Title page

Exploration of the clinical effect of modified peroneal nerve block in foot operation under the plane of the ankle joint: a non-randomized clinical feasibility observational study.

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Exploration of the clinical effect of modified peroneal nerve block in foot operation under the plane of the ankle joint: a non-randomized clinical feasibility observational study.

[Abstract] Background This study was aimed at exploring the clinical effect of a modified dorsal peroneal nerve block in foot operation under the ankle plane. Methods The study was observational study, thirty patients (n=30) were observed with single-center and non-randomized. The patients were treated with an ankle nerve block (including the posterior tibial nerve, superficial peroneal nerve, saphenous nerve, and sural nerve block in the plane of the ankle) and a deep peroneal nerve block (7.5 mg/ml). The primary outcomes were intraoperative visual analogue scale score (0-10 points), numeric rating scale score (0-10 points), and Neuropen score (0-2 points). The secondary outcomes were postoperative pain VAS (visual analogue scale) and NRS (numeric rating scale scores) (0-10). Histograms and normal probability QQ plots were used to test the distribution of normality. Results We analyzed the data of 30 patients. It was found that after 20 min of ankle block and deep peroneal nerve block, 23 patients achieved a perfect block effect (VAS and Neuropen scores = 0), and the operation was performed smoothly. Six patients experienced slight pain (VAS: ≤ 3, Neuropen score = 1). An intravenous sedative drip (dexmedetomidine 4 µg/ml, 1 µg/kg dexmedetomidine hydrochloride injection 2 ml:0.2 g; Jiangsu Nhwa Pharmaceutical Co., Ltd., China) was used. The block failed in one patient, and the operation was performed under general anesthesia with a laryngeal mask in this patient. Conclusions The modified deep peroneal nerve block combined with an ankle nerve block can meet the anesthesia needs for foot surgery under the ankle plane. However, due to the limited number of patients evaluated, it is difficult to accurately predict the effect and a large degree of uncertainty exists regarding these findings. Trial registration This study had been registered at http://www.chictr.org.cn/index.aspx with No. ChiCTR2000037880 on Sep 3, 2020. It was a retrospectively registered. Keywords

peroneal nerve block, foot operation, ultrasound guidance
Introduction

The most common types of foot surgery under the plane are hallux valgus osteotomy, high arch osteotomy, fixation for foot fracture, as well as surgery for common foot trauma. Foot and ankle nerve blocks are effective ways of ensuring anesthesia and analgesia [1]. The distribution of the foot nerves is not complicated. However, the nerves in the foot are often accompanied by blood vessels and the sheath of each nerve and vessel, which could easily be damaged due to vascular compression injury.

The innervation of the foot under the plane of the foot and ankle includes the tibial, superficial peroneal, saphenous, sural, and deep peroneal nerves. The block point of the tibial meridian in the foot and ankle is located in the middle of the line between the Achilles tendon and the medial malleolus, which is in the ankle canal, and the superficial peroneal nerve. The deep peroneal nerve and dorsalis pedis artery coexist in a narrow space in the anterior part of the ankle [2].

Foot operations can be performed by blocking the foot nerves through the ankle. The analgesic effect after foot operation is similar to that achieved with the femoral nerve and sciatic nerve block, while patient comfort is increased because a nerve block at the far end of the limb can make the movement of the affected limb more convenient. Foot and ankle nerve blocks are not rare; however, they are often associated with serious complications. An important clinical consideration is the narrow gap at the block site, because of which it is easy to cause local nerve injury or even ischemic limb necrosis after drug injection. This complication is more likely to occur when the deep peroneal nerve is blocked. Some studies have shown that blocking the deep peroneal nerve in the front of the foot and ankle can cause foot limb necrosis due to compression of the dorsal foot artery [3-4]. Therefore, the application of a foot
nerve block for ankle operations is limited.

A cadaver study found that the deep peroneal nerve divides into internal and external terminal branches at the foot and ankle, from the medial terminal to the far dorsum of the foot, and the internal terminal branch is distributed on the dorsum skin opposite to the first and second toes [5-6]. Only this branch is the sensory branch in foot operations under the plane of the foot and ankle. Therefore, we attempted to block the medial terminal branch of the deep peroneal nerve at the dorsum of the foot, which could also block the innervation of the deep peroneal nerve in the sensory area of the foot.

