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Success Rate of Spinal Anesthesia by Anesthesia Resident: Comparing Ultrasonography Versus Traditional Method, a Randomized Clinical Trial

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ABSTRACT

Background: Previous studies have suggested the use of ultrasonography for more success in spinal anesthesia. The purpose of this study was to compare the effect of ultrasonography and traditional method on the success rate of spinal anesthesia by an anesthesia resident.

Methods: In this clinical trial study, patients who were candidate for leg or lower abdominal surgery under spinal anesthesia and referred to Firoozgar and Rasoul-e-Akram hospitals in 2019 were randomly assigned to techniques: 1) common surface marking techniques and 2) the use of ultrasonography to find the spinal canal. The dural puncture success rate at the first needle entry attempt, time required for determining the needle entry site, time required for needle entry until CSF exit, number of needle redirection without complete skin exit, and needle entry after complete needle withdrawal in each group were measured and recorded.

Results: The success rate of dural puncture at the first attempt of entry and the time required to determine the needle entry site in the ultrasonography group (55.2%) was significantly higher than that in Landmark group (21.4%) ($P<0.05$). The time required for needle entrance to CSF exit, the total procedure time for patients, the number of needles redirection without complete removal of the skin, and the number of needle entry after complete removal of the skin in the ultrasonography group was significantly lower than that in Landmark group ($P<0.05$).

Conclusion: The use of ultrasonography in comparison with the traditional method has been effective on the success rate of spinal anesthesia by an anesthesia resident.

Keywords: Ultrasonography, Landmark, Spinal Anesthesia, Surgery

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Introduction

In recent years, development in technology has resulted in a revolution in preparing anesthesia. In particular, the ultrasound applications have been considered in anesthesia, and ultrasonography has become an indispensable instrument. Some guidelines have recommended procedures such as the central venous catheter, and the peripheral nerve block under ultrasound as a standard by anesthesia specialists should be done (1).

Despite considerable improvements in the quality of needle, catheters, medications, and epidural and spinal delivery systems, technical aspects of this method have not been altered in the past 70 years.

As an experience with a peripheral nerve block, final development in spinal and epidural techniques will be possible until we can have a visual procedure.

A safe and efficient neuraxial block is the basis of spinal anesthesia. Performing spinal and epidural anesthesia in the traditional method is based on superficial landmark touch. Multiple conditions such as obesity, edema, and scoliosis, and other spine anomalies make the diagnosis of these landmarks difficult. Even though superficial landmarks are successfully detected, anesthesia experts may not be successful in finding arbitrary vertebral space. MRI indicated that anesthesia experts had found correct arbitrary vertebral space in less than 30% of cases. Almost in all cases of error, they selected intrathechal space more than the expected space, which it can have adverse effects (1).

Spinal ultrasonography has been significantly popularized in the last decade. Beginner trainees using ultrasound before procedure have had a higher success rate in the epidural catheter placement. This finding was confirmed by a recent meta-analysis on the placement of the epidural or lumbar punctures using ultrasound and resulted in increased levels of success and reduction for the possibility of injury to healthy tissues and trauma (2-5).

Pre-spinal sonography from the spine accurately identifies the corresponding anatomy, and it can help identify the following cases: Favorite inter-vertebral space, the best place for inserting the needle, the angle of needle insertion and its route, and estimated depth of epidural space. In the obese and scoliosis cases, neuraxial anesthesia is challenging. In both populations, ultrasonography has led to a half of the frequency of effort for insertion attempts, doubling the success rate of the first attempt to compare with the landmark technique (6-10).

Hence, ultrasonography can be utilized as a guidance for training to recognize the exact placement of the spinal needle. According to the description, as mentioned above, this research surveyed the impact of utilizing ultrasonography compared to the conventional method in the success rate of spinal anesthesia by an anesthesia assistant.

Materials and Methods

The study was conducted between July 2019 and December 2019 at Firoozgar and Rasoul-e-Akram hospitals and registered in Iranian Registry of Clinical Trials (IRCT20140109016151N8) before recruitment. The study protocols were approved by the Ethics Committee of Iran University of Medical Sciences (Ethical code: 1396.951174004), and written informed consent was obtained from all patients. The number of samples required for the present study was determined based on the Chin *et al.* study (2). Maximum sample size was calculated by considering the 95% confidence level and 90% power ($\alpha = 0.05$ and $\beta = 0.1$) and the result, according to the formula $N = \sum \times (Z1 - \alpha/2 + Z1 - \beta)^2 \times (\sigma2/\sigma2)/(\mu_1-\mu_2)$, was 28 people in each group. Also, considering at least 30% drop in sample size and level of training of resident, we considered to evaluate 50% more to reach the calculated sample for analysis.

