

Assessment of health-related quality of life of male patients with ileal orthotopic neobladder compared to cutaneous ureterostomy

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Introduction The aim of this article was to compare patients' health-related quality of life (HR-QoL) outcomes between ileal orthotopic neobladder (IONB) and standard bilateral cutaneous ureterostomy (CU) using validated diversion-specific HR-QoL questionnaires.

Material and methods This study utilized a retrospective cohort design, including all male patients who underwent open radical cystectomy with either IONB or CU from January 2010 until December 2017. In total, 69 and 57 male patients with a minimum of 12 months of follow-up were included in each group respectively, after applying the following exclusion criteria: female, pre- and postoperative radio- and chemotherapy and palliative surgery. For every patient, HR-QoL was evaluated using the European Association of Research and Treatment of Cancer Quality of Life Core (EORTC-QLQ-C30) and Functional Assessment of Cancer Therapy for patients undergoing radical cystectomy (FACT-BI-Cys) validated questionnaires.

Results In multivariable analysis, the type of the urinary diversion, and the occurrence of early and late postoperative complications were independently associated with the change of scores of HR-QoL domains. When comparing the 2 surgical methods (IONB vs. CU), after adjusting for confounders, such EORTC-QLQ-C30 domains as physical functioning (66.5 vs. 57.9, $p = 0.011$) and global health status (58.1 vs. 42.6, $p < 0.001$) were superior in the IONB arm which was statistically significant. Similarly, functional health (15.3 vs. 11.9, $p < 0.001$) and total score (110.1 vs. 101.7, $p = 0.009$) from the FACT-BI-Cys questionnaire were superior in the IONB arm.

Conclusions In our study, patients with IONB possessed statistically significant, better scores of HR-QoL domains assessed with EORTC-QLQ-C30 and FACT-BI-Cys questionnaires compared to those with CU. The occurrence of early major and late complications negatively affected patients' HR-QoL.

Key Words: radical cystectomy ↔ urinary diversion ↔ orthotopic neobladder
↔ cutaneous ureterostomy ↔ health-related quality of life

INTRODUCTION

Bladder cancer represents the 9th most common cancer worldwide among both genders [1]. Roughly 25% of cases appear to be muscle-invasive at the

time of diagnosis. In addition, another 10 to 30% of non-muscle invasive cases further progress to muscle-invasive disease [2]. For all those patients, radical cystectomy with pelvic lymphadenectomy and subsequent urinary diversion remains

a gold standard treatment for local control of the disease [3]. An important issue when considering the selection of the type of urinary diversion is the postoperative health-related quality of life (HR-QoL). In 2012, the ICUD-EAU international consultation on urinary diversions concluded that well-functioning ileal orthotopic neobladder (IONB) is better in terms of HR-QoL compared to other types of urinary diversions [4]. Nevertheless, IONB is one of the most difficult urinary diversions and is associated with a higher rate of major early postoperative complications reaching up to 22% [5]. In contrast, cutaneous ureterostomy (CU), being the simplest type of urinary diversion, is associated with fewer early postoperative complications [6]. It is believed to increase the rate of late stomal stenosis and is, therefore, reserved for elderly and sick patients [6, 7]. However, the data on CU are old and recent studies with the modification of the surgical technique have shown better results regarding stomal stenosis [8, 9]. In terms of HR-QoL, only a few studies, with a small number of patients and short follow-up periods are available so far [9, 10]. Therefore, up-to-date data on patients' HR-QoL following CU is required for proper consultation of those patients. The aim of the current study was to compare the health-related quality of life among a larger number of patients undergoing radical cystectomy with either ileal orthotopic neobladder or bilateral cutaneous ureterostomy construction.

MATERIAL AND METHODS

In total, 366 patients underwent open radical cystectomy with subsequent IONB or CU from January 2010 until December 2017. The data of deceased patients (total number – 143 patients) were excluded from our study. The further applied exclusion criteria included gender (females were excluded due to low numbers and the aim to have more similar comparison groups), patients receiving pre- and postoperative radio- and chemotherapy, patients undergoing radical cystectomy for palliative reasons. As a result, 126 male patients were available for the assessment of HR-QoL in the current study. Patients' perioperative data were gathered from medical records from the 2 highest volume hospitals in Armenia, performing more than 35 radical cystectomies annually. All surgeries were performed by a fixed single expert surgeon in each of the hospitals. Early postoperative complications were graded according to the Clavien-Dindo classification and >IIIa were considered as major complications [11]. HR-QoL was calculated for patients with a minimum of 12 months of follow-up. All patients were

invited to the clinics and both of the HR-QoL questionnaires were administered after receiving their written consent. The questionnaires were administered by a doctor-investigator not involved in the treatment process of any patient. The study was approved by the local ethics committee.

