

Quality of life outcomes after radical cystectomy: long-term standardized assessment of Studer Pouch versus I-Pouch

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Abstract

Purpose To investigate whether the ileal length used for the formation of two different orthotopic bladder substitutes [Studer (S)-Pouch vs. I-Pouch; 60 vs. 40 cm] impacts quality of life (QoL).

Materials and methods In this cross-sectional study, a total of 56 patients underwent radical cystectomy with ileal neobladder for bladder cancer [S-Pouch: 23 pat, 19 men, 4 women); I-Pouch: 33 pat (26 men, 7 women)]. They completed general (SF-36), cancer-specific (QLQ-C30) and bladder cancer-specific questionnaires (QLQ-BLM30) as well as a novel neobladder-specific questionnaire (TNQ). The questionnaire-based follow-up was 66 months (IQR 41–104; total range 9–161).

Results I-Pouch patients reported better SF-36 physical health status ($p = 0.026$), QLQ-BLM30 continence scores ($p < 0.001$) and a more favorable QLQ-C30 total score compared to S-Pouch patients ($p = 0.044$). S-Pouch patients reported better QLQ-BLM30 general health status ($p = 0.001$). For the TNQ, no significant difference was found between both groups ($p = 0.09$). S-Pouch patients reported use of condom urinals more frequently ($p = 0.026$). S-Pouch patients tended to be on vitamin B12

substitution ($p = 0.06$). I-Pouch patients reported significantly higher micturition volumes (≥ 300 ml) compared to S-Pouch patients (30/33 vs. 16/23; $p = 0.040$). No differences were found with regard to bicarbonate supplementation and recurrent urinary tract infections.

Conclusion Non-neobladder-specific questionnaires show controversial results for QoL outcomes of patients with Studer and I-Pouch. The TNQ suggests that none of these two types of neobladder is superior to the other in terms of QoL. Hence, general questionnaires are not valid enough to adequately address QoL aspects in patients with different neobladders. Development and validation of neobladder-specific questionnaires are needed.

Keywords Orthotopic · Neobladder · Quality of life · Questionnaire · Functional

Introduction

Radical cystectomy (RC) represents the mainstay of treatment for muscle-invasive bladder cancer (MIBC) [1]. As oncologic outcomes have evolved in the last decades [2], quality of life issues (QoL) related to the urinary diversion after RC have come to the focus of clinicians and patients alike [3].

Orthotopic bladder substitutes (OBS) represent a well-accepted form of urinary diversion for the majority of patients undergoing RC for MIBC [4–8]. OBS aim to store urine at low pressure while providing a voiding pattern similar to that of the native bladder [9, 10].

Health-related quality of life (HRQoL) questionnaires are instruments which are used to assess the impact of treatment-related morbidity on HRQoL in patients after major oncological procedures [11]. For this, several types of questionnaires exist including general, cancer- and

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bladder cancer-specific ones. Whether these questionnaires are useful to assess the impact of different OBS on HRQoL outcomes after RC is unclear as none of these have been developed in patients with neobladders.

To our knowledge, literature provides sparse information comparing long-term HRQoL outcomes of patients with different types of OBS. Most series compared outcomes of S-Pouch and Hautmann neobladder (both made of the same ileal length) to sigmoid neobladder or ileal conduit. These series include a low number of patients, and evaluation of HRQoL is based only on a single questionnaire [12–14].

We therefore hypothesized that the length of ileum used for the formation of an ileal reservoir might have an impact on HRQoL when compared to another reservoir made of a different ileal length.

Materials and methods

Patient selection

This is an institutional review board-approved, prospective, cross-sectional study (63/2012BO2). Patient search was performed on February 2012 via a prospectively maintained database of patients treated with RC for BC between 2002 and 2011.

