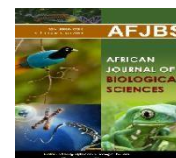


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Comparative Assessment of Clinical Performances of Ketorol-DT and Dan-P in Managing Postoperative Pain Related To Irreversible Pulpitis: An Original Research Study

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Abstract

Background and Aim: Irreversible pulpitis is one of the most common conditions which involves moderate to severe dental pain. This pain is pertinent before and sometimes even after the endodontic interventions. Several pharmacological measures have been experimented to control this pain especially after completion of endodontic therapy. Therefore, this study was proposed, abstracted and conducted to assess and compare the clinical performances of Ketorol-DT and Dan-P in managing postoperative pain related to irreversible pulpitis.

Materials and Methods: This study was executed in the department of conservative dentistry and endodontics wherein total 80 patients (including both male and female) were selected by systemic method of sample selection. Patients were recalled after one and two days of endodontic treatment. Patients were questioned about the overall level of satisfaction about pain control using visual analog scale (VAS). Group 1 consisted of 40 patients with Ketorol-DT and Group 2 consisted of 40 patients with Dan-P. Informed consent was obtained from all participating patients. P value less than 0.05 was taken as significant.

Statistical Analysis and Results: Data was subjected to basic statistical analysis with SPSS software. Out of 80 studied patients, 52 were males and 28 were females. In Group 1, 32 patients were highly satisfied whereas 7 patients were not satisfied. In Group 2, 29 patients were highly satisfied whereas 9 patients were not satisfied. P value was highly significant for 9 non-satisfied patients. The inferences of One-way ANOVA test confirmed that level of significance (p value) was highly significant for ANOVA test conducted between groups.

Conclusion: Authors concluded that both of the studied analgesics are rationally efficient however, the overall level of pain control and associated patients satisfaction was high in Ketorol-DT. Dan-P showed slightly higher number of non-satisfied cases. Authors also presume some other future studies to be executed to substantiate and validate our results.

Keywords: Irreversible Pulpitis, Ketorol-DT, Dan-P, Pain, Endodontic, Visual Analog Scale

Introduction

Dental pain can be of different variety or intensity like sharp, throbbing, dull and achy. Pain of any kind poses severe difficulty during biting and chewing. Dental pain is usually radiating to the nearby craniofacial structures hence causing intense stress and psychological disturbances. There are several sources of dental pain including tooth decay, cracked tooth and infection of dental pulp tissue.¹ Most of the dental pulp infections/inflammations are treated by endodontic therapies. Controlling the pain during and after the endodontic treatment is a challenging task for operators.² In clinical setups, patients usually report with severe pain associated with some pulpal disease. Moreover, patients pain and pain perception is also altered by the raised anxiety levels during treatment. Intra-operative pain is spontaneously controlled by giving local anesthesia. However, post-operative pain must be managed pharmacologically within the safety limits of the patient.³ Researchers defined pain as multidimensional and bio-psychological event

in which unpleasant sensation ranges from mild discomfort to severely disturbing distress.⁴ Literature has also shown that there are several predisposing factors for pain. These are genetics, psychological condition, ethnicity, gender, age and surroundings.⁵ With the development and advancements in the field of pharmacology, several drug trials have been conducted in the recent past to explore the ideal analgesic for controlling endodontic pain.^{6,7} Literature is encumbered with the studies conducted on the clinical and pharmacological behavior of Ketorol-DT. Nowadays, Ketorol-DT and Dan-P are very frequently advised drugs especially for dental pain management. However, they may not be prescribed in all clinical scenarios blindly. Therefore this study was planned, abstracted and executed to assess and compare the clinical performances of Ketorol-DT and Dan-P in managing postoperative pain related to irreversible pulpitis.

