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Clinical Effects of Amoxicillin-clavulanate and Calcium Hydroxide as Intracanal Medicament on Inter appointment Pain among Symptomatic Apical Periodontitis

Naresh Kumar, Rajesh Kumar, Priya Harjani, Sarang Suresh

ABSTRACT

Objective: To compare the clinical effects of Antibiotic amoxicillin-clavulanate and calcium hydroxide on inter appointment pain in cases of Symptomatic Apical Periodontitis.

Methodology: It was a single blind randomized controlled trial study performed in operative Dentistry Department of Liaquat University of Medical and Health Sciences Jamshoro. This study was conducted from 02-Jan-2017 to 27-June-2017. Total n=324 patients with symptomatic apical periodontitis were targeted. Patients were randomly allocated into two groups. Total n=162 patients in group1 treated with Antibiotic amoxicillin-clavulanate and n=162 patients in group 2 of calcium hydroxide. Procedure was performed by single operator. Clinical effect was assessed if pain present or absent after 24 hours and 7 days on recalled visit and was labeled as positive when there was no pain (0-3 on VAS) and as negative when there was pain (4-10 on VAS). Data of the study was analyzed by using the SPSS version 20. Mean and standard deviation was calculated for quantitative variables like age and pre and postoperative pain. Frequency and percentages were calculated for type of tooth. Both groups were compared by using Chi- square test for clinical effect.

Results: The average age of the patients was 39.807.36 years. There were 50% male and 50% female. Clinical effectiveness was significantly high in group 1 than group 2 [79.01% vs. 65.43% p=0.006].

Conclusion: The findings of this study are encouraging that patients in which Amoxicillin-clavulanate was used as intracanal medicament appeared to show a greater decrease in pain levels over the observation period when compared to the control group.

Keywords: Amoxicillin-clavulanate, Calcium Hydroxide, Flareup, Pain, Symptomatic Apical Periodontitis.

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INTRODUCTION:

Pain due to pulpal pathology has been a main primary objective for the clinician during and after treatment. Main cause of pulpal pathology is different type of microorganism that leads to clinical sign and symptom.[1] Infection spread from pulp to apical area through apical foramen leads to inflammation. Symptomatic apical periodontitis can be defined as inflammation of supporting structures of the tooth in area, surrounding the apex of tooth.[2] Literature suggests that healing is 10-15% less when symptomatic apical periodontitis is present compared to isolated pulpal pathology after root canal treatment.[3] Unable to decrease enough bacterial load that is required for perfect healing despite of good chemo mechanical preparation of root canals, due to presence of complex anatomy, canal ramification and cementum erosions.[4] Therefore, additional antimicrobial local intracanal medication is required to eliminate most of bacteria.[4-6] Most commonly used local intracanal medication is calcium hydroxide but it has limited effectiveness in eliminating all micro-organism. According to the study calcium hydroxide has been efficient in removing 81.8% of the intracanal bacteria after 7 days[8] and the inclusion of other antimicrobials promotes improved disinfection.

The semi-synthetic antibiotic amoxicillin is combined with the lactamase inhibitor clavulanate potassium to form Augmentin. Amoxicillin-clavulanate is a broad-spectrum antibacterial agent that is bactericidal to most Gram-positive and Gram-negative pathogens.[9] It was first used as a replacement for minocycline in triple antibiotic paste. Antibiotic amoxicillin-clavulanate is 100% effective against common endodontic infections.[10] As an intracanal

Naresh Kumar
Assistant Professor, Department of Operative Dentistry
Bhittai Medical & Dental College, Mirpurkhas

Rajesh Kumar
Consultant, Department of Operative Dentistry
Liaquat University of Medical & Health Sciences, Jamshoro

Priya Harjani
Lecturer, Department of Oral Pathology
Shaheed Mohtarma Benazir Bhutto Medical University, Larkana

Sarang Suresh
FCPS Resident, Department of Operative Dentistry,
Liaquat University of Medical & Health Sciences, Jamshoro
E-Mail: hotchandaniss@hotmail.com

