



# Quality of life and functional outcomes after radical cystectomy with ileal orthotopic neobladder replacement for bladder cancer: a multicentre observational study

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## Abstract

**Purpose** Ileal orthotopic neobladder (IONB) reconstruction is the preferred urinary diversion among selected patients who have undergone radical cystectomy (RC) for bladder cancer (BCa). There is insufficient data regarding patients' quality of life (QoL), sexual and urinary outcomes. Our objectives were to assess QoL in a multicentre cohort study, and to identify related clinical, oncological and functional factors.

**Methods** Patients who underwent RC with IONB reconstruction for BCa from 2010 to 2017 at one of the three French hospitals completed the following self-reported questionnaires: European Organization for Research and Treatment of Cancer (EORTC) generic (QLQ-C30) and bladder cancer specific instruments (QLQ-BLM30). To assess urinary symptoms, patients completed the Urinary Symptom Profile questionnaire (USP) and a three-day voiding diary. Univariate and multivariate analyses were computed to identify clinical, pathological, and functional predictors of global QoL score.

**Results** Seventy-three patients completed questionnaires. The median age was 64 years and 86.3% were men. The median interval between surgery and responses to questionnaires was 36 months (range 12–96). Fifty-five percent of patients presented a high global QoL (EORTC-QLQC30, median score 75). A pre-RC American Society of Anesthesiologists score > 2, active neoplasia, sexual inactivity, and stress urinary incontinence were associated with a worse QoL. After a multivariate analysis, sexual inactivity was the only independent factor related to an altered QoL.

**Conclusion** Patients with IONB reconstruction after RC have a high global QoL. Sexual activity could independently impact the global QoL, and it should be assessed pre- and post-operatively by urologists.

**Keywords** Radical cystectomy · Ileal orthotopic neobladder · Bladder cancer · Quality of life · Functional outcomes · Name of questionnaires

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## Introduction

Radical cystectomy (RC) following neoadjuvant chemotherapy is the standard-of-care for muscle-invasive bladder cancers (BCa) as well as selected high risk, non-muscle-invasive ones [1]. RC oncologic results have been assessed and are well described in literature [2]. In selected patients undergoing RC, ileal orthotopic neobladder (IONB) reconstruction is currently the preferred method for urinary diversion, especially since it allows the preservation of body image [3]. A growing interest in quality-of-life (QoL) parameters in Uro-oncology has been highlighted [4]. RC has been described as one of the most traumatic oncologic surgeries in terms of QoL impairment [5]. The relationship between QoL and urinary diversion remains controversial. According to published data, IONB urinary diversion was associated with marginally better QoL scores when compared to ileal conduit (IC) diversion [6, 7]. This was confirmed in a meta-analysis of non-randomized comparative studies ( $p < 0.0001$ ) [8]. There is a lack of data considering QoL and long-term urinary and sexual functional outcomes in patients who underwent IONB.

The primary endpoint of our study was to assess QoL parameters in patients who underwent RC with IONB substitution for BCa. Secondary endpoints were to assess the long-term functional outcomes of IONB and identify clinical, oncological and functional factors related to global QoL.

## Patients and methods

### Study design

We conducted a non-interventional, multicentre, retrospective study on BCa patients who underwent an RC with IONB urinary diversion. Patients from three public centres were included: two university hospitals and one general hospital. All patients who underwent surgery between January 2010 and February 2017, at one of these three hospitals received our questionnaires. We contacted patients by e-mail, phone and post, at least three times before considering them as lost. The following patients were excluded: death, participation refusal, follow-up lost and patients who had an IONB removal at the time of the questionnaires.

### Variables

The following clinical-pathologic variables were extracted from the patients' medical charts: age at the time of surgery, sex, body mass index ( $BMI = kg/m^2$ ), pathological tumour node metastasis (pTNM) stage as defined by the Union for

International Cancer Control [9], comorbidities (defined as prior abdomino-pelvic surgery and cardiovascular diseases), short-term ( $< 90$  days) post-operative Clavien–Dindo [10] complications and long-term ( $> 1$  year) complications. Data were collected with the agreement of our Ethics Committee “French Data Protection Authority” (CNIL n°2139966v0).

