Oral Health Case Reports
ISSN: 2471-8726
Prathiba and Mahesh Kumar, Oral health case Rep 2018, 4:1
DOI: 10.4172/2471-8726.1000143
Research Article
Open Access

A Comparative Study of the Combination of Drugs - Amoxicillin with Metronidazole and Ofloxacin with Ornidazole In the Treatment of Dentoalveolar Abscess

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Abstract

To compare the efficacy of combination of capsule. amoxicillin 500 mg with tablet. metronidazole 400 mg at 8 hrly interval with fixed dose combination of tablet. Ofloxacin (200 mg) + ornidazole (500 mg) at 12 hrly interval for 5 days in the treatment of dentoalveolar abscess.

Materials and method: This comparative study included sample size of 160 patients recorded within 6 months and diagnosed clinically with dentoalveolar abscess visiting dental unit of Saveetha Medical college: in order to match the estimated sample size a few patients from Mohit private dental clinic, Valasaravakam were included. A standardized method for data collection and oral examination was followed. The patients were recruited to anyone of the two groups to which the investigator was blind. The treatment allotment code was kept confidentially with the treating dentist and only at the end of the study the code was broken and revealed to the investigator. The patients were advised to come for check up on the third day. In case if any problem arised before the advised visit, due to the condition or the therapy, the patients were informed to contact the treating dentist. Assessment of clinical improvement in swelling size, mouth opening, pain, lymph node condition and body temperature were carried out during the assessment visits on the third day and the fifth day. If clinical improvement was present- the patient was advised anyone of the following treatments that suited his/her clinical condition. The tooth was treated either by root canal treatment or extraction. The subject's whose clinical condition was not improved on the third day was advised to take the prescribed medicine for two more days and to come for dental checkup on the fifth day.

Results: The efficacy of both therapies was similar. No significant difference in adverse drug reaction. Patient compliance was in favour of ofloxacin and ornidazole group. Cost of fixed dose combination of ofloxacin and ornidazole therapy was slightly cheaper than amoxicillin and metronidazole.

Conclusion: We conclude that the efficacy of both the therapies was similar with no significant difference in adverse drug reaction. The patient compliance was in favor of oflaxacin and ornidazole group of drugs which was relatively cheaper than amoxicillin and metronidazole.

Keywords: Oflaxacin; Amoxicillin; Dentist; Dentoalveolar; Penicillin

Introduction

Dentoalveolar abscess is frequently underestimated in terms of its morbidity and mortality. The risk of potential serious consequences arising from the spread of a dental infection from the abscess is still relevant today with many hospital admissions for dental sepsis. Dentoalveolar abscess is defined as "An abscess situated within the alveolar process of jaw most often caused by the extension of infection from adjacent non-vital tooth usually periapical abscess" [1].

Dentoalveolar abscess is a critical condition that requires immediate intervention with antibiotics and drainage of pus as an adjuvant measure which is a routine procedure. Anaerobes constitute major proportion of the miroflora of the dentoalveolar abscess thus the drugs effective against the anaerobes were employed in the study. The antimicrobials were chosen to cover the broad spectrum of microbes that includes gram positive and gram-negative bacteria. For the antibiotic to be successful in overcoming the associated symptoms, it must be active against the microorganisms and to be given in adequate dose, frequency and duration to aid in resolution of the systemic symptoms [2].

Penicillin and fluoroquinolone groups were selected to combat the gram positive and gram-negative organisms, and nitro-imidazole group of drugs were co-administered to act against the anaerobes.

The purpose of this study was to compare the combination of drugs capsule. Amoxicillin 500 mg with tablet. Metronidazole 400 mg at 8 hrly interval and tablet. Ofloxacin (200 mg) + ornidazole (500 mg) fixed dose combination at 12 hrly interval for 5 days in the treatment of dentoalveolar abscess.

Aim of the Study

To compare the efficacy of combination of capsule. amoxicillin 500 mg with tablet. metronidazole 400 mg at 8 hrly interval with fixed dose combination of tablet. Ofloxacin (200 mg) + ornidazole (500 mg) at 12 hrly interval for 5 days in the treatment of dentoalveolar abscess.