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medicament, amoxicillin-clavulanate paste is helpful in eliminating periapical lesions and encouraging apical closure of an immature tooth with necrotic pulp.[11] Antibiotics as an intracanal medicament are crucial in regenerative treatment. Antibiotic combinations such as triple and quadruple antibiotic pastes might raise the risk of bacterial resistance even when used for short periods. Amoxicillin-clavulanate is drug of choice for management of acute peri radicular infection. Although limited research is available on its local application as intracanal medicaments, according to studies, Amoxicillin-clavulanate can eliminate 100% primary and persisted bacteria from canal.[12] Another pilot study was performed in which Amoxicillin-clavulanate was 70% effective in relieving inter appointment pain.[13] Hence, this study was aimed to compare the clinical effects of Antibiotic amoxicillin-clavulanate and calcium hydroxide on inter appointment pain in cases of symptomatic apical periodontitis.

METHODOLOGY:

It was a single blind randomized controlled trial study performed in operative Dentistry Department of Liaquat University of Medical and Health Sciences Jamshoro. This study was conducted from 02-Jan-2017 to 27-June-2017. Study approval was obtained from institutional review board vide letter LUMHS/FD/0063/20. Total n=324 patients were selected for this study including 162 in each group. The expected population proportions for groups 1 and 2 were 70% and 81.8 percent, respectively, using the WHO sample size calculator with an alpha of 5% and a power of 80. They were divided in two groups 162 patient each with help of lottery method as group A (Amoxicillin-clavulanate 1g) and group B (Calcium Hydroxide). All permanent teeth diagnosed with symptomatic apical periodontitis of either gender, having age from 18 to 50 years were included in this study. Immature and previously endodontically treated or periodontally weakened teeth, allergy to Amoxicillin-clavulanate, patient having systematic medical disease or on any analgesic drug were excluded from study. Written informed consent was obtained from all the patients before start of treatment. Before start of treatment preoperative pain score was recorded by using visual analog scale after giving local anesthesia with lignocaine 2%, teeth were isolated with rubber dam. Access opening was done with round bur in high-speed hand piece. Working length was measured on periapical radiograph using ISO K file # 15 .Canal was prepared with rotary protaper file system along with sodium hypochlorite 2.5% . Canal was dried with paper points. . In group A (Amoxicillin-clavulanate paste was prepared by mixing 1g of antibiotic powder with normal saline until creamy mix obtained) and in group B (calcium hydroxide powder mixed with normal saline until creamy paste obtained), then paste was inserted with the help of lentulo spiral up to working length followed by cotton pledged and cavity was sealed with temporary filling (CAVIT). Clinical effect was assessed if pain present or absent after 24 hours and 7 days on recalled visit.

Clinical effect was labeled as positive when there was no pain (0-3 on VAS) and as negative when there were pains (4-10 on VAS). Data of the study was entered and analyzed by using the SPSS version 20. Mean and standard deviation was calculated for quantitative variables like age and pre and postoperative pain. Frequency and percentages were calculated for type of tooth. Both groups were compared by using Chi- square test for clinical effect.

RESULTS:

Total n=324 patients with symptomatic apical periodontitis were divided into two groups. The average age of the patients was 39.80±7.36 years. Similarly average age and pain score at specific time is shown in table 1. Comparison of the clinical effect of Amoxicillin-clavulanate and calcium hydroxide on inter appointment pain stratified for teeth in table 2. Comparison of the clinical effect of Amoxicillin-clavulanate 1g and calcium hydroxide on inter appointment pain in cases of symptomatic apical periodontitis is shown in table 3. Clinical effectiveness was significantly high in group 1 than group 2 [79.01% vs. 65.43% p=0.006].

