

Prospective randomized study of preprocedural ultrasound scan for spinal anesthesia comparison between using 2nd prototype of PASS and skin marking technique to locate needle entry point

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Abstract

Background: Pre-procedure ultrasound scans can indicate the midpoint of the puncture site of spinal injection. However, there are limitations of the technic.

Objectives: To compare the success rate of spinal anesthesia by preprocedural ultrasound scan to compare 2 needle puncture technics between using Point-Assisted Spinal Sonography (PASS) and skin marking.

Methods: Forty-eight patients undergoing elective spinal anesthesia were randomized to receive preprocedural ultrasound scan with transverse interspinous view to locate the needle puncture, using either the 2nd prototype of PASS (n=24) or skin marking (conventional) (n=24). The conventional technic was done by making the intersection point of the two lines across the

short and long edges of the transducer, whereas the other used PASS to guide the needle trajectory. The primary outcome was the success rate of spinal tap at the first attempt. The number of total attempts and spinal tap duration to obtain the CSF were recorded as secondary outcomes.

Results: The success rate of spinal tap at the first attempt was 9/24 (37.5%) patients in PASS and 11/24 (45.8%) in skin marking group (P=0.55). Spinal tap duration and the number of total attempts were not statistically different (P=0.55 and 0.49 respectively).

Conclusion: The 2nd prototype of PASS produces comparable successful spinal block with using skin marking technic in terms of success rate at the first attempt and procedure time. Needling without marks or gel in PASS technic might take less risk of intrathecal contamination.

Keywords: mark, skin, spinal, ultrasound-assisted

Ultrasound (US)-assisted neuraxial block has become a necessary tool to identify the intervertebral space, and to access the trajectory to the intrathecal or epidural space, especially in the difficult cases.⁽¹⁻³⁾ US pre-procedural scanning, however, has some drawbacks. Skin marking and ultrasound media are needed and possibly introduced inside by the spinal needle. This possibly induces risks of both infection and chemical reaction. The depth to the intrathecal space is usually underestimated by the image due to the compression of the probe on the skin surface. Point-assisted Spinal Sonography or PASS is a device that has a frame attached to the US transducer and the needle guide set guides the puncture site and the needle trajectory. After the 1st prototype of PASS was studied in a soft cadaver, we modified the design to improve the accuracy of the needle point. Then we developed the 2nd prototype, which is made of medical-grade polyvinyl chloride (PVC) (Figure 1). There are 2 major parts of the 2nd prototype of PASS, the frame and the needle guide set. The frame is a customized product by 3-dimension printing technology to fit the ultrasound transducer (GE LOGIQ™ P9, GE Medical Systems Thailand LTD.) The needle guide set, which is composed of a bracket and an insert, is fitted to the frame after transducer removal (Figure 2). The device works by the sagittal guiding slot of the bracket attached to the insert to lock the opening in a rectangular shape to control the puncture point and the trajectory of the needle (Figure 2). After the needle tip position is in proper position, the whole parts of the PASS can be easily removed by one hand while the needle is stabilized with



Figure 1 Parts of the 2nd prototype of PASS: label 1: frame; label 2,3: needle guide set; label 2: bracket; label 3: insert.

the other hand. Then the anesthetic-filled syringe can be secured to the needle for an injection with two-handed technique. PASS can be sterilized with Ethylene Oxide and its needle-guided set is disposable to avoid cross-contamination. The objective was to compare the success rate of ultrasound-assisted spinal anesthesia between PASS and skin marking technique.

