· Original article ·

Apraclonidine versus brinzolamide-timolol combination to prevent intraocular pressure elevation after laser capsulotomy

Erkan Çelik, Gonul Altun, Gursoy Alagoz

Department of Ophthalmology, Sakarya University Medical Education and Research Hospital, Sakarya 54000, Turkey
Correspondence to: Erkan Çelik. Sakarya University Medical Education and Research Hospital, Sakarya 54000, Turkey. drerkancelik@gmail.com
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阿拉可乐定与布林唑胺-噻吗洛尔滴眼液预防激光晶状体囊切开术后眼压升高的对照研究

Erkan Çelik, Gonul Altun, Gursoy Alagoz
(作者单位:土耳其,萨卡里亚 54000,萨卡里亚大学医学教育和研究院,眼科)
通讯作者:Erkan Çelik. drerkancelik@gmail.com

摘要

目的:比较 1% 布林唑胺和 0.5% 噻吗洛尔联合制剂(FCBT)与 0.5% 阿拉可乐定(APRA)滴眼液预防接受 Nd:YAG 激光晶状体囊切开术患者术后眼压升高的疗效。

方法:前瞻随机对照临床研究。研究包括 90 例(90 眼)接受 Nd:YAG 激光晶状体囊切开术治疗后囊膜混浊(PCO)患者。患者术前 1h 随机给予 APRA(n=45)或 FCBT(n=45)治疗。一名设盲检查者使用 Goldmann 压平眼压计检查术前及术后 1,2,3,24h 和 7d 的眼压。眼压检查结果分为以下两类:术后眼压升高 5~<10 mm Hg 和眼压升高≥10 mm Hg。眼压升高<5 mm Hg 认为没有临床上的显著改变。

结果:APRA 组和 FCBT 组术前当天的平均眼压分别为 14.1±2.1 mm Hg 和 13.2±2.1 mm Hg,差异无统计学意义(P=0.066)。随访期间,FCBT 组的平均眼压较低但差异无统计学意义。APRA 组中的 6 名患者(13.3%)和 FCBT 组中的 4 名患者(8.9%)术后至少有一次眼压升高 5~<10 mm Hg,差异无统计学意义(P=0.243)。眼压升高≥10 mm Hg 在 APRA 组与 FCBT 组中分别出现 3 眼(6.7%)和 1 眼(2.2%),差异无统计学意义(P=0.542)。

结论:APRA 和 FCBT 均可有效预防眼压升高且 APRA 足以应对常规病例。对于需要加强降低眼压的患者-如预先存在青光眼的患者(其术后眼压升高的风险更大)可选择 FCBT。

关键词:阿拉可乐定;布林唑胺;噻吗洛尔;激光晶状体囊切开术

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Abstract

• AIM: To compare the efficacy of fixed combination of brinzolamide 1% and timolol 0.5% (FCBT) with apraclonidine 0.5% (APRA) in preventing intraocular pressure (IOP) elevations after neodymium: yttrium-aluminum-garnet (Nd: YAG) laser posterior capsulotomy.

• METHODS: This prospective randomized clinical study included 90 eyes of 90 consecutive patients who had Nd: YAG laser posterior capsulotomy for posterior capsule opacification (PCO). Patients were randomized to receive APRA (n=45) or FCBT (n=45) at 1h before laser surgery. A masked observer measured IOP by Goldmann applanation tonometry before the procedure and at 1, 2, 3, 24h and 7d after laser treatment. IOP outcome measures were grouped into the following categories: post laser IOP elevation of 5 to <10 mm Hg, and post laser IOP elevation of 10 mm Hg or more. IOP elevation of <5 mm Hg was not considered a clinically significant change.

