



## **Quality of life associated with orthotopic neobladder and ileal conduit in women: A multicentric cross-sectional study**

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**Title:** Quality of life associated with orthotopic neobladder and ileal conduit in women: A multicentric cross-sectional study

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## INTRODUCTION

Anterior pelvic exenteration with urinary tract diversion is currently considered the standard of care in women with non-metastatic muscle invasive bladder cancer or non-muscle invasive bladder cancer after failed intra-vesical therapy [1]. Although, it is associated with satisfying mid-term oncological outcomes, this invasive procedure has regularly been reported to significantly decrease quality of life [2]. In order to limit this potential impact, orthotopic neobladder (ONB) has been suggested as an interesting alternative to the classical ileal conduit diversion (IC) [3]. Indeed, such a reconstructive surgery is supposed to minimize the alteration of the body image, while maintaining micturitions through the urethra, without increasing peri-operative complications [4–6]. However, it has been reported to expose the patient to specific long-term complications, such as urinary incontinence or urinary retention requiring the introduction of intermittent self-catheterization [7,8]. Furthermore, its impact on quality of life has rarely been studied in women, nor even directly compared to IC [9]; when results issued from male cohorts have recently been reported to be contradictory [10–12]. Thus, there is an urgent need to evaluate the gain in quality of life provided by ONB in the female population.

The present multicentric cross-sectional study aimed to retrospectively compare quality of life and functional outcomes associated with ONB and IC after anterior pelvic exenteration for bladder cancer in women.

## **METHODS**

### **General Methodology**

The protocol has been approved by the French Advisory Committee on Information Processing in Material Research in the Field of Health (n° 15.957). All women which have undergone an anterior pelvic exenteration associated with ONB or IC for a bladder cancer between January 2004 and December 2014 and that were still alive in February 2016 were considered eligible. The present work was designed as a multicentric cross-sectional study, implicating 3 French university hospital centres and was carried out in the first half of year 2016. After data collection and participation agreement, all included patients were asked to fill-in 3 distinct quality of life auto-administered questionnaires. Epidemiological, oncological and surgical data were firstly extracted from computerised medical record. Epidemiological data included date of birth, weight (kg), high (m), ECOG-PS (Eastern Cooperative Oncology Group Performance Status) and ASA score (American Society of Anaesthesiologists score) at the time of surgery. Oncological data included the history of a neo-adjuvant therapy - cytotoxic chemotherapy or radiation therapy - the histological type, the cytological grade, the pTNM stage - tumour, node, metastasis - according to the 2004 WHO (World Health Association) classification of bladder tumour, the occurrence of a post-operative recurrence and the need for an adjuvant therapy - cytotoxic chemotherapy or radiation therapy. Surgical data included the type of surgical approach - laparotomy or laparoscopy - and the presence of a sparing surgery - vagina or uterus sparing surgery. A phone call was then planned to obtain verbal participation agreement. During the same interview, the patients were asked about the maintenance of a regular sexual activity. In patients with ONB, urinary incontinence - defined as the occurrence of >1 urinary leakage during the last week - and the need to perform self-intermittent catheterization to empty the bladder were also specified.

The EORTC QLQ-C30 (European Organisation for Research and Treatment of Cancer generic questionnaire), the EORTC QLQ-BLM30 (European Organisation for Research and Treatment of Cancer muscle invasive bladder cancer module) and the SF-12 (Short Form health survey) questionnaires were sent by post accompanied with an information sheet and a written participation agreement to complete. The EORTC QLQ-C30 questionnaire has been validated to specifically assess the quality of life and the importance of related-disease symptoms associated with oncological pathologies. Different aspects of the quality of life are explored through 6 distinct sub-scores: “global health status”, “physical functioning”, “role functioning”, “emotional functioning”, “cognitive functioning” and “social functioning”. Each of these sub-scores is quoted from 0 to 100, with a higher value corresponding to a better quality of life or a better functioning. Similarly, 9 distinct related-disease symptoms are successively explored and quoted from 0 to 100, with a higher value corresponding to a higher disturbance. The EORTC-QLQ BLM30 questionnaire has been validated to specifically assess the quality of life associated with muscle-invasive bladder cancer. The urinary, digestive and sexual symptoms and functioning as well as the body image are successively explored and quoted from 0 to 100, with a higher score corresponding to a better functioning or a better body image acceptance. The SF-12 is a more generic questionnaire that has been validated to assess quality of life without focusing on any specific conditions. It is constituted of 2 distinct sub-scores: the “physical health” sub-score as well as the “mental health” sub-score for which a maximal note of 56.6 and 60.8 is attributed, respectively. Here, a higher value corresponds to a better quality of life.

