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Objętość krwi i odczuwanie bólu podczas pobierania krwi z palca: czy wszystkie lancety bezpieczne są takie same?

A. Serafin, M. Malinowski,
A. Prażmowska-Wilanowska

Streszczenie

Badanie miało na celu ocenę różnych typów nakłuwaczy bezpiecznych pod kątem objętości krwi i odczuwania bólu podczas pobierania krwi włośniczkowej – rutynowej procedury nakłuwania palca w celu uzyskania niewielkiej ilości krwi do wykonywania różnych badań przesiewowych i diagnostycznych.

Metody
Dane zebrano od 100 dorosłych, zdrowych ochotników przy pomocy procedury nakłucia palca. Przetestowano cztery różne typy nakłuwaczy bezpiecznych (Acti-Lance, Prolance, Medlance Plus i MediSafe Solo). Każdy typ ma kilka wersji zatem łącznie w badaniu wykorzystano 16 różnych wersji lancetów bezpiecznych.

Wyniki
Stwierdzono istotną różnicę w średniej objętości krwi włośniczkowej między bezpiecznymi lancetami wyposażonymi w ostrze i igłę. Lancet typu MediSafe Solo nie posiadał wersji z ostrzem, stąd jego użycie wiązało się z najniższą średnią objętością pobranej krwi włośniczkowej (42,4 µl). Lancety typu Acti-Lance i Medlance Plus miały po jednej wersji ostrza, a średnia objętość pobranej krwi włośniczkowej wynosiła odpowiednio 82,2 i 99,0 µl. Lancet typu Prolance posiadał dwie wersje lancetów z ostrzem, a jego stosowanie wiązało się z największą średnią objętością krwi włośniczkowej (118,3 µl). Poziom nasilenia bólu był oceniany przez większość pacjentów jako niski dla wszystkich nakłuwaczy. Najmniej bolesny był Medlance Plus, a przy Acti-Lance poziom bólu był najbardziej odczuwalny. W skali bólu od 0 do 10 75% nakłuć zostało ocenionych przez uczestników na poziomie nieprzekraczającym 3 punktów.

Wnioski
Badanie to sugeruje, że chociaż wszystkie przetestowane lancety bezpieczne osiągają odpowiednią wydajność w zakresie niezbędnej objętości krwi włośniczkowej do przeprowadzenia diagnostyki testu, to lancety wyposażone w ostrza różnią się istotnie od tych wyposażonych w igły pod względem średniej uzyskanej objętości krwi włośniczkowej. Ponadto, chociaż wszystkie urządzenia powodowały stosunkowo niski poziom bólu, stwierdzono, że ból powodowany przez wersje z ostrzami bezpiecznych lancetów jest większy niż w przypadku wersji igłowych.

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Blood volume and pain perception during finger prick capillary blood sampling: are all safety lancets equal?

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CLINICAL FEATURE
ORIGINAL RESEARCH

Blood volume and pain perception during finger prick capillary blood sampling: are all safety lancets equal?

A. Serafin, M. Malinowski and A. Prażmowska-Wilanowska

Regulatory Affairs Department, HTL-Strefa S.A, Ozorków, Poland

ABSTRACT

Objectives: This study aimed to assess various types of safety lancets in terms of blood volume and pain perception during capillary blood sampling, a routine finger-puncture procedure for obtaining a small amount of human blood for running various screening and diagnostic tests.

Methods: Data were collected from 100 adult healthy volunteers following finger-puncture procedure. Four different types of safety lancets were tested (Acti-Lance, Prolance, Medlance Plus, and MediSafe Solo). Each type has its own versions, giving 16 different safety lancets in total.

Results: A significant difference in the mean capillary blood volume was found between blade and needle equipped safety lancets. MediSafe Solo type lancet had no blade version, and hence its use was associated with the lowest mean collected capillary blood volume (42.4 µL). Acti-Lance and Medlance Plus type lancets had one blade version and the mean collected capillary blood volume was 82.2 and 99.0 µL, respectively. Prolance type lancet had two blade versions, and its use was associated with the highest mean capillary blood volume (118.3 µL). The level of pain intensity was evaluated as low by the majority of patients for all lancets. Medlance Plus was the least painful and Acti-Lance was the most painful type of safety lancet. On a 0-to-10 scale of pain, 75% of punctures were assessed by the participants at a level not exceeding 3 points.

