



Pain Control Satisfaction after Third Molar Surgery in a Non-Opioid Regimen

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Summary

Purpose

To assess patient self-report on pain level and pain control satisfaction after third molar surgery without altering the regular protocol used in the study center, that includes non-steroidal anti-inflammatory drugs (NSAIDs) only.

Patients and Methods

Fifty-six patients that underwent third molar surgery in a mayor hospital in Costa Rica were included in the study. In this observational clinical study, no alterations or interventions were made by the researchers in the regular surgical or pharmacological protocol followed in the center. Eight days after surgery subjects were asked to rate their average pain level and to rate their satisfaction with pain control, using a verbal numerical scale.

Results

Fifty-six patients who gave consent to participate were included after inclusion/exclusion criteria were applied. At one week follow up after third molar surgery: 14% reported no pain, 66% reported mild pain, 29% had moderate pain and 5% reported severe pain. Twenty-six subjects indicated feeling totally satisfied with the pain control received. Twenty patients reported felt very satisfied. Six patients indicated being neutral and three patients were unsatisfied with the pain control received with NSAIDs.

Conclusion

The results of this study support the fact that pain control after third molar surgery can be achieved with NSAIDs. On the other hand, opioid medications should be reserve for selected cases only; due to their well know implications.

Introduction

Opioid medications have been used for centuries to treat severe acute pain, as it is reflected in ancient writings about the famous Galen. He was a physician from the Roman Empire who noticed the properties of opium as a painkiller, though he was also aware of its addictive potential [1]. Nowadays, the potential long-term dependency of these medications is well-known by the dental and medical community. Indeed, a clear example is the ongoing opioid overuse crisis, being probably the US one of the most affected countries. According to the National Institute on drug Abuse an average of 128 people die per day in the United States after overdosing on opioids, including addiction to prescription pain relievers, heroin and synthetic opioids [2]. The Dental field has contributed enormously to this crisis, being one of the reasons the common prescription/request of strong medications for pain management after dental procedures [3]. Pain is a complete subjective phenomenon that involves nociceptive and cognitive processes. Its definition was recently revised by the IASP "as an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage [4]". For instance, many factors such as believes, social context, level of education, behaviors, previous experiences, dental anxiety, the need or the lack or a medication can have an impact on the pain experience.

One of the most common surgical procedures performed in dentistry is third molar surgery. Even though the American Academy of Oral and Maxillofacial Surgery recognizes the debate about timing and indications, the removal of third molars seems to be appropriate when evidence of pathology is observed and/or prevention of the same can be achieved [5], depending on clinical situations and clinician expertise. Pain and inflammation are expected after the manipulation of hard and soft oral tissues usually involved in third molar surgeries. These nociceptive-physiological expected consequences are added to the natural fear of the patient towards the procedure. Therefore, some clinicians aiming to minimize patients' reaction and possible dissatisfaction following third molar surgery may have the common practice of prescribing opioids (e.g., Oxycodone, Hydrocodone) after these procedures. Moreover, in other cases is the patient the one who request these medications after all kinds of dental invasive procedures [3]. On the other hand, it has been tested and proved that post-operative oral surgical pain can be successfully managed with non-steroidal anti-inflammatory drugs (NSAIDs), which have a safer profile and minimal risk of dependence compared with opioids [6-8]. The main purpose of this pragmatic observational study was to assess pain severity and pain control satisfaction using only non-steroidal anti-inflammatory drugs (NSAIDs) in a hospital setting following the regular protocol for pain and inflammation control used in this center.

Materials and Methods

Ethical considerations, allocation and patient selection

This study was approved by the local institutional bioethical committee (NoCCSSHJ-5247.), in concordance with the

ethical principles for medical research involving human subjects from the Declaration of Helsinki. A total of 56 patients from the Oral and Maxillofacial surgery clinic at the Hospital San Juan de Dios were included. All the patients provided informed consent and were recruited between September 15th 2019 to December 15th 2019.

