TOPICAL DICLOFENAC RELIEVES PAIN FROM CORNEAL RUST RING

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SUMMARY

A prospective double-masked placebo controlled trial to assess the potential benefit of topical diclofenac in the treatment of corneal rust ring of 40 patients attending the eye casualty department was carried out. Patients allocated to the diclofenac group had significantly reduced pain scores at 48 hours after starting treatment compared with patients allocated to the placebo group (p = 0.008 and p = 0.042 for visual analogue and Likert pain scales respectively). No difference was noted between groups in terms of rate of epithelial healing or degree of inflammation. Topical diclofenac offers improved analgesia in the treatment of corneal rust ring.

Corneal rust ring is a common reason for presentation at the eye casualty department, being responsible for up to 26% of eye injuries in some units.[1,2] The condition is associated with significant short-term morbidity and loss of man-hours in the workplace.[1] To date the mainstay of treatment of this condition has been to offer patching, topical antibiotic and mydriatic after debridement of the rust ring. Selection of pain relief following removal of corneal rust ring is restricted, as systemic medication gives poor control of local symptoms and may lead to systemic upset. The aim of the study was to assess pain relief, rate of healing and resolution of inflammation following removal of the corneal rust ring and treatment with topical diclofenac in conjunction with established therapy.

MATERIALS AND METHODS

Between 1 March 1994 and 21 September 1994 patients seen at Aberdeen Royal Infirmary eye casualty department suffering from corneal rust ring were considered for entry into the trial. Ethics committee approval was granted for the trial and all patients gave informed consent. Forty patients were entered into the randomised controlled trial after fulfilling the following criteria: the patient was over 18 years of age, the rust ring was of less than 96 hours duration, there was no evidence of other ocular injury such as large abrasion, hyphaema, ocular penetration or history of previous corneal pathology such as dry eye, herpes simplex keratitis or marginal ulceration.

After details of the relevant history and Snellen visual acuity (pinhole) had been recorded a detailed slit lamp examination was carried out. The presence of foreign body and infiltrate were recorded, and inflammatory activity in the anterior chamber was graded (by estimation of the number of anterior chamber cells, graded from 0 to 4, where 0 = no cells and 4 = >50 cells; estimation of flare, graded 0 to 4; and presence keratic precipitates). Subjective pain was measured with a visual analogue scale (the scale ranged from 0 to 100, with 0 representing no pain and 100 representing severe pain) and a Likert pain scale (ranging from 1 to 5, 1 representing no pain and 5 representing severe pain), before removal of the corneal rust ring using topical G. amethocaine 0.5% and a burr. The abrasion height and width were measured by comparison with the slit beam of a Haag–Streit 900 slit lamp.

The patients were randomised to receive either 4 hourly G. diclofenac 0.1% and Oc. chloramphenicol, or identically packaged 4 hourly G. placebo and Oc. chloramphenicol. Patching of the affected eye for 4 hours was offered. Co-proxamol tablets were provided for supplementary analgesia and patients were asked not to take other analgesics throughout the duration of the trial. After 2 days subjective pain was remeasured with the visual analogue and the Likert scale, and the abrasion size, infiltrate and

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Table I. Summary of data from the diclofenac group

Patient no.	Visual analogue pain day 0	Visual analogue pain day 2	Likert pain day 0	Likert pain day 2	Abrasion size (mm^2)	Eye	Eye protection worn	Tablets taken	History
14	30	16	4	3	0.4	R	N	4	Welding
15	44	12	3	2	1	R	N	0	Blown in
12	45	0	4	1	0.49	R	N	7	Hammering
17	56	0	4	1	1	L	N	0	Grinding
11	15	0	2	1	1	L	N	0	Welding
10	70	28	4	2	1	R	Y	0	Blown in
4	34	0	3	1	1	L	N	1	Sawing
3	10	0	2	1	0.5	R	N	0	Welding
1	27	2	3	1	1	L	Y	0	Grinding
40	37	17	3	2	2.25	L	N	1	Grinding
27	37	0	3	1	1.44	R	Y	0	Grinding
36[a]	83	43	5	3	12.25	L	Y	2	Welding
31	20	0	2	1	1	R	Y	0	Welding
37	8	9	2	2	1	R	N	0	Not known
24	26	6	2	1	1	R	N	0	Grinding
38	71	0	4	1	1	R	N	0	Welding