Conclusions: This study suggests that although all investigated safety lancets achieve adequate performance regarding the necessary capillary blood volume to run a diagnostic of test, lancets equipped with blades differ significantly from those equipped with needles in terms of the mean obtained capillary blood volume. Further, although all devices produced relatively low levels of pain, the amount of pain caused by blade versions of safety lancets has been found to be higher than that of needle versions.

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Capillary blood sampling; safety lancet; pain perception; single-use medical device; blade; needle

1. Introduction

The latest developments in the quality and market accessibility of highly sensitive and specific analytical methods have led to an increased attention to the use of microsamples (volume <50 µl). A medical procedure used for obtaining a small amount of blood is capillary blood sampling [1]. Small volumes of biological samples are applied in clinical studies, public healthcare, and clinical practice. Dried blood spot (DBS) analysis is the most popular and well-known method using capillary blood samples for running different tests [2]. The idea of placing capillary blood sample on laboratory filter paper was described for the first time in the 1860s for glucose level testing. A hundred years later these methods were used for running screening tests for metabolic disorders in newborn babies [3]. Further, relatively small volumes of capillary blood directly coming from a finger stick are used in point-of-care testing. Test results are immediately available, allowing rapid treatment initiation to prevent disease symptoms and improve patient's health status [4]. Capillary blood samples are routinely used for checking, especially in adults, of such parameters as serum glucose, glycated hemoglobin, cholesterol, hemoglobin, cardiac enzymes, bilirubin, blood gases, and electrolytes [5,6]. Another medical application for DBS is in the early and rapid screening test for viruses, such as HIV [7], hepatitis B virus (HBV), and hepatitis C virus (HCV) [8], and also for therapeutic drug monitoring [9].

Until the seventies, only metal lancets and needles were used – freehand and without control of depth. Usually, these devices were rather painful, might have caused deep wounds, and carried the risk of infection because of the possibility to be used by/on several patients. In order to reduce the pain associated with capillary blood sampling and the risk of cross-infection and simultaneously obtain the necessary blood volume, the design of the lancet devices has been changed. In subsequent years, more automatic lancing devices were introduced and became popular because of the comparative lack of pain associated with their use. Currently available on the market safety lancets are sterile, single-use medical devices used to carry out skin punctures for the purpose of collecting capillary blood samples. They are intuitive, comfortable for use, easy to grip, and with an ergonomic shape. These medical devices also possess safety features to prevent accidental injury, consisting of a fully hidden needle in housing,

CONTACT A. Serafin anna.serafin@htl-strefa.pl HTL-Strefa S.A., Ozorków, Poland

and a protective cap guaranteeing needle sterility. Moreover, after activation, the needle retracts into the housing and the device cannot be triggered again, reducing the risk of accidental needle stick injuries, which is crucial to prevent cross-infections. The suitable speed of the puncture process is responsible for weak pain perception and adequate puncture of the skin to obtain an appropriate amount of blood. Safety lancets differ in body design, activation method (push-button activation and contact activation), needle or blade size, and penetration depth. The activation method should not have any influence on the obtained capillary blood volume and pain perception. Safety lancets of different types (needle or blade) and sizes are used to obtain different blood volumes [10]. Most of them are used by health-care professionals, but some of them are also used by lay-users. The target population for these devices is mostly adults. For a pediatric population, special devices have been designed and have been available on the market for a while (e.g. Tenderfoot®; International Technidyne Corp., Edison, NJ, USA). The heel incision devices are equipped with a blade to obtain a heel blood sample. The blade with an appropriate size adequately controls the puncture depth, preventing from heel or bone injury.

The capillary blood sampling technique usually consists of puncturing a finger; in rare occasions, the ear lobe in adults and children or the heel in neonates and infants up to 6 months of age is punctured [11]. If the puncture is performed on a finger, the recommended site is the fingertip side of the middle or ring finger, because these places have sufficient tissue depth, which prevents accidental bone injury. The puncture area must be properly cleaned with an appropriate disinfecting agent. In the case of adult patients, ethanol is the preferred agent for cleaning the site. Even though several antiseptic agents have been used in neonates for many years, there is no consensus guidance regarding the best antiseptic for this target population [12,13]. The site is selected and prepared according to the local recommendation so it is ready for a prick to be made with a medical device. Capillary blood sampling is a simple, quick, easy, and cheap procedure compared to venous blood sampling. This procedure is recommended for running specific tests in children, adult patients, in patients with severe burns, extremely obese patients, geriatric patients, individuals anxious about sampling, patients with a tendency toward thrombosis, patients whose surface veins need to be preserved for intravenous therapy, and patients with fragile or inaccessible veins [14–16]. Till now, only a few studies describing the usage of safety lancets in capillary blood sampling in regards to the blood volume and pain perception have been published [10,17]. Most of them include the newborn's' blood sampling and excluded the adult population. This study aimed to assess several types of safety lancets in terms of blood volume and pain perception during capillary blood sampling.

