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Main Article

Effectiveness of local anaesthesia (clonidine and fentanyl) infiltration for post-submucosal resection pain relief: a randomized, double-blinded clinical trial

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Abstract

Background: Submucosal resection is accompanied by significant post-operative pain and discomfort. The aim of this randomized, double-blinded clinical trial was to study the efficacy of a local block anaesthetic, delivered after induction of general anaesthesia, in reducing post-operative pain.

Methods: Patients aged 16 years and over who were scheduled for elective submucosal resection were randomly assigned to receive either standardized general anaesthesia, general anaesthesia with local anaesthetic infiltration or general anaesthesia with placebo infiltration. Haemodynamic stability, intra-operative blood loss, post-operative pain (over a seven day follow-up period), analgesics consumption, hospital stay, and the patient's and surgeon's levels of satisfaction were assessed.

Results: We found significantly lower results for pack removal pain score, volume of intra-operative blood loss, number of patients suffering from headache, altered dental sensation or nasal pain, number of patients who consumed analgesics, and length of hospital stay, comparing the infiltration group with the general anaesthesia and placebo groups ($p < 0.05$).

Conclusion: This clinical trial showed that infiltration with the local anaesthetics fentanyl and clonidine substantially reduced post-operative pain and shortened patients' hospital stay.

Key words: Nasal Septum; Perioperative Pain; Otorhinolaryngologic Surgical Procedures; Anaesthesia, Local

Introduction

Submucosal resection of deviated nasal cartilage and bone is one of the most frequently performed operations in otolaryngology.[1,2] Submucosal resection of the nasal septum, with its multiple variations, is considered the best available procedure to manage septal deviation. This procedure, which is considered simple and safe, is not without discomfort and complications, including bleeding, infection, septal haematoma, and post-operative pain or discomfort.[3]

A local anaesthetic block, using a mixture of the local anaesthetics fentanyl and clonidine, has been used at our institution since 1999 in order to reduce post-operative pain following submucosal resection. Initial results have pointed to significantly reduced post-operative pain, shortened hospital stay and less consumption of analgesics.

The aim of this randomized, double-blinded clinical trial was to corroborate our observational results and to study the efficacy of block anaesthesia, delivered after induction of general anaesthesia, according to several parameters, including intra-operative blood loss, post-operative pain, altered dental sensation and consumption of analgesics.

Material and methods

Following ethical committee approval and the granting of written informed consent, 100 patients aged between 16 and 66 years who were scheduled for elective submucosal resection between January 2004 and December 2004 were randomly assigned (using the sealed opaque envelope technique, based on computer-generated random numbers) to one of three groups: standardized general anaesthesia (GA) (GA, $n = 32$), GA with anaesthetic mixture infiltration (infiltration, $n = 34$) or GA with placebo infiltration (placebo, $n = 34$).

Exclusion criteria included an age of less than 16 years for females and 18 years for males, and a history of allergy to local anaesthesia. We excluded patients with suspected malignant neoplasm or bleeding deficiencies and those in whom it was not possible to conduct a telephone follow-up interview.

The GA group received standardized general anaesthesia alone. The infiltration group received a total of 6 ml of local anaesthetic mixture in addition to GA. The placebo group received the same volume of 0.9 per cent normal saline, using the same injection technique, in addition to general anaesthesia.

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Neither the surgeon nor the anaesthetist were aware of the injected solution content; neither were they involved in data collection. Neither the patients nor the trained nurses who collected the data were aware of the patient's assigned group.

Protocol for general anaesthesia

General anaesthesia was induced by intravenous fentanyl (1.5 μg/kg), midazolam (2–3 ml) and propofol (1–2 mg/kg), followed by endotracheal intubation facilitated by atracurium (0.5 mg/kg). Anaesthesia was subsequently maintained with sevoflurane (1–3 per cent), fentanyl (3–4 μg/kg), nitrous oxide (70 per cent) and oxygen (30 per cent). The sevoflurane concentration was adjusted with the intention of keeping heart rate and blood pressure within ±25 per cent of pre-induction values. At the end of the operation, residual neuromuscular blockade was antagonized with neostigmine (0.05 mg/kg) and atropine (0.01 mg/kg).