There are two reasons for choosing such a block method: (1) The requirement of muscle relaxation in foot operation is low, and the block can meet the requirements of the operation, and (2) improved deep peroneal nerve block could reduce the overall risk associated with an ankle nerve block. Ankle nerve block for patients undergoing foot surgery afforded greater postoperative comfort.

Methods

Patients and design

This was a single-center, non-randomized clinical feasibility observational study in The second affiliated hospital of Inner Mongolia Medical University. This study had been registered at http://www.chictr.org.cn/index.aspx with No. ChiCTR2000037880 on Sep 3, 2020. It was conducted according to the principles of good clinical practice.

Ethical approval for this study (Ethical Committee NO.Y K D2019192) was provided by the Ethical Committee of Inner Mongolia Medical University. Hohhot, Inner Mongolia, China(Prof GuangMing Niu) on 4 January 2019.
We selected appropriate patients for foot surgery. Written informed consent was obtained from all patients prior to their inclusion in the study.

From January 2019 to June 2019, we screened patients who had undergone foot surgery under the ankle plane for inclusion in the study. Thirty patients were included (17 men and 13 women, age range: 18-60 years, weight: 45-90 kg, physical status classification: ASA(American Society of Anesthesiologists grade) I-II. Thirteen patients were treated with hallux valgus osteotomy, six patients were treated by removal of internal fixation, and 11 patients were treated for fracture of the toes. The exclusion criteria were as follows: pregnancy, diabetes mellitus, hypoesthesia of the lower limbs, daily use of opioids, or allergy to block drugs.

All patients were treated with four nerve blocks (posterior tibial nerve, superficial peroneal nerve, saphenous nerve, and sural nerve) (Figure 1) and modified deep peroneal nerve block (Figure 2). After nerve block administration under ultrasound guidance, the operation was completed. In patients with a visual analog scale (VAS) and numeric rating scale(NRS) score of ≥3 for pain, general anesthesia was administered using a laryngeal mask.

**Statistical methods**

SAS 9.3 was used for statistical analysis. Histograms and normal probability QQ plots were used to test the distribution of normality. The measurement data that showed normal distribution are described as mean values (standard deviation and 95% confidence interval). Count data that do not conform to normal distribution are described as median values (interquartile spacing).

**Anesthesia and surgery**
Blood pressure, peripheral capillary oxygen saturation (SpO₂), and electrocardiography findings were routinely monitored. Under ultrasound guidance, the nerve block was performed with a No. 22 puncture needle (PAJUNK GmbH Medizintechnologie Mod: 001156-71 NanoLine, Germany) (Figures 3 and 4). The drug used for the block was ropivacaine (7.5 mg/ml, 0.9% NS dilution) (Naropin, ropivacaine hydrochloride injection, 10 ml:100 mg; AstraZeneca). The drug doses used for the block in the foot and ankle were 3 ml each for the posterior tibial and gastrocnemius nerves and 4 ml each for the superficial peroneal and saphenous nerves. The dose was 3 ml for the modified deep peroneal nerve in the dorsum of the foot. To reduce the deviation, all blocking operations were performed by the same anesthesiologist and we used the same 13-5 MHz linear sensor (Ultrasound System Mod: M-Turbo, USA). The patients were administered midazolam 2 mg (midazolam injection 2 ml:2 mg; YiChang Human Well Pharmaceutical Co., Ltd., China) and dezocine 5 mg (dezocine injection 1 ml:5 mg; Yangtze River Jiangsu Nhwa Pharmaceutical Co., Ltd., China) through a vein 30 min before the operation. The same type of operation was performed by the same group of orthopedic doctors. All operations were routine; no modified procedures or complex procedures were used. During the operation, a tourniquet was tied to the patient’s ankle or not used.

**Regional block and success assessment**

We defined the end time of the drug injection as the beginning of the observation period. Before the operation, we measured the pain score every 5 minutes to achieve the ideal analgesic effect (VAS = 0, NRS = 0, neuron open = 0). After the operation, we measured the pain score every 3 hours until the foot sensation returned to normal. The proportion of patients with pain scores (VAS, NRS, Neuropen) of 3 or
more was determined. The time of pain score of the foot area of patients with the block from injection to VAS < 3, NRS < 3, and the time of foot sensory recovery of all patients were recorded.

