Comparison Between Freehand and Needle Guide Techniques for Teaching Percutaneous Renal Biopsy on a Synthetic Model: a Randomised Controlled Trial

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Abstract

Background: Percutaneous renal biopsy is an essential diagnostic tool in nephrology. There are two common variations: the freehand and the needle guide methods. Using the freehand method, the needle and ultrasound probe can move independently. With the needle guide method, the needle is held in alignment with the ultrasound probe by the needle guide, and the needle path anticipated by predictive throw lines. This study aims to compare the two techniques for teaching the skill of ultrasound guided percutaneous renal biopsy on native kidneys.

Methods: A single-center prospective, randomised controlled trial of junior medical staff was conducted at a metropolitan hospital. Participants were randomised to either the freehand or needle guide groups. Participants underwent standardised education, and then attempted a renal biopsy on a synthetic model, which was assessed by a senior interventional nephrologist. Assessors and participants completed an assessment of the difficulty of multiple elements of the procedure. The primary outcome was the combination of both the safety and the adequacy of the biopsy attempt. Secondary outcomes included the proportion of inferior pole biopsies, biopsies with adequate needle visualisation, and adequate biopsies; total procedural time and subjective participant and assessor assessments. Analyses were undertaken with SPSS.

Results: After randomisation (n=91), using a hierarchical conditional backward logistic regression model, use of a needle guide increased the likelihood of the primary outcome (adjusted RR 3.2 (95% CI 1.1-9.6; p=0.036)) as did previous ultrasound experience (adjusted RR 3.1 (95% CI 1.0-9.5; p=0.049)) and male gender (adjusted RR 4.4 (95% CI 1.5-12.9; p=0.007)). Total procedure time was shorter in the needle guide group (p=0.01).

Conclusions: Among novice operators learning percutaneous renal biopsy, needle guide use, ultrasound experience and male sex were associated with the primary outcome of a safe and adequate biopsy. The use of a needle guide was associated with a shorter procedural time. There was no association between use of a needle guide and performing an adequate biopsy.

Trial registration: The trial was prospectively registered with the Australian and New Zealand Clinical Trials Registry on 11/02/20 (ACTRN12620000132943p).

Background

Percutaneous renal biopsy (PRB) is an essential diagnostic tool in nephrology. It is generally performed under real-time ultrasound guidance, allowing simultaneous visualisation of the kidney and biopsy needle (1). There are 2 common variations (2):

1. The “freehand (FH) method” where the operator uses one hand to maneuver the ultrasound (US) probe and the other to manipulate the biopsy needle in an independent manner, and

2. The “needle guide (NG) method” where the biopsy needle is passed through a guide fixed to the ultrasound probe so the probe and needle remain in the same relative 2 dimensional plane at all times. Additionally, predictive throwlines on the ultrasound screen provide a predetermined needle course.

As with any biopsy, adequacy and safety of the procedure are critical. In PRB, adequacy refers to the ability to make a histological diagnosis based on the specimen, or the glomeruli yield (3). In terms of safety, bleeding is the most common complication of PRB. Bleeding can occur into the collecting system, presenting as macroscopic haematuria, or a subcapsular/perinephric haematoma most commonly presenting as flank pain or shock. A recent meta-analysis showed that post PRB, the incidence of macroscopic haematuria was 3.5% and perinephric hematoma 11% (4). The bleeding can be transient and self-limiting, but in some can it requires a further procedure such as packed red blood cell transfusion, angioembolisation or nephrectomy, and rarely patients have died (4). Other complications post PRB include pain and damage to surrounding structures (1).

In Australia, the skill of percutaneous renal biopsy is generally performed by nephrology advanced trainees taught by nephrologists (5). There is no standardised method for teaching or assessing competence in performing this skill, and there is significant between centre variability. In the hands of experience operators, there is mixed evidence regarding the differences in safety and adequacy of the FH and NG techniques (6-8). Currently there is no literature regarding the optimal method to teach ultrasound-guided PRB to doctors in training.

Methods

This prospective, randomised controlled trial aims to compare the safety and adequacy of the FH and NG methods for teaching PRB on a synthetic model to novice operators.

