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RESEARCH ARTICLE

Evaluation of Functional Bladder Recovery in Patients with a Chronic Foley Catheter for Urinary Retention: A Randomized, Prospective, Blind and Comparative Study with 18 Months of Follow-up

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Abstract

Purpose: To analyze the repercussions of chronic Foley catheter use in patients with urinary retention on the functional recovery of the bladder following corrective surgery.

Methods: Twenty-four men were randomly selected from the waiting list for prostate surgery in our urology outpatient service database and divided into two groups. One consisted of men with intermediate/severe Lower Urinary Tract Symptoms (LUTS) and other consisted of patients with urinary retention managed with a Foley catheter for a long time, consequent to benign prostatic enlargement. Both groups underwent prostatic surgery. Prior to their operations and at the 6th, 12th, and 18th month follow-ups, they completed the IPSS and ICIQ-SF questionnaires and received a urodynamic evaluation.

Results: There were no statistically significant differences in questionnaire scores or in urodynamic parameters at the end of the 18 months of follow-up.

Conclusions: Patients experiencing urinary retention, who have been chronic users of a vesical catheter, have a similar postoperative outcome as patients with obstruction but without retention. Preoperative detrusor contraction force seems to be a very important factor in functional vesical recovery outcomes.

Keywords

Urinary retention, Low urinary tract symptoms, Bladder outlet obstruction, Urodynamics, Foley catheter

Introduction

Latin American countries suffer from significant socio-economic inequality. Despite improvement in human de-

velopment index values observed in Latin America since 1980, the Gender Inequality Index (Gini) remains well below the ideal relative to European countries such as Norway and Sweden [1]. Even in countries such as Brazil, which has achieved reductions in poverty and introduced universal health coverage [2], inequalities in access to health services and health outcomes driven by social determinants of health remain a major challenge.

In 2008, the Brazilian Urology Society, via its president, sent an official letter to the Brazilian Ministry of Health warning of the difficulties that the country's citizens were facing in obtaining urological care at public hospitals [3]. At the time, the waiting period for a urology specialist consultation was up to 180 days, depending on the area of the country, and the waiting time for a surgeon often reached 2 years [3]. Unfortunately, this situation has not yet improved substantially.

With the aforementioned prolonged waiting times, patients who develop acute urinary retention arising from benign prostatic enlargement endure long periods living with a Foley bladder catheter awaiting resolution of the obstruction. The repercussions of such chronic catheter use on the functional recovery of the bladder following corrective surgery are uncertain. For the first time, here, we used a series of urodynamic evaluations to analyze the vesical effects of this prolonged catheterization over a medium-term postoperative period.

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Methods

Patients

The participants were selected randomly from the waiting list for prostate surgery in our urology outpatient service database at the Servidores do Estado Federal Hospital (Rio de Janeiro - Brazil) by one of this study's authors using a computer based exclusively on their medical record (hospital registration) number. All of the patients were Brazilian nationals. Between February and June of 2014, we recruited two groups of men. One consisted of men with intermediate/severe Lower Urinary Tract Symptoms (LUTS) stemming from benign prostatic hyperplasia that was resistant to oral pharmacotherapy with alpha blockers and/or 5-alpha-reductase enzyme inhibitors. The other group consisted of patients with urinary retention arising from benign prostatic hyperplasia that was resistant to oral pharmacotherapy who were using a vesical Foley catheter. All catheters were placed by an experienced urologist in the emergency department of our hospital.

For the entire study cohort, we collected an anamnesis, performed a physical examination (including a digital rectal examination), measured total prostate-specific antigen serum levels, performed a transrectal prostatic ultrasound, conducted an urodynamic evaluation, and measured fasting glucose and serum creatinine levels. Drugs prescribed to manage LUTS were suspended for 90 days before the operation. The exclusion criteria were as follows: Total serum prostate-specific antigen levels > 4.0 ng/dL, fasting glucose > 99 mg/dL, serum creatinine > 1.2 mg/dL, suspicion of malignant neoplasm in digital rectal examination, neuropathy, diabetes mellitus, kidney dysfunction, urodynamic changes compatible with ureteropathy or detrusor hypcontractility, prior pelvic surgeries, dysuria, pain when emptying the bladder, and history of pelvic radiation therapy.

