

*Research Paper*

## **Analgesics in Dental Practice: Prescribing Scenario in National Capital Region**

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(Received on 30 July 2018; Accepted on 01 July 2019)

Pain is the most common reason for patients approaching dental practitioners. Large variety of analgesics and their fixed dose combinations (FDCs) are available in the Indian market. It is important to periodically review the prescribing practices to evaluate and sensitize dental practitioners regarding analgesic prescribing. Hence the present study was conducted to investigate the knowledge and prescribing pattern of analgesics and their fixed dose combinations among dental practitioners of the National Capital Region of India. A self-designed questionnaire was administered to 667 dental practitioners holding degrees of Bachelors, Masters and those pursuing their masters, working in academic institutes and private clinics, of whom 539 (80.8%) responded. Pearson chi square and Fisher's exact test were used for analysis. Out of 539 responders, 66.4% prescribed by brand name, 27.8% by generic and 5.19% prescribed by both generic and brand name. Of the total analgesics prescribed, 48.6% were prescribed as fixed dose combinations (FDCs). Ibuprofen + paracetamol (30.3%) were the first choice. Serratiopeptidase and other proteolytic enzyme-based combinations constituted 22.6% of total FDCs prescribed. Ibuprofen+paracetamol (39.4%) and ketorolac (67.6%) were the preferred analgesic for mild to moderate and severe pain respectively. Nimesulide was prescribed by 7.7% practitioners for pain in children of <12 years age. Analgesic prescribing is not always evidence based and irrational use of analgesic FDCs may increase the risk of adverse effects as well as overall healthcare cost. There is an urgent need of guidelines and continuing medical education to improve dental prescribing practices.

**Keywords:** NSAIDs; Prescribing Practices; Dentistry; Generic; Fixed Dose Combinations

### **Introduction**

Analgesics form an important part of dental prescribing as adjunct to appropriate dental treatment. Paracetamol and NSAIDs provide excellent pain relief in most dental conditions (Hargreaves and Abbott, 2005; Hersh *et al.*, 2011). However, opioids such as codeine and tramadol are used in situations where NSAIDs do not give adequate relief or are contraindicated. Various fixed dose combinations (FDCs) of analgesics are present in the Indian market. However, the data is insufficient to suggest if most such FDCs have superior efficacy over either drug alone (Bailey *et al.*, 2014).

Availability of vast choices, in the absence of

appropriate analgesic use guidelines mandates periodic regional review of prescribing preferences and rationality of such preferences. Results of such studies can be utilized for ongoing learning and to influence the behaviour as appropriate. Hence, the aim of this study was to observe the prescribing pattern of analgesics and their FDCs to consequently evaluate the rationality of such prescribing behaviour.

### **Material and Methods**

This was a questionnaire-based study performed among dental practitioners of National Capital Region (NCR) of India. A total of 667 dental practitioners (BDS and above), working in academic institutions and private clinics were approached. Students pursuing

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BDS were excluded. The questionnaire was to assess the preference of prescribing (by brand/trade name or generic name), use of fixed dose combinations (FDCs), most preferred analgesics in mild to moderate pain and severe pain, preference of serratiopeptidase based combinations and analgesics preference in selected special conditions like dentoalveolar abscess, space infections, dry socket etc. The study tool was pretested with 20 dental practitioners beforehand.

The study was approved by the Institutional Ethics Committee with a waiver of participant consent.

### **Statistical Analysis**

Data was analysed using Stata version 12.0. Pearson chi-square test and Fisher's exact test were used to examine the association between variables. The data was analysed with respect to qualification [graduates (BDS), postgraduates (MDS) and those Pursuing MDS] and the practice settings (academic institution and private practice) with  $p < 0.05$  set as the limit of significance.

### **Results and Discussion**

In over one-year duration, out of 667 dental practitioners who were approached, 539 (80.8%) responded. Of those participated, 41% were males and 59% were females with the mean age of  $27.9 \pm 7.0$  years. There were 24% BDS, 30% MDS and 46% pursuing post-graduation. Academic institutions accounted for 68% and private clinics for 32% participants.

Practitioners were asked for their preference of prescribing by brand name or generic name. Of the total practitioners, 358 (66.4%) prescribe by brand name, 150 (27.8%) by generic name and 28 (5.19%) prescribe by both generic and brand name.

Of 539 practitioners, 403 practitioners responded to the question on choice of analgesics. (Table 1). Ibuprofen+paracetamol was the most preferred FDC and ketorolac was the most preferred single drug though a wide range of analgesics and their fixed dose combinations were being prescribed. Similar trend has been reported in Punjab (Datta *et al.*, 2015). For children <12 years, paracetamol (57%) and ibuprofen (51%) were the preferred choices. Although, nimesulide is banned for use in children <12 years age since 2010, 7.8% practitioners were still

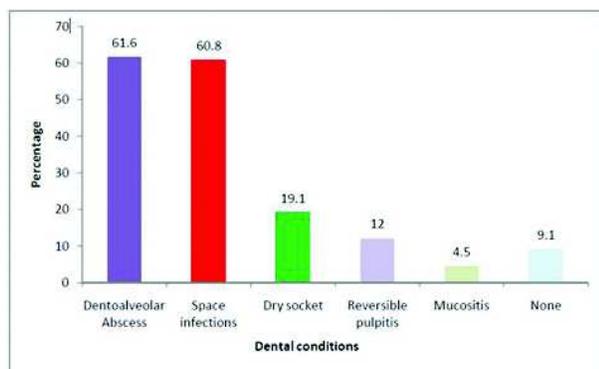
prescribing it, indicating lack of awareness and updated information. Tramadol was being prescribed for children by 0.7%.

