
THE MAINTENANCE OF PER-OPERATIVE MYDRIASIS IN PHACOEMULSIFICATION WITH TOPICAL DICLOFENAC SODIUM

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SUMMARY

Purpose: To determine whether the use of topical diclofenac sodium (diclofenac) pre-operatively improves the maintenance of per-operative mydriasis, in conjunction with irrigating solutions containing adrenaline.

Methods: Sixty-four consecutive patients undergoing phacoemulsification were randomised to receive either diclofenac or no diclofenac in conjunction with cyclopentolate 1% and phenylephrine 10% pre-operatively. They subsequently underwent routine phacoemulsification by one consultant surgeon. Irrigating solutions of balanced salt solution contained adrenaline 1:10⁶. Pupil diameters were measured pre-sclerostomy, post-phacoemulsification, post-irrigation/aspiration and on day 1 post-operatively. These were then compared by Student's *t*-test.

Results: The two groups were statistically similar in age and sex. The mean pre-sclerostomy pupillary diameters were 8.1 mm in both groups. The mean post-phacoemulsification diameters were 7.6 mm in those receiving diclofenac and 7.2 mm in those not ($p = 0.03$). The mean diameters after infusion/aspiration were 7.7 mm in those receiving diclofenac and 7.1 mm in those not ($p = 0.008$). The mean pupillary diameters on day 1 were 5.3 mm in those receiving diclofenac and 4.6 mm in those not ($p = 0.003$).

Conclusion: Diclofenac improves the maintenance of per-operative mydriasis, in the presence of irrigating solutions containing adrenaline.

In small-incision surgery, safety and complication rate can be improved by maintenance of maximal pupillary dilation. This is of particular importance whilst learning the technique. Pre-operative mydriasis for cataract extraction is usually achieved by

application of a topical adrenergic agonist such as phenylephrine in combination with a cholinergic antagonist such as cyclopentolate. Adrenaline has been shown to help maintain mydriasis during extracapsular cataract surgery when used in irrigating solutions, by directly stimulating the dilator pupillae.¹

Surgical trauma during phacoemulsification, such as manipulation of the iris both mechanically and with irrigation solutions, leads to prostaglandin release and miosis. These reactions are independent of cholinergic and adrenergic receptors.² Diclofenac sodium (diclofenac) is a powerful inhibitor of prostaglandin synthesis. Topical diclofenac has been shown to decrease cataract-induced blood-aqueous barrier breakdown.³ It has been shown to reduce surgically induced miosis in extracapsular surgery and in animal models.⁴⁻⁹ It has also been used to decrease pseudophakic cystoid macular oedema¹⁰ and post-operative inflammation without any increase in intraocular pressure.¹¹⁻¹⁴

Many phacoemulsification units routinely use adrenaline in irrigating solutions. We investigated prospectively whether the use of topical diclofenac pre-operatively had any additional benefit in the presence of irrigating solutions containing adrenaline.

PATIENTS AND METHODS

Sixty-four consecutive patients due to undergo routine phacoemulsification were enrolled into the study. Patients with diabetes or a past history of inflammatory eye disease were excluded. Pre-operatively they were instilled with one drop of guttae phenylephrine 10% and cyclopentolate 1% four times. Patients were randomised to receive either four doses of guttae diclofenac (Voltarol Ophtha) pre-operatively concurrently with their dilating drops, or no diclofenac.

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Patients then underwent routine phacoemulsification by one experienced consultant surgeon. This was done through a scleral tunnel, with implantation of a 5.5 mm optic (IOLAB). Hydroxymethylcellulose was used as a viscoelastic and irrigating solutions were balanced salt solution with adrenaline 1:10⁶.

Horizontal pupil diameters were measured on a masked basis to the nearest 0.5 mm by callipers at set points during the surgery. These were pre-sclerostomy, post-phacoemulsification, post-infusion/aspiration (automated) and on day 1 with a Haag-Streit slit lamp.

The patient groups were analysed for sex and eye by chi-squared with Yates' correction and for age by Student's *t*-test. The pupil diameters were analysed by Student's *t*-test.