Infiltration technique

The block technique followed a thorough understanding of the sensory supply to the septum and nose. The septum is innervated by the anterior ethmoidal nerve, the nasopalatine nerve and a branch of the anterior superior alveolar nerve. The nasal cavities and the skin of the nose are innervated by maxillary and ophthalmic branches of the trigeminal nerve in a complex distribution.[4]

Following induction of GA and preparation of the skin, the anaesthetist performed the block technique by injecting a total of 6 ml of the appropriate solution, disseminated at the following points marked bilaterally: supratrochlear area, infra-orbital area, medial to the medial canthus, nasal sill and anterior septum (Figure 1). Each of the nasal cavities was packed for five minutes in situ with one cotton pledget soaked in the same solution, to account for mucosal sensation blockade.

The block infiltration mixture was prepared in a 10 ml syringe (Becton Dickinson, Franklin Lakes NJ, USA), which then contained 3 ml of lindocaine 2 per cent, 3 ml of lindocaine 2 per cent with adrenaline 1/200 000, 3 ml of bupivacaine 0.5 per cent, 0.5 ml of fentanyl 50 μg/ml and 0.5 ml of clonidine 150 μg/ml.

Type of surgical procedure

After adequate preparation and draping of the nose, the septum was infiltrated with a solution of xylocaine with 1 per cent adrenaline to ensure hydrodissection and vasoconstriction. The septum was then approached via a hemitransfixion incision in which the mucoperichondrial and mucoperiosteal flaps were elevated and the deviated part of the septum resected. Septal scoring was performed when needed. The flaps were then sutured together using Vicryl sutures and packed using two Merocel packs (Medtronic Xomed, Jacksonville FL, USA), which were removed in the clinic after 24 hours. Patients were asked to report back to the clinic after seven days.

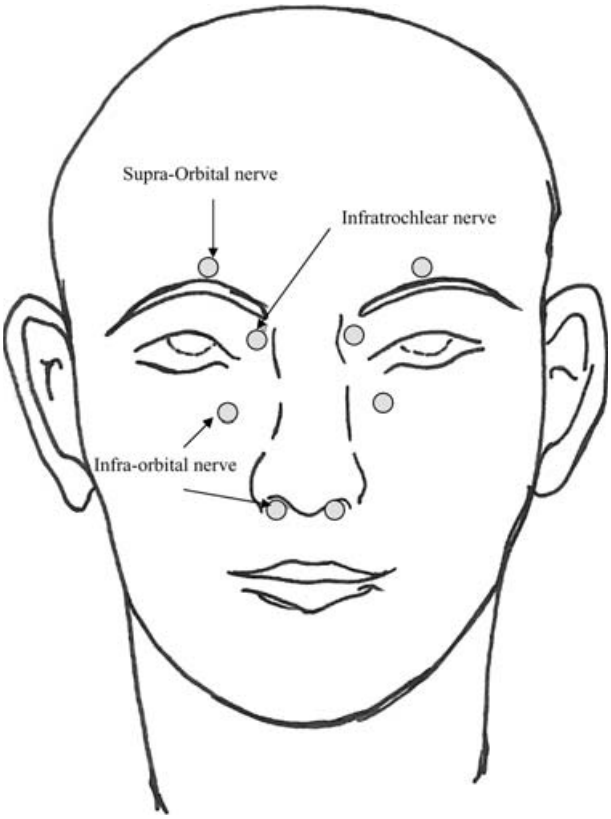

FIG. 1
Landmarks for local anaesthetic injection points.

Haemodynamic monitoring

Mean arterial pressure (in mm Hg), heart rate (per minute) and arterial oxygen saturation (as a percentage) were observed systematically and recorded before (i.e. baseline), during and after the operation (the latter in the recovery room).

