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Orthotopic ileal neobladder creation according to the original surgical method "Belgrade pouch" – A ten-years experience

Ortotopska ilealna neobešika kreirana po originalnoj hirurškoj metodi "*Belgrade pouch*"– desetogodišnje iskustvo

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Abstract

Background/Aim. The principle of continent urinary derivations is based on the formation of a reservoir as similar as native bladder is, with satisfactory capacity, high level of continence, low pressure and small resorbent surface as possible to prevent metabolic disorders. **Methods.** This prospective and partially retreospective study included 148 patients with organ confined muscle invasive bladder cancer, operated on in a ten-year period, and followed up in a 3-year period. After a radical cystectomy, an original surgical technique of creating "U" shaped orthotopic neobladder using a short ileal segment, average length of 30 cm, called "Belgrade pouch", was performed. **Results.** The results of 126 male and 22 female patients, three years following the surgery, showed average pouch capacity of 477 (330–659) mL, insignificant residual urine of 52 (0–92) mL, and the averageurinary frequency was five times within 24 h. Day time continence was present in 90% of patients and nighttime continence in 88% of patients, 7% of patients had mild acidosis, and 3% of patients had vitamin B12 deficiency. **Conclusion.** The neobladder created according to the "Belgrade pouch" technique showed excellent results comparabile with standard techniques, with adequate capacity, high continence rate, favourable 24 h voiding frequency, insignificant residual urine, and a significantly lower rate of metabolic complications during the 3 years of the follow-up period.

Key words:
colonic pouches; postoperative complications; serbia; treatment outcome; urinary bladder neoplasms; urological surgical procedures.

Apstrakt

Uvod/Cilj. Princip kontinentnih urinarnih derivacija je zasnovan na kreiranju arteficijalnog rezervoara za urin, što sličnijeg mokraćnoj bešici, adekvatnog kapaciteta, visokog stepena kontinencije, niskog pritiska i što manje resorptivne površine, u cilju sprečavanja pojave metaboličkih komplikacija. **Metode.** Prospektivnom i delom retrospektivnom studijom obuhvaćeno je 148 bolesnika koji su u periodu od 10 godina bili operisani zbog tumora mokraćne bešike ograničenog na organ sa invazijom mišićnog sloja (pT2), i kojima je nakon radikalne cistektomije originalnom hirurškom tehnikom *Belgrade pouch* kreirana neobešika od kratkog segmenta ileuma u obliku slova „U", prosečne dužine 30 cm. Period praćenja posle operacije iznosio je tri godine. **Rezultati.** Kod 126 muškaraca i 22 žene operisanih tehnikom kreiranja neobešike *Belgrade pouch*, posle tri godine prosečna zapremina neobešike bila je 477 (330–659) mL, zapremina rezidualng urina je bila klinički beznačajna [52 (0–92) mL], a prosečna frekvencija 24-časovnog mokrenja iznosila je pet puta na dan. Dnevnu kontinenciju je imalo 90% operisanih, a noćnu 88%. Kod 7% bolesnika utvrđena je blaga acidoza, a kod 3% nedostatak vitamina B12. **Zaključak.** Neobešika kreirana po metodi *Belgrade pouch* pokazala je odlične rezultate, uporedive sa standardnim tehnikama obezbeđujući odličan kapacitet, visok stepen kontinencije, dobru 24-časovnu frekvenciju mokrenja, beznačajan rezidualni urin i značajno nižu stopu metaboličkih komplikacija u trogodišnjem periodu praćenja.

Ključne reči:
creva, rezervoari; postoperativne komplikacije; srbija; lečenje, ishod; mokraćna bešika, neoplazme; hirurgija, urološka, procedure.

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Introduction

Radical cystectomy (RC) represents the gold standard for managing of the muscle invasive organ-confined urinary bladder cancer [1]. The principle of continent urinary derivations is based on forming a reservoir of a satisfactory capacity, low pressure with resorbent surface as small as possible, which can ensure a high level of continence. Numerous techniques of orthotopic urinary derivations were described aimed at creating a urinary reservoir resembling a urinary bladder as much as possible. Despite that, after creating an orthotopic neobladder, numerous subsequent complications can arise, such as incontinence, urinary retention, acidosis and other metabolic disorders, infections, calculosis, vitamin B12 deficiency, stenosis in the site of ureter and neobladder anastomosis, hydronephrosis, neobladder-ureteric reflux, etc. Standard techniques most often recommend the use of the terminal ileum segment 40–65 cm long for creating a neobladder that gives satisfactory results. The length of the intestinal segment from which the neobladder is created directly affects its capacity and over time also the residual urine volume. From the time it is created to the first year of its use, the neobladder increases its volume 3.5–4 times on average, and over time this growth can be up to 8 times [2].

