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The impact of automatic devices for capillary blood collection on efficiency and pain response in newborns: A randomized controlled trial

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ABSTRACT

Background: The heel stick is the method of choice in most neonatal units for capillary blood sampling, and it represents the most common event among all painful procedures performed on newborns. The type and design of heel stick device and the clinical procedure to collect a blood sample may have an impact on newborn pain response as well.
Objective: To compare the pain response and efficiency of different automated devices for capillary blood collection in newborns.
Design: Randomized clinical trial.
Setting: Postnatal ward of a tertiary-care university hospital in Italy.
Participants: Newborn infants at gestational age ≥34 weeks undergoing the metabolic screening test after the 49th hour of life.
Methods: A total of 762 neonates were recruited and randomized into 6 groups (127 babies in each group) assigned to 6 different capillary blood collection devices (Ames Minilet™ Lancet; Cardinal Health Gentleheel®; Natus Medical NeatNick™; BD Quikheel™ Lancet; Vitrex Steriheel® Baby Lancet; Accriva Diagnostics Tenderfoot®).
Main outcome measures: The following data were collected and assessed for each of the 6 groups evaluated: a) number of heel sticks, b) pain score according to the Neonatal Infant Pain Scale (NIPS) and c) need to squeeze the heel.
Results: The Ames Minilet™ Lancet device was found to perform by far the worst compared to the five device underexamination: it required the highest number of sticks (mean = 3.91; 95% CI: 3.46–4.36), evoked the most intense pain (mean = 3.98; 95% CI: 3.77–4.20), and most frequently necessitated squeezing the heel (92.9%; 95% CI: 86.9–96.3). The five devices under examination appeared to be similar in terms of the number of sticks required, but differed slightly in NIPS score and in need to squeeze the heel.
Conclusion: The Accriva Diagnostics Tenderfoot® device demonstrated the greatest efficiency for blood sampling and evoked the least pain. With this device, the metabolic screening test could be performed with a single skin incision in the large majority of infants (98.4%), heel squeezing was limited to only 6.3% of infants, and the NIPS score turns out to be lower than other devices in our study (1.22; 95% CI 1.05–1.39).

What is already known about the topic?

- Heel stick is a painful procedure commonly used for capillary blood collection in neonates.
- Automatic incision devices have been shown to be less traumatic and more effective than manual lancet-type devices.

What this paper adds

- The Tenderfoot® automatic heel stick device was associated with a

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lesser need for heel squeezing, fewer repeated skin sticks and a lower pain response.
- Automated devices with an arc-like incision might represent the most appropriate devices for heel stick in newborns.

1. Introduction

A heel stick is the most commonly used procedure for capillary blood sampling in neonates, particularly for metabolic screening tests performed within the first hours of life in all newborn infants (Balk, 2007; Losacco et al., 2011; Shah and Ohlsson, 2011).

Although universally accepted as standard blood collection technique, a heel stick is not without its consequences. Infants undergoing a heel stick experience pain that has been associated with the breakage of the skin, squeezing of the heel and bruising, and the short-term complication of infection (Lindh et al., 1999; Shepherd et al., 2006; Onesimo et al., 2011; Koklu et al., 2013).

Although evidence suggests the use of venipuncture for blood sampling in neonates (Shah and Ohlsson, 2011), heel stick still constitutes the method of choice in most neonatal units and represents the most common painful event among all procedures performed on newborns (Carbajal et al., 2008; Cruz et al., 2016).

The rationale for the widespread use of heel stick in newborns is associated mainly with their limited arterial and venous patrimony, thus limiting the use of venipuncture; performing a heel prick is an easy procedure that can be conducted by one nurse working alone, which represents a common situation in many neonatal wards.

Pain-related stress in neonates, particularly in preterm infants, has been associated with possible long-lasting detrimental effects on brain organization and neuroendocrine responses to stress (Grunau et al., 2005; Smith et al., 2011; Grunau, 2013; Vinall and Grunau, 2014). Sophisticated magnetic resonance studies in preterm babies at school age demonstrated an association between pain exposure and microstructural changes in the developing brain (Brummelte et al., 2012). In addition, epigenetic changes have been reported in preterm babies exposed to high levels of pain-related stress during the neonatal period (Provenzi et al., 2015; Montirosso et al., 2016). Pharmacological as well as non-pharmacological strategies are highly recommended to prevent and control pain in newborn infants (Hall and Anand, 2014; Committee on Fetus and Newborn and Section on Anesthesiology and Pain Medicine, 2016).

