Original article

Evaluation of the pain in varicose vein surgery under tumescent local anaesthesia using sodium bicarbonate as excipient without any intravenous sedation

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Abstract

***Objective*:** In order to simplify varicose vein surgery, we studied the possibility of tumescent local anaesthesia (TLA) using sodium bicarbonate 1.4% as excipient without any intravenous sedation.

***Methods*:** For three months, 215 patients were included in two centres for ambulatory varicose vein surgery performed without any intravenous sedation. Clinical results and pain were evaluated according to the type and duration of surgery.

***Results*:** Mean perioperative pain was evaluated at 2.7 on a visual scale (0–10). In 91% of the cases, surgery was deemed to be slightly painful. Preoperative pain was not linked to the technical means of surgery but to the psychological and organizational environment of the centre.

***Conclusions*:** In many of the cases, varicose vein surgery could be performed under TLA without any intravenous sedation. Ambulatory varicose vein surgery without any intravenous sedation could be highly cost-effective.

Keywords: varicose vein; ambulatory surgery; tumescence; sodium bicarbonate

Introduction

For a long time, tumescent local anaesthesia (TLA) has been used in plastic surgery and for phlebectomy.[1,2] Usually, the Klein solution was used, which is adrenaline and lidocaine diluted in a saline serum. In these solutions, sodium bicarbonate at a low concentration was used to neutralize lidocaine acidity and render injections less painful.

There are few studies about stripping surgery performed with TLA[3–6] and in these studies TLA is often associated with intravenous sedation, which sometimes makes ambulatory surgery difficult or uncomfortable. The use of sodium bicarbonate 1.4% as pure excipient greatly facilitates TLA.[7] Anaesthesia is immediate and deeper, which enables us to make surgery even easier without any sedation. The aim of this survey was to study the feasibility of varicose vein surgery under TLA using sodium bicarbonate 1.4% as excipient and without any intravenous sedation.

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Accepted 21 June 2011

Methods

For three months, 215 patients were included in two private surgical centres in France. In a centre (DC), after being informed during the preoperative consultation, 53% of the patients chose this type of anaesthesia, which represented 130 cases; in another centre (BR), 96% of the patients chose this type of anaesthesia, that is to say 85 cases. Explanations were given to the patients; those who were too stressed or reluctant to undergo this type of anaesthesia were excluded.

Mean age was 51.0 ± 13.8 years (range = 19.0–91.0) with a majority of women (82.8% women and 17.2% men). The patients' occupations were recorded as well as their weight and height.

Preoperatively, varicose vein pain was evaluated on an analogue scale ranging from 1 to 10. The CEAP (clinical, aetiological, anatomical and pathological elements) class C classification, VCSS score, arrival time, waiting time before surgery, surgery duration and complete length of stay in hospital were recorded.

Each limb was divided into 32 zones according to a previous publication.[8] After preoperative duplex scan mapping, the number of surgery areas that included either phlebectomies or stripping or thermo-ablation of truncular segments was noted. Patients were told to arrive in the morning after eating breakfast, as usual. Surgery was performed in an operating room without any particular monitoring. The patients' faces were not covered with sterile operative fields in order to communicate visually and orally. On the day before surgery, for some patients (BR), premedication was carried out thanks to homeopathic granules (Lachésis® 15 CH) and for others (DC) thanks to 1/4 or 1/2 Lexomil® tablet (Bromazépan).

All the operations were performed under TLA. The tumescent liquid was obtained by diluting lidocaine 1% (20 mL contain 200 mg lidocaine). A solution of 14 mL of 1% lidocaine (with 1:100.000 epinephrine) was diluted in a bottle with 500 mL of sodium bicarbonate 1.4% (lidocaine dilution at about 0.028%). Injections were performed with 25 Gauge needles, with syringes or an electric pump. The tumescence volume was recorded.

All the operations included phlebectomies; their number was recorded. Elements likely to be painful (flush ligation, redo incision, stripping and stripping length) were also recorded. Some other surgery factors requiring additional punctures were also recorded (perioperative sclerosis, endovascular procedure). All these surgical elements were performed in the least aggressive way: incisions for phlebectomy with an 18 Gauge needle, the smallest possible incisions, minimal dissections and invagination stripping. All the incisions were sown with intradermal sutures or Steri-Strips. Double compression with a class II elastic stocking was placed for 48 hours and then replaced with one single stocking for one week.