Methods

This prospective and partially retrospective study included 148 out of 210 patients operated on in a ten-year period (2008–2017) at the Urology Clinic, Military Medical Academy (MMA) in Belgrade. Indication for radical cystectomy was organ-confined, muscle-invasive bladder transitional cell tumor. Indication for orthotopic urinary derivation was in conformity with the European Association of Urology (EAU). The Ethics Committee of the MMA approved this study, within scientific project "Modification of surgical techniques for orthotopic ileal neobladdder creation following cystectomy – VMA/08-10/B.1." All patients gave their signed consent for approval for this surgical procedure. Patients with systemic disorders, diabetes mellitus, obstructive pulmonary disease, chemotherapy and other conditions with potential influence on the results were excluded from the study. All patients had serum creatinine levels less than 140 μmol/L. Patients were given questionnaires about continence and voiding frequency six month after the surgery, and annually in the three-year follow-up period. Pouch capacity and postvoid residual urine were measured by ultrasound.

Surgical technique "Belgrade pouch"

After cystoprostatectomy in males or cystectomy, radical hysterectomy and removal of anterior wall of vagina in females, pelvic lymphadenectomy was performed. In the absence of malignancy on the resection margins, resection of the terminal ileum with a length around 30 cm and a distance no less than 20 cm from the ileocecal valve was performed (Figure 1). Before that, mobility and tension-free postitioning

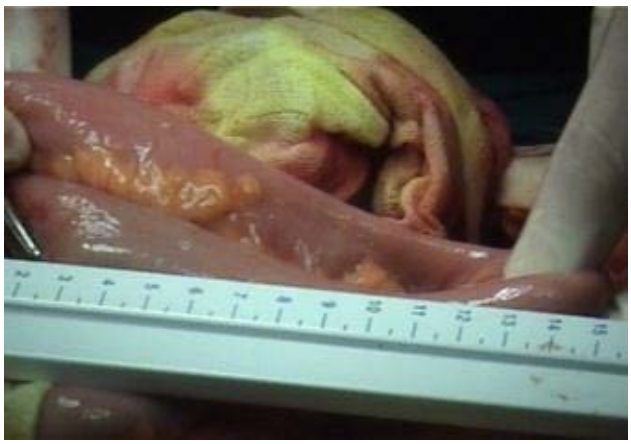

Fig. 1 – Measuring the selected segment prior to resection (in this case the pouch was made of the ileal segment about 30 cm long).

of the ileal segment on the bottom of the *pelvis minoris* was done. Transluminescence of the mesointestine may obtain maximal preservation of the intestinal segment vascularization (Figure 2). After detubularization, a "U"-shaped ileal plate was formed by using a continuous suture (Figure 3). Neobladder was created from the part of the terminal ileum 29 cm in

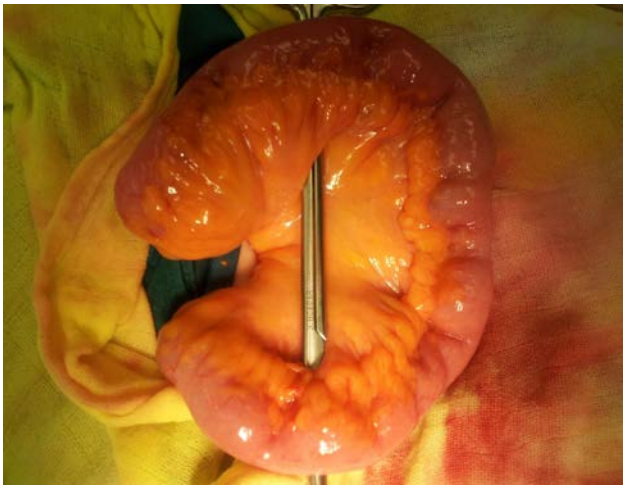

Fig. 2 – Minimal incision length on the meso allows also maximum preservation of the ileal segment vascularization.

