INFORMATION BRIEF (RAPID REVIEW)

Portable Ultrasound with Artificial Intelligence Application Using KOSMOS Platform

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Medical Development Division
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TITLE: PORTABLE ULTRASOUND WITH ARTIFICIAL INTELLIGENCE APPLICATION USING KOSMOS PLATFORM

PURPOSE

To review the effectiveness, safety and cost-effectiveness of portable ultrasound device with artificial intelligence (AI) application using the KOSMOS platform based on request from the Primary Care Section of Family Health Development Division, Ministry of Health Malaysia following a proposal from a medical company to implement its use to optimise healthcare delivery in Sabah.

BACKGROUND

Ultrasound or ultrasonography is an imaging technique that uses soundwaves to examine the internal structures of the body. It is convenient, non-invasive and provides real-time results making it in some ways superior to other medical imaging modalities. Because of that, ultrasound imaging is being used extensively in numerous medical fields.[1]

Miniaturisation of technology, from computers to telephones, has been the trend of late and the same can be said for ultrasound devices. Traditional ultrasound machines are bulky, requiring a cart for transport. Portable ultrasound imaging devices had been developed since 1998. Currently, portable handheld ultrasound devices (HUD) of varying sizes are widely available and this allows for bedside or point-of-care ultrasound to be performed.[2] This is especially useful in emergency medicine and in resource limited settings such as in rural areas.

Computer-aided diagnosis has been utilised in medical imaging for decades.[3] More recently artificial intelligence (AI) and deep learning (DL) technology is being applied in health care including in diagnostic imaging. This technology can assist in both image diagnostics and image enhancement. Point-of-care ultrasound (POCUS) imaging is an ideal application for DL techniques because it encompasses a wide variety of applications and a diverse group of users with a considerable disparity of training.[4]

Taking cardiac POCUS as an example, AI-guidance and DL technology in ultrasound devices can have many applications such as in detection and prediction automation [e.g. estimation of cardiac ejection fraction (EF)], intelligence augmentation (e.g. extraction of left ventricular EF from various types of cardiac scans), automated image segmentation, measurement and labelling (e.g. automated labelling and annotation of cardiac images), improving decision support system (e.g. automatic determination of fine ventricular fibrillation to identify responders to cardiac defibrillation), assessment of image quality (e.g. recognition of suboptimal images in real-time in predicting accuracy of the diagnosis) and data mining for research (e.g. development of an image search engine).[4]

KOSMOS Ultrasound is advertised as AI-driven diagnostic imaging with continuous-wave (CW) and pulsed-wave (PW) Doppler. Its AI platform is based on novel, deep learning techniques. KOSMOS ultrasound is intended for non-invasive imaging of the human body of the cardiac, lung and abdominal application.[5]

EVIDENCE SUMMARY

Twenty-six articles were retrieved from scientific databases of Medline and PubMed, general search engine (Google Scholar) and reference list on portable ultrasound device with AI application using the following search terms "*ultrasound, ultrasonography, portable, point-of-care and artificial intelligence".* The last search was done on 15th July 2022. Only five studies were included in this review which consisted of one meta-analysis, one systematic review, two cross-sectional studies and one validation study. Only two of the studies directly involved KOSMOS ultrasound device.

EFFICACY/ EFFECTIVENESS

A systematic review and meta-analysis by Jenkins S et al. compared diagnostic accuracy of HUD with transthoracic echocardiography (TTE) for assessment of left ventricular (LV) structure and function. The reviewers systematically search MEDLINE and EMBASE databases for diagnostic studies using HUD and TTE imaging to determine LV dysfunction. Study selection, data extraction and risk of bias assessment were conducted by two authors and any disagreements were discussed with a third author. The review included studies that compare any type or size of HUD used by operators of any level of experience with the reference standard of TTE performed by experienced imagers. A total of 6022 participants from 33 studies were included. It was shown that compared to TTE, when HUD was used by experienced operators, it can detect reduced LV ejection fraction (LVEF), wall motion abnormalities (WMA), LV dilatation and LV hypertrophy with pooled sensitivities of 88%, 85%, 89% and 85%, respectively, and pooled specificities of 96%, 95%, 98% and 91%, respectively. When used by inexperienced hands, pooled sensitivities measured were 83%, 78%, 68%, and 80%, respectively and specificity were 89%, 88%, 95%, and 87% respectively. Meta-regression analysis showed experience to be a significant factor in the detection of any degree of LV dysfunction ($p=0.04$) and WMA ($p=0.01$). The meta-analysis concluded HUD as a useful tool for predicting LV size and systolic function and its diagnostic yield was superior when performed by experienced echocardiographers, therefore, its use by inexperienced operator should be done under direct supervision or validated by a more experienced user.[6]