Methodology

The study on dentoalveolar abscess was planned, designed and a detailed protocol was written. It was presented to the Scientific Review

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Received: December 17, 2017; **Accepted:** February 25, 2018; **Published**: March 04, 2018

Citation: Prathiba S, Mahesh Kumar P (2018) A Comparative Study of the Combination of Drugs - Amoxicillin with Metronidazole and Ofloxacin with Ornidazole In the Treatment of Dentoalveolar Abscess. Oral health case Rep 4: 143. doi:10.4172/2471-8726.1000143

Board of Saveetha Medical College and then to the Institutional Human Ethical Committee and approval was obtained to conduct the study in the presented form. This comparative study included sample size of 160 patients recorded within 6 months and diagnosed clinically with dentoalveolar abscess visiting dental unit of Saveetha Medical College and in order to match the estimated sample size a few patients from Mohit Dental Care, Valasaravakam a private dental clinic was included.

The sample size was calculated to be 160. Random blood glucose was done as a part of investigation for all persons who were interested to join the study and when the test was done 6 of them had high random blood glucose and they were not included. At the end of the 6th month, we were able to recruit only 96 patients. The reduction in sample size was a limitation. The 96 patients were randomized in two groups-GROUP I (amoxicillin and metronidazole) and GROUP II (ofloxacin and ornidazole). GROUP I had 50 patients and the other group recruitment was 46. There were four dropouts-3 in GROUP I and 1 in GROUP II. All the four came only for the initial visit and were lost to follow up. Two in GROUP 1 went out of station and other two could not be contacted (Tables 1 and 2).

Age group	Patient number
18-30 yrs	18 (36%)
31-45 yrs	18 (36%)
46-74 yrs	14 (28%)
Total number in group I	50

Table 1: Age wise distribution of patients in Group I.

Age group	Number
18-30 yrs	14 (30%)
31-45 yrs	14 (30%)
46-74 yrs	18 (40%)
Total number in group II	46

Table 2: Agewise distribution of patients in Group II.

Severity of pain					
Visit	No. of patients	Severe	Moderate	Mild	No pain
Initial visit	50	43	7	0	0
Assessment visit I	47	0	7	39	1
Assessment visit Ii	47	0	0	0	47

Table 3: This table shows the severity assessment of pain in group I patients.

Severity of pain					
Visit	No. of patients	Severe	Moderate	Mild	No pain
Initial visit	46	39	7	0	0
Assessment visit I	45	0	7	35	3
Assessment visit II	45	0	0	0	45

Table 4: This table shows the severity assessment of pain in group II patients.

Severity of pain					
Visit	No. of patients	Severe	Moderate	Mild	No pain
Initial visit	50	43	7	0	0
Assessment visit I	47	0	3	39	5
Assessment visit II	47	0	0	0	47

Table 5: This table shows the severity assessment of pain in group I patients.

Severity of pain					
Visit	No. of patients	Severe	Moderate	Mild	No pain
Initial visit	46	38	8	0	0
Assessment visit I	45	0	3	37	5
Assessment Visit II	45	0	0	0	45

Table 6: This table shows the severity assessment of pain in group II patients.

Tooth mobility	Initial visit	Assessment visit I	Assessment visit II
Present	36	0	0
Absent	14	47	47
Total	50	47	47

Table 7: This table shows the tooth mobility–Group I patient.

Tooth mobility	Initial visit	Assessment visit I	Assessment visit II
Present	37	0	0
Absent	9	45	45
Total	46	45	45

Table 8: This table shows the tooth mobility –Group II patient.

Lymph node	Initial visit	Assessment visit I	Assessment visit II
Present	42	8	0
Absent	8	39	47
Total	50	47	47

Table 9: This table indicates the progress seen in lymph node status in group I.

Lymph node	Initial visit	Assessment visit I	Assessment visit II
Present	35	9	0
Absent	11	36	45
Total	46	45	45

Table 10: This table indicates the progress seen in lymph node status in group II.

Assuming 90% of patients with dentoalveolar abscess have severe or moderate pain the sample size was estimated to be 80 in each of the two groups in order to have a significant difference of 20% between the two groups for a power of 95% at 5% level of significance. The statistical method followed was inferential and descriptive statistics.

Patients above the age of 18 yrs, clinically diagnosed with dentoalveolar abscess were included in the study. Patients with history of hepatic, renal failure, hypersensitivity to drugs and uncontrolled diabetes were excluded from the study along with pregnant women. All the patients were thoroughly investigated on blood sugar level after obtaining concern for their willingness to participate in the study.

A standardized method for data collection and oral examination was followed. During the initial visit, the patients were recruited to anyone of the two groups to which the investigator was blind. The treatment allotment code was kept confidentially with the treating dentist and only at the end of the study the code was broken and revealed to the investigator.

The patients were advised to come for check up on the third day (Assessment Visit I). In case if any problem arised before the advised visit, due to the condition or the therapy, the patients were informed to contact the treating dentist.

