Local anesthesia electronically controlled in small procedures and superficial interventions.

Authors: **Roberto Kasuo Miyake[*], M.D., Ph.D; Ronald Fidelis[*], M.D.; Flavio Duarte[**], M.D.; Rodrigo Kikuchi[**], M.D.; Hiroshi Miyake[*], M.D., Ph.D.; Elisabeth Miyake, M.D.[***]; John Davidson, M.D.[****]**

*Vascular Surgeon – MD; PHD / **Vascular Surgeon / ***Anesthesiologist / ****Radiologist

E-Mail: kasuomiyake@hotmail.com

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Abstract

Background: Among the limitations of the traditional local anesthesia are the facts that the flow delivery rate is not constant, having the performer's hand by plunger, making flow rate control rather difficult and painful.
Objective: This study aimed to evaluate local anesthesia efficiency when a computerized anesthetic delivery system is used for ambulatory treatment of minor varicose veins.
Methods: Twenty patients were submitted to 23 procedures for reticular varicose veins treatment. Both techniques were used: traditional and computerized. A visual analog scale was used for pain score.
Results: Computerized anesthesia delivery was as effective as traditional syringe technique. Eighty percent of the patients reported the computerized local anesthesia delivery to be less painful than traditional syringe injection.
Conclusion: The computer-controlled local anesthetic delivery is as effective as the traditional syringe injection and it also provides the patient a more pleasant experience during delivery.

Resumen

Antecedentes: *Entre las limitaciones de la anestesia local tradicional es un hecho que en la ejecución manual, el flujo aplicado no es constante, tener un control de cantidad y velocidad de flujo es bastante difícil y resulta doloroso.*
Objetivo: *El objetivo del estudio fue evaluar la eficiencia de la anestesia local, utilizando la administración computarizada de la misma, para el tratamiento ambulatorio de várices menores.*
Método: *Veinte pacientes fueron sometidos a 23 procedimientos para tratamiento de várices reticulares. Se utilizaron ambas técnicas: anestesia tradicional y computarizada. Una escala analógica visual de dolor se utilizó para la comparación.*
Resultado: *La anestesia computarizada fue tan efectiva como la técnica tradicional con jeringa. El ochenta por ciento de los pacientes informó que la aplicación computarizada de la anestesia local resultó ser menos dolorosa que la tradicional.*
Conclusión: *El equipo de liberación controlada computarizada del anestésico local es igual de eficaz que la tradicional jeringa de inyección y también proporciona al paciente una experiencia más agradable durante el procedimiento.*

Introduction

Local injection anesthesia is often used on small ambulatory procedures and superficial interventions.

Despite the advantages of traditional local anesthesia by injection, there are some limitations to its technique. Among the most important ones is the fact that it can be painful and the pain increases if the flow rate delivery is not constant. Another problem is the fact that the plunger that drives the syringe embolus is the performer's hand, making the precise control of flow rate rather difficult. Such characteristic makes it difficult to standardize the anesthesia delivery.

Milgrom et al[1] published, in 1997, a study analyzing the fear reactions aroused by the perspective of anesthetic injection in the oral cavity, and in the same year Friedman et al[2], described the use of a computerized local anesthesia delivery (CLAD)* in dental procedures. That system* allows precise delivery of drug at a constant flow rate (0,005 ml by bip= 20 bips for 0,1 ml) despite varying tissue resistance (Fig 1). A drop of the anesthetic solution deposited ahead of the needle tip anesthetizes the access path of the needle for the injection. Additionally, the delivery flow rate is low and constant making the anesthesia process less painful and more effective. Another advantage described is the delivery operated by foot pedal, allowing the performer a pen-like grasp, providing a lot more preciseness and accuracy during delivery, thus, reducing needle tip oscillation in the tissues[3].

Despite the described advantages of this new technique, no study has yet been published to evaluate and compare this type of procedure on the skin.

This paper aims at evaluating the local anesthesia efficiency when the CLAD system is used compared to the traditional injection technique, taking into account the amount of pain referred to by the patients during puncture for each of the methods. The tested hypothesis was that CLAD could offer the same anesthetic effect as the traditional syringe technique during the procedure performance while providing greater comfort to patients.

