

Effectiveness of Ibuprofen versus Novafen in Reducing Pain after Molar Extractions

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Abstract

Background and objectives: Tooth extraction is often associated with pain and discomfort for patients. There are still controversies over the proper painkiller with minimum side effects to be prescribed after extractions. Therefore, the current study aims to compare the pain-relieving effect of Novafen versus Ibuprofen after maxillary and mandibular molar extractions.

Materials and methods: The present cohort study consisted of 80 healthy individuals who were candidates for extraction of their molar teeth under local anesthesia. Patients were randomly divided into two groups (N = 40) and were instructed to use Novafen or Ibuprofen, respectively, every 6 hours post-extraction. Pain assessment was conducted using Visual Analogue Scale (VAS). Data analysis was performed using SPSS v25. The Chi square test was performed for qualitative and t-tests for quantitative variables. Pain relief times were compared using Kaplan-Meier curves and Cox regression, with hazard ratios assessing differences between the two drugs.

Results: The findings revealed that both medications affected similarly up to 12 hours post-treatment; however, Novafen exhibited a shorter time to pain relief than Ibuprofen after 12 hours. Thus, Novafen demonstrated a significantly faster time to pain relief than Ibuprofen ($P < 0.005$). Moreover, the hazard ratio for the analgesic effect of Novafen relative to Ibuprofen was 2.55, indicating that Novafen has a shorter time to pain relief than Ibuprofen ($P < 0.002$).

Conclusion: Both Novafen and Ibuprofen are effective in reducing pain after molar extractions; however, Novafen can be a more reliable choice in reducing pain and discomfort.

Keywords: Molar Extraction; Pain management; Ibuprofen; Novafen; Analgesics.

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1. Introduction

Pain relief can be achieved by increasing the pain threshold through actions that affect the central or peripheral nervous system without affecting awareness or perception of other sensations. Analgesics are drugs that affect the central or

peripheral nervous system in this way. One of the most common types of analgesics is Nonsteroidal Anti-inflammatory Drugs (NSAIDs), which include Ibuprofen as the most commonly used painkiller. There are also combination pain relievers, such as Novafen, that are available nowadays. These have been shown to be very

effective in relieving pain in patients who have had a tooth extracted (1).

Ibuprofen is a propionic acid derivative that can treat mild to moderate pain, postoperative inflammation, toothache, migraines, osteoarthritis, and rheumatoid arthritis. It has a half-life of two hours and is taken every four to six hours. It has a maximum daily dose of 2400 mg and is available in 200-400 mg tablets. Ibuprofen causes fewer gastrointestinal (GI) problems than other NSAIDs, but it still has some side effects such as abdominal pain, nausea, vomiting, GI bleeding, and stomach ulcers (1, 2).

Novafen is a novel combination drug that comprises 325 mg of acetaminophen, 200 mg of Ibuprofen, and 40 mg of caffeine. Acetaminophen in this drug is readily and completely absorbed through the gastrointestinal tract. Acetaminophen exerts its effect on the central and peripheral nervous system. The daily dose of acetaminophen should not exceed 4000 mg. Ibuprofen in Novafen is an opioid analgesic with anti-inflammatory properties (3-5).

Lastly, the caffeine in this drug is a crystalline powder with a bitter taste, and this compound is incorporated into many non-steroidal anti-inflammatory and analgesic compounds nowadays. It is likely that this substance enhances the pharmacological efficacy of drugs such as acetaminophen by increasing the absorption rate (6-8).

This study examines the pain-relieving effect of Novafen versus Ibuprofen, a more common drug, in patients after the extraction of upper and lower first molar teeth.

2. Materials and methods

This cohort study, involved 80 patients selected from the dental clinics of Mazandaran Medical Sciences Faculty. All patients were fully informed about the study and provided written consent to participate.

Inclusion criteria for this study were as follows:

1. Patients aged 18-60 years without systemic issues or history of drug use.
2. No history of taking analgesics within 8 hours prior to treatment or taking drugs that interfere with NSAIDs.
3. Patients who visited for the selective removal of their first or second molar tooth had crowns on these teeth, allowing for a simple extraction using only forceps.