### **Primary endpoint**

The primary endpoint was the “global health status” sub-score extracted from the EORTC QLQ-C30 questionnaire.

## **Secondary endpoints**

The secondary endpoints were the functional sub-scores and symptoms sub-scores obtained with the EORTC QLQ-C30 questionnaire as well as the sub-scores obtained with the EORTC QLQ-BLM30 and the SF-12 questionnaires. Regarding “sexual functioning” assessed using the QLQ-BLM30 questionnaire, we reported data issued from the overall population as well as from the sexually active population, defined by a sexual activity in the last 4 weeks.

## **Statistical analysis**

Data are expressed as median [range] for quantitative variables and count (percentage) for categorical variables. Patients, tumour and surgical procedure characteristics were compared between women with ONB and those with IC. Quantitative variables and ordered categorical variable were compared with Mann-Whitney U tests and categorical variables with Fisher's exact tests. No statistical comparison was done for categorical variables with a modality frequency <5. Comparison of response to the EORTC QLQ-C30, QLQ BLM30 and SF-12 questionnaires between women with ONB and those with IC were studied with Mann-Whitney U tests. Statistical testing was conducted at the two-tailed  $\alpha$ -level of 0.05. Data were analysed using the SAS software version 9.4 (SAS Institute, Cary, NC).

## **RESULTS**

### **Patients characteristics**

Between January 2004 and December 2014, within the 3-participating university hospital centres, 113 women have undergone an anterior pelvic exenteration associated with ONB or IC for a bladder tumour. 56 women were still alive in February 2016. Among them, 8 women were not interested or able to participate and 8 more were lost of follow-up at the time of inclusion. 40 women were finally included in the study (17 ONB, 23 IC).

Women with ONB were significantly younger (60.0 [47.0-75.0] vs 71.0 [37.0-84.0],  $p = 0.008$ ) and presented with a significantly lower ASA score ( $p = 0.005$ ) at the time of surgery when compared with IC (Table 1). None of the 40 included women received any neo-adjuvant therapy, and, at the time of surgery, all women were considered to be metastasis free. Adjuvant therapy was administered in 1 woman with ONB (1 radiotherapy) and in 2 women with IC (1 cytotoxic chemotherapy and 1 radiotherapy). Recurrence was diagnosed in 1 ONB woman as well as in 1 IC woman after a follow-up of 77 and 16 months, respectively. Tumour characteristics at the time of surgery were comparable between the two types of urinary diversion (Table 1). In women with ONB, vagina sparing surgery was significantly more frequent when compared with IC (35.3% vs 4.4%,  $p=0.030$ ) (Table 1). The maintenance of a regular sexual activity at the time of questionnaires submission was reported in 5 (29.4%) women with ONB and 2 (8.7%) women with IC ( $p=0.11$ ). Among ONB women, 10 (58.8%) reported >1 episode of urinary incontinence during the last week and 7 (41.2%) used to perform self-intermittent catheterization on a regular basis.

Women with IC were significantly older at the time of questionnaires submission when compared with ONB (65.0 [57.0; 77.0] vs 75.0 [40.0; 86.0],  $p = 0.015$ ), while the delay between surgery and questionnaires completion – expressed in months - were comparable between the two types of urinary diversions (42.0 [18.0 ; 137.0] vs 50.0 [4.0 ; 109.0],  $p=0.64$ ).

### **Primary endpoint**

The primary endpoint defined as the “global health status” sub-score extracted from the EORTC QLQ-C30 questionnaire was comparable between the ONB and IC women (83.3 [16.7; 100.0] vs 66.7 [33.3; 100.0]  $p=0.22$ ) (Table 2, Fig1).

