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ORIGINAL ARTICLE

Mandibular third molar surgery in 396 patients at a Norwegian university clinic: morbidity recorded after 1 week utilizing an e-infrastructure for clinical research

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ABSTRACT

Objective To evaluate morbidity 1 week after mandibular third molar (3M) surgery in the authors' department. **Materials and methods** A prospective 1-year clinical study of patients followed up for 1 week after 3M surgery was performed. Consecutive patients of 18 years or older having 3M surgery under local anaesthesia were included. Patients not able to attend a follow-up appointment after 1 week were excluded. Demographic data, indication for surgery and clinical findings were recorded. Outcome variables were days requiring analgesic, days absent from work/school and complications. All data recording was performed utilizing an e-infrastructure for clinical research (InReach, University Health Network, www.uhnsl.com). **Results** Three hundred and ninety-six patients were examined 1 week after surgery. Mean number of days requiring analgesics was 3.8 and mean number of days absent from work/school after surgery was 0.6. Minor complications were reported by 7% of patients. Female patients reported more days requiring analgesics compared to male patients. Smokers had a higher odds ratio for being absent $\geq$3 days. Prophylactic removal of 3Ms was associated with fewer days requiring analgesics and days absent from work/school as compared to teeth with local disease. **Conclusion** Overall morbidity after 3M surgery was low. Compared to patients subjected to therapeutic removal of 3Ms, patients undergoing prophylactic removal seem to have less pain and a faster return to normal activities.

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Introduction

Removal of mandibular third molars (3Ms) is probably one of the most common surgical procedures performed by dentists. A Norwegian study from 1994 estimated that ~75 000 third molars were removed annually, of which 55 000–60 000 were removed by general practitioners and the rest by oral surgeons.[1] Reasons for removal of 3Ms may be local disease, such as caries, soft tissue inflammation and cyst formation or to prevent future disease in younger patients.[2]

Whether to remove or not remove partially erupted and asymptomatic 3Ms with no associated pathology has been debated. Indications for removal of such teeth have been described as 'prophylactic'. The main argument for prophylactic removal of 3Ms is to prevent future disease, such as infections and development of cysts and tumours. Prophylactic removal of 3Ms are usually performed in younger patients (under 25–30 years) and the risk for complications and post-operative morbidity are reported to be lower compared with older patients.[3] There is little evidence to support routine prophylactic removal of 3Ms.[4]

Surgical removal of 3Ms normally give rise to some discomfort such as pain, swelling, trismus, and mild bleeding. Patients may be absent from work, school or social activities for a limited period of time.[5] Post-operative sequelae after 3M surgery range from minor complications such as alveolar osteitis and prolonged pain, to more severe complications such as haemorrhage, infection, osteomyelitis, temporomandibular disorders, neurosensory dysfunction and jaw fracture.[6–8]

It is important to perform quality assessment of clinical procedures to improve outcome and reduce complications. A recent study from our research group, focusing on neurosensory dysfunction after 3M surgery, showed a low incidence of permanent inferior alveolar nerve injuries.[9] Recording of data in clinical research can be time-consuming for the researcher. In our experience, many researchers are still using 'the pen and paper method' when in a clinical setting. Primary recording of data using computer-based software may reduce the workload for the clinician and can facilitate export of data for further analysis. University Health Network (UHN) is an e-infrastructure launched by the University of Oslo and other European universities, which allows for secure storage and sharing of anonymized patient data. The idea of having a computer-based and accessible system for recording clinical data is not new. Hu et al. [10] developed and tested a web-based system to record surgery outcomes of anaesthesia and third molar removal in 2000. In the present study, all data were collected utilizing UHN.

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The aim of the present study was to evaluate morbidity during the first week after 3M surgery performed under local anaesthesia, defined as number of days requiring analgesics, number of days absent from work or school, and post-operative complications.

