

<b>Title:</b>	<b>Intravascular Ultrasound (IVUS) July 2001</b>
<b>Agency:</b>	Medical Services Advisory Committee (MSAC) Commonwealth Department of Health and Ageing GPO Box 9848 Canberra ACT 2601 Australia <a href="http://www.msac.gov.au">http://www.msac.gov.au</a>
<b>Reference:</b>	<b>MSAC application 1032. Assessment report ISSN 1443-7120</b>

## **Aim**

To assess the safety and effectiveness of Intravascular Ultrasound and the circumstances under which public funding should be supported for the service.

## **Conclusions and results**

### *Safety*

Overall, IVUS appears to be a relatively safe procedure. Adverse events appear to relate primarily to vasospasm which can be readily treated with intravenous nitrate therapy. The rate of major acute procedural complications associated with IVUS, such as dissection or vessel closure, has been reported to be approximately <0.5%, with major complications more likely to occur in patients undergoing therapeutic IVUS rather than diagnostic IVUS imaging.

### *Effectiveness*

**Diagnostic applications** IVUS appears to offer additional and complementary information over that provided by coronary angiography. It is able to more accurately demonstrate the likely extent of coronary and peripheral vessel lesions; appears to have good sensitivity and specificity for detection of plaque dissections and media rupture but lower sensitivity for the detection of plaque rupture and thrombus formation; has quite high accuracy in predicting the likely functional severity of lesions; and can also provide information on the composition of plaques. There is some evidence to suggest that it may be able to predict clinical events, and alter management of patients with angiographically indeterminate or ambiguous lesions.

**Therapeutic applications** Based on RCT evidence, stent placement using IVUS guidance results in a statistically significant reduction in the odds of patients requiring target lesion revascularisation (TLR) procedures at 9–12 months in the IVUS guided compared to non-IVUS guided treatment groups (Odds Ratio (OR) 0.73, 95% confidence interval 0.54 – 0.99, p=0.04). It is unclear at this stage whether the reduction in TLR is sustained over a longer follow-up period or will result in improvements in either Q-wave myocardial infarction or survival, as the trials were not powered to detect significant differences in these parameters.

### *Cost-effectiveness*

Using published RCT evidence, the baseline cost per clinically-driven target lesion revascularisation (TLR) prevented from IVUS guided stent deployment is estimated to be approximately \$26,000. This estimate varies from approximately \$12,000 to \$800,000 per TLR prevented over the evidence based ranges examined in sensitivity analyses.

## **Recommendations**

MSAC recommended against public funding as there is currently insufficient evidence of the effectiveness and cost-effectiveness of IVUS as either a diagnostic or therapeutic tool.

## **Method**

A systematic literature review addressing (a) the diagnostic accuracy of IVUS and (b) its role as an adjunct to coronary interventions was conducted by the NHMRC Clinical Trials Centre using biomedical electronic databases, existing reviews, the Internet and international health technology assessment organisation websites. For (a) the literature was searched from 1990 to August 2001 and, for (b), from 1999–2000, with pre-1999 papers identified from a recent comprehensive HTA by Berry et al. 2000<sup>1</sup>

Produced by Kirsten Howard (epidemiologist) and Sally Wortley, NHMRC CTC, Australia.

<sup>1</sup>Berry, E. et al (2000) "Intravascular ultrasound-guided interventions in coronary artery disease: a systematic literature review, with decision-analytic modelling, of outcomes and cost-effectiveness", *Health Technology Assessment (South Hampton, NY)*, vol. 4, no. 35, pp. 1-117.