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Long-term results of augmentation ileocystoplasty in spinal cord injury patients

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Katica Pavlović University Clinical Hospital in Mostar Clinic of Urology Kralja Tvrtka Street 88000 Mostar, Bosnia and Herzegovina katicapavlovic555@gmail. com Introduction The aim of this article was to report the long-term results of increased ileocystoplasty in 58 patients with spinal cord injury (SCI) with an impact on overall renal function and quality of life. In a representative number of patients, where we followed individual subjects for more than 20 years, we wanted to determine their quality of life and preservation of renal function after surgery. Material and methods After unsuccessful conservative therapy of urinary incontinence, increased ileocystoplasty was performed. In addition to biochemical analysis, intravenous urography (IVU) was performed preoperatively (urography and/or ultrasound assessment of the upper urinary tract) and urodynamic tests were performed in all patients preoperatively.

Results After a follow-up of patients within the group (>20 years), 2 patients reported being incontinent. The median elapsed time of action was 20 (13–24) years. Vesical capacity increased in all cases postoperatively when the median vesical capacity was 420.0 (387.5–460.0) ml (p <0.001). Long-term complications included use of bladder chambers, kidney stones and urosepsis. Creatinine clearance confirmed satisfactory renal function after the elapsed time period from surgery.

Conclusions The results confirmed that augmentation ileocystoplasty had excellent long-term outcomes in the definitive therapy of refractory neurogenic detrusor overactivity in patients with SCI.

Key Words: spinal cord injury () ileocystoplasty () continence

INTRODUCTION

Guided by the idea of the importance of preserving overall renal function and improving the quality of life (QoL) in patients with neurogenic bladder developed after spinal cord injury (SCI), we wanted to show the long-term results of our patients. In a representative number of patients where we followed individual subjects for more than 20 years we wanted to determine their QoL and the preservation of renal function after surgery. The results of previously published studies were done on a significantly smaller number of respondents considering that we have a representative number of patients and longterm follow-up. Since one surgeon performed all operations and at the same time monitored all patients throughout the period, we considered it important to show the satisfaction of our patients, preserved overall renal function in the reference interval and a significant QoL. One of the most important surgical forms of treatment for refractory neuropathic bladder arising after SCI is certainly augmentation ileocystoplasty (ACI). The resulting suprasacral spinal cord injuries can cause incurable incontinence, consequent secondary nephropathy which in turn can have a significant impact on QoL [1].

The introduction of clean intermittent self-catheterization by Lapides et al., resulted in a more widespread use of augmentation cystoplasty [2, 3]. Bladder augmentation cystoplasty is used in the adult population for neurogenic bladder dysfunction, as well as for such inflammatory conditions as tuberculosis cystitis that result in a severely contracted bladder, interstitial cystitis and reconstruction of iatrogenic bladder injury [4]. Augmentation cystoplasty is a procedure with long-term effects and high rates of patient satisfaction, but not without risk of complications and potential increased risk of malignancy [5, 6].

According to the European Association of Urology guidelines, bladder augmentation is a valid option to decrease detrusor pressure and increase bladder capacity, whenever more conservative approaches have failed [7]. Bladder augmentation was found to be beneficial, especially with such underlying neurological disorders as SCI, multiple sclerosis and myelodysplasia [8, 9, 10].

We report on long-term results of ACI in the treatment of patients with neurogenic detrusor overactivity (NDO) and associated symptoms of severe urinary urgency, frequency and urge incontinence.

MATERIAL AND METHODS

The study was organized as a retrospective study.

We collected retrospective data on 58 patients with suprasacral spinal injuries, with refractory NDO and urge incontinence, who underwent ileocystoplasty in the period 1991–2013. All surgeries were performed by a single surgeon (IG). SCI in most of our subjects were the result of war wounds.

We included solely the patients who underwent clam cystoplasty. All patients were confirmed the neurological diagnosis at least two years before the urological treatment. Preoperative treatment included medical history sampling, urodynamic evaluation, biochemical analysis (complete blood count, serum acid and creatine level) and creatinine clearance to assess renal function.

In the preoperative assessment of renal function, tests of serum creatinine, urea and creatinine clearance were used, as well as ultrasound examination (US) of the urinary tract, intravenous urography (IVU), and multislice computed tomography urography (MSCTU). Creatinine clearance was calculated for all patients according to the creatinine clearance (Cockcroft-Gault Equation) formula as recommended by the monitoring guidelines [11].

