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The impact of needle diameter and penetration depth of safety lancets on blood volume and pain perception in 300 volunteers: A randomized controlled trial

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The aim of the study is to determine and measure the blood volume as well as level of pain of the study volunteers after being punctured with different safety lancets (varying sizes) from 20 s to 2 m. Blood sample can be used in a number of ways: for diagnosis, to determine health condition generally and for screening. 300 subjects were punctured 4 times with different safety lancets. After each puncture their blood was collected into the capillary with the volume calculated. After the lancing, the perceived pain was recorded on VAS scale. It was found that with increased thickness of the needle, the amount of blood sample increases too. Blood volumes obtained after puncturing with different types of safety lancets with the same needle diameter (Gauge) vary depending on the manufacturer. The level of pain in the VASt majority of cases was assessed as minimal or low. Based on the results obtained from a group of 300 volunteers (1200 punctures) it can be concluded that all types of safety lancets are efficient and safe for both patients and medical personnel.

Key words: Blood, test, rapid, safety, lancet, capillary, diagnostic, volume, puncture, pain.

INTRODUCTION

An average adult has a blood volume of 4.7 liters roughly (World Book Rush-Presbyterian-St, 1995). Blood performs many important functions within the body, including supplying of oxygen and nutrients such as glucose, amino acids, and fatty acids to tissues, as well as removal of waste products such as carbon dioxide, urea, and lactic acid. Blood has immunological functions, including circulation of white blood cells, and detection of foreign material by antibodies, coagulation, transport of hormones and signaling of tissue damage; it also regulates body temperature and hydration (Nathanson and Chun, 1989; AdvaMedDx, 2016). Blood is very easy to get to perform diagnostic test. It can be used in a number of ways, such as helping to diagnose as well as assessing the health of certain organs or screening for some genetic conditions. High prevalence of infectious

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diseases in developing countries, rising preference for home diagnostics, increasing availability and awareness about infectious disease, prevention of infectious human diseases across the globe, and growing government initiatives supporting the adoption of point of-care diagnostic products cause an increase in demand for point-of-care diagnostic products. Due to the material collected for the diagnosis, we distinguish among others blood, urinary and stool rapid tests. (NLM), medlineplus (2017). Krausse et al 2008; Paño Pardo JR (2017), The predominant number of the rapid test requires the capillary blood to be conducted. Rapid diagnostic test is segmented into: glucose monitoring products, infectious disease testing products, coagulation testing products, cardiometabolic testing products, hematology testing products, urinalysis testing products, cholesterol testing products, drugs abuse testing products, tumor/cancer marker testing products, pregnancy and fertility testing products, fecal occult testing products, and other point of care products (multi-assay testing, liver testing, hepatitis A & B testing, and vitamin assay testing). Moody (2002),(MarketsandMarkets (2017). CDC (2014).

The volume of diagnostic material that is needed to perform the correct diagnosis depends on the type of test and is specified by the test manufacturer. In order to ensure optimal blood volume for performing diagnosis with a relatively low pain sensation and to meet the needs of consumers such as: nurse and patient safety, sufficient blood volume, sterility, suitable speed of the puncture process, easiness of use, appropriate ergonomics, manufacturers of medical devices design safety lancets with different needles or blade sizes and penetration depths, activation methods and safety mechanisms, as a natural response to the market needs. (Lancet, 2006).

MATERIALS AND METHODS

Safety lancets are single-use devices for capillary blood sampling used by healthcare professionals. Currently some of them are also available for patients use. Capillary blood monitoring has become a common practice in clinical use and its use is still growing. Safety lancets differ in: body construction, activation method (push-button, side button and contact activation), needle or blade size and penetration depth. Different safety lancet types and sizes are required to obtain different blood volumes. Capillary blood sampling is becoming more precise, therefore precise blood amounts are needed.

Clinical trial

This work is a randomized, single blind, uni-center study done with healthy volunteers to determine their capillary blood volume and pain perception. It was obtained by puncturing with different safety lancets. This work is a randomized clinical trial.

The aim of this work was to determine the capillary blood volume collected after a single puncture of the volunteers' fingertips. The secondary objective was to determine perceived pain directly after puncture as well as after the whole puncture procedure was finished.

Healthy volunteers agreed to sign the consent form at the hospital in Poland, BioResearch Group Sp. z o. o., Mokra 7 St, Kajetany, 05-830 Nadarzyn, from December 2017 to April 2018. The volunteers were between 18 and 65 inclusive and good physical and mental health.

Three hundred participants were punctured 4 times (four different fingertips) with different safety lancets, giving a total of 1200 punctures. After punctures the blood was collected into the capillary and its volume was calculated. Finger lancing was undertaken in a standardized way, plus 30 s of finger massage before the finger was lanced. The fingers were gently pressed during the blood collection. After the lancing the perceived pain was recorded on a visual analog scale (VAS, numeric scale). The subjects marked on the scale the number (in 0-10 scale) that represents their perception of pain (VAS, numeric scale) (Figure 1). Just before leaving the site the subjects were asked to fill again the VAS scale (30 ± 5 min after the procedure).

1200 safety lancets of various companies and various types were used to perform the study: 775 of HTL-STREFA and 425 competitive safety lancets.