### Quality of Life and Functional Assessment

The patients completed the following four self-reported questionnaires: the European Organization for Research and Treatment of Cancer (EORTC) generic (QLQ-C30) and BCa-specific instruments (QLQ-BLM30), the Urinary Symptoms Profile (USP), and a complete three-day voiding diary. The EORTC QLQ-C30 has been validated [11] and incorporated nine multi-item scales: five functional scales (Physical, Role, Cognitive, Emotional and Social Functioning); three symptom scales (Fatigue, Pain and Nausea/Vomiting); and a Global Health Status/QoL (gHS/QoL) scale [11]. Six single-item scales were also included (Dyspnea, Insomnia, Loss of appetite, Constipation, Diarrhea and Financial Difficulties). Regarding the functional and gHS/QoL scales, a high-scale score represented a high/healthy level of functioning (score from 0 to 100). Regarding the symptoms scales and single items, a high-scale score represented a high level of symptomatology (0–100). Concerning gHS/QoL in the EORTC QLQ-C30 questionnaire, a cut-off score of 70 has recently been defined as the cut-off between a high and a low QoL population [12]. The QLQ-BLM30 is a 30-item questionnaire, designed for patients who underwent a RC for BCa [13]. It assessed urinary, bowel and sexual symptoms, difficulties associated with the use of a catheter, and body image. A high score represented a high level of symptomatology (0–100). The USP is a validated instrument [14] including eleven items that assess three symptom scores: stress urinary incontinence (SUI), overactive bladder, and low stream. A high score represented a high level of symptomatology. The three-day voiding diaries assessed daily diuresis, voiding frequency, nocturia, IONB functional capacity, continence status, and pad-wearing habits.

### Statistical analysis

Continuous variables were presented as median, interquartile range (IQR) and number of missing data. The association between gHS/QoL score and variables (from the EORTC-QLQC30 and the EORTC BLM30) was assessed using the Mann–Whitney test for categorical variables, or the Spearman's rank correlation coefficient ( $r$ ) for continuous variables. A multivariable logistic regression model was performed to identify independent factors associated with high or low gHS/QoL. All reported  $p$  values were two-sided with

a 5% significance level. The statistical analyses were performed using STATA Version 13 software.

## Results

### Patients' characteristics

A total of 162 patients underwent RC with IONB diversion for BCa between 2010 and 2017. Among them, 73 (45%) responded to our questionnaires (Suppl Fig. 1). The patients' baseline characteristics are presented in Table 1. Median age at surgery was 64 years old. The median time between RC and responses to questionnaires was 36 months (range 12–96). RC was conducted by open laparotomy in

55 patients (77.3%) and by robot assisted laparoscopy in 18 patients (24.7%).

### Quality-of-life assessment

The median gHS/QoL score was 75 (Suppl Fig. 2). The highest levels of functioning scale appeared in these three domains: “role”, “cognitive” and “social” domains (Suppl Fig. 3a). Fatigue was the only symptom that was reported by more than half of the respondents (Suppl Fig. 3b). Most of the patients signalled no digestive disorders, no pain, no dyspnea, no insomnia and no financial difficulties. The most frequent symptoms were sexual symptoms, whereas urinary symptoms were the least reported (Suppl Fig. 3c). Importantly, the sexual domain of the EORTC QLQ-BLM30 questionnaire was calculated only for patients who were sexually active (32/75, 44.4%). Then, we analysed the impact of symptoms and functions on gHS/QoL with a correlation test. Preserved social, emotional, role and physical functions were positively associated with a gHS/QoL improvement. Among all the symptoms scales, fatigue ( $r = -0.64$   $p = 0.001$ ) and pain ( $r = -0.54$ ;  $p = 0.001$ ) were those that mostly impacted gHS/QoL in a negative way (Fig. 1). Indeed, sexual symptoms also deteriorated gHS/QoL.

