

Quality of Patients Life after Tooth Extraction????

Dr. Ujjwal Prem¹, Dr. Ankur Mittal², Dr. S.K. Gupta³, Dr. Smiti Jassar⁴

^{1,2,3,4}(Department of Oral & Maxillofacial surgery, D.J. college of dental sciences & research, modinagar, INDIA)

Abstract: A double-blind, randomized controlled clinical trial was carried out in oral & maxillofacial surgery department on 300 patients to evaluate the analgesic effect of two formulas of Diclofenac i.e. diclofenac sodium 50mg with diclofenac potassium 50mg by observing the pain after a simple tooth extraction. Efficacy of the drugs was assessed over an observation period of 3,6, 24 hour, 2nd to 7th day hours following extractions by using Visual Analogue Scale (VAS). There were no statistically significant differences in analgesic efficacy between both the formulas were equally effective in controlling of pain. Present study results suggested that both the formulas of diclofenac are effective in relieving postoperative dental pain.

Keywords: Clinical Trial, Diclofenac Potassium, Diclofenac Sodium and post – operative pain management .

I. Introduction

Pain has been associated with the practice of dentistry from beginning and this fear of pain keeps the patient away from dental clinic even in the presence of tooth related problems. After the introduction of local anaesthesia in the dentistry this phobia of pain reduces but phobia regarding pain of post-operative pain remains the same. Advances in pharmacological sciences have led to the introduction of analgesics anti-inflammatory drugs (NSAIDs). These drugs have been quite effective in controlling this pain but the plethora of drugs in this category has been a source of confusion to the dental profession with regard to the ideal NSAID to control post extraction pain. Diclofenac is one of them & available in various combinations. The most commonly used formulation of diclofenac is the 50 mg tablet of diclofenac sodium & diclofenac potassium. Literature revealed that diclofenac potassium gets absorbed quickly and starts analgesic activity in a much quicker time than diclofenac sodium. Both sodium and potassium salts of diclofenac are different in nature and function and cannot be treated as equivalent though their dose may be same. So we decided to conduct a study to evaluate the analgesic effect of two formulas of Diclofenac i.e. diclofenac sodium 50mg and diclofenac potassium 50mg.

II. Material And Methods

A double blind randomized controlled trial was done on 300 patients who seek multiple tooth extraction. Patients were assigned by simple randomization into one of the two groups by using computer generated randomization scheduled.

II.1. Inclusion criteria

- Age: 18 years and above
- Both sex
- Multiple extractions of teeth.

II.2. Exclusion criteria:

- Refusal of informed consent,
- Patients who were on medication which interfere with pain response and patients taking analgesics within 7 days of extraction
- Patients allergic to Ibuprofen or Diclofenac sodium
- Pregnant and lactating mothers
- Patients suffering from peptic ulcer
- Renal and liver failure patients
- Grade I , II & III mobile tooth

Patient was randomly divided into two groups

Group A - Patients prescribed with Tab. Diclofenac potassium 50 mg

Group B – Patients prescribed with Tab. Diclofenac sodium 50 mg

The first dose of analgesic was given immediately after extraction. From operative day onwards medicine were prescribed SOS, but diclofenac potassium and diclofenac sodium were not supposed to exceed

more than three in a day & patient were also instructed not to seek any medical help elsewhere for post extraction complications, if any they must report back to the department.

Following was evaluated pre-operatively

- Preoperative pain assessment using Visual Analogue Scale just before the LA administration
- Following were evaluated during the procedure
- Duration of procedure.
- Evaluation of procedur.
- Following were evaluated post-operatively
- Number of analgesics taken postoperatively.
- Frequency of analgesics taken postoperatively.
- Pain assessment using Visual Analogue Scale throughout the period of 7 days. (3rdhr, 6th hr, 24th hr, 2nd - 7th day).

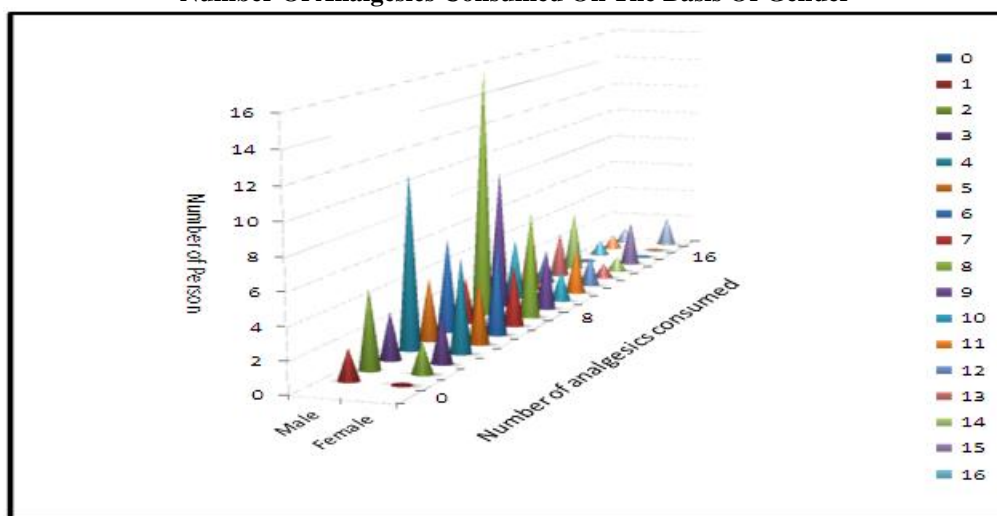
III. Results

The data was collected and was evaluated in a computer controlled programme SPSS and using fisher's Test. A total of 300 patients those met inclusion criteria were divided into two groups

