Technoleg Iechyd Cymru
Health Technology Wales

Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

- Determine the quantity of evidence available for a technology of interest.
- Identify any gaps in the evidence.
- Inform decisions on topics that warrant fuller assessment by Health Technology Wales (HTW).

Topic exploration report number:	TER462
Topic:	IVUS (Intravascular ultrasound) to guide percutaneous coronary intervention (PCI) for people with cardiovascular conditions
Summary of findings:	IVUS is used as a diagnostic tool to provide a 360-degree image of lumen and vessel wall structures of blood vessels during PCI for people with cardiovascular disease. Health Technology Wales (HTW) researchers identified one NICE guideline on cardiovascular disease, 10 systematic reviews with meta-analysis on IVUS-PCI when compared with standard care (angiography-PCI), one UK based HTA in 2000 and three economic evaluations. The identified evidence includes several different procedures involving PCI such as stent implantation and different population groups including those with chronic total occlusions and people with acute myocardial infarction. Reported outcomes include incidence of major adverse cardiovascular events (MACE), cardiac death, myocardial infarction, target vessel revascularisation, stent thrombosis, total procedure time, total stent length and total number of stents. For all outcome measures the reviews were in favour of IVUS when compared with angiography-guided PCI, with only few reviews reporting no statistically significant outcomes between the two intervention groups. Findings from the economic evaluations were mixed, although the most recent paper in 2021 concluded that IVUS-PCI is likely to be cost-effective when compared with angiography guidance alone. Key uncertainties include considerations of a narrowed population and/or procedure group if this topic were to proceed to a fuller appraisal, and that it is unclear at this stage whether the international economic evidence would be applicable to the UK.

Introduction and aims

IVUS is a minimally invasive procedure using sound waves to check for narrow blockages inside blood vessels which can compromise blood flow. IVUS uses a catheter to access and evaluate blood vessel tissue. IVUS can provide important information about the vessel lumen, dimensions, plaque characteristics, stent deployment, and the mechanisms of device failure. Coronary angiography is the current standard procedure used to diagnose coronary artery disease and to guide PCI. Coronary angiography has a range of key limitations, it doesn't reflect the 3D coronary lumen and therefore has difficulties in evaluating plague composition, vessel diameter diffuse reference vessel disease, lesion severity, as well as the result of stent deployment. Studies show that IVUS, which can reflect the 3D coronary lumen, may improve clinical outcomes when compared to coronary angiography.

In the UK, there were 118 PCI centres that performed 102,258 PCI procedures in 2017 through to 2018 which was an 1.2% increase from the previous year (NICOR, 2019).

HTW researchers searched for evidence on IVUS guided PCI when compared to angiography guided PCI across any population undergoing PCI procedures.

Evidence overview

Guidance

NICE published guidance on cardiovascular disease: risk assessment and reduction, including lipid modification (NICE 2014) which covers the assessment and care of adults who are at risk of or who have cardiovascular disease (CVD), such as heart disease and stroke although the guidance does not report on IVUS to guide PCI for people with cardiovascular conditions.

Health Technology Assessments

HTW researchers identified an NHS UK health technology assessment published in 2000 entitled, 'Intravascular ultrasound-guided interventions in coronary artery disease: a systematic literature review, with decision-analytic modelling, of outcomes and cost-effectiveness' (Berry et al. 2000). However, the authors reported that the available evidence was too weak for any implications for clinical practice.

Systematic reviews

HTW researchers identified 10 systematic reviews with meta-analysis about the clinical effectiveness of IVUS guided PCI when compared to angiography guided PCI (Zhong et al. 2022, Wang et al. 2022, Groenland et al. 2022, Chugh et al. 2022, Saleem et al. 2021, Yang et al. 2020, Darmoch et al. 2020, Buccheri et al. 2017, Elgendy et al. 2016, Zhang et al. 2015). Each review varied in terms of the population group and procedure including people with chronic total occlusions (CTO) (Zhong et al. 2022, Chugh et al. 2022), stent implantation procedures (Wang et al. 2022, Buccheri et al. 2017, Elgendy et al. 2016, Zhang et al. 2015), people with acute myocardial infarction (Groenland et al. 2022), left-main coronary artery intervention procedures (Saleem et al. 2021), people with coronary bifurcation lesions (Yang et al. 2020) and generic comparative evidence of IVUS-PCI when compared with angiography-PCI (Darmoch et al. 2020).