2. Methods

This was a prospective, uni-center, single-blind, randomized study designed to assess the capillary blood volume and pain perception for several safety lancets during one standardized lancing procedure.

2.1. Study participants

Subjects received compensation for their participation and had given their informed consent prior to inclusion. None of them had participated in a similar study. They had to be able to communicate well with the investigator and comply with the requirements of the study and to be in good physical and mental health. Patients were considered not eligible if they met one or more of the following exclusion criteria: pregnant or lactating (self-reported); confirmed or suspected malignant cancer; history of poor blood circulation; any skin condition on the fingers that prevented blood sampling; needle phobia or fear of finger pricks; history of clotting disorders (including bleeding); neuropathy or other condition causing weak sensation in hands; history of blood-borne infection (e.g. HIV, HBV, HCV, syphilis, malaria, babesiosis, brucellosis, leptospirosis, arboviral infections, relapsing fever, T lymphotropic virus Type 1, or Creutzfeldt-Jakob disease); currently participating in another study; history of drug or alcohol abuse within 12 months prior to screening or visible evidence of such abuse; intake of alcohol within 48 h prior to the start of the study (self-reporting); donation or loss of 400 mL or more of blood within 4 weeks prior to the start of the study; any prescription or taking of OTC medication (e.g. aspirin, heparin, ibuprofen, or acetaminophen) within 1 week of starting the study that might have affected either the pain perception or obtained blood volume; any other condition that in the investigator's opinion might have negatively influenced subject's participation in the study.

Participants were randomly assigned to receive four punctures in four different fingertips with four different safety lancets. After the lancing procedure, the volume of blood obtained with lancing was measured and perceived pain was assessed 5 min after the lancing procedure on the visual analogue scale (VAS, numeric scale).

2.2. Lancing medical devices

This was a single-blind study where only the investigator or a designee was aware of the type of used safety lancets. Four different types of safety lancets manufactured by HTL-STREFA S.A. (Ozorków, Poland) were tested (Table 1). Three of them (Acti-Lance, Prolance, and MediSafe Solo) are push-button activated, and one (Medlance Plus) is a contact-activated lancet. All of them have safety features preventing from accidental needle sticks. Each type has several versions that differ in the type of puncturing component (needle or blade), diameter, penetration depth, and colors, which allows their identification.

2.3. Primary objective

The primary objective of this study was to determine the capillary blood volume collected after a single lancing of the fingertip. After lancing, the finger was gently pressed for 2 min and the blood was sampled in glass capillaries.

Table 1. Features of the examined single-use safety lancets.

No	Type of the safety lancet	Version of the safety lancet	Penetrating part	Activation method	Needle/blade size	Penetration depth
1	Acti-Lance	Acti-Lance Lite (A1)	Needle	Push-button	28G	1.5 mm
2		Acti-Lance Universal (A2)	Needle		23G	1.8 mm
3		Acti-Lance Special (A3)	Blade		17G	2.0 mm
4	Medlance Plus	Medlance Plus Super Lite (M1)	Needle	Contact-activated	30G	1.2 mm
5		Medlance Plus Lite (M2)	Needle		25G	1.5 mm
6		Medlance Plus Universal (M3)	Needle		21G	1.8 mm
7		Medlance Plus Extra (M4)	Needle		21G	2.4 mm
8		Medlance Plus Special (M5)	Blade		0.8 mm	2.0 mm
9	Prolance	Prolance Micro Flow (P1)	Needle	Push-button	28G	1.6 mm
10		Prolance Low Flow (P2)	Needle		25G	1.4 mm
11		Prolance Normal Flow (P3)	Needle		21G	1.8 mm
12		Prolance High Flow (P4)	Needle		18G	1.8 mm
13		Prolance Max Flow (P5)	Blade		1.5 mm	1.6 mm
14		Prolance Pediatric (P6)	Blade		1.5 mm	1.2 mm
15	MediSafe Solo	MediSafe Solo (S1)	Needle	Push-button	29G	1.5 mm
16		MediSafe Solo (S2)	Needle		23G	2.0 mm

2.4. Secondary objective

Five minutes after the lancing procedure, the pain perception was recorded on a VAS scale. The subjects marked on the scale the number (on a 0–10 scale) that represented their perception of pain (VAS scale).

