

# Are there Detection Rate Differences of Transperineal Freehand US/MRI Fusion Target Prostate Biopsy in Two Different Patient Settings: Under Local Anesthesia or Under Deep Sedation?

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## ABSTRACT

**Introduction:** MRI-targeted prostate biopsy is the best diagnostic tool for clinically significant Prostate Cancer (PCa) detection. However, compared to the cognitive approach, the superiority of the approach with US/MRI fusion software for the detection rate is still unanswered. The study aim to assess possible differences in the detection rate of transperineal Freehand US/MRI fusion target prostate biopsy using the Esaote MyLab™9 System® in two different settings: outpatient setting with local anesthesia and patients undergoing deep sedation.

**Case Study:** A retrospective monocentric study was carried out at "San Pio" Hospital of Castellaneta, Italy, including 81 patients undergoing transperineal prostate biopsy from January 2021 to June 2022. The fusion biopsy was performed under local anesthesia or under deep sedation. All the enrolled patients performed a multiparametric prostate MRI before undergoing a prostate biopsy. All the Freehand US/MRI fusion target prostate biopsies were performed using the Esaote MyLab™9 System®, standard sampling, and targeted sampling. We evaluated the detection rate differences between the local anesthesia approach and that under deep sedation.

**Results:** There are no statistically significant differences between the two approaches to PI-RADS 4 ( $p > 0,05$ ;  $p = 0,63$ ) and Prostate Imaging Reporting and Data System (PI-RADS) 5 lesions.

**Conclusion:** These data highlight the lack of potential detection rate benefits of the deep sedation approach over the procedure under local anesthesia.

**Keywords:** Transperineal Prostate Biopsy • Fusion-Targeted Biopsy • Diagnosis • Magnetic Resonance Imaging • Prostate Cancer • Detection Rate

## INTRODUCTION

The prostate biopsy is considered the gold standard technique for Prostate Cancer (PCa) diagnosis.

MRI-targeted biopsy is considered better for clinically significant PCa detection than the random procedure for both previous negative and biopsy-naïve [1-3]. US/MRI fusion

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software for US-guided prostate biopsy is taking place, but there is still no evidence of detection rate superiority compared to the cognitive approach.

There are multiple types of techniques to perform targeted prostate biopsy:

- Cognitive approach: It consists in performing a prostate biopsy on a target after evaluating the position of the lesion on MRI sequences, with the assistance of transrectal ultrasonography but without using US/MRI fusion software [4].
- Fusion technique: It is performed on a target with the assistance of transrectal ultrasonography but employing US/MRI fusion software [5].
- In-bore technique: It is a targeted prostate biopsy performed using an MRI guide [6].

There is no solid evidence that one approach is better than the others for PCa detection rate [7]. It has been demonstrated the superiority of the transperineal approach for prostate biopsy compared to the transrectal one, probably also for a better detection rate of the lesions of the anterior zone of the prostate, but certainly for the lower infectious complications [8].

In this study, we used Esaote MyLab™9 System® for prostatic fusion biopsy. This system which allows a targeted ultrasound-guided prostate biopsy, fusing real-time MRI and ultrasound images through the assistance of a magnet positioned close to the patient's lower abdomen and a tracking device positioned on the transrectal probe [4]. This clinical investigation was carried out to assess detection

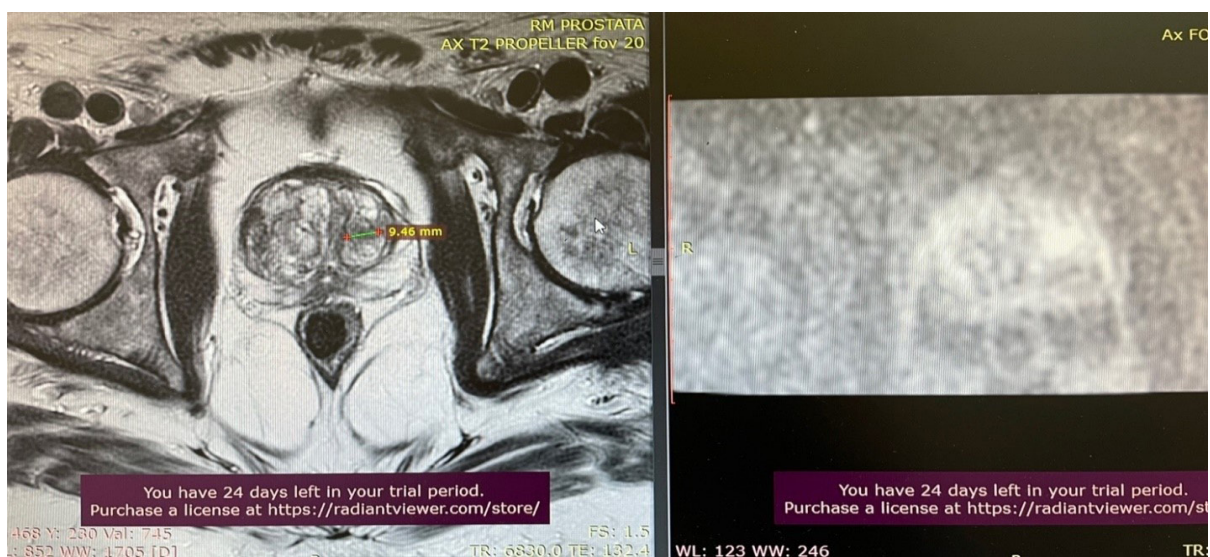
rate differences of Transperineal Freehand US/MRI fusion target prostate biopsy under local anesthesia or under deep sedation.

