

ANALYSIS OF TRENDS IN THE PERFORMANCE OF URINARY DIVERSIONS AFTER TOTAL CYSTECTOMY: A 15-YEAR EXPERIENCE

Dragoslav Bašić^{1,2}, Ivan Ignjatović^{1,2}, Ljubinka Janković-Veličković^{1,3}, Aleksandra Ignjatović^{1,4}, Marija Mihajlović², Aleksandar Pejić², Bratislav Pejić², Aleksandar Skakić^{1,2}, Milan Potić^{1,2}, Tomislav Stamenić²

The aim of our study was to analyse trends in urinary diversion (UD) in patients who underwent radical cystectomy (RC) from 2008 to 2023, with special reference to the period of the COVID-19 pandemic. A total of 283 study patients (pts) (243 men and 40 women, mean age 65.07 ± 7.73 years) were divided by the type of UD into the following groups: Mainz-pouch II (MP II) – 85 pts, ileal conduit (IC) – 89 pts, ureterocutaneostomy (UCS) – 105 pts, percutaneous nephrostomy (PCN) – 4 pts. The relative share of incontinent and continent UD was 70% and 30%, respectively. MP II was the most represented UD from 2008 to 2013, IC from 2014 to 2019, and UCS from 2019 to 2023. The most common UD was UCS (37.1%), followed by IC (31.4%), MP II (30.0%) and PCN (1.4%). Temporal UD trends were variable, with relatively stable annual shares of MP II and IC and the lowest annual share of UCS until the period of the COVID-19 pandemic, when it significantly increased, with a peak in 2022. Trend analysis shows a significant increase of UCSs in the period 2008–2023 ($p < 0.001$), without significant change of trends in the other groups ($p > 0.05$). The trends of continent and incontinent UD after RC, shown in our study, are consistent with the data reported in the current literature.

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Key words: urinary diversions, trends, Mainz-pouch II, ileal conduit, ureterocutaneostomy

¹University of Niš, Faculty of Medicine Niš, Niš, Serbia

²University Clinical Center Niš, Clinic of Urology, Niš, Serbia

³University Clinical Center Niš, Pathology and Pathological Anatomy Center, Niš, Serbia

⁴University of Niš, Faculty of Medicine, Department of Medical Statistics and Informatics, Niš, Serbia

Contact: Dragoslav Bašić
81 Dr. Zorana Djindjića Blvd., 18000 Niš, Serbia
E-mail: basicdr@gmail.com

Introduction

Recent epidemiological data show that bladder cancer (BC) is the 2nd most common genitourinary malignancy and 10th among all cancers in the general population, with the incidence rates of 9.5 in men and 2.4 in women (per 100,000), mortality rates of 3.3 in men and 0.9 in women, and a total of 573,278 new cases in

2020 worldwide. Overall incidence rates range from 3.1 in low/medium human development index (HDI) countries to 11.7 per 100,000 in high/very high HDI countries (1). Reported age-standardized incidence rates are 20 and 4.6 for the male and female populations in Europe (2). About 70–75% of BCs are detected at $\leq T1$ stages, as non-muscle-invasive bladder cancer (NMIBC), which are amenable to treatment and associated with longer survival, while the remaining 25–30% are detected at later, $\geq T2$ stages, as muscle-invasive bladder cancer (MIBC) (2, 3). Among all histopathological types of BC, the largest share belongs to urothelial carcinoma (UC) ($> 90\%$), while the total share of other types, including squamous cell carcinoma, adenocarcinoma and neuroendocrine carcinoma of the urinary bladder is less than 10% (4, 5). The primary treatment of choice for MIBC includes radical cystectomy (RC) with pelvic lymphadenectomy and urinary diversion (UD) (6, 7). So far, numerous UD techniques have been described, from simple ureterocutaneostomy (UCS) to orthotopic neobladder (ONB). There is still debate as to which UD is best in terms of feasibility, long-term outcomes, and patient quality of life. However, the more complex the

operative technique for creating UD, the higher the criteria for patient selection.

