

# A Double-Blind Comparison of Nimesulide and Diclofenac Sodium in Impacted Third Molar Surgery\*

## GÖMÜLÜ ÜÇÜNCÜ MOLAR CERRAHİSİNDE NİMESULİD VE DİKLOFENAK SODYUMUN ETKİLERİNİN KARŞILAŞTIRILMASI

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### Summary

**Purpose:** In this study the efficacy of nimesulide was compared with diclofenac sodium when administered orally to patients after impacted third molar surgery.

**Materials and Methods:** Using randomised, double blind method nimesulide and diclofenac sodium were given postoperatively to 50 patients who had symmetrically impacted third molars. Quantity of pain was measured with four pain point descriptive scale and also a radiographic method was used for measuring postoperative edema. Study forms were analyzed with student's t-test and Mann-Whitney U test.

**Results:** The statistical evaluation showed that nimesulide group was significantly more effective than diclofenac sodium.

**Conclusion:** Both medicals were effective and well-tolerated in the treatment of postoperative pain and edema however the statistical evaluation revealed that the effect of nimesulide was significantly better than diclofenac sodium.

**Key Words:** Postoperative pain and edema, Nimesulide, Diclofenac sodium

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### Özet

**Amaç:** Bu çalışmada gömülü üçüncü molar dişlerinin cerrahi çekimi sonrasında hastalara oral olarak verilen nimesulid ve diklofenak sodyumun etkilerinin karşılaştırılması amaçlanmıştır.

**Materyal ve Metod:** Karşılaştırmalı, çift kör yöntemle simetrik gömülü üçüncü molar dişi olan 50 hastaya postoperatif nimesulid ve diklofenak sodyum verilmiştir. Ağrı şiddeti dört noktalı ağrı skalası ile ölçülmüş, ayrıca postoperatif ödemin belirlenmesinde de radyolojik metod kullanılmıştır. Çalışma formlarındaki veriler Student's t-test ve Mann-Whitney U test'i ile değerlendirilmiştir.

**Sonuçlar:** İstatistiksel analizler nimesulid grubunun diklofenak sodyum grubuna göre önemli oranda daha etkin olduğunu göstermiştir.

**Anahtar Kelimeler:** Postoperatif ağrı ve ödem, Nimesulid, Diklofenak sodyum

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Intense pain and impairment of mastication are frequent results of surgical removal of impacted third molar surgery. Patients experiencing these results are often treated with postoperative oral analgesics and nonsteroidal anti-inflammatory drugs. Nimesulide is an NSAID that possesses anti-inflammatory, analgesic and antipyretic properties and is well tolerated in human beings (1,2). Pharmacodynamic studies have demonstrated that nimesulide inhibits prostaglandin synthesis with less effect on the synthesis of protective prostoglandins of gastric mucosa than other NSAIDs (3). In addition,

nimesulide has oxygen free-radical scavenging activity (4).

In the present study, the efficacy of nimesulide was compared with diclofenac sodium when administered orally to patients after impacted third molar surgery.

### Materials & Methods

50 out patients who had bilaterally impacted third molars that showed similar positions and bone retention on panoramic x-ray were included in this study. The study was conducted on 20 male and 30 female patients and their ages ranged