Non-pharmacological approaches, including breastfeeding, oral glucose, skin to skin contact, and wrapping with warm drapes, have been shown to be effective in pain control with a synergic effect (Aguilar Cordero et al., 2014; Morrow et al., 2010). To prevent or reduce the pain experienced in the context of a heel stick, non-pharmacological approaches have been incorporated into clinical practice.

The primary painful aspects associated with heel stick consist of skin breakage, squeezing of the heel and subsequent localized bruising of the sampling site. Factors such as the type and design of the heel stick device and the method to collect blood sample may have an impact on newborn pain response as well (Lindh et al., 1999; Shepherd et al., 2006; Cruz et al., 2016). Techniques such as warming the heel prior to the stick have been shown to be ineffective in reducing the need for heel squeezing or the stress it creates (Barker et al., 1996; Janes et al., 2002).

previously published studies measured the distance between the skin and the perichondrium of the calcaneum by using ultrasound scanning in order to define the safe area for heel stick. Accepted practice dictates that the depth should be restricted to 2.2 mm or less to avoid complications (Arena et al., 2005).

Automatic devices are designed to penetrate the skin at a controlled, safe depth, exposing the vascular bed while avoiding contact with deep pain fibres, thus limiting tissue damage, pain, trauma and the need for heel squeezing (Barker et al., 1994; Kellam et al., 2001). Most published studies that have compared manual to automatic lancet devices are consistent in demonstrating a lower pain response with use of automatic devices (Barker et al., 1994; Kellam et al., 2001 Kellam et al., 2001). Moreover, Vertanen et al. (2001) demonstrated that the use of the automatic device was associated with reduced heel bruising and inflammation.

A variety of automatic heel stick devices for capillary blood collection in newborns are commercially available. However, there are no published studies comparing these devices relative to their efficacy and evoked pain in newborn infants.

This study was designed to test the hypothesis that the efficiency of blood sampling and pain-control can be improved when a carefully selected heel stick device for neonates is adopted. With this objective, benefits and harms of different commercially available automatic heel stick devices were compared and assessed based on the number of repeated sticks required for the metabolic screening test, the need to squeeze the heel to obtain sufficient blood, and the pain response elicited during the procedure.

Furthermore, the possible influence of the professional profile and the nurse work shift have been considered in the outcome measurements.

2. Methods

2.1. Study design

This monocentric randomized clinical trial was carried out on 6 groups of newborn infants in the postnatal ward of a tertiary-care university hospital in Milan, Italy, that has approximately 7000 live births per year. The study was conducted after approval of the local Ethics Committee on 12th October 2012 (reference number: 338/2012).

As reported in the study protocol, with the usual significance level of 0.05, 127 neonates per group were required to detect, with a power of 80%, a difference of at least 0.5 in the number of heel sticks needed to collect a sufficient blood sample between each of the five devices under evaluation (Cardinal Health Gentleheel®; Natus Medical NeatNick™; BD Quikheel™ Lancet; Vitrex Steriheel® Baby Lancet; Accriva Diagnostics Tenderfoot®) and the Ames Minilet™ Lancet device routinely used by the caregivers in the clinical. The rationale for the selection of these five automated devices was the commercial availability of heel prick devices in Italy. We chose the more commonly used devices in the Italian postnatal wards as we wanted the study to be representative of the real-life setting of the neonatal units in Italy.

The sample size was computed to allow for the Dunnett's multiple comparison procedure (Dunnett, 1955), using the PASS 2002 software (NCSS, Kaysville, UT, USA). The value of 0.5 was chosen as the minimum clinically important difference since it avoids a further heel stick to a neonate out of two. A standard deviation (SD) of the number of heel sticks of 0.77 was calculated based on previous data collected at the same investigation site using the Ames Minilet™ Lancet device. Parents received the consent form at the time of neonatal ward admittance. Information was provided by either the principal investigator or the staff nurses, and signed parental informed consent was collected by staff nurses just before the metabolic screening test was performed.

2.2. Inclusion criteria

All inborn infants with a gestational age ≥34 weeks and admitted to the neonatal ward, undergoing the metabolic screening test after the 49th hour of life, were eligible for study participation.

2.3. Exclusion criteria

Participants were excluded from the study if they were admitted to the Neonatal Intensive Care Unit before the 49th hour of life and if they