Every patient filled in a questionnaire to evaluate the surgery pain on an analogue scale ranging from 0 to 10, along with pain duration (from some seconds to some minutes or much longer). Surgery global pain was also rated by the patient according to four types: 'extremely,' 'rather,' 'slightly' and 'not at all' painful.

On the day following surgery, the patients could go back home and filled in the same questionnaire; antalgic medication taken at home was recorded too. Work resumption date was mentioned. Two months later, the patients had to bring back their questionnaire while undergoing a postoperative consultation. We studied the factors that could have had an influence on the patients' pain during surgery, either objective (surgery traumatism) or subjective (preoperative waiting time or surgery duration) elements.

Procedure cost was calculated by taking into account (French) medical fees and operation expenses reimbursement rate.

Statistical analysis

Descriptions were carried out by traditional elements: average, standard deviation, median and quartiles for the quantitative variables, effective and percentages for the qualitative variables, missing data. The comparisons of averages were carried out by variance analyses and the comparisons of proportions by Khi^2 tests. Since pain is a qualitative variable, we compared the distribution of the influencing factors, objective and subjective, pain being present or not (Khi^2). For some statistical evaluations, the analogue scale results or the four answers evaluation ('extremely,' 'rather,' 'slightly' and 'not at all' painful) were brought together in three groups: slightly pain group (0–3), moderate pain group (4–6) and painful group (7–10).

Results

Population

Working people represented 69.9% (craftsmen, farmers, workers and traders amounted to only 6.4%). This population was similar to other French eastern populations with varicose veins investigated in another study.[9] Mean body mass index was 23.8 ± 13.8 (16.8–42.1). The majority of the patients were classified C2, 30 were classified C3, 26 were C4a, four were C4b, one was C5 and one was C6, mean VCSS score was 1.5 ± 1.4 (1.0–13.0), and mean varicose vein pain evaluated by the patients before surgery was 3.0 (Figure 1). For 63.6% of the patients the pain was evaluated as light (0–3), for 24.3 as moderate (4–6) and for only 12.1% as severe (7–10).

Surgery

In this series, we had no failures, that is to say no conversion into intravenous sedation during

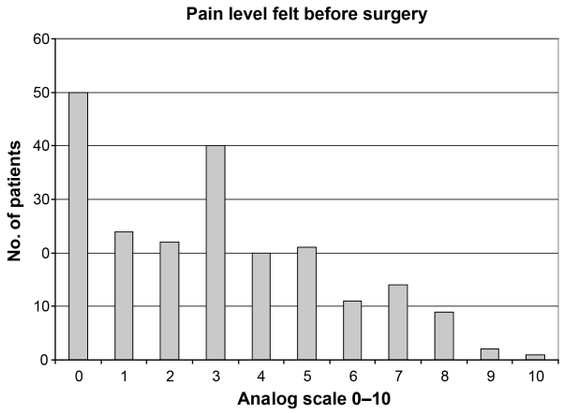

Figure 1 Distribution of the pain level felt by the patients on the leg before surgery and evaluated on an analogue scale ranging from 0 = no pain to 10 = extremely painful

surgery. We did not need any waiting period between tumescence injections and surgery; anaesthesia was always immediate after tumescence injections. We did not observe any precipitation in the tumescent solution after the addition of lidocaine.

The descriptions of different types of operation are reported in Table 1. Inguinal incisions were carried out for saphenous trunk ligation under the collaterals of the SFJ as well as for flush ligation or for redo surgery. Mean length of stripping was 30.1 ± 21.7 cm (range = 12.0–115.0 cm). Complete phlebectomies were performed for all the operations.

Mean number of operated on zones was 6.1 ± 2.6 (1.0–17.0). Mean number of phlebectomies was 24.0 ± 13.0 (3.0–63.0). Mean volume of tumescence was 268.1 ± 127.1 mL (range = 20.0–750.0 mL). Taking into account the dilution of lidocaine epinephrine and the patients' mean weight (65.7 ± 12.0 kg; 42.0–106.0), it corresponded to a mean 75.1 ± 35.6 mg of lidocaine and 0.037 ± 0.0178 mg of epinephrine injected to the patients, which represents means of 1.17 ± 0.54 mg of lidocaine per kg bodyweight and 0.58 ± 0.27 μg epinephrine/kg bodyweight.