Assessment of clinical improvement in swelling size, mouth opening, pain, lymph node condition and body temperature were carried out during the visits. If clinical improvement was present-the patient was advised anyone of the following treatment that suited his/her clinical condition. The tooth was treated either by root canal treatment or extraction. The subject's whose clinical condition was not improved on the third day was advised to take the prescribed medicine for two more days and to come for dental check up on the fifth day (Assessment Visit II).

Results

The results have been described in the following tables and figures (Tables 3-12) (Figures 1-11).

The limited mouth opening seen during the initial visit in both the groups had improved drastically and there was statistical significance in the progress obtained in both the groups but when the statistical analysis was done to find out if there was any difference in the progress obtained between the two groups pertaining to mouth opening, there was not any statistical significance (Tables 13-16).

Group	Number	Mean swelling size initial visit (cm)2	Assessment visit I(cm)2	Assessment visit II (cm)2
I	50	6.53	0.64	0
II	46	6.86	0.65	0

Table 11: The diagram shows the decline in swelling size during the assessment visit I on the 3rd day in both the groups.

Group	Patient number	Mean value during initial visit(cm)	Mean value assessment visit I (cm)	Mean value assessment visit II (cm)
Group I	50	2.97	3.86	3.87
Group II	46	2.94	3.85	3.86

Table 12: This table shows the statistical significance progress obtained in both the groups.

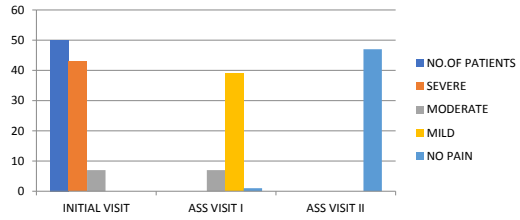

Figure 1: This figure shows the severity assessment of pain in group I patients.

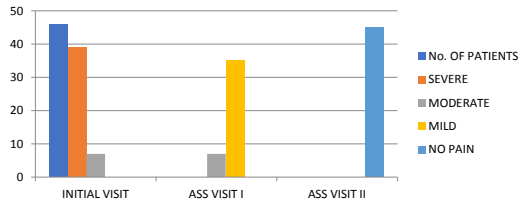

Figure 2: This figure shows the severity assessment of pain in group II patients.

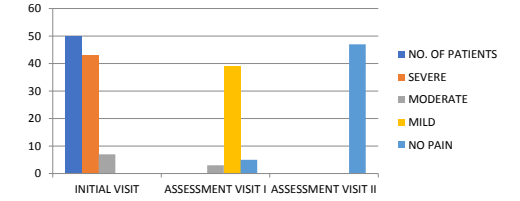

Figure 3: This figure shows the severity assessment of pain in group I patients.

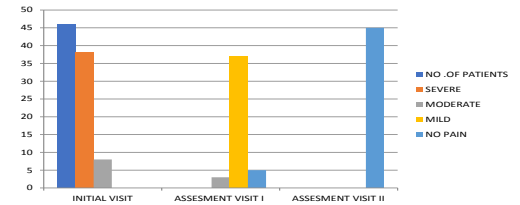

Figure 4: This figure shows the severity assessment of pain in group II patients.

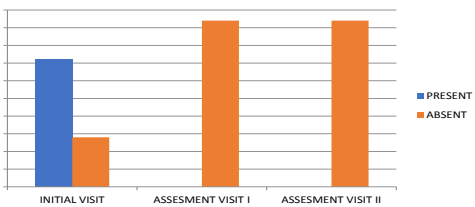

Figure 5: The above figure depicts the improvement seen in tooth mobility in group I.

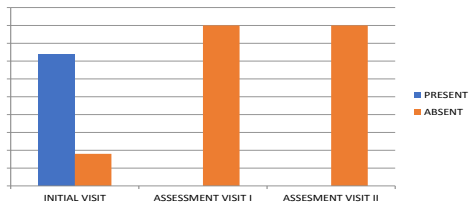

Figure 6: The bar diagram above indicates the progress in tooth mobility in group II.

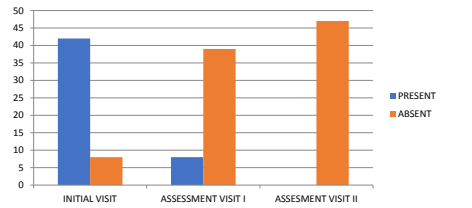

Figure 7: The above diagram illustrates the progress seen in lymph node status in group I.

