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APPARATUS

A needle guidance device compared to free hand technique in an ultrasound-guided interventional task using a phantom

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Summary

In this in vitro study, a needle guidance device and a 'free hand' technique for ultrasound guided needle insertion were compared in a simulated ultrasound-guided interventional task using a porcine phantom. Residents inexperienced in using ultrasonography were asked to insert a needle, using an in-plane techniques, and to make contact with metal rods at a depth of 2 and 4 cm in the phantom. The transducer made angles of 90°, 60° and 45° with the surface of the phantom. The times to perform the procedures were significantly shorter and the needle visualisation was significantly better when using the needle guidance device. The residents ranked their satisfaction with the needle-guidance device significantly better than the 'free-hand' technique. This device may be beneficial when performing ultrasound guided peripheral nerve blocks, especially by inexperienced operators.

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Continuous visualisation of the needle during the performance of ultrasound guided interventions is essential when inserting into tissues which are in close proximity to vessels, pleura or nerves. Without accurate identification of the needle, damage to collateral structures may occur [1]. Needle insertion can be performed using the in-plane (IP) technique, in which the entire needle and the tip can be visualised, or the out-of-plane (OOP) technique. The latter results in the needle being imaged on cross-section, which has the disadvantage that the needle will cross the ultrasound beam only once [2].

The major obstacle for the IP technique is to keep the needle exactly in the path of the ultrasound beam. The beam width is thin, so even slight movements might prevent the visualisation of the needle.

Some ultrasound systems provide needle guidance devices for their transducers. These secure the needle to the transducer and direct the needle in a predetermined direction to various depths from the transducer surface, depending on the selected angle of the guide relative to the transducer [3, 4].

Needle guides tend to be costly but may be helpful for the inexperienced user [5]. However, once the needle is secured in the needle guidance device, angles and approaches to the target cannot be changed. This is a major disadvantage when, for example, a thin needle bends away from its desired path because of tissue inhomogeneity and shaft deflection or when non-optimal local anaesthetic spread necessitates redirection of the needle.

In order to overcome these problems, a different needle guidance device was designed by Giesen Design Consultancy, Breda, the Netherlands. The 11 × 3 × 2 cm (length × width × height) needle guide was produced out of Duraform® PA, a polyamide plastic which can be sterilised by hot steam in autoclaves (at 134 °C). With this apparatus, the needle is kept in-plane with the ultrasound beam, without restricting angulation or direction of the needle (Fig. 1). This enables maximum flexibility. The needle is inserted through the device in the skin directly

Figure 1 Ultrasound transducer, needle guide device and needle on the porcine phantom.

into the ultrasound beam. This provides flexibility while maintaining the entire needle shaft and tip in the ultrasound beam.

The purpose of this study was to compare the performance time and the needle visibility between using the needle guidance device and using a 'free-hand' technique. This was tested with inexperienced residents, performing a simulated ultrasound-guided interventional task using a porcine phantom.

Methods

After giving written informed consent, 20 clinical anaesthesia residents were prospectively enrolled in this study. They had no visual disturbances and no prior experience with ultrasound guided procedures.

The phantom

The porcine phantom was prepared as described by Xu et al. [6]. A 20 × 12 × 8 cm (length × width × height) piece of pork ham was deodorised in alcohol for 24 h. In our model, the tendons in the model of Xu et al. were replaced by two metal rods with a length of 8 cm and a diameter of 0.35 cm at a depth of 2 and 4 cm from the surface. The whole phantom was wrapped in a transparent par film and reinforced exteriorly by tape and a surgical paper towel.

Preparation on the interventional task

All residents received a presentation giving an overview of the ultrasound machine and transducer (Micromaxx, Sonosite Inc. Bothell, WA, USA). Descriptions of the essential buttons and dials and how to use them were provided. It was demonstrated how to hold the probe to perform an examination in the phantom and images were provided from the metal rod in short axis view. Needle visualisation using an in plane technique was explained

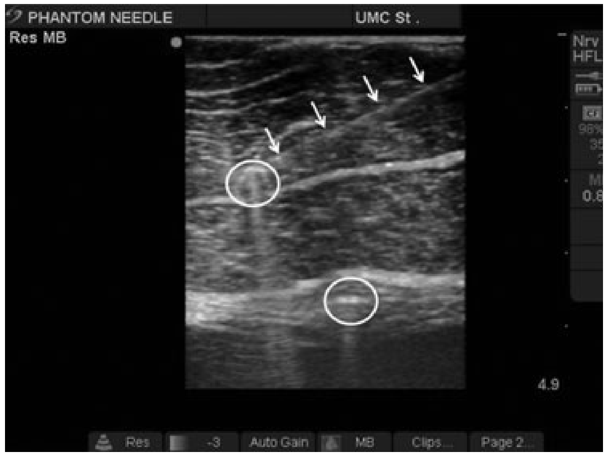

Figure 2 Using an in plane technique, the 22-gauge needle (white arrows) is approaching the short axis visualised metal rod (encircled reflection) at a depth of 2 cm. The reflection and shadowing of the metal rod at 4 cm is also visible.

and images were provided from the needle approaching the metal rod (Fig. 2). The needle guidance device was shown and images were provided illustrating its use.

