Value of Technology

Inequitable patient access to clinically and cost effective medical technology: Fractional flow reserve to diagnose and guide treatment of coronary heart disease

BACKGROUND

Coronary heart disease (CHD), also known as coronary artery disease (CAD), is the most common type of cardiovascular disease in Australia. It is caused by narrowing or blocking of arteries due to build up of plaque, which restricts blood flow and reduces the amount of oxygen going to the heart.

CHD remains the leading cause of death in Australia - 22,729 deaths in 2007 due to CHD (17% of all deaths and 49% of deaths from cardiovascular disease). Approximately half of CHD deaths result from acute myocardial infarction (MI) (heart attack). The incidence of CHD increases with age and the number of people with CHD is expected to increase in future years as the ageing population increases.

Figure 1

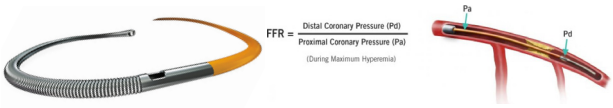

Image: St. Jude Medical

Current guidelines advise the use of FFR-guided for percutaneous coronary revascularisation as gold standard - class IA European Society of Cardiology and class IIA American Heart Association practice guideline recommendations.

Cost savings are maintained up to 15 years follow-up with PCI deferral as indicated by FFR resulting in equivalent or better patient outcomes to stenting in the absence of pressure wire.

ISSUE – FINANCIAL DISINCENTIVE TO USE A PRESSURE WIRE IN THE PRIVATE SECTOR

- In the private system, private health insurance companies either do not or only partially cover the cost of the pressure wire.
- Initial upfront cost of a pressure wire is around $1300 - private hospitals do not routinely receive any additional benefit for using a pressure wire
- Medicare item number for coronary angiography with use of a pressure wire pays less than the item number for PCI and stent(s).

Financial analysis demonstrates that FFR measurement would reduce expenditure on stents by private health insurers to the extent of savings of $1434.50 per procedure. Additional cost savings would be gained if the costs of direct hospitalisation for death and myocardial infarction are taken into account. The use of a pressure wire would provide substantial savings, however the method of reimbursement in the private sector is not conducive to its use.

Private health insurance funds may be expected to achieve significant savings by reimbursing the use of FFR.

RECOMMENDATIONS

FFR is a proven technology for guiding PCI and improved outcomes for patients. Furthermore, FFR use will provide cost savings for the Australian Federal and State/Territory Governments in the public sector and for the Private Health Funds in the private sector.

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Acknowledgement

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FRACTIONAL FLOW RESERVE

Fractional flow reserve (FFR) is a measurement that determines the severity of blood flow blockages in the coronary arteries and allows the identification of a specific lesion(s) (blockage causing blood flow restriction) that is responsible for a patient's ischemia (a restriction of blood flow to the heart).

FFR is measured by a pressure wire which features a miniaturised, high fidelity pressure sensor (Figure 1). Measurements are taken by placing the pressure wire across the lesion of interest to determine if the narrowing is causing ischemia. FFR measurement is defined as the ratio of maximal blood flow in a stenotic artery to normal maximal flow.

FFR measurements:
- 1.0 indicates an artery with normal blood flow
- above 0.80 indicates that ischaemia is very unlikely
- below 0.75 is 100% specific in identifying that the blood flow blockage caused by the narrowing is responsible for a patient's ischemia.

BENEFITS OF FFR TO GUIDE PCI

- Accurately identify lesions responsible for cardiac ischaemia by providing a more detailed, physiological analysis of blood flow blockages in the heart to determine the extent/severity of ischaemia.
- Decrease the need for urgent revascularisation compared with the best available medical therapy alone.
- Decrease the number of revascularisation procedures.
- As standard clinical practice improves clinical outcomes by increasing quality-adjusted life years and reducing the number of cardiac events (reducing the incidence of MI and death).

Deferral of PCI of a functionally non-significant stenosis is associated with a favourable follow-up at 15 years without signs of late 'catch-up' phenomenon. Assessment of ischaemia using FFR is associated with improved clinical outcomes and provides potential cost savings gained through:
- Shorter hospital stay
- Lower non-fatal myocardial infarction
- Lower repeat revascularisation

An Australian study showed that contemporary use of FFR measurement in the cardiac catheterisation lab saves money in both the public and private sector. Mean savings in the public sector were $1200 per patient and in the private sector the savings were $5000 per patient (Table 1).

Table 1: Costs associated with treatment of the patient with or without the use of FFR in public and private sector

PUBLIC (N=120)		
ITEM	**FFR COST ($)**	**NO FFR COST ($)**
AD HOC PCI POST FFR	$10,000	$0
AD HOC PCI ALONE	$0	$40,8000
PCI ON RETURN	$0	$8,000
O/N STAY	$15,000	$46,800
CABG	$198,000	$306,000
DES	$109,800	$109,800
BMS	$15,600	$15,600
PW	$169,500	$0
MIBI/SE	$0	$21,000
CLOPIDOGREL^	$49,000	$78,000
TOTAL	**$480,500**	**$626,000**
COST SAVINGS GAINED THROUGH FFR USE		**$145,500**
COST SAVINGS GAINED PER PUBLIC PATIENT WITH FFR USE		**$1212.50**

PRIVATE (N=120)		
ITEM	**FFR COST ($)**	**NO FFR COST ($)**
38218*	$0	$317,200
38246/38241*	$691,600	$0
38246/38306*	$0	$952,000
38246/38306/38241*	$360,500	$0
38306/38243*	$0	$131,500
CABG	$209,000	$323,000
O/N STAY	$31,475	$98,202
DAYSTAY	$71,345	$39,052
DES	$90,000	$296,250
BMS	$6,000	$16,000
PW	$159,900	$0
MIBI/SE	$0	$21,000
CLOPIDOGREL^	$49,000	$78,000
TOTAL	**$1,668,820**	**$2,272,204**
COST SAVINGS GAINED THROUGH FFR USE		**$603,384**
COST SAVINGS GAINED PER PRIVATE PATIENT WITH FFR USE		**$5028.20**

Adapted from Murphy et al., 2014.

*MBS item numbers attached to theatre fees: 38218 diagnostic angiography, 38246 diagnostic angiography and coronary intervention/FFR, 38241 FFR 38306 stent placement, 38243 coronary invention without diagnostic angiography.
^Clopidogrel treatment for one year was added after stenting when the patient was clinically stable and had not had any other coronary stents within the previous 12 months.
Abbreviations: BMS, bare metal stent; CABG, coronary artery by pass grafting; DES, drug-eluting stent; FFR, fractional flow reserve, MIBI/SE, MIBI scanning or stress echocardiography; O/N overnight; PCI, percutaneous coronary intervention; PW, pressure wire.