

Should we change how to assess early continence after rhabdosphincter reconstruction in patients undergoing robotic prostatectomy? Results of a randomized controlled trial

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Abstract

Introduction & Objectives Posterior rhabdosphincter reconstruction (PRRS) following radical prostatectomy was designed to improve early urinary continence. We executed a randomized clinical trial comparing early continence rates in patients undergoing urethrovesical anastomosis with or without periprostatic reconstruction.

Materials & Methods We conducted a randomized clinical trial (NCT03302169) intended to detect a 20% difference in 1-month continence defined by a patient response of 0 to question 3 of the EPIC26 questionnaire urinary domain, comparing standard running vesicourethral anastomosis (controls) to PRRS followed by standard running vesicourethral anastomosis (PRRS treated). Further continence outcomes were assessed by time to have no leakage (dry pad first date), 24-hour pad weights and time until stop using pad/any protection (pad 0 first date), ICIQ-SF and IPSS questionnaires. Patients had clinically localized prostate cancer and were blinded. Surgeons were notified of computer randomization (random.org) after prostate excision. Patients and data gatherers were blinded to treatment allocation.

Results A total of 158 patients were randomized between January 2017 and September 2018. 153 patients completed the 6 months study first analysis. Preoperative clinical and functional variables were equivalent between study arms. 50th percentile of patients with dry pad and patients without any protection in the PRRS group was 23 and 34 days, respectively. While 49 and 81 were the equivalent distribution of the control group. Univariate analyses showed that the type of reconstruction was related with absence of any protection 1 month after the surgery (p=0.012) but it wasn't associate with the dry pad status. No differences were found at 6 months or using the questionnaires specific domains. We performed a multivariate analysis including PSA, BMI, age, prostate volume, lymphadenectomy, nerve-sparing technique and the reconstruction type. PRRS was the only independent predictor of dry pad status and use of any protection at 1 month (pad 0). The Kaplan-Meier curve demonstrated the statistically significant difference between both techniques in time to recovery early urinary continence.

Conclusions In this randomized clinical trial posterior rhabdosphincter showed a clear benefit in early urinary continence. To determine the date of dry pad and pad 0 seems to be more reliable than apply validated questionnaires in established time frames in order to assess continence status after radical prostatectomy.

OBJECTIVE

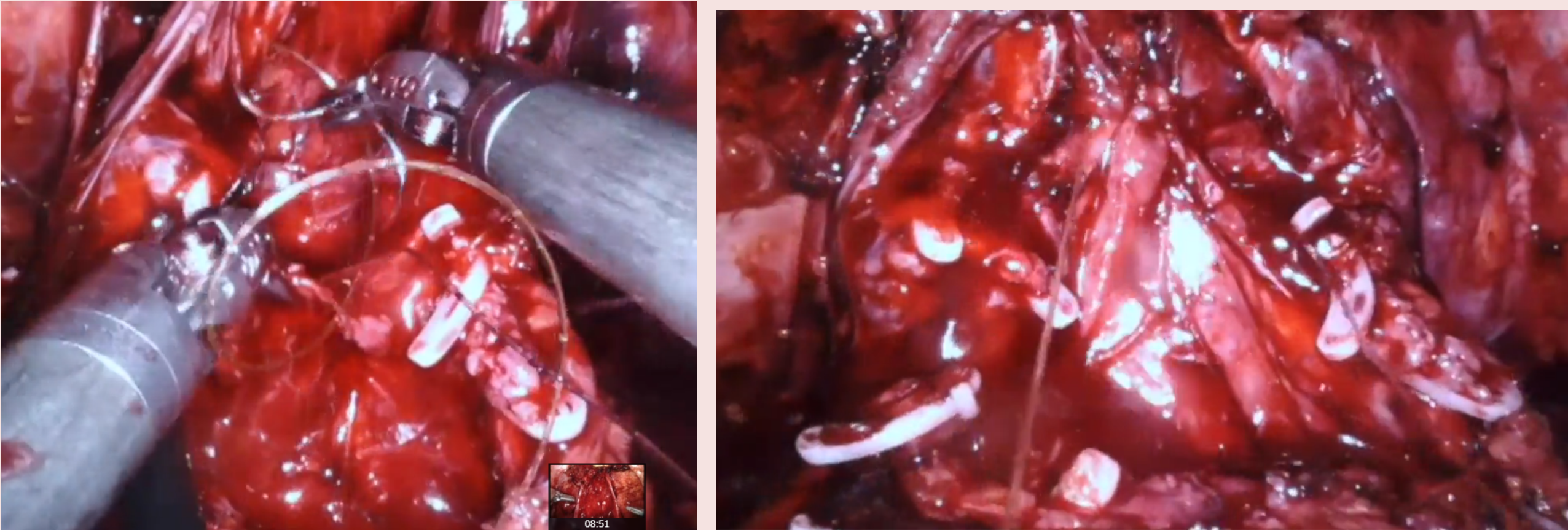
To compare early continence rates in patients undergoing urethrovesical anastomosis with or without posterior reconstruction of the rhabdosphincter (PRRS) following robotic radical prostatectomy.