Exclusion criteria included patients who experienced dry socket and those who did not take their medication on time or at all.

Gelofen 400mg (Dana Pharmaceutical Co., Tehran, Iran) and Novafen (each capsule containing 325mg acetaminophen, 40mg caffeine, and 200mg ibuprofen; Alvahi Co., Tehran, Iran) were used to ensure identical drug formulation.

Patients took one medication every 6 hours post-extraction, and compliance was monitored via phone calls. Prior to tooth extraction, patients were instructed to assess their pain intensity using a Visual Analogue Scale (VAS), a

100mm horizontal line with 0 indicating no pain and 100 indicating the most severe pain, after patient education.

The candidate's teeth were extracted by a maxillofacial surgeon to minimize interference. Anesthesia was administered using 2% lidocaine with 1:80,000 epinephrine, with a maximum of 3 capsules if additional anesthesia was required. Teeth were first loosened with an elevator before extraction using specialized forceps. Patients received post-treatment instructions both verbally and in writing. Eight capsules were placed in an envelope, and provided to patients. The groups were matched in terms of age, gender and type of teeth.

Pain intensity was measured using a Visual Analogue Scale (VAS), with patients instructed on its use before the procedure. Pain was assessed at 4, 8, 12, 24, and 48 hours post-extraction. Data were collected through follow-up phone calls to ensure compliance and accurate reporting. Demographic and clinical characteristics were described using frequency and percentage for qualitative variables and mean and standard deviation for quantitative variables. Chi-square tests were used to compare the distribution of qualitative values, while Student's t-tests were used to compare means of quantitative values. Pain reduction time for the two drugs was compared using the Kaplan-Meier curve and log-rank test, followed by an adjusted Cox regression model based on gender and age. Analysis was performed using SPSS v25 (SPSS Inc., Chicago, IL, USA), with a significance level of 0.05 for all tests.

3. Results

Table 1 presents the descriptive demographic values of the patients and the comparison of variables between the two drug groups. Descriptive statistics for age showed a mean ($\pm$ SD) of 35.85 ± 11.13 years in the Ibuprofen group and 35.95 ± 11.49 years in the Novafen group. Chi-square test results indicate a homogeneous distribution of gender and tooth position variables across both groups. Additionally, Student's t-test results reveal no statistically significant difference in patient age between the two treatment groups. The similarity in demographic characteristics between the groups suggests that differences in outcomes are likely due to the intervention.

In assessing the time to pain relief for Ibuprofen and Novafen medications, the event of interest is the duration until complete recovery following tooth extraction in patients, which is considered a positive outcome.

Table 2 displays the number of observed events and censored observations by treatment group.

Unadjusted survival functions were estimated via the Kaplan-Meier method, and the distribution of time to event occurrence was subsequently described. Figure 1 depicts the survival curves for pain intensity in the Novafen and Ibuprofen groups. The Novafen curve lies below that of Ibuprofen during the study treatment period, indicating faster time to pain relief for Novafen. Both medications de-

Table 1. A table presenting descriptive values and comparison of patient demographic characteristics between treatment groups.

			Ibuprofen	Novafen	Test results
Qualitative values- Chi-square test	Gender	Male (%)	(37.5%) 15	(45.0%) 18	0.051
		Female (%)	(62.5%) 25	(55.0%) 22	
	Tooth	Mandibular first molar	(42.5%) 17	(52.5%) 21	0.501
		Maxillary first molar	(57.5%) 23	(47.5%) 19	
Quantitative values- Student's t-test	Age (standard deviation ± mean)		35.85± 11/13	35/95± 11/49	0.960

Table 2. The count of observed pain relief events and censored observations, stratified by group.