* The Wand™. Milestone Scientific™.

Methods

This study was designed to evaluate this new method of local anesthesia during phlebectomy, a procedure known worldwide.

Patients in this study were seen at Clinica Miyake from February through August 2002. Inclusion criteria was the presence of varicose veins in the lower limbs requiring surgery, whose problematic areas were eligible to undergo procedures with local anesthesia. In order to avoid the interference of naturally painful pathological processes, excluded from the study were patients that showed symptoms of phlebitis, or any painful manifestation near the varicose veins between the moment of the indication and the actual surgery.

All patients signed an informed consent agreeing on participating in the study after receiving explanation of the entire procedure.

Technique:

Spots were selected to be anesthetized along the vein to be removed (at maximum 20 spots per patient), marked by dots and identified by either a numerical or an alphabetical sequence, randomized by raffling the first one and then alternating the CLAD (W) and the syringe (S) dots.

For local anesthesia, a standard technique called "anesthesia in two steps" was used. Dots distant from each other about one centimeter set the varicose veins path. A 27-gauge ½-inch needle and prilocaine chlorhydrate 3% was

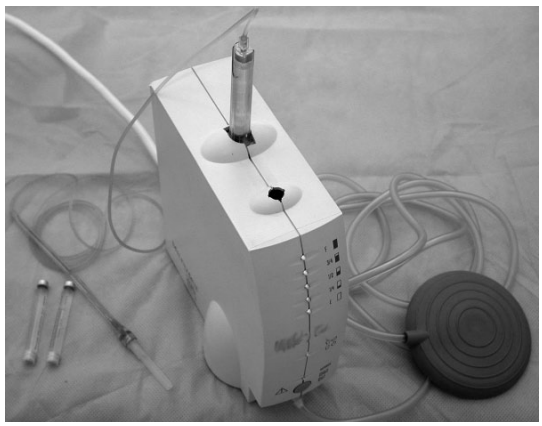


Fig. 1: Computerized local anesthesia delivery device (CLAD).

used. In the first step, one dot from a group of three (or more, depending on proximity) was anesthetized. After five minutes, injection on the intermediate dots starts by inserting the needle through the former dots, to reach the missing areas. This way, only 1/3 of the total anesthetic punctures are needed for the due leg extension in a first phase. The remaining areas of the leg are punctured in the second step when the anesthetics effect of the first pass is already taking place (Figs.2 and 3).

A minimal distance of 2cm was kept between infiltrations, attempting to avoid interference from the previous puncture on the next one. A volume of 0,1ml was delivered with the needle placed perpendicularly onto the skin surface, either measured by a 3ml syringe in the traditional injection technique, or measured by 20 beeps in CLAD.

Twenty-three phlebectomies were performed on 20 patients over a period of six months. Two men and 18 women were operated on. Ages ranged from 27 to 71 years. Clinical profiles of these patients are shown in Table-1.

Fig. 2: Anesthetic procedure in two steps. The figure demonstrates the first moment using the traditional injection technique .

Fig. 3: Anesthetic procedure using the CLAD. The letters mark the first step of the anesthetic technique.

Pain evaluation:

For the objective pain score during delivery a visual analog scale5 (V.A.S) was used. It is a visual graduated numeric scale (0-10) in one side and a visual non-graduated scale on the other side. A plastic transparent slider is placed by the patient when requested by the observer. On the numeric side zero equals no pain, and ten equals excruciating pain. The numbered side of VAS was showed only to the observer. The more intense the pain, the higher was the number marked by patients (Fig 4 and 5).

Data record:

An independent observer on a card especially designed for this study recorded the results.

All patients were blinded to the randomization process. Even during manual syringe injection CLAD was operated, so the patients would hear the beeps and could not differentiate the kind of injection they were being given.

Anesthetic effectiveness evaluation:

Effectiveness of anesthesia on each dot was tested by a pinch with a 40x12 needle on the

Table 1: Patients profile

Sex	
Female	18
Male	02
Previous pregnancy	10
PI	03
PII	04
PIII	01
PIV	02
Smokers	02
Contraceptive use	02
Varicose vein surgery	02
High blood pressure	01
Family history of varicose veins	11
Sedentarism	12

infiltrated place. The need of any anesthetic supplement was accounted for as failure of the initial infiltration, and it was recorded on a specific field on the data card.