Materials and methods

Study design

The study was designed as a prospective clinical study to evaluate morbidity during the first week after 3M surgery in our department. The study population comprised patients undergoing 3M surgery from 1 September 2012 to 31 August 2013. Patients had to be seen 1 week after surgery to be included in the study. Initiation of clinical data collection was reported to the Norwegian Social Science Data Services. The study was considered a quality assessment of clinical procedures due to Norwegian law and, thus, ethical approval was not needed. Patients were included after giving written informed consent. Inclusion criteria were age ($\geq$ 18 years), indication for surgical removal of one or both 3Ms and ability to present for a clinical examination 1 week after surgery. Indications for surgical removal of 3Ms were based on the National Institutes of Health's Consensus Statement (1979) [11] and the American Association of Oral and Maxillofacial Surgeons White Paper on Third Molar Data (2007).[2] Indications were further defined as 'prophylactic' or 'therapeutic'. Prophylactic indications were only applicable in patients $\leq$ 30 years with partially erupted teeth (soft tissue impactions) with no visible clinical or radiological findings or previous episode(s) of pain associated with eruption and no sign(s) or symptom(s) of pericoronitis within the last 12 months. Therapeutic indications included clinical and/or radiological pathological findings, such as recent acute pericoronitis, chronic pericoronitis and signs of inflammation, chronic pericoronitis and symptoms during the last 12 months, cyst formation, resorption/caries of the second or third molar and other pathological findings. Asymptomatic, fully bony impacted teeth, with no associated pathological changes were not removed. Exclusion criteria were age ($<$ 18 years), no indication for removal of at least one 3M, teeth removed by simple extraction and failure to present at a clinical examination 1-week post-operatively. No economical compensation was offered.

Study variables

Several demographic variables were recorded for each patient, including age, gender, smoking habits and occupation. All patients classified as ASA 1 or 2 according to the ASA physical status classification. Indication for 3M surgery was obtained from the patients' charts. Patients were asked about work or school-related absence due to surgery, number of days using analgesics, use of antiseptic mouth rinse, post-operative antibiotics and specific complications. Patients were given written information about the study immediately after surgery. When patients returned for a post-operative visit after 1 week, those willing to participate in the study signed informed consent forms.

Surgical procedure and medication

All patients were given a pre-operative mouth rinse with 0.2% chlorhexidine (Corsodyl 2 mg/ml, GlaxoSmithKline AS, Oslo, Norway) for 1 min. All operations were performed under local analgesia (Xylocaine Dental Adrenaline, Dentsply Ltd., Surrey, England) alone or combined with oral sedatives. After elevation of a full-thickness mucoperiosteal flap, ostectomy was performed at the buccodistal aspect of the tooth utilizing a high-speed surgical bur under sterile saline irrigation. If indicated, sectioning of the tooth was performed with a high-speed surgical bur under sterile saline irrigation. All teeth were completely removed. An oxytetracycline (Terramycin-Polymyxin B, Pfizer, Pfizer Inc. New York, NY) impregnated gauze drain was routinely placed in the extraction socket. Non-resorbable sutures (Supramid 3-0, B. Braun Melsungen AG, Melsungen, Germany) were used for wound closure. Eight different residents in oral surgery performed the operations. Patients were given either 1 mg Rohypnol (Rohypnol, F. Hoffmann-La Roche AG, Basel, Switzerland) or 12 mg Midazolam (Actavis, Actavis Group, Hafnarfjordur, Iceland) according to the surgeons' preference when oral sedatives were indicated. Systemic antibiotics were not routinely administered or prescribed. All patients were provided with two tablets containing 500 mg paracetamol and 30 mg codeine (Pinex Forte, Actavis, Actavis Group, Hafnafjordur, Iceland) for the immediate post-operative period. Thereafter, patients were recommended to use over-the-counter analgesics (paracetamol 500 mg and ibuprofen 400 mg) with daily dosages according to body weight, for as long as necessary. Patients were scheduled for removal of sutures and drain after 1 week, but were free to return for post-operative consultations at any time.

Data collection methods

All patients undergoing 3M surgery were examined and interviewed after 1 week. Study parameters were recorded using a questionnaire created and accessed through UHN. Questionnaires to be used for recording of clinical data were created within the UHN-database and accessed through a clinical module called 'InReach'. Data collected using InReach were consolidated and exported for statistical analysis (Figure 1). A 1-week pilot trial was performed prior to initiating the study to ascertain that all clinicians were calibrated in the clinical procedures as well as in using the software. Clinical data were collected by a total of 12 different surgeons (four consultants and eight residents).

Data analysis

The data were exported from InReach to the principal investigator's database within UHN, consolidated and exported directly to SPSS (version 17.0, IBM Corp., Armonk, NY). Chi-square and independent *t*-tests were used to analyse the data. Regression analysis was applied to estimate the relationships among data variables. The significance level was set to 5%.

