

ORIGINAL RESEARCH

Comparative evaluation of a low-cost solar powered otoscope with a traditional device among health care workers in Malawi

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Abstract

Objectives: To comparatively evaluate a low-cost otoscope with a traditional device among health care workers in Malawi.

Methods: The study is a prospective, comparative, qualitative observational survey of health care worker's opinions using 5-point Likert rating scales and tick box categories in a 10-item survey questionnaire. Twenty-five mixed cadre health care workers from the Ear, Nose, and Throat Department of the Queen Elizabeth Hospital, Blantyre in Malawi were recruited. Outcomes measures used were ease of speculum attachment, handling, insertion, stability, the quality of view, color, build, brightness, overall ease of use, and their suitability for local work.

Results: The low-cost otoscope scored statistically higher in overall combined performance, as well as in the remaining four out of the nine attributes. Notably, 54.2% of users rated the low-cost device more suitable than the traditional device for use in low-middle income countries, 25% were equivocal, and 20.8% preferred the traditional device.

Conclusion: This study found the Arlight otoscope to be an appropriate and practical substitute for more expensive traditional otoscopes for the delivery of ENT services in low resource settings.

Level of Evidence: N/A

KEYWORDS

education, health resources, Malawi, otoscopes, quality-adjusted life years

1 | INTRODUCTION

According to the World Health Organization, there are currently over 450 million people worldwide with disabling hearing loss. This represents over 6% of the world's population.¹ It has also been noted that 50% of this hearing loss could have been prevented.²

The total number of annual disability-adjusted life-years due to undiagnosed and untreated ear disease is estimated to be greater than 2 million per annum.^{1,3} Children are especially affected³ with studies from Africa showing that 7% of children there were affected by hearing loss.⁴ Ear disease and associated hearing loss are more common in low- and middle-income countries (LMICs)

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with impacted cerumen and chronic suppurative otitis media affecting an estimated 200 million people annually.^{3,5} Some studies in poorer countries have shown that 61% of children aged 1 to 4 can be affected by acute otitis media.⁵ As the burden of disease continues to be greatest in poorer regions of the world, access to diagnostic tools can be challenging⁶ and the main tool available is the otoscope.⁷ There is good evidence that earlier and more accurate diagnosis with prompt and appropriate treatment can improve outcomes reducing long-term disability and this is particularly true in children.⁶ The main obstacle however to accessing even the basic otoscope in LMICs continues to be a combination of both high initial cost and difficulty obtaining hard to find and expensive consumables such as batteries and bulbs to maintain devices in working order.

The Lancet Commission has described these issues in detail, highlighting that most new medical technologies focus on the needs of the wealthy.^{7,8} Many new techniques have been proposed but most rely on smartphone technology.^{9,10} This is becoming available in Africa but has been assessed at being available to less than 30% of the population in most African countries.¹¹ They also require a power source to recharge. Relevant low-cost diagnostic tools designed for users in lower resource settings and potentially no access to a power source are neglected limiting the diagnostic capacity of already under resourced and stretched health care systems.

This study aims to evaluate a novel low cost, frugally engineered, solar powered otoscope called the Arclight Otoscope (AO)¹² (Figure 1). The device uses an LED light source powered by a surface mounted solar panel and internal rechargeable battery with the aim of making it “consumable-independent.”¹² The simplified compact design (110 mm long × 26 mm wide × 9 mm thick, weighing 18 g) makes it highly portable and robust. With the removal of superfluous features, it can be manufactured at low cost and be made available for around £10 per unit to users in LMICs.¹² As well as being an otoscope, it is a direct ophthalmoscope and anterior segment loupe for eye examinations broadening its potential diagnostic use to another major disability of LMICs, blindness. The AO may therefore offer the opportunity to reduce disability, overcoming some of the barriers to the access of functional otoscopes in LMICs. It can achieve this by improving diagnostic capacity and consequently early and appropriate treatment improving outcomes. As yet, however, there are no comparative studies published that evaluate the effectiveness of the AO (ideal for harsher rural settings) compared to a traditional otoscope (TO) from a lower resource setting.

Consequently, the purpose of this study was to compare the AO with a TO, the Welch Allyn 3.5 V Diagnostic Otoscope with Specula 25020, among health care professionals working and training in an Ear, Nose and Throat (ENT) Department in Queen Elizabeth Hospital, Blantyre in Malawi.



