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UNIVERSITÄTSKLINIKUM Schleswig-Holstein

Development of a 2% lidocaine gel for local anaesthesia of the eye prior to intravitreal injection

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Background and importance:

Intravitreal injection is a very common eye surgery. The preparation of the injection is time-consuming and labour-intensive, because patients receive several ophthalmic drugs beforehand like local disinfecting, pupil dilating and local anaesthetic eye drops. Additionally, eye drops containing oxybuprocaine must be applied 3 to 5 times at minute intervals for a sufficient anaesthetic effect. There are indications in the literature that a 2% lidocaine gel is effective on the eye. [1]

Aim and objectives:

To simplify the process, a local anaesthetic eye gel preparation with sufficient local anaesthetic effect after a single dose was requested. A corresponding product is not available on the German market, so the development of an in-house product based on NRF instructions was needed.

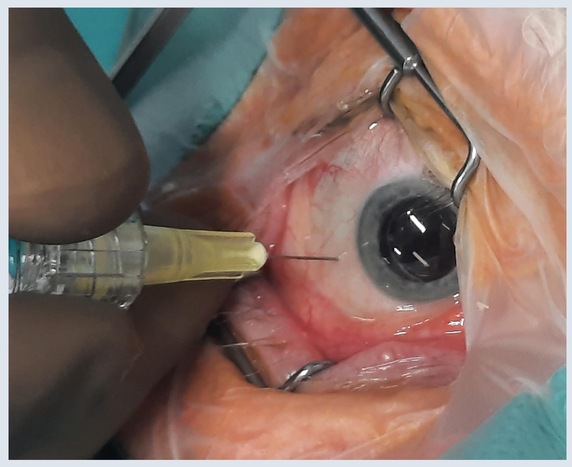

Fig. 1
Intravitreal injection

METHODE:

Lidocaine hydrochloride monohydrate	7,47 g	*2 % (m/m)* calculated on the hydrochloride
Sodium chloride	1,68 g	*0,48 % (m/m)*
Sodium monohydrogen phosphate dodecahydrate	0,875 g	*0,25 % (m/m)*
Hydroxyethylcellulose 250 (Natrosol® 250 G pharm)	8,75 g	*2,5 % (m/m)*
Water for injection	ad 350 g	

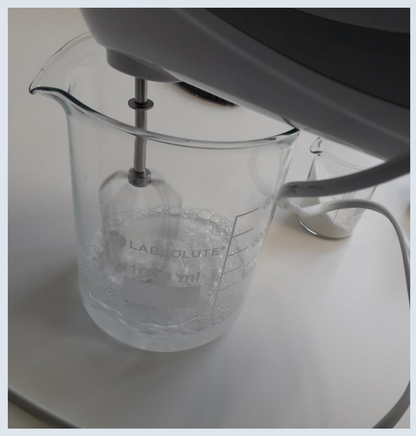

Fig. 2
Solution and gelling agent are stirred

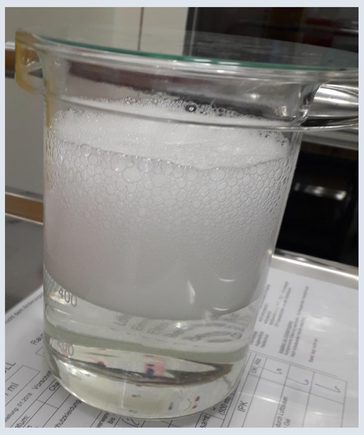

Fig. 3
The preparation stands overnight. The gelling agent can swell and air bubbles settle out

Material and methods:

1. Dissolve Lidocaine, NaCl (isotonic additive) and $Na_2HPO_4 \cdot 12\ H_2O$ (pH adjustment) in approx. 300 ml hot water for injection (approx. 50 °C), then sprinkle HEC onto the hot solution while stirring vigorously.
2. After cooling, fill up to the final weight with WFI and stir well.
3. Cover the gel and let it swell (overnight if necessary), then fill 1 ml into single-dose containers using a syringe and autoclave the product.
4. Check single-dose containers for leaks, then label each one and pack them in labelled secondary packaging.

Primary packaging: Redipac® single-dose containers
Shelf Life: 6 months, determined in analogy to NRF 7.13 / 7.15 [2]
Use-by period: Discard leftovers after opening.

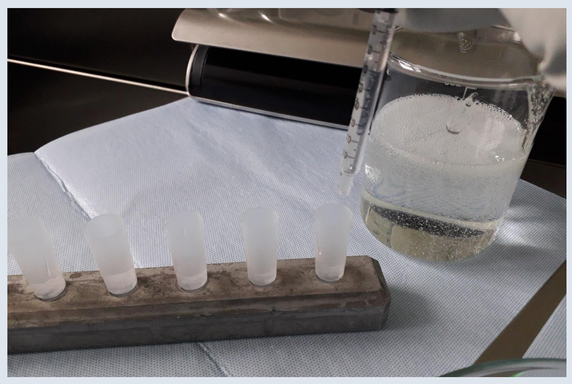

Fig. 4
The gel is filled in single-dose containers using a syringe

Quality control:

The identity and content of the preparation are checked using photometry.
pH: 5,9 – 6,7 ($\mu \pm 3\ \sigma$, n = 35); Osmolality: 316 – 358 mosmol/kg ($\mu \pm 3\ \sigma$, n = 35)

Results:

The described lidocaine gel preparation has a viscosity suitable for the application and is sufficiently anaesthetically effective after a single dose. The gel is preservative-free and can be stored at room temperature. A positive side effect is, that the eye is moistened by the gel form during the surgical intervention: According to the experience of the UKSH ophthalmologists, patients complain less about symptoms of dry eyes. The preparation is used regularly in the eye surgery on the campus Lübeck.

Conclusion and relevance:

The lidocaine gel in single-dose containers has significantly accelerated and simplified the preparation of intravitreal injections in the UKSH Eye Clinic.

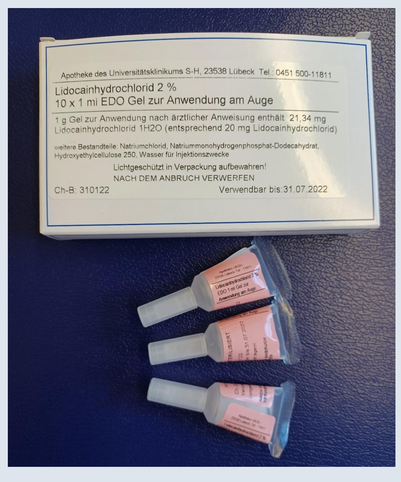

Fig. 5
Finished preparation with primary and secondary packaging

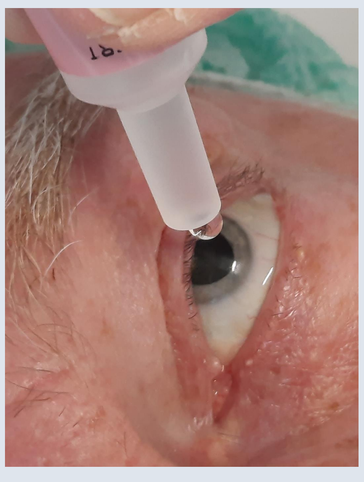

Fig. 6
Application of the gel

[1] The Effectiveness of 2% Lidocaine Gel Compared to 0.5% Tetracaine Eye Drop As Topical Anesthetic Agent for Phacoemulsification Surgery.; Anesth Pain Med. 2018 Apr 28;8(2): e68383.
[2] www.dac-nrf.de

Wissen schafft Gesundheit

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