# Targeted Transperineal Prostate Biopsy:

# A Local Anaesthetic Approach

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**Abstract**

**Background**

Despite high rates of disease misclassification and sepsis, the use of transrectal biopsy remains commonplace. Transperineal mapping biopsies mitigate these problems but carry increased cost and patient burden. Local anaesthetic (LA), multiparametric MRI (mpMRI)-targeted transperineal biopsy may offer an alternative.

**Objective**

The objective was to determine the feasibility and tolerability of using a novel LA transperineal visually estimated prostate biopsy technique.

**Design, Setting, and Participants**

Consecutive men whose pre-biopsy mpMRI showed a visible lesion and underwent LA transperineal targeted prostate biopsy were included. Pathology and mpMRI data was collected.

**Intervention**

Biopsies were performed in a visually estimated manner, using both mpMRI images and pictorial radiology reports. LA was administered to the rectum, perineal skin and by peri-prostatic block.

**Outcome Measurements and Statistical Analysis**

Primary outcomes were detection of significant cancer, adverse events and visual analogue scale (VAS) pain scores. Significant cancer was defined by UCL definitions one and two and by the presence of Gleason 4 disease. Secondary outcomes were detection of any cancer, detection by Likert score and by presenting PSA. Differences were assessed using Chi-squared tests ($p < 0.05$).

**Results and Limitation**

216 men with 284 lesions were included. There were no episodes of sepsis or readmissions. Median VAS score was 1.6. 116/216 (54%) had UCL definition 1 disease,

155/216 (72%) had UCL definition 2 cancer. Any cancer was detected in 168/216 (78%). Significant disease was more likely in higher scoring lesions and in men with PSAs ≥10ng/mL.

**Conclusions**

This approach to prostate biopsy is feasible, tolerable and can be performed in ambulatory settings.

**Patient Summary**

This study looked at whether a prostate biopsy technique under local anaesthetic could improve existing prostate cancer pathways. The procedure has excellent cancer detection rates, minimal side effects and is well tolerated, thus could represent an alternative to traditional transrectal biopsies.

**Text**

**Introduction**

The transrectal ultrasound (TRUS) guided prostate biopsy led diagnostic pathway remains commonplace. However, this leads to misclassification of disease in men at risk of prostate cancer[1]. Under-sampling of the anterior gland and the deployment of the needle blind to the location of the lesion can potentially miss clinically significant disease whilst also failing to directly hit the highest grade disease[1]. Additionally, this pathway can also result in overdiagnosis and overtreatment[2]. The primary issue is the limited ability of this pathway to discriminate between whether cancer is present and whether it is clinically significant or insignificant. Furthermore, there is a significant risk of systemic sepsis following TRUS biopsy and this is increasing alongside a rise in antimicrobial resistant coliforms[3]. Despite this, the TRUS biopsy still remains the first line diagnostic test in prostate cancer[4].

The diagnostic pathway requires improvement. Two separate diagnostic innovations may address the need for improved accuracy and safety. First, the implementation of a pre-biopsy multi-parametric MRI can facilitate targeted sampling of a suspicious area with the potential of reduced number of cores whilst improving the detection rates of significant disease[5]. Targeted biopsies may be equally good as a template approach in detecting clinically significant disease[6]. Second, the prostate may be approached transperineally rather than via the rectum, easing access to all areas of the prostate, and conferring sepsis rates of less than 0.5%[7]. Transperineal biopsies are often applied in a mapping technique, sampling the whole-gland with a fixed sampling frame of 5-10mm. This method has demonstrable diagnostic accuracy when compared to the reference standard of radical prostatectomy[8]. However, barriers to widespread adoption include the necessity of general or spinal anaesthetic; operating room time; pathology resources/costs and increased risks of urinary retention, haematuria, haematospermia and temporary erectile dysfunction. Despite this, the approach has gained considerable momentum in the last decade.

Nonetheless, reductions to these burdens are needed in order to facilitate widespread dissemination of a transperineal approach to prostate biopsy, capitalising on reduced sepsis rates.

The optimal biopsy strategy is likely to have the following elements. Firstly, it should be mpMRI led and suspicious areas undergo a targeted biopsy. Secondly, a transperineal approach should be used to capitalise on significantly reduced sepsis rates and improved gland sampling. Lastly, these biopsies should be conducted under local anaesthetic. In this study, our objective was to determine the feasibility, patient acceptability, pain scores, adverse events and estimates of cancer detection using such a pathway.