## **Secondary endpoints**

All quality of life sub-scores and the symptoms sub-scores obtained with the EORTC QLQ-C30 questionnaire (Table 2, Fig1) as well as the functional sub-scores obtained with the EORTC QLQ-BLM30 questionnaire (Table 2, Fig2) were comparable between the ONB and IC women. Similarly, no statistical difference could be pointed out in terms of “physical health” sub-score and “mental health” sub-score obtained with the SF-12 questionnaire between the two types of urinary diversions (Table 2, Fig3).

## **DISCUSSION**

In the present study, no significant differences were reported in terms of quality of life and functional outcomes between women with ONB and IC following anterior pelvic exenteration for bladder cancer after a median follow-up of 42.0 months and 50.0 months, respectively. Only a trend was observed in the “physical functioning” sub-score obtained with the EORTC-QLQ-C30 questionnaire, which tended to be higher in the ONB group. This result, corresponding to a higher aptitude to perform daily activities, has probably more to do with the younger age and the lower ASA score in this group than with the type of urinary diversion itself. In fact, it seems important to note that in spite of a lower age and less comorbidities, the ONB group did not present any significant differences in terms of quality of life and functional outcomes when compared with the IC group.

Similar results have already been demonstrated in a smaller series. Gacci et al. compared 9 women with ONB to 16 women with IC after anterior pelvic exenteration performed for bladder cancer through a cross-sectional study [9]. These patients were submitted to different auto-administered questionnaires, including the EORTC QLQ-C30 and the EORTC QLQ-BLM30, more than 36 months after surgery.



The authors did not report any significant difference between these two types of urinary diversions. As supported by recent publications, we think that the specific problems encountered with the ONB, such as urinary incontinence and the requirement of self-intermittent catheterization for urinary retention may partly explain the absence of gain in terms of quality of life associated with the confection of ONB in our cohort. Indeed, in a study conducted on 89 patients (women = 95%) after ONB, Henningsohn et al. demonstrated that the introduction of self-intermittent catheterization for urinary retention was associated with a significant increase in the level of anxiety [8]. Within our study, nearly half of the patients with ONB reported to regularly perform self-intermittent catheterization at the time of questionnaires submission. Furthermore, Zahran et al. recently assessed the impact of urinary incontinence on quality of life in women with ONB using the EORTC QLQ-C30 questionnaire [7]. Among the 74 included patients, 29 (39,2%) reported urinary incontinence. In these patients, the “global health status” sub-score and the “social functioning” sub-score was significantly lower when compared with continent patients. Within our cohort, more than half of the women with ONB reported urinary incontinence at the time of questionnaires submission. As a result, according to Hedgepeth et al., more than the respect of the body image, the satisfactory function of the urinary derivation - whatever its type - is fundamental in maintaining a good quality of life after pelvic exenteration [13].

Because the advantage of the ONB over the IC could have been considerably limited by the important rate of urinary incontinence and urinary retention associated with it, we assume that the future efforts to gain in quality of life associated with urinary diversion in women after pelvic exenteration should follow two distinct axes. Firstly, an effort has to be made in improving the ONB function. This step should include a complete pre-operative assessment - in order to select the women that will most benefit of a ONB - associated with improvement

in technical aspects of the reconstruction. As a second axe, we assume that the place of continent pouches has to be reconsidered in this indication. Therefore, we advocate further studies to directly compare the quality of life and functional outcomes associated with ONB and continent pouches after pelvic exenteration in women performed for bladder cancer.

To our knowledge, the present study is currently the largest one to compare quality of life and functional outcomes between ONB and IC performed after pelvic exenteration for bladder cancer in women. The large panel of validated auto-administered questionnaires allowed us to precisely assess the quality of life, the related-disease symptoms as well as the urinary, digestive and sexual functions associated with these two types of urinary diversions. However, we agree with the limitation due to a potential lack of power associated with our study. Indeed, it seems reasonable to think that a larger cohort could have shown a significant difference between the two types of urinary diversion in terms of quality of life and/or functional outcomes. Furthermore, the absence of pre-operative assessment as well as the lack of bladder diary, pad-test and measurement of the post-void residual volume within ONB women, could have made our evaluation difficult to interpret. Moreover, the results regarding the sexual functioning should be taken with caution due to the small numbers of women reporting an active sexual life at the time of questionnaires submission. Finally, it is important to note that the French version of the QLQ-BLM30 questionnaire has not been fully validated by the EORTC.