Prior to their operations, the patients filled out the *International Prostate Symptom Score* (IPSS) questionnaire [4] and the validated Portuguese version of the *International Consultation on Incontinence Questionnaire-Short Form* (ICIQ-SF) [5]. We completed a preoperative urodynamic study using the Dynapack MPX816™ device (Dynamed™, São Paulo, Brazil) with Urofive™ software (Dynamed™, São Paulo, Brazil). The urodynamic investigations and evaluations were performed according to the standards recommended by the International Continence Society [6]. We performed this study in accordance with the norms of our hospital's ethics committee. All patients signed informed consent forms.

Surgical techniques

Transurethral Resection of the Prostate (TURP) was performed for prostates with a volume up to 80 mL on transrectal sonography; and Open Prostatectomy (OP) was performed for prostates with a volume > 80

mL. The OP and TURP treatments were performed by one experienced urologist and carried out under spinal anesthesia with intravenous sedation. TURP was performed with a continuous flow resectoscope (26 French gauge) and monopolar diathermy, with a mannitol/sorbitol irrigation solution. OP was performed in accordance with Millin's open prostatectomy technique [7] or by classic transvesical suprapubic prostatectomy [8].

Follow-up

The patients returned for outpatient review on 1st, 3rd, 6th, 12th, and 18th month following the operation. At the 6th, 12th, and 18th month follow-ups, they completed the IPSS and ICIQ-SF questionnaires and received a urodynamic evaluation. The urodynamic parameters analyzed were maximum flow rate (Q_{max}) and Postvoid Residual (PVR) urine with spontaneous uroflowmetry as well as detrusor Pressure at Q_{max} ($PdetQ_{max}$) in pressure-flow studies. We calculated the Bladder Outlet Obstruction Index (BOOI) as follows [9]: $BOOI = PdetQ_{max} - 2Q_{max}$. The BOOI was classified binarily as < 20 (unobstructed) or ≥ 20 (equivocal or obstructed).

Two urologists participated in postoperative outpatient evaluation. A uroneurologist, was responsible for the postoperative urodynamic evaluations. Neither participated in patient selection, the operations, or the immediate postoperative care. During the consultations and urodynamic examinations, these physicians did not have access to the patients' records and thus were unable to identify which patients had experienced urinary retention and chronic use of a bladder catheter preoperatively, making this a blind study. A fourth urologist who knew the group assignments was responsible for distributing the patients for outpatient care and follow-up urodynamic studies.

Data analysis

Group data were compared with Student's t-tests for continuous data and with Mann-Whitney tests for categorical data, with a significance value of $p < 0.01$. Statistical analysis was performed in Prism™ software, version 5 (GraphPad, La Jolla, CA).

Results

The study cohort of 24 patients included 10 who had pharmacotherapy-resistant LUTS without retention (LUTS group) and 14 who had urinary retention involving the use of a Vesical Catheter (VCath group) for an average period of 9 months (range, 6-24 months). Of the 14 patients in the VCath group, 4 were lost during the course of the study: 2 patients were exited for medical reasons (one because a cerebrovascular disease and the other because of urethra stenosis); and we lost communication with 2 others postoperatively. Thus, the final analysis at 18 months postoperatively involved 10 patients in the LUTS group with a mean age of 66 years (range, 56 - 86) versus 10 patients in the VCath group with a mean age of 69 years (range, 56 - 84).

