Original Article

Impact of Oral Antibiotics on Health-related Quality of life after Mandibular Third Molar Surgery: An Observational Study

RO Braimah, KC Ndukwe[1], JF Owotade[1], SB Aregbesola[1]

Department of Dental and Maxillofacial Surgery, Usmanu Danfodio University Teaching Hospital, Sokoto, [1]Department of Oral and Maxillofacial Surgery and Oral Pathology, Obafemi Awolowo University Teaching Hospitals Complex, Ile-Ife, Osun State, Nigeria

Abstract

Aim: To compare the impact of antibiotics on health-related quality of life (QoL) outcomes following third molar surgery. **Materials and Methods:** The study population consisted of 135 subjects that required surgical extraction of mandibular third molar under local anesthesia and met the inclusion criteria. The subjects were randomized into three study groups of 45 subjects each: Group A - extended amoxicillin/clavulanic acid (GlaxoSmithKline Beecham England), 1 gram pre-operatively and then 625 mg BD for 5 days Group B - prophylactic amoxicillin/clavulanic acid (GlaxoSmithKline Beecham England) 1 gram pre-operatively only, and Group C - prophylactic levofloxacin 1 gram pre-operatively only. Patients were assessed pre- and post-operatively on days 1, 3, 5, 7, and 14 using the United Kingdom oral health-related QoL (OHRQoL) questionnaire. **Results:** This study showed that surgical removal of impacted teeth exerted a negative influence on patient's QoL across various physical, social, and psychological aspects of life. Comparing the three groups, Group A showed a slightly better QoL score; although, there was no statistically significant difference among them. Studies have shown better clinical recovery following administration of antibiotics after third molar surgery. **Conclusion:** There was a significant deterioration in OHRQoL in the immediate postoperative period, particularly postoperative days 1 and 3 following third molar surgery. QoL was also observed to be slightly better in Group A than Groups B and C, although this was not statistically significant.

Keywords: *Amoxicillin/clavulanic acid, antibiotic prophylaxis, levofloxacin, quality of life, third molar surgery*

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Introduction

The impact of oral diseases and oral procedures on quality of life (QoL) is very obvious following third molar surgery.[1] Problems created by the disturbances in postextraction wound healing and physiologic sequelae of third molar surgery can significantly affect the patient's QoL.[1,2] Before consenting to surgery, patients are informed of the risks and benefits of having their third molars removed. Most of the information available to both clinicians and patients focuses on clinical outcomes.[3] Although this information is important, patients want to know about the surgical procedure and expectations during recovery. Interestingly, there has been increasing calls for greater understanding of the effects of third molar removal on patients' day-to-day living, as there are few such studies published.[4]

It is important to understand levels of presurgical morbidity typically experienced by patients so that clinicians can inform patients about the types of expected impacts on daily life if patients have symptoms and choose to forego or delay treatment. Furthermore, the severity of any presurgical morbidity may help

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Address for correspondence: Dr. RO Braimah, Department of Dental and Maxillofacial Surgery, Usmanu Danfodio University Teaching Hospital, Sokoto, Nigeria. E-mail: robdeji@yahoo.com

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clinicians and patients select treatment alternatives in circumstances where clinical indicators alone do not provide clear-cut information of whether to proceed with surgery. For example, patients whose QoL is adversely affected by presurgical conditions may elect to have surgery, even when clinical criteria suggest that surgery and conservative management could be equally effective. Finally, if there is additional information about the impact of the surgery on QoL, clinicians can advise patients about the expected levels of morbidity that can be anticipated during recovery relative to their presurgical morbidity.

The topic of preventive antibiotic administration in third molar surgery in healthy individuals is still controversial; some authors have reported the need for such method.[5-9] Other authors have reported a lack of efficacy.[10,11] Merits of the appropriate use of prophylactic antibiotic include; reduction in the incidence of transient bacteremia thereby reducing postoperative patient morbidity, promptness to resume work, reduced cost of returning to the dentist, and cost effectiveness regarding buying less drugs.[12] It also reduces the total amount of antibiotics to be consumed by the population thereby minimizing the development of bacteria resistance.

