

ORIGINAL ARTICLE

Anaesthetic digital block with epinephrine vs. tourniquet in ingrown toenail surgery: a clinical trial on efficacy

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Abstract

Background Current evidence shows that anaesthetic digital block with epinephrine is safe in surgical selected patients. There are no controlled studies that have examined the efficacy of local anaesthesia with vasoconstrictor in chemical matricectomy without using tourniquet to control bleeding.

Objectives A controlled, prospective and randomized study was conducted to examine primarily the rate of recurrence after segmental phenolization matricectomy with anaesthetic digital block with epinephrine vs. tourniquet. As secondary aims, duration of anaesthetic effect, post-operative bleeding and pain were analysed in both groups.

Methods Forty-four healthy subjects with ingrown hallux nails (70 toes) were enrolled. A total of 34 toes were anaesthetized with a solution of 2% mepivacaine with (1 : 100 000) epinephrine and operated without tourniquet (experimental group) vs. 36 toes anesthetized with a solution of 2% mepivacaine without epinephrine and operated with tourniquet (control group).

Results There was no statistically significant difference in recurrence rates ($P = 0.478$). Post-operative bleeding was significantly higher in the group with anaesthetic digital block without vasoconstrictor and with tourniquet ($P = 0.001$). Anaesthetic effect was higher in the group with anaesthetic digital block with vasoconstrictor and without tourniquet ($P = 0.001$). No post-operative complications occurred in any of the treatment groups.

Conclusions The use of local anaesthetic with vasoconstrictor to perform chemical matricectomy likely to be an effective procedure to reduce the disadvantages of using digital tourniquet (post-operative bleeding and lower anaesthetic effect) without increasing the risk of recurrence. The addition of epinephrine may reduce the need for a tourniquet and produce better and longer perioperative pain control.

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Conflicts of interest

The authors have no conflict of interest to declare.

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Introduction

Most nail surgery procedures are undertaken with strict surgical ischaemia to avoid bleeding and enable a correct visualization of the operative field. In digital surgery it is common to achieve a bloodless operative field through the use of tourniquets. Tourniquet removal after surgery results in a reactive hyperaemia in the toe which increases in a standing position. This hyperaemia may increase the bleeding and lower the anaesthetic effect rapidly which can determine patient welfare during the post-operative period.

Chemical matrix phenolization for ingrown toenails is the most common surgical procedure and its simplicity and effectiveness rate have contributed to a great extent to its popularity. Historically, the success of the procedure has been associated

with the use of tourniquets which avoids the presence of blood in the operative field.^{1,2} Use of the digital tourniquet is relatively safe and efficacious, however, there are cases reported in the literature of ischaemic complications due to the excessive compression of the tissues.^{3,4}

The strength of current evidence shows that in healthy subjects, digital blocks using local anaesthetic with a vasoconstrictor from 1 : 100 000 to 1 : 200 000 concentrations are safe.⁵ Prospective studies agree in stating that the use of local anaesthetic with a vasoconstrictor brings advantages associated to the increase in the anaesthetic effect, decrease of bleeding and reduction in the risk of systemic toxicity.^{6–9} Despite the existing evidence, it is still common that ingrown nail surgery continues to be performed with local anaesthetic without vasoconstrictor and

using a tourniquet in the toe base. For many specialists of nail surgery, the infiltration of an excessive volume of anaesthetic is more dangerous than the use of an anaesthetic with epinephrine. The addition of epinephrine may reduce the need for a tourniquet and produce better and longer pain control during surgery.¹⁰

There are few studies which have analysed the efficacy of using local anaesthetic with a vasoconstrictor in nail surgery. Solitary prospective study has analysed the efficacy of 2% lidocaine with (1 : 100 000) epinephrine vs. 2% lidocaine without epinephrine after chemical matricectomy with phenol. Nevertheless, the study authors applied a rubber-band tourniquet around the base of the hallux to the toes of both groups.¹¹

To date there has been no study which has analysed the recurrence rate after segmental matrix phenolization by using anaesthetic with epinephrine and without digital tourniquet. The present study was conducted to compare the rate of recurrence after segmental phenolization with anaesthetic digital block with epinephrine vs. anaesthetic digital block and tourniquet.