Rykkje A et al. on the other hand conducted a systematic review comparing HUD with high-end ultrasound system focussing on abdominal and pleural application. They systematically search PubMed, EMBASE, Web of Science and Cochrane Library databases for articles directly comparing HUD with a high-end ultrasound system concerning abdominal and/or pleural application. Selected studies were review and appraised by two authors and any discrepancies were resolved by consensus. In total, 16 articles were included. There was wide variation on the level of experience of operators using HUD between the studies. Two articles that looked at pleural applications of HUD showed good overall agreement when compared with high-end ultrasound systems. Patients in both studies were either hospitalised or seen in an outpatient clinic and the operators of the HUD were nurses with dedicated training for the device. Four studies on ascites showed good agreement between HUD with high-end ultrasound systems, with operators made up of post-graduate medical doctors, physicians and experienced sonographers. One study showed 93.75% sensitivity and 100% specificity for HUD in detecting cholelithiasis with expert users and 93% sensitivity and 88% specificity when used by non-experts. Two studies found excellent agreement between the devices in identifying hydronephrosis while another study found significant differences between HUD and high-end systems when measuring the size of the liver, spleen and kidney. The review concluded that there was an overall good agreement for HUD and high-end ultrasound systems in the detections of ascites and hydronephrosis, and for examining pleural cavities. However due to heterogeneity of the included studies, the authors were unable to draw definitive conclusions.[7]

A clinical validation study was conducted by Papadopolou SL et al. to evaluate the reliability and diagnostic accuracy of a novel HUD with AI-assisted algorithm to automatically calculate ejection fraction (autoEF) in a real-world patient population. The HUD studied was KOSMOS from EchoNous equipped with a 2- to 5-MHz phased-array transducer. The study population was 100 patients referred to echocardiography laboratory, aged >18 years old, haemodynamically stable, and underwent a clinically indicated transthoracic echocardiogram without contrast. Patient with atrial fibrillation or flutter and frequent atrial and ventricular ectopic beats were excluded from the study. Standard echocardiography of the patients was done using a commercially available cart-based system by an expert investigator. The patients were also examined using HUD by the same expert.

Image quality for the cart-based systems compared to HUD was assessed as good in 45% vs 31%; moderate in 50% vs 57%; and poor in 5% vs 12% of cases. The average time for obtaining EF by manual tracing was 84±17 seconds for cart-based system, whereas the HUD autoEF algorithm calculation took about 15 seconds. There was good agreement between the calculated cart-based-EF and KOSMOS autoEF with intra-class correlation coefficient, ICC=0.85; 95% CI 0.78 to 0.90. Linear regression analysis showed a coefficient correlation, $r=0.87$, $p<0.001$ and Bland–Altman analysis gave a non-significant bias of -1.42% with limits of agreement 14.5%. Paired comparison of the LVEF calculation by cart-based-EF and KOSMOS autoEF did not show a significant difference [56% (IQR 40 to 62%) vs. 53% (IQR

43 to 59%), p=0.106]. The HUD AI-assisted algorithm was able to detect abnormal LV function (EF<50%) with 90% sensitivity (95% CI 75 to 97%), 87% specificity (95% CI 76 to 94%), 81% PPV (95% CI 66 to 91%), 93% NPV (95% CI 83 to 98%), and total diagnostic accuracy of 88%.[8]

A cross-sectional study by Narang A et al. tested whether novice users could obtain 10-view transthoracic echocardiographic studies of diagnostic quality using a DL-based software. They recruited eight nurses who had not previously conducted echocardiograms and trained them with AI system. The training consisted of one hour of didactic session, nine training scans and three qualification scans. Each of the nurses then scanned 30 patients using AI-guided ultrasound to obtain 10 standard TTE views. Each patient also received a control scan done with the same hardware but without AI guidance by a registered cardiac sonographer and a clinical echocardiogram. Four primary end points were evaluated for the study; whether the nurse examination, was of sufficient quality for the expert readers to make qualitative visual assessment of LV size, LV function, right ventricular (RV) size, and the presence of nontrivial pericardial effusion. Secondary end points assessed were six additional echocardiographic qualitative assessment (RV function; left atrium size; structural assessment of the aortic, mitral, and tricuspid valves; and qualitative assessment of inferior vena cava (IVC) size) and comparison of the diagnostic content of nurse scans with sonographer scans.