**Table 1** Patient characteristics

|  |                  |
|--|------------------|
| Number, <i>n</i>   | 73               |
| Age, year, median (IQR)                                    | 64 (58–68)       |
| Follow up time, months, median (IQR)                       | 36 (20–54)       |
| BMI (kg/m <sup>2</sup> ), median (IQR)                     | 25.3 (23.6–27.7) |
| Sex, <i>n</i> (%)  |                  |
| Male   | 63 (86.3)        |
| Female   | 10 (13.7)        |
| ASA score, <i>n</i> (%)                                    |                  |
| 1  | 9 (12.9)         |
| 2  | 51 (72.9)        |
| 3  | 10 (14.3)        |
| Missing  | 3                |
| Comorbidities, <i>n</i> (%)                                |                  |
| Prior abdomino pelvic surgery                              | 27 (37.0)        |
| Prior pelvic radiotherapy                                  | 0 (0)            |
| Cardiovascular disease                                     | 17 (23.6)        |
| Prior intravesical instillation                            | 21 (28.8)        |
| Pathological stage before radical cystectomy, <i>n</i> (%) |                  |
| ≤ T1   | 18 (24.7)        |
| ≥ T2   | 55 (75.3)        |
| Neoadjuvant chemotherapy, <i>n</i> (%)                     | 36 (49.3)        |
| Cystectomy techniques, <i>n</i> (%)                        |                  |
| Open   | 55 (75.3)        |
| Robotic assisted   | 18 (24.7)        |
| Urinary diversion type, <i>n</i> (%)                       |                  |
| Hautmann   | 52 (71.2)        |
| U-shape  | 13 (17.8)        |
| Camey II   | 4 (5.4)          |
| Annerstedt   | 2 (2.8)          |
| Z-shape  | 2 (2.8)          |
| Post-RC oncologic status                                   |                  |
| Active neoplasia (Bladder and/or others)                   | 10 (13.7)        |
| No active neoplasia  | 63 (86.3)        |

RC radical cystectomy, IQR interquartile range, BMI Body mass Index

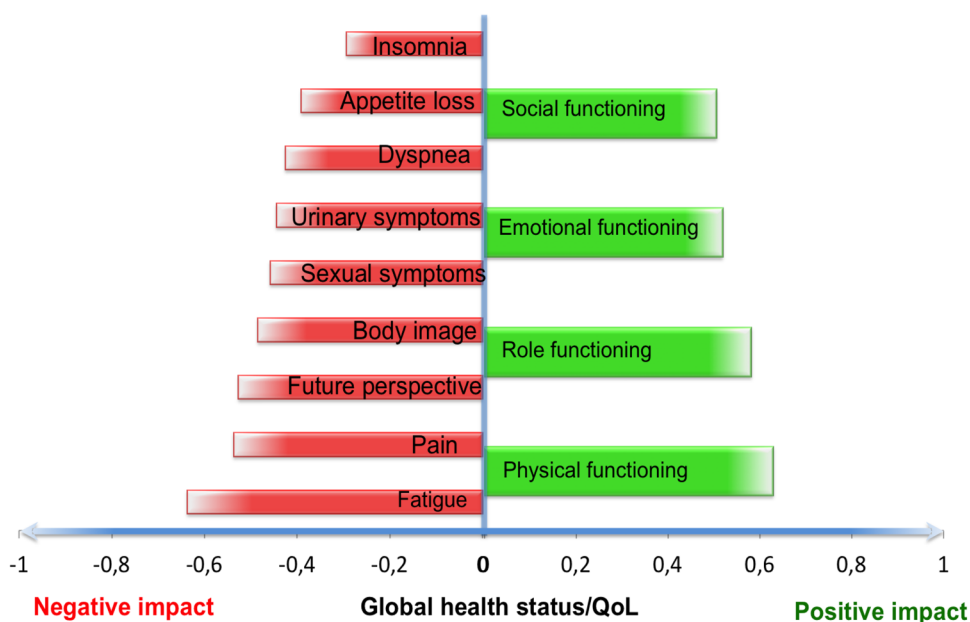
### Long-term IONB functional outcomes

Most of the patients were not totally continent when filling in the USP questionnaire (Suppl. Table 1 and Suppl. Fig. 4a): 64.3% had SUI and nocturnal enuresis (50% > once a week). As regards voiding, eight patients (11%) needed to perform self-intermittent catheterisation due to chronic neobladder retention. Forty-seven patients completed the voiding diary (Suppl. Table 1 and Suppl. Fig. 4b). Median diuresis volume on a full day was 2173 ml (IQR 1750–2503). Median number of times micturition in a day was 5.7 (IQR 5–6.6) and 1.5 (IQR 0.6–2) at night. The median functional bladder capacity was 400 ml (IQR 293–547).