Although the present data will not allow any definitive conclusion, they constitute preliminary data for future research. Therefore, the results reported here, will undoubtedly help research protocols, comparing quality of life and functional outcomes between ONB and IC in women, to be designed.

## **CONCLUSION**

In this multicentric, retrospective series, we found no evidence, in a context of anterior pelvic exenteration for bladder cancer, that ONB is superior to IC in terms of quality of life. Further prospective studies are needed to validate our findings.

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## **CONFLICT OF INTEREST**

The authors have no conflict of interest to declare.

## **ABBREVIATIONS**

ASA score : American Society of Anaesthesiologists score

ECOG-PS : Eastern Cooperative Oncology Group Performance Status

EORTC QLQ-BLM30 : European Organisation for Research and Treatment of Cancer muscle  
invasive bladder cancer module

EORTC QLQ-C30 : European Organisation for Research and Treatment of Cancer generic  
questionnaire

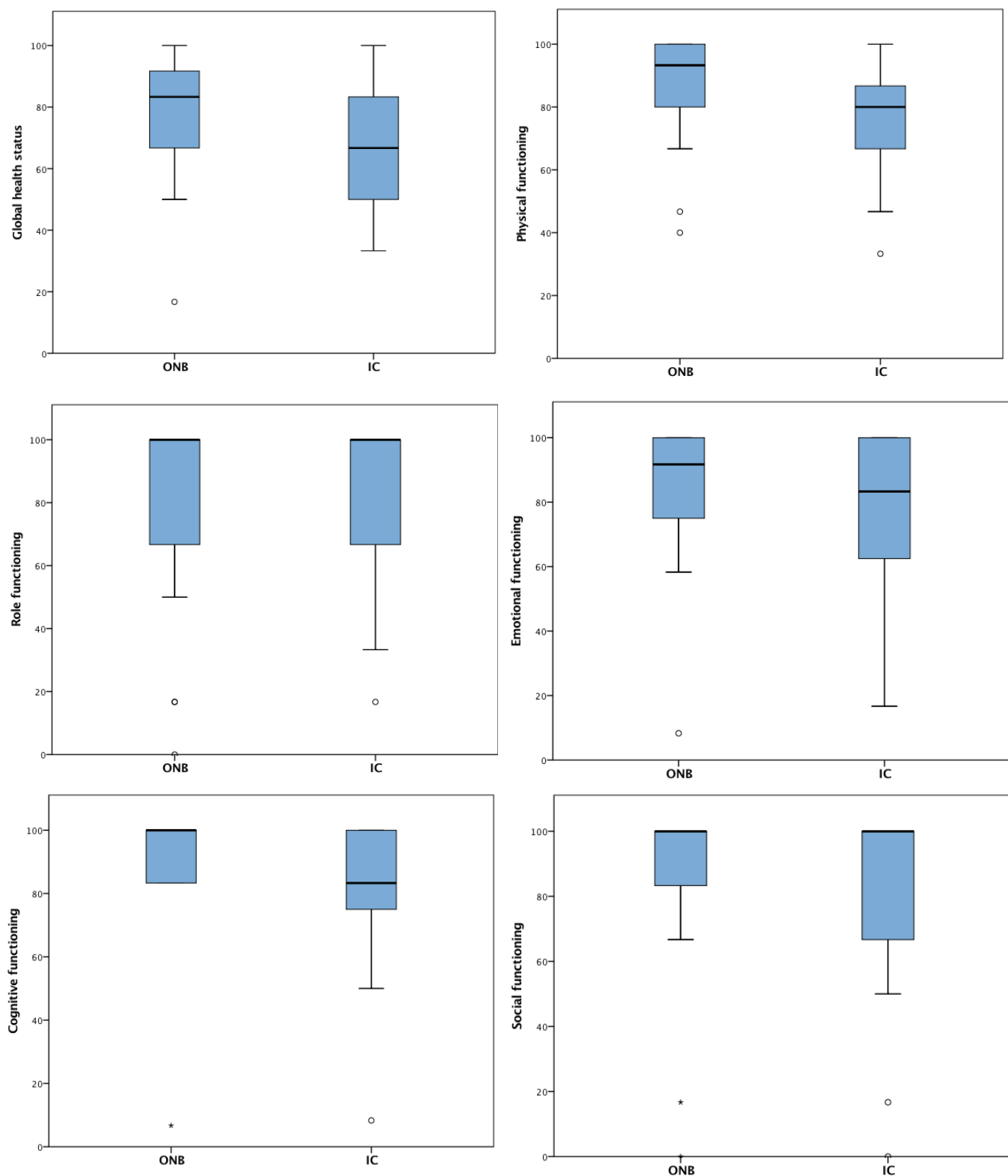
IC : Ileal conduit

ONB : Orthotopic neobladder

SF-12 : Short Form health survey

WHO : World Health Association

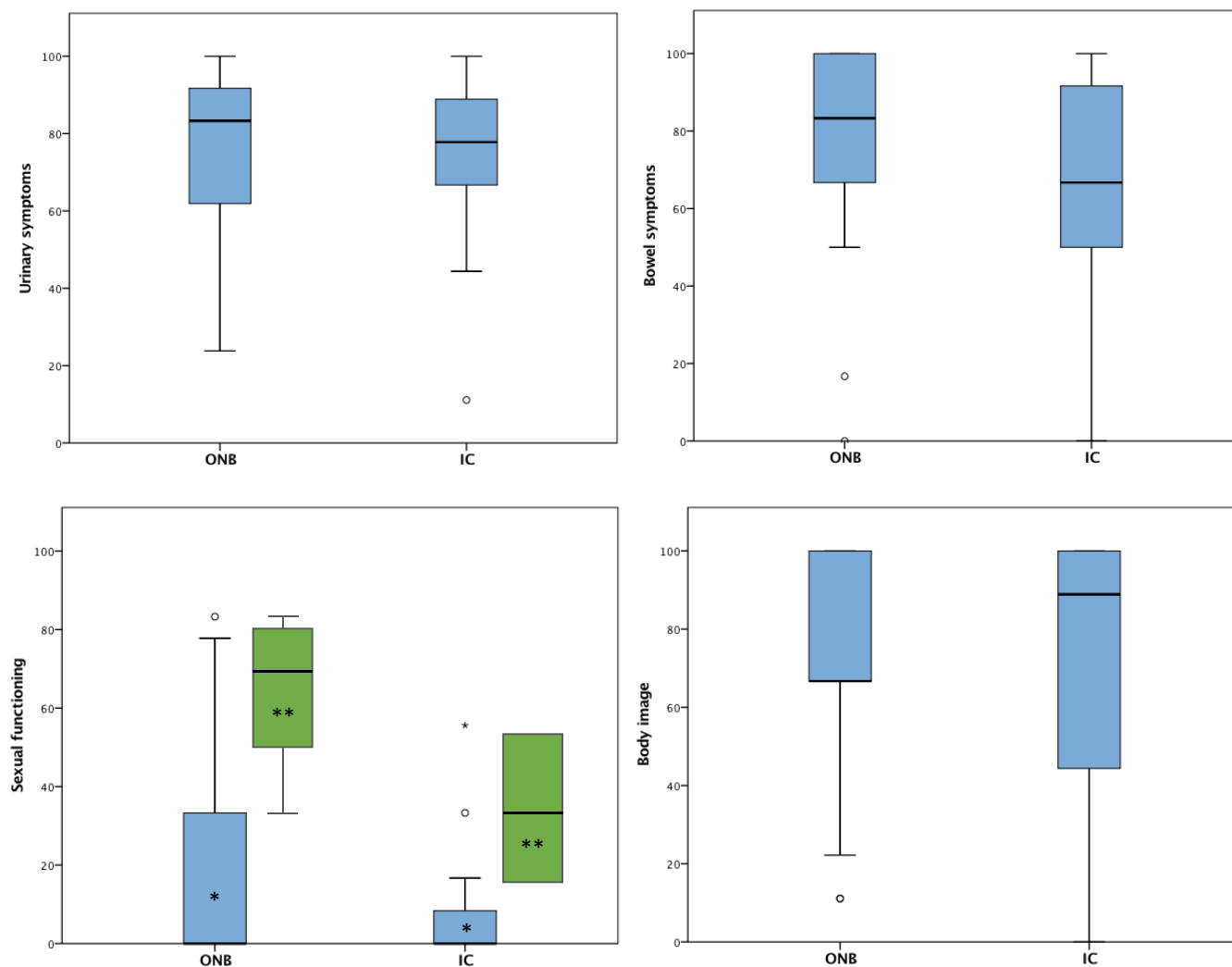
**Figure 1: Distribution of sub-scores issued from the EORTC QLQ-C30 questionnaire between women with ONB and those with IC – Boxplots**



ONB: Orthotopic neobladder; IC: Ileal conduit

Each of these sub-scores is quoted from 0 to 100, with a higher value corresponding to a better quality of life or a better functioning.

