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Increase in volume of dental local anaesthetic solution while maintaining the tissue lidocaine and adrenaline concentration does not increase acute postoperative pain after gingivectomy

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Abstract

A randomised, single-blind, within-patient, crossover study was done in 45 patients (29 women and 16 men, mean age 49 years, range 37–71) who had bilateral "identical" gingivectomies. On one occasion a standard volume of local anaesthetic containing 2% lidocaine and 1/80 000 adrenaline was infiltrated into the mucosal tissue before operation. On the other, double the standard volume with 1% lidocaine and 1/160 000 adrenaline was infiltrated. The intensity of postoperative pain was recorded by the patients on a 100 mm visual analogue scale every hour for an 11-hour observation period. The time courses and the sum of pain intensity after injection of the double and standard volumes did not differ significantly. Doubling the volume of local anaesthetic while maintaining the total lidocaine and adrenaline concentration that was infiltrated does not influence the intensity of acute pain after gingivectomy.

Keywords: Postoperative pain; Local anaesthetic; Lidocaine; Adrenaline; Volume; Gingivectomy

Introduction

Local anaesthetic agents with adrenaline as the vasoconstrictor used for surgical soft-tissue and bone interventions in the oral region tend to cause more postoperative pain than local anaesthetics without adrenaline as the vasoconstrictor.[1,2] Controlled clinical trials have shown that the adrenaline concentration is essential as a contributing factor in inducing postoperative pain after the use of local anaesthetics in oral surgical procedures.[3,4]

The question of whether the actual volume of the local anaesthetic solution itself can contribute to acute postoperative pain, however, remains unclear. We have previously published a paper in this journal which reported that doubling the volume and dose of infiltrated local anaesthetic (lidocaine and adrenaline) increased acute pain after gingivectomy.[5]

The aim of this paper was to investigate the effect of doubling the volume of local anaesthetic solution without changing the total dose (standard dose) given of lidocaine and adrenaline on acute postoperative pain after gingivectomy.

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Patients and methods

Study design and ethical considerations

The trial was a randomised, single-blind, within-patient, crossover study. Informed consent was obtained from all subjects after the nature and intentions of the study had been explained to them. The trial protocol was approved (S-03097) by the Regional Committee for Medical Research Ethics South, Norway (REK SOUTH).

Patients and operative technique

Patients referred to a specialist practice in periodontology who required identical bilateral gingivectomies on two separate occasions within the same jaw were included. Patients who had good oral hygiene after initial conservative periodontal treatment, but had persistent bilateral diseased areas were asked to take part in the study. Those with furcation involvement of teeth were not asked to participate. Patients taking anti-inflammatory drug during the month before operation were excluded. Pregnant women, lactating mothers, and people with diagnosed diabetes or untreated hypertension, were excluded from the trial. The participants had to be able to cooperate verbally and in writing.

All patients had had initial conservative periodontal treatment by a dental hygienist for three sessions, and scaling and root-planing of the teeth for at least two sessions by the specialist (LJ) before operation.

The patients were allocated at the time of the first gingivectomy to one of two treatment groups according to a randomised list. Before the first operation the patients were given either a standard volume or a double volume of local anaesthetic. The total dose (standard dose) given was identical on both occasions; only the volume differed. The standard volume was defined as the volume of local anaesthetic that an experienced surgeon would use for gingivectomy of a defined gingival area. Double volume was defined as twice the standard volume. All actual volumes were noted. The patients assessed their subjective postoperative pain independently of the surgeon and were unaware of the amount of the local anaesthetic given. In the one treatment session, commercially available 2% lidocaine hydrochloride 20 mg/ml with 1/80 000 adrenaline 12.5 μg/ml (Xylocain adrenalin, Astra, Södertälje, Sweden) was injected as standard volume, standard dose. In the other treatment session a prescribed formulation of 1% lidocaine 10 mg/ml with 1:160 000 adrenaline 6.25 μg/ml (Hospital Pharmacy, Rikshospitalet University Hospital, Oslo, Norway), manufactured according to Good Manufacturing Practice, was injected as double volume of standard dose. The prescribed formulation was made from the commercial recipe with the exception only of the lidocaine and the adrenaline concentration. All local anaesthetics were supplied in capped vials. Neither premedication nor topical anaesthetic was given.

Local anaesthetic was infiltrated into the gingival areas to be operated on with thin 27 G disposable hypodermic needles for dental use (0.4 × 0.4 mm, B. Braun Melsungen AG, Melsungen, FRG) by the same surgeon (LJ). The needle was inserted gently in one continuous movement into the gingival target area where the local anaesthetic solution was slowly injected supraperiostally during a 2 min period. Movements that could induce scraping of the periosteum were avoided. No local anaesthetic solution leaked during infiltration and successful infiltration was confirmed by transient tissue ischaemia.

The operation started immediately after the anaesthetic injection had been given. All gingivectomies were done by the same surgeon (LJ) as described by Ramfjord and Ash without removing any bone.[6] Gingivectomies comprised buccal and palatinal or lingual soft tissue that was encircling the teeth in all cases. Periodontal dressings (Coe-Pak, Coe Laboratories Inc., Chicago, IL, USA) were applied as wound dressings. Efforts were made to make the periodontal dressings similar in shape and extension for all comparable bilateral surgical areas. The time used from incision to finished periodontal dressing was noted. Time between bilateral gingivectomies was set to be at least 14 days.

Assessments of pain and statistical analyses

The patients were given clinical record forms on which they were instructed to assess their subjective postoperative pain intensity on visual analogue scales running from 0 mm = no pain to 100 mm = pain cannot be worse. The assessments started when the operation had been completed, and continued hourly for the next 11 h. This observation period was chosen because it had previously been shown that the major transitory pain course in this model occurs on the day of operation.[7] The primary outcome variable was the sum of pain intensity which was calculated by adding the hourly VAS scores over the 11-hour observation period.

The patients were instructed not to drink any alcohol during the 11-hour observation period, and not to take any analgesic medication unless it was absolutely necessary. If any analgesic was taken, the time, the number of tablets, and type of medication was to be noted on the form. If any analgesic was taken, the pain score at the time of medication should indicate any consecutive score until the end of the observation period. The patients returned to the clinic 14 days after each gingivectomy for removal of the periodontal dressings and for wound control. The record forms were collected and the patients were asked if they had taken any analgesic drugs. The verbal answer to this question was checked with the patients' record forms. Any wound complication was also noted.

Estimation of sample size was made using PS-Power and Sample Size Calculations (ver. 2.1.30) assuming normal distribution of data.[8] Calculations were made with data estimated subjectively based on previous experience and was