The use of pocket-size imaging devices: a position statement of the European Association of Echocardiography

Rosa Sicari*, Maurizio Galderisi, Jens-Uwe Voigt, Gilbert Habib, Jose L. Zamorano, Patrizio Lancellotti, and Luigi P. Badano

CNR, Institute of Clinical Physiology, Italy

Received 27 November 2010; accepted after revision 6 December 2010; online publish-ahead-of-print 7 January 2011

Pocket-size imaging devices are a completely new type of echo machines which have recently reached the market. They are very cheap, smartphone-size hand-held echo machines with limited technical capabilities. The aim of this European Association of Echocardiography (EAE) position paper is to provide recommendations on the use of pocket-size imaging devices in the clinical arena by profiling the educational needs of potential users other than cardiologists experts in echo. EAE recommendations about pocket-size imaging devices can be summarized in: (1) pocket-size imaging devices do not provide a complete diagnostic echocardiographic examination. The range of indications for their use is therefore limited. (2) Imaging assessment with pocket-size imaging devices should be reported as part of the physical examination of the patient. Image data should be stored according to the applicable national rules for technical examinations. (3) With the exception of cardiologists who are certified for transthoracic echocardiography according to national legislation, specific training and certification is recommended for all users. The certification should be limited to the clinical questions that can potentially be answered by pocket-size devices. (4) The patient has to be informed that an examination with the current generation of pocket-size imaging devices does not replace a complete echocardiogram.

References

1. Recent technological advances and price abatement particularly in the latter type of machines have raised the need for a re-assessment of their clinical use by the reference community. The aim of this European Association of Echocardiography (EAE) position paper is to provide recommendations on the use of pocket-size imaging devices in the clinical arena by profiling the educational needs of potential users other than cardiologists experts in echo.

The machines

At present, a variety of small echo machines offer features which make them very similar to the most advanced high-end, high-performance echo machines. On the other hand, others have only essential diagnostic modalities, with the advantage of excellent transportability and low cost. Currently available echo machines may be classified into four main categories (Table 1): (1) stationary high-end systems (i.e. fully equipped systems with 3D and other advanced modalities). Despite having wheels, they are quite heavy and not supposed to be moved. (2) Mobile systems, equipped with standard modalities, but not necessarily all the advanced modalities. They are smaller than machines in category 1, on wheels, and can be easily transported inside health-care facilities. (3) Portable machines that can be carried by a person and usually offer all essential modalities to perform a complete echo study but not all advanced modalities. (4) Pocket-size, hand-held imaging devices.

The following text exclusively refers to pocket-size imaging devices (category 4) and their current state of capabilities. Recommendations will be subject to adaptations depending on technological progress.

Current pocket-size imaging devices offer diagnostic quality 2D and—in part—colour Doppler imaging in real-time. They come with a broad-bandwidth, phased array probe (1.7–3.8 MHz). The
Table 1  Classification of currently available echo machines according to their size and functions

<table>
<thead>
<tr>
<th>Echo machines</th>
<th>Capabilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stationary high-end systems</td>
<td>Full range of standard echo modalities and measurements (MM, 2D, PW, CW, Colour, TVI, TEE), and advances modalities (3D, contrast)</td>
</tr>
<tr>
<td>Mobile (smaller machines on wheels, middle range technology)</td>
<td>Full range of standard echo modalities and measurements (MM, 2D, PW, CW, Colour, TVI, TEE)</td>
</tr>
<tr>
<td>Portable (small machines that can be carried by a person)</td>
<td>Basic, standard echo modalities and measurements (MM, 2D, PW, CW, Colour)</td>
</tr>
<tr>
<td>Hand-held or pocket-size imaging devices</td>
<td>Limited functions (2D, Colour) and measurement package</td>
</tr>
</tbody>
</table>

2D, two-dimensional; 3D, three-dimensional; Colour, colour Doppler; CW, continuous Doppler; MM, M-mode; PW, pulsed Doppler; TVI, tissue velocity imaging.

Flow sector represents blood flow within an angle of 30°. Images and videos (automatic autocycle without the need for ECG trace) can be stored in examination folders, recalled via a gallery function, and transferred to PC or USB throughout a docking station.

