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ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ

Медицинские новости Грузии

საქართველოს სამედიცინო სიახლენი

GEORGIAN MEDICAL NEWS

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GMN: Georgian Medical News is peer-reviewed, published monthly journal committed to promoting the science and art of medicine and the betterment of public health, published by the GMN Editorial Board since 1994. GMN carries original scientific articles on medicine, biology and pharmacy, which are of experimental, theoretical and practical character; publishes original research, reviews, commentaries, editorials, essays, medical news, and correspondence in English and Russian.

GMN is indexed in MEDLINE, SCOPUS, PubMed and VINITI Russian Academy of Sciences. The full text content is available through EBSCO databases.

GMN: Медицинские новости Грузии - ежемесячный рецензируемый научный журнал, издаётся Редакционной коллегией с 1994 года на русском и английском языках в целях поддержки медицинской науки и улучшения здравоохранения. В журнале публикуются оригинальные научные статьи в области медицины, биологии и фармации, статьи обзорного характера, научные сообщения, новости медицины и здравоохранения. Журнал индексируется в MEDLINE, отражён в базе данных SCOPUS, PubMed и ВИНИТИ РАН. Полнотекстовые статьи журнала доступны через БД EBSCO.

GMN: Georgian Medical News – საქართველოს სამედიცინო სიახლენი – არის ყოველთვიური სამეცნიერო სამედიცინო რეცენზირებადი ჟურნალი, გამოიცემა 1994 წლიდან, წარმოადგენს სარედაქციო კოლეგიისა და აშშ-ის მეცნიერების, განათლების, ინდუსტრიის, ხელოვნებისა და ბუნებისმეტყველების საერთაშორისო აკადემიის ერთობლივ გამოცემას. GMN-ში რუსულ და ინგლისურ ენებზე ქვეყნდება ექსპერიმენტული, თეორიული და პრაქტიკული ხასიათის ორიგინალური სამეცნიერო სტატიები მედიცინის, ბიოლოგიისა და ფარმაციის სფეროში, მიმოხილვითი ხასიათის სტატიები.

ჟურნალი ინდექსირებულია MEDLINE-ის საერთაშორისო სისტემაში, ასახულია SCOPUS-ის, PubMed-ის და ВИНИТИ РАН-ის მონაცემთა ბაზებში. სტატიების სრული ტექსტი ხელმისაწვდომია EBSCO-ს მონაცემთა ბაზებიდან.

WEBSITE

www.geomednews.com

К СВЕДЕНИЮ АВТОРОВ!

При направлении статьи в редакцию необходимо соблюдать следующие правила:

1. Статья должна быть представлена в двух экземплярах, на русском или английском языках, напечатанная через **полтора интервала на одной стороне стандартного листа с шириной левого поля в три сантиметра**. Используемый компьютерный шрифт для текста на русском и английском языках - **Times New Roman** (**Кириллица**), для текста на грузинском языке следует использовать **AcadNusx.** Размер шрифта - **12**. К рукописи, напечатанной на компьютере, должен быть приложен CD со статьей.

2. Размер статьи должен быть не менее десяти и не более двадцати страниц машинописи, включая указатель литературы и резюме на английском, русском и грузинском языках.

3. В статье должны быть освещены актуальность данного материала, методы и результаты исследования и их обсуждение.

При представлении в печать научных экспериментальных работ авторы должны указывать вид и количество экспериментальных животных, применявшиеся методы обезболивания и усыпления (в ходе острых опытов).

4. К статье должны быть приложены краткое (на полстраницы) резюме на английском, русском и грузинском языках (включающее следующие разделы: цель исследования, материал и методы, результаты и заключение) и список ключевых слов (key words).

5. Таблицы необходимо представлять в печатной форме. Фотокопии не принимаются. **Все цифровые, итоговые и процентные данные в таблицах должны соответствовать таковым в тексте статьи**. Таблицы и графики должны быть озаглавлены.

6. Фотографии должны быть контрастными, фотокопии с рентгенограмм - в позитивном изображении. Рисунки, чертежи и диаграммы следует озаглавить, пронумеровать и вставить в соответствующее место текста **в tiff формате**.

В подписях к микрофотографиям следует указывать степень увеличения через окуляр или объектив и метод окраски или импрегнации срезов.

7. Фамилии отечественных авторов приводятся в оригинальной транскрипции.

