

Original Article

A randomised controlled trial of periconal eye blockade with or without ultrasound guidance^{*}

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Summary

We randomly allocated 129 participants with normal eyes to periconal blockade with ($n = 69$) or without ($n = 60$) ultrasound guidance before cataract surgery. There was no difference in the rates of complication, 1/69 and 0/60, respectively, $p = 1.0$. The rate of intraconal needle placement was 1/69 with ultrasound and 12/60 without ultrasound, a relative risk (95% CI) of 0.07 (0.01–0.55), $p < 0.0001$.

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Accepted: 5 November 2014

**Presented in abstract at the European Anaesthesiology Congress, Barcelona, Spain, 2013.*

Introduction

Regional anaesthesia has almost completely replaced general anaesthesia for ophthalmic surgery in adults [1], which was first achieved by injecting local anaesthetic behind the globe (retrobulbar anaesthesia), inside the muscle cone [2]. The onset of 3–5 ml of local anaesthetic injected behind the globe is rapid, but the needle may damage nearby structures including the globe and the optic nerve, and could induce brainstem anaesthesia [3–7]. Retrobulbar anaesthesia has been progressively replaced by other anaesthetic methods, including the peribulbar technique that places 6–12 ml of local anaesthetic outside the muscle cone [8–12]. The periconal or posterior peribulbar variant uses a needle 25 mm long, longer than that used in other peribulbar techniques but shorter than the needle used in retrobulbar anaesthesia [13]. The categorisation of regional ophthalmic techniques is approximate as the

operator does not know where the needle tip is after it has been blindly inserted through the skin [14].

Our aim was to evaluate the feasibility, efficacy and complications of periconal blockade with and without ultrasound guidance, and to determine the position of the needle tip in patients with normal eyes.

Methods

The Rio de Janeiro Federal State University Ethics Committee approved this prospective randomised controlled trial. We recruited adults aged 18–90 years, of ASA physical status 1–2, scheduled for cataract surgery. Participants provided written informed consent. We did not study patients with one eye or with axial globe lengths > 26 mm and patients with staphyloma or emergencies. Participants were allocated to blockade with or without ultrasound guidance immediately

before anaesthetic management. Group allocation was retrieved from one of two sealed opaque envelopes contained in a dark box. After allocation, the envelope was resealed and returned to the container.

We monitored participants with digital pulse oximetry, a three-lead ECG and non-invasive blood pressure, recorded every 5 min. All participants breathed spontaneously through a Hudson face mask supplemented with oxygen flowing at $2 \text{ l}\cdot\text{min}^{-1}$. We placed a 22-G intravenous catheter and sedated participants with intravenous midazolam 2–3 mg and fentanyl 30–50 μg . We placed a B-Scan linear array ultrasound transducer at the supraorbital rim (Sonomed Escalon; Master-Vu USB Ultrasound System, New York City, NY, USA), which emitted waves at 12 MHz with a circular footprint focussed at 6 cm [15–19]. Longitudinal and axial approaches obtained transocular images of the globe and axial length, respectively. We applied topical iodine and injected 0.5 ml lidocaine 1% intradermally at a point lateral to the junction of the medial two thirds and lateral third of the inferior orbital rim to decrease the likelihood of block-induced strabismus [20]. One anaesthetist with extensive ophthalmic and ultrasound experience performed all blocks. Another anaesthetist, who was aware of treatment allocation, collected data.

For blockade under ultrasound guidance, the anaesthetist stood behind the patient, his non-dominant hand holding the transducer gently on the upper eyelid with its marker directed towards the 7 o'clock meridian (right eye) or 5 o'clock meridian (left eye) (Fig. 1). The anaesthetist held the 25-mm long 23G needle in his dominant hand and introduced it through the anaesthetised skin into the periconal space. He kept the needle in the plane of the ultrasound beam. For blockade without ultrasound guidance, participants were asked to stare upwards and forward. The needle was inserted through the anaesthetised skin along the orbital floor with the bevel facing up, to advance past the equator of the eye. The anaesthetist tilted the needle tip up and medially, advancing it towards an imaginary point located behind the macula, without crossing the sagittal plane of the visual axis, when he thought that it had passed the orbital equator. After needle placement was complete, the position of the needle was sought with