Data collection

Patients' characteristics were recorded, including: age, gender, height, weight and duration of surgery. Post-operative pain at rest and on pack removal were assessed using a visual analogue scale (in which 0 = no pain and 10 = worst possible pain) at different time intervals (i.e. at 0, 6 and 12 hours during the first post-operative day and then once daily for the following seven day period). Post-operative nausea and vomiting was recorded as definite if the patient had experienced either nausea for more than 10 minutes or frank retching and/or vomiting, at predetermined intervals during the follow-up period. Post-operative pulsatile frontal headache, nasal pain and altered dental sensation in the distribution of the anterior sector of the maxillary nerve were recorded as present or absent (i.e. yes or no). The number of patients who needed tramadol hydrochloride, dextropropoxyphene or paracetamol analgesia was assessed during the follow-up period.

To determine the quantity of intra-operative bleeding, no gauze was used for bleeding control, and, when irrigation was applied, the volume of this

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was subtracted from the total amount of fluid collected in order to record the net quantity of blood loss in millilitres.

Nurses blinded to the infiltration technique were responsible for allocating patients to groups, drawing up the injection solutions and assessing patients' pain scores. The investigators were not involved in any of these steps in order to achieve blinding. Once patients were discharged, their pain scores were assessed by telephone, being recorded as the average of the patient's recordings throughout the day.

Discharge from hospital

The decision to discharge a patient from hospital was made solely by the surgeon in charge of that patient, according to established clinical criteria, and was not influenced or affected by the investigators. The criteria for hospital discharge were: pain score of less than four, no nausea and vomiting, and haemodynamic stability.

Patient's and surgeon's satisfaction

Patients were asked to assess their level of satisfaction with the procedure, based on their comfort level and ability to return to normal daily activities, rating these issues on a scale of one to four. Patients were interpreted from a rating of four to be satisfied, from three to be moderately satisfied, and from one or two to be unsatisfied.

The surgeon's level of satisfaction was rated at the end of the follow-up period as satisfied or unsatisfied, based on: (a) intra-operative bleeding, (b) pain on pack removal and (c) post-operative pain reported by the patient.

Pharmacological management of post-operative pain

During the first six post-operative hours, intravenous tramadol hydrochloride (1–1.5 mg/kg; Grunenthal GmbH, Aachen, Germany) was administered if the pain score was four or more. For the rest of the follow-up period, if the pain score was four or more, two tablets of an oral combination of dextropropoxyphene (30 mg) and paracetamol (400 mg) (Diantalvic, Hoechst-Mirian, Roussel, France) were administered every six hours as the primary analgesic. If the pain score was less than four, two tablets of oral paracetamol 500 mg were prescribed every six hours.

Statistical analysis

Based on our previous, observational data, we calculated that 30 patients were necessary for each group in order to detect a 30 per cent difference in pain scores between the three groups, with a confidence level of 95 per cent ($\propto = 0.05$) and a power of 90 per cent ($ß = 0.90$).

Analysis of variance tests were performed to determine statistically significant differences between mean group values for age, height, weight, heart rate, mean arterial pressure, arterial oxygen saturation, surgery duration, pack removal pain and bleeding. Chi-square tests were used to assess differences between the groups for sex, nausea, surgeons' satisfaction, patients' satisfaction, hospital stay, frequency of patient headache, frequency of patient altered dental sensation, frequency of patient nasal pain, and patients' need for supplementary analgesics. Analysis of variance with repeated measurements and Bonferroni *post hoc* tests were used to test any significant difference between the groups. A p value of <0.05 was considered significantly different.

Results

Results from 96 patients were entered into the final data analysis, due to loss to follow up of one patient from the GA group, two from the infiltration group and one from the placebo group. The study groups were comparable with respect to sex, age, weight, height and duration of surgery (Table I). No statistically significant differences were observed between the three groups regarding haemodynamic stability (Table I). Bleeding volume was significantly lower in the infiltration group compared with the other two groups ($p = 0.0001$) (Table I).

