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ARTICLE

Can we predict the development of symptomatic lymphocele following robot-assisted radical prostatectomy and lymph node dissection? Results from a tertiary referral Centre

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ABSTRACT

Objectives: Robot-assisted radical prostatectomy (RARP) has been established as first-line surgical therapy for organ-confined prostate cancer (PCa). Pelvic lymph node dissection (PLND) is recommended in case of intermediate and high-risk localized PCa however symptomatic lymphocele (SL) formation is a common complication. Still no certain clinical and surgical predictors of SL have been found in the robotic era. Aim of this study was to identify clinical and surgical predictors of SL after RARP and PLND.

Methods: We retrospectively evaluated all consecutive patients undergone RARP and PLND from 01/2017 to 06/2019, at our institution. All procedures were performed by experienced robotic surgeons. Baseline patients' characteristics, as well as peri- and post-operative features, were recorded and compared among those patients experiencing SL after surgery and those who did not.

Results: Overall, 282 patients were included. Of these, 21 (7.5%) developed SL after surgery. Patients with SL showed higher median BMI (30.4 vs 25.8) and a more frequent history of vascular surgery or lymph-vascular disease (23.8% vs 8.4%) compared to patients without SL ($p < 0.05$). The lymphadenectomy technique adopted during the surgery was also found different in patients diagnosed with SL. At the multivariable analysis (MVA), only the increase of BMI (OR 1.72; CI: $1.47 - 2.81$) was found predictor of developing SL.

Conclusion: In our experience, the increase of BMI was a significant predictor of SL development in pCa patients submitted to RARP and PLND. This further evidence may be of great help for clinicians in daily clinical practice, in particular during preoperative counseling.

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Introduction

Radical prostatectomy (RP) has been established as first-line surgical therapy for organ-confined prostate cancer (PCa) and, currently, radical prostatectomy with a transperitoneal robot-assisted approach (RARP) constitutes the most commonly used technique [1]. According to the European Association of Urology (EAU) guidelines, pelvic lymph node dissection (PLND) is recommended in intermediate and high-risk patients, as it is considered the most effective method for detecting lymph nodes (LNs) status assessment [2].

However, PLND is not devoid of complications as possible vessel damages or ureteric injuries. However, the most common drawback after this procedure is represented by lymphocele formation which showed a variable incidence ranging from 9% up to 50%, according to the literature [3,4]. While most lymphoceles are asymptomatic and resolve spontaneously, symptomatic lymphoceles (SL) can appear in up to 16% of cases and may cause pain and discomfort mainly due to their compression in the lower abdominal quadrants [5]. Complications like lower extremities edema, deep venous thrombosis, constipation, voiding dysfunctions, infection, abdominal and legs pain may also occur. Frequently, SL leads to hospital readmissions with a large impact for both patients and hospital resources. Despite the clinical relevance of this topic, only few studies evaluated the factors that may increase the risk of lymphocele development after RARP and PLND [3,5], although this has been well established in open series [6,7]. In fact, Frohener et al. evaluated 2437 patients submitted to open RP and PLND and attested the lymphoceles rate at 26.1% [6].

To fill this gap, in the current study we aimed to identify potential clinical and surgical predictors of SL formation after RARP and PLND.

Materials and methods

Techniques and clinical management

After obtaining of the institutional review board approval (IRB 1248/16), we retrospectively evaluated all consecutive patients undergone RARP and PLND for not-metastatic

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prostatic cancer from January 2017 to June 2019, at our institution. All procedures were performed by a single equip composed by experienced (>250 RARP) robotic surgeons. Patients were excluded from the study in case of postoperative anastomotic leakage.

All patients had a standard six-port transperitoneal RARP as previously extensively reported in literature [6]. PLND was performed according to the preoperative 2012 Briganti nomogram [8]. We performed extended PLND including the nodes overlying the common and the external iliac artery and vein, those within the obturator fossa located cranially and caudally to the obturator nerve, and the nodes medial and lateral to the internal iliac artery. According to the surgeon's preferences, lymphatic vessels were sealed using three different techniques: extensive use of clipping for both large and small vessels, clips only on main vessels or vessels cauterization with the bipolar instrument. The peritoneum was not closed in any case after PLND. Abdominal drainage was placed according to the surgeon's choice and, if present, removed when the amount of lymph drained for a day (mL/24 h) was <50 mL. Postoperative ultrasound (US) examinations or CT scans were performed only in case of lymphocele suspicious, based on patient's symptoms, or whether the drainage supplied more than 400 ml for three consecutive days.