2.5. Sample size

Considering the randomization scheme, the number of punctures per one lancet type should have been equal to 25. Due to the fact that 16 lancets were tested and four punctures were done per a subject, the required sample size was 100 subjects who finished the study. Assuming normality of blood volume distribution and 75% standard deviation of the mean, this sample size allowed to estimate the above-mentioned parameters with 29.5% precision and 95% confidence limit.

2.6. Statistical analysis

Statistical analysis was mainly descriptive, including mean, STD, min, median, max, and upper and lower quartile values. Moreover, 95% confidence intervals were calculated for the blood volume and perceived pain for each version of the safety lancet. Shapiro-Wilk and D'Agostino–Pearson tests were used to further estimate differences in capillary blood volume and pain perception between the devices and their versions. The overall threshold for acceptance was set to a p value ≤ 0.05. To estimate the dependence of the mean capillary blood volume and pain perception on the needle size or needle length, the coefficient of determination and Pearson's correlation coefficient were calculated.

2.7. Lancing procedure

Before the procedure, each participant washed hands with soap and warm water for about 1 min. Due to the fact that the study was single-blinded, the participant was seated behind a screen and was not able to see which type or version of safety lancet was used. A well-trained nurse prepared a proper set of safety lancets according to the randomization list. Then, the subject exposed his/her hand which was indicated by the nurse whereas the other hand was placed on a warm thermophore (Rubber Thermophore; Albert Polska, Dobczyce, Poland). The nurse massaged the middle finger (of the left or right hand) three times toward the puncture site, and then disinfected this site. She took the first safety lancet out of the subject's allocated bag, twisted the protective cap and took it out. After the disinfectant evaporated from the skin, the study nurse informed the subject about the finger prick, and then the finger was pricked. Afterward, the hand was placed below the subject's elbow level. The blood from the puncture site was collected into capillaries by pressing the finger for 2 min, and then the amount of the blood was measured using a calibrated ruler. The ruler was placed on the table and the capillary with the blood was put to the scale of the ruler, then the length of the blood in the capillary was read in millimeters and the amount of blood was converted into µL. When all blood was collected, the puncture site was protected with a sterile gauze pad. Five minutes after pricking, the subject noted in his/her worksheet the intensity of the perceived pain and the time of assessment. The procedure was repeated for other three fingers with three different randomly chosen safety lancets.

2.8. Tested medical devices

2.8.1. Acti-Lance safety lancets type

There are three versions of the Acti-Lance safety lancet that differ in the puncturing element (needle and blade), diameter of the needle (23G and 28G), penetration depth (1.5 mm and 1.8 mm), and colors, which allow their identification. Version A3 is a blade version with a penetration depth of 2.0 mm.

2.8.2. Prolance safety lancets type

Prolance type is offered in six versions which differ in the type of the puncturing element (needle or blade), diameter of the needle (28G–18G), penetration depth (1.4–1.8 mm), and colors. Two versions have blade as a puncturing element and differ in penetration depth (1.6 mm and 1.2 mm). The color of the push-button is used to differentiate the marketed versions of the medical device.

2.8.3. Medlance Plus safety lancets type

There are five versions of Medlance Plus that differ in the puncturing element (needle or blade), diameter of the needle (30G-21G), penetration depth (1.2–2.4 mm), and colors. This brand also includes one version of safety lancet with a blade (M5).

2.8.4. MediSafe Solo safety lancets type

There are two versions of MediSafe Solo type 520 that differ in the diameter of the needle (29G and 23G), penetration depth (1.5 mm and 2.0 mm), and colors.

2.9. Ethics and authorizations

The protocol was approved by the local ethics committee in Poland. All study participants signed informed consent forms before entering the study and were free to withdraw from the study at any time. The study was conducted in compliance with the World Medical Association Declaration of Helsinki and its amendments, the current Good Clinical Practice (GCP) guidelines, and Polish state law governing the conducting of clinical investigations. The trial was registered at ClinicalTrials.gov under the number NCT04001348.

