

Effect of Alkalinised Versus Non-Alkalinised Peribulbar Anaesthesia on Ocular Akinesia in Cataract Surgery: A Randomised Controlled Trial

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Abstract

Purpose

To evaluate the effect of alkalinised versus non-alkalinised peribulbar anaesthesia on the onset and duration of ocular akinesia, injection pain, and the requirement for supplemental anaesthesia in patients undergoing cataract surgery.

Methods

A prospective, double-masked, randomised controlled trial with 224 adults (≥ 40 years) scheduled for cataract surgery at two centres in Nigeria. Participants were randomised (1:1) to receive a peribulbar block with either an alkalinised mixture (2% lignocaine with adrenaline, 0.5% bupivacaine, and 7.5% sodium bicarbonate; $n = 112$) or a non-alkalinised mixture ($n = 112$). Ocular motility and anaesthesia were assessed at 2, 5, 10, and 15 minutes post-injection. Primary outcomes were the time to achieve surgical akinesia (score 0–4) and patient-reported injection pain.

Results

The alkalinised group achieved higher rates of successful akinesia at 2 minutes (75.0% vs 58.0%; $p < 0.001$) and 5 minutes (94.6% vs 78.6%; $p = 0.029$). Mean injection pain scores were significantly lower in the alkalinised group (3.50 ± 1.5 vs 4.7 ± 7.3 ; $p < 0.001$). While total surgical duration and supplemental anaesthesia requirements (3.6% vs 5.4%) were comparable, the alkalinised group demonstrated a significant delay in the first request for post-operative analgesia ($p < 0.001$), with 57.1% requiring relief only after 120 minutes compared to 24.1% in the control group.

Conclusions

Alkalinisation of the peribulbar anaesthetic mixture significantly accelerates the onset of akinesia, reduces injection pain, and prolongs the period of post-operative comfort. These findings support the routine use of sodium bicarbonate as an adjuvant to optimise surgical workflow and patient experience.

Trial Registration:

Pan African Clinical Trial Registry; ID: PACTR202212745220111.

INTRODUCTION

Cataract surgery is the most frequently performed ophthalmic procedure globally, demanding a surgical environment that is safe, efficient, and painless. Achieving optimal patient cooperation through effective regional anaesthesia and globe akinesia is fundamental to surgical success. This requirement is particularly acute in teaching institutions; surgeons-in-training benefit significantly from the stable surgical field provided by profound akinesia, which enhances both trainee confidence and patient safety outcomes.^[1–4]

The efficacy of local anaesthetic agents is intrinsically linked to their chemical properties. Most local anaesthetics are weak bases, yet they are commercially prepared in acidic solutions (pH 4.0–6.0) to ensure stability and solubility. The relationship between the dissociated and non-dissociated forms of the drug is defined by the Henderson-Hasselbalch equation, $\text{pKa} - \text{pH} = \log (\text{LH}+)/(\text{L})$ ^[5–9]. In this equation (LH+) represents the ionised (cationic) form and (L) represents the non-ionised (base) form. Within the physiological environment, only the non-ionised form can readily lipid-diffuse across neuronal membranes. Alkalinisation of the anaesthetic solution, typically through the addition of sodium bicarbonate, shifts this equilibrium, increasing the fraction of non-ionised drug. Theoretically, this results in a more rapid onset of sensory and motor blockade and reduces the nociceptiveness of the injection itself by narrowing the pH gradient between the solution and host tissues.^[5–9]

While international literature, including studies by Ashok *et al.* and Bhabhor *et al.*, suggests that alkalinised peribulbar anaesthesia significantly reduces injection pain and accelerates the onset of akinesia, there is a paucity of data regarding these effects within the Nigerian population.^[10, 11] Given that ethnic variations in pain perception and tissue morphology may influence regional block efficacy, localised data are essential. Consequently, this study was designed to evaluate the effect of alkalinised versus non-alkalinised peribulbar anaesthesia on injection pain, as well as the onset and duration of globe akinesia and anaesthesia, in patients undergoing cataract surgery in Nigeria.

METHODS

Study Design and Setting

This prospective, double-masked, randomised controlled trial (RCT) was conducted between February and August 2023. The study utilized a parallel-group design and was multi-centre, involving the Guinness Eye Centre, Lagos University Teaching Hospital (LUTH), and St. Mary Catholic Eye Hospital, Ago Iwoye. Ethical approval was obtained from the Health Research Ethics Committees of both institutions (LUTH: ADM/CST/HREC/APP/5490 St. Mary: EEIERC008). The trial adhered to the tenets of the Declaration of Helsinki and was registered with the Pan African Clinical Trial Registry (PACTR202212745220111). Written informed consent was obtained from all participants following a pilot study conducted at a secondary facility to refine the study protocol.