More recently, a Cochrane review on the use of antibiotics in third molar removal concluded that antibiotics may be beneficial following removal of the third molar in diseased gum and severely decayed tooth.[13]

The purpose of this study was to examine the impact of oral antibiotics administered as single dose preoperative regimen and extended dose regimen using a fluoroquinolone (levofloxacin) and amoxicillin/clavulanic acid on oral health-related QoL (OHRQoL) in otherwise healthy patients.

Materials and Methods

This is an observational study conducted in the Department of Oral and Maxillofacial Surgery, Obafemi Awolowo University Teaching Hospitals Complex, Ile-Ife, Osun State, Nigeria between May 2011 and February 2012. A total of 135 healthy patients, 18–35 years old, volunteered with a written document to partake in the study. The criterion for including a patient in the study was an otherwise healthy subject that presented in the Oral and Maxillofacial Surgery Clinic for the surgical extraction of an impacted lower third molar tooth under local anesthesia. The study was conducted in accordance with good clinical practice and declaration of Helsinki as amended in Somerset West, Republic of South Africa, in 1996. The protocol was approved by the hospital ethics committee, and written, dated, informed consent was obtained from all patients before study entry. Exclusion criteria included subjects with history suggestive of underlying systemic diseases, e.g., diabetes mellitus, congestive cardiac failures, chronic nephritis, chronic liver disease, systemic malignancy, sickle cell disease, presence of acute pericoronal infection, subjects that are immune-compromised, subjects that require antibiotic prophylaxis for endocarditis, subjects with history of allergy to Penicillin and fluoroquinolone, subjects with dyspeptic symptoms or who are being treated for peptic or duodenal ulcer disease, pregnant subjects and breastfeeding mothers.

Study design

One hundred and thirty-five opaque brown and sequentially numbered envelops were used for the concealment of allocation to study groups. The three medications were designated Groups A, B, and C by an independent observer without the knowledge of the investigator. Each medication was labeled with a medication code number according to the allocation sequence that was generated online before the commencement of the study.[14] The three groups of envelopes were arranged according to the allocation sequence that was generated online and kept in the custody of an independent observer (registrar) who also dispensed the drugs to the subjects.

Eligible patients were divided into three groups of 45 patients each to receive one of the following three regimens.

1. Group A (extended amoxicillin/clavulanic acid [GlaxoSmithKline Beecham England]), 875 mg/125 mg in a single dose 1 h before surgery and after that 500/125 mg amoxicillin/clavulanic acid (GlaxoSmithKline Beecham England) 12 hourly for 5 days
2. Group B (Prophylactic Amoxicillin/clavulanic acid [GlaxoSmithKline Beecham England]), 875 mg/125 mg in a single dose 1 h before surgery
3. Group C (prophylactic levofloxacin (ATOZ Pharmaceuticals Pvt Ltd., India): 1000 mg levofloxacin in a single dose 1 h before surgery.

The subjects QoL was assessed preoperatively using the 16 item United Kingdom OHRQoL measure (UK-OHRQoL).[15]

All patients were placed on the same analgesic (tabs ibuprofen 400 mg 8 hourly for 3 days). Patients

were instructed not to take any other medication except the ones provided. All surgery was performed by the same surgeon using a standardized procedure under local anesthesia (2% lignocaine with 1:100,000 adrenaline).

Evaluation criteria

A review appointment was scheduled for postoperative days (PODs) 1, 3, 5, 7, and 14. On each of these days subjects were asked to complete the questionnaire (UK-O HRQoL).[15] Each item was scored: Very bad effect-score – 1, Bad effect-score – 2, No effect-score – 3, Good effect-score – 4, Very good effect-score – 5. Total scores range from 16 to 80. A lower score indicates poorer QoL. Domain scores were presented in the result.

Statistical analysis

Data analysis was carried out using Stata 10 (Statacorp College Station, Texas, USA). Descriptive statistics was carried out for sociodemographic variables. For descriptive variables that are categorical, simple frequency, and percentages were determined. Statistical analysis was performed using intention-to-treat analysis.[16] The psychometric properties of the UK-OHRQoL instrument were evaluated using internal reliability (Cronbachs' α). The effect of the intervention was determined using analysis of variance (ANOVA). Statistical significance was inferred at $P < 0.05$.