3. Results

One hundred healthy subjects (73 women; median age, 37.4 years, range 18–65 years) participated in this study. All patients were Caucasian and only 4 of 5 described types of skin were included (Table 2). No participant had a very thin skin. The study population was diverse regarding the age, height, weight, body mass index (BMI), and systolic and diastolic blood pressure values (Table 3).

3.1. Capillary blood volume

Four hundred single measurements from 100 participants were collected to assess the capillary blood volume for the 16 safety lancets. Table 4 presents the units and ranges of obtained results for total blood volume after removing the outlier values. Further, the mean, standard deviation, 95% CI for mean, the minimum, maximum, and median values are shown for each version of the safety lancet.

The graphic picture presents the mean capillary blood volume calculated for each safety lancet (Figure 1). When the safety lancets were grouped according to their type (Acti-Lance, Medlance Plus, Prolance, and MediSafe Solo; Table 5), it was observed that the mean of obtained capillary blood volume depended on the number of safety lancets equipped with a blade in each group (blade version).

The mean of capillary blood volume was significantly different between safety lancets equipped with a blade (A3, M5, P5, and P6) and those equipped a needle for each type of safety lancet. As the MediSafe Solo type lancet has no such device, it was associated with the lowest mean capillary blood volume (42.4 µL). In contrast, Acti-Lance and Medlance Plus type lancets have one such device and the mean capillary blood volume was 82.2 and 99.0 µL, respectively. The Prolance type has two such devices; hence, the mean capillary blood volume was the highest (118.3 µL).

The Pearson coefficient (−0.315 and 0.24) and the coefficient of determination (0.0995 and 0.058) showed that the relationships between the capillary blood volume and needle gauge and between the capillary blood volume and penetration depth were weak (10% and 6%, respectively).

Further, each type of safety lancet was estimated separately in regard to the obtained capillary blood volume. In case of Acti-Lance type, a significant difference regarding the capillary blood volume for each version (A1, A2, and A3) was observed (Table 4). However, it was not possible to determine which factor (gauge of the needle or/and penetration depth) had an impact on this value. It was not possible to indicate which factor had an influence on the capillary blood volume or to indicate whether it could have been a combination of these two factors. In case of Prolance, a difference regarding the capillary blood volume for each needle versions (P1, P2, P3, and P4) was observed (Table 4). Although the difference was not significant, it was concluded that a thicker needle and a bigger penetration depth provided a bigger capillary blood sample. In this case, similarly to Acti-Lance type, it was impossible to indicate which factor had significant influence on the capillary blood volume or if it could have been a combination of these two factors. The differences between Medlance Plus safety lancets version M1 and M3 and M1 and M4 were statistically significant (Table 4). Versions M2, M3, and M4 did not differ significantly. All needle versions (M1–M4) differed significantly in terms of the average amount of blood from the blade version (M5). In case of M3 and M4 versions, it was observed that the amount of blood did increase when one of the factors (penetration depth) was changed. It could indicate that capillary blood volume increment depends on the combination of both factors – gauge and penetration depth. The difference in regard to the capillary blood volume for two versions of MediSafe Solo was not significant (Table 4). Nor correlation between the amount of obtained blood and gauge and/or penetration depth was found. Based on Acti-Lance results, it was expected that the volume of blood would be higher and not lower, as it was noted. However, these

Table 2. Summary of statistics for demographic variables.

Variable	Group	N	%	In total
Sex	Female	73	73	100
	Male	27	27	
Ethnic origin	Caucasian	100	100	100
Type of the skin	Thin skin	21	21	100
	Normal skin	60	60	
	Thick skin	16	16	
	Very thick skin	3	3	

Table 3. Summary of statistics for demographic variables.

Variable	N	Mean	SD	Min	Max	Median	Q1	Q3
Age	100	37.4	12.1	18.0	63.0	36.5	28.0	46.0
Height	100	167.7	7.7	150	191	168	162	172.5
Weight	100	73.7	17.4	47.4	154.3	71.9	60.9	82.8
BMI	100	26.1	5.5	17.7	54.7	25.0	22.2	28.8
Pulse	100	71.1	8.9	52	98	71	64	76
Systolic BP	100	118.0	16.1	90	180	120	110	130
Diastolic BP	100	79.8	9.8	60	100	80	74.5	85

Table 4. Capillary blood volume (µL) results for each safety lancet.

