

ECONOMIC-EVALUATION OF PERCUTANEOUS CORONARY INTERVENTIONS (PCI) AGAINST OPTIMAL MEDICAL THERAPY (OMT) FOR MANAGEMENT OF PATIENTS WITH SINGLE VESSEL CORONARY ARTERY DISEASE (SV-CAD) WITHOUT LEFT MAIN CORONARY ARTERY (LMCA) INVOLVEMENT

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SUMMARY

Single vessel coronary Artery disease (SV-CAD) is often usually referred to as the presence of at least a $\geq 70\%$ stenosis of a major coronary artery (left anterior descending, left circumflex, or right coronary arteries) or one of their respective major branches and associated with a higher burden of comorbidities, left ventricular dysfunction, and cardiovascular risk. Optimal medical therapy and revascularization are the required treatment to alleviate symptoms, avert disease progression, prevent Cardiovascular events, and decrease mortality. A Health technology Assessment (HTA) was undertaken to see which treatment modality between percutaneous coronary interventions (PCI) with optimal medical therapy (OMT) and OMT alone is the better alternative for managing patients with SV-CAD. Overall study suggested PCI is not a cost-effective strategy for management of SV-CAD as compared to OMT.



POLICY

RECOMMENDATIONS

- **OMT would have been the better option of treatment both clinically and cost-effectiveness wise**
- **Study recommends that in cases of SV-CAD, the mainstay treatment be centered around the use of OMT therapy alone.**
- **PCI may be considered as the second line of treatment in cases requiring revascularization as per clinical experts' opinion.**

INTRODUCTION

Coronary artery disease (CAD) disease of the blood vessels supplying to the heart muscle) are mostly involves single vessel and multi-vessel coronary artery disease. Single vessel disease (SV-CAD) is usually referred to as the presence of at least a $\geq 70\%$ stenosis of a major coronary artery (left anterior descending, left circumflex, or right coronary arteries) or one of their respective major branches. Single vessel disease is often associated with a higher burden of comorbidities, left ventricular dysfunction, and cardiovascular risk. All patients with CAD first require optimal medical therapy (OMT) to alleviate symptoms, avert disease progression, prevent Cardiovascular events, and decrease mortality. Revascularization is indicated in patients who remain symptomatic despite OMT, for this the patient may either undergo percutaneous coronary intervention (PCI) and coronary artery bypass graft (CABG) surgery along with

optimal medical therapy (OMT) or in some cases only OMT. PCI is generally preferred in patients with single or low risk two vessel. A Health Technology Assessment was conducted to assess which treatment modality between percutaneous coronary interventions (PCI) with optimal medical therapy (OMT) and OMT alone is the better alternative for managing patients with SV-CAD. Conceptual framework and transitions used in the study shown in figure 1 and 2.

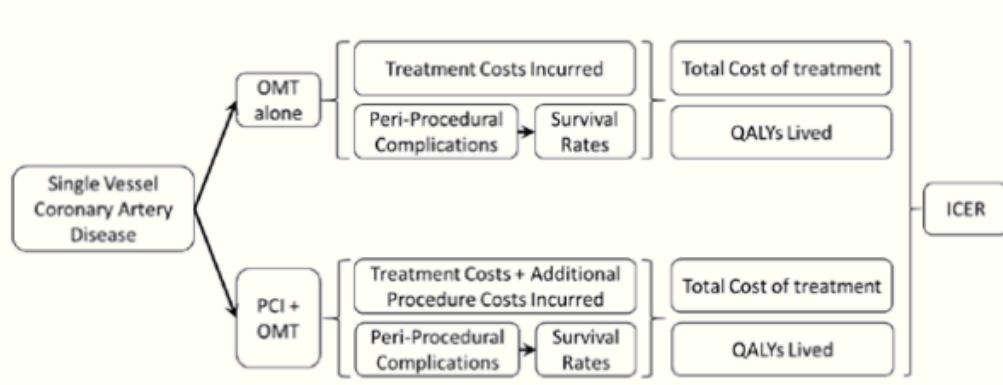


Figure 1: Conceptual Framework for the processes to be modelled and generated in treatment of patients with SV-CAD with either PCI + OMT or OMT alone

RESULTS

The results are as summarized in the table 1. Separate ICERs and Net Benefit values were calculated as per the prices of drugs in the Jan Aushadhi list. In terms of Net Health Benefit (NHB) there is an overall loss of health benefits if we spend in providing treatment with PCI + OMT as opposed to simply treating patients with OMT alone. There is also a net monetary loss if an investment is made in PCI rather than OMT as per our findings. As per the sensitivity analysis the parameter most likely to influence results was the rate of revascularization in the PCI arm followed by hospitalization for ACS in OMT and PCI + OMT arms respectively. The next 7 parameters are listed in the diagram in descending order of their tendency to have an effect on the ICER values(figure3).