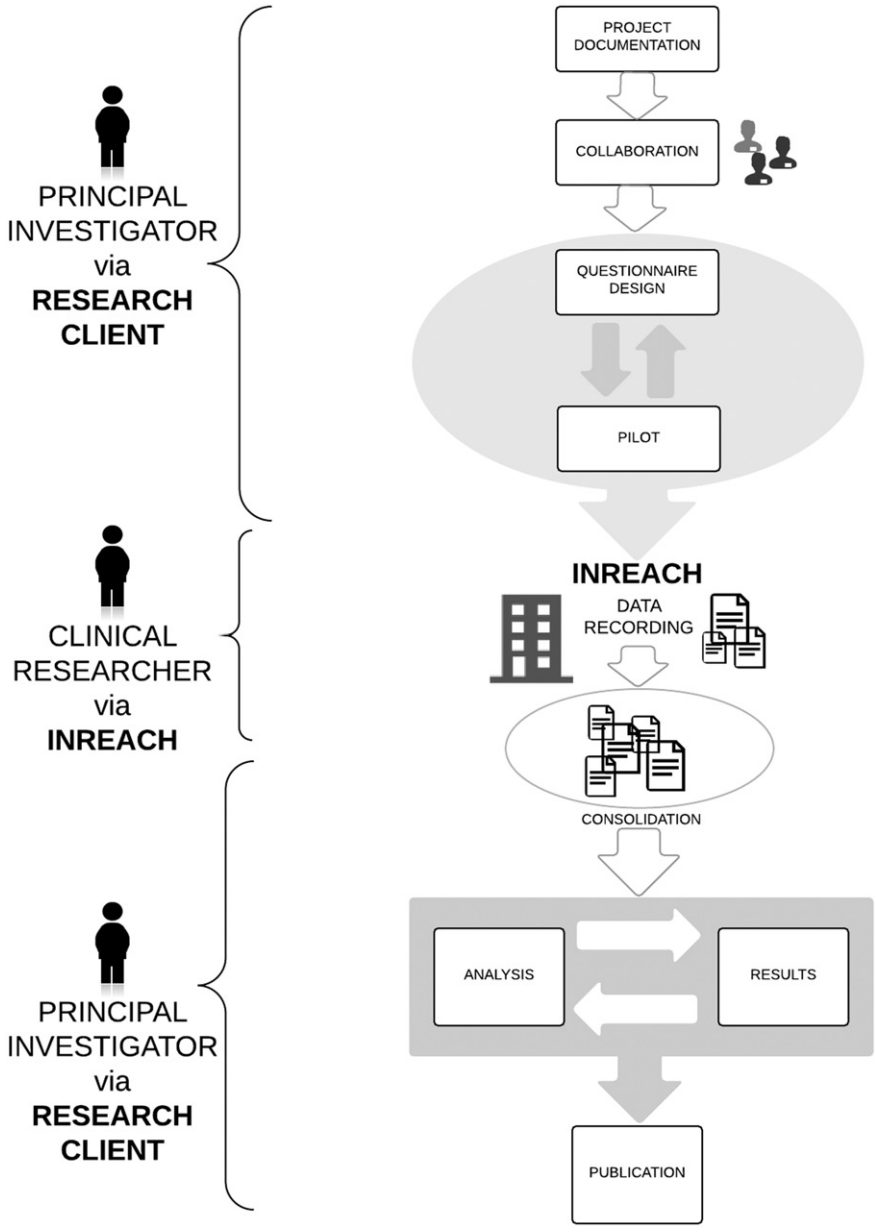

Figure 1. UHN flowchart. Using Research Client, the principal investigator, alone or in collaboration with fellow researchers, can design a questionnaire for the planned clinical study. The questionnaire is launched via InReach Client and can be tested in a pilot study and modified if needed. Clinical researchers access the questionnaire(s) through InReach Client in the clinic and are, thus, able to record patient data. Recorded data are stored and sent to the principal investigator for reviewing and consolidation via Research Client. The consolidated data are then exported for further statistical processing according to the researchers' preferences. At all stages, data are securely stored and can be distributed anonymously amongst researchers both within the same institution and between collaborating institutions through an encrypted network.

Results

The material comprised clinical recordings 1 week after 3M surgery during a 1-year period. Out of 527 consecutive patients who underwent 3M surgery in the study period, 396 accepted to participate in the present study. This gave an inclusion rate of 75%. Patient characteristics are presented in Table 1.