In a randomized clinical trial, a total of 91 patients were selected based on the inclusion and exclusion criteria. The present research was conducted in the operation room of Firoozgar and Rasoul-e-Akram hospitals on patients who were candidate for lower limb orthopedic surgery or lower abdominal surgery, under covering spinal anesthesia. Written informed consent was obtained from all patients.

Inclusion criteria included patients over 18 years of age, both gender, having informed written consent form, no contraindication for performing spinal anesthesia, BMI between 24 and 35 kg/m^2, candidates for orthopedic surgery of lower limb or other low-abdominal surgery, and lack of surgical history on lumbar vertebrae.

Exclusion criteria were bradycardia or severe tachycardia during insertion of needle, lack of patients unmoving during procedure, patients' dissatisfaction and asking for general anesthesia.

Failure cases include 1) more than three attempts to find space, and finally, use the paramedian method or doing by senior assistant,

2) lack of success and performing general anesthesia.

Patients were randomly divided into two groups. Simple randomization was handled using numbered sheets inside the envelope. Patients with even codes were assigned to the landmarking group and those with odd codes were assigned to the ultrasound group. An anesthesia resident (second grade) was charged with training in spinal infusions, with at least five successful spinal anesthesia with ultrasound and landmarking conduction.

Standard monitors (ECG, NIBP, and POM) were used. The peripheral IV line was established, and the patients were hydrated before performing the procedure with 5 ml/kg of crystalloid liquid in 10 min.

Spinal anesthesia in the LM group was done midline using 25 Gauge needle by the anesthesia assistant in sitting position, after touching the iliac crest and finding the intervertebral space. If a puncture was unsuccessful after three attempts, the assistant was allowed to use other methods to find an interlaminar space, such as a paramedian approach, or asking a senior assistant for help.

The patients of the US group were set in a sitting position. Before spinal anesthesia, the sonography of the spinal column was done with a curved probe at low frequency (2-5 MHz). The sonography used for procedures was S-Nerve Ultrasound system, SonoSite, inc., the USA, L38xi/10-5 MHz Transducer.

The probe was longitudinally located on the lumbosacral vertebra for the parasagittal view. Continuous line of hyperechoic is the sacrum, and interlaminar spaces L2-L3, L3-L4, and L4-L5 were marked with counting towards up from sacrum. Then, the probe was turned 90° until transfer view of the spinal column was seen. L2-L3, L3-L4, and L4-L5 spaces were detected by observing intrathecal between ligamentum flavum, Dura mater, and posterior part of the vertebral body.

Two points were marked on the skin: 1- Middle line point: In the center of the upper surface of the probe, 2- Point through space: The middle point of the lateral surface in probe. The crossing of these two points is guide of the midline approach (5). Then, needle was inserted at the crossing point with the angle set as the probe showed in advance.

Statistical Analysis

The collected data were analyzed using SPSS version 22. First, the normality of quantitative variables was assessed based on the Kolmogorov-Smirnov test and was not confirmed. Therefore, quantitative variables in two groups were compared using independent t-test or Mann-Whitney U test, and qualitative variables in two groups were compared using Chi-square or Fisher's exact test. Also, quantitative variables before and after surgery were compared using paired t-test or Wilcoxon test. Statistical significance level was considered at $P<0.05$.

Results

In this study, 57 patients who referred to the operating room of Firoozgar and Rasoul-Akram Hospitals for lower-limb orthopedics surgery or other surgery in 2019 and required general anesthesia, were included. Twenty-nine patients were in the ultrasonography group and 28 patients were in the traditional group (Figure 1).

There was no significant difference between age, sex, and BMI of patients in the two groups ($P>0.05$) (Table 1).