VAS, NRS, and Neuropen scores were assessed 20 minutes after anesthesia. The cold test (5°C) was performed on the dorsolateral skin of the opposite side of the 1.2 phalanx of the foot, which was innervated by the medial branch of the deep peroneal nerve. A cold bottle was used to evaluate sensory function, and the pain sensation in this area was evaluated by Neuropen. The sensory score (normal sensation = 2, reduced sensation = 1, no sensation = 0), VAS pain score (0 = no pain, 10 = severe pain), NRS pain score (0 = no pain, 10 = the most severe pain imaginable) after the block were measured and recorded, and the posterior tibial nerve, superficial peroneal nerve were detected using the same approach that was used for assessing the sensory function of the sural and saphenous nerves.

After the VAS, NRS, and Neuropen scores of the foot reached 0, the operation began, and the scores were monitored until the end of the observation period. After the operation, we transferred the patient to the resuscitation room. Within 12 hours after the operation, the patient received an injection of 120 mg flurbiprofen axetil (flurbiprofen axetil injection 5 ml:50 mg; Beijing Tide Pharmaceutical Co., Ltd., China), followed by 400 mg × 3 ibuprofen (ibuprofen sustained-release capsules 0.3 g SK & F) on the second day after the operation for oral analgesia. During the observation period, the patients did not receive opioids and glucocorticoids.

Results

Primary results: after 20 minutes of block, 23 patients achieved the ideal analgesic effect (VAS = 0, NRS = 0 and Neuropen = 0), and the operation proceeded smoothly; ② 6 patients experienced slight pain
(VAS, NRS ≤ 3, Neuropen = 1), and intravenous sedation drugs (4 µg/kg/h dexmedetomidine) were used; the ideal analgesic effect (VAS = 0, NRS = 0 and Neuropen = 0) was achieved 10 min later, and the operation was carried out smoothly. ③ The block failed in one patient, who then received general anesthesia under laryngeal mask. ④ After 16.38 min (95% CI = 15.04-17.71), the VAS decreased to 0; after 17.41 min (95% CI = 15.68-19.15), the NRS decreased to 0; and after 16.38 min (95% CI = 15.04-17.71), the Neuropen score was 0, and the patient experienced no feeling.

Secondary results: ① After 1184.48 min (95% CI = 1134.31-1234.65), all patients began to recover. ② After 1358.28 min (95% CI = 1324.47-1392.09), all patients felt normal.

Results: In the foot operation under the plane of the foot and ankle, a nerve block of the foot and ankle can complete the operation, but after the improvement, the block of the deep peroneal nerve was changed to a block of the medial branch of the deep peroneal nerve of the foot back. The procedure was successful in 23 of the 30 patients who were assessed in this clinical observational study, yielding a success rate of 77%. Among the seven cases in which a complete block could not be achieved with intravenous drugs, the operation was completed in six, while the procedure failed in the seventh case.

As for the onset time of anesthetic drugs, an NRS score of 0 appeared slightly later than VAS and Neuropen scores of 0. We believe that this may be due to the discomfort caused by some deep sensation, the small number of cases, and because the scores cannot distinguish between pain and discomfort. Of course, the overall findings of this clinical observational study suggest that the improved deep peroneal nerve block causes no major change in the whole foot and ankle block and shows positive effects in reducing complications and promoting foot and ankle block.
The average time of recovery was 22 hours after the operation. With postoperative oral medication, patient discomfort was greatly relieved. More importantly, patients’ leg movement after the operation was normal, and they reported substantial relief from discomfort.

**Discussion**

To our knowledge, this is the first clinical observational study to evaluate the effect of deep peroneal nerve block via the dorsalis pedis in foot surgery. We found that this block shows no significant difference from the traditional anterior tibial block. Before designing this prospective clinical observational study, we assessed a large amount of anatomical and clinical anesthesiologic data to determine if this improved block could achieve the ideal anesthesia effect. However, due to the small sample size, although this report presents positive results, there are many uncertain and negative aspects to be considered, which should be the main topics for future research on this block. Some of the debatable issues related to the results are outlined below.

First, some experts suggest that the anesthesia effect of deep peroneal nerve innervation can be solved by skin infiltration anesthesia, which can not only reduce the risk of acupuncture but also make anesthesia simpler. However, our literature review suggested that this is not feasible for the following reasons: (1) skin infiltration anesthesia cannot guarantee an ideal anesthesia effect and anesthesia time, while injection of the drug solution into the peripheral nerve can ensure an ideal anesthesia effect [7].

Although an improved block is still a traumatic operation, it is essential to ensure the appropriate anesthesia effect in patients. ② In the three types of regional evaluations, the dynamic pain score reached the ideal value slightly later than the static score. The anatomical literature suggests that the
Probability of variations in nerve branches is very high\cite{5,6}, and the sensory nerves that may dominate the region will also be distributed in the deep facial block, so the effect of a block at the nerve branches is higher than that of skin infiltration.

