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Original Research

Comparison of the effectiveness of pain control with two regimens of acetaminophen following uncomplicated intra-alveolar extraction Olawole W.O[1], Okoje V.N[1], Ibikunle A.A[2], Arotiba J.T[1]

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ABSTRACT

Paracetamol is a frequently prescribed drug for post-extraction pain control. However, the optimum regimen to be prescribed remains controversial. Thus, a need to determine the efficacy of commonly prescribed regimens arises. This study compared the effectiveness of post-extraction pain control using two regimens of paracetamol. Subjects were randomly distributed into two groups; subjects in group A had postoperative oral administration of acetaminophen 1 g 2 h after the extraction and then 1 g every 8 h for 24 h, while subjects in group B had extended postoperative oral administration of acetaminophen. Thereafter, subjects recorded their postoperative pain experiences. Data were analyzed using IBM SPSS Statistics for Windows version 20. Level of statistical significance was set at $P < 0.05$. Data from 200 subjects were analyzed. An overall male/female ratio of 1:1.2 and a mean (± SD) age of 44.27 (16.09) years were observed. A comparison of pain experience between groups at all evaluation points revealed no statistically significant difference ($p > 0.05$). Also, the type and number of teeth extracted exerted no statistically significant influence on pain experience ($p > 0.05$). There was no significant difference between the effectiveness of post-extraction pain control using the two paracetamol regimens. Therefore, extended administration of paracetamol may be unwarranted.

1. Introduction

Routine extraction is one of the most commonly performed procedures in dental clinics worldwide [1,2]. This is particularly true in our climes where patients often present with advanced dental diseases that necessitate extraction [1]. Routine extraction of teeth is often associated with some degree of damage to both hard and soft tissues. Consequently, patients often experience pain of varying intensities postoperatively. Pain experience among patients who have had intra-alveolar extraction of teeth typically commences a few hours post-operatively, corresponding to the waning action of local anaesthesia and may last for as long as seven days, thus impacting negatively on patients' postoperative quality of life [3–5].

The advantageous effects of the peri-operative use of analgesics following routine extraction are well documented in the literature [3,6]. Acetaminophen is one of the most frequently used analgesics for post extraction pain control [7–9]. Its popularity is related to its availability, wide safety margin, tolerability by peptic ulcer patients, comparatively low cost and relatively rare side effects [10–12]. While there is reasonable consensus on the effectiveness of Acetaminophen as an effective post-extraction analgesic, there is some controversy about the most effective regimen advisable [12,13]. Some authors support the prescription of analgesics for only 24 h, while others are in support of a more prolonged use.

The prescription protocol of Acetaminophen for post-extraction analgesia remains equivocal [12–14]. It is therefore imperative to evaluate the adequacy of different regimens of Acetaminophen with a view to proposing a standard protocol for its use following routine dental extractions.

2. Materials and methods

This is a prospective randomized study done at the exodontia clinic of our hospital. Ethical approval was obtained from the Ethical Review

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Committee of the hospital (UI/EC/11/0157). The sample size for this study was calculated by using the formula $N = (Z\alpha + Z\beta)^2 [P_1(1-p_1) + P_2(1-p_2)] / (P_1-P_2)^2$.

In the formula above the following abbreviations were used:

N = sample size

$Z\alpha$ = standard normal deviate corresponding to 5% level of significance = 1.96

Z_β = standard deviation corresponding to power of 80% = 0.84

P_1 = proportion with effective pain control in the control group = 88% (prevalence)

P_2 = proportion with effective pain control in the experimental group = 88% + 10% = 98%

This translated into: $N = (Z\alpha + Z\beta)^2 [P_1(1-p_1) + P_2(1-p_2)] / (P_1-P_2)^2$

$= (1.96 + 0.84)^2 [0.88(1-0.88) + 0.98(1-0.98)] / (0.98-0.88)^2 =$ 98 per group.

Assuming 10% non response rate, each group would have 108 subjects

Therefore, a total of 216 subjects were recruited into the study.