**Figure 2: Distribution of sub-scores issued from the EORTC QLQ-BLM30 questionnaire between women with ONB and those with IC – Boxplots**



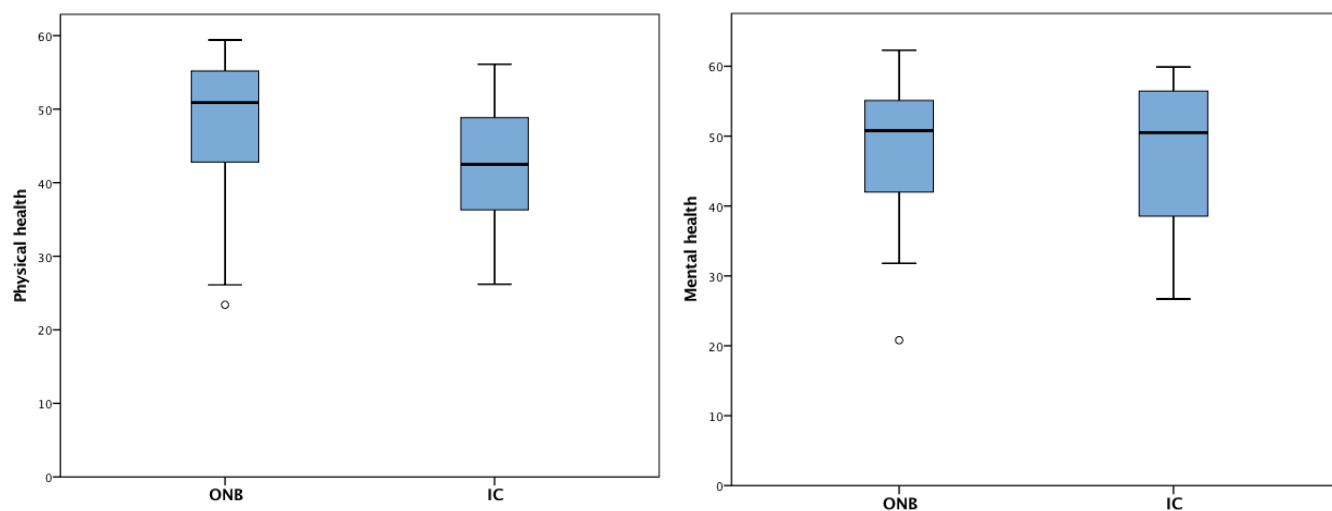
ONB: Orthotopic neobladder; IC: Ileal conduit

Each of these sub-scores is quoted from 0 to 100, with a higher score corresponding to a better functioning or a better body image acceptance.

\*: overall

\*\* : sexually active patients (5 ONB patients and 2 IC patients)

**Figure 3: Distribution of sub-scores issued from the SF-12 questionnaire between women with ONB and those with IC – Boxplots**



ONB: Orthotopic neobladder; IC: Ileal conduit

The “Physical health” and the “Mental health” sub-scores are quoted from 0 to 56.6 and 0 to 60.8, respectively, with a higher value corresponding to a better quality of life.



**Table 1: Comparison of population, tumor and surgical procedure characteristics between women with ONB and those with IC**