Type of medicine	The overall number of patients	Recovered patients (%)	Censored patients (%)
Ibuprofen	40	17(42.50)	23(57.50)
Novafen	40	34(85.00)	6(15.00)
Overall	80	51(63.75)	29(36.25)

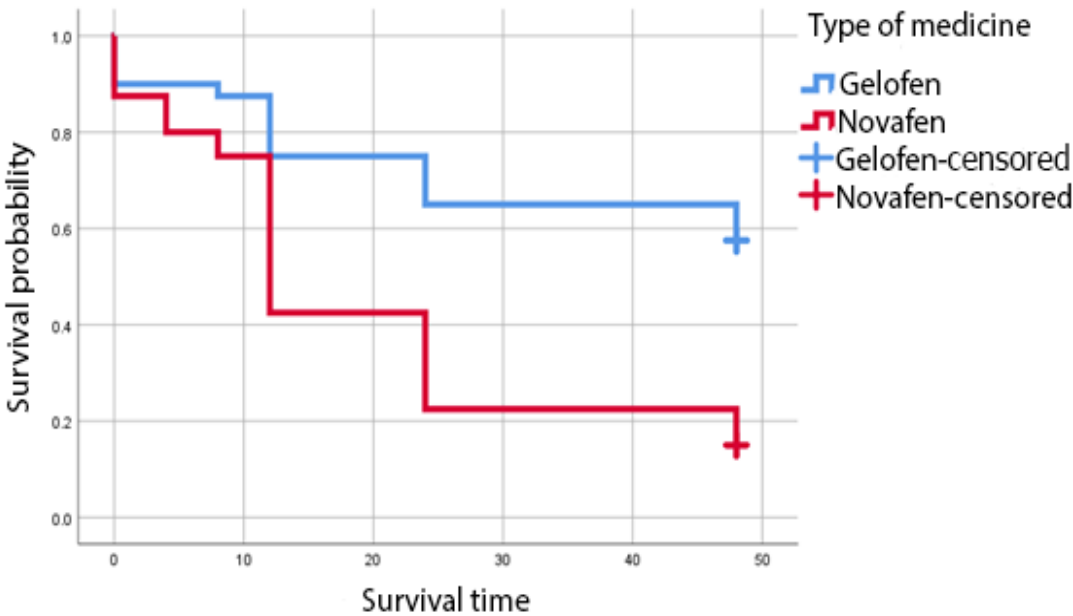


Figure 1. The estimated survival function for time to pain relief, as determined via the Kaplan-Meier method, is depicted in the form of survival curves for patients treated with Ibuprofen (blue curve) and Novafen (red curve). Both observed events and censored observations (loss to follow-up) are displayed for each curve.

monstrated similar efficacy in reducing pain intensity up to 12 hours post-treatment, after which Novafen exhibited a shorter time to pain relief than Ibuprofen. A log-rank test was conducted to assess the statistical significance of the difference in survival time distributions between the two

medications. The distributions were found to be significantly different, with Novafen demonstrating a faster time to pain relief than Ibuprofen ($\chi = 15.66$, $P < 0.001$). The measurements suggested that the two groups had diffe-

rent VAS over time and this difference was statistically significant and Novafen had better pain control (Table 3 and Figure 2).

A Cox regression model was employed to adjust for the effects of pre-extraction pain levels. Results (Table 4) indicate that for each unit increase in pre-extraction pain, the average time to pain relief following extraction is reduced by 1.4% ($P < 0.04$). Additionally, the hazard ratio for the analgesic effect of Novafen relative to Ibuprofen is 2.55, indicating that Novafen has a shorter time to pain relief than Ibuprofen ($P < 0.002$).

The survival time graph for the Cox regression model is also displayed below (Figure 3).

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The survival time graph for the Cox regression model is also displayed below (Figure 3).

4. Discussion

In this cohort study, the effectiveness of Ibuprofen 400mg and Novafen pain relievers in reducing pain after upper and lower molar teeth extraction was assessed. The main findings of this study indicate that Novafen provides faster pain relief after 12 hours compared to Ibuprofen, which has significant implications for clinical practice in dental pain management. The observed differences in pain relief between the two drugs could influence the choice of analgesic in post-extraction care.

