



RANDOMIZED CONTROLLED TRIAL ASSESSING THE IMPACT OF EARLY DORSAL VENOUS COMPLEX (EDVC) LIGATION ON URINARY CONTINENCE RECOVERY AFTER ROBOT-ASSISTED RADICAL PROSTATECTOMY (RARP): FULL REPORT ONE MONTH AFTER SURGERY.

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INTRODUCTION

The ligation of the dorsal venous complex (DVC) is a delicate step of radical prostatectomy and may affect continence recovery. We hypothesized that the early ligation of the DVC before the lateral dissection and nerve sparing procedures during RARP might allow for a better preservation of urethral sphincter and thus improved continence recovery over the traditional technique.

MATERIALS AND METHODS

- 312 consecutive patients treated with robotic prostatectomy have been randomly assigned to the experimental group (early DVC ligation, n=156) and to the control group (standard technique, n=156).
- Primary endpoint: continence recovery at 1 and 4 months from surgery. Continence defined as 0-1 pad/die
- According to power analyses, the sample size was calculated to achieve a statistically significant difference of 15% between the two groups.
- Secondary endpoints:
 - 90-day complications (Clavien-Dindo classification)
 - Positive surgical margins rate

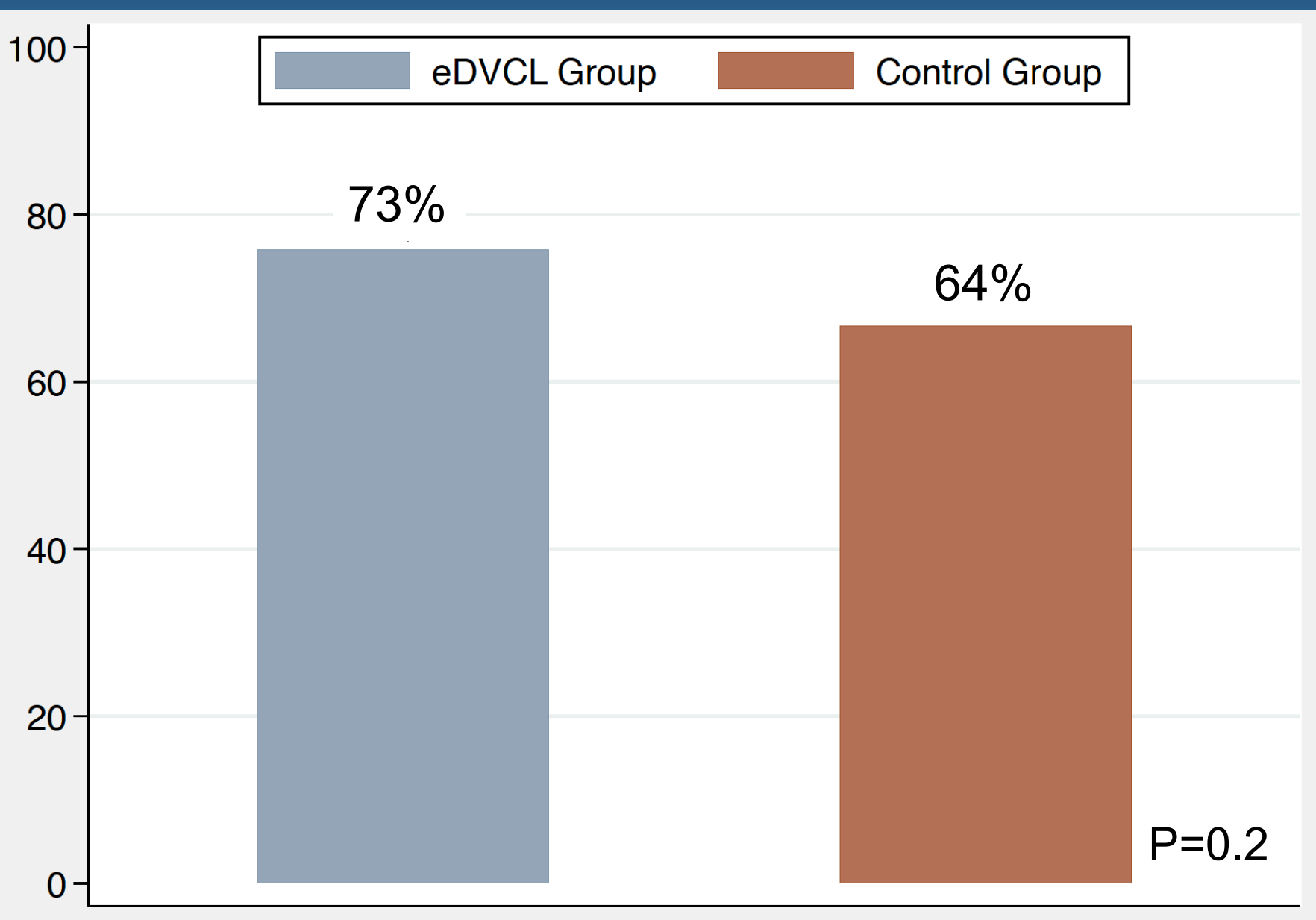
DESCRIPTION OF THE TECHNIQUES

Standard technique: the DVC is ligated after the bladder neck incision and the development of the postero-lateral aspect of the prostate.

Experimental technique: ligation of the DVC before the bladder neck incision and nerve sparing lateral dissection, right after the incision of the endopelvic fascia.

Continence rates 1 month after surgery		
eDVCL Arm (N=156; 50%)	Control Arm (N=156; 50%)	P value
23%	28%	0.4

Continence rates 4 months after surgery in 199 patients with available data for analyses



Descriptive characteristics of the study cohort.
The number in parenthesis indicates the number of patients with available data for interim analysis.

	eDVCL Arm (N=156; 50%)	Control Arm (N=156; 50%)	P value
Age, years	64 (59, 68)	66 (60, 70)	0.15
BMI	25 (23, 27)	25 (24, 27)	0.3
Total preoperative PSA, ng/ml	7.0 (5.1, 10.0)	6.3 (4.9, 10.0)	0.3
Biopsy ISUP grade (N=310)			
1	25 (16%)	20 (13%)	0.13
2-3	96 (62%)	87 (56%)	
4-5	33 (21%)	49 (31%)	
Clinical T Stage (N=304)			
T1	89 (59%)	94 (61%)	0.4
T2	43 (28%)	34 (22%)	
T3	19 (13%)	25 (16%)	

Positive surgical margins rate and Clavien-Dindo complications rates

	eDVCL Arm (N=156; 50%)	Control Arm (N=156; 50%)	P value
Positive Surgical Margins (N=311)	35 (22%)	36 (23%)	0.9
Clavien-Dindo ≥2 complications (N=311)	20 (13%)	16 (10%)	0.5
Clavien-Dindo ≥3 complications (N=311)	10 (6%)	11 (7%)	0.8

CONCLUSIONS

Our results suggest that early DVC ligation does not increase the risk of positive margins or complications. Awaiting longer follow-up, we did not find evidence that the timing of DVC ligation affects functional outcomes after robotic radical prostatectomy.