Urodynamic testing was performed in all patients prior to surgery to assess intra-bladder pressure and bladder functional capacity.

Postoperatively urodynamic examination was performed in patients with unacceptable results after ileocystoplasty. Those results include persistent urge incontinence, the need for self-catheterization at intervals shorter than 3 hours and the need for anticholinergic therapy. The Hospital Ethics Committee did not approve postoperative urodynamic testing on all study participants in early postoperative recovery due to the invasiveness of the diagnostic test and the reluctance of patients to consent to it.

Postoperative functional augmented bladder capacity was determined as the average number of capacity recorded by the patients during the month ('voiding diary') by measuring the volume after each self-catheterization. Patients who did not have incontinent episodes between two self-catheterizations were considered continent.

The indication for ACI was an unsuccessful conservative treatment for at least 24 months (anticholinergics with occasional self-catheterization). At the time of the study, botulinum toxin A was not used in clinical practice in our country due to war conditions.

Patients with inflammatory bowel disease (Crohn's disease), enteritis-induced radiotherapy, malignant bladder disease, who were unable to perform occasional clean self-catheterization (manual dexterity or cognitive function) have a contraindication for ACI.

Complications were identified from case notes and surgery database. All early surgical complications were systematized according to the Clavien-Dindo classification [12].

Subjective assessment was carried out by means of a previously validated questionnaire.

Urogenital Distress Inventory (UDI-6) and Incontinence Impact Questionnaire (IIQ-7) were used. These are standardized guides that are not validated in our country, but we requested permission to use a validated questionnaire in Germany by Utomo at al. [13]. We also used a previously formulated questionnaire, developed specifically for the use in this context. The questionnaire was modified by Kelly et al. to cover urinary tract symptoms in ACI patients [14]. This questionnaire is available for use in the English language and it underwent bilingual translation according to the instructions on translation and use of foreign questionnaires in the research. Patient satisfaction with QoL after surgery was rated with a numerical scale from 0 to 10. We collected objective long-term outcome parameters: incontinence, need for further treatment, urinary infections requiring antibiotics, lithiasis and metabolic acidosis and subjective overall satisfaction through standard questioning during history taking. The data were collected during clinical rounds.

Procedures

All surgeries were carried in accordance with the surgical technique originally described by Bramble [15]. Basically, the bladder is double-buried in the coronal plane, 'like shells' and supplemented by a segment of detubolarized ileum of approximately 20 cm in length, and is taken about 20 cm in close proximity to the terminal ileum, which sought to preserve its attachment to its own mesentery. After detubularization and reconfiguration of the ileal segment, it is extraperotonealized through a small incision in the peritoneum. The extraperitonelized segment of the ileum is then augmented to the bladder. Compared to the standard procedure, this is the only difference. Detubularization at the antimesenteric border, at reconfiguration when made in U or W form provides a low pressure reservoir and increases capacity [16]. A technical point of vital importance is that both ends of the incision are extended right down to the base to ensure deactivation of the overactive bladder. Over the years, the surgical procedure did not change for all operated patients.

Follow-up

All patients were monitored postoperatively within 3 months of surgery, following the values of laboratory tests (serum urea and creatinine levels and a complete blood count with monitoring of mineral status).

Further follow-up after 9 months to one year included radiological ultrasound examination of the urinary system, in addition to a repeated analysis of serum urea and creatinine levels and creatinine clearance to assess renal function. MSCT urography was done in patients within the first 5 years of surgery. The functional capacity of bladder was assessed based on keeping a urination diary by measuring the amount of urine after each self-catheterization.

Five years after the procedure, cystoscopy was introduced into the monitoring protocol once a year. We receive all subsequent surgical interventions and complications from our surgical base and make a note on the case.

In the follow-up of patients in the postoperative course, the biggest obstacle was the inconsistency of control examinations in the same time period. Therefore, not all data were analyzed in the postoperative follow-up for the same time period elapsed since the operation.

The questionnaire was completed during follow-up clinical visits.

Statistical analysis

IBM SPSS Statistics 25 was used for statistical analysis. The results are reported as number and %, mean and standard deviation (M ±SD) or median

and interquartile ranges (C [Q1–Q3]). The χ^2 test, McNemar test, and Wilcoxon Signed Ranks Test were used to test for significance of differences. The significance limit was set to 0.05. P values that could not be expressed to three decimal places are reported as P <0.001.