Comparisons with previous studies reveal both consistencies and discrepancies. For example, while Dejkam et al. (9) found that Novafen was more effective within 8 hours post-treatment, our study shows similar efficacy for up to 12 hours, followed by superior performance by Novafen. These differences may be attributed to variations in study design, patient population,

Table 3. The results of the Log-Rank test to compare the survival function curve of Ibuprofen and Novafen.

The type of test	Chi-Square	df	p-value
Log Rank (Mantel- Cox)	15.662	1	< 0.001

Table 4. VAS measurements in each group.

Group	No.	Mean	Std. Deviation	Sig
Pre-VAS	Ibuprofen	40	39.4750	0.141
	Novafen	40	31.5000	
	Total	80	35.4875	
VAS-4	Ibuprofen	40	40.6000	0.010
	Novafen	40	27.7750	
	Total	80	34.1875	
VAS-8	Ibuprofen	40	27.8250	0.012
	Novafen	40	17.1250	
	Total	80	22.4750	
VAS-12	Ibuprofen	40	25.1500	0.004
	Novafen	40	11.0250	
	Total	80	18.0875	

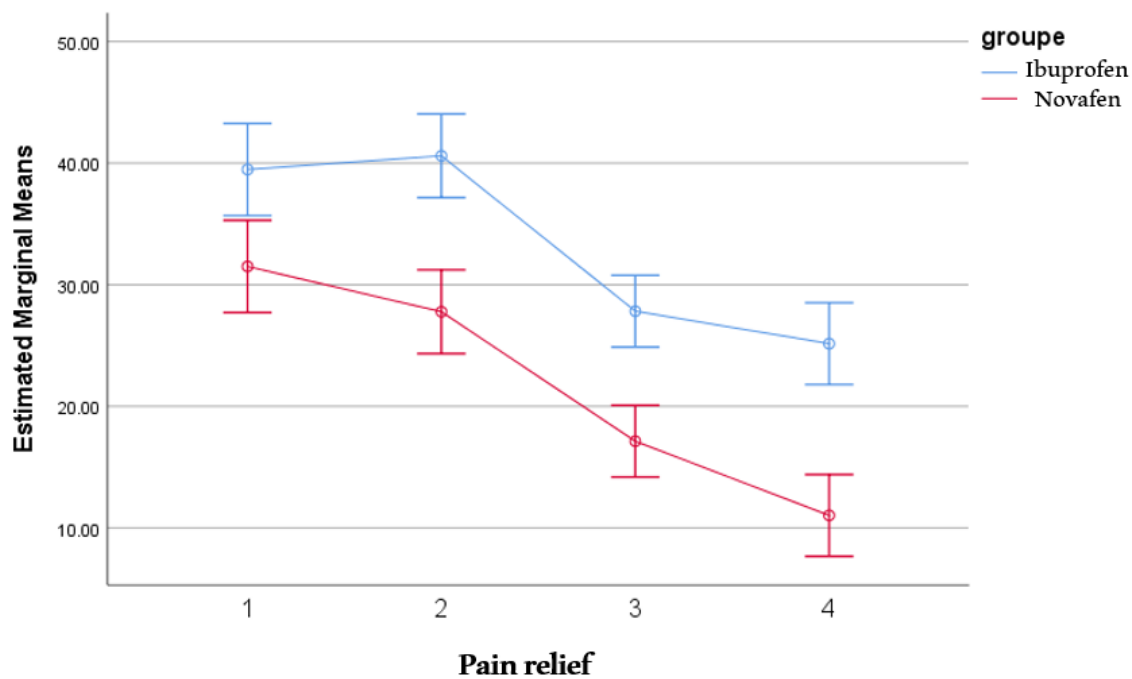


Figure 2. Comparison of the pain relief effect among the two groups.