Main outcome measures

The capillary blood volume was measured after puncturing each subject after 20 s and 2 min, as well as the level of pain during the puncture and at the end of the procedure. A total amount of 1200 capillary blood collections was taken. The results were given in microliters (µL).

Description of the puncture procedure

Before puncture, the study team member massaged the middle or ring finger (of the left or right hand) for a full 30 s, and then the test site was disinfected. Immediately after the puncture, each subject recorded in his/her worksheet (VAS scale) intensity of the perceived pain (numeric value) and time of starting and finishing the blood collection and informed the study team member about this action. The blood from the puncture site was collected to the capillary immediately after puncture. The blood volume was noted after 20 s and until the end of bleeding or up to 2 min. The procedure was repeated with further 3 fingers. The pain perception for each finger lanced was measured for the second time before leaving the site 30 ± 5 min after finishing the puncture procedure.

RESULTS

On blood volume and pain assessment

An analysis was made on the basis of the blood volume obtained after 1200 punctures with different lancets: 775 punctures with HTL-STREFA safety lancets and 425 punctures with competitive safety lancets.

Influence of needle diameter on blood volume and pain assessment

Blood volume after 20 s

Depending on the needle diameter or blade width, the

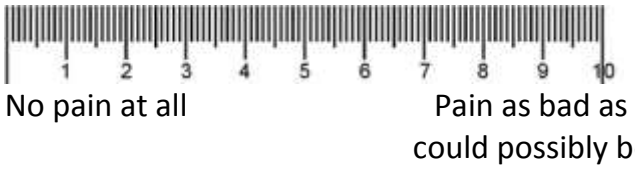

Figure 1. VAS, numeric scale. Scoring and Interpretation: no pain (0 – 0.4 cm); mild pain (0.5 – 4.4 cm); moderate pain (4.5 – 7.4 cm); severe pain (7.5 – 10 cm).

Table 1. Volume of blood after 20 s (µl) (Safety lancets of all companies).

Variable	Group	N	Mean	SD	Min	Max	Median	Q1	Q3
Volume of blood after 20 s (µl)	Thin Safety Lancets (30G-29G)	350	18.6	19.4	0.1	70.8	11.1	4.6	28.5
	Medium Safety Lancets (21G-25G)	575	25.4	22.1	1.3	87.2	20.0	10.1	33.4
	Thick Safety Lancets (18G-0.8mm)	275	32.5	26.7	1.1	102.6	26.9	11.9	44.9

Table 2. Volume of blood after 20 s (µl) (HTL-STREFA safety lancets).

Variable	Group	N	Mean	SD	Min	Max	Median	Q1	Q3
Volume of blood after 20 s (µl)	HTL -STREFA Thin Safety Lancets (30G-28G)	150	20.0	22.1	0.3	82.0	11.0	4.7	29.4
	HTL-STREFAA Medium Safety Lancets (21G-25G)	350	26.0	22.3	1.1	83.0	20.3	9.9	34.5
	HTL-STREFA Thick Safety Lancets (18G-0.8 mm)	275	32.5	26.7	1.1	102.6	26.9	11.9	44.9

Table 3. VAS result during the puncture (0-10cm) (Safety lancets of all companies).

Variable	Group	N	Mean	SD	Min	Max	Median	Q1	Q3
VAS result during the puncture (0-10 cm)	Thin Safety Lancets (30G-29G)	350	1.4	1.3	0.0	4.4	0.9	0.4	2.1
	Medium Safety Lancets (21G-25G)	575	2.0	1.8	0.1	6.7	1.6	0.7	2.8
	Thick Safety Lancets (18G-0.8mm)	275	2.4	1.9	0.0	7.1	2.1	1.1	3.4

lancets were divided into three groups: thin (30G - 29G), medium (21G - 25G), thick (18G – 0.8 mm).

The statistical significant influence of safety lancet needle diameter (G – Gauge) for the blood volume after 20 s was observed – with the diameter increase of 1G; the blood volume is reduced by 1,178 µl on average (95% CI 0.833 – 1,523). After 20 s, the lowest blood volumes were observed in the group of the thinnest lancet, while the highest blood volumes were observed in the group of the thickest lancets (Table 1). The average volume of blood obtained after 20 s in the group of HTL-STREFA thin and medium safety lancets is greater than the average volume of blood of all tested lancets (925 safety lancets) for particular groups (350 thin safety lancets; 575 medium safety lancets). In the clinical trial, thick lancets were provided only by HTL-STREFA company, so the results in both groups were the same (Table 2).

Pain assessment on VAS scale during the puncture

After conducting the analysis of the impact of needle diameter on pain perception during the puncture, the statistical significant influence on this parameter was observed. With the diameter increase of 1G, the pain assessment is reduced by 0.100 cm on average (05% CI 0.065 – 0.135). The least pain sensation at level 1.4 cm was during puncture with thin safety lancets and the greatest pain sensation at level 2.4 cm was during puncture with the thickest safety lancets (Table 3).

