

# MP11-02 OUTCOMES OF A PHASE III RANDOMIZED CONTROLLED TRIAL COMPARING PREVENTIVE VERSUS DELAYED LIGATION OF DORSAL VASCULAR COMPLEX DURING ROBOT-ASSISTED RADICAL PROSTATECTOMY



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## INTRODUCTION

The ligation of the dorsal vascular complex (DVC) during robot-assisted radical prostatectomy (RARP) can be done either before (preventive ligation, PL) or after (delayed ligation, DL) its transection.

We evaluated in a **prospective randomized setting whether a DL of the DVC impacted on perioperative, functional and oncological outcomes as compared to PL during RARP.**

## MATERIALS AND METHODS

RARP was performed through a transperitoneal approach with either **PL (1-0 Monocryl® CT-1, before bladder neck dissection)** or **DL (3-0 Monocryl® UR-6, once the prostatectomy completed).**

**Primary endpoint was estimated blood loss (EBL);** considering significant a difference <sup>3</sup>30 ml, a sample size of 226 patients were calculated (two-sided  $\alpha$  of 0.05 and 80% power). **Secondary endpoints were: transfusion rate, positive surgical margins (PSMs), apical PSMs and 1-month PSA and continence (0-1 security pad/day).** Differences were compared using Pearson chi-square test or Mann-Whitney test as appropriate ( $p < 0.05$  was considered statistically significant).

*Figure. a-b: preventive ligation of DVC:* after opening the endopelvic fascia and lateral dissection of prostate up to the apex, a eight-figure 1-0 CT-1 stitch was given, without including pubo-prostatic ligaments; transection of the DVC was postponed at the end of prostatectomy before the section of the urethra.

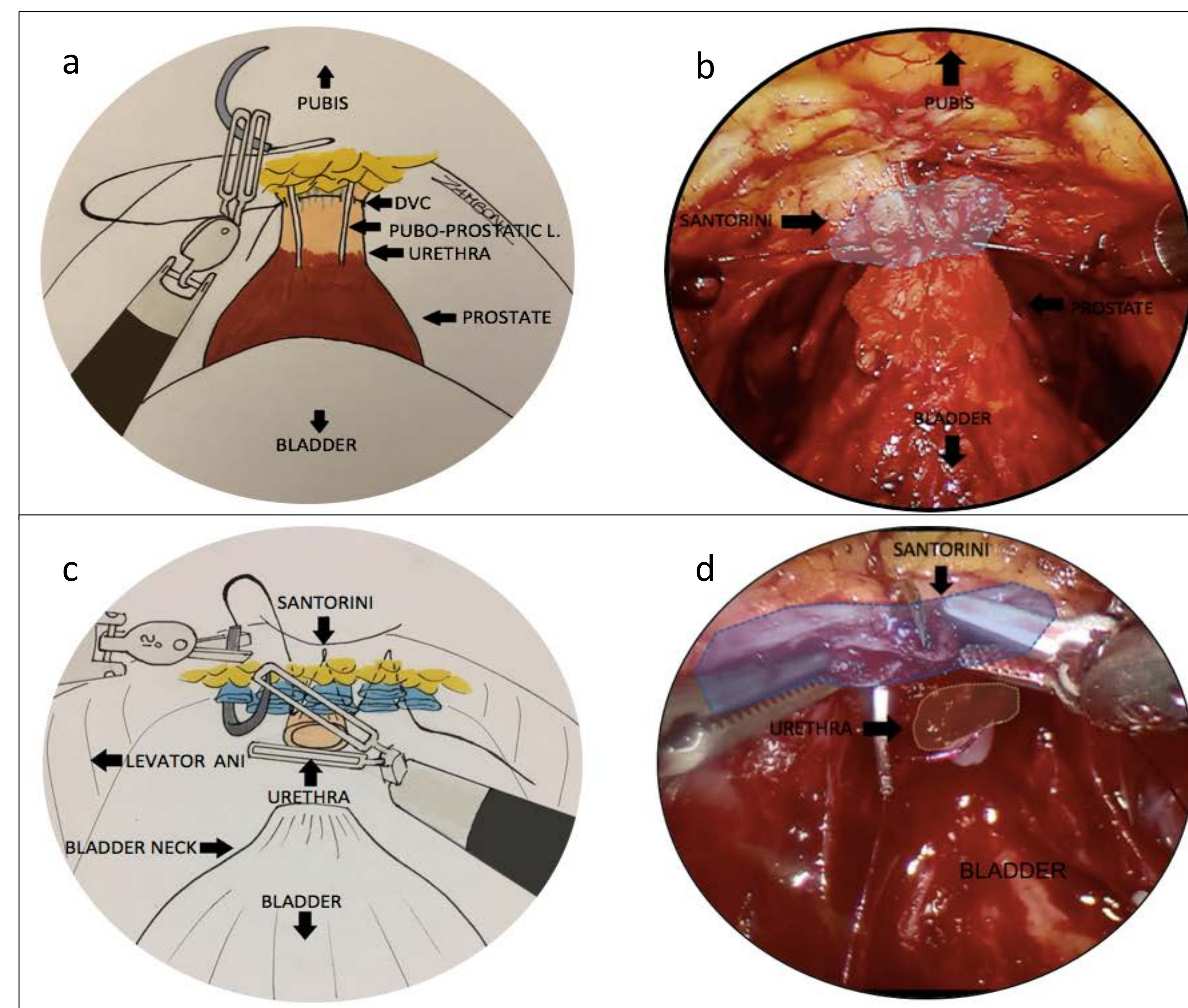
*c-d delayed ligation of DVC:* at the end of prostatectomy, prior to apex dissection, the DVC was transected; once completed the detachment of prostate, a vertical running suture with 3-0 UR-6 needle, side-to-side, right to left, was given.

