P30 Standard vs delayed ligature of the dorsal vascular complex during robot-assisted radical prostatectomy: Results from a randomized controlled trial

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Introduction & Objectives: During RARP, the dorsal vascular complex (DVC) could be suture either before or after its transection. This randomized study aimed at comparing standard vs delayed approach to DVC (s-DVC vs d-DVC) during RARP.

Materials & Methods: Patients scheduled for RARP were randomized into a 1:1 ratio to receive either s-DVC or d-DVC. In s-DVC arm an 8-shaped single stitch was given at the beginning of prostatectomy and the DVC was subsequently cut at time of apical dissection; in d-DVC arm the plexus was transected prior to apical dissection and then sutured at the end of prostatectomy (fig 1). Primary endpoint was difference in estimated blood loss (EBL). Secondary endpoints were: Positive surgical margins (PSM), 1-month PSA and continence and potency rate. Setting a difference of 30 ml in EBL (α error of 0.05, power of 85%), a sample size of 226 cases was calculated and an interim analysis was planned after two third of recruitment. Significance was set for two-sided $p<0.05$.

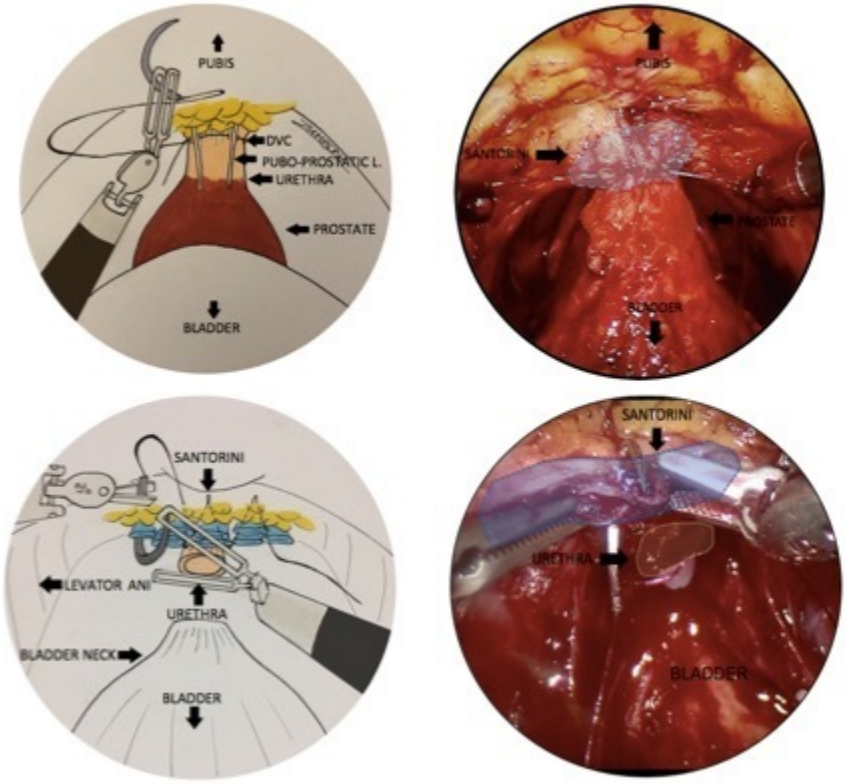

Figure 1. *Standard ligation of DVC*: after opening the endopelvic fascia and lateral dissection of prostate up to the apex, a eight-figure 1-0 CT-1 stitch was given, without including pubo-prostatic ligaments; transection of the DVC was postponed at the end of prostatectomy before the section of the urethra.
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: Endpoint was reached at ad interim analysis after 162 cases (81 s-DVC, 81 d-DVC) and recruitment was therefore interrupted. Baseline and tumor characteristics were overlapping. EBL was significantly higher in d-DVC arm (mean EBL 107 vs 65 ml, p=0.003), but without differences in post-operative hemoglobin, transfusions and complications. Overall PSM rate was higher in d-DVC arm (21.0% vs 14.8%, p=0.323), with

statistical significance relatively to organ-confined disease (15.5% vs 3.6%, p=0.031). Apical involvement was instead significantly higher in s-DVC arm (prevalence in PSM patients 66.7% vs 23.5%, p=0.020) (tab. 1). Post-operative PSA, continence and potency rates were similar between