During this period, a total of 171 patients underwent RC with OBS. Of the 171 patients, 73 were alive or traceable (42.7 %) and recruited via phone call. A total of 56 patients (76.7 %) provided informed consent to participate in this study. Of these, 23 (19 men, 4 women) received a Studer (S-) Pouch and 33 an I-Pouch (26 men, 7 women).

In our department, every patient who is scheduled for radical cystectomy is informed in depth about all types of urinary diversion including both continent and incontinent diversions and the final decision is based on a broad consent between patient and surgeon. Orthotopic bladder substitution is performed in patients that lack the following contraindications: severely reduced life expectancy, a positive urethral margin on frozen section, a glomerular filtration rate of less than 50 ml/min, prior high-dose pelvic radiotherapy, severe hepatic impairments, complex urethral strictures, stress urinary incontinence and physical and mental impairments that would preclude the ability to perform clean intermittent catheterization in case of retention. The decision to perform either a Studer or I-Pouch is mainly based on the length of the remaining ureteral stumps after bladder removal as the I-Pouch has no afferent limb that would allow for a more proximal resection of the ureters.

After postal sending, questionnaires were sent back by the patients within 2 weeks. The median questionnaire-based follow-up was 66 months (IQR 41–104; total range

9–161). All 56 patients were staged cM0 at the time of RC. Tumor characteristics were compared between both groups.

Radical cystectomy

RC was performed either open according to standardized techniques. In men, RC included the removal of the tumor-bearing bladder, prostate and seminal vesicles, and in women, the tumor-bearing bladder, anterior vaginal wall, uterus and adnexa. Bilateral pelvic lymph node dissection was performed in all patients [1].

Studer Pouch technique

The technique of the S-Pouch is described elsewhere [15, 16]. In brief, an ileal segment of about 55–60 cm length is isolated 15–20 cm proximally to the ileocecal valve. The afferent limb remains intact and serves for ureteral implantation, whereas the main reservoir is formed of the remaining 40–45 cm of ileum.

I-Pouch technique

The I-Pouch technique was described first in 2010 [9]. For I-Pouch reconstruction (named for the vertically implanted ureters into the pouch), an ileal segment of 40 cm length is isolated about 20 cm proximally to the ileocaecal valve (see Fig. 1a). Following restoration of bowel continuity, about 8 cm of the paramesenteric borders are sutured together to form the basis of the subserosal trough (see Fig. 1b). The bowel is completely opened at its antimesenteric border, and a U-shaped ileal plate is formed (see Fig. 1c, d). The widely spatulated and conjoined ureters (according to Wallace technique) are placed into the trough (see Fig. 1d–f) and the ileal leafs closed above the trough, thereby creating an antirefluxive mechanism. Finally, the reservoir is cross-folded and closed (see Fig. 1g).