[a]Not included in the statistical analysis because of the large abrasion size.

inflammatory response reassessed. Also the number of tablets taken was recorded. Treatment was continued until the epithelial defect was healed and the patients were asymptomatic. Patients were reviewed every 48 hours until this was achieved. Pain scores were analysed by the non-parametric Mann–Whitney *U*-test, with p set at the 0.05 level for significance.

RESULTS

Forty patients were enrolled in the study (all male, mean age 33.5 years). Of these, 26 patients (65%) completed the study (15 diclofenac, 11 placebo), 13 defaulted from follow-up (32.5%; 4 from the diclofenac group, 9 from the placebo group) and 1 patient from the diclofenac group was withdrawn from the statistical analysis because of a concomitant large corneal abrasion. The difference in the number of defaulters from each group was not significant (Student's *t*-test $p = 0.096$). Individual patient details of those who completed the study are recorded in Tables I and II.

At presentation the mean pain scores of the diclofenac group and the placebo group showed no significant difference (using a non-parametric Mann–Whitney *U*-test, $p = 1.00$ for the visual analogue scale and $p = 0.62$ for the Likert scale).

At day 2 the mean pain scores of the diclofenac group and the placebo group were significantly different (using a non-parametric Mann–Whitney *U*-test, $p = 0.0075$ for the visual analogue scale and $p = 0.042$ for the Likert scale). Statistically the two groups did not differ significantly in terms of age, rust ring site, abrasion size or anterior chamber inflammation (Student's *t*-test). The mean tablet consumption for the diclofenac group was 0.87 tablets (SD 2.00) and for the placebo group was 1.45 tablets (SD 1.63); however, a parametric Student's *t*-test did not find this difference in tablet consumption to be significant ($p = 0.43$). Acceptance of patching of the affected eye for 4 hours was variable, with many patients admitting removal of the patch to drive home. All epithelial defects healed within 1 week and no side effects were encountered. Statistical analysis is summarised in Fig. 1.

DISCUSSION

Diclofenac is a cyclo-oxygenase inhibitor which reduces the production of prostaglandins. Prostaglandins are implicated in the production of painful

Table II. Summary of data from the placebo group

Patient no.	Visual analogue pain day 0	Visual analogue pain day 2	Likert pain day 0	Likert pain day 2	Abrasion size (mm^2)	Eye	Eye protection worn	Tablets taken	History
13	22	7	2	2	0.25	R	N	0	Grinding
16	55	31	4	2	1	R	N	3	Grinding
29	50	1	3	1	0.04	R	N	0	No history
9	64	19	4	2	0.04	R	N	0	Hammering
8	22	78	2	4	1	L	Y	4	Grinding
7	24	18	2	3	1	R	N	1	Welding
5	19	3	2	1	1	R	Y	2	Welding
32	29	51	3	4	1	L	N	4	No history
34	23	38	2	3	1	L	N	0	Not known
21	36	9	3	2	1	L	N	0	Blown in
26	68	4	4	1	1	R	N	2	Welding