This study involved junior medical staff at Liverpool Hospital, Sydney, Australia. The trial protocol was approved by the South Western Sydney Local Health District Human Research Ethics Committee and registered with the Australia and New Zealand Clinical Trial Registry on 11/02/2020 (Registration number ACTRN12620000132943p).

We recruited participants in May-June 2020. Medical students, junior medical officers and basic physician trainees at Liverpool Hospital, who had no previous experience performing renal biopsies, were eligible to participate. Participants were approached either in person at an education session or via email. They were provided with the Participant Information Sheet. Participants provided written informed consent to participate.

Participants provided written information about their self-reported gender (male or female), medical seniority (medical student or doctor), previous experience with ultrasound (yes or no) and dominant hand (left or right). Randomisation was performed using a computer-generated allocation (MinimPy). A minimisation protocol was used to randomise participants by the variables described above. Participants

watched an educational video created by the investigators detailing how to perform a renal biopsy that was specific to their allocation. This video showed the equipment used, and then demonstrated a safe and adequate renal biopsy on the model the participants were using. Elements emphasised in the educational video included the importance of performing an inferior pole biopsy, as well as being able to see the needle tip at the time of biopsy. Participants then had 5 minutes to familiarise themselves with an automatic spring-loaded biopsy needle (Max-Core™ Disposable Core Biopsy Instrument 16G x 16cm) and ask any questions of a nephrologist. They then directly entered the simulation room where an assessor, an ultrasound machine (GE Logiq S7, GE Healthcare, Wisconsin, USA) with all imaging settings pre-optimised, a synthetic human model (Blue Phantom Renal Biopsy Ultrasound Training Model, USA) and a curvilinear probe (C1-5D,1.8 – 5 MHz) with or without a needle guide attached (Ultra-Pro II™ In-Plane Ultrasound Needle Guides-Multi-Angle, GE Healthcare, Wisconsin, USA) were setup for the procedure. The assessor was one of six local interventional nephrologists who have each performed an extensive number of biopsies and have experience supervising and teaching trainees to perform renal biopsies. Blinding of participants and assessors to randomisation was unable to be performed secondary to the nature of the trial. Each participant was asked to perform three passes.

The NG was pre-fitted to the ultrasound probe by the assessor. It was set to the most vertical setting and was not altered throughout the trial. Corresponding predictive throwlines were set on the ultrasound screen for the NG group (Figure 1). The FH group used the same ultrasound machine and probe with the same optimised settings.

Each participant wore gloves. The timing began when they picked up the US probe. The time taken to complete 3 passes was recorded with timing ending when the participant put the ultrasound probe down. Whilst performing each of the 3 passes, the assessor judged whether each pass would have biopsied the inferior pole, whether they could visualise the needle tip at the time of biopsy, and whether the pass would have biopsied renal cortical tissue. Once the participant had completed 3 passes, they exited the assessment room. Both participant and assessor then completed a questionnaire about the experience. Answers were provided using a visual analogue scale (VAS). This involved participants and assessors answering a range of questions by making a single vertical mark that intersected a 10cm long horizontal line. The distance along the horizontal line was measured and entered as a value in millimeters.

The primary outcome of the trial was a combination of adequacy and safety. To meet the primary outcome, participants had to fulfill the criteria of both an adequate biopsy and a safe biopsy. This was defined by:

- Adequate biopsy: adequacy was achieved if 2 of the 3 passes performed by one individual participant were judged to have biopsied cortical tissue based on ultrasound visualisation by the assessor.
- Safe biopsy: safety was achieved if both the inferior pole biopsy was performed in 100% of attempts, and the needle tip was visualised at the time of biopsy in 100% of attempts.

Secondary outcomes assessed were the proportion of participants in each group who performed an adequate biopsy (2 of 3 passes would have obtained cortical renal tissue), the proportion of participants in each group who performed an inferior pole biopsy in 100% of attempts, the proportion of participants in each group who adequately visualised the needle at the time of biopsy in 100% of attempts, the average total procedural time between the two groups, and the participant and the assessor's assessment of the participant's difficulty undertaking various components of the renal biopsy between the two groups.