Similarly, discharged patients evaluated in outpatient or emergency department with clinical suggestive of SL, were investigated with abdominal radiological imaging. SL was defined as the presence of lymphatic storage with signs of infection, such as fever and elevated WBC count, or resulting in mechanical compression causing abdominal pain, lower extremities edema or compression on the mail vessels [7].

Data collection

We recorded and analyzed preoperative, perioperative and postoperative variables. Age, body mass index (BMI), American Society of Anesthesiologist (ASA) score, presence of diabetes or cardiovascular diseases, smoking habit, preoperative PSA serum level, previous history of abdominal surgery, peripheric vascular/lymphatic disease or peripheric vascular surgery as well as the use of anticoagulants or antiplatelets therapy [9], were considered. In particular, peripheric lymphatic disease was defined as the presence of fluid retention in peripheric vascular district due to lymphatic system disease, while "previous vascular surgery" was defined as any intervention on major abdominal or lower limbs vascular district. Operative time, techniques of lymphadenectomy and intraoperative or late complications were also recorded, including the treatment in case of SL. The severity of complications was graded according to the modified Clavien-Dindo classification system [10]. Finally, we recorded drainage placement, days of drainage, length of hospital stays, tumors histopathological characteristics and readmission rate. Related to postoperative thromboprophylaxis, our region and institution encourage the use of low molecular-weight heparin (LMWH) in all patients submitted to RARP and PLND from the day before the surgery to the 12^{th}-18^{th} postoperative day, according to patients' stratification risk.

Statistical analysis

Categorical, continuous parametric and not-parametric variables were reported as frequencies and proportions, mean and standard deviation (SD) or as median and interquartile range (IQR), respectively. Unpaired *T*-Test, Mann-Whitney and Pearson's chi-square tests were used to compare variables, as appropriate. Statistical significance in this study was set as $p \leq 0.05$. Univariable logistic regression analysis was performed for those variables attested significative at the descriptive analysis and for those with potential impact on the developing SL. Multivariable analyses (MVA), using logistic regression analysis, was then employed for significant predictors of SL at the univariable analysis. Analyses were performed with SPSS version 25.0 (SPSS Inc, Chicago, IL, USA).

Results

Overall, 285 patients were submitted to RARP and PLND. After excluding 3 patients experiencing postoperative anastomotic leakage, 282 were included for quantitative analysis and, out of these, 21 patients (7.5%) developed SL after surgery. Baseline and postoperative patients' features are extensively depicted in Table 1.

Overall, the two cohorts were found to be comparable in most of preoperative characteristics.

However, median BMI was found to be significantly higher in patients experiencing postoperative SL (25.8 (IQR 23.1–28.3) vs 30.4 (IQR 30.1–31); $p < 0.01$). Moreover, the percentage of those with history of vascular surgery or peripheric vascular/lymphatic disease was also significantly higher in the subgroup of patients diagnosed with SL (8.4% vs 23.8%; $p = 0.02$).

Related to peri-operatory factors, we noted that the lymphadenectomy technique was used differently in those patients developing postoperative SL ($p = 0.04$). In particular, in this cohort the main approach was seen to be the bipolar cauterization of the lymphatic vessels (38.1%), while an extended use of clips was used only in four patients (19%). Conversely, in patients who were not been affected by SL, the approach was mainly based on surgical clips (81.5%).

Three intraoperative complications were collected (one damage at the internal iliac artery and two bladder lesions) and all occurred in patients who did not experienced SL.

Postoperative complication rate, on the other hand, was naturally higher in patients with SL as well as length of hospital stay and readmission rate. Lymphoceles were treated with broad spectrum antibiotics in 7 (33%) cases (Clavien-Dindo II), while 14 (67%) patients had an abdominal drainage placed (Clavien- Dindo IIIa).

