Use of preservative-free multidose dispenser (Comod system) for glaucoma medications

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ABSTRACT

Purpose
To describe our experience in the use of preservative-free Comod system in glaucoma patients.

Methods
120 glaucoma patients were recruited and randomly assigned to group I (conventional system) or group II (Comod system). Schirmer’s test, tear-breakup time (BUT), and culture and sensitivity (CS) tests were performed. A self-administered questionnaire was given to participants to evaluate ease of application, ocular stinging, and dryness.

Results
The Comod system did not cause any ocular stinging (p < 0.01) and was easy to use. Tear BUT and Schirmer’s test were not different between the 2 groups. CS tests of the Comod at week 11 did not yield any organism.

Conclusion
The Comod system was more comfortable, easy to use, and can be used as a multidose system in administering glaucoma medications.

A PRESERVATIVE is important for two reasons: to prevent the patient from introducing microbiologically contaminated drugs into his eye(s) and to maintain the potency of the ophthalmic drug.1,2 The inclusion of preservatives in eye-drop dispensers, however, does not guarantee sterility. A high contamination rate was reported by Schein et al.3 (29%), Marion and Tampert4 (27%), Hovding and Sjursen5 (12.9%).

The Comod eye-drop dispenser, introduced recently in Malaysia, has a shelf life of 2 years and can be used for 12 weeks after it has been opened.6 As a sealed system, it has an “airless pump” that works without air equalization and prevents the reflux of external air and liquid when the solution is dosed. It also has an average drop size of 32.5 ± 2.5 ul, which is equivalent to the capacity of the inferior conjunctival fornix.

Timolol, a commonly used maintenance medication for glaucoma, comes in both the conventional eye-drop dispenser and in Timo-Comod system. We evaluated our experience using both systems. We performed the Schirmer’s test, tear-breakup time (BUT), and graded the conjunctival injection by fluorescein. Culture and sensitivity for bacterial contamination were done for the Comod system.

One hundred twenty patients with open-angle glaucoma were randomly assigned to conventional Timolol 0.25% (Group I, 60 patients) or Comod system (Group II, 60 patients). Patients in both groups were instructed on the correct method of application specifically in avoiding any contact between the dropper tip and the eye or lid to maintain sterility.

This open-label study was divided into two phases: a comparison of the Comod system with the conventional system in phase 1, and determination of sterility of the Comod system in phase 2. Patients were also given a self-administered questionnaire to grade the convenience of application, severity of ocular stinging, and dryness of eyes.

Convenience of application was graded as follows: (1) Difficult—frequent spillage, (2) Moderately difficult—spillage of more than 10 times in a month, (3) Easy—spillage less than 10 times in a month, and (4) Extremely easy—no spillage. Spillage was defined as any drop that
Ocular stinging was graded as: Grade 0—no stinging, Grade I—mild, Grade II—moderate, and Grade III—severe.

The conjunctival injection was graded as area of injection involving the bulbar conjunctiva: Grade 0—nil, Grade I–1 quadrant, Grade II–2 quadrants, Grade III–3 quadrants, Grade IV–4 quadrants, Grade V–4 quadrants with upper or lower palpebral conjunctival involvement.

An assistant wearing a mask and sterile gloves collected samples for culture and sensitivity test. Each bottle was uncapped, the tip swabbed with alcohol and allowed to dry. The first drop of the solution was discarded and the second drop placed onto blood agar plate and sent to the microbiology lab. The plates were incubated at 37°C and bacterial growth was assessed at 24 and 48 hours. Any growth was subjected to standard microbiological testing for identification and antibiotic-sensitivity testing.

Data analysis was done using Statistical Products and Services Solution software. The Schirmer’s tests, tear film BUT, and intraocular pressures (IOP) in the two groups at 3 weeks were compared using the Student’s t-test. The Chi-square test was used to analyze grade of convenience and ocular stinging. A level of significance of $p < 0.05$ was used.

Results indicated no difference in the distribution of the patients in the 2 groups in terms of ethnicity, gender, duration, and types of glaucoma. The mean IOP for both groups at baseline and 3 weeks were similar. Mean tear film BUT were also comparable (Table 1). The Schirmer’s test values indicated diminished tears (< 10 mm) in both groups at baseline, with mild improvement in group II when compared to group I (Table 2) at 3 weeks, but not statistically significant.

No group II patients reported ocular stinging during the study, in contrast to those in group I who reported mild (58%) and moderate stinging (25%) ($p < 0.001$).

### Table 1. Mean tear-breakup time.

<table>
<thead>
<tr>
<th>Eye/Treatment Period</th>
<th>Teardrop-Breakup Time (seconds)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group I (n=60)</td>
<td>Group II (n=60)</td>
<td></td>
</tr>
<tr>
<td>Right eye at baseline</td>
<td>12.53 ± 6.17</td>
<td>12.02 ± 5.61</td>
</tr>
<tr>
<td>Left eye at baseline</td>
<td>12.30 ± 5.98</td>
<td>11.57 ± 4.70</td>
</tr>
<tr>
<td>Right eye at 3 weeks</td>
<td>12.80 ± 6.05</td>
<td>12.75 ± 5.70</td>
</tr>
<tr>
<td>Left eye at 3 weeks</td>
<td>12.03 ± 5.76</td>
<td>12.48 ± 5.23</td>
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</tbody>
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Conjunctival injection was negative in both groups and cultures were also negative, even at 11 weeks.

Although several patients initially complained of some difficulty in using the Comod system, it becomes easier with repeated use.

### Table 2. Mean Schirmer’s test.

<table>
<thead>
<tr>
<th>Eye/Treatment Period</th>
<th>Schirmer’s Test (mm)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group I (n=60)</td>
<td>Group II (n=60)</td>
</tr>
<tr>
<td>Right eye at baseline</td>
<td>10.8 ± 0.89</td>
<td>8.2 ± 0.77</td>
</tr>
<tr>
<td>Left eye at baseline</td>
<td>10.8 ± 0.86</td>
<td>8.9 ± 0.80</td>
</tr>
<tr>
<td>Right eye at 3 weeks</td>
<td>10.1 ± 0.88</td>
<td>9.7 ± 0.81</td>
</tr>
<tr>
<td>Left eye at 3 weeks</td>
<td>9.3 ± 0.77</td>
<td>9.6 ± 0.79</td>
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### References

### Tuberous sclerosis in a 17-year-old female

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### ABSTRACT

**Objective**
To report a classic case of tuberous sclerosis complex.

**Methods**
This is a case report.

**Results**
A 17-year-old female presented with bilateral blurring of vision with left temporal headaches and seizures. Physical examination showed she had adenoma sebaceum, ash-leaf spots, and shagreen patches. Computed tomography revealed hydrocephaly, tubers, and subependymal nodules while magnetic resonance imaging revealed a giant-cell astrocytoma, later confirmed through histopathologic examination. Renal ultrasound showed findings consistent with an angiomyolipoma. Ophthalmologic findings included left cortical cataract, papillidema, and retinal astrocytoma.

**Conclusion**
The findings were consistent with tuberous sclerosis.

TUBEROUS sclerosis complex (TSC) is a multisystemic and neurocutaneous, autosomal-dominant disorder...