Power calculations were difficult given the paucity of evidence in this field. The outcome rates were agreed upon based on the local experience of the interventional nephrologists. We predicted a safe and adequate biopsy would occur in 70% of participants in the NG group and 30% in the FH group. Based on these assumptions and Type 1 error two-sided probability of 0.05, we calculated 84 participants would be required to be able to reject the null hypothesis with 80% power. We planned to recruit an extra 15% (98 participants) to allow for dropout due to the unpredictable workload of junior medical staff that might preclude their participation as planned.

Participants were randomised as they arrived to partake in the study. All outcomes were analysed in an intention to treat analysis which included all randomised participants. Analysis of continuous variables was performed using the relevant parametric or non-parametric test. The primary outcome was analysed using a hierarchical conditional backward binary logistic regression and expressed as a relative risk with 95% confidence intervals. Time taken to perform biopsies (a continuous variable) was analysed using a hierarchical conditional backward stepwise generalised linear regression model. Statistical models controlled for gender, experience and seniority and where relevant interactions terms if $p<0.20$. Data was analysed using SPSS v.27 (California, United States of America).

Results

Ninety eight participants were enrolled and 91 participants underwent randomisation (46 in FH and 45 in NG group; Fig. 2). Two participants watched the incorrect video for their allocation. One participant in the NG group watched both videos, and a second participant in the NG group watched the FH video. Both completed the biopsy attempt with a NG (Fig. 2). There were no group differences in participant characteristics (Table 1).

Primary outcome

Univariate analysis showed that use of a NG was not associated with achieving the primary outcome of a safe and adequate biopsy (RR 2.38 (95% CI 0.89–6.34); $p = 0.08$). In the NG group, 33% of participants achieved the primary outcome compared to 18% in the needle guide group (Table 2). However, previous US experience (RR 2.72 (95% CI 1.0-7.4; $p = 0.047$) and male gender (RR 4.19 (95% CI 1.5–11.6; $p = 0.004$) were associated with the primary outcome (Table 2).

Given this result, we performed a *post hoc* analysis of each gender separately. Whilst we were underpowered to perform this analysis, we found that there was a trend for females to be more likely to achieve the primary outcome when using a needle guide than females using the freehand method (p = 0.048). There was no statistically significant difference for males. Additionally, there were significantly more males using the freehand method who achieved a safe and adequate biopsy compared to females using the freehand method (p = 0.01), whereas there was no difference between the two genders when using a needle guide (p = 0.09) (Table 3)

A hierarchical conditional backward logistic regression model was used to account for the interaction between gender and allocation. Variables entered into the model were previous ultrasound experience, allocation to NG group and male gender. The use of a NG increased the likelihood of performing a safe and adequate biopsy (adjusted RR 3.2 (95% CI 1.1–9.6; p = 0.036)), as did previous ultrasound experience (adjusted RR 3.1 (95% CI 1.0–9.5; p = 0.049)) and male gender (adjusted RR 4.4 (95% CI 1.5–12.9; p = 0.007)) (Table 2).

Secondary outcomes

The NG group required less time to complete the biopsy compared to the FH group (213 vs 287 seconds respectively, p = 0.01).

The use of a NG was not associated with performing an adequate biopsy (NG 58% vs FH 59%; p = 0.93). Only male gender was associated with a higher proportion of adequate biopsies, RR 2.47 (95% CI 1.02–5.80; p = 0.046).

A higher proportion of inferior pole biopsies was performed by the NG group than the FH group (NG 69% vs FH 48%; RR 2.42 (95% CI 1.03–5.69); p = 0.043) (Fig. 3).

A higher degree of needle visualiation occurred in the NG group compared to the FH group (NG 51% vs FH 22%; RR 5.3 (95% CI 1.89–14.83); p = 0.001) (Fig. 3). This difference remained even after adjustment for other significant factors including previous US experience (adjusted RR 3.4, 95% CI 1.14–10.14, p = 0.029) and male gender (adjusted RR 2.65, 95% CI 1.01–6.96, p = 0.049).

Using the VAS, participants reported that the use of a NG increased the ease of aligning the needle and US probe (57mm vs 35mm; p < 0.001). There was no difference in the participants perception of overall ease of the procedure, using the US probe or biopsy needle between FH and NG groups.

