Aim

To determine whether retinal photography with a non-mydriatic retinal camera (RP-NMRC) is safe, effective and cost-effective for the detection of diabetic retinopathy (DR) in patients with diagnosed diabetes. The assessment was undertaken to inform whether RP-NMRC for the described population should be publicly funded in the primary care setting.

Methods

A systematic literature review was conducted using a protocol developed *a priori*. The literature review included evidence comparing RP-NMRC and no eye examination, or RP-NMRC and standard management, i.e. ophthalmoscopy with mydriasis by a general practitioner (GP) or complete eye examination (CEE) by an optometrist or ophthalmologist, to detect DR in diabetes patients. Pre-specified PICO (Population, Intervention, Comparator, Outcome) criteria determined which studies were included for each research question. The evidence was appraised for quality using standardised tools.

Conclusions and results

Safety and patient acceptability

No studies on the comparative safety of RP-NMRC were identified. There was no literature that reported safety outcomes related to RP-NMRC use *without mydriasis*. In one case series one of the 75 patients who underwent RP-NMRC *with mydriasis* later developed angle-closure glaucoma.

Ten studies reported evidence on the patient acceptability of RP-NMRC (two compared RP-NMRC with ophthalmological examination and eight studies were non-comparative). RP-NMRC was found to be highly acceptable among the majority of patients across the studies, and a majority expressed they would return for yearly screening. Up to one fifth of patients experienced some level of discomfort during the procedure. One Australian study found that in a small sample of Indigenous diabetes patients 90% were very positive about using RP-NMRC in their local health service.

Effectiveness

Indirect evidence linking diagnostic accuracy to change in patient management was used to determine the effectiveness of RP-NMRC as no direct evidence was identified. Thirty-one diagnostic accuracy studies were included, of which 23 contributed data for meta-analyses.

A meta-analysis of 13 studies showed that RP-NMRC could accurately detect *any level* of DR (sensitivity 91.2%, 95% CI 81.7, 96.1; positive likelihood ratio (LR+) 3.88, 95% CI 2.79, 5.40) with a trade-off in the ability to *rule out* DR (specificity 76.5%, 95% CI 67.4, 83.6; negative likelihood ratio (LR-) 0.11, 95% CI 0.05, 0.24). Meta-analysis also suggested that RP-NMRC was more likely to confirm the presence of *severe non-proliferative DR or worse* than it was to confirm the presence of *any DR* (specificity 98.1%, 95% CI 95.4, 99.2 versus 76.5%, 95% CI 67.4, 83.6), but was less sensitive (76.3%, 95% CI 60.2, 87.3 versus 91.2%, 95% CI 81.7, 96.1).

There was no appreciable difference in sensitivity or specificity for RP-NMRC *with* or *without mydriasis* for the detection of *any DR* or *DR requiring urgent referral*. Sub-group analysis showed there was improved sensitivity with fundus cameras that utilised *multiple* rather than *one field* for image acquisition, and for those studies published after the year 2000.

Evidence on change in management indicated that compared to a traditional surveillance model (self-organised CEE), opportunistic RP-NMRC in a primary health care setting resulted in significantly greater compliance (three studies). An Australian study found that among Indigenous patients, follow-up with an eye specialist after RP-NMRC and referral by a GP was substantially higher than follow-up with an eye specialist after traditional surveillance (90% vs 15% respectively; p<0.001).

Cost-effectiveness

RP-NMRC is likely to be a cost-effective option for diagnosing DR in patients with diabetes who would not otherwise receive regular eye examinations. The estimated incremental cost per QALY was $14,870 in the broader Australian population and $12,380 in the Indigenous population, while the cost per case of blindness prevented was approximately $51,600 and $46,600, respectively. The model was most sensitive to the cost of treatment and the quality-of-life weighting applied to the advanced sight-threatening DR health state, but the ICER remained below $45,000/QALY in all modelled scenarios.

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