Journal of Optometry (2016) xxx, xxx–xxx

Journal of Optometry

www.journalofoptometry.org

ORIGINAL ARTICLE

Efficacy of an eye drop mixture for pupillary dilatation: A randomized comparative study

Patama Bhurayanontachai[a,*], **Suwapat Saengkaew**[b], **Penjamaporn Apiromruck**[b]

[a] *Department of Ophthalmology, Faculty of Medicine, Prince of Songkla University, Hat Yai, Songkhla 90110, Thailand*
[b] *Songklanagarind Hospital, Hat Yai, Songkhla 90110, Thailand*

Received 15 February 2016; accepted 23 April 2016

KEYWORDS
Diclofenac;
Mydriatic;
Phenylephrine;
Pupillary dilatation;
Tropicamide

Abstract
Purpose: Pupillary dilatation with three types of eye drops is used regularly in the clinic; however, a mixture of these drops in a single bottle may be more beneficial in reducing workloads and resources. This study compared the efficacy in pupillary dilatation between two protocols of dilating drop instillation.
Methods: This prospective, randomized, comparative study included 30 eligible Thai patients. The patients randomly received preoperative pupillary dilatations by either the conventional protocol (1% tropicamide (T), 10% phenylephrine (P) and 0.1% diclofenac (D) in three separate bottles) or the fixed combination (TPD) protocol which had the three types of eye drops mixed in a single bottle in a ratio of 4:3:3. The chi-square test and independent *t*-test were used to analyze the data.
Results: The conventional protocol group and TPD protocol group each had 15 patients. Sixty minutes after the initial instillation, all patients in the TPD protocol and 13 patients (86.7%) in conventional protocol achieved at least 6 mm in the shortest diameter. The mydriatic rate between protocols showed no difference. In patients who received the TPD protocol, the systemic effects on the mean arterial blood pressure and pulse rate decreased over time.
Conclusion: The mixture of tropicamide, phenylephrine and diclofenac had a comparable efficacy for a pupillary dilatation to the conventional dilating drops in separate bottles. The systemic complications on blood pressure and arterial pulse of the TPD mixture were less than the conventional protocol.
Trial registration: TCTR20130325001.

* Corresponding author at: Department of Ophthalmology, Faculty of medicine, Prince of Songkla University, Hat Yai, Songkhla 90110, Thailand.
E-mail addresses: patama103@yahoo.com.au, patamabhu@gmail.com (P. Bhurayanontachai).

http://dx.doi.org/10.1016/j.optom.2016.04.007

Please cite this article in press as: Bhurayanontachai P, et al. Efficacy of an eye drop mixture for pupillary dilatation: A randomized comparative study. *J Optom.* (2016), http://dx.doi.org/10.1016/j.optom.2016.04.007

PALABRAS CLAVE
Diclofenaco;
Midriático;
Fenilefrina;
Dilatación de la pupila;
Tropicamida

Eficacia de la mezcla de gotas oculares para la dilatación de la pupila: estudio aleatorizado y comparativo

Resumen
Objetivo: La dilatación de la pupila con tres tipos de gotas oculares se utiliza normalmente en la práctica clínica; sin embargo, la mezcla de dichas gotas en un único envase puede resultar más beneficiosa a la hora de reducir las cargas de trabajo y los recursos. Este estudio comparó la eficacia entre dos protocolos de dilatación de pupilas.
Métodos: Este estudio prospectivo, aleatorizado y comparativo incluyó a 30 pacientes tailandeses elegibles. A dichos pacientes se les dilató aleatoria y preoperatoriamente la pupila utilizando el protocolo convencional (1% tropicamida (T), 10% fenilefrina (P) y 0,1% diclofenaco (D) en tres envases separados), o el protocolo de combinación fija (TPD), que contenía los tres tipos de gotas oculares mezclados en un único envase, a un ratio de 4:3:3. Se utilizaron las pruebas de χ^2 y la prueba independiente t para analizar los datos.
Resultados: Tanto el grupo de protocolo convencional como el grupo TPD incluyeron a 15 pacientes. A los sesenta minutos de la instilación inicial, todos los pacientes del protocolo TPD y 13 pacientes (86,7%) del protocolo convencional lograron un mínimo de 6 mm en el diámetro menor. La tasa midriática entre ambos protocolos no reflejó diferencia alguna. En los pacientes del protocolo TPD, los efectos sistémicos sobre la presión sanguínea media y el índice de pulso disminuyeron con el tiempo.
Conclusión: La mezcla de tropicamida, fenilefrina y diclofenaco mostró una eficacia comparable a la de las gotas para dilatación de pupilas suministradas en envases separados. Las complicaciones sistémicas sobre la presión sanguínea y la presión arterial de la mezcla de TPD fueron menores a las del protocolo convencional.
Registro del ensayo: TCTR20130325001.

Introduction

Pupillary dilatation is necessary for a fundus examination and ophthalmic procedures. The mydriatic agents that are generally available in the eye clinic are tropicamide and phenylephrine. For an intraocular examination or operation, a non-steroidal anti-inflammatory drug is additionally required to prolong the mydriatic effect and lessen post-operative inflammation.[1,2] The conventional formula of pre-operative pupillary dilatation commonly used in the hospital is 1% tropicamide, 10% phenylephrine, and 0.1% diclofenac in separate bottles. Each eye-drop bottle contains preservatives to inhibit microbial contamination. However, these preservatives have been linked to unwanted ocular surface side effects, such as stinging, redness and corneal punctate epithelial erosion. A combination of pre-operative eye drops in one bottle may not only reduce the frequency of multiple eye drop administrations but may also reduce the ocular and systemic complications.[3–5] There were some reports on the efficacy and safety of a combination of tropicamide and phenylephrine,[4–6] but there is no report on a combination of tropicamide, phenylephrine and diclofenac.

The objective of this study is to compare the mydriatic efficacy of a mixture of tropicamide, phenylephrine and diclofenac in a single eye-drop bottle to the conventional practice of applying the eye drops from separate bottles.

Methods

Inclusion criteria

This randomized prospective study was performed in accordance with the declaration of Helsinki and was approved by the Ethics Committee of the Faculty of Medicine, Prince of Songkla University, Thailand (EC 56-153-02-1-2). We followed our institution protocols regarding patient data protection. Written informed consents were obtained from 30 consecutive, eligible patients before the study began. The inclusion criteria were patients of 18 years old or older and scheduled for an operation at Songklanagarind Hospital, Prince of Songkla University, Thailand from April to July 2013. The pre-operative fasting plasma glucose of all diabetic patients was less than 200 mg/dl. The resting systolic pressure was $\leq$160 mmHg and the resting diastolic pressure was $\leq$90 mmHg.

Exclusion criteria

Patients with a risk of angle-closure, uncontrolled blood pressure, pregnancy, iris or pupil abnormality, or a history

Please cite this article in press as: Bhurayanontachai P, et al. Efficacy of an eye drop mixture for pupillary dilatation: A randomized comparative study. *J Optom*. (2016), http://dx.doi.org/10.1016/j.optom.2016.04.007