Comparison of sub-Tenon's block with i.v. fentanyl for paediatric vitreoretinal surgery †

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Background. Vitreoretinal (VR) surgery is associated with moderate to severe pain and significant postoperative nausea and vomiting (PONV). The study aimed to assess the effectiveness of sub-Tenon's block for providing perioperative analgesia in children undergoing VR surgery.

Methods. In a randomized, observer-blinded trial, after obtaining institutional ethical committee approval and parental consent, 200 ASA grade I–II children aged 5–16 yr were allocated to receive either a sub-Tenon's block (Group SB) or 2 μ g kg⁻¹ i.v. fentanyl (Group F) after induction of anaesthesia and topical anaesthesia of the conjunctiva with proparacaine 0.5% drops. Patients in Group F received fentanyl 0.5 μ g kg⁻¹ and those in Group SB were given a corresponding volume of normal saline i.v. every hour from preloaded syringes. Increases in heart rate or mean arterial pressure by more than 20% of baseline were treated with additional 0.5 μ g kg⁻¹ i.v. fentanyl boluses in both groups. The incidence of oculocardiac reflex (OCR), need for additional analgesics, postoperative pain, and PONV were recorded for the first 24 h after surgery.

Results. More patients in Group F (47.96%) had moderate to severe pain in the first 24 h when compared with Group SB (31.36%) (P=0.023). The need for postoperative ibuprofen was higher in Group F (66.3%) compared with Group SB (47.95%) (P=0.012). The incidence of OCR was significantly higher in Group F (31.6%) compared with Group SB (5.1%) (P<0.001). The incidence of PONV was similar in both groups.

Conclusions. Sub-Tenon's block provides more effective analgesia than i.v. fentanyl for paediatric VR surgery.

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Vitreoretinal (VR) surgery involves extensive intra- and extraocular dissection and is one of the most painful ophthalmic surgical procedures.¹ The surgery is prolonged, associated with a high incidence of oculocardiac reflex (OCR) and postoperative nausea and vomiting (PONV).² Goals of anaesthesia for children undergoing VR surgery are to ensure a stable intraoperative period with adequate pain relief and a low incidence of PONV. This would facilitate lying prone after operation so as to ensure adequate tamponade of an oil or gas bubble against the detached retina.

Sub-Tenon's block is an established regional anaesthesia technique in adults and children undergoing cataract and strabismus surgery.³⁻⁶ It has also been used for VR surgery in adults;⁷⁻¹¹ however, no study has been

performed to assess the effectiveness of sub-Tenon's block in paediatric VR surgery.

The aim of this study was to assess whether sub-Tenon's block would provide adequate perioperative analgesia in children undergoing VR surgery under general anaesthesia.

Methods

After obtaining Institutional Ethics committee approval and informed parental consent, 200 ASA grade I and II

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children aged 5-16 yr undergoing VR surgery from September 2006 to December 2008 in our hospital were enrolled in the study. The following children were excluded:

- (i) children whose parents were unwilling to give consent;
- (ii) children with mental retardation or deafness with whom communication would be difficult in the postoperative period;
- (iii) children with a history of allergy to local anaesthetics or had undergone previous VR surgery;
- (iv) children undergoing silicone oil removal surgery;
- (v) children with endophthalmitis or inflammatory eye pathology.

The children were randomly divided into two groups by a computer-generated randomization table. Two hours before surgery, all children received oral diazepam 0.2 mg kg^{-1} as premedication. I.V. cannulae were inserted while parents were present. In the operating theatre, after instituting standard monitoring, including heart rate (HR), ECG, non-invasive arterial pressure, and oxygen saturation (Sp_{0}) , baseline haemodynamic data were recorded. After i.v. induction of anaesthesia with propofol $3-5 \text{ mg kg}^{-1}$, an appropriately sized Proseal laryngeal mask airway (PLMA) was inserted. Anaesthesia was maintained with oxygen, nitrous oxide (50%), 1% inspired concentration of isoflurane (fresh gas flow of 0.85-1 litre min⁻¹), and vecuronium. Ventilation was controlled to maintain normocarbia. In both groups, one to two drops of proparacaine 0.5% were instilled into the eye to be operated every 5 min while the eye was being cleaned and prepared for surgery, up to the time of conjunctival incision.

After conjunctival incision, children in the sub-Tenon's group (Group SB) were administered the sub-Tenon's block by the operating surgeon and the children in the fentanyl group (Group F) received fentanyl 2 μ g kg⁻¹ i.v. The anaesthetist present at this time prepared syringes containing fentanyl 0.5 μ g kg⁻¹ for Group F and a corresponding volume of normal saline for Group SB and labelled them 'X'.

