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Prophylactic tamsulosin in cataract surgery under general anesthesia for preventing urinary retention: a randomized clinical trial

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Received: 2013-09-18 Accepted: 2013-12-12

术前应用坦索罗辛对全麻白内障患者尿潴留的预防作用

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摘要

目的:检测术前应用坦索罗辛对全麻白内障患者尿潴留的预防作用。

方法:对 67 名男性患者行全麻白内障手术,口服坦索罗辛,每日 0.4mg(32 例)或安慰剂(35 例)。比较两组术后尿潴留和软盘虹膜综合征发生率。

结果:两组患者年龄,坦索罗辛组:68.16±8.72 岁;安慰剂组:71.37±8.60 岁,(P=0.38)。术后坦索罗辛组尿潴留发生率较低(3.1% *vs* 48.6%,P<0.001;Odds ratio=29.28,95% *CI* 3.59~238.79)。安慰剂组中 1 例(2.9%)发生软盘虹膜综合征(P=0.52;Odds ratio=1.03,95% *CI* 0.97~1.09)。

结论:全麻白内障手术前口服坦索罗辛可有效防止术后尿潴留,而不增加软盘虹膜综合征发生的风险。

关键词:术后尿潴留;坦索罗辛;软盘虹膜综合征

引用:Bazzazi N, Mousavi Bahar H, Kimiaei Asadi H, Akbarzadeh S, Fouladi DF. 术前应用坦索罗辛对全麻白内障患者尿潴留的预防作用. 国际眼科杂志 2014;14(1):1-3

Abstract

• AIM: To examine the effect of prophylactic tamsulosin in male candidates of cataract surgery on general anesthesia in preventing urinary retention.

• METHODS: In this double blind clinical trial, 67 male candidates of cataract surgery under general anesthesia randomly received oral tamsulosin (0.4mg daily for one week prior to cataract surgery, n=32), or placebo (n=35). Rates of post-operative urinary retention and floppy iris syndrome were compared between the two groups.

• RESULTS: The two groups were matched for the patients' age (tamsulosin group: 68.16±8.72 years, placebo group: 71.37±8.60 years, P=0.38). Post-operative urinary retention occurred less frequently in tamsulosin receivers (3.1% *vs* 48.6%, P<0.001, Odds ratio=29.28, 95% *CI* 3.59-238.79). There was only one case (2.9%) with floppy iris syndrome in the control group (P=0.52, Odds ratio=1.03 95% *CI* 0.97-1.09).

• CONCLUSION: Short-term prophylactic administration of oral tamsulosin before cataract surgery on general anesthesia is effective in preventing post-operative urinary retention without increasing the risk of floppy iris syndrome.

• KEYWORDS: postoperative urinary retention; tamsulosin; floppy iris syndrome
DOI:10.3980/j. issn. 1672-5123. 2014. 01. 01

Citation: Bazzazi N, Mousavi Bahar H, Kimiaei Asadi H, Akbarzadeh S, Fouladi DF. Prophylactic tamsulosin in cataract surgery under general anesthesia for preventing urinary retention: a randomized clinical trial. *Guoji Yanke Zazhi* (*Int Eye Sci*) 2013;14(1):1-3

INTRODUCTION

Cataract is a very common problem among the elderly[1,2]. Despite an increasing tendency to perform cataract surgery under local anesthesia, general anesthesia is inevitable in some cases. Urinary retention may complicate these cases, noting that many of such patients primarily suffer from prostatic hyperplasia and detrusor muscle weakness[3,4]. Although using bladder catheters can resolve this problem, it may be accompanied with other complications such as infection[5]. Instead, different drugs, such as α_1 adrenergic antagonists (terazosin, doxazosin, alfuzosin) and 5 α-reductase inhibitors (finasteride, dutasteride) have been proposed to prevent postsurgical urinary retention[6].