No significant difference was observed between the three groups regarding post-operative nausea (Table II).

Levels of surgeon and patient satisfaction were significantly higher in the infiltration group compared with the placebo and GA groups ($p = 0.006$ and 0.002, respectively). All patients in the infiltration group (100 per cent) were discharged from hospital within 24 hours, compared with 81.8 per cent of the placebo group and 77.4 per cent of the GA group ($p = 0.019$). Patients' pain scores on pack removal were significantly lower in the infiltration group compared with the other two groups ($p = 0.0001$).

Patients' average pain scores at rest for the whole follow-up period were significantly lower in the infiltration group compared with the placebo and GA groups (by analysis of variance and Bonferroni *post hoc* analysis) (Table III). The number of patients suffering post-operative headache was significantly lower in the infiltration group compared with the other two groups, for the first three post-operative days ($p < 0.05$) (Table IV).

Tables V and VI show that the numbers of patients in the placebo and GA groups experiencing altered dental sensation and nasal pain, respectively, were significantly higher compared with the infiltration group, for the first four post-operative days ($p < 0.05$).

Analgesics consumption in the GA and placebo groups was significantly higher compared with the infiltration group ($p < 0.05$) (Table VII).

Discussion

It was important for us to find a method that substantially reduced post-operative pain and allowed a faster, uncomplicated recovery for patients undergoing submucosal resection.

The main finding of the present prospective, randomized, blinded, controlled clinical trial was a significant improvement in post-submucosal

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TABLE I

PATIENT DEMOGRAPHIC AND CLINICAL DATA

	GA	INF	Placebo	*p*
Patients (*n*)	32	34	34	
Female patients (*n* (%))	15 (46.9)	17 (50)	18 (52.9)	0.886
Age (years (mean (SD)))	27.31 (10.44)	27.82 (9.02)	27.33 (11.34)	0.974
Height (cm (mean (SD)))	170.62 (8.63)	168.79 (8.30)	167.94 (6.83)	0.381
Weight (kg (mean (SD)))	70.0 (15.62)	69.58 (13.31)	66.41 (14.27)	0.539
HR (bpm (mean (SD)))				
Pre	82.5 (1.26)	79.74 (8.97)	81.24 (8.71)	0.485
Peri	83.90 (12.45)	77.02 (11.50)	80.35 (14.81)	0.105
Post	79.93 (10.08)	75.64 (8.55)	79.97 (10.96)	0.126
MAP (mm Hg (mean (SD)))				
Pre	108.00 (24.42)	106.11 (28.26)	112.17 (22.72)	0.601
Peri	101.53 (18.60)	99.32 (22.70)	103.91 (21.46)	0.669
Post	99.34 (14.79)	96.58 (17.91)	101.73 (25.30)	0.568
SAO_2 (saturation (mean (SD)))				
Pre	98.53 (0.84)	98.61 (0.82)	98.50 (0.82)	0.845
Peri	98.68 (0.73)	98.76 (1.01)	98.70 (0.83)	0.931
Post	98.34 (1.26)	98.47 (0.99)	98.32 (0.63)	0.804
Bleeding (ml (mean (SD)))	152.23 (22.08)	42.0 (9.19)	154.82 (24.05)	0.0001
Surg duration (min (mean (SD)))	29.32 (4.26)	27.69 (4.37)	27.42 (4.53)	0.182

GA = general anaesthesia only; INF = general anaesthesia + local anaesthesic infiltration; placebo = general anaesthesia + placebo infiltration; HR = heart rate; bpm = beats per minute; pre = pre-operative; peri = peri-operative; post = post-operative; MAP = mean arterial pressure; SAO_2 = arterial oxygen saturation; Surg = surgery

resection pain relief in patients receiving a GA and a local anaesthetic mixture infiltration, compared with patients who received general anaesthesia alone or with a placebo infiltration.