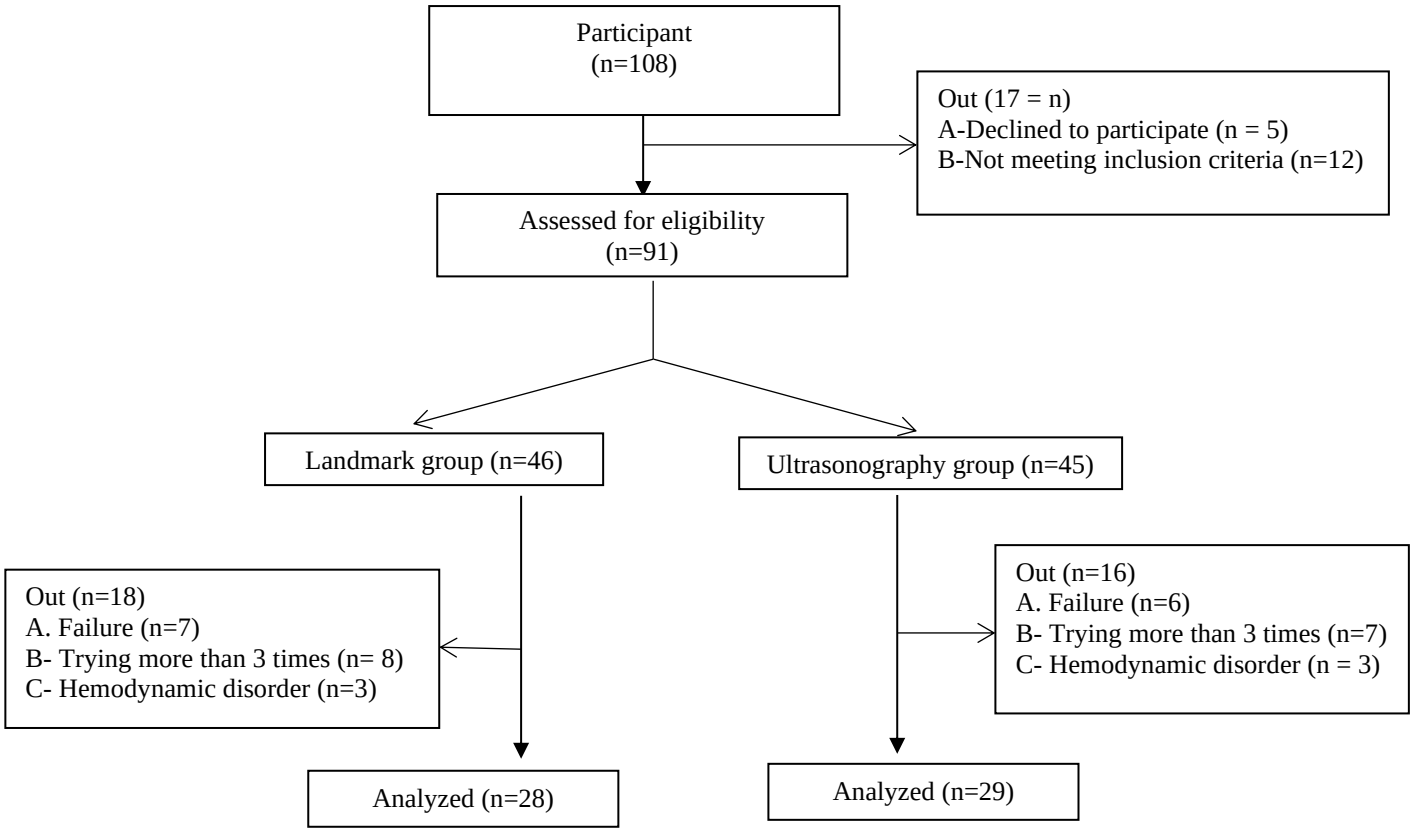

Figure 1. Consort flowchart.

Table 1. Comparison of demographic data in the two groups

Variable	Group		P-value
	Ultrasonography	Landmark	
Age (year) **(**Mean±SD**)**	47.93±14.3	40.25±16.02	0.061
Sex			
Male	23 (79.3%)	20 (71.4%)	0.55
Female	6 (20.7%)	8 (28.6%)	
BMI (kg/m^2) **(**Mean±SD)	27.37±2.92	27.32±3.3	0.626

There was a significant difference between time required to determine the needle insertion point, the time required for entry needle to exit CSF, overall procedure time, number of needle redirection without complete removal of the skin, and number of needle entry after complete removal of the skin of patients in the two groups (P<0.05) (Table 2) (Figures 2 and 3).

There was a significant difference between dural puncture results in the first needle insertion attempt in patients in the two groups (P<0.05) (Table 2).