Most meta-analyses included a mixture of randomised controlled trials and observational studies. Some outcomes were mixed, although most outcomes favoured IVUS guided PCI when compared with angiography guided PCI. Outcomes included incidence of MACE, cardiac death, myocardial

infarction, target vessel revascularisation, stent thrombosis, total procedure time, total stent length and total number of stents.

MACE

Eight systematic reviews reported on the relative incidence of MACE with follow-up durations varying from one to two years. Across a variety of population groups, five systematic reviews found that the use of IVUS guided PCI when compared with angiography PCI reduced the risk of, or incidence of MACE (Wang et al. 2022, Groenland et al. 2022, Yang et al. 2020, Elgendy et al. 2016, Zhang et al. 2015). Three reviews found similar results in relation to MACE or found no statistical difference between the two intervention groups (Zhong et al. 2022, Chugh et al. 2022, Saleem et al. 2021). Zhong et al. (2022) found that when compared to the angiography-guided group, IVUS-guided PCI showed no significant reduction in the incidence of MACE (P = 0.457). Chugh et al. (2022) found IVUS-guided CTO-PCI had similar MACE. Saleem et al. (2021) found no difference observed in the odds ratio (OR) of the stent thrombosis (OR 0.57, p = 0.07) and stroke (OR 1.7, p = 0.35) between the two groups.

Myocardial infarction

Four reviews reported a lower rate of, or relative risk of myocardial infarction with IVUS (Wang et al. 2022, Saleem et al. 2021, Darmoch et al. 2020, Buccheri et al. 2017). Two studies found no statistical difference in the rates of myocardial infarction between IVUS PCI and angiography-guided PCI (Zhong et al. 2022, Chugh et al. 2022).

Cardiac Death

Seven reviews found lower rates of mortality/cardiac death using IVUS when compared with angiography-guided PCI (Groenland et al. 2022, Saleem et al. 2021, Yang et al. 2020, Darmoch et al. 2020, Buccheri et al. 2017, Elgendy et al. 2016, Zhang et al. 2015). Three reviews did not find a significant difference in relation to mortality rates between the two intervention groups (Zhong et al. 2022, Wang et al. 2022, Chugh et al. 2022).

Need for revascularisation

Target lesion revascularization refers to the need to restore blood flow to the heart or another organ after the arteries have become clogged with cholesterol plaque. Six reviews reported lower rates of, or lower risks of target lesion revascularization in the IVUS group when compared to the control group (Wang et al. 2022, Groenland et al. 2022, Saleem et al. 2021, Darmoch et al. 2020, Buccheri et al. 2017, Elgendy et al. 2016). Similar rates of target lesion revascularizations or non-statistically significant outcomes between the two intervention groups were reported in three papers (Zhong et al. 2022, Chugh et al. 2022, Yang et al. 2020).

Stent thrombosis

Six reviews found a lower risk of stent thrombosis because of using IVUS when compared to angiography-guided PCI (Wang et al. 2022, Chugh et al. 2022, Darmoch et al. 2020, Buccheri et al. 2017, Elgendy et al. 2016, Zhang et al. 2015). Two reviews did not find a statistically significant difference in intervention groups for this outcome (Saleem et al. 2021, Yang et al. 2020).

Procedure time

One review, Chugh et al. (2022) found that IVUS-guided chronic total occlusion-PCI resulted in shorter procedure time, shorter fluoroscopy time, and less contrast volume use. The review also

reported a shorter total stent length and a lower number of total number of stents when compared to the control group.

Primary evidence

Due to the availability of secondary evidence, we did not search for any additional primary evidence.