### Univariate and multivariate analyses of factors related to EORTC QLQ-C30 global HS/QoL

Univariate analyses are described in Supplementary Table 2. Patients with a preoperative ASA score > 2 and with an active neoplasia at the time of the questionnaires had a significantly worse gHS/QoL compared to others. SUI significantly impacted gHS/QoL. Sexually active patients showed a significantly better gHS/QoL compared to those being sexually inactive (83.3 vs. 66.6,  $p = 0.026$ ). No sexuality was associated with lower gHS/QoL (OR 0.27; 95% CI 0.09–0.86), and it was the only independent factor related to gHS/QoL in multivariate analysis (Table 2).

**Fig. 1** Significant correlations between gHS/QoL and functions and symptoms scales (from the EORTC QLQ C30 and EORTC BLM30). In green, positive correlations between functions scales and gHS/QoL. In red, negative correlations between symptoms and gHS/QoL. Only factors that significantly impacted gHS/QoL with a  $p$ -value  $< 0.05$  are represented; Horizontal axis = rho calculated with the Spearman correlation test. gHS/QoL: global health status/ quality of life



**Table 2** Multivariate analysis of factors associated with EORTC QLQ-C30 gHS/QoL scale

|                             | OR   | 95% CI    | P            |
|-----------------------------|------|-----------|--------------|
| ASA score 3                 | 0.23 | 0.05–1.15 | 0.073        |
| Active neoplasia            | 0.24 | 0.05–1.16 | 0.075        |
| Stress urinary incontinence | 0.42 | 0.13–1.40 | 0.159        |
| No sexual activity          | 0.27 | 0.09–0.86 | <b>0.027</b> |

CI confidence interval, OR odds ratio, ASA American Society of Anesthesiologists

Significant values are represented in bold

## Discussion

To our knowledge, our study is the first one that offers a specific focus on clinical, neoplastic and functional factors related to gHS/QoL in a population who underwent RC and IONB reconstruction for BCa. One of the advantages of this study was to present a long-term specific assessment of sexual and urinary functional outcomes with self-reported and validated questionnaires. This will be extremely valuable to inform our future patients.

The gHS/QoL in our population was comparable to other studies using the same EORTC QLQ-C30 questionnaire to assess QoL in post-RC-IONB patients (71.2 mean score in our study, 88.8 and 64.9 in two others [15, 16]). Interestingly, we observed that the mean gHS/QoL in our population was very close to another study of a European population with almost the same age without cancer [17], and more different from all cancer populations with EORTC QLQ-C30 reference values [18]. Considering

gHS/QoL as a continuous variable, a 70 cut-off score has been recently defined to separate high from low gHS/QoL among patients with active neoplasia, to identify those patients with unmet needs for further support [12, 19]. Hence, we can state that 55% of our cohort presented a high gHS/QoL. Three main aspects could explain this. First, most of our patients described a low level of symptomatology. Second, only few patients ( $n = 10/73$ ) had an active neoplasia which greatly impaired QoL (the EORTC reference value for mean gHS/QoL of people with cancer is 56.3) [18]. Finally, our population showed a good preoperative health status which may explain the good postoperative gHS/QoL.

Regarding patient-derived outcomes, we found that age had no significant impact on gHS/QoL. This finding is backed up by recent publications indicating that RC-IONB replacement can be safely performed even among a cohort of elderly patients [20]. No significant differences between QoL and post-operative time course were observed. Our results are in line with Kretschmer et al. findings who showed no potential time course in QoL patients after orthotopic urinary diversion [21]. Preoperative health status, evaluated with ASA score, had a significant impact on postoperative QoL. Given that QoL measurements take multiple aspects into consideration, including physical status, general health and social interaction, it seems intuitive that patients with a better preoperative health status benefit more from a procedure that aims to allow an unaltered, active lifestyle.

