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ABSTRACT

MATERIAL AND METHODS

RESULTS

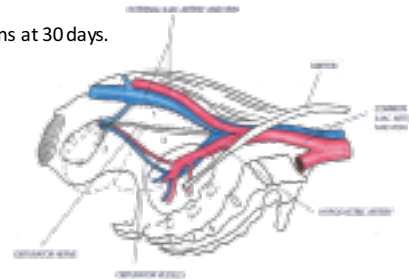
Introduction. Pelvic lymph node dissection (PLND) in prostate cancer is controversial. Although it represents the most reliable procedure for lymph node staging, the extended PLND was reported to be associated with increased morbidity.

Materials and methods. Between October 2011 and March 2017, men were consented to the trial and underwent radical prostatectomy at Memorial Sloan Kettering Cancer Center. The study design was a cluster randomization with crossover. Each surgeon was randomized to use a limited (external iliac nodal packet) vs. extended (external iliac, obturator fossa and hypogastric nodal packets) PLND template for a 3-month period. At the end of the 3-month period, surgeons were once again randomized. Morbidity data within 30 days of surgery was prospectively graded and collected in the clinical research database.

Results. A total of 1574 patients were randomized: 811 randomized to the extended and 763 to the limited template. Overall the rate of complication was 10.5% in the limited PLND group vs. 8.5% in the extended PLND group. There were no grade IV or V complications. Rates for grade II and III complications were similar (7.2% in limited vs. 6.3% in extended).

Conclusion. In this large randomized trial the overall rate of grade II and III complications was low. There was no significant difference in complication rates between the limited and extended PLND.

- ✓ **Study period:** October 2011 and March 2017
- ✓ **Type of study:** Clinically integrated randomized trial
- ✓ **Randomization:** surgeon-level cluster crossover randomization. Surgeons were cluster-randomized every 3 months using randomly permuted blocks of 4.
- ✓ **Endpoint:** Complications at 30 days.
- ✓ **Intervention:** PLND
 Limited: (1)
 Extended: (1,2,3)



RESULTS

Table 1 : Complication grade within 30 days of surgery

Complication Grade	Limited PLND	Extended PLND
	N: 723 (49%)	N: 757 (51%)
None	647 (89%)	692 (91%)
1	24 (3.3%)	17 (2.2%)
2	27 (3.7%)	25 (3.3%)
3	25 (3.5%)	23 (3.0%)
≥ 2	52 (7.2%)	48 (6.3%)

Table 2 : List of complications within 30 days of surgery

Complication	Limited PLND			Extended PLND		
	Grade 1	Grade 2	Grade 3	Grade 1	Grade 2	Grade 3
Angina or cardiac arrest	0	1	0	0	2	0
Supraventricular Arrhythmia	1	2	0	0	0	0
Ventricular Arrhythmia	1	0	0	0	0	0
Deep Venous Thrombosis	0	4	0	1	2	0
Pulmonary Embolus	0	2	1	0	5	0
Hemorrhage	4	13	4	0	7	4
Hypotension or Shock	0	0	0	0	1	0
Paralytic Ileus	0	2	0	2	3	0
Small Bowel Obstruction	0	1	1	0	0	0
Wound Infection	1	1	0	4	4	0
Intra-abdominal Infection	0	0	5	0	0	8
Lymphocele or Chylous Ascites	1	1	5	0	0	1
Anastomotic Leak	4	1	5	4	0	7
Ureteral Injury	0	0	1	0	0	2
Motor Neuropathy	1	0	0	0	0	0
Sensory Neuropathy	1	0	0	0	0	0
Gastrointestinal Injury	0	0	0	0	1	0

CONCLUSION

In this large randomized trial the overall rate of grade II and III complications was low. There was no significant difference in complication rates between the limited and extended PLND.