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Background

Vision impairment affects at least 2.2 billion people globally, with 1 billion cases being preventable or unaddressed. The problem is exacerbated by an ageing population and lifestyle changes. In Malaysia, where 15.6% of adults have diabetes, conditions such as diabetic retinopathy, untreated cataracts, and glaucoma are leading causes of blindness, with 86.3% of these cases being avoidable. Poor access to eye care services remains a major barrier, hindering progress toward universal health coverage and Sustainable Development Goal 3. Fundus photography, which captures detailed images of the eye's internal structures, is critical for diagnosing and managing conditions like diabetic retinopathy, glaucoma, and age-related macular degeneration. The introduction of handheld fundus cameras provides an opportunity to improve access to eye care, especially in underserved areas, by making screening more accessible.

The development of fundus cameras began in 1926, with modern systems offering advanced features like wide-field imaging and portability. Traditional tabletop fundus cameras, though effective, are bulky, expensive, and limited in application to primary care settings. In contrast, handheld fundus cameras, such as a prototype that provides a 50º retinal field of view, offer comparable imaging quality and are more portable and cost-effective. However, a 2015 review conducted in Pahang State found inconclusive evidence regarding the effectiveness of handheld fundus cameras for diabetic retinopathy screening, with mixed results on sensitivity and specificity. The updated review aims to reassess the effectiveness, safety, and cost-effectiveness of handheld fundus cameras for detecting diabetic retinopathy and other retinal disorders, given recent technological advancements.

Objective/ aim

This technology review aimed to reassess the effectiveness, safety, and cost-effectiveness of handheld fundus cameras for detecting diabetic retinopathy, hypertensive retinopathy, or other retinal disorders such as age-related macular degeneration and glaucoma.

Methods

Literature search was conducted by an *Information Specialist* who searched for published articles on handheld fundus camera. The following electronic databases were searched through the Ovid interface: Ovid MEDLINE® In-Process & Other Non-Indexed Citations and Ovid MEDLINE® 1946 to July 2024. Parallel searches were run in PubMed, US FDA and INAHTA database. Some limitations applied during search (animal study). Additional articles were identified from reviewing the references of retrieved articles. The last search was performed on 25 July 2024.

Results and conclusion:

Efficacy/ effectiveness

Handheld fundus cameras have demonstrated high sensitivity and specificity in screening for various eye conditions, including diabetic

retinopathy (DR), glaucoma, and other retinal abnormalities, making them comparable to traditional tabletop cameras. Sensitivity rates for DR detection range from 83% to 96.9%, with specificity rates up to 100%. In glaucoma screening, handheld devices showed nearly equivalent results to gold-standard dilated fundus exams, with sensitivity and specificity above 94%. While non-mydriatic imaging is practical and effective, particularly in settings where dilation is impractical, mydriatic imaging offers slightly higher sensitivity and specificity and improves diagnostic reliability, especially for ungradable or complex cases. These cameras are particularly valuable in community and low-resource settings, proving their effectiveness for remote and routine screenings, especially in detecting vision-threatening conditions.

Safety

Multiple studies have confirmed that handheld fundus cameras are safe for clinical use, particularly in screening for diabetic retinopathy, glaucoma, and other retinal conditions. These studies reported no significant safety concerns, and patients generally tolerated the devices well. Handheld cameras were found to be non-invasive and comfortable for patients, even those with existing ocular conditions. In both diabetic retinopathy and glaucoma screening, the use of handheld fundus cameras resulted in no adverse events or complications. Additionally, their safety in broader applications, such as screening for various retinal conditions in clinical and community settings, has been well-established. Overall, the safety profile of handheld fundus cameras, combined with their diagnostic accuracy and portability, supports their widespread use in eye care, especially in resource-limited environments.

Organisational issues

The implementation of handheld fundus cameras in clinical settings presents several organisational challenges, particularly regarding training, standardisation, and integration into existing healthcare systems. Adequate training for non-specialist healthcare providers is necessary to ensure consistent image quality and accurate diagnoses, but this requires significant investment in training programs. Variability in operator skills may affect diagnostic outcomes, highlighting the need for standardised protocols. Additionally, integrating these devices into healthcare workflows could require adjustments to clinic operations, including patient flow, data management, and IT infrastructure upgrades to handle digital images and ensure compatibility with electronic health records. The use of AI-assisted grading systems for images, such as DeepDR, demonstrated high accuracy in diabetic retinopathy (DR) screening. However, its performance is influenced by image quality and operator expertise, with occasional misdiagnoses of mild DR and limited generalizability highlighting the need for further refinement and validation. Addressing these challenges is essential for the successful adoption and effective use of handheld fundus cameras in clinical practice.

Economic implication

The reviewed studies indicate that handheld fundus cameras offer significant economic benefits, particularly in resource-limited settings. These devices are much more affordable than traditional tabletop cameras, with some costing around [redacted] compared to [redacted] for conventional systems, making them a cost-effective option for clinics and screening programs. Handheld cameras have proven feasible in

low- and middle-income countries, where general physicians, after training, can use them effectively, potentially reducing the need for specialist consultations. Additionally, these devices can enhance the efficiency of screening programs by enabling quicker examinations, reducing the time and cost of follow-up visits or more expensive diagnostic procedures. While initial training investment is required, handheld cameras could support more cost-effective and sustainable eye care programs, especially in underserved areas.

Conclusion

A substantial body of retrievable evidence has demonstrated that handheld fundus cameras have proven to be highly effective and safe tools for screening a variety of eye conditions, including diabetic retinopathy and glaucoma. Their affordability and portability offer significant advantages, particularly in resource-limited settings, making them a viable alternative to traditional tabletop cameras. Although non-mydriatic imaging is practical and effective, but mydriatic imaging offers higher accuracy and is better for complex or ungradable cases, highlighting the complementary benefits of both approaches. Despite their potential, the successful adoption of these devices requires addressing organisational challenges, such as standardised training for operators and integration into existing healthcare systems. Economically, handheld cameras reduce costs and improve the efficiency of screening programs, especially in underserved areas. However, limitations such as variability in operator skill and the need for further validation of newer devices should be considered when interpreting the results of current studies.