Cost Utility and Budget Impact Analyses of Closed Loop Upper Airway Stimulation (UAS) for the Treatment of Moderate to Severe Obstructive Sleep Apnea from an Australian Health Care System Perspective

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BACKGROUND AND OBJECTIVE

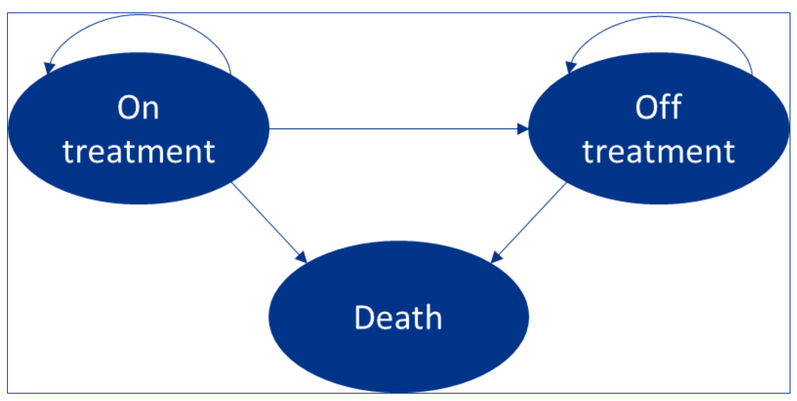
- Obstructive sleep apnoea (OSA) is a sleep breathing disorder characterised by repetitive collapse of the upper airway during sleep resulting in nocturnal hypoxemia and recurrent arousals.[1]
- Continue positive airway pressure (CPAP) is the first line of therapy for moderate to severe OSA.[2] However, CPAP is not tolerated by some patients, adherence is highly variable with reports of adherence between 39% to 60%.[3]
- Closed loop Upper airway stimulation (UAS) is the intended second line therapy for these patients. This study aimed to assess the cost-effectiveness and budget impact of closed loop UAS therapy versus conservative medical management from the Australian healthcare system perspective.

METHOD

COST UTILITY ANALYSIS

- A de novo Markov model was developed in Microsoft Excel (Redmond, WA, USA).
- Patients implanted with UAS system enter the model in the 'On treatment' state. In the first cycle, patients in 'On treatment' state may stay in the same heath state, have the device explanted and move to 'Off treatment' state, or die. From second cycle onwards, patients will remain in the same health state only until they die.
- All patients in the comparator arm will enter the model in the 'Off treatment' state and will remain in this state until they die.

Figure 1: Decision Analytic Structure of the Economic Evaluation



- **Time horizon**: Lifetime (45 years)
- **Cycle length**: One year
- **Discount rate**: Costs and outcomes were discounted at 5%[4]
- **Model outcomes**: Costs, Quality-adjusted life years (QALYs), and ICER

Table 1: Model Transitions

Model Parameter	Value	Source/ Assumption
Transition probability from 'On treatment' to 'Off treatment' state	2.4%	3 out of 126 patients had the device explanted by 5 years in STAR trial[5]
Mortality HR associated with OSA		
Patients On Treatment	1.5	Young 2008[6]
Patients Off Treatment	3.0	Young 2008[6]

HR=Hazard ratio; OSA= Obstructive sleep apnoea

- For QoL improvement, a published algorithm based on UK tariffs was used to convert ESS score to EQ-5D utility.[2] The ESS score at baseline and at 12 months from the STAR trial was assigned to 'Off treatment' and 'On treatment' patients, respectively.