Days requiring analgesics

Including the day of surgery, the mean number of days (mean ± SD) requiring analgesics was 3.8 ± 2.4 for all patients. Eight patients reported no use of analgesics (2%). Female patients reported a higher number of days requiring analgesics (4.1 ± 2.4) compared with male patients (3.3 ± 2.2). This result was highly significant ($p < 0.001$). Patients with therapeutic indications for 3M surgery used analgesics for a longer period than patients undergoing prophylactic 3M surgery (Table 2). This difference was statistically significant ($p = 0.002$). We found no statistically significant difference regarding number of days requiring analgesics in patients ≤25 or >25 years, nor for smokers vs non-smokers.

Days absent from work/school in the post-operative period

Close to 70% of the patients did not miss work or school after surgery. The mean number of days absent from work or school

Table 1. Characteristics of patients undergoing mandibular third molar surgery.

Characteristics	All patients *n* (%)
Mean age (years)	25.5 (Range 18–52)
Age groups	
≤25 years	202 (51)
>25 years	194 (49)
Gender	
Female	244 (62)
Male	152 (38)
Smokers	43 (11)
Work status	
Employee	161 (55)
Student	220 (40)
Other	15 (4)
Indication for surgery	
Prophylactic	120 (30)
Therapeutic	276 (70)

n, number.

Table 2. Morbidity related to indication for surgery.

Variables	Prophylactic indication, *n*	Therapeutic indication, *n*	*p* value
Days requiring analgesics (mean ± SD)[a]	3.3 ± 2.0	4.0 ± 2.5	0.002
Days absent from work or school (mean ± SD)[a]	0.4 ± 0.9	0.6 ± 1.3	0.018
Pain as main reason for absence	17 (14.2%)	73 (26.4%)	0.043

[a]Independent *t*-test.
n, number; SD, Standard Deviation.

after surgery was 0.6 ± 1.2 for all patients. Patients with therapeutic indications for 3M surgery reported a longer time away from work or school compared with patients undergoing prophylactic 3M surgery ($p = 0.018$), see Table 2. No statistically significant difference was found between genders or between patients aged ≤ 25 or > 25 years. A third of patients being absent from work or school after surgery reported pain (23%) and swelling (9.5%) as reasons for being absent. The remaining 2/3 of patients gave no specific reason for their absence. Female patients more frequently reported pain as the main reason for being absent compared with male patients ($p = 0.035$). Patients with therapeutic indications for 3M surgery also reported pain to be the main reason for being absent more often than patients undergoing prophylactic 3M surgery ($p = 0.043$). Smokers did not report a higher number of days absent from work or school in the post-operative period compared with non-smokers. The majority of the patients (95%) were absent less than 3 days post-operatively. Smoking was identified as the only risk factor for being absent ≥3 days post-operatively. The odds for being absent ≥3 days were 1.9 for smokers compared with non-smokers.

Complications

No major complications such as mandibular fractures, serious haemorrhages or severe infections were recorded at the 1-week follow-up and no patients required hospitalization. Minor complications were noted amongst 7% of the patients. Alveolar osteitis was the most commonly reported minor complication (3.5%). Regarding complications, there were no differences between the patients who underwent prophylactic 3M surgery or surgery on therapeutic indications or between genders. Seventeen patients (4.3%) were prescribed systemic antibiotics and 368 (92.9%) patients reported use of antiseptic mouth rinse during the post-operative period. Thirteen patients reported difficulties eating after 1 week (3.3%), of whom 12 had 3Ms removed due to therapeutic indications. This finding was statistically significant ($p = 0.011$). Four patients (1%) reported neurosensory disturbances (NSD) of the inferior alveolar nerve (IAN). No NSD of the lingual nerve (LN) was noted. NSD was seen in 2.5% of patients who underwent prophylactic 3M surgery and in 0.4% of patients with therapeutic indications for 3M surgery. These findings were statistically significant. Regular follow-up of these patients revealed that all NSD resolved within 3 months. One patient reported an allergic reaction, which was found to be nausea after use of analgesics containing codeine. Regression analysis showed that gender, smoking or patient age did not affect the overall complication rate.

Data collection method

All clinical recordings were successfully completed using InReach and easily transferred to the researcher database within UHN. Consolidation of data and export to SPSS was uneventful and no data were lost.

Discussion

Our results indicate that 3M surgery in general was associated with low morbidity, as previously shown by several authors.[3,5–7,12] The overall complication rate was low and most patients seem to return to normal daily activities after a few days.

