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Efficacy and Safety of a 2% Dorzolamide/ 0.5% Timolol Fixed-Combination Brand: Mardozia®

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Abstract

Objective: To evaluate efficacy and safety of Mardozia® (2% Dorzolamide/0.5% Timolol fixed combination) drugs in glaucoma patients, specifically in Thai population.

Methods: The multicenter, prospective, randomized, open label study in POAG, NTG and OHT which used brand name (Cosopt®) with or without PGs at least 3 months then drug washout for one month and switch to generic drug (Mardozia®), total study seven months period. The IOP was measured baseline on branded medication, month 0 and post-switch at month 1, 3 and 6. The questionnaire on the discomfort symptoms and discomfort score for the use of eye drops answered by the patients before baseline on branded medication and month 6 after received.

Results: A total of 60 eyes who receive brand name with or without PGs at least 3 months were enrolled in the study (71.7% female, median age 68.5 years old). At the end of the follow-up month 6 (visit 5) of Mardozia®, mean IOP was 13.82 ± 3.22 mmHg, reduced from baseline 2.7 ± 3.03 mm Hg (14.88%, $p < 0.001$) and IOP reduction was not significant difference compared with brand name at baseline on branded medication (0.91mmHg) (-5.35%). There was, likewise, significant difference in the discomfort score ($P < 0.001$).

Conclusion: Mardozia® is effective in reducing IOP for glaucoma patients. The effect was seen significantly since first month and continued until the last follow-up. After the switch, the IOP-lowering effect of the generic drug Mardozia® was comparable to the brand name. Overall safety is better after switching. Patients had less adverse drug reactions and were more comfortable with Mardozia® significantly.

Keywords: primary open angle glaucoma, normal tension glaucoma, ocular hypertension, dorzolamide, timolol

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Introduction

Glaucoma is a chronic eye disease that is a leading cause of blindness. The World Health Organization estimates that 60.5 million people worldwide had glaucoma and 8.4 million people were blinded in 2010. The number of people with glaucoma is expected to increase to 79.6 million by 2020, and there were increasing trend with blindness to 11.2 million in the same year.[1] For the situation in Thailand, the incidence of glaucoma has been reported to be approximately 2.5 - 3.8 percent of the population, or 1.7 - 2.4 million people. Glaucoma disease is found in people over 40 years of age. Therefore, glaucoma is considered an eye disorder that is a major public health problem that patients need to receive continuous treatment[2]. There are several ways to treat glaucoma, depending on the type of glaucoma and the stage of the disease. Currently, using eye drops for glaucoma is the most effective and popular treatment. However, ophthalmologists may adjust the medication periodically as appropriate. Therefore, the key of treatment is regular visits to the doctor and continue using medicine. Most patients with glaucoma in the early stages are treated with monotherapy. If intraocular pressure cannot be controlled, monotherapy will be changed to fixed combination for more effective to control intraocular pressure, good compliance, reduce the exposure to preservatives, and help patients have a better quality of life.

In 2022, only 300,005 patients received the brand name glaucoma drug 2% Dorzolamide/0.5% Timolol[3], it was 12-18% of glaucoma patients in Thailand. Currently, there are many brands of 2% Dorzolamide/0.5% Timolol fixed combination drugs to market in Thailand. Mardozia® is 2% Dorzolamide/0.5% Timolol fixed combination drug imported from the European Union and has been used in various Thai hospitals, but it has never been studied of this generic drug in Thai population. This study which evaluates the efficacy and safety in Mardozia® (2% Dorzolamide/0.5% Timolol Fixed Combination) in Thai population with primary open angle glaucoma (POAG), normal tension glaucoma (NTG) and ocular hypertension (OHT) will provide an alternative for doctors and patients, increasing access of medicines and reduction of the country's drug costs.

Materials And Methods

This study was performed as a prospective multi-center trial approved by the institutional review board by Thammasat Hospital, Thabo Crown Prince Hospital, Nong Khai and Ratchaphiphat Hospital, Thailand. The study was conducted in accordance with the ethical principles described in the Declaration of each institute. Before the enrollment in the study, the subjects received information regarding the study and written informed consent was obtained from each subject.

The subjects were Thai glaucoma patients who had been receiving treatment with Brand name (Cosopt®) with or without Prostaglandin (PGs) at least 3 months. Patients with a history of a laser treatment or ocular surgery within 3 months, previous glaucoma surgery, conditions preventing intraocular pressure (IOP) measurement by applanation tonometry, and discomfort increased by other ocular disease, except an ocular surface disease, were excluded from the study.