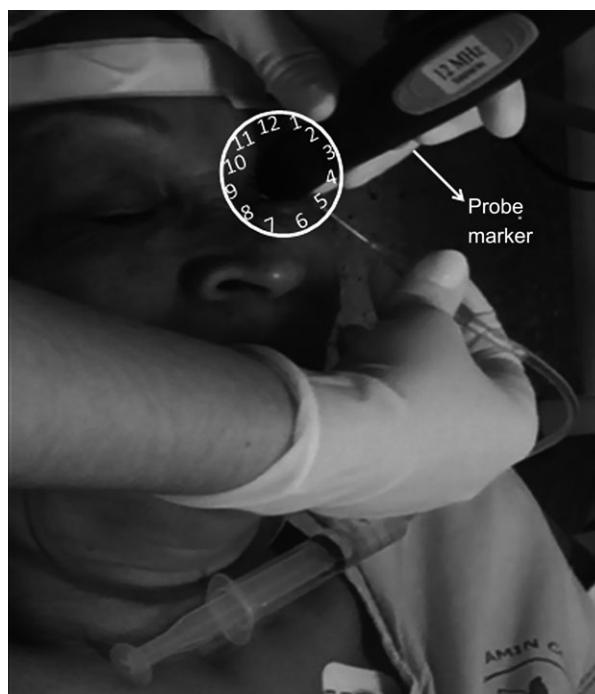


Figure 1 Ultrasound-guided periconal block. The probe marker should be directed to the 5 o'clock position for the left eye and the 7 o'clock position for the right eye.

the ultrasound probe placed on the upper eyelid. The needle tip was withdrawn if it was within the muscle cone. If blood was not aspirated, an auxiliary staff member injected 6 ml levobupivacaine 0.75% containing hyaluronidase 40 $\text{IU}\cdot\text{ml}^{-1}$ through an extension; injectate spread was viewed with ultrasound. A Homan's balloon was applied to the eyelid after the needle was removed.

The ultrasound image was rated 'satisfactory' if the anatomy needed to guide the needle could be seen and if the axial globe length was measured. We recorded the time taken from needle insertion to finalising needle placement. We also recorded the distance between the needle tip and the optic nerve, the depth and angle of needle insertion in relation to the plane of the iris, the duration of surgery, any complications, and procedural and intra-operative pain. We categorised eye movements immediately after injection and twice more at 5-min intervals: 'normal', movement in four directions; 'partial', movement in one or two directions; or 'none' [21]. Participants reported corneal sensitivity on instillation of povidone-iodine 1% eye

drops at the same times: strong; slight; or no burning sensation. The block was repeated if the eye retained normal movement and strong burning sensation.

We calculated that a minimum of 50 participants in each group would be needed to demonstrate a 20% difference in the composite rate of retrobulbar haemorrhage, globe damage or optic nerve injury at a significance level of 0.05 with 80% power. We used the chi-squared and Fisher's exact tests to analyse categorical variables and Student's t-test for continuous variables. Relative risk with 95% CI and number needed to treat were calculated for the rate of unintentional intraconal positioning of the needle (InStat 3.0; Graph-Pad Software, San Diego, CA, USA). We considered a p value < 0.05 significant.

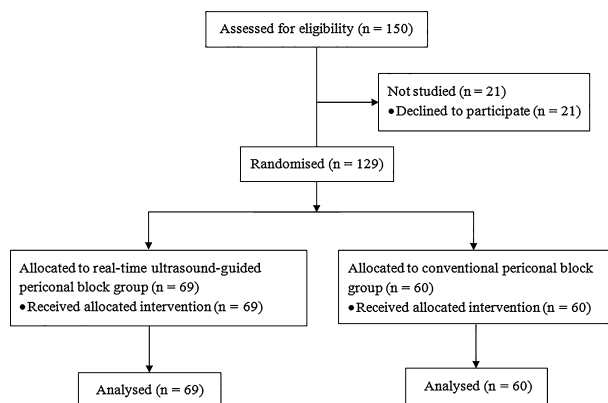


Figure 2 Patient flow diagram.

