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Cost-effectiveness of pressured-controlled intermittent coronary sinus occlusion (PiCSO) in primary percutaneous coronary intervention: a threshold analysis on the cost of the device

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Background

Rapid reperfusion of the epicardial coronary artery by primary percutaneous coronary intervention (PPCI) is the guideline-recommended treatment for ST-segment elevation myocardial infarction (STEMI). However, PPCI is still associated with poor clinical outcomes in some patients, many of whom have severe coronary microvascular obstruction or dysfunction after the procedure.

Final infarct size (IS) as well as presence and extent of microvascular obstruction are major independent predictors of long-term mortality and heart failure in survivors of STEMI.

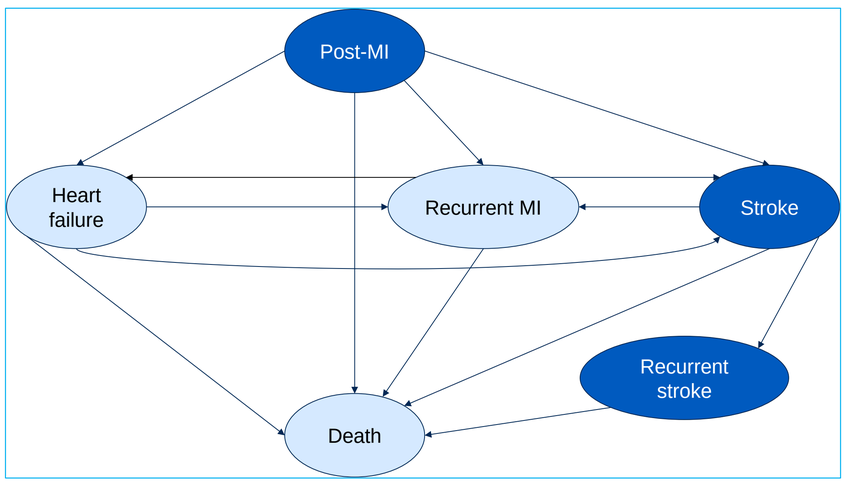
Objectives

Aim of the study was to evaluate the cost-effectiveness of PPCI combined with PiCSO compared to PPCI alone for the treatment of patients with STEMI from the National Healthcare Service (NHS) perspective in Italy.

Methodology

Model:

A Markov model was developed to estimate quality-adjusted life years (QALYs) and costs associated with PPCI+PiCSO versus PPCI alone in an adult population with anterior STEMI undergoing PPCI. Patients enter in the "post-MI" health state; they may remain in the "post-MI" state or experiment subsequent events such as heart failure, reinfarction, stroke or death.



Model Inputs:

Transition probabilities and costs for the management of events were derived from published literature.

Discount Rate and cycle length:

A discount rate of 3% was considered for both costs and QALYs, and the cycle length was established to be one month.

Horizon:

A lifetime horizon was applied for the baseline analysis.

WTPs and Sensitivity analysis:

As in Italy the cost of PiCSO® is not currently covered by DRGs, one-way sensitivity analyses were performed on the cost of the technology according to different willingness-to-pay (WTP) thresholds: 50'000€, 30'000€ and 15'000€.

Technology description

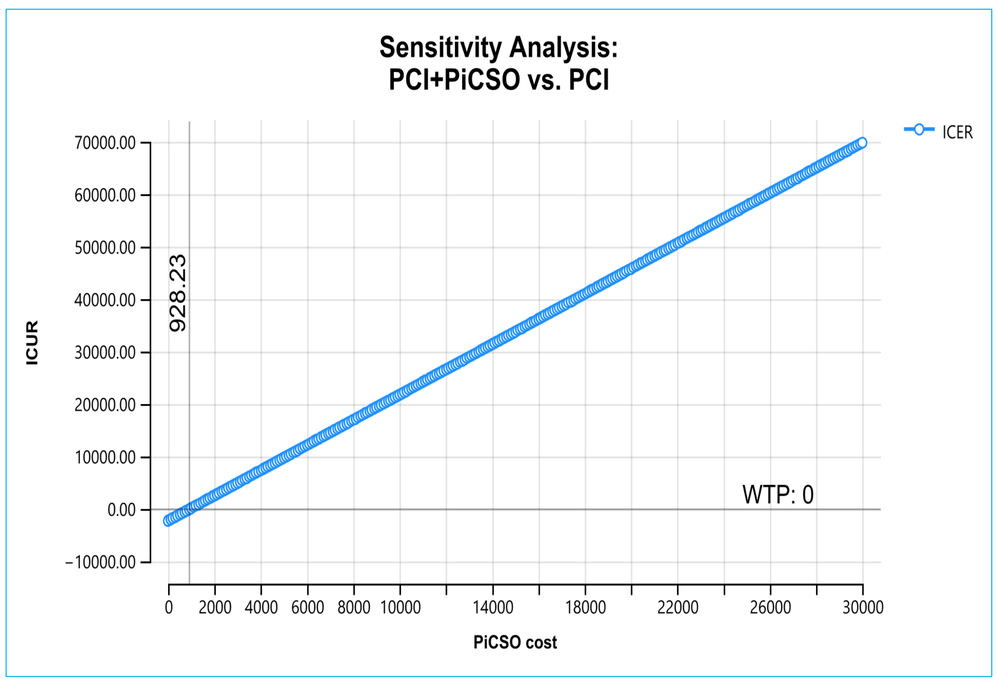
The PiCSO (Pressured-controlled Intermittent Coronary Sinus Occlusion) Impulse System is intended to reduce infarct size by intermittently occluding the coronary sinus outflow in patients older than 18 years of age, evidencing anterior STEMI, with symptom on-set time no greater than 12 hours and a TIMI flow 0 or 1 at presentation in whom percutaneous coronary intervention (PCI) is amenable. It is composed of:

– the PiCSO Impulse Console, which automates and monitors the balloon inflation and deflation cycles by tracking the coronary sinus pressure and the patients ECG
– the PiCSO Impulse Catheter (8Fr), which is balloon-tipped and inserted into access the coronary sinus via a femoral venous access
– the PiCSO Impulse Detachables (e.g. ECG cable, CSP cable, power cord, gas cartridge …).

Preliminary data suggest that the IS reduction obtained with PiCSO might lead to a 34% diminution in hospitalizations for heart failure and 25% decrease in mortality at one year. As PiCSO is not yet used routinely in clinical practice, evidence on its clinical and economic value may be useful to policymakers to support the assessment and appraisal activities on the device.

Results

Over a lifetime horizon, PPCI+PiCSO may lead to 15.87 life years and 12.16 QALYs, compared to 15.37 and 11.74 for PCI alone, respectively. Considering a WTP threshold of 50,000€, PPCI+PiCSO shows to be a cost-effective strategy compared to PCI alone when assigning a cost lower than 21'700€ to the medical device. **When assuming WTP thresholds of 30'000€ and 15'000€, PPCI+ PiCSO appears to be a cost-effective option versus PCI alone for a cost for the medical device lower than 13'400€ and 7'100€, respectively**



Conclusion

Early cost-effectiveness modeling suggests that a cost lower than 21'700€ may be good value for money for the PiCSO, a technology that may avoid cardiac events and improve patients' life expectancy and quality of life.