

Radical Prostatectomy **Without** Prior Biopsy in Selected Patients Evaluated by ¹⁸F-Labeled PSMA PET CT and mpMRI: A Single- Center, Prospective, Single-Arm Trial

Dr. Shashank Agrawal

DrNB (Urology)

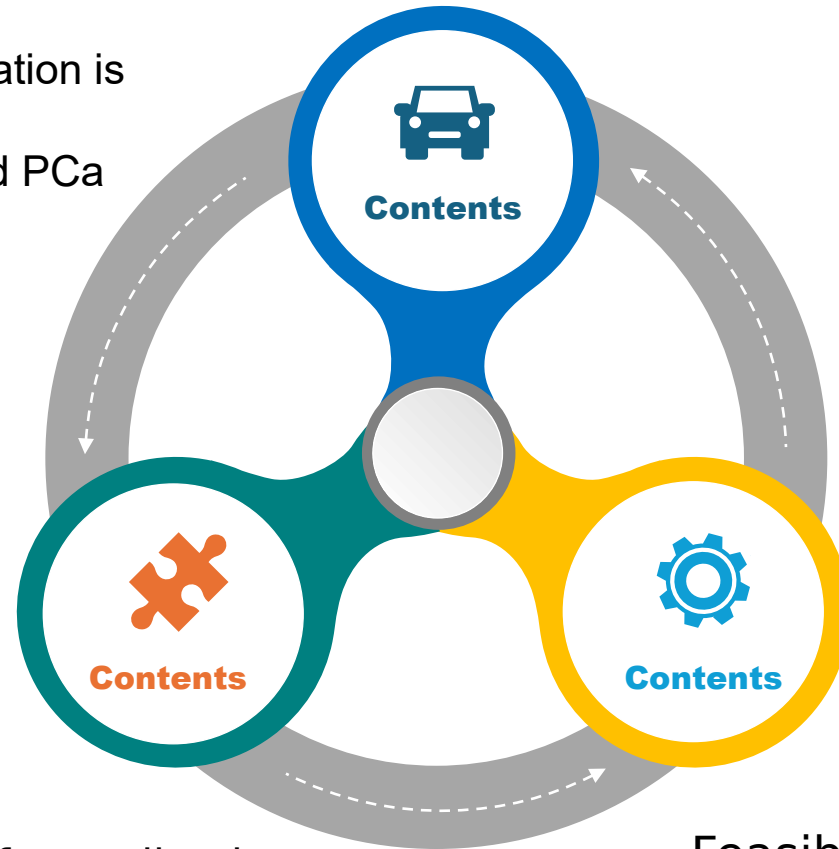
Fellowship in Uro-Oncology & Robotic Surgery

Consultant Uro-oncologist

Sindhu Hospital, Hyderabad

Introduction

Biopsy with pathological confirmation is mandatory before RP in localized PCa



Risk of complication.

Feasibility of RP without prior
biopsy is being actively
discussed

Intent of the study

To verify the feasibility and short-term prognosis of prostatectomy
without biopsy.



Methods



01

PSA levels ranging from 4 to 30 ng/mL were scheduled

02

On 3T MRI, PI-RADS 4 or 5 lesions led to surgery without prior biopsy.

03

For patients who agreed to surgery without biopsy, PSMA PET/CT scans were conducted.

04

Patients with PSMA PET/CT-positive lesions, no T3/T4 or distant metastasis, and who gave consent

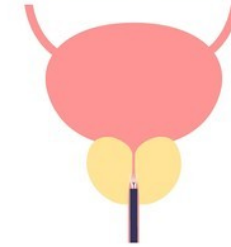
Exclusion criteria



Surgical Contraindication



**Previous Radiation or
Hormone therapy**



TURP



Prior Biopsy

Index Tumor Analysis

1) Lesion Identification: Lesions positive on both MRI and PSMA PET were jointly identified by 2 radiologists and 2 nuclear medicine physicians.

2) Index Tumor (IT) Selection Criteria:

Single co-positive lesion → designated as the **Index Tumor (IT)**.

Multiple co-positive lesions → calculate **Lesion Score** = *PI-RADS* + *miPSMA* score.

*Lesion with the **highest score** is designated as IT.*

*If scores are equal, lesion with the **larger diameter** is selected as IT.*

3) Pathological Definition of IT:

Tumor with the highest Gleason score.

If Gleason scores are equal → the largest volume lesion is considered IT.

4) Imaging–Pathology Correlation: Correspondence defined as dominant lesion localization on imaging and pathology using a 12-region mapping scheme

Outcome of the Study

01

PRIMARY

Clinically significant (cs) PCa detection rate:

Defined as ISUP GG ≥ 2 .

02

SECONDARY

IT localization response rate

Positive surgical margins



The background of the image is a blurred financial candlestick chart. The chart features green and red candlesticks representing price movements over time. A white grid is overlaid on the chart. The word "Results" is centered in a large, bold, white sans-serif font. Below the text is a thin, white, slightly wavy horizontal line.

