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Evaluating the efficacy of Etoricoxib in reducing post-operative pain associated with minor oral surgery. A randomized clinical trial

Avaliação da eficácia do Etoricoxibe na redução da dor pós-operatória associada à cirurgia oral menor: ensaio clínico randomizado

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ABSTRACT

Etoricoxib, a new cyclooxygenase-2-selective inhibitor has demonstrated a rapid onset analgesic effect for relieving acute pain especially when prescribed as a pre-emptive medication. On these bases, this study may provide useful information and guidance for clinicians working in the field of oral surgery, as regards handling odontogenic pain and postoperative pain precisely with cyclooxygenase-2 inhibitors. **Objective:** the study aimed to measure the quantifiable efficacy of Etoricoxib in reducing post-extraction pain in subjects undergoing minor oral surgical intervention as compared to Naproxen (a traditional NSAID) which is commonly used to control postoperative pain. **Material and Methods:** a 120 mg film-coated tablet of Etoricoxib was given to each of the twenty patients representing the study group, and a 500 mg tablet of Naproxen was given to each of the other twenty subjects representing the positive control group. According to manufacturer instructions, the tablets were given to the subjects 30 minutes pre-operatively (before dental extraction). Post-operative pain was assessed for each subject using eleven points from zero to ten, visual analog scale. **Results:** showed no statistically significant difference between Etoricoxib and Naproxen in decreasing post-extraction odontogenic pain, suggesting that Etoricoxib is as efficient as Naproxen in the control of discomfort with dental origin taking into consideration the patient's status when prescribing the medication. **Conclusion:** this study suggests that Etoricoxib can be handled as a pre-emptive medication to reduce post-operative pain for subjects seeking traditional or surgical extraction of any of their teeth.

KEYWORDS

Etoricoxib; Pain; Oral surgery; Clinical Trial.

RESUMO

O Etoricoxibe, um novo inibidor seletivo da ciclooxigenase-2, demonstrou um efeito analgésico de início rápido para aliviar a dor aguda, especialmente quando prescrito como medicação preventiva. Com base nesses fundamentos, este estudo pode fornecer informações úteis e orientação para clínicos que trabalham no campo da cirurgia oral, no que diz respeito ao manejo da dor odontogênica e da dor pós-operatória de forma precisa com inibidores da ciclooxigenase-2. **Objetivo:** o estudo teve como objetivo medir a eficácia quantificável do Etoricoxibe na redução da dor pós-extração em indivíduos submetidos a intervenção cirúrgica oral menor, comparado ao Naproxeno (AINE tradicional) que é comumente usado para controlar a dor pós-operatória. **Material e Métodos:** um comprimido revestido com um filme de 120 mg de Etoricoxibe foi administrado a cada um dos 20 pacientes representando o grupo de estudo, e um comprimido de 500 mg de Naproxeno foi administrado a cada um dos outros vinte sujeitos representando o grupo de controle positivo. De acordo com as instruções do fabricante, os comprimidos foram administrados aos indivíduos 30 minutos antes da cirurgia (antes da extração dentária). A dor pós-operatória foi avaliada para cada sujeito usando uma escala analógica visual de onze pontos, de zero a dez. **Resultados:** não mostraram diferença estatisticamente significativa entre o Etoricoxibe e o Naproxeno na diminuição da dor odontogênica pós-extração, sugerindo que o Etoricoxibe é tão eficiente quanto o Naproxeno no controle do desconforto de origem dentária, levando em consideração o estado do paciente ao prescrever a medicação. **Conclusão**: este estudo sugere que o Etoricoxibe pode ser administrado como medicação preventiva para reduzir a dor pós-operatória em indivíduos que buscam extração dentária tradicional ou cirúrgica de qualquer um de seus dentes.

PALAVRAS-CHAVE

Etoricoxibe; Dor; Cirurgia oral; Ensaio Clínico.

