

Exploring the effect of TachoSil on lymphocele formation after extended pelvic lymph node dissection in prostate cancer

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Introduction

Our goal was to prospectively explore the lymphostatic effects of TachoSil in patients undergoing transperitoneal extended pelvic lymph node dissection (ePLND) with or without radical prostatectomy (RP).

Development of a lymphocele is a frequent complication after ePLND for nodal staging in prostate cancer. The majority of these are asymptomatic and resolve spontaneously by one year, but symptomatic lymphoceles can occur (1-3).

Methods

From 2013 to 2016, 100 patients with prostate cancer who were set to undergo a staging ePLND before external beam radiotherapy (n = 50) or ePLND concomitant with RP (n = 50) were prospectively randomized 1:1 between bilateral TachoSil placement or nonplacement (ClinicalTrials.gov: NCT02001857).

Primary end points were the development and volume of radiographic lymphoceles at one week and one month postoperatively, and the duration and produced volume of the postoperative drainage catheters (lymphorrea).

Table 1. Patient and tumor characteristics

SOLE ePLND	Total (n = 50)	TachoSil (n = 25)	Control (n = 25)	p-value
Age, years	73 [52-84]	75 [52-84]	72 [54-83]	0.48
ASA score > II	22%	13%	30%	0.15
Prostate volume, mL	45 [13-110]	38 [13-103]	45 [23-110]	0.64
iPSA, ng/mL	17.0 [2.77-270]	18.0 [5.0-270]	16.0 [2.8-144]	0.47
cT stage > 2	64%	60%	68%	0.56
cN1 stage	13%	13%	13%	1
Grade group (WHO)				0.60
1-3	36%	32%	40%	
4-5	64%	68%	60%	

RP + PLND	Total (n = 50)	TachoSil (n = 25)	Control (n = 25)	p-value
Age, years	67.5 [55-79]	67 [55-77]	68 [55-79]	0.65
ASA score > II	12%	17%	8%	0.37
Prostate volume, mL	42 [14-106]	40 [17-90]	42.3 [18-106]	0.62
iPSA, ng/mL	11 [1.93-31.1]	10.3 [1.93-31.1]	12.0 [4.50-26.0]	0.59
cT stage > 2	12%	12%	12%	1
cN1 stage	4.5%	4.5%	4.5%	1
Grade group (WHO)				0.144
1-3	64%	68%	60%	
4-5	36%	32%	40%	

Table 2. Surgical characteristics

SOLE ePLND	Total (n = 50)	TachoSil (n = 25)	Control (n = 25)	p-value
Follow-up, mo	14 [1-33]	14 [1-33]	14 [1-33]	0.91
Lymph node yield	18 [6-54]	18 [7-24]	18 [6-54]	0.08
Pathological N1 stage	38%	40%	36%	0.67

RP + PLND	Total (n = 50)	TachoSil (n = 25)	Control (n = 25)	p-value
Follow-up, mo	31 [4-45]	29 [4-45]	32 [7-43]	0.09
R+	30%	36%	24%	0.36
Lymph node yield	14 [8-26]	14 [8-24]	14 [10-26]	0.15
Pathological N1 stage	12%	8%	16%	0.67
Nerve sparing	84%	88%	80%	0.72

Results

Patient, tumor, and surgical characteristics of the TachoSil and the control groups did not differ significantly (Table 1 and 2). Significantly less radiographic lymphoceles were observed one week postoperatively for patients who underwent sole PLND and one month postoperatively for patients who underwent PLND with RP in the TachoSil group compared with the control group (highlighted in bold in Table 3). The other postoperative characteristics presented no significant differences between the 2 groups, neither for sole PLND nor for PLND with RP.

Table 3. Postoperative characteristics

SOLE ePLND	Total (n = 50)	TachoSil (n = 25)	Control (n = 25)	p-value
Drain stay, d	1 [1-10]	1 [1-8]	1 [1-10]	0.80
Total drain V, ml	146 [1-1705]	160 [7-1420]	115 [1-1705]	0.43
Mean drain V/d	67 [1-169]	68 [4-169]	58 [1-159]	0.50
Rad. Lymphocele				
Week 1	16 (32%)	4 (16%)	12 (48%)	0.024
Month 1	23 (46%)	12 (48%)	11 (44%)	0.75
Symp. lymphocele				
Week 1	7 (14%)	2 (8%)	5 (20%)	0.31
Month 1	7 (14%)	2 (8%)	5 (20%)	0.21
Lymphocele V, ml				
Week 1	19 [3-317]	71 [4-170]	19 [3-317]	0.60
Month 1	13 [1-750]	18 [1-750]	10 [2-280]	0.50

RP + PLND	Total (n = 50)	TachoSil (n = 25)	Control (n = 25)	p-value
Drain stay, d	3 [1-12]	4 [1-12]	3 [1-6]	0.086
Total drain V, ml	683 [87-3790]	1020 [102-3790]	645 [87-1705]	0.085
Mean drain V/d	129 [26-322]	132 [26-322]	115 [44-218]	0.24
Rad. Lymphocele				
Week 1	19 (38%)	10 (40%)	9 (36%)	0.86
Month 1	19 (38%)	6 (24%)	13 (52%)	0.047
Symp. lymphocele				
Week 1	8 (16%)	6 (24%)	2 (8%)	0.24
Month 1	6 (12%)	2 (8%)	4 (16%)	0.66
Lymphocele V, ml				
Week 1	29 [1-330]	31 [4-71]	28 [1-330]	0.72
Month 1	35 [1-160]	34 [1-85]	35 [3-160]	0.83

Conclusions

Patients undergoing bilateral TachoSil placement after ePLND seem less likely to develop a radiographic lymphocele early postoperatively. Nevertheless, the clinical relevance of the use of TachoSil remains highly debatable.

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