	ONB N = 17		IC N = 23		p-value
Population characteristics at the time of surgery					
Age	Median [range]	60.0 [47.0-75.0]	71.0 [37.0-84.0]		0.008
BMI	Median [range]	23.2 [18.9-29.4]	24.7 [0.0-35.8]		0.45
ECOG PS					
0		15 (88.2%)	16 (69.6%)		0.26
1		2 (11.8%)	7 (30.4%)		
≥ 2		0 (0.0%)	0 (0.0%)		
ASA score					
I		7 (41.2%)	1 (4.4%)		0.005
II		9 (52.9%)	17 (73.9%)		
≥ III		1 (5.9%)	5 (21.7%)		
Tumor characteristics at the time of surgery					
Histological type					
Transitional cell carcinoma		16 (94.1%)	21 (91.2%)		NA
Other histological types		1 (5.9%)	2 (8.8%)		
Cytology					
Low grade		2 (11.8%)	3 (13.0%)		1.00
High grade		15 (88.2%)	20 (87.0%)		
pT stage					
pT0		5 (29.4%)	4 (17.4%)		0.60
pTcis-pT1-pT2		7 (41.2%)	9 (39.1%)		
≥ pT3		5 (29.4%)	10 (43.5%)		
pN stage					
pN0		15 (88.2%)	18 (78.3%)		0.68
≥ pN1		2 (11.8%)	5 (21.7%)		
Surgical procedure characteristics					
Surgical approach					
Laparotomy		15 (88.2%)	21 (91.2%)		NA
Laparoscopy		2 (11.8%)	2 (8.8%)		
Sparing surgery					
Vagina sparing surgery		6 (35.3%)	1 (4.4%)		0.030
Uterus sparing surgery		5 (29.4%)	2 (8.7%)		0.11
Population characteristics at the time of questionnaires submission					
Age	Median [range]	65.0 [57.0-77.0]	75.0 [40.0-86.0]		0.015
Delay from surgery (months)	Median [range]	42.0 [18.0-137.0]	50.0 [4.0-109.0]		0.64
Active sexual life		5 (29.4%)	2 (8.7%)		0.11

Values are expressed with number (percentage) unless otherwise indicated.

*p* values were computed using fisher's exact tests for categorical variables and Quantitative and ordinal variables were compared with Mann-Whitney U tests. NA= not applicable for case of small sample.

**Table 2: Comparison of response to questionnaires between women with ONB and those with IC**

	ONB N = 17		IC N = 23		p-value
EORTC QLQ-C30					
Global health status	83.3	[16.7-100.0]	66.7	[33.3-100.0]	0.22
Functional scales					
Physical functioning	93.3	[40.0-100.0]	80.0	[33.3-86.7]	0.06
Role functioning	100.0	[0.0-100.0]	100.0	[16.7-100.0]	0.75
Emotional functioning	91.7	[8.3-100.0]	83.3	[16.7-100.0]	0.40
Cognitive functioning	100.0	[6.7-100.0]	83.3	[8.3-100.0]	0.15
Social functioning	100.0	[0.0-100.0]	100.0	[0.0-100.0]	0.95
Symptom scales					
Fatigue	22.2	[0.0-100.0]	22.2	[0.0-100.0]	1.00
Nausea and vomiting	0.0	[0.0-50.0]	0.0	[0.0-100.0]	0.63
Pain	0.0	[0.0-100.0]	0.0	[0.0-66.7]	0.67
Dyspnea	33.3	[0.0-66.7]	0.0	[0.0-66.7]	0.27
Insomnia	0.0	[0.0-100.0]	33.3	[0.0-100.0]	1.00
Appetit loss	0.0	[0.0-100.0]	0.0	[0.0-100.0]	0.77
Constipation	0.0	[0.0-100.0]	0.0	[0.0-100.0]	0.11
Diarrhea	0.0	[0.0-100.0]	0.0	[0.0-100.0]	0.55
Financial difficulties	0.0	[0.0-100.0]	0.0	[0.0-100.0]	0.60
EORTC QLQ-BLM30					
Urinary symptoms	83.3	[23.8-100.0]	77.8	[11.1-100.0]	0.78
Bowel symptoms	83.3	[0.0-100.0]	66.7	[0.0-100.0]	0.19
Sexual functioning*	0.0	[0.0-83.3]	0.0	[0.0-55.6]	0.50
Sexual functioning**	72.2	[33.3-83.3]	36.1	[16.7-55.6]	0.19
Body image	66.7	[11.1-100.0]	88.9	[0.0-100.0]	0.83
SF-12					
Physical health	50.9	[23.4-59.4]	42.5	[26.2-56.1]	0.15
Mental health	50.8	[20.8-62.3]	50.5	[26.7-59.9]	0.98

Values are expressed with median [range]

p values were computed using Mann-Whitney U tests

\*: overall

\*\*\*: sexually active patients (5 ONB patients and 2 IC patients)