The average feeling of pain during the puncture obtained in thin and medium HTL-STREFA lancets groups is smaller by 0.3 cm in the VAS scale for thin safety lancets group and by 0.1 cm in the VAS scale for medium safety lancets group than the average feeling of pain of all tested lancets (925 safety lancets) for particular groups (350 thin safety lancets; 575 medium

Table 4. VAS result during the puncture (0-10cm) (HTL-STREFA Safety lancets)

Variable	Group	N	Mean	SD	Min	Max	Median	Q1	Q3
VAS result during the puncture (0-10 cm)	HTL -STREFA Thin Safety Lancets (30G-28G)	150	1.1	1.2	0.0	4.2	0.7	0.2	1.8
	HTL-STREFA Medium Safety Lancets (21G-25G)	350	1.9	1.6	0.1	6.1	1.5	0.7	2.6
	HTL-STREFA Thick Safety Lancets (18G-0.8mm)	275	2.4	1.9	0.0	7.1	2.1	1.1	3.4

Table 5. Volume of blood after 2 min (µl) (Safety lancets of all companies)

Variable	Group	N	Mean	SD	Min	Max	Median	Q1	Q3
Volume of blood after 2 min (µl)	Thin Safety Lancets (30G-29G)	350	44.1	51.7	0.1	197.2	25.6	8.3	59.5
	Medium Safety Lancets (21G-25G)	575	79.1	83.1	2.4	329.5	52.5	23.2	101.1
	Thick Safety Lancets (18G-0.8mm)	275	124.9	113.4	5.8	427.2	93.6	43.6	169.9

Table 6. Volume of blood after 2 min (µl) (HTL-STREFA Safety lancets).

Variable	Group	N	Mean	SD	Min	Max	Median	Q1	Q3
Volume of blood after 2 min (µl)	HTL -STREFA Thin Safety Lancets (30G-28G)	150	53.8	64.8	0.3	237.6	29.4	9.7	73.0
	HTL-STREFA Medium Safety Lancets (21G-25G)	350	84.3	88.3	2.2	350.4	55.5	23.0	111.7
	HTL-STREFA Thick Safety Lancets (18G-0.8mm)	275	124.9	113.4	5.8	427.2	93.6	43.6	169.9

Table 7. VAS result at the end of the puncture procedure (0-10cm) (Safety lancets of all companies).

Variable	Group	N	Mean	SD	Min	Max	Median	Q1	Q3
VAS result at the end of procedure (0-10cm)	Thin Safety Lancets (30G-29G)	350	0.2	0.5	0.0	2.1	0.0	0.0	0.1
	Medium Safety Lancets (21G-25G)	575	0.4	0.9	0.0	4.0	0.0	0.0	0.2
	Thick Safety Lancets (18G-0.8mm)	275	0.4	0.9	0.0	4.1	0.0	0.0	0.1

safety lancets) (Tables 3 and 4.). In the clinical trial, thick lancets were provided by HTL-STREFA company only, so the result in both groups were the same (Table 4.)

Blood volume after 2 min

In the clinical trial, statistical significant influence of safety lancet needle diameter for the blood volume at the end of the procedure was observed. With the diameter increase of 1G, the blood volume is reduced by 6.722 µl average (95% CI 5.094 – 8.350). The lowest blood volumes at the end of procedure were observed in the group of the thinnest lancets (30G needle diameter), while the highest blood volumes were observed in the group of the thickest lancets (18-23G needle diameter) (Table 5). The average volume of blood obtained after 2 min in HTL-STREFA group of thin and medium lancets is greater than the average volume of blood of all tested lancets (925 safety lancets) for particular groups (350 thin safety lancets; 575 medium safety lancets). In the clinical trial, thick lancets were tested only for HTL-STREFA safety lancets, so the result in both groups was the same (Table 6).

Pain assessment on VAS scale at the end of procedure

In the assessment of pain at the end of the procedure (after 30 min +/- 5 min from puncture), statistical significant influence of safety lancet needle diameter for the pain assessment was observed. With the diameter increase of 1G, pain assessment is reduced by 0.019 cm on average (95% CI 0.007 – 0.031) (Table 7).

The average pain perception at the end of the procedure obtained in HTL-STREFA group of thin lancets is smaller by 0.1 cm in the VAS scale than the average feeling of pain of all tested lancets (350 safety lancets). In medium safety lancets group, the feeling of pain at the end of procedure was similar (0.4 cm in the VAS scale) and no statistical significant differences were observed (Tables 7 and 8.). In the clinical trial, thick lancets were

Table 8. VAS result at the end of procedure (0-10cm) (HTL-STREFA Safety lancets).

Variable	Group	N	Mean	SD	Min	Max	Median	Q1	Q3
VAS result at the end of procedure (0-10cm)	HTL -STREFA Thin Safety Lancets (30G- 28G)	150	0.1	0.5	0.0	1.9	0.0	0.0	0.0
	HTL-STREFA Medium Safety Lancets (21G-25G)	350	0.4	0.9	0.0	4.0	0.0	0.0	0.3
	HTL-STREFA Thick Safety Lancets (18G-0.8mm)	275	0.4	0.9	0.0	4.1	0.0	0.0	0.1

Table 9. The results of blood volume (ul) and pain level in the VAS scale (0-10 cm) for 30G and 21G (needle diameter) safety lancets.

Lancet name	Volume of blood after 20 s (ul)				Volume of blood after 2 (two) min(ul)			VAS result during the puncture (0-10 cm)			VAS result at the end of procedure (0-10 cm)		
	N	Mean	SD	Median	Mean	SD	Median	Mean	SD	Median	Mean	SD	Median
Safety lancets 30G x 1.2 - 1.5 mm	100	16.5	18.6	9.3	36.9	47.9	18.9	1.2	1.3	0.5	0.1	0.5	0
Safety lancets 21G x 1.8 - 2.4 mm	325	26.4	23.4	20.7	86.4	93.2	57.5	2.2	1.8	1.7	0.4	1.0	0

tested only from HTL-STREFA company, so the results in both groups were the same (Table 8).