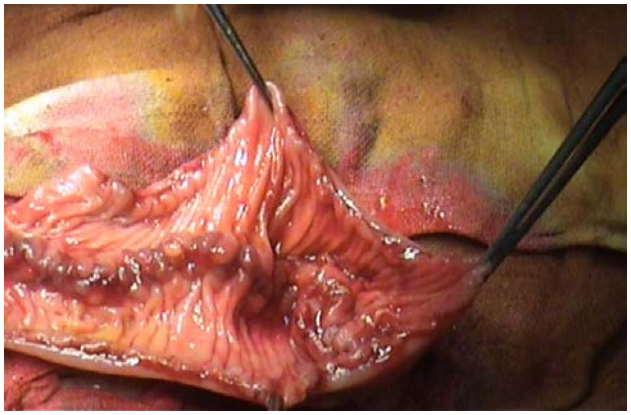

Fig. 3 – Creating an ileal plate from a 30 cm long "U" shaped intestine segment.

length (24–35 cm) on average (Figure 4). The ureters were spatulated in the length of 5 mm and implanted in the neobladder through special openings on its posterior-lateral side, bilaterally, by the direct anastomosing technique with taking out ureteral silicone tubes from the ureter through the neobladder wall to the abdominal wall skin. The neobladder roof was sutured in a letter-like manner. On the lower end of the newly formed ileal bladder, an opening of a 5–7 mm in diameter was formed, around which the perimeter suture was placed. The urethra and the neobladder anastomosis was made with 5–7 individual Vicryl 3–0 sutures (Figure 5), and the neobladder was placed in a definitive position (Figure 6).

Fig. 4 – The size of the created neobladder according to the "Belgrade pouch" technique.

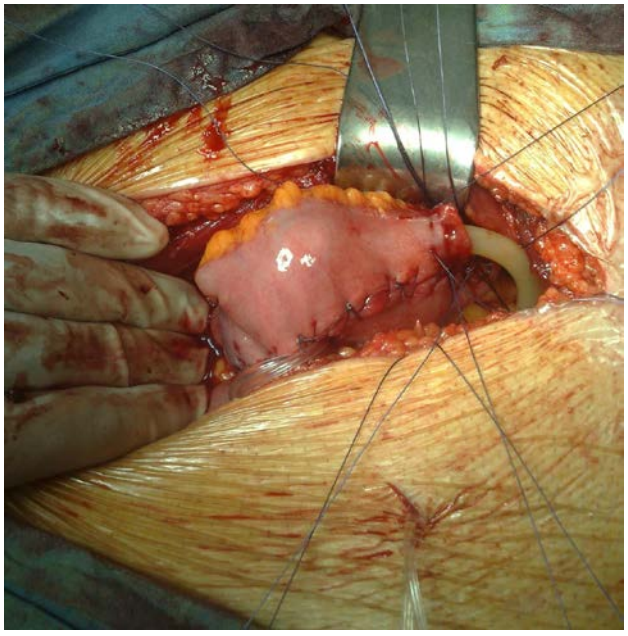

Fig. 5 – Placing of 5-7 stitches for ureteral-neobladder anastomosis.

Fig. 6 – Definite position of the neobladder. Infraumbilical incision about 10 cm long, through which operation was performed.

Foley Ch18 urinary catheter was inserted and 0.5 kg traction was applied to the catheter on the first day, 0.25 kg traction on the second day and then the traction was removed from the catheter on the third day. After the removal of the urinary catheter and for quicker mastering the new method of voiding and faster achieving of continence, all patients were advised to urinate every 2 or 3 hours during the first three months even if they do not feel the need to void. It was recommended that the patients wake up twice at night to an alarm clock in order to void.

