



Developing a five-step training model for transperineal prostate biopsies in a naïve residents' group: a prospective observational randomised study of two different techniques

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Abstract

Purpose To evaluate a five-step training model for transperineal prostate biopsies (TPPB) and the differences in terms of the detection rate (DR) and the ease of execution when using either the “fan technique” (FT) or the use of a Free Hand technique (FH).

Methods A prospective observational randomised study was conducted from September 2015 to November 2017. Six naïve residents, who underwent the same five-steps training model, were randomly subdivided into two different groups of three residents based on the selected TPPB technique: A (FT) and B (FH). Patient characteristics (age, PSA, prostatic volume, DRE, MRI), intraoperative (operative time, number of samples) and postoperative parameters (histologic, pain) were evaluated in the 2 groups. The overall and stratified DR for PSA ranges and prostate volume (PV), operative time and complications were compared.

Results The overall detection rate was very high in both groups (FT 58.2% vs FH 59.6%) and not statistically different between the two techniques. There were no differences in terms of complication rates and pain. The FH showed a better detection rate in prostates smaller than 40 cc ($p = 0.023$) and a faster operative time ($p = 0.025$) compared to FT.

Conclusions Within the TPPB, FH is associated with a higher detection rate in patients with prostate < 40 cc compared to an FT when performed by inexperienced trainees. Standardised training organised in consecutive steps seems to contribute to the achievement of overall high detection rates with both methods.

Keywords Prostate cancer · Prostate biopsy · Transperineal prostate biopsy · Training · Residents

Introduction

Although the popularity of fusion biopsy technique is spreading, the standard prostate biopsy remains the gold standard for prostatic mapping. It can be performed either by transrectal (TRPB) or transperineal (TPPB) approach [1,

2]. The main advantages of the TRPB are its low cost and ease of execution, while the main advantages of the TPPB are a lower risk of infection, a better sampling and a higher detection of cancer in the apex and anterior part of the prostate [3, 4]. For these reasons, TPPB is increasingly becoming the first choice approach.

TPPB can be performed in two different ways: by co-axial technique either using a brachytherapy template or “free hand” (FH) or by a not co-axial technique derived from the “fan technique” (FT) [5, 6].

Current literature provides a single report comparing the two different approaches (co-axial and not co-axial), which was done by experienced urologists [6].

Transperineal prostate biopsies are one of the first invasive diagnostic procedures performed by urology residents during their training. This is why it is important to discover

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which approach is easiest and which guarantees the best results in a shorter timeframe.

A specific five-step training for both “fan technique” (FT) and “free hand” co-axial technique (FH) TPPB was built. A prospective observational randomised study was then conducted and primary endpoints were the evaluation of detection rate (DR) and the ease of execution.

Materials and methods

Study design

A prospective observational randomised study was conducted from September 2015 to November 2017. According to our institutional board that does not require an Ethic Committee approval for an observational study regarding outcomes of two different techniques both already used in the department, we only obtained informed consent from all the patients enrolled.

Six naïve residents were randomly subdivided into two different groups of three residents based on the selected TPPB technique: A (FT) and B (FH).

All the trainees underwent the following training:

- First step. Specific frontal lessons about ultrasound of the prostate (including anatomy, basic principles of sonography, normal and specific findings during a TRUS).
- Second step. Ultrasound practical training of at least 75 TRUSs,
- Third step. Specific frontal lessons and video-training about the selected technique.
- Fourth step. They attended 10 procedures performed by an experienced tutor (> 2000 TPPB performed).
- Fifth step. They started performing biopsies.

They had an expert tutor with them during the entirety of their training according to the rules of our University.

Patients referred to our department for a suspicious prostate cancer (PCa) due to increased PSA levels and/or a suspicious digital rectal examination (DRE) were considered for the enrolment. Patients on active surveillance for PCa were excluded from the study. Patients were blinded to the type of biopsy performed. Each surgical theatre list was performed by a single resident using a randomised technique and, therefore, the patients’ randomisation. All 6 residents followed each other in the biopsy list using the sequence Group A–Group B–Group A–Group B, etc scheme. Patients’ characteristics (age, PSA, prostate volume, DRE, MRI, previous negative biopsies), intraoperative (operative time and number of cores) and postoperative parameters (pathology report and number of positive cores) were evaluated. The global and stratified DR for PSA (4–10 ng/ml; > 10 ng/ml) and prostatic volume (VP) (< 40 g; > 40 g), operative times, and any technical

difficulties in execution/early complications were then compared. The severity of the complications was graded according to Clavien–Dindo classification [7]. Patients were asked to assess their pain at the time of discharge using a Visual Analogue Scale (VAS) from 1 (no pain) to 10 (the worst possible pain).