Results

Cronbach's α were calculated for all the domains of the UK-OHRQoL instrument, and high values were obtained. For the symptom level domain, it was 0.89, for the body function level domain it was 0.81, for the personality level domain, it was 0.82, and for the social function level domain, it was 0.81.

The number of patients assessed at each study visit is shown in Table 1. The patients' age and the sex distributions are listed in Table 2 whereas the preoperative clinical status is shown in Table 3. Table 4 shows the distribution of mean QoL score according to domains from POD through the postoperative review periods. There was statistically significant difference in the symptom level domain on POD 1 ($P = 0.016$; ANOVA).

Table 5 shows the distribution of mean QoL scores in patients groups at preoperative and PODs. The mean QoL was worst among the groups on POD 1, but this gradually returned to the preoperative level by day 3. On POD 14, Qol was better as compared to preoperative value. Subjects in Group C had the least mean QoL on POD 1 (41.1 ± 4.5) whereas those in Group A had the least mean QoL (44.1 ± 4.6) on the POD 3. On POD 14, subjects in Group A had the best QoL (48 ± 4.6) although no statistically significant difference was observed ($P = 0.77$; ANOVA).

Table 1: Patients assessed at each visit

	Patient groups, *n* (%)		
	Group A	Group B	Group C
Day 0 (surgery)	45 (100.0)	45 (100.0)	45 (100.0)
Day 1	45 (100.0)	45 (100.0)	45 (100.0)
Day 3	42 (93.3)	45 (100.0)	45 (100.0)
Day 5	44 (97.8)	44 (97.8)	44 (97.8)
Day 7	45 (100.0)	44 (97.8)	43 (95.6)
Day 14	31 (68.9)	31 (68.9)	29 (64.4)

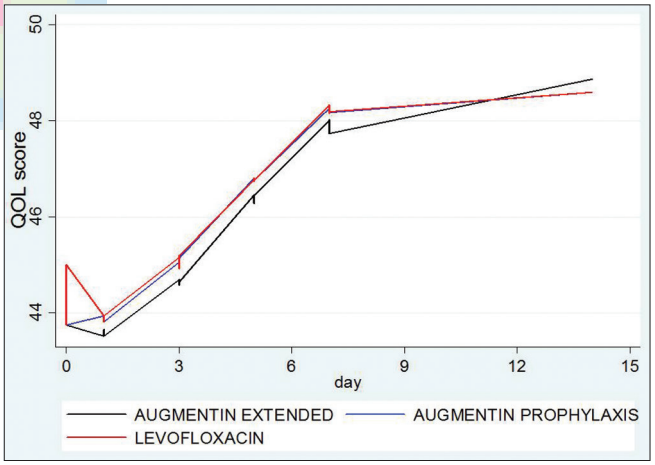

Figure 1: Plot showing trend in quality of life over time

Table 2: Sex distribution by mean age of patients in the groups

Sex	Patient groups								
	Group A			Group B			Group C		
	Frequency (%)	Age range	Mean±SD (years)	Frequency (%)	Age range	Mean±SD (years)	Frequency (%)	Age range	Mean±SD (years)
Female	26 (57.8)	18-35	23.9±4.8	21 (46.7)	19-35	23.7±5.4	25 (55.6)	18-35	25.7±5.9
Male	19 (42.2)	18-35	27.7±5.7	24 (53.3)	19-31	23.7±3.3	20 (44.4)	18-35	24.5±4.2
Total	45 (100)	18-35	25.5±5.5	45 (100)	19-35	23.7±4.3	45 (100)	18-35	25.2±5.2