Inclusion criteria were:

- i. Patients undergoing third molar surgery due to periodontal or Orthodontic indication agreeing to participate;
- ii. Patients without uncontrolled systemic diseases, e.g., ASA 1 or ASA 2;
- iii. Patients in complete emotional and mental faculties;
- iv. Age range of 16-45 years;
- v. Patients having impacted third molars, in a position according to the Pell and Gregory classification (class-IIB) and Winter classification (mesio-angulated, horizontal or vertical) according to radiographic evaluation [9].

Exclusion criteria were:

- i. High-risk pregnancy;
- ii. Mentally ill patients (major depression, or major mental disease. e.g., psychosis);
- iii. Inability to give informed consent;
- iv. Allergy to NSAIDs;
- v. Patients denying usual pharmacological therapy or who did not complete the pharmacological prescription;
- vi. Patients with uncontrolled systemic disease such as cardiovascular disease, metabolic disease, autoimmune disease.

Sample and study design

This study population is made up of an estimated total of 250 subjects, using as an indicator that the rate of care for this type of surgery is 19 patients per week and that the study was to be carried out in a period of three months. This Sample design considers two aspects: determination of sample size and selection or allocation. The formula used is the following, with correction for continuity

$$n_0 = \left(\frac{Z_{\alpha/2} * \sigma}{d} \right)^2 Z_{\alpha/2} = n = \frac{n_0}{1 + \frac{n_0}{N}}$$

Where: n = Total sample size $Z_{\alpha/2}$ = Value of t

Where: n=Total sample size. $Z_{\alpha/2}$ = Value of the standard normal distribution associated with the level of confidence considered, in this case 91%. $\sigma=0.5$ Value of the standard deviation of the main variable to obtain a maximum sample. d=Sampling error considered by the researcher for the case 0.10

The sample considered amounts to a total of 56 patients. The sampling method used to achieve a representative sample is systematic random sampling with an interval equal to five, so that the selected sample falls on the last patient seen for Third Molar Surgery on each of the days included in the period study. In this pragmatic prospective observational clinical study, no alterations or interventions were made by the researchers in the regular surgical or pharmacological protocol (described below) used in the abovementioned center. Eligible subjects were asked for participation and signed informed consent on the follow up appointment 7-8 days after the procedure was performed.

Surgical and pharmacological protocol

All surgical procedures were performed by the same two clinicians (A, C-Ch. J, R-J). Before surgery patients signed the consent form, they were asked to perform a rinsing with 0.12% chlorhexidine for one minute. Extraoral antisepsis was made with alcoholic solution or iodine solution. Afterwards, patients were anesthetized using topical lidocaine and received inferior alveolar block with 2% lidocaine with epinephrine 1:100000 with a 27-gauge needle. The surgery was started with a linear mucoperiosteal incision in the distal region of the second lower molar, with or without a vestibular relaxing incision in the middle vestibular second molar region followed by a mucoperiosteal flap elevation with a No. 9 molt periosteal elevator. A Minnesota or Langenbeck retractor was applied to the operative field. When necessary, osteotomy and root resection were performed using a No. 702 carbide bur or Lindemann bur with abundant irrigation with 0.9% saline. Extraction of the molars was completed with curved and straight Seldin extractors. The alveolus was irrigated with sterile saline, bone spurs or edges were rounded. The flap was repositioned and sutured with 3-0 Catgut surgical sutures. All surgical procedures

were performed in the morning between 7am and 11:30am. Each patient was prescribed 400mg of Ibuprofen plus 500mg of Acetaminophen 500mg every 8 hours per 7 days, as it is usually done in this center. In addition, a starting dose of intramuscular Sodium Diclofenac 75mg/1ml was used for most complex procedures. After the surgery, patients were instructed to maintain a soft cold diet, to apply ice extra orally 10 minutes 3 times per day, to avoid sun exposure or physical activity and to come for follow up in a week.

Follow up, pain assessment and satisfaction level

Routine follow up was accomplished by the same clinician who performed the surgery, where soft tissue status, mouth opening, and evidence of no infectious process were assessed. Every patient that was eligible was asked to participate during the follow up appointment and for consent. This was carried out this way in order to avoid personal bias during the recovery face. However, participation was completely voluntary, and many patients decided not to provide information. Each subject was explained about what they were going to provide her or his self-report of satisfaction about pain control after the surgery and pain level. Patient who reported not taking the medication as prescribed were excluded. Average post-operative pain felt during the recovery period and degree of satisfaction with the medication prescribed (10 extremely satisfied 0 totally dissatisfied) were collected using a verbal numerical rating scale [10,11]. In addition, complications after the surgery were evaluated using a dichotomous response (yes/no).

