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VivaScope® 1500 and 3000 systems for detecting and monitoring skin lesions: a systematic review and economic evaluation.

Edwards SJ, Mavranezouli I, Osei-Assibey G, Marceniuk G, Wakefield V, Karner C. *Health Technol Assess.* 2016 Jul;20(58):1-260. doi: 10.3310/hta20580.

ABSTRACT

BACKGROUND: Skin cancer is one of the most common cancers in the UK. The main risk factor is exposure to ultraviolet radiation from sunlight or the use of sunbeds. Patients with suspicious skin lesions are first examined with a dermoscope. After examination, those with non-cancerous lesions are discharged, but lesions that are still considered clinically suspicious are surgically removed. VivaScope(®) is a non-invasive technology designed to be used in conjunction with dermoscopy to provide a more accurate diagnosis, leading to fewer biopsies of benign lesions or to provide more accurate presurgical margins reducing the risk of cancer recurrence. **OBJECTIVES:** To evaluate the clinical effectiveness and cost-effectiveness of VivaScope(®) 1500 (Caliber Imaging and Diagnostics, Rochester, NY, USA; Lucid Inc., Rochester, NY, USA; or Lucid Inc., MAVIG GmbH, Munich, Germany) and VivaScope(®) 3000 (Caliber Imaging and Diagnostics, Rochester, NY, USA) in the diagnosis of equivocal skin lesions, and VivaScope 3000 in lesion margin delineation prior to surgical excision of lesions. **DATA SOURCES:** Databases (MEDLINE, EMBASE and The Cochrane Library) were searched on 14 October 2014, reference lists of included papers were assessed and clinical experts were contacted for additional information on published and unpublished studies. **METHODS:** A systematic review was carried out to identify randomised controlled trials (RCTs) or observational studies evaluating dermoscopy plus VivaScope, or VivaScope alone, with histopathology as the reference test. A probabilistic de novo economic model was developed to synthesise the available data on costs and clinical outcomes from the UK NHS perspective. All costs were expressed as 2014 prices. **RESULTS:** Sixteen studies were included in the review, but they were too heterogeneous to be combined in a meta-analysis. One of two diagnostic studies that were deemed most representative of UK clinical practice reported that dermoscopy plus VivaScope 1500 was significantly more sensitive than dermoscopy alone in the diagnosis of melanoma (97.8% vs. 94.6%; $p=0.043$) and significantly more specific than dermoscopy alone in the diagnosis of non-melanoma (92.4% vs. 26.74%; $p<0.000001$). The results of another study suggest 100% [95% confidence interval (CI) 86.16% to 100%] sensitivity for dermoscopy plus VivaScope 1500 versus 100% (95% CI 91.51% to 100%) for dermoscopy alone. Specificity varied from 51.77% to 80.2% depending on the analysis set used. In terms of margin delineation with VivaScope, one study found that 17 out of 29 patients with visible lentigo maligna (LM) had subclinical disease of >5 mm beyond the dermoscopically identified margin. Using 'optimistic' diagnostic data, the economic model resulted in an incremental cost-effectiveness ratio (ICER) of £8877 per quality-adjusted life-year (QALY) (£9362 per QALY), while the 'less favourable' diagnostic data resulted in an ICER of £19,095 per QALY (£25,453 per QALY) in the diagnosis of suspected melanomas. VivaScope was also shown to be a dominant strategy when used for the diagnostic assessment of suspected basal cell carcinoma (BCC). Regarding margin delineation of LM, mapping with VivaScope was cost-effective, with an ICER of £10,241 per QALY (£11,651 per QALY). However, when VivaScope was used for diagnosis as well as mapping of LM, then the intervention cost was reduced and VivaScope became a dominant strategy. **LIMITATIONS:** There is an absence of UK data in the included studies and, therefore, generalisability of the results to the UK population is unclear. **CONCLUSIONS:** The use of VivaScope appears to be a cost-effective strategy in the diagnostic assessment of equivocal melanomas and BCCs, and in margin delineation of LM prior to surgical treatment. **FUTURE WORK:** High-quality RCTs are required in a UK population to assess the

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diagnostic accuracy of VivaScope in people with equivocal lesions. STUDY REGISTRATION: This study is registered as PROSPERO CRD42014014433. FUNDING: The National Institute for Health Research Health Technology Assessment programme. PMID:27483991 PMCID:PMC4983709DOI:10.3310/hta20580