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The Use of Cryotherapy in Conjunction with Surgical Removal of Mandibular Third Molars: a Single-Blinded Randomized Controlled Trial

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ABSTRACT

Objectives: Cryotherapy is frequently used to diminish postoperative sequelae following mandibular third molar surgery. The objective of this single-blinded randomized controlled trial was to assess the therapeutic efficiency of 30 minutes continuous cryotherapy on postoperative sequelae following surgical removal of mandibular third molars compared with no cryotherapy.
Material and Methods: Thirty patients (14 male and 16 female) including 60 mandibular third molars were randomly allocated to 30 minutes of immediately cryotherapy or no cryotherapy. Outcome measures included pain (visual analogue scale score), maximum mouth opening (trismus) and quality of life (oral health impact profile-14). Outcome measures were assessed preoperatively and one day, three days, seven days and one month following surgical removal of mandibular third molars. Descriptive and generalized estimating equation analyses were made. Level of significance was 0.05.
Results: No cryotherapy following surgical removal of mandibular third molars revealed a statistically significant lower visual analogue scale score of pain compared to thirty minutes of continuous cryotherapy after one day ($P < 0.05$). However, no statistically significant difference in trismus or oral health-related quality of life were revealed at any time point compared with no cryotherapy.
Conclusions: The therapeutic effect of 30 minutes continuous cryotherapy following surgical removal of mandibular third molars seem to be negligible. Thus, further randomized controlled trials assessing a prolonged application period of cryotherapy, alternative devices or use of intermittent cryotherapy are needed before definite conclusions and evidence-based clinical recommendations can be provided.

Keywords: cryotherapy; dentistry; mandible; pain; third molar; trismus.

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INTRODUCTION

The most common surgical intervention undertaken in oral and maxillofacial surgery is surgical removal of mandibular third molars (SRM3). Postoperative pain, facial swelling, trismus and deterioration in postoperatively oral-health related quality of life are common and expected sequelae. Various therapies have been investigated to diminish postoperative sequelae including analgesics, antibiotics, corticosteroids, cryotherapy, low-laser therapy and compression [1-3]. Cryotherapy is a non-pharmacologic intervention that is frequently used following SRM3. Though, the therapeutic effect of cryotherapy seems to be controversy, which is emphasized in several systematic reviews [4].

Different techniques and devices are available for application of cryotherapy, including intermittent (applied for a shorter time and is reapplied several times over the duration of treatment) or continuous (applied for the duration of treatment and then removed) cryotherapy [4-6]. Frozen gel packs, ice packs wrapped in a washcloth or Hilotherm device are frequently used to reduce the skin and subcutaneous tissue temperature following SRM3 [5,7-11]. However, there are no evidence-based clinical recommendations regarding the most optimal technique, device or duration of treatment [4].

Cryotherapy is an easy, simple and non-pharmacologic intervention, which is generally accepted by most patients following SRM3. Use of continuous cryotherapy for a shorter period of time will have the least influence on the patient's daily life, whereas long-lasting intermittent cryotherapy with the use of Hiloterm is time consuming, expensive and difficult to implement in dental practice. From a clinical and patient perspective, it would therefore be an advantage if continues cryotherapy for a limited period of time was capable of diminishing postoperative sequelae following SRM3. The objective of the present single-blinded randomized controlled trial was therefore to test the null-hypothesis of no difference in pain, trismus and oral health-related quality of life following SRM3 with 30 minutes of immediate cryotherapy compared with no cryotherapy.

MATERIAL AND METHODS

Study design

The study was designed as a split-mouth single-blinded randomized controlled trial and conducted at the Department of Oral and Maxillofacial Surgery, Rigshospitalet, Copenhagen University Hospital, Denmark between October 2018 and January 2019. The study protocol was approved by Research Ethics Committee and the Danish Data Protection Agency (approval no.: N-20170016) and performed in accordance with the Declaration of Helsinki II and the Consolidated Standards of Reporting Trials (CONSORT) statement [12].

Patients scheduled for SRM3 prior to orthognathic surgery were screened. Patients with bilateral and comparable impacted mandibular third molars according to Pell and Gregory classification were invited to participate in the study [13]. Oral and written information regarding the study were explained to the patients, and written informed consent was obtained from every patient prior to enrolment. Participation in the study was voluntary and included patients could at any given time withdraw from the study.