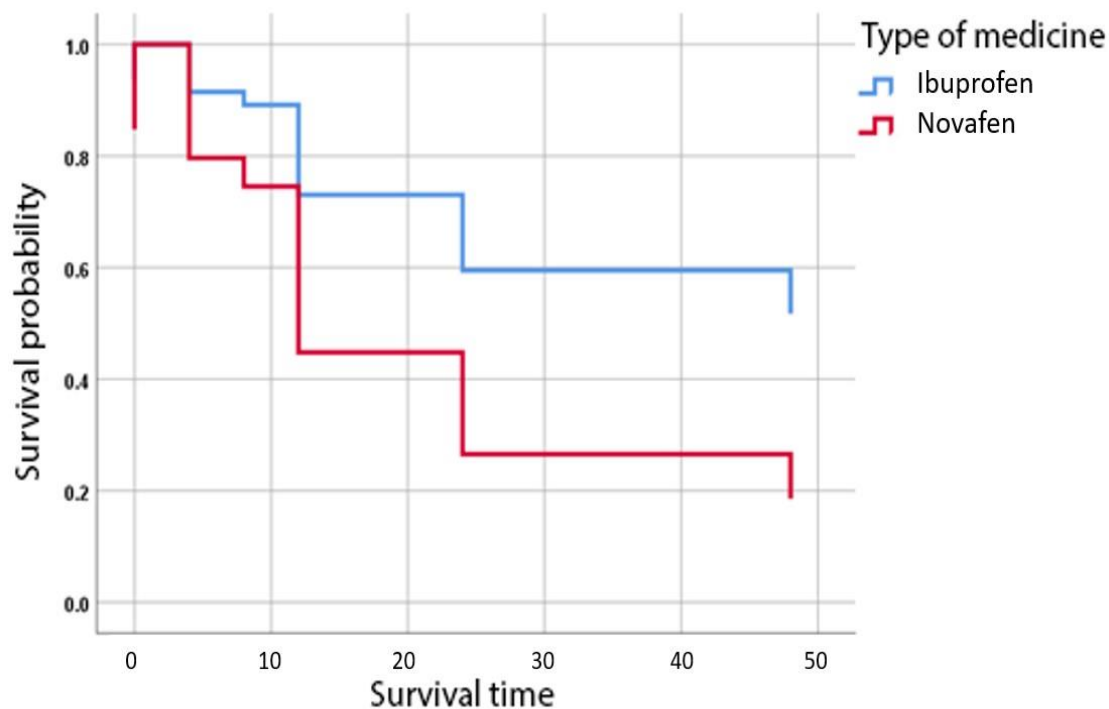


Figure 3. After adjusting for the pain variable prior to tooth extraction, the Cox regression model's survival function showed that the analgesic effect of Novafen was significantly greater than that of Novafen, with a P-value less than 0.002.

or dosage regimens. Teeth may need to be extracted for various reasons, including decay, trauma, and orthodontics. There are two

primary methods of tooth extraction: simple extraction, used for teeth visible in the mouth (10), and surgical extraction, used for teeth that are not easily visible or

accessible in the mouth. This may occur if a tooth has broken at the gum line or has not fully erupted (11).

Post-operative pain is a common consequence of tooth extraction and can be a significant source of discomfort for patients. The invasiveness of the procedure can influence the level of pain experienced. To control for this factor, this study only included teeth with a clinical crown that could be extracted using a simple method.

Numerous studies have examined the efficacy of various analgesics in dental procedures. For instance, Kashefimehr et al. (2017) investigated the prophylactic use of Novafen in reducing postoperative pain following periodontal surgery. They found that pain levels at 30 minutes, 1 hour, 3 hours, 1 day, 2 days, and 3 days post-surgery were significantly lower in the Novafen group compared to the placebo group (12). Similarly, Atkinson et al. (2015) compared the effectiveness of Ibuprofen and acetaminophen in reducing pain after oral surgery. Their results showed that all combined doses resulted in greater pain reduction compared to placebo following surgical removal of impacted third molars (13). These findings are in accordance with those of the present study.