Questionnaires

The HR-QoL was calculated using the European Association of Research and Treatment of Cancer Quality of Life Core Questionnaire (EORTC-QLQ-C30) and Functional Assessment of Cancer Therapy for patients undergoing radical cystectomy (FACT-BI-Cys) validated questionnaires [12]. EORTC-QLQ-C30 is a 30-item questionnaire including multi-item scales covering physical, role, social, emotional and cognitive functioning, global health status and single item symptom scales. It is calculated according to EORTC guidelines from 0 to 100. The higher the scores the better are the outcomes [13]. In our study, we analyzed multi-item scales separately and combined single item symptom questions into one symptom scale.

The FACT-BI-Cys questionnaire is a 44-item questionnaire including 4 domains on physical, emotional, social, functional health and 1 domain on additional concerns designed to assess patients' HR-QoL specifically after radical cystectomy with different types of urinary diversions [14]. Similarly, a higher score implies a better outcome.

Statistical analysis

Statistical analyses were performed using SPSS v. 21.0 (SPSS Inc., 2012). Mean, standard deviation (SD), median and interquartile range (IQR) were used to describe continuous, and proportions for categorical variables. Outcome variables were health domains of HR-QoL questionnaires. The main independent variable was the type of urinary diversion, whereas secondary independent variables were age, follow-up time, tumor stage, American Society of Anesthesiologists (ASA) physical status score, preoperative hydronephrosis, and the occurrence of early and late complications. All the variables were first tested in univariable models. Thereafter, separate multiple linear regressions were performed for all domains and item scales of both of the questionnaires (as dependent variables) with all the factors which appeared to be statistically significant in the univariable analysis as independent variables. $P < 0.05$ was considered statistically significant. Statistical analysis was carried out by M.B., a specialist included in neither surgical team.

RESULTS

Patient characteristics

Table 1 summarizes patients' baseline and operative characteristics. All operated patients were males. In total, 69 patients were included in IONB and 57 in standard bilateral CU arms. The patients' median age at the time of surgery was 57 in the IONB arm and 65 in the CU arm. About 70% of all patients were younger than 65 years. Median follow-up for the whole group was 45 months ranging from 13 to 107 months. Importantly, 66.7% of all patients had at least 36 months of follow-up. More than 50% of patients suffered from locally advanced bladder cancer. Early postoperative complications were documented in 26 (20.6%) patients, out of them 13 (10.3%) were considered as major complications. A vast majority of major complications occurred in IONB arm.

Quality of life

The association of the type of urinary diversion with other factors and HR-QoL domains was checked in univariable analysis. We identified that

people operated with standard CU had statistically significantly worse scores in physical functioning ($p = 0.012$) and global health status ($p < 0.001$) per EORTC-QLQ-C30 questionnaire and worse scores in functional health ($p < 0.001$), and total score ($p = 0.019$) per FACT-BI-Cys compared to IONB arm on univariable analyses (Tables 2, 3). The other statistically significant factors on univariable analyses were the absence of early major and late postoperative complications and stage of the cancer. On multivariable analysis, however, cancer stage was not associated with any change in HR-QoL, whereas the type of the urinary diversion, occurrence of early major and late postoperative complications remained statistically significant in many of the HR-QoL domains. Importantly, all three variables affected the total score of the FACT-BI-Cys questionnaire significantly. According to the final multiple regression, after controlling for other independent variables, IONB was related to the increase of 9.9 points in FACT-BI-Cys total score as compared to CU, absence of early major complications was related to the increase of 14.9 points in FACT-BI-Cys total score and absence of late complications was related to the increase of 8.3 points in FACT-BI-Cys total score (Table 4).