Results

A total of 56 patients receiving third molar surgery were included in this study. Thirty-three were females representing 59% of the sample. The age group with the highest frequency was 14 to 19 years old (n=25), representing 45% of the study population, followed by the group aged between 20 to 30 years with 36% and the group over 30 years, with 11% of the total sample. The degree of pain was classified as no pain (0), mild (1-3), moderate (4-7) and severe (8-10). From the treated sample, eight (14%) patients reported that they had not pain (0) in their recovery period. Twenty-nine patients (66%) reported mild pain, sixteen (29%) reported moderate pain (4-7) and three (5%) reported severe pain as shown in (Figure 1). Regarding the level of satisfaction, as can be seen in Table 3 twenty-six patients (46%) indicated feeling totally satisfied with the pain control received after their surgery, while twenty patients (35%) reported feeling very satisfied. Six patients (11%) indicated feeling neutral, three patients (5%) indicated feeling unsatisfied and one patient reported not to be satisfied at all. About, the self-report of associated complications such as trismus, edema and fear of infection. Four patients answered yes and reported the presence of any of the above. No complications were reported by the operators by the time of the follow up.

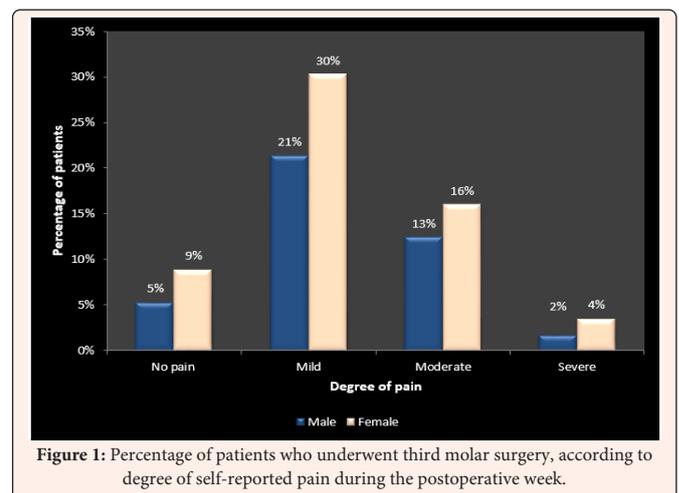


Figure 1: Percentage of patients who underwent third molar surgery, according to degree of self-reported pain during the postoperative week.

Discussion

This study evaluated self-reported pain control satisfaction of patients, after having third molar surgery. Non-opioid medications were used (NSAIDs), specifically Ibuprofen and acetaminophen were used for post-surgical pain and inflammation. One of the major strengths of the study was that the data were obtained after the post-operative period, trying to minimize personal bias on the subject prior to the recovery period and to evaluate satisfaction. In addition, this study uses a pragmatic design because no



different intervention was carried; only was tested the effect of the systemic analgesics that are prescribed in a regular basis for these procedures in the study center. This study was born over the enormous debate about opioids in oral surgery. Are necessary or not for pain control in invasive dental procedures? To discuss this issue, it is important to consider many factors surrounding pain control. Moreover, it is evident the impact that social and cultural implications have when someone is requesting (patient) or suggesting (clinician) opioids medications for pain control after common oral surgical treatments [12]. In a cross-sectional study In the USA was determined that dentist are one of the top prescribers of opioids (12%) only after family physicians (15%). Moreover, 1 in 2 of those patients are over prescribed [3]. Our study showed complete satisfaction by only using NSAIDs for pain control after oral surgery, however, it is to remark that the average patient in Costa Rica does not ask or even know about opioid medications for controlling oral/dental pain. According to different studies extraction of retained third molar induces pain that is generally consistent in severity, allowing good discrimination between weak and strong pain relievers. In percentage terms, after surgical removal of third molars, 63% of patients undergoing this procedure experience moderate pain and the remaining 37% severe pain [13,14]. Several reviews have shown considerable efficacy of ibuprofen alone or in combination for the treatment of acute pain such as the wisdom teeth acute pain or pain after surgery [6,15].