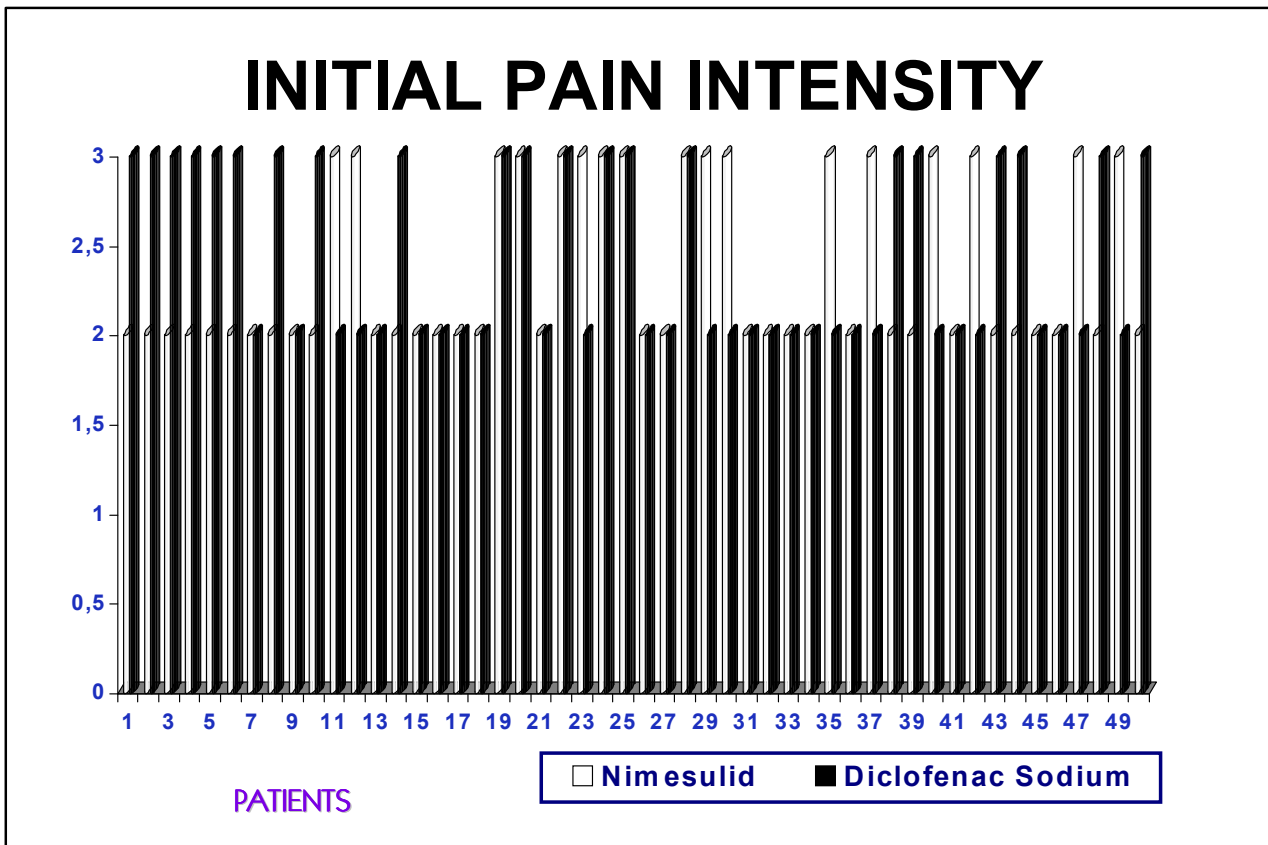


Figure 1. Initial pain intensity.

between 18 and 40. Nimesulide (MESULID) 100mgr and Diclofenac sodium (DIKLORON) 100mgr were used in this study. Sensitive vernier gauge 0.05mm was used to measure preoperative and postoperative mouth opening.

Quantity of pain was measured with four pain point descriptive scale as defined previously (5). Also a radiographic method was used for measure postoperative edema, which Forman (6) described. The radiologic records were taken at Hacettepe University, Faculty of Dentistry, Department of Orthodontics. Patients were informed about the drugs to be used and their consents were obtained. The study forms included the codes of drugs to be used, preoperative mouth opening values and preoperative radiologic measurements. The positions of impacted third molars were evaluated with the panoramic radiographs preoperatively. The positions of all bilateral impacted molars were similar.

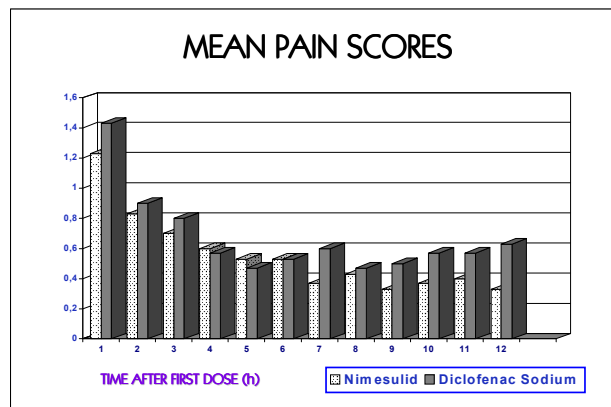


Figure 2. Mean pain scores.

Using a randomized, double blind method, the drugs were given to the patients postoperatively. Mouth opening values and radiologic measurements were obtained 48 hours after surgery. Statistical analysis (Student’s t-test,