Table 1. Baseline and operative characteristics of study population

Patients	Total (n-126)	Surgical technique	
		CU (n-57)	IONB (n-69)
Age (years), median (IQR)	61 (54–66)	65 (59–71)	57 (38–70)
Age <65 years, n (%)	88 (69.8)	29 (50.9)	59 (85.5)
BMI (kg/m ²), median (IQR)	27.6 (23.6–29.8)	26.8 (23.2–29.4)	27.6 (23.6–30.2)
Preoperative hydronephrosis, n (%)	21 (16.7)	15 (26.3)	6 (8.7)
Diabetes, n (%)	16 (12.3)	8 (14.0)	8 (11.6)
Cancer stage, n (%)			
Bladder confined (pT1–2, N0, M0)	62 (49.2)	19 (33.3)	43 (62.3)
Locally advanced (pT3–4a, N0, M0)	64 (50.8)	38 (66.7)	26 (37.7)
Tumor Grade, n (%)			
G1	7 (5.6)	3 (5.3)	4 (5.8)
G2	71 (56.3)	31 (54.4)	40 (58.0)
G3	48 (38.1)	23 (40.4)	25 (36.2)
Blood loss (ml), median (IQR)	400 (350–450)	400 (350–450)	400 (350–450)
ASA score (3 and 4), n (%)	43 (34.1)	22 (38.6)	21 (30.4)
Follow-up (months), median (IQR)	45 (30–60)	36 (26–51)	50 (38–70)
Follow-up >36 months, n (%)	84 (66.7)	55 (79.7)	29 (50.9)
Early complications, n (%)	26 (20.6)	7 (12.3)	19 (27.5)
Early major complications, n (%)	13 (10.3)	1 (1.8)	12 (17.4)
Late complications, n (%)	53 (42.0)	23 (40.4)	30 (43.5)

BMI – body mass index; CU – cutaneous ureterostomy; IONB – ileal orthotopic neobladder; ASA – American Society of Anesthesiologists; SD – standard deviation; IQR – interquartile range

Table 2. Bivariate analyses of the type of urinary diversion and patients' quality of life domains (EORTC-QLQ-C30)

Patients	Total (n-126) Mean (SD) Median (IQR)	Surgical technique		P-value
		CU (n-57) Mean (SD) Median (IQR)	IONB (n-69) Mean (SD) Median (IQR)	
Global health status	51.0 (18.0) 50.0 (16.7–83.3)	42.6 (12.7) 41.7 (16.7–66.7)	58.1 (18.9) 58.3 (16.7–83.3)	<0.001
Physical functioning	62.6 (19.1) 66.7 (13.3–93.3)	57.9 (18.2) 60.0 (13.3–93.3)	66.5 (19.0) 73.3 (20.0–93.3)	0.012
Emotion functioning	73.3 (15.8) 75.0 (8.3–100.0)	72.4 (14.6) 75.0 (33.3–100.0)	74.0 (16.8) 75.0 (8.3–100.0)	0.559
Social functioning	57.1 (19.8) 66.7 (16.7–83.3)	53.2 (21.9) 50.0 (16.7–83.3)	60.4 (17.4) 66.7 (33.3–83.3)	0.043
Role functioning	69.2 (16.4) 66.7 (16.7–100.0)	68.8 (17.1) 66.7 (16.7–88.3)	69.6 (15.9) 66.7 (16.7–100.0)	0.793
Cognitive functioning	78.2 (13.7) 83.3 (50.0–100.0)	78.1 (13.4) 83.3 (50.0–100.0)	78.3 (14.1) 83.3 (50.0–100.0)	0.939
Symptoms scale	42.4 (14.5) 43.6 (7.7–89.7)	40.9 (8.9) 41.0 (17.9–60.0)	43.7 (17.8) 43.6 (7.7–89.7)	0.289

EORTC-QLQ-C30 – European Association of Research and Treatment of Cancer Quality of Life Core Questionnaire; SD – standard deviation; IQR – interquartile range

Table 3. Bivariate analyses of type of the urinary diversion and patients' quality of life (FACT-BI-Cys)

Patients	Total (n-126) Mean (SD) Median (IQR)	Surgical technique		P-value
		CU (n-57) Mean (SD) Median (IQR)	IONB (n-69) Mean (SD) Median (IQR)	
Physical health	18.4 (4.9) 19.0 (4–28)	17.6 (4.4) 18.0 (4–27)	19.1 (5.2) 20.0 (7–28)	0.097
Social health	19.2 (4.4) 20.5 (9–26)	18.8 (4.6) 20.0 (10–25)	19.6 (4.2) 21.0 (9–26)	0.316
Emotional health	18.0 (4.2) 19.0 (2–24)	17.7 (3.8) 18.0 (9–23)	18.3 (4.5) 19.0 (2–24)	0.484
Functional health	13.8 (4.5) 13.0 (3–24)	11.9 (3.2) 12.0 (3–18)	15.3 (4.8) 16.0 (4–24)	<0.001
Additional concerns	36.9 (7.4) 36.0 (16–60)	35.7 (5.0) 36.0 (23–48)	38.0 (8.9) 38.0 (16–60)	0.081
Total score	106.3 (20.4) 108.0 (47–154)	101.7 (15.4) 101.0 (54–132)	110.1 (23.2) 115.0 (47–154)	0.019

FACT-BI-Cys – Functional Assessment of Cancer Therapy for patients undergoing radical cystectomy questionnaire; SD – standard deviation; IQR – interquartile range

DISCUSSION

In our study, we compared HR-QoL of 126 patients using EORTC-QLQ-C30 and FACT-BI-Cys validated questionnaires with a median follow-up period of 45 months. Investigated patients were operated either with IONB or with CU techniques following radical cystectomy.