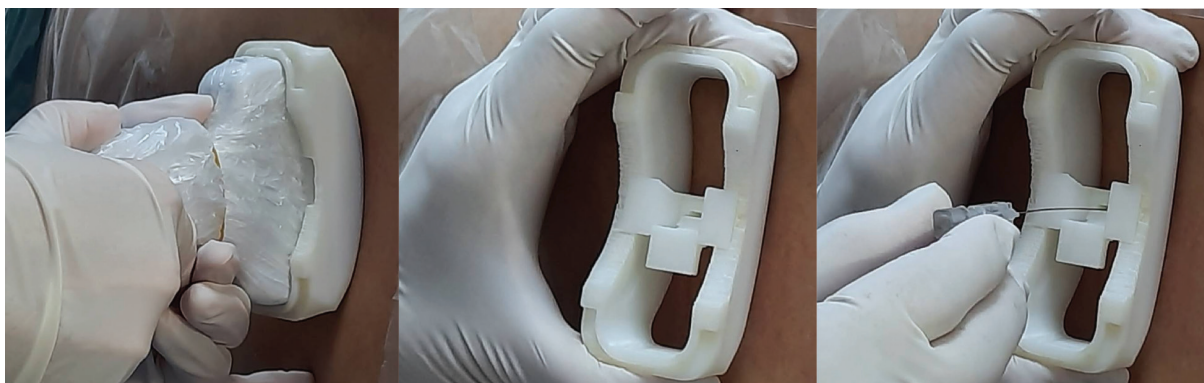


Figure 2 Steps of using 2nd prototype of PASS. Left: the frame is attached to the ultrasound transducer. Middle: the needle guide set is fitted to the center of the frame. Right: the needle guide set locates the needle entry point and direction to ITS.

Materials and methods

After approval by the Research Ethics Committee, Faculty of Medicine, Chulalongkorn University (IRB No. 398/63, COA No.1154/2020), we studied an open label randomized controlled trial comparing the 2nd prototype of PASS with the skin marking technic. Forty-eight patients undergoing spinal anesthesia below T10 dermatome for surgery at King Chulalongkorn Memorial hospital were included after all the written informed consent was obtained. The inclusion criteria were patients who had normal anatomical structure, 18-80 years old, BMI under 35 kg/m². Exclusion criteria were pregnancy, patients who had contraindication for neuraxial block, e.g., previous lumbosacral spine surgery, coagulopathy, etc. The procedures were performed by three anesthesiologists who have clinical experience more than 3 years in neuraxial ultrasound scanning. Stratified block of 4 randomization was generated with a computer random number to 1:1 allocation ratio. Sixteen patients were equally allocated for each anesthesiologist.

The allocation was concealed until the time to start spinal anesthesia. The total number of patients in each group was 24. The patients were under standard monitoring, and aseptic technic was prepared on patient's skin for spinal anesthesia in lateral position. Then the 2-5 MHz curvilinear US transducer with gel, covered by sterile bag, was used to identify the sacrum, and subsequently moved cranially to over the L4 or L5 spinous process. Then a transverse scan was performed through the interspinous space (transverse interspinous view). To obtain the optimal position of the transducer, the image should simultaneously include the posterior complex (PC), intrathecal space (ITS), anterior complex (AC), the spinal canal in the midline, and the articular processes (AP) or the transverse processes symmetrically (Figure 3). On the skin marking group (Figure 4), the puncture site was marked by a sterile surgical marking pen to make an intersection point of the two lines across the short and long edges of the transducer to indicate a needle puncture site. Subsequently, the 27-G, 90 mm (BD, Franklin- Lakes, NJ and USA)

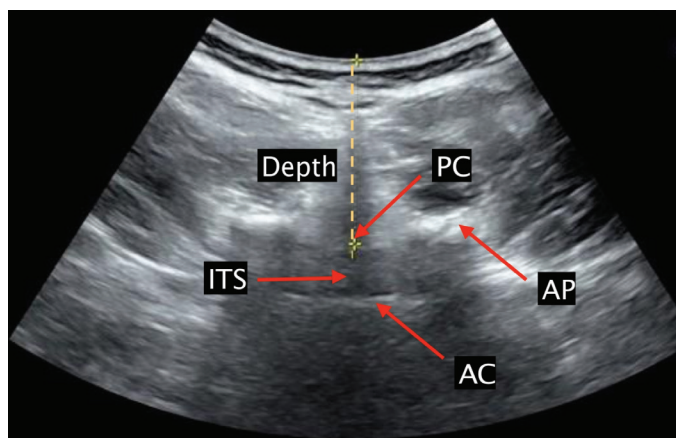


Figure 3 US image of transverse interspinous view. Abbreviation: AC, anterior complex; AP, articular process; ITS, intrathecal space; PC, posterior complex.