Aim

The aim of the present study was to analyse trends in UD in patients who underwent RC and UD in our clinic over a period of 15 years, with special reference to the period of the COVID-19 pandemic.

Materials and Methods

For the present retrospective study, we identified a total of 283 consecutive patients (243 men and 40 women, mean age 65.07 ± 7.73 years) who underwent RC and UD during a 15-year period, from 2008 to 2023. Based on the patients' medical records, the following data were analysed: patient demographics, indication for RC, the date of the operation, type of UD and histopathological report of the RC specimen (type of cancer, pathological grade and stage). In order to analyse temporal variations in UD trends, patients were examined both in relation to the type of UD and the time period, with special reference to the period of the COVID-19 pandemic. This study was conducted according to the Declaration of Helsinki ethical principles, with guaranteed discretion of personal data, and had been approved by the Ethics Committee of the University Clinical Center Niš, protocol number 28305.

According to the type of UD, patients were divided into the following groups:

1. Group MP II consisting of 85 patients with sigma-rectum pouch (Mainz-pouch II) UD
2. Group IC consisting of 89 patients with ileal conduit UD
3. Group UCS consisting of 105 patients with ureterocutaneostomy UD
4. Group PCN consisting of 4 patients with percutaneous nephrostomy UD.

Statistical data are presented in the form of arithmetic mean, standard deviation, minimum and maximum values. The comparison of categorical features was performed using the Chi-square test. For the trend analysis of the number of UD in the monitoring period, joinpoint regression analysis was used. The analysis was done in the program package Joinpoint regression Analysis Joinpoint Regression Program, Version 4.8.0.1. April 2020; Statistical Research and Applications Branch, National Cancer Institute). Other statistical analyses were performed in the OpenEPI Info software package.

Results

Over the study period, a total of 283 patients underwent RC with UD. Of these, incontinent diversion (ID) was performed in 198 patients (70%), and continent diversion (CD) in

85 patients (30%). The annual number of cystectomies in the study period shows significant variations, ranging from 4 to 46 per year, without the existence of a linear trend of increase or decrease (Table 1). The lowest annual number of operations was performed in 2017 ($n = 4$) and the highest in 2022 ($n = 46$). Figure 1 shows the time trends and relative share of CD and ID after cystectomy.

In 2008, 2009, 2017 and 2023, the annual number of operations was low (< 10 per year), while 2010, 2011, 2013, 2014 and 2015 had been characterized by a slightly higher number of operations (10–20 per year). During 2012 and 2018–2022, there were more than 20 operations per year, with the largest annual number in 2022 ($n = 46$). The annual number of operations is shown in Table 1.

Table 2 shows the demographic and clinical characteristics of the studied population. The average age of the entire examined population was 65.07 ± 7.73 years (37 years, 82 years). In relation to gender distribution, 83.5% of patients were male and 16.5% female. The most common UD was UCS (37.1%), followed by IC (31.5%), MP II (30.0%) and PCN (1.4%). In terms of histological grade (HG), the most common was HG 3 (75.6%), followed by HG 2 (21.8%), HG 4 (1.8%) and HG 1 (0.8%) (Table 2). The highest relative share of pT4 stage was in the UCS group (35.2%), followed by MP II group (10.6%), IC group (13.5%) and PCN group (25%). There is no statistically significant difference among the groups in terms of gender ($p = 0.452$), age ($p = 0.525$) and HG ($p = 0.504$). In all groups, the most represented age category was 60–69 years (Table 2).

According to the histopathological report of the RC specimen, the most common indication for RC was UC of the bladder, in 91.5%. Other indications were less prevalent, as follows: UC with squamous differentiation (3.6%), pure neuroendocrine carcinoma (1.1%), colonic adenocarcinoma (1.1%), undifferentiated UC (0.7%), urothelial adenocarcinoma (0.4%), UC of prostatic urethra (0.4%), prostate adenocarcinoma (0.4%), vesico-intestinal fistula (0.4%) and nonresectable inflammatory conditions of the bladder (0.4%).