Economic evidence

The UK based HTA published in 2000 reported on cost effectiveness data from five studies that were included in their decision-analytic model, although we have not extracted any figures due to them potentially being out of date. The above systematic reviews with meta-analysis did not report economic evidence and thus, HTW researchers searched separately for any evidence on the cost-effectiveness of IVUS when compared to standard care since 2000. HTW researchers identified three studies reporting on the cost-effectiveness of IVUS guided PCI versus angiographic guided PCI published in 2001 (Gaster et al. 2001), 2003 (Mueller et al. 2003) and 2021 (Zhou et al. 2021). Costs are in Danish krone (DKK) in (Gaster et al. 2001), US dollars in (Mueller et al. 2003) and Australian dollars in (Zhou et al. 2021).

Gaster et al. (2001) found that the initial cost of performing IVUS guidance was more costly due to extra procedure time, IVUS catheters and slightly more balloons and stents, however fewer people in the IVUS guided group needed re-intervention when compared to the angiography guided group. IVUS was therefore considered more costly but more clinically effective. Mueller et al. (2003) found that hospital costs were initially slightly higher in the IVUS group, however at two years follow-up, the costs for cardiac hospitalisations were slightly lower in the IVUS group and the costs for medication and indirect costs were similar for both groups. The study concluded that in 55.3 percent of bootstrap resamples, IVUS was less expensive and more effective.

More recently, Zhou et al. (2021) constructed a decision-analytic Markov model comparing the cost-effectiveness of IVUS to angiography guidance during drug-eluting stent implantation from an Australian healthcare system perspective. The results found that in the base case, IVUS guidance was cost-effective compared with angiography guidance alone. IVUS was associated with increased lifetime costs of 823 Australian dollars per person and benefits of 0.04 life years and 0.05 quality adjusted life years (QALYs) compared with angiography, yielding an incremental cost-effectiveness ratio of 17,539 dollars per QALY gained. The study concluded that IVUS guidance during PCI is likely to be cost-effective compared with angiography guidance alone among people undergoing drug-eluting stent implantation.

Areas of uncertainty

There are multiple systematic reviews with meta-analyses on different procedures and population groups. If this topic were to progress to a fuller appraisal, consideration could be given to the exact population group or procedure to focus on.

Based on this initial scoping search, no economic evidence on IVUS from a UK perspective has been identified since 2000. It is unclear at this stage how applicable the latest economic studies would be to an NHS UK perspective.

Literature search results

Health technology assessments and guidance

Berry E, Kelly S, Hutton J, 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 Technol Assess. 4(35): 1-117.

NICE. (2014). Cardiovascular disease: risk assessment and reduction, including lipid modification Clinical guideline [CG181]. National Institute for Health and Care Excellence. Available at: https://www.nice.org.uk/guidance/cg181/ [Accessed 21 March 2023].

Evidence reviews and economic evaluations

Buccheri S, Franchina G, Romano S, et al. (2017). Clinical Outcomes Following Intravascular Imaging-Guided Versus Coronary Angiography-Guided Percutaneous Coronary Intervention With Stent Implantation: A Systematic Review and Bayesian Network Meta-Analysis of 31 Studies and 17,882 Patients. JACC Cardiovasc Interv. 10(24): 2488-98. doi: 10.1016/j.jcin.2017.08.051

Chugh Y, Buttar R, Kwan T, et al. (2022). Outcomes of Intravascular Ultrasound-Guided Versus Angiography-Guided Percutaneous Coronary Interventions in Chronic Total Occlusions: A Systematic Review and Meta-Analysis. J Invasive Cardiol. 34(4): E310-e8.