INTRODUCTION

Pain has been defined as a negative subjective emotional experience brought on by an unhealthy stimulation of the sensory nerve endings that may be linked to tissue damage. Dental pulp or the periodontal ligament might be the source of dental pain (a toothache). Dental pain is profound, and somatic, and presents a variety of central excitatory consequences and effects [1]. On the other hand, Trigeminal nerve-innervated muscles may develop trigger points, autonomic effects, and spasm induction because of referred pain. Dental pain is described as a dreary, oppressive sensation that is occasionally throbbing, scorching, strong, and transient pain. It might be confused with other sources of pain because it is frequently hard for the patient to recognize the exact damaged tooth or site and may indicate that the pain is coming from another tooth or location in one of the jaws or on the face and neck [2]. When oral tissue is injured, the inflammatory response is triggered, releasing a variety of inflammatory and pain mediators. Peripheral nociceptors are more sensitive to and excited by mediating substances such as prostaglandins and bradykinins, which typically exhibit little natural action underneath usual circumstances [1].

The non-steroidal anti-inflammatory drugs (NSAIDs), which include well-known nonselective medicines like cyclooxygenase inhibitors-1 (COX1) and a subclass of selective cyclooxygenase-2 (COX-2) inhibitors, are a diverse class of medications with similar therapeutic effects and side effects. Such medications are the preferred method for treating mild to moderate pain, and the World Health Organization recommends using them on the following bases (WHO) [3]. Antipyretic, anti-inflammatory, and analgesic are the NSAIDs' three primary benefits; however, these medicines can block the COX (1 or 2) enzyme to a greater or lesser extent depending on their subclass, characteristics, and structural chemistry variations. Moreover, COX-2, which participates most in the ability to reduce inflammation and provide pain relief, is of great importance [4,5]. NSAIDs are the most often prescribed drugs for dental pain relief after third molar extraction [6,7]. For the treatment of osteoarthritis [8] and post-surgical dental pain, selective cyclooxygenase-2 (COX-2) inhibitor NSAIDs are just as clinically effective as nonselective (COX-2) NSAIDs [9]. Mechanisms of dental pain: Inflammation is the primary cause of postoperative dental pain, and prostaglandins produced by cyclooxygenase are essential mediators of pain by sensitizing free nerve endings to histamine, bradykinin, adenosine triphosphate, and low pH [10,11]. Glutamate, an excitation-inducing amino acid, and substance P are two elements released by free nerve endings' central ends that depolarize and produce their impulse [12,13]. When compared to other surgical procedures, dental surgical trauma includes soft tissue and bone, although the resulting defect surface is comparatively tiny. Nonetheless, a significant rise in prostaglandins can be seen locally and systemically [14,15]. Further enhancing pain transmission is the central nervous system's (CNS) production of Prostaglandins and other molecules that increase or decrease pain sensitivity [10-12]. Because of this, conventional NSAIDs prevent both the final production of prostaglandins (PGE1 and PGE2) and cyclooxygenase isoforms (COX-1 and COX-2) [16]. COX-1 has been categorized as exclusively the constitutive COX isoform in charge of producing prostaglandin mediators that participate in numerous homeostatic pathways such as gastrointestinal cytoprotection (i.e., prostaglandin E2) and platelet aggregation (i.e., thromboxane A2); COX-2 has also been categorized as solely the upregulated isoform responsible for making prostaglandin compounds elaborate in pain and inflammation (i.e., PGE2) [17]. A once-daily dose of 120 mg film coated-tablets, Etoricoxib, a non-steroidal anti-inflammatory drug, acts by obstructing the end-products of cyclo-oxygenase-2 (COX-2) enzymes such as prostaglandins which cause pain and inflammation resulting in reduced quantities of prostaglandins produced, thereby alleviating pain and inflammation [18]. Naproxen (a well-known NSAID) is used for adults' painful conditions such as ankylosing spondylitis, osteoarthritis, and rheumatoid arthritis. The standard dosage is 500 mg to 1g per day in two divided doses at 12-hour intervals [8]. NSAIDs are contraindicated in patients who have formerly shown allergic responses "e.g. asthma, rhinitis, angioedema or urticaria in reaction to Ibuprofen, Aspirin, or other non-steroidal anti-inflammatory drugs". [10]

Aim of the study

This clinical trial aimed to evaluate whether a pre-emptive high dosage of Etoricoxib can decrease postsurgical pain in subjects undergoing minor oral surgery.

The objective of the study

The aim of this study was fulfilled by evaluating the efficacy of Etoricoxib in reducing post-extraction pain in subjects undergoing minor oral surgical intervention as compared to Naproxen which is commonly used to control postoperative pain.