Results

Table 1. *Demographic Characteristics of Study Patients*

Characters	Patients (n = 47)	
Age, mean (SD), y	66.4	(7.5)
BMI, mean (SD), kg/m ²	25.6	(3.1)
Preoperative PSA (ng/mL)		
tPSA, mean (SD)	10.5	(5.4)
fPSA, median (Q1, Q3)	0.98	(0.72, 1.45)
F/T ratio, mean (SD)	0.12	(0.05)
Prostate volume, mean (SD), mL	35.4	(12.4)
PSAD, mean (SD), ng/mL ²	0.24	(0.19, 0.38)

❖ **csPCa** was confirmed in **all 47 patients** enrolled in the study.

❖ **Adverse Pathology Findings:**

11 patients (23.4%) exhibited EPE or SV invasion postoperatively.

❖ **Lesion-Level Findings**

80 tumor foci identified (avg. 1.7 per patient).

63 lesions were **csPCa**.

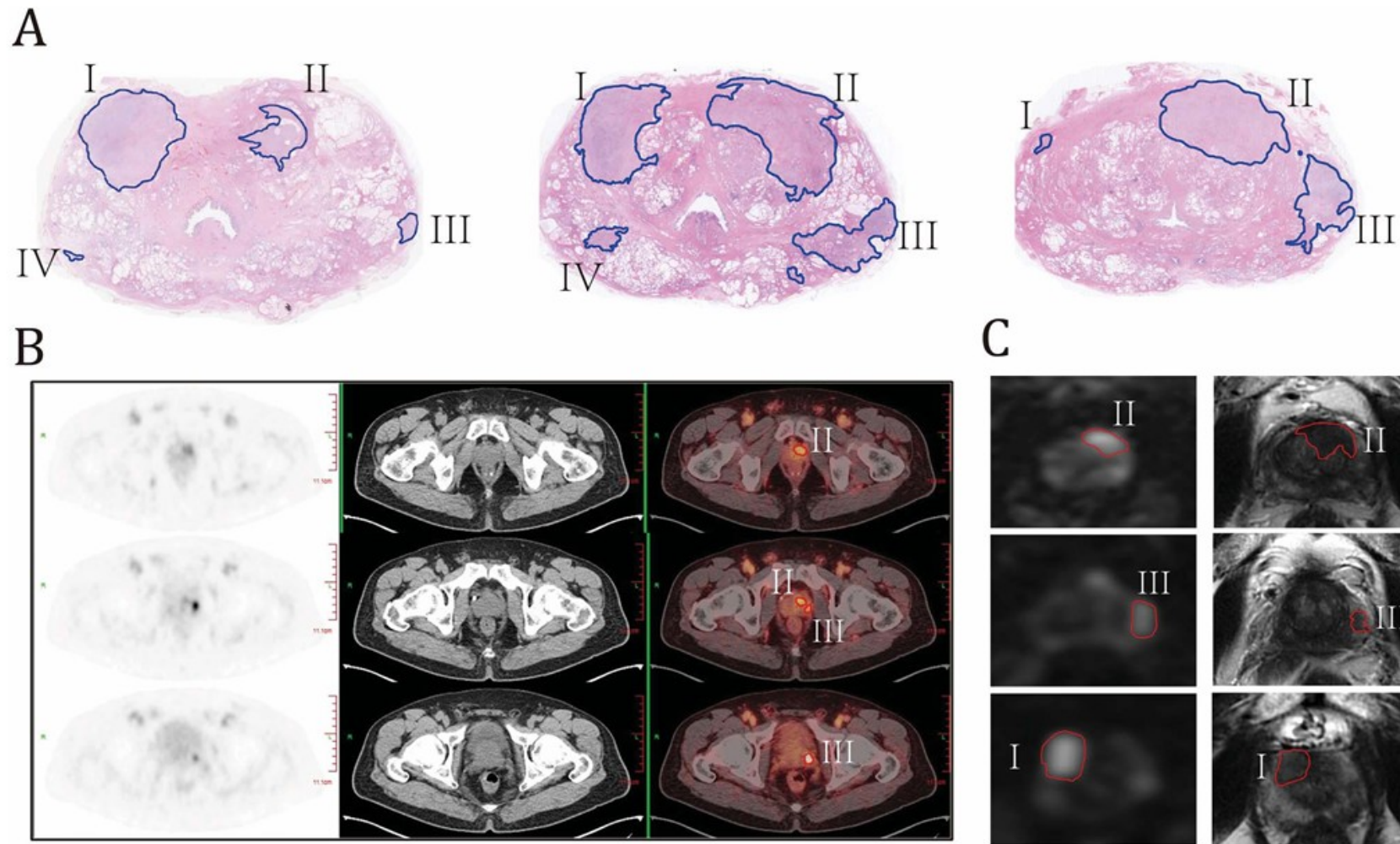
57 lesions (71.3%) detected on **mpMRI** or **PSMA PET/CT**.

23 lesions (28.7%) missed on imaging → mostly **ISUP ≤ 2** or **≤ 15 mm**.