• RESULTS: The mean IOP before surgery on the day of the procedure was 14.1±2.1 mm Hg in the APRA group and 13.2±2.1 mm Hg in the FCBT group. There was no statistically significant difference between the APRA and the FCBT groups of baseline IOPs measured (P=0.066). During the follow-up time, the mean IOP was lower in FCBT group, but this was not statistically significant. Six patients (13.3%) in APRA group and 4 (8.9%) in FCBT group had IOP elevations of 5 to <10 mm Hg at least one postoperative IOP measurement. This difference was not statistically significant (P=0.243). IOP elevations of 10 mm Hg or more occurred in 3 eyes (6.7%) in the APRA group and 1 eyes (2.2%) in the FCBT group; this was not statistically significant (P=0.542).

• CONCLUSION: Both of APRA and FCBT are effective for prevention and APRA is enough for most of routine cases. FCBT may be an option for the eyes those need more IOP reduction such as pre-existing glaucoma patients who are at higher risk for postoperative IOP elevations.

• KEYWORDS: apraclonidine; brinzolamide; timolol; laser capsulotomy
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INTRODUCTION

Posterior capsule opacification (PCO) is the most common complication of modern cataract surgery. It is caused by the retrolental migration of lens epithelial cells left in the capsular bag equator. Standard treatment for PCO is a neodymium: yttrium-aluminum-garnet (Nd:YAG) laser capsulotomy[1-2]. Intraocular pressure (IOP) elevation after laser treatment is a common and potentially serious complication after anterior segment laser surgery. Studies show the incidence of IOP elevation of 5 mm Hg or greater after Nd:YAG laser posterior capsulotomy varies from 20% to 95%[3-7].

Various topical ocular hypotensive agents have been used prophylactically in an attempt to prevent the postlaser IOP rise. Apraclonidine hydrochloride 0.5% (Iopidine®, Alcon Laboratories, Rijksweg, Puurs, Belgium) is a widely used alpha-adrenergic agonist that reduces IOP by reducing aqueous production and increasing uveoscleral outflow[8]. Fixed combination of brinzolamide 1% and timolol 0.5% (Azarga® Alcon Laboratories, Inc., Fort Worth, TX, USA) is a highly efficacious ocular hypotensive agent that provides clinically meaningful IOP reductions in patients with open-angle glaucoma or ocular hypertension[9].

To our knowledge, there are no published reports of the effectiveness of fixed combination of brinzolamide 1% and timolol 0.5% (FCBT) in preventing IOP elevation after laser treatment. This study examined the IOP lowering effects of apraclonidine 0.5% (APRA) versus FCBT for prophylaxis of IOP elevation after Nd:YAG laser posterior capsulotomy.

SUBJECTS AND METHODS

This prospective, randomized, double-masked clinical trial enrolled 90 patients having YAG laser posterior capsulotomy at the Sakarya University Medical Education and Research Hospital Ophthalmology Department between Mar. 2012 and Jan. 2014. Patients were randomized to receive APRA (n = 45) or FCBT (n = 45) at 1h before laser surgery. Randomization was performed using the order of entrance in the study, with alternate assignment to APRA and FCBT (Azarga®; Alcon Laboratories, Inc., Fort Worth, TX, USA) groups.

The research followed the tenets of the Declaration of Helsinki, and all patients signed informed consent after they received an explanation of the nature and possible consequences of the procedure. Institutional review board approval was also obtained.

Study enrollment was comprised of consecutive clinic patients. Patient data included age, sex, and race. Patients in the study were older than 18y with visually significant PCO. Only one eye in each patient was enrolled for study. Patients were excluded if they had previous ocular laser treatment and intraocular surgery except cataract operation. Patients were also excluded if they had a history of glaucoma, had active inflammation or infection, had asthma, obstructive pulmonary disease, arrhythmia, renal failure, had known allergy to carbonic anhydrase inhibitors (CAIs) or alpha-adrenergic agonists, were <21y of age, were taking systemic clonidine or topical apraclonidine, and IOP greater than 21 mm Hg before the procedure.