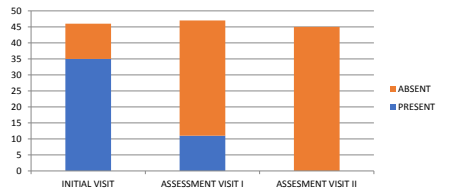

Figure 8: The diagram shows the progress seen in the lymph node condition in group II.

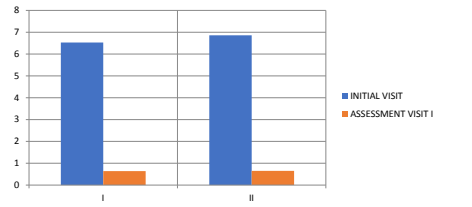

Figure 9: The diagram shows the decline in swelling size during the assessment visit I on the 3rd day in both the groups.

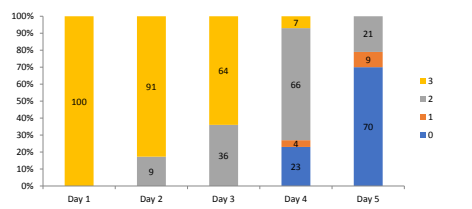

Figure 10: The above figure illustrates the patient compliance in group I patients.

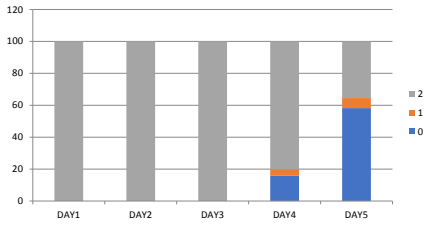

Figure 11: The above figure illustrates the patient compliance in group II patients.

Pyrexia	Initial visit	Assessment visit I	Assessment visit II
Present	42	0	0
Absent	8	47	47
Total	50	47	47

Table 13: The above tables indicate the change in pyrexia during the assessment visit I on the 3rd day in Group I patient.

Pyrexia	initial visit	assessment visit I	Assessment visit II
Present	39	0	0
Absent	7	45	45
Total	46	45	45

Table 14: The above tables indicate the change in pyrexia during the assessment visit I on the 3rd day in Group II patient.

Frequency of drug intake	Day 1	Day 2	Day 3	Day 4	Day 5
Thrice a day	100%	91%	64%	7%	0%
Twice a day	-	9%	36%	66%	21%
Once a day	-	-	-	4%	9%
Not taken	-	-	-	23%	70%

Table 15: This table shows the frequency with which the patients had taken the prescribed medicine.

Frequency of drug intake	Day 1	Day 2	Day 3	Day 4	Day 5	
Twice a day	-	100%	100%	100%	80%	35.5%
Once a day	-	-	-	-	4%	6.3%
Not taken	-	-	-	-	16%	58.2%

Table 16: This table shows the frequency with which the patients had taken the prescribed medicine.

Discussion

Dentoalveolar abscess is one of the most common conditions seen in dental practice. It is more often a sequela of dental caries resulting in periapical abscess. The routine treatment of dento alveolar abscess is pus drainage and administration of antibiotics. The judicious use of antibiotics can shorten the periods of infection and minimize the associated risks such as the spread of infection to adjacent anatomical spaces or systemic involvement [3,4].

There are only few clinical trials regarding dentoalveolar abscess. The spectrum of bacteria that causes dentoalveolar abscess is polymicrobial containing both gram positive and gram-negative bacteria along with anaerobes predominantly [5,6].

The most commonly used antibiotics in this condition is a combination of beta-lactam antibiotics like penicillin or cephalosporins along with nitroimidazole like metronidazole, in the eradication of causative microbes [7]. There are previous studies indicating the efficacy of amoxicillin in combination with other drugs and there is a single study proving the efficacy of moxifloxacin over clindamycin in the management of dental abscess [8].

It is common practice in dentistry to prescribe amoxicillin with metronidazole along with an analgesic in the management of dentoalveolar abscess. Moreover, there are reports stating the increased incidence of resistance to amoxicillin [9]. Thus, we made an attempt to compare the efficacy of fixed dose combination of ofloxacin and ornidazole with a combination of amoxicillin and metronidazole in the treatment. Ofloxacin has a wider spectrum and ornidazole has a long t 1/2 requiring twice a day administration. The latter choice was expected to be a better than the former. Hence the study was undertaken [10].

Ofloxacin was the chosen drug for the treatment because it has excellent tissue penetration and attains high concentration in the soft tissues and bones. It also covers anaerobes and is relatively immune to the development of resistance.

However, there is not sufficient data comparing the efficacy of these two drug combinations in Indian population.