SD=Standard deviation

Table 3: Distribution of preoperative clinical status among patient groups

Preoperative clinical status	Patient groups, frequency (%)			Total
	Group A	Group B	Group C	
Indications for extraction				
Pericoronitis	35 (77.8)	32 (71.1)	33 (73.3)	100 (74.1)
Apical periodontitis	10 (22.2)	13 (28.9)	12 (26.7)	35 (25.9)
Impaction type				
Mesioangular	24 (53.3)	19 (42.2)	27 (60.0)	70 (51.9)
Distoangular	13 (28.9)	14 (31.2)	2 (4.4)	29 (21.4)
Vertical	5 (11.1)	6 (13.3)	8 (17.8)	19 (14.1)
Horizontal	3 (6.7)	6 (13.3)	8 (17.8)	17 (12.6)
Associated pathology				
No pathology	16 (35.6)	20 (44.4)	11 (24.4)	47 (34.8)
Pocket	10 (22.2)	9 (20.0)	13 (28.9)	32 (23.7)
Pocket + caries	15 (33.3)	10 (22.2)	12 (26.7)	37 (27.4)
Caries + periapical cyst	3 (6.7)	3 (6.7)	3 (6.7)	9 (6.7)
Caries+periapical cyst + pocket	1 (2.2)	3 (6.7)	6 (13.3)	10 (7.4)

Table 4: Distribution of mean quality of life score domains in patient groups at pre- and post-operative days

Quality of life at pre- and post-operative days	Performance score (mean±SD)			*P*
	Group A	Group B	Group C	
Preoperative				
Symptom level	5.3±1.0	5.3±0.9	5.5±1.0	0.6657
Body function level	13.8±1.8	14.2±1.4	14.0±1.6	0.6571
Personality level	14.3±1.7	13.3±1.6	14.0±1.7	0.6571
Social level	11.4±1.2	11.6±1.3	11.2±1.3	0.5008
Postoperative day 1				
Symptom level	5.1±0.9	5.5±1.0	4.9±0.7	0.0155*
Body function level	11.9±1.9	11.9±1.8	11.9±1.7	1.0000
Personality level	13.2±1.5	14.2±1.2	13.6±1.8	0.1645
Social level	11.2±1.2	11.2±1.1	10.7±1.3	0.0858
Postoperative day 3				
Symptom level	5.6±0.8	5.8±0.7	5.8±0.8	0.2967
Body function level	13.2±2.1	13.5±1.8	13.4±1.9	0.7565
Personality level	14.4±1.6	14.9±0.6	14.7±1.5	0.1762
Social level	11.3±1.5	11.6±0.9	11.5±1.5	0.5022
Postoperative day 5				
Symptom level	5.8±0.2	5.5±0.8	6.1±0.6	0.2060
Body function level	14.4±1.1	14.9±1.4	14.7±0.9	0.1736
Personality level	14.9±0.4	15.2±1.0	15.0±0.9	0.1673
Social level	11.7±1.1	12.1±0.7	11.8±1.1	0.2237
Postoperative day 7				
Symptom level	5.9±0.5	6.2±0.7	6.0±0.7	0.1772
Body function level	14.8±1.1	15.2±1.5	14.7±0.9	0.1458
Personality level	15.0±0.7	15.2±1.5	15.0±0.9	0.6966
Social level	12.0±0.5	12.2±1.2	12.0±0.8	0.5230
Postoperative day 14				
Symptom level	6.1±0.5	6.1±0.4	6.2±0.5	0.4806
Body function level	15.3±1.2	15.2±0.9	15.2±0.9	0.7944
Personality level	15.3±1.1	15.2±0.9	16.0±5.6	0.5390
Social level	12.1±0.7	12.1±0.7	12.0±0.0	0.6282

*Statistically significant. SD=Standard deviation

Table 5: Distribution of mean quality of life scores in patients groups at pre- and post-operative days

Pre- and post-operative days	Quality of life scores (mean±SD)			
	Group A	Group B	Group C	*P*
Preoperative	44.8±4.9	45.4±4.7	44.8±5.0	0.841
Postoperative day 1	41.8±4.7	42.5±4.5	41.2±4.5	0.399
Postoperative day 3	44.1±4.6	46.1±3.3	45.3±5.4	0.135
Postoperative day 5	47.4±3.3	47.6±3.1	47.6±2.6	0.699
Postoperative day 7	47.6±1.6	48.6±5.0	47.8±2.9	0.343
Postoperative day 14	48.9±3.4	48.5±2.9	48.4±1.3	0.769

SD=Standard deviation

Discussion

QoL has been considered a vague and ethereal concept. However, the importance of the subjective perception of the subjects on their own health status, measured with instruments (questionnaires) that require validation before use, has been increasingly recognized.[15] Clinical researchers began, gradually to include this type of study in clinical trials and the follow-up of subjects. Recovery for health-related QoL (HRQoL) measures includes subjects' perception of recovery, which in turn includes a return to a usual lifestyle and recovery of oral function.[15]