Sample size calculation and study population

For obtaining a statistically significant treatment difference, a sample size was determined, expecting a difference of 20 mm in VAS score of pain at the first postoperative day, with an alpha value of 0.05 and a statistical power of 0.8. The sample size calculation was conducted using Clincalc.com (http://clincalc.com/stats/samplesize.aspx, accessed 9th March 2017).

Position of the mandibular third molars on panoramic radiographs were classified using Pell and Gregory system and Winter's classification [13]. The inclusion and exclusion criteria are outlined in Table 1.

Table 1. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
- Bilateral symmetrical impacted mandibular third molars. - Indication for removal of mandibular third molars. - Age between 18 and 40 years.	- Infections and inflammatory symptoms in the oral cavity at the time of surgery. - Previous maxillofacial trauma. - Craniofacial clefts or syndromes. - Systemic bone disease (i.e. arthritis) or diabetes mellitus. - Active acne vulgaris, viral, and fungal infections. - Psychological disease. - Pregnancy and breastfeeding. - Failure to attend follow-up.

Randomization and blinding

The mandibular third molars were randomly allocated to 30 minutes of immediate continuous cryotherapy or no cryotherapy using a computer-aided block randomization. A randomization sheet with a serial number from 1 to 30 were made (http://www.randomization.com, Randomization.com, date: 22nd August 2018). The numbers were stored in sealed envelopes, and every patient opened an envelope with a number. The assistant nurse combined the number with the randomization sheet to allocate the mandibular third molar to cryotherapy or no cryotherapy. The randomization sheet was kept by the assistant nurse until the study was unblinded.
The assistant nurse placed the cold gel pack on the patient´s cheek following SRM3 and removed the gel pack after 30 minutes. Surgeon and assessor were therefore blinded in relation to the applied treatment.

Surgical procedure

The included patients underwent SRM3 in local anaesthesia by the same surgeon (MKL) using a standard technique. One mandibular third molar was removed at each time. Surgical removal of the second mandibular third molar was performed approximately one to six weeks after the first surgery.
Prior to the surgery, the patients received prophylactic analgesic including 400 mg ibuprofen (Ipren® - Takeda Pharma A/S; Hobro, Denmark) and 1,000 mg paracetamol (Pinex®, Actavis Nordic A/S; Søborg, Denmark).
The inferior alveolar nerve and the lingual nerve were anaesthetized with 20 mg/mL mepivacaine hydrochloride and 5 µg/mL adrenaline (Carbocain-Adrenalin® - AstraZeneca; Copenhagen, Denmark). An incision from the anterior border of the ascending ramus of the mandible to the distal part of the lower first molar was performed. The mucosal flap was elevated and the bone around the mandibular third molar was removed with a round burr under irrigation with 0.9% saline solution. If necessary, the mandibular third molar was sectioned with a fissure bur. The tooth was elevated out, and the extraction socket and surrounding bone was irrigated with 0.9% saline solution. The surgical site was sutured with resorbable suture (Ethicon Vicryl Rapide™ suture 4-0 - Johnson and Johnson Medical Gmbh; Norderstedt, Germany). Time of surgery was measured from the incision until the last suture was made.
If the mandibular third molar was allocated for cryotherapy, a freezable cold gel pack (Cool Jaw® Soft Stretch Jaw Wrap with Cold Packs - Medico International Inc.; Palmer, Pennsylvania, USA) and a jaw bra was applied on the cheek immediately following SRM3 for 30 minutes.
All patients received standard postoperative instructions and pain medication including mouth rinse with 0.12% chlorhexidine three times a day (Klorhexidin Mundskyl 0.12% - Faaborg Pharma; Faaborg, Denmark), 400 mg of ibuprofen three times a day (Ipren®) and 1,000 mg paracetamol four times a day (Pinex®).