The different levels of pain sustained during surgery and evaluated by the patients are recorded in Figure 2. Mean pain level was 2.7 ± 2.1 (0.0–9.0). In 69.3% of the cases, the pain was considered 'light' (0–3); in 25.5%, it was considered 'middle' (4–6) and 'severe' (7–10) in 5.2%. In 91.9% of the cases, surgery was considered as 'very little' or 'not at all' painful. In 8.1% of the cases, surgery was considered as rather painful (for 81.2% of those patients, pain lasted for only a few seconds and for 17.4%, some minutes). No patients considered this surgery as extremely painful. When asked whether they would undergo this type of anaesthesia again, 97.7% of the patients said they would.

As for hospital stay, 66.5% of the patients waited for less than two and a half hours before the beginning of surgery. Mean waiting time was two hours and 18 minutes (30 minutes – 8 hours). Mean surgery time between the first TLA injection and the last phlebectomy was 32 ± 14 minutes (8–77 minutes). In 82.8% of the cases, the patients were dismissed less than two hours after surgery. Mean postoperative duration was one hour and 45 minutes (30 minutes – 7 hours). Mean length of hospital stay was four hours and 10 minutes (2–9 hours).

Distances between the hospital and the patients' homes are recorded in Figure 3. Mean distance was 41.9 ± 42.1 km (1–200 km).

Table 1 Classification of the operations and different parts of the operations (one operation could incorporate several parts)

	n = 215	%
Left surgery	110	51.1
Right surgery	83	38.6
Bilateral surgery	22	10.2
GSV territory	166	77.2
SSV territory	45	20.9
GSV + SSV territory	4	1.8
Inguinal or popliteal incision	40	18.6
Inguinal redo incision	2	0.9
Stripping GSV or SSV	69	32.1
Radiofrequency GSV or SSV	26	12
Endovenous laser GSV or SSV	7	3.2
Perioperative foam sclerotherapy	41	19.1
Steam vein sclerosis GSV	3	1.3
Radiofrequency-induced thermotherapy (RFITT)	1	0.04
Phlebectomies	215	100

GSV, great saphenous vein; SSV, small saphenous vein

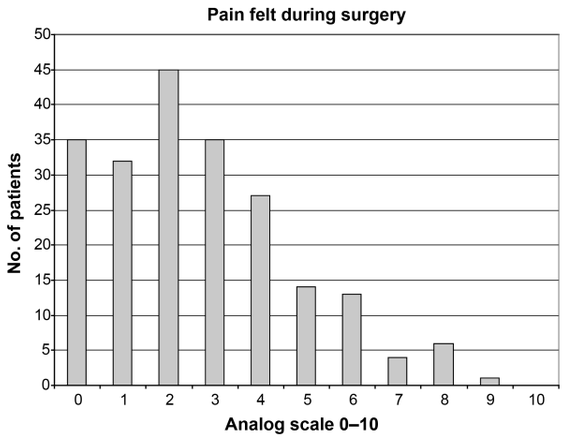

Figure 2 Distribution of the pain felt by the patients during surgery evaluated on an analogue scale ranging from 0 = no pain to 10 = extremely painful