Assessment

VAS score by patients on assessment visit I showed significant improvement in both Group I and II compared to the initial visit. There was statistical significance in the progress obtained in both the groups. Yet, there was no significant difference seen between the groups and in the second assessment visit all the patients were symptom free.

The clinical assessment by the investigator on assessment visit I and visit II correlated well with the patients score and the correlation value was found to be 83.5% with p value<0.001. The clinical improvement seen in this study was in accordance to the dentoalveolar abscess trial done in the year 2011.

When the results were compared statistically between the two groups, the p value was calculated for each parameter and it was <0.001 for all the outcome parameters, indicating that there was significant improvement with either of the treatments and there was no statistical difference found between the two groups.

Adverse Drug Reaction (ADR)

In Group I, 10 patients reported diarrhoea. It was mild and did not warrant discontinuation of the drug. In Group II, 9 patients experienced adverse effect in which 5 patients had dizziness and one had nausea, 3 people reported diarrhoea. Even in Group II, the adverse effects were mild, and the patients continued with the medication

Patient Compliance

Patients in Group I was prescribed amoxicillin with metronidazole combination thrice a day, whereas in Group II patients were instructed to take ofloxacin and ornidazole combination twice a day for 5 days. Analgesic combination of diclofenac with paracetamol was given to patients belonging to both the groups. All the patients took the medication on the first day as prescribed. The analysis of results for patient compliance showed better results with Group II, whereas the percentage of patients following the prescription had considerably reduced on each day in Group I. So, this might be because the patients were comfortable with twice a day administration rather than thrice a day drug intake. Statistically the trend was significant with a P value of <0.001.

Cost of Medication

Group I

Cap. Amoxicillin (500 mg): Rs. 6.50 × 3=19.50/day

and

Tab. Metronidazole (400 mg): Rs. 0.50 × 3=1.50/day and Rs.21.00 × 5=Rs. 105.00/course

Group II

Tab. Ofloxacin and Ornidazole (FDC): Rs.9.30 × 2=Rs. 18.60 /day and Rs.18.60 × 5=Rs.93.00/course

The cost wise the difference in the drug therapy was Rs.12.00/course. Thus, the single blind study on dentoalveolar abscess showed no significant difference in the efficacy and adverse effects. The cost of the therapy showed little variation as the ofloxacin combination was slightly cheaper than the other. The patient compliance was significantly better with ofloxacin and ornidazole than the other group.

Conclusion

From the study we conclude

- The efficacy of both therapies was similar.
- No significant difference in adverse drug reaction.
- Patient compliance was in favour of ofloxacin and ornidazole group.
- Cost of fixed dose combination of ofloxacin and ornidazole therapy was slightly cheaper than amoxicillin and metronidazole.

References

1. Weine F (1995) Text book of Endodontic therapy. (5th edn). St. Louis: Mosby. 3: 248-255.
2. Burns RC (2002) Pathways of the pulp. Cohen Text book of Endodontics. (8th ed). St. Louis: Mosby. 4: 46-49.
3. Fazakerley MW, McGowan P, Hardy P, Martin MV (1993) A comparative study of cephradine, amoxycillin and phenoxymethylpenicillin in the treatment of acute dentoalveolar infection. Br Dent J 174: 359-363.
4. Lewis MA, McGowan DA, MacFarlane TW (1986) Short-course high-dosage amoxycillin in the treatment of acute dento-alveolar abscess. Br Dent J 161: 299-302.
5. Ramachandran Nair PN, Pajarola G, Schroeder HE (1996) Types and incidence of human periapical lesions obtained with extracted teeth. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 81:93-102
6. Dailey YM, Martin MV (2001) Are antibiotics being used appropriately for emergency dental treatment. Br Dent J 191: 391-393.
7. Lewis MA, Meechan C, MacFarlane TW, Lamey PJ, Kay E (1989) Presentation and antimicrobial treatment of acute orofacial infections in general dental practice. Br Dent J 166: 41-45.
8. Sobottka I, Wegscheider K, Balzer L, Böger RH, Hallier O, et al. (2011) Comparative efficacy and safety of moxifloxacin and clindamycin in the treatment of odontogenic abscesses and inflammatory infiltrates: A phase II, double-blind, randomized trial. Antimicrob Agents Chemother 55: 1142-1147.
9. Roche Y, Yoshimori RN (1997) *In-vitro* activity of spiramycin and metronidazole alone or in combination against clinical isolates from odontogenic abscesses. J Antimicrob Chemother 40: 353-357.
10. Martin MV, Longman LP, Hill JB, Hardy P (1997) Acute dentoalveolar infections: an investigation of the duration of antibiotic therapy. Br Dent J 183: 135-137.