Influence of needle diameter on obtained blood volume

After conducting the analysis for a 30G (needle diameter) and 1.2– 1.5 mm (penetration depth) safety lancet, one of the thinnest safety lancets available on the market in 92% scores, a statistically significant blood volume needed for diagnostic test was obtained with minimized perceived pain at 1.2 cm (mild pain) in VAS scale during the puncture. Eight safety lancets per 100 (one hundred) safety lancets with 30G (needle diameter) did not give statistically significant blood volume. After calculating the entire clinical trial with 1200 punctures, it gave a score of 0.7% (Table 9). Migration to thinner needles (30G - 29G) with lower penetration depth help to minimize pain perception during the puncture even up to 42% compared to thicker safety lancets (18G – 0.8 mm) (Table 9).

INFLUENCE OF DEPTH OF PUNCTURE ON BLOOD VOLUME AND PAIN ASSESSMENT

Blood volume

Depending on the manufacturer and type of safety lancet, most common safety lancets are 21G, 23G and 25G. Table 10 shows the results for 21 Gauge, 23 Gauge and 25 Gauge. In the clinical study examination, 325 safety lancets of 21 Gauge were tested, including 150 safety lancets with a depth penetration of 1.8 mm, 50 safety lancets with a depth penetration of 2.0 mm, 25 safety lancets with a depth penetration of 2.2 mm and 100 safety lancets with depth penetration of 2,4mm. Also 125 safety lancets of 23 Gauge were tested, including 75 safety lancets with a depth penetration of 1.8 mm, 25 safety lancets with a depth penetration of 2.0 mm and 25 safety lancets with a depth penetration of 2.2 mm; 125 safety lancets of 25 Gauge were tested, including 50 safety lancets with a depth penetration of 1.4 mm, 25 safety lancets with a depth penetration of 1.5 mm, 25 safety lancets with a depth penetration of 1.8 mm and 25 safety lancets with depth penetration of 2.0 mm. After analysis of the influence of penetration depth on the blood volume after 20 (twenty) s and at the end of the procedure, there was no statistical significant impact of this parameter on the blood volume for all safety lancets which were tested in clinical trial (1200 safety lancets). For the purpose of the clinical trial, the safety lancets with penetration depth in the range from 1.0 to 2.4 mm were used.

Pain assessment on VAS scale during the puncture

Depending on the penetration depth, the safety lancets were divided into three groups: safety lancets with a penetration depth of 1.0 – 1.5 mm; safety lancets with a penetration depth of 1.6 – 1.8 mm; safety lancets with a penetration depth of 2.0 – 2.4 mm.

The statistical significant influence of penetration depth for the VAS scale assessment during the puncture was observed. With the penetration depth increase of 1 mm, the result rises by 0.729 cm on average (95% CI 0.185 – 1.274), increasing pain perception. The lowest pain assessment during the puncture was observed in the group of lancets with shallow penetration depth (1.0 – 1.5 mm); the highest VAS scale assessment (meaning increased pain perception) was observed in the group of

Table 10. Volume of blood (µl) (Safety lancets 21 Gauge and 23 Gauge).

Group	Volume of blood after 20 s (µl)			Volume of blood after 2 min (µl)	
	N	Mean	SD	Mean	SD
Safety lancets 21G x 1.8 mm	150	24.9	22.2	80.5	90.1
Safety lancets 21G x 2.0 mm	50	32.2	26.5	120.9	129.33
Safety lancets 21G x 2.2 mm	25	18.8	17.6	55.2	74.3
Safety lancets 21G x 2.4 mm	100	27.8	25.2	86.0	85.9
Safety lancets 23G x 1.8 mm	75	25.2	20.4	75.3	75.7
Safety lancets 23G x 2.0 mm	25	28.7	21.86	87.19	69.68
Safety lancets 23G x 2.2 mm	25	14.2	8.49	32.24	20.83
Safety lancets 25G x 1.4 mm	50	26.7	22.7	87.2	95.8
Safety lancets 25G x 1.5 mm	25	15.6	18.77	38.3	44.88
Safety lancets 25G x 1.8 mm	25	27.9	27.76	83.7	97.48
Safety lancets 25G x 2.0 mm	25	24.6	20.09	53.2	48.75

Table 11. VAS result during the puncture (0-10 cm).

Variable	Group	N	Mean	SD	Min	Max	Median	Q1	Q3
VAS result during the puncture (0-10 cm)	Safety lancets with a penetration depth 1.0 - 1.5 mm	350	1.5	1.4	0.0	5.2	1.1	0.4	2.1
	Safety lancets with a penetration depth 1.6 - 1.8 mm	525	2.0	1.7	0.1	6.3	1.6	0.8	2.9
	Safety lancets with a penetration depth 2.0 - 2.4 mm	325	2.2	1.7	0.1	6.8	1.8	1.0	3.1

Table 12. VAS result at the end of procedure (0-10 cm).