Dejkam et al. (2015) conducted a study investigating the use of Ibuprofen and Novafen in reducing pain following endodontic treatment. Pain levels were recorded using the VAS scale before and at 4, 8, 12, 24, and 48 hours post-treatment. Results indicated that both Novafen and Ibuprofen had significant analgesic effects during the study period, with the Novafen group experiencing significantly less pain within 8 hours post-treatment compared to the other two groups (9). These findings differ from those of the present study, where Novafen and Ibuprofen had similar effects for up to 12 hours, after which Novafen was more effective in reducing pain. However, both studies agree that Novafen has a better analgesic effect than Ibuprofen.

Pahlavani et al. (2012) conducted a study on 105 children aged 6-11 years undergoing molar tooth extraction. The children were randomly assigned to one of three groups of 35: the first group received acetaminophen syrup at a dose of 15 mg/kg, the second group received Ibuprofen syrup at a dose of 5 mg/kg, and the third group received a combination of acetaminophen syrup at a dose of 7.5 mg/kg and Ibuprofen syrup at a dose of 2.5 mg/kg. Medications were administered one hour prior to tooth extraction. Results showed that the groups receiving either acetaminophen or Ibuprofen alone had greater analgesic effects than the group receiving both medications together (14). These findings differ from those of the present study, as well as those of Dejkam et al. (9) and Merry et al. (15). Merry et al. conducted a study on adults over 16 years of

age with one or more wisdom teeth. They compared three medications: a combination tablet of acetaminophen 500 mg and Ibuprofen 150 mg (Maxigesic), a tablet containing only acetaminophen 500 mg, and a tablet containing only Ibuprofen 150 mg. Results showed that Maxigesic tablets were more effective in reducing pain after oral surgery than either acetaminophen or Ibuprofen alone (15). This difference may be due to the synergistic effects of the two drugs when combined.

In another study, Gazal et al. (2007) examined 200 children divided into four groups: 47 children received Ibuprofen alone (5 mg/kg), 51 children received a combination of paracetamol and Ibuprofen at a ratio of 15 and 5 mg/kg, 48 children received a high dose of paracetamol (20 mg/kg), and 55 children received a normal dose of paracetamol (15 mg/kg) as a control group. Results showed that the group receiving Ibuprofen alone and the group receiving the combination of Ibuprofen and paracetamol had significantly greater reductions in pain and stress compared to the control group (16). These findings are consistent with those of the present study.

The clinical relevance of these findings is underscored by the potential for Novafen to improve patient comfort and reduce postoperative recovery time. Safety profiles for both drugs were similar, but further research is needed to assess long-term effects and side effects, particularly with chronic use.

Study limitations include the relatively small sample size, the short duration of follow-up, and the exclusion of patients with certain medical conditions. Future research should focus on larger, more diverse populations and explore additional outcomes such as patient-reported quality of life and long-term pain management strategies.

5. Limitations

Since the Visual Analogue Scale (VAS) relies on subjective self-reporting and affects the reliability of pain measurement, it is suggested that further studies use updated methods for pain assessment.

6. Conclusion

The current investigation suggested that both Novafen and Ibuprofen can be useful in reducing pain after molar extractions up to 12 hours post-treatment. Nevertheless, from 12 hours after taking the medication, Novafen is significantly more effective in reducing pain intensity than Ibuprofen. In conclusion, Novafen appears to be a more effective option for reducing post-extraction pain, particularly after the first 12 hours. These findings support the use of Novafen as a first-line analgesic in dental

procedures, with consideration for individual patient needs and potential side effects. However, further studies should be conducted to assess the side effects of each medication and compare their overall effect on the patients.

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Ethics

The study protocol obtained ethical approval from the Mazandaran University of Medical Sciences (ethics code: IR.MAZUMS.REC.96.2820).

Author contributions

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Leyli Sadri: Conceptualization, Writing - Review & editing

Conflict of interest

The authors declare no conflict of interest.

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