Figure 4 Skin marking by pre-procedural ultrasound technic. Left: skin marking on the middle points of short and long edges of the transducer. Middle: the two lines across both edges to indicate a needle puncture site. Right: Needling at the indicated site with estimated direction to ITS.

spinal needle with Quincke bevel was inserted at the indicated site by estimated direction to ITS. For the PASS group, an ultrasound probe was fitted to the frame as the same unit. When the best image of L3-4 or L4-5 posterior complex was identified, the transducer was removed while the frame was still fixed at the same position and direction. Then the needle guide set was placed onto the frame and guided the needle trajectory

to ITS. The primary outcome was the success rate of spinal tap at the first attempt of needle insertion between the PASS and skin marking technics to obtain cerebrospinal fluid (CSF). The secondary outcomes were needle inserted attempts and spinal tap duration from skin touch of ultrasound transducer to CSF appearance.

Sample size calculation

Kampitak et al. reported the success rate

at the first attempt of 45% by skin-marking technic.⁽⁴⁾ Accordingly, we had initially estimated a sample size of 66 patients per group to detect a 50% difference between PASS and skin-marking technics with a power of 80% and 2-sided alpha value of 0.05. However, this study was as a part of research and development (R&D) of PASS; therefore, we studied its clinical use in 24 patients as the first stage in the development process and compared with 24 patients in skin-marking group.

Statistical analysis

All statistical analysis was performed by the using SPSS version 22 (IBM corporation, Armonk, NY, USA). Continuous data were reported as mean or median (interquartile range [IQR]) as appropriate. Mann-Whitney U test and Chi-square test was used for two independent variables. A two-tailed P value <0.05 was indicated as statistical significance.

Results

The CONSORT diagram is shown in Figure 5. Patient demographic characteristics are shown in Table 1. The success rate of spinal tap at the first attempt of needle insertion was 9 (37.5%) patients in PASS and 11 (45.8%) in skin marking group ($P=0.55$) (Table 2). The spinal tap duration using PASS was comparable (159 secs, IQR 104 to 255) to skin marking technic (167 secs, IQR 124 to 214) (Table 2). Needle attempts were not statistically different (9/5/4/6 vs. 11/7/5/1 times at the 1st/2nd/3rd/ $>3^{\text{rd}}$ attempts respectively, $P=0.49$) (Figure 6). There was 1 case of failed block in the skin marking group, which it was successful by surface anatomical landmark.

Discussion

Landmark-guided spinal anesthesia is traditionally practiced. However, Tuffier's line between the iliac crest is not always a correct position and may produce a risk of spinal cord injury.^(1, 2) Ultrasound scanning can improve the accuracy of the required interspinous level, evaluate the patency of the spinal space and the depth of the needle to approach the target.⁽³⁾ Ultrasound scanning is especially beneficial for some high-risk patients who have an abnormal anatomical structure of spine and coagulation condition.^(1, 5) Moreover, failed block after multiple attempts induces more complications and increases cost, whereas reduces clinical productivity. Real time ultrasound-guided technic by paramedian sagittal oblique view requires more technical skills and has more limitations of anatomical structure and the poorly identified image of the needle.⁽³⁾

US pre-procedure scan in transverse interspinous view can help to identify the optimal intervertebral space and point out the puncture site to the target. Making a line across the short and long edges of the probe produces an intersection point for the needle insertion. However, this technique has some limitations. Firstly, when the marking step is done prior to aseptic skin preparation, the gel-smeared area of the skin makes unstained and easy-removed marking, which leads to errors to identify the center. Additionally, skin marking is a common problem after antiseptic application. Secondly, there is always an error of the mark in case the short-edged part of the curved transducer does not contact the skin. Rearranging the probe to