Participant Selection

Adults aged 40 years and older scheduled for elective manual small incision cataract surgery under peribulbar local anaesthesia were screened for eligibility. Exclusion criteria included monocularity, axial length > 26 mm, known hypersensitivity to the study medications, or pre-existing mental health disorders that could impede cooperation or pain assessment.

Sample Size and Sampling Technique

The sample size was determined using the formula for comparing two means in a clinical study^[12]:

$$n = \left[\frac{(Z_{\alpha} + Z_{\beta}) \sigma}{\Delta} \right]^2$$

Where:

n = total number of participants

Z α = standard normal deviation for α value of 5% = 1.96

Z β = standard normal deviation for when power is 0.8.0% (β is 20.0%) = 0.84

σ = standard deviation of onset of akinesia from previous study⁴⁶ (5.89 + 3.82) / 2 = 4.855

Δ = difference between the onset of akinesia in the two groups from the previous study^[13]

$$(8.86 - 7.51) = 1.35$$

$$n = \left[\frac{(1.96 + 0.84) 4.855}{1.35} \right]^2$$

$$n = \left[\frac{(2.8) 4.855}{1.35} \right]^2$$

$$n = [10.07]^2$$

$$n = 101.4$$

The initial calculation required 102 participants per group. Adjusting for a 10% attrition rate, the final sample size was set at 112 participants per arm (N = 224). Recruitment was stratified proportionally based on monthly surgical volume: 27.3% (n = 60) from LUTH and 72.7% (n = 164) from St. Mary Catholic Eye Hospital.

Randomisation and Allocation Concealment

Participants were assigned to either the alkalinised (Group B) or non-alkalinised (Group A) group in a 1:1 ratio using the asymptotic maximal randomisation method. This approach utilized a Maximal Tolerated Imbalance (MTI) of 10 to prevent chronological bias and ensure allocation unpredictability.^{14]}

Randomisation sequences were generated by an independent statistician and concealed in sequentially numbered, opaque, sealed envelopes. These envelopes were stored in plastic containers in blocks of ten. Upon recruitment, participants selected an envelope, which was then opened by a second research assistant who prepared the anaesthetic solution.

Masking and Intervention

This was a double-masked study; participants, surgeons (with similar years of experience, one in each centre), the principal investigator, and the residents administering the block were masked to the group allocation. The study solutions were prepared freshly before each surgical list to maintain pH integrity:

- **Group A (Non-alkalinised):** 3 ml of 2% lignocaine with adrenaline and 2 ml of 0.5% bupivacaine (pH 6.37).
- **Group B (Alkalinised):** 3 ml of 2% lignocaine with adrenaline and 7.5% sodium bicarbonate, plus 2 ml of 0.5% bupivacaine (pH 6.85).

Both interventions resulted in a 5 ml colourless solution.

Outcome Measures

1. **Injection Pain:** Assessed during the administration of the anaesthetic (excluding the initial needle prick) using a Visual Analogue Scale (VAS) ranging from 0 (no pain) to 10 (worst imaginable pain).^[15–18] Pain rating was categorised as follows: 0 = no pain, 1–3 = mild, 4–6 = moderate, 7–10 = severe.
2. **Ocular Akinesia:** Motility was evaluated at 2, 5, and 10 minutes post-injection in four quadrants (superior, inferior, medial, lateral) and the upper eyelid. Each excursion was scored as: 2 (movement > 2 mm), 1 (movement ≤ 2 mm), or 0 (no movement).
 - Successful Akinesia: A total score of 0–4.
 - Inadequate Akinesia: A total score of 5–10.
3. **Anaesthesia:** Sensory blockade was confirmed by grasping the bulbar conjunctiva with Moorfields forceps on the nasal and temporal sides at the same time intervals.
4. **Duration:** Recorded from the confirmed onset of blockade until the eye was padded post-surgery.

If neither successful akinesia (score 0–4) nor anaesthesia was achieved by 10 minutes, a supplemental 2 ml injection was administered. These participants remained in the analysis under the intention-to-treat

principle.

Data Analysis

Data was analysed using IBM SPSS Statistics (Version 25.0) on an intention-to-treat (ITT) basis. Normality was assessed using the Shapiro-Wilk test. Continuous variables are presented as mean $\pm$ standard deviation or median (interquartile range) and compared using the independent Student's t-test or Mann-Whitney U test, respectively. Categorical data are presented as frequencies and percentages, compared using Chi-square or Fisher's exact tests. For binary endpoints, the Cochran-Mantel-Haenszel (CMH) test was used to adjust for the recruitment site. Statistical significance was set at $p < 0.05$.