Neobladders are a form of continent urinary diversion but are not free of continence issues. Continence was defined as the full absence of urinary leaks during the week prior to the answers of the USP questionnaire. Continence rates vary

depending on the surgical technique used, the time after the operation and the moment of the day [22]. In our study, the total continence rate was 14.1%. This rate is low compared to other reports that show total continence rates ranging up to 58% [23, 24]. This may be explained by the strict definition of continence and the real-life self-reported status, compared to other studies where, often, one pad is considered as continence. For daytime continence, we chose to detail urinary symptoms through the USP questionnaire rather than only reporting a continence rate, as in many studies. In this way, we had a much better view of the urinary leakage situation. To our knowledge, we are the first to report the use of an USP questionnaire to assess SUI and UUI in a general RC-IONB population. SUI was significantly associated in an univariate analysis with worse gHS/QoL, in line with other studies [25, 26]. Patients with a neobladder are generally less continent at night than during the day. Half of our patients showed correct night-time continence with  $\leq$  once a week nocturnal enuresis. This score falls within the range of previous studies showing that between 23% and 77.6% of patients were continent at night three years after surgery [27, 28]. We noted a high prevalence of nocturnal polyuria among 58% of our patients. As far as we know, this is the first study to report a nocturnal polyuria rate in an IONB population.

Effects on erectile and sexual functions are important considerations after RC. All patients received the questionnaire concerning sexual symptoms. Only 44.4% of our patients were sexually active after surgery, and they suffered from a high level of symptomatology in their sexuality. However, patients who declared no sexual activity did not answer the following questions regarding sexual symptoms. This induced a bias because the lack of sexual activity could be a consequence of an important sexual dysfunction secondary to the surgery. It is commonly accepted that a significant proportion of patients presents a sexual dysfunction after an orthotopic bladder replacement [29]. Indeed, only 23.7 to 35.5% of patients could achieve erections after neobladder diversion [30, 31]. We observed that sexually active patients had a better QoL. Sexual activity was the only factor independently related to gHS/QoL in the multivariate analysis. Kretschmer *et al.* showed that a high erectile function score (IIEF-5) and nerve-sparing were associated with better QoL in their RC-IONB population [21]. Such a positive association between sexual activity and a better QoL in post-RC populations is not extensively described in literature. Nevertheless, studies from large prostate cancer reports showed better QoL outcomes after nerve-sparing prostatectomies highlighting the impact of sexual preservation after major pelvic surgery [32]. In the same way, it was found that nerve-sparing cystectomies produce better sexual outcomes compared to standard cystectomies [33]. Another limitation is the lack of information regarding the preservation of neuro-vascular bundles. In our clinical practice, preservation is decided

case by case on selected patients, according to prior sexuality and carcinoma extension. Further studies are needed to assess the efficacy of nerve-sparing cystectomies on global QoL.

Our study assesses the impact of both clinical and functional outcomes of IONB on gHS/QoL after RC. It shows QoL analyses from various follow-up periods, providing an idea of the QoL natural process after RC. A major drawback was the retrospective design that did not allow stratification, and the fact that it did not measure QoL at specific time points either. Other limitations were the lack of a baseline QoL assessment in the pre- or peri-operative period, to assess the short-term impact of the surgery and compare it to the long-term data. The response rate was only 45%. It might be partly explained by the high mortality due to urothelial carcinoma (22.8% people were died at the time of questionnaire) (Suppl. Figure 1). This suggests a bias on whether those with better QoL were the ones who decided to answer to the questionnaire. However, this response rate is in line with other studies. For instance, two other studies using same questionnaires obtained a response rate of 34% and 11.2% [7, 20].

In conclusion, patients operated by RC with IONB urinary diversion had a high global QoL at long-term follow-up. A high pre-RC ASA score and post-RC active neoplasia were related to gHS/QoL impairment. Functional issues, such as SUI and sexual inactivity, led to a lower gHS/QoL. Sexual activity independently impacted gHS/QoL after RC-IONB replacement; thus, urologists should assess this disorder pre- and post-operatively to solve it.

**Author contributions** VT: Protocol/project development, Data collection, Manuscript writing. BC: Data analysis. GV, JG, PC, JZ, MT, MS, XG: Data collection. JBB: Protocol/project development, Manuscript writing. EPT: Manuscript writing. MR: Protocol/project development.

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**Availability of data and material** The data that support the findings of this study are available from the corresponding author (VT) upon reasonable request.

## Compliance with ethical standards

**Conflict of interest** All authors had nothing to disclose.

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