GROUPS	NO. OF PATIENTS	DRUG USED
GROUP A	150	DICLOFENAC POTASSIUM 50 mg
GROUP B	150	DICLOFENAC SODIUM 50 mg

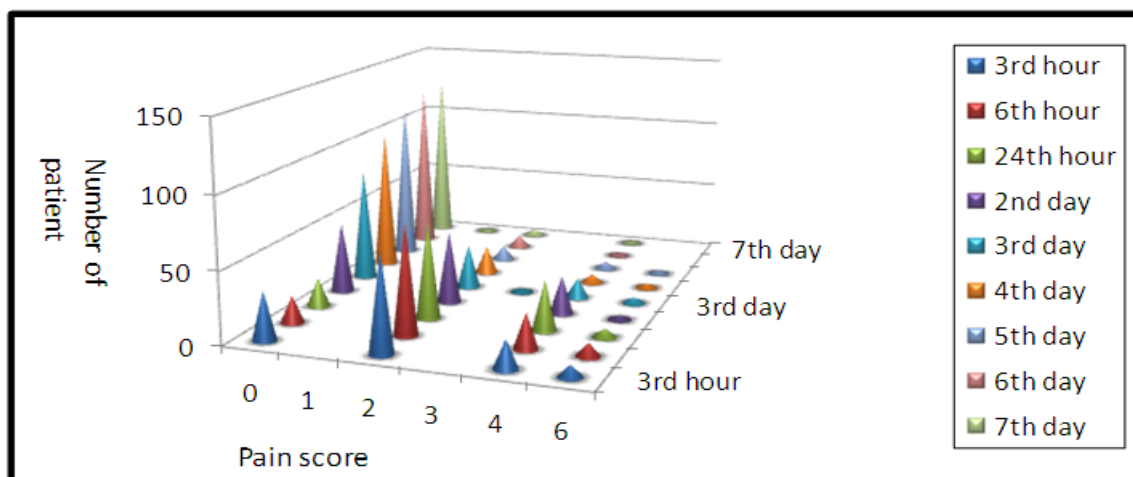
Graph 1: shows number of analgesic consumed by males and females. Male patients took more number of analgesics when compared with females(p value 0.707) signifies that that there is no significance difference in analgesics used on the basis of gender.

Number Of Analgesics Consumed On The Basis Of Gender



Graph 2 shows frequency of pain perceived by the patients on 3rd, 6th 24th hour, 2nd to 7th day. On applying fisher exact test p value is more than 0.005 which represents that there is no significance between these two drugs in reducing post-operative pain after tooth extraction. Both have same effect.

FREQUENCY DISTRIBUTION OF POST EXTRACTION PAIN ON 3RD,6TH & 24TH HOUR,2ND,3RD,4TH,5TH,6TH & 7TH DAY



IV. Discussion

Pain (algia) is an ill-defined, unpleasant sensation, usually evoked by an external or internal noxious stimulus. It is a warning signal and primarily protective in nature but causes discomfort and suffering may even be unbearable dental pain is usually acute in nature and is the most important symptom for which the patient comes to the dentist.³¹ International Association for the Study of Pain (IASP) defined pain as “Unpleasant sensory and emotional experience associated with actual or potential tissue damage.” When a person thinks about losing one of their tooth the situation itself induces anxiety and fear. Perhaps oral surgery encompasses a number of treatments but the most important are extraction. Inflammatory mediators released at the site of extraction which increased prostaglandin synthesis and cause pain. Non-steroidal Anti-inflammatory drugs (NSAIDs) acts by blocking prostaglandin synthesis and help in prevention of post extraction pain. Management of pain after non- surgical extraction is important, particularly as most patients are treated in outpatient clinics. Postoperative pain after non- surgical extraction can be adequately controlled with the use of NSAIDs but it remains a topic of debate that which NSAIDs has to be prescribed to control post extraction pain with more efficacy and reduced pain more efficiently. A lot of literature suggest the use of analgesics for post extraction pain management but the topic of debate remains the same which NSAIDs is more effective with minimum side effects. So we decided to conduct a study to find out which NSAIDs is more effective and safer in reducing post extraction pain –Diclofenac potassium or Diclofenac sodium???

The present study was conducted to evaluate the efficacy of drugs in managing post operative dental pain. It was concluded that both the formulations were equally effective in pain control following tooth

extraction. In R. Bakshi et al study, diclofenac potassium was found superior to placebo, and a relatively delay in onset for the diclofenac sodium. Observations in their study confirmed that diclofenac potassium was superior to diclofenac sodium in controlling postoperative dental pain. In contrast, in this study diclofenac potassium was not found superior to the diclofenac sodium when the mean VAS was compared among the groups. Both the formulas of diclofenac have been demonstrated to be significantly effective and equally better than a placebo.

In another study by Zungia JR et al, in a double-blind placebo-controlled trial confirmed rapid onset of action and thus proved clinical efficacy. However, in a long-term pain control, present study proves both the formulations to be equally effective in 3rd, 6th, 24th hour, 2nd to 7th day period.

In the R.Bakshi et al study, male subjects were 51 and in the current study were 38, while female subjects in R.Bakshi were 54 whereas in this study there were 37 females In R. Bakshi the effectiveness for diclofenac potassium was 33%, diclofenac sodium 41% and placebo was 59%. However, the results in our study showed the mean VAS score for drug A was 1.8 whereas the mean VAS score for drug B was 1.7 which is almost equal. It can be seen from the present study that both the formulations of diclofenac potassium are equally effective in controlling postoperative extraction patients.

V. Conclusion

No statistically significant differences have been recorded in terms of the analgesic efficacy of diclofenac sodium with respect to Diclofenac potassium though an increased tendency to use more medication was observed during the two first days of the postoperative period in the diclofenac group; statistical significance was not reached ($p > 0.05$).

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