IONB, representing one of the most difficult urinary diversions, is associated with the highest rates of early and late postoperative complications. Even in experienced centers, the rate of early and late postoperative complications is prevalent [5, 15, 16]. On the other hand, CU represents the simplest uri-

nary diversion method following radical cystectomy. Its advantages are the minimization of operating time and intra-operative blood loss, avoidance of intestinal violation leading to a reduced rate of early postoperative complications [17]. The drawback of CU is a high rate of late stomal stenosis limiting its widespread use, and preserving this method of diversion for morbid patients [7, 18]. Recent advancements in the surgical technique and modifications, however, have improved the rate of stomal stenosis proposing this method as an option for existing surgical gold standards in selected patients [8, 17, 19]. In terms of patients' HR-QoL, continent diversion following radical cystectomy is thought to be

Table 4. Final multivariable linear regression results

QoL health domains Factors*	Coefficient (Standard error)	Confidence Interval	P-value
EORTC-QLQ-C30			
Global health status			
Urinary diversion – IONB	16.2 (3.1)	10.0–22.4	<0.001
Cancer stage – Locally advanced (pT3-4a, N0, M0)			NS
Physical functioning			
Urinary diversion – IONB	9.1 (3.5)	2.1–16.0	0.011
Late complications – yes	6.5 (3.3)	0.1–13.0	0.047
Cancer stage – Locally advanced (pT3-4a, N0, M0)			NS
Symptom scale			
Early major complications – yes	8.8 (4.2)	0.4–17.3	0.041
Late complications – yes	5.8 (2.5)	0.7–0.8	0.025
FACT-BI-Cys			
Physical health			
Early major complications – yes	3.7 (1.4)	0.9–6.5	0.009
Late complications – yes	1.8 (0.8)	0.1–3.4	0.036
Cancer stage – locally advanced (pT3-4a, N0, M0)			NS
Functional health			
Urinary diversion – IONB	3.8 (0.8)	2.3–5.3	<0.001
Cancer stage – locally advanced (pT3-4a, N0, M0)			NS
Additional concern			
Late complications – yes	3.1 (1.3)	0.6–5.7	0.016
Total score			
Urinary diversion – IONB	9.9 (3.7)	2.5–17.3	0.009
Early major complications – no	14.9 (5.8)	3.3–26.4	0.012
Late complications – no	8.3 (3.5)	1.4–15.1	0.019
Cancer stage – locally advanced (pT3-4a, N0, M0)			NS

QoL – quality of life; EORTC-QLQ-C30 – European Association of Research and Treatment of Cancer Quality of Life Core Questionnaire; IONB – Ileal orthotopic neobladder; FACT-BI-Cys- Functional Assessment of Cancer Therapy for patients undergoing radical cystectomy questionnaire

*Comparison groups: urinary diversion – cutaneous ureterostomy; cancer stage – bladder confined (pT1-2, N0, M0); Early major complications – Yes; Late complications – Yes

better compared to other urinary diversions [4]. Several studies comparing IONB and ileal conduit (IC) have shown better HR-QoL and superior sexual function in patients with IONB [20]. Similarly, physical functioning and general health were found to be superior in patients with IONB compared to IC. In addition, higher scores of mental and emotional functioning were described by several authors [20]. On the other hand, many other studies fail to show any statistically significant difference in terms of patients HR-QoL of these two methods [20]. In systematic reviews of non-randomized clinical studies, significantly better HR-QoL for patients with IONB compared to patients with IC was reported [21, 22]. In contrast, in a systematic review and a meta-analysis study by Yang et al. neither of the urinary diversion methods was found to be superior from another [20]. After a thorough analysis, the authors came to the conclusion that patients' choice was the most important factor to be considered for the selection of urinary reconstruction. Despite many studies in this particular field, most of them were retrospective and compared continent urinary diversion and conduit urinary diversion [21, 22].