All patients had complete baseline eye examinations including best corrected Snellen visual acuity, slit lamp biomicroscopy, fundus examination, central corneal thickness (CCT) measured by ultrasonographic pachymetry, central macular thickness (CMT) measured by optical coherence tomography (OCT). The baseline IOP was measured by Goldmann applanation tonometry approximately 3h before the laser procedure.

To qualify for YAG capsulotomy, the posterior capsule had to be sufficiently opacified causing an objective decrease in best corrected visual acuity. The eyes were dilated with topical tropicamide 1%. Both groups received the drops 1h before the laser procedure. A Q-switched Nd:YAG laser (Laserex SuperQ, Indonesia) was used. All procedures were performed by the same surgeon (Altun G) who was masked to treatment assignment and the drops were applied by other researchers. Laser spots were applied until the capsule was opened to approximately 4.0 mm in diameter. We also recorded the total amount of the laser power and the number of applications.

Patients were prescribed dexamethasone sodium phosphate 0.1%, 4 times a day for 1wk. IOP, heart rate, blood pressure, and any adverse reactions were recorded at 1, 2, 3, 24h, 3d and 7d after the laser treatment. Postlaser measurements of IOP were done by the physician who measured the IOP prelaser. The patient and the physician measuring the IOP were unaware of the treatment assignment. If at any point an unacceptable IOP elevation (IOP≥30 mm Hg) was observed, the patient would have received other IOP-lowering medication(s) as needed and would have been removed from the study. IOP outcome measures were grouped into the following categories: postlaser IOP elevation of 5 to < 10 mm Hg, and postlaser IOP elevation of 10 mm Hg or more. IOP elevation of <5 mm Hg was not considered a clinically significant change.

Statistical analysis was performed using SPSS software for Windows version 20 (SPSS, Chicago, IL, USA). The Chi-square test was used to compare the demographic and clinical variables between two groups. Student t-test and Mann-Whitney U test were used to compare the IOP values between the groups. P values less than 0.05 were considered as statistically significant.

RESULTS

The demographic and clinical data of the patients were summarized at Table 1. There were no statistically significant differences between the two groups.

The mean IOP before surgery on the day of the procedure was 14.1±2.1 mm Hg in the APRA group and 13.2±2.1 mm Hg in the FCBT group. There was no statistically significant difference between the APRA and the FCBT groups of baseline IOPs measured (P = 0.066). No clinically significant side effects, such as cystoids macular edema detected by OCT, were noted.

Table 1 Demographic and clinical data

Parameter	APRA group	FCBT group	*P*
Number of patients	45	45	
Sex, Female, *n* (%)	24 (53.3)	21 (46.7)	0.520
Age (a)	68.2±9.5	68.6±8.4	0.317
CCT (μm)	545.6±34.5	544.8±28.8	0.866
Surgery-laser interval (mo)	57.5±25.5	55.6±24.3	0.824
Total laser energy (mJ)	40±23.8	41±21.6	0.175

APRA: Apraclonidine hydrochloride 0.5%; FCBT: Fixed combination of brinzolamide 1% and timolol 0.5%; mJ: Milijoule.

The mean IOP changes from baseline were shown in two groups at 1, 2, 3, 24h and 7d after laser treatment at Figure 1. During the follow-up time, the mean IOP was lower in FCBT group, but this was not statistically significant. Six patients (13.3%) in APRA group and 4 (8.9%) in FCBT group had IOP elevations of 5 to <10 mm Hg at least one postoperative IOP measurement. This difference was not statistically significant ($P=0.243$). IOP elevations of 10 mm Hg or more occurred in 3 eyes (6.7%) in the APRA group and 1 eyes (2.2%) in the FCBT group; this was not statistically significant ($P=0.542$).