FIGURE 1 Arclight device with features

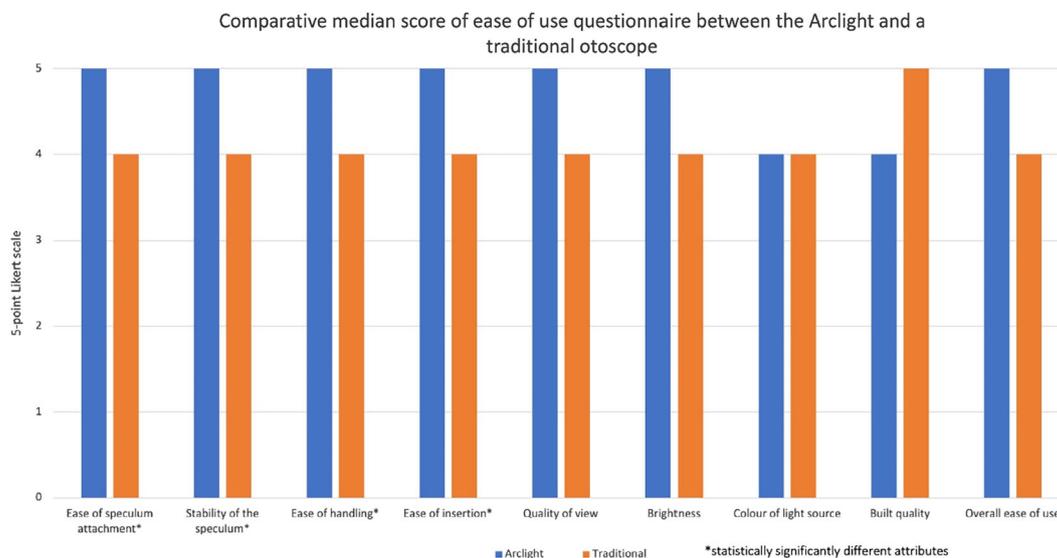


FIGURE 2 Comparative median score of ease-of-use questionnaire

2 | MATERIALS AND METHODS

The study is a prospective comparative observational survey of health care worker opinion using rating scales and tick box categories. Ethical approval was obtained from the College of Medicine Research of Ethics Committee Malawi (UP.05/18/64) and the University of St. Andrews (MD13870). Participants were local health care professionals or local trainees voluntarily recruited prior to routine departmental training from the ENT department of the Queen Elizabeth Hospital, Blantyre in Malawi. Participant information sheets were issued, and consent forms completed before the study training sessions.

At the start of each 60-minute session a short review of how to use both devices (AO and TO) was given. The participants then engaged in a training session examining each other's ears as well as simulation ears, alternating examinations between the AO and the TO. During the session, the participants familiarized themselves with both devices before completing a 10-element questionnaire. The questionnaire aimed to evaluate the relative merits of the two different devices as well as an overall preference of suitability for use in a low resource setting. It is described below:

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. Color quality of the light
8. Perceived build quality and robustness
9. Overall ease of use of the device
10. Which device do you feel is most suitable for use in your work in Malawi?

A 5-point Likert scale (1-lowest, 5-highest) was used to quantify elements 1 to 9 and element 10 required qualitative yes/no answers. The median scores of the paired ordinal data were compared using the Wilcoxon Signed rank test.

3 | RESULTS

Twenty-five participants from the ENT department in Queen Elizabeth Hospital, Blantyre were recruited. These included seven ENT Clinical Officers, six ENT Nurses, five ENT Clinical Officer Trainees, five Student Nurses, an ENT Student Nurse, and an Audiology Technician. All participants regularly use a TO in their daily work. None were familiar with the AO.

3.1 | Questionnaire feedback

All 25 participants completed the training session and recorded feedback on both devices (Figure 2). Combining the scores of all nine attributes, the AO was scored statistically significantly higher compared to the TO, median scores 5 vs 4, $P = 0.002$.

The particular domains that the AO performed better than the TO were ease of attachment of the speculum (5 vs 4, $P = 0.020$), stability of the speculum (5 vs 4 $P = 0.037$), ease of holding the otoscope (5 vs 4 $P = 0.002$) and ease of insertion into the ear canal (5 vs 4 $P = 0.045$), respectively. There was no statistical difference in the other five attributes with participants considering the AO to be comparable to the TO in quality of view of the eardrum, brightness and color quality of the light, perceived build quality and robustness as well as overall ease of use of the device.

With regard to which device participants felt was most suitable for use for their ENT work in Malawi 54% of the participants

considered the AO more suitable with 21% preferring the TO and 25% equivocal.

4 | DISCUSSION

4.1 | Synopsis of key findings

Globally, the majority of people affected with hearing loss are considered preventable or treatable if diagnosed promptly.³ Overstretched training institutions and health care systems in LMICs, however, struggle to train and equip health care workers to deliver ENT services in the regions where the greatest burden of hearing impairment resides.^{3,13,14} In these low-resource settings, an otoscope, essential for early diagnosis of the majority of common ear conditions, is impractically expensive to acquire and hard to maintain in a working order.^{13,14} Consumables such as bulbs or batteries are not just expensive but typically almost impossible to acquire. When otoscopes stop working, they tend to be discarded.^{13,14} A lower cost, consumable independent, alternative to the TO such as the AO would assist in the prevention and treatment of ear disease and unnecessary hearing loss reducing the burden of needless disability in these regions. The development of such low-cost devices has been identified by the Lancet as a priority with the ENT community citing lack of equipment as the most frequent limitation in providing services in sub-Saharan Africa.⁷

Our study has shown that despite its stripped back and simplified design the low-cost AO performs as well as a more expensive TO and can be considered a practical and appropriate substitute for the provision of ear care in a low-resource setting.