**Methods**

In this prospective study, which was part of a clinical service innovation approved by the institution and receiving research ethics committee exemption, consecutive men whose pre-biopsy mpMRI showed a visible lesion and underwent a local anaesthetic transperineal targeted prostate biopsy were included.

MpMRI acquisition was performed according to the European guidelines of Uro-radiology previously described by the UCL group[5, 6, 9]. Each scan was reported by an experienced, uro-radiologist as previously described [10]. Lesions were scored using a Likert-like scale of 1-5[11]. Lesions scoring 3 (figure 1) were indeterminate, and those scoring 4 (figure 2) or 5 (figure 3) were thought 'likely' or 'highly likely' to contain a malignant lesion which was either ≥0.2mL in volume and/or had high grade components within (Gleason ≥3+4)[12].

Biopsies were performed by twelve urologists experienced in transperineal mapping and transperineal cognitive biopsy. All were performed in a non-operating theatre procedure room as ambulatory day cases, with one urologist and two nursing assistants.

One hour prior to biopsy, men received oral analgesia (Tramadol 100mg) and topical 2% diltiazem ointment to relax the anal sphincter. They were placed in the lithotomy position and given a single dose of intramuscular antibiotics (gentamicin 80mg).

The scrotum was supported with adhesive tape with the scrotal skin protected by non-adhesive dressings. 20mL of lidocaine infused gel (Instillagel®) was inserted into the rectum and applied to the anus. After two minutes, a bi-planer 7.5MHz ultrasound transducer was inserted transrectally. The perineum was then cleaned with Chloraprep® and 20mL of 0.5%

bupivacaine with adrenaline (1 in 200,000) was infiltrated in the perineal skin just anterior to the anus as well as deep into sub-cutaneous tissue. After two minutes, a peri-prostatic block was performed transperineally by infiltration of the peri-prostatic nerves with 0.5% bupivacaine 10mL and 1% lidocaine 10mL (figure 4). Finally, the probe was attached to a brachytherapy stepper and cradle. Transperineal targeted biopsies were performed in a cognitive manner by evaluating the mpMRI images and a pictorial diagrammatic report provided by the uro-radiologist.

In the first 14 patients, pain scores were collected to determine tolerability. Adverse events were also evaluated along with baseline demographics, prostate volume, lesion size and number of biopsies taken. Overall cancer detection rates were determined as was the rates of detection for measures of clinically significant disease using a number of thresholds. The definition of disease according to the UCL criteria for clinical significance developed for transperineal biopsies were used[13]. Definition 1 was the presence of Gleason ≥4+3 and/or maximum cancer core length ≥6mm and definition 2 was the presence of Gleason ≥3+4 and/or maximum cancer core length ≥4mm. The detection rate of lesions containing Gleason pattern 4 alone regardless of cancer core length were considered separately. Epstein criteria were not used, as these have not been validated on targeted biopsies[14]. Differences in cancer detection rates by Likert score were compared for significance using the Chi-squared test ($p<0.05$).

Additionally, the group was separated into men presenting with a PSA ≥10ng/mL and <10ng/mL. Differences between these groups were evaluated for prostate volume (Student's T-test [$p<0.05$]) and lesion volume (one-way analysis of variance (ANOVA [$p<0.05$]). PSA dependent differences in the attributable Likert score on mpMRI were compared (Chi-squared test [$p<0.05$]). Statistical analysis was conducted using *SPSS version 22* (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp).

## Results

### *Baseline Demographics (Table 1a):*

Between September 2013 and January 2016, 216 consecutive men with 284 lesions on mpMRI underwent targeted prostate biopsy under local anaesthetic. Mean age at the time of biopsy was 68 (range 46 to 92). 183 biopsies were performed prior to any treatment with 33 being performed afterwards.

Median PSA was 9.4ng/mL (interquartile range [IQR] 5.9-23.0ng/mL). Median prostate volume was 45mL (IQR 32-66mL). Median target lesion volume was 0.5mL (IQR 0.2-2.0mL). 163 men had a single targeted lesion, 39 had two, 13 had three and one had four. Of the 284 lesions targeted, 78 (27%) scored 3 on the radiological Likert-like scale, 107 (38%) scored 4 and 99 (35%) scored 5. A median of five (IQR 4-6) cores were taken per lesion.

***Primary outcome 1 - Tolerability and adverse events***

There were no episodes of sepsis, none had bleeding requiring catheterisation and no catheter requirement post-biopsy. There were no admissions following discharge. The first 14 men were assessed by the visual analogue scale for pain to assess for tolerability. The median intraoperative score was 1.6 (range 0 to 7; IQR 0.8-2.6). One procedure was abandoned due to patient discomfort.