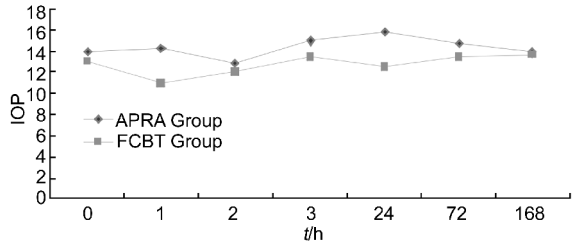

Figure 1 The mean IOP changes of groups from baseline during follow-up During the follow-up time, the mean IOP was lower in FCBT group than the APRA group, but this was not statistically significant. FCBT: Fixed combination of brinzolamide 1% and timolol 0.5%; APRA: Apraclonidine hydrochloride 0.5%; IOP: Intraocular pressure.

DISCUSSION

Nd: YAG laser capsulotomy is a common and effective procedure used to treat PCO, which can develop in patients following uneventful cataract surgery. However, this procedure can result in significant morbidity arising from postoperative complications. These include transient immediate IOP elevation, new onset of glaucoma, worsening of preexisting glaucoma, IOL damage, iris damage, hyphema, cystoid macular edema, and retinal detachment[4,10].

Laser capsulotomy procedure is known to increase the IOP in many patients in the short term[5,11-12]. To protect against rises in IOP, we use topical antiglaucomatous drugs and try to minimize debris release during the capsulotomy by using a low energy level and making a small, well-centred hole in the capsule with the fewest necessary laser applications[1]. Prophylaxis of IOP rises occurring after YAG laser capsulotomy is routinely done, because it is difficult to predict in which eyes significant damages will develop. Many drugs are used for prophylaxis of IOP spikes after YAG laser posterior capsulotomy. Alfa adrenergic agonists such as apraclonidine and brimonidine tartrate, CAIs like topical dorzolamide, brinzolamide and oral acetozolamide, and prostaglandin analogs such as bimatoprost and latanaprost, and timolol as a beta-blocker have been used for prophylaxis[2,5-6,13-15]. Our study compared the effectiveness of FCBT with that of APRA in preventing post-laser capsulotomy IOP rises. To our knowledge, there are no published reports of the effectiveness of FCBT in anterior segment laser procedures.

Fixed combinations of IOP-lowering drops provide the effectiveness of multiple active agents with the convenience of a 1-bottle regimen. Modern fixed combinations have paired the beta-blocker timolol with various prostaglandin analogs, an adrenergic agonist or a CAI [16]. Recently, a new fixed combination product, FCBT has been introduced and received regulatory approval by the European Medicines Agency in November 2008 for the treatment of patients[17]. FCBT is comprised of the CAI brinzolamide and the beta blocker timolol. The concentration of brinzolamide is 1% (10 mg/mL), equal to that of brinzolamide ophthalmic suspension (Azopt; Alcon Laboratories, Inc., Fort Worth, TX, USA) and the timolol concentration is 0.5% (5 mg/mL), equal to that of single-agent timolol[18]. Brinzolamide is a topical CAI that lowers IOP by decreasing aqueous humour secretion, whereas timolol is a beta-adrenergic blocking agent that reduces IOP by slowing the rate of aqueous humour formation[19-20].

Lanzl *et al*[21] used FCBT in a multicenter, observational study, including 14 025 patients, to document the efficacy and tolerability of the FCBT in daily practice throughout Germany. They reported that FCBT produced better IOP control all previous therapies analyzed and demonstrated favorable tolerability and a high satisfaction rating, resulting in a strong patient preference for FCBT over previous therapies[21].

In a prospective, randomized, double-masked study, comparing the safety and efficacy of FCBT versus dorzolamide 2% + timolol 0.5%, designed by Manni *et al*[9], they demonstrated that mean IOP reduction with FCBT ranged from 7.2 to 9.1 mm Hg, representing 28% to 35% reductions from baseline; and they concluded that FCBT produced clinically meaningful IOP reductions from baseline that were non-inferior to those seen with dorzolamide 2% + timolol 0.5%, additionally with a better ocular comfort.