The assessors reported use of a NG increased the ease of aligning the needle and US probe (54mm vs 28mm; p < 0.0001), increased ease of using the biopsy needle (51mm vs 39mm; p = 0.031), and increased the ease of using the ultrasound probe (53mm vs 39mm, p = 0.009) using the same VAS. There was no difference in the assessor's perception of overall difficulty of the procedure between the FH and NG groups.

Discussion

This is the first study to compare the NG and FH methods for teaching the skill of percutaneous renal biopsy of native kidneys to novice trainees. Our results favour the use of a NG, as its use was associated with the primary outcome of a higher proportion of safe and adequate biopsies, as well as a shorter procedural time, higher proportion of inferior pole biopsies and higher proportion of biopsies with adequate needle visualisation. Additionally, there was a trend towards more participants with previous US experience allocated to the FH group. Given previous US experience was independently associated with achieving the primary outcome, this may have confounded our findings and reduced the impact of the NG.

Though there is no previous evidence examining the use of needle guides in an educational context, our safety results are in keeping with those in the hands of experienced operators by Prasad *et al* (1). Prasad *et al* performed a retrospective analysis comparing the complication rate and glomeruli yield of 2138 PRB performed with or without NG by nephrologists. They found a significantly lower risk of complications with NG compared to FH methods (2.1% vs 6.7%; $p < 0.001$). Other smaller retrospective trials of experienced operators performing PRB with or without NG found less or no significant differences between the two groups (2, 3). In our trial, both assessors and participants reported that participants using a NG showed greater ease in continuously holding the needle and ultrasound probe in alignment. Experienced operators are likely proficient at this technique already, which may lead to less benefit being seen in establish operators who were included in the retrospective studies published to date.

This study was a simulation conducted on a model and there are clear differences between this and performing a biopsy on a real patient. With human patients there are intricacies involving patient position, significant variation in the depth and position of the kidney and movement of the kidney with respiration, which do not occur when using a model. Despite these differences, we elected to use a model, as it provides a standardised method for assessing all participants without the variations that occur between human patients. Given the positive result of our trial conducted on a synthetic model, which is considered a technically simpler procedure, we would anticipate an even greater benefit on real patients, especially in the case of a deep kidney, where alignment of the needle and US probe is even more critical.

In the setting of using a model, surrogate safety endpoints were required because assessment for common complications such as macroscopic hematuria or perinephric hematomas was not possible. The safety endpoints of inferior pole biopsy and adequate needle visualisation were selected as surrogate endpoints, as these would minimise the risk of inadvertent damage to major vessels or surrounding structures, and maximise the probability that the biopsy will be of renal cortical tissue (rather than hilum). Whilst in our trial the use of a needle guide was associated with a higher proportion of inferior pole biopsies and biopsies with adequate needle visualisation, this study does not address whether this will translate to less clinical complications. Further randomised controlled trials on human patients will be needed to assess these outcomes.

The use of a synthetic model also precluded a microscopic assessment of adequacy by glomeruli count. Instead, adequacy was determined based on assessor ultrasound visualisation that the pass was likely to have biopsied cortical renal tissue. This meant that assessors were aware of participant's allocation raising the possibility of assessor bias. This could be minimised in future if human subjects or animal kidneys were used rather than a synthetic model. Adequacy could then be determined retrospectively by assessing the glomeruli count by a blinded observer.

The effect modification of gender was unanticipated. Despite using a minimisation protocol to distribute genders evenly between the NG and FH groups, a difference in the effect of gender was seen depending on allocation. This study was underpowered to assess the primary outcome for each gender separately. Female participants having lower baseline procedural skill than their male counterparts has precedent within the surgical literature. One retrospective study of medical students and residents in the United States of America showed that overall women displayed lower initial skill levels using validated surgical measures (9). A range of reasons for the difference in baseline procedural skills between the genders have been postulated. This includes differences in neural structure and function, hormonal exposure, varied educational opportunities, and different levels of exposure to ball sports and video games (10). The difference in procedural competence between males and females was eliminated with instructor feedback and individualised training (9). Additionally, it has been postulated in psychosocial literature that males tend to display more risk-taking behavior, and surgical literature has shown that males are more confident than females whilst displaying equivalent competence (11). These factors may contribute to male gender being associated with a shorter total procedural time in our study.