Subjects included persons who were at least 18 years of age, required intra-alveolar dental extractions, ASA I and subsequently had uncomplicated extractions. Patients with teeth requiring surgical tooth removal, cognitive problems and those with underlying systemic diseases such as hypertension, diabetes, sickle cell disease etc, were excluded. Furthermore, cigarette smokers, patients on antibiotics and/or steroid therapy, patients with odontogenic abscesses or grossly mobile teeth (grade II or III) and those with difficult extractions were excluded. A difficult extraction was classified as one which required an extraction time of greater than 5 min. Also excluded were patients who had intraoperative complications such as fractured roots and/or crowns, alveolus etc. Informed consent was obtained from all participants.

Consenting subjects were randomly assigned to two groups (groups A and B) using a computer generated table of random numbers using a computer soft ware – Winpepi version 11.4. Allocation of subjects into groups was done by a trained nurse who was not directly involved in other aspects of this study. Subjects in group A had postoperative oral administration of acetaminophen 1 g 2 h immediately after the extraction and then 1 g every 8 h for 24 h, which was to be commenced 8 h after the first dose. Subjects in group B had postoperatively administered oral tablets of acetaminophen 1 g two hours immediately after the extraction and then 1 g every 8 h for 3 days (9 doses) to be commenced 8 h after the first dose.

Data collected included Biodata, occupation, duration of extraction and the type and number of teeth extracted.

All extractions were performed under local anaesthesia (2% Xylocaine in 1: 100,000 adrenaline of the same brand, batch number and expiring date) with forceps and/or elevators as required. The extractions were all performed by the researcher and two senior residents of comparable skills and experience between the hours of 8:00h and 12:00h. The duration of extraction was defined as the period between forceps or elevator application till the time of tooth delivery. The durations of extractions were recorded by a trained assistant using a stop-watch.

The Acetaminophen tablets used were from the same manufacturer and the same batch. Subjects were instructed to report back to the hospital or call specific phone numbers in case of any complications or if they required any clarifications.

Subjects were instructed to record their postoperative pain experience at 8 a.m., 2 pm and 8 pm in the Pain Intensity Forms (PIFs) on postoperative days 0 (day of extraction), 1, 2, 3 and 7. Reminders in form of text messages were sent to all subjects 10 min before the due time of recording their pain experiences. Subjects were reviewed on postoperative days 2 and 3. Subjects who developed complications were managed in accordance with the hospital protocol specific to their complaints and/or diagnoses. Subjects who complained of pain after completing their regimen were prescribed further dosages as required, while those whose pain experience was not amenable to Acetaminophen were prescribed appropriate analgesics and also excluded from the study. The PIFs were retrieved on the 7th postoperative day from all subjects who fulfilled the requirements.

The primary outcome was defined as the difference in pain experience between subjects in groups A and B during the 7 days immediately succeeding the operative day.

Data was analyzed using the SPSS version 17. Descriptive statistics such as frequency counts, percentages, mean and standard deviation were utilized. Comparison of mean values for continuous variables was done using t-test, while categorical variables were compared using Chi square. Fisher's exact test was used instead of X^2 where more than 25% of the cells had expected count < 5 and where observed value was zero in many of the cells. Statistical tests for associations between pain experience and variables such as age, gender, type of teeth and number of teeth extracted were done. Subjects were dichotomized into those aged less than 45 years and those aged 45 years and above. Logistic regression analysis was carried out to probe further the association between the independent variables and pain intensity. Level of statistical significance was set at 5%.

3. Results

Two hundred and sixteen subjects who had two hundred and thirty (230) extractions participated in this study. However, 200 subjects who had 212 teeth extracted participated in all phases of this study and were included in the final analysis. Overall, 92 (46%) males and 108 (54%) females had their data analyzed, giving a male/female ratio of 1:1.2. The group specific male to female ratios were 1:1.1 [47 males/51 females] and 1:1.2 [45 males/57 females] for groups A and B respectively. The overall mean age (± SD) was 44.27 (16.09). The mean age (± SD) was 48.48 (± 17.31) and 43.53 (± 14.03) years for groups A and B respectively. No statistically significant difference was observed between the two groups in relation to the age and gender distributions ($p > 0.05$).

The lower molars and premolars accounted for the greatest proportion of teeth extracted in this study 110 (55.0%); with groups A and B subjects accounting for 57 (58.2%) and 53 (52.9%) of all the posterior teeth extractions respectively. Notably, lower anterior teeth (incisors and canines) constituted the lowest proportion of extracted teeth, with groups A and B representing 4 (2%) and 1 (0.5%) correspondingly. A comparison of the groups based on the number of teeth extracted per visit showed no statistically significant difference ($p > 0.05$).