8. При оформлении и направлении статей в журнал МНГ просим авторов соблюдать правила, изложенные в «Единых требованиях к рукописям, представляемым в биомедицинские журналы», принятых Международным комитетом редакторов медицинских журналов - http://www.spinesurgery.ru/files/publish.pdf и http://www.nlm.nih.gov/bsd/uniform_requirements.html
В конце каждой оригинальной статьи приводится библиографический список. В список литературы включаются все материалы, на которые имеются ссылки в тексте. Список составляется в алфавитном порядке и нумеруется. Литературный источник приводится на языке оригинала. В списке литературы сначала приводятся работы, написанные знаками грузинского алфавита, затем кириллицей и латиницей. Ссылки на цитируемые работы в тексте статьи даются в квадратных скобках в виде номера, соответствующего номеру данной работы в списке литературы. Большинство цитированных источников должны быть за последние 5-7 лет.

9. Для получения права на публикацию статья должна иметь от руководителя работы или учреждения визу и сопроводительное отношение, написанные или напечатанные на бланке и заверенные подписью и печатью.

10. В конце статьи должны быть подписи всех авторов, полностью приведены их фамилии, имена и отчества, указаны служебный и домашний номера телефонов и адреса или иные координаты. Количество авторов (соавторов) не должно превышать пяти человек.

11. Редакция оставляет за собой право сокращать и исправлять статьи. Корректура авторам не высылается, вся работа и сверка проводится по авторскому оригиналу.

12. Недопустимо направление в редакцию работ, представленных к печати в иных издательствах или опубликованных в других изданиях.

При нарушении указанных правил статьи не рассматриваются.

REQUIREMENTS

Please note, materials submitted to the Editorial Office Staff are supposed to meet the following requirements:

1. Articles must be provided with a double copy, in English or Russian languages and typed or compu-ter-printed on a single side of standard typing paper, with the left margin of **3** centimeters width, and **1.5** spacing between the lines, typeface - **Times New Roman** (**Cyrillic**), print size - **12** (referring to Georgian and Russian materials). With computer-printed texts please enclose a CD carrying the same file titled with Latin symbols.

2. Size of the article, including index and resume in English, Russian and Georgian languages must be at least 10 pages and not exceed the limit of 20 pages of typed or computer-printed text.

3. Submitted material must include a coverage of a topical subject, research methods, results, and review.

Authors of the scientific-research works must indicate the number of experimental biological species drawn in, list the employed methods of anesthetization and soporific means used during acute tests.

4. Articles must have a short (half page) abstract in English, Russian and Georgian (including the following sections: aim of study, material and methods, results and conclusions) and a list of key words.

5. Tables must be presented in an original typed or computer-printed form, instead of a photocopied version. **Numbers, totals, percentile data on the tables must coincide with those in the texts of the articles.** Tables and graphs must be headed.

6. Photographs are required to be contrasted and must be submitted with doubles. Please number each photograph with a pencil on its back, indicate author's name, title of the article (short version), and mark out its top and bottom parts. Drawings must be accurate, drafts and diagrams drawn in Indian ink (or black ink). Photocopies of the X-ray photographs must be presented in a positive image in **tiff format**.

Accurately numbered subtitles for each illustration must be listed on a separate sheet of paper. In the subtitles for the microphotographs please indicate the ocular and objective lens magnification power, method of coloring or impregnation of the microscopic sections (preparations).

7. Please indicate last names, first and middle initials of the native authors, present names and initials of the foreign authors in the transcription of the original language, enclose in parenthesis corresponding number under which the author is listed in the reference materials.

8. Please follow guidance offered to authors by The International Committee of Medical Journal Editors guidance in its Uniform Requirements for Manuscripts Submitted to Biomedical Journals publication available online at: http://www.nlm.nih.gov/bsd/uniform_requirements.html
http://www.icmje.org/urm_full.pdf
In GMN style for each work cited in the text, a bibliographic reference is given, and this is located at the end of the article under the title "References". All references cited in the text must be listed. The list of references should be arranged alphabetically and then numbered. References are numbered in the text [numbers in square brackets] and in the reference list and numbers are repeated throughout the text as needed. The bibliographic description is given in the language of publication (citations in Georgian script are followed by Cyrillic and Latin).

9. To obtain the rights of publication articles must be accompanied by a visa from the project instructor or the establishment, where the work has been performed, and a reference letter, both written or typed on a special signed form, certified by a stamp or a seal.