Lancet Id	Mean	Standard deviation	95% CI for mean		Min	Max	Q1	Median	Q3
A1	38.2	22.5	28.5	47.9	2.2	87.0	17.4	39.1	47.2
A2	71.5	45.9	51.1	91.8	4.4	157.6	30.9	80.9	107.4
A3	182.5	126.4	129.1	235.8	4.3	483.7	86.7	165.7	289.1
M1	46.7	34.9	32.0	61.5	0.0	138.1	24.2	44.0	60.9
M2	74.6	53.8	52.3	96.8	5.4	196.7	28.3	60.9	113.0
M3	78.9	53.7	56.3	101.6	15.2	198.9	36.2	58.1	125.6
M4	66.4	44.1	46.8	86.0	11.9	178.3	31.8	62.4	88.0
M5	143.5	111.1	96.6	190.4	25.0	437.0	62.7	94.0	215.0
P1	42.6	25.3	31.7	53.5	1.1	96.8	22.8	39.1	54.9
P2	83.7	58.2	59.1	108.3	1.1	225.0	40.8	76.6	112.8
P3	86.4	58.5	61.7	111.1	1.1	192.4	43.8	76.6	120.4
P4	98.2	61.4	72.2	124.0	9.7	241.3	51.9	85.8	140.0
P5	265.0	160.5	195.6	334.4	52.2	610.9	145.1	207.6	395.1
P6	138.4	91.7	97.7	179.0	1.1	288.0	69.6	134.8	198.9
S1	47.3	40.9	30.5	64.2	2.2	141.3	8.6	35.8	70.7
S2	37.3	38.5	21.0	75.9	0.0	134.8	7.3	20.6	61.4

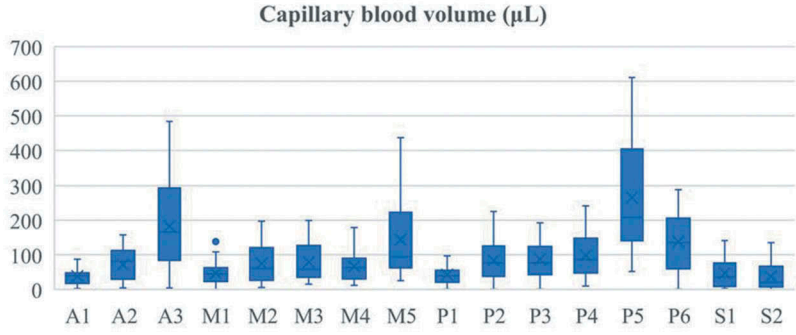

Figure 1. The mean capillary blood volume (µ) for each safety lancets.

Table 5. Capillary blood volume (µL) results for 4 types of safety lancets.

Lancet	N	Mean	Standard deviation	95% CI for mean		Min	Max	Q1	Median	Q3
MediSafe Solo	49	42.4	39.7	31.0	53.8	0.0	141.3	7.6	30.4	69.6
Medlance Plus	119	82.2	72.3	69.1	95.3	0.0	437.0	33.1	60.9	105.4
Acti-lance	69	99.0	100.9	74.8	123.2	2.2	483.7	30.4	76.1	120.7
Prolance	140	118.3	110.6	99.8	136.7	1.1	610.9	42.1	87.5	156.8

unexpected results may be due to the fact that for version S2 no blood flow was reported in one case.

Considering all versions with a blade, a significant difference was noted in regard to the capillary blood volume between the blade version (M5, P5, P6, and A3) and the rest of safety lancets with needles within a given design type. As far as the needle versions are concerned, for Medlance Plus type the only significant difference was observed for version M1 compared to the others, while for Prolance type a significant difference was observed for version P1. For Acti-Lance, the significant difference was observed for A1 and A2 versions contrary to MediSafe Solo where no significant difference between these two versions was detected. For Acti-Lance and Prolance type, the amount of capillary blood increased according to the decreasing gauge, which means a thicker needle and a higher penetration depth. For Prolance type, no significant difference in blood volume was observed in regard to usage of a bigger needle gauge. Detailed analysis of results indicated that there was an increase in blood volume when a bigger gauge was used. However, the difference was not statistically significant.