Use of a NG was associated with a shorter procedural time compared to the FH method. Whilst the difference of 74 seconds for the entire procedure is statistically significant, it is unclear whether this would be clinically significant. One key component when performing PRB on human patients is the patient holding their breath whilst the needle is introduced the final distance and subsequently deployed. Even a small reduction in the amount of time the patient is holding their breath would likely improve patient comfort. This study did not analyse where during the procedure this time was saved, and so cannot definitively comment on whether this difference is clinically significant.

Conclusions

In conclusion, we found that using a NG increased the likelihood of a novice operator performing a safe and adequate PRB on a synthetic model. Amongst novice operators, male gender and previous ultrasound experience were also associated with performing a safe and adequate biopsy. Use of a NG reduced the total procedural time and increased the proportion of inferior pole biopsies and biopsies during which there was adequate needle visualisation. Use of a NG was not associated with an adequate biopsy being performed. Assessors and participants both reported that needle guides significantly increased the ease of aligning the needle and US probe. We believe that these results support further trials to ascertain whether the same positive results are seen on real patients, prior to introduction into clinical practice for teaching PRB.

Abbreviations

PRB Percutaneous Renal Biopsy

FH Freehand

US Ultrasound

NG Needle guide

VAS Visual analogue scale

RR Relative risk

CI Confidence Interval

Declarations

Ethics approval and consent to participate

The trial protocol was approved by the South Western Sydney Local Health District Human Research Ethics Committee. Participants read the Participant Information Sheet (PIS) and were able to ask questions of a trial coordinator. They signed a written informed consent form if they agreed to participate. This research was in adherence to the Declaration of Helsinki.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analysed during the current study are not publicly available due to not having ethics approval to share this data, but are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

All authors contributed significantly to this work, and all are in agreement with the content of the manuscript. ED, TS and JW were involved in trial idea conception. ED, AM, GN, AA, TS, HN, KM and JW were involved in trial design. ED, GN, AA, TS, HN, KM and JW collected data. ED and AM conducted statistical analysis. ED, GN, AA, TS, HN, KM and JW completed manuscript preparation.