Variable	Group	N	Mean	SD	Min	Max	Median	Q1	Q3
VAS result at the end of procedure (0-10 cm)	Safety lancets with a penetration depth 1.0 - 1.5 mm	350	0.2	0.6	0.0	2.6	0.0	0.0	0.1
	Safety lancets with a penetration depth 1.6 - 1.8 mm	525	0.4	0.9	0.0	4.1	0.0	0.0	0.2
	Safety lancets with a penetration depth 2.0 - 2.4 mm	325	0.3	0.8	0.0	3.4	0.0	0.0	0.2

lancets with deepest puncture penetration depth (2.4 mm) (Table 11).

Pain assessment on VAS scale at the end of procedure

Despite the fact that during the puncture, penetration depth affects the pain, the statistical significant influence of penetration depth for the VAS scale assessment at the end of the procedure was not observed (Table 12).

Influence of activation method on blood volume and pain assessment on VAS scale

Blood volume

A statistical significant influence of the activation method on the blood volume after 20 s was observed. Push button activation method gives volumes of statistical significantly larger than contact or side button activation method. The last two methods do not differ significantly. There was no statistical significant effect of the activation method on blood volume after 2 min (Tables 13 and 14).

Pain assessment on VAS scale

A statistical significant influence of the activation method on the pain assessment on VAS scale during the puncture was observed. Push button method gives statistical significantly higher pain assessment than contact activation method, the side button and contact activation methods do not differ statistical significantly. There was no statistical significant effect of the activation method on pain assessment at the VAS scale at the end of the procedure (Table 15).

Table 13. Volume of blood after 20 s (µl).

Variable	Group	N	Mean	SD	Min	Max	Median	Q1	Q3
Volume of blood after 20 s (µl)	Activation method: contact	475	22.8	23.3	0.0	188.0	15.6	6.1	33.4
	Activation method: push button	625	27.4	24.8	0.0	169.1	20.6	8.9	39.0
	Activation method: side button	100	20.6	19.0	0.0	102.3	15.6	7.6	28.1

Table 14. Volume of blood after 2 min (µl).

Variable	Group	N	Mean	SD	Min	Max	Median	Q1	Q3
Volume of blood after 2 min (µl)	Activation method: contact	475	68.1	83.8	0.0	482.7	36.7	13.3	87.3
	Activation method: push button	625	91.4	101.9	0.0	909.8	56.7	21.1	125.7
	Activation method: side button	100	58.1	83.1	0.0	503.8	31.5	13.5	66.5

Table 15. VAS result (0-10 cm).

Variable	Group	N	Mean	SD	Min	Max	Median	Q1	Q3
VAS result during the puncture (0-10 cm)	Activation method: contact	475	1.6	1.7	0.0	10.0	1.0	0.4	2.2
	Activation method: push button	625	2.1	1.9	0.0	10.0	1.5	0.5	3.0
	Activation method: side button	100	2.2	1.8	0.0	8.0	1.7	0.8	3.1
VAS result at the end of procedure (0-10 cm)	Activation method: contact	475	0.3	0.9	0.0	9.0	0.0	0.0	0.0
	Activation method: push button	625	0.3	1.0	0.0	9.0	0.0	0.0	0.1
	Activation method: side button	100	0.3	0.9	0.0	6.0	0.0	0.0	0.1

Table 16. Volume of blood after 20 s (µl).

Variable	Group	N	Mean	SD	Min	Max	Median	Q1	Q3
Volume of blood after 20 s (µl)	Age: (18.30)	476	24.0	23.2	0.0	188.0	17.8	7.8	32.2
	Age: (30.45)	452	24.5	24.1	0.0	113.5	16.7	6.7	34.5
	Age: (45.65)	272	27.7	24.5	0.0	169.1	20.0	8.5	42.3

Analysis of influence of age, sex and skin type on blood volume and pain assessment

From the analysis made on the basis of the blood volume obtained after 1200 punctures with different safety lancets, both women and men in the age range from 18 to 65 years old.

Influence of age on blood volume and pain assessment

Blood volume after 20 s

A statistical significant influence of age on the volume of blood was observed after 20 s (with the increase of the age by 1 year, the obtained volume increases on average at 0.151 µl (95% CI 0.035 – 0.266). The lowest blood volume after 20 s was observed in the age group (18 – 30); the highest in the age group (45 - 65) (Table 16).

Pain assessment on VAS scale during the puncture

There was no statistical significant effect of age on pain assessment on VAS scale during the puncture (Table 17).

Blood volume after 2 min

For the capillary blood collection after 20 s, the statistical

Table 17. VAS result during the puncture (0-10 cm).

Variable	Group	N	Mean	SD	Min	Max	Median	Q1	Q3
VAS result during the puncture (0-10 cm)	Age: (18.30)	476	2.1	1.7	0.0	8.5	1.6	0.8	3.0
	Age: (30.45)	452	1.8	1.8	0.0	8.7	1.1	0.5	3.0
	Age: (45.65)	272	1.8	1.9	0.0	10.0	1.2	0.5	2.7

Table 18. Volume of blood after 2 min [µl].