Questionnaires

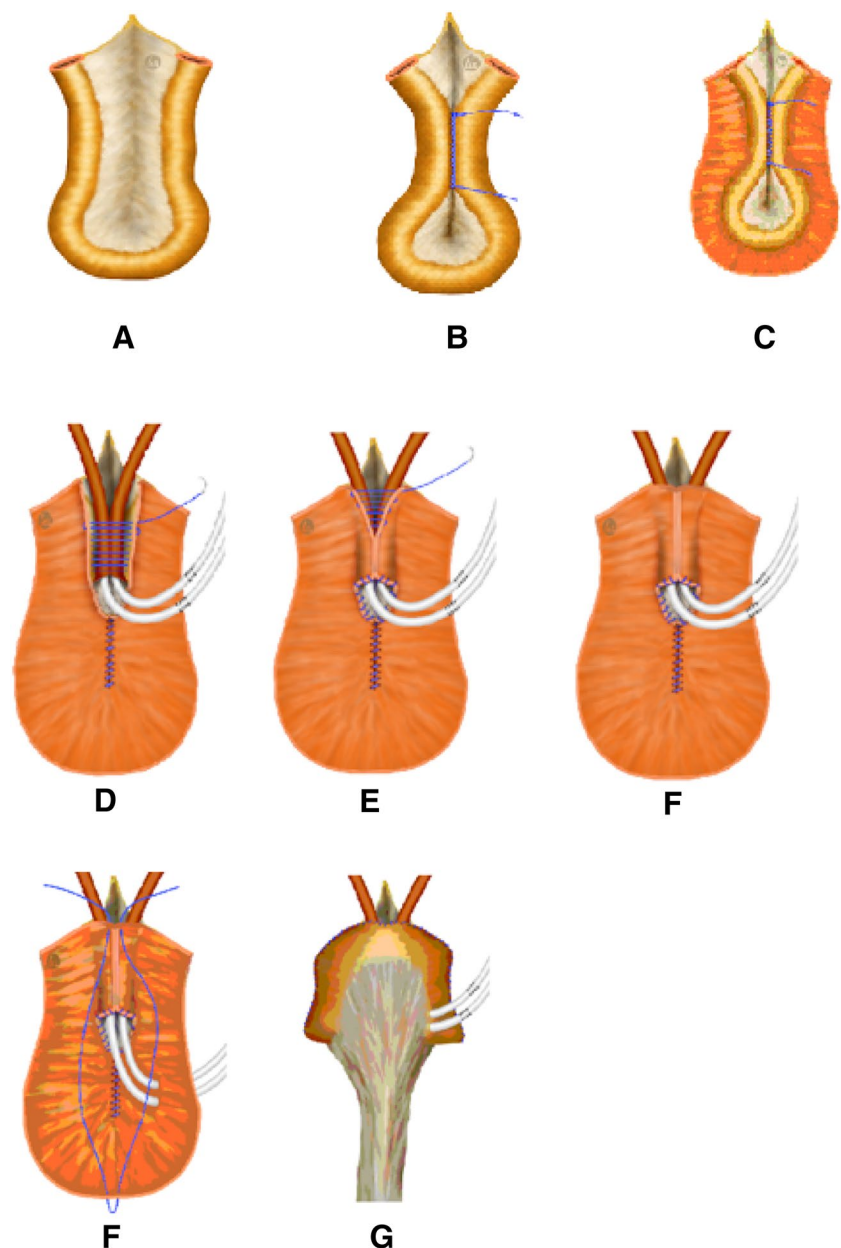
Short Form-36 item (SF-36)

The SF-36 includes 36 questions which assess limitations in eight health domains (see Table 1). The lowest and highest possible scores are set at 0 and 100 %, respectively [17, 18]. Scoring is performed according to the RAND 36-item health survey (version 1) which is a two-step process [19].

European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ)—cancer patients-30 questions (C30)

The EORTC-QLQ-C30 represents an instrument for assessing HRQoL issues in cancer patients. It comprises nine

Fig. 1 Formation of the I-Pouch (**a** isolation of ileal loop of 40 cm length, **b** para-mesenteric borders are sutured together to form the basis of the subserosal trough, **c** opening of ileum at its antimesenteric boarder, **d** formation of a U-shaped ileal plate with conjoined ureters (according to Wallace technique) placed into the trough (see **e** ileal leafs closed above the trough thereby forming an antirefluxive system. **f** Cross-folding of the reservoir according to Goodwin's principle, **g** closure of the reservoir using an interrupted running suture thereby



multi-item scales (Table 1). A low score (score 1) indicates absence of problems, whereas a high score (score 4) reports discomfort at most. Question no. 30 assesses overall HRQoL [20].

EORTC muscle-invasive bladder cancer module 30 questions (BLM30)

The EORTC-QLQ-BLM30 subsumes 30 questions for patients with MIBC. It contains also a module assessing problems associated with the use of catheters for bladder emptying. Moreover, it addresses postoperative sexual and bowel habits. The scoring equals to that of the QLQ-C30 questionnaire [21].

