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P.L.E.A.T. - *P*reventing *L*ymphocele *E*nsuring *A*bsorption *T*ransperitoneally: a novel robotic technique

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Declaration of interest

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Abstract

Objectives

To reduce the risk of symptomatic lymphocele after robotic pelvic lymph node dissection (PLND), we present a novel technique (P.L.E.A.T.): the peritoneum is 'pleated' along its midline, leaving two lateral openings and allowing lymphatic fluid to drain away from the pelvis and into the abdomen.

Methods

We analysed a single-surgeon series of PLNDs during Robotic Radical Prostatectomy, comparing 195 'standard' PLNDs (in which the peritoneum was 're-approximated' or left completely open) with 176 cases in which P.L.E.A.T. was performed.

Results

In the group without P.L.E.A.T., 8 cases of symptomatic (Grade ≥3, according to the Clavien Dindo Classification) lymphoceles (4.1%) were recorded. Only one P.L.E.A.T. patient complained of symptoms due to a lymphocele (p=0.039). No patient reported complications due to the procedure.

Conclusions

The P.L.E.A.T. technique is a fast, easy-to-perform and safe method of reducing the risk of symptomatic lymphocele after transperitoneal robotic PLND.

Introduction

The formation of a pelvic lymphocele is a complication which may follow robotic pelvic lymph node dissection (PLND). Most cases of lymphocele are asymptomatic (incidence reaches 30%) and are often an incidental finding during follow-up[1,2]. When symptoms do occur (incidence after robotic PLND 0-8% - Grade ≥3, according to the Clavien Dindo Classification[3]), they are typically related to compression of surrounding structures (pelvic pain, leg edema, deep vein thrombosis)[4].

An injury to the lymphatic vessels is the main causative factor in the formation of a lymphocele. Potential risk factors for its development are: surgical approach (laparotomy vs. laparoscopy/robotic), number of lymph nodes removed, lymph node status, and type of cancer.

Several studies have shown a lower incidence of lymphocele after robotic radical prostatectomy (RARP) with PLND, by means of a transperitoneal approach rather than traditional open or extraperitoneal approaches. Initial peritoneotomy is probably the main reason for the decreased incidence of lymphocele formation during transperitoneal PLND. The opening created during this approach allows lymphatic fluid to drain away from the pelvis and into the abdomen. Nevertheless, the incidence of lymphocele is also higher than anticipated, in view of the believed protective effect of the transperitoneal approach[5,6].

The aim of this study was to analyse the incidence to date of symptomatic lymphocele and to assess the protective role of a novel surgical technique to prevent its formation in a

large cohort of patients followed after robotic PLND and transperitoneal RARP for prostate cancer.

Materials and Methods

We analysed a single-surgeon (FDM) series of PLNDs during RARP, comparing 195 'standard' PLNDs (in which the peritoneum was 're-approximated' or left completely open) with 176 cases, in which a 'partial' closure of the peritoneum was performed.

The aim of this novel technique, named P.L.E.A.T. (acronym: Preventing Lymphocele Ensuring Absorption Transperitoneally) is to create a pathway lined by peritoneum, to direct lymphatic fluid out of the pelvis and into the peritoneal cavity where it can be absorbed: the peritoneum is 'pleated' along its midline and fixed to the fibers of the *rectus abdominis* muscles, near the pubis. The P.L.E.A.T. technique, leaving two lateral openings, allows lymphatic fluid to drain away from the pelvis and into the abdomen [Figure #1].

We excluded the first 50 cases of PLND performed by the surgeon FDM from this series: in these cases we found 4 symptomatic lymphoceles, but because the cooperation with other surgeons and a non-standardized technique, we decided to exclude the above cases in order to avoid any bias due to the initial learning curve. Although including the first 50 cases would have allowed us to increase the level of significance of this study (p value from 0.038 to 0.01), it would not have been methodologically correct.

All patients were managed similarly in the perioperative period (i.e. same timing for catheter/pelvic drain removal). In view of Deep Vein Thrombosis (DVP) prophylaxis, we treated all patients with subcutaneous low molecular weight heparin (Enoxaparin) at a dosage of 3000 UI/day (modified according to specific risk, renal function, body mass index) and graduated compression stockings. We usually continued Enoxaparin administration for one month after surgery.