Table 1 Variables for participants allocated to periconal injection with or without ultrasound guidance. Values are mean (SD) or number (proportion). The complication was conjunctival oedema.

| | Ultrasound (n = 69) | No ultrasound (n = 60) | p value |
|--------------------------------|------------------------|---------------------------|----------|
| Ultrasound satisfactory | 67 (97.1%) | 59 (98.3%) | 1.0 |
| Needle tip not located | 1 (1.4%) | 0 | 0.36 |
| Needle tip in muscle cone | 1 (1.4%) | 12 (20%) | < 0.0001 |
| Needle tip to optic nerve; mm | 12.1 (4.4) | 8.2 (3.7) | < 0.0001 |
| Needle inserted; mm | | | |
| From skin | 25.1 (1.6) | 26.7 (2.4) | < 0.0001 |
| In ultrasound image | 11.7 (2.6) | 14.7 (3.5) | < 0.0001 |
| Axial length; mm | 22.9 (1.2) | 22.7 (1.2) | 0.38 |
| Block procedure; s | 47.4 (35.4) | 32.4 (32.7) | 0.01 |
| Local anaesthetic spread seen | 66 (95.7%) | 60 (100%) | 0.10 |
| Angle of needle insertion; ° | 87.4 (8.8) | 86.5 (9.3) | 0.58 |
| Length of surgery; min | 37.1 (14.7) | 39.6 (21.8) | 0.44 |
| Complications | 1 (1.4%) | 0 | 1.0 |
| Absence of pain during surgery | 69 (100%) | 60 (100%) | 1.0 |
| Satisfied participants | 43 (62.3%) | 49 (81.7%) | 0.01 |

Results

Figure 2 shows the CONSORT flow chart of participant recruitment and group allocation. Ultrasound did not reduce the rate of complications, but it did reduce the length of needle inserted into the orbit and the rate of intraconal needle tip placement, relative risk (95% CI) 0.07 (0.01–0.55), p < 0.0001, equivalent to preventing one intraconal injection in every six procedures (Table 1). Figure 3 illustrates periconal and intraconal needle placement. Figure 4 illustrates periconal anaesthetic injection and Fig. 5 illustrates the distances measured. There were no differences in corneal pain or eye movement (Table 2). No participant required additional blockade.

Discussion

Ultrasound did not affect the rate of complications in this study, which was our primary outcome. Ultrasound did reduce the rate of intraconal placement of the needle tip, which suggests that one in six peribulbar placements are intraconal retrobulbar injections [22].

We chose to study local anaesthetic blockade for cataract surgery as more than 10 million cataract procedures are performed globally every year and by 2020, around 160 million people in the world will lose vision due to cataracts [1]. Local anaesthetic injection is more likely to prevent eye movement than topical application [14]. The standard needle length for

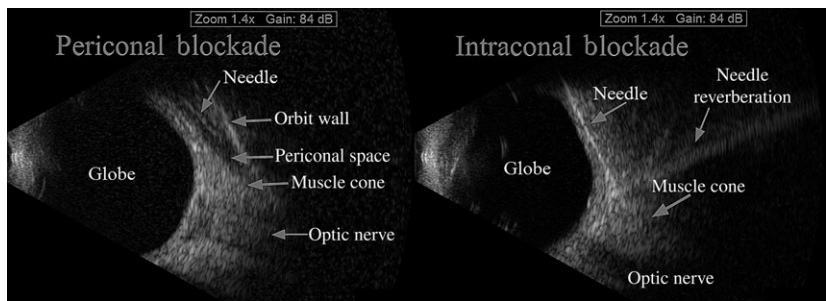


Figure 3 Periconal and intraconal needle tip placement.

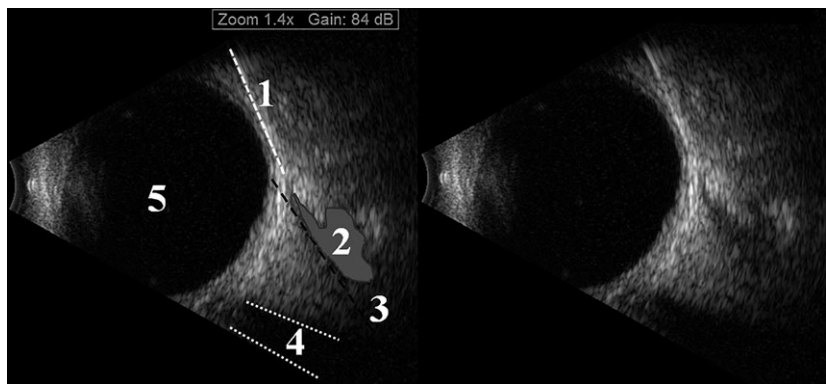


Figure 4 Ultrasound-guided periconal block: 1, needle shaft; 2, local anaesthetic; 3, muscle cone; 4, optic nerve; 5, globe.

