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Journal of Dentistry and Oral Hygiene

 Table of Content: Volume 7 Number 1 January 2015

## **ARTICLES**

1

**Research Articles** 

Is routine antibiotic prescription following exodontias necessary? A randomized controlled clinical study Babatunde O. Akinbami and Babatope B. Osagbemiro

## academicJournals

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Journal of Dentistry and Oral Hygiene

Full Length Research Paper

# Is routine antibiotic prescription following exodontias necessary? A randomized controlled clinical study

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The importance of routine antibiotics following exodontias should not be addressed in isolation but in conjunction with other factors. Information obtained included patient bio-data, oral hygiene status, tooth extracted, type of exodontias (routine or surgical) and duration of extraction (< or > than 10 min). Randomized patients for extractions were divided into two groups, method of randomization and allotment of patients were done by blind masking. Selection of group was done by picking closed ballot papers which had been designated as 1 or 2, 1-signifies no antibiotic and 2-signifies antibiotic prescription. The first group was given antibiotics following extraction and second group which served as the control were not given antibiotics. There were a total of 262 patients that had exodontias within the study period, 104 (39.7%) males and 158 (60.3%) were under the age range 15 to 96 years, and mean (standard deviation) of 35.2 (14.6) years. There were 162 (61.8%) patients in the first group and 100 (38.2%) patients in the second group (no antibiotics), 95 (36.3%) patients in the second group had nontraumatic extractions and 5 had traumatic extractions. 45 patients in second group had extractions that lasted more than 10 min. Out of 240 (91.6%) routine extractions done, 96 (36.6%) were in the second group and of 22 (8.4%) surgical extractions, 4 (1.5%) were in the second group. This study showed that routine antibiotic used was not necessary following all exodontias procedures, and variables such as type of extraction, difficulty of extraction and adherence to post operative instructions were important associated factors that determined the occurrence of postoperative complications. The registration number of this trial is PACTR201408000861302. Registered with the Pan-African Clinical Trial Registry.

Key words: Exodontia, complications, antibiotics, associated factors.

#### INTRODUCTION

Tooth extraction secondary to various etiologies is the commonest dentoalveolar surgery (Scottish Intercollegiate Guidelines Network (SIGN), 2000). Similar to other minor procedures, controversies exist based on the need of antibiotic prescription to prevent postoperative infection

(Martin et al., 2000). Various countries have formulated policies that guide the use and dosage of antibiotics in minor oral and dentoalveolar procedures (SHEA, APIC, CDS, SIS Consensus Paper, 1992). This has become very vital considering the prevalence of cardiac and renal

\*Corresponding author: E-mail: akinbamzy3@yahoo.com. Tel: 08068556516. Author(s) agree that this article remain permanently open access under the terms of the <u>Creative Commons Attribution</u> <u>License 4.0 International License</u> pathologies in the population and the risk of acquiring severe systemic and organ specific superimposed bacterial infection following these oral procedures (Mangram et al., 1999). However, regardless of the presence of disorders in these vital organs, some surgeons or dentists still deem the use of antibiotics to prevent severe pain, dry socket, localized infections, soft tissue space infections and osteomyelitis very necessary (Lockhart and Schmidtke, 1994). Such surgeons justify their position on the fact that the oral cavity is laden with a significant amount of normal flora which can become pathogenic with disruption in the integrity of the vasculature to the periodontal ligaments, periapical tissues and mucoperiosteum (Palmer et al., 200).

However such opinion can be contested by the fact that adequate local and systemic immunity without antibiotic use can also prevent the occurrence of post operative complications, although other factors like duration of prcedure, degree of trauma induced, level of operator and compliance to post extraction instructions play contributory roles (Kaczmarzyk et al., 2007). It is however important to have some evidence based facts concerning the relevance of routine use of antibiotics. Therefore, the aim of this study was to assess the necessity of the use of antibiotics and to determine the associated factors that predispose to post-operative complications following exodontias in a tertiary hospital.

