

Incidence of Steroid Induced-Ocular Hypertension in Postoperative Pterygium Excision

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Background: Steroid eye drops were widely used for suppression ocular inflammation in many conditions. Unfortunately, steroid eye drops can cause many side effects; the important one was steroid-induced ocular hypertension that may progress to secondary glaucoma.

Objective: To evaluate incidence of steroid responder, following topical dexamethasone use after pterygium excision with amniotic membrane graft.

Design: Prospective descriptive study.

Material and Method: The present study was designed to evaluate intraocular pressure (IOP) change from topical dexamethasone eye drops in postoperative pterygium excision with amniotic membrane grafting. The subjects were routinely prescribed CD-oph (1 mg/ml dexamethasone sodium phosphate, 5 mg/ml chloramphenicol, and 0.25 mg/ml Tetrahydrozoline hydrochloride) eye drops every 1 hour for 1 week, then every 2 hours until 1 month, then four times daily until 3 months postoperatively. The subjects were measured IOP at 1 week, 1 month, and 3 month postoperatively by applanation tonometer. The steroid responder was defined as an elevation of IOP at least 10 mmHg from preoperative. The incidence was calculated, trend of IOP rising and timing of peak IOP were assessed.

Results: Of the 62 patients, 6 were diagnosed as steroid responders (IOP ≥ 10 mmHg), 9.68% (95% CI 3.6-19.9). Mean of peak IOP rising was 4.02 ± 3.18 mmHg with maximum IOP rising was 11 mmHg. 4 of 6 cases of steroid responders occur at 3 month postoperative, 2 another cases occur at 1 week and 1 month postoperative. Most of the subjects had IOP rising in range of 0-4 mmHg (62.90%), follow by 5-9 mmHg (27.42%), and ≥ 10 mmHg (9.68%), respectively. Maximum IOP mostly in range of 16-20 mmHg (43.55%), follow by 11-15 mmHg (40.32%), 21-25 mmHg (9.68%), and more than 26 mmHg (6.45%), respectively. 45.16% of subjects showed the time of peak IOP at postoperative 1 month.

Conclusions: Steroid response is a common problem in steroid use, especially with topical steroid eye drops. The incidence of steroid responder from this study was 9.68%, which may differ from the others by type, frequency of the topical steroid used, including criteria to diagnosis of steroid responder.

Keywords: Steroid responder, Ocular hypertension, Pterygium excision, Dexamethasone

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Steroid eye drops were widely used for suppression ocular inflammation in many conditions including allergic conjunctivitis, viral conjunctivitis, uveitis, and most frequently in postoperative conditions, such as postoperative cataract surgery, par plana vitrectomy, trabeculectomy, and pterygium excision. Steroids can cause many side effects; the important one was steroid-induced ocular hypertension that may progress to secondary glaucoma.

Armaly and Becker first reported steroid-induced ocular hypertension in 1965. Becker classified intraocular pressure (IOP) after the use of topical 0.1% Betamethasone into 3 groups, the first was non-responders group that defined as IOP ≤ 20 mmHg, the second group was responders group that defined as IOP > 20 mmHg, and super responders group that defined as IOP > 31 mmHg. The Becker's study found that all of primary open-angle glaucoma (POAG) patients were in responders group, and 92% were in the super responders group, but only 30% in the responders group and 4% in super responders group were in the normal population⁽¹⁾. In Armaly's study, one third of normal population and 90% of POAG had IOP rising more than 6 mmHg after 4-weeks of using topical 0.1%

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dexamethasone⁽²⁾.

The mechanisms of steroid-induced ocular hypertension or secondary glaucoma is mainly from the obstruction of aqueous outflow, steroids inhibit the releasing of catabolic enzyme from lysosome then cause deposition of glycosaminoglycan at extracellular matrix of trabecular meshwork⁽⁴⁾. Another hypothesis believes that steroids can cause impairment of phagocytosis of endothelial cells⁽⁵⁾ and decrease prostaglandin that affect the drainage of aqueous⁽⁶⁾. Southren⁽⁷⁾ and Weinstein⁽⁸⁾ found that opened-angle patients have increased risk of steroid-induced ocular hypertension due to abnormality of glucocorticoid metabolism of trabecular meshwork in these patients.