Post-operative pain was found to be reduced in infiltration group patients throughout the follow-up period (specifically, pain at rest, post-operative headache, dental sensation and nasal pain). Furthermore, a significantly reduced need for analgesics, shorter hospital stay, and higher levels of both patients' and surgeons' satisfaction were found in the infiltration group when compared with the other two groups.

The results of the present study corroborate our previous pilot observations of superior pain relief, reduced analgesics consumption and shortened hospital stay following an anaesthetic regimen consisting of general anaesthesia combined with modified infiltration of a mixture of local anaesthetics (fentanyl and clonidine).

The rate of altered dental sensation in the GA and placebo group patients was very similar to that reported by MacDougall and Sanderson.[5] In contrast, just three patients in our infiltration group complained of altered dental sensation.

TABLE II

FOLLOW-UP PARAMETERS

	GA	INF	Placebo	*p*
Patients (*n*)	31	32	33	
Nausea & vomiting (*n* (%))				
0 h	4 (12.9)	4 (12.5)	2 (6.1)	0.599
6 h	10 (32.3)	8 (25.0)	9 (27.3)	0.807
12 h	4 (12.9)	2 (6.38)	5 (15.2)	0.506
Day 1	2 (6.5)	3 (9.4)	3 (9.1)	0.899
Days 2–7	0 (0)	0 (0)	0 (0)	NA
Surgeon's satisfaction (*n* (%))				
Satisfied	22 (71.0)	30 (93.8)	24 (72.7)	0.045
Unsatisfied	9 (29.0)	2 (6.3)	9 (27.3)	
Patient's satisfaction (*n* (%))				
Satisfied	13 (41.9)	27 (84.4)	14 (42.4)	0.002
Moderately satisfied	10 (32.3)	4 (12.4)	9 (27.3)	
Unsatisfied	8 (25.8)	1 (3.1)	10 (30.3)	
Hospital stay (*n* (%))				
<1 day	24 (77.4)	32 (100)	27 (81.8)	0.02
≥1 day	7 (22.6)	0 (0)	6 (18.2)	
Pack removal pain (mean VAS score (SD))	4.92 (1.29)	1.34 (1.33)	4.91 (1.04)	0.0001

GA = general anaesthesia only; INF = general anaesthesia + local anaesthesic infiltration; placebo = general anaesthesia + placebo infiltration; NA = not applicable; VAS = visual analogue scale; SD = standard deviation

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TABLE III

PAIN*

Time point	GA	INF	Placebo	$p^{\dagger}$
0 h	4.32 (1.81)	1.06 (1.21)	4.21 (1.61)	0.0001
6 h	3.74 (1.78)	1.03 (1.12)	3.67 (1.57)	0.0001
12 h	3.389 (1.56)	1.06 (1.34)	3.12 (1.51)	0.0001
Day 1	3.06 (1.45)	0.69 (0.89)	2.94 (1.45)	0.0001
Day 2	2.71 (1.41)	0.53 (1.01)	2.70 (1.357)	0.0001
Day 3	2.16 (1.46)	0.53 (1.10)	2.06 (1.71)	0.0001
Day 4	1.68 (1.24)	0.41 (0.94)	1.27 (1.46)	0.0001
Day 5	1.19 (1.07)	0.28 (0.81)	0.85 (1.17)	0.003
Day 6	0.77 (0.95)	0.13 (0.33)	0.48 (0.87)	0.005
Day 7	0.32 (0.59)	0.09 (0.29)	0.21 (0.48)	0.167

*Reported by patients as a visual analogue scale score. †By analysis of variance, comparing the three groups at each time interval. Data presented as mean pain score (standard deviation). GA = general anaesthesia only; INF = general anaesthesia + local anaesthesic infiltration; placebo = general anaesthesia + placebo infiltration