Further intraoperative monitoring was carried out by an anaesthetist blinded to the analgesic technique used. Children in both groups received either fentanyl or normal saline through the pre-prepared syringes labelled 'X' every hour till the end of surgery. In addition, an increase in HR or mean arterial pressure by more than 20% of the baseline in both groups was treated with i.v. boluses of fentanyl 0.5 μ g kg⁻¹ administered through separate syringes. A sudden decrease in HR to <60 beats min⁻¹ or <20% of baseline associated with surgical manipulation was taken to be an OCR. This was treated by cessation of the surgical stimulus which if ineffective was followed by administration of atropine 10 μ g kg⁻¹ i.v.

Technique of sub-Tenon's anaesthesia

After topicalization, a small incision was made in the conjunctiva and underlying Tenon's capsule after lifting them with a non-toothed forceps in the infero-temporal quadrant of the eye. This is the site where first sclerotomy is usually performed for the infusion port. After the bare sclera was seen, a blunt 19 G, 25 mm curved metallic cannula was passed through the limbal aperture beyond the equator of the globe, and local anaesthetic (equal mixture of bupivacaine 0.5% and lidocaine 2%) was gently injected (1.5–2.0 ml for children aged 5–10 yr and 2.0–3.0 ml in older children).

Nitrous oxide was switched off 15 min before the end of surgery in both groups. After the eye was bandaged, residual neuromuscular block was reversed using neostigmine (50 μ g kg⁻¹) and glycopyrrolate (10 μ g kg⁻¹) and the PLMA removed after ensuring adequate respiratory effort.

A modified Steward score¹² was used to assess awakeness after anaesthesia immediately after operation and thereafter at 15, 30, and 45 min after operation or until the patients were fully awake in the post-anaesthesia care unit (PACU). Once the children were fully awake, pain was assessed using the AIIMS pain score¹³ in children up to 7 yr of age. In addition, older children (aged 8–16 yr), if they were able to localize the eye pain, were asked to rate it as mild (slight pain), moderate (hurts enough to need medication), or severe (worst possible).

Fentanyl boluses of 0.5 μ g kg⁻¹ were administered to children having moderate to severe pain i.v. every 10 min till the pain subsided. At the end of 2 h, the patients were transferred from the PACU to the ward where the pain was assessed at 6 and 24 h. In between these time points, the patients were monitored by ward nurses blinded to the study group who were allowed to administer oral ibuprofen 10 mg kg⁻¹ at 6 hourly intervals as per our usual hospital protocol.

PONV was assessed for the first 2 h in the PACU and subsequently in the ward at 6 and 24 h using a PONV score.¹⁴ Children who had persistent nausea or more than a single episode of vomiting were administered ondanse-tron 100 μ g kg⁻¹ i.v.

Statistical analysis

Sample size was calculated using a prior pilot study which found an incidence of moderate to severe pain of 27% in the sub-Tenon's group compared with 50% in the fentanyl group. The calculated sample size was 101 per group with 5% level of significance and 90% power, and 78 per group for 80% power; we were able to enrol 100 patients in each group in the given time period. Statistical analysis was carried out using Stata 9.0 (College Station, TX, USA). Data are presented as number (%) or mean (sD) as appropriate. Baseline categorical and continuous characteristics of the patients between the groups were compared using the χ^2 test and Student's *t*-test, respectively. χ^2 test was used to compare difference in proportions of pain, PONV, and awakeness between the groups. HR and mean arterial pressure were compared between the groups using the generalized estimating equation, since the observations are correlated. A *P*-value of <0.05 was considered statistically significant.

Results

Data from 196 patients were analysed, as postoperative records for the entire 24 h post-surgery were not available for four patients. Ninety-eight patients were studied in each group. Baseline characteristics (age, sex, type, and duration of surgery) were comparable (Table 1). VR surgery alone included pars plana vitrectomy and laser therapy. In patients who underwent scleral buckling, a circumferential or segmental silicone band was sutured to the sclera to appose it to the retina and it involved extensive dissection of the Tenon's fascia away from the sclera (retinal detachment surgery).

HR and mean arterial pressure recordings of the two groups were similar at baseline and during surgery (data not shown). Eleven children in Group F and five in Group SB were administered supplementary fentanyl during surgery (P=NS) (Table 2). Four out of the 11 children in Group F needed two boluses each, whereas one patient in Group SB needed two boluses of fentanyl. This supplementary fentanyl was in addition to the fentanyl 0.5 µg kg⁻¹ boluses administered to Group F at the end of every hour.