Tübingen Neobladder Questionnaire (TNQ)

A questionnaire consisting of twelve items was developed which assesses relevant aspects of HRQoL after OBS. These include continence (pad use per day/night, use of condom urinal), necessity of clean intermittent catheterization, rate and feverishness of urinary tract infections (UTI), micturition volume, residual urine volume, bowel habits, flank or abdominal pain during micturition, straining during micturition, visible mucous in urine and neobladder-related medication. Each item is scored as “1” if present or “0” if absent. The total score ranges from “0” to “12”. A higher score indicates worse HRQoL. Table 1 lists all questionnaires.

Table 1 Assessment of specific domains by questionnaires used in the study (General well-being, bowel-, urinary-, sexual-, bladder- and neobladder-specific items)

Type of questionnaire	Domains	No. of items	General well-being	Bowel	Urinary	Sexual	Bladder-specific	Neobladder-specific
EORTC-QLQ-C30	Global health, functional symptom scales	30	Yes	Yes	No	No	No	No
EORTC-QLQ-BLM30	Urinary sexual psychosocial	30	No	No	Yes	Yes	Yes	No
SF-36	Physical, mental, social, emotional status	36	Yes	No	No	No	No	No
TNQ (Tübingen Neobladder Questionnaire)	Voiding, sexual, functional status, pain, medication	12	No	No	Yes	Yes	Yes	Yes

Statistical analysis

Kaplan–Meier analysis was used to evaluate recurrence-free survival. For univariable analysis, the Fisher exact test was used for nominal data and Student's *t* test for scaled data. *p* values are two-sided, and $p < 0.05$ was considered as level of significant difference. Statistical analysis was performed with JMP® 11.0. Values are given as mean \pm SEM for normally distributed variables or as median (range) for non-normally distributed variables.

Results

Median age at surgery was 67 years (IQR 61–72) in patients with an I-Pouch and 64 years (IQR 52–70) in patients with an S-Pouch ($p = 0.051$). Patients with an S-Pouch exhibited a higher rate of locally advanced pathologic tumor stage than I-Pouch patients ($p = 0.001$). Tumor recurrence was noted in two (1 I-Pouch, 1 S-Pouch) of the 56 patients. The 5-year recurrence-free survival for patients with an I-Pouch was 96.9 and 95.7 % for patients with an S-Pouch. No further differences were found for the other pathologic characteristics listed in Table 2.

I-Pouch patients reported better SF-36 physical health status (I-Pouch, median 100; IQR 50–100 vs. S-Pouch, median 75; IQR 0–100; $p = 0.026$), better QLQ-BLM30 continence score (I-Pouch, median 2; IQR 2–3 vs. S-Pouch, median 4; IQR 3–7; $p < 0.001$) and better QLQ-C30 total score (I-Pouch, median 39; IQR 31–46 vs. S-Pouch median 44; IQR 34–63; $p = 0.044$) compared to S-Pouch patients. S-Pouch patients reported better QLQ-BLM30 general health status compared to I-Pouch patients (median 19, IQR 11–24 vs. median 29, IQR 26–34; $p = 0.001$). No difference was found for both groups in terms of QLQ-C30 quality of life question no. 30 (median 6 vs. median 5; $p = 0.12$).

For the TNQ (Table 3), no significant difference was found between both groups (I-Pouch, median 5, IQR 3–5; S-Pouch, median 6, IQR 4–6; $p = 0.09$). I-Pouch patients tended to be on vitamin B12 substitution compared to S-Pouch patients (1/33 vs. 4/23; $p = 0.06$). No difference was found between both groups in terms of bicarbonate supplementation (13/33 vs. 6/23; $p = 0.29$), clean intermittent catheterization (4/33 vs. 3/23; $p = 0.35$) and number of overall (14/33 vs. 12/23; $p = 0.37$) and febrile UTI (4/33 vs. 6/23; $p = 0.13$). S-Pouch patients used significantly more frequently condom urinals compared to I-Pouch patients (2/33 vs. 6/23; $p = 0.026$). I-Pouch patients reported significantly higher self-reported micturition volumes (≥ 300 ml) compared to patients with an S-Pouch (30/33 vs. 16/23; $p = 0.040$).