Variable	Group	N	Mean	SD	Min	Max	Median	Q1	Q3
Volume of blood after 2 (two) min [µl]	Age: [18-30]	476	75.2	91.2	0.0	627.3	42.0	17.7	98.2
	Age: (30-45]	452	77.6	92.4	0.0	497.2	43.9	14.9	101.2
	Age: (45-65]	272	89.7	102.5	0.0	909.8	65.4	19.9	116.0

Table 19. VAS result at the end of the puncture procedure (0-10 cm).

Variable	Group	N	Mean	SD	Min	Max	Median	Q1	Q3
VAS result at the end of procedure (0-10 cm)	Age: (18-30)	476	0.2	0.7	0.0	6.0	0.0	0.0	0.1
	Age: (30-45)	452	0.2	0.8	0.0	7.0	0.0	0.0	0.0
	Age: (45-65)	272	0.6	1.4	0.0	9.0	0.0	0.0	0.3

Table 20. Volume of blood after 20 s (µl).

Variable	Group	N	Mean	SD	Min	Max	Median	Q1	Q3
Volume of blood after 20 s (µl)	Sex: Female	548	24.9	23.7	0.0	169.1	18.1	7.8	35.5
	Sex: Male	652	25.1	24.1	0.0	188.0	17.8	7.8	35.7
Volume of blood after 2 min (µl)	Sex: Female	548	81.6	100.9	0.0	909.8	47.1	17.7	101.2
	Sex: Male	652	77.5	88.6	0.0	627.3	46.7	15.6	103.4

significant effect of age on the volume of blood at the end of the procedure was observed (with the age increase by 1 year, the blood volume obtained drops by an average of 0.650 µl (95% CI 0.211 – 1,087)). The lowest blood volumes at the end of the procedure were observed in the age group (18 – 30), the highest being in the age group of 45- 65 (Table18).

Pain assessment on vas scale at the end of procedure

In contrast to the pain sensation during the puncture, the statistical significant effect of age on pain assessment at the VAS scale was observed at the end of the procedure (with the age increase by 1 year, the score increased on average by 0.006 cm (95% CI 0.002 – 0.011). The lowest scores at the end of the procedure were observed in the age group (18 – 30) and (30 - 45), the highest being in the age group of 45 - 65 (Table 19).

Influence of sex on blood volume and pain assessment

Blood volume

In the clinical trial, there was no statistical significant effect of sex on the volume of blood after 20 (twenty) seconds and at the end of the puncture procedure (Table 20).

Pain assessment on VAS scale

There was a statistical significant effect of sex on the

Table 21. VAS result during the puncture (0-10 cm).

Variable	Group	N	Mean	SD	Min	Max	Median	Q1	Q3
VAS result during the puncture (0-10 cm)	Sex: Female	548	2.2	1.9	0.0	10.0	1.8	0.7	3.0
	Sex: Male	652	1.7	1.7	0.0	10.0	1.1	0.4	2.5
VAS result at the end of procedure (0-10 cm)	Sex: Female	548	0.4	1.2	0.0	9.0	0.0	0.0	0.2
	Sex: Male	652	0.2	0.7	0.0	9.0	0.0	0.0	0.0

Table 22. Volume of blood after 20 s (µl).

Variable	Group	N	Mean	SD	Min	Max	Median	Q1	Q3
Volume of blood after 20 s (µl)	Skin type: Normal skin	520	27.7	26.1	0.0	188.0	21.1	7.8	37.8
	Skin type: Moderate thickness	332	22.2	22.2	0.0	155.7	15.6	7.0	29.8
	Skin type: Severe thickness	348	23.7	21.4	0.0	94.5	16.7	7.2	36.7
Volume of blood after 2 min (µl)	Skin type: Normal skin	520	91.2	111.1	0.0	909.8	53.1	17.8	115.8
	Skin type: Moderate thickness	332	66.7	75.6	0.0	430.4	39.0	16.8	86.5
	Skin type: Severe thickness	348	73.9	80.7	0.0	423.8	43.7	14.9	103.5

Table 23. VAS result during the puncture (0-10 cm).

Variable	Group	N	Mean	SD	Min	Max	Median	Q1	Q3
VAS result during the puncture (0-10 cm)	Skin type: Normal skin	520	2.1	1.9	0.0	10.0	1.5	0.5	3.0
	Skin type: Moderate thickness	332	1.9	1.6	0.0	8.1	1.5	0.5	3.0
	Skin type: Severe thickness	348	1.7	1.7	0.0	10.0	1.1	0.5	2.5
VAS result at the end of procedure (0-10 cm)	Skin type: Normal skin	520	0.3	1.0	0.0	9.0	0.0	0.0	0.1
	Skin type: Moderate thickness	332	0.3	0.9	0.0	7.0	0.0	0.0	0.1
	Skin type: Severe thickness	348	0.3	0.9	0.0	9.0	0.0	0.0	0.0

assessment of pain on the VAS scale during the puncture and at the end of the study, as well as after averaging both results (in case of men the value of pain assessment is lower). During the puncture respectively, for male, the level of pain is 1.7 cm in VAS scale and for female, 2.2 cm; while at the end of the procedure pain sensation for males is 0.2 cm in VAS scale and for females, 0.4 cm (Table 21).

Influence of skin type on blood volume and pain assessment

Blood volume

A statistical significant effect of skin type on the volume of blood after 20 s and 2 min was observed. Subjects with moderate skin thickness and severe skin thickness obtain statistical significantly lower blood volumes of about 17% than subjects with normal skin (Table 22).