On day 0, 58 (59.2%) of the subjects in group A reported mild pain intensity, while 10 (10.2%) subjects reported moderate pain experience (Fig. 1). In the experimental group, 63 (61.8%) and 12 (11.7%) of the participants reported mild and moderate pain experience, respectively (Fig. 1). A comparison of pain experience reports among subjects in each group revealed no statistically significant difference ($X^2 = 0.467$, $p = 0.792$).

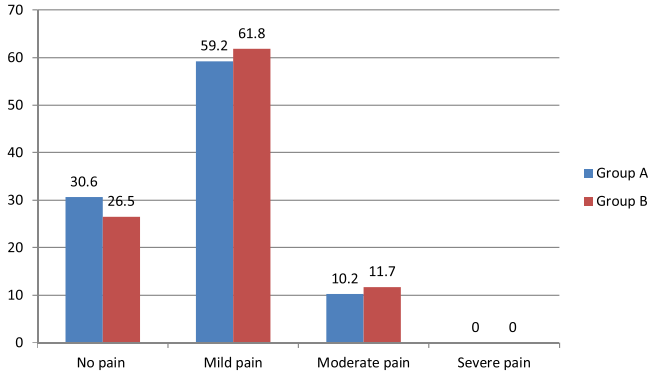

Fig. 1. Pain intensity among patients in groups A and B on POD 0.

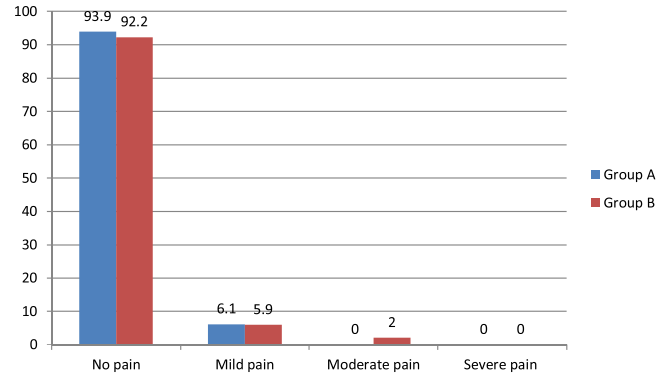

Fig. 2. Pain intensity among patients in groups A and B on POD 1.

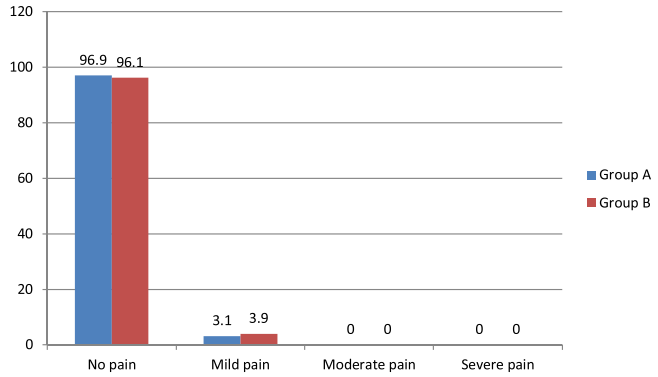

Fig. 4. Pain intensity among patients in groups A and B on POD 3.

By evening of the first postoperative day (32–36 h) 6 (6.1%) subjects in the group A had mild pain experience, while none of them reported moderate or severe pain (Fig. 2). At the same postoperative evaluation point (32–36 h postoperatively), 6 (5.9%) and 2 (2.0%) subjects in the experimental group had mild and moderate pain intensity respectively (Fig. 2). A comparison of the pain experience among subjects in the groups was not statistically significant (P = 0.620).

By evening of the second postoperative day (56–60 h post extraction), only 6 (6.1%) and 5 (4.9%) subjects had mild pain experiences in groups A and B respectively (X^2 = 0.143, p = 0.705) (Fig. 3). None of the subjects reported moderate or severe pain.