Materials and methods

This was a single-centre, prospective, randomized, single-blind trial to evaluate the efficacy of anaesthetic digital block with epinephrine in chemical matricectomy with phenol. The study procedures were conducted at Área Clínica de Podología de la Universidad de Sevilla (Spain). The first participant was enrolled in January 2011 and the last participant completed the study in December 2013. The Ethics and Experimental Committee of the University of Seville approved the study and written informed consent was obtained from all participants. The study involved 44 participants with unilateral or bilateral ingrown toenail of the hallux who underwent chemical partial nail matricectomy using a 100% liquefied phenol. A total of 70 toes were prospectively enrolled and randomly assigned to one of two groups; using hallux block technique, 36 toes were anaesthetized with a 4 mL solution of 2% mepivacaine with (1 : 100 000) epinephrine (Scandinibsa forte, Inibsa, Spain) and operated without tourniquet (experimental group) vs. 34 toes anaesthetized with 4 mL solution of 2% mepivacaine without epinephrine (Scandinibsa, Inibsa, Spain) and operated with tourniquet (control group). Patients with known peripheral vascular disease, diabetes mellitus, Raynaud's syndrome, systemic sclerosis, smoker or patients with any vasospastic disorder were not included in the study (Fig. 1).

Surgical procedure

In both groups, the surgical procedure consisted of partial ablation associated with segmental phenolization on both nail folds of the hallux as follows. A digital block of the hallux was performed using a 4 mL of 2% mepivacaine with or without vasoconstrictor. Tourniquet was used only in control group. Using a Freer elevator, the affected nail plate

was separated from the nail bed and eponychium and partial removal of the nail plate was performed using a nail splitter and haemostat. After partial nail plate avulsion, a cotton ball soaked in 100% phenol was applied with a swab for 1 min to the matrix and the nail bed. The residual blood from the operative field was duly dried with cotton ball before applying phenol in toes of the study group. The zone was then irrigated with 76% ethanol for 1 min and then with physiological saline solution. The cauterized tissue with a whitish appearance was carefully removed with scalpel and curette. All surgical wounds were dressed using water-soluble nitrofurazone ointment and covered using a sterile, non-adherent polypropylene dressing. Five gauzes were placed around the hallux and covered using a sterile compressive bandage. Then in the toes of the control group, tourniquet was removed.

Patient screening criteria and outcome measures

To assess the effectiveness of the experimental group, we designed a parallel group randomized, single-blind controlled trial. Using the program Random Allocation Software 2.0 (Microsoft 2008, Redmond, WA, USA) qualified patients were randomized in a 1 : 1 ratio to receive either anaesthetic solution with or without vasoconstrictor for subcutaneous injection. After 48 h, all participants returned for regular, standardized dressing changes by independent blinded researcher. All parties involved in post-operative care, with the exception of the surgeon (A.C.-F.) were blinded. The main variable of the study – recurrence rate – was considered present when there was symptomatic regrowth (including nail spicules/inclusión cysts) or asymptomatic nail spikes after a minimum post-operative follow-up of 1 year. A qualitative and comparative evaluation was made of bleeding establishing three categories: light (the dressing showed no external staining; only the non-stick polypropylene dressing in contact with the wound, and the gauze in contact with that were partly stained); moderate (the dressing showed slight staining on the back or sides; the non-stick dressing was completely stained, and the gauze in contact with that was partly stained); and abundant (the external dressing was completely or almost completely stained). To measure the post-operative pain, an analogue chromatic visual scale for self-evaluation of pain (scale from 1 = absence of pain to 10 = unbearable pain) was used. The intensity of pain was recorded subjectively for both groups, according to colours from white to dark red, corresponding to the numbers from 1 to 10 during the 3 days following surgery. Post-operative pain was treated with 500 mg of acetaminophen orally every 6–8 h (no more than 4 g/day). The first analgesic drug was always taken after reporting the first peak of pain after the disappearance of the anaesthetic effect. Patients recorded the time that was necessary to take the first analgesic. All patients completed a questionnaire where pain intensity was scored