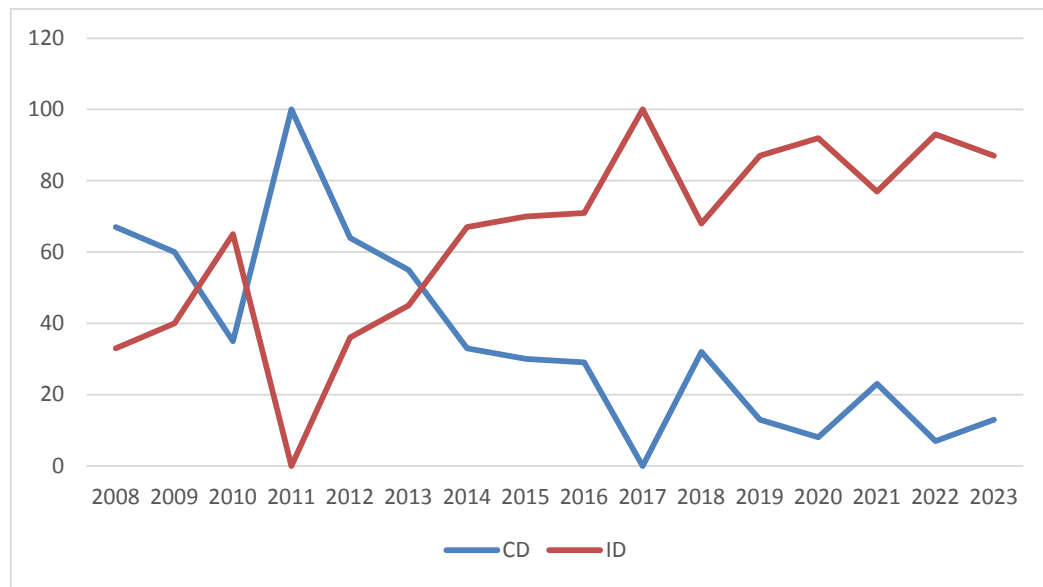


Figure 1. Time trends of CD and ID

Table 1. Number of cystectomies with UD by type

Year	Continent diversion (CD)		Incontinent diversion (ID)					CD + ID	
	MP II		IC	UCS	PCN	ID	TOTAL	TOTAL	
	No	%	No	No	No	No	%	No	%
2008	6	67	1	-	2	3	33	9	100
2009	3	60	1	-	1	2	40	5	100
2010	5	35	9	-	-	9	65	14	100
2011	11	100	-	-	-	-	-	11	100
2012	16	64	8	-	1	9	36	25	100
2013	6	55	5	-	-	5	45	11	100
2014	5	33	7	3	-	10	67	15	100
2015	3	30	5	2	-	7	70	10	100
2016	6	29	12	3	-	15	71	21	100
2017	-	0	3	1	-	4	100	4	100
2018	8	32	9	8	-	17	68	25	100
2019	3	13	10	10	-	20	87	23	100
2020	2	8	4	19	-	23	92	25	100
2021	7	23	9	15	-	24	77	31	100
2022	3	7	6	37	-	-	-	46	100
2023	1	13	-	7	-	-	-	8	100
TOTAL	85	100	89	105	4	198	100	283	100

Table 2. Demographic and clinical characteristics of the studied population

		MP II		IC		PCN		UCS		p
Characteristic		No	%	No	%	No	%	No	%	
Gender	Male	73		73	82.0	3	75.0	94	89.5	0.452
	Female	12	14.1	16	18.0	1	25.0	11	10.5	
	Total	85	100	89	100	4	100	105	100	
Age	< 50	3	3.5	2	2.2	1	25.0	5	4.8	0.525
	50–59	23	27.1	21	23.6	0	0.0	18	17.1	
	60–69	45	52.9	45	50.6	2	50.0	54	51.4	
	70–79	13	15.3	20	22.5	1	25.0	26	24.8	
	80 +	1	1.2	1	1.1	0	0.0	2	1.9	
Histological grade (HG) *	I	1	1.2	1	1.2	0	0.0	0	0.0	0.504
	II	22	27.2	17	20.2	0	0.0	18	19.1	
	III	58	71.6	65	77.4	3	100.0	72	76.6	
	IV	0	0.0	1	1.2	0	0.0	4	4.3	
Pathological tumor stage (pT) **	NEM	0	0.0	1	1.1	0	0.0	0.0	0.0	
	pTa	5	5.9	3	3.4	0	0.0	6	5.7	
	pT1	6	7.41	8	9.0	0	0.0	4	3.8	
	pT2	25	29.4	24	27.0	1	25.0	20	19.0	
	pT3	37	43.5	41	46.1	2	50.0	34	32.4	
	pT4	9	10.6	12	13.5	1	25.0	37	35.2	