Data collection

Clinical assessment was obtained preoperatively (T0), one day (T1), three days (T2), seven days (T3) and one month (T4) following SRM3. All data were collected by the same assessor (MKL).
Pain was evaluated by a 100-mm VAS-score obtained preoperatively (T0), one day (T1), three days (T2), seven days (T3), and one month (T4) postoperatively. All patients were carefully instructed in the use of VAS and had to mark on the line the point that represented their pain.
Mouth opening was measured as the maximum distance between the upper and lower incisal edges with a ruler preoperatively (T0), three days (T2), seven days (T3) and one month (T4) following SRM3.
Oral health-related quality of life was evaluated by oral health impact profile 14 (OHIP-14) questionnaire obtained preoperatively (T0), seven days (T3), and one month (T4) following SRM3. OHIP-14 is composed of 14 questions and organised into seven dimensions including functional limitation, physical discomfort, psychological discomfort, physical disability, psychological disability, social disability and handicap (Table 2). The OHIP-14 scale ranged from 0 to 56 and dimension score ranged from 0 to 8. The values of the 14 items and each dimension were summed to calculate the OHIP-14 severity score with higher scores indicating poorer oral health-related quality of life. Patients were carefully instructed in the OHIP-14 questionnaire and completed the questionnaires by themselves.
Complications including infections, alveolitis sicca, lost sutures and dehiscence were registered three days (T2), seven days (T3) and one month (T4) following SRM3.

Statistical analysis

Anatomical position of the mandibular third molars was presented as counts and percentage on each treatment group. The time of surgery was presented with mean, standard deviation, minimum and maximum.

Table 2. OHIP-14 score

	Question[a]
Functional limitation	Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?
	Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?
Physical pain	Have you had painful aching in your mouth?
	Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?
Psychological discomfort	Have you been self-conscious because of your teeth, mouth or dentures?
	Have you felt tense because of problems with your teeth, mouth or dentures?
Physical disability	Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?
	Have you had to interrupt meals because of problems with your teeth, mouth or dentures?
Psychological disability	Have you found it difficult to relax because of problems with your teeth, mouth or dentures?
	Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?
Social disability	Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?
	Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?
Handicap	Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?
	Have you been totally unable to function because of problems with your teeth, mouth or dentures?

[a]Answers: 0 = never; 1 = hardly ever or nearly never; 2 = occasionally; 3 = fairly often or many times; 4 = very often.

Mean difference in pain and trismus were analysed with a generalized estimating equation (GEE) analysis for repeated observations. Oral health-related quality of life was presented with mean and standard deviation for OHIP-14 score. Missing observations in outcome variables were assumed to be missing randomly. The estimated mean value for pain, trismus and oral health-related quality of life were expressed with a 95% confidence interval (CI). Statistical significance of the P-value was set at 0.05. The analyses were descriptive and adjusted for age, sex, smoking and time of surgery. Parametric data were expressed as mean and standard deviation (M [SD]).

Data management and statistical analysis was performed with Excel version 2013 (Microsoft; Redmond, Washington, USA) and R software version.3.6.1 (R Foundation for Statistical Computing; Vienna, Austria; http://www.r-project.org).

RESULTS

Study population

Thirty patients (14 male and 16 female) with a mean age of 22.6 (SD 4.7) years were included resulting in 60 mandibular third molars (Figure 1). Length of surgery was 10.13 (SD 3.94) minutes with no statistically significant difference between test and control group (P = 0.438) (Table 3). The contralateral third molar was removed after 21 days (range 7 to 35 days).

