

Title Digital Blood Pressure (BP) Measurement Sets

Agency HTA Malaysia, Health Technology Assessment Section, Medical Development Division, Ministry of Health Malaysia
Level 4, Block E1, Parcel E, Presint 1,
Federal Government Administrative Center, 62590 Putrajaya, Malaysia
Tel: +603 88831229, Fax: +603 88831230; htamalaysia@moh.gov.my, www.moh.gov.my

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Aim

To update evidence on the efficacy, safety and cost-effectiveness of digital BP measurement sets compared to mercury sphygmomanometer device.

Conclusions and results

Effectiveness: In Children, fair level of retrievable evidence to suggest that the Systolic Blood Pressure (SBP) readings were significantly higher using digital BP measurement sets as compared to mercury sphygmomanometer [Mean Difference (MD): 2.53 mmHg; 95% Confidence Interval (CI): 0.57, 4.50] but no significance difference with the Diastolic Blood Pressure (DBP) readings (MD: 1.55 mmHg; 95% CI: -0.20, 3.31). **In Adults**, the BP readings varies with population and settings. There was limited retrievable evidence to suggest that digital BP measurement sets were associated with lower SBP and DBP readings in patients with cardiac illness and arteriosclerosis.

Validation studies in adults, showed no significant differences between digital BP measurement sets and mercury sphygmomanometer (within 5 mmHg). Among atrial fibrillation patients, fair level of retrievable evidence reported higher SBP and DBP readings when digital BP measurement sets were used as compared to manual sphygmomanometer but the difference was not significant. The correlation coefficient (r) of digital BP and manual sphygmomanometer showed the association was stronger for SBP ($r=0.89$, 95% CI: 0.84, 0.94) than DBP values ($r=0.76$, 95% CI: 0.70, 0.81). There was limited poor level of retrievable evidence to suggest that digital BP measurement sets were comparable to mercury sphygmomanometer in measurement of BP among pregnant women with no severe health problems (MD: 4 ± 2 mmHg).

Safety: Digital BP measurement sets have received US FDA approval. The main concern of toxic producing and environmental hazard by mercury sphygmomanometer are the reasons why digital BP measurement sets are replacing the mercury sphygmomanometer. Mercury sphygmomanometers have been banned in France and Germany since February 2000 but to date, the same measures have not been introduced in the UK. The Medical Device Authority (MDA) is looking closely at the situation and says that a ban may be imposed in the future. The MDA Guidelines recommend that consideration be given to the selection of mercury-free products when the opportunity

arises, or for replacement of dysfunctional equipment. This is in agreement with the government circulars regarding MINAMATA convention on mercury on September 2014. Malaysia must comply with the obligation to this convention which is the prohibition of manufacturing, importation and exportation of product containing mercury

Organizational Calibration

World Health Organization (WHO) also emphasised that to ensure a comparable accuracy of mercury-free sphygmomanometer, a proper maintenance, calibration and validation on that device is needed. Devices should meet the requirements of regular calibration and maintenance according to manufacturer specifications.

Recommendations (if any)

Based on the review, Digital BP measurement sets can be used to measure blood pressure as it is comparable to mercury sphygmomanometer. However, mercury sphygmomanometer should be used for confirmation of BP value in the patients with cardiac illness, arteriosclerosis, renal disease and children. Also, digital BP measurement sets need regular maintenance and calibration.

Methods

The following electronic databases were searched through the Ovid interface: Ovid MEDLINE® In-process and other Non-indexed citations and Ovid MEDLINE® 1946 to present, EBM Reviews - Cochrane Central Register of Controlled Trials - August 2017, EBM Reviews - Cochrane Database of Systematic Reviews - 2005 to September 2017, EBM Reviews - Health Technology Assessment – 4th Quarter 2016, EBM Reviews – NHS Economic Evaluation Database 1st Quarter 2016, and EMBASE. The references of published papers were scrutinised for additional articles. The search was limited to studies published from 2002 to current. The last search was conducted on 21 November 2017.

Further research/reviews required

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Written by

Atikah Shaharudin, MaHTAS, Malaysia