Considering drainage placement, pathological tumor stages and ISUP grade, number of removed LNs and presence of positive LNs at histopathological examination, we did not record a meaningful difference comparing patients

Table 1. Overall characteristics of patients submitted to radical prostatectomy with lymph node dissection.

	No lymphocele group (*n.* 261, 92.6%)	Lymphocele group (*n.* 21, 7.4%)	*p*-Value
Age (years), median; IQR	67 (61–72)	65 (58–71)	0.86
BMI (kg/m^2), median; IQR	25.8 (23.1–28.3)	30.4 (30.1–31)	**<0.01**
ASA, median; IQR	2 (2–2)	2 (2–2)	0.69
Diabetes, n. %	29 (11.2)	4 (19)	0.28
Cardiovascular disease, *n.* %	127 (48.7%)	11 (52.4)	0.74
Smoking habit, *n.* %			
Never	143 (54.7)	11(52.2)	0.61
Former	57 (21.8)	5 (23.9)	
Current	61 (23.5)	5 (23.9)	
Preoperative PSA, median; IQR	7.8 (5.1–12.1)	7.5 (6.6–11.5)	0.94
Previous abdominal surgery, *n.* %	107 (41)	12 (57.1)	0.14
Previous vascular surgery or peripheric vascular/lymphatic Disease, *n.* %	22 (8.4)	5 (23.8)	**0.02**
Anticoagulant or antiplatelets therapy, *n.* %	39 (14.9)	4 (19)	0.61
Lymphadenectomy technique, *n.* %			
Extended use of clips	110 (42.3)	4 (19)	**0.04**
Clips only on main vessel	102 (39.2)	9 (42.9)	
Bipolar	48 (18.5)	8 (38.1)	
Operative time, median; IQR (min)	185 (150–220)	190 (150–225)	0.94
Estimated Blood Loss; median (IQR) (ml)	125 (80–180)	150 (70–180)	0.71
Intraoperative Complication, *n.* %	3 (1.1)	/	0.62
Postoperative Clavien Dindo complication, *n.* %			
1	16 (6.1)	2 (9.5)	**0.01**
2	16 (6.1)	7 (33)	
3	4 (1.5)	14 (67)	
4	1 (0.1)	/	
Drainage placement, *n.* %	204 (78.2)	19 (90.5)	0.18
Days of drainage, median; IQR	1 (1–3)	2 (1–11)	0.76
Length of Hospital stay, median; IQR (days)	3 (3–4)	5 (4–7)	**0.01**
Pathological Tumor, *n.* %			
2 a b c	68 (26.1)	3 (14.3)	0.48
3 a	131 (50.2)	12 (57.1)	
3 b	62 (23.8)	6 (28.6)	
ISUP grade, *n.* %			
1	2 (0.8)	/	0.29
2	55 (21.2)	1 (4.8)	
3	97 (37.3)	13 (61.9)	
4	66 (25.4)	4 (19)	
5	38 (14.6)	3 (14.3)	
Number of lymph nodes removed, median; IQR	16 (12–23)	18 (14–22)	0.57
Patients with positive lymph nodes, *n.* %	50 (19.2)	6 (28.6)	0.29
Readmission rate, n. %	4 (1.5)	9 (42.9)	**0.01**
Treatment of the lymphocele, *n.* %			
Antibiotics treatment	/	7 (33)	/
Drainage US/CT guided	/	14 (67)	
Time to SL detection, median; IQR (days)	/	8 (4–15)	/
Follow-up, median; IQR (months)	18 (11-24)	20 (11-25)	0.33
Lost at follow up, *n.* %	8 (3.1)	1 (4.8)	0.67

BMI: body mass index; ASA: American Society of Anesthesiologists: CCI age adjusted: charlson comorbidity index age adjusted; US: ultrasound; CT: computer tomography; SL: symptomatic lymphocele.
Bold values are the significant results.

diagnosed with postoperative SL and their counterpart ($p > 0.05$).

At the univariable analysis BMI, lymphadenectomy technique and history of vascular surgery or peripheral lymphvascular disease were found significantly associated with lymphocele formation (Table 2).

