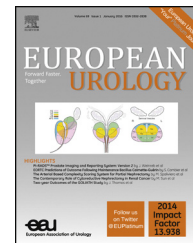


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Platinum Priority – Brief Correspondence

Editorial by XXX on pp. x–y of this issue

Prospective Randomized Trial Comparing Titanium Clips to Bipolar Coagulation in Sealing Lymphatic Vessels During Pelvic Lymph Node Dissection at the Time of Robot-assisted Radical Prostatectomy

Pietro Grande, Giovanni Battista Di Pierro, Livio Mordasini, Matteo Ferrari, Christoph Würnschimmel, Hansjörg Danuser, Agostino Mattei*

Klinik für Urologie, Luzerner Kantonsspital, Lucerne, Switzerland

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Abstract

Lymphocele is the most common complication after pelvic lymph node dissection (PLND). Over the years, various techniques have been introduced to prevent lymphocele, but no final conclusion can be drawn regarding the superiority of one technique over another. In this prospective study, 220 patients undergoing robot-assisted radical prostatectomy between 2012 and 2015 were randomized to receive titanium clips (group A, $n=110$) or bipolar coagulation (group B, $n=110$) to seal lymphatic vessels at the level of the femoral canal during extended PLND (ePLND). Ultrasound examination was used to detect lymphoceles at 10 and 90 d after surgery. Lymphocele was defined as any clearly definable fluid collection and was considered clinically significant when requiring treatment. There were no statistically significant differences between groups A and B regarding overall lymphocele incidence (47% vs 48%; difference -0.91% , 95% confidence interval [CI] -2.6 to 0.7 ; $p=0.9$) and the rate of clinically significant lymphocele [5% vs 4%; difference 0.75% , 95% CI, 0.1 – 3.2 ; $p=0.7$]. The two groups were comparable regarding mean (\pm SD) lymphocele volume (30 ± 32 vs 35 ± 39 ml; $p=0.6$), lymphocele location (unilateral, 37% vs 35%, $p=0.7$; bilateral, 13% vs 14%, $p=0.9$), and time to lymphocele diagnosis (95% vs 98% on postoperative day 10; $p=0.5$). In conclusion, this trial failed to identify a difference in lymphocele occurrence between clipping and coagulation of the lymphatic vessels at the level of the femoral canal during robot-assisted ePLND for prostate cancer.

Patient summary: In this study we compared the frequency of postoperative complications after sealing lymphatic vessels from the leg to the abdomen using metallic clips or electrical coagulation during robot-assisted surgery for prostate cancer. We found no difference in postoperative complications between the two methods.

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* Corresponding author. Klinik für Urologie, Luzerner Kantonsspital, CH-6000 Luzern 16, Switzerland. Tel. +41 41 2054532; Fax: +41 41 2054531.
E-mail address: agostino.mattei@luks.ch (A. Mattei).

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Pelvic lymph node dissection (PLND) is the most effective method for detecting lymph node metastases in patients undergoing radical prostatectomy (RP) for prostate cancer [1]. In addition, PLND has been considered to play a therapeutic role in patients with limited node disease [1].

However, the benefit of PLND must be carefully weighed against associated morbidity and costs. The most frequent complication after PLND is pelvic lymphocele [2–5]; occurrence depends on various factors, including the extent of dissection [2–4], surgical approach [5], and the technique used to seal lymphatic vessels [3,5].

Previous studies have assessed the incidence and risk factors for lymphocele formation after PLND [3–7]. However, no final conclusion can be drawn yet regarding preventive measures during robot-assisted PLND. Indeed, despite the increasing use of a robotic approach for PLND, no prospective randomized trial has investigated the role of surgical measures to improve lymphocele rates after PLND.

The objective of this prospective randomized study was to compare titanium clips to bipolar coagulation when sealing lymphatic vessels to prevent lymphocele occurrence during extended PLND (ePLND) in patients undergoing robot-assisted RP (RARP).

Between 2012 and 2015, 231 patients undergoing ePLND and RARP at our institution were enrolled in the study. Patients were randomized to two groups by a computer-based prospective random sequence generator. In group A, lymphatic vessels were sealed during ePLND at the level of the femoral canal using titanium clips; in group B, lymphatic vessels were sealed using bipolar coagulation.