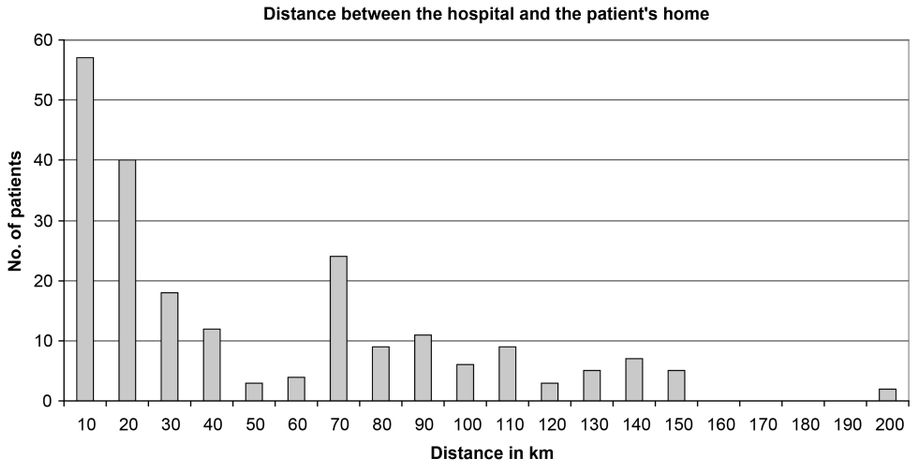

Figure 3 Distribution of the distances (in km) between the hospital and the operated on patients' homes

There were no complications of the bicarbonate 1.4% injections either locally during surgery or in general after surgery. There were, in particular, no signs of lidocaine or epinephrine overdosage.

Relations between painful feelings and environmental elements

A weak correlation is observed between the pain felt during surgery and the pain felt by the patient before surgery (Spearman's correlation $r = 0.24$, $P = 0.0003$).

Patients who had waited for more than two and a half hours before surgery felt pain much more often than others (global pain was rated by patients according to four types: 'extremely,' 'rather,' 'slightly' and 'not at all' painful) (84.7% versus 15.3%, $P < 0.01$).

Pain felt by patients was on average at 2.4 ± 2.2 for patients operated on in less than six zones and at 3.2 ± 1.8 for patients operated on in more than six zones (Anova: $P < 0.01$).

Mean surgery time, less or more than 30 minutes, did not influence perioperative pain (Khi^2: $P = 0.2321$).

When more than 30 incisions were performed, patients felt a pain significantly more important (3.4 ± 2.1) than when 16–30 incisions (2.2 ± 1.9) or less than 16 incisions (2.8 ± 2.2, Anova: $P < 0.01$) were performed.

Patients operated on by BR felt significantly less pain than patients operated on by DC (1.9 ± 2.3 versus 3.2 ± 1.8; Anova: $P < 0.0001$).

As for surgery elements that could be painful, none of them were factors likely to increase pain (Anova stripping: $P = 0.4304$, Anova flush ligation or redo surgery: $P = 0.9035$).

Results on the following day and at 60 days

Out of 125 questionnaires gathered at 60 days, only 11.4% of the patients took analgesics on the day following surgery. The pain of the evaluated limb amounted to 2.1 ± 1.6 on the analogue scale on the day following surgery. Among the patients who went back to work, 51.2% went back on the day following surgery; the others (48.8%) took an average 10-day sick leave (10.0 ± 4.8 days). This rather long time was not related to the pain but to the type of occupation (comfort sick leave). When asked whether they would undergo this type of anaesthesia again, 96.0% of the patients said they would.

Cost-saving

In France intravenous sedation has to be performed by an anaesthesiologist. The cost generated by the presence of an anaesthesiologist includes preoperative consultation, set up and surveillance of the sedation. There were five different types of cost for five different types of operation. Without an anaesthesiologist, the cost-saving was 44% for unilateral phlebectomies, 41.1% for bilateral phlebectomies, 38.8% for a stripping, 36.1% for a stripping with controlateral phlebectomies and 31.2% for inguinal redo incision with controlateral phlebectomies. In total, the cost-saving concerning the 215 cases performed under TLA without intravenous sedation was 22,051€. For the same operations with parenteral sedation carried out with an

anaesthesiologist, it would have cost 52,839€ instead of 30,788€.

Discussion

The use of pure sodium bicarbonate 1.4% as tumescent solution facilitates surgery by eliminating the onset time and using even less lidocaine. Therefore, it is used at 0.028% with a 1.17 mg/kg bodyweight concentration, which makes it easy to be ambulatory and without any sedation. In fact, 97.7% of the patients said that, if needed, they would be willing to undergo this type of anaesthesia again.