The study consisted of 5 scheduled visits over 7 months (baseline on branded medication , post-washout baseline, month 1, 3 and 6). At post-washout baseline, Brand name with or without PGs was switched to Mardozia®. The administration time of Mardozia® was set at 6 months. The IOP value was measured by Goldmann applanation tonometry, while the measurement time for each patient was decided based on the time of the baseline measurement. For

the evaluation of the adverse events, a questionnaire survey (Table 1) about the discomfort symptoms and the overall discomfort score was conducted at baseline on branded medication and month 6 after switching to Mardozia®. For discomfort score was assessed and scored i.e. Not at all: No discomfort; eyes feel normal or better (1), Slightly: Minor, brief discomfort; tolerable and doesn't disrupt daily tasks (2), Moderate uncomfortable: Noticeable discomfort (e.g., irritating, itching, redness) but still manageable for daily activities (3), Severe: Significant discomfort impacting daily tasks; requires rest or relief (4) and Very Severe: Unbearable pain; unable to open eyes or function; may need immediate medical attention (5).

Statistical analyses were performed using IBM SPSS statistics 22 (IBM® SPSS® Statistics. NY, USA). The IOPs and IOP reduction of each period were compared using repeated measures analysis of variance. At visit 1 and 5, the adverse events were compared using a McNemar test while the mean discomfort scores and IOP difference before and after switching treatment were compared using the paired *t*-test. Significant is considered at alfa = 0.05

Table 1 Questionnaire on discomfort.

1.	**What trouble did you experience while using eye drops? Check the item (duplicated check is allowed)**	**Yes**	**No**
1)	Conjunctival injection	☐	☐
2)	Bitter taste	☐	☐
3)	Burning sense	☐	☐
4)	Foreign-body sense	☐	☐
5)	Itchiness	☐	☐
6)	Dryness	☐	☐
7)	Epiphora	☐	☐
8)	Depression	☐	☐
9)	Blurred vision	☐	☐
10)	Headache	☐	☐
11)	Nausea/vomiting	☐	☐
12)	Dyspnea/palpitations	☐	☐
2.	**How uncomfortable do you feel with the current eye drops?**		
1)	☐ Not at all		
2)	☐ Slightly uncomfortable		
3)	☐ Moderately uncomfortable		
4)	☐ Severe		
5)	☐ Very severe		

Not at all=1, slightly uncomfortable=2, moderately uncomfortable=3, severe=4, very severe=5

Results

We enrolled 60 patients' eyes, ages ranging from 40 to 90 years old (median 68.5). All patients were diagnosed with unilateral or bilateral treatment of primary open angle glaucoma, normal tension glaucoma and ocular hypertension with history of IOP ≥ 22 mmHg and using brand name with or without PGs for at least 3 months. 71.7% (n = 43) of the patients were female. Patients had the following underlying diseases: cardiovascular disease (CVS) 31.67% (n = 19), and other conditions such as dyslipidemia, diabetes mellitus, and emphysema, 3.33% (n = 2). Comprehensive demographic data are provided in Table 2.

Table 2 Patient Demographics

Sex: female (%)	43 (71.70)
Age (median, range)	68.50 (40-90)
Underlying diseases (no, %)	
- No	39 (65.00)
- CVS	19 (31.67)
- Others	2 (3.33)
Drugs (no, %)	
- No	14 (23.33)
- Artificial tear	22 (36.67)
- Other Antiglaucoma	14 (23.33)
- Others	10 (16.70)
- Allergy (no, %)	8 (13.30)
Eye discomfort (no, %)	
- None/mild	54 (90)
- Moderate-severe	6 (10)

CVS, cardiovascular system

The IOP when using brand name were 14.73 mmHg at baseline on branded medication (visit 1). Baseline IOP after drug washout was 16.52 mm Hg (visit 2). After switching to generic drug, IOP was reduced to 14.9, 14.2 14.3 and 13.82 mmHg at month 1, 3, 6, respectively (Figure 2). There was statistically significant difference in IOPs. ($P < 0.001$).