Definition of steroid-induced ocular hypertension or steroid responder was different in each study. Becker used absolute IOP as the criterion, with >20 mmHg being a clinically significant response⁽¹⁾, while Armaly classified the IOP response as a relative difference (treated vs. untreated eye), with a difference of 6 mmHg being the lower limit of a clinically significant response⁽⁹⁾. Stewart et al proposed that an increase in IOP of ≥ 10 mmHg over baseline should be considered clinically significant⁽¹⁰⁾. The ophthalmic community readily accepted this value; the United States FDA has since adopted it, and many subsequent studies have associated an increase in IOP of ≥ 10 mmHg over baseline with clinical significance⁽¹¹⁾.

Risk factors of steroid-induced ocular hypertension were reported by many studies, the main risk factors are primary open-angle glaucoma, recent ocular hypertension or history of previous steroid-induced ocular hypertension, and old age⁽¹⁴⁾. David reported that younger patients (<65 years) with high myopia (axial length ≥ 29.0 mm) had a higher risk for a steroid response after uneventful cataract surgery, while a steroid response was defined as an IOP increase greater than 25% followed by a decrease of more than 25% after topical steroid was discontinued⁽¹⁵⁾. Genetics is another factor; an increase of myocillin genes after the use of topical dexamethasone was reported⁽¹⁶⁾.

The incidence of steroid-induced ocular hypertension also depends on duration, frequency of drug use, and concentration and potency of the steroid. IOP elevation almost never occurs in less than 5 days and rarely in less than 2 weeks, but failure of IOP to rise after 6 weeks of therapy dose not ensure that the patient will maintain normal IOP after several months of therapy⁽⁴⁾. Espildora found that IOP could reduce to baseline if cessation the steroid before 8 weeks, but long-term use of steroid, more than 4 years, can cause

permanent IOP elevation⁽¹⁷⁾; thus, we should stop using the steroid as fast as possible.

Many previous studies reported incidence of ocular hypertension or secondary glaucoma from steroid use, they frequently studied in postoperative cataract surgery that will have intraocular inflammation postoperatively and can cause IOP elevation. This study has proposed to evaluate incidence of steroid-induced ocular hypertension in postoperative pterygium excision to avoid effect of intraocular inflammation that may confound the result of the study.

Material and Method

The present study is a prospective descriptive study that was carried from October 2013 until January 2014 at Department of Ophthalmology, Thammasat University, Pathumtani, Thailand.

Subjects

Including the patients that had pterygium excision with amniotic membrane graft. Exclusion criteria are patients with history of glaucoma or IOP >21 mmHg pre-operatively, loss follow-up or not use medication as protocol of the study, and who has history of chloramphenicol allergy.

Methods

Data of all patients were collected pre-operatively, including sex, age, underlying diseases, and ocular disease. The patients had ocular examination to evaluate visual acuity, IOP by air-puff tonometer, and general exam for screening ocular abnormalities by slit lamp biomicroscopy. Pterygium excision with amniotic membrane graft was done in all patients, then CD-oph[®] (Dexamethasone sodium phosphate 1 mg/ml, Chloramphenicol 5 mg/ml, Tetrahydrozoline hydrochloride 0.25 mg/ml) was prescribed in every 1 hour for 1 week, follow by every 2 hours in second to forth week, then four times a day in fifth week until 3 months postoperatively. The patients have to follow-up at 1 week, 4 week and 3 month postoperatively to evaluate visual acuity, IOP by Goldmann applanation tonometer and air-puff tonometer and exam surgical wound to evaluate inflammation and complication that may occur by slit lamp biomicroscopy. All patients will have stitches off at postoperative 1 week.