The study found the nurse scans have adequate quality to assess the clinical parameters in nearly all patients for the primary end points (237 of 240 or 98.8% of scans for LV size, LV function, and pericardial effusion and 222 of 240 or 92.5% of scans for RV size). When nurse scans were compared with sonographer scans, there was no significant difference in the assessment of the primary endpoints or secondary clinical parameters, except for IVC size.[9]

A different cross-sectional study by Le MT et al. attempted to compare four common HUD for ease of use, image quality, and overall satisfaction. They recruited 24 POCUS experts from several specialty (emergency, critical care, hospital, paediatrics, and pulmonary medicine). The experts were required to scan the same three standardized patients to obtain three standard POCUS views using four commercially available HUD (Butterfly iQ+™ (Butterfly Network, Inc.) probe connected to an Apple iPhone™; KOSMOS™ (EchoNous, Inc.) probe connected to a proprietary tablet as one unit; Lumify™ (Philips Healthcare) connected to an Apple iPad™, and Vscan Air™ (GE Healthcare) connected wirelessly to a Samsung Galaxy S7™ tablet. The experts were then asked to rate the devices for ease of use (physical characteristics, software navigation, manoeuvrability of the probe and tablet for imaging, and overall satisfaction), image quality (the detail resolution, contrast resolution, penetration, clutter, and overall satisfaction) and overall ranking (satisfaction and recommendation for purchase). The ratings were made using standardised statements on a Likert scale of 1 (“strongly disagree” or “very dissatisfied”) to 5 (“strongly agree” or “very satisfied”).

For ease of use, Vscan Air™ was rated highest for physical characteristics and manoeuvrability, while Butterfly iQ+™ was rated highest for software navigability. Overall ease of use was highest with the Vscan Air™. For image quality, Lumify™ was rated highest for detail resolution, contrast resolution, and clutter, while KOSMOS™ was rated highest for penetration. Overall image quality was highest for Lumify™. In terms of overall satisfaction, the Lumify™ and Vscan Air™ received the highest number of "satisfied" responses. Additionally, when asked about the most important characteristics of handheld devices, the top five characteristics listed were image quality, ease of use, portability, total costs, and availability of different probes. There were some limitations to this study where the POCUS experts could not be blinded to the different devices, and they completed the procedure in the same room. The experts were not provided training on the different devices and that may have limited their ability to navigate the software and devices. Some experts might have prior experience with some of the devices and not others which might influence their evaluations. The authors concluded that no single device was perceived to be superior in all categories.[10]

SAFETY

There was no evidence retrieved on the safety of KOSMOS AI-guided portable ultrasound. However, ultrasound imaging has been used for over 20 years and has an excellent safety record.[11] The KOSMOS ultrasonic pulsed doppler imaging system has received a Class II US Food & Drugs Administration (USFDA) 510(k) clearance. It is intended for use by qualified and trained healthcare professionals in the clinical assessment of the cardiac, pulmonary and abdominal systems by acquiring, processing, displaying, measuring, and storing synchronized ultrasound images, electrocardiogram rhythms, and digital auscultation sounds and waveforms.[12]

COST-EFFECTIVENESS

There was no retrievable evidence on the cost-effectiveness of KOSMOS AI-guided portable ultrasound system. The cost for KOSMOS platform with its portable ultrasound device is stated as [redacted].[13]

CONCLUSION

There was limited evidence suggesting portable ultrasound device is comparable to traditional ultrasound, but user experience may yield superior outcome. There was very limited evidence retrieved that is directly related to AI-guided ultrasound device with KOSMOS platform to suggest its superiority to other ultrasound devices, AI-guided or otherwise. As with all new medical tools, adequate training is important to ensure correct use and reliable results. Hence, the portable AI-guided ultrasound device should be used cautiously with proper training and certification plan. More study is needed to support its mass use.

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