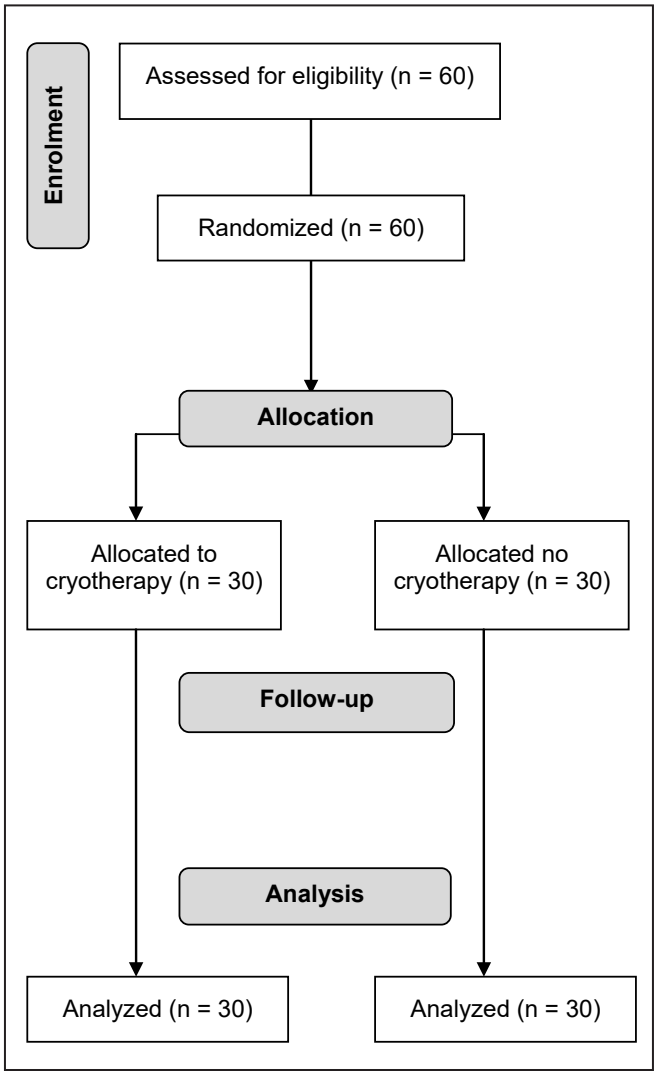

Figure 1. Consort flow diagram.

Table 3. Anatomical position of mandibular third molars and time of surgery in the two groups and total

Variable	Level	No cryotherapy (n = 30)	Cryotherapy (n = 30)	Total (n = 60)
Anatomical position (Winter), N (%)	**1**	2 (6.7)	6 (20)	8 (13.3)
	2	5 (16.7)	7 (23.3)	12 (20)
	3	18 (60)	14 (46.7)	32 (53.3)
	4	5 (16.7)	3 (10)	8 (13.3)
Anatomical position (Pell and Gregory transversal), N (%)	**1**	0 (0)	0 (0)	0 (0)
	2	23 (76.7)	25 (83.3)	48 (80)
	3	7 (23.3)	5 (16.7)	12 (20)
Anatomical position (Pell and Gregory vertical), N (%)	**1**	3 (10)	5 (16.7)	8 (13.3)
	2	19 (63.3)	20 (66.7)	39 (65)
	3	8 (26.7)	5 (16.7)	13 (21.7)
Time of surgery (minutes)	**Mean (SD)**	9.83 (4.06)[a]	10.43 (3.87)[a]	10.13 (3.94)[b]
	Q1; Q3	7.25; 11	8.25; 12	7.75; 12
	Min; max	0; 20	0; 19	0; 20

n = number of wisdom teeth; Q1 = first quartile; Q3 = third quartile; SD = standard deviation.
[a]Missing one mandibular third molar.
[b]Missing two mandibular third molars.

Postoperative instructions were followed by all patients. Infection involving either fever, chills, sore lymph nodes and pus occurred following removal of five third molars, which were treated sufficiently with antibiotics involving phenoxymethylpenicillin 800 mg (Primcillin® - Meda A/S; Ballerup, Denmark) four times a day and metronidazole 500 mg (Metronidazol "DAK" - Takeda Pharma A/S; Hobro, Denmark) two times a day for seven days.

Pain

VAS score of pain with cryotherapy was 2.79 (SD 7.34) (T0), 60.97 (SD 21.66) (T1), 36.86 (SD 16.11) (T2), 11.30 (SD 11.96) (T3) and 5 (SD 100) (T4). VAS score of pain without cryotherapy was 2.71 (SD 6.95) (T0), 49.61 (SD 27.53) (T1), 29.64 (SD 22.1) (T2), 18.57 (SD 20.27) (T3) and 4 (SD 100) (T4). Patients without cryotherapy had a statistically significant lower VAS score of pain compared with 30 minutes of cryotherapy after one day ($P < 0.05$). There was no statistically significant difference between the two treatment modalities at any other time point (Table 4).
In addition, there was no statistically significant difference in VAS score of pain between the two treatment modalities at any time points, when groups were adjusted for sex, smoking and time of surgery. However, VAS score of pain was 1.28 mm higher, when the age increased with 1 year after 1 month (T4), which was statistically significant ($P < 0.05$).