10. Articles must be signed by all of the authors at the end, and they must be provided with a list of full names, office and home phone numbers and addresses or other non-office locations where the authors could be reached. The number of the authors (co-authors) must not exceed the limit of 5 people.

11. Editorial Staff reserves the rights to cut down in size and correct the articles. Proof-sheets are not sent out to the authors. The entire editorial and collation work is performed according to the author's original text.

12. Sending in the works that have already been assigned to the press by other Editorial Staffs or have been printed by other publishers is not permissible.

Articles that Fail to Meet the Aforementioned Requirements are not Assigned to be Reviewed.

ავტორთა საყურადღებოდ!

რედაქციაში სტატიის წარმოდგენისას საჭიროა დავიცვათ შემდეგი წესები:

1. სტატია უნდა წარმოადგინოთ 2 ცალად, რუსულ ან ინგლისურ ენებზე,დაბეჭდილი სტანდარტული ფურცლის 1 გვერდზე, 3 სმ სიგანის მარცხენა ველისა და სტრიქონებს შორის 1,5 ინტერვალის დაცვით. გამოყენებული კომპიუტერული შრიფტი რუსულ და ინგლისურენოვან ტექსტებში - **Times New Roman (Кириллица)**, ხოლო ქართულენოვან ტექსტში საჭიროა გამოვიყენოთ **AcadNusx.** შრიფტის ზომა – 12. სტატიას თან უნდა ახლდეს CD სტატიით.

2. სტატიის მოცულობა არ უნდა შეადგენდეს 10 გვერდზე ნაკლებს და 20 გვერდზე მეტს ლიტერატურის სიის და რეზიუმეების (ინგლისურ, რუსულ და ქართულ ენებზე) ჩათვლით.

3. სტატიაში საჭიროა გაშუქდეს: საკითხის აქტუალობა; კვლევის მიზანი; საკვლევი მასალა და გამოყენებული მეთოდები; მიღებული შედეგები და მათი განსჯა. ექსპერიმენტული ხასიათის სტატიების წარმოდგენისას ავტორებმა უნდა მიუთითონ საექსპერიმენტო ცხოველების სახეობა და რაოდენობა; გაუტკივარებისა და დაძინების მეთოდები (მწვავე ცდების პირობებში).

4. სტატიას თან უნდა ახლდეს რეზიუმე ინგლისურ, რუსულ და ქართულ ენებზე არანაკლებ ნახევარი გვერდის მოცულობისა (სათაურის, ავტორების, დაწესებულების მითითებით და უნდა შეიცავდეს შემდეგ განყოფილებებს: მიზანი, მასალა და მეთოდები, შედეგები და დასკვნები; ტექსტუალური ნაწილი არ უნდა იყოს 15 სტრიქონზე ნაკლები) და საკვანძო სიტყვების ჩამონათვალი (key words).

5. ცხრილები საჭიროა წარმოადგინოთ ნაბეჭდი სახით. ყველა ციფრული, შემაჯამებელი და პროცენტული მონაცემები უნდა შეესაბამებოდეს ტექსტში მოყვანილს.

6. ფოტოსურათები უნდა იყოს კონტრასტული; სურათები, ნახაზები, დიაგრამები - დასათაურებული, დანომრილი და სათანადო ადგილას ჩასმული. რენტგენოგრამების ფოტოასლები წარმოადგინეთ პოზიტიური გამოსახულებით **tiff** ფორმატში. მიკროფოტოსურათების წარწერებში საჭიროა მიუთითოთ ოკულარის ან ობიექტივის საშუალებით გადიდების ხარისხი, ანათალების შეღებვის ან იმპრეგნაციის მეთოდი და აღნიშნოთ სურათის ზედა და ქვედა ნაწილები.

7. სამამულო ავტორების გვარები სტატიაში აღინიშნება ინიციალების თანდართვით, უცხოურისა – უცხოური ტრანსკრიპციით.

8. სტატიას თან უნდა ახლდეს ავტორის მიერ გამოყენებული სამამულო და უცხოური შრომების ბიბლიოგრაფიული სია (ბოლო 5-8 წლის სიღრმით). ანბანური წყობით წარმოდგენილ ბიბლიოგრაფიულ სიაში მიუთითეთ ჯერ სამამულო, შემდეგ უცხოელი ავტორები (გვარი, ინიციალები, სტატიის სათაური, ჟურნალის დასახელება, გამოცემის ადგილი, წელი, ჟურნალის №, პირველი და ბოლო გვერდები). მონოგრაფიის შემთხვევაში მიუთითეთ გამოცემის წელი, ადგილი და გვერდების საერთო რაოდენობა. ტექსტში კვადრატულ ფჩხილებში უნდა მიუთითოთ ავტორის შესაბამისი N ლიტერატურის სიის მიხედვით. მიზანშეწონილია, რომ ციტირებული წყაროების უმეტესი ნაწილი იყოს 5-6 წლის სიღრმის.

