Utility of the Tono-Pen in Measuring Intraocular Pressure in Trinidad

A Cross-sectional Study

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ABSTRACT

Aim: *To determine the sensitivity and specificity of the Reichert™ Tono-Pen AVIA® when used by novice medical students in an ethnically diverse population in Trinidad.*

Subject and Methods: *Participants were residents of Trinidad between the ages of 20 and 90 years attending the Ophthalmology Clinic at the Eric Williams Medical Sciences Complex (EWMSC). Intraocular pressure (IOP) was measured using the Goldmann applanation tonometer (the gold standard) for ophthalmology clinic patients as part of their routine care. Intraocular pressure measurements were then taken using the Tono-Pen.*

Results: *One hundred persons participated, consisting of Indo-Trinidadians (55%), Afro-Trinidadians (36%), Mixed (8%) and 1% of Caucasian descent. Fourteen per cent reported a diagnosis of glaucoma with 70.6% of these being of African descent. One hundred and ninety-eight readings of IOP were taken. At a cut-off point of 21 mmHg, there were nine true positives, four false positives, seven false negatives and 178 true negatives. The sensitivity and specificity were found to be 56.3% (95% CI 33.2, 76.9) and 97.8% (95% CI 94.5, 99.1), respectively. The positive predictive value was calculated as 69.2% (95% CI 42.4, 87.3) while the negative predictive value was 96.2% (95% CI 92.4, 98.2). The prevalence of elevated IOP in this population was 8.1% (95% CI 4.8, 13.0). The likelihood ratio of a positive result was calculated to be 25.6 (95% CI 8.6, 73.9).*

Conclusion: *The high specificity and negative predictive value suggests that the Tono-Pen can be used with minimal training, and can prove beneficial at the primary care level in the exclusion of increased IOP in an ethnically diverse high-risk Caribbean population.*

Keywords: Glaucoma, primary healthcare, sensitivity, specificity, Tono-Pen, Trinidad

Utilidad del Tono-Pen en la Medición de la Presión Intraocular en Trinidad

Un Estudio Transversal

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RESUMEN

Objetivo: *Determinar la sensibilidad y especificidad del tonómetro Reichert™ Tono-Pen AVIA® cuando es utilizado por los estudiantes principiantes de medicina en una población étnicamente diversa en Trinidad.*

Sujetos y métodos: *Los participantes entre las edades de 20 y 90 años, eran residentes de Trinidad que acudían a la Clínica de Oftalmología en el Complejo de Ciencias Médicas Eric Williams (EWMSC, siglas en inglés). La presión intraocular (PIO) se midió con el tonómetro de aplanación de Goldmann (estándar de oro) usado con los pacientes de la Clínica de Oftalmología como parte de su servicio de rutina. Luego se hicieron mediciones de la presión intraocular utilizando el Tono-Pen.*

Resultados: *Cien personas participaron, como sigue: indotrinitarios (55%), afrotrinitarios (36%), mixtos (8%), y 1% de descendencia caucásica. El catorce por ciento tuvo un diagnóstico de glaucoma, siendo el 70.6% de ellos de ascendencia africana. Se realizaron ciento noventa y ocho lecturas de PIO.*

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DOI: 10.7727/wimj.2014.125

A un límite de corte de 21 mmHg, hubo nueve verdaderos positivos, cuatro falsos positivos, siete falsos negativos, y 178 verdaderos positivos. Se halló que la sensibilidad y especificidad fueron 56.3% (95% IC 33.2, 76.9) y 97.8% (95 IC 94.5, 99.1), respectivamente. El valor predictivo positivo se calculó como 69.2% (IC del 95%: 42.4, 87.3) mientras que el valor predictivo negativo fue de 96.2% (95% IC 92.4, 98.2). La prevalencia de PIO elevada en esta población fue 8.1% (95% IC 4.8, 13.0). El cociente de probabilidad de un resultado positivo se calculó como 25.6 (95% IC 8.6, 73.9).

