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RESEARCH ARTICLE

Evaluation of the effectiveness of tube drain on postoperative discomfort in mandibular third molar surgery: prospective randomized split-mouth study

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ABSTRACT

Introduction: The present randomized split-mouth study aimed to investigate the clinical effectiveness of postoperative discomfort of the use of a surgical drain after lower third molar extraction.

Materials and methods: It was conducted a prospective randomized split-mouth study involving 30 patients with bilateral symmetric lower third molar. Each patient underwent two operations for the extraction of impacted teeth: test site (tube drain) and control site (conventional total closure of surgical flap), resulting in 30 cases in the test group, and 30 cases in the control group. Pain, swelling, and mouth opening were evaluated immediately before the surgeries, after 1, 3 and 7 days postoperatively in both groups. Data were analyzed with non-parametric test (Kruskal-Wallis test and the post hoc Dun test, and Wilcoxon matched-pairs signed rank test).

Results: Facial swelling ($p < .001$) was significantly less in test group compared with the control group on all examined days. Trismus is significantly reduced only on the third day ($p < .001$); Pain measurements did not differ statistically significantly between the two groups on all post-operative days ($p > .05$).

Conclusion: The use of the tube drain reduced facial swelling and trismus, but had no influence on the subjective perception of postoperative pain.

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KEYWORDS
Tube drain; impacted third molar; facial swelling; trismus; pain

1. Introduction

Impacted third molars are most commonly found in the mandible, and they are often associated with clinical diseases including pericoronitis, damage to adjacent teeth, or odontogenic cysts; these are the main indications for dental extraction [1]. Regarding the various types of inclusion, a lot of classifications have been proposed for the third lower molars, based on their position and the surgical difficulty of the extraction; among these the most frequently used are that of Winter and Pell and Gregory [2].

The extraction of an impacted wisdom tooth is, nowadays, the most common surgical procedure performed by oral surgeons [3].

Third molar surgeries are associated with postoperative discomfort, referred to as postoperative morbidity, which is more common in the mandible than in the maxilla [4].

Postoperative morbidity is mainly represented by complications such as bleeding, dry socket, nerve injury, delayed healing, periodontal pocketing, and infection, and by physiological tissue responses due to surgical trauma such as facial swelling, trismus and pain [5].

Factors affecting postoperative discomfort have been the subject of much research, focusing mainly on the methodology of the surgery [6,7] or the pharmacological therapies [8].

In particular, the wound closure technique can consist of primary closure, in which the mucoperiosteum is hermetically sealed, or secondary closure, in which a window is present or is created to allow healing by secondary intention [4].

It was proposed that the intraorally placement of a surgical drain is a procedure that could reduce the extent of the postoperative discomfort ensuring the drainage of blood and serum or the expulsion of potential dead tissues [9].

Although there are some clinical studies analyzing the effect of the drainage, the results are still contradictory, and as supported by the systematic review of Liu et al. [10], the quality of the present studies is still low, and more randomized studies of high quality are needed.

The present randomized split-mouth study aimed to investigate the effect of the use of a surgical drain after lower third molar extraction. Specifically, to analyze if there are differences in terms of swelling, trismus and pain between the group receiving the placement of the surgical drainage and the one receiving the conventional closure of the surgical flap.

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2. Materials and methods

2.1. Study design and sampling

The present split-mouth Randomized Controlled Trial (RCT) was designed and conducted in the Oral Surgery Division of the Multidisciplinary Department of Medical-Surgical and Dental Specialties, University of Campania 'Luigi Vanvitelli' (Naples, Italy). The study protocol was approved by our institution's ethics committee on 12 June 2005 (Second University of Naples [SUN] Internal Registry: Experimentation #914).

The inclusion criteria were age 17–40 years old; bilaterally symmetrical lower third molars (Figure 1) that were in mesio-angular or horizontal position (Winter classification) with completely formed roots and classified as class II–II and class A–B according to Pell and Gregory classification (Evaluations carried out on orthopantomogram); FMBS (full mouth bleeding score) ed FMPS (full mouth plaque score) <15%; no history of facial trauma, any medical condition; and no pericoronitis or pain before surgery. The design of the study was explained to each participant. The details about the surgical procedure and possible complications were also informed. An informed written consent was obtained from the patients before the study.