RESULTS

Baseline Characteristics

A total of 224 participants were enrolled and randomly assigned to the alkalinised ($n = 112$) or non-alkalinised ($n = 112$) group. The cohort comprised 106 males (47.3%) and 118 females (52.7%). In the alkalinised group, the mean age was 64.54 ± 8.5 years, compared to 65.49 ± 9.3 years in the non-alkalinised group. There were no significant differences in baseline sociodemographic characteristics between the two arms.

Injection Pain Perception

Pain perception during peribulbar injection was significantly lower in the alkalinised group. In this group, 50.9% of participants reported only mild pain, whereas 89.3% of the non-alkalinised group experienced moderate to severe pain ($p < 0.001$). The mean VAS score for the alkalinised group was significantly lower (3.50 ± 1.5) than that of the non-alkalinised group (4.7 ± 7.3 ; $p < 0.001$).

Akinesia and Anaesthesia Onset

The alkalinised group demonstrated significantly lower (better) mean scores for globe and lid akinesia at all early time intervals compared to the non-alkalinised group ($p < 0.001$). As shown in Table 1, the proportion of participants achieving successful surgical conditions (akinesia and anaesthesia) was significantly higher in the alkalinised group at the 2-minute and 5-minute marks. By 15 minutes, all participants in both groups had achieved full blockade.

Table 1
Comparison of Akinesia and Anaesthesia Achievement Over Time

	Alkalinised n = 112 n(%)	Non-alkalinised n = 112 n(%)	χ^2	p-value
Akinesia				
Time interval				
2 mins	84(75.0)	65(58.0)	14.275	< 0.001*
5 mins	106(94.6)	88(78.6)	4.766	0.029*
10 mins	108(96.4)	106(94.6)	0.419	0.518
15 mins	112(100.0)	112(100.0)	0.000	1.000
Anaesthesia				
2 mins	95(84.8)	73(65.2)	11.524	0.001*
5 mins	106(94.6)	94(83.9)	6.720	0.010*
10 mins	108(96.4)	106(94.6)	1.675	0.196
15 mins	112(100.0)	112(100.0)	0.000	1.000

Surgical Outcomes, Adverse Events, and Supplemental Anaesthesia

Four participants in the alkalinised group required supplemental anaesthesia after 10 minutes, compared to six in the non-alkalinised group ($p > 0.05$). The mean duration of surgery and the total duration of akinesia were comparable between groups (24.03 ± 6.8 minutes for alkalinised vs 23.83 ± 6.6 minutes for non-alkalinised). A total of 10.7% of participants in the alkalinised group and 12.5% of participants in the non-alkalinised group experienced adverse events. This makes a total of 11.6% of the total number of participants that came down with ocular adverse events ranging from subconjunctival haemorrhage to chemosis (p value of 0.677). No participant had systemic adverse events.

Post-operative Pain and Analgesia Requirements

While the mean post-operative pain scores recorded on the ward were similar between groups (Table 2), the timing of first analgesic request differed significantly (Table 3).

Table 2
Post-operative VAS Pain Assessment

Pain Category	Alkalinised n = 112 n(%)	Non-alkalinised n = 112 n(%)	χ^2	p-value
Mild	13(11.6)	17(15.2)	1.877	0.391
Moderate	69(61.6)	73(65.2)		
Severe	30(26.8)	22(19.6)		
Mean $\pm$ SD	6.09 $\pm$ 2.9	5.83 $\pm$ 2.7	0.721**	0.291

*significant; **Independent Student t-test

Table 3
Distribution of Time to First Post-operative Analgesic Request

Duration (minutes)	Alkalinised n = 112 n(%)	Non-alkalinised n = 112 n(%)	χ^2	p-value
< 30	0(0.0)	0(0.0)	43.270	< 0.001*
30–60	10(8.9)	39(34.8)		
61–90	12(10.7)	22(19.6)		
91–120	11(9.8)	19(17.0)		
121–150	23(20.5)	13(11.6)		
151–180	41(36.6)	14(12.5)		
181–210	15(13.5)	5(4.5)		
210–240	0(0.0)	0(0.0)		

In the non-alkalinised group, 34.8% of participants requested analgesia within the first hour, compared to only 8.9% in the alkalinised group. By the second hour, 71.4% of non-alkalinised participants had requested relief, whereas the majority of the alkalinised group (36.6%) delayed their request until the 151–180 minute interval ($p < 0.001$).

DISCUSSION

The demographic profile of this study, with a predominant age range of 60–69 years and a slight female preponderance, aligns with established epidemiological trends in Nigerian cataract research.^[20–24] The gender distribution likely reflects superior health-seeking behaviour and a higher life expectancy among females in the region.