Discussion

In this study, we aimed to investigate whether the length of ileum used for the formation of neobladder reservoir impacts HRQoL. As a prerequisite, both types of OBS are regularly performed in our department for the restoration of the lower urinary tract, and our medical and nursing staff has a long-lasting experience in treating patients with both types of orthotopic diversion.

For the present study, we selected only four questionnaires as we assumed that patients would most likely participate in this study when the time frame for answering the questionnaires would not exceed half an hour and could be easily done without the assistance of a physician or nurse.

An ideal questionnaire should be valid (measures what it reports to measure), reliable (able to give the same result on several occasions given stable disease) and responsive (able to detect true but clinically meaningful changes) [11]. In this regard, the first two questionnaires have been validated in prior studies [22–25]. By contrast, the QLQ-BLM30

Table 2 Pathologic characteristics in the 56 patients undergoing radical cystectomy with ileal neobladder

	I-Pouch	S-Pouch	<i>p</i>
Median age at surgery (in years)	67	64	0.051
IQR	61–72	52–70	
Gender			
Male	26	19	1.0
Female	7	4	
pT-stage at RC			
pT0/pTis/pTa	5/1/5	0/3/2	0.001
pT1	10	1	(≥pT3a vs. ≤pT2b)
pT2a/pT2b	3/5	3/4	
pT3a/pT3b	3/1	7/2	
pT4a/pT4b	0	1	
pN-stage at RC			
pN0	32	19	0.14
pN1–3	1	4	
Soft tissue surgical margins			
Positive	1	2	0.56
Negative	32	21	
Lymphovascular invasion			
LV0	22	17	0.12
LVI	2	6	
LVX	9	0	
Histological subtype			
Urothelial	31	23	0.50
Squamous	2	0	
Adeno	0	0	
Mixed	0	0	
Tumor grading			
GX	9	0	0.26
G1	1	2	
G2	9	8	
G3	14	13	
Number of retrieved LN			
Median	23	18	0.22
IQR	17–29	14–28	

IQR interquartile range, LN lymph nodes, RC radical cystectomy

represents a regularly used additional module not fully validated yet [7, 26]. Nonetheless, the true sensitivity of these questionnaires to distinguish small, albeit significant differences in HRQoL issues between patients with different types of OBS remains elusive. Strikingly, we found that I-Pouch patients reported better SF-36 physical health status, QLQ-BLM30 continence score and QLQ-C30 total score, whereas S-Pouch patients reported better QLQ-BLM30 general health status. These results are contradictory and suggest that these questionnaires are not generally useful to evaluate HRQoL issues in patients with different OBS.

Table 3 Analysis of items in the TNQ questionnaire between both groups

No. of patients	I-Pouch <i>N</i> = 33 (%)	S-Pouch <i>N</i> = 23 (%)	<i>p</i>
Bicarbonate substitution	13 (%)	6 (%)	0.29
Vitamin B12 substitution	1 (3.0)	4 (17.3)	0.062
Use of condom urinal on daily basis	2 (6.1)	6 (26.1)	0.026
Volume of micturition			
≥300 ml	30 (90.9)	16 (69.6)	0.040
<300 ml	3 (9.1)	7 (30.4)	
UTI	14 (42.4)	12 (52.2)	0.37
UTIs per patient/year (IQR)	2.1 (IQR)	2.3 (IQR)	
Febrile UTI per year (≥1 episode/year)	4 (12.1)	6 (26.1)	0.13
Abdominal straining during voiding	22 (66.7)	11 (47.9)	0.21
Clean intermittent catheterization			
Overall no. of patients	4 (12.1)	3 (13.0)	0.35
Mean daytime	4.7	5.0	0.82
Mean nighttime	2.3	2.5	0.08
Flank pain at voiding	4 (12.2)	2 (8.7)	0.21
Use of pads			
Overall daytime	28	18	1.0
Pads/per day/per patient	1.3	2.7	
Overall nighttime	29	17	0.30
Pads/per night/per patient	1.3	2.0	
Mucous in urine			
Present	20	16	0.64
Absent	9	2	
Not sure	4	5	