So far very few studies have focused on patients' HR-QoL following CU [9, 10, 17]. Longo et al. compared HR-QoL between single stoma cutaneous ureterostomy and IC [17]. In total, 70 patients were analyzed, 35 of which had CU and the remaining 35 IC. The authors were able to show improved postoperative outcome in patients with CU without impairment of their HR-QoL. According to authors, CU was a valid alternative for elderly patients with significant comorbidities [17].

The HR-QoL of patients' with IONB and CU was further compared in 2 studies. These studies, however, did not identify any significant difference between those patients [9, 10]. Saika et al. studied the data of 109 patients, 56 operated with IC, 31 with CU and 22 with orthotopic urinary reservoir [10]. Similar to our study, they used the EORTC-QLQ-C30 questionnaire for the assessment of the HR-QoL. As mentioned, no statistical differences were found between the three groups; however, orthotopic urinary reservoir appeared to be more preferred method for patients in their study [10].

Another study by Vakalopoulos et al. examined patients' HR-QoL following intubated ureteroureterocutaneostomy and IONB [9]. They included

39 patients and used 4 questionnaires. Although statistically not significant, the HR-QoL scores were better with uretero-ureterocutaneostomy [9]. However, the median follow-up of those patients was only 15 months compared to 45 months in our cohort. As shown previously, the HR-QoL scores tended to improve within the first 12 months after an initial decrease following the surgery, and continue to worsen in its all domains after 12 months [23]. In addition, at a 3-year follow-up, the HR-QoL was even worse compared to 1-year follow-up, probably, because of the loss of hope for a successful recovery. Thus, ensuring more than 36 months of follow-up was found to be a critical factor in terms of postoperative changes in HR-QoL [24]. Follow-up duration of our study was consistent with the recommendations above. The median follow-up of our cohort was 45.0 months ranging from 13 to 107 months. Importantly, among 2/3 of the patients, the follow-up period was more than 36 months.

In our study, CU was not performed solely for comorbidity indications but also based on socioeconomic/financial considerations (more specifically, CU entails less financial expense for patients). Thus, a proportion of patients in the CU arm were comparable with the IONB arm in terms of patients' characteristics and preoperative health statuses. Unfortunately, we were unable to retrieve the actual number of patients undergoing CU for financial considerations and quantify its impact on the choice of the diversion method.

Apart from the type of urinary diversion, according to our results, the occurrence of early major and late postoperative complications was shown to affect patients' HR-QoL after radical cystectomy. The suffered domains were symptoms scale per EORTC-QLQ-C30 questionnaire and physical health, functional health, additional concern domains, and total score of HR-QoL per FACT-BI-Cys questionnaire. Although early postoperative complications were treated and patients were discharged only after total rehabilitation, the occurrence of those might have changed patients' expectations from the surgery and further perception of HR-QoL. In fact, the scores of the quality of life were the lowest for patients with IONB diversion experiencing postoperative complications, even in comparison with patients with CU. It seems that IONB without compli-

cations carries the best outcomes. However, when complications occur, the quality of life decreases to the minimum. Our results are controversial to existing data regarding early postoperative complications [25]. In their paper, Ritch et al., failed to show any association between early complication and HR-QoL of patients, however, the HR-QoL evaluation was conducted within the postoperative first 12 months, without a longer follow-up investigation [25]. Previous data regarding late postoperative complications are in line with our results and indicate that higher rate of late postoperative complications diminishes the HR-QoL irrelative to the type of urinary diversion [26].

To our knowledge, this is the first study assessing and comparing HR-QoL in a large group of patients with CU. Results of our study support IONB in a long follow-up period both in the terms of patients' preference and their HR-QoL. In general, a number of limitations are apparent for this study. The main limitation is its retrospective nature. The retrospective setting does not allow for the investigation of patients' baseline HR-QoL and evaluation of the HR-QoL changes in each surgical group. In line with this main drawback we were not able report patients' clinical conditions according to Charlson comorbidity index (CCI). While the CCI is a more informative tool to assess patients' comorbidities, the current study used ASA score to assess the perioperative status of the patients. Another drawback of this study is that the data were collected from 2 departments. This might have limited the homogeneity of the study population. Nonetheless, both of the selected centers had high caseloads of >35 radical cystectomies annually and all the procedures were performed by one expert surgeon in each of the institutions.

CONCLUSIONS

In our study, patients with IONB possessed statistically significant, better scores of HR-QoL domains assessed with EORTC-QLQ-C30 and FACT-BI-Cys questionnaires compared to CU. The occurrence of early major and late complications negatively affected patients' HR-QoL.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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