*Available for 275 patients; **available for 262 patients.

The annual number of UD across all studied groups is shown in Figure 2. During the period 2008–2013, not a single UCS was performed. UCS has been implemented since 2014 (3 cases), and after that, only a few cases were done per year, ending in 2017. From 2018, an increasing trend in the annual number of UCS was observed, peaking in 2022, with as many as 37 cases. There was no statistically significant trend of change in the number of cases in other studied groups ($p > 0.05$).

Figure 3 shows the annual number of UCS from 2008 to 2023. Trend analysis shows that there was a statistically significant trend of increasing the number of UCS in the period 2008–2023, with an annual percentage change (36.0, 95% CI 24.4–48.7, $p < 0.001$).

Figure 4 shows the variability of the number of UCS UD performed over 4 time intervals during the entire period: 2008–2010, 2011–2014, 2015–2018, and 2019–2023. The frequency of UCS changed statistically significantly during the study period ($p < 0.001$). In relation to the total number of UCS ($n = 105$), the relative share of the time interval 2019–2023 was 66.2%, while in other time intervals it was less: 23.3% in 2015–2018, 4.8% in 2011–2014, and 0% in 2008–2010.

There were a total of 59 patients (20.8%) with pT4 stage. The relative share of pT4 stage was the highest in the UCS group (35.2%), and this difference compared to the other groups is statistically significant (MP II-10.6%, IC-13.5%, PCN-25%) ($p < 0.001$) (Figure 5).