On the third postoperative day pain assessments done between 68–72 h, showed that only 3 (3.1%) and 4 (3.9%) subjects still experienced mild pain intensity in the control and experimental groups respectively (Fig. 4). A comparison of the proportions between the two groups showed no statistically significant difference (P = 0.741) (Table 1). By the third postoperative day evaluation, 95 (96.9%) subjects in group A had effective pain control and 98 (96.1%) subjects in group B had effective pain control (P = 0.999) (Fig. 4 and Table 1).

An assessment of the pain experience among subjects at the completion of analgesics by the evening of day 1 for the subjects in group A and the morning of day 3 for subjects in group B showed that 92 (93.9%) of the subjects in group A had effective pain control while 98 (96.1%) of the subjects in group B had effective pain control (Table 2). Though the proportions differ, a comparison of the effectiveness of pain control between subjects in the two groups was not statistically significant (P = 0.531).

Six (6.1%) subjects in group A and 4 (3.9%) subjects in group B required additional analgesia during the postoperative period. A comparison of the proportions of subjects who required additional analgesia between the two groups was not statistically significant (p = 0.531). Overall, most of the subjects were satisfied with postoperative pain control by the time of completion of prescribed analgesics (i.e POD 1 for patients in group A and POD 3 for patients in group B (Table 3). No

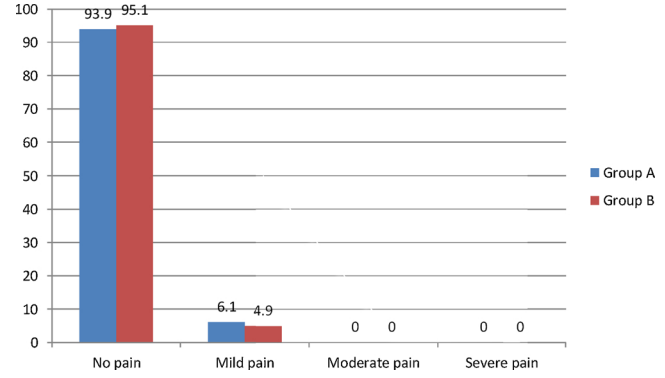

Fig. 3. Pain intensity among patients in groups A and B on POD 2.

Table 1
Comparison of the effectiveness of pain control between groups A and B from POD 0, to POD 3 following tooth extraction.

Effectiveness of pain control		Group A frequency (%)	Group B frequency (%)	P value
Day 0	Effective	30 (30.6)	27 (26.5)	0.517
	Not effective	68 (69.4)	75 (73.5)	
Day 1	Effective	92 (93.9)	94 (92.2)	0.634
	Not effective	6 (6.1)	8 (7.8)	
Day 2	Effective	92 (93.9)	97 (95.1)	0.705
	Not effective	6 (6.1)	5 (4.9)	
Day 3	Effective	95 (96.9)	98 (96.1)	0.999*
	Not effective	3 (3.1)	4 (3.9)	

* Fischer's exact.

Table 2
Comparison of the effectiveness of pain control between subjects in group A and B at the completion of analgesics.

	Group A frequency (%)	Group B frequency (%)	Total frequency (%)	P value
Effective	92 (93.9)	98 (96.1)	190 (95)	0.531*
Not effective	6 (6.1)	4 (3.9)	10 (5)	
Total	**98 (100)**	**102 (100)**	**200 (100)**	

Fisher's exact *.

Table 3
Comparison of the levels of satisfaction between both groups.

	Group A frequency (%)	Group B frequency (%)	Total frequency (%)	P value
Not satisfied	8 (8.2)	5 (4.9)	13 (6.5)	0.875
Satisfied	90 (91.8)	97 (95.1)	187 (93.5)	0.350
Total	**98 (100)**	**102 (100)**	**200 (100)**	

statistically significant difference was observed in this regard between the two groups (P > 0.05).

By the evening of day 0, 12 (25.0%) and 18 (36.0%) subjects below 45 and ≥ 45 years respectively, reported no pain in the group A, while 36 (75.0%) and 32 (64.0%) subjects below 45 and ≥ 45 years respectively, reported pain (p = 0.238). In the experimental group, 18 (29.5%) and 9 (22.0%) subjects below 45 and ≥ 45 years respectively, reported no pain on day 0, while 43 (70.5%) and 32 (78.0%) subjects below 45 and ≥ 45 years respectively, reported pain (p = 0.396). Six (6.1%) participants in group A and 4 (3.9%) in group B took additional analgesia for pain control. A comparison of these figures between the two groups was not statistically significant (P = 0.531).

