

Patient Reliability in the Administration of Topical Ocular Medication

C L Cheng, S P Chee, D T H Tan

ABSTRACT

Purpose: To evaluate patient's reliability in the administration of eyedrops.

Method: The study is based on a randomised, controlled clinical trial in which a steroid-containing drug delivery system (DDS) was directly compared to conventional steroid eyedrops after cataract surgery. 32 eyes undergoing extracapsular cataract extraction with intra-ocular lens insertion received a DDS, while 31 eyes received 0.1% dexamethasone eyedrops q.d.s for 30 days. Patients with DDS were given a placebo eyedrop in the form of 0.9% sodium chloride, while all 63 eyes received topical chloramphenicol eyedrops q.d.s for 30 days. At the conclusion of the 30 day visit, the eyedrop containers were collected and the residual volume of medication remaining in each bottle was then measured to the nearest 10 microlitre using a pipette.

Results: 31 patients returned the complete set of eyedrop containers. There was no statistical significant difference in the volume used between the types of eyedrops, sex and diabetic status. All the patients used more than the prescribed amount. Older patients tended to use less medication.

Conclusion: The amount of medication that patients actually administered in this trial varied widely according to the individual, and patient age may be a factor affecting compliance in using eyedrops.

Keywords: Eyedrops, Reliability

Singapore Med J 2001 Vol 42(6):252-254

INTRODUCTION

This prospective, placebo-controlled randomised clinical trial is a definitive method to evaluate hypothesis by a methodical comparison of two treatment regimes performed within a carefully monitored clinical trial setting. Ophthalmic clinical trials determining efficacy of topical ocular medications must rely on patient compliance with

eyedrop regimes for accurate data. The aim of this study is to investigate the reliability of patients in complying with the use and dosing instructions of eyedrops.

PATIENTS AND METHODS

This study is based on a randomised, controlled clinical trial to evaluate a new intraocular drug delivery system (DDS) which was directly compared to conventional steroid eyedrops after cataract surgery. A seven day release DDS containing 60 micrograms of dexamethasone, was placed in the anterior chamber of 32 eyes undergoing extracapsular cataract extraction with intraocular lens insertion. These patients were given a placebo eyedrop in the form of 0.9% sodium chloride q.d.s. Another 31 eyes received 0.1% dexamethasone eyedrops q.d.s whilst all 63 eyes received chloramphenicol eyedrops q.d.s. All patients were instructed to use the eyedrops accordingly for a total of 30 days.

At the conclusion of the 30 day visit, the eyedrop containers were collected and the residual volume of medication in each bottle was measured to the nearest 10 microlitre using a pipette. The control for the study (expected volume of medication used) was determined by measuring the total volume of the three eyedrops as prescribed for the duration of the study. The following method was used. Digital pressure was applied to the inverted bottle to release a single drop. The pressure was released after each drop to allow all forces to equilibrate. A mechanical thumb release counter was used to count the maximum number of drops from each eyedrop container.

RESULTS

This study was based on 31 complete sets of eye drops as eight patients failed to return any of the bottles issued and 21 patients returned an incomplete set of eyedrop containers. Of those included in this study, there were 16 females and 15 males included in the study. Eight patients were diabetic. The mean age was 64.7 years. The amount of eyedrops used varied widely among patients. This

Singapore National
Eye Centre
11 Third Hospital
Avenue
Singapore 168751

C L Cheng, MBBS,
FRCS (Ed),
MMed (Ophth)
Registrar

S P Chee, MBBS,
FRCS (G),
MMed (Ophth),
FRCS (Ed),
FRCOphth,
Senior Consultant

D T H Tan, MBBS,
FRCS (G),
FRCS (Ed),
FRCOphth, FAMS
Senior Consultant,
SNEC;
Associate Professor,
Faculty of Medicine,
National University
of Singapore

Correspondence to:
Dr C L Cheng
Tel: (65) 227 7255
Fax: (65) 227 7290

Fig. 1 Distribution of vol of antibiotic eyedrops used.