2.2. Surgical procedure

Each patient underwent two oral surgeries (test site and control site) for impacted teeth removal with the same surgical technique except for the closure of the flap. All surgeries were performed by the same surgeon in two different appointments.

After inferior alveolar nerve blockade (carbocaine 3%) and local infiltration of the buccal fold with carbocaine (2%) and epinephrine (1:100,000), a triangular mucoperiosteal flap was sculpted, with a vertical incision between first and second molar. Osteotomy was performed around the impacted tooth using a drilling burr, and the tooth was sectioned under irrigation with physiological saline. The tooth was removed. In the control group, the flap was repositioned and sutured with simple interrupted sutures using 3–0 braided silk (Figure 2(a)), and in the test group, after suturing a small surgical tube drain (2 cm long, 2 mm diameter) was inserted into the socket of incision on buccal side, and sutured on the flap (Figure 2(b)).

The drainage tube was removed on the third postoperative day, and in both groups, the sutures were removed on the 7th day. All patients followed antibiotic therapy with amoxicillin + clavulanic acid (875 mg + 125 mg) for 5 days twice daily and anti-inflammatory therapy for the first 3 postoperative days with ibuprofen 600 mg twice daily.

2.3. Measurement methods

Patients were examined immediately preoperatively and on the first, third, and seventh postoperative days.

The pain was evaluated and recorded in the postoperative period *via* Visual Analog Scale (VAS) from 0 (no pain) to 10 (worst pain imaginable).

Facial swelling was measured using a flexible millimeter ruler, following a measurement scheme inspired by the one described by Ristow et al. [11] The one used in this RCT consisted of two horizontal and one vertical measurement (Figure 3(a)): the horizontal measurements correspond to the distance between the corners of the mouth to the ear tragus and between soft tissue pogonion to the ear tragus. The vertical measurement was the distance between the outer canthus of the eye to the angle of the mandible.

The maximum mouth opening was evaluated by measuring the distance between the incisal edges of the upper and lower central incisors, using a caliper (Figure 3(b)).

2.4. Sample size calculation and randomization

The ideal sample size calculation was done using the 'pwr' package on R software (Version 1.4.1103) [12] to ensure adequate power for the study. Thirteen patients were sufficient to provide an 80% power with α of 0.05.

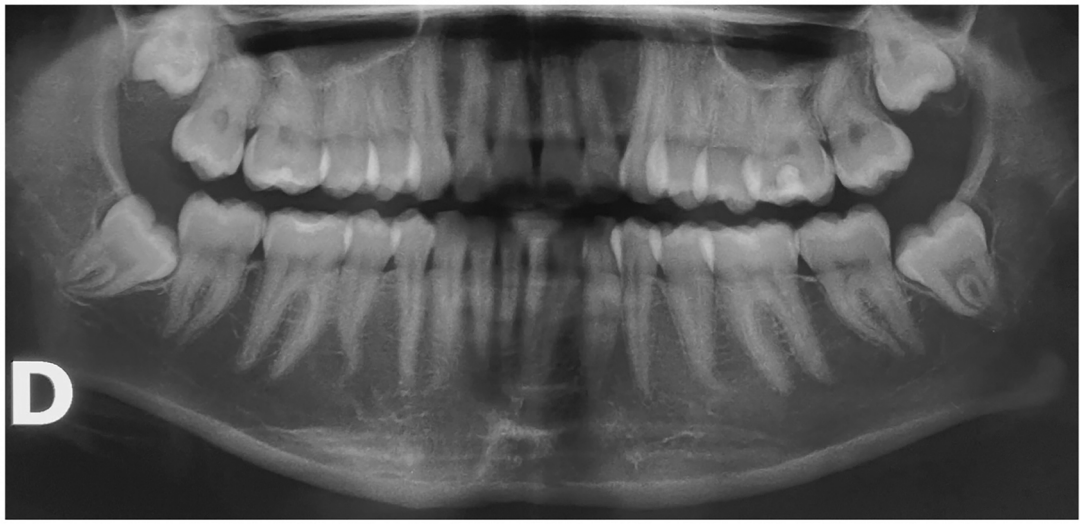

Figure 1. Orthopantomographic image showing bilaterally symmetrical lower third molars.