RESULTS

The study included 58 patients; 43 (74.1%) were male and 15 (25.9%) were female. Men were significantly more prevalent in the sample ($\chi^2 = 13.517$; p <0.001). The mean age of patients at the time of surgery was 33.34 ±11.74 years. The youngest patient was 9 and the oldest was 60 years old. Today, the mean age of patients is 52.05 ±12.04 years.

Median elapsed time since surgery is 20 (13–24) years. Less than 20 years have passed since the operation in 25 (43.1%) patients, and in 33 (56.9%) more than 20 years.

Table 1. Early and long-term complications and treatment

	Number (%) of patients	umber (%) Treatment f patients	
Early complications			
Prolonged postoperative ileus	6 (10.3)	Conservative	
Transient urinary fistula	3 (5.2)	Conservative	
Bleeding requiring operating	1 (1.7)	Reoperation	
Thrombo-embolic complications	1 (1.7)	Conservative	
Wound infection	3 (5.2) Conservative + Surgical		
Metabolic complications	52 (89.7)		
Long-term complications			
Hyperchloremic acidosis requiring bicarbonate treatment	0		
Urinary stone formation after ileocystoplasty	6 (10.3)		
Cystoplasty perforation	0		
Bowel disturbance	13 (22.4)		
Urologic surgery after ileocystoplasty	2 (3.4)		
Diverticulization of the intestinal patch	1 (1.7)		
Urethral stricture precluding CIC	1 (1.7)		
Renal stones	3 (5.2)	Lithotripsy	
Bladder stones	3 (5.2)	Cystolithalopaxy	
Clavien-Dindo Classification of Surgical Co	omplications		
Grade I	9 (15.5)		
Grade II	35 (60.3)		
Grade IIIa	8 (13.8)		
Grade IIIb	6 (10.3)		

CIC - clear intermittent catheterization

An overview of complications (early and long-term) and treatment are shown in Table 1. Surveillance ultrasonography, along with biochemical renal function monitoring, did not show hydronephrosis nor renal dysfunction in any of the cases. There were no cases of metabolic derangements (hyperchloremic acidosis) who needed alkalizing therapy, although we had a significantly high percentage 52 (89.7%) of laboratory-detected changes in metabolic status as an early complication. Surveillance cystoscopies did not detect any bladder neoplasms. The diverticulization of the intestinal patch was noticed in one patient. In our study 6 (13.7 %) patients were treated for urinary lithiasis. The results showed 3 patients had bladder stones and 3 had renal stones. The classification of patients according to the Clavien-Dindo Classification of Surgical Complications shows significant differences in the prevalence of individual degrees of complications ($\chi^2 = 38.966$; p < 0.001). Grade 2 complications are significantly more prevalent than other stages (Table 1).

A significant difference was found in the number of incontinent patients before and after surgery (Table 2). During the most recent (>20 years) followup 2 patients reported being incontinent (both men, more than 20 years have passed since the surgery), while before surgery all 58 patients had a certain degree of incontinence (they used a minimum of one urinary cartridge for 24 hours). It should also be noted that 29 (21 men and 8 women) of these 56 patients indicated that they were incontinent occasionally. During the clinical examination, they explained this by finding themselves in exceptional situations (they were not at home and did not perform timing self-catheterization, they had symptoms of urinary infection and other personal reasons).

In our research 3 patients required anticholinergic suppression at the latest postoperative follow-up. The methods of bladder drainage at the latest followup were; clean intermittent catheterization in 57 patients and suprapubic catheter in one patient.

Preoperative urodynamic tests showed median pressure of 68.00 (64.0–84.25) cm H_20 , while after surgery no urodynamic tests were performed. A significant difference was found in the capacity before and after surgery (Table 3). After surgery the capacity was significantly higher – all patients had an increased capacity after surgery.

Two of the patients were noted to have low-grade unilateral (grade II) vesicoureteral reflux (VUR) before surgery. After ACI, there were no longer radiographic signs of VUR. Significant difference was found for urea and creatinine. Before surgery, some patients had urea and creatinine values outside the reference values (they had lower or higher values than
 Table 2. Distribution of patients according to incontinence and bladder capacity before and after surgery

		Number (%) of patients		s*	
		Yes	No	p.	
Incontinent	before surgery after surgery	58 (100.0) 2 (3.4)	0 56 (96.6)	<0.001	
		in RI	not in RI		
Urea	before surgery after surgery	45 (77.6) 58 (100.0)	13 (22.4) 0	<0.001	
Creatinine	before surgery after surgery	47 (81.0) 58 (100.0)	11 (19.0) 0	<0.001	