A review of prospective quality-of-life studies on 3Ms indicates that most discomfort occurs on the first day after surgery and most patients are able to return to work after 2–3 days. The rate of discomfort seems to be reduced to ~25% during the first post-operative week.[7]

The present study revealed that most patients required analgesics for almost 4 days, including the day of surgery. All our patients were provided with two tablets containing 500 mg paracetamol and 30 mg codeine and were strongly motivated to use analgesics at least immediately after surgery. One week after surgery, most patients (94%) were not in need of analgesics. Berge [13] studied patterns of post-operative self-administration of analgesics (500 mg paracetamol and 30 mg codeine) after 3M surgery in 201 patients. In his study, mean consumption was 4.9 tablets during the first week, of which 3.6 tablets were used on the day of surgery and only 4% of the patients reported inadequate pain relief. In the present study, female patients required significantly more analgesics compared to the males. This finding may indicate that female patients experience more pain or have a lower threshold for self-administration of analgesics after 3M surgery than male patients. A multi-centre study of the possible effects of age and sex on recovery after 3M surgery concluded that female patients older than 21 years should be informed that 3M surgery reduces oral function and pain recovery will be prolonged compared with younger patients and men.

Recovery for female patients was significantly longer than for male patients.[14] Recording days requiring analgesics is, in our opinion, a simple and practical approach and may to some extent provide a brief overview of the patients' pain experience. The exact relationship between days requiring analgesics and patients' perceptions of pain is not investigated in the present study, which may be considered a weakness.

The majority of patients in the present study (70%) did not miss work or school after surgery. Mean number of days absent from work or school after surgery was 0.6 ± 1.2 for all patients and only 5% of all patients were absent for 3 days or more. Bienstock et al. [15] found a mean duration of post-operative disability of 1.4 ± 1.8 days after 3M surgery. Compared with results from other studies on morbidity after 3M surgery, the majority of patients in our study returned earlier to work or school.[7,8] Faster patient recovery and an early return to normal daily activities are positive factors for the patients and in a socio-economic perspective. We found no correlation between number of days absent from work or school, age or gender. Female patients more often than male patients reported pain as the main reason for being absent. This corresponds with the significantly higher number of days using analgesics reported by female patients. Smokers in general did not report a higher number of days absent from work, but they were at higher risk of being absent for 3 or more days than non-smokers. It has previously been shown that smokers report more and longer post-operative discomfort after 3M surgery,[5] and that smokers tend to be less compliant regarding post-operative instructions.[16]

Prophylactic removal of 3Ms is debated and both supporting and opposing views upon the subject have been published.[12,17]. A systematic review did not identify evidence either to support or refute routine prophylactic removal of asymptomatic impacted 3Ms in adults.[18] In our study, patients with therapeutic indications for 3M surgery reported a longer absence from work or school and used analgesics for a longer period than patients undergoing prophylactic 3M surgery. Prophylactic 3M surgery is by many authors considered to be associated with less general post-operative discomfort.[3,7]

It has been reported that ~10% of patients undergoing 3M surgery will experience complications. Most of the complications are minor and self-limiting.[7] Complications requiring hospitalization are considered rare.[19] Minor complications were noted amongst 7% of patients in our study and no severe complications were seen. Four patients (1%), all under 30 years old, reported NSD of the IAN. Studies have shown that paraesthesia related to 3M surgery occurs in 0.4% [20] to 8.4% [21] of the cases. A recent prospective study of removal of 1220 3Ms in our department showed that all patients younger than 30 years of age had full recovery of their IAN injury after 3–4 months.[9] Follow-up of the four patients in the present study revealed that none of the IAN injuries were permanent. Our study population had a mean age of 25.5 years, which may explain the low incidence of NSD. We have no good explanation for why significantly more patients having prophylactic 3M surgery experienced NSD of the IAN. We have not been able to identify any studies focusing on this aspect of temporary dysfunction of the IAN.

Only 4.3% of the patients in our study received systemic antibiotics in conjunction with or following 3M surgery. Reasons for pre-operative administration of systemic antibiotics in the present study included higher risk of infections due to immunodeficiency and risk of endocarditis. Post-operatively, antibiotics were prescribed for treatment of a few minor infections. Pre- or post-operative use of systemic antibiotics was not associated with any of the general variables or outcomes, such as post-operative complications. A recent systematic literature review by Lodi et al. [22] indicated that prophylactic antibiotics in 3M surgery may reduce risk of infection and alveolar osteitis and give less pain. The authors concluded though that treating healthy patients with antibiotics is likely to do more harm than good due to the increasing number of resistant bacteria. Calvo et al. [23] stated that prescription of antibiotics in 3M surgery is unnecessary when pre-operative infection is absent.