A comparison of the type of tooth extracted and the intensity of postoperative pain experience among subjects in each group showed no

Table 4
A comparison of effect of type of teeth extracted on pain intensity between groups A and B on day 0.

Type of teeth extracted	Group A			Group B		
	No pain Frequency (%)	Pain present Frequency (%)	Total Frequency (%)	No pain Frequency (%)	Pain present Frequency (%)	Total Frequency (%)
Upper anterior	2 (28.6)	5 (71.4)	7 (100)	3 (33.3)	6 (66.7)	9 (100)
Upper posterior	10 (33.3)	20 (66.7)	30 (100)	11 (28.2)	28 (71.8)	39 (100)
Lower anterior	0 (0.0)	4 (100)	4 (100)	1 (100)	0 (0.0)	1 (100)
Lower posterior	18 (31.6)	39 (68.4)	57 (100)	12 (22.6)	41 (77.4)	53 (100)
Total	30 (30.6)	68 (69.4)	98 (100)	27 (26.5)	75 (73.5)	102 (100)
			P = 0.727*			P = 0.384*

(*fisher's exact).

statistically significant difference between the groups (P = 0.384) (Table 4). Also, a comparison within the groups based on the number of teeth extracted per visit showed no statistically significant difference (Group A, *P = 0.567*; Group B, *P = 0.564*).

4. Discussion

Not enough attention has been given to post-operative pain experience after simple exodontia despite the fact that it is one of the most commonly performed surgical procedures in Oral Surgery Clinics [14]. Many of the existing studies on post-extraction pain are focused on patients who have had surgical extractions [15,16]. In this study, pain intensity peaked on day 0 post-extraction. Most subjects, regardless of their group, experienced mild pain during the postoperative evaluation period. This finding is similar to that of Cheung et.al. who conducted a randomized prospective study aimed at evaluating differences in post-operative infection rates following dental extraction [17]. They found that 50 (83%) and 7 (11.6%) subjects with normal healing alveoli reported mild and moderate pain respectively during the postoperative period. In contrast, Al-Khateeb and Anahar while assessing pain experience after simple uncomplicated tooth extraction reported that 82% of their subjects experienced moderate pain intensity by the evening of the extraction day (day 0) [14]. This might be due to the fact that in the present study, analgesics were administered immediately post-operatively, before the onset of pain. This contrasts with the methodology of the study by Al-Khateeb and Anahar who administered analgesics after the inception of pain [14].

This study corroborates previous studies that alluded to the effectiveness of Paracetamol in controlling pain after routine dental extractions [7,12]. Over 90% of the subjects in both groups reported effective pain control at completion of the prescribed regimens. Indeed, the difference in pain experience between subjects in both groups was not statistically significant. This is similar to a previous finding by Adeyemo et al., who reported 88% effective pain control by the third day following simple uncomplicated tooth extraction [3]. However, Al Khateeb and Alnaha reported a higher proportion of patients (15.2%) with mild pain until postoperative day 7 as against 4.2% reported by Adeyemo et.al, and 2.6% in the present study [3,14].

In this study, no subject experienced severe pain in both groups. This is similar to the findings of Adeyemo et al. and Al-Khateeb and Anahar [3,14]. In contrast, Cheung et.al. reported that 17% of their subjects experienced moderate to severe pain [17]. Notably, medically compromised subjects including diabetics and patients with history of radiotherapy were included in the study by Cheung et al. [17] This may have impacted on the result of their study. This assertion is corroborated by the study by Koo et.al. who investigated post-operative issues after uncomplicated tooth extractions in healthy and medically compromised patients and found that the use of analgesics was considerably higher among medically compromised patients in comparison with healthy patients [18]. They concluded that medically compromised patients experienced pain more frequently than healthy ones.