Approval of the study

The study was registered by the Oral and Maxillofacial Surgery Department/College of Dentistry Scientific Committee / Mosul University on 14 September 2022. Before starting the study, the Research Ethics Committee at the College of Dentistry / Mosul University (reference number UoM.Dent/H.41/22 on 26 December 2022) granted ethical approval for its protocol.

MATERIALS AND METHODS

This study was designed as a controlled, parallel, clinical study conducted in a double-blind fashion. It was carried out from the 2nd of October 2022 until the 10th of November 2022. The study subjects were recruited from the patients attending the Oral Surgery Clinic at the College of Dentistry, the Department of Oral and Maxillofacial Surgery, and Mosul University. The patients were informed of the study protocol and potential risks before participating. Upon acceptance, each patient signed a written consent form to participate in the study.

Inclusion and exclusion criteria

1. Age range 18-70 years old males and females.
2. Healthy subjects i.e., with no systemic diseases or conditions or physiologic status such as pregnancy for females that may contraindicate the administration of any of the study's medications.
3. No allergy to any of the selected medications.
4. Taking any analgesic or anti-inflammatory drug before their participation for at least 1 hour is forbidden.
5. Fully aware patients, i.e., those who can communicate and give full information about themselves and can give consent.

Study groups

Based on the selection criteria, forty healthy subjects arranged to go through surgical intervention for one of their teeth were recruited in the research. The 40 subjects were distributed equally into two treatment groups: the Etoricoxib group and the Naproxen group.

Medications

Two NSAID medications were used including

1. Etoricoxib 120 mg film-coated tablets from United Pharmaceutical Manufacturing Limited Company, Amman/ Jordan.
2. Naproxen 500 mg tablets from Wockhardt UK Ltd. Company.

Protocol and measures

To avoid bias and to assure the double-blinded path of the study, a qualified oral surgeon was assigned to provide the study's medications to the subjects. On the other hand, neither the researchers nor the subjects knew the medication type given to each subject until the time of the results analysis. Accordingly, either a 120 mg Etoricoxib tablet or a 500 mg Naproxen tablet (sealed in a similar premade package), was given to each patient 30 minutes pre-operatively.

An eleven-point (0–10) visual analog scale (VAS) was used for pain assessment measures. It is commonly employed to evaluate the frequency or severity of various symptoms in epidemiological and clinical studies [19]. For instance, the degree of discomfort that a subject experiences can be anywhere along a continuum, from none to extremely high levels. The categories of none, mild, moderate, and severe would imply that this spectrum is divided into discontinuous jumps, but the subject views it as a continuous range. The VAS was developed to capture this notion of an underlying continuity [20]. It was utilized to calculate pain "0, no pain; 1-3, mild pain; 4-6, moderate pain; 7-9, severe pain; and 10, miserable pain".

Statistical analysis

Data were analyzed using SPSS software Statistics for Windows, version 18, Chicago: SPSS Inc. USA. As the study data were not normally distributed (pain VAS measures are always finite and subjective), median and interquartile range (IQR) were used to present the results of the study. Non-parametric statistical tests were used for comparisons between and within the two study groups. Mann-Whitney test was used for the comparison of VAS measures between

Table I - Descriptive Statistics of Etoricoxib group

Naproxen 500 mg tablets	N	Male	Female	Age Range per year	Median	Pain Score Interquartile Range
				21-65	0	0
	20	14	6	31-65	0	0
				21-56	0	0

Table II - Descriptive Statistics of Naproxen group

Etoricoxib 120 mg tablets	N	Male	Female	Age Range per year	Median	Pain Score Interquartile Range
				23-68	0	0
	20	12		35-68	0	0
			8	23-57	0	3.25

Table III - Pain comparisons between the two study groups

Comparisons	p-value*
Etoricoxib 20 Patients versus Naproxen 20 Patients	0.144
Etoricoxib 12 Males versus 14 Naproxen Males	0.911
Etoricoxib 8 Females versus 6 Naproxen Females	0.106

*Mann-Whitney Test, p-value>0.05 (Non-significant)

Table IV - Pain comparisons within the two study groups

Comparisons	p-value*
Etoricoxib 12 Males vs Etoricoxib 8 Females	0.109
Naproxen 14 Males vs Naproxen 6 Females	1

*Wilcoxon Signed Rank Test, p-value >0.05 (Non-significant)

Etoricoxib group and Naproxen group, as they were non-related groups. Wilcoxon Signed Rank test was used for the comparison of VAS measures between males and females within the same group. Differences were considered statistically significant only if the p-value was <0.05.