Results

The average age of the operated patients was 60 (42–73) years, 16% of them were older than 70 years. Eighty five percentage of the operated patients were males. The average operation time was 205 (150–340) min. Intraoperatively, 49% of the patients received blood transfusion with an average volume of 440 (300–940) mL of blood. Postoperatively, 8% of the patients were subjected to he blood transfusion. In 7% of the operated patients, subocclusion or paralytic ileus occurred in the immediate postopertive course where the patients were treated conservatively with the extended use of nasogastric tube and peristaltic activity stimulation with prokinetics and the correction of the electrolyte disbalance (most often potassium and calcium deficiency). The wound dehiscence occurred in one patient and it was treated by secondary suture. Extended lymphorrhea occurred in 5% of the operated patients. Urinary fistula occurred in two patients. These patients were managed conservatively, fistulas were healed spontaneously by a prolonged catheter wearing until the 27th and 29th postoperative day. Febrility that lasted for more than two days was recorded in 5% of the operated patients. In patients who had fever over 38°C, a hemoculture test was performed, but the results of all the samples were negative. Other parameters and complications are shown in Table 1.

Table 1

Characteristics of operated on patients and some postoperative complications during the three-year period after operation

Parameter	Postoperative period			
	6 months	1 year	2 years	3 years
Daytime continence (%)	72	88	91	90
Nighttime continence (%)	67	84	87	88
Neobladder capacity (mL), mean (min–max)	307 (220–378)	425 (285–514)	458 (305–582)	477 (330–659)
Residual urine volume (mL), mean (min–max)	13 (0–18)	20 (0–39)	29 (0–40)	52 (0–92)
24-h urinary frequency (n)	9	7	6	5
Acidosis (%)	0	3	4	7
Vitamin B12 deficiency (%)	0	0	0	3
Neobladder calculosis (%)	0	0	3	7
Hydronephrosis (%)				
bilateral	10 (gr. I)	3 (gr. I)	3 (gr. I)	3 (1, gr. I; 2, gr.II)
unilateral	0	1 (gr. II)	3 (1, gr. II; 2, gr. III)	6 (1, gr I; 2, gr. II; 3, gr. III–IV, twice-re-pouch-anastomosis)

gr.– gradus

Discussion

A more seldom occurrence of urinary bladder cancer in female patients and the later introduction of orthotopic derivations in women in clinical practice are the reasons for male predominance in our study. A patient's mature years may not represent a contraindication for performing this procedure, however, the emphasis is put on the so-called "biological age of a patient", comorbidity, life expectancy, etc. In patients over 75 years of age, a greater complication rate can be expected, particularly incontinence, perioperative complications, pyelonephritis and a fatal outcome in the early postoperative course. We reported 16% of patients older than 70 years in our study, and this data may influence our results.

Hautmann et al. [3] believe that by using 40–44 cm long intestinal segment for creating a neobladder, an optimum capacity of 450–500 mL can be achieved. Moreover, by using a 60 cm long segment, a pouch of double capacity can be obtained which in the early postoperative course may result in a larger continence percentage. However, a neobladder created in such a way becomes unnecessarily large over time, resulting in frequent urinary infections and a larger percentage resulting in the need for catheterization [4]. In their study, Bachor et al. [5] presented results of an average neobladder capacity in patients for whom pouches were created by a classical surgical technique shaped as a letter "W" or "M", with the capacity of 770 mL (330–2,000 mL) three months after the operation [5]. Here, the unnecessarily huge capacity of the neobladder created by Hautmann's classic technique was already emphasized in the first months following the operation, with a reminder that the pouch would continue to increase its capacity over time. Constantinides et al. [6] presented the results achieved with patients for whom a neobladder of approximately 36 cm was created, and they recorded an average pouch capacity of 672 mL one year after the operation. At the same time, according to the literature availabvle to us, there are studies where the results of creating a neobladder from the shortest intestinal segment had been presented until our technique was published. In our study, we went a step further by creating a pouch of a 30 (24–35) cm long terminal ileum on average [7].

The capacity of a neobladder and the urination biomechanics is not only influenced by the length of the intestinal segment used for creating a pouch, but by numerous other factors as well: the width of the intestinal segment from which the neobladder was created, the shape and position of the neobladder, a patient's level of training in a new voiding method, the abdominal press strength, the level of potential stenosis in the site of anastomosis of the neobladder and the urethra, body mass index etc. In our study, in the first six months the capacity of the neobladder created by using the "Belgrade pouch" technique was smaller than the average capacity in reference studies, so the percentage of continent patients in this period was significantly lower. However, the neobladder created by

using the "Belgrade pouch" technique achieved a satisfactory capacity over time, which also enabled the growth of the continence percentage in patients after the first six months, and on the other hand in a three-year follow-up period the average capacity of a neobladder created in such a way did not reach unnecessarily big capacity described in other studies and, according to this parameter, it represented a more suitable replacement for the native urinary bladder.