The incidence of OCR was significantly higher in Group F compared with Group SB (Table 2). The time to achieving a maximal Steward score of 4, that is, time to full wakefulness, was similar between the two groups. The majority of the children (86 in Group SB and 75 in Group F) were awake 15 min after the end of surgery. All children in both the groups were fully awake 30 min after surgery.

The incidence of mild pain was comparable between the two groups in the time intervals studied and also in the first 24 h after operation. In any given time interval studied (i.e. the first 2 h after operation, from 2 to 6 and 6 to 24 h), the number of children having moderate to severe pain was higher in Group F compared with Group SB, although this difference was not statistically significant (Fig. 1). The total number of children who had moderate to severe postoperative pain in the entire 24 h after surgery, however, was significantly higher in Group F (47 out of 98, 47.9%) compared with Group SB (31 out of 98, 31.4%) (P=0.023). The mean difference in the incidence of moderate to severe pain between Group SB and Group F was 16.6% (95% CI 1.4-28.6). The number of children having the worst possible pain, that is, persistent moderate pain or severe postoperative pain, was 17 out of 98 (17.4%) in Group F compared with 11 out of 98 (11.2%)

Table 1 Patient characteristics presented as mean (range), mean (SD) or number

| Variable | Group SB (<i>n</i> =98) | Group F (<i>n</i> =98) |
|-------------------------------|--------------------------|-------------------------|
| Age (yr) | 11.0 (5-16) | 11.1 (5-16) |
| Gender (M:F) | 82:16 | 79:19 |
| Weight (kg) | 30.8 (9.0) | 30.1 (9.2) |
| VR surgery:scleral buckling | 56:42 | 59:39 |
| Duration of anaesthesia (min) | 99.9 (30.7) | 99.0 (31.1) |
| Duration of surgery (min) | 81.6 (28.2) | 79.9 (29.6) |

Table 2 Supplementary drug requirements and incidence of OCR presented as n (%). *P<0.001; **P=0.012

| | Group SB (<i>n</i> =98) | Group F (<i>n</i> =98) |
|---------------------------------------|--------------------------|-------------------------|
| Intraoperative supplementary fentanyl | 5 (5.1) | 11 (11.1) |
| Intraoperative OCR | 5 (5.1) | 31 (31.6)* |
| Intraoperative atropine | 2 (2.0) | 5 (5.1) |
| Postoperative fentanyl requirement | 21 (21.4) | 28 (28.6) |
| Postoperative ibuprofen requirement | 47 (48) | 65 (66.3)** |

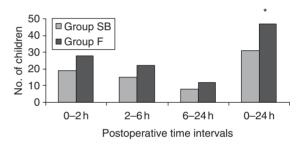


Fig 1 Number of patients having moderate to severe pain in the different time intervals studied and in total 24 h after surgery. *P<0.05.

Table 3 Incidence of PONV in the first 24 h presented as n (%). *Nausea preceding or after vomiting or persisting in two time intervals studied

| | Group SB (n=98) | Group F (<i>n</i> =98) |
|--|-----------------|-------------------------|
| No nausea/vomiting | 50 (51.6) | 46 (46.9) |
| Nausea not associated with vomiting | 12 (11.3) | 14 (14.3) |
| Single episode of vomiting | 15 (15.5) | 18 (18.4) |
| Persistent nausea*/>2 episodes of vomiting | 21 (21.7) | 20 (20.4) |

in Group SB (P=0.075). Children in both groups undergoing scleral buckling were more likely to have moderate to severe pain (54.4%) compared with those having vitrectomy alone (45.5%) (P>0.05). The postoperative fentanyl requirement of the two groups was comparable in the first 2 h after surgery (Table 2). The need for one or more ibuprofen doses was significantly higher in Group F compared with Group SB in the period from 2 to 24 h after surgery (Table 2).

The incidence of postoperative nausea vomiting was comparable between the two groups in the different time intervals studied and also over the entire 24 h studied (Table 3).

Discussion

In this study, the incidence of moderate to severe pain in the first 24 h after VR and scleral buckling surgery was significantly lower in children who received a sub-Tenon's block compared with those receiving i.v. fentanyl. This finding is consistent with that of Farmerv and colleagues⁹ and Bergman and colleagues¹¹ who demonstrated significantly lower pain scores in adults in the first 12 h after VR surgery under sub-Tenon's block and general anaesthesia when compared with general anaesthesia alone. The marked differences in the pain scores in the block group and the fentanyl group in the immediate postoperative period were not apparent in our study because of the different anaesthetic technique used. The repeated administration of fentanyl every hour in Group F resulted in some patients having received fentanyl just 30 min before the end of surgery and lower pain scores in the immediate postoperative period.