#### PATIENTS AND METHODS

This was a prospective double blind randomized clinical trial carried out in the Department of Oral and Maxillofacial Surgery, University of Port Harcourt Teaching Hospital, between November, 2013 and June, 2014, Approval to conduct the research was given by the hospital ethics and research committee and informed consent was obtained from each patient. All consenting patients who presented to the clinic for extraction of any tooth for any indication were enrolled. Information obtained included patient bio-data, oral hygiene status, and systemic illnesses; tooth extracted, type of exodontias (routine or surgical) and duration of extraction (< or > than 10 min). Patients with controlled diabetes mellitus with fasting blood sugar of ≤110 mg/ml were included in the study. Patients with uncontrolled diabetes mellitus, end-stage renal disease, valvular/ congenital heart diseases and immunocompromised status as well as patients with dentoalveolar abscess and other preoperative infections were excluded from the study because they were routinely covered with prophylactic antibiotics.

Randomized patients for extractions were divided into two groups, method of randomization and allotment of patients were done by blind masking. Selection of group was done by picking closed ballot papers which had been designated as 1 or 2, 1signifies antibiotic prescription and 2-signifies no antibiotic prescription. The first group was given antibiotics following extraction and second group which served as the control were not given antibiotics. Extractions were classified as routine extraction when teeth were removed without reflecting mucoperosteum and surgical extraction when mucoperiosteum was raised. Patients in the first group were given amoxicillin 500 mg capsule eight-hourly for 5 days and metronidazole 400 mg eight-hourly for 5 days (Palmer et al., 2000). Periapical radiographs were taken before extractions to assess the level of difficulty that will possibly be encountered during the extraction. Features related to the crown of the teeth, roots morphology and relationship to the maxillary sinuses, inferior alveolar canals, adjacent tooth and bone, alveolar bone density and periapical pathologies were evaluated. For impacted teeth, evaluation also included the type and depth of impaction. Routine extractions were done by clinical students under supervision, house-officers, resident doctors, and surgical extractions by supervised house-officers, resident doctors or consultants. Patients in both groups were followed given acetaminophen 1000 mg tablet eight-hourly for 3 days or diclofenac potassium 50 mg tablet twelvehourly for 5 days if extraction was difficult, surgical or more than 10 min.

Patients were review after 1 week to ascertain the occurrence of any form of post-operative complication such as pain, swelling, delayed healing, dry socket and infection. Data was obtained with SPSS 16.0 (SPSS Inc, Chicago, IL, USA). Means and standard deviation of age was done using the univariate and multivariate analysis of variance; F and adjusted R squared values were determined for the differences in the occurrence of post operative complications between the two groups and p value  $\leq 0.05$  were considered significant. Regression analysis was done to determine the association of each complication to postoperative instructions in both groups.

#### RESULTS

There were a total of 262 patients who had 262 teeth extracted, out of which 22 (8.4%) were impacted third molar, 104 (39.7%) males and 158 (60.3%) under the age range of 15 to 96 years, and mean (standard deviation) of 35.2 (14.6) years. There were 162 (61.8%) patients in the first group and 100 (38.2%) patients in the second group (no antibiotics). Overall, 227 (86.6%) patients had no systemic illness, 8 (3.1%) had diabetes mellitus and 13 (5.0%) had hypertension (Table 1). The oral hygiene status of the patients in both groups is shown in Table 2.

During review, there were four complications documented and these included pain (mild, moderate, severe) based on visual analogue scale, swelling, delayed healing and dry socket. Table 4 shows the occurrence of these complications in the 2 groups in relation to different operators. There were 151 (93.2%) patients in the first group and 92 (92.0%) patients in the second group who had no complication. There were complications in a total of 19 (7.3%) patients in the study, 11 (6.2%) and 8 (8.0%) patients, respectively. Three (1.9%) patients in the first group and no (0%) patient in the second group had delayed healing. One (0.6%) patients had dry socket, in the first group, none (0%) in the second group. Swelling was reported in 3 (1.9%) and 1 (1%) patient, respectively; in all, 4 (2.5%) and 7 (7.0%) patients had pain.