No incident of malfunction was reported for any of the studied safety lancets.

3.2. Pain perception

A total of 400 single measurements coming from 100 participants were collected to assess pain perception for the 16 safety lancets. Table 6 presents the range of study scores obtained for subjects' pain perception after removing the outlier values. Further, the mean, standard deviation, 95% CI for mean, the minimum, and maximum and median values are shown for each version of the safety lancet.

The graphic picture presents the mean pain rating (VAS scale) calculated for each safety lancet (Figure 2). Considering the differences between the safety lancets equipped with a blade or a needle, tested medical devices were grouped into the type categories (Acti-Lance, Medlance Plus, Prolance, and MediSafe

Table 6. Pain rating according to VAS scale for each safety lancet.

Lancet Id.	Mean	SD	95% CI for mean		Min	Max	Q1	Median	Q3
A1	1.3	1.3	0.8	1.9	0	4	0	1	2.2
A2	2.0	1.2	1.4	2.5	0	5	1	2	3
A3	2.1	1.3	1.6	2.7	0	5	1	2	3
M1	0.7	0.7	0.4	1.0	0	2	0	1	1
M2	0.7	0.7	0.4	1.0	0	2	0	1	1
M3	1.1	1.0	0.7	1.5	0	3	0	1	2
M4	1.5	1.4	0.9	2.1	0	5	0.7	1	2
M5	1.5	1.3	1.0	2.1	0	5	1	1	2
P1	1.4	1.0	1.0	1.9	0	4	1	1	2
P2	2.0	1.5	1.4	2.6	0	5	1	2	3
P3	2.3	1.3	1.7	2.8	0	5	2	2	3
P4	2.6	1.4	2.0	3.1	1	6	1	2	4
P5	3.2	1.9	2.5	4.0	1	6	1	3.5	5
P6	2.9	2.0	2.0	3.7	0	8	2	3	3
S1	1.4	1.2	0. 9	1.9	0	4	0.5	1	2
S2	1.2	1.0	0.8	1.6	0	3	0	1	2

Solo) to assess the pain perception results. The results are presented in Table 7.

Medlance Plus was the least painful and Acti-Lance was the most painful type of safety lancets. According to the value of quartile 3 in each type of safety lancets, 75% of punctures were assessed by the participants at a level not exceeding 3 points on VAS scale. As stated by the subjects, blade-equipped safety lancets were the most painful. However, assessed blade versions varied considerably in regard to pain perception.

The Pearson coefficient (–0.2557 and 0.19) and the coefficient of determination (0.17 and 0.029) showed that the relationships between pain perception and needle gauge and between pain perception and penetration depth were weak (6.5% and 2.9%, respectively).

4. Discussion

This clinical study conducted on 100 participants aimed to assess the performance of several types of safety lancets in terms of obtained capillary blood volumes and pain perception. Obtained results showed that the mean volume of blood obtained by all tested safety lancets is sufficient to run most of the commercially available screening and diagnostic rapid tests, while the amount of associated pain was low for all devices.

Capillary blood sampling is a procedure aimed to obtain the necessary blood volume accompanied by the lowest pain perception to run a diagnostic or screening test. Safety lancets are mostly used by health-care professionals in secondary care (hospitals, private clinics, nursing homes, long-term care facilities, outpatient facilities, blood banks, or other health-care institutions) and primary care such as doctor's offices. The most popular tests conducted in clinics or physician's office are determination of blood glucose or C-reactive protein (CRP) levels [18,19]. Capillary blood sampling is especially recommended for specific tests that require small quantities of blood (point-of-care tests) [15]. Point-of-care tests are rapidly expanding in all health-care areas, especially in the poorest regions of the world with the highest burden of mortal viral infections. In such areas it is highly recommended performing rapid screening tests for HBV, HCV, and HIV infections, especially in pregnant women, to allow quick and effective implementation of preventive strategies [20–22]. Point-of-care tests require only a small sample volume and provide quick, accurate, and precise results [23–25]. The availability and simplicity of such tests make them acceptable by the potential users [26] and useful in places with limited access to health-care facilities (e.g. prisons and detention settings), where the blood sampling in a conventional way and its transportation to the analytical laboratory would be inconvenient or even impossible [27]. Previous research has shown that the necessary amount of capillary blood to run a point-of-care test is 2.5–14 µL, whereas phlebotomy for traditional laboratory testing is associated with a potential blood loss of 25–125 mL [28]. Based on the labeling of point-of-care tests for virus detection available on the market, the capillary blood volume needed for their running is 2.5–50 µL [29–31].

