Title: Cardiac Imaging Systems for Cardiac Catheterization: Effectiveness, Reliability and Accuracy

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Context and policy issues:

A recent Canadian study\(^\text{1}\) using detailed clinical registry data that captures all patients undergoing cardiac catheterization in Alberta suggests that the optimal catheterization rate to detect high-risk coronary artery disease in Alberta is greater than 638.1 per 100,000 adults over age 20 among men and greater than 314.0 per 100,000 among women. In comparison with other countries, Canada is considered to have a “medium” cardiac catheterization rate, similar to that of Australia, Belgium and Germany, with lower rates reported in the Netherlands, Sweden, the United Kingdom, Hungary and Poland, and the highest rates in Brazil and the United States.\(^\text{2,3}\)

Performed in the catheterization lab, cardiac imaging systems are done to patients with acute coronary syndrome and suspected coronary artery disease, and provide X-ray images of the heart and coronary vessels to provide information on cardiac function, congenital defects, and stenoses in the arteries. Functionality of imaging systems, image quality and radiation dose to patients are among features that contribute to the decision-making process for cardiac imaging systems selection.

Research questions:

What are the clinical effectiveness, reliability and accuracy of the Siemens Axiom Artis and the GE Innova Imaging System for cardiac catheterization in patients with acute coronary syndrome or coronary artery disease?

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Methods:

A limited literature search was conducted on key health technology assessment resources, including PubMed, OVID Embase, The Cochrane Library (Issue 4, 2007), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international HTA agencies, and a focused Internet search. Results include articles published between 2002 and the present, and are limited to English language. No filters were applied to limit the retrieval by study type.

Summary of findings:

Our literature search identified a 2005 comparative report of three flat panel cardiovascular systems, including the GE Innova 2000, the Siemens Axiom Artic dFC and the Philips Allura Xper FD10F. All of the systems evaluated were used to perform a range of diagnostic and interventional cardiac examinations. No problems regarding patients’ safety were identified in their use. The design and operation of the system support and stand were acceptable for all the systems. In order to minimize the radiation dose to the patient and staff, all of the systems provided additional filtration and pulsed fluoroscopy. Patient radiation entrance dose rates and detector input dose rates were smaller with the GE and Siemens systems compared to the Philips system. According to the image quality criteria based on the European Guidelines on Quality Criteria for Diagnostic Radiology images, clinical image quality was found to be acceptable for all systems assessed, with the Philips system displaying better image quality due to the difference in dose rate, as indicated by the threshold contrast detectability performance.

An updated (2006) version compared the Siemens Axiom Artis dFC, the Philips Allura Xper FD10F and the Toshiba Infinix CSI/FPD. The authors also found no problems on safety in their use, with the protection system against collision on all systems found to be too sensitive. Users for all evaluated systems commented on the effort needed to move the monitor cradle. The report did not reveal data on clinical effectiveness, reliability and accuracy of the evaluated systems.

Management of pediatric radiation dose using the GE Innova 2100 and the Innova 2000 imaging systems presented in an article sponsored by the industry showed the products are useful in pediatric imaging, due to a number of dose-reduction features. A 2006 study included 457 patients undergoing angioplasty with the GE Innova system compared the standard antiscatter gridded image to a gridless airgap image. The use of a flat panel detector, airgap gridless angiography reduced the radiation dose to the patient and staff without significantly affecting image quality. The average dose-area product was significantly reduced from a mean (SD) of 26.2 Gy.cm² with the grid to 16.1 Gy.cm² with the grid out (p = 0.01) A quantitative comparison study on images of the flat panel-based system (GE Innova 3100) and conventional image intensifiers showed that the flat panel detectors, while providing better image quality, do not influence the results of quantitative coronary and vascular analyses. Image quality and dose parameters from a flat panel system were evaluated and compared to similar parameters evaluated for a conventional image intensifier system in another study. This study indicated that flat panel system has better high contrast resolution, and similar low contrast resolution and threshold contrast than a conventional image intensifier system, without significant dose performance between the two systems.

Another study using Siemens Axiom Artis showed overall radiation dose reductions of 70-90% can be achieved with pediatric patients through optimal selection of equipment variables such as fluoroscopy pulse rates, image receptor field-of-view, automatic dose control mode and optimal positioning of the patient.
Conclusions and implications for decision making:

According to image assessment criteria based on the European Guidelines on Quality Criteria for Diagnostic Radiology images, flat panel cardiac imaging systems such as GE Innova and Siemens Axiom Artis can provide good image quality with acceptable radiation dose. There is a gap in the literature regarding the clinical effectiveness, reliability and accuracy of different cardiac imaging systems. Evidence on cost-effectiveness for different systems is also lacking for purchase or policy making decisions. Health Canada issued a recall in July 2006 for the Axiom Artis device because the system may sporadically exhibit unrequested movement in the unit’s traversing range, and thus cause potential collision between the parts. A software update corrected this issue.\textsuperscript{12} The Innova 2100 device was also recalled in June 2006 due to various not reported software and hardware problems.\textsuperscript{13}

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