The high proportion of participants with effective pain control in both the control and experimental groups suggests that the need for additional analgesics might be unnecessary. Al-Khateeb and Anahar stated that a significant proportion of their subjects (16%) experienced pain till the 7th day after extraction [14]. Hence, they recommended extended administration of analgesics during this period. However, their methodology revealed that extractions were performed by a mix of under-graduate and post-graduate students, in contrast to the present study where extractions were performed by post graduate students of comparable experience only. Additionally, this study excluded subjects who had difficult extraction (extraction time greater than 5 min), thus indicating that subjects may have been subjected to less operative trauma and may therefore experience lower pain intensities than patients who have had difficult extractions. This is supported by various studies that concluded that the degree of tissue injury affects post surgical pain intensity [19–22].

A significant number of subjects 84 (82.4%) in group B did not complete the prescribed regimen of Paracetamol because they stopped feeling pain. This indicates that prescribing analgesics for as long as three days after extraction may be unjustified. This assertion is further substantiated by Tozoglu et.al., who compared naproxen sodium 550 mg with a placebo following extraction of uncomplicated mandibular third molars in a cross over study and found that the difference in pain intensity between the two groups was not statistically significant and stated clearly that uncomplicated tooth extraction did not cause a significant pain and there was no need to use analgesia [23].

Many factors are said to affect subjective pain experiences following surgical procedures [24–26]. In this study, factors such as age, sex, type and number of teeth extracted were considered. Age and gender had no statistically significant effect on pain intensity following uncomplicated intra-alveolar extraction in both groups, although in both groups, more subjects below 45 years reported having pain than those above 45 years. Also, no statistically significant difference was noted in a comparison of pain experiences between genders. However, a higher proportion of females reported having pain in both the control and experimental groups. Reports of various studies on the effect of age and gender on pain perception have been conflicting in their conclusions [26–28].

While some authors concluded that age and gender were not statistically significantly correlated with pain intensity, others have contrasting conclusions. Attempts to explain gender differences in pain experience include that of Wiesenfeld-Hallin who stated that sex differences are attributed mainly to differences in biologic mechanisms and partly to psychologic and sociocultural factors [29]. He suggested that normal males have a higher level of activity in the endogenous analgesic system compared with normal females [29]. Furthermore, pain sensitivity, tolerance, and threshold in women vary with the stage of menstrual cycle [29].

The number of teeth extracted was found in this study to have no significant effect on pain intensity experienced by the subjects in both groups. This is in contrast with previous studies about surgical

procedures. For example Penarrocha et.al., found that the increase in number of teeth treated with periapical surgery increased pain post-operatively [30]. The present finding is probably due to the fact that difficult extractions were excluded, coupled with the fact that the number of subjects who had two adjacent teeth extraction (n = 12) was significantly lower than those who had single tooth extraction (n = 179).

Furthermore, the type of teeth extracted had no statistically significant effect on pain intensity among subjects, regardless of the group. This finding is in agreement with the report of Al-Khateeb and Anahar who assessed pain experience among patients who had simple tooth extraction [14]. This contrasts with the experimental work of Sabino et.al. using animal model [31]. They found that the activation of trigeminal neurons bilaterally after tooth extraction induced more pain sensation compared with ipsilateral neuron activation. Sabino et.al. also found that extraction of central incisors in the rat induced substance P receptors internalization of both ipsilateral and contralateral neurons [31]. On the other hand, molar extraction induced only ipsilateral substance P receptor internalization. They suggested that structures damaged around the midline induced more pain but this may be attributed to the lower number of extracted teeth around the midline (n = 21).

5. Conclusion

Following uncomplicated simple tooth extraction, majority of the subjects experienced mild to moderate pain intensity that can be managed effectively with paracentamol. There is no significant difference between the effectiveness of pain control following administration of paracentamol for 24 h and 3 days after uncomplicated intra-alveolar extraction. Hence administration of paracentamol for three days may be unwarranted.

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Ethical approval

Ethical approval for this study was obtained from the Ethical Review Committee of the hospital.

Informed consent

Written informed consent was obtained from all participants.

Guarantor

Olawole W. is the guarantor.

Contributorship

Olawole W. and Okoje N. conceived and fine tuned the idea. Okoje N. and Olawole W. were responsible for data management. Olawole W., Ibikunle A. and Arotiba J. performed literature search, developed analysis plan and analysed data. Ibikunle A. drafted the paper (Perused by Okoje N.). All authors contributed in interpretation of results and in making an important intellectual contribution to the manuscript.

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We declare that all authors have viewed and agreed to this submission.

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