The mean IOP were as follows: 16.52 ±4.07 mmHg at post-washout baseline (visit 2) and 13.82 ±3.22 mmHg at month 6 post-switch (visit 5), respectively. There was also statistically significant difference in IOP of generic drug at post-washout baseline (visit 2) and month 6 post-switch ($P < 0.001$, Figure 1). And mean IOP with baseline on branded medication (visit 1) was 14.73 ±3.58 mmHg and at month 6 post-switch (visit 5) was 13.82 ±3.22 mmHg , respectively. There was no statistically significant difference IOP was observed after switching from the brand name to the generic drug (Figure 2)

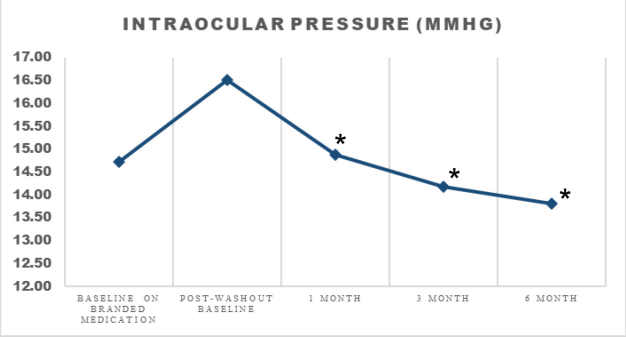

Figure 1 Mean intraocular pressure (IOP) after switching to generic drug. There was significant difference between post-washout baseline (visit 2), month 1, 3 and 6 post-switch (visit 5). *(P <0.001, repeated measures analysis of variance [ANOVA]).

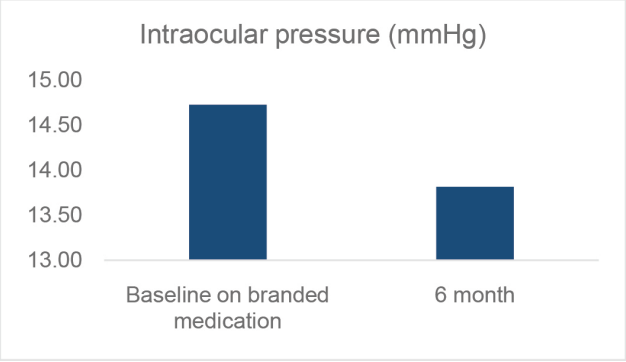

Figure 2 Mean intraocular pressure (IOP) with baseline on branded medication (visit 1) and generic drug treatment at month 6 post-switch (visit 5). There was no statistically significant difference in Mean IOP between brand name and generic drug (paired *t*-test).

The adverse events were also evaluated through the questionnaire survey, which were conjunctival injection, bitter taste, burning sense, foreign-body sense, itchiness, dryness, epiphora, depression, blurred vision, headache, nausea/vomiting and dyspnea/palpitations.

Adverse events were reported for total 31 patients (60 eyes). At visit 1, 39% of patients reported no adverse events, 52% felt slightly uncomfortable, and 10% felt moderately uncomfortable. After switching to the generic drug for 6 months (Visit 5), 97% of patients reported no adverse events, and 3% felt slightly uncomfortable. Overall safety is better after switching. Patients had less adverse drug reactions.

The most common adverse events with baseline on branded medication (visit 1) were epiphora (46.7%), dryness (46.7%), and irritation (36.7%). With the generic drug (visit 5), the respective rates were 16.7%, 10.0%, and 13.3%. Conjunctival injection were similar between brand name and generic drug (6.0% vs 6.0%). , Other adverse effect were bitter taste (16.0% vs 6.0%), burning sense (19.0% vs3.0%), irritation (35.0% vs 13.0%), itchiness (19.0% vs 6.0%), dryness (45.0% vs10.0%) and epiphora (45.0% vs16.0%). Depression was not found in generic drug (3.0% vs 0.0%). Blurred vision (13.0% vs 3.0%) was also transient and was a mild symptom caused by a burning sensation after drug instillation. Headache (10.0% vs 6.0%) was found more in brand name than generic drug. Nausea/vomiting (3.0% vs0.0%) were transient symptoms after drug instillation and there were no vomiting symptoms in generic drug group, Dyspnea/palpitations were found 6.0% vs 3.0%) Some patients did not have any adverse event (29.0% vs 68.0%), respectively. No cardiovascular and pulmonary adverse events were reported during the study. Summary of all adverse events was statistically significant difference baseline on branded medication (visit 1) and post-switch to generic drug (visit 5), Table 3. The discomfort scores representing the overall comfortable sensation at pre-switch and month 6 post-switch were 12 (38.7%) and 30 (96.8%) in brand name and generic drug, respectively. These findings indicate that the generic drug was significantly more comfortable than the brand-name drug ($P < 0.001$, Table 4). The number of patients, who had adverse events at visit 5 was significantly reduced by 21.67% compared to visit 1 ($p = 0.0010$).

