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A mixed methods comparative evaluation of a low cost otoscope (Arclight) with a traditional device in twenty-one clinicians

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Conflict of Interest

AB is seconded to the University of St Andrews from NHS Fife. The University owns a social enterprise subsidiary company, for which AB acts as an unpaid adviser. The social enterprise sells Arclights to users in high resource countries with profits being used to fund distribution and education exercises with the device in low-income countries via the University's Global Health Team.

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Key Points

- WHO estimates up to 330 million people worldwide (4% of world population) have chronic ear infections with a significant proportion of these suffer from disabling hearing loss.

- The majority of people with treatable ear diseases reside in low and middle-income countries where access to otoscopes is limited.

- A novel, low-cost, LED-illuminated, solar-powered otoscope, the Arclight has been developed as a practical and economical alternative to traditional and more expensive devices.

- In comparison to a traditional otoscope, the Arclight has been shown in our study to be equally effective in identifying common ear conditions.

- By overcoming the barriers to acquisition and maintenance of a conventional otoscope in low resource settings, the Arclight has potential to assist in reduction of chronic ear diseases and the subsequent hearing loss in LMICs.

Background

According to the World Health Organisation estimate, the global burden of illness from chronic ear infection affects about 4% of the world population (65 to 330 million) with ear discharge, 60% of whom (39 to 200 million) suffer from significant hearing impairment [1]. Alarmingly, over 90% of the burden of chronic ear infections is borne by low- and middle-income countries (LMICs) [1].

Although otitis media is largely preventable and treatable, over-stretched healthcare budgets in LMICs with minimal funding to equipment for clinics, either in the community or local hospitals, impose a significant barrier to the provision of basic ear and hearing care [2] [3]. In these low-resource settings, a traditional otoscope, essential for early diagnosis of common ear conditions, can be unrealistically expensive to acquire (with an average cost of £150) and impractical to maintain. With the lack of early recognition of ear infections with an appropriate device, treatment is unlikely to be effective with persistence of ear disease and its consequence of loss of hearing. A lower cost, consumable independent alternative to the traditional otoscope would assist in the prevention and treatment of chronic ear infections, thus reducing the burden of needless disability in these regions.

The 'Arclight' is a new, low cost solar-powered otoscope, that has been developed to meet the needs of health care workers in LMICs [4] [Figure 1]. A key patented design of the device is to employ a Light Emitting Diode (LED), which can be charged by an integrated photovoltaic (solar) panel. This eliminates the needs for expensive and bulky batteries and replacement filament bulbs. It is also slim and lightweight (110 mm long x 26 mm wide x 9 mm thick, 18g), making it highly portable. In addition, the Arclight has an integrated magnifying loupe and can also function as an ophthalmoscope. Despite its multi-functionality, when sold in bulk to users in LMICs, it can be purchased for around £10.

As yet, however, there are no comparative studies published that evaluate the effectiveness of the Arclight compared to a traditional otoscope.

The aim of our study was, therefore, to assess the performance of the Arclight otoscope (AO), in comparison to a traditional otoscope (TO), in identifying common ear conditions by clinicians and to evaluate its ease-of-use.

Methods

21 clinicians were recruited from within the ear, nose and throat (ENT) departments of NHS Tayside and Fife. The participants included ENT consultants (7), ENT trainees (6), GP trainees (3), foundation year doctors (4) and a nurse practitioner (1). The TO used in this study was a WelchAllyn.

Each participant assessed 14 different outer and middle ear simulation slides displayed in random order by an Oto-SIM© trainer. The simulations included commonly encountered outer and middle ear conditions such as a normal ear, wax impaction, foreign body in ear canal, exostoses, acute otitis externa, acute otitis media, tympanic membrane perforation, congenital and acquired choleasteatoma, tympanotomy tube, tympanosclerosis and a retraction pocket.

Utilising a randomised cross-over strategy, 11 clinicians started with an AO to examine the simulations, before switching to a TO to repeat the assessment; while the remaining 10 clinicians started with a TO before switching to an AO. The participants were asked to identify each simulation. Every correct answer received one mark with the time taken to reach an answer recorded by an independent assessor. The maximum score was therefore 14 using either otoscope. The scores and time taken were normally distributed and a paired t-test was used to analyse the data.

On completion of the study, each participant was asked to complete an 8 element questionnaire as listed below as well as an overall ease of use score.