Kwok and colleagues⁷ and Lai and colleagues¹⁰ used sub-Tenon's block for providing anaesthesia for adults undergoing VR surgery. In both these studies, the block had to be supplemented intraoperatively (in $69\%^7$ and 37% patients,¹⁰ respectively). Similarly, Li and colleagues⁸ found that a single injection of sub-Tenon's block (11 ml) provided effective anaesthesia for vitrectomies lasting <3 h; however, the block had to be supplemented in 31.3% patients undergoing more painful procedures (cryotherapy and scleral buckling). Since surgery was performed under general anaesthesia in our paediatric patients, the need for intraoperative block supplementation could not be elicited.

In addition to the significantly more number of children having moderate to severe pain in the first 24 h after surgery, the requirements for oral ibuprofen were significantly higher in Group F compared with Group SB. The ibuprofen was given by the ward nurses who were unaware of the intraoperative analgesic technique used and who regularly dispense analgesics to children after operation. This was an independent surrogate marker of pain occurring in the fentanyl group after the surgery and is similar to other studies.⁴

The haemodynamic variables were comparable and stable between the two groups, as also demonstrated in the study by Farmery and colleagues⁹ where the block group had a significant decrease in intraoperative hypertensive episodes and opioid consumption compared with the general anaesthesia group. Bergman and colleagues¹¹ demonstrated lower mean arterial pressures and a decrease in the sevoflurane requirement in the block group. In our study too, the need for intraoperative fentanyl boluses was more in Group F when compared with Group SB, although the study was not powered to show a significant difference.

The incidence of OCR was considerably lower in Group SB compared with Group F as has been demonstrated in

other studies where the incidence has been reported to be 56.7% and 57%, respectively, in the control group.^{5 9} As the tendons of the extraocular eye muscles and the sensory nerves to the globe (branches of the trigeminal nerve, afferent arc of the OCR) traverse through the sub-Tenon's space, a block here decreases the incidence of OCR during VR surgery.^{3 15}

The incidence of PONV in Group SB (36.7%) was comparable with previous studies in children undergoing VR surgery under general anaesthesia with a peribulbar block.²¹⁴ The higher incidence of PONV in the control group in these studies (77%, 81.3%) compared with our study (38.7%) could be because the long-acting opioids (morphine and meperidine) used in the control group in these studies are more likely to cause PONV compared with fentanyl.¹⁶ The use of isoflurane in our study could have contributed to PONV in both groups, as volatile anaesthetic use has been found to be the single most important factor contributing to early PONV (0-2 h).¹⁷ In contrast, the use of propofol infusion for maintenance of anaesthesia and avoidance of volatile anaesthetics could have contributed to lower PONV scores in adults undergoing VR surgery⁹ and in children undergoing strabismus surgery (5.3% PONV incidence in the block group when compared with 36.8% in the control group).⁵ Although the incidence of OCR was lower in Group SB, it did not result in lower incidence of PONV as incidence of OCR may not always correlate with PONV.¹⁶

The main limitation of our study was that the sub-Tenon's block could not be repeated at the end of surgery. This might have resulted in still lower incidence of postoperative pain, especially as the total volume of local anaesthetic administered at one time is small. As 3-5 ml sub-Tenon's local anaesthetic in adults undergoing VR surgery was found to provide adequate anaesthesia without increasing the intraocular pressure or producing conjunctival chemosis,¹⁵ we used 1.5-2 ml in younger children and 2-3 ml in those above 10 yr of age. Another limitation is that some observers and the surgeon were not blinded. However, the administration of a sham sub-Tenon's injection of saline in the fentanyl group was not performed, as it was considered unethical to administer saline without giving any benefit to these children, many of whom were myopes with long axial length eyeballs and as there are reports of globe rupture,¹⁸ orbital haemorrhage,¹⁹ and posterior vitreous detachment²⁰ with sub-Tenon's block. The safety of sub-Tenon's block in VR surgery is potentially enhanced as some dissection of the sub-Tenon's space and visualization of the posterior segment of the eye are parts of the surgery itself. In our study, apart from conjunctival chemosis, no other complications were noted.

The AIIMS pain and behaviour score was used to assess pain in younger children. The score measures physiological signs of pain (ventilatory frequency and HR), behavioural manifestations (cry and discomfort), and some self-reporting of pain. It could not be combined with a visual analogue scale or face scale for assessing pain as some of the children had markedly decreased visual acuity in both eyes (bilateral retinal detachment and high myopes). However, in older children, a more detailed numeric rating scale would have been more comprehensive than the three-point score used.

In conclusion, sub-Tenon's block in combination with general anaesthesia provided stable intraoperative haemodynamics, a low incidence of intraoperative OCR, and effective perioperative analgesia in children undergoing VR surgery.

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