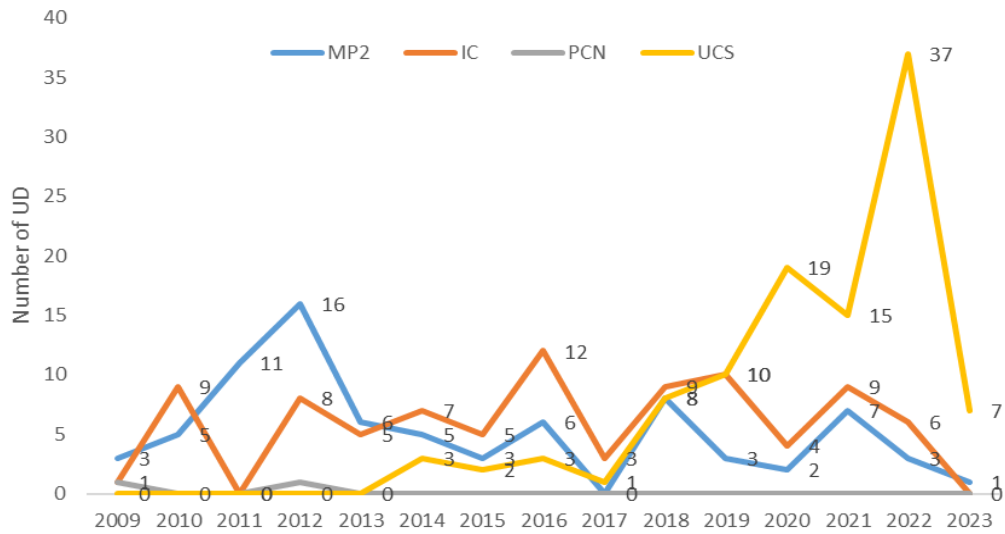


Figure 2. Number of urinary diversion by type

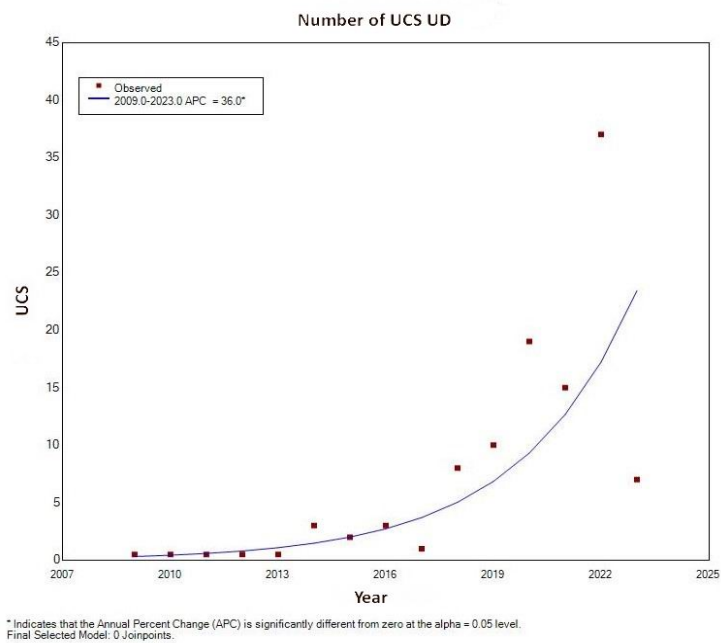


Figure 3. Number of UCS UD in the study period

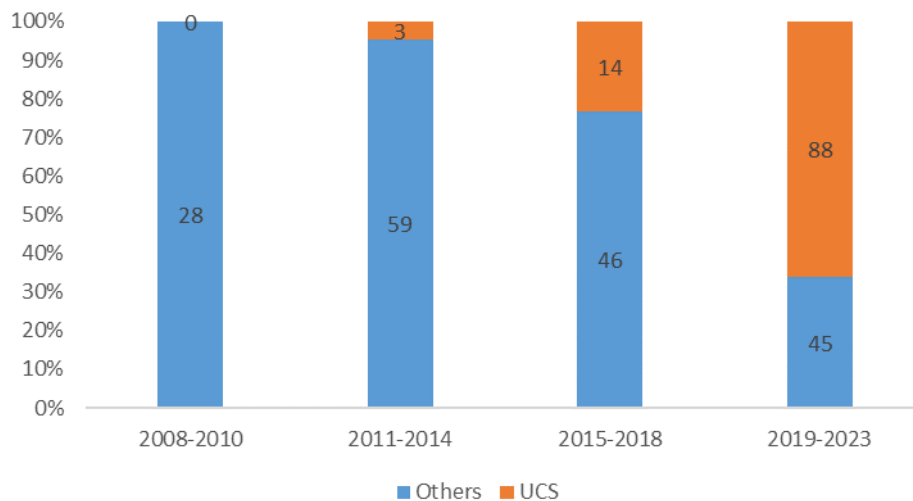


Figure 4. Proportion of UCS UD in the study period

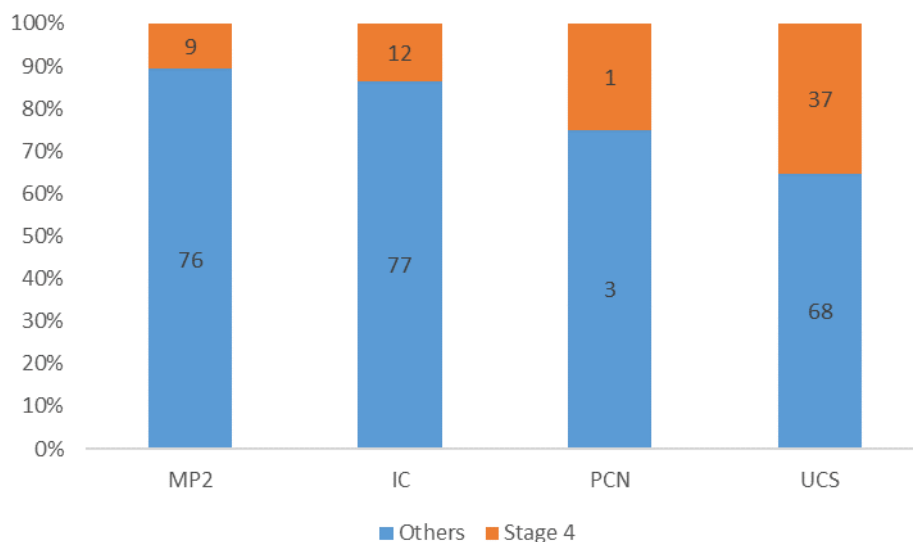


Figure 5. Proportion of T4 stage in the study period

Discussion

A recent report by Farber et al. on the disparity in the use of CD after RC for BC, in a sample of 76,040 patients operated in the United States of America (USA) from 2001 to 2012, showed IC and CD rates of 90.8% and 9.2%, respectively (8). The relative share of CDs had an increasing trend, with a peak in 2008 (almost 12%), with a significant decreasing trend thereafter. A higher proportion of CDs was associated with urban areas, high-volume academic hospitals and patients from the western regions of the country. Similarly, the California group published an analysis of 10-year trends (2004–2013) in the USA on the use of ID and CD after RC in 27,170 patients (6). It was shown that the relative share of ID and CD was 85.5% and 14.5%, respectively. However, the relative share

of CD showed a statistically significant decrease, from 17.2% during the first three years to 12.1% during the last 3 years (6). Comparing early operative results of IC versus CD after RC for BC in the USA, Rezaee et al. reported that of 4,755 RCs for BC in 2019 and 2020, 677 patients (14.2%) received CD (9).

In our series, the proportion of ID and CD was 70% and 30%, respectively. Temporal variations were most pronounced in 2011 (ID-0%; CD-100%) and 2017 (ID-100%; CD-0%), while in other periods the difference was more moderate. The increase in the share of ID compared to CD has been recorded since 2013/2014, with a relatively stable ratio until 2023 (Table 1, Figure 2). As in the presented series, the proportion of female patients in our series is significantly lower compared to men (6, 8). When it comes to pathohistological indications for RC, UC was