All patients underwent routine ultrasound examination of the kidneys and pelvis by an experienced urologist at 10 and 90 d after surgery. The patient and the urologist performing the ultrasound were blinded to the treatment arm to which the patient was randomized.

Lymphocele (defined as any clearly definable fluid collection in the pelvis) was considered symptomatic and clinically relevant when requiring any medical or surgical treatment. Symptomatic collections were further clarified via computed tomography (CT) imaging. Further details of the study and methods are described in the Supplementary material.

In total, 220 patients were included in our analysis (Supplementary Fig. 1). Eleven patients (5%) were excluded from the trial because of leakage of the vesicourethral anastomosis on cystography.

Groups A and B were comparable regarding baseline and perioperative characteristics (Tables 1 and 2). Overall (10 and 90 d after surgery), lymphoceles were detected in 105/220 (48%) patients. There was no significant intergroup difference regarding the overall incidence: lymphoceles were observed in 52/110 (47%) patients in group A and in 53/110 (48%) patients in group B (95% confidence interval [CI] –2.6 to 0.7; $p = 0.9$). On day 10 after surgery, lymphoceles were found in 48/110 patients (44%) in group A and 53/110 patients (48%) in group B (95% CI –18 to 9; $p = 0.5$).

A total of 11/220 (5%) patients suffered from symptomatic lymphocele and required treatment, of whom

Table 1 – Baseline demographic characteristics

	Total cohort	Group A (clips)	Group B (no clips)
Patients (n)	220	110	110
Mean age, yr (SD)	63.9 (6.0)	64.2 (5.7)	63.6 (6.3)
Mean BMI, kg/m ² (SD)	26.8 (3.7)	26.7 (3.9)	26.8 (3.5)
Clinical stage, n (%)			
T1	112 (51)	58 (53)	54 (49)
T2	99 (45)	46 (42)	53 (48)
T3	9 (4)	6 (5)	3 (3)
Biopsy Gleason score, n (%)			
≤6	54 (24)	24 (22)	30 (27)
7	134 (61)	70 (64)	64 (58)
≥8	32 (15)	16 (14)	16 (15)
Mean PSA, ng/ml (SD)	12.6 (14.5)	12.0 (12.0)	13.3 (16.5)
D'Amico risk group, n (%)			
Low	29 (13)	13 (12)	16 (14)
Intermediate	121 (55)	62 (56)	59 (54)
High	70 (32)	35 (32)	35 (32)
Charlson comorbidity index, n (%)			
≤1	98 (44)	47 (43)	51 (46)
2	66 (30)	32 (29)	34 (31)
3	41 (19)	23 (21)	18 (17)
≥4	15 (7)	8 (7)	7 (6)
Mean prostate volume, cm ³ (SD)	49.3 (21.0)	48.0 (21.1)	50.7 (20.9)

BMI = body mass index; PSA = prostate-specific antigen.

six (5%) patients were in group A and five (4%) in group B (95% CI 0.1 to 3.2; $p = 0.7$). Treatment was necessary in 8/11 (73%) patients because of infection (one case with heavy septicemia with totally drug-resistant bacteria) and in 3/11 (27%) because of iliac vessel compression, as demonstrated by CT imaging. Nine patients were treated using percutaneous drainage (Clavien grade IIIA), one patient underwent laparoscopic fenestration (Clavien grade IIIB), and another underwent open revision because of abscess formation (Clavien grade IIIB). For all patients who developed symptomatic lymphocele, this occurred before the 90-d postoperative follow-up, and no readmissions for lymphocele-related complications occurred after 90 d (Table 2).

Additional logistic regression models illustrating predictors of lymphoceles are reported in Supplementary Table 1.

Despite technical refinements and various preventive measures, lymphocele remains the most frequent PLND complication, with a reported incidence of up to 61%, leading to additional morbidity and costs [2–5,7].

No technique has so far proven to be superior over another in reducing the risk of postoperative lymphocele. However, lymphocele rates appear to be lower for laparoscopic than for open surgery; this might be attributable to lymphatic fluid reabsorption by the peritoneum, and to the use of ultrasound scissors instead of bipolar and monopolar instruments [2,5].

It must be emphasized that most evidence regarding lymphocele is from open PLND series (Supplementary Table 2). Therefore, no direct conclusions can be drawn from the literature regarding robotic PLND, and further studies are warranted.

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