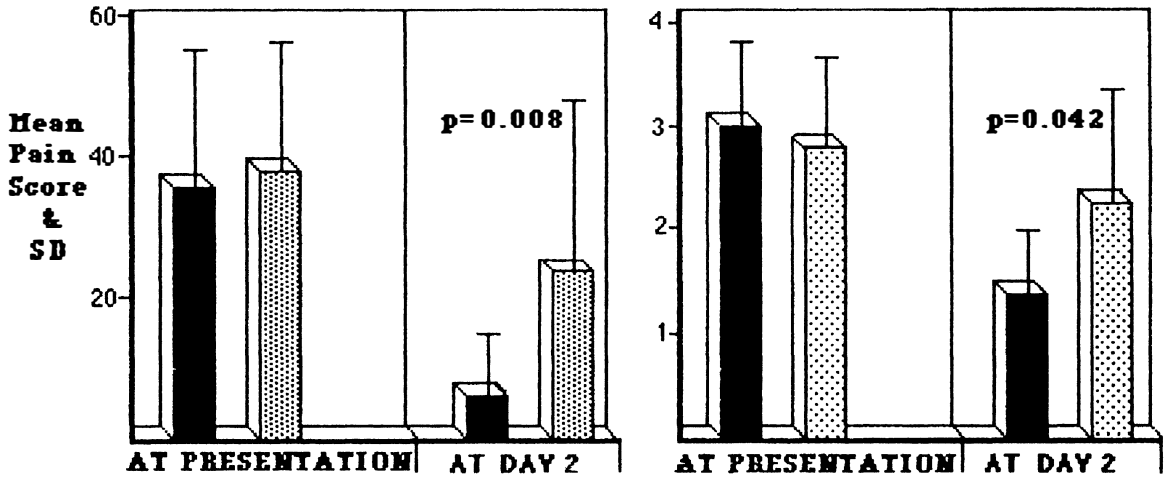

Fig. 1. *Graphical summary of the statistical analysis of mean pain scores in the diclofenac group (black columns) and placebo group (stippled columns). Left: visual analogue scale. Right: Likert scale.*

sensation by causing hypersensitivity and by acting as part of the acute inflammatory response.[3] Support for the analgesic effect of topical diclofenac in the ophthalmic field has come from a number of studies reporting improved pain control in photorefractive keratectomy,[3,4] posterior segment surgery,[5] corneal abrasions[6] and reduction of corneal sensation in normal subjects.[7]

In this study patients allocated to the diclofenac group had significantly reduced pain scores at 48 hours after starting treatment compared with patients allocated to the placebo group (p = 0.008 for visual analogue scale and p = 0.042 for Likert pain scale). Usage of topical diclofenac in the UK is limited to 28 days, and therefore there are few data concerning the potential long-term hazards of the use of topical diclofenac; however, reported adverse reactions include moderate burning sensation, rarely blurring of vision immediately after instillation, hypersensitivity, photosensitivity and keratitis punctata. There is also a theoretical possibility of prolongation of the bleeding time in patients with known haemostatic defects or other medications which interfere with clotting. No evidence of side-effects was seen during the short period of usage of diclofenac in this study. Like other non-steroidal anti-inflammatory agents, diclofenac is contraindicated in patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by drugs with prostaglandin synthase inhibiting activity.

This study can be criticised because of the small patient numbers involved, variability in the acceptance of patching, and the number of defaulters. Defaulting may be related to the nature of the young male attenders, who are aware of the short-term nature of the condition and that resolution is usually spontaneous following removal of the rust ring. The higher defaulting rate of the placebo group is difficult to explain; however, the difference in the numbers of defaulters from the two groups was not statistically significant. A larger study would be of benefit in minimising such potential sources of error. Masking of the study was carefully controlled as randomisation and results were handled by an individual isolated from the clinical assessment and collection of data from the patients.

Seventy-seven per cent of the subjects in our study were not wearing eye protection at the time of the injury. This correlates with other studies[2,8] where the majority of patients did not wear eye protection because they either found the goggles were uncomfortable, caused visual handicap, or they did not feel they were at risk at the time. The treatment of ocular foreign body, therefore, should primarily be preventive, via education and legislation.

Corneal foreign bodies are a common cause of morbidity and loss of man-hours in the workplace. We have carried out a small study which shows that diclofenac significantly reduces the pain experienced after the removal of a rust ring, without producing a delay in healing. With the use of diclofenac, therefore, we may expect a reduction in the lost man-hours and the discomfort associated with this all too common condition.

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Key words: Analgesia, Corneal foreign body, Diclofenac.

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