## CASE STUDY

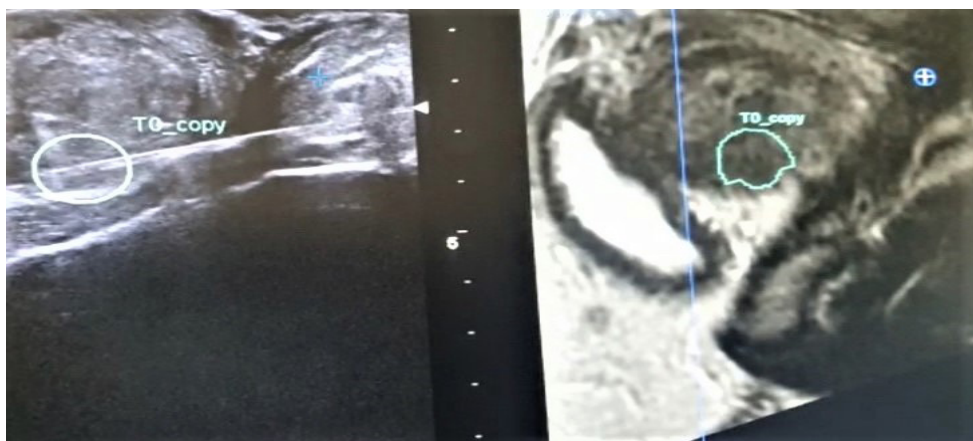
### Study Design and Patient Population

From January 2021 to June 2022, 81 men with at least one prostatic suspicious lesion (PI-RADS  $\geq$  4) based on multiparametric MRI underwent Fusion Bx (Figure 1) [9,10]. We have excluded only from the study, but not from the diagnostic biopsy path, the patients with PI-RADS 3 lesions to avoid limitations due to the low positivity rate of the PI-RADS 3 lesions. The study protocol is based on a systematic 12 core standard biopsy plus 3 cores per targeted lesion. Two experienced urologists performed all the procedures.

The fusion biopsy was performed on 48 patients under local anesthesia and 33 patients under deep sedation. The patient's comorbidities are sensitive to pain and will lead to the choice to perform a fusion prostate biopsy under local anesthesia or deep sedation. Each patient could have more than one PI-RADS 4 or 5 lesions [9,10]. All the Freehand US/MRI fusion target prostate biopsies were performed using the Esaote MyLab™9 System®, standard sampling, and targeted sampling. Esaote MyLab™9 System® is a US system that allows you to import MRI data sets. The lesions can be identified using spherical targets. The TLC 3-13 Bi-Plane endocavitary probe ultrasound images were collimated with those of MRI through communication between the US probe equipped with a tracking device and a magnet that is



**Figure 1:** Two mpMRI Sequences of prostate with a PI-RADS 4 lesion of the Transition zone (In Order from Left to Right: Axial T2 sequence, Diffusion-weighted imaging (DWI) sequence).



**Figure 2:** Real time Virtual Target sampling. The Hyperechoic Line in the Left Image is the Biopsy Needle during sampling on the Target (Circular image).

placed near the patient’s abdomen to give real-time spatial coordinates of the biopsy needle and the virtual targets to be biopsied (Figure 2). The patients undergoing local anesthesia received an ultrasound-guided peri-prostatic block using Lidocaine and sodium bicarbonate [11]. The patients undergoing deep sedation received intravenous protocol. In both cases, the biopsies were performed in the lithotomy position.

### Clinical Assessments

All the patients were subjected to a prostatic multiparametric MRI using a PI-RADSv2 and PI-RADSv2.1 system to classify the lesions [9,10]. An initial screening visit was performed to determine Digital Rectal Examination (DRE) positivity, symptoms such as hemospermia, Prostate-Specific Antigen (PSA) values, other parameters, and eligibility for prostatic fusion biopsy based on MRI detection of suspicious lesions. The study’s primary endpoint was to assess possible detection rate differences between the local anesthesia approach and the approach under deep sedation.