Perioperative management and anaesthesia

An antibiotic prophylaxis with oral fluoroquinolones was started the day before the procedure and continued for a total of 3 days [8]. Patients were asked to perform an enema the evening before the procedure. Patients were admitted the same morning of the biopsy and discharged without transurethral catheter after an observation time of 3 h.

The biopsies were done with the patients in dorsal lithotomy position, exposing the perineum and executing an accurate digital rectal examination (DRE) and TRUS as preliminary procedures.

A standard 12-samples biopsy is routinely performed (for each side: 2 lateral-peripheral samples, 2 median-peripheral, 1 paramedian and 1 at the apex). Additional samples are taken according to imaging suspicious findings, previous negative biopsies or huge prostate volumes.

Procedures were performed with patient sedation using Propofol in continued infusion and assisted ventilation with an oxygen balloon mask.

Postoperative pain control was carried out through the use of Paracetamol 1 g.

The fan technique

The patient is positioned in dorsal lithotomy position. After accurate perineal disinfection, firstly a TRUS is performed through a MyLab 25 Gold Esaote with a transrectal 8 MHz probe and then the biopsy is performed with a Tru-Core 18 ga × 20 cm needle gun.

This technique was performed by sampling the prostate through a single access for each prostatic lobe, angling the needle gun to reach the targeted area (Fig. 1).

The “free hand” template

A coaxial technique can be performed either using a brachiterapy template device or “free hand” without the use of any device. The difference in the former is the need of a puncture for each single core taken which allows the needle gun not to be angled. In our series, the whole biopsies performed with a coaxial technique were done “free hand” (Fig. 2).

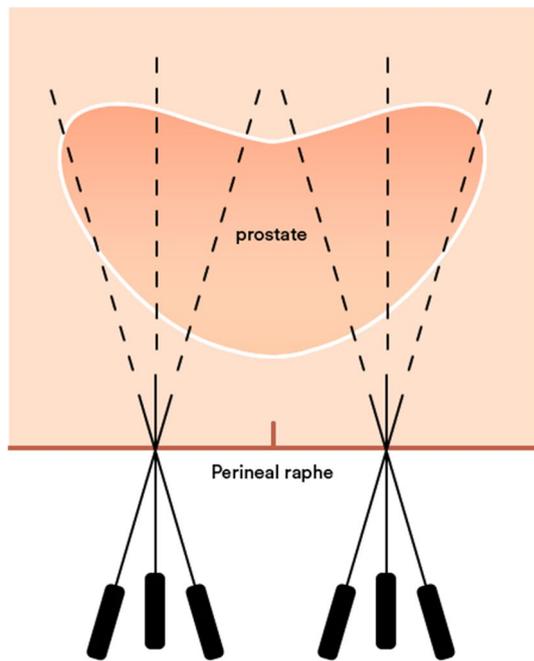


Fig. 1 The fan technique

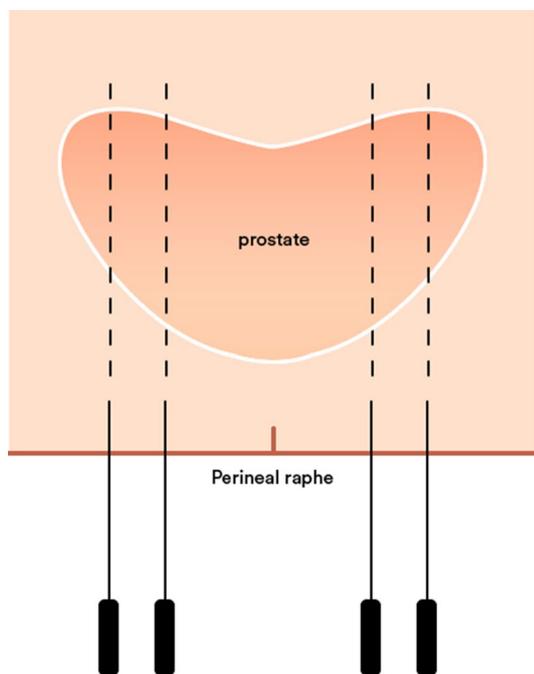


Fig. 2 The “free hand” template coaxial technique

Statistical analysis

A descriptive statistical analysis was performed to evaluate the sample characteristics and reported as mean \pm standard deviation (SD), median (1st and 3rd quartile) or as

proportion. The overall and stratified DR for PSA ranges and prostate volume, operative time, pain and complications were compared. Continuous variables with nonparametric distribution were compared using the Mann–Whitney test, while the frequencies were compared using the chi-squared test. Two-tailed tests were used for all comparisons; a p value < 0.05 was considered statistically significant. Data were acquired and analysed with SOFA Statistic 1.4.6.

