Oman Eye Study 2005: validity of screening tests used in the glaucoma survey

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صلاحية اختبارات التحري المستخدمة في مسوحات الزرق: دراسة حول العيون في سلطنة عُمان 2005

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الخلاصة: قام الباحثان بإجراء دراسة لتقييم صلاحية تدابير تحري الزَّرَق المستخدمة أثناء المسح الذي أُجري في سلطنة عُمان في عام 2005 لفحص عيون 3324 شخصاً (6644 عيناً) في سن الثلاثين أو أكبر. وكان ضغط العين الداخلي، وتغيُّرات قاع العين هما المتثابتَيْن المستخدمَيْن للتحري: فوُجد الزَّرَق في 433 عيناً. وكانت الحساسية بالنسبة لضغط العين الداخلي 49.7٪، والنوعية 95.6٪. أما بالنسبة لتغيرات قرص العصب البصري فكانت الحساسية 48.4٪، والنوعية 97.9٪. ولدى جمع الاثنين من خلال الاختبار المتوازي، تحسَّنت الحساسية لتصل إلى 67.3٪ في حين بلغت النوعية 96.5٪. وعلى هذا، فيمكن باستخدام هذين المتثابتَيْن أن يعلن الفاحص خلوَّ العين من الزَّرَق، ولو أنه لا يمكنه تشخيص الإصابة بالزَّرَق باستخدامهما.

ABSTRACT We carried out a validity assessment study for glaucoma screening procedures used during the survey conducted in Oman in 2005 on 6644 eyes in 3324 people ≥ 30 years. Ocular pressure and fundus changes were the screening parameters used: glaucoma was found in 433 eyes. Sensitivity for ocular pressure was 49.7% and specificity 95.6%. For optic disc changes, sensitivity was 48.4% and specificity 97.9%. Combining both through parallel testing, sensitivity improved to 67.3% and specificity to 96.5%. An eye may, thus, be declared as not having glaucoma, but cannot be labelled as having glaucoma, using these parameters.

Étude sur l'œil réalisée à Oman en 2005: validité des tests de dépistage utilisés dans l'enquête sur le glaucome

RÉSUMÉ Nous avons réalisé une étude visant à évaluer la validité des procédures de dépistage du glaucome utilisées lors de l'enquête menée à Oman en 2005 sur 6644 yeux de 3324 sujets âgés de 30 ans et plus. Les paramètres utilisés pour l'examen étaient la tension oculaire et les altérations du fond de l'œil. Un glaucome a été observé sur 433 yeux. La sensibilité du test pour la tension oculaire était de 49,7 % et sa spécificité de 95,6 %. S'agissant des altérations du disque optique, la sensibilité était de 48,4 % et la spécificité de 97,9 %. La combinaison des deux grâce à des tests en parallèle a permis de faire passer la sensibilité à 67,3 % et la spécificité à 96,5 %. Si l'on utilise ces paramètres, il est possible de déclarer qu'un œil n'est pas atteint de glaucome, mais pas de certifier qu'il est atteint de glaucome.

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Received: 19/02/06; accepted 03/07/06

Introduction

Glaucoma was included in the World Health Organization (WHO) Eastern Mediterranean Region disease control strategy of the VISION 2020 initiative to address avoidable blindness [*1*]. Many member countries, however, lack the necessary community-based information on glaucoma to plan public health policies. The methodology used to generate evidence-based information on glaucoma is a matter of debate [*2*]; a variety of tests are used and hence international comparison of the outcomes is difficult. Simple and practical screening tools that can be used in developing countries at primary level would assist health planners to promote such tests.

Finding an acceptable screening tool for glaucoma has been a challenge for decades [*3*]. In a hospital set-up, diagnosis has become more accurate using modern sophisticated technologies; these can also be used for early detection of glaucoma [*4*]. In a field situation, however, even skilled ophthalmologists find it difficult to diagnose glaucoma as only limited, portable instruments are available. The improvement of the gold standard in glaucoma units in hospitals has raised concern about the validity of community-based surveys carried out with these limited tools [*5*]. Within the time constraints, even the dilation of a pupil for proper viewing of the optic disc and surrounding retina is often not possible in surveys. Owing to co-morbidities like cataracts and corneal pathologies in the elderly population in developing countries, viewing fundus details is also a challenge.