IQR interquartile range, UTI urinary tract infection

Since validated neobladder-specific questionnaires are lacking in literature, we developed a questionnaire (TNQ) that addresses relevant HRQoL issues of patients with neobladders [27]. In this regard, the TNQ has not been validated thus far. While the total scores for this questionnaire did not differ significantly between both groups, a trend toward significance was noted for vitamin B12 substitution in favor of I-Pouch patients. This difference may be attributable to the reduced length of ileum used for the formation of the reservoir. However, no differences between both groups for bicarbonate supplementation or UTIs were noted, which suggests that the reabsorption of acidic components through the neobladder mucosa is of minor importance in the long term.

Surprisingly, patients with an I-Pouch were at lower risk for severe incontinence (as documented by the use of condom urinals in males). Notably, a higher rate of advanced tumor stage was found for S-Pouch patients, but only one of them developed recurrence. Moreover, when patients

were asked to document their emptied maximum micturition volume, a significant difference was noted in favor of I-Pouch patients. This result may also provide an explanation for the better QLQ-BLM30 continence scores of patients with an I-Pouch. Yet, a prior study showed that S-Pouch patients had similar continence rates as compared to patients with an hemi-Kock pouch [14].

Our study has several limitations which have to be taken into account in the interpretation of the results. As it has been already outlined above, the decision to use either the Studer or I-Pouch was based on the length of the remaining ureteral stumps after bladder removal as the I-Pouch has no afferent limb that would allow for a more proximal resection of ureters. In this regard, the advantage of the I-Pouch is that the directly implanted ureters lie on the dorsal wall of the pouch which facilitates instrumentation of the upper tract at a later time point. As this is a cross-sectional study that describes long-term outcomes of HRQoL after neobladder, no baseline assessment was available at study initiation. Therefore, we could not demonstrate changes of HRQoL on a longitudinal basis. We could also not adjust for the number of surgeons, their surgical preferences and experiences with types of neobladder techniques. However, all patients were treated in our center that is dedicated to OBS. Although questionnaires were sent back within 2 weeks, a recall bias has to be taken also into account when comparing questionnaire-based outcomes between two different groups. As the TNQ is a novel neobladder-specific questionnaire, its clinical applicability needs to be assessed by external validation. Another limitation of this study is its limited sample size which might explain to some extent the heterogeneity in the study findings. In addition, due to the limited sample size, the validity of a multivariable analysis or match-comparison addressing, the impact of ileal length on HRQoL outcomes would be hampered a priori.

Nonetheless, to our knowledge, this series includes the highest number of patients with different types of ileal neobladders ever reported on a long-term questionnaire-based follow-up. Therefore, despite these limitations, this study attempts for the first time to address the impact of the length used for the formation of ileal neobladder on HRQoL outcomes.

Conclusion

The EORTC-QLQ-C30, BLM30 and the SF-36 questionnaires showed controversial results for the Studer Pouch and I-Pouch. Hence, these questionnaires are not valid enough to adequately address HRQoL aspects in patients with different types of neobladder. The results of the TNQ suggest that none of these two types of neobladder is

superior to the other in terms of HRQoL. Development of specific questionnaires is needed in order to address more specifically the impact of ileal length of OBS on HRQoL after RC.

Conflict of interest The authors declare that no funding or other financial support was received. The authors declare that they have no conflict of interest.

Ethical standard The study has been approved by the appropriate ethics committee and has therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. All patients gave their informed consent prior to their inclusion in the study.

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