Concerning local anaesthesia, it has been speculated that the pain linked to infiltration may result from the acidity of the anaesthetic solution. However, alkalinization of local anaesthetic solutions may cause precipitation.[10] Actually, it has been demonstrated that 1 mL of 1% sodium bicarbonate solution may be used to alkalinize this range of local anaesthetics without the risk of precipitation.[11]

Usually the solution used for TLA is a saline solution or lactated Ringer's solution which generally contains sodium, chloride, potassium and lactate.

For our liquid of tumescence, sodium bicarbonate 1.4% was used instead of saline solution or Ringer's solution. Very good efficiency and anaesthesia duration are both the main advantages of this excipient as well as painless injection and the absence of onset time.

Lidocaine is most often used at a concentration of 500 mg/L saline solution.[12,13] Another proposes the use of a lower lidocaine concentration of 400 mg/L saline solution.[14] Thanks to the excipient made of pure sodium bicarbonate at 1.4%, operations with lidocaine at a concentration of 280 mg/L bicarbonate are commonly carried out.

In our experience, lidocaine was used without any onset and it was much more diluted than the one currently recommended by many authors: lidocaine dilution (0.05% to 0.1%) and epinephrine dilution (1:1,000,000).[13,15,16] In our study, lidocaine dilution was 0.028% and epinephrine dilution was 0.14:1,000,000 (Table 2).

Usually the recommended dose of lidocaine is 35–45 mg/kg bodyweight and these doses should not exceed 55 mg/kg bodyweight;[15,17–19] for epinephrine, the total dosage should not exceed 50 μg/kg bodyweight.[20] In our study, mean concentration of lidocaine was far lower: 1.17 ± 0.54 mg/kg bodyweight (almost 50 times lower) and the concentration of epinephrine at 0.58 ± 0.27 μg/kg bodyweight, hence far below the maximum recommendation, almost 100 times lower.

Table 2 Comparison of concentration lidocaine volume % in the usual recommendations[13,15,16] and in our practice[7]

	Saline serum 0.9% (mL)	$NaHCO_3$ 1.4% (mL)	Lidocaine epinephrine	Concentration lidocaine volume (%)
[13]	450	60	50 mL 1%	0.1
[15]	450	60	50 mL 2%	0.2
[16]	400	60	100 mL 2%	0.4
Personal[7]		500	14 mL 1%	0.028

This demonstrates the high potentiating role of pure sodium bicarbonate 1.4% used as excipient in TLA. It enables us to use less lidocaine epinephrine, to dilute it 10 more times to obtain a quicker and better efficiency and to inject almost 50 times less product per kg bodyweight.

Our population did not really differ from a population with varicose veins. Since we noted a higher proportion of executive-liberal professions, it may have included more people who were motivated, asking for no or for a short sick leave. It also included fewer very obese or very thin people. But, except for these differences, TLA can be applied to a great number of patients, all the more since our types of operations correspond to all the operations performed with intravenous sedation.

Patients were selected according to psychological criteria. In a centre (BR) this kind of TLA without any sedation had been taken for granted for several years; therefore, the surgeon chose it almost systematically. In the other centre (DC), it has been experimented with for five years only and the absence of sedation was discussed with each patient.

It is interesting to observe that the feeling of pain did not depend on surgical or technical elements but on psychological ones, such as the waiting period of time before surgery. Pain was linked to the importance of the operation (number of operated on zones and incisions) but not to surgery duration. Pain was not only experienced by particularly sensitive patients since it was not linked to the pain felt on varicose veins before the operation.

Organizing and monitoring patients' psychological treatment during their hospital stay is essential to obtain successful results with TLA, without any sedation. This may explain why there is a significant difference concerning the two centres. During the same time, 247 patients were operated on in the first centre (DC) and only 89 patients in the other centre (BR). In this last centre, the patients' environmental and psychological factors may have been considered with greatest care, which can explain why these patients' operations were less painful.

TLA without any sedation makes it possible to perform varicose vein surgery in external ambulatory surgery centres, which are outside conventional hospital centres. Thanks to efficient organization, patients spend only four hours in the surgery centre. Weak lidocaine and adrenaline injected doses along with the absence of any sedation and premedication makes ambulatory varicose vein surgery particularly easy for patients living far away from hospital (over several hundred kilometres away).