Table 3 Summary Of Adverse Events

Symptoms, n(%)	Baseline on branded medication (visit 1) Brand name	Post-switch (visit 5) Generic drug
Conjunctival injection	2 (6)	2 (6)
Bitter taste	5 (16)	2 (6)
Burning sense	6 (19)	1 (3)
Irritation	11(35)	4(13)
Itchiness	6 (19)	2 (6)
Dryness	14 (45)	3 (10)
Epiphora	14 (45)	5 (16)
Depression	1 (3)	0 (0)
Blurred vision	4 (13)	1 (3)
Headache	3 (10)	2 (6)
Nausea/vomiting	1 (3)	0 (0)
Dyspnea/palpitations	2 (6)	1 (3)
No adverse event	9 (29)	21 (68)

One patient may have experienced more than one adverse event

Table 4 Discomfort Scores In The 2 Groups

	Baseline on branded medication (visit 1)	Post-switch (visit 5)	*P*-value[a]
	Brand name	Generic drug	
Mean discomfort scores	0.32 ± 0.47	0.02 ± 0.13	0.001

[a]McNemar test

Discussion

More than 50% of glaucoma patients will need more than one drug to reach their target IOP.[4,5] Reducing the number of drops by including more than one medication in a fixed combination will reduce the side effects and increase compliance.[6,7] This study is to evaluate efficacy and safety of generic drug (2% Dorzolamide/0.5% Timolol fixed combination) drugs in glaucoma patients, specifically in Thailand population. Regarding of a comparison between 2% dorzolamide/0.5% timolol fixed combination: From Bhartiya S. and Dhingra D. study they found that brand name has efficacy and side effects similar to generic[5].

In this study, the IOP-lowering effects and safety of generic drug is evaluated, we found that generic brand has efficacy in reducing IOP at the similar level as the brand name. Mean IOP reduction was 14.9% from 16.52 ± 4.07 mmHg to 13.8 ± 3.22 mmHg. Mean IOP was similar when patients use the brand name (14.73 ± 3.58 mmHg). The study results showed that brand name and generic drug had similar IOP-lowering effects, regardless of whether PGs were used or not used. These findings are consistent with the recent studies, Tae-Woo Kim, Martha Kim et al.[8] that reported an IOP change of -23.7% at week 12 post-treatment in the normal-tension glaucoma patients treated with 2% Dorzolamide/0.5% Timolol fixed combination The finding is complied with Target IOP reduction required about a 20% IOP reduction in mild cases and progressively greater decrease for more advanced cases[10]. The previous studies of Yong Il Kim, Jee Hyun Kim et al.[11] also showed similar efficacy of brand name and generic drug.

Conversely, in antiglaucoma drugs, the study on Xalatan (Pfizer, New York, NY) showed that the IOP-lowering effect of Xalatan was higher compared with the corresponding generic drug in primary open-angle glaucoma and ocular hypertension patients. The difference in IOP lowering could be caused by the difference in adjuvants.[12]

The safety of generic drug was evaluated based on their discomfort symptoms and discomfort scores. There were significant differences in terms of all discomfort symptoms and the discomfort score. Discomfort symptoms in baseline on branded medication (visit 1) were three times higher than post-switch (visit 5) (70 vs 23 events). Discomfort score in baseline on branded medication (visit 1) was higher than post-switch (visit 5), 38.7% vs 96.8%. These results were difference to previous studies of Yong Il Kim, Jee Hyun Kim, et al.[11], which showed no differences in terms of adverse events between the generic drug and brand name drugs A difference in adjuvants could lead to differences in viscosity, surface tension, and pH, which could cause a different discomfort symptoms between generic and brand-name drugs.[14,15]

For 2% Dorzolamide/ 0.5% Timolol Fixed-Combination brand : Mardozia®, there are no differences

in terms of active ingredients, preservative (0.0075% benzalkonium chloride) and other excipients compared with brand drug. More than that, the generic brand did the same characteristics of eyes drop i.e. pH, specific gravity, viscosity, osmolality, surface tension etc. with brand name. Therefore, generic drug can be effectively substituted and provide the same clinical benefit as the brand name.

