
ASSESSMENT OF EFFICACY OF TEAR SUBSTITUTES BY SCHIRMER’S TEST
Kawtikwar PS*, Kshirsagar SN and Vibhute SK
S.N. Institute of Pharmacy, Nagpur road, Pusad– 445 204, Maharashtra, India.

Received on : 14.10.2009                Revised : 21.01.10                         Accepted : 27.01.10

INTRODUCTION
Dry eye syndrome (also known as Keratoconjunctivitis sicca) occurs when there is a problem with the tear film that normally keeps the eye moist and lubricated 1. The causes of dry eye include: aging, medication, illness increased evaporation of tears, blepharitis and other unknown causes 2. The symptoms of dry eyes are – eye irritation, slight blurring of vision and dislike towards bright lights. The symptom for a contact lens wearer is discomfort. Possible complications of dry eyes are inflammation of the conjunctiva or the cornea at the front of the eye (keratitis) 3, 4, 5. In severe cases, small ulcers may develop on the cornea. If left untreated, loss of vision may occur 6. The prevalence of dry eye is more in developed countries than in the developing or the underdeveloped countries. A dry eye affects about 7 % people in their 50s, and about 15 % people in their 70s 7. It is estimated that approximately 12 million Americans are suffering from dry eye syndrome. However, the data of Indians is not available. Women are more affected by this than men 9.

The goals of treating dry eyes are to control the dryness of the eye, relieve symptoms, improve quality of life, minimize risk factors and prevent ocular damage. Though there is no absolute cure for dry eye syndrome, treatment includes symptomatic relief; tear substitutes, eye ointment and other medications are generally used. Tear substitutes or artificial tears enjoy significant advantages over other measures used in the treatment of dry eye. Various viscosity enhancing agents like HPMC, sod CMC, PVA, PVP-K30, PEG-400, propylene glycol etc. are used in composition of tear substitutes. HPMC and sod CMC show synergistic effect 10. Sodium CMC also acts as modulator of corneal epithelial wound healing 11.

MATERIAL AND METHOD
Schirmer’s test-I was performed on nine healthy New Zealand albino rabbits. The permission for this work was obtained from Institutional Animal Ethical Committee. The animals were provided by animal house department of Sudhakarrao Naik Inst. of Pharmacy, Pusad, Maharashtra (India). Schirmer’s tear strips (Contacare Ltd.) were provided by Dr.Rewanwar M.S. (Ophth), Pusad. Atropine sulphate (1%) drops were purchased from market. The polymers; CMC and HPMC were received as gift samples from Ajanta Pharma, Mumbai. GlyTears containing 0.5% sodium CMC (Sun Pharma) were purchased from market. The ‘test preparation’ was prepared using sodium CMC (0.1%) and HPMC (0.1%) and GlyTears was used as ‘standard preparation’.

Schirmer’s test was described by a German ophthalmologist Otto Schirmer in 1903 12, 13. The Schirmer’s tear strip is employed for this test which is a specialized filter paper strip having a marking or a scale in mm on it. The Schirmer’s tear strip is placed in the lateral third of the lower eye lid. Schirmer’s test-I (without anesthesia) determines the basic and reflex secretion 14, 15, 16. The general outline of Schirmer’s test is as follows:

Selection of animals
Maintenance on healthy feed / observation
Initial tear production assessment
Desiccation / drying of animal eyes using 1 % atropine sulphate instillation
Tear production assessment after atropine instillation
Actual test using test, standard and control groups of animals

Among the available New Zealand albino rabbits; nine healthy animals having average body weight of 2.5 Kg were selected for the study. All of these animals were kept on the same healthy feed for a week. Meanwhile

*Correspondence : pskawtikwar@rediffmail.com
all the animals were under observation for any abnormal changes. After re-ensuring the health of animals after observation period; tear production in animals was assessed using Schirmer’s tear strips. Atropine sulphate (1%) was instilled in the eyes of the animals at regular intervals until ‘dry eyes’ were produced. Tear production is again assessed after atropine sulphate instillation for a week. Next all the animals with ‘dry eyes’ were categorized into three groups each group comprising of three animals viz. test, standard and control. Two drops of test preparation was instilled into the eyes of the test group animals. Two drops of the marketed preparation of lubricating eye drop – GlyTears containing 0.5 % sodium CMC (Sun Pharma) was instilled into the eyes of the standard group. The third group of animals was kept as a control group. Schirmer’s test-I was performed as shown in Fig 1. The Schirmer’s tear strip readings suggest following significance:

- < 5 mm wetting in 5 min is sign of clinical dry eye
- 5-10 mm wetting in 5 min suggests borderline dry eye
- > 10mm wetting in 5 min indicates normal secretion

RESULT AND DISCUSSION

Table 1 shows the tear strip readings before and after instillation of atropine sulphate (1%). Before atropine sulphate (1%) instillation the average tear strip reading was found to be 20.7 and after atropine sulphate instillation tear average strip reading was found to be 6.4 which is quite less than the required one; and it indicates that dry eye was being produced among all the animals.

After one hour of instillation of tear substitutes in the dry eyes of animals, the lubrication was quite high; 25 mm in test group and 26 mm in standard group. Lubrication was quite less i.e. 06 mm in the control group in which no tear substitute was instilled; indicating desiccation of the eyes of the animals. Over a period of time, the lubrication got decreased due to evaporation of tear film. But the required lubrication of 10 mm was maintained up to six hours (Table 2). After six hours, the tear strip reading in the test group was found to be 11 ± 1.35 mm, in the standard group it was 10 ± 1.58 mm while in the control group no significant change was observed. SEM (Standard error in mean) values observed in the different groups are as follows: Test- 2.254, Standard-2.694, Control-0.26; P value: Test>0.1. Standard> 0.01 Control = 0.06.

One-way Analysis of Variance (ANOVA): The P value is 0.0030, considered very significant. Variation among column means is significantly greater than expected by chance.

CONCLUSION

The results of the study suggest that the marketed preparations of tear substitute (GlyTears) as well as the test preparation; both are capable of providing desired ocular lubrication for six hours. That means these preparations need less frequency of instillation; 2 to 3 times a day to provide relief from dry eye syndrome. The test preparation has shown slightly better lubricating efficacy than standard preparation even in less concentration of polymers. This is due to the fact that sodium CMC and HPMC have synergistic effect; in enhancing viscosity and thus prevent the tear film evaporation by coating the eye ball for a longer period of time.
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ACKNOWLEDGEMENT

The authors are thankful to Principal, Sudhakarrao Naik Inst. of Pharmacy, Pusad, for providing facilities for the work. The gift samples from Ajanta Pharma, Mumbai and tear strips from Dr. Rewanwar, Pusad, are greatly acknowledged. The authors feel in-debted for Dr. Susi Burgulassi, Italy for valuable guidance in the work.

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