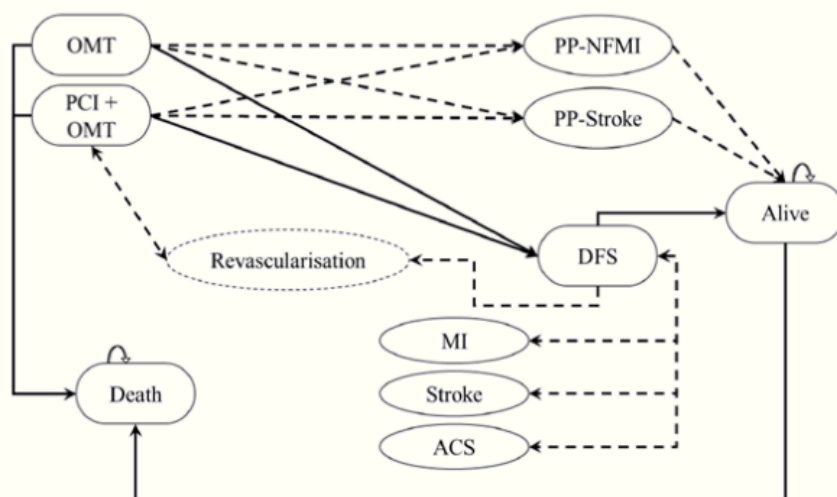


Figure 2: Illustration of the Markov model with the various transitions used in this study

Overall, only 48% of the total generated ICER iterations from the PSA fall in the cost-effective range as per our cost-effectiveness threshold (kept at one time the current GDP per capita per person of India). Findings of the study found that the use of PCI + OMT is not something that can be recommended easily over OMT alone therapy, specifically for SV CAD.

Also, seen that even at a high willing-to-pay (WTP) threshold of INR 8,00,000, the use of PCI will have a maximum of 60% chances of being cost-effective. To sum up, as per our findings, the ICER is higher than the CEA threshold which means that using PCI + OMT to treat SV-CAD, as against those treated with OMT alone, is not a cost-effective strategy in India.

Table 1: Results for the base case scenarios

Result (per patient)	With BPPI Price rates of OMT Drugs	With Average Market Price rates of OMT Drugs
Incremental QALYs (in years)	0.311	0.311
Incremental Cost (in INR)	66,286.6	75,565.5
ICER per QALY (in INR)	2,12,979.69	2,42,793.09
ICER : CEA Threshold*	1.4	1.6
NHB (in QALYs)	-0.125	-0.187
NMB (in INR)	-19,043.17	-28,322.12

ICER = Incremental Cost-Effectiveness Ratio, GDP = Gross Domestic Product (per capita per person), NHB = Net Health Benefit, NMB = Net Monetary Benefit, QALY = Quality Adjusted Life Year, INR = Indian National Rupee, BPPI = Bureau of Pharma Public Sector Undertakings of India, *CEA Threshold = GDP per capita per person of India (INR 1,51,793.69 as of May 31st, 2020 as per World Bank)

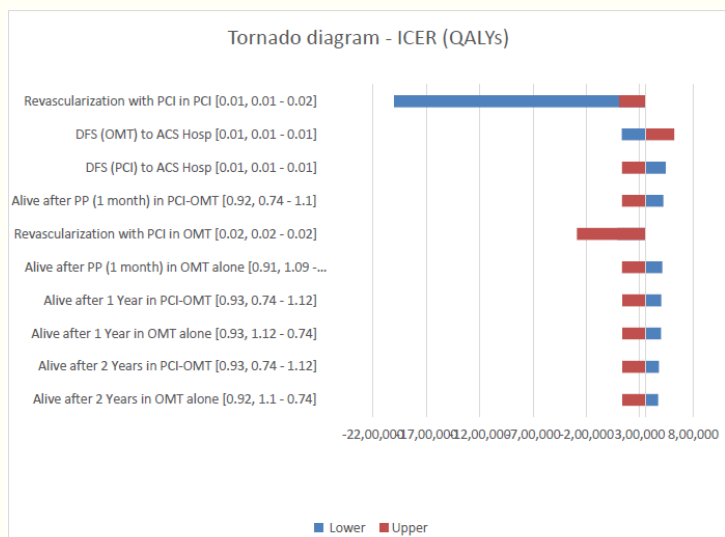


Figure 3: Tornado diagram illustrating the top 10 parameters likely to influence the ICER values based on changes in independent values of the parameters

SUMMARY

As evident from results of our study, PCI is not a cost-effective strategy for management of SV-CAD as compared to OMT. Even in terms of net benefits, investing in PCI results in a negative net health benefit for the patient meaning that OMT would have been the better option of treatment both clinically and cost-effectiveness wise. Considering that just for a gain of 0.3 QALYs the incremental cost per patient is INR 66292, PCI does not seem to be an effective strategy for treatment. Thus, this study concluded that in cases of SV-CAD, the mainstay treatment be centered around the use of OMT therapy alone. PCI may be considered as the second line of treatment in cases requiring revascularization as per clinical experts' opinion.