Hence, it is crucial that available data generated through well-defined parameters be tested using epidemiological principles, and that the validity of such parameters is derived so that scientists can adopt glaucoma-screening methodologies of acceptable standards.

A national community-based glaucoma survey was carried out in 2005 in Oman [*6*]. We used data from that survey to determine the validity of the screening tests.

Methods

The 2-phase, cross-sectional, community-based study/survey was approved by the National Research Committee. To conduct a glaucoma survey house-to-house, it is essential to have portable tools. Fundus examination with the help of an ophthalmoscope to note cup and disc changes due to glaucoma and ocular pressure measurement with tonometer are 2 easy and practical methods that were used in the survey. We tested the validity of these 2 screening methods.

The details of survey methodology are given in other publications [*7,8*]. Ophthalmologists examined the anterior segment of the eye with the help of torchlight and a magnifying loupe (× 2.5). The posterior segment of the eye was examined using direct ophthalmoscope. The pupils were not dilated. Ocular pressure was measured using a Tono-Pen XL applanation tonometer (Medtronic, Jacksonville, Florida).

Ocular pressure measurements and evaluation of optic cup, optic disc and surrounding retina through fundus examination were carried out in participants' homes. If the cup: disc (C:D) ratio in vertical or horizontal meridian was > 0.5 or there was haemorrhage on the disc, overpass phenomenon, nicking of blood vessels or nerve fibre layer defect was noted, the eye was declared to have glaucomatous cupping. If the C:D ratio was lower, but other signs were present, it was also considered glaucomatous cupping.

To determine the validity of the screening tools, we used the findings of a panel of 3 ophthalmologists as a gold standard: they used all the information available (pressure, fundus findings, field of vision charts, his-

tory of person, etc.). The "eyes suffering from glaucoma" labelled during the field survey using different screening tools were compared to the eyes labelled as having/ not having glaucoma as determined by the panel (gold standard). The sensitivity, specificity, positive predictive value, negative predictive value, false positives and false negatives were estimated.

Sensitivity was defined as the probability of testing positive if glaucoma was truly present. Specificity was calculated by estimating the probability of screening negative if glaucoma was truly absent. Positive predictive value in our study meant the proportion of correctly identified eyes among those eyes with glaucoma; negative predictive value was calculated as the proportion of correctly found eyes without glaucoma among all normal eyes. The eyes without glaucoma that were incorrectly classified as test positives were labelled as false negatives, while we considered false positive results as those eyes that had glaucoma, but ophthalmologists had incorrectly classified as test negatives [*9*]. We used 2 screening methods, fundus examination and ocular pressure, at the same time in each person with a positive result in any test considered as positive. This is called administration of screening tests in parallel method.

The data per eye were evaluated using *SPSS*, version 9, and *Epi6 Statcalc* to compare the ocular pressure and fundus findings. We also used a combination of pressure and fundus findings to label an eye as having or not having glaucoma.

Results

Profile of the study sample

In the survey, field staff examined 6644 eyes of 3324 persons. Owing to the presence of co-morbidities in the ocular media, detailed fundus examination could only be carried out in 5326 (80.2%) eyes. During the house-to-house screening, the ophthalmologists declared that 433 (6.5%) eyes in 403 (9.6%) persons had glaucoma. They were referred to regional hospitals and 321 (79.7%) presented for re-examination. On repeat examination of 55 glaucoma suspects at home, 36 of had confirmed glaucoma, 9 did not have glaucoma (ocular pressure normal, fundus findings not suggestive of glaucomatous changes and no past history of glaucoma), and in 10 persons, glaucoma status remained inconclusive even after the hospital tests.

Ocular pressure measurement for screening

Owing to the presence of severe corneal opacity, corneal dystrophy or phthisical or absent eyeball in some participants, ocular pressure measurement was carried out in only 6304 eyes; glaucoma was present in 433 eyes: 164 were true positives, 262 were false positives, 166 were false negatives and 5715 were true negatives. The sensitivity and specificity of this test were 49.7% and 95.6% respectively (Table 1).

