A double-masked evaluation of lignocaine-prilocaine cream (EMLA) used to alleviate the pain of retrobulbar injection

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Abstract

A randomised, placebo controlled, double-masked study was undertaken in 115 patients undergoing cataract surgery to assess the efficacy of the anaesthetic cream EMLA (eutetic mixture of local anaesthetic, lignocaine-prilocaine) in alleviating the pain of retrobulbar injection. Sixty three patients received the EMLA cream and 52 the placebo cream. The pain was assessed objectively by the anaesthetist, who observed the reaction of the patient on needle insertion, and subjectively by the patient. Significantly lower pain scores were recorded in patients treated with EMLA cream (anaesthetist's observation: p<0.01, patient's assessment: p<0.006). No patients experienced serious side effects in either treatment group.

Day case cataract surgery is now commonly performed in the United States of America and Canada. It is becoming commoner in the United Kingdom, with increasing use of local anaesthesia, either retrobulbar or peribulbar.2-4 Both retrobulbar and peribulbar injections which involve insertion of a needle through the skin of the periorcular region can be painful procedures. Pain increases the anxiety of elderly patients undergoing cataract surgery, causing the experience to be unpleasant for them and the procedure potentially more difficult for the surgeon.

A topical preparation which can be applied to the skin without discomfort and which alleviates the pain of needle insertion would be helpful to both patients and staff. The local anaesthetic cream EMLA (eutetic mixture of local anaesthetics) which contains a mixture of lignocaine and prilocaine has been shown to reduce the pain associated with skin puncture and other superficial skin procedures in both children and adults.5-12 Local skin reactions have been minor and transient.5-12 Previous studies, which have been concerned mainly with pain on venepuncture, have identified a minimum application period of 45 minutes in adults to ensure maximal analgesic effect.5 This study was performed to assess the efficacy of EMLA cream in alleviating the pain of retrobulbar injection and identify possible unwanted side effects of the preparation.

Patients and methods

One hundred and fifteen patients between the ages of 57 and 95 years who presented to the Department of Ophthalmology, Southport and Formby District General Hospital, for day case cataract surgery under local anaesthetic were included in the study. Informed, written consent was obtained from all the patients. The study protocol was approved by the Hospital Ethical Committee.

EMLA 5% cream consists of a mixture of lignocaine base 25 mg/ml (107 mmol/l) and prilocaine base 25 mg/ml (113 mmol/l). The remaining ingredients are an emulsifier, a viscosity increasing agent, and water. The placebo cream, a mixture of light liquid paraffin, white soft paraffin, and wool fat, was visually identical to EMLA.

The study was a double-masked comparison of EMLA cream with the placebo. The treatments were distributed at random, and at the end of the study 63 patients had received EMLA cream and 52 patients the placebo cream. Oral premedication was not used for any patient.

A thick layer of cream, about 2 ml, was applied in the ward by a nurse to the skin in the region of the outer half of the inferior orbital margin at least one hour preoperatively. The cream was covered with a Tegaderm (3M) occlusive dressing. Great care was taken while applying the cream and the occlusive dressing to prevent the cream from entering the eye. On the patient's arrival at the operating theatre anaesthetic room the occlusive dressing was removed and the cream wiped off with a dry swab. Local reactions, if any, were recorded by the person administering the retrobulbar injection, who was unaware of the identity of the topical cream.

Retrobulbar injections were performed with a 23 standard wire gauge, 30 mm long disposable needle. The needle was introduced at the junction of the lateral one-third and the medial two-thirds of the inferior orbital rim. Up to 5 ml of 0.5% bupivacaine hydrochloride with 1500 units hyaluronidase was slowly injected after aspiration to eliminate possible intravascular injection. This technique was used for all the study patients.

The person who administered the retrobulbar injection was required to make two assessments. The first was of the patient's reaction at the
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Figure 1 Pain on retrobulbar injection as determined by the anaesthetist.

Pain moment of skin penetration, which was graded on the following scale:
- 0 (no pain) – no reaction to injection;
- 1 (mild or moderate pain) – transient grimace, slight groan or minor reflex movement;
- 2 (severe pain) – loud or continuous verbal complaint, intensive or continuous reflex movement.

The second was of the subjective intensity of the pain felt by the patient. The patients were requested to grade pain on a scale between 0 (no pain) and 10 (intolerable pain).

The statistical significance of the difference between the patients who received the EMLA cream and those who received the placebo was analysed by the $\chi^2$ test for the results of the patient’s reaction to the retrobulbar injection as observed by the anaesthetist. The Mann-Whitney test with rank sums and the unpaired $t$ test were used for analysing the results of the patient’s subjective assessment of pain.

Results
The results from 115 patients undergoing cataract surgery were analysed. No patient’s results were excluded. There were 63 patients in the EMLA group comprising 21 males and 42 females, with a mean age of 78.2 (SD 7.6) years. Of the 52 patients in the placebo group 16 were male and 36 were female, with a mean age of 79.2 (SD 8.2) years. There was no statistically significant difference between the two groups in their baseline characteristics.

Fig 1 shows the patients’ reactions to the retrobulbar injection as observed by the anaesthetist. Treatment with EMLA cream resulted in significantly less pain on retrobulbar injection compared with placebo ($\chi^2=9.36$, df=2, $p<0.01$).

Fig 2 shows the pain of retrobulbar injection subjectively assessed by the patients. The individual pain scores after the application of the placebo cream were scattered over the whole scale, while the majority of scores after EMLA cream were near the ‘no pain’ end of the scale. Patients who received EMLA cream (mean pain score 2.6, SD 1.9) scored significantly less pain compared with those who received the placebo (mean pain score 3.8, SD 2.3; Mann-Whitney test, $Z=2.812$, $p<0.006$; unpaired $t$ test, $t=3.069$, $p<0.005$).

No significant local side effects were noted, and there were no cases of marked erythema, scaling, oedema, or allergic reaction in either the EMLA or placebo group. Some EMLA cream inadvertently leaked on to the eyes of three patients in the time between its application and the arrival of the patient at the operating theatre. All the three eyes showed congested conjunctiva with loss of the corneal epithelium in one eye. The latter could have been due to the preoperative ocular biometry or the EMLA cream. The placebo cream leaked on to the eyes of two patients. Of these, one eye was unaffected and the other had mild conjunctival congestion. All the above five eyes underwent uneventful cataract extraction with intraocular lens implantation.

Discussion
EMLA cream has proved to be effective in reducing the pain of venepuncture in both children and adults. It penetrates the intact skin and has been used successfully as a topical analgesic for superficial skin procedures, lumbar punctures, and arterial cannulation. Our study of elderly patients undergoing cataract surgery demonstrates the efficacy of EMLA cream in alleviating the pain of retrobulbar injection. This benefit the patient undergoing cataract surgery because it reduces anxiety, and the doctor because the retrobulbar injection is administered more easily if the patient does not react adversely to the needle puncturing the skin.

There were no unwanted local effects of any significance. Despite great care in application, the study creams leaked on to the eyes of five patients. The EMLA cream produced transient stinging, congested conjunctiva and possibly in one patient corneal epithelial denudation. However, uncomplicated cataract-intraocular lens surgery was possible in all the patients.

In conclusion, EMLA cream is effective in alleviating the pain of retrobulbar injection in patients undergoing cataract surgery. We now

Figure 2 Pain on retrobulbar injection as indicated by the patient.
use this cream routinely for all patients undergoing intraocular surgery under local anaesthetic.

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