Residents were asked to visualise the metal rod in the phantom by turning on the machine, finding and imaging the metal rod. The instructor provided help, if needed, with changing the gain, depth, and resolution in order to obtain the best image. For 5 min, the residents were allowed to practise with the needling technique, but not with the needle guidance device. The residents were instructed only to advance the needle when it was completely visualised. Following this, the task, they had to perform was explained. Ad random (by drawing an envelope), the subjects were assigned to one of two groups, F-group (free-hand group) and G-group (guidance group).

Interventional tasks

The F (free hand)-group started with the following tasks: Using an in plane approach with the metal rod in short axis view and a 'free-hand' technique, the needle (22 gauge Stimuplex A, B.Braun, Melsungen, Germany) was inserted and advanced to make contact with the metal rod. First, the ultrasound transducer was held perpendicular (angle of 90°) to the phantom. This procedure had to be performed on two metal rods, which were placed at a depth of 2 and 4 cm from the surface, respectively (Task 90/2 and 90/4).

The same task was repeated but now, in order to complicate the previous task, making an angle with the transducer of 60° and 45° with the surface of the phantom (Task 60/2, 60/4, 45/2 and 45/4). For this, a custom-made wooden triangle with an angle of 60° was mounted onto the echo transducer, so that the basis of

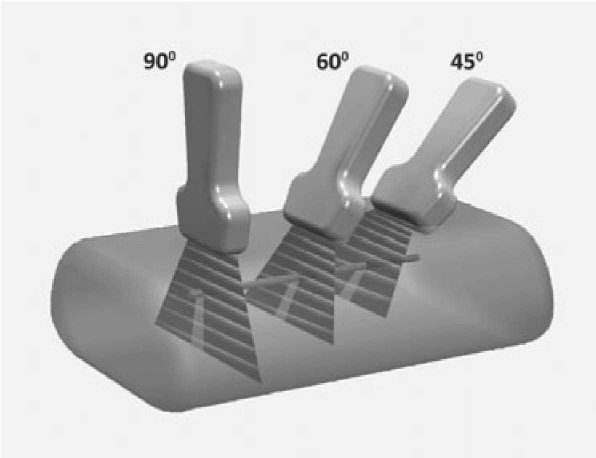

Figure 3 Visualisation of the metal rod in short axis view, with different insonation angles (90°, 60° and 45°) to the phantom surface.

the triangle contacted the surface of the phantom (Task 60/2 and 60/4). Then the angle was changed to 45°, with the aid of another wooden triangle and the procedure was performed again (Task 45/2 and 45/4) (Fig. 3).

Next, the needle guidance device was placed on the transducer and the interventional tasks as described above were repeated. Thus, with assistance of the needle guidance device, the two metal rods were punctured at angles of 90°, 60° and 45° at two depths of 2 and 4 cm.

The G (guidance)-group started with performing the interventional tasks with help of the needle guidance device as described above. Then the bracket was removed and the same tasks using a 'free-hand' technique were performed.

Evaluation

Two unblinded observers evaluated all procedures. The time from needle insertion to successful contact with the metal rods was recorded (= procedure time) for both techniques. After having performed the procedures, subjects were asked to rank their satisfaction with both procedures on a scale from 1 (lowest score) to 10 (best score).

The procedures performed by the last 10 residents were videotaped and also used for extended analysis. The time that the needle was completely visualised by ultrasound was measured and noted. Also the ratio of this time to the overall task performance time was calculated.

In all, 120 paired observations of procedure times were collected and assembled in an EXCEL database and combined with the other variables, such as demographics, angle and rod depth. Data were analysed with SAS statistical procedures (SAS Institute Inc., Cary, NC, USA). Statistical significance of the differences between the two groups was tested with Wilcoxon's signed rank tests. p-values <0.05 were considered statistically significant. Data are presented as mean (median; interquartile range).

Results

Five female and 15 male residents performed the ultrasound-guided interventional task. The time to perform the procedures was significantly shorter while using the needle guidance device in all subgroups (Table 1). The needle visibility during the interventional task performance (as percentage of procedure time) was significantly better using the needle guidance device (Table 2). Every resident ranked the needle guidance device technique better than the free-hand technique. The needle-guide device technique was ranked with an average score of 8, the free-hand technique with 5 ($p < 0.001$).

Discussion

The use of the described needle guidance device shortened the ultrasound guided interventional procedure time with an improved needle visibility.

Needle visibility is the key to ultrasound-guided regional anaesthesia techniques. Only the in-plane technique enables visualisation of the entire needle and needle tip. But keeping the needle in the ultrasound beam of only 0.3 mm is a demanding procedure. Several devices have been made to ease this task. A laser-unit mounted onto an ultrasound transducer to align the ultrasound scanning plane and laser-line projection plane, thereby

Table 1 Mean procedure time (median; IQR) in seconds for the interventional tasks in both techniques presented.

