

BRIEF COMMUNICATION



Comparison between a laser-lancing device and automatic incision lancet for capillary blood sampling from the heel of newborn infants: a randomized feasibility trial

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INTRODUCTION

Capillary blood sampling is routinely performed using a heel stick in newborn infants to draw a small amount of blood for various blood tests. Automatic incision lancets, which are less painful, less traumatic, and more effective than manual needle lancets have been recommended as a standard heel stick sampling device in newborn infants [1]. However, these infants still experience pain and skin complications, such as incisional wounds, bruises, and infections [2]. Their developmental immaturity of the central nervous system makes them more likely to feel pain and may have adverse neurodevelopmental consequences [3]. Furthermore, manufacturing automatic lancing devices and disposing of associated medical waste are expensive, and their use is polluting.

Recently, a laser-lancing device, LMT-5000 (HandyRay-Lite, LAMEDITECH, Seoul, Korea) that can collect capillary blood without a needle or blade lancet was developed. In previous studies with adults, this device reduced pain and improved patient satisfaction more than manual needle lancets did [4, 5]. In this study, we aimed to determine the feasibility of using a laser-lancing device in the neonatal population, we compared the clinical effectiveness and safety of a laser-lancing device with an automatic incision device for capillary blood sampling from the heels of newborn infants.

METHODS

We conducted a randomized crossover non-inferiority trial at Korea University Ansan Hospital in Korea between June 2020 to September 2021. Institutional Review Board approval was obtained from the hospital prior to study initiation (approval no. 2020AS0077). This study was registered at the Clinical Research Information Service on April 8, 2020 (registration no. KCT0004901). Full-term infants required capillary blood sampling were enrolled, and informed consent was obtained from their legal guardians for participation in this study. The following infants were excluded: infants with major congenital malformations and infants with an unstable hemodynamic status requiring respiratory support or inotropes. An automatic lancet (BD Quick heel Premie Lancet; Becton, Dickinson and Company, Paramus, New Jersey; depth: 0.85 mm, width: 1.75 mm) was used, which is appropriate for when a low blood volume is required from full-term infants. LMT-5000 is a laser-lancing device. The energy of LMT-5000 can be categorized into five levels of power. The initial energy power

of LMT-5000 was level 4 (4270 mJ) for between 2500 g and 3000 g, and level 5 (5320 mJ) for 3000 g and above.

Procedures

Heel lancing was performed by an experienced neonatal nurse who drew the same amount (100 µL) of blood in both groups. All infants received 1 mL of 10% glucose orally 2 min before the heel stick procedure. The medial aspect of the heel was cleansed with alcohol and dried completely. The skin was incised and blood was collected according to the technique previously described in the literature [6]. The puncture site was recorded by taking an optical micrograph every 24 h.

Sample size definition

For a crossover design, a sample size of 42 in each sequence, totaling 84, achieves a power of 80.005% to detect a difference of 0.114 using a one-sided non-inferiority test against a bound of 0.21 with a significance level of 0.05, when the standard deviation of paired differences is 0.323 and the dropout rate is 15%. In this study, 42 term infants were eligible to participate; however, two infants were excluded. We generated a random allocation randomization using Excel.

Table 1. Demographics of the studied newborn infants.

	N = 40
Gestational age (weeks)	38.6 ± 1.1
Birth weight (g)	3,220 [2762–3641]
Postnatal age (days)	7 [5–10]
Body weight during the study (g)	3193 [3002–3683]
Sex: Male (%)	23 (57.5)
Cesarean section (%)	22 (55.0)
Apgar score	
1 min	8 [8–9]
5 min	9 [9–10]

Values are expressed as numbers (%), means ± standard deviations, or medians [interquartile ranges].