Mouth opening

Maximum mouth opening with cryotherapy was 48.72 (SD 9.25) mm (T0), 30.79 (SD 5.92) mm (T2), 41.26 (SD 8.31) mm (T3) and 48 (SD 11.22) (T4). Maximum mouth opening without cryotherapy was 50.03 (SD 8.82) mm (T0), 33.31 (SD 9.1) mm (T2), 40 (SD 8.18) mm (T3) and 42.6 (SD 10.97) mm (T4). There was no statistically significant difference between the two treatment modalities at any time point (Table 4).
There were statistically significant differences in maximum mouth opening between the two treatment modalities, when the groups were adjusted for age, sex, smoking and time of surgery. Mouth opening was restricted with 0.1 mm, when the age increased with one year after one month (T4), which was statistically significant ($P < 0.05$). Females had a statistically significant decreased mouth opening compared with males after one month ($P < 0.05$). Maximum mouth opening was statistically significant restricted after seven days (T3) and one month (T4), when the patients were smokers ($P < 0.05$). Maximum mouth opening was statistically significant decreased with increasing length of surgery ($P < 0.05$). The mouth opening decreased by 2.95 mm after seven days (T3), when length of surgery increased by one minute.

Oral health-related quality of life

Mean OHIP-14 score with 30 minutes of cryotherapy was 9.5 (SD 23.1) (T0) and 18.9 (SD 26.4) (T3), and mean OHIP-14 score without cryotherapy was 9.5 (SD 19.8) (T0) and 14.4 (SD 25.7) (T3) (Table 5). The mean OHIP-14 score was highest with 30 minutes of cryotherapy compared to no cryotherapy.

Table 4. Results before removal of M3 (T0) compared with one day (T1), three days (T2), seven days (T3) and one month (T4)

	Cryotherapy	T1-T0				T2-T0				T3-T0				T4-T0			
		Estimate	95% CI	SE	P	Estimate	95% CI	SE	P	Estimate	95% CI	SE	P	Estimate	95% CI	SE	P
Pain	without cryotherapy	**Reference**	-	-	-	**Reference**	-	-	-	**Reference**	-	-	-	**Reference**	-	-	-
	with cryotherapy	11.15	0.72; 21.57	5.32	< 0.05	6.87	-0.91; 14.66	3.971	0.083	-7.07	-15.34; 1.19	4.216	0.093	7.5	-5.23; 20.23	6.495	0.248
Trismus	without cryotherapy	**Reference**	-	-	-	**Reference**	-	-	-	**Reference**	-	-	-	**Reference**	-	-	-
	with cryotherapy	-	-	-	-	-1.4	-6.41; 3.61	2.554	0.584	3.68	-0.87; 8.23	2.321	0.113	1.45	-12.38; 15.28	7.054	0.837

CI = confidence interval; M3 = mandibular third molar; SE = standard error; VAS = visual analog scale.
Third molars allocated to no cryotherapy were used as reference for the group with cryotherapy.
Pain: assessed by VAS. Estimated value reveals differences in VAS score of pain in millimetres with cryotherapy compared with no cryotherapy.
Trismus: assessed by a ruler. Estimated value shows how many mm the incisal distance has increased or decreased compared to no cryotherapy.
Mean difference in pain and trismus were analyzed with a generalized estimating equation (GEE) analysis for repeated observations.