TABLE V

ALTERED DENTAL SENSATION

Time point	GA	INF	Placebo	p^{*}
0 h	11 (35.5)	3 (9.4)	11 (33.3)	0.031
6 h	17 (54.8)	4 (12.5)	14 (42.4)	0.002
12 h	17 (54.8)	4 (12.5)	15 (45.5)	0.001
Day 1	17 (54.8)	5 (15.6)	15 (45.5)	0.004
Day 2	17 (54.8)	4 (12.5)	15 (45.5)	0.001
Day 3	13 (41.9)	4 (12.5)	12 (36.4)	0.025
Day 4	11 (35.5)	3 (9.4)	10 (30.3)	0.039
Day 5	8 (25.8)	2 (6.3)	7 (21.2)	0.102
Day 6	3 (9.7)	0 (0)	2 (6.1)	0.216
Day 7	3 (9.7)	0 (0)	2 (6.1)	0.216

*By chi-square tests, comparing the three groups at each time interval. Data presented as *n* (%). GA = general anaesthesia only; INF = general anaesthesia + local anaesthesic infiltration; placebo = general anaesthesia + placebo infiltration

It was noted that the amount of blood loss in infiltration group patients was significantly less than that in patients in the other two groups, owing to the haemodynamic stability secured by pre-incisional infiltration.

In keeping with our previously published experience with a fentanyl–clonidine local anaesthetic mixture, other authors have also found a surprisingly long duration of analgesia following use of this mixture in different types of surgery.[6–9] Co-administration of clonidine and opioids within a local anaesthetic solution has been found capable of prolonging the duration of peripheral nerve blocks.[10,11] Our observed period of analgesia following use of the fentanyl–clonidine mixture was greater than would be expected for an additive or even synergistic effect of these drugs; instead, this finding infers a pre-emptive analgesic action.[12]

Although pre-emptive analgesia has been validated in various experimental pain models, very few studies have been able to substantiate this concept in the clinical setting.[13,14] A recent study by Giannoni *et al.*, in paediatric tonsillectomy patients, showed improved post-operative analgesia for five days following pre-incision infiltration of tonsillar fossae with a mixture of local anaesthetic and clonidine.[15] Lavand'homme and Eisenach have also shown prolonged periods of pain relief following administration of local anaesthetic–clonidine solutions close to injured nerves.[16] Based on these results and those of our own previous studies, clonidine can be understood to cause this effect by interaction with the immune system, resulting in reduced recruitment of macrophages and lymphocytes at the nerve injury site and a shift in the proportion of macrophage types from the pro- to the anti-inflammatory phenotype.[16]

- **Submucosal resection of the nasal septum is one of the most frequently performed operations in otolaryngology. It is often accompanied by post-operative discomfort**
- **This study sought to determine the effectiveness of a local anaesthetic (clonidine and fentanyl) infiltration, administered at induction of general anaesthesia, in improving the post-operative management of patients undergoing submucosal resection**
- **The average post-operative pain scores at rest were significantly lower in the infiltration group in comparison with placebo, suggesting that block anaesthesia should be used routinely in patients undergoing septal surgery**

TABLE IV

HEADACHE

Time point	GA	INF	Placebo	p^{*}
0 h	24 (77.4)	5 (15.6)	23 (69.7)	0.0001
6 h	24 (77.4)	7 (21.9)	23 (69.7)	0.0001
12 h	24 (77.4)	10 (31.3)	23 (69.7)	0.0001
Day 1	24 (77.4)	11 (34.4)	22 (66.7)	0.001
Day 2	23 (74.2)	7 (21.9)	21 (63.6)	0.0001
Day 3	17 (54.8)	6 (18.8)	15 (45.5)	0.01
Day 4	12 (38.7)	4 (12.5)	10 (30.3)	0.057
Day 5	11 (35.5)	3 (9.4)	9 (27.3)	0.045
Day 6	8 (25.8)	2 (6.3)	6 (18.2)	0.110
Day 7	3 (9.7)	1 (3.1)	7 (9.1)	0.538