Statistical analysis

Data of patients' characteristic was reported in percentage and mean \pm SD. Incidence of steroid-

induced ocular hypertension or steroid responder was calculated in percentage. IOP at each follow-up period and thorough 3 months period were reported in mean \pm SD.

Ethics

Informed written consent was obtained from all participants before the operation at department of ophthalmology or at the operating room. The present study had approved by the Human Research Ethics Committee of Thammasat University (No. 1: Faculty of Medicine), Thailand. The authors verified that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during this study, adhering to the tenets of the Declaration of Helsinki.

Results

Eighty-four patients had pterygium excision with amniotic membrane graft, 24 males and 60 females. Twenty-two patients were excluded from the study, 21 patients lost follow-up and another 1 patient changed type of topical steroid.

Totally 62 patients were included in the study, 14 males (22.5%) and 48 females (77.42%). Mean of age of the patients was 55.44 ± 11.59 years (range of 29-95 years). Thirty-two (51.61%) were right eyes and 30 (48.39%) were left eyes. Mean pre-operative IOP was 13.13 ± 2.67 mmHg (range of 9-21 mmHg) (Table 1).

After operation of pterygium excision with amniotic membrane graft, all patients were prescribed CD-oph follow protocol as previous described for 3 months. The results of IOP in follow-up period at 1 week, 1 month, and 3 months were recorded.

1 week after topical dexamethasone was used, mean IOP was 14.58 ± 3.30 mmHg with maximum IOP 23 mmHg and minimum IOP 9 mmHg. The mean IOP rising from a pre-operative baseline was 1.90 ± 2.45 mmHg with maximum IOP rising 10 mmHg and minimum was no rising in IOP. Mean of IOP rising from the pre-operative baseline in percentage was 25.82% (0-100%).

At 1 month postoperatively, mean IOP was 15.61 ± 3.70 mmHg with maximum IOP 27 mmHg and

minimum IOP 9 mmHg. Mean IOP rising from pre-operative baseline was 2.65 ± 2.73 mmHg with maximum IOP rising 10 mmHg and minimum was no rising in IOP. Mean of IOP rising from the pre-operative baseline in percentage was 21.34% (0-80%)

At 3 months postoperatively, mean IOP was 14.60 ± 4.02 mmHg with maximum IOP 28 mmHg and minimum IOP 8 mmHg. Mean IOP rising from pre-operative baseline was 2.08 ± 2.84 mmHg with maximum IOP rising 11 mmHg and minimum was no rising in IOP. Mean of IOP rising from the pre-operative baseline in percentage was 16.25% (0-84.62%). Peak IOP of each patient in postoperative 3 months period was recruited, the result showed that mean of peak IOP was 17.16 ± 4.13 mmHg with maximum peak IOP 28 mmHg and minimum peak IOP 11 mmHg. Most patients had peak IOP in range of 16-20 mmHg (27 patients; 43.55%), follow by 11-15 mmHg (25 patients; 40.32%), 21-25 mmHg (6 patients; 9.68%), and ≥ 26 mmHg (4 patients; 6.45%), respectively (Table 2). Peak IOP rising, compare the peak IOP in each patient with their preoperative baseline IOP, has mean value was 4.03 ± 3.18 mmHg with maximum 11 mmHg and minimum was no rising in IOP. Mean of peak IOP rising from the pre-operative baseline in percentage was 31.97% (0-100%) (Table 3).

The present study, defines "steroid responder" as IOP that increase from baseline at least 10 mmHg, found 6 patients have IOP result in criteria of steroid responder; the incidence was 9.68% (95% CI 3.6-19.9). If we consider patients that have IOP rising from baseline at least 8 mmHg, 10 patients are in this group and calculated as 16.13%. And if IOP rising from baseline at least 6 mmHg is used for determination, 20 patients are in this group that are calculated as 32.26% (Table 4). Increasing of IOP at least 25% from pre-operative baseline, as are the criteria in the David study⁽¹⁵⁾, were found in 30 patients or 48.39%.