MATERIAL & METHODS

Design and Participants: Randomized clinical trial (NCT03302169) comparing standard running vesicourethral anastomosis (controls) to PRRS followed by standard running vesicourethral anastomosis (PRRS treated)

Continence outcomes were assessed by time to have no leakage (dry pad first date), 24-hour pad weights and time until stop using pad/any protection (pad 0 first date), EPIC26, ICIQ-SF and IPSS questionnaires.

Figure 1. Posterior reconstruction of rhabdosphincter



Statistical Analysis: SPSS v22

RESULTS

Table 1. Demographic and clinical characteristics of the population

VARIABLE	Non-PRRS group (n=72)	PRRS group (n=71)	p value
Age, years, median (IQR)	64,07 (60-69,75)	63,43 (58,8-70)	0,509
BMI, kg/m² (IQR)	25,92 (23,99-28,31)	27,13 (24,96-29,07)	0,025
CharlsonAge, n (%)			0,025
1	2 (2,8)	4 (4,9)	
2	40 (55,6)	57 (70,4)	
3	30 (41,7)	20 (24,7)	
Total PSA level, ng/mL (IQR)	6,78 (4,32-8,78)	7,42 (4,72-9,25)	0,135
Prostate volume, g (IQR)	43,11 (27,75-54,25)	48,36 (30-65)	0,276
ISUP score at biopsy, n (%)			0,023
1	25 (34,7)	16 (19,8)	
2	32 (44,4)	37 (45,7)	
3	8 (11,1)	17 (21)	
4	6 (8,3)	11 (13,6)	
5	1 (1,4)	0 (0)	
Clinical T stage, n (%)			0,361
cT1c	60 (83,3)	63 (77,8)	
cT2ab	11 (15,3)	15 (18,5)	
cT2c	1 (1,4)	0 (0)	
cT3a	0 (0)	3 (3,7)	

Table 2. Comparison of continence distribution measured “Dry pad” and “No pad use” between Non-PRRS group and PRRS

	Non-PRRS group	PRRS group	P value
Days to dry pad, p50 (IQR)	49 (14-116)	23 (9,5-75,5)	0,08
Days to no pad, p50 (IQR)	81 (26,5-141)	34 (17,75-81,75)	0,012

Figure 2. Kaplan-Meier survival curves comparing having “No-pad” after RP in group 1 (non-RPPS, blue line) and group 2 (PRRS, green line). A. Results at 1 month.