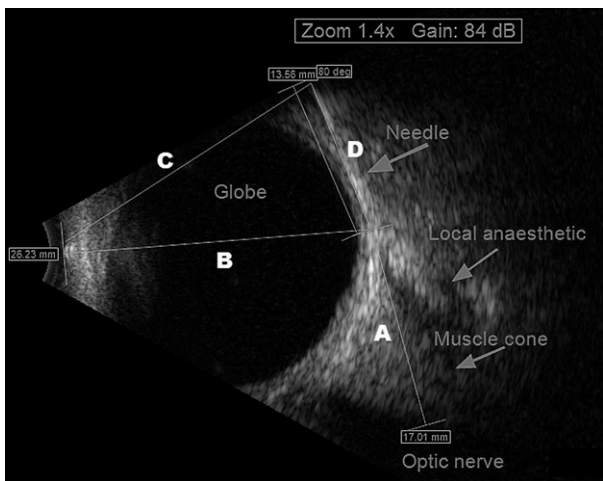


Figure 5 Ultrasound measurements: A, distance from the needle tip to the optic nerve (17.01 mm); B, distance from the needle tip to the plane of the iris (26.23 mm); C, angle of needle insertion compared with the plane of the iris (80°) and D, needle length (13.56 mm).

Table 2 Corneal pain and eye movement after block. Values are numbers.

| | Ultrasound (n = 69) | No ultrasound (n = 60) | p value |
|-----------------------------|---------------------|------------------------|---------|
| Corneal pain* | | | |
| Immediately after injection | 0/2/67 | 0/1/59 | 0.62 |
| 5 min later | 0/1/68 | 0/0/60 | |
| 10 min later | 0/0/69 | 0/0/60 | |
| Movement† | | | |
| Immediately after injection | 0/33/36 | 0/31/29 | 0.40 |
| 5 min later | 0/2/67 | 0/1/59 | |
| 10 min later | 0/2/67 | 0/1/59 | |

*strong/slight/none.

†normal/partial/none.

extraconal injection is 25 mm [23–26], but long needles could increase the rate of complications [5, 6, 11, 14, 27–30]. Ultrasound is used by ophthalmologists as a diagnostic tool, but infrequently as an aid to

ophthalmic regional anaesthesia when it might reduce damage caused by needles to the globe and optic nerve [1, 8, 31]. In some images, the needle abutted the globe, consistent with previous research [32]. There is little clinical difference between extraconal and intraconal spaces, which are separated by an incomplete barrier through which local anaesthetic could be seen to communicate in our study [24, 33–35].

There is an argument that ultrasound-guided periconal blockade is unnecessary as traditional techniques are reliable and safe [1]. Extraconal and intraconal blocks cause more severe complications than other peripheral nerve blocks [3, 36]. Accidental globe perforation and rupture are the most devastating complications of eye blocks [11]. Highly myopic participants are prone to globe perforation [2, 30], which may blind [2]. The rate of intraneural injection of 0.3–0.8% may be underestimated as injection of a small volume of local anaesthetic may not cause clinical sequelae [7]. However, atrophy of the optic nerve is a late complication that may also be caused by direct injury to the central retinal artery or injection or bleeding into the nerve sheath [7]. The arguments against ultrasound techniques, such as the time that they take to learn and perform, should be secondary to safety concerns, particularly as we found that ultrasound prolonged blockade by only 15 s. To limit any heat damage and mechanical disruption that ultrasound can cause to the retina, practitioners should abide by the British Medical Ultrasound Society safety limits, which are a thermal index < 1.0 and a mechanical index < 0.23 [16, 17, 19]. Fewer participants were satisfied with the ultrasound-guided technique, possibly as a result of discomfort caused by pressure exerted on the eye by the probe.

One limitation of the final position of the needle tip as an outcome was that it was not independent of the intervention, i.e. the needle tip was sited under ultrasound guidance. A better design would have been to assess the success rate, i.e. extraconal positioning of the needle tip when performing the periconal block, with an alternative technology, such as computed tomography [37, 38]. Nevertheless, although computed tomography would have uncoupled the intervention from the outcome, it would have made the study more difficult to perform.

In summary, ultrasound may reduce the rate of intraconal needle placement and thereby reduce the infrequent but devastating consequences that may follow.

Acknowledgements

We thank Lidia Raquel de Carvalho for statistical analysis, Talita Weber for recruiting and obtaining informed consent from participants and for data collection, and Evadne Najman for proofreading this article. The ultrasound equipment was funded by Fundação de Auxílio à Pesquisa do Estado de São Paulo – FAPESP.

Competing interests

No competing interests declared.

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