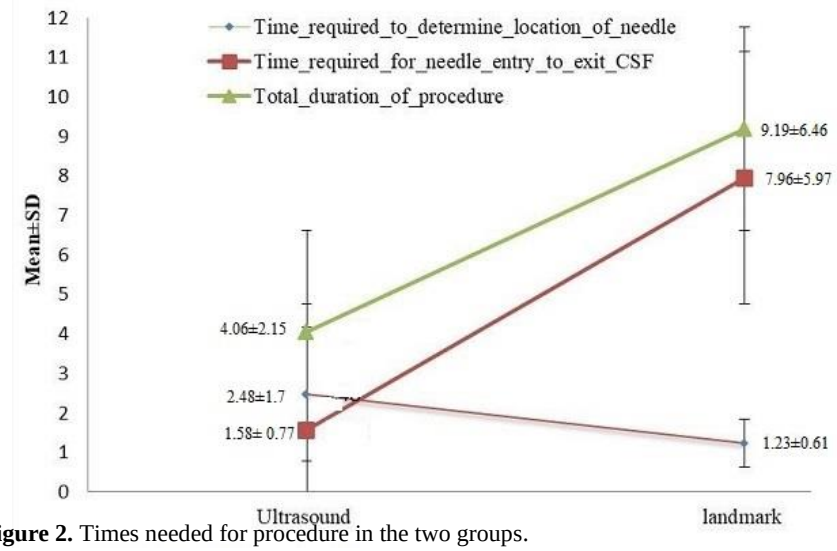

Figure 2. Times needed for procedure in the two groups.

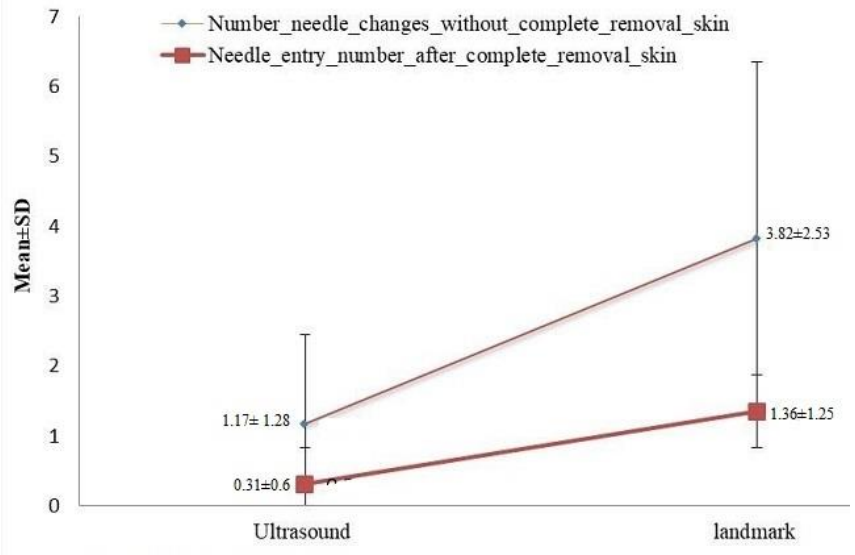

Figure 3. Number of attempts in the two groups.

Table 2. Comparison of measured parameters between 2 groups

Variable	Group		P-value
	Ultrasonography	Landmark	
The time required to determine the needle insertion site (min)	2.48±1.7[+]	1.23±0.61	<0.001
Time required for entry needle to exit CSF (min)	1.58± 0.77	7.96±5.97	<0.001
Overall procedure time (min)	4.06±2.15	9.19±6.46	0.005
Number of needle redirection without complete removal of the skin	1.17± 1.28	3.82±2.53	<0.001
Number of needle entry after complete removal of the skin*	0.31±0.6	1.36±1.25	<0.001
Dural puncture results in the first needle insertion attempts			0.014
Failure	13 (44.8%)	22 (78.6%)	
Success	16 (55.2%)	6 (21.4%)	

[+]Mean±SD, #Frequency (%).

*The first attempt is nothing to the number of needle entry after complete removal of the skin.

Discussion

Based on the results of the present study, the use of ultrasonography in comparison with the conventional method was effective on the success of performing spinal anesthesia by an anesthesia assistant under training.