1. Ease of attachment of the speculum
2. Stability of the speculum
3. Ease of holding the otoscope
4. Ease of insertion into the ear canal

5. Quality of view of the eardrum
6. Brightness of the light
7. Colour of light source
8. Perceived build quality

A 5-point Likert scale (1 - lowest score and 5 - highest score) was used to gain numerical feedback on each element. The Wilcoxon Signed rank test was used to analyse this non-parametric paired data.

Results

Pathology identification

Using the AO, clinicians achieved a mean score of 9.5 out of 14 compared to 10.0 with a TO ($p = 0.39$).

Time taken to diagnosis

The mean time taken to identification using the AO was 10.2 seconds and 9.1 seconds for the TO ($p = 0.50$).

There was no statistically significant difference demonstrated between the two devices in either accuracy of diagnosis or the time taken to achieve a diagnosis.

Feedback questionnaire

The overall median feedback score was 4 for AO, compared to 5 for TO ($p = 0.005$). This difference was statistically significant. Among the items assessed, the qualities of view obtained, colour of the light source, speculum insertion and build of the AO were rated statistically lower by users compared to a TO. The feedback scores on the ease of attachment, ease of handling, stability, and brightness were however all similar with no statistical difference noted. [Figure 2]

Discussion

Synopsis of key findings

Early identification of ear diseases such as chronic suppurative otitis media relies upon recognition on otoscopy [5, 6] for a good outcome. Unfortunately, most medical devices including the TO are manufactured for high-income country (HIC) markets [7]. For users in LMICs, they tend to be impractically expensive to buy and often require costly and hard to source consumables, such as batteries and filament bulbs. If they break down, they are hard to fix and without regular maintenance, can become less effective. As a result, even if a health care worker in LMICs is donated a TO, like most other medical devices, after a period of intensive use, it is likely be found in a non-functional state in the 'graveyard drawer' [7] [8]. The AO overcomes the shortcomings associated with the TO being designed with the users in LMICs in mind but until this point, no evaluation of its performance to cost ratio, an essential factor for devices used in LMICs [9] had been performed.

Our study has demonstrated that the objective diagnostic performance of the AO is non-inferior to the TO in assisting clinicians to identify pathologies presented on a simulated outer and middle ear device. In addition, the users took the same period of time to make the diagnosis. The subjective scores by the clinicians however was that the AO scored lower for the quality of view obtained, the colour of the light source, the ease of speculum insertion and the build quality compared to the TO.

Strengths and limitations; Comparisons with other studies

The main strength of this study is that it is the first to make a comparative assessment of the AO and demonstrate its non-inferiority in performance against a TO. Using a cross-over design adds weight to the validity of the findings.

There are, however, a few limitations to this study. Firstly, a simulated ear, independent of its fidelity, can never replicate a real patient's ear. Secondly, in order to reveal the true potential of the AO, it needs to be evaluated by its target users in a LMIC setting - ours was not. Thirdly, the diagnostic performance of the AO needs to be formally assessed against an agreed reference standard in a sufficiently powered study to assess the AO's diagnostic

sensitivity and specificity potential. And lastly, as none of the users were exposed to an AO prior to the study, it is possible that the clinicians' unfamiliarity with the new device and its perceived 'cheapness' introduced a negative bias, in particular as the assessment took place in specialist UK centres where a TO is always available as a 'gold standard' option. In view of the limitations, further assessments addressing these issues are recommended.

As the Arclight is a new device, no preceding study has assessed its otoscope function. Nevertheless, its ophthalmoscope function has been evaluated. Blundell et al showed the Arclight ophthalmoscope to be as effective as the traditional direct ophthalmoscope at the hands of Malawian healthcare workers in diagnosing diabetic retinopathy in simulated eye study [10]. In addition, Lowe et al demonstrated the AO to be as effective as the traditional direct ophthalmoscope when assessing the optic nerve head cup to disc ratio in human eyes in Tanzania. This is important in the assessment of glaucoma [11]. Interestingly, in both of these two studies, the clinicians preferred the Arclight over the traditional device mainly because it was easier to use.

Clinical applicability of the study

This study is a stepping stone toward further evaluation of the Arclight as a practical low cost alternative to the TO. The Arclight, due to its multi-functionality, could prove an important device in empowering the healthcare workers to diagnose a range of not only ear, but also eye conditions in LMICs. With such a high performance to cost ratio and in an era of efficiency savings, the Arclight could also be used in the National Health Service (NHS) in the UK, even though the NHS clinicians are not the initial target end users.

In conclusion, the AO is an effective and economical alternative to the TO. Moreover, preliminary studies demonstrate that the Arclight has the potential, not only to combat chronic ear infections and preventable hearing impairment in LMICs, but also an array of other conditions due to its versatility.

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