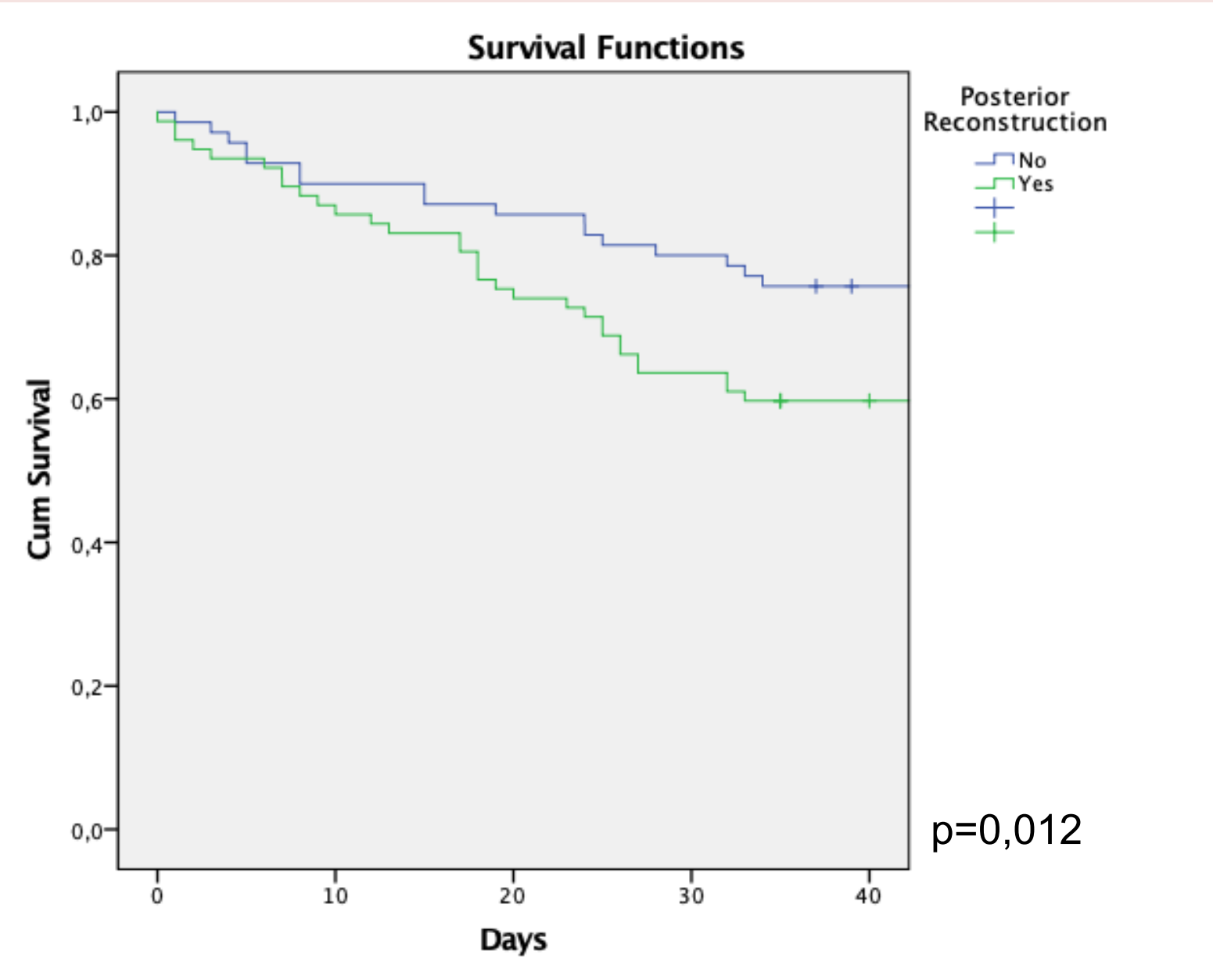


Table 3. Multivariate analysis

	1 month Dry pad		1 month No-pad		6 months Dry pad		6 months No-pad	
	HR (95% CI)	P value	HR (95% CI)	P value	HR (95% CI)	P value	HR (95% CI)	P value
Age	0,96 (0,9-1)	0,09	0,98 (0,92-1,04)	0,46	0,96 (0,88-1,05)	0,37	0,98 (0,9-1,06)	0,56
BMI	0,98 (0,85-1,11)	0,72	0,96 (0,83-1,1)	0,55	0,95 (0,76-1,17)	0,61	1,03 (0,85-1,25)	0,78
Prostate volume	1 (0,98-1,01)	0,99	0,99 (0,97-1,01)	0,31	0,98 (0,96-1)	0,18	1 (0,98-1,03)	0,63
Lymph node dissection	1,56 (0,64-3,77)	0,33	1,87 (0,78-4,48)	0,16	0,81 (0,2-3,39)	0,78	0,9 (0,25-3,15)	0,85
NVB preservation	0,9 (0,82-2,86)	0,86	1,14 (0,34-3,76)	0,83	0	0,99	0,89 (0,18-4,47)	0,89
Posterior reconstruction	2,4 (1,14-5,04)	0,021	2,24 (1,05-4,78)	0,037	1,98 (0,59-6,68)	0,27	1,88 (0,63-5,57)	0,25

NVB: neurovascular bundles

CONCLUSIONS

In this randomized clinical trial posterior rhabdosphincter showed a clear benefit in early urinary continence. To determine the date of dry pad and pad 0 seems to be more reliable than apply validated questionnaires in established time frames in order to assess continence status after radical prostatectomy.