Table 2. *Operative Variables and Histopathological Results*

Variables	Patients (n = 47)	
Nerve-sparing techniques, No. (%)		
Unilateral	11	(23.4)
Bilateral	10	(21.3)
Extrafascial	26	(55.3)
Operative time, median (Q1, Q3), min	128	(120, 155)
Operative blood loss, median (Q1, Q3), mL	50	(50, 100)
Blood transfusion, No. (%)	0	(0)
PCa patient detection, No. (%)		
Overall	47	(100)
csPCa	47	(100)
ITs detection in both images, No. (detection rate %)	45	(95.7)
Pathological ISUP grade, No. (%)		
1	0	
2	12	(25.5)
3	19	(40.4)
4	6	(12.8)
5	10	(21.3)
EPE	11	(23.4)
Cancerous lesions detection, No.	80	
ISUP grade of lesions, No. (%)		
1	17	(21.3)
2	24	(30.0)
3	20	(25.0)
4	7	(8.8)
5	12	(15.0)





- ❖ **Index Tumor (Focus II):** → Left transition zone → Detected on both **PSMA PET & mpMRI**
- ❖ **Focus I:** Right transition zone, ISUP 3 → **Visible on mpMRI only**
- ❖ **Focus III:** Left posterior peripheral zone, ISUP 2 → **Seen on both images**
- ❖ **Focus IV:** Right posterior peripheral zone, ISUP 2 (8 mm) → **Missed on imaging**



Results

Image Findings for mpMRI, PSMA PET/CT, & Combined Images

Table 3. *Imaging Finding*

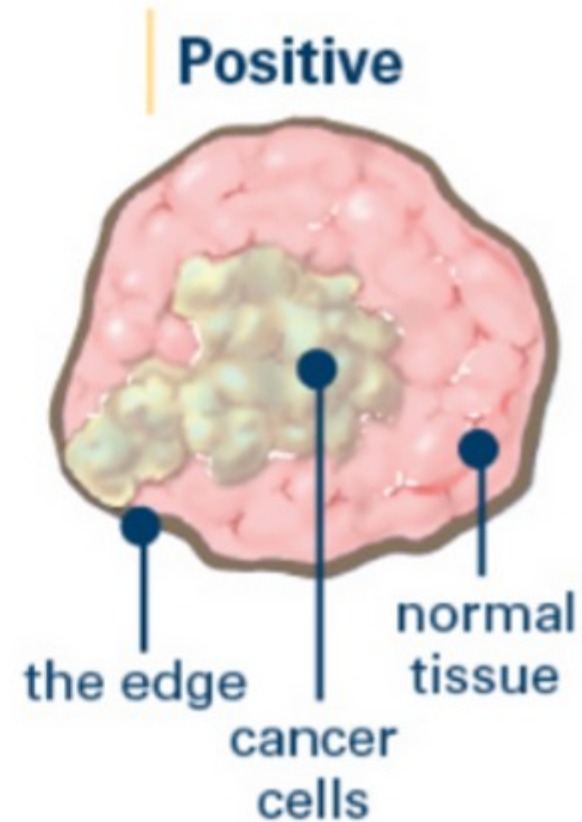
	Images	No. lesions finding (mean per patient)	Sensitivity (%)	PPV (%)
✔	mpMRI			
	PI-RADS > 3	58 (1.23)		
	Overall PCa	56 (1.19)	70.0	96.6
	csPCa	55 (1.17)	87.3	94.8
✔	PSMA PET/CT			
	miPSMA > 1	55 (1.17)		
	Overall PCa	52 (1.11)	65.0	94.5
	csPCa	52 (1.11)	82.5	94.5
✔	Combined images			
	PI-RADS > 3 and miPSMA > 1	51 (1.09)		
	Overall PCa	51 (1.09)	63.8	100
	csPCa	51 (1.09)	81.0	100
✔	Either image			
	PI-RADS > 3 or miPSMA > 1	62 (1.32)		
	Overall PCa	57 (1.21)	71.3	91.9
	csPCa	56 (1.19)	88.9	90.3



Results

PSM Analysis

- ❖ **PSM detected in 9 patients (19.1%)**
- ❖ **By PSA level:**
 - 6 patients: PSA 4–10 ng/mL
 - 3 patients: PSA 10–20 ng/mL
- ❖ **By ISUP grade:**
 - ISUP 2: 2 patients
 - ISUP 3: 2 patients
 - ISUP 4: 1 patient
 - ISUP 5: 4 patients



Results

Limitations



- ❖ **Small Sample Size:** Limits the generalizability of the findings.
- ❖ **Risk of Over-Investigation:** Routine use of both PSMA PET/CT and mpMRI → unnecessary imaging & increased patient cost.
- ❖ **Short Follow-Up Duration:** Insufficient data to assess long-term oncological outcomes.



Imaging

1

Combined
**mpMRI +
PSMA
PET/CT**
enables
accurate
diagnosis of
cs **PCa**

PSM

2

**Biopsy-
free
RARP→**
safe &
feasible in
**PI-RADS 4
& miPSMA
2,**

without
increasing
PSM rates



Conclusi