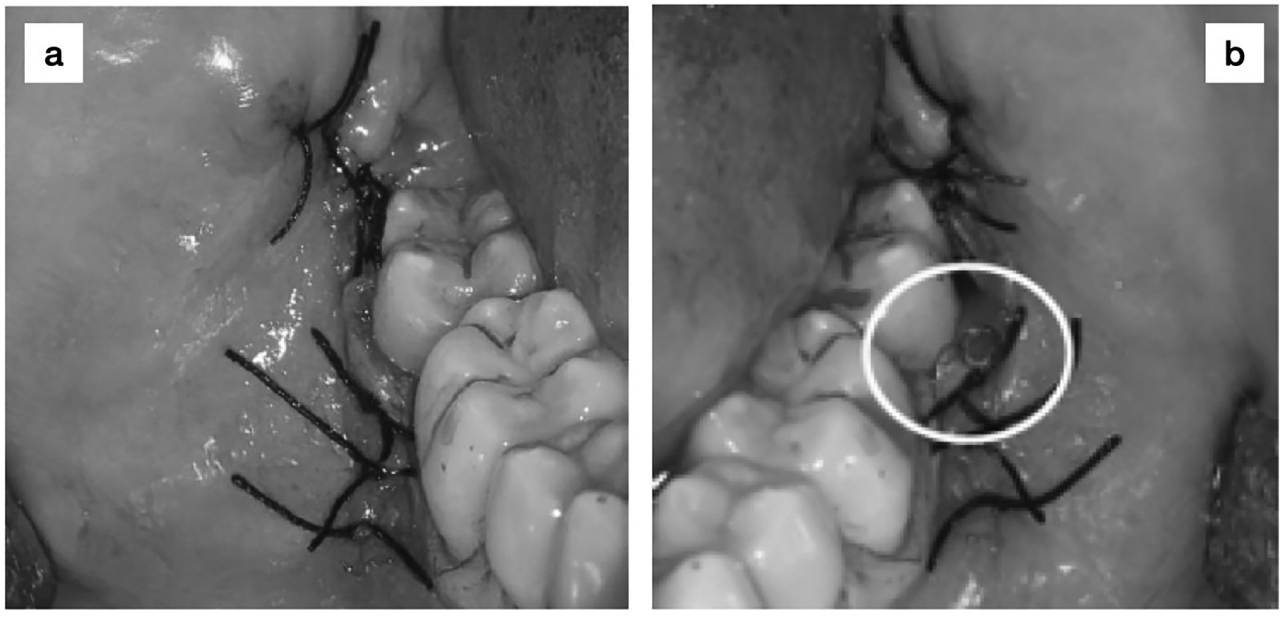

Figure 2. (a) Control group with conventionally primary closure of flap. (b) Test group with the tube drain in buccal side.