An oxytetracycline impregnated gauze drain was routinely placed in the socket after tooth removal. In conjunction with 3M surgery, this practice has been standard care in our department for over 30 years. Local application of an oxytetracycline impregnated gauze drain may prevent alveolar osteitis.[24] In the literature, the prevalence of alveolar osteitis after 3M surgery ranges from 1–30%.[25,26] Alveolar osteitis was seen in 3.5% of all patients in our study and was the most commonly reported complication. Compared with the prevalence of alveolar osteitis reported in the literature, our number is fairly low. We found no differences in the occurrence of alveolar osteitis between indications for surgery, gender, age groups or smokers vs non-smokers. A systematic review of local interventions to prevent alveolar osteitis found some evidence that rinsing with chlorhexidine (0.12% and 0.2%) or placing chlorhexidine gel (0.2%) in the sockets of extracted teeth was beneficial. The authors further concluded that there was insufficient evidence to determine the effects of other preventive interventions.[27] In our study, all patients performed a pre-operative mouth rinse with chlorhexidine 0.2% and 92.9% of all patients reported using chlorhexidine mouth rinse regularly in the post-operative period. These factors may also have contributed to the low incidence of alveolar osteitis. Due to the limitations of the present study, the effect of the oxytetracycline impregnated gauze drain on post-operative morbidity could not be properly assessed. However, a low rate of alveolar osteitis and post-operative infection may indicate that the intervention has a beneficial potential. Further studies on the subject are advised.

In our department, nearly all 3Ms are surgically removed under local analgesia alone or in combination with oral sedatives. Rarely, 3Ms are removed under i.v. sedation or general anaesthesia. In the study period, 12.2% of all patients undergoing 3M surgery received oral sedatives due to anxiety. This has been our practice for over 25 years and we have so far not registered any major adverse effect such as anaphylaxis, respiratory depression or hospitalization associated with this treatment. It has been reported that patients having treatment under general anaesthesia may have more post-operative discomfort and longer job disruption.[28] Compared with treatment under i.v. sedation or

general anaesthesia, local analgesia alone or in combination with oral sedatives is a safe and cost-effective alternative in 3M surgery. In our experience, this treatment is well tolerated by patients.

Most patients undergoing 3M surgery in our department consented to participate in the study and were, thus, registered in InReach. The inclusion of 75% of the patients in our study still entails a shortfall of 25%. Unfortunately, we have no information about those not included in the study. Some patients may have consented to participate but were for unknown reasons not included. In the future, patients' reasons for not consenting should be recorded, thus giving better information regarding participation, non-participation and drop-outs. Other reasons for non-participation, such as lack of time or forgetfulness, should also be recorded. Calibration and constant motivation of the clinicians examining the patients are important factors to secure patient inclusion and recording of clinical data. Computerized registration does not correct human errors. A pilot study is advised when introducing a new system for data recording and management in clinical research.

Conclusion

Our study of morbidity 1 week after removal of 3Ms indicated that the procedure is well tolerated by a majority of the patients and that post-operative morbidity was low. Female patients reported more days requiring analgesics than male patients. Gender, smoking or patient age did not seem to affect the number of days absent from work or school, although the odds of being absent ≥ 3 days was higher for smokers. Overall complication rate was not affected by gender or smoking. Patients undergoing prophylactic removal of 3Ms reported significantly fewer days requiring analgesics and days absent from work or school than patients whose 3Ms were removed due to local disease. Within the limitation of this study, the effect of the oxytetracycline impregnated gauze drain on post-operative morbidity cannot be properly assessed. However, a low rate of alveolar osteitis and post-operative infection may indicate that the intervention has a beneficial potential. Further studies on the subject are advised.

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Declaration of interest

The authors report no conflicts of interest. Pål Barkvoll and Janicke Liaaen Jensen have been involved in the development of University Health Network, but they have no financial interests. None of the authors have received any grants related to this project or to its publication. The present paper has not been published. Parts of the results have been presented at the 40th ADEE Annual Meeting 2014, Riga, Latvia, at the IADR General Session 2015, Boston, MA, and the SFOMK Congress 2015, Copenhagen, Denmark.

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