Stenzl et al. [8] in their studies referred to a residual urine volume larger than 100 mL as clinically important, and found that 22% of the patients over the first year of follow-up had residual urine larger than this limit value. Our study recorded a clinically insignificant increase in the residual urine volume which, on average, over a three-year follow-up period was significantly below the value of 100 mL. The latest studies show that around 12% of the patients in the first year following the operation cannot urinate spontaneously, therefore, they are inserted a urinary catheter. This percentage increases over time [9]. Urinary retention can occur quite early, in the first days of the postoperative course due to the catheter clogging by the mucus plug. The production of a larger quantity of mucus is directly proportional with the neobladder surface area. In order to prevent the clogging of the urinary catheter by the mucus plug, it is recommended that the urinary catheter is flushed out by a physiological saline solution in the early postoperative period, 2–3 times a day. Urinary retention in the pouch in the early postoperative period may result in urinary leakage between the pouch sutures, infection, pouch dehiscence and even acidosis [10]. In the later postoperative course, a larger mucus amount may indicate infection. Early and late urinary retention due to the catheter, i.e. urethra clogging by mucus plug, in reference studies occurs in 3% of the cases [10]. Unresolved urinary retention issue may result in a rare, however, life-threatening complication – pouch rupture which more often occurs in patients who receive chemotherapy, particularly cisplatin [11]. In our series of patients, there were no patients who had a catheter inserted due to increased residual urine volume and the values of residual urine in the follow-up period were better than those in the reference studies [12].

Hydronephrosis in the site of stenosis of the ureter and the neobladder anastomosis, pouch, kidney or ureteral calculi, as well as the reflux of infected urine towards the pyelon may be additional predisposing factors for the occurrence of a complicated urinary infection. In our series, there were no patients with urosepsis, the residual urine volume was small and clinically insignificant with a low percentage of neobladder calculosis which resulted in the absence of complicated urinary infections in the study group. Based on the above-stated, it can be concluded that by creating a neobladder from a shorter segment, predisposing factors for the urinary infection development can be significantly reduced.

Hydronephrosis may occur due to stenosis at the level of the ureter and the neobladder anastomosis, pouch-ureteral reflux, kidney or ureteral calculosis, recurrent urinary infections, urinary retention or novel tumor appearance etc. [11]. In the beginning, many authors favoured the antireflux techniques because it was believed that they would prevent urinary reflux towards the upper parts of the urinary tract as they represent a true imitation of a natural antireflux mechanism. Other than a major anatomic similarity with a natural antireflux mechanism, the advocates of such type of anastomosis believe that in this way they will prevent the migration of intestinal bacteria from the pouch to the ureter, i.e. the kidney and thus the occurrence of pyelonephritis [13]. Hautmann et al. [3] recommended using direct anastomosis of the ureter and the ileal pouch as this is a low pressure reservoir with a small probability of urinary reflux towards the upper parts of the urinary tract. They elaborated the results of several studies that showed the occurrence of a significant number of stenoses in the site of the ureter and the pouch anastomosis when using some of the antireflux techniques, by which kidney function is permanently weakened over time. The same authors reported that direct anastomosis of the ureter and the neobladder might pass refluxed urine towards the kidney only in case of a very large capacity and pressure within the pouch, but even then this reflux is of lower intensity. Varol and Studer [10] argue that antireflux techniques are not necessary for preventing the reflux of infected urine towards the upper parts of the urinary tract because a low pressure pouch is antirefluxive by its nature which is in agreement with the study by Thurairaja et al. [4]. Stenoses in the site of the ureter and the neobladder anastomosis most often occur in the first year after the operation and often result in asymptomatic ureterohydronephrosis due to its slow occurrence and course [14]. Stenosis in the site of anastomosis is around 3.3% in direct methods of ureteral implantation [15]. Our study showed a larger number of hydronephroses in the first six months due to reflux. However, after urinating, hydronephrosis completely spontaneously regressed in all patients except in two who were subjects to repouch-anastomosis. In time, as the neobladder capacity grew, the percentage of hydronephroses declined, so the results obtained in our series in the twenty-fourth month in this study group were in conformity with the reference studies. Thus, we showed that the application of a direct ureter and pouch anastomosis is justified even with a pouch made of the shorter ileal segment with the expected larger percentage of reversible moderate ureterohydronephrosis caused by the urinary reflux, however, without permanent morphological and functional consequences to the kidney.