Task angle (°)/ depth; cm	Procedure time; s device	Procedure time; s free hand	p-value Wilcoxon signed rank test
90/2	16 (10.5; 6.5–14.5)	43 (33; 21–55)	0.0006 (*n* = 20)
90/4	17 (12.5; 6.5–21)	46 (34.5; 16–48)	0.0006 (*n* = 20)
60/2	9 (9; 5–11.5)	44 (29; 14–50)	<0.0001 (*n* = 20)
60/4	13 (11; 6.5–18.5)	53 (34; 17.5–83)	<0.0001 (*n* = 20)
45/2	11 (7; 4–16.5)	60 (52; 31–83.5)	<0.0001 (*n* = 20)
45/4	15 (14; 9.5–18)	77 (56; 25.5–127)	<0.0001 (*n* = 20)

Table 2 Needle visibility (expressed as percentage of the procedure time) in the interventional tasks in both techniques.

Task angle (°)/ depth; cm	Visibility (% of procedure time) device	Visibility (% of procedure time) free-hand	p-value Wilcoxon signed rank test
90/2	82 (85; 75–94)	46 (56; 20–63)	0.002 (n = 10)
90/4	85 (86; 76–100)	48 (47; 21–72)	0.003 (n = 10)
60/2	87 (89; 75–100)	32 (32; 22–40)	0.001 (n = 10)
60/4	80 (85; 65–100)	40 (26; 19–80)	0.001 (n = 10)
45/2	81 (100; 59–100)	28 (27; 9–48)	0.002 (n = 10)
45/4	70 (74; 62–88)	39 (33; 27–50)	0.01 (n = 10)

assisting with in-plane needle alignment, was described by Tsui [7]. This interesting approach may guide needle insertion but does not prevent 'desynchronised' involuntary movements of the echo transducer in one hand and needle in the other hand during the procedure. Furthermore, the usefulness of this method is unclear while tilting the echo transducer (angles between skin and echo transducer > or <90°) which is sometimes needed to optimise visualisation of the nerve.

Commercially available needle guides direct the needle in a predetermined direction but restrict re-angulation and re-direction of the needle. This is a major drawback in ultrasound regional anaesthesia, where changes of the needle position during the procedure are needed to assure optimal spread of local anaesthetics. Therefore, this needle guidance device was developed and designed to allow maximum flexibility for re-angulation and re-direction.

Thin needles are known to potentially bend away from their desired paths because of tissue inhomogeneity and shaft deflection [8]. Although the thin 22-gauge needle used in our study was fixated in the needle guide, bending away from the ultrasound beam in the phantom was also observed in our study. This may explain why the needle is not visible during the entire procedure time. Only small corrections in the alignment of the ultrasound transducer without moving the needle were necessary in order to visualise the needle again. Interestingly, in a pilot study, in a water bath (which prevents needle bending), we were able to visualise the entire needle 100% of the time using the guidance device. Larger needles can be more easily captured by ultrasound and are more rigid with less bending away, but are more painful when inserted. This should be considered while choosing a needle size for ultrasound guided regional anaesthesia techniques.

A phantom for evaluation of needle visibility contains material that simulates a body of tissue in its interaction with ultrasound, and is used to mimic ultrasonic interactions in the human. Commercial phantoms from agar, urethranes, epoxies and liquid may be used for the evaluation. We chose the porcine phantom because it most resembles human tissue characteristics with fascia, muscle and fat [6]. For the target, metal rods were used because ultrasound waves hitting the rod are equally reflected from all directions and increase visibility.

Poor needle visibility occurs at small angles of insonation. Good needle visibility is expected in tissues that are relatively sonolucent and when angles of insonation approach 90°. Needle visualisation may become a problem with targets of increased depth or tissue echogenicity and when targets require small angles of insonation [9]. Although ultrasound equipment with compound imaging can help to overcome this problem, targeting deeper structures is more complicated [10]. This is reflected in the longer performance times for the intervention at 4 cm compared to the task at 2 cm.

The interventional task was performed under three angles to the phantom surface, in order to simulate daily practice of ultrasound guided peripheral nerve blocks. Anisotropy of nerves makes it necessary to tilt with the transducer in order to obtain the best quality image of the nerve [11]. Hitting the target with a tilted transducer is more complicated [12]. This is also reflected in the results, which show an increased procedure time and decreased needle visibility when the task was performed under shallower angles. Nonetheless, the developed needle guidance device enabled excellent needle visibility independent of puncture depth and transducer position.

In conclusion, optimal needle visibility is important for precision and safety in ultrasound-guided interventional procedures. The present in vitro study shows an increased needle visibility and shorter procedure times when the interventions were performed using the newly developed needle-guidance device compared to the free hand technique. This device may be beneficial when performing ultrasound guided peripheral nerve blocks especially by inexperienced operators. However, clinical studies have to be performed in order to prove this assumption.

Acknowledgements

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