Most of the patients had peak IOP rising in the of range of 0-4 mmHg (39 patients; 62.90%), followed by 5-9 mmHg (17 patients; 27.42%), and ≥ 10 mmHg (6 patients; 9.68%), respectively.

Time of peak IOP rising mostly occurs at postoperative 1 month as 45.16%, at postoperative 1

Table 1. Preoperative data of the patients

Sex		Site		Age (years)		IOP (mmHg)	
Male	Female	Right eye	Left eye	Mean \pm SD	Range	Mean \pm SD	Range
14 (22.58%)	48 (77.42%)	32 (51.61%)	30 (48.39%)	55.44 ± 11.59	29-95	13.15 ± 2.67	9-21

Table 2. Range of peak IOP in each postoperative follow-up period

Tn max/time	≤10 mmHg	11-15 mmHg	16-20 mmHg	21-25 mmHg	≥26 mmHg	Total (patients)	%
1 wk	0	9	9	2	0	20	32.26
1 mo	0	8	16	3	1	28	45.16
3 mo	0	8	2	1	3	14	22.58
Total (patients)	0	25	27	6	4		
%	0	40.32	43.55	9.68	6.45		

Table 3. Result of peak IOP, peak IOP rising, and percentage of peak IOP rising

	Peak IOP (mmHg)	Peak IOP rising (mmHg)	% of peak IOP rising (%)
Mean	17.16	4.03	31.97
SD	4.13	3.18	25.42
95%CI	16.11-18.21	3.22-4.84	25.51-38.42
Min-max	11-28	0-11	0-100

Table 4. Number and percentage of patients that have peak IOP rising in vary cut-off points

Peak IOP rising (mmHg)	No. of patients	%
≥6 mmHg	20	32.26
≥8 mmHg	10	16.13
≥10 mmHg	6	9.68

week as 32.26%, and at postoperative 3 months as 22.58%, respectively. However, in subgroups of patients that have peak IOP rising at least 10 mmHg, we found that most of these patients had peak IOP rising at postoperative 3 months (4 in 6 patients) (Table 2 and 5).

In cases of steroid-induced ocular hypertension, some patients received 0.5% Timolol to reduced IOP, depended on decision of physicians by evaluated IOP, increased IOP form baseline, and risk for developing glaucoma in each patient. Totally, 8 patients received 0.5% Timolol, and all of them stopped 0.5% Timolol and CD-oph at postoperative 3 months.

All cases of steroid-induced ocular hypertension decreased in IOP to be close to baseline pre-operative IOP after stopping CD-oph at 2 months.

Discussion

The present study found the incidence of steroid-induced ocular hypertension or steroid responder, defined as rising of IOP from baseline pre-

operative IOP at least 10 mmHg, was 9.68% (6 in 62 patients). This may differ from previous studies due to the difference in the definition of steroid responder, the different types and frequency of the topical steroid used, including status of the patients in each study.

Compare with the result of Armaly⁽²⁾, used 0.1% Dexamethasone same as this study, found patients that had rising in IOP 6-15 mmHg or intermediate responders group 29%, but found 20 patients or 32.26% in the present study. The patients that had rising in IOP >15 mmHg or high responders group were 5% in Armaly's study, but not found any patients who had rising in IOP >15 mmHg in the present study. The present study showed the incidence of intermediate responders approximately same as Armaly's, but not seen any patients in the high responders group.

In Becker's study⁽¹⁾, they used 0.1% Betamethasone that different in type but equal in potency to Dexamethasone in the present study, and classified the IOP response of topical steroids into non-responders, responders, and super responders. Becker found patients in the non-responders group (IOP <20 mmHg) 58%, in the responders group (IOP 20-31 mmHg) 36%, and the super responders group (IOP >31 mmHg) 6%; but these results were 74% (46 patients), 26% (16 patients), and 0% in the present study, respectively. The results showed that IOP after use of topical steroids in this study seemed to be lower than Becker's study.