Conclusión: *La alta especificidad y valor predictivo negativo sugiere que el Tono-Pen se puede utilizar con un mínimo de entrenamiento, y puede resultar beneficioso a nivel de la atención primaria para excluir el aumento de la PIO en una población caribeña étnicamente diversa de alto riesgo.*

Palabras claves: Glaucoma, atención primaria de la salud, sensibilidad, especificidad, Tono-Pen, Trinidad

West Indian Med J 2015; 64 (4): 368

INTRODUCTION

In 2002, the number of people with visual impairment worldwide was in excess of 161 million; of these, about 37 million were blind. Globally, the top three contributors to this morbidity are cataracts, glaucoma and age-related macular degeneration (1). Regionally, the Barbados Eye Study (BES) 2010 reports that age-related cataract and open-angle glaucoma (OAG) accounted for 73.2% of blindness and diabetic retinopathy (DR) for 8.9%; cataracts caused two-thirds of decreased vision (2).

Glaucoma is an ocular disease characterized by damage to the optic nerve and studies reveal that it is common among the Afro-Caribbean population. The BES reported that in following 3222 participants over nine years, the incidence of *definite* open angle glaucoma (OAG) was 4.4% and among those with *suspected/probable* OAG, the incidence was 9.4%. (3). That study also indicated that incidence increased with increasing age and that men (8.3%) had a higher incidence than women [5.7%] (3). Earlier reports from the BES reported that OAG accounted for 28% of the primary cause of blindness among those with bilateral blindness and that the visual impairment rates were higher in Caribbean blacks compared with other populations (4).

Baseline intraocular pressure (IOP) has been associated with the risk of developing OAG in the nine-year follow-up of the BES (5). Although there may be other risk factors for developing glaucoma, for example, many of the participants who developed OAG in the BES had normal baseline IOP (5), both medical and surgical treatments for OAG lower IOP and reduce the risk for optic nerve damage over the short to medium term. A recent systematic review suggests that currently, the treatments that best prevent visual disability and improve patient-reported outcomes are unclear (6). The evidence for screening for glaucoma is not uncomplicated. The United States Preventative Task Force (USPTF) reported in 2013 that many persons with primary OAG do not have increased IOP and not all persons with increased IOP have or will develop glaucoma. Therefore, screening with tonometry alone may be inadequate to detect all cases of primary OAG (7).

The USPTF do qualify their statement, however, recognizing that persons of African heritage have a higher risk. Additionally, the USPTF found clear evidence that treatment of increased IOP and early glaucoma reduces the number of persons who develop small, clinically unnoticeable visual field defects and that treatment of early asymptomatic primary OAG decreases the number of persons whose visual field defects worsen.

In the United States of America, glaucoma accounts for 9–12% of all blindness, but blindness from glaucoma is 6–8 times more common in African Americans than Caucasians (8). In the Caribbean, primary OAG is an aggressive disease often presenting with very high pressures in relatively young patients. The disease is often already at an advanced stage at presentation. A prevalence study involving more than 1600 subjects in St Lucia was conducted in 1986–87; 364 subjects (8.8%) were diagnosed with glaucoma (9). After ten years, the group was re-evaluated and it was found that between one-third and one-half of the subjects had reached end-stage disease (10).

There is good evidence for the protective role of low IOP to reduce the progression of the visual field defects associated with OAG. The advanced glaucoma intervention study [AGIS] (11), the Ocular Hypertension Treatment Study [OHTS] (12), Collaborative Normal Tension Treatment Study (13), the Early Manifest Glaucoma Trial [EMGT] (14), and other similar studies have convincingly demonstrated that lower IOP reduces the progression of visual field loss.

The high incidence rate in the Afro-Caribbean population and the benefit of early treatment suggest that this population may benefit from early detection through screening. In West Indian primary care populations, the use of the hand-held tonometer is an attractive means for recording IOP. The aim of this study was to determine the sensitivity and specificity of the Reichert™ Tono-Pen AVIA® (15) when used by novice medical students in Trinidad.