Results

The overall population was 219 patients and the mean age was 70 years old (66–76), while the mean PSA before biopsy was 8.16 ng/ml (5.86–12.75). Group A (FT) was made up of 110 patients while Group B (FH) was made up of 109 patients.

Table 1 shows the main characteristics of both groups. The two groups were not statistically different in terms of PSA, age, DRE, prostate volume, previous negative biopsies, MRI, and number of samples.

In the execution of the FT, difficulties were reported in the withdrawal of the apical sample in 3 patients with repeated execution of the same sample.

Three Clavien–Dindo Grade I complications related to the procedure were noted in Group A, while two in the Group B. In the first group, three patients developed postoperative urethral bleeding, while in the second there was a case of urethral bleeding and acute urinary retention treated with the insertion of a urethral catheter (See Table 2).

The mean operative time was shorter (14.4 ± 4 min) for the FH compared to FT (15.9 ± 5.9 min; $p = 0.025$). On the other hand, the average number of positive cores was 2.6 ± 3 in Group A, compared to 3.3 ± 4.1 in Group B ($p = 0.24$).

Table 1 The main characteristics of both groups

| | Group A (FT) | Group B (FH) | p |
|--------------------------------|------------------|-------------------|------|
| No. patients | 110 | 109 | |
| Mean age (years) | 70 (66–76) | 71 (66.5–76) | 0.32 |
| Mean PSA (ng/ml) | 8.13 (5.85–13.4) | 8.29 (5.83–12.62) | 0.61 |
| No. DRE + | 33 | 29 | 0.55 |
| No. DRE – | 59 | 56 | |
| No. DRE doubtful | 18 | 24 | |
| Prostate volume (g) | 50 (40–60) | 55 (40–70) | 0.06 |
| No. previous negative biopsies | 26 | 18 | 0.23 |
| No. MRI + | 36 | 45 | 0.21 |
| No. MRI – | 1 | 3 | |
| No. MRI not done | 73 | 61 | |
| No. of cores | 13 (12–16) | 13 (12–14) | 0.4 |

Table 2 Comparison between the two groups

| | Group A (FT) | Group B (FH) | <i>p</i> |
|---|----------------|----------------|----------|
| Complications | 3/110 (2.7%) | 2/109 (1.8%) | 0.65 |
| Mean operative time (min) (SD) | 15.9±5.9 | 14.4±4 | 0.025 |
| Detection rate (DR) | 64/110 (58.2%) | 65/109 (59.6%) | 0.82 |
| Detection rate HGPIIN-ASAP | 10/110 (9%) | 9/109 (8.2%) | 0.83 |
| DR PSA 4 -10 ng/ml | 39/71 (54.9%) | 39/69 (56.5%) | 0.88 |
| DR PSA > 10 ng/ml | 25/39 (64.1%) | 26/40 (65%) | 0.93 |
| DR VP < 40 cc | 9/20 (45%) | 18/22 (81.8%) | 0.023 |
| DR VP > or Eq. 40 cc | 55/90 (61.1%) | 47/87 (54%) | 0.34 |
| Number of + cores (SD) | 2.6±3 | 3.3±4.1 | 0.24 |
| Length of cores (mm) | 11±2.1 | 10.4±1.6 | 0.031 |
| Length of + cores (mm) | 11.6±2.3 | 11±2.1 | 0.067 |
| PCa microfoci out of total positive cores (%) | 9% | 10.5% | 0.39 |
| DR Pre-MRI Biopsies | 22/36 (61.1%) | 30/45 (66.7%) | 0.60 |

As shown in Table 2, the overall detection rate was very high in both cases and not statistically different between the two techniques. Similarly, the stratified detection rate for PSA values showed no statistical difference between the two groups. In the case of small prostate biopsies (< 40 cc), FH was the technique with the best detection rate (45% vs 81.8%, $p = 0.023$). The mean length of cores was 11 ± 2.1 mm in the Group A and 10.4 ± 1.6 mm in the Group B ($p = 0.031$). In Group A, 20 patients had at least a well differentiated < 3 mm of length microfocal PCa, for a total of 26 cores (3.14% of all cores among PCa+ patients and 9% of all PCa+ cores), while in Group B the patients were 25 for a total of 38 cores (4.4% of all cores among PCa+ patients and 10.5% of all PCa+ cores) ($p = 0.39$).