At MVA only increasing BMI was confirmed as a possible predictor of developing SL (OR 1.72; IC $1.47 - 2.81$; $p < 0.001$) (Table 3).

Discussion

PLND at the time of radical prostatectomy for prostate cancer is considered to be the most accurate and reliable staging procedure for detecting nodal invasion although it can significantly increase the risk of complications [1,2].

Results on the reduced risk of PLND-related complications during robotic-assisted procedure over laparoscopic and open approach are controversial despite well noted advantages such as magnified tridimensional vision and Endowrist technologies [4]. Indeed, accidental vessel damages or ureteric injuries could happen during PLND dissection, although the most frequent complication is lymphocele formation [3,4]. The overall incidence of SL is variable and ranged from 0.4% to 16% and, when present, has shown to be associated with increasing hospitalizations and morbidity [5].

Lymphoceles are usually asymptomatic and are thus undetected in many patients, if not investigated. On the other side, the SL could be associated with several presentations including abdominal pain, lower limb pain, and edema, bothersome urinary symptoms, deep venous thrombosis or infectious complications [11–13].

Table 2. Univariable logistic regression analysis.

	OR (95% IC)	*p*-Value
Lymphadenectomy technique	2.2 (1.96–3.16)	**0.02**
Previous vascular surgery or peripheric vascular/lymphatic disease	1.02 (1.01–2.91)	**0.03**
Body mass index	1.59 (1.16–2.99)	**0.001**
Number of lymph nodes removed	1.04 (0.95–1.06)	0.84
Diabetes	2.14 (0.76–3.91)	0.91
Presence of positive lymph nodes	1.19 (0.88–2.11)	0.65
Previous abdominal surgery	1.22 (0.68–2.81)	0.72

Bold values are the significant results.

Table 3. Multivariable loigic regression analysis for lymphocele formation.

	OR (95% IC)	*p*-Value
Lymphadenectomy technique	3.50 (0.96 − 4.36)	0.06
Previous vascular surgery/ or peripheric vascular/lymphatic disease	0.73 (0.44 − 7.91)	0.39
Body mass index	1.72 (1.47 − 2.81)	**0.001**

Bold values are the significant results.

Several studies have attempted to identify factors leading to SL development in patients undergoing RP with PLND. In this regard, the presence of extracapsular extension, surgeon's experience, the use of LMWH, pelvic drains, hemostatic agents and the size of the gland have been variably reported as potential agents [6,12–18]. However, the available data are mainly related to the open surgery and the evidence are either minimal or have been refuted in other studies.

The current study, aiming to explore the potential predictors of SL formation following PLND for pCa in the robotic era, found that the increase in BMI statistically affected the risk of developing lymphoceles. This may due to the fact that more adipose tissue is present in the pelvis and around the lymph nodes in these patients. As the adipose tissue is known to be a site of inflammation [19], it is possible that, in this subgroup of patients, lymphoceles became more likely symptomatic due to a preexisting inflammatory condition around the LNs which was triggered by the surgery. Previously, BMI was studied frequently as possible factor leading to lymphocele formation, but the studies failed to show any statistical association [20,21]. Recently, Seetharam and his group reported similar data showing that increased BMI was linked to a higher risk of lymphocele needing drainage after RARP, in line with our results [22]. Other authors found that patients with metabolic syndrome, and in particular with diabetes, were more likely affected by SL after RARP and PLND [3,12].

Gotto et al. in 2011 suggested that the preoperative use of LMWH may be associated with SL following open RP. Our findings did not support these correlations, but the relatively small sample collected may have prevented identifying other clinically significant predictors. Moreover, our internal thromboprophylaxis protocol may have biased a possible correlation between LMWH and SL.

Capitanio et al. in 2010 evaluated clinical predictors in developing SL and lymphorrhoea in 552 patients treated with open radical prostatectomy and PLND [23]. They found that age and number of LNs removed were independent risk factors significantly associated with the formation of SL. In particular, every additional LN removed and every additional year of age, improved the risk of having a SL by 5%. In our study, age as well as the number of lymph nodes removed, were not different in those patients who developed SL. Nevertheless, Capitanio et al. showed that this correlation increased when the number of removed LNs were >20 in patients >65 years of age. Our population was younger compared to the one enrolled by Capitanio and also the median number of LNs removed was smaller, leading to such results' discrepancy.

