

Cost-Effectiveness of Neuromuscular Electrical Stimulation for the Treatment of Mild Obstructive Sleep Apnea: An Exploratory Analysis

Shan Liu PhD^{1, 2}; Khoa N. Cao MBBS MS², Abigail M. Garner MS²; Simon A. Weber PhD^{2, 3}, Naresh M. Punjabi MD⁵; Jan B. Pietzsch PhD^{2*}
¹University of Washington, Seattle, WA USA., ²Wing Tech Inc., Menlo Park, CA USA ³Cellogic GmbH, Berlin, Germany ⁴University of Miami, Miami, FL USA * jpietzsch@wing-tech.com

BACKGROUND AND OBJECTIVE

- Neuromuscular electrical stimulation (NMES) is emerging as a non-invasive daytime therapy for mild obstructive sleep apnea (OSA).
- Recently, daytime stimulation with a novel intraoral NMES device (eXciteOSA®, Signifier Medical Technologies Ltd., London, UK) has been investigated [1].
- Our objective was to assess the potential cost-effectiveness of this novel treatment approach compared to existing treatments for mild OSA.

METHODS

- A decision-analytic Markov model (Figure 1) was developed to estimate health state progression, incremental cost, and quality-adjusted life year (QALY) gain of NMES compared to no treatment, continuous airway pressure (CPAP), or oral appliance (OA) treatment.
- The base case assumed no cardiovascular (CV) benefit for any interventions, while potential CV benefit was considered in scenario analyses.
- Effectiveness was based on a recent multi-center trial for NMES [1], and on the TOMADO [2] and MERGE [3] studies for OA and CPAP (Table 1).
- Costs, considered from a United States payer perspective, were projected over lifetime for a 48-year-old cohort, 68% of whom were male (Table 1).
- An incremental cost-effectiveness ratio (ICER) threshold of \$150,000 per QALY gained was applied.

