATOMS placement, and the blind evaluation taken between urodynamic data and postoperative results.

## 5 | CONCLUSIONS

The use of urodynamics to predict results of PPI treatment is highly controversial. We found that not only filling phase urodynamic factors, but also voiding factors can be determinant for persistent urinary incontinence after ATOMS implantation. The incorporation of these parameters to current clinical factors and patient preferences could help to improve the continence results and facilitate the decision of physicians to implant one device or another. Under this view, more serious urodynamic studies are required for the different devices.

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