Clinical experience shows that subjects experience certain difficulties following removal of impacted third molar teeth. However, in the past, there was a lack of data recording changes in aspects that may influence the QoL, but now, QoL assessment is regarded as an essential component for assessing outcomes.[17] Although different methods have been used to assess QoL, it can be difficult to measure as it may mean different things to different people. Thus, such measures are subjective and multidimensional.[18] Other factors such as gender,

analgesic use, and duration of surgery can also affect QoL after third molar surgery.[19] However, the main focus of the current study is the influence of oral antibiotics on QoL after third molar extraction. Studies on the effect of these variables on QoL are paramount, especially in sub-Saharan Africa were such studies are still scarce.

Results from this study showed that the surgical removal of impacted teeth exerted a negative influence on patient's QoL across various physical, social, and psychological aspects of life such as limitation in daily routine, ability to chew food, ability to open mouth, ability to speak, comfort, laughing and smiling and sleep. A significant deterioration was seen among the three groups on POD 1 at the symptom level ($P < 0.0155$) as measured by oral health QoL-UK (OHQoL-UK-16) scores [Table 4]. This domain (symptom level) which comprised comfort and breath odor showed a significant difference among the three groups with regard to comfort after third molar surgery. Similar to this study, McGrath *et al*.[20] showed deterioration in QoL in the immediate postoperative period following third molar surgery as measured by Oral Health Impact Profile-14 scores and OHQoL-UK-16. Furthermore, White *et al*.[21] reported that the median number of days required to return to daily activity and social life after third molar surgery was 3 days with recovery for chewing and return to regular diet taking 5–7 days respectively.[21] Colorado-Bonnin *et al*.[19] also concluded that lower third molar surgery significantly influences patient's QoL, especially during the first 3 days of the postoperative period. Observations from this study are similar to previous studies as subject recovery started by POD3 as evident by Mean QoL returning to the preoperative period after third molar removal in the three groups and by POD7 mean QoL has increased more than the preoperative period [Table 5].

Comparing the three groups, the Augmentin (GlaxoSmithKline Beecham England) extended group showed a slightly better QoL; although, there was no statistically significant difference among the three groups [Figure 1]. This finding could not be explained, however in a study comparing the efficacy of amoxicillin treatment in preventing postoperative complications in patients undergoing third molar extraction, better recovery of subjects were observed in the extended group.[22] Furthermore, in a study on the impact of intravenous antibiotics on HRQoL outcomes and clinical recovery after third molar surgery in 116 subjects, Foy *et al*.,[23] noticed that incidence of delayed clinical recovery was higher in the group without antibiotics (28% of 60 subjects) as compared with the group that had antibiotics (4% of 56 subjects). They concluded that administration of intravenous antibiotics before third molar surgery might improve clinical recovery in healthy adult patients.

The findings in this study could not be compared to any local study as none of such comparative study on QoL after third molar surgery was found in Nigeria and sub-Saharan Africa. This study which observed that QoL was severely compromised, especially in the first three PODs after mandibular third molar surgery could serve as baseline data from this part of the world. However, further studies from other centers are needed to validate these results.

Conclusion

There was a significant deterioration in QoL in the immediate postoperative period particularly POD 1 and 3 following third molar surgery, which slowly returned to preoperative level by the 7th day. QoL was also observed to be slightly better in the amoxicillin/clavulanic extended group than the single bolus levofloxacin and amoxicillin/clavulanic groups; although, this was not statistically significant and would still need further research.

Patients undergoing mandibular third molar extraction should be adequately informed of the possible sequelae of the procedure on their QoL, especially in the immediate postoperative period to know what to expect and how to cope with such when they arise.

The limitation of this study is that placebo-controlled may have aided comparison of the effects of the antibiotics on the QoL after third molar extraction; however, this was not ethically possible as supported by the 2013 Cochrane review of antibiotic prophylaxis after the third molar extraction in the diseased environment.

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Conflicts of interest

There are no conflicts of interest.

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