9. სტატიას თან უნდა ახლდეს: ა) დაწესებულების ან სამეცნიერო ხელმძღვანელის წარდგინება, დამოწმებული ხელმოწერითა და ბეჭდით; ბ) დარგის სპეციალისტის დამოწმებული რეცენზია, რომელშიც მითითებული იქნება საკითხის აქტუალობა, მასალის საკმაობა, მეთოდის სანდოობა, შედეგების სამეცნიერო-პრაქტიკული მნიშვნელობა.

10. სტატიის ბოლოს საჭიროა ყველა ავტორის ხელმოწერა, რომელთა რაოდენობა არ უნდა აღემატებოდეს 5-ს.

11. რედაქცია იტოვებს უფლებას შეასწოროს სტატია. ტექსტზე მუშაობა და შეჯერება ხდება საავტორო ორიგინალის მიხედვით.

12. დაუშვებელია რედაქციაში ისეთი სტატიის წარდგენა, რომელიც დასაბეჭდად წარდგენილი იყო სხვა რედაქციაში ან გამოქვეყნებული იყო სხვა გამოცემებში.

აღნიშნული წესების დარღვევის შემთხვევაში სტატიები არ განიხილება.

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COMPARISON OF THE EFFICACY OF TRAMADOL AND DICLOFENAC IN RELIEVING POSTOPERATIVE PAIN OF LAPAROSCOPIC CHOLECYSTECTOMY

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Abstract.

Tramadol and diclofenac are effective analgesics for pain relief of any complication, however, there are few studies showing the superiority of one over the other. This study aimed to evaluate and compare the analgesic efficacy of diclofenac and tramadol for postoperative pain treatment of laparoscopic surgery of cholecystectomy. There were 120 patients recently operated by laparoscopic surgery of cholecystectomy, who were randomly distributed in two groups: tramadol and diclofenac, administered intramuscularly for a maximum period of five days and demographic and clinical data were collected, as well as the pain evolution during the study period using the verbal numerical scale (VNS) and the functional activity scale (FAS). The results showed a predominance of the male population and an excess of patients with obesity in the tramadol group, and there were no significant differences between the analgesics, but a faster acceptance was observed with tramadol. In conclusion, tramadol is slightly superior to diclofenac, but it cannot be affirmed because there were no significant differences, more studies combining both and comparing them with placebos are suggested.

Key words. Analgesics, diclofenac, postoperative pain, tramadol.

Introduction.

Choledocholithiasis consists in any persistent stone in the bile duct, the most worldwide frequent (95% of the cases) is the lodged one from the gallbladder to the bile duct through the cystic duct. The laparoscopic surgery is currently one of the most accepted removal methods in general surgery, especially for the procedure of laparoscopic cholecystectomy [1-5].

ASA indicates that postoperative pain can appear due the same disease, surgical procedure, or a combination of both cases [6]. In this regard, although it is the most frequent with the open technique in the case of cholecystitis surgeries, cases have also been reported in which there is a significant presence of pain in laparoscopic surgery (LS) [5].

On the other hand, two groups of analgesics are used to relieve these pains: Nonsteroidal anti-inflammatory drugs (NSAIDs) and opioids [7]. Administering high doses of these drugs can mostly counteract postoperative pain; however, doses that may induce undesirable effects on the patient's well-being are necessary to obtain an effective analgesia [8].

Recent studies have shown that there is no significant difference between opioids and non-opioids in terms of pain intensity reduction, however, the use of opioids was also associated with a lower need for supplementary analgesics [9,10]. For this reason, evidence-based analgesic selection is important, although there is little literature comparing these two groups [7].

The most commonly NSAIS used is diclofenac. In presence of biliary colic, antispasmodics such as butylhioscine and a dose of 75 mg of diclofenac intramuscularly are recommended [11]. On the other hand, tramadol is a synthetic opioid [8,12], it also inhibits the reuptake of serotonin and norepinephrine, which makes it an agent among the opioids with a good safety and tolerability profile [13]. This study aimed to evaluate and compare the analgesic efficacy of diclofenac and tramadol for the treatment of postoperative pain of laparoscopic surgery of cholecystectomy.