***Primary outcome 2 – detection of clinically significant cancer***

On a patient level, 116/216 (54%) had UCL definition 1 disease and 155/216 (72%) had UCL definition 2 cancer. 150/216 (69%) had any Gleason pattern 4 or greater with 61/216 (28%) dominant pattern 4 or greater. On a lesion basis, 127/284 (45%) had UCL definition 1 disease and 184/284 (65%) had UCL definition 2 disease. 176/284 (62%) had any Gleason pattern 4 or greater with 64/284 (23%) dominant pattern 4 or greater.

***Secondary outcomes***

***a) Overall cancer detection:*** Prostate cancer was detected in 168/216 (78%). When analysed by lesion (table 2a), 210/284 (74%) had prostate cancer detected. Overall, the

median number of positive cores for each lesion was 2 (IQR 1-4). The maximum cancer core length involvement was median 6mm (IQR 3mm to 10mm).

***b) Detection rates by radiology score***

Of the 78 lesions scoring 3 on mpMRI, 38 (49%) had cancer detected of whom 24 (63%) contained Gleason pattern 4 disease (table 2b). Thirteen (54%) of these men reached criteria for UCL definition 1 for clinical significance and 24 (100%) met the criteria for UCL definition 2 disease. Of the 107 lesions scoring 4 on mpMRI, cancer was detected in 78/107 (73%) of which 65 (83%) contained Gleason pattern 4 or higher. Forty (37%) reached UCL definition 1 for clinical significance and 70 (90%%) the criteria for UCL definition 2 disease. Finally, 99 lesions (35%) were scored 5 on mpMRI. Any cancer was detected in 94 (95%) of which 87 (88%) contained Gleason pattern 4 or higher. Of these, 74 (75%) reached UCL definition 1 for clinical significance and 90 (96%) met the criteria for UCL definition 2 disease. In all scenarios, namely any cancer detected, UCL definition 1 and 2 and any Gleason 4 disease detected there was a statistically significant correlation with higher Likert scores (Chi-squared test, $p < 0.00001$).

***c) Cancer detection by PSA (Table 1b)***

102 men (47%) with 131 lesions (46%) had a PSA of ≥10ng/mL. By comparison, 114 men (53%) with 153 lesions (54%) had a PSA <10ng/mL.

Men with a PSA ≥10ng/mL had significantly larger prostates (Student's T-test, p=0.002). Men presenting with a PSA ≥10ng/mL also had significantly larger lesions (one-way ANOVA, p=0.002).

Of 153 mpMRI lesions identified in men with a PSA <10ng/mL, 52 (34%) were scored 3 on the Likert scale, 69 (45%) scored 4 and 32 (21%) scored 5. Of 131 mpMRI lesions identified in men with a PSA ≥10ng/ml, 26 (18%) scored 3 on the Likert scale, 38 (29%) scored 4 and 67 (51%) scored 5. Men with higher PSA levels were more likely to have higher scoring lesions on mpMRI (Chi-squared, p<0.00001).

Clinically significant disease (UCL definitions 1 and 2) was found in 85 (59%) of lesions in men presenting with a PSA <10ng/mL and 99 (65%) of lesions in men presenting with a PSA ≥10ng/mL. These differences were statistically significant (Chi-squared, p=0.03).

## Discussion

***In summary,*** to the best of our knowledge this is the first time that local anaesthetic transperineal mpMRI-targeted prostate biopsy has been reported. We have shown that this technique is feasible, acceptable and tolerable by patients, has very minimal adverse events and no sepsis. It also seems to be highly accurate in detecting clinically significant cancer with 96% of men scoring 4 or 5 on mpMRI harbouring Gleason pattern 4 disease.

### *Methodological limitations*

Before discussing the clinical implications of our results, we would like to highlight some limitations. First, the analysis was retrospective with a heterogenous population including biopsy-naïve men and those undergoing risk stratification or post-treatment evaluation. Second, some argue that targeted biopsies alone without sampling of normal appearing gland on mpMRI risks missing significant disease. Our change in strategy for this group of men occurred after our paired analyses of mpMRI versus transperineal template mapping biopsies in men demonstrated that mpMRI visually directed biopsies were equivalent in detection rate to full mapping biopsies when both were conducted in the same men under general anaesthetic[15]. This has been supported by other studies with one recent study showing that only 4% of clinically significant disease would have been missed with a target alone strategy[16]. Other authors have also demonstrated negative predictive values of 90% or higher[17-19]. Third, consensus is lacking regarding the definition of clinically significant cancer. Therefore, we used a number of definitions to incorporate professional uncertainty. Fourth, multiple radiologists and urologists were involved in the reporting of mpMRI scans and biopsies.