Table 5. OHIP-14 score

Question		T0												T3											
		Cryotherapy (n = 29)						No cryotherapy (n = 29)						Cryotherapy (n = 25)						No cryotherapy (n = 25)					
		0	1	2	3	4	SDS	0	1	2	3	4	SDS	0	1	2	3	4	SDS	0	1	2	3	4	SDS
Functional limitation	**1**	19	5	5	-	-	-	18	5	3	-	-	-	12	3	10	1	-	-	9	13	1	1	-	-
	2	23	2	1	-	-	19	24	3	-	-	-	14	16	5	2	3	-	44	14	6	1	2	-	32
Physical pain	**3**	9	7	12	1	-	-	7	8	12	-	-	-	1	3	12	6	4	-	1	5	8	4	5	-
	4	10	9	8	-	1	63	10	7	7	3	-	62	2	4	9	6	5	121	2	4	8	5	4	104
Psychological discomfort	**5**	12	6	5	4	2	-	12	7	4	4	1	-	14	3	5	3	1	-	18	-	3	3	-	-
	6	9	10	7	2	1	70	11	5	9	1	1	61	8	5	7	2	4	67	7	4	7	4	1	49
Physical disability	**7**	15	9	3	2	-	-	14	8	5	-	1	-	6	7	6	5	2	-	8	3	9	1	3	-
	8	17	9	2	-	1	38	15	8	3	-	2	44	7	8	7	4	-	76	9	8	2	3	1	61
Psychological disability	**9**	15	5	5	3	-	-	9	10	5	1	1	-	4	8	10	2	2	-	8	7	2	5	1	-
	10	16	2	7	3	1	53	15	7	4	1	1	49	14	4	7	0	1	64	14	4	5	1	-	47
Social disability	**11**	17	10	2	-	-	-	19	6	2	1	-	-	9	8	8	-	-	-	16	4	3	1	-	-
	12	26	3	-	-	-	17	21	5	2	-	-	22	11	6	4	2	3	56	12	4	5	2	1	37
Handicap	**13**	21	3	5	-	-	-	18	5	4	1	-	-	13	4	4	4	-	-	11	5	4	1	1	-
	14	27	2	-	-	-	15	23	4	1	-	-	22	15	5	3	3	-	44	18	5	-	-	1	29
Total OHIP-14 score		275						274						472						359					
Mean (SD)		9.5 (23.1)						9.5 (19.8)						18.9 (26.4)						14.4 (25.7)					

0 = never; 1 = hardly ever or nearly never; 2 = occasionally; 3 = fairly often or many times; 4 = very often.
n = number of wisdom teeth; OHIP-14 = oral health impact profile 14; SD = standard deviation; SDS = subscale dimension score.

Physical pain, psychological disability and discomfort presented highest OHIP-14-dimension score, while handicap and functional limitation exhibited the lowest score.

OHIP-14 questionnaires were missed in one case with 30 minutes of cryotherapy and in five cases with no cryotherapy.

DISCUSSION

The objective of the present single-blinded randomized controlled trial was to test the null-hypothesis of no difference in pain, trismus and oral health-related quality of life following SRM3 with 30 minutes of immediate cryotherapy compared with no cryotherapy.

A significant lower VAS score of pain was seen with no cryotherapy after one day compared with 30 minutes of cryotherapy ($P < 0.05$), whereas no significant differences were seen after three days ($P = 0.083$), seven days ($P = 0.093$) and one month ($P = 0.248$), respectively. Furthermore, no significant difference in trismus or oral-health related quality of life was observed at any time point. Consequently, 30 minutes of immediate continuous cryotherapy seems not to diminish postoperative sequelae following SRM3.

Pain is an expected sequelae following SRM3, which may interfere with patients' immediate oral health-related quality of life [14,15]. Within the first 24 hours postoperatively, the pain reaches highest intensity and gradually resolves after seven days [16,17]. Previous published systematic reviews have reported negligible effect of short-term continuous cryotherapy, which is in accordance with the results of the present study [18-20]. Consequently, continuous short-term cryotherapy seems not to diminish postoperative sequelae following SRM3. However, previous studies assessing long-lasting intermittent cryotherapy have demonstrated a significant beneficial effect on pain following SRM3 compared with the use of no cryotherapy [8,21]. Intermittent cryotherapy therefore appears to be more effective on postoperative pain fooling SRM3 compared with continuous cryotherapy [8,21]. During continuous cryotherapy with a gel pack, the temperature will not be held constant during the treatment period. The initial temperature will be low, and the end temperature will be warmer. In addition, the thickness of the subcutaneous adipose tissue may also influence the therapeutic effect of cryotherapy [22]. The therapeutic effect of continuous and intermittent cryotherapy on pain following SRM3 is inconclusive. Further studies are needed before final conclusions can be made.