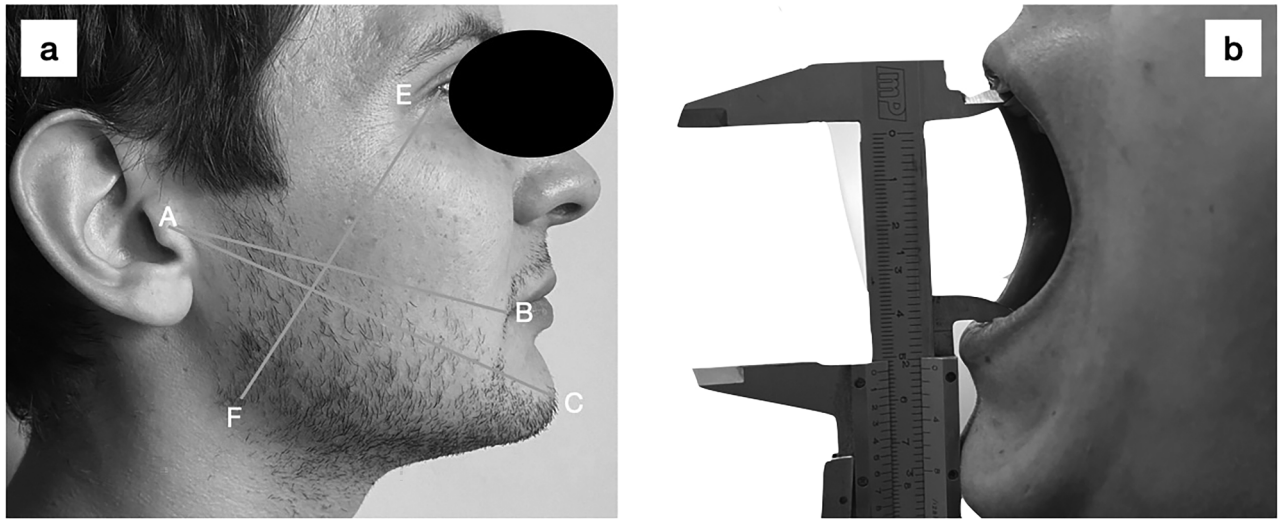

Figure 3. (a) Measurement scheme of facial swelling. (b) Measurement of maximum mouth opening.

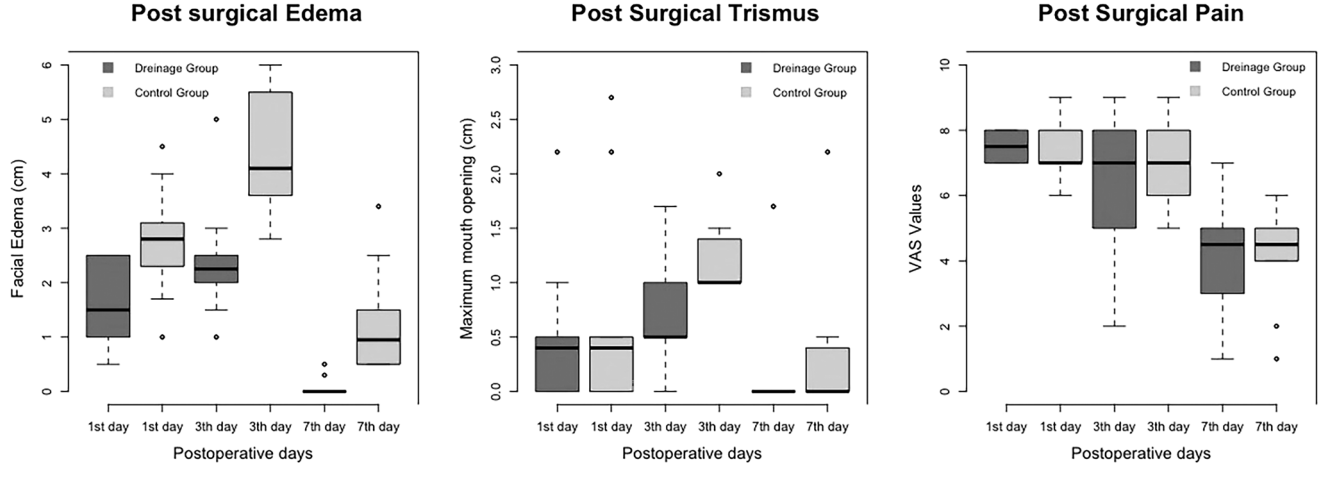

Figure 4. Box plots of the distribution of the outcome values in each of the days examined.

Participants were informed about the randomization but did not know which side will be drained before the first surgery. Before the first surgery, a random assignment tool determined whether the wound shall be drained or primarily closed. In the second intervention, on the contralateral side, the opposite procedure was applied.

2.5. Statistical analysis

The data was analyzed and graphically represented (Figure 4) using the statistical software R (Version 1.4.1103). Differential values were used for the edema and trismus variables. These values were calculated by subtracting the size measured post-operative from the pre-operative size of the mouth opening or of facial measurement, to obtain the measure of the reduction of the mouth opening or the measure of the increase in facial measurement due to edema. For pain, the values reported by the patients on each of the days evaluated were used.

After testing (Shapiro–Wilk test, $p < .05$) the not normal distribution of the data, non-parametric statistical texts were used for the analysis. The level of significance was set at $p \leq .05$.