*By chi-square tests, comparing the three groups at each time interval. Data presented as *n* (%). GA = general anaesthesia only; INF = general anaesthesia + local anaesthesic infiltration; placebo = general anaesthesia + placebo infiltration

TABLE VI

NASAL PAIN

Time point	GA	INF	Placebo	p^{*}
0 h	15 (48.4)	2 (6.3)	14 (42.4)	0.001
6 h	16 (51.6)	4 (12.5)	14 (42.4)	0.003
12 h	17 (54.8)	5 (15.6)	14 (42.4)	0.004
Day 1	17 (54.8)	6 (18.8)	13 (39.4)	0.012
Day 2	15 (48.4)	6 (18.8)	12 (36.4)	0.045
Day 3	11 (35.5)	3 (9.4)	9 (27.3)	0.045
Day 4	8 (25.8)	1 (3.1)	6 (18.2)	0.041
Day 5	5 (16.1)	0 (0)	3 (9.1)	0.067
Day 6	3 (9.7)	0 (0)	2 (6.1)	0.216
Day 7	2 (6.5)	0 (0)	1 (3.0)	0.339

*By chi-square tests, comparing the three groups at each time interval. Data presented as *n* (%). GA = general anaesthesia only; INF = general anaesthesia + local anaesthesic infiltration; placebo = general anaesthesia + placebo infiltration

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TABLE VII

ANALGESIC CONSUMPTION*

Time point	Analgesic*	GA	INF	Placebo	$p^{\dagger}$
0 h	T	17 (54.9)	2 (6.2)	19 (57.6)	0.0001
6 h	D	11 (35.5)	0 (0)	10 (30.3)	0.0001
	P	12 (38.7)	4 (12.5)	15 (45.5)	
12 h	D	7 (22.6)	1 (3.1)	5 (15.2)	0.0001
	P	16 (51.6)	3 (9.4)	17 (51.5)	
Day 1	D	5 (16.1)	0 (0)	4 (12.1)	0.0001
	P	16 (51.6)	2 (6.3)	16 (48.5)	
Day 2	D	4 (12.9)	0 (0)	4 (12.1)	0.0001
	P	14 (45.2)	2 (6.3)	15 (45.5)	
Day 3	D	1 (3.2)	0 (0)	3 (9.1)	0.007
	P	12 (38.7)	3 (9.4)	13 (39.4)	
Day 4	D	1 (3.2)	0 (0)	1 (3.0)	0.486
	P	5 (16.1)	2 (6.3)	6 (18.2)	
Day 5	D	0 (0)	0 (0)	0 (0)	0.250
	P	3 (9.7)	1 (3.1)	5 (15.2)	
Day 6	D	0 (0)	0 (0)	0 (0)	0.339
	P	2 (6.5)	0 (0)	1 (3.1)	
Day 7	D	0 (0)	0 (0)	0 (0)	NA
	P	0 (0)	0 (0)	0 (0)	

*Analgesic, when needed, comprised intravenous tramadol hydrochloride 1.5 mg/kg (T) at 0 h, and tablets containing either dextropropoxyphene 30 mg and paracetamol 400 mg (D), or paracetamol 500 mg (P), thereafter. †By chi-square tests, comparing the three groups at each time interval. Data presented as *n* (%). GA = general anaesthesia only; INF = general anaesthesia + local anaesthesic infiltration; placebo = general anaesthesia + placebo infiltration; NA = not applicable

Conclusion

The present randomized, blinded, controlled clinical trial showed that infiltration with a mixture of local anaesthetics (fentanyl and clonidine) substantially reduced patient post-operative pain and analgesic consumption. It also allowed a shorter hospital stay, resulting in apparent cost savings for the healthcare system and a quicker return to normal activities for the patient. Thus, these positive results appear to merit more widespread use of this technique in patients undergoing submucosal resection.

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