Materials and Methods

This study was performed in the Department of Conservative Dentistry and Endodontics of the college with the target of comparing Ketorol-DT and Dan-P for post endodontic pain control. All participating subjects were selected from the regular outpatient department. All patients were selected particularly in their post-operative recall phases to record their responses. Total 80 patients (including both male and female) were selected by systemic method of sample selection. Randomization was also taken care of for providing equal opportunity of selection to each patient. Inclusion criteria included 1) patients in the age range of 25-40 years, 2) patients wherein endodontic treatment has been completed in lower first molar of either side, 3) patients those reporting to the department for their pain related issues. Exclusion criteria included 1) patients with any follow-up issue, 2) patients with any undergoing heavy medication which can interfere with actual pain responses/compromised data quality, 3) patients with known systemic disease condition. Standard endodontic procedure was used in all 80 patients with similar steps and identical armamentarium. All 80 patients were divided into 2 groups based on their analgesic used after endodontic treatment. Patients were recalled after one and two days of endodontic treatment. Patients had been explained about the purpose of the study/pain related questionings. Only willing patients were included in the study. On the second day, patients were asked for pain and its related parameters. We asked about the pattern of rise/fall of pain and overall effectiveness of drug in reducing pain. Patients were lastly questioned about the overall level of satisfaction about pain control. We used visual analog scale (VAS) to quantify the extent and level of pain. Group 1 consisted of 40 patients wherein Ketorol-DT (Ketorolac Tromethamine Dispersible Tablets 10 mg) was utilized. Group 2 consisted of 40 patients wherein Dan-P (Diclofenac Sodium 50 mg & Paracetamol Tablets I.P. 325 mg) was used for pain control. Dan-P (Unison Pharmaceuticals Pvt Ltd, India) is well known for its short term pain relief, inflammation and swelling. Dan-P works by blocking the action of chemical messengers responsible for pain, inflammation and swelling. Ketorol-DT (Dr. Reddy's Laboratories Ltd, India) is factually non-steroidal anti-inflammatory drug which assist in pain relieve by decreasing inflammation and stopping the production of pain mediators. Informed consent was obtained from all participating patients. Statistical analysis was performed to outline the outcomes and results. P value less than 0.05 was taken as significant.

Statistical Analysis and Results

All the recorded data were checked at initial stages for presence of any obvious integrated confounders. Post hoc analysis was not attempted so as to ensure data quality with minimal errors. Afterward data was subjected to basic statistical analysis with SPSS statistical package for

the Social Sciences version 22 for Windows. Nonparametric test, namely, chi-square test, was used for further data analysis; p-value. Out of 80 studied patients, 52 were males and 28 were females [Table 1, Graph 1]. P-value was highly significant for age group 25-28 years. Here p value was 0.01. All the other age groups showed non-significant p values for their calculations and inferences. Maximum 28 patients were noticed in age group 25-28 and 29-32 years (each). Table 2 illustrates about the basic statistical description with level of significance evaluation using “Pearson Chi-Square” test for Group 1; n=40 patients. Here, Ketorol-DT [Ketorolac Tromethamine Dispersible Tablets 10 mg] was used and responses were interpreted as satisfactory or non-satisfactory during second day of post endodontic phase. Total 32 patients were highly satisfied whereas 7 patients were not satisfied. Moreover, 1 patient showed Questionable response. P value was highly significant for 7 non-satisfied patients. The measured value of p value was 0.01. Table 3 illustrates about the basic statistical description with level of significance evaluation using “Pearson Chi-Square” test for Group 2; n=40 patients. Here, Dan-P [Diclofenac Sodium 50 mg & Paracetamol Tablets I.P. 325 mg] was used and responses were interpreted as satisfactory or non-satisfactory during second day of post endodontic phase. Total 29 patients were highly satisfied whereas 9 patients were not satisfied. Moreover, 1 patient showed Questionable response. P value was highly significant for 9 non-satisfied patients. The measured value of p value was 0.01. Table 4 demonstrated about the basic evaluation conducted amongst all studied groups using one-way ANOVA test. The inferences confirmed that level of significance (p value) was highly significant for ANOVA test conducted between groups. It was appreciably 0.002.

Table 1: Age & Gender based statistical explanation of contributing patients

Age Group (Yrs)	Male	Female	Total	P value
25-28	15	13	28	0.01*
29-32	19	9	28	0.50
33-36	10	4	14	0.20
37-40	08	2	10	0.80
Total	52	28	80	*p<0.05 Significant