Statistics Analysis:
In order to compare data, the analysis that was carried out observed the following assertions:

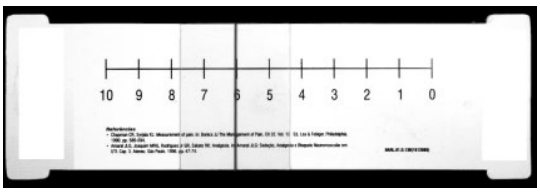


Fig. 4: Visual Analog Scale. The figure shows the numeric scale side (only seen by the test performer).

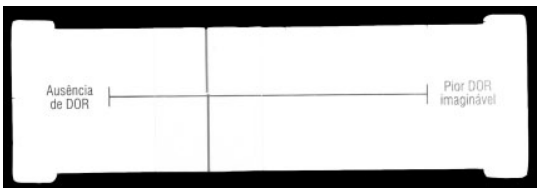


Fig. 5: Visual Analog Scale. The figure shows the non-numeric scale (as shown to patients).

1. Two means were compared: pain W and pain S – without CLAD.
2. Paired samples.

For assertions 1 and 2 of our sample, Student´s t-test was used following the rule for paired samples. $P < 0,05$ was considered statically significant.

Results

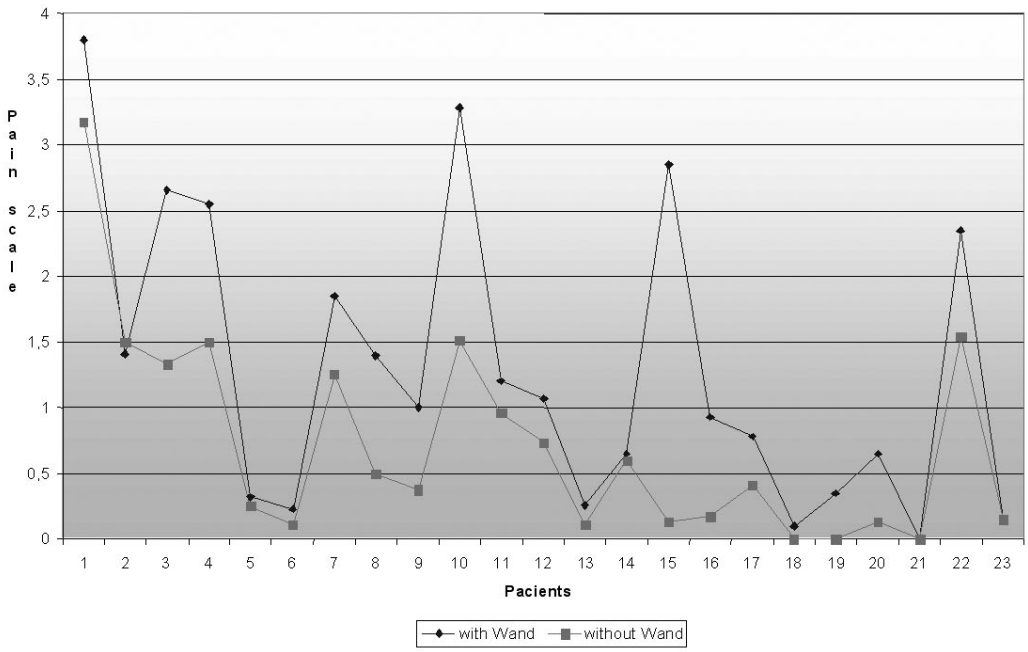
The 23 procedures accounted for a total of 157 punctures with CLAD and 136 punctures without CLAD.

Only one patient (2) presented the mean score on the superior end of the pain scale with the use of CLAD. Two patients (21 and 23) had the same mean score on the pain scale for both procedures, with and without CLAD.

The mean scores on the pain scale were different with and without the use of CLAD, and such difference was considered to be highly significant for the study when data were submitted to the statistical analysis (Table-2).