Several factors affect the continence level: patient's age, mental status, intact ureteral sphincter and its preserved innervation, functional length of the urethra, pressure within the pouch, pouch capacity, absence of urinary infection, training to void in a different manner, etc. [11]. The patients first maintain daytime continence which in referent studies reaches 80%–90% one year after the operation [16]. Older patients initially have weakened sphincter tonus which causes major incontinence postoperatively, thus the percentage of patients over 75 who have preserved daytime continence ranges between 56% and 75% whereas nighttime continence is about 25% [3]. Around 30% of patients at this

age have catheters due to urinary retention after a neobladder created. In our series, we had 16% of patients over 70 years, which certainly influenced the percentage of daytime and nighttime continence [17]. Some studies showed that the neobladder shape might affect continence. Therefore, it was concluded that a sphere-shaped neobladder allows larger continence than a neobladder of a different shape, but only in the first 3–6 months, whereas this percentage is identical one year after the operation, irrespective of the pouch shape [18]. In our series, the pouch of ellipsoidal shape was created. "Nerve sparing" procedures certainly affect the continence and improve it [19]. According to referent studies, retention more often occurs in women – even in 25%–40% of operated women due to increased mobility of the urethra, whereas the percentage of daytime continence is around 75%–90% [20]. A smaller percentage of nighttime continence is recorded in women, and according to the results published so far, it ranged between 55%–66% [21]. In our series, one female patient had a urinary catheter placed due to incontinence, and there were no female patients that had a catheter placed due to significant residual urine, i.e. retention. This information largely deviates from the quoted results of major series in which a significantly larger percentage of urinary retention and catheterisation has been mentioned. In our series, the patients had a lower continence rate in the first months, which was expected due to a significantly lower capacity. Between the sixth and the twelfth month after the operation, the capacity of the "Belgrade neobladder" exceeded 350 mL and it still recorded a mild growth which correlated with the constant increase in the daytime continence percentage in this group, even without a major increase of pressure in the neobladder [21]. Since the neobladder capacity shall continue to increase over time, we can understand at this point the advantage of creating a neobladder from a shorter ileal segment, which may result in "optimum capacity" and excellent daytime continence 9–12 months after the operation which may be preserved over time. Achieving nighttime continence is much slower and its proper evaluation is made 12–24 months after the operation. Some studies report that the nighttime incontinence percentage ranges between 20% and 40%. However, some authors presented the results with a high level of nighttime continence of about 90% [3, 11, 13]. In order to increase the nighttime continence level, the patients are advised to void right before going to bed, to avoid sleeping pills and alcohol, and to wake up to an alarm clock 1–2 times during the night and to stop taking large amounts of liquid two hours before going to bed, which we also advised the patients in our series [22]. Although this study did not include the comparison of nycturia prior to operations in all patients, we shall present the information we obtained from a part of the patients within a wider study. The study showed that 47% of the patients experienced nycturia 1–2 times a night even before the operation, so the advice to wake up to an alarm clock every 3–4 hours during the night in order to void in the first months after the operation did not represent any special inconvenience for them. In our series, the nighttime continence percentage was increasing over time. The studies showed that using a 25 mg dose of imipramine hydrochloride right before going to bed might improve the nighttime continence level in 25% of operated patients, although we had no experience in this kind of the treatment [23].

It is a well-known fact that in time, with the neobladder capacity growth and in the absence of any infection, the urinary frequency decreases. Madesbacher et al. [24] have found that the urinary frequency comes down to 6–7 times in 24 hours, twelve months after the operation. After the catheter removal, patients are advised to void every two hours during the day, and every 3 hours during the night, by waking up to an alarm clock in the first three months. Identical recommendations were given by the most experienced urologists in the field of cystectomy [4, 11], which certainly had an effect on a higher urinary frequency in the first several months of the follow-up. In our series, the urinary frequency considerably declined over time, following the neobladder volume growth. This showed that creating a neobladder from a shorter intestinal segment shall not considerably increase the urinating frequency in comparison to patients whose neobladder was created of a standard-length intestinal segment.