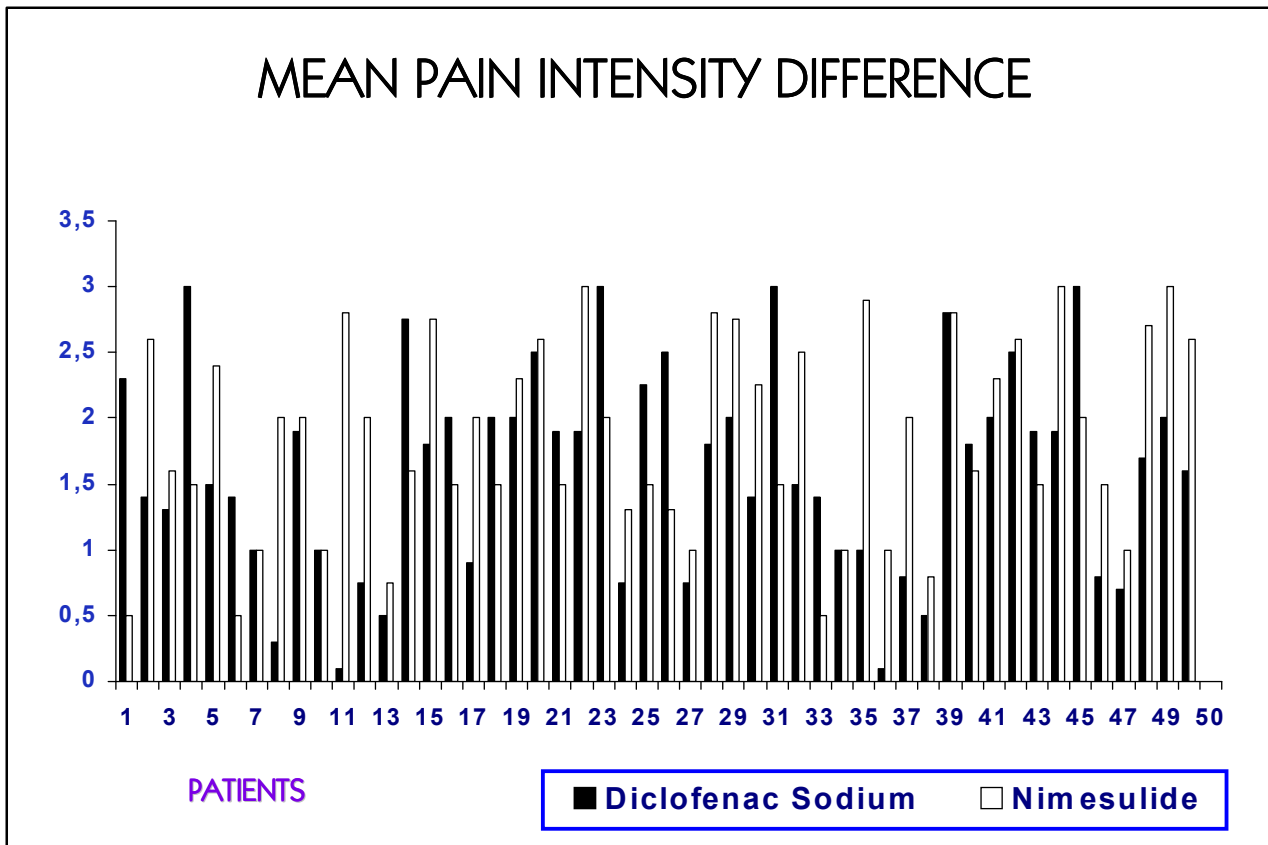


Figure 3. Mean pain intensity difference.

Mann-Whitney U test) were obtained with the scores in the study forms.

### Results

Perioperatively no significant differences were observed both in nimesulide and diclofenac sodium groups ( $p>0.05$ ).

The difference between preoperative and postoperative mouth openings as well as radiological findings was significant in the nimesulide group ( $p<0.05$ ).

Respectively edema in the nimesulide group was less than the diclofenac sodium group and the difference between them was significant ( $p<0.05$ ) (Figure 1). According to the initial pain values there was no significant difference between nimesulide and diclofenac sodium groups ( $p<0.05$ ).

Mean pain scores and mean pain intensity differences that the patients indicated every hour

for 12 hours following the first drug intake postoperatively are shown on Figure 2 and Figure 3. The difference between these parameters was significant ( $p<0.05$ ).

Investigations of pain relief scores showed that nimesulide was significantly effective (Figure 4,5). The difference between the therapy groups was statistically significant ( $p<0.05$ ).

### Discussion

In this clinical trial, nimesulide and diclofenac sodium were administered at the recommended dosages in order to reflect as closely as possible current clinical practice. The study was designed to provide a reliable impression of the efficiency and safety of both drugs in the treatment of postoperative pain and edema.

All nimesulide patients results were more significant than diclofenac sodium as assessed by patient global evaluation pain intensity and pain

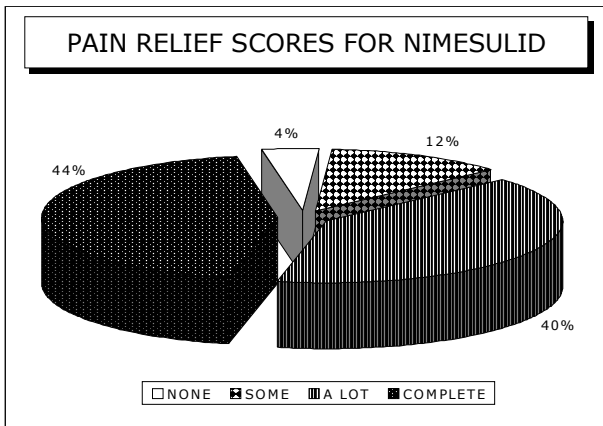


Figure 4. Pain relief scores for nimesulide.