We considered as 'symptomatic' any patient who presented with pelvic symptoms such as pelvic fullness, fever, or lower abdominal pain, even if slight, with ultrasound/CT/MRI feedback showing a lymphocele, according to Kim's criteria[7].
Patients who developed DVT complained of pain, swelling, or discoloration of the affected extremity; diagnosis was confirmed with doppler/compression ultrasonography.

Statistical analysis was performed with application of Fisher's, Mann-Whitney and Pearson's Chi-Square Tests.

Results

The demographic and clinical characteristics of patients in both groups were comparable, as was lymph nodes status ($p>0.05$). There were statistically significant differences in the pathological staging of cancers ($p<0.05$), and the median number of lymph nodes removed (5 vs 10 in standard and P.L.E.A.T. groups, respectively; $p<0.00001$) [see Table #1].
The cases of extended PLND (25 vs 35, in standard and P.L.E.A.T. groups, respectively) were not statistically different ($p=0.064$). In the 195 PLNDs without P.L.E.A.T. reconstruction, we found symptomatic lymphocele (Grade ≥3, according to the Clavien Dindo Classification[3]) in 8 cases (4.1%) distributed homogeneously (and not grouped in the first cases). Only one P.L.E.A.T. patient complained of symptoms due to a bilateral lymphocele, which required percutaneous drainage ($p=0.039$). Specific data concerning these patients and the management of complications are shown in Table #2. No patient reported either complications related to the procedure or any kind of abdominal/pelvic discomfort.

Comment

The problem of preventing lymphocele after PLND remains an interesting challenge, particularly in cases of extended PLND. Various solutions have been proposed to limit the risk, such as the use of new energy sources, or collagen patches coated with human coagulation factors which provide rapid and reliable hemostasis by creating a robust fibrin clot adhering to the tissue surface[8,9].

Considering exclusively surgical techniques, a 'peritoneal fenestration' is proposed to prevent the above-mentioned complications: this concept has been extensively studied to prevent lymphocele development in renal transplantation and a recent review confirmed its effectiveness[10].

In fact, during open radical prostatectomy or extraperitoneal RARP, the occurrence of lymphocele is significantly lower with fenestration, and the formation of symptomatic lymphocele requiring surgical intervention was *de facto* eliminated, without an increase in postoperative morbidity, as documented by Stolzenburg et al.[11].

Nevertheless, although transperitoneal PLND, as opposed to traditional open or extraperitoneal approaches, has shown a lower incidence of lymphocele, it still remains significant[12]: it may be due to spontaneous 're-approximation' of the edges of the peritoneum, incised laterally to the medial obliterate ligaments. In many cases, after release of the pneumoperitoneum after a RARP with PLND, even though the bladder is left 'dropped', perivesical fat adheres to the PLND bed, creating a closed space in which lymphatic fluid accumulates. As reported by Lebeis et al., the bladder often forms the medial wall of the lymphocele cavity[13].

In addiction, when the peritoneum is 're-approximated', the final result is similar to an extraperitoneal open/laparoscopic radical prostatectomy.

Some authors have proposed the insertion of a peritoneal flap, created by dropping the bladder from the abdominal wall and fixing it to the lateral aspect of the bladder, at the end of the procedure: the 'window' prevents scarring to the bladder over the PLND area, allowing lymphatic fluid to drain into the peritoneal cavity and thus be reabsorbed[13]. As reported by the authors, this peritonealization of the lateral aspect of the bladder with a. interposed flap is effective in preventing post-operative lymphoceles. However, this technique fixes the bladder inferiorly.

As previously reported[14], during RARP we usually perform the CoRPUS reconfiguration, in which, after the creation of a complete support for the urethra, we put a final stitch from the anterior wall of the bladder to the pubis allowing the bladder, bladder neck and/or posterior urethra axis to be properly aligned. With this technique, the solution proposed by Lebeis et al. is not feasible.

It was from these considerations that we devised and applied the P.L.E.A.T. surgical technique. The unique nature of this strategy is that the two lateral 'openings' do not collapse when the pneumoperitoneum is removed, because pleating the bladder (into a more natural position) means that we pull the peritoneum medially, thereby avoiding any possible spontaneous re-approximation.