Pocket-size imaging devices are not echo machines and have been equipped with just 2D and colour Doppler modalities on purpose. Their technical characteristics may be summarized as: (i) grey-scale images have a 2D sector angle <75°, depth <25 cm; (ii) colour flow imaging (available in one product only) has a fixed colour box size and a fixed pulse repetition frequency; (iii) measurements are restricted to distances and areas; (iv) options for patient identification are limited; (v) connectivity requires dedicated software tools.

Therefore, technical characteristics and image quality are usually sufficient for the qualitative evaluation of: left and right ventricular function, pericardial and/or pleural effusion, B-lines evaluated by lung ultrasound as a sign of extravascular lung water, size and respiratory changes of inferior vena cava, and extent of calcification and motion of aortic cusps. If available, valve regurgitation can be assessed by colour Doppler.

Workflow

Current pocket-size imaging devices should only be considered as screening tools or used to complement the physical examination since they do not allow the performance of a complete echocardiographic examination. This has the potential to deliver a marked change in cardiac care. Pocket-size devices should complement the physical examination in outreach clinics, coronary and intensive care units, and may serve as a tool for fast initial cardiac assessment in emergency units, during cardiologic counselling in- or outside health-care facilities and hospitals, for first cardiac evaluation in ambulances and for screening programmes in schools, industries, and other community activities. Moreover, pocket-size imaging devices may be used for the triage of the patient in need of a complete echocardiographic examination. Pocket-size imaging devices may further become a valuable teaching tool in medical schools (Table 2).

All these applications would allow faster and more accurate clinical diagnoses, save health-care resources, reduce waiting lists for inpatient echocardiographic examinations, and improve teaching by allowing the immediate check of physical signs and auscultatory findings. However, since such devices are so powerful and are supposed to be used not only by cardiologists but also by general medicine practitioners, anesthesiologists, emergency medicine specialists, and internists, the cost/effectiveness of their clinical use is necessarily linked to proper training and education of users.

Table 2  Summary of indications for pocket-size devices

<table>
<thead>
<tr>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Complement to a physical examination in the coronary and intensive care unit</td>
</tr>
<tr>
<td>2. Tool for a fast initial screening in an emergency setting</td>
</tr>
<tr>
<td>3. Cardiologic counselling in- or outside health-care facilities and hospitals</td>
</tr>
<tr>
<td>4. First cardiac evaluation in ambulances</td>
</tr>
<tr>
<td>5. Screening programmes in schools, industry, and community activities</td>
</tr>
<tr>
<td>6. Triaging candidates for a complete echocardiographic examination</td>
</tr>
<tr>
<td>7. Teaching tool</td>
</tr>
<tr>
<td>8. Semi-quantification of extravascular lung water</td>
</tr>
</tbody>
</table>

Training and quality control

Expert (accredited) echocardiographers do not need any training for the use of pocket-size imaging devices. Conversely, specific training is recommended for cardiologists not fully conversant with echocardiography. For non-cardiologists and/or other medical professionals, a dedicated training and revision of basic cardiac physiology and pathology knowledge should be mandatory. This appears to be the only way to avoid abuse and potential harm to patients due to both over- and under-diagnosis of serious heart diseases.

The EAE promotes the idea of a training specifically tailored to the information that can be obtained from this new class of devices as mandatory part of a certification process. This would ensure a widespread use of this new technology with certified competence, avoiding abuse and potential misuse.

Reimbursement in EU countries

Health-care providers and controllers should take into account this rapid development in ultrasound technology. Although policies may differ in certain EU member countries, the position of the EAE is that current-generation pocket-size imaging devices do not allow for a complete diagnostic examination and should
be rather regarded as a tool to complement a physical examination. Therefore, no reimbursement should be warranted.

EAE recommendations on the use of pocket-size echo devices

Recommendation 1. Pocket-size imaging devices (category 4 of the present classification) do not provide a complete diagnostic echocardiographic examination. The range of indications for their use is therefore limited as specified in Table 2.

Recommendation 2. Imaging assessment with pocket-size imaging devices should be reported as part of the physical examination of the patient. Image data should be stored according to the applicable national rules for technical examinations.

Recommendation 3. With the exception of cardiologists who are certified for transthoracic echocardiography according to national legislation, specific training and certification is recommended for all users. The certification should be limited to the clinical questions that can potentially be answered by pocket-size devices.

Recommendation 4. The patient has to be informed that an examination with the current generation of pocket-size imaging devices does not replace a complete echocardiogram.

Conflict of interest: J.-U.V. has received research grants from GE, Siemens and Philips. L.B. has received research grants from GE.

References