Fundus examination for glaucoma screening

Presence of opaque or hazy media prohibited viewing of the retina by ophthalmoscopy and evaluation of disc is not possible. Hence only 5326 eyes could be examined with ophthalmoscope: 200 had signs of glaucoma. The sensitivity and specificity of this screening method were 48.4% and 97.9% respectively (Table 1).

Combined screening parameters

When results of ocular pressure measurement and fundus findings for glaucoma screening were combined through parallel testing, the validity of the screening test

Table 1 **Ocular pressure measurement and disc and fundus evaluation and their validity (Oman eye study 2005)**

Variable	Glaucoma[a]	
	Present	Absent
Ocular pressure		
≥ 22 mmHg (***n*** = 426)	164	262
< 22 mmHg (***n*** = 5881)	166	5175
Total (***n*** = 6307)[b]	330	5997
Sensitivity (%)	49.7	
Specificity (%)	95.6	
Predictive +ve (%)	38.5	
Predictive –ve (%)	97.2	
Disc and fundus evaluation		
Positive (***n*** = 200)	92	108
Negative (***n*** = 5126)	98	5028
Total (***n*** = 5326)[a]	190	5136
Sensitivity (%)	48.4	
Specificity (%)	97.9	
Predictive +ve (%)	46.0	
Predictive –ve (%)	98.1	
Combined findings[c]		
Positive (***n*** = 433)	222	211
Negative (***n*** = 5871)	198	5763
Total (***n*** = 6304)	330	5974
Sensitivity (%)	67.3	
Specificity (%)	96.5	
Predictive +ve (%)	51.3	
Predictive –ve (%)	98.2	

[a]Measured by the gold standard.
[b]Owing to the presence of comorbidities or absent eyeball in some participants, ocular pressure measurement and detailed fundus examination could not be carried out in all 6644 eyes.
[c]Using both tests in parallel at the same time in each person; a positive finding in any test was recorded as positive.

improved: sensitivity was 67.3% and specificity 96.5% (Table 1).

Discussion

No single test was adequate to promote as a glaucoma screening tool in our study. Use of all available information was the best option to label an eye as having glaucoma. This should include ocular pressure, fundus examination, history taking and field testing of vision.

It is desirable, but not always possible, to have a test that has high specificity and sensitivity. Neither ocular pressure > 22 mmHg nor the optic disc parameters used were of an acceptable level of validity. In our study, both screening tools had very good specificity > 95%, but the sensitivity was below our expectation of 75%.

By combining the findings for the screening tools, an eye could safely be declared as not having glaucoma, but declaring an eye as having glaucoma with certainty was not possible. Therefore in a community-based glaucoma survey carried out by a skilled ophthalmologist using the ophthalmoscope, findings will produce a number of certain cases of glaucoma but also a substantial number of suspected glaucoma cases. Combining screening methods could be used as a filter to identify eyes that have higher risk of glaucoma. Such patients would be referred for detailed eye check-ups in an institute with better facilities.

The validity of a screening tool is also dependent on the prevalence of a disease for which screening is carried out. 4.75% prevalence of glaucoma that was found justifies high specificity and relatively low sensitivity [*8,9*].

In the survey, ophthalmologists examined the fundus and optic disc of persons in houses once only. It could be argued that this might affect the validity of the screening. However, Hanson, Krishnan and Phillips observed that observer reproducibility does not increase with experience [*10*].

Drawing a sketch of the optic disc and optic cup has been replaced by a new grading system. It correlated very well with field changes [*11*]. This initiative in screening for glaucoma is likely to be more valid com-

pared to our method of evaluating fundus changes of glaucoma.

A study using modern technologies for community-based glaucoma screening in Canada stressed the need for re-evaluating public health approaches to glaucoma screening [*12*]. Our study suggested that by using simple and less-costly technology, validity of glaucoma screening by single test was not very good. But combination of 2 tests improved the validity and could be the solution for conducting effective glaucoma screening in the community.

Relatively poor sensitivity and high specificity of the measurement tools resulted in 13% of cases diagnosed as doubtful. These were reviewed by senior ophthalmologists at eye units using additional tools and in certain cases more sophisticated investigations. This shows the importance of 2-phase screening: in the first phase, simple and portable tools can be used to identify cases of suspected glaucoma and in the second phase they can be reviewed in detail before commencing management of glaucoma.

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