Other studies that reported incidence of steroid-induced ocular hypertension such as Biedner

Table 5. Range of peak IOP rising in each postoperative follow-up period

IOP rising	0-4 mmHg	1 week	1 month	3 months
No. of patients	39	11	16	7
%	62.90%			
	5-9 mmHg			
No. of patients	17	5	11	1
%	27.42%			
	≥10 mmHg			
No. of patients	6	1	1	4
%	9.68%			
	Total	17	28	12
	%	27.42%	45.16%	19.35%

Table 6. IOP responded after used of topical steroid in studies of Becker and Armaly

	Becker		Armaly	
Topical steroid	0.1% betamethasone		0.1% dexamethasone	
Frequency	QID		TID	
Duration	6 weeks		4 weeks	
Parameter	Final IOP		IOP change	
Type of responder	IOP (mmHg)	%	IOP (mmHg)	%
Low	<20	58	<6	66
Intermediate	20-31	36	6-15	29
High	>31	6	>15	5

Table 7. Other studies that reported the incidence of steroid induced-ocular hypertension

	Biedner BA	HV Nema	Dodiya Kamal S
Topical steroid	0.1% Dexamethasone	0.1% Betamethasone TID + Triamcinolone	0.1% Dexamethasone or 0.1% Prednisolone
Frequency	QID	EO HS	6 times/day x 1 week 4 times/day x 5 weeks
Duration	6 weeks	6 weeks	
IOP change 6-15 mmHg	9%	10.7%	18%
IOP change >15 mmHg	2%		3%

BA that used topical 0.1% Dexamethasone in 44 vernal conjunctivitis children, found children that had IOP rising at least 6 mmHg in 11%. HV Nema used topical 0.1% Betamethasone and Triamcinolone eye ointment in 28 allergic conjunctivitis patients, found patients that had IOP rising at least 6 mmHg in 10.7%. Dodiya Kamal S. reported patient that had IOP rising at least 6 mmHg 21% in postoperative uncomplicated cataract surgery. All of these studies show the lower incidence of patients that had IOP rising at least 6 mmHg than the

present study (32.26%).

Reasons that cause the incidence of steroid-induced ocular hypertension in the present study differ from previous studies are the criteria to define term of steroid-induced ocular hypertension or steroid responder; the different in types and frequency to use topical steroid, including different in condition of patients in the studies, can all cause a difference in the incidence of steroid responder between the studies. Intraocular surgery, especially in postoperative cataract

surgery, may cause intraocular inflammation that may be a confounding factor with the results of study. The present study evaluated patients in postoperative pterygium excision group that are considered an extra ocular surgery to avoid this factor that may effected the IOP.

Conclusion

Steroid response is a common problem in steroid use, especially with topical steroid eye drops. The incidence of steroid responders in this study, defined as rising in IOP from baseline at least 10 mmHg, was 9.68%, which may differ from the other studies by type and frequency of the topical steroid, including criteria to diagnosis of steroid responder. Timing of the peak IOP mostly occurred at postoperative 1 month and all of patients that had raised IOP, found that IOP could reduce to closely the baseline IOP.

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Potential conflicts of interest

Researchers have no financial interest in any products or instruments mentioned in this study.