Graphic 1 represents the mean score of pain for both methods for each of the patients.

In graphic 2 the total S and W means are showed, and a lower mean value for anesthesia with CLAD can be noticed.



Graphic 1: Means representation for each patient

In graphic 3 the percentage of each technique accounting for the numeric total of pain for each patient is quantified. The traditional syringe technique, once more, showed to be more painful than CLAD. At procedure 21, no value was given to any of the punctures, neither with CLAD, nor with the syringe.

Regarding anesthetic efficacy of each technique, the S technique was effective 92% of the times, and CLAD technique did not need any supplement 89% of the times, but this was not a statistically significant difference.

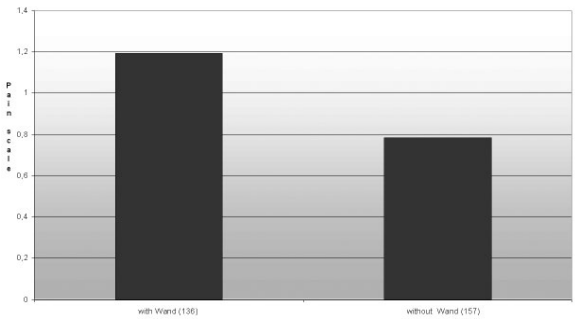
Discussion

Resection of lateral varicose veins, and even insufficient saphenous veins, has been safely performed and well accepted at ambulatory level7-12 since the beginning of the 70´s, despite the only late publishing of guidelines for outpatient surgery in 19856. However, nothing had been recorded so far comparing traditional injection technique to CLAD.

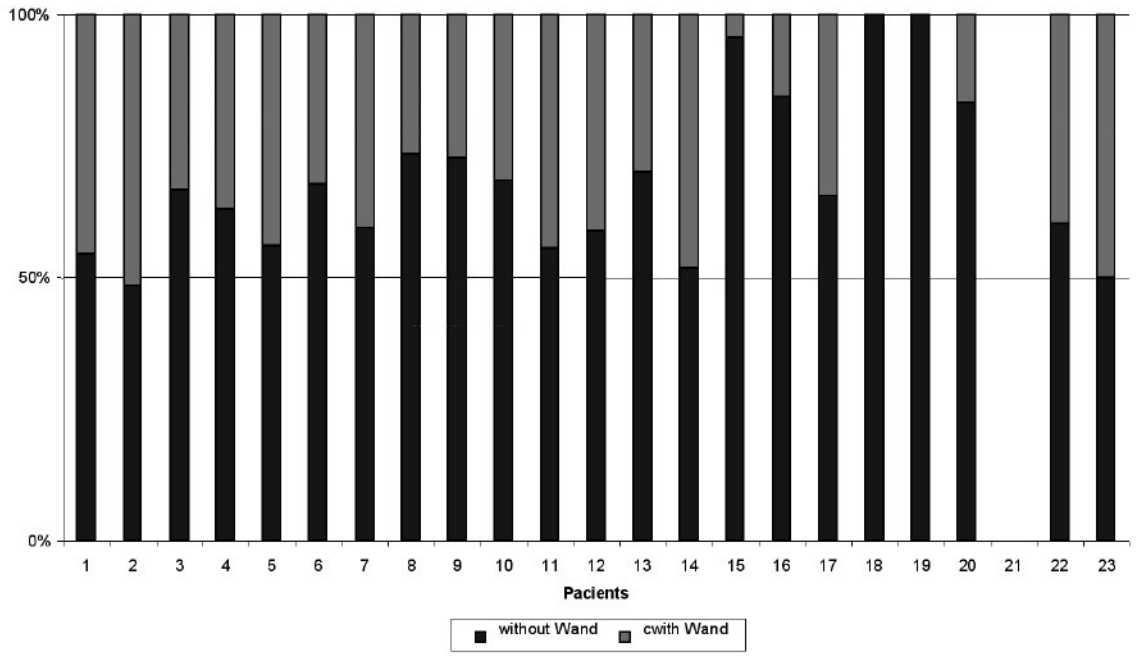
The use of CLAD for dental anesthesia started just a few years ago13-17.

