Efficacy of aceclofenac and diclofenac sodium for relief of postoperative pain after third molar surgery: A randomised open label comparative study

Sir,

Surgical removal of impacted third molar is the common surgical procedure in oral and maxillofacial surgery, which can result in considerable post-operative pain, swelling and trismus. Postoperative pain is an acute localized pain of varying intensity caused by increased prostaglandin synthesis. Pain reaches maximum intensity within 3-5 h postoperatively.[1] Non steroid antiinflammatory drugs (NSAID) are the staples of acute pain therapy, among which diclofenac sodium is one of the potent and time tested, commonly prescribed drug. Diclofenac is a non-selective inhibitor of cyclooxygenase and also appears to reduce synthesis of leukotrienes. Being a non-selective inhibitor, it is associated with gastrointestinal adverse effects, thereby limiting its use in patients predisposed to gastrointestinal disease.[2] Aceclofenac has anti-inflammatory properties similar to those of diclofenac and yields good results in the control of dental pain.[3] Aceclofenac, being a predominantly cox-2 inhibitor, demonstrates improved gastrointestinal tolerability compared to conventional NSAIDs. They do not have any significant effect on platelet functions as non-selective inhibitors.[4] Innumerable clinical studies have been done to evaluate the efficacy and safety of orally administered analgesics.

This study was conducted among fifty patients, aged from 18-60 years, who require surgical removal of impacted mandibular third molars. Patients with blood dyscrasias, with peptic ulcer, pregnant women, patients who had NSAID in the previous 24 h, hypersensitivity to any of the drugs used in this study, surgical time in excess of 45 minutes, patients failure to comply with the prescribed medication were excluded from the study. The patients were randomized into two groups; to receive aceclofenac 100 mg twice daily and diclofenac sodium 50 mg eighth hourly. The patients likewise received the questionnaires to be completed in the course of the 24 hours. Each patient evaluated his or her pain symptoms at specified time points (0, 0.5, 1, 1.5, 2, 3, 4, 5, 6, 7, 8, 12, 24 h. after administration of the study drug.) and recorded them using established rating scales (category grading scale). In addition, adverse effects of the drugs were noted in all cases. *Pain intensity* was recorded on a four-point scale (0 = none to 3 = severe) at base line and at the same specified times following the administration of a single dose of the study drug. *Pain relief* was recorded on a five-point scale (0 = none to 4 = complete) at the same post dose time points. In addition, patients rated the study drug using a five-point *global evaluation* scale (0 = poor to 4 = excellent) at specified post dose time points. *Total pain relief over eight hours (TOPAR8)*, calculated by multiplying the pain relief score at each post-dose time point by the duration (in hours) since the preceding time point and then summing these values (up to eight hours). *Pain intensity difference (PID)*, calculated as the baseline *pain intensity* score minus the *pain intensity* score at each post dose time point. *Summed PID over eight hours (SPID8),* calculated by multiplying the PID score at each post dose time point by the duration (in hours) since the preceding time point and then summing these values (up to eight hours).

Early onset of analgesia in aceclofenac group with mean time of 30.6 (±7.34) minutes compared to 72.2 (±21.6) minutes in diclofenac sodium group ($P < 0.01$). TOPAR8 was 24.5 (±0.43) for aceclofenac group and 17.8 (±3.0) for diclofenac sodium group. TOPAR 24 was 72.7 (±8.54) for aceclofenac group and 58.4 (±12.4) for diclofenac sodium group. SPID8 was 15.1 ±

Table 1: Summed pain relief and pain intensity scores

Drugs	Mean TOPAR (±SD)		Mean SPID (±SD)
	8 h	24 h	8 h
Aceclofenac	24.5 (±3)	72.7 (±8.54)	15.1 (±4.18)
Diclofenac sodium	17.8 (±3)	58.4 (±12.4)	10.0 (±3.55)

TOPAR=Total pain relief over; SPID=Summed PID over

Table 2: Adverse events profile of study drugs

Adverse event	Aceclofenac (*n*=25)	Diclofenac sodium (*n*=25)
Nausea	-	2
Gastritis	1	3
Epigastric pain	1	4
Fluctuance	1	2
Indigestion	1	3
Hypersensitivity reactions	1	1
Dizziness	2	4
Total	7	19

(4.18) for aceclofenac group and 10.0 (±3.55) for diclofenac sodium group ($P < 0.03$) [Table 1]. The incidence of adverse effects, especially epigastric pain and nausea were significantly more with diclofenac sodium compared to aceclofenac. One patient of aceclofenac group and five patients of diclofenac sodium group complained nausea and gastric irritation [Table 2].

Patients' assessment of pain relief also demonstrated significantly greater efficacy with aceclofenac.[3] Kudaravalli Jyothsna *et al.*, in their study found that at the end of 8 hrs of surgery, 39% reduction in *pain intensity* in aceclofenac group as compared to 27% reduction in the diclofenac group, which was statistically significant.[5] Gastrointestinal side effects like epigastric pain and nausea were greater in the diclofenac sodium group compared to aceclofenac group. Both the drugs do not have any significant effect on platelet function as COX-1 and 2 inhibitors.[4] The use of predominant COX-2 inhibitors has not been possibly reported to have increased the cardiovascular and cerebrovascular adverse effects unlike, selective COX-2 inhibitors.[6] Patient's global assessment was also significantly better for aceclofenac compared with diclofenac. Patient's compliance is also an important factor, which is favourable with aceclofenac.[5] This comparative study demonstrated that Aceclofenac is an effective and superior analgesic in the treatment of moderate to severe acute pain resulting from third molar surgery, with rapid onset and longer duration of action compared to diclofenac. Furthermore, aceclofenac showed tolerability profile superior to diclofenac.

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