Of interest, LN status (pN1 vs pN0) was associated with increased risk of developing SL, in line with our findings. In fact, RARP candidates usually show a limited LN metastatic spread not extended enough to cause lymphatic leakage [23].

At the univariable analysis, we also found that the lymphadenectomy technique (extended use of clips vs clips on main vessels vs bipolar cauterization) could potentially correlate with increased SL formation (Table 2). In fact, PLND in patients who developed such complication was more frequently approached with the bipolar instrument instead of clipping (38.1% vs 19%). This evidence lost its significance at the MVA (Table 3) but it is supported by previous reports. Indeed, Orvieto et al. showed a 7.6% rate of SL in patients treated with extended PLND sealing the lymphatic vessels with the only use of bipolar energy [13].

History of previous vascular surgery (or peripheric lymphatic disease) was also found more frequent in patients experiencing SL (23.8% vs 8.4%, $p = 0.02$) and also potentially impactful at the univariable analysis (OR 1.01; CI 1 − 2.91; $p = 0.03$), based on our findings. Despite a reduced competence in lymph reabsorption by the vascular system in such patients has been demonstrated in literature [24], this association has not been validated at the MVA.

Related to different tips aiming to prevent lymphocele formation after PLND, Stolzenburg et al. described a four-point peritoneal flap fixation at the end of RARP that reduce lymphocele occurrence following PLND [25].

Another trick to prevent the SL, according to the clinical practice, is the drainage placement. As previously mentioned, a drain was arbitrarily placed at the end of the procedure based on the surgeon's preference. It is commonly thought that the prophylactic placement of an abdominal or retroperitoneal drain may prevent the formation of fluid

collections (including lymphocele) and support the early detection of postoperative bleeding and anastomotic leakage [7,26].

Nevertheless, in the current comparison, the percentage of patients with drainage did not differ between patients diagnosed with postoperative SL and those who did not experience such inconvenient (78.2% vs 90%, $p = 0.18$). This finding is in line with what reported in a recent systematic review by Kowalewsky et al. including 936 patients who were submitted to RARP grouped in who received drainage at the end of the procedure and who did not. Despite the authors did not mention the number of patients undergoing PLND, they showed no difference in terms of SL formation, hematoma and urinary retention at the MVA between the two groups [20]. Indeed, also in our experience either adult either pediatric population submitted to robot-assisted upper urinary tract reconstruction, no substantial differences in terms of perioperative safety and efficacy outcomes were noticed in the subgroups of patients who did not receive postoperative abdominal drainage [21,27].

To conclude, the present paper is not avoided of limitations: First of all, the number of events studied (onset of SL) was low ($n = 21$) to draw definitive conclusions. Second, the retrospective nature of the study may have limited the significance of the outcomes examined. Finally, few SL may have been missed especially in patients coming from other Italian regions.

Although these considerations, the present study represents an interesting report assessing clinical and pathological variables that may predict SL after RARP and PLND in the current scenario which lacks of meaningful data. The clinical application of the results reported is the strength point of the paper: In fact, this study has important implications at least at three stages during the management of patients with prostate cancer: (1) Preoperative counseling (2) intraoperative technique and (3) managing of the postoperative period.

Conclusion

Lymphocele remains a common complication related to PLND, even when robotic assistance is applied, and its risk should be weighed against the benefit of PLND during RARP. According to our findings, higher BMI, lymphadenectomy strategy and previous exposition to vascular surgery may be possibly associated with the risk of developing SL. However, the most informative variable is increased BMI, as confirmed by the MVA. For these considerations, the present study represents a useful piece of information that may help clinicians in daily clinical practice.

Geolocation information

The study was conducted in Florence. All patients included were Italians.

Disclosure statement

No potential conflict of interest was reported by the author(s).

Research involving human participants

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and national research Committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent

Informed consent was obtained for all individual participants included in the study from parents or legal guardians.

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