Tamsulosin is a rather novel α_1 adrenergic antagonist. Its affinity to α_{1A} adrenergic receptors, which are the major contributing receptors to benign prostatic hyperplasia (BPH), is 20-38 times more than its affinity to α_{1B} receptors. The high affinity to α_{1A} subtype adrenergic receptors makes tamsulosin more cardiovascular-friendly and better tolerated in combination with antihypertensive drugs in comparison with similar medications [7,8]. This study aims to investigate the effect of prophylactic tamsulosin in preventing urinary retention in patients undergoing cataract surgery on general anesthesia.

SUBJECTS AND METHODS

Subjects After receiving the approval of the ethics committee of Hamadan University of Medical Sciences, male candidates of cataract surgery under general anesthesia (over 50 years old) were recruited from two teaching eye centers (Besat and Farshchian) from 2008 through 2010. Written informed consents were obtained from the patients prior to involvement in the study. The authors adhered to the tenets of the Declaration of Helsinki in this work. Ninety-seven patients agreed to participate. A questionnaire including 7 symptoms questions of the International Prostate Symptom Score (IPSS) were handed to each patient [2].

Methods Patients with IPSS score of 15-25 ($n=67$) were randomized in two groups: 1) Those who received oral tamsulosin (Farabi Pharmaceutical, Iran) 0.4mg daily for one week prior to cataract surgery (the case group, $n=32$). 2) Those who received placebo daily for one week prior to cataract surgery (the control group, $n=35$).

Exclusion criteria were: hypersensitivity to tamsulosin, cardiovascular disease (previous myocardial infarction and/or hypertension), antipsychotic drugs use, and IPSS score under 15 and/or higher than 25.

All the patients were under tight supervision during 12h hospital stay postoperation. Urinary volume was recorded regularly in this period. The patients were also revisited 24 and 72h, postoperation and any possible complication was recorded. Urinary retention was defined as " inability to voluntarily void urine or any help asking for urination" [9].

Cataract surgery was performed in all patients using standard horizontal chop phacoemulsification method, and foldable lens were inserted through 2.8mm incision by injector. The mean time of surgery was 20min. To achieve general anesthesia, endotracheal intubation was performed using fentanyl (1mL), lidocaeine (1mg/kg), thiopental (5mg/kg), and atracurium (0.5mg/kg). Maintenance was achieved using halothane (1%). Floppy Iris Syndrome (IFIS) was defined by the presence of the triad of: a flaccid or floppy iris, a marked propensity for the iris to prolapse in the main and side-port surgical incisions, and progressive pupil constriction during surgery [10-13].

Intraoperative epinephrine was not used and no cases underwent mechanical dilatation of the pupil in this series. Overall, the pre-, intra-, and post-operative management was the same in all the patients. Patients who developed urinary retention after cataract surgery underwent urinary catheterization.

Table 1 Demographics and the studied variables in the studied patients with cataract

Variables	Cases ($n=32$)	Controls ($n=35$)	P
Age (a)	68.16±8.72 (62-84)	71.37±8.60 (62-89)	0.38
Urinary retention	1 (3.1)	17 (48.6)	<0.001
Floppy iris syndrome	0 (0)	1 (2.9)	0.52

Data are presented as mean±standard deviation (range), or frequency (%).

Statistical Analysis Data were analyzed using SPSS software (Ver. 19, IBM Co., USA) and shown as mean±standard deviation or frequency (%). For categorical variables, analysis was performed using the Chi-square or Fisher's exact tests, when appropriate. For numerical data, the Independent samples t test was used. A P value <0.05 was considered statistically significant.