Ambulatory varicose vein surgery under TLA allows reduction of the cost of nearly all the operations. Nowadays, for most psychologically motivated patients, this cost can still be reduced by using this kind of anaesthesia without any intravenous sedation, therefore without an anaesthesiologist.

References

1 Breuninger H, Wehner-Caroli J. Subcutaneous infusion anesthesia with prilocaine diluted with Ringer's lactate (in German). *Hautarzt* 1998;**49**:709–13
2 Smith SR, Goldman MP. Tumescent anesthesia in ambulatory phlebectomy. *Dermatol Surg* 1998;**24**:453–6
3 Proebstle TM, Paepcke U, Weisel G, Gass S, Weber L. High ligation and stripping of the long saphenous vein using the tumescent technique for local anesthesia. *Dermatol Surg* 1998;**24**:149–53
4 Sommer B, Sattler G. High ligation and stripping of the long saphenous vein. In: Hanke CW, Sommer B, Sattler G, eds. *Tumescent Local Anesthesia*. Berlin, Heidelberg: Springer-Verlag, 2001:160–70
5 Balducci D, Morandi O, Mazzetti S, Tonni M, Becchetti A, Pancaldi R. Ambulatory saphenectomy: 80 operated cases using tumescent anesthesia. *Chir Ital* 2002;**54**: 77–82 (in Italian)
6 Sadick NS, Schanzer H. Combined high ligation and stab avulsion for varicose veins in an outpatient setting. *Dermatol Surg* 1998;**24**:475–9
7 Chastanet S, Pittaluga P. L'anesthésie locale dans le traitement chirurgical des varices des membres. *Phlébologie* 2009;**62**:67–8
8 Pittaluga P, Chastanet S, Rea B, Barbe R. Midterm results of the surgical treatment of varices by phlebectomy with conservation of a refluxing saphenous vein. *J Vasc Surg* 2009;**50**:107–18
9 Allaert FA, Cazaubon M, Vin F, Ionescu L. La première consultation pour maladie veineuse chez l'angiologue/phlébologue (Etude Privila). *Angéiologie* 2006;**58**:37–43
10 Koitabashi T, Sekiguchi H, Miyao H, Kawasaki J, Kawazoe T. Precipitation of pH-adjusted local anesthetics with sodium bicarbonate. *Masui* 1995;**44**:15–20
11 Milner QJ, Guard BC, Allen JG. Alkalinization of amide local anaesthetics by addition of 1% sodium bicarbonate solution. *Eur J Anaesthesiol* 2000;**17**:38–42
12 Habbema L. Efficacy of tumescent local anesthesia with variable lidocaine concentration in 3430 consecutive cases of liposuction. *J Am Acad Dermatol* 2010;**62**:988–94
13 Sommer B, Breuninger H. Composition of the solution for tumescent anesthesia. In: Hanke CW, Sommer B, Sattler G, eds. *Tumescent Local Anesthesia*. Berlin, Heidelberg: Springer-Verlag, 2001:9–13
14 Böni R. Tumescent liposuction: efficacy of a lower lidocaine dose (400 mg/l). *Dermatology* 2010;**220**:223–5
15 Klein JA. The tumescent technique. Anesthesia and modified liposuction technique. *Dermatol Clin* 1990;**8**: 425–37
16 Klein JA. Tumescent technique for local anesthesia. *West J Med* 1996;**164**:517
17 Ostad A, Kageyama N, Moy RL. Tumescent anesthesia with a lidocaine dose of 55 mg/kg is safe for liposuction. *Dermatol Surg* 1996;**22**:921–7
18 Klein JA. Tumescent technique for local anesthesia improves safety in large-volume liposuction. *Plast Reconstr Surg* 1993;**92**:1085–98
19 Głowacka K, Orzechowska-Juzwenko K, Bieniek A, Wiela-Hojeńska A, Hurkacz M. Optimization of lidocaine application in tumescent local anesthesia. *Pharmacol Rep* 2009;**61**:641–53
20 Mysore V, IADVL Dermatosurgery Task Force. Collaborators (16), Mysore V, Savant S, Khunger N, *et al*. Tumescent liposuction: standard guidelines of care. *Indian J Dermatol Venereol Leprol* 2008;**74**(Suppl.):S54–S60