4.2 | Strengths of the study

Our study is the first to compare the novel low-cost Arclight device with a TO in a low resource setting among local ENT health care workers. The results confirm that despite its low cost and simplified design, the AO should be considered an appropriate and practical substitute for the provision of ear care in LMICs. All of the participants work in an ENT department in Malawi and therefore are familiar with the range of pathologies and challenges of delivering care in this setting. Malawi is one of the poorest countries in the world and like many sub-Saharan African countries, has a major undiagnosed and untreated burden of ear disease. The study was consequently performed in the setting that the device was designed for.

There are only two ENT surgeons and three audiologists in a country of over 17 million. Most of the care is given by clinical officers in remote locations¹⁶ and as a simple, robust tool the AO was designed specifically with the needs of these users and settings in mind. These needs drove a simplified engineering approach with low production costs. The end result has been the creation of an inexpensive diagnostic tool that despite its low cost and simplified design still works well but in addition is highly portable and

independent of consumables. These attributes make it ideal for use in a low resource setting but also for high volume distribution too hard to reach and distant sites. The consequence of this frugal design philosophy may have unintentionally led to some clinically relevant positive attributes. The device is light and compact and consequently scored statistically higher for ease of holding and insertion into the ear canal compared to the heavier and bulkier traditional device. In addition, the simplified yet strong “click on click off” design for the earpiece appears to have led participants to score attachment and stability higher as well.

4.3 | Comparison with other studies

While the practical attributes and diagnostic effectiveness of the Arclight device were also comparatively evaluated in a similar study design by Hey et al.,¹⁵ there were several important differences with this current study. The previous study was performed among ENT practitioners in a high resource country (United Kingdom) and within a secondary care setting. Participants were not from a low resource setting and were not from the range of mid-level ENT practitioners that the AO was originally developed for. Although Hey et al.¹⁵ also demonstrated the non-inferiority of the AO to a traditional device, the opinions relating to acceptability and usability should not be assumed to be the same as those from a different range of cadres from an LMIC. Our study is therefore unique in exploring opinions of a different range of users from a different and more relevant resource setting. This knowledge can be used to inform the effective potential roll out of the device in resource constrained health care systems and assist in future iterations of the device.

Notably, in contrast to the outcome by Hey et al.¹⁵ where the TO was favored in many aspects, our study has shown that the AO was significantly preferred over a TO by ENT health care workers in Malawi. This has not only highlighted the appeal of a low-cost and easily maintained otoscope, but also further illustrated the differences in users' emphasis in device selection from different resource settings.

4.4 | Limitations of the study

A criticism of the study is that, despite English being the professional medical language in Malawi, it is not the “first” language for our participants. Given the language used for the questionnaire was English, this may have compromised understanding of the attributes being explored. The sample size was also relatively small. This may reduce reliability of the results of the questionnaire leading to greater variability of responses, which may in turn lead to some bias. The novelty of the AO equipment should also be considered as a source of potential bias with participants favoring it simply because it is new and different. In addition, the participants were highly trained with good access to equipment in their unit. Further studies could use questionnaires in the local language and include more participants working in community primary where there is much less access and familiarity with TO's.

4.5 | Clinical applicability of the study

This study adds further evidence supporting the role of the AO as a practical substitute for the TO in a low resource setting. Further, the AO satisfies the recommendations of the Lancet Commission on the need for the development and implementation of low-cost yet clinically effective diagnostic tools for poorly funded health systems.⁸ In addition to low cost and clinical effectiveness, the device has additional intrinsic attributes such as being independent of consumables, portable, easy to use and robust. These properties also make the device ideally suited for use in LMICs. The AO can also be quickly and simply attached to the camera of a smartphone allowing acquisition of videos or images of the ear canal and tympanic membrane. With the increasing availability of more powerful mobile phones in Africa combined with widespread and reliable mobile phone networks in Africa, this function offers educational as well as telemedicine potential enhancing ENT services in regions where capacity is least.

5 | CONCLUSION

In conclusion, the AO is an effective and practical alternative to the TO for use in LMICs. Further evaluations should focus on long-term real world clinical use to assess the longevity of the device in the field. The outcomes of these studies will help determine if NGOs and ministries of health should adopt the device into their wider service delivery and how best to do this to strengthen ENT care in LMICs.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHOR CONTRIBUTIONS

Andrew Blaikie and **Wakisa Mulwafu**: Contributed to the conception of the study. **Katharine Balfour**, **Amy McCarthy**, **Emmanuel Singano**, and **Shi Ying Hey**: Carried out the data collection and writing of the manuscript. **Shi Ying Hey**, **Obaid Kousha**, **Wakisa Mulwafu**, **David F. D. L. Walker**, and **Andrew Blaikie**: Had contributed to the editing of the article. The manuscript has been seen and approved by all authors.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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