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Background

In Malaysia, overall diabetes prevalence in adults ≥18 years in National Health & Morbidity Survey (NHMS) 2015 and 2019 was 13.4% and 18.3% respectively. Prevalence for overall diabetes for adults age 30 years and above was 24.1% in NHMS 2019. The proportion of patients with diabetic foot ulcers remains at 1.23% and 1.24% in 2019 and 2020, respectively. Similarly, the proportion of patients with amputations remains at 0.68% and 0.73% for both years.

Peripheral arterial disease (PAD) is associated with delayed diabetic foot ulcer (DFU) healing and increased risk of lower limb amputation. Its accurate diagnosis is imperative to allow for restoration of blood supply. The detection of PAD in diabetes can be challenging as symptoms are often masked by the presence of neuropathy. Currently, there are several non-invasive modalities used to detect ischaemia and impaired macrocirculation of the lower-limb including ankle-brachial index, toe blood pressure measurement, digital subtraction angiography, and colour Doppler flow imaging. However, these techniques have some limitation when examining the microcirculation of skin adjacent to a diabetic foot ulcer.

Transcutaneous oxygen monitoring, more specifically, transcutaneous partial pressure of oxygen (TcPO2) measurement was first used in neonatology, followed by paediatric intensive care units and then spread to other disciplines including plastic surgery, vascular surgery, anaesthesiology, orthopaedics and hyperbaric medicine. Transcutaneous oxygen measurement is a metabolic test while ankle brachial index, plethysmography and Doppler systolic pressure are haemodynamic index. It provides information about the supply and delivery of oxygen to the underlying microvascular circulation by recording the partial pressure of oxygen at the skin surface. The amount of oxygen detected by the sensor is a balance of oxygen delivery and local physiologic demands and reflects the metabolic status of the skin. The TcPO2 measurement is used in determining amputation level, wound healing evaluation, hyperbaric therapy, and peripheral arterial disease assessment, including the status of spinal cord stimulation and revascularisation procedures.

Hence, this Technology Review (TR) was requested by an Orthopaedic Specialist, Hospital Sultanah Nur Zahirah to assess the feasibility of the technology to be used as one of the modalities in assessing wound healing in Ministry of Health facilities.

Objective

The objective of this technology review was to assess the effectiveness, cost-implication, safety and organisational issues related to the application of transcutaneous oxygen pressure monitoring (TcPO2).

Methods

Electronic databases were searched through the Ovid interface: Ovid MEDLINE(R) ALL <1946 to January 28, 2022>. EBM Reviews - Cochrane Central Register of Controlled Trials January 2022, EBM Reviews - Cochrane Database of Systematic Reviews 2005 to January 23, 2022, EBM Reviews - Database of Abstracts of Reviews of Effects 1st Quarter 2016, EBM Reviews - Health Technology Assessment 4th Quarter 2016, EBM Reviews - NHS Economic

Evaluation Database 1st Quarter 2016. Searches were also run in INAHTA database, PubMed database and U.S. Food and Drug Administration (USFDA) website. Google and Google Scholar were also used to search for additional web-based materials and information. Additional articles were identified from reviewing the references of retrieved articles. Last search was conducted on 28th January 2022.

Results and conclusion:

A total of 559 records were identified through the Ovid interface and PubMed, and seven were identified from other sources (references of retrieved articles). After removal of 77 duplicates, 489 records were screened and 397 were excluded. Of these, 92 relevant abstracts were retrieved in full text. After reading, appraising, and applying the inclusion and exclusion criteria to the 92 full text articles, 12 full text articles were included and 80 full text articles were excluded.

There was fair to good level of evidence retrieved to suggest that TcPO2 may predict wound healing, amputation and mortality among patients with diabetic foot ulcer, critical limb ischaemia and underlying peripheral arterial disease. However, there was no evidence that TcPO2 is suitable to substitute other modalities. The suggested threshold value for wound healing/tissue perfusion is >25mmHg. No evidence retrieved on the safety.