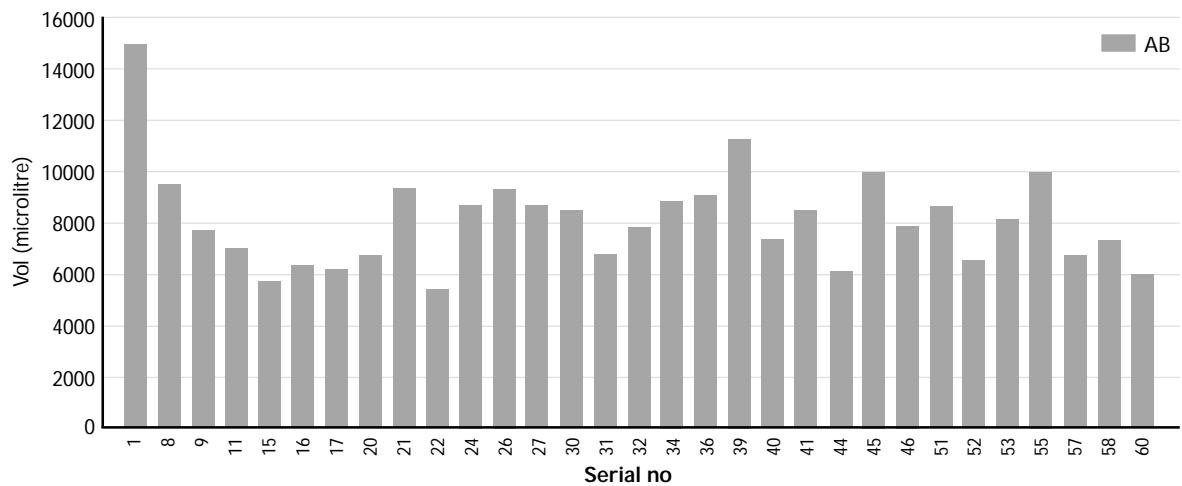


Fig. 2 Graph of mean vol of eyedrops used compared with control.

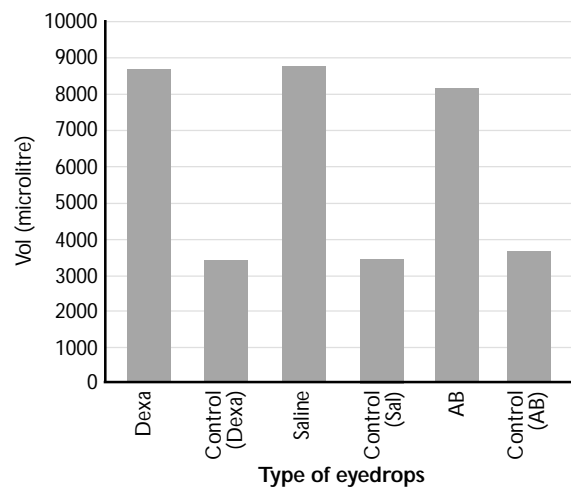
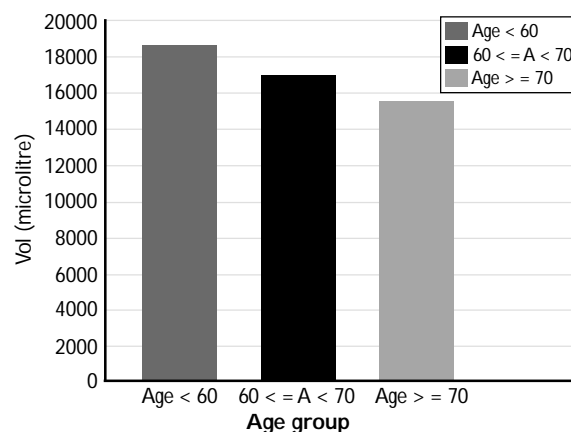


Fig. 3 Graph of mean vol of eyedrops used with age.



was irrespective of the type of eyedrop used (Fig. 1). All patients without exception used more than the amount prescribed with the majority consuming double or more (Fig. 2). Older patients were found to use less medication compared to younger patients (Fig. 3). The gender and diabetic status of the patients did not affect the amount of eyedrops used.