The duration of the urine contact with the intestinal mucus, the resorbent surface area, i.e. neobladder volume, residual urine volume, urinary frequency and urinary infection are the predisposing factors for the occurrence of acidosis [4, 25]. In the study that discussed metabolic disorders in patients for whom neobladder was created, the percentage of patients with acidosis was 25%–50% [23, 26]. Metabolic complications occur more often in patients with compromised kidney function. A significant decrease in metabolic complications and acidosis percentage was recorded in the absence of urinary infection and in patients for whom intestinal segment shorter than 45 cm was used for creating the neobladder [3]. This is the point where we came up with the idea of attempting to additionally shorten the intestinal segment used for creating a neobladder thus decreasing the percentage of metabolic complications that are classified as the most frequent subsequent complications, and, at the same time, we attempted to preserve satisfactory capacity and high continence level in patients. The percentage of patients with acidosis in our series was significantly lower than in reference studies and, at the end of the third year, it was only 7%, at which none of the patients used alkaline agents for regulating pH value of arterial blood. Such good results were achieved thanks to the reduced neobladder capacity, i.e. smaller resorbent surface, smaller residual urine volume and seldom occurrence of urinary infections, as proven factors that affect the occurrence of metabolic disorders, primarily acidosis [25–27]. This should be particularly considered in patients for whom antireflux ureter and neobladder anastomosis was created because ureterhydronephrosis may occur, and it can result in permanent failure of kidney function if it is not treated properly results which, by the reduction of kidney buffer system, significantly affects the occurrence of acidosis and its serious consequences. Long-term metabolic acidosis causes mobilization of calcium from the bones, which may

be the cause of reduction of bone marrow density, with consequential hypocalcemia [28]. Reacting to hypocalcaemia, parathyroid gland secretes parathyroid hormone (PTH) in higher concentration attempting to normalize the values of serum calcium. In a few published study results available to us, a direct connection is made between acidosis, bone calcium mobilization and consequential hypocalcemia and the increase of PTH value in blood. These changes become more expressed over time in patients with neobladder created by standard techniques from 45–60 cm of small intestine, and they are directly initially connected with the neobladder capacity, i.e. resorbent surface [29]. In our patients, a slow and mild growth in PTH values in the blood was recorded over time, within reference values [30]. Vitamin B12 absorption is conducted in the terminal ileum, so this process is inversely proportional to the length of the intestinal segment of the ileum from which the neobladder shall be created, and it is in positive correlation with the length of the remaining native part of the ileum [31]. In the studies in which the patients with neobladder were followed for over several years, some authors mentioned the occurrence of vitamin B12 deficiency which, should it last for over an extended period of time, might cause irreversible hematological and neurological sequelae. Some authors reported that around one third of patients after creating a neobladder might develop vitamin B12 deficiency, and this percentage can be even higher particularly in patients for whom the ileum segment longer than 60 cm was used for the creation of a neobladder. The Anticipated time of vitamin B12 deficiency occurrence is three years after the operation [31, 32]. Nieuwenhuijzen et al. [33] stated that around 15% of patients with vitamin B12 deficiency had been operated on in the three-year follow-up period. In the third year of our study we recorded 3% of patients with vitamin B12 deficiency without neurological disorders, which is a significantly better result in comparison to standard techniques of creating a neobladder.

Conclusion

Neobladder created according to the "Belgrade pouch" technique may obtain a high percentage of continence, without increasing the urinary frequency, with neobladder capacity similar to natural urinary bladder and minimal volume of residual urine. This method significantly reduces the percentage of delayed metabolic complications such as acidosis, vitamin B12 deficiency and the increase in PTH levels with the percentage of ureterhydronephrosis occurrence comperable with reference studies. This technique can be applied to both sexes, although certain advantages in terms of reducing the occurrence of retention (in a small number of operated on patients in our studies) have been recorded in women. Depending on the comorbidity and biological age of patients, this technique can also be applied at a later age. It is suitable for the laparoscopic approach, or robot surgery, where we expect shorter operative time due to the shorter sutured length of intestinal segment used for pouch creation.

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