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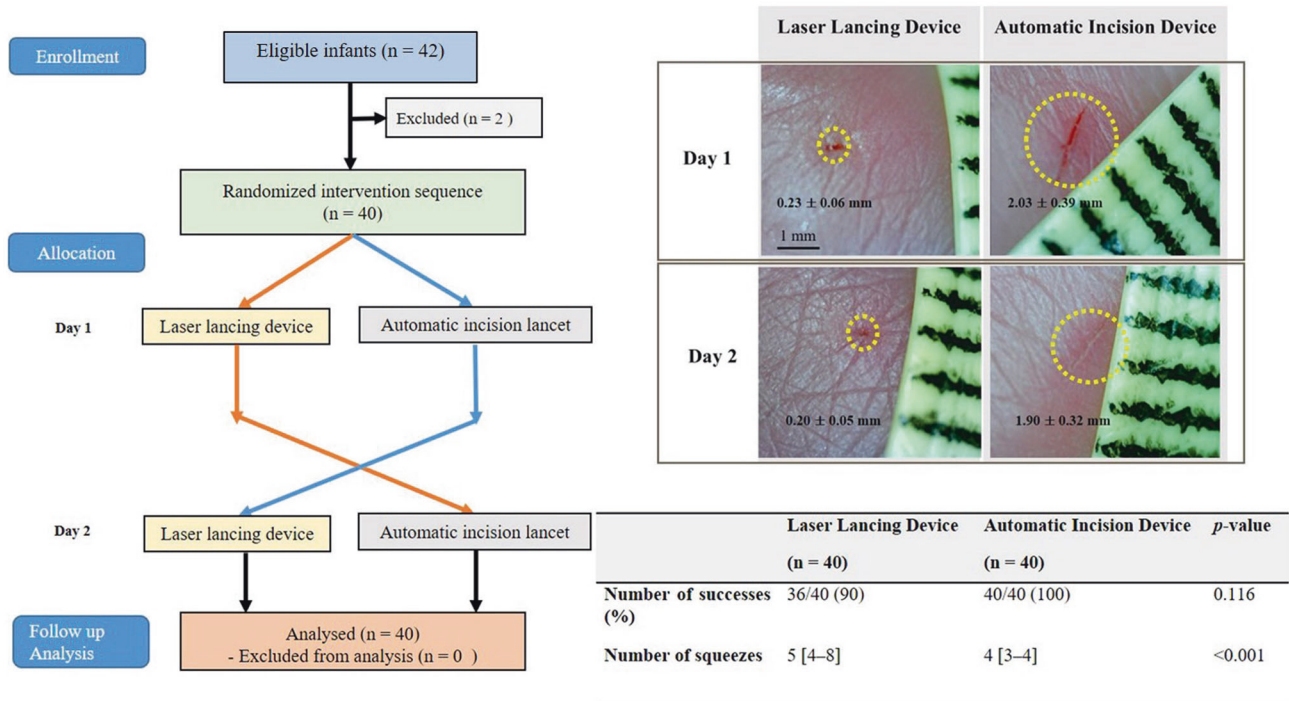


Fig. 1 Study flow diagram and lancing injuries of the first day and the next of the examination of each of the two groups.

RESULTS

The mean gestational age at birth was 38.6 ± 1.1 weeks, and the mean birth weight was 3220 [2762–3641] g (Table 1). The capillary blood sampling success rates in the laser-lancing device and automatic incision device groups were 90% (36/40) and 100% (40/40), respectively. The risk difference comparing the success rate between the laser-lancing device and automatic incision device groups was 0.1 (10%), which was lower than the 95% confidence interval of 0.14 in a one-sided non-inferiority test. The number of heel squeezes was statistically higher in the laser-lancing device group than in the automatic incision device group (5 [4–8] vs. 4 [3, 4], $P < 0.001$). The laser-lancing group had a significantly smaller lancing injury length (0.2 ± 0.1 mm) than did the automatic incision device group (2.0 ± 0.47 mm; $P < 0.001$) at 30 min after the lancing procedure (Fig. 1). There were no sustained bleeding and wound infections in both groups.

DISCUSSION

To our knowledge, this is the first study to demonstrate that the clinical effectiveness and safety of a laser-lancing device is feasible as a heel stick for capillary blood sampling in the neonatal population. In previous studies of adult populations, two studies have reported that the success rates of laser-lancing devices on the first attempt are 100%, equal to those of manual needle-lancing devices. The success rate of the laser-lancing device in this study was lower than that of adult studies and we used higher energy levels (270 mJ or 320 mJ) than those used for the fingers of adults [4]. As the water content and skin thickness of newborn infants is different from that of the fingers of adults [7] and the amount of blood needed from infants was higher than that needed from adults (100 μ L vs. 5–30 μ L).

The laser-lancing group experienced a significantly smaller lancing injury than did the automatic incision device group. The previous adult study reported that with a laser energy of 210 mJ, the mean injury length was 0.5 mm and the penetration depth into the fingers of the participants was 0.6–0.9 mm [5]. However, we did not confirm the penetration depth in this study. In addition

to this limitation, we did not compare the pain response elicited during the lancing procedure in both groups. Further large-scale trials are needed before the alternative use of laser-lancing devices for capillary blood sampling in the newborn population and should include the comparisons of the pain response with various lancing devices. And in assessing safety, trials should define the penetration depth on the heel using a laser-lancing device, to select the most appropriate energy level of the laser.

DATA AVAILABILITY

The data that support the findings of this study are available from the corresponding author, upon reasonable request.

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AUTHOR CONTRIBUTIONS

CKY, methodology, investigation, data curation, writing, and final approval of the manuscript. EKC, conceptualization, methodology, investigation, data curation, writing, revising, and final approval of the manuscript. HJK, investigation, data curation, and final approval of the manuscript. JK, methodology, investigation, and final approval of the manuscript. BCP, methodology and final approval of the manuscript. KP, methodology, investigation, and final approval of the manuscript. BMC, conceptualization, methodology, investigation, data curation, writing, revising, and final approval of the manuscript.

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COMPETING INTERESTS

The authors declare no competing interests.

ADDITIONAL INFORMATION

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