Globally, only two samples in Group A and one in Group B showed the absence of prostatic tissue. Two of them were marked as peripheral samples and the third as apical. Not significant difference was found in the cancer location: in Group 1, the 61.5% of positive cores were peripheral, 24.7% paramedian and 13.8% in the apex, while in Group 2 were respectively the 55.9%, 29.2% and 14.9% ($p = 0.32$).

The VAS referred by the patients was similar: 1.84 ± 1.1 in the FH group and 1.74 ± 1.06 in the FT group ($p = 0.63$).

Discussion

Although today is the era of image-guided targeted biopsies [9–11], due to the high costs of systems required and the lack of their widespread availability, the classic prostatic biopsies with transrectal and transperineal approach remain the standard method for the histological diagnosis of prostate cancer [12].

In some studies, the transperineal method seems to guarantee a higher detection rate and a lower rate of infectious complications compared to the transrectal approach [6, 12,

13]. However, while there are many comparative contributions between TRPB and TPPB in terms of detection rates and complications [1, 2, 4, 12–15], there are few studies comparing different techniques of transperineal TPPB [6]. Likewise, there are many reports focusing on training and/or simulation models in the field of robotics [16], laparoscopy [17] and endourology [18–23], while paradoxically less are those concerning first line but fundamental urological manoeuvres which are among the first to be carried out during the diagnostic-surgical training of a specialising student.

Our study shows a high global DR with both methods (58.2% Group A, 59.6% Group B) comparable with the results reported in the literature and without significant difference between the 2 Groups [1, 4, 5, 24–27]. The detection rate was found to be significantly higher in Group B (45% vs. 81.8%) in patients with small prostates (< 40 cc). In our opinion, it is possible that in small prostates the operator performing the FT tends to angle the needle gun less, probably for fear of sampling outside of the prostate and this results in peripheral sampling cores comprising a good part of paramedian prostate tissue, which is less subject to PCa localisation. Moreover, in a "limited" target space with FT it may be more difficult and laborious to obtain the correct angle to more precisely sample the area desired. The anatomical approach to the prostate might be also the explanation for the global higher length of cores when using FT, without higher length of PCa positive cores. Furthermore, the FH showed a shorter execution time compared to FT (14.4 min vs. 15.9 min, $p = 0.025$). In both methods, the rate and type of complications were aligned with those reported in the literature, confirming that TPPB is a safe procedure and free from major complications [5]. The low VAS score demonstrates that both methods are well tolerated by the patient, with values between 1 (no perceived pain) and 2 (minimum pain). While most authors use spinal or locoregional anaesthesia with a periprostatic nerve block for FT

and general or spinal anaesthesia for co-axial approaches [5], we prefer sedation with Profolol by continuous infusion and assisted ventilation with an oxygen balloon mask, as well as paracetamol as pain control for both procedures.

Although most likely positively influenced by the favourable characteristics of the sample (median PSA elevated, DRE + and MRI +), our study shows how a standardised training including a gradual theoretical-practical approach can be of great importance in achieving optimal results in a short amount of time in prostate biopsies. A learning process structured in steps gives the trainee the time to learn the concepts, tips and tricks before moving on to the next step. The use of video and supplemental instructional media, as in other procedures, could contribute to improved and more rapid learning [28–30]. The presence of a tutor that accompanies the resident throughout the entire learning process remains fundamental.

Conclusions

Within the TPPB, FH is associated with a higher detection rate in patients with prostate < 40 cc compared to an FT when performed by inexperienced trainees. Standardised training organised in consecutive steps seems to contribute to the achievement of overall high detection rates with both methods.

Author contributions GM Project development, data analysis and manuscript writing. AP Data collection and data analysis. RA Data collection and data analysis. MC Data collection and data analysis. FD Data collection and data analysis. AO Data collection and data analysis. GP Manuscript editing. GP Manuscript editing. MM Manuscript editing. CT Project development and manuscript editing.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Informed consent Informed consent was obtained from all individual participants included in the study.

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