RI - referral interval; * McNemar test

 Table 3. Bladder capacity and creatinine clearance before and after surgery

C [Q1-Q3] p*	
Preoperative 130.0 [110.0-160.0] <0.0 Postoperative 420.00 [387.5-460.0] <0.0	Capacity
Creatinine Preoperative 119.1 [90.32–142.66] <0.0 clearance Last control 76.62 [61.79–105.79] <0.0	Creatinine clearance

C – median; [Q1 – Q3] – [First Quartile – Third Quartile]; * Wilcoxon Signed Ranks Test

allowed), while after surgery all patients had values in the referral interval (Table 2). A statistically significant difference was found in creatinine clearance values before surgery and at the last control examination (p <0.001). Creatinine clearance values were significantly lower at follow-up (Table 3).

Prior to surgery, the predominant symptoms were urination with urgency and urge incontinence (91.4%). Urge incontinence significantly affects ability to travel ($\chi^2 = 4.414$; p = 0.036), social life ($\chi^2 = 36.483$; p <0.001), emotional health ($\chi^2 = 39.724$; p <0.001) and frustrated feeling ($\chi^2 = 19.931$; p <0.001). Urge incontinence led to a loss of ability to travel in 63.8% of patients, damaged the social aspect of life (89.7%), affected emotional health (anxiety, upset depressive episode) in 91.4% of patients and caused frustration in 79.3% of patients. All of these patients rated the impact of incontinence as strong.

Urge incontinence significantly affected patients' ability to perform household duties ($\chi^2 = 37.310$; p <0.001), physical activity like walking, swimming ($\chi^2 = 31.690$; p <0.001) and leisure activities like going to the movies, going to the concert ($\chi^2 = 68.931$; p <0.001). Influence on the ability to perform household duties and physical activity was rated by the patients as moderate, while the impact on leisure activities was rated as slight.

Respondents were very satisfied with the quality of life after surgery (9.5 ± 1.1) . One respondent rat-

ed quality of life after surgery with grade 2, and all others rated it with grades 9 and 10 (offered range 1–10). All 58 patients would recommend this type of treatment for conservative incapacity incontinence to other patients, and also agree to surgery again. All patients reported no change in sexual function. In our research 13 (22.4%) patients reported significant changes in bowel habit (diarrhea from 3 to 6 months). All patients reported mucus production to a greater or lesser extent over the years. Caesarean section was done in one patient with transversal myelitis who underwent augmentation ileocystoplasty in our research.

DISCUSSION

The aim of ACI is to make the patient dry (continent) between two self-catheterizations and to keep the overall renal function intact. We included in the study a homogeneous group of patients with refractory NDO as a consequence of SCI who underwent ACI (clam ileocystoplasty).

The results of our study show that ACI has the potential to fulfill both tasks. Comparing our research with the published papers so far, we have noticed that the value of our research is in the size of the tested sample and in the length of time elapsed since the surgery was done.

We consider important evaluation of success from a patient's perspective if symptoms and QoL have improved, and we can therefore accept such perception as 'successful' results of surgical treatment [1]. Basically, ACI converts high-pressure and low-capacity co-occurrence with consequent urge incontinence into a low-pressure and large-capacity system with consequent continence. The low-pressure and large capacity system protects the upper urinary tract from damage on a long-term basis. All patients underwent urodynamic testing prior to surgery to measure cystometric pressure and bladder capacity. Postoperatively, we did not perform urodynamic tests due to the circumstances of the health system, but also patients included in the study who did not readily agree to repeat the urodynamic testing. Therefore, the shortcoming of this study is precisely in that fact. Resorted to non-invasive diagnostic methods to assess bladder capacity (amount of urine measured after each voiding diary) and obtained a significant increase in bladder capacity, although aware that these are two different monitoring methods.