Table 1. Intra-group analysis.

		Test group			Control group	
Facial		1 Day	3 Day		1 Day	3 day
swelling	3 Day	0.0403		3 Day	*0.0004	
	7 Day	*0.0000	*0.0000	7 Day	*0.0002	*0.000
Trismus		1 Day	3 Day		1 Day	3 Day
	3 Day	0.2141		3 Day	*0.0002	
	7 Day	*0.0008	*0.0000	7 Day	0.081	*0.0000
Pain		1 Day	3 Day		1 Day	3 Day
	3 Day	0.0582		3 Day	0.03175	
	7 Day	*0.0000	*0.0000	7 Day	*0.0000	*0.0000

Results of intra-group analysis with Kruskal Wallis test and Dunn *post hoc* test. *Results with statistical significance.

Table 2. Facial swelling increase at 1, 3, 7 days compared to the preoperative measurement.

	Test group		Control group		
	Mean (cm)	SD	Mean (cm)	SD (cm)	*p*-Value
1 Day	1.53	0.74	2.77	0.98	<.0001
3 Day	2.4	1.04	4.31	1.04	<.0001
7 Day	0.08	0.17	1.28	0.97	<.0001

Table 3. Reduction of the maximum opening of the mouth at 1, 3 and 7 days postoperative compared to the preoperative measurement.

	Test group		Control group		
	Mean (cm)	SD (cm)	Mean (cm)	SD (cm)	*p*-Value
1 Day	0.52	0.64	0.67	0.94	.951
3 Day	0.7	0.54	1.22	0.32	<.0001
7 Day	0.17	0.52	0.31	0.67	.719

An intra-group analysis was first performed using the Kruskal–Wallis test and the *post hoc* Dun test, and then an iter-group analysis was performed using the Wilcoxon matched-pairs signed rank test to evaluate the differences in means of swelling, pain, and trismus between drainage group ad control group. In order to control for patient-specific variables such as age and sex, linear regression analysis and Wilcoxon respectively was performed.

3. Results

The sample of 30 patients consisted of 16 males and 14 females; patients underwent a total of 60 surgeries ($n = 30$ test and $n = 30$ control) of the impacted mandibular third molars. The mean age of the patients at the time of the first surgery was 23.18 years (SD ± 6.89). The time between the first and the second surgery was 7.3 weeks in average (SD ± 2.8).

The intra-group analysis (Table 1) revealed that the edema was more severe on the third postoperative day and less severe on the 7° postoperative day ($p < .000$), although in the test group the difference in values is not significant between the first and third post-operative day.

The same relationship emerged from the analysis of trismus ($p < .000$), although in the test group the first and third postoperative day did not differ significantly ($p > .05$) in terms of maximum opening of the mouth, instead in the control group there was no difference between 1° and 7° postoperative day ($p > .05$).

Regarding the analysis of postoperative pain, in both groups, it was maximum on the first postoperative day and then progressively reduced to 3 and 7 days, showing a non-statistically significant difference between the first and third day.

The inter-group analysis found that the test group had statistically significantly reduced facial swelling (Table 2) compared to the control group on all three days evaluated ($p < .001$).

Analysis of the trismus (Table 3) showed that although there was a reduction in the test group compared to the control group on both the third and seventh days, there was a statistically significant difference only on the third day ($p < .001$).

Regarding perceived pain (Table 4), the analysis showed that in the test group there is reduction in average pain on all analyzed days ($p > .05$).

4. Discussion

Surgery for the extraction of mandibular third molars is the most frequent intervention in oral surgery, and it is

Table 4. Pain scores (VAS) on days 1, 3, and 7 postoperatively.

	Test group			Control group			
	Median (cm)	Mean (cm)	SD	Median (cm)	Mean (cm)	SD (cm)	*p*-Value
1 Day	7.5	7.5	0.5	7	7.3	0.79	.137
3 Day	7	6.5	2.04	7	6.9	1.55	.6885
7 Day	4.5	4	1.93	2.2	4.5	1.56	.6888

associated with post-operative discomfort represented by facial edema, trismus and pain. These clinical signs are caused by tissue responses to surgical trauma, represented by the activation of inflammatory pathways and the release of chemical mediators which lead to the widening of blood vessels, migration of inflammatory cells to the operation site, and the development of edema and pain [13]. Inflammation of the mastication muscles causes painful spasms and limitation of the mouth opening results in trismus [14].