This study had some limitations. First , regression to the mean could affect the result of IOP measurements, since the IOP measurement was not blinded. Second, we could not decide that the side effects discovered were solely caused by the prescribed eye drops. This is because most of the patients who came for a routine ophthalmology check-up experienced some sort of blepharitis and dry eye, meanwhile, it was hard to monitor the regression or progression of those signs especially that they were spotted at 6 months, not throughout the whole period. Some potential side effects such as conjunctival hyperemia, ocular itching, or blurred vision from prostaglandin analogs, it's possible that these symptoms are not directly due to dorzolamide/timolol. In addition, efforts were made to eliminate prejudice by explaining to the patients that the active ingredients of the brand name and generic drugs were the same. Nevertheless, despite these limitations, the design of this study reflected the common clinical situation of switching from a brand name drug to a generic drug. This study is the first one to evaluated efficacy and safety of a 2% Dorzolamide/ 0.5% Timolol Fixed-Combination brand to Mardozia® in Thai population. After switching, the IOP-lowering effect of Mardozia® was found to be similar to that of brand name with or without PGs. In addition, there was an improvement in both discomfort symptoms and discomfort scores for patients receiving monotherapy and combination therapy with PGs.

Conflicts of interest

This study was conducted with financial support from Symgens Co.,LTD. However, Symgens Co., LTD. only provide funding. And it was not involved in management of our data.

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การศึกษาประสิทธิผลและความปลอดภัยในการลดความดันตาของยาต้อหิน 2% ดอร์โซลาไมด์ /0.5% ทิโมลอล ยาหยอดตาต้อหินสูตรผสม (มาร์โดเซีย®)

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บทคัดย่อ:

วัตถุประสงค์: เพื่อศึกษาประสิทธิภาพและความปลอดภัยในการลดความดันตาของยาต้อหิน 2% ดอร์โซลาไมด์/0.5% ทิโมลอล ยาหยอดตาต้อหินสูตรผสม (มาร์โดเซีย)

วิธีการศึกษา: เป็นการศึกษาแบบการวิจัยกึ่งทดลองในหลายสถาบัน ไม่มีการแบ่งกลุ่มการศึกษา ผู้ที่เข้าร่วมโครงการวิจัยได้รับการวินิจฉัยว่าเป็นโรคต้อหินแบบมุมเปิดปฐมภูมิ, ต้อหินชนิดความดันตาปกติ, ภาวะความดันตาสูง หรือมีประวัติเคยมีภาวะความดันตาสูง โดยมีระยะเวลาศึกษา 7 เดือน

ผลการศึกษา: มีผู้ที่เข้าร่วมโครงการวิจัยทั้งหมด 60 ตาพบว่าร้อยละ 71.7% เป็นเพศหญิง มีอายุเฉลี่ย 68.5 ปี เมื่อสิ้นสุดการใช้ยาต้อหิน 2% ดอร์โซลาไมด์/ 0.5% ทิโมลอล ยาหยอดตาต้อหินสูตรผสม (มาร์โดเซีย) ในเดือนที่ 6 พบว่าความดันตาเฉลี่ยลดลงเป็น 13.82 ± 3.22 มม.ปรอท ซึ่งลดลงจากค่าพื้นฐาน 2.7 ± 3.03 มม.ปรอท (14,88%, $p < 0.001$) และลดลง 0.91 มม.ปรอท (-5.35%) เมื่อเทียบกับการใช้ยาต้นแบบ ก่อนเปลี่ยนยา รวมทั้งประเมินอาการไม่พึงประสงค์จากการใช้ยาและคะแนนความไม่สบายตาหลังได้รับยามาร์โดเซีย ในเดือนที่ 6 พบว่ามีอาการไม่พึงประสงค์ลดลงและรู้สึกสบายตามากขึ้นแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ($P < 0.001$)

สรุป: ในผู้ป่วยโรคต้อหิน ประสิทธิภาพและความปลอดภัยในการลดความดันตาของยาต้อหิน 2% ดอร์โซลาไมด์/0.5% ทิโมลอล ยาหยอดตาต้อหินสูตรผสม (มาร์โดเซีย) ไม่แตกต่างกันกับยาต้นแบบ

คำสำคัญ: ต้อหินแบบมุมเปิดปฐมภูมิ, ต้อหินชนิดความดันตาปกติ, ภาวะความดันตาสูง, ดอร์โซลาไมด์, ทิโมลอล

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