

# FAST TRACK PROTOCOL APPLIED TO PATIENTS TREATED WITH RADICAL CYSTECTOMY AND INTESTINAL URINARY DIVERSION: AN UPDATE OF A TWO YEAR PROSPECTIVE RANDOMIZED STUDY IN A HIGH-VOLUME CENTER



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## Introduction and objective

The aim of this study is to evaluate **perioperative outcomes** of patients who underwent our **Fast Track protocol** at a single, tertiary Centre.

## Material and methods

- We prospectively collected data from **130 patients** who underwent **RC with intestinal urinary diversion for BCa** at our institution **between January 2016 and January 2018**.
- Patients were randomized in **two groups: Fast track (n=47) vs Standard protocol (n=83)**.
- **Fast Track protocol** consists of a **series of pre-operative** (ex. minimal starvation), **intra-operative** (ex. minimal tissue handling) and **post-operative** (ex. early mobilization and enteral nutrition) **interventions**, realized with the intention of **shortening hospitalization** and **optimizing patients' perioperative outcomes**.
- **Primary outcomes** were: **post-operative vomiting, time from surgery to first flatus, time to defecation, post-operative pain (VAS Score), 30-days complication rates and hospitalization**.
- Differences in categorical and continuous variables were analyzed using the chi squared test and the Mann-Whitney U-test, respectively.

**Table 1.** Preoperative characteristics of patients who underwent radical cystectomy, stratified according to the perioperative management (fast track vs. standard approach).

	Overall	Fast track group	Control group	P value
Number of patients	130	47	83	-
Age Median (IQR)	69 (60-75)	70 (64-76)	69 (60-74)	0.6
Gender, n (%)				1
Male	97 (74.6)	35 (74.5)	62 (74.7)	
Female	33 (25.4)	12 (25.5)	21 (25.3)	
BMI Mean ± SD	26.3 ± 3.7	26.2 ± 3.3	26.3 ± 3.9	0.8
CCI				
<2	7 (5.4)	2 (4.3)	5 (6)	
2-4	67 (51.5)	26 (55.3)	41 (49.4)	
4-6	43 (33.1)	12 (25.5)	31 (37.3)	0.3
6-8	13 (10)	7 (14.9)	6 (7.2)	
Clinical stage, n (%)				
cTis, cTa, cT1	52 (40)	18 (38.3)	34 (41)	
cT2	69 (53.1)	23 (48.9)	46 (55.4)	
cT3	7 (5.4)	5 (10.6)	2 (2.4)	0.2
cT4	2 (1.5)	1 (2.1)	1 (1.2)	
WHO clinical Grade, n(%)				
Low Grade (G1-G2)	4 (3.1)	1 (2.1)	3 (3.6)	0.5
High Grade (G3-G4)	126 (96.9)	46 (97.9)	80 (96.4)	

## Results

**Table 2.** Intraoperative and pathologic characteristics of patients who underwent radical cystectomy, stratified according to the perioperative management (fast track vs. standard approach).

	Overall	Fast track group	Control group	P value
Urinary diversion, (%)				
Ileal conduit	79 (60.8)	30 (63.8)	49 (59)	0.7
Neobladder	51 (39.2)	17 (36.2)	34 (41)	
Operative time (min)				
Median (IQR)	285 (240-330)	275 (230-320)	300 (245-340)	<b>0.02*</b>
Intraoperative blood transfusion (%)				
No	93 (71.5)	32 (68.1)	61 (73.5)	0.6
Yes	37 (28.5)	15 (31.9)	22 (26.5)	
Pathologic stage, (%)				
pT0-pTis-pT1- pT2 a- pT2b	86 (66.2)	32 (68.1)	54 (65.1)	
pT3a-pT3b	34 (26.2)	12 (25.5)	22 (26.5)	0.9
pT4a-pT4b	10 (7.7)	3 (6.4)	7 (8.4)	
Pathologic Grade, (%)				
pG0	13 (10)	4 (8.5)	9 (10.8)	
pG1-2	8 (6.2)	1 (4.3)	6 (7.2)	0.7
pG3	109 (83.8)	41 (87.2)	68 (81.9)	
LN retrieved, Median (IQR)	16 (10-24)	15 (12-20)	16 (10-26)	0.4
Pathologic Nodal status (%)				
pN0	99 (76.2)	36 (86.6)	63 (75.9)	1
pN+	31 (23.8)	11 (23.4)	20 (24.1)	

**Table 3.** Postoperative outcomes of patients who underwent radical cystectomy, stratified according to the perioperative management (fast track vs. standard approach).

	Overall	Fast track group	Control group	P value
Postoperative vomiting, n (%)				
No	102 (78.5)	38 (80.9)	64 (77.1)	0.7
Yes	28 (21.5)	9 (19.1)	19 (22.9)	
Postoperative pain (VAS score)				
Mean ± SD	3.3 ± 1.2	3.3 ± 1.2	3.3 ± 1.2	0.9
Median (IQR)	3 (3-4)	3 (3-4)	3 (3-4)	0.6
Time to flatus (days)				
Mean ± SD	3 ± 1	2 ± 1	3 ± 1	<b>0.001</b>
Median (IQR)	2 (2-3)	2 (1-3)	3 (2-4)	<b>0.02</b>
Time to defecation (days)				
Mean ± SD	6 ± 2	6 ± 2	6 ± 2	0.2
Median (IQR)	6 (4-7)	6 (4-7)	6 (4-7)	0.9
Hospitalization (days)				
Mean ± SD	16 ± 9	13 ± 5	17 ± 10	<b>0.01</b>
Median (IQR)	13 (11-16)	12 (9-15)	14 (12-17)	<b>0.2</b>
Complications within 30 post-operative days (%)				
No	80 (61.5)	23 (48.9)	57 (68.7)	<b>0.04</b>
Yes	50 (38.5)	24 (51.1)	26 (31.3)	
Clavien Dindo grade complications within 30 post-operative days (%)				
I-II	33 (66)	19 (79.2)	14 (58.8)	<b>0.08</b>
III-IV-V	17 (34)	5 (20.8)	12 (46.2)	
Readmission within 90 days, n (%)	23 (17.7)	5 (10.6)	18 (21.7)	0.09

## Conclusions

Our **Fast Track Protocol** allowed to **shorten** the time to flatus and the hospitalization. However, **no further** postoperative advantages were found. Moreover, **overall 30-days complication rate** was **higher** in the FT group. Therefore, a **more consistent caseload** may be necessary to evaluate the **real benefits of the FT protocol** and probably identify some **predictors of FT failure**, in order to lead to a **better selection process** of patients.