present in 91.5% of our patients. The relative share of other UC morphological subtypes and benign indications was 7.7% and 0.8%, respectively.

According to the 2022 WHO classification, as well as the data presented by Amin et al. and Comp  rat et al., urothelial carcinoma is the most common morphological subtype of UC occurring in > 90% of patients with MIBC, which is consistent with our results (4, 5, 10). Benign diseases as indications for cystectomy are very rare, including neurogenic bladder, post-irradiation conditions, interstitial cystitis and urinary incontinence (11–16).

Our results show evident temporal variability of UD during certain time periods in our series. Thus, MP II was the most represented UD from 2008 to 2013, IC from 2014 to 2019, and UCS from 2019 to 2023.

Mainz-pouch II is a modification of the ureterosigmoidostomy (USS) and was originally presented by Fisch in 1993 (17). It has fewer contraindications compared to ONB and is acceptable for a large number of candidates, including those with advanced stages of BC. The operative technique is relatively simple compared to other CDs and has been promoted as their alternative, with low complication rates and good health related quality of life (HRQoL) (18–20). It has been successfully applied in our clinic since 1995, to overcome the drawbacks of UCS, USS and ONB, including insufficient support for the needs of stoma devices, postoperative care and nutrition, as well as the management of surgical and metabolic complications. Several series of our results have been published, confirming that the technique is associated with low complication rates and good HRQoL, with certain disadvantages such as malignant transformation of the ureterointestinal anastomosis and metabolic acidosis (18–21).