DISCUSSION

A randomised, controlled clinical trial to evaluate a new intraocular drug delivery system (DDS) in which a steroid-containing DDS was directly compared to conventional steroid eyedrops after cataract surgery. The efficacy of the eyedrops group was evaluated based on the assumption that patients were compliant with administering these medications precisely as instructed. We decided to ascertain patient compliance in eyedrop instillation by determining individual eyedrop utilisation patterns.

At the conclusion of the 30-day visit, it was noted that highly variable quantities of eyedrop contents were being returned. In addition, a significant proportion of the patients requested for additional bottles of study eyedrops.

Topical administration has traditionally been one of the commonest route of treatment for patients with ophthalmic conditions. However, the highly significant individual variation in eyedrop utilisation in our study questions the reliability of eyedrops as a precise mode of delivery of medication to the eye. Although both under-utilisation as well as over-utilisation were found, the close to doubling of eyedrop volumes for all three medications suggest that the majority of patients tended to overuse eyedrops. One should note, however, that total volume utilisation within the study period does not necessarily equate to actual patient compliance or total actual eyedrop volume entering the eye. Extraneous variable or confounding factors within this study include inadvertent placement of drops outside the eye due to difficulty in getting the eyedrop medication into the eye during the first attempt, difficulty in controlling the number of drops dispensed or loss of eyedrop bottles.

A trend suggesting that older patients in the trial utilised lower eyedrop volumes was a surprising

finding, as it had been expected that older patients would have encountered greater difficulty in instilling eyedrops. This would have implied greater wastage and consumption of a higher volume of eyedrops. However, our finding was contrary to this. Possible explanations include the possibility that other family members instilled the eyedrops for the patient, or that there was in fact less compliance occurring in the elderly age group.

Although diabetic patients have been shown to develop a more significant post-operative intraocular inflammation^(3,4,5), the diabetic patients in our study were not found to use larger volumes of eyedrops as compared to non-diabetic patients.

CONCLUSION

In conclusion, the use of eyedrops within a controlled clinical trial may be an inaccurate means of drug administration, which may result in potential errors in the evaluation of safety and efficacy trial parameters.

The amount of medication that patients actually administered in this trial varied widely according to the individual, with the majority tending towards overuse following intraocular surgery. A more reliable means of drug delivery which does not depend upon the patient such as the intraocular DDS would be superior as the precise quantum of drug can be delivered over a fixed duration following intraocular surgery.

REFERENCES

1. Charles M. Lederer, Ralph E. Harold. Drop Size of Commercial Glaucoma Medications. *Am. J. Ophthalmol.* 1986; 101:691-4.
2. Brown RH, Hotchkiss ML, Davis EB. Creating smaller eyedrops by reducing eyedropper tip dimensions. *Am. J. Ophthalmol.* 1985; 99:460-4.
3. Krupsky S, Zalish M, Oliver M, Pollack A. Anterior segment complications following extra- capsular cataract extraction and posterior chamber intraocular lens implantation. *Ophthalmic Surg* 1991; 22:526-30.
4. Cunliffe IA, Flanagan DW, George ND, Aggarwal RJ, Moore AT. Extra-capsular cataract surgery with lens implantation in diabetics with and without proliferative retinopathy. *Br. J. Ophthalmol* 1991; 75:9-12.
5. Hykin PG, Gregson RM, Stevens JD, Hamilton PA. Extra-capsular cataract extraction in proliferative diabetic retinopathy. *Ophthalmology* 1993; 100:394-9.