Graph 1: Patients demographic allocation and related details

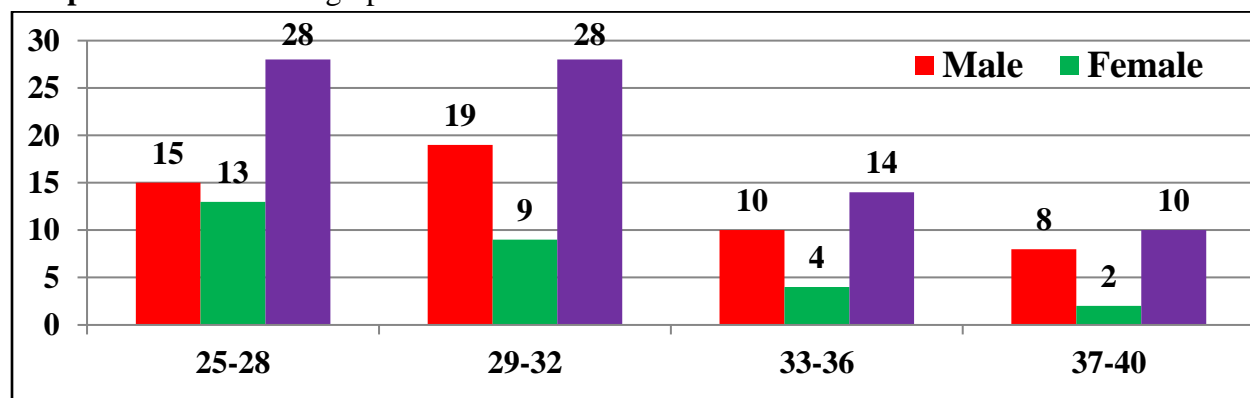


Table 2: Basic statistical description with level of significance evaluation using “Pearson Chi-Square” test (Group 1; n=40 patients wherein Ketorol-DT [Ketorolac Tromethamine Dispersible Tablets 10 mg] used) and interpreted as satisfactory or non-satisfactory during second day of post endodontic phase

Status	n	Stat. Mean	Std. Dev.	Std. Error	95% CI	Pearson Chi-Square	df	P value
Satisfactory	32	1.84	0.940	0.376	1.96	1.549	1.0	0.07
Non-satisfactory	07	1.04	0.930	0.536	1.12	1.947	2.0	0.01*
Questionable	01	1.01	0.695	0.942	1.43	1.153	1.0	0.20
*p<0.05 significant								

Table 3: Basic statistical description with level of significance evaluation using “Pearson Chi-Square” test (Group 2; n=40 patients wherein Dan-P [Diclofenac Sodium 50 mg & Paracetamol Tablets I.P. 325 mg] used) and interpreted as satisfactory or non-satisfactory during second day of post endodontic phase

Status	N	Stat. Mean	Std. Dev.	Std. Error	95% CI	Pearson Chi-Square	df	p value
Satisfactory	29	1.78	0.021	0.835	1.46	1.659	1.0	0.06
Non-satisfactory	09	1.15	0.093	0.238	1.24	1.237	2.0	0.01*
Questionable	02	1.02	0.753	0.021	1.22	1.323	1.0	0.50
*p<0.05 significant								

Table 4: Evaluation amongst all studied Groups using one-way ANOVA

Variables	Degree of Freedom	Sum of Squares Σ	Mean Sum of Squares $m\Sigma$	F	Level of Sig. (p)
Between Groups	3	2.039	1.238	1.1	0.002*
Within Groups	18	2.918	0.125		-
Cumulative	122.42	12.536			*p<0.05 significant

Discussion

Literature has well evidenced about the efforts and experiments made by clinicians and researchers for effective management of post endodontic pain and related symptoms. Buckley and associates in the year 1990 reviewed about pharmacodynamic and pharmacokinetic properties of Ketorolac. They also discussed about the therapeutic potential of Ketorolac in controlling dental pain. Later their results were confirmed and verified by several pioneer studies.⁸ Forbes and colleagues had studied in detail about the initial development of ketorolac, ibuprofen, acetaminophen, and an acetaminophencodeine combination in post-operative phases of dental surgeries. Their results were very significant since they emphasized ketorolac predominantly. These inferences were in accordance with our results and inferences.⁹ Johansson and other coworkers studied about the analgesic usefulness and security comparison of Ketorolac tromethamine and Doloron for controlling dental pain. They found that Ketorolac

tromethamine was highly efficient and satisfactory in therapeutic usage.¹⁰ Fosland and colleagues studied about the placebo-controlled assessment of single intramuscular Ketorolac tromethamine and Pethidine for management of postoperative pain. Their results were also in accordance with our results since they also confirmed Ketorolac tromethamine as most efficient and safest.¹¹ Curtis and other researchers experimented about the various aspects of dental post endodontic pain and their related possible management. They checked the incidence and severity of complications and pain following periodontal surgery with concomitant administration of Ketorolac tromethamine. They also found Ketorolac tromethamine very effective in most of the pain related to dental soft tissues.¹² Hungund and other coworkers had conducted a case control study about the effect of pretreatment with ketorolac tromethamine on operative pain during periodontal surgery. They noticed that ketorolac tromethamine was highly effective and efficient in pain management.¹³ Few other pioneer researchers including Sabino-Silva, Shamszadeh and Smith have also studied about the clinical effectiveness of ketorolac tromethamine and found it to be highly useful in dental pain management.^{14,15,16}

Conclusion

Within the limitations of the study authors concluded that both of the studied analgesics are potentially efficient in managing post endodontic pain. However, the overall level of pain control and associated patients satisfaction was high in Ketorol-DT. Cases administered with Dan-P showed slightly higher number of non-satisfied cases. However, inferences were statistically significant for non-satisfied cases in both the groups. Additionally, both of the tested drug treatment methods have their own advantages and disadvantages with established indications and contraindications. Therefore, selection of the perfect analgesic is highly influential and crucial in clinics and hospital. Authors also expect some other future studies to be performed to verify and validate our results.

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