Since its introduction by Bricker in 1950, IC has become widely accepted due to the absence of metabolic complications and has since evolved into the gold standard for UD (22). Farber et al. reported that from 2001 to 2012 in the USA, IC was the UD of choice after RC in nearly 90% of cases (8). There are several reasons for this disparity in favour of IC, including the technical simplicity of the procedure, shorter operative time, better training of urologists for this type of procedure, fear of possible complications, the increasing use of robotic surgery and the poor financial benefit of CD (8, 23). In a five-year series of the total number of cystectomies with UD from 2001 to 2005 in the USA, Gore et al. reported that out of 27,494 patients, 83.5% underwent IC and 16.5% underwent CD (24). Analysing five-year trends in UD at a high-volume tertiary urology clinic in the USA, Lowrance et al. stated that IC was the most frequent UD, with a relative participation of 63%, with an increasing time trend, while ONB was performed in 37% of cases. The authors also point out that there is a trend of IC, especially associated with female gender, advanced age,

locally advanced disease and significant comorbidity factors (25). Furthermore, the recommendations of the American Urological Association (AUA) Guidelines include mandatory preoperative counselling with the patient regarding the choice of IC or CD as UD (26). In our series, IC was more prevalent compared to MP II in the age group 70–79 years (15.3% vs. 22.5%), as well as in pT3/T4 stages (60% vs. 56%). A meta-analysis of 18 large studies on the overall HRQoL of patients after IC or CD did not find significant differences (27).

The simple technique of UCS dates back to the 19th century, when Hayes Agnew from Philadelphia performed a ureterocutaneous stoma on the abdominal wall due to an injury to the ureter (2, 20). In a recent systematic review comparing IC and UCS, Korkes et al. concluded that UCS is more feasible than IC, especially in elderly and fragile patients, not only because of the avoidance of bowel surgery, but also due to shorter operative time, perioperative care and hospitalization, as well as lower rates of bleeding, transfusion and complications (28). Deliveliotis et al. emphasize that UCS is particularly indicated in high-risk elderly patients, as well as in patients with a solitary kidney, with certain disadvantages including higher rates of ureterocutaneous stenosis and ascending UTIs, compared to techniques with ureteral diversion through intestinal cutaneostomy (29). The occurrence of stomal stenosis can be successfully prevented by postoperative ureteral double-J stenting, and Kozacio  lu reported positive experiences in this regard (30).

Comparing the complications of three UD, including IC, UCS, and colon conduit (CC), a study by Picha et al. showed that major diversion-related complications were significantly more frequent in IC and CC and absent in UCS, while late reinterventions had occurred more frequently in IC (20%) compared to CC (5.8%) and UCS (2.4%), highlighting this as an important advantage of UCS, especially with regard to HRQoL (31). A recent meta-analysis by Nabil et al. on long-term outcomes between IC and UCS, including 10 studies with 3,689 patients, showed advantages of UCS over IC in terms of length of stay, with similar results in terms of major complications, HRQoL and survival rates (32).

As already mentioned, there were 17 UCS from 2008 to 2018, and 88 from 2019 to 2023 in our series. A statistically significant increase in the number of UCS was observed throughout all analysed time periods, with progressive peaks recorded during 2019, 2020 and 2022, making the relative share of UCS in this period as much as 66.2% of the total number of UCS in the entire series. In addition, the relative share of pT4 stage in the UCS group was 62.7% (37 out of 59 patients), significantly higher compared to the other groups. It is evident that the increase in the number of UCS coincides with the beginning of the COVID-19 pandemic and the corresponding restructuring of health capacities, in accordance with certain measures in the fight against the

pandemic. These measures included a whole series of systemic solutions, related to patient admission protocols, repurposing of spatial capacities, redirection of human resources, preservation of equipment, prevention of iatrogenic infection, while giving certain priorities to elective oncological operations in circumstances of limited resources (33). In an attempt to precisely define the criteria for establishing priorities in the triage of uro-oncological elective operations, several clinical guidelines have been published containing the same provisions regarding urgent indications, including radical cystectomy for MIBC, radical or partial nephrectomy for renal cell carcinoma (RCC) in T3 tumours and nephroureterectomy for high-grade and/or clinical T1+ tumours (34, 35).