SUBJECTS AND METHODS

This study was conducted as part of the medical students' Year 2 research skills training in the Unit of Public Health and Primary Care at The University of the West Indies, St Augustine. This was a cross-sectional study. Patients had their IOP meas-

ured by the Tono-Pen (by trained medical students) and the Goldmann applanation tonometer (by the ophthalmology consultant or residents). Patients of all ethnicities attending the ophthalmology clinic in EWMSC who were having their IOP measured as part of their routine visit were eligible. Patients were excluded if under age 18 years, had diminished mental capacity, were non-English speakers or pregnant.

Medical students were trained by a specialist ophthalmologist (DM) in the use of the Tono-Pen, prior to the commencement of the study. Patients at the clinic had a topical anaesthetic applied to the eyes in preparation for routine measurements of their IOP. The patients were seated and positioned in front of a fixation target and asked to focus on the target. An Ocu-Film tip cover was placed on the transducer of the Tono-Pen to eliminate the risk of cross-contamination. The Operator's button on the Tono-Pen was depressed and the transducer tip gently tapped on the patient's anaesthetized cornea, with the tip perpendicular to the central cornea. Intraocular pressure measurement was recorded as seen on the Tono-Pen's LCD screen. Patients were then asked to proceed to the Goldmann applanation tonometer for IOP measurements to be taken by ophthalmology residents. Residents were unaware of the results obtained by the Tono-Pen. In other cases, the patients had Goldmann applanation tonometer performed prior to Tono-Pen. Again, blinding was maintained. Results obtained from both instruments were compared to determine whether the Tono-Pen's specificity and sensitivity are equivalent to that of the Goldmann applanation tonometer.

Permission for conducting the study was granted by the institutional review boards of the North Central Regional Health Authority and The University of the West Indies, Faculty of Medical Sciences, St Augustine, Trinidad.

RESULTS

There were 100 participants with 198 readings of IOP being taken. Participants aged 21–50 years made up 33%, those 51–70 years made up 51% and those 71 years and older made up 26% of the study. There were 61 females and 39 males. Participants consisted of Indo-Trinidadian (55%), Afro-Trinidadian (36%), Mixed (8%) and 1% of Caucasian descent. Fourteen per cent reported a diagnosis of glaucoma, with 70.6% of these being of African descent. At a cut-off point of 21 mmHg, there were nine true positives, four false positives, seven false negatives and 178 true negatives. The sensitivity and specificity were found to be 56.3% (95% CI 33.2%, 76.9%) and 97.8% (95% CI 94.5%, 99.1%), respectively. The positive predictive value was calculated as 69.2% (95% CI 42.4%, 87.3%) while the negative predictive value was 96.2% (95% CI 92.4%, 98.2%). The prevalence of elevated IOP in this population was 8.1% (95% CI 4.8%, 13.0%). The likelihood ratio of a positive result was also calculated as 25.6 (95% CI 8.6, 73.9).

Among the 36 participants of Afro-Trinidadian descent, 71 readings of IOP were taken. There were four true positives, two false negatives, one false positive and 64 true negatives. In this sub-population, the sensitivity of the Tono-Pen AVIA was 66% (95% CI 24.1, 94.0) and the specificity was 98.5% (95% CI 90.5, 99.9%). The positive predictive value was 80% (95% CI 29.9, 98.9) and the negative predictive value was 94.1% (95% CI 88.5, 99.5%). The likelihood ratio of a positive result was also calculated as 43 (95% CI 5.7, 328.4) for the Afro-Trinidadian population.

DISCUSSION

The sensitivity and specificity of the Reichert™ Tono-Pen AVIA® when used by medical students in Trinidad were found to be 56.3% and 97.8%, respectively. For every 1000 patients with an elevated IOP, the Tono-Pen, in the hands of medical students, would detect 563 cases as being elevated. Four hundred and thirty-seven patients with elevated IOP would be missed. For every 1000 patients with normal IOP, the Tono-Pen, in the hands of medical students, would detect 978 of these as being normal. The value of the Tono-Pen is thus in the detection of patients without an elevated IOP.