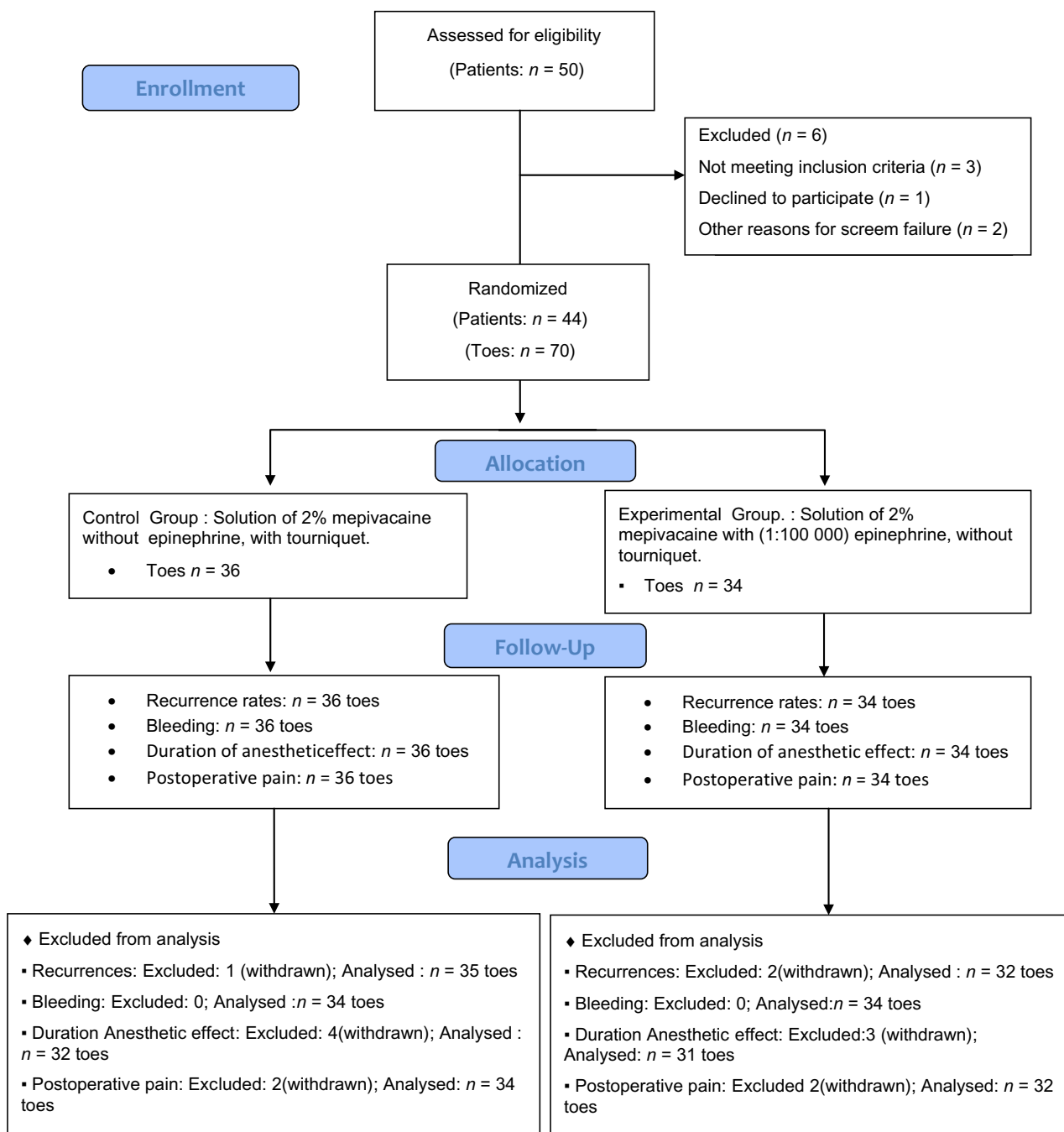


Figure 1 Study flow diagram.

according to the scale in each of their feet for the 3 days following surgery.

Statistical methods

To accomplish the objectives set for this study, the sample size was calculated according to the type of design and to the main

dependent variable (recurrence rate) object of analysis. In our study, we wanted to know whether the recurrence proportion was higher with regard to the two categories of the independent variable ‘the use or not of a vasoconstrictor’. We concluded that to be able to estimate the proportion of patients with an accuracy of $\pm 5\%$ and an alpha error of 5%, 31 toes were

required in each group. For the statistical analysis, we used the statistical package SPSS, version 15.0 (SPSS, Inc., Chicago, IL, USA).