Table 2: Model Utilities

Health State	ESS Score[5]	Estimated Utility
Off Treatment	11.6	0.780
On Treatment	7.0	0.825

ESS= Epworth Sleepiness Scale

Table 3: Selected Cost Inputs Used in the Economic Model

Resource item	Total cost	Source/ Assumption
Initial UAS system	AU$36,600	Inspire Medical
Replacement UAS IPG	AU$26,300	Inspire Medical
Pre Surgery Costs	AU$161	MBS Handbook[9]
Surgical services for UAS System Implantation	AU$6,308	MBS Handbook[9]; AR-DRG[7,8]
Surgical services for UAS System Removal	AU$4,473	MBS Handbook[9]; AR-DRG[7,8]
Surgical services for Replacement UAS IPG*	AU$4,492	MBS Handbook[9]; AR-DRG[7,8]
Follow-up visit	AU$38/visit	MBS Handbook[9]

*UAS= Upper airway stimulation; IPG- implantable pulse generator; AR-DRG=Australian Refined Diagnosis Related Groups; MBS=Medicare Benefits Schedule; *The cost of replacement UAS IPG and surgical services cost for replacement were applied to alive patients after every 11 years*

BUDGET IMPACT ANALYSIS

- The eligible population estimated to receive closed loop UAS using epidemiological analysis is large (20,091). It is very unlikely that the Australian healthcare system will have the capacity to provide this therapy to all eligible patients due to significant training requirement and limited number of ENTs in Australia.
- It is estimated that three centres would be able to provide the service in Year 1 increasing to 15 centers in Year 5 with capability of performing 8–10 procedures per centre per year which consistent on a per capita basis with USA, Germany and Japan.
- Costs used for the budget impact analysis were the same as the economic analysis.

RESULTS

COST UTILITY ANALYSIS

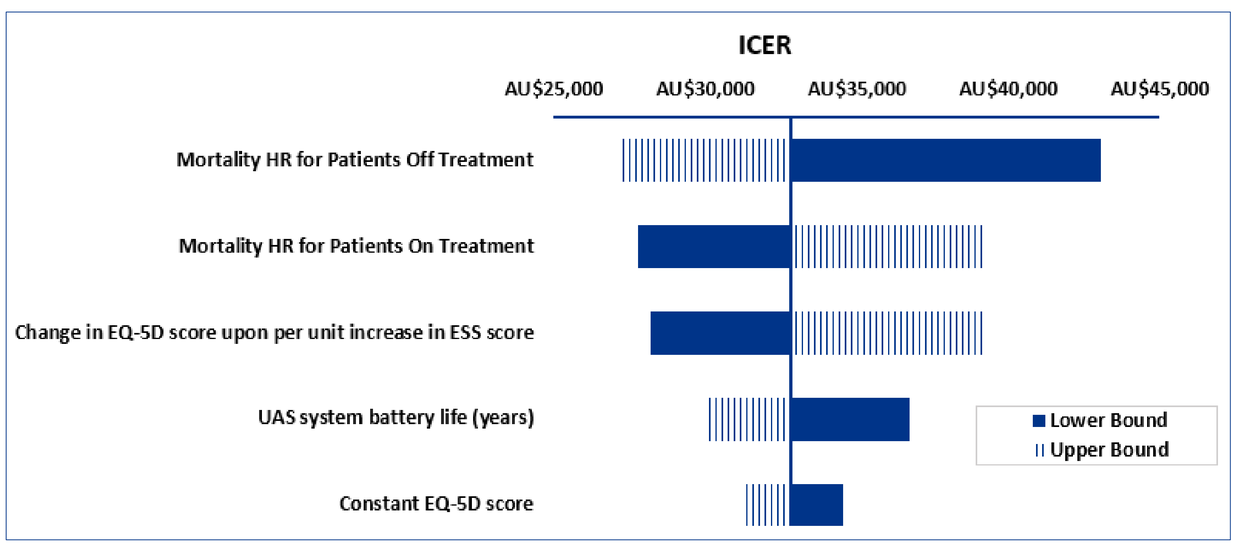
- Closed loop UAS system was associated with an incremental QALY gain of 2.07, at an incremental cost of AU$67,769 compared to conservative medical management.
- Closed loop UAS system is likely to be cost-effective with an ICER of AU$32,814/QALY gained, which is below the typically accepted cost-effectiveness thresholds (range: AU$45,000-AU$75,000) recommended by the Australian authorities[10].
- One-way sensitivity analysis (OWSA) showed that CE results were robust and most sensitive to mortality HRs, the regression equation used to transform ESS scores to EQ-5D utilities and battery life of UAS system (**Figure 2**).