Table 1: Descriptive Statistics of Age & Pain

Variables	Group1 n=162		Group 2 n=162	
	Mean	Std. Deviation	Mean	Std. Deviation
Age (Years)	39.49	7.405	40.12	7.323
Pre-operative pain score	6.85	.858	6.94	.889
Pain Score After Day 1	2.75	1.366	3.60	1.463
Pain Score After 7 days	1.55	1.549	2.14	1.746

Table 2: Comparison of the Clinical Effect of Amoxicillin-clavulanate and Calcium Hydroxide on Inter Appointment Pain Stratified for Teeth

Group		Effective	Not Effective	Total (n=324)
Group A	Molar	39 58.20%)	28 (41.80%)	67
	Premolar	43 87.75%)	06 (12.25%)	49
	Canine	46 (100%)	00	46
Group B	Molar	39 (52%)	36 (48%)	75
	Premolar	18 (72%)	7 (28%)	25
	Canine	49 79.03%)	13 (20.97%)	62

Table 3: Comparison of the Clinical Effect of Amoxicillin-clavulanate and Calcium Hydroxide on Inter Appointment Pain in Cases of Symptomatic Apical Periodontitis

Group of Study	Effective	Not Effective	Total	P Value
GROUP 01	128(79.01%)	34 (20.9%)	162	.006
GROUP 02	106(65.43%)	56(34.57%)	162	.006
TOTAL	234	90	324	.006

DISCUSSION:

Occurrence of interappointment pain is of very severe intensity during or after completion of procedure is called flareup. It occurs even following standard protocol of treatment[14,15] due to various factors like persistent microorganism, mechanical and chemical damage by extrusion of material from apical foramen into periapical area results in inflammation.[16] Other factor also modifies inter appointment pain like preoperative pain intensity, age, and gender.[17-19] The frequent leading cause of pain is remaining microorganism that cannot be removed by conventional protocol because these microorganisms reside in area where conventional protocol doesn't have access. But it is suggested that use of antimicrobial intracanal medicament can eliminate these bacteria so that pain can be effectively eliminated.[20]

The calcium hydroxide is the white odorless powder with pH 12.5-12.8. The high pH of this pure powder form is bacteriostatic. B.W. Herman developed it as a pulp capping agent in 1920. It was then used for intracanal medicaments, endodontic sealers, apexification, and pulpotomies.[21] The success rate of apical periodontitis patients varied from 67 to 88.97 percent. Trope et al[22] found an 80% healing rate with calcium hydroxide in two visits. Friedman et al[23] evaluated 4- to 6-year endodontic treatment results for teeth with apical periodontitis and found a 74% recovery rate. Paredes Vierya et al.[24] found that calcium hydroxide-treated teeth had an 88.97 percent success rate.

In present study Amoxicillin-clavulanate used as intracanal medicament to reduce these microorganism as it has broad spectrum anti-microbial effect and used as topical so that systematic effects are avoided. According to present study Amoxicillin-clavulanate found more effective compared to standard calcium hydroxide. Clinical effectiveness of Amoxicillin-clavulanate is 79.01% compared to calcium hydroxide 65.43 with P value .006. Another pilot study had also shown that Amoxicillin-clavulanate is more effective.[13]

Presence of preoperatively pain in experimental group is 6.85 is significantly of severe intensity but that is decreased with time after 24 hours and 1 week time. There was no significant difference found with in age and gender variable. But amoxicillin-clavulanate was found to be 100% effective in eliminate pain in canine teeth, while success in molar is not up to mark , was effective in 39 cases out of 67(58.2%). The reason for not getting promising results in molar teeth is presence of multiple canals, complex morphology, difficult to place intracanal medicament due to curved and narrowed canal. The results of present study are very promising to decrease interappointment pain used as intracanal medicament compared to control group. But effectiveness in molar was not appriciable so larger study is needed in future to evaluate effectiveness of Amoxicillin-clavulanate in molars as intracanal effectiveness.

CONCLUSION:

The findings of this study are encouraging that patients in which amoxicillin-clavulanate was used as intracanal medicament appeared to show a greater decrease in pain levels over the observation period when compared to the control group.

Authors Contribution:
Naresh Kumar: Conception or design of the work; or the acquisition, analysis, or interpretation of data for the work and Final approval of the version to be published
Rajesh Kumar: Acquisition & analysis of data and Final approval of the version to be published
Priya Harjani: Interpretation of data and Final approval of the version to be published
Sarang Suresh: Drafting of the work and Final approval of the version to be published

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