Conclusion

In our study, a total of 283 RC with UD performed from 2008 to 2023 were analysed. Of these, ID and CD were performed in 198 (70%) and 85 (30%) patients, respectively. The annual number of operations ranged from 4 to 46, depending on the number of patients. The most represented UD was UCS, followed by IC, MP II and PCN. The highest relative share of pT4 stage was in the UCS group, followed by the MP II group, the IC group and the PCN group. The most common indication for cystectomy was urothelial carcinoma of the bladder. The annual share of MP II and IC was relatively stable, with slight variations. The annual share of UCS shows the lowest values until the period of the COVID-19 pandemic, when it increases significantly, with a peak in 2022. Due to its simplicity and feasibility, UCS has proven to be a suitable UD during the COVID-19 pandemic. The trends regarding ID and CD after RC, shown in our study, are consistent with the trends reported in the current literature.

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ANALIZA TRENDOVA U IZVOĐENJU URINARNIH DERIVACIJA NAKON TOTALNE CISTEKTOMIJE: PETNAESTOGODIŠNJE ISKUSTVO

Dragoslav Bašić^{1,2}, Ivan Ignjatović^{1,2}, Ljubinka Janković Veličković^{1,3}, Aleksandra Ignjatović^{1,4}, Marija Mihajlović², Aleksandar Pejić², Bratislav Pejić², Aleksandar Skakić^{1,2}, Milan Potić^{1,2}, Tomislav Stamenić²

¹Univerzitet u Nišu, Medicinski fakultet, Niš, Srbija

²Univerzitetski klinički centar Niš, Klinika za urologiju, Niš, Srbija

³Univerzitetski klinički centar Niš, Centar za patologiju i patološku anatomiju, Niš, Srbija

⁴Univerzitet u Nišu, Medicinski fakultet, Katedra za medicinsku statistiku i informatiku, Niš, Srbija

Kontakt: Dragoslav Bašić

Bulevar dr Zorana Đinđića 81, 18000 Niš, Srbija

E-mail: basicdr@gmail.com

Cilj našeg istraživanja bila je analiza trendova urinarnih derivacija (UD) kod bolesnika koji su bili podvrgnuti radikalnoj cistektomiji (RC) od 2008. do 2023. godine, s posebnim osvrtom na vreme pandemije kovida 19. Ukupno 283 bolesnika (243 muškarca i 40 žena, prosečne starosti 65,07 godina \pm 7,73 godine) klasifikovana su prema tipu UD-a u sledeće grupe: *Mainz pouch II* (MP II) – 85 bolesnika; ileumski provodnik (engl. *ileal conduit* – IC) – 89 bolesnika; ureterokutaneostomija (engl. *ureterocutaneostomy* – UCS) – 105 bolesnika; perkutana nefrostomija (engl. *percutaneous nephrostomy* – PCN) – 4 bolesnika. Relativni udeo inkontinentnih i kontinentnih UD-a iznosio je 70% i 30%, redom. MP II je bio najzastupljeniji UD od 2008. do 2013. godine, IC od 2014. do 2019. godine, a UCS od 2019. do 2023. godine. Najzastupljeniji UD bio je UCS (37,1%), a onda slede IC (31,4%), MP2 (30,0%) i PCN (1,4%). Trendovi UD-a menjali su se kroz vreme, s tim što su MP II i IC imali relativno stabilan udeo na godišnjem nivou, a UCS najmanji udeo do izbijanja pandemije kovida 19; tada je značajno povećan udeo UCS-a, a vrhunac je dostigao 2022. godine. Analiza trenda pokazuje značajno povećanje UCS-a između 2008. i 2023. godine ($p < 0,001$), dok značajnije promene trendova u preostalim grupama nisu zabeležene ($p > 0,05$). Trendovi kontinentnih i inkontinentnih UD-a nakon RC-a predstavljeni u ovoj studiji odgovaraju podacima iz savremene literature.

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Ključne reči: urinarne derivacije, trendovi, *Mainz pouch II*, ileumski konduit, ureterokutaneostomija

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