## RESULTS

Overall, 243 patients were randomized from August 2016 to August 2017 (**136 patients with PL and 107 with DL**). A shift from DL to PL was observed in 26 patients (24%) and from PL to DL in 8 (6%). These patients were excluded from final analysis.

The two groups had **comparable baseline characteristics. EBL was higher in DL group** (mean  $91 \pm 120$  SD vs  $107 \pm 134$  SD in PL and DL respectively) **but not significant ( $p = 0.251$ ).** Two patients (1.6%) in PL and 1 (1.3%) in DL group required transfusion ( $p = 0.854$ ).

**PSM rate was 19.4% and 21.1% in PL and DL, respectively** ( $p = 0.712$ ); among patients with PSM, **apical involvement was significantly higher in PL group (57.8% vs 20%,  $p = 0.027$ ).** At 1- 3- 6-months, median PSA values and continence rate were **comparable between groups.**



Patients' features	PL (136 patients)	DL (107 patients)	p
Age, mean ( $\pm$ SD)	66.76 ( $\pm$ 8.57)	65.04 ( $\pm$ 6.36)	0.319
Pre-operative PSA, mean ( $\pm$ SD)	9.87 ( $\pm$ 12.56)	8.17 ( $\pm$ 5.73)	0.993
ASA score, mean ( $\pm$ SD)	2.06 ( $\pm$ 0.54)	2.11 ( $\pm$ 0.59)	0.521
Clinical stage, number (%)			0.557
cT1	89 (69.5%)	61 (75.3%)	
cT2	37 (28.9%)	19 (23.4%)	
cT3	2 (1.6%)	1 (1.3%)	
Pathological stage, number (%)			0.869
pT2a	13 (10.1%)	8 (9.9%)	
pT2b	4 (3.1%)	1 (1.3%)	
pT2c	79 (61.7%)	49 (60.5%)	
pT3a	26 (20.3%)	16 (19.7%)	
pT3b	8 (6.2%)	7 (8.6%)	
pT4	1 (0.6%)	0	
Pathological GS, number (%)			0.137
6	54 (42.2%)	28 (34.6%)	
7	38 (29.7%)	33 (40.7%)	
8	7 (5.5%)	1 (1.3%)	
9	11 (8.5%)	9 (11.1%)	
Not assessable	18 (14.1%)	10 (12.3%)	
LAD, number (%)			0.717
Yes	57 (44.5%)	34 (42%)	
No	71 (55.5%)	47 (58%)	
Nerve sparing, number (%)			0.857
Yes	68 (53.1%)	42 (51.8%)	
No	60 (46.9%)	39 (48.2%)	
Operative time (min), mean ( $\pm$ SD)	209.5 ( $\pm$ 42.2)	200.2 ( $\pm$ 32.2)	0.182
Blood loss (ml), mean ( $\pm$ SD)	91 $\pm$ 120	107 $\pm$ 134	0.251
Transfusion rate, number (%)	2 (1.6%)	1 (1.3%)	0.854
PSM rate, number (%)	7 (19.4%)	5 (21.1%)	0.712
Apical involvement, number (%)	4 (57.8%)	1 (20%)	0.027
Continence rate, number (%)			
1 month	114 (83.8%)	81 (75.7%)	0.207
3 months	129 (94.8%)	97 (90.6%)	0.400
6 months	132 (97.0%)	104 (97.1%)	0.807

## CONCLUSIONS

A DL of the DVC is **not detrimental on perioperative outcomes** and it could play a **protective role in managing the prostate apex**. These findings could allow the surgeon to opt for the best method tailored on patient needs and disease characteristics.