For foot surgery under the sole ankle plane, such as procedures for hallux valgus, phalange fracture, foot trauma, etc., there is almost no requirement for muscle relaxation at the operation site, so the nerve block only needs to ensure disappearance of sensation to allow the operation. Such anesthesia can be completed through the ankle joint area block, and the traditional ankle joint block mode has been gradually abandoned because of the risk of compressing the nerve and blood vessels. However, in recent years, ultrasound-guided nerve blocks have greatly reduced the risks associated with such blocks.

Ultrasound can be used to conduct more detailed operations involving nerve blocks \cite{2}. In this clinical observational study, 23 of our 30 patients achieved the ideal anesthesia effect within 20 minutes for surgery; six patients underwent smooth operations after 10 minutes of auxiliary sedative drugs; and the protocol failed in only one case. Thus, the improved block does not influence the anesthesia effect of the whole block, and the position of the new block point can avoid the narrow internal drug injection space and reduce the risk of compression, yielding a positive effect.

The ankle regional block has minimal effects on lower limb movement and the patients' systemic circulation and cardiovascular system \cite{8}. It is suitable for daytime operations and short procedures for both feet. The postoperative complications are fewer; safety is greatly improved; the duration of hospitalization is reduced; and a lot of medical resources are saved \cite{9}. This is especially applicable to underdeveloped countries and regions with underdeveloped economies and limited medical resources,
since this technique can reduce the burden of patients and hospitals in such cases\textsuperscript{[10]}. Improvements in the deep peroneal nerve block, which has the highest risk of complications among ankle blocks, can promote the application of ankle blocks in such operations. The sensory branch of the deep peroneal nerve is located at the intersection of the proximal phalanx of the second toe and the proximal phalanx of the third toe, where the deep peroneal nerve block does not show an anesthetic effect, thereby reducing the risk of injury of the deep peroneal nerve-muscle branch and the risk of vascular compression due to the passage of the artery to the sole. In the current clinical observational study, we assessed only a small number of samples without a control group or randomization, which limited the generalizability of the findings. We expect to improve on these aspects in subsequent study designs. The main purpose of our clinical observational study was to provide some information for the optimal design of a randomized controlled double-blind experiment that could meet ethical and clinical requirements with the improved technique. Thus, the application of this technique has great clinical significance. For the six patients who required sedative drugs and the one patient for whom the technique was a failure, we concluded that the 20-min period was insufficient. Thus, the starting time of the operation should be adjusted to achieve the purpose of completing the operation only through the block. In the follow-up clinical observational studies, we hope to assess the psychological and physiological factors of the patients and adjust the type and measurement of preoperative medication to ensure the safety of patients. In summary, this improved technique can provide the same blocking effect as the original technique,
providing much supports for a follow-up study. However, there is no clinical data to support whether the novel block can completely replace the original block. This report presents a mostly positive trend, which is significant for our hypothesis of providing patients with an effective and safe new block point.

**Conclusion**

The modified deep peroneal nerve block combined with the ankle nerve block can meet the anesthesia needs of foot surgery under the ankle plane. However, considering the limited number of observation samples, its effect is not completely predictable, and the uncertainty ratio in the existing observation patients is still large, necessitating further data to support these findings.

**Abbreviations**

- VAS: visual analogue scale
- NRS: numeric rating scale scores
- ASA: American Society of Anesthesiologists grade
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**Declarations**

**Ethic approval and consent to participate**

Our study was approved by Medical ethics committee of Inner Mongolia Medical University. After obtaining approval [No. Y K D2019192], we collected patient data from the patients record system at The Second Affiliated Hospital of Inner Mongolia Medical University.

**Consent for publication**

Consent for publication was obtained from all participants.

**Availability of data and materials**

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

**Competing interests**

The authors declare that they have no conflict of interests.

**Authors’ contributions**

Ya Tuo, XueQiang Fu and Yi Qiu contributed equally to this work.

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**Contributions**

YT: original draft writing, conceptualization, and draft writing. XQF: Conceptualization and original draft writing. YQ: Original draft writing, conceptualization, and draft writing. XDW: Statistical analysis. SJY: Data collection. YRG: Data collection. YQH drew figures 1 and 2 and copyrighted them. All authors read
and approved the final manuscript.

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