The postoperative instruction compliance was good in 145 (55.3%) patients, out of which 43 (16.4%) were in the second group. The compliance was fair in 110 (42.0%) patients and 54 (20.6%) were without antibiotics. Only 3

	<b>O</b> and an	Antibiot	Antibiotic given		
History of systemic liness	Gender	Yes	No	— Total	
Neg	Male	62 (23.7)	30 (11.4)	92 (35.1)	
None	Female	82 (31.3)	53 (20.2)	135 (51.5)	
	Total	144 (55.0)	83 (31.6)	227 (86.6)	
	Male	3 (1.1)	0 (0.0)	3 (1.1)	
Diabetes mellitus	Female	4 (1.5)	1 (0.4)	5 (1.9)	
	Total	7 (2.7)	1 (0.4)	8 (3.0)	
Kidney stones	Male	1 (1.1)	0 (0.0)	1 (1.1)	
Lunartanaian	Male	3 (1.1)	2 (0.8)	5 (1.9)	
Hypertension	Female	2 (0.8)	6 (2.2)	8 (3.0)	
	Total	5 (1.9)	8 (3.0)	13 (4.9)	
Peptic ulcer	Female	2 (0.8)	3 (1.1)	5 (1.9)	
Asthmatic	Male	1 (0.4)	2 (0.8)	3 (1.1)	
	Female	1 (0.4)	3 (1.1)	4 (1.5)	
Arthritis	Female	1 (0.4)	0 (0.0)	1 (0.4)	
Total		162 (61.8)	100 (38.2)	262 (100)	

 Table 1. Gender distribution of 262 patients in both groups based on systemic disease.

Table 2. Distribution of 262 patients in both groups based on oral hygiene status, type, difficulty and duration of exodontias.

	Antibiot			
Parameter	Yes	No	lotal	
Oral hygiene status				
Good	39 (14.9)	9 (3.4)	48 (18.3)	
Fair	105 (40.1)	72 (27.5)	177 (67.6)	
Poor	18 (6.9)	19 (7.2)	37 (14.1)	
Type of extraction				
Routine	144 (55.0)	96 (36.6)	240 (91.6)	
Surgical	18 (6.9)	4 (1.5)	22 (9.4)	
Difficulty of extraction				
Non traumatic	142 (54.2)	95 (35.8)	237 (90.5)	
Traumatic	20 (7.6)	5 (1.9)	25 (9.5)	
Duration of extraction				
<10 min	91 (34.7)	55 (21.0)	146 (55.7)	
>10 min	71 (27.1)	45 (17.2)	116 (44.3)	
Total	162 (61.8)	100 (38.2)	262 (100)	

De et energie energie etien		Antibiot	<b></b>		
Post-exodontia complication	Compliance to post-exodontia instruction	Yes No		lotal	
Severe poin	Good	2 (0.8)	3 (1.1)	5 (1.9)	
Severe pain	Total	2 (0.8)	3 (1.1)	5 (1.5)	
	Good	96 (36.6)	39 (14.9)	135 (51.5)	
None	Fair	53 (20.2)	53 (20.2)	106 (40.4)	
None	Poor	2 (0.8)	0 (0.0)	2 (0.8)	
	Total	151 (57.6)	92 (35.1)	243 (92.7)	
	Good	1 (0.4)	0 (0.0)	1 (0.4)	
Poor healing	Poor	2 (0.8)	0 (0.0)	2 (0.8)	
	Total	3 (1.1)	0 (0.0)	3 (1.1)	
Dry sockot	Fair	1 (0.4)	0 (0.0)	1 (0.4)	
Dry Socker	Total	1 (0.4)	0 (0.0)	1 (0.4)	
	Good	1 (0.4)	1 (0.4)	2 (0.8)	
Mild pain	Fair	1 (0.4)	0 (0.0)	1 (0.4)	
Mild part	Poor	0 (0.0)	1 (0.4)	1 (0.4)	
	Total	2 (0.8)	2 (0.8)	4 (1.5)	
Madarata pain	Poor	0 (0.0)	2 (0.8)	2 (0.8)	
	Total	0 (0.0)	2 (0.8)	2 (0.8)	
Swelling	Good	2 (0.8)	0 (0.0)	2 (0.8)	
Swennig	Fair	1 (0.4)	1 (0.4)	2 (0.8)	
	Total	3 (1.1)	1 (0.4)	4 (1.5)	

Table 3. Relationship of post-operative complications and post-operative instruction compliance in both groups.