To analyse the results of the main variable of the study according to the statistical data obtained, a contingency table and chi-squared test were used. To analyse the behaviour of the variable 'bleeding' with regard to the categories of the independent variable, contingency tables and the statistical chi-squared test (Fisher's exact test) were used. As there was no bleeding of category 'light' in the control group, the categories 'light' and 'moderate' for the two groups were both considered jointly for the statistical analysis. To corroborate whether there were statistically significant differences with regard to the duration of the anaesthetic effect and pain peak registered after anaesthetic effect between groups, the Mann-Whitney *U*-test was used. For the analysis of the variable 'pain' in each group during the 3 days following surgery, Friedman's two way analysis of variance by ranks was used. To facilitate comparison of average pain during the three post-operative days, were considered four ranges or categories of pain and extreme values were excluded. Statistical significance was set at *P* less than 0.05.

Results

The final study sample consisted of 70 toes of 44 patients (31 men and 39 women; mean \pm SD age, 26.28 \pm 15.82 year). Median age was statistically different between the treatment groups (*P* = 0.015). In the same way, significant differences were found regarding the distribution of gender (*P* = 0.003). The characteristics and distribution of the study population are listed in Table 1.

After a 2.1 year follow-up (range: 1.3–2.8), chi-squared test did not show statistically significant differences regarding the distribution of the recurrence variable regarding the two categories of the independent variable. With a confidence interval of 95%, we can affirm that the distribution of the recurrence variable is the same for both categories (Table 2). The chi-squared test was significant (*P* < 0.0001) for bleeding that is, it detected significant differences [94.4% (34/36) of toes presenting abundant bleeding with the control treatment and 17.65% (7/36)

Table 1 General features of patients

	Control group	Study group	Total analysed
Patients	25 (56.8%)	22 (50%)	44
Males	16	6	21 (47.7%)
Females	9	16	23 (52.2%)
Toes	36 (51.4%)	34 (48.5%)	70
Males	22	9	31 (44.2%)
Females	14	25	39 (55.7%)
Average age	22.8	29.5	26.2
Standard deviation	17.2	13.8	15.8
Median (range)	14 (10–64)	25 (11–57)	20 (10–64)

Table 2 Comparison of outcomes between the groups in recurrence rate

Anaesthetic solution		Recurrence		Total
		Yes	No	
With epinephrine	Recount	2	32	34
	% Recurrence	5.88%	94.11%	100%
Without epinephrine	Recount	1	35	36
	% Recurrence	2.77%	97.22%	100%

N = 70 toes (44 patients). Chi-squared test: *P* < 0.478; CI (95%).

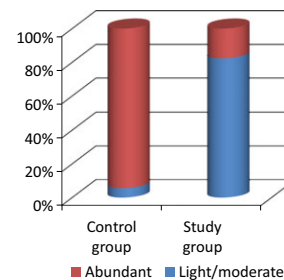


Figure 2 Distribution of the variable bleeding according to established categories in both groups.

with the experimental treatment] (Fig. 2). Regarding to the duration of anaesthetic effect (minutes) registered in both group, the average recorded in the experimental group was higher than the study group. The Mann-Whitney *U*-test showed significant differences between groups (Table 3). Regarding the mean pain registered in the 3 days following surgery, there were no significant differences between the groups. The first pain peak registered after anaesthetic effect in the study group has been slightly higher, although there are no statistically significant differences (Table 4). Despite the variable behaving in a similar way in both groups when using Friedman's two tails analysis of variance by ranks of related samples, there were significant differences in the groups regarding the pain evolution between the first and the third day. The test shown that the pain means

Table 3 Comparison of differences regarding duration of the anaesthetic effect between groups

Minutes	Control group	Study group	<i>P</i> value
Median (minimum, maximum)	180 (45, 335)	390 (120, 1040)	
Mean \pm SD	184.86 \pm 82.03	390.78 \pm 197.19	0.001*
Typical mean error	82.03	197.19	
95% CI (lower limit, upper limit)	(157.11–212.62)	(319.68–461.88)	

N = 68 toes (43 patients).

*The Mann-Whitney *U*-test; CI (95%).

Table 4 Mean of the first pain peak registered after anaesthetic effect and mean of the post-operative pain measured in 3 post-operative days for both groups (scale from 1 to 10 for self-evaluation of pain)

	Day	Control (N = 36)	Study (N = 34)	
Pain	1	3.92 ± 1.85	4 ± 2.74	$P > 0.05^*$
	2	4.64 ± 1.98	4.07 ± 2.26	
	3	2.94 ± 1.98	3.24 ± 1.73	
First pain peak		3.92 ± 1.85	4.00 ± 2.74	

N = 68 toes, 43 patients.

*Mann–Whitney U-test; CI (95%).