None of the patients exhibited detrusor stability changes (range, 60 - 130 mL) for the VCath group and 120 mL (range, before or after the operation. The mean prostrate volume, 50 - 140) for the LUTS group. In the VCath group, intravesical according to preoperative ultrasound studies, was 100 mL de-obstruction was achieved by OP in 8 cases (6 Millin's OPs

Table 1: Comparative urodynamic data of postoperative bladder functional recovery between LUTS (LUTS without urinary retention) and VCath (urinary retention involving use of a Vesical Catheter) groups (BOOI: Bladder Outlet Obstruction Index; Pdet Qmax: detrusor pressure at Qmax; PVR: Post-Void Residual Urine Volume; Qmax: peak urinary flow rate).

Qmax (ml/s)	Before surgery	6 months	12 months	18 months	p
VCath group	Range: 0	Range: 10 a 23	Range: 10 a 26	Range: 10 a 30	0.26
	Mean: 0	Mean: 18.4	Mean: 18.2	Mean: 17.7	
LUTS group	Range: 3 a 13	Range: 10 a 26	Range: 10 a 39	Range: 10 a 34	
	Mean: 7.4	Mean: 18.5	Mean: 18.4	Mean: 19.5	
Pdet Qmax (cm H₂O)	Before surgery	6 months	12 months	18 months	p
VCath group	Range: 60 a 127	Range: 26 a 60	Range: 12 a 80	Range: 6 a 80	0.43
	Mean: 99	Mean: 42	Mean: 38	Mean: 41	
LUTS group	Range: 50 a 152	Range: 5 a 85	Range: 22 a 78	Range: 21 a 82	
	Mean: 92	Mean: 31	Mean: 40	Mean: 45	
PVR (ml)	Before surgery	6 months	12 months	18 months	p
VCath group	Range: 40 a 450	Range: 0 a 130	Range: 0 a 50	Range: 0 a 104	0.27
	Mean: 220	Mean: 30	Mean: 5	Mean: 13	
LUTS group	Range: 80 a 350	Range: 0 a 50	Range: 0 a 57	Range: 0 a 20	
	Mean: 170	Mean: 10	Mean: 17	Mean: 2	
BOOI	Before surgery	6 months	12 months	18 months	p
VCath group	Range: 52 a 139	Range: -19 a 40	Range: -30 a 39	Range: -43 a 48	0.83
	Mean: 85	Mean: -6.8	Mean: -5.2	Mean: 5.0	
LUTS group	Range: 38 a 135	Range: -27 a 59	Range: -56 a 62	Range: -21 a 63	
	Mean: 82	Mean: -6.1	Mean: -5.4	Mean: 5.6	

Table 2: Comparative results of the scores obtained on IPSS (International Prostate Symptom Score) and ICIQ-SF (International Consultation on Incontinence Questionnaire - Short Form) questionnaires between LUTS (LUTS without urinary retention) and VCath (urinary retention involving use of a Vesical Catheter) groups.

IPSS	Before surgery	6 months	12 months	18 months	p
VCath group	Range: notapplicable	Range: 0 a 14	Range: 0 a 9	Range: 0 a 10	0.40
	Mean: notapplicable	Mean: 4	Mean: 4	Mean: 3	
LUTS group	Range: 10 a 34	Range: 0 a 8	Range: 0 a 9	Range: 0 a 6	
	Mean: 22	Mean: 3	Mean: 4	Mean: 3	
ICIQ-SF	Before surgery	6 months	12 months	18 months	p
VCath group	Range: notapplicable	Range: 0	Range: 0 a 6	Range: 0	0.96
	Mean: notapplicable	Mean: 0	Mean: 1	Mean: 0	
LUTS group	Range: 0 a 10	Range: 0	Range: 0	Range: 0 a 6	
	Mean: 2	Mean: 0	Mean: 0	Mean: 1	

and 2 classic transvesical suprapubic prostatectomies) and by TURP in 2 cases. Among the 10 patients in the LUTS group, 9 received OPs (8 Millin's OPs and 1 classic transvesical suprapubic prostatectomy) and 1 received a TURP. All patients urinated in the immediate postoperative period. As reported in Table 1 and Table 2, there were no statistically significant differences in questionnaire scores or in urodynamic parameters at the end of the 18 months of follow-up.