(1.1%) patients with poor compliance and without antibiotics had complications (Table 3). There were 35 mobile teeth extracted in 35 (13.5%) patients, 15 (5.7%) were not given antibiotics and only 1 (0.4%) of this had complication of swelling, all 20 (7.6%) patients with mobile tooth given antibiotics had no complication.

Multivariate analysis of variance showed no significant difference in the post-operative complication between the two groups; F value was 0.013, adjusted R squared value was -0.004 and significance value was 0.909, but there was significant difference as regards to compliance to postoperative instruction between the two groups; F of 8.801, adjusted R squared value was 0.029 and significance value of 0.003. Univariate analysis of variance for multiple factors is as shown in Table 5. Multinominal logistic regression values of association of the complications with post-extraction instruction compliance in both antibiotic and control groups are reflected as shown in Table 6.

#### DISCUSSION

A lot of debate surrounds the prescriptions of antibiotics

following extraction. Some proponent base their argument on the fact that oral cavity has a lot of microbes that can become pathogenic once there is a disruption of the integrity of the tissues and exposure of socket (Martin et al., 2000; SHEA, APIC, CDS, SIS Consensus Paper, 1992; Mangram et al., 1999; Pallasch and Slots, 1991; Lockhart and Schmidtke, 1994), while the opponents stated that antibiotics do not really permeate into the socket as a result of the thromboses of the microvasculature of the sockets (Palmer et al., 2000; Kaczmarzyk et al., 2007; Al-Rousan et al., 2011; Poeschl et al., 2004). However, these evidence based results and anecdotal reports in literature have not sufficiently proved the interaction of the use of antibiotics and other factors in the reduction of postoperative complications after extraction. The incidence of complications was 7.3% in our study and this was comparable to reports obtained from previous studies (Peterson, 1990; Piecuch et al., 1995; Hochwald et al., 1983). Similar to a retrospective study, there were more females in this study, with male to female ratio of 1 to 1.5 (Akinbami and Thikan, 2014).

Many authors do not support the indiscriminate administration of antibiotics routinely, since the incidence of postoperative infections is too low to justify such action

Dest such attendentie somelisetien	Evedentiat	Antibioti	Tatal		
Post-exodontia complication	Exodontist	Yes	No	- Iotai	
	Consultant	3 (1.1)	0 (0.0)	3 (1.1)	
	Registrar	68 (26.0)	41 (15.6)	109 (41.6)	
None	House officer	32 (12.2)	24 (9.2)	56 (21.4)	
	Student	48 (18.3)	27 (10.3)	75 (28.6)	
	Total	151 (57.6)	92 (35.1)	243 (92.7)	
	Registrar	2 (0.8)	0 (0.0)	2 (0.8)	
Poor healing	Student	1 (0.4)	0 (0.0)	1 (0.4)	
	Total	3 (1.1)	0 (0.0)	3 (1.1)	
Developt	Registrar	1 (0.4)	0 (0.0)	1 (0.4)	
Dry socket	Total	1 (0.4)	0 (0.0)	1 (0.4)	
	House officer	2 (0.8)	1 (0.4)	3 (1.1)	
Mild pain	Student	0 (0.0)	1 (0.4)	1 (0.4)	
	Total	2 (0.8)	2 (0.8)	4 (1.5)	
	Registrar	0 (0.0)	1 (0.4)	1 (0.4)	
Moderate pain	Student	0 (0.0)	1 (0.4)	1 (0.4)	
	Total	0 (0.0)	2 (0.8)	2 (0.8)	
	Consultant	0 (0.0)	1 (0.4)	1 (0.4)	
	House officer	1 (0.4)	2 (0.8)	3 (1.1)	
Severe pain	Student	1 (0.4)	0 (0.0)	1 (0.4)	
	Total	2 (0.8)	3 (1.1)	5 (1.9)	

Table 4. Relationship of post-operative complications and exodontist in both groups

Table 5. Univariate analysis of variance showing relationship of each variable with antibiotics and post-operative complication.