Materials and Methods.

Experimental design:

It was about a prospective randomized and controlled test of parallel groups.

Performance place:

The study place was at National Hospital Edgardo Rebagliati Martins of the Social Health Insurance (EsSalud), located in the district of Jesús María, Lima, and performed in October 2022.

Sample selection:

The sample consisted of 120 patients recently operated by laparoscopic surgery of cholecystectomy between 18-50 years old. Patients allergic to analgesics were excluded, who had a state of ASA > III, histories of peptide ulcers, gastrointestinal bleeding, starts of stomach or liver cancer, use of analgesics at least one month prior to surgery, those who did not accept to be part of the study, patients with previous pleural effusion or significant pulmonary disease, reported intraoperative complications, and specific cases of modifications to the standardized anesthetic regimen. Two randomized groups were divided [14]: 1) tramadol 100 mg (Tramal®; Grünenthal GmbH, Aachen, Germany) and placebo (0,9 % NaCl) and 2) diclofenac sodium 75 mg (Fortfen®; Compu Pharmaceutical Products, South Africa) and placebo, where the National Hospital Edgardo Rebagliati Martins' drugstore made the coding and blinding of vials.

Pain evaluation:

The determination of pain levels in patients was measured through the verbal numerical scale (VNS) [15], where the patient scores pain in the interval from 0 to 10, where 0 is pain absence and 10 is the most painful level. Likewise, this was complemented with the functional activity scale (FAS) recommended by recent studies [16], which evaluates if the pain prevents the patient from doing permissible physical activities and premorbid state, having three levels: a) no limitation, b) slight limitation and c) significant limitation [17]. The score evaluation of pain was made at 1, 3, 6, 12 and 24 hours of

administrating the study drug and, after, each 6 hours on the 5th day.

Analgesics supply:

Study drugs were administered intramuscularly for a maximum period of five days and discontinued earlier if there was no further need for analgesia (VNS= 0), as suggested by previous studies [7,14].

Clinical data collection:

Demographic and clinical data were recorded, as well as the pain evaluation of the patients in each group on the VNS and complemented with FAS.

Statistical analysis:

The data collected were analyzed in the statistical software SPSS version 25. They were analyzed through analysis of variance (ANOVA). A significance threshold of $p < 0,05$ was assumed.

Ethical aspects of the research:

The study complied with the ethical principles of the Declaration of Helsinki reviewed in 2013. It also complies with current regulations on clinical research and bioethics. The authorization of the Institutional Committee of Ethics and Research of the National Hospital Edgardo Rebagliati Martins was obtained. Medical records were consulted, preserving patients' confidentiality and privacy.

Results.

Table 1 shows the demographic and clinical data of the distribution of patients in randomized groups for analgesic administration. The average age of the tramadol group was 44.76 and 45.35 for diclofenac group, these are close values and there were no significant differences between the distribution. The male sex predominated in both groups; there was no significant difference between the groups. There was a significant difference in their distribution in the average weight and height after operation. There were no patients with previous analgesic administration (less than one month before the operation). There was one patient with diabetes in each group. The distribution of smokers showed significant differences, with more smokers in the diclofenac group.

Table 2 shows the efficacy comparison of tramadol and diclofenac in post-operated patients. The average score of VNS was slightly lower after administering diclofenac against tramadol, however, there is no significant difference between both groups. On the other hand, the FAS score was of three levels: 1, 2 and 3, the average was the same in both analgesics and there was no significant difference. The days with postoperative pain are slightly more than two days with both administration groups. The score was 0 on the last day of the experiment in both cases. The number of patients requiring rescue analgesic administration was higher in the diclofenac group, there were also significant differences, however, the number requiring more than two rescue doses was the same in both groups.

Figure 1 shows the score of both groups on the 5th day of experiment. The mean was 1.765 in the tramadol group and 1.941 in the diclofenac group, there were no significant differences in the results.

Discussion.

In terms of demographic and clinical data, most of the results coincide in terms of distribution with similar studies [7,15] however, the weight data was higher for the tramadol group, a criterion that could have affected the efficacy of pain relief, because the analgesic dosage must be calculated in proportion to the extra weight of each patient [18].