Table 5 Comparison of differences regarding the pain evolution between the first and the third day between groups (scale from 1 to 10 for self-evaluation of pain)

Post-operative day	Median	Mean	P value
1	4 (1–10)	4.37 ± 2.12	0.001*
2	3 (1–8)	3.08 ± 1.86	
3	2 (1–10)	2.36 ± 1.79	

N = 68 toes, 43 patients.

*Friedman's two tails test; CI (95%).

values differ at the three moments of the study for both groups (Table 5).

Discussion

Chemical matrix phenolization for ingrown toenails is the most common surgical procedure. The need to improve procedures and make the post-operative period bearable requires the establishment of protocols which may reduce the inconveniences associated with the most common nail surgery techniques. Existing meta-analysis shows that in the studies comparing a surgical intervention to a surgical intervention with application of phenol, the addition of phenol is probably more effective in preventing recurrence and regrowth.^{12,13} Traditionally the success of the procedure has been associated with the use of tourniquets which avoids the presence of blood in the operative field which may counteract phenol's caustic effect. Some specialists of nail surgery suggest that the addition of epinephrine to the local anaesthetic may reduce the need for a tourniquet and produce better and longer pain control during surgery.^{10,11} The results of present study show that the recurrence rate is not higher when the technique is done with anaesthetic solution with vasoconstrictor 1 : 100 000 and in absence of digital tourniquet. Altinyazar *et al.*¹¹ analyse the recurrence rate in two groups that were given local anaesthetic with and without vasoconstrictor respectively. As in our study, the authors conclude that there are no significant differences regarding the recurrence rate registered in each group. Nevertheless, it is interesting to observe that the technique adopted by the authors could not influence the result as in

both groups because a tourniquet around the base of the hallux of both groups was applied. This circumstance obviously makes it impossible that the phenol's caustic effect could be affected by the presence of remaining bleeding in the operative field. In present study, the ischaemia caused by the effect of the vasoconstrictor in the toes of study group, together with drying the remaining blood with a cotton ball from the operative field prior to the application of phenol may have contributed to reduce the potential risk of recurrence.

The existing meta-analysis has also shown that segmental phenolization increases the risk of delay healing.¹² To reduce this disadvantage, technique variants such as curettage of the cauterized tissue have been suggested, however, the existing trials show that the curettage increases post-operative bleeding after removing the tourniquet.¹⁴ Using the same criteria and categories of bleeding that the ones used in this study, Córdoba-Fernández *et al.*¹⁵ analysed the haemostatic effect of the platelet gel vs. to control after non-chemical partial matrix excision. As in this study, post-operative bleeding was significantly higher in the control group, although the application of anaesthetic with a vasoconstrictor seems to be a simpler and more cost-effective method.

The results referred to the post-operative anaesthetic effect registered in this study show that the association of epinephrine to the anaesthetic solution guarantees a longer duration of the anaesthesia. The mean duration of anaesthesia (mean time of the first peak pain score after surgery) was more than double in the study group than in the control group. These results are similar to the ones published by other authors. Andrades *et al.*,⁶ using 2% lidocaine with vasoconstrictor 1 : 100 000 in the study group obtained a mean time of anaesthesia lower (276 min) than that registered by us in our study group. This circumstance is probably due to the fact that the anaesthetic technique was used for post-traumatic interventions in fingers and toes, where the post-operative bleeding typical of these wounds could decrease the effect of the administered anaesthetic solution. Alhelail *et al.*,⁷ using 1% lidocaine with vasoconstrictor 1 : 100 000 in digital fingers block obtain a median time of anaesthesia quite lower [321 min (228–463)] than that registered by us in our study group. This difference can be due to the type and concentration of the administered anaesthetic.

When comparing the difference of pain means between the first and the third day in each group, statistically significant differences were found in both groups. This shows that the evolution of the surgical procedure has been equally favourable in both treatments.

We consider that the differences registered in the distribution of age variable between the groups have not influenced the results for any of the dependent studied variables, as the mean age in both groups corresponds with young and healthy subjects. However, the absence of homogeneity in gender variable between the groups could have caused bias in the results regarding the post-operative pain registered in each group.

In summary, the study provides reasonably strong evidence about the efficacy of anaesthetic digital block with epinephrine and without tourniquet in chemical matricectomy with phenol. Although statistically it has reached sufficient sample size to analyse the primary variable of study, the small size of this trial makes it difficult to generalize results and further prospective controlled studies with longer term follow-up are required for such conclusions to be truly evidence based.

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