Deremeter	Adjusted R square -	Antibi	otics	Post operative complication	
Falameter		F value	Sig.	F value	Sig.
Age	0.007	1.672	0.192	2.282	0.132
Gender	0.001	2.188	0.140	0.034	0.854
Systemic disease	0.010	4.579	0.033	0.103	0.749
Difficulty of extraction	0.052	4.162	0.042	12.268	0.001
Type of extraction	0.054	4.386	0.037	12.689	0.000
Oral hygiene	0.033	10.377	0.001	0.558	0.456
Exodontist	-0.007	0.161	0.689	0.039	0.843
Duration of extraction	0.000	0.031	0.861	2.001	0.158
Mobility	-0.006	0.373	0.542	0.006	0.936
Post operative instruction	0.060	8.962	0.003	9.676	0.002

(Sisk et al., 1986; Schwartz and Larson, 2007; Worrall, 1998; Classen et al., 1992; Thomas and Hill, 1997). Although, the effective size of our outcome was not very high, our findings also support this view because there was also no statistically significant difference in the incidence of postoperative infections in our study.

Goldberg et al. (1985) documented that antibiotic prophylaxis was not useful in preventing postoperative infection. Curran et al. (1974) also concluded that antibiotic prophylaxis was not useful for the prevention of postoperative infection. Mitchell (1986) also reported no significant difference between the incidence of infection in

Post-exodontia		Standard	-16	Sig.	95% Confidence interval for exp(B)	
complication		error	ar		Lower bound	Upper bound
Severe pain	Post-operative instruction	0.000	1	-	3.597E-9	3.597E-9
	Antibiotic	1.493	1	0.186	0.007	2.595
Poor booling	Post-operative instruction	1.414	1	0.078	0.753	192.623
Poor healing	Antibiotic	0.000	1	-	7.680E7	7.680E7
Dry socket	Post-operative instruction	1.903	1	0.407	0.116	201.775
	Antibiotic	0.000	1	-	1.012E8	1.012E8
Mild pain	Post-operative instruction	1.326	1	0.596	0.150	27.148
	Antibiotic	1.546	1	0.529	0.018	7.822
Moderate pain	Post-operative instruction	3512.78	1	0.995	0.000	-
	Antibiotic	4831.90	1	0.997	0.000	-

Table 6. Mutinominal regression analysis of the association of post-operative instruction and antibiotics with individual complication.

the study and placebo groups.

Some laboratory markers of infection have been used to evaluate antibiotic prophylaxis for impacted third molars. The levels of C-reactive protein and alpha-1 antitrypsin pre-operatively and post-operatively were determined in patients who had either prophylactic antibiotics or placebos by Bulut et al. (2001). They concluded that antibiotic prophylaxis is not always indicated in patients who undergo surgery for the removal of third molars. Furthermore, Capuzzi et al. (1994) found no statistical difference with the assessment of pain and swelling when they compared postoperative amoxicillin for four days with no antibiotics in 146 patients and Monaco et al. (1999) in their study on the incidence of dry socket and antibiotics documented no significant difference between the group receiving amoxicillin and the group with no administration of antibiotics.

Ideally, prophylactic antibiotics are prescribed before a procedure and if needed, single additional dosages are given some hours after the procedure (Zeitler, 1995), but such guidelines could not be followed because of avoidance of delay of treatment and at times financial constrains. However, it has been stated that prophylactic antibiotics given beyond the perioperative period in other forms of 'clean-contaminated' surgery provided no additional benefit (Poeschl et al., 2004).

