Lymph node staging with 18F-PSMA PET/CT in newly diagnosed prostate cancer using histopathological evaluation as reference

MINT TRIAL : Moleculair Imaging in lymph Node sTaging

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Conflicts of interest

Type of affiliation / financial interest	Name of commercial company
Receipt of grants/research supports	Janssen Pharma, Ipsen
Receipt of honoraria or consultation fees	Intuitive Surgical
Stock shareholder	None
Other support (please specify):	None

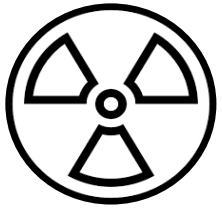
Background

- PSMA PET/CT is increasingly used in primary prostate cancer staging.
- No histopathological validation study has been conducted concerning ^{8}F-PSMA-1007 radiotracer.
- Aim: To evaluate the diagnostic accuracy of ^{18}F-PSMA-1007 PET/CT for lymph node invasion, compared to histopathological results of extended pelvic lymph node dissection (ePLND) in men with intermediate or high-risk PCa.

Study design

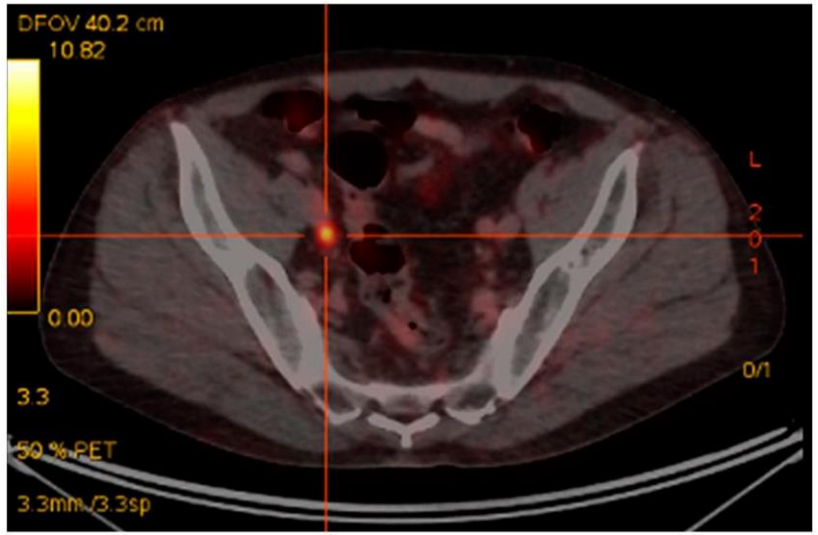
Men with newly diagnosed intermediate to high risk PCa (EAU)

