INTRODUCTION

Extraction of teeth is a common procedure in Dental Outpatient Department and generally a postoperative prescription is given for pain management. Most of the dental practitioners have their own preferences for the management of pain. In hospitals and dental schools, generally there is a policy of prescription or departmental protocol followed for effective pain management. Following extraction of a tooth, little pain and discomfort is expected for some days. The pain experienced by patients after tooth extraction is variable and depends on patient threshold and degree of surgical trauma to the extraction site.

Clinicians prescribe non-steroidal anti-inflammatory drugs (NSAIDs) on a routine basis for a range of mild-to-moderate pain. NSAIDs are the most commonly prescribed analgesic medications worldwide, and their efficacy for treating acute pain has been well demonstrated. A number of pain killers are available for pain management. Diclofenac is a potent non-steroidal anti-inflammatory drug (NSAID), has also been shown to exert a pronounced analgesic effect when used to treat various acute painful conditions. The most commonly used formulation of diclofenac is the 50 mg tablet of diclofenac sodium. It is also available with the potassium salt as diclofenac potassium also in 50 mg oral tablets. As far as response time is concerned, it is diclofenac potassium that 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. Most studies claim diclofenac potassium is immediate release, while Diclofenac sodium is delayed release.

Many researchers have compared the use of specific drugs, either alone or in combination, for their effectiveness as postoperative analgesics. None have compared the two formulations as postoperative regimen to control pain. This study was conducted in order to find out an effective analgesic following tooth extraction and to find out superiority of diclofenac potassium over diclofenac sodium as generally perceived by the literature and clinicians.
METHODOLOGY

For the purpose of study 75 patients were selected, who were healthy, aged 18-65 years and had undergone dental extraction. The study was conducted in oral & maxillofacial department of Baqai Dental College by convenient sampling technique; the duration of study was 3 months, from July 2012 to October 2012.

The patients included were cooperative and consenting outpatients of both genders who had undergone tooth extraction and patients presenting to department of oral and maxillofacial surgery for extraction of teeth.

Patients were excluded from the study if there was past history of systemic diseases or were taking any other medications for pain relief. Patients allergic to NSAIDs, asthmatic patients or with any history of peptic ulcer/gastrointestinal bleeding or serious intestinal diseases, severe renal, cardiac, hepatic, neurologic, or suffering from hematologic disorders, alcoholics and smokers or those who had any drug dependency, patients with surgical extractions were also excluded, pregnant women and breast feeding mothers were also excluded.

Seventy five patients were selected using the technique of convenient sampling. The approval of the study was obtained from the Ethical Committee of Baqai Medical University. These patients were requested to fill up a consent form for the study purpose and the study proforma, with all their personal information. All participants were assigned numbers and were randomly divided into three groups namely group A, group B and group C, comprising of 25 individuals in each. The subjects in Group A received diclofenac potassium, Group B received diclofenac sodium and Group C received vitamin B complex as placebo on alternative basis. The patients were instructed to evaluate the pain intensity after extraction using Visual Analogue Scale (VAS) and were asked to continue the use of drugs for a period of 72 hrs following extractions on eight hourly basis. Subject’s pain score was assessed on a 10 point VAS (visual analogue scale) after explaining the procedure of marking them on this scale 0=no pain, 1=mild pain, 2=mild pain, 3=mild pain, 4=mild pain, 5=moderate pain, 6= moderate pain, 7= moderate pain, 8= severe pain, 9= severe pain, 10=extreme pain. The mean VAS scores were calculated and all the data were statistically analyzed with SPSS 17.

RESULTS

Out of 75 patients, 38 were male and 37 were female, of age group 18-65 years, participated in a placebo controlled study conducted in the department of oral & maxillofacial surgery, Baqai Dental College.

Table 1 shows the distribution of the subjects. These participants were randomly divided into three groups and were assigned a number who were give drug A, B and C alternatively after non-surgical extractions. Table 2 shows distribution of drugs. The results are given in Table 3, the mean VAS score for drug A was 1.4 whereas the mean VAS score for drug B was 1.5 (p value 0.01) which was almost equals hence, it proves that both the drugs are equally effective in pain control. However the mean VAS score for drug C was 6 which showed that a placebo plays no significant role in pain control.

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<th>TABLE 1: DISTRIBUTION OF THE SUBJECT</th>
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<th>TABLE 2: DISTRIBUTION OF DRUGS n=75</th>
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<tr>
<td>Drug ‘A’: Diclofenac Potassium</td>
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<td>Drug ‘B’: Diclofenac Sodium</td>
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<td>Drug ‘C’: Placebo</td>
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<th>TABLE 3: MEAN VISUAL ANALOGUE SCALE SCORE</th>
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<td>Mean VAS for Drug ‘A’</td>
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DISCUSSION

Diclofenac potassium and diclofenac sodium are potent NSAIDs and they have been used in other studies.13,22 Over the years different studies have been carried out to find out about the efficacy of potent analgesics to relief postoperative dental pain.13,14

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.15

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.16 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 Zuniga JR et al., 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 72 hours 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 1.4 whereas the mean VAS score for drug B was 1.5 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.

The limitations of the current study were small sample size and difficulty in following up of patients which is limited in any outpatient clinical trial. Therefore, larger clinical trials are suggested.

CONCLUSION

Pain management is an integral part of dental practice. It was concluded that both the formulas of diclofenac were better than a placebo. Prescribing analgesics to patients is necessary and is superior to a placebo in post operative pain control. Furthermore, we did not find diclofenac potassium to be superior compared to diclofenac sodium as perceived by the literature. It is recommended that larger clinical trials under controlled conditions will be required for further elaboration in this regard.

REFERENCES


