

Longitudinal assessment of health related quality of life: head to head comparison between robot-assisted and open radical cystectomy from a single center randomised trial

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Background: Radical Cystectomy (RC) with urinary diversion (UD) is still considered a complex surgery associated with significant morbidity and unfavorable impact on Quality of Life (QoL). Open radical cystectomy (ORC) remains the reference option of treatment, even if adoption of robot-assisted RC (RARC) is rapidly increasing. In this study, we performed an interim analysis of 1-yr QoL outcomes from an ongoing randomised controlled trial (RCT) comparing ORC and RARC with totally intracorporeal UD (Clinical Trials: NCT03434132).

Material and methods:

- Study period: from Jan 2018 to date
- Inclusion criteria:
 - T2-4, N0-N1, M0 Bladder Cancer (BC)
 - Recurrent high-grade non-muscle invasive BC
 - No anesthesiologic contraindications to robotic surgery
- Variables of Randomisation: gender, BMI, ASA score, preoperative Hgb, planned UD (intracorporeal ileal neobladder or conduit), neoadjuvant chemotherapy and clinical T-stage randomization process available at <https://clinicaltrials.gov/show/NCT03434132>.
- Quality of life evaluation: European Organization for Research and Treatment of Cancer [EORTC] generic (QLQ-C30) and bladder cancer specific instruments (QLQ-BLM30).
- Continuous variables were compared with Student *t* test

Table 1 - EORTC Quality of Life – Longitudinal assessment at 1yr of follow-up

	RARC (15) Mean ± SD		p Value	ORC (18) Mean ± SD		p Value
	Baseline	1yr		Baseline	1yr	
Global health status / QoL	79.9 ± 14.0	63.5 ± 26.1	0.16	73.0 ± 23.4	65.7 ± 28.4	0.298
Functional scales						
Physical functioning	95.1 ± 7.8	83.6 ± 16.9	0.014	86.6 ± 22.1	73.0 ± 27.2	0.044
Role functioning	91.6 ± 15.3	79.9 ± 29.0	0.147	90.7 ± 24.4	74.1 ± 34.4	0.027
Emotional functioning	82.8 ± 20.0	80.0 ± 28.8	0.574	84.3 ± 26.8	70.3 ± 34.8	0.037
Cognitive functioning	92.2 ± 21.6	86.7 ± 22.0	0.264	89.8 ± 22.9	81.5 ± 31.8	0.206
Social functioning	91.1 ± 12.4	81.1 ± 23.5	0.034	85.4 ± 26.2	71.6 ± 32.1	0.034
Symptoms scale						
Fatigue	16.1 ± 15.4	28.8 ± 25.9	0.038	19.6 ± 25.6	32.0 ± 27.2	0.083
Nausea and vomiting	1.1 ± 4.4	6.7 ± 17.6	0.239	7.4 ± 18.3	6.5 ± 23.7	0.878
Pain	6.7 ± 12.2	11.1 ± 20.6	0.299	11.1 ± 28.0	31.5 ± 35.2	0.126
Dyspnoea	2.2 ± 8.5	15.5 ± 21.3	0.028	11.0 ± 16.0	24.1 ± 33.9	0.087
Insomnia	15.6 ± 33.0	11.1 ± 27.2	0.542	11.1 ± 28.0	31.5 ± 35.2	0.069
Appetite loss	6.6 ± 13.7	13.3 ± 27.6	0.419	11.1 ± 28.0	16.7 ± 32.8	0.186
Constipation	8.8 ± 23.5	22.2 ± 37.1	0.208	14.7 ± 28.5	37.0 ± 37.7	0.029
Diarrhoea	2.2 ± 8.5	8.9 ± 23.5	0.332	3.8 ± 10.6	9.3 ± 19.1	0.093
Financial difficulties	13.3 ± 27.6	15.6 ± 27.8	0.711	11.1 ± 19.8	27.8 ± 36.6	0.045
Urinary symptoms and problems	12.3 ± 19.5	25.1 ± 21.9	0.097	9.9 ± 13.9	27.9 ± 23.8	0.043
Future perspective	34.7 ± 25.2	34.9 ± 29.4	0.974	24.7 ± 23.0	36.4 ± 29.8	0.132
Abdominal bloating and flatulence	19 ± 16.4	14.5 ± 26.6	0.424	11.1 ± 13.9	29.7 ± 28.8	0.014
Body Image	10.3 ± 14.1	19.6 ± 33.1	0.180	10.8 ± 18.6	33.2 ± 34.6	0.01
Sexual functioning	31.4 ± 29.2	19.1 ± 30.4	0.031	56.8 ± 26.7	16.8 ± 23.1	0.001

Conclusions:

- potential benefits of RARC with intracorporeal UD in most items of functional and symptoms scales
- patients receiving RARC had negligible impact on self-assessed body image and urinary symptoms and problems.

Results: Interim analysis of first **58** consecutive patients enrolled (**30 RARC, 28 ORC, 50% of estimated sample size**) at 1-yr of follow-up

Both cohorts reported significant worsening in terms of physical functioning, social functioning and sexual functioning (all p<0.044, Table 1)

ORC cohort:

Impairment of:

- role functioning
- emotional functioning
- constipation
- financial difficulties
- urinary symptoms and problems
- abdominal bloating and flatulence
- body image

RARC cohort:

Impairment of:

- fatigue
- dyspnoea