***Clinical implications***

The diagnosis and subsequent management of prostate cancer is still driven by TRUS biopsy despite its accepted inaccuracy. Indeed, the original six-core TRUS biopsy technique was described as *random systematic* by Stamey in 1989[20]. Subsequently, the procedure was expanded to a 10 to 12-core technique over time. This was somewhat successful in increasing the negative predictive value of TRUS biopsy. However, it also led to the detection of increased numbers of low risk disease. Histological studies have demonstrated this is present in more than 40% of men over the age of 50[21]. Furthermore, the TRUS biopsy is poor at detecting disease in anterior and apical aspects of the gland leading to misclassification of disease that is upgraded at prostatectomy[22].

Due to these concerns, transperineal mapping biopsy is becoming more popular. However, concerns regarding its cost, the need for general anaesthetic and increased complications in the form of haematuria, haematospermia and urinary retention are likely to have prevented its wider dissemination. With the advent of mpMRI, which has shown high levels of accuracy for the detection of clinically significant cancer when compared to whole-mount histological specimens[23] and transperineal mapping biopsies[15], an image-guided approach to prostate biopsy in line with current practice in other solid organ malignancies can now be contemplated[24]. A number of centres have reported their experiences with mpMRI-targeted biopsy when compared to systematic biopsy strategies, demonstrating improved cancer detection rates[5, 25], improvements in biopsy efficiency[5] and reductions in missed diagnoses of significant cancer[26].

Additionally, some centres have described their use of transperineal biopsy (non-targeted) under local anaesthetic with encouraging results[27-30]. Novella et al compared the procedure to 102 consecutive patients[27]. Only 11 (15.3%) reported intraoperative pain levels of moderate or higher[27]. Kubo et al compared intraoperative pain levels in 45 patients who underwent both 12-core TRUS biopsy and 14-core transperineal biopsy solely under local anaesthetic[28]. The median VAS score was 2.67 for TRUS and 2.93 for transperineal biopsy with no significant difference demonstrated[28]. Iremashvili et al reported a randomised clinical trial where 150 patients underwent 12-core transperineal prostate biopsy under local anaesthesia, some with a pudendal nerve block[29]. Those who received a pudendal

nerve block did experience less intraoperative pain at a median of 1.83 on VAS[29]. However, even without this the median VAS suggested mild intraoperative pain levels at a median of 2.41[29]. Most recently, Smith et al described a series of 50 consecutive patients that underwent sector transperineal biopsies solely under local anaesthetic[30]. Only 2 (4%) of men reported that they would not undergo the same procedure again[30].

Whilst the use of transperineal template mapping biopsies has shown a significant growth in use due to its highly accurate detection and risk stratification of disease, it has met with criticism due to its healthcare and patient burden. For the one million men who have a TRUS biopsy in the USA or Europe each year to undergo template mapping biopsies would be unsustainable. MpMRI has shown performance characteristics in high volume experienced centres that make it a viable alternative to TRUS and template biopsies. As a result, many centres have adopted mpMRI-targeted biopsies. However, much of this still relies on traversing the rectum. Our strategy to combine the key elements of an optimal diagnostic pathway may facilitate the wider adoption of transperineal prostate biopsy which is known to have minimal risk of sepsis whilst retaining diagnostic accuracy.

**Conclusion**

Local anaesthetic, transperineal visual estimated targeted mpMRI-targeted prostate biopsy is a novel approach that is feasible, tolerable and can be performed in an ambulatory setting. It carries high levels of cancer detection and may offer a sustainable and legitimate alternative to transrectal biopsies.

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**Figure and Table legends**

**Figure 1:** MpMRI images (T2, ADC, and DCE) of a Likert 3 lesion.

**Figure 2:** MpMRI images (T2, ADC, and DCE) of a Likert 4 lesion.

**Figure 3:** MpMRI images (T2, ADC, and DCE) of a Likert 5 lesion.

**Figure 4:** Diagram of the application of local anaesthetic.

**Table 1:** Baseline demographics for the whole cohort and as separated by PSA.

**Table 2:** Cancer detection in men and by mpMRI lesion.