Table 4: Results of Cost-Utility Analysis

	Total Costs	Total QALYs	Δ Costs	Δ QALYs	ICER ($/QALY)
Closed loop UAS System	AU$68,713	11.83	AU$67,769	2.07	AU$32,814
Conservative medical management	AU$944	9.77			

UAS= Upper Airway Stimulation

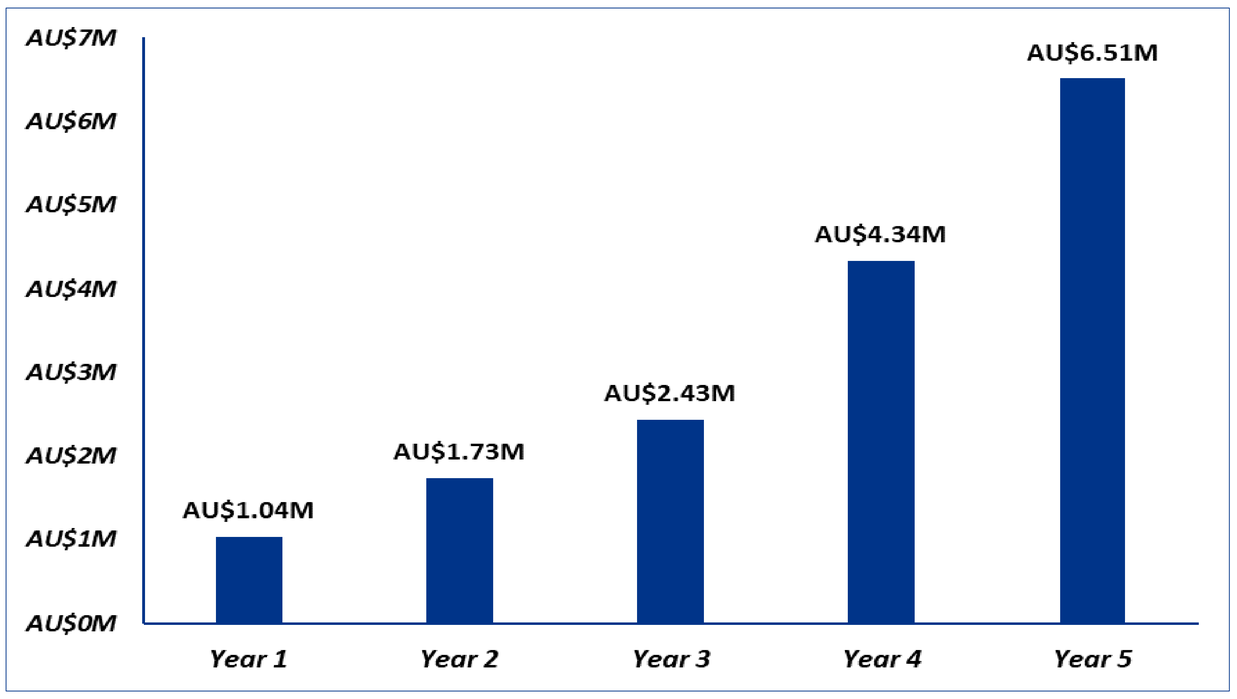
Figure 2: One-way Sensitivity Analysis Results



BUDGET IMPACT ANALYSIS

- It is expected that 24 patients will likely use closed loop UAS in Year 1 which will increase to 150 patients in Year 5 in the base case analysis.
- The estimated incremental budget impact due to introduction of closed loop UAS to the Australian healthcare system ranges from AU$1.04 million in Year 1 to AU$6.51 million in Year 5 (**Figure 3**).

Figure 3: Total Costs for Implementation of Closed loop UAS over 5 years



CONCLUSIONS

- Closed loop UAS system is a cost-effective therapy compared to conservative medical management for patients with moderate to severe OSA.
- Model results were robust to varying parameters in one- way sensitivity analysis.
- The introduction of closed loop UAS system is expected to have a modest impact on the budget of the Australian health care system.

FINANCIAL DISCLOSURES

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