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Tables

Tables 1 to 3 are available in the Supplementary Files section

Figures

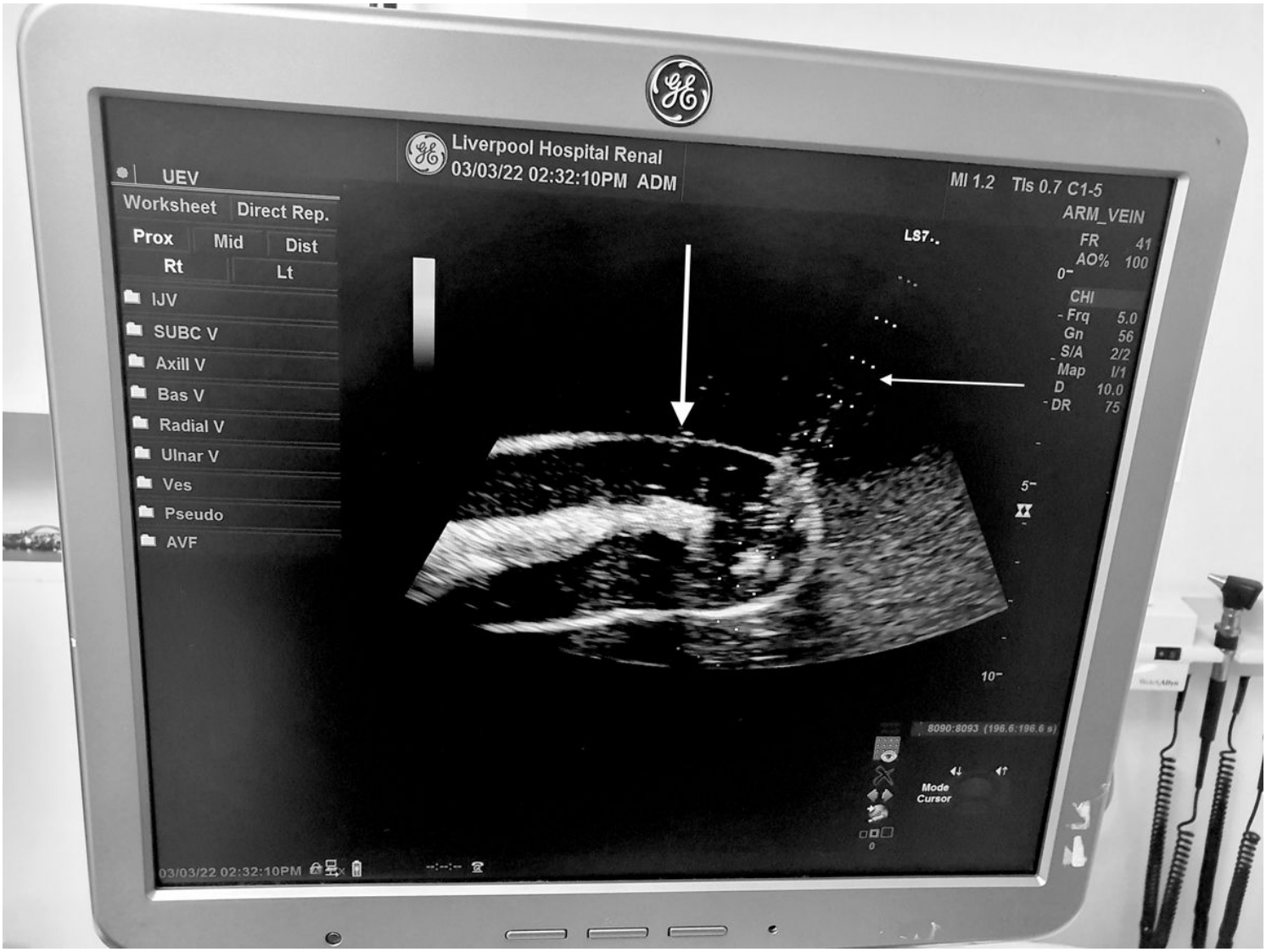

Figure 1

The ultrasound screen as seen by those in the NG group. Displayed on the screen are the synthetic kidney (thick arrow) and predictive throw lines (thin arrow).

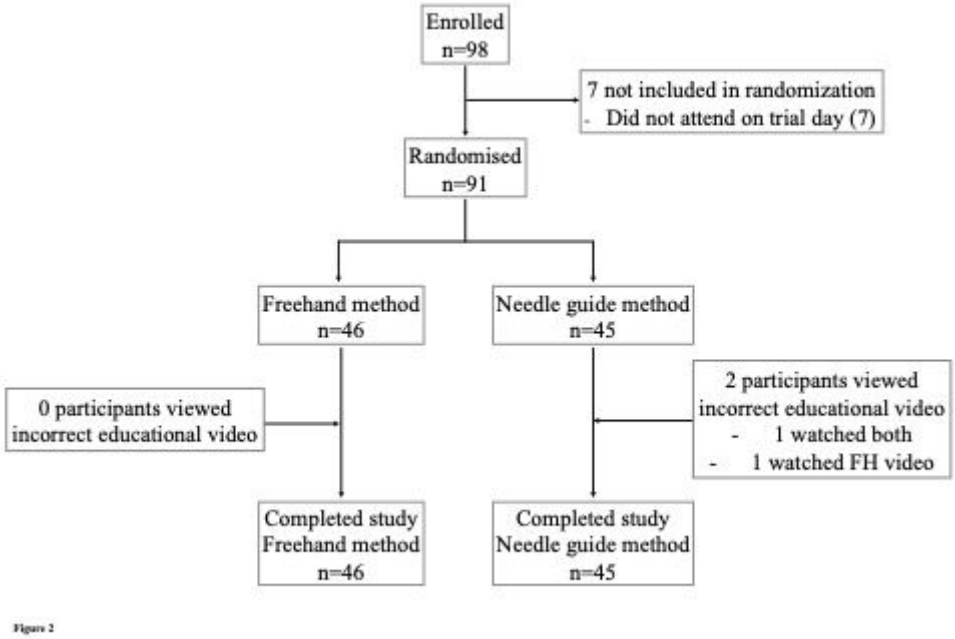

Figure 2

Consort diagram. Of the 7 participants that did not attend after enrolment, 1 was unwell, 1 had moved hospitals and 5 did not attend due to work demands.