In the reports on dental anesthesia, CLAD proved to be more comfortable for the patient than traditional syringe injection, but just as efficient. Besides, evaluation of the patient's anxiety level showed reduction of about 88% with the CLAD anesthesia.

Based on that information, Tan et al.18, carried out a comparative study between CLAD and traditional injection technique for minor anal procedures. In that study, a statistically significant difference was found in the results of 20 patients. Patients were randomized to receive anal anesthesia using either CLAD or traditional syringe technique to a randomly selected half of the anoderm (right or left). Therefore, the patients acted as their own control. Results



Graphic 2: Mean of pain reported of all applications



Graphic 3: Comparative distribution of the total values of the pain scale for each patient

showed that 80% of the patients reported CLAD delivery to be less painful than traditional syringe technique. CLAD anesthetic effectiveness was similar to the traditional syringe technique in the delivery of local anesthesia.

This present study expands the application of CLAD on the skin surface anesthesia, dealing with resection of feeble veins, yet painless. Considering several anesthetized spots on a single patient allowed for an objective comparison of the two techniques, being the individual his/her own control. It should be pointed out that the alternating of W spots and S spots reflected the authors concern about pairing up both techniques, also regarding the different areas studied with their respective differences of sensitivity. In this study, 87% of the patients considered the CLAD anesthesia delivery to be less painful but as effective as the traditional syringe technique.

Table 2: Significance level

Patient	Without Wand	With Wand	Difference between means
1	3,80	3,18	0,62
2	1,41	1,50	-0,09
3	2,66	1,33	1,33
4	2,55	1,50	1,05
5	0,32	0,25	0,07
6	0,23	0,11	0,12
7	1,85	1,25	0,60
8	1,40	0,50	0,90
9	1,00	0,375	0,63
10	3,28	1,51	1,77
11	1,20	0,96	0,24
12	1,07	0,74	0,33
13	0,26	0,11	0,15
14	0,65	0,60	0,05
15	2,85	0,13	2,72
16	0,93	0,17	0,76
17	0,78	0,41	0,37
18	0,10	0,00	0,10
19	0,35	0,00	0,35
20	0,65	0,13	0,52
21	0,00	0,00	0,00
22	2,35	1,54	0,81
23	0,15	0,15	0,00
Mean of total of applications	1,194 (136)	0,784 (157)	0,58
t=4,3629	p<0,001		

The reasons for CLAD delivery to be less painful are speculative, but the authors of this study believe that the low and constant flow rate during the infiltration process is the main cause for this effect (0.005ml/second). At a low flow rate, infiltration causes less tissue distention and therefore less pain. Malamed19, in a handbook of local anesthesia, recommends a syringe infiltration rate lower than 0.1ml/second.

Besides infiltration flow rate, the possibility of a steadier manipulation of the injector device avoids undesired trembling (in any direction), since the operator's thumb is not the plunger of the syringe anymore. That may also be a factor favoring CLAD once those movements are usually painful.

Factors related to psychological aspects of the patient, such as the notion of the CLAD delivery and the absence of the traditional syringe needle may have contributed to the observed differences favoring the CLAD. These aspects cannot be measured though.

Old and complex reports are found in the literature attempting to standardize and develop a universal language to evaluate the intensity and treatment of pain. Huskisson20 published a meta-analysis where several methods of pain quantification are described, from purely descriptive scales, through numeric scales, to visual scales. They all have advantages and disadvantages, but none of them has managed to avoid the biggest problem of such type of evaluation: subjectivity. The pain scale used in this study was found to be, based on literature, the most reproducible and least subjective among the known and tested scales. In this study, the absolute values of the pain scale do not have any value by themselves, however, information of minimal, maximal, and middle values on the pain scale for both techniques made a comparative evaluation possible.

A single individual referred complete absence of pain on all punctures. Despite being an unusual result, such datum clearly demonstrates the pain tolerance differences between patients.

Conclusion

The difference between CLAD and the traditional syringe delivery was highly significant for the studied sample. The CLAD it is not only as effective as the traditional syringe injection, but it also provides the patient a more pleasant experience during delivery.

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