Influence of alveolar tampon packing on incidence of pain and quality of life in the week following third molar surgery

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The aim of this study is to assess the influence of alveolar tampon packing on incidence of pain, swelling, trismus, alveolar osteitis, and QoL in the week following M3 surgery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43633

Source
ToetsingOnline

Brief title
M3TAMPspQoL

Condition

- Other condition
- Head and neck therapeutic procedures

Synonym
M3 extraction, removal of mandibular wisdom teeth

Health condition

dental extractions, post-interventional recovery

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: lower jaw (mandible), pain, quality of life, third molar (M3), trismus, wisdom tooth extraction, wound tampon

Outcome measures

Primary outcome

Postoperative pain measurements (VAS scores, 11-points NRS) and quality of life

(QoL) evaluations with OHIP-14 questionnaires.

Secondary outcome

Postoperative infection and alveolaire osteitis (AO).

Study description

Background summary

Third molar (M3) removal is among the most common surgical procedures performed annually in the Netherlands and represents a major proportion of the outpatient surgical procedures performed by oral and maxillofacial surgeons (OMFS). As such, numerous studies have been devoted to evaluate all aspects of M3 surgery, including indications for removal, radiographic analyses for surgical planning, estimates of difficulty and risk factors for difficulty, as well as complications by rate and type. Studies devoted to complications have garnered significant attention, due to the fact that a large volume of cases results in significant numbers of complications, even though the overall incidence remains relatively low. The complications and costs associated with the removal of unerupted or partially erupted third molars are considerable and the routine prophylactic removal of all impacted wisdom teeth has become unacceptable. The criteria for surgical intervention in literature are recurrent pericoronitis, caries not amenable to restorative measures, dentigerous cyst, internal or external resorption, and periodontal disease to which the M3 is contributing (criteria produced by the National Institute of Clinical Excellence (NICE) in the United Kingdom). Wisdom teeth in a fracture line and those who require removal as part of an orthodontic treatment plan are included in the criteria

for removal.

Postoperative pain, swelling, and trismus are almost universal and many studies report overall complication rates for M3 surgeries close to approximately 20%, with most complications occurring postoperatively. Although these data suggest that 1:5 patients will experience a complication, care should be taken not to overestimate the risk to patients from M3 removal. Among the intraoperative complications, few patients experience what would be considered serious, debilitating complications requiring further treatment (e.g., nerve injuries, jaw fractures). The largest proportion of postoperative complications (45.3%) is due to alveolar osteitis (AO), a well-known complication with identifiable risk factors and well-established clinical management protocols. However, the frequent complications in M3 surgery can have a significant impact on the patient*s postoperative quality of life (QoL). The sensation of pain is of course subjective and there are no uniform criteria for its measurement. Pain sensation depends on each individual*s subjective pain threshold, which may be influenced by diverse factors including age, gender, anxiety, and surgical difficulty.

QoL has become a widely known concept and has been studied in many research fields. Numerous QoL measures have been constructed, many are health related. The recognition of health as a fundamental factor in ones QoL has led to the usage of subjective measures instead of clinical indicators. Thus ones personal perspective of the impact of health on QoL became increasingly important. Among these instruments is the Oral Health Impact Profile (OHIP-49), developed by Slade and Spencer in 1994. The OHIP-49 and its shorter derivative, the OHIP-14, have been given a great deal of attention and are among the most extensively used instruments in dental research. Both instruments are frequently applied in cross-sectional and longitudinal studies and are aimed to evaluate the physical, psychological, and social impacts of oral health on people*s QoL. Earlier studies have confirmed the suitability of the OHIP-14 questionnaires after M3 surgery.

Study objective

The aim of this study is to assess the influence of alveolar tampon packing on incidence of pain, swelling, trismus, alveolar osteitis, and QoL in the week following M3 surgery.

Study design

Single-center prospective comparative study using a crossover design in which eligible subjects will be assigned to surgical removal of an impacted wisdom tooth in the lower jaw with a tampon and surgical removal of a wisdom tooth without a tampon.

Intervention

After surgical removal of the mandibular third molar, the patients will receive on one side postoperative treatment with a tampon and the contralateral side will be treated without a tampon (or vice versa).

Study burden and risks

The use of tampons is used a lot by clinicians, however the postoperative effects have never been well researched. There are no negative effects associated with postoperative recovery. The assumed advantages are reduction in postoperative pain and wound infection.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients referred to the Department of Oral & Maxillofacial Surgery of the Amstelland Hospital
(Ziekenhuis Amstelland) for extraction of only impacted mandibular M3 requiring an ostectomy
- Patients who are going to have bilateral mandibular M3 surgery
- Patients without previous history of oral disease, free of periodontal disease, no discernable active
pathology associated with the M3, and without acute pericoronitis
- Patients that signed an informed consent form
- Patients >=18 years of age

Exclusion criteria

- Patients with a previous history of periodontal disease or local pathology (e.g. cysts or tumors)
associated with the M3s
- Patients with ibuprofen allergy
- Patients with iodine allergy
- Patients with known medical history of renal failure, blood dyscrasia or chronic liver disease of any
type, uncontrolled diabetes mellitus, HIV infection,
- Patients with a history of recent and/or symptomatic peptic ulcer
- Patients on anticoagulants or corticosteroids prior (< 15 days) to entry into this study
- Pregnant or lactating female patients
- Patients with recent local infection prior to surgery (< 15 days)
- Patients with previous radiation therapy to the maxillofacial region
- Organ or marrow transplant candidates or recipients
- Patients requiring antibiotic prophylaxis for endocarditis
- Patients that did not sign an informed consent form
- Patients < 18 years

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2016
Enrollment:	66
Type:	Actual

Ethics review

Approved WMO

Date:	09-03-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL52968.018.15