RESULTS

The patients' characteristics and study variables are summarized and compared between the two groups in Table 1. The mean age of the patients in the case group was 68.16±8.72 (range: 62-84) years, *vs* 71.37±8.60 (range: 62-89) years in the control group (Independent samples t test, $P=0.38$). Urinary retention was reported in 18 patients (67%), 1 patient (3.1%) in the case and 17 patients (48.6%) in the control group. Urinary retention after surgery occurred significantly more frequent in the control group (Chi-square test, $P<0.001$, Odds ratio=29.28 95% *CI* 3.59-238.79). There was only one case (2.9%) with floppy iris syndrome in the control group (Fisher's exact test, $P=0.52$, Odds ratio=1.03 95% *CI* 0.97-1.09).

DISCUSSION

Both BPH and acute urinary retention are common findings in the elderly [14]. Acute urinary retention is also a common complication after operations, particularly those with general anesthesia. The rate of acute urinary retention has been reported between 5 to 70 percent in operated patients under general anesthesia [15]. Post-operative urinary retention manifests itself as poor urinary stream with intermittent flow, straining, a sense of incomplete voiding and hesitancy [16,17]. Since cataract is a very prevalent condition in the elderly that needs surgical correction, the incidence of post-operative urinary retention is expected to be high in cataract surgery. Higher frequency of BPH in older men further increases the likelihood of post-operative urinary retention after cataract surgery. Therefore, using prophylactic medications against this condition highly makes sense in the patients who require cataract surgery under general anesthesia. Tamsulosin is one of these medications, which is basically a systemic sympathetic α_{1A} antagonist. It is assumed that this drug causes facilitation of urine outflow by blocking α receptors in prostate and bladder neck [4,6]. In the present work, the effect of prophylactic tamsulosin against the emergence of post-operative urinary retention in cataract surgery was investigated. According to the obtained results, using this medication significantly decreased the rate of post-operative urinary retention in comparison with controls (3.1% *vs* 48.6%; $P<0.001$). In a similar study by Chapple *et al* [7], oral tamsulosin was used once daily at a dose of 0.4mg. They

showed a significant improvement in Boyarsky symptom score and maximum flow rate following tamsulosin use. In another series by Narayan [18], tamsulosin therapy for the treatment of BPH signs and symptoms caused a decrease in American Urological Association Symptom Score, an increase in peak and average urine flow rate, and an improvement of quality-of-life index. Although our results are in conformity with previous reports in terms of the usefulness of tamsulosin in cataract surgery, there are, at the same time, some reports that have raised concern regarding the complication of this medication in cataract surgery. According to these reports, α adrenergic blockers could induce abnormal iris behavior during cataract surgery, which is called intra operative floppy iris syndrome (IFIS). IFIS was first described by Chang and Campbell in 2005, and is identified by decreased tone and fluctuating of iris, lack of sufficient pupillary dilatation and iris prolapse during phacoemulsification cataract surgery [10,11,19]. We did not find any case with IFIS in the study group, while there was a patient with this complication in the control group. Thus, in contrary to some previous reports [20-22], use of tamsulosin starting a week prior to cataract surgery neither did not increase the risk of IFIS. Several pharmacological and mechanical strategies have been suggested for preventing of IFIS including using maximal dilatation regimens before surgery, intraocular injection of dilating agents, bimanual micro incision surgical techniques, highly retentive viscoelastic agents, low flow rate during surgery, and mechanical dilatation of iris by iris hooks or iris rings. In addition, careful attention to incisional construction has been advised [19]. Other alleged side effects of tamsulosin such as dizziness, headache, rhinitis, pharyngitis, asthenia, postural hypotension and syncope [7] were not detected in the present study. Short-term use of tamsulosin may justify the low incidence of IFIS or other complications that have been declared to be connected with this medication use in cataract patients. Lack of quantitative tests, uroflowmetry, post void urine volume and peak urine flow rate measurements are limitations of our study, which merit to be acknowledged here, and be rectified in future studies. Possible effects of the type of surgery [23] and age of patients [24] need to be investigated in further studies.

Short-term prophylactic use of oral tamsulosin before cataract surgery is effective in preventing post-operative urinary retention, with no increased risk of floppy iris syndrome or other complications.

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