RESULTS

Forty subjects were involved in the study divided into two treatment groups Etoricoxib 120 mg (n = 20) and Naproxen sodium 500 mg (n = 20). Both groups were equal for the starting point pain intensity, period of surgery, and number of teeth extracted. Data for both groups included number, gender, age range, and pain scores with median and IQR for both treatment group, as shown in Tables I and II.

Statistical analysis showed that there were no statistically significant differences (p-value > 0.05) between the two treatment groups and within each group (males versus females), as shown in Table III and Table IV.

DISCUSSION

Following dental surgery, dental patients may have discomfort and pain; hence, analgesics and/or anti-inflammatory medications are frequently administered to alleviate moderate or severe pain and to prevent the spread of pain, especially for vulnerable individuals, or those who require analgesics [21]. NSAIDs primarily function by blocking the cyclooxygenase enzyme (COX) which is necessary for the production of pain and inflammatory mediators such as prostaglandins, thromboxane, and prostacyclin by converting arachidonic acid into prostaglandins, and these in turn to the other mediators [22]. Nonsteroidal anti-inflammatory medications have been utilized a lot to lessen problems after third molar surgery [23,24], and are frequently used to treat acute inflammatory pain disorders as well as persistent neuropathic pain [25,26]. In their clinical trial, Malmstrom et al. 2004 demonstrated that the higher painkilling outcome of Etoricoxib and Naproxen along with Acetaminophen/Codeine was established by the percentage of patients suffering no or slight pain after receiving the required dose of the medication. Most of the patients on Etoricoxib or Naproxen experienced

no or slight pain, as compared to less than half of the patients on Acetaminophen/Codeine [27]. The alimentary harmfulness linked with NSAIDs is believed to be initiated by the simultaneous inhibition of COX-1 [28], an undesirable side effect of NSAIDs [29], which falls in favor of Etoricoxib. Regarding results, showed the efficacy of etoricoxib was better than that of placebo and similar to that of naproxen; both etoricoxib and naproxen were also generally well tolerated [30], so inadequate postoperative pain management resulted in a significant deterioration in the quality of life of the patients after teeth removal [31]. Etoricoxib reached the cerebrospinal fluid (CSF) and the surgical site in an effective concentration and reduced the production of PGE2 at the presumed site of action [32]. This process resulted in complete blockade of PGE2 production in the surgical wound of extraction and CSF. This phenomenon can lead to pain relief and reduce demands for post-operative analgesics. A single 120 mg dose of Etoricoxib, a new COX-2 targeting agent, offered superior analgesic effect compared with placebo. Etoricoxib 120 mg also offered superior analgesic effect to 2 tablets of Acetaminophen/Codeine (total dose 600/60 mg), an opioid-containing analgesic, while the analgesic effect of etoricoxib 120 mg was similar to that of naproxen sodium 550 mg, a non-selective NSAID. Which is an accepted, sensitive, and validated model for assessing acute pain of moderate to severe intensity [21]. The similar efficacy demonstrated between Etoricoxib and Naproxen in this study. This is likely explained by the fact that the biological variation of the selected cases in our study.

CONCLUSION

In a similar manner to NSAIDs, this study suggests that Etoricoxib can be used as a pre-emptive medication to reduce post-operative pain for patients undergoing extraction or surgical extraction of any of their teeth, avoiding the undesirable side effects of other NSAIDs drugs such as Naproxen.

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Author's Contributions

YHAM: The idea of the research and writing the introduction and materials and methods. ZHD: Surgical part of the study and results with statistic and discussion references writing. ASK: Aid in surgical part and plagiarism paraphrasing and discussion writing.

Conflict of Interest

The authors have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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Regulatory Statement

This study was conducted following all the provisions of the local human subject's oversight committee guidelines and policies of the Oral and Maxillofacial Surgery Department/College of Dentistry Scientific Committee / Mosul University on 14 September 2022. The Research Ethics Committee. The approval code for this study is UoM.Dent/H.41/22 on 26 December 2022.

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