Web-based MSKCC nomogram LNI risk > 5%

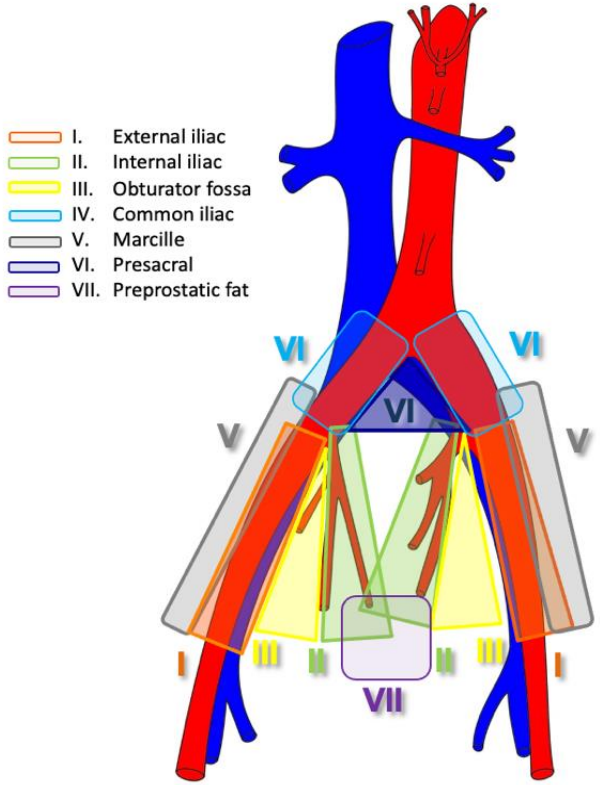


18F-PSMA PET/CT

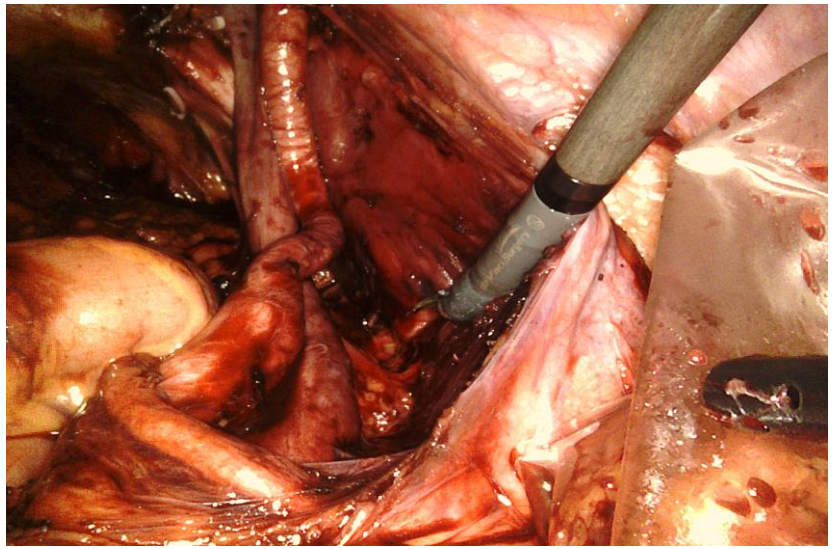
Study design



Cognitive or probe image guided



Template based resection and histopathological evaluation



Extendend pelvic lymph node dissection

Results

Baseline Characteristics of 99 men	
Age at time of biopsy yrs (SD)	68,1 (6.6)
EAU risk n(%) Intermediate High	 35 (35.0) 64 (65.0)
Serum PSA (mg/ml), median (IQR))	9.5 (6.5-15.3)
Time between PSMA-PET/CT and surgery in weeks, median (IQR)	4.0 (2.0-7.0)
Total resected lymph nodes, n Resected lymph nodes per patient, median (IQR)	2294 22 (17-28)
Total positive lymph nodes, n Patients with pN1 status, n (%)	69 30 (30.3)
Size of lymph node metastasis (mm), median (IQR)	3.5 (2.0 -6.0)

Results

Patient based % (95% CI)				
	pN1	pN0	Total	
miN1	16	7	23	Positive predictive value 69.6 (51.2-83.3)
miN0	14	62	76	Negative predictive value 81.6 (75.0-86.8)
Total	30	69	99	
	Sensitivity 53.3 (34.3-71.7)	Specificity 89.9 (80.2-95.8)		

		Template based % (95% CI)		
	pN1	pN0	Total	
miN1	8	26	34	Positive predictive value 23.5 (12.7-39.5)
miN0	54	1100	1154	Negative predictive value 95.3 (94.9-95.7)
Total	62	1126	1188	
	Sensitivity 12.9 (5.7-23.9)	Specificity 97.7 (96.6-98.5)		

Comparison of results

Patient based

	Median resected LN	Sensitivity	Specificity	Positive predictive value	Negative predictive value
^{18}F-PSMA-1007 PET/CT (MINT)	22	53.3 (34.3-71.7)	89.9 (80.2-95.8)	69.6 (51.2-83.3)	81.6 (75.0-86.8)
^{18}F-DCFPyl PET/CT (SALT)	18	41.2 (19.4-66.5)	94.0 (86.9-97.5)	53.8 (26.1-79.6)	90.4 (82.6-95.0)
^{68}Ga-PSMA-PET/CT (PEPPER)	14	41.5 (26.7-57.8)	90.9 (79.3-96.6)	77.3 (54.2-91.3)	67.6 (55.6-77.7)

Conclusion and discussion

^{18}F-PSMA-1007 PET/CT showed high specificity but moderate to

low sensitivity for detection of lymph node metastases in men with intermediate and high risk PCa.

^{18}F-PSMA-1007 PET/CT is inferior to extended pelvic lymph node dissection

We started a national randomised controlled trial to determine if PSMA-PET may replace pelvic lymph node dissection in primary diagnostic pathway in intermediate or high-risk prostate cancer : **PSMA –Select trial** (https://clinicaltrials.gov/ct2/show/NCT05000827)

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