Discussion

The scientific evidence relating to functional vesical recuperation after obstruction removal surgery in patients with acute urinary retention remains scarce. A recent review conducted by the Agency for Healthcare Research and Quality (U.S. Department of Health and Human Services) identified 11 original studies and 2 systematic reviews capable of fulfilling rigorous inclusion criteria. The researchers' conclusion was unsatisfying, stating that "the evidence was insufficient due to risk of bias and imprecision, and we were not able to evaluate consistency of results across studies" [10].

Optical microscopy studies have demonstrated that a bladder subjected to chronic obstruction that evolves into urinary retention shows significant cellular changes [11], such as an increased detrusor muscle cell diameter and intense intrafascicular collagen deposition. These changes may explain, at least in part, the development of detrusor hypoactivity as a terminal vesical situation [12]. However, from a functional point of view, our findings indicate that when contractile detrusor force is preserved, a bladder with urinary retention can recover normal function, even when maintained under chronic vesical catheterization.

Contractile detrusor force, expressed as PdetQmax in the preoperative urodynamic evaluation (see Methods), seems to be an important predictive factor for vesical recovery. In this study, the mean preoperative PdetQmax values obtained indicated that both the VCath group with retention (99 cm H₂O) and the LUTS group without retention (92 cm H₂O) had strong detrusor musculature. Our findings are consistent with prior shorter follow-up period studies (1 - 6 months) showing that when PdetQmax values are lower than 20 cm H₂O [13], 28 cm H₂O [14] or 32 cm H₂O [15], the chances of postoperative failure with a need for new vesical catheterization are elevated [14,15].

Another factor that influences vesical reestablishment is patient age. The present study cohort was middle-aged, under 70-years-old. Prior studies have shown that the failure rate after obstruction removal surgery requiring new vesical catheterization for postoperative urinary retention is elevated in patients over 80-years-old [14,15]. Our follow-up period was 3 times longer than that of these studies of older patients, which included only 6 months of follow-up. Our study also differed in terms of our focus being on evaluation of chronic use of a vesical catheter.

We should emphasize that, although we observed similar vesical recovery between patients with versus without

a chronic vesical catheter, the use of a vesical catheter for long periods of time can cause various undesirable sequelae. Notably, development of squamous cell carcinoma [16,17], persistent urinary infection due to biofilm formation [18], lower urinary tract lithiasis [19], ureocutaneous fistula [20], and urethral meatus trauma [21] are among the main complications associated with prolonged use of a Foley catheter. The potential for these complications calls into question the model of medical care offered to these patients in some Latin American countries.

This study had two limitations. First, the study included a small number of patients in each group. However, we believe that the rigorous methodology we used compensates, to some extent, for the small sample size. That is, we conducted a computer-randomized, prospective, blind, and comparative study with a medium-term follow-up yielding a favorable Jadad score [22]. Second, the surprising absence of significant detrusor hyperactivity preoperatively in both groups precluded evaluation of whether the presence of involuntary detrusor muscle contractions - a relatively common condition in bladders of patients with obstructions - might compromise postoperative functional vesical recovery. Notwithstanding, the present results shed light on a topic that is still poorly understood.

Conclusion

In conclusion, our findings demonstrate in a novel way that the bladder of patients experiencing urinary retention, who have been chronic users of a vesical catheter, have a similar postoperative outcome as patients with obstruction but without retention. Preoperative detrusor contraction force seems to be a very important factor in functional vesical recovery outcomes. Nevertheless, the potentially damaging effects of long-term catheterization on the bladder that should not be discounted and the prolonged waiting times for surgeries in certain Latin American countries should be re-evaluated. Finally, it is worth mentioning that the effects of chronic vesical catheterization on functional vesical recovery postprostatectomy have not yet been researched.

Disclosure of Potential Conflicts of Interest

The authors declare that they have no conflict of interest.

Ethical Approval

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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