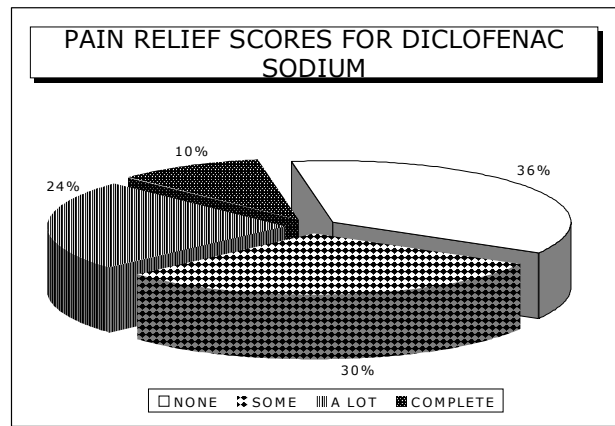


Figure 5. Pain relief scores for diclofenac sodium.

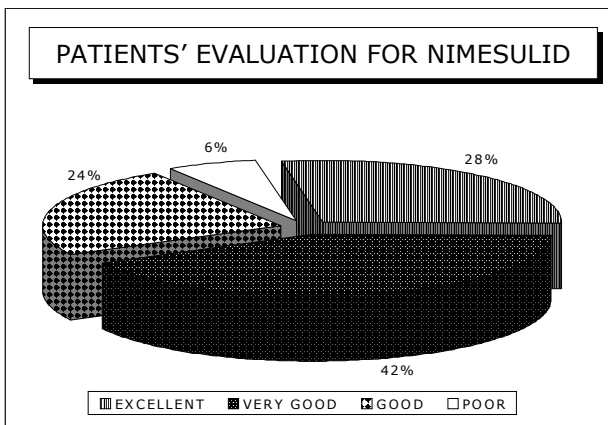


Figure 6. Patients evaluation for nimesulide.

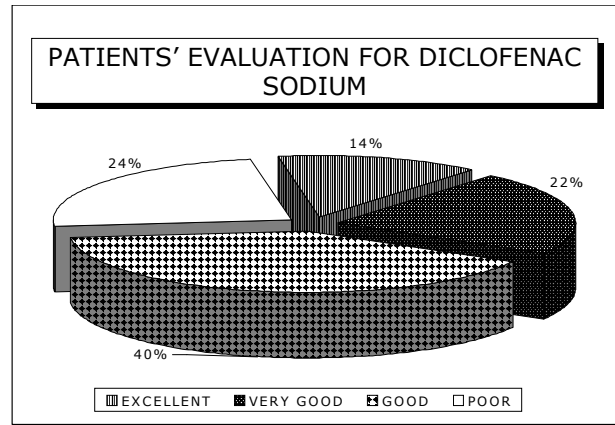


Figure 7. Patients evaluation for diclofenac sodium.

relief scores. Also most patients preferred nimesulide rather than diclofenac sodium, due to its fast anti-inflammatory effect.

Treatment of inflammatory oral conditions with nimesulide has been studied in 2 similarly designed double-blind trials. Cornaro (7) treated 49 patients with postoperative inflammation after oral surgery with nimesulide or placebo. Nimesulide was significantly superior to placebo for all symptomatic measures of analgesia or anti-inflammatory activity and was more rapidly effective.

Scolari (8) et al used nimesulide therapy on 148 patients with severe postoperative pain. Their results were presented that nimesulide was

effective and well tolerated in the treatment of acute dental pain.

Kriegel (9) et al compared the long term efficiency and safety of nimesulide and naproxen in patients with osteoarthritis and they showed that nimesulide was effective as well as naproxen and also well tolerated in gastrointestinal system.

NSAID's are frequently administered in combination with other medication indicating a considerable propensity for interactions. NSAID's inhibit the synthesis of prostoglandins but the action of nimesulide appears to differ from that of most conventional NSAID's in this respect (10,11). Indeed, nimesulide selectively inhibits the formation of pro-inflammatory prostoglandins with

less effect on those prostoglandins that have a gastroprotective action. As a consequence, nimesulide is better tolerated by the gastrointestinal tract than most other NSAIDs, while exerting equivalent efficacy (12-15).

Biscarini et al. (16) reported that nimesulide would appear to be a valid alternative to other NSAIDs since it has a rapid onset of action. The results of the present study confirm these properties and corroborate the results of studies demonstrating the efficacy of nimesulide in the treatment of patients undergoing oral surgery.

These results suggest that nimesulide offers a welcome alternative to available NSAIDs for the treatment of inflammatory complications of oral surgery.

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