CONSORT

TRANSPARENT REPORTING of TRIALS

CONSORT 2010 Flow Diagram

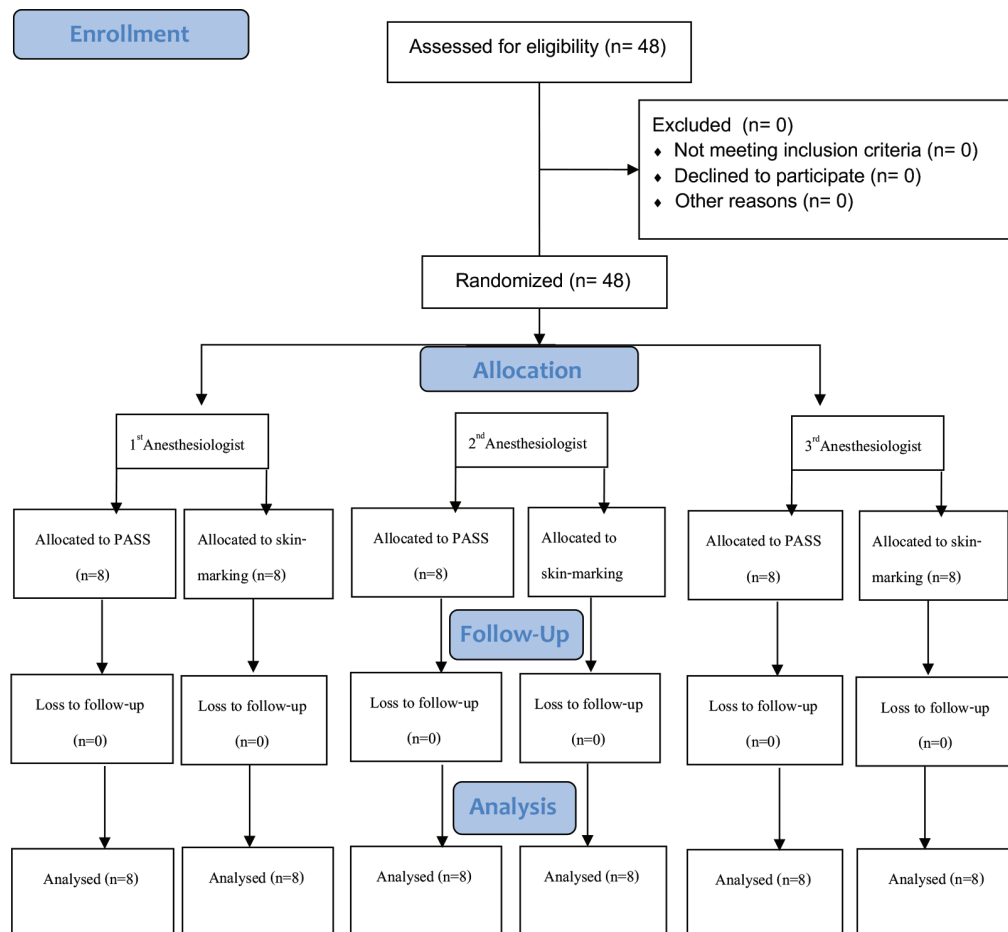


Figure 5 CONSORT flow diagram

reidentify the ITS leaves several different marks, which can be confusing. Thirdly, the staining chemical of marks or gel can contaminate the ITS during puncture and cause a distinct neuroinflammatory reaction.⁽⁶⁾ Fourthly, in some difficult cases such as patients with bony or calcified structure, skin marking alone may not be adequate for accurately identifying the puncture site. Finally, the ITS depth can be underestimated

due to the compression of the probe on patients' skin, especially those who have thick subcutaneous tissue. Pilot studies using PASS were initially conducted in a soft human cadaver, through which findings have been used to improve the design. Subsequently, the prototype was approved by the Ethics Committee for a clinical trial. According to this study, both spinal tap duration and numbers of patients with various