Table 1. *Demographic and clinical data of post-operated patients.*

Variable	Tramadol	Diclofenac	P value
	n=60	**n=60**	
Age (years old)	44.76	45.35	0.86
Sex (men)	42.00	39.00	0.77
Post-operation weight (kg)	80.54	70.25	0.00*
Height (cm)	165.43	160.57	0.03*
Oxytocin (n)	19.00	20.00	0.07
Previously administered (n)	0.00	0.00	-
Previously operated (n)	1.00	0.00	0.42
Diabetes (n)	1.00	1.00	-
Smoker (n)	8.00	10.00	0.01*

Note: (*) Variables that showed significant differences

Table 2. *Efficacy comparison of tramadol and diclofenac in post-operated patients.*

Parameter	Tramadol	Diclofenac	P value
	n=60	**n=60**	
VNS pain score after 1 hour administration (mean, IQR, min-max)	4, 3.2, 1-7	3.5, 3, 0-9	0.797
FAS pain score after 1 hour administration (mean, IQR, min-max)	1, 1.1, 1-3	1, 1.5, 1-3	0.537
Number of painful days (VNS > 5) (mean, IQR, min-max)	2.45, 1.5, 1-5	2.54, 3.5, 2-5	0.862
VNS score on 5th day (mean, IQR, min-max)	0, 0, 0-1	0, 0.5, 0-1	0.922
Number of patients requiring rescue medication (out the schedule) (%)	15 (25%)	24 (40%)	0.020
Number of patients requiring 2 or more doses of rescue medication (%)	12 (20%)	12 (20%)	1.000
Total number of times that the rescue drug was administered (mean, IQR, min-max)	0, 1.4, 0-6	0, 1.5, 0-4	0.536

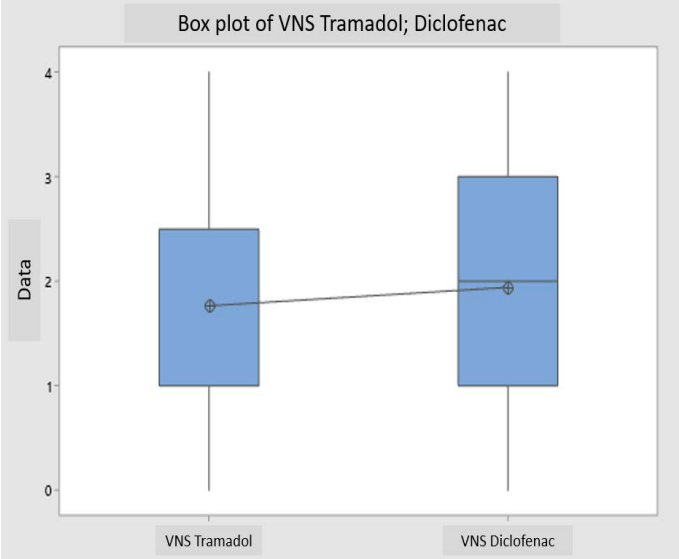

Figure 1. *Verbal numerical scale (VNS) score on the 5th day of experiment.*

Diclofenac is effective as a preventive agent, which is why it is not evaluated as a therapeutic agent to reduce pain in the framework of a clinical test [19], because excess administration is associated with alterations in the function of internal organs such as reduced extrapancreatic activity [21], decreased renal injury [20], decreased inflammation of the perirenal fatty tissue [21], liver injury [21] and lung injury [22]. On the other hand, tramadol is related to the structure of morphine and codeine [13], in a relatively high concentration, it is an NMDA (N-methyl D-aspartate) receptor antagonist, which may further contribute to pain control [13]. In view of this, it is important to dose the right amount of analgesics [7,18].

There were no significant differences in this study between the administration of both analgesics and its post-operative pain relief; this coincides with the results of previous studies in which the analgesic superiority between both drugs has not yet been shown [17]. However, tramadol resulted to be more effective and in record time for a slight difference, so patients responded faster to their administration, this statement is supported by a previous report in which the analgesic activity of tramadol was reported to be greater than diclofenac's, referring to other pain conditions such as traumatic musculoskeletal pain which can be shown from moderate to severe pain [23].

The limitation of this study was probably the sample size and distribution of patients in each group due to their clinical condition, as the case of obesity was, and the proportional supplementary supply that could interfere with the slight advantage of tramadol. In addition, it is necessary to study the analgesic effect in different complications to provide a substantiated information.

Conclusion.

This study showed that tramadol is slightly superior in terms of its analgesic efficacy, however, there is no significant difference of importance to compare both drugs. More studies combining both and compare them with placebos are suggested.

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