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การศึกษาอุบัติการณ์ภาวะความดันตาสูงจากการใช้ยาสเตียรอยด์หยอดหลังการผ่าตัดลอกต้อเนื้อ

มัญชิมา มะกรวัฒน์, วรณิศา สุกเจียรพันธ์

วัตถุประสงค์: เพื่อศึกษาอุบัติการณ์ภาวะความดันตาสูงจากยา dexamethasone หยอดเพื่อลดภาวะการอักเสบหลังการผ่าตัดลอกต้อเนื้อ

วัสดุและวิธีการ: เก็บข้อมูลผู้ป่วย ได้แก่ เพศ อายุ โรคประจำตัว และโรคทางตา ตรวจระดับการมองเห็น (visual acuity) ความดันตา (intraocular pressure; IOP) และผลการตรวจตาด้วย slit lamp biomicroscope ก่อนผู้ป่วยจะได้รับการผ่าตัดลอกต้อเนื้อและเย็บวางเยื่อหุ้มรก หลังผ่าตัดผู้ป่วยจะได้รับยา CD-Oph[®] (Dexamethasone sodium phosphate 1 mg/ml, chloramphenical 5 mg/ml, tetrahydrozoline hydrochloride 0.25 mg/ml) หยอดตาข้างที่ผ่าตัดทุก 1 ชั่วโมงเป็นเวลา 1 สัปดาห์ ทุก 2 ชั่วโมง ในสัปดาห์ที่ 2-4 และ 4 เวลาต่อวันในสัปดาห์ที่ 5 จนถึง 3 เดือนหลังผ่าตัด โดยตรวจติดตามวัดความดันตาที่ 1 สัปดาห์ 4 สัปดาห์และ 3 เดือนหลังผ่าตัดเพื่อประเมินการเพิ่มขึ้นของความดันตาและระยะเวลาที่ความดันตาขึ้นสูงสุดหลังได้ยาสเตียรอยด์หยอด

ผลการศึกษา: จากผู้ป่วยต้อเนื้อที่เข้าร่วมการศึกษาทั้งหมด 62 คน มีผู้ป่วยทั้งสิ้น 6 คนที่อยู่ในกลุ่ม steroid responder (โดยนิยามให้เท่ากับ ความดันตาที่เพิ่มขึ้นมากกว่าหรือเท่ากับ 10 mmHg) ซึ่งคิดเป็นร้อยละ 9.68 (95%CI 3.6-19.9) โดยพบค่าเฉลี่ยของความดันตาที่ขึ้นสูงสุด 4.02 ± 3.18 mmHg ซึ่งมีค่าการเพิ่มขึ้นสูงสุดที่ 11 mmHg โดย 4 คน ในกลุ่ม steroid responder พบความดันตาขึ้นสูงสุดที่ 3 เดือน อีก 2 คนพบที่ 1 สัปดาห์และ 1 เดือนหลังผ่าตัด ผู้ป่วยส่วนใหญ่พบความดันตาขึ้นสูงสุดอยู่ในช่วง 0-4 mmHg (ร้อยละ 62.90) ตามด้วย 5-9 mmHg (ร้อยละ 27.42) และมากกว่าหรือเท่ากับ 10 mmHg (ร้อยละ 9.68) ตามลำดับ ส่วนค่าความดันตาสูงสุดส่วนใหญ่อยู่ในช่วง 16-20 mmHg (ร้อยละ 43.55) ตามด้วย 11-15 mmHg (ร้อยละ 40.32) 21-25 mmHg (ร้อยละ 9.68) และมากกว่าหรือเท่ากับ 26 mmHg (ร้อยละ 6.45) ตามลำดับ ซึ่งระยะเวลาที่ความดันตาเพิ่มขึ้นสูงสุดส่วนใหญ่พบที่ 1 เดือนหลังผ่าตัด คิดเป็น ร้อยละ 45.16

สรุป: ความดันตาสูงจากยาสเตียรอยด์เป็นภาวะที่พบได้บ่อยโดยเฉพาะการได้รับยาสเตียรอยด์ชนิดหยอด ซึ่งจากการศึกษานี้พบอุบัติการณ์ของภาวะนี้ร้อยละ 9.68 ซึ่งต่างจากการศึกษาอื่น โดยอาจเนื่องจากความแตกต่างของชนิดยาสเตียรอยด์ที่ใช้ ความถี่ในการหยอดยา รวมถึงการให้คำจำกัดความของ steroid responder ที่ต่างกันในแต่ละการศึกษา