In 1980, the idea for using sonography was presented as a safe guideline in the regional anesthesia field. This equipment has a real evaluation capability, which is a live image. On the other hand, lack of locating through radiologic rays, easiness, and low cost for using, it causes this device to be an acceptable alternative for most of anesthesia experts. Sonography device is more affordable than a fluoroscope, CT scan, or MRI. Nowadays, by the progression and development of the indices of sonography devices, quality, and image clarification, the use of sonography has been universal. By applying these devices in the anesthesia part, a new revolution in the spinal anesthesia field has been made during this decade so that in this situation, sonography has been a desirable method for performing spinal anesthesia (6). Based on literature, there were different studies on the evaluation of the effect of ultrasonography utilization in comparison with the conventional method on the success of performing spinal anesthesia. In the previous studies, like the present study, the efficiency of using ultrasonography in comparison with the conventional method on the success of performing spinal anesthesia has been reported. As an example, Li *et al*. found that using ultrasonography in comparison with the landmark in performing spinal anesthesia for fat women under Caesarean can be helpful in reducing the number of needle insertion and puncture attempts, lowering the total time required for inserting the needle and satisfaction of patients with success improvement for the first time (7). Ekinci *et al.* reported that ultrasonography in comparison with the landmark in performing spinal anesthesia of women under Caesarean is an efficient method for reducing puncture attempts, improvement of success in the availability to subarachnoid for the first time, and the decline for the necessity to multifold puncture. Ultrasonography lasts general time for needle insertion (8). Urfalioğlu *et al.* showed that using ultrasonography in comparison with the landmark in performing spinal anesthesia of pregnant fat women under Caesarean can increase the success for needle insertion. Of course, the general time for needle insertion in the ultrasonography group is longer than that of the landmark group. Also, there is no difference between the times of spinal block onset between two groups. Still, skin punctures and the number of needle insertion in ultrasonography is less than that of the landmark group (9). Geng *et al.* reported that using ultrasonography in comparison with the landmark in performing spinal anesthesia of older people under the surgery of lower limbs is an efficient and safe method for increasing success in the first attempt, decreasing the number of attempts for needle insertion and the change in needle direction. Of course, the necessary time for detecting the location of needle insertion in the ultrasonography group is significantly more than that in the landmark group. But, the time required for finishing needle insertion in the ultrasonography group is significantly less than that in the landmark group (10). Kallidaikurichi Srinivasan *et al.* found that the number of attempts for needle entrance to subarachnoid space in the ultrasonography group is lower than that in the landmark group in performing spinal anesthesia for the patients under joint and thigh surgery, and the time to find needle entrance location in the ultrasonography group is significantly more than that in the landmark group (11). Creaney *et al.* also found that the number of needle entrances in the ultrasonography group is lower than that in the landmark group in performing spinal anesthesia for the women under Caesarean surgery. Although, the exact time to detect needle location in the ultrasonography group is significantly more than that in the landmark group (3). Chen *et al.* concluded that the success of puncture dural in the first attempt of patients' needle entrance under orthopedic surgery in the ultrasonography group is significantly more than that in the landmark group. The number of needle entrance and the number of attempts for needle entrance in the ultrasonography group was lower in comparison with the landmark group in performing spinal anesthesia in patients under the hip joint and the thigh bone surgery. Of course, the necessary time for using landmarks in the ultrasonography group is significantly more than that in the landmark group (2).

Inconsistent with the results of the present study, some researches showed that using ultrasonography in comparison with the conventional method had no effect on the success of performing spinal anesthesia. For

example, Rizk *et al.* found that there is no significant difference between the success of dural puncture in the first attempt of needle entrance, the number of attempts and the number of needle entrance and patients' satisfaction in both groups of ultrasonography and landmark in performing spinal anesthesia for the patients under elective surgery (12). Elsharkawy *et al.* concluded that there is no significant difference between the number of attempts and the time of needle insertion, the success of block and patients' satisfaction in both groups of ultrasonography and landmark in performing spinal anesthesia for the patients under arthroplasty surgery of thigh or knee (13). Also, Turkstra *et al.* reported that there is no significant difference between the number of attempts and the time of needle insertion or any other secondary result in both groups of ultrasonography and landmark in performing spinal anesthesia of the women under pregnancy surgery (14).

The discrepancies between the results of previous researches with those of the present study can be due to the difference in the selection of understudying patients and lack of simple randomization of two investigations, or maybe due to more experience of someone who was in charge of doing the procedure.

One of the strengths of this study is that it was an experimental study with a control group. However, the present study had some limitations. One of the limitations of this study is that there was a lack of recording the patients' satisfaction with the two methods of spinal anesthesia. Although patient satisfaction is largely related to complications and headaches from anesthesia, it seems to be of great importance, and the incidence of low back pain should be taken into account in future studies.

In all previous studies that reviewed in this field, all steps have been performed by experts in ultrasound-guided regional anesthesia, and this is the first research in which all procedures have been conducted by an anesthesia resident. So, according to the findings of this study, it can be inferred that performing ultrasound even by a novice assistant in training is helpful to find a suitable intrathecal space and has an educational role.

Finally, according to the findings of previous studies as well as the present study, it seems that the use of ultrasonography in comparison with the traditional method has been effective in increasing the success rate of spinal cord anesthesia by the anesthesia resident.

Conflict of interests

The authors declare that they have no conflict of interests.

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