RESULTS

There were 32 patients in each group. Thirteen patients were male and 19 female in the diclofenac group and 7 were male and 25 were female in the no diclofenac group ($0.5 < p < 0.1$). There were 15 right eyes and 17 left eyes in the diclofenac group and 19 right eyes and 13 left eyes in the no diclofenac group ($0.5 < p < 0.1$). The mean age in the diclofenac group was 77 years (range 58–94 years) and the mean age was 75 years (range 54–92 years) in the no diclofenac group ($p = 0.3$). Four patients in the diclofenac group and 3 patients in the no diclofenac group were operated on under general anaesthetic. The remainder of the operations were all performed under local anaesthetic using peribulbar injections. There were no per-operative complications.

The mean pupillary diameters before the sclerostomies were 8.1 mm in both groups ($p = 0.7$ by *t*-test; Table I, Fig. 1). The mean diameters post-phacoemulsification were 7.6 mm in the diclofenac group (range 6–9 mm) and 7.2 mm in the no diclofenac group (range 5–8.5 mm). This difference of 0.4 mm was statistically significant ($p = 0.03$). The difference between mean diameters post-infusion/aspiration was greater by 0.6 mm, being 7.7 mm in the diclofenac group (range 6–9 mm) and 7.1 mm in the no diclofenac group (range 5.5–8.5 mm). This was reflected in a greater statistical significance ($p = 0.008$). The mean diameters on day 1 were 5.3 mm (range 4–7 mm) and 4.6 mm (range 3–7 mm), again a difference of 0.6 mm ($p = 0.003$).

Table I. Mean horizontal pupil diameters in millimetres during the surgery

Stage	No diclofenac	Diclofenac
Pre-sclerostomy	8.1	8.1
Post-phacoemulsification	7.2	7.6
Post-infusion/aspiration	7.1	7.7
Day 1 post-surgery	4.6	5.3

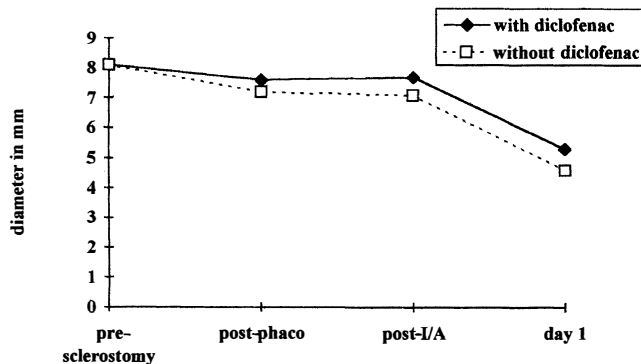


Fig. 1. Mean horizontal pupillary diameters during the surgery, with and without diclofenac sodium. I/A, infusion/aspiration.

DISCUSSION

Activation of phospholipase A₂ following tissue injury leads to the breakdown of cell membrane phospholipids to arachidonic acid. This is then converted to prostaglandins by cyclo-oxygenase, or to hydroxy acids and leukotrienes by 5-lipoxygenase.¹⁵ Cataract extraction is associated with increased prostaglandin levels in the aqueous.¹⁶ Surgery also leads to protein influx into the anterior chamber due to breakdown of the blood–aqueous barrier,¹⁷ and miosis resistant to atropine.² These changes are mediated in part by prostaglandins. Diclofenac reduces prostaglandin activity mainly by inhibition of cyclo-oxygenase.²

Diclofenac has been shown to be effective in maintaining mydriasis in rabbit models.⁴ Previous investigations in extracapsular cataract surgery in humans have shown variable results.^{5–9} In the absence of adrenaline two studies showed a significant benefit^{5–7} and two showed statistical but limited benefit.^{8,9} Our series, with an improvement of 0.6 mm at best, would confirm this limited benefit. However, no patients in either group had a pupillary diameter of less than 5 mm per-operatively – which previous authors have used as a surgically significant cut-off.¹

The fact that any miosis occurs indicates either that prostaglandin synthesis has been incompletely blocked, or that other mechanisms which are too great to be overcome by adrenaline are present. Mediators that have been implicated include substance P¹⁸ and vasoactive intestinal polypeptide.¹⁹ To fully prevent miosis during cataract surgery, further investigation of these factors is required. Careful cost–benefit analysis would be required, however, to confirm the clinical benefit of additional agents.

This study shows that in the presence of irrigating solutions containing adrenaline, topical diclofenac has a statistically significant but clinically small additive effect in maintaining per-operative mydriasis.

Key words: Cataract, Surgery, Mydriasis.

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