An earlier review on this topic concluded that ileocystoplasty per se should not have adverse outcomes on overall renal function [17, 18]. In our study, we followed patients over a long period of time emphasizing the importance of preserving overall renal

function over the years. As a significant indicator, we monitored the values of creatinine clearance taking into account the elapsed time, the current age of the patient and the loss of muscle mass. According to our results, there was an increase in creatinine as well as a decrease in creatinine clearance, but they were still within the reference interval for satisfactory renal function. According to the results of our study, more than 50% of the subjects underwent the surgery more than 20 years ago. All respondents completed a questionnaire on QoL and satisfaction after the procedure at one of the last control visits to the clinic. The research we conducted regarding the experience of a patient with SCI who underwent surgical treatment of ACI due to refractory NDO showed utmost satisfaction with the outcome of surgery. The patients stated that there was a significant improvement in QoL, and that they would go through the same procedure again and recommend it to their friends. According to the literature the mortality rate from ACI was reported to be 0-3.2% [1, 19]. In our study mortality was 0%. If the bladder is inadequately bi-valved, the intestinal patch may be diverticularized. This diverticulum will fill during voiding and empty into the bladder at the end of voiding causing significant residual urine [20]. In our study there was one such patient.

Biochemical disturbances of acid-base and electrolyte equilibrium due to ammonia and ammonium chloride reabsorption and to a lesser extent secretion of bicarbonate by the isolated intestinal segment occur in almost all patients. It is important to emphasize that this is clinically relevant in a very small number of cases [17]. Although in our study there was a high percentage 52 (89.7%) of patients with established laboratory changes in mineral status and metabolic disorder during early postoperative recovery, there were no cases of metabolic derangements (hyperchloremic acidosis) who needed alkalizing therapy in our study.

The amount of mucus produced by the ileum segment used for ACI averages 35–40 g daily. Despite the fact that villous atrophy of the mucosal segment of the intestinal patch occurs over time, the amount of mucus produced does not decrease significantly over time [19]. In our study, all patients had a greater or lesser problem with mucus formation, which did not deviate from similar results published so far [1]. Asymptomatic bacteriuria with mixed organisms is reported to occur in 50–100% of patients who have undergone ACI. It is important to emphasize that the frequency of significant UTI is lower (4–43%) [20, 21]. All our patients had bacteriuria, although they rarely showed signs of clinically manifested uroinfection. We believe that asymptomatic bacteriuria is not an indication that we are trying to sterilize the urine at any cost by administering medication. If we can achieve this, it is a short-term effect. We have given greater importance to proper education on self-catheterization and conduction as much as possible in aseptic conditions. Recurrent urinary tract infections requiring antibiotic treatment occurred frequently as early complications in the postoperative period of 3 months. They were then sporadic and less frequent and did not always require antibiotic treatment.

In addition, one of the common complications that occur after ileocystoplasty is the formation of stones of the urinary system, especially bladder stones, which occur in 3–40% of cases [22, 23]. If stones are detected, they should be removed, otherwise they will be a source of infection and tend to increase if left untouched. As we have already stated in the results there were 6 patients with detected urinary stones. of which two patients had recurrent bladder stones that were successfully treated with laser lithotripsy. Bladder irrigation protocols with normal saline and antibiotics (gentamycin) have been shown to reduce the incidence of bacteriuria and mucus, and to significantly reduce the formation of stones [24]. Comparing the results obtained with those reached in a similar study, there are no significant discrepancies [1].

Spontaneous bladder perforation has a reported incidence of 0.8-13% [25]. The most usual site of perforation is the junction between the bowel and bladder wall. Most ruptures are intraperitoneally, and laparotomy exploration is recommended [25]. We did not have any case of bladder perforation.

In general, women with ACI should aim to deliver vaginally. Caesarean section should be reserved sole-

ly for obstetric indication, to avoid possible injury to the bladder and pedicle of the augmentation bowel [26]. We reported one result of Caesarean section that had been done in one patient with transversal myelitis. Following two patients with VUR in our study after ACI, there were no longer radiographic signs of VUR. All complications that occurred within 3 months of surgery were considered early complications. After that time, we considered all the complications to be late postoperative complications. Our results are consistent with the previously reported results, which have shown that ileocystoplasty without ureteral reimplantation can resolve VUR, even when a high grade of VUR is present [27, 28].

CONCLUSIONS

In conclusions, it is our view that ileocystoplasty has excellent long-term outcomes in the definitive management of refractory neurogenic detrusor overactivity (NDO) and preservation of overall renal function over the long term in patients with spinal cord injury (SCI). The conducted questionnaire confirmed a significantly better quality of life (QoL) after surgery. A significant shortcoming of our research is the lack of urodynamic testing after surgery due to various circumstances that were an obstacle to its implementation. This would immeasurably contribute to the quality of this research. Future researches should certainly keep in mind the importance of conducting urodynamic testing as an indispensable method in assessing the condition of neurogenic bladder.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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