Strengths and limitations

In conducting the validation of a new test, several standards should be achieved. These include having a population which resembles that to which the intended new test will be applied, having a reference test which is recognised as being a "gold standard", assuring that all participants are tested by both the new test and the reference standard, and ensuring blinding between the persons conducting the new test and the reference test. It could be argued that the populations do not quite match since this paper is advocating for application in a primary care setting, and the setting of this study was a tertiary care one. This was a matter of convenience since this was where the Goldmann applanation tonometer and ophthalmology staff was available. All the other standards were adhered to.

Comparison with existing literature

This paper is unique in providing sensitivity and specificity of the Tono-Pen AVIA®. We found three studies reporting use of the Reichert™ Tono-Pen AVIA® instrument (16–18), and others reporting on the Tono-Pen XL instrument (19, 20). These papers attest to the validity of the Tono-Pen; however, we could find none that does a comparison of the Tono-Pen AVIA® in practice against the Goldmann applanation tonometer.

Implications for research and/or practice

Support for glaucoma screening in general practice

There is a strong history of advocacy for screening for glaucoma in general practice (21, 22). In one extensive survey, screening found that 12% of those referred to an ophthalmologist had glaucoma at a cost to the system of £408 per case detected (23). Further, a survey of Yorkshire general practitioners found that 80% would consider setting up a glaucoma screening clinic if it could be shown to be of benefit (24). This cur-

rent paper supports the case made by these previous authors, for a similar application to a Caribbean setting with potentially more destructive disease.

The role of serial testing over time in primary care

A strength of primary care is the fact that patients can be repeatedly reviewed over time. Parallel testing, where any positive result is regarded as being positive can improve sensitivity. The resultant net sensitivity is calculated from the following: net sensitivity = sensitivity 1 + sensitivity 2 – [sensitivity 1 × sensitivity 2] (13). Therefore if the Tono-Pen is applied twice, over time the sensitivity of the test increases to: 0.563 + 0.563 - (0.563 × 0. 563) = 1.123 - 0.317 = 80.3%. This improvement, however, is at the expense of a diminished specificity, leading to increased false positives (25).

The positive predictive value

The positive predictive value (in our case = 69.2%) indicates the proportion of people with a positive test that actually have the condition. This implies that for every 1000 patients tested as positive with the Tono-Pen, 308 will not have elevated IOP. This may create increased patient anxiety and a burdening of the healthcare system where increased resources are now required to confirm the presence of increased IOP and of glaucoma. Further testing of the role of combining family history of glaucoma and current IOP readings to increase the positive predictive value to detect the presence of glaucoma is needed. The detection rate can be further enhanced when combined with optic nerve examination by fundoscopy and basic field testing.

How this fits in

Whilst many other studies present the accuracy of the Tono-Pen reading to an actual Goldmann applanation tonometer reading, this paper presents the sensitivity and specificity of the Tono-Pen using the Goldmann applanation tonometer as a gold standard in a population of patients. It also does this in an ethnically diverse population which has been shown to have a higher morbidity from glaucoma. Additionally, the Tono-Pen was used by novice medical students to illustrate the possibility of the rapid application of this tool in a Caribbean primary care setting where opportunities for screening exist.

RECOMMENDATION

Throughout the English-speaking Caribbean, there is a well-developed primary healthcare system. For all the reasons alluded to in this paper, we recommend that in this limited resourced community, which has a high prevalence of this potentially debilitating disease, the screening for glaucoma be integrated into primary care settings through use of instruments such as the Tono-Pen.

CONCLUSION

The sensitivity and specificity of the Reichert™ Tono-Pen AVIA®, when used by novice medical students in Trinidad, was found to be 56.3% and 97.8%, respectively. The high specificity and negative predictive value suggests that the Tono-Pen is a useful tool that requires minimal training, and can prove beneficial at the primary care level in the exclusion of increased IOP. Serial parallel testing improves the net sensitivity of the Tono-Pen to 80.3%. In the current situation in the Caribbean where no screening is carried out in the public health centres, this can be a useful addition to the primary care armamentarium, when combined with assessment of the cup-disc ratio by fundoscopy and visual field study (26).

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