The results demonstrated the significant protective effect of this technique in preventing symptomatic lymphocele, compared with the widespread standard approach, although the number of lymph nodes removed in the P.L.E.A.T. group was significantly higher ($p<0.00001$).

The strengths of this study are: 1. the surgical technique for both limited and extended PLND was standardized (with only one Hem-o-lock® clip distal to Cloquet's node and bi-

polar coagulation); 2. In view of the incidence of symptomatic lymphocele reported in the literature, the number of patients enrolled was adequate (powered statistical analysis); 3. the technique is simple and easy-to-perform (2-3 min) and is thus easily replicable; 4. the absence of complications due to the technique allows us to conclude that it is safe.

The limitations of this study are: 1. all the procedures were performed by the same skilled robotic surgeon: although this avoided any bias due to the differing proficiency and/or technique of several surgeons, we realize that it may represent a limitation. In effect, it was in order to reduce the impact of the learning curve that we decided not to consider the first 50 cases; 2. this is a non-randomized study, based on analysis of medical records; 3. both limited and extended PLND were examined in the same analysis, although both techniques were similarly distributed in the two groups, nullifying any bias (25 vs 35 extended PLNDs in the standard and P.L.E.A.T. groups, respectively; $p>0.05$). Although not significantly higher, the number of extended PLNDs performed in the second 'era' far from being a demonstration of an improvement in technique, only demonstrates an increase in the number of indications of more clinically extended neoplasms, as confirmed by the different percentage of pT2/pT3 in the two groups. Considering that both the number of lymph nodes removed and the type of cancer represent well-documented risk factors for symptomatic lymphoceles, this distribution of cases reinforces the protective role of the P.L.E.A.T. technique.

Conclusions

Our preliminary analysis confirms that the P.L.E.A.T. technique is a fast, economic, easy-to-perform and safe method for reducing the risk of symptomatic lymphocele after transperitoneal robotic PLND. Randomized clinical trials (preferably multi-institutional) are

needed to confirm the efficacy of P.L.E.A.T., maching other recently reported studies comparing differing techniques for lymphoceles.

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Legends:

Figure #1: (A) Drawing and (B) Intraoperative photo showing bladder peritoneum ‘pleated’ along midline, leaving two lateral openings, according to the P.L.E.A.T. technique.

269 Table 1. Comparison of patient characteristics in 'standard' Group and P.L.E.A.T. Group.

	Group 1 (standard)	**Group 2 (P.L.E.A.T.)**	*p*
Parameter			
Number of Patients	**195**	**176**	
Pathological Staging (%)			*0.03*[*]
pT0	10 (5.1)	1 (0.6)	
pT2(a-b-c)	110 (56.4)	98 (55.7)	
pT3(a-b)/pT4	75 (38.5)	77 (43.7)	
Lymph Nodes Removed			
Median (IR)	5 (0-11)	10 (6.5-15)	*<0.00001*[§]
Positive Nodes (%)	5 (2.6)	11 (6.25)	*0.12*[#]
Extended PLNDs (%)	25 (12.8)	35 (19.9)	*0.068**
Symptomatic Lymphocele (%)	8 (4.1)	1 (0.6)	*0.038*[#]
Symptomatic Lymphocele in Extended PLNDs (%)	1/25 (4)	1/35 (2.9)	*n.s.*
Follow-up days (median, IQR)	1951 (1678-2192)	731.5 (508-1033)	
			[*]*Chi-Square* [§] *Mann-Whitney test* [#]*Fisher's test*

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272 Table 2. Patients with symptomatic lymphocele

Case #	Technique	Symptoms	Postop Day #	Management	Successful
2	no PLEAT	fever, DVT	36	PC Drainage	yes
18	no PLEAT	pain	45	PC Drainage	yes
82	no PLEAT	fever	11	PC Drainage	yes
91	no PLEAT	fever, LUTS	38	PC Drainage	yes
98	no PLEAT	fever	145	Antibiotics	yes
120	no PLEAT	fever, gain	26	PC Drainage	yes
177	no PLEAT	fever, DVT	32	PC Drainage	yes
182	no PLEAT	DVT	25	PC Drainage	yes
367	PLEAT	DVT	26	PC Drainage	yes

273 *DVT: Deep Venous Thrombosis; LUTS: Low Urinary Tract Symptoms; PC: Percutaneous*
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