Of the total analgesics prescribed, 51.4% were prescribed as single drug formulations (SDFs) and 48.6% as fixed dose combinations (FDCs). Most common FDC prescribed was ibuprofen+paracetamol (47.1%). FDC prescribing is common practice both in medical as well as dental practice. FDCs may have advantages like decrease in pill burden and increase in medication adherence. However, most FDCs are irrational, with no added advantage and potential increase in overall health care cost due to ADRs. FDCs are said to be rational if (i) the drugs in combination act by different mechanisms, (ii) the pharmacokinetics is not widely different and (iii) the combination does not have supra-additive toxicity (19th WHO Model List of Essential Medicines [Internet], 2015). According to the above recommendations, 28.2% FDCs in our study prescribed were irrational. Many FDCs being introduced in India are not rational and recently banned (Central Drugs Standard Control Organization [Internet]). A survey reported that there are 124 FDCs of NSAIDs in Indian market of which only 27% are approved centrally by CDSCO (McGettigan *et al.*, 2015). In our survey, 30.4% of the preferred FDCs were found in the list of centrally approved FDCs by CDSCO in 2013.

For mild to moderate pain, ibuprofen + paracetamol was the most preferred (39.4% of 467 respondents) and in severe pain, Ketorolac (67.6%) and tramadol (7.7%) were most preferred.

Serratiopeptidase based combinations also constituted a major part of FDC prescribing (22.6%). Few dental conditions were given and practitioners were asked to select conditions where they prefer serratiopeptidase based combinations. Out of 94.2% practitioners who responded, more than 60% give serratiopeptidase based combinations in dentoalveolar and space infections (Fig. 1).

A high prescribing of serratiopeptidase based combination was observed. Although they are neither approved by USFDA nor recommended in standard text books and guidelines. A study conducted by Shetty *et al.*, 2013, showed a significant difference in reduction of facial edema with serratiopeptidase therapy than placebo in patients who underwent



**Fig. 1: Percentage of practitioners prescribing serratiopeptidase-based analgesic combinations in different dental conditions (n = 508)**

bimaxillary orthognathic surgery (Shetty and Mohan, 2013). However, Chopra *et al.*, claimed no significant analgesic and anti-inflammatory activity of serratiopeptidase as compared to paracetamol, ibuprofen and betamethasone in dental impaction pain model (Chopra *et al.*, 2015). There is no clear-cut evidence on the efficacy of these proteolytic enzymes (Bhagat *et al.*, 2013), yet they are widely available in the market and constitute 9.7% sales of NSAID FDCs in India. (19th WHO Model List of Essential Medicines [Internet]. 2015, National List of Essential Medicines of India [Internet]. 2011, National Formulary of India [Internet]. 2011, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations [Internet]). These combinations are increasing the overall cost of the formulation as diclofenac + paracetamol combination cost less than 15 INR for 10 tablets, whereas the same combination with serratiopeptidase cost more than 80 INR (CIMS n.d).

Practitioners were asked for protocol they follow in the presence of systemic conditions like chronic kidney disease (CKD) (45.5% responded) and chronic hepatic disease (CHD) (38.2% responded). Of these, 49.5% and 42.7% prefer paracetamol for dental pain in the presence of CKD and CHD respectively. Less

**Table 1: Analgesics most commonly prescribed by dental practitioners (n=403)**

| Analgesics                                | Frequency (%) |
|---|---------------|
| Ibuprofen+paracetamol                     | 122 (30.3)    |
| Ketorolac                                 | 84 (20.8)     |
| Diclofenac+paracetamol                    | 50 (12.4)     |
| Diclofenac+paracetamol+serratiopeptidase  | 30 (7.4)      |
| Paracetamol                               | 19 (4.7)      |
| Ibuprofen                                 | 14 (3.5)      |
| Diclofenac                                | 13 (3.2)      |
| Aceclofenac+paracetamol                   | 11 (2.7)      |
| Aceclofenac+paracetamol+serratiopeptidase | 11 (2.7)      |
| Nimesulide                                | 8 (1.9)       |
| Paracetamol+tramadol                      | 5 (1.2)       |
| *Miscellaneous                            | 36 (8.9)      |

\*Analgesics prescribed with frequency <1%

than 15% consult the patients treating physician which is recommended to minimize analgesic induced adverse drug reactions (Greenwood and Meehan, 2003; Brockmann and Badr, 2010).

These prescribing choices were not affected by qualification ( $p = 0.106$  for BDS vs MDS vs Pursuing MDS) or by practice settings ( $p = 0.080$  for academic vs private practice).

Wide range of analgesics and their FDCs are commonly prescribed by dental practitioners of NCR of India, most common of which were NSAIDs. Insufficient knowledge related to prescribing of analgesics in different conditions observed could be due to lack of guidelines leading to irrational drug prescribing. Educational programs and training sessions are required to update dental practitioners of ongoing activities. Thus, there is an urgent need of guidelines, Continuing Medical Education programs, seminars etc. to update practitioners of recent advances and trends in therapeutic prescribing.

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