### Statistical Analysis

Windows Excel for macOS was used to conduct all the statistical analyses, such as mean values, median, maximum and minimum values, *p* values, and other statistical analyses. A Probability level of *p*<0.05 was considered statistically significant.

## RESULT

### Patient Characteristics

81 men, from 51 to 80 years old (mean age ± SD:67,7 years ± 7,7). The mean total PSA before the biopsy was 10,7

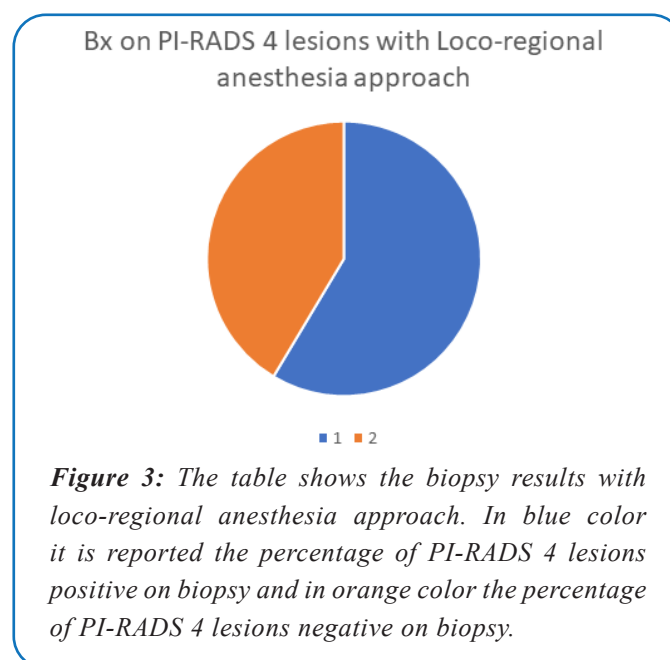
ng/ml, and the median value was 7,28 ng/ml (Maximum value=69 ng/ml; Minimum value=0,69 ng/ml). The mean PSA density was 0,192 ng/ml<sup>2</sup>, and the median value was 0,17 ng/ml<sup>2</sup> (Table 1).

**Table 1:** Values and data of patients characteristics.

	Mean	Median
Age	67,7 ± 7,7	
Total PSA	10,7 ± 10,3	7,28
PSA Density	0,192 ± 0,14	0,17

### Bx detection rate of PI-RADS 4

Among the 58 prostate lesions biopsies performed with local anesthesia on PI-RADS 4 lesions, 34 had positive results (58,6%) and 24 negative results (41,4%) for prostate cancer detection (Figure 3).



**Figure 3:** The table shows the biopsy results with loco-regional anesthesia approach. In blue color it is reported the percentage of PI-RADS 4 lesions positive on biopsy and in orange color the percentage of PI-RADS 4 lesions negative on biopsy.

### Bx on PI-RADS 4 lesions with Deep sedation approach



**Figure 4:** Among the 6 prostate biopsies performed with local anesthesia and the 3 biopsies under deep sedation on PI-RADS 5 lesions, all had positive results (100%).

Among the 30 prostate biopsies performed under deep sedation on PI-RADS 4 lesions, 16 tested positive (53,3%), and 14 tested negatives (46,7%) for PCa detection (Figure 4). Although there is a slight difference in favor of the approach with local anesthesia, there are no statistically significant differences between the two approaches to PI-RADS 4 lesions ( $p>0,05$ ;  $p=0,63$ ). Also, there are no differences between the two approaches to clinically significant PCa detection. However, defining what is clinically significant and what is insignificant PCa is difficult. Usually a PCa is defined as clinically insignificant when the International Society of Urological Pathology (ISUP) grade is 1 [12], but

it is important to take into account other factors, including imaging prior to biopsy [13,14].

### Bx detection rate of PI-RADS 5

Among the 6 prostate biopsies performed with local anesthesia and the 3 biopsies under deep sedation on PI-RADS 5 lesions, all had positive results (100%).

## DISCUSSION

The deep sedation leads the patient to sleep, so he cannot move. For the importance of precision in the targeted prostate biopsy, we could reasonably have thought that this approach was better for detection rate than that in loco-regional anesthesia with an awake patient. Instead our study shows that there is no difference in the detection rate. These results, although obtained in a monocentric study and on a limited number of patients, give precise information about our study question for a widely used technique and allow us to reasonably perform prostate fusion biopsy also in an outpatient setting under local anesthesia without detection rate differences. The present data need to be confirmed in more extensive multisite clinical study.

## CONCLUSION

The present data show no differences in the detection rate of PCa, performing transperineal freehand US/MRI fusion target prostate biopsy on PI-RADS 4 and PI-RADS 5 lesions under loco-regional anesthesia or under deep sedation, but need to be confirmed in a larger multisite clinical study.

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