Ibuprofen alone or combined with Acetaminophen, were the two analgesics that are used in the center where this study was carried. Both medications have shown through multiple studies their efficacy for controlling oral postsurgical pain with minimal risk of exposure to a potential addictive characteristic. It can be said that 400 mg of ibuprofen every eight hours is sufficient for postoperative pain control after third molar surgery [16,17]. On the other hand, it is well known that a single exposure to a drug with potential for addiction, such as oral opioids, can become the trigger in a susceptible subject for drug abuse [3]. Therefore, it might be worth to avoid this risk if there are options like NSAIDs medications that are as efficient during the postoperative period. Evaluating patient satisfaction on regular practices and different settings is becoming of high relevance within the framework of health quality measurement. If a center is about to offer higher quality services it is on the need to evaluate satisfaction in users, family members and providers. This task becomes permanent and dynamic, a so called ongoing process [18,19]. Nowadays, tools like questionnaires or surveys through email or social media should be implemented regularly in current dental practices, especially in regards to pain that is the mayor cause of fear and avoidance for getting dental treatments [20,21]. Although satisfying the expectations of users in health services constitutes a complex process due to its subjectiveness. The ultimate goal of health services should not be different from that of any other type of service: satisfying users (patients and companions) [22]. Concern about patient satisfaction related to pain is a conditioned and complex process. Furthermore, it is significantly and functionally related to specific health behaviors such as compliance with prescriptions to monitoring of results, or even preventive behaviors of the disease, to personal habits or believes [18,23] (Table 1).

Table 1: Percentage of Third Molar Surgery Patients by Age and Gender, Included in the Study.

Age Range	Gender				Total	
	Male		Female			
	Number	%	Number	%	Number	%
14 to 19	11	20%	14	25%	25	45%
20 to 30	7	13%	13	23%	20	36%
More than 30	5	9%	6	11%	11	20%
Total	23	41%	33	59%	56	100%

When talking about of satisfaction, it is important taking into account the distinction between general satisfaction, referring to the degree of satisfaction of the patient with the health care received, and specific satisfaction, which is the degree of satisfaction with the use of a specific service, or regarding specific aspects of the services received [24]. In our case, specific satisfaction of pain control by the medications prescribed was tested and showed on average higher values than expected. This study underwent limitations such as the fact that in Costa Rica Clinical trials in the social security health system are not allowed because of this reason a pragmatic study design was selected in were no intervention was carried, was only observed the outcome of a regular practice. In addition, due to the fact that patients were asked to participate and report their outcomes at the follow up appointment, the majority of patients did not see a reason to participate. Some authors have pointed oral surgery treatments and particularly third molar extraction as

the first contact/exposure of people particularly teenagers to oral opioids [3,8]. This has risen concern worldwide in the dental community. Moreover, considering the impact and consequences of the current opioid crisis is bringing to the population; new alternatives should be considered besides the use of oral opioids for postoperative pain. The first step should be to promote education to the medical/dental community and patients in regard to this topic. Studies like ours support the fact that there is no need for opioid medications in controlling post-operative pain and NSAID should be recommended as first line treatment option; leaving opioids only for very specific cases (Table 2).

Table 2: Percentage of Third Molar Surgery Patients according to Degree of Pain Control Satisfaction by Gender, Included in the study.

Degree of Satisfaction	Gender				Total	
	Male		Female			
	Number	%	Number	%	Number	%
Unsatisfied	0	0.00%	1	1.79%	1	1.79%
Little satisfied	3	5.36%	0	0.00%	3	5.36%
Neutral	3	5.36%	3	5.36%	6	10.71%
Very Satisfied	4	7.14%	16	28.57%	20	35.71%
Totally satisfied	13	23.21%	13	23.21%	26	46.43%
Total	23	41%	33	59%	56	100%

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