Over the years, various methods have been proposed to reduce discomfort and improve the quality of life in patients in the postoperative period; these include ozone therapy [8], drugs (corticosteroids, non-steroidal anti-inflammatory drugs, and combination analgesic) [15], low-level laser therapy [16], different surgical techniques as raised surgical flaps and bone removal techniques [6,17,18] and the surgical drainage [1].

Different types of drainage have been described such as tube drain, rubber drain, and drainage gauze [10]. The present work focused on evaluating the effect of surgical drainage in lower wisdom tooth surgery, through a prospective randomized spit-mouth study to analyze whether the use of a tube drain affects the extent of post-operative discomfort in terms of trismus, edema and pain.

The choice of identifying and including only patients with symmetrically positioned toothed elements, and the choice of a single surgeon who performed all the interventions, is due to the reduction of the variables that could affect the extent of surgical trauma and distort the results of the outcomes.

The same pharmacological therapy was administered, both antibiotic and anti-inflammatory, to further standardize the sample. Furthermore, although antibiotic therapy is not strongly recommended, as shown by the latest systematic review and meta-analysis on the topic [19], antibiotic therapy (in any dose or regimen) is an independent factor in the reduction of the rate of third party post-surgical infections molars. Furthermore, as attested by the same systematic review and meta-analysis, antibiotic therapy has no statistically significant effects on the reduction of post-operative pain, trismus and edema [19], therefore its administration should not have affected the effect of surgical drainage.

Regarding facial edema, the use of drainage compared to conventional flap closure significantly reduced its entity in all the days examined, also leading to an almost complete recovery on the seventh day. These results are in agreement with the previous literature, having found similar results also the studies of Kumar et al. [20], Cerqueira et al. [21], Khaitan et al. [22], and with those that emerged from the systematic review of Liu et al. [10]

From the analysis of the extent of the trismus, the data of the analysis showed that in the experimental group the reduction of the maximum opening of the mouth is significantly less only on the third postoperative day, in the other postoperative days no real advantage emerged in the use of drainage.

Furthermore, postoperative medication such as nonsteroidal anti-inflammatory drugs could affect pain [23]. In the present study, it was decided to assign a single therapeutic pharmacological protocol to standardize the sample and reduce the possible influences on the parameter measurements.

In the pain assessment using the VAS scale, the patients did not perceive an improvement in symptoms and the statistical analysis revealed that on all three days there were no differences between the two groups. This could be linked to the discomfort and irritation due to the presence of the tube in the mouth, being made of a semi-rigid material.

The results of the present studio are partially in agreement with the data emerging from the latest systematic review and meta-analysis of Liu et al. [10], which showed that the tube drain does not appear to be effective in reducing late pain.

Therefore, if on the one hand, the drainage appears useful in reducing edema and, partially the trismus, on the other hand, the pain does not seem to benefit.

The use of surgical drainage is a simple and low-cost technique, moreover, it leads to benefits in discomfort linked to parameters that can be measured through objective scales; but it must be considered that the tube drain does not have high compliance of the patients, mainly due to the presence of the tube in the mouth and the number of extra visits that are required to remove the drainage. In addition to this critical aspect, it should be noted that pain is the main symptom experienced by the patients, and that, in the postoperative period, make the quality of life worsen; in this studio considering the postoperative pain, the patients did not notice significant differences between test and control site.

5. Conclusion

The findings of this study suggest that the use of a tube drain significantly reduced postoperative swelling, and partially trismus after extraction of mandibular third molars, so conventional wound closure with a tube drain may be an effective way to minimize them, but it does not improve the subjective outcome, that is, the patient's perception of post-operative pain.

Author contributions

DM and LL contributed to conception and design. DM and DR contributed to data acquisition. PM contributed to analysis and interpretation of the data. PM and DR drafted the manuscript. PM and LL revised the manuscript. All authors gave final approval and agreed for all aspects of the work.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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