Darmoch F, Alraies MC, Al-Khadra Y, et al. (2020). Intravascular Ultrasound Imaging-Guided Versus Coronary Angiography-Guided Percutaneous Coronary Intervention: A Systematic Review and Meta-Analysis. J Am Heart Assoc. 9(5): e013678. doi: 10.1161/jaha.119.013678

Elgendy IY, Mahmoud AN, Elgendy AY, et al. (2016). Outcomes With Intravascular Ultrasound-Guided Stent Implantation: A Meta-Analysis of Randomized Trials in the Era of Drug-Eluting Stents. Circ Cardiovasc Interv. 9(4): e003700. doi: 10.1161/circinterventions.116.003700

Gaster AL, Slothuus U, Larsen J, et al. (2001). Cost-effectiveness analysis of intravascular ultrasound guided percutaneous coronary intervention versus conventional percutaneous coronary intervention. Scand Cardiovasc J. 35(2): 80-5. doi: 10.1080/140174301750164673

Groenland FTW, Neleman T, Kakar H, et al. (2022). Intravascular ultrasound-guided versus coronary angiography-guided percutaneous coronary intervention in patients with acute myocardial infarction: A systematic review and meta-analysis. Int J Cardiol. 353: 35-42. doi: 10.1016/j.ijcard.2022.01.021

Mueller C, Hodgson JM, Schindler C, et al. (2003). Cost-effectiveness of intracoronary ultrasound for percutaneous coronary interventions. Am J Cardiol. 91(2): 143-7. doi: 10.1016/s0002-9149(02)03099-0

Saleem S, Ullah W, Mukhtar M, et al. (2021). Angiographic-only or intravascular ultrasound-guided approach for left-main coronary artery intervention: a systematic review and meta-analysis. Expert Rev Cardiovasc Ther. 19(11): 1029-35. doi: 10.1080/14779072.2021.2004122

Wang S, Liang C, Wang Y, et al. (2022). The long-term clinical outcomes of intravascular ultrasound-guided versus angiography-guided coronary drug eluting stent implantation in long de novo coronary lesions: A systematic review and meta-analysis. Front Cardiovasc Med. 9: 944143. doi: 10.3389/fcvm.2022.944143

Yang RR, Lv YH, Guo C, et al. (2020). Intravascular ultrasound-guided percutaneous coronary intervention for patients with coronary bifurcation lesions: A systematic review and meta-analysis. Medicine (Baltimore). 99(37): e20798. doi: 10.1097/md.0000000000020798

Zhang YJ, Pang S, Chen XY, et al. (2015). Comparison of intravascular ultrasound guided versus angiography guided drug eluting stent implantation: a systematic review and meta-analysis. BMC Cardiovasc Disord. 15: 153. doi: 10.1186/s12872-015-0144-8

Zhong Z, Zhao L, Chen K, et al. (2022). The Clinical Effects of Intravascular Ultrasound-Guided Percutaneous Coronary Intervention in Patients with Chronic Total Occlusion: A Meta-Analysis. Cardiol Res Pract. 2022: 4170060. doi: 10.1155/2022/4170060

Zhou J, Liew D, Duffy SJ, et al. (2021). Intravascular Ultrasound Versus Angiography-Guided Drug-Eluting Stent Implantation: A Health Economic Analysis. Circ Cardiovasc Qual Outcomes. 14(5): e006789. doi: 10.1161/circoutcomes.120.006789

Individual studies
We did not search for any additional primary studies
Ongoing research
We did not identify any ongoing evidence due for completion in 6-12 months.
Other references
National Institute for Cardiovascular Outcomes Research (NICOR) (2019). National Audit for Percutaneous Coronary Intervention: 2019 Summary Report (2017/18 Data). Available at: https://www.nicor.org.uk/wp-content/uploads/2019/09/NAPCI-2019-Summary-Report-final.pdf [Date accessed: 25 April 2023].

Date of search:	**March 2023**
Concepts used:	IVUS (Intravascular ultrasound), percutaneous coronary intervention, Coronary angiography, suspected cardiovascular conditions.

Proposed research question and evidence selection criteria (if selected)

Proposed research question	**What is the effectiveness and cost effectiveness of IVUS-guided PCI when compared to angiography-only guided PCI?**

	Included	Excluded
Population	People with cardiovascular conditions	
Intervention	Intravascular ultrasound for percutaneous coronary intervention	
Comparison/ comparators	Coronary angiography (current standard)	
Outcomes	Reduction of adverse cardiac events e.g., myocardial infarction Procedure time	
Study design	Usual evidence hierarchy	