Number of patients

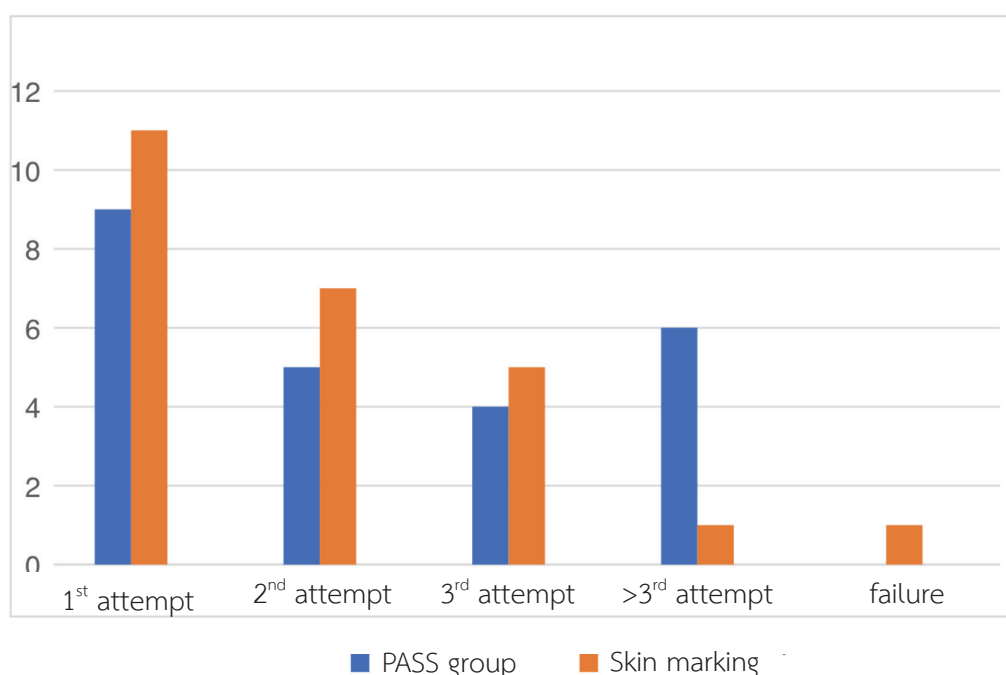


Figure 6 Number of needle attempts. Chi-square for trend test $P = 0.49$.

Table 1 Demographic data

Patient characteristics	PASS 2 nd prototype (n=24)	Skin marking (n=24)
Age (yr)	54.4 (16.5)	49.3 (15.7)
Weight (kg)	65.2 (16.7)	67.1 (12.8)
Height (cm)	165.5 (27.4)	160.6 (7.9)
BMI (kg/m ²)	25.4 (5.4)	26.2 (4.8)

Data report as mean $\pm$ SD

Table 2 Number of the 1st attempt success rate and spinal tap duration

	PASS 2 nd prototype (n=24)	Skin marking (n=24)	<i>P</i>
1 st attempt success rate (n, %)	9 (37.5)	11 (45.8)	0.55
Duration to CSF appearance (sec, IQR)	159 (104-255)	167 (124-214)	0.44

Chi-square test for success rate, and Mann-Whitney U test for duration (median and interquartile range, significant at $P < 0.05$)

needle attempts were comparable between the 2 groups. The median of spinal tap duration was about two and a half minutes in both groups. We justified the spinal tap duration of both groups by using the same starting point at skin contact of the transducer on the aseptic prepared skin. Both spinal tap duration and the number of needle attempts were not statistically significant. This might be the limitation of the study by a small sample size. Consequently, PASS's design should be developed to reduce some errors of locating the needle entry for better results. It is noted that there was one failed block in skin marking group due to a marking error on the short sides of the curvilinear probe, which was not in contact with the skin surface of the lean patient. However, we did not experience this problem with PASS technic.

This first clinical trial on the 2nd prototype of PASS demonstrates that spinal anesthesia is feasible without gel or dye contamination. However, further designed development and clinical skill practice are required to improve the success rate, especially in those who have clinical predictors of difficult neuraxial block.

Conclusion

The 2nd prototype of PASS produces comparable successful spinal block with using skin marking technic in terms of success rate at the first attempt and procedure time. Needling without marks or gel in PASS technic might take less risk of intrathecal contamination.

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