The most frequently used analgesics to control postoperative pain following SRM3 are paracetamol and non-steroidal anti-inflammatory drugs either alone or in combination [23]. A systematic review have shown, that non-steroidal anti-inflammatory drugs in conjunction with SRM3 diminish the physiological inflammatory response, reduce the average pain scores and the overall consumption of analgesics [24]. In the present study, patients' total consumption of analgesics was not systematically registered and completing VAS score of pain according to the time of ingestion of analgesics was not standardized, which potentially have influenced patient's perception of pain. Consequently, further randomized control trials assessing cryotherapy in conjunction with SRM3 should therefore monitor total consumption of analgesic including standardized regimes for ingestion of analgesic according to completion of VAS, questionnaires or alternative assessment methods.

Gender, age, smoking, time of surgery, surgical difficulty, flap design and intraoperative visibility of the inferior alveolar nerve are considered as predictive variables for increased pain following SRM3 [15,25]. In the present study, increasing age revealed a higher VAS sore of pain compared with younger, whereas no significant difference in VAS score of pain was revealed according to smoking habits, length of surgery or gender. Uniformity of patient sample are therefore mandatory to diminish confounding variables. The included patients of the present study disclosed no significant difference in patient demographic, position of the mandibular third molars and time of surgery between the two treatment modalities.

Temporary trismus occurs frequently following SRM3 [26]. Linear measurement of the interincisal distance using various measurement tools is a simple and reliable method, which is commonly used for assessment of trismus following SRM3 [7,21]. In the present study, linear interincisal measurements revealed no significant difference in trismus following SRM3 with short term continuous cryotherapy compared with no cryotherapy. However, long-lasting intermittent cryotherapy have demonstrated a significant reduction in trismus compared with no cryotherapy [8]. Consequently, future studies assessing different application methods and treatment periods are needed before the beneficial effect of cryotherapy on trismus can be concluded.

Prolonged time of surgery results in increased trismus following SRM3, which is in accordance with the results of this randomized controlled trial [27-29].

Furthermore, smokers demonstrated more trismus compared to non-smokers, which previously has been reported [29]. Temporary trismus following SRM3 are influenced by the length of surgery, smoking habits and the surgical trauma, while the effect of cryotherapy seems negligible.

Deterioration in oral health-related quality of life is frequently seen following SRM3 [16,30]. In the present trial, 30 minutes of cryotherapy revealed a higher mean OHIP-14 score compared to no cryotherapy. Previous studies have demonstrated that continuous and intermittent cryotherapy improve oral health-related quality of life following SRM3 [5,8,31]. Oral health-related quality of life is influenced by age, gender, occlusion, present dental disease, previous dental experience, socioeconomic status, education, physical pain, psychological discomfort and psychological disability [32-34]. OHIP-14 evaluates patient´s overall oral impairment and does not focus on a specific surgical intervention as i.e., SRM3. Consequently, further studies assessing oral health-related quality of life following SRM3 should include additional self-administrated questionnaires focusing on patient´s perception of SRM3. Furthermore, self-administrated questionnaires are also recommended to include an association between oral health-related quality of life and demographic factors and socioeconomic status.

No statistically significant differences in pain and trismus between 30 minutes of continuous cryotherapy compared to no cryotherapy were seen. Though, the present randomized controlled trial is characterized by certain limitations including small sample size, no systematically registration of consumption of analgesics and no registration of the applied temperature of the jaw bra, which may have affected the outcome. In addition, socioeconomic status, educational background and level of daily physical activity were not registered, which significantly influence patient's perception of recovery, pain and oral health-related quality of life following SRM3 [32,34]. Therefore, the conclusions drawn from the results of this study should be interpreted with caution.

CONCLUSIONS

The therapeutic effect of 30 minutes continuous cryotherapy following surgical removal of mandibular third molars seems to be negligible.

Further randomized controlled trials assessing longer therapy of cryotherapy, intermittent application and other devices for cryotherapy are therefore needed before definite conclusions and evidence-based clinical recommendations can be provided in diminishing postoperative sequelae following surgical removal of mandibular third molars.

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