Our findings demonstrate that alkalinisation significantly reduces injection pain. The non-alkalinised group predominantly reported moderate to severe pain, whereas the alkalinised group experienced significantly milder sensations. This is biochemically consistent with a reduction in the hydrogen ion concentration in the anaesthetic solution. Acidic solutions (pH 4.0–6.0) act as direct chemical stimuli to nociceptors; elevating pH toward physiological levels attenuates the initial noxious stimulus.^[5–9] While some smaller studies, such as that by Minasian *et al.* (n = 60), found no significant difference, our results support the findings of Sodani *et al.* and Bhabhor *et al.*^[11, 26, 27]. We observed mean pain scores of 3.50 ± 1.5 in the alkalinised group versus 4.7 ± 7.3 in the control. The discrepancy in absolute values compared to Bhabhor *et al.* may stem from their inclusion of hyaluronidase, which facilitates rapid drug dispersion and potentially further moderates tissue distension pain.

The rapid onset of motor and sensory blockade in the alkalinised group (94.6% achieving akinesia by 5 minutes) underscores the clinical utility of sodium bicarbonate. This accelerated onset is explained by the increased fraction of non-ionised, lipophilic molecules available to penetrate the neuronal lipid bilayer.

Our results parallel the work of Nazareth *et al.* and Jaichandran *et al.*, who reported superior early-phase blockade with alkalinization.^[13, 28] Interestingly, while Sodani *et al.* did not observe faster akinesia with alkalinisation alone, they noted that hyaluronidase was a more potent factor for onset speed.^[26] In our study, the absence of hyaluronidase enabled clearer isolation of the pH effect, confirming that alkalinisation independently enhances the speed of the block.

A striking finding was the significant delay in the first request for post-operative analgesia in the alkalinised group. While the non-alkalinised group required rescue medication within 60–90 minutes, over one-third of the alkalinised group remained comfortable for up to three hours. This suggests that alkalinisation not only accelerates the onset but may also improve the quality or effective plateau of the sensory block, even if the total pharmacological half-life remains similar.

The requirement for supplemental anaesthesia was low in both groups (3.6% vs 5.4%). The higher supplemental rates reported by Jaichandran *et al.* (24%–36%) likely reflect their earlier assessment point at 5 minutes, whereas our 10-minute assessment allowed sufficient time for the "slow-onset" blocks in the non-alkalinised group to reach surgical thresholds.^[28]

The primary limitation of this study was the inability to measure the precise offset of akinesia via direct clinical examination because institutional safety protocols required postoperative patching. Consequently, the duration of the block was proxied by the time to first analgesic request. While pain thresholds vary individually, the large sample size (N = 224) provides sufficient power to validate the observed trends.

In conclusion, alkalinisation of peribulbar anaesthetic solutions with sodium bicarbonate is an effective, low-cost intervention that significantly reduces injection pain, accelerates the onset of ocular akinesia,

and prolongs post-operative analgesia. For surgical trainees, this protocol would provide a more stable and cooperative surgical field, potentially reducing intra-operative complications. Therefore, clinicians could consider sodium bicarbonate routinely as an adjuvant in ophthalmic regional anaesthesia, particularly in high-volume or training settings. Further multi-centre research across diverse Nigerian populations is warranted to establish these findings as a national standard of care for black African patients.

Declarations

Author Contribution

Gbemisola Racheal Borisade (Principal Investigator) was responsible for the study conception, design, and coordination. Gbemisola Racheal Borisade performed the data acquisition and drafted the primary manuscript. Oluwatobi Idowu and Olufisayo Aribaba contributed to the conceptualisation and provided clinical supervision and oversight. Gbemisoal Racheal Borisade , Oluwatobi Idowu , Olufisayo Aribaba, Folohunso Yusuf, Adetunji Adenekan, Pamela Agbamu and Folasade Akinsola contributed to the study design and the critical revision of the manuscript for important intellectual content. All authors have read and approved the final manuscript, and they collectively assume responsibility for the integrity and accuracy of the data and the data analysis.

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Data Availability

De-identified participant data, including the study protocol and informed consent forms, may be made available to researchers upon reasonable request to the corresponding author (****gbemie001@yahoo.com****). Data sharing is subject to a formal request review by the investigative team and the execution of a signed data-sharing agreement to ensure the protection of participant confidentiality.

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Data Sharing statements:

De-identified participant data, including the study protocol and informed consent forms, may be made available to researchers upon reasonable request to the corresponding author (gbemie001@yahoo.com). Data sharing is subject to a formal request review by the investigative team and the execution of a signed data-sharing agreement to ensure the protection of participant confidentiality.

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