In another prospective, double blind, randomised, placebo-controlled clinical study by Sekhar et al. (2001) on 150 patients divided into 3 groups, the first group was given metronidazole 1 h before, the second group was given 400 mg of oral metronidazole eight-hourly for five days postoperatively and the third group was the placebo. Pain, swelling, trismus between days 1 and 6 postoperatively, and state of the wound were evaluated. They documented no significant differences in the outcome between the three groups and concluded that antimicrobial prophylaxis did not seem to reduce morbidity after removal of third molars.

In a 2012 Cochrane review (Lodi et al., 2012), the authors stated that although various prophylactic antibiotics were beneficial to a large extent in the reduction of postoperative infection and dry socket following third molar surgeries in healthy patients, side effects such as anaphylaxis and bacterial resistance observed in very few patients outweighs the benefits of the drugs. However, they recommended that even for patients who do not have rheumatic/congenital heart disease, immunosuppression and other systemic illnesses, antibiotic prophylaxis following minor/sub major surgeries should still be left to the discretion of the dentists.

The findings of Yoshii et al. (2002) and Piecuch et al. (1995) documented that antibiotics can be given as a prophylaxis for mandibular third molar surgery in healthy patients for 1 day, but their study was unable to detect post-operative complications in patients with no antibiotic prophylaxis since such group was not included in the comparison. Periodontal disease is usually the main cause of tooth mobility and quite a lot of mixed microbes are expected within the periodontal pockets (Yoshii et al., 2002; Piecuch et al., 1995; Marciani, 1992) and extraction sockets of such teeth (Barclay, 1987; Kaziro, 1984). In our study, the incidence of complication with such tooth was quite low even without antibiotics prescriptions.

Our choice of combination therapy and regimen was appropriate because of strict anaerobes which are part of the constituents of the oral flora and are resistant to only amoxicillin. In addition to the poor oral hygiene maintenance of our patients and low level of compliance to instructions, amoxicillin and metronidazole were used mostly because of mixed microbes which are susceptible to these combination antibiotics. Amoxicillin and other broad spectrum antibiotics have been found to improve the redox potential that enhances the elimination of anaerobes, but some obligate anaerobes still remain especially in debris filled extraction sockets.

In our study, no side effect of the antibiotics was observed, probably because of the non-allergic and minimal gastric irritation effects of amoxicillin as well as emphasis on the use of metronidazole after food (Mac Gregor and Addy, 1980). Despite our findings which corroborate some previous studies, it was opined that prophylactic antibiotics should be used in healthy patients with poor oral hygiene.

With the advent of Clindamycin, a single therapy antibiotic prophylaxis has become more effective in the prevention of multidrug resistance, post-operative complications and infective endocarditis, because of better penetration into bone and sloughs, but the risk of necrotizing enterocolitis still remain in some patients (Chapnick and Diamond, 1992).

Systematic reviews have proved that chlorhexidine (0.12 or 0.2%) rinses or gel (0.2%) in the sockets of extracted teeth minimized dry socket and such local antimicrobial agents have reduced the risk of anaphylaxis and antibiotic resistance encountered with systemic antibiotics especially the peniccillins (Shepherd, 2005). However, the use of surgical gauze pack has been found to increase the incidence (Alexander, 2000).

There was an association of three factors with occurrence of post operative complication and these included the type of extraction (routine or surgical), difficulty of extraction and compliance to post operative instructions (particularly use of warm sail mouth bath) between the two groups. Other factors did not show any association individually, but interplay or influence of multiple factor effects must be considered when taking ultimate decisions.

In conclusion, our study showed that routine antibiotic use was not very necessary following all exodontias procedures and, factors such as status of oral hygiene, type of extraction, difficulty of extraction and adherence to postoperative instructions were very important factors that determined the occurrence of postoperative complications. The combination of non traumatic procedure and adequate instruction compliance without antibiotics will eradicate postoperative complication especially in routine extractions.

#### **Conflict of Interest**

The authors hereby declare that no conflict of interest exist with regard to this manuscript.

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