Pain assessment on VAS scale

No statistical significant influence of the skin type on pain perception directly after puncture, at the end of the procedure and after averaging both results was observed (Table 23).

DISCUSSION

In a clinical trial conducted on 300 volunteers in multivariable models, the thickness of the needle was

Table 24. The results of blood volume (µl) and pain level in the VAS scale (0-10 cm) for HTL-STREFA safety lancets.

Lancet name	Volume of blood after 20 (twenty) sec (ul)				Volume of blood after 2 (two) min(ul)			VAS result during the puncture (0-10cm)			VAS result at the end of procedure (0-10cm)		
	N	Mean	SD	Median	Mean	SD	Median	Mean	SD	Median	Mean	SD	Median
ergoLance Micro Flow 30G x 1.5 mm	25	15.1	21.4	7.1	34.2	53.5	16.0	1.0	1.1	0.5	1.0	0.1	2.0
Medlance Plus Super Lite 30G x 1.2 mm	25	17.7	21.2	7.8	47.0	62.4	18.4	1.0	1.4	0.2	2.0	0.2	3.0
MediSafe Solo 29G x 1.5 mm	25	19.9	18.9	14.5	56.9	66.5	27.8	1.0	1.1	0.9	1.1	0.1	1.3
Acti-Lance Lite 28G x 1.5 mm	25	18.4	18.4	8.9	64.6	71.3	33.3	1.6	1.3	1.0	3.0	0.1	0.8
Haemolance Micro Flow 28G x 1.6 mm	25	19.8	23.3	13.4	58.3	79.3	30.0	1.2	1.3	1.0	1.9	0.0	0.5
Prolance Micro Flow 28G x 1.6 mm	25	29.2	29.5	14.5	61.7	55.9	51.2	0.9	1.0	0.6	1.5	0.2	4.0
ergoLance Normal Flow 25G x 1.8 mm	25	27.9	27.8	18.9	83.7	97.5	31.1	1.1	0.7	1.0	1.5	0.2	4.3
Haemolance Low Flow 25G x 1.4 mm	25	31.1	28.3	23.4	105.2	122.0	69.0	1.5	1.5	1.0	2.0	0.1	2.2
Medlance Plus Lite 25G x 1.5 mm	25	15.6	18.8	9.2	38.3	44.9	21.1	0.9	1.1	0.5	1.0	0.2	2.0
Prolance Low Flow 25G x 1.4 mm	25	22.3	17.1	21.1	69.2	69.5	42.3	1.8	1.7	1.3	2.0	0.3	2.0
Acti-Lance Universal 23G x 1.8 mm	25	22.2	22.1	15.6	73.0	88.9	32.6	2.1	1.4	2.0	3.0	0.3	3.0
Medlance 23G x 1.8 mm	25	27.0	18.5	21.1	78.6	68.3	53.4	2.0	1.5	2.0	3.0	0.5	5.0
MediSafe Solo 23G x 2.0 mm	25	28.7	21.9	21.1	87.2	69.7	75.6	2.3	2.3	1.5	2.5	0.6	6.0
ergoLance High Flow 21G x 2.0 mm	25	36.3	26.0	30.0	145.1	128.3	94.5	1.8	1.7	1.5	2.0	0.3	3.1
Haemolnace Normal Flow 21G x 1.8 mm	25	15.8	17.4	10.0	48.2	70.9	28.9	2.3	2.2	2.0	3.0	0.7	9.0
Medlance Plus Universal 21G x 1.8 mm	25	23.3	25.7	17.7	84.4	111.2	47.5	2.0	2.3	1.0	3.0	0.4	5.0
Medlance Plus Extra 21G x 2.4 mm	25	28.4	20.6	24.1	105.4	102.0	86.5	1.7	1.2	1.5	3.0	0.1	2.0
Medlance 21G x 1.8 mm	25	30.8	26.6	22.0	105.7	123.9	77.9	1.8	1.8	1.4	3.0	0.2	2.0
Medlance 21G x 2.4 mm	25	29.8	25.7	27.6	83.9	78.5	61.7	2.6	1.7	2.0	4.0	0.8	6.0
Prolance Normal Flow 21G x 1.8 mm	25	24.5	16.1	22.0	71.8	60.7	55.3	2.5	1.9	2.0	3.1	0.7	4.0
Haemolance High Flow 18G x 1.8 mm	25	15.3	13.2	11.1	60.2	55.7	38.9	3.1	2.1	2.8	5.0	0.7	7.0
Prolance High Flow 18G x 1.8mm	25	30.2	22.0	31.1	96.4	81.8	80.1	1.7	1.6	1.3	2.0	0.4	3.0
Acti-Lance Special 17G x 2.0mm	25	29.4	27.6	21.1	98.8	95.9	70.1	2.8	2.0	2.6	4.0	0.1	1.0
Haemolance Max Flow 1.5mm x 1.6mm	25	40.8	35.5	34.5	189.0	192.0	149.0	3.1	2.5	2.0	4.1	0.4	3.0
Haemolance Pediatric 1.5 mm x 1.2 mm	25	36.6	30.4	31.1	142.4	117.9	111.2	2.0	1.7	2.0	2.8	0.6	7.0
Medlance 1.5 mm x 1.5 mm	25	35.3	24.8	31.1	133.4	101.5	128.3	2.4	1.9	2.0	3.1	0.4	3.1
Medlance 1.5 mm x 2.0 mm	25	32.3	23.5	22.2	136.8	118.2	100.7	2.7	1.8	2.5	4.0	0.3	3.0
Medlance 1.5 mm x 1.0 mm	25	30.6	24.1	25.6	85.8	85.3	48.9	1.5	1.6	1.0	2.0	0.4	6.0
Prolance Max Flow 1.5 mm x 1.6 mm	25	39.0	35.8	32.3	156.9	155.4	93.4	3.1	2.1	3.0	4.0	0.4	6.0
Prolance Pediatric 1.5mm x 1.2 mm	25	35.0	30.3	30.0	136.5	131.3	84.5	2.7	2.1	2.0	4.5	0.2	2.0
Medlance Plus Special 0.8 mm x 2.0 mm	25	33.2	26.8	25.6	137.9	112.4	124.8	1.4	1.1	1.5	2.0	0.3	4.1