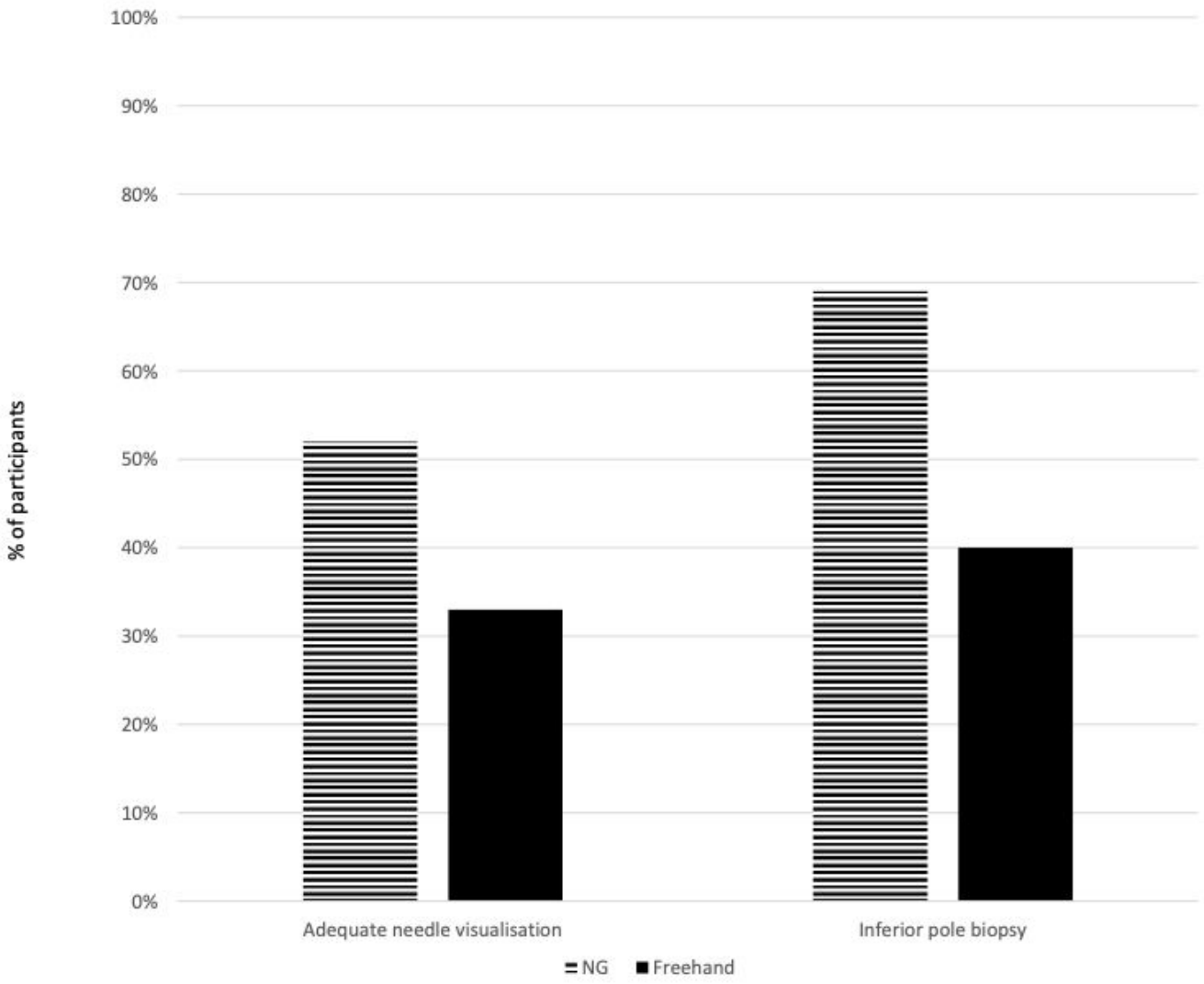

Figure 3

Figure 3

Comparison of the percentage of participants achieving the two secondary safety endpoints of adequate needle visualisation and inferior pole biopsy

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Table1.png
- Table2.png
- Table3.png