Kaback *et al*[22] tested FCBT in a randomized, double-masked, multicenter trial of 523 patients with open-angle glaucoma or ocular hypertension to compare its efficacy to that of each monotherapy (brinzolamide alone or timolol alone). FCBT produced IOP reductions from baseline (8.0±3.7 to 8.7±3.9 mm Hg) that were greater than reductions from either brinzolamide (5.1±3.9 to 5.6±3.4 mm Hg) or timolol (5.7±3.6 to 6.9±3.6 mm Hg) alone. These IOP reductions by FCBT were not only significantly greater than either monotherapy, at all time points and visits, but they were also

clinically relevant, ranging from 1.5 to 3.0 mm Hg improvements over monotherapy[22].

Systemic safety of FCBT has been demonstrated in several randomized studies. In two of the randomized, controlled studies, the only systemic adverse event related to FCBT was dysgeusia, a distortion of taste, at an incidence of 3.2% in the Manni *et al*'s[9] non-inferiority study and 0.8 in the Mundorf *et al*[23] patient preference study. With respect to ocular adverse events, the FCBT group from the Manni *et al*'s[9] study had a significantly lower incidence of ocular irritation and pain. The reason for the superior comfort is likely due to the pH 7.2 of FCBT, which is much closer to physiologic pH.

In a study designed by Cai *et al*[24], evaluating the effective prophylaxis of 0.5% timolol maleate for IOP rise following YAG laser capsulotomy, they concluded that pre-treatment with a topical application of 0.5% timolol is effective in preventing IOP elevation after YAG laser capsulotomy. In another study comparing the effectiveness brinzolamide and apraclonidine for IOP spikes after Nd:YAG capsulotomy, it was reported that both drugs were effective in preventing post-laser IOP spikes[15].

This study compared 1 drop of fixed combination of brinzolamide 1% and timolol 0.5% with 1 drop of apraclonidine 0.5% given at 1h before laser capsulotomy. We observed that the mean IOP was lower in FCBT group during the follow-up time but this was not statistically significant. Thirteen point three percent of patients in APRA group and 8.8% of patients in FCBT group had IOP elevations of 5 to < 10mm Hg at least one postoperative IOP measurement. This difference was not statistically significant. IOP elevations of 10 mm Hg or more occurred in 6.7% of eyes in the APRA group and 2.2% of eyes in the FCBT group; and also this was not statistically significant. The incidence of IOP spikes of 5 mm Hg or higher in apraclonidine-treated patients having Nd:YAG laser posterior capsulotomy is reported to be between 6% and 22% in other studies[8,25-27]. In our study, 20% of patients receiving apraclonidine had IOP elevations of 5 mm Hg or greater, indicating our results are comparable to those in previous reports. This ratio was 11% in patiens treated with FCBT. No patient in either group in our study reported any ocular or systemic side effects.

Pre-existing glaucoma is a well-known risk factor for having a transient increase in IOP after laser procedures. It is logical that patients with an underlying impairment of outflow facility would have less physiological reserve to handle any further resistance to outflow. Lin *et al*[28] designed a study to evaluate the long-term IOP control of glaucomatous eyes following Nd:YAG laser capsulotomy and they reported that the rate of "disease progression" rate was 11.6% at 4mo and 20.3% at 6mo. They acclaimed that a need for more aggressive therapy could be applied in glaucoma patients following a Nd:YAG laser posterior capsulotomy[28]. Because a long-term increase in IOP following laser capsulotomy is common in glaucomateous eyes, FCBT may be an option for the eyes with pre-existing glaucoma.

To the best of our knowledge, our study is the first prospective, comparative study evaluating the effectiveness of FCBT in preventing IOP elevation after Nd:YAG laser posterior capsulotomy. In conclusion, both drugs seem to be effective for prevention and APRA is enough for most of routine cases. FCBT may be an option for the eyes those need more IOP reduction such as pre-existing glaucoma patients who are at higher risk for postoperative IOP elevations and visual loss. Larger prospective and comparative studies should be done to better define the differences in efficacy between FCBT and APRA for laser capsulotomy.

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