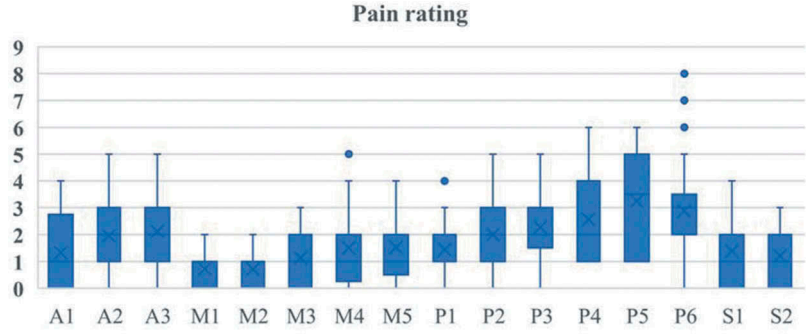

Figure 2. The mean pain rating (VAS scale) for each safety lancets.

Table 7. Pain rating for types of safety lancets.

Lancet	n	Mean	Standard deviation	95% CI for mean	Min	Max	Q1	Median	Q3
Medlance Plus	123	1.1	1.1	0.9–1.3	0	5	0	1	2
Prolance	48	1.3	1.1	1.0–1.6	0	4	0	1	2
MediSafe Solo	73	1.8	1.3	1.5–2.1	0	5	1	2	3
Acti-lance	149	2.4	1.6	2.1–2.7	0	8	1	2	3

Choosing the proper version of safety lancets depends on the user. Health-care professionals are expected to take into account patients' characteristics, such as social-economic, health status, occupation, age, ethnicity, and skin type, when choosing the appropriate safety lancet. These factors may determine patients' skin type and/or have a significant influence on pain perception. This is a second study where a variety of safety lancets' versions have been tested. As stated by the previous study, the penetration depths and gauge of the needle may have an impact on the capillary blood volume and pain perception, whereas the activation method (push-button and contact-activated safety lancets) not [10]. In our study, three push-button safety lancets and one contact-activated safety lancet were tested. In line with the results of the previous study, our findings suggest that the method of activation does not have a statistical significance on the blood volume, as the impact of pushing the button does not seem to be important for the obtained blood volume. In most cases, we observed that the capillary blood volume increased with the gauge and penetration depth. However, the differences were significant only for the presence/absence of the blade and not for different gauges and penetration depths. It can be assumed that if each version of safety lancets had been tested in participants with the same skin type the differences would have been significant. The study population was diverse in regard to skin type, age, and BMI. However, the type of the skin was not estimated by any validated method [28], but was based on the subjective evaluation by the investigator. Due to the fact that participants were healthy Caucasians, mostly of female sex, these three characteristics may be considered as limitation factors of the study. Safety lancets are considered as low-risk devices in which undesirable side effects are not severe in nature. Taking into consideration no issue relating to safety was reported, all tested types of safety lancets are thought to be safe for patients and health-care professionals. All tested medical devices provide an appropriate capillary blood volume and the results have clinically proven their intended use. Pain perception was described as low. Due to the clinical results all investigated safety lancets can be used for capillary blood sampling in a safe and effective way.

5. Conclusion

This study found significant differences between safety lancets equipped with blades and needles in terms of the mean capillary blood volume, with the lowest mean of collected capillary blood volume for safety lancets equipped exclusively with needles and the highest mean capillary blood volume for safety lancets available in several blade versions. All lancets achieved adequate performance regarding the necessary capillary blood volume to run a diagnosis of the test. All devices produced relatively low levels of pain. However, the pain caused by blade versions of safety lancets has been found to be higher than that of needle versions. The causes of this phenomenon were not completely elucidated. Further studies with larger samples are needed to verify the current results and evaluate their clinical impact.

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Declaration of interest

Anna Serafin, Mariusz Malinowski, Aleksandra Prazmowska-Wilanowska are full-time employees of HTL-STREFA S.A.

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ORCID

A. Serafin http://orcid.org/0000-0002-8831-456X
M. Malinowski http://orcid.org/0000-0002-1632-8647
A. Prażmowska-Wilanowska http://orcid.org/0000-0002-5550-5247

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