identified as the main parameter statistically and significantly affecting the blood volume and pain assessment, along with the increase of needle

thickness, both the volume of blood and the VAS score increases. While the puncture penetration depth does not statistical significantly affect the blood volume, it affects the sensation of pain during the puncture; with the increase of penetration depth, the pain score also increases. The normal thickness of the epidermis of the middle fingers is about 0.3 mm, and that of the dermis is 1.5 mm. The papillary layer has about 0.3 to 0.4 mm thickness. (Cormack D (1987; Moore et al. (2003) Analyzing the above results, it is reasonable to choose a lancet depending on the appropriate needle diameter and not penetration depth but not shorter than 1 mm. (Kim S (2010), Since the needle diameter is a parameter that influences blood volume, those safety lancets should be chosen, which will give a sufficient blood volume to perform the blood test at a relatively low pain sensation. Too deep penetration depth increases the sensation of pain and can cause inflammation in the site or accidental contact with the bone which can cause osteomyelitis. Therefore, safety lancets with penetration depth to 3 mm should be selected. (Klieger DM (2010).

Other parameters affecting the volume of blood obtained after the puncture are age, skin type and activation method. In multifactorial models, age was identified as a parameter statistical significantly affecting the blood volume after seconds and 2 min and pain assessment at the end of the procedure. With the increase of age, the volume of blood obtained increases after 20 s and 2 min and the value of VAS assessment increases at the end of the procedure. This is conditioned by the flexibility of capillaries. With age, due to changes that occur in the human body and the aging process, they lose their flexibility and thus become more vulnerable to mechanical damage (Xu et al., 2017; McDuell and Booth, 2002). Because epidermal thickness is associated with age, gender, skin type, pigmentation, blood content, smoking also the type of skin statistical significantly affects the blood volume after a puncture with the safety lancet (Sandby-Moller et al., 2003)

Subjects with moderate skin thickness and severe skin thickness gain significantly lower blood volumes than subjects with normal skin, although the type of skin does not significantly affect the pain assessment. In addition, the activation method significantly affects the volume of blood after 20 (twenty) seconds. Contact activated lancets may not provide sufficient blood volume and are suitable for smaller blood samples (one drop of blood). Push-button activated safety lancets are suitable if bigger blood samples are required (several blood drops).

Analyzing the above clinical results, it can be concluded that not only the needle diameter and depth penetration influence the volume of blood and the pain perception, but also individual human factors and parameters of safety lancet. To avoid a repeated puncture in a situation where not enough blood is obtained to perform a blood test or there is a need to get a larger blood volume, safety lancet should be selected depending on the testing purpose and expected effect (µl). The puncture procedure used in the clinical trial also helps to obtain an expected blood volume minimizing patients' discomfort at the same time.

Conclusion

Based on the clinical results for all of the 48 safety lancets the study clearly demonstrated that all the safety lancets were well tolerated. Safety features (i.e. single-use device, no needle exposure) of all safety lancets were fulfilled and did not differ from information described in the Investigator's Brochure.

Based on the results obtained from a group of 300 volunteers (1200 punctures) it can be concluded that all types of safety lancets are safe for both patients and medical personnel. Moreover, it has been found that as the thickness of the needle increases, the amount of blood sample increases too. The influence of safety lancets activation method on blood volumes or the pain sensation was not observed. All the tested safety lancets give an optimal and sufficient volume of blood after puncture and are suitable for professional use, whereas the blood volume obtained after puncturing with different types of lancets but the same needle diameter (Gauge) varies depending on the company. Tested safety lancets do not pose a risk to health and are safe for all users.

All safety lancets tested in clinical trial are consistent with their intended use and have shown their effectiveness in capillary blood sampling. In addition, safety lancets have been highly evaluated by research personnel in terms of comfort of puncture process for both patients and the research staff. The level of pain in the VASt majority of cases was assessed as minimal or low.

Based on the above, safety lancets manufactured by HTL-STREFA S.A. can be used for capillary blood diagnostic tests from few µl to over 100 µl as they show high quality, efficacy and convenience clinically proven. Table 24 shows the dependence of the size of HTL-STREFA safety lancets on volume of blood and pain perception according to the VAS scale, to align proper safety lancet size to blood test requirements recommended for various diagnostic assays.

CONFLICT OF INTERESTS

The authors have not declared any conflict of interests.

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