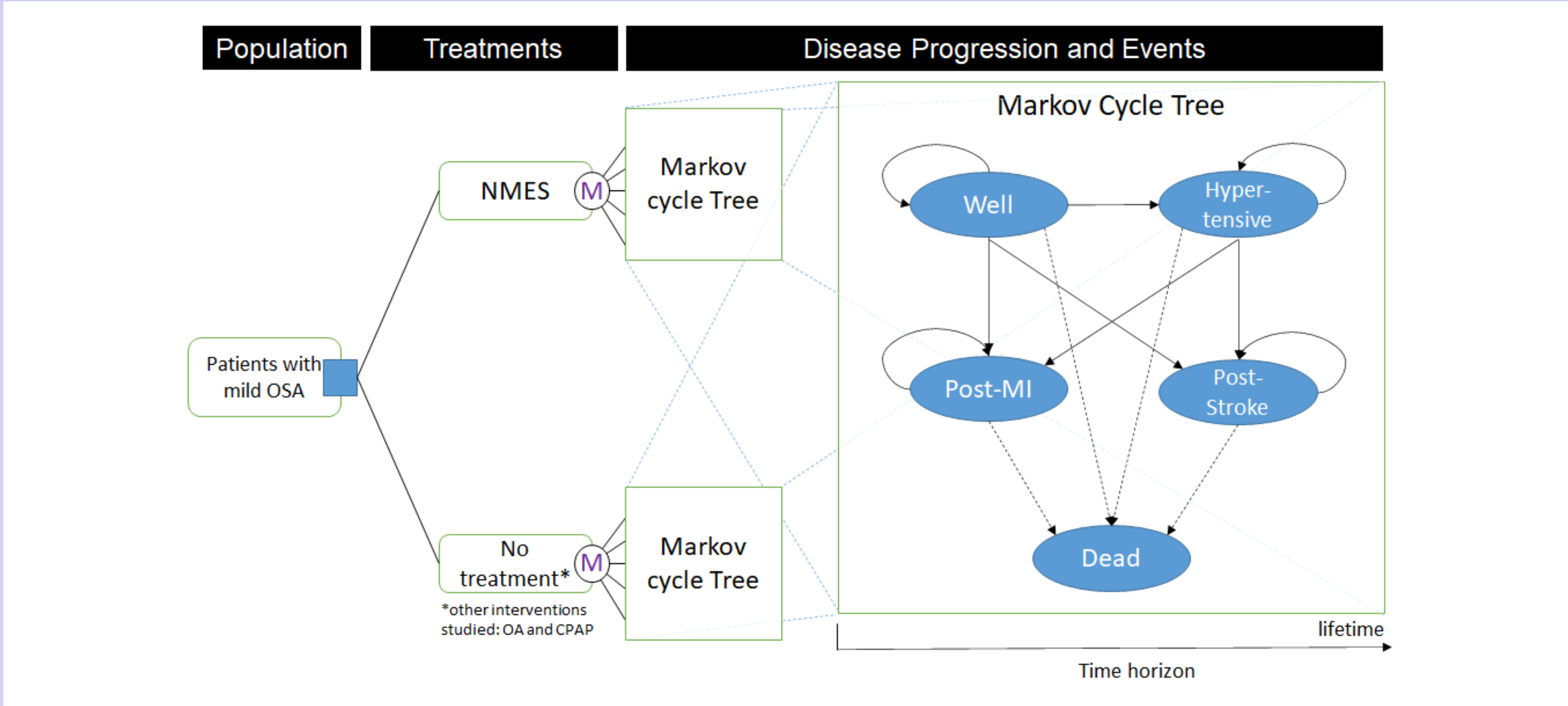


Figure 1. Model structure: Decision tree and Markov disease progression model.

Table 1. Key input parameters.

Parameter	Value	Range/ scenarios	Source
Age (yrs.)	48	65	[1], mild OSA
Sex (%male)	68%	0-100%	[1], mild OSA
NMES long-term adherence	75%	65%	
CPAP, OA long-term adherence	55%		
CPAP nightly utilization	100%	60%	
Baseline AHI	10.2		[1], mild OSA
AHI on NMES treatment	6.8		[1], mild OSA
AHI on OA treatment	7.0		TOMADO
AHI on CPAP treatment	1.4		MERGE
Resulting OSA excess CVD risk reduction with NMES	61%		Regression based on AHI-dependent CV event data (Marin, 2005)
Resulting OSA excess CVD risk reduction OA	58%		
Resulting CVD event reduction CPAP	100%		
NMES therapy initiation cost	\$2,181		Manufacturer-provided suggested retail price plus visits per CMS fee schedule
NMES annual cost mouthpieces	\$600		
NMES controller replacement cost (every 5 yrs.)	\$1,631		
OA therapy initiation cost	\$1,962		CMS (Medicare) DME schedule
OA device replacement (every 5 yrs.)	\$1,562		
CPAP therapy initiation	\$1,048		
CPAP disposables annual cost	\$965		75% of maximum CMS resupply volume

References

- Nokes B, Baptista PM, de Apodaca PMR, et al. Transoral awake state neuromuscular electrical stimulation therapy for mild obstructive sleep apnea. *Sleep Breath* 2022 (in-press).
- Quinnell TG, Bennett M, Jordan J, et al. A crossover randomised controlled trial of oral mandibular advancement devices for obstructive sleep apnoea-hypopnoea (TOMADO). *Thorax*. 2014;69(10):938-945.
- Wimms AJ, Kelly JL, Turnbull CD, et al. Continuous positive airway pressure versus standard care for the treatment of people with mild obstructive sleep apnoea (MERGE): a multicentre, randomised controlled trial. *Lancet Respir Med*. 2020;8(4):349-358.

Disclosures

Wing Tech Inc. employees Dr. Pietzsch, Dr. Cao, and Ms. Garner and Wing Tech Inc. consultants Dr. Shan Liu and Dr. Simon Weber provided health-economic consulting services for Signifier Medical Technologies Ltd.

RESULTS

- From a baseline AHI of 10.2 events/hour, NMES, OA and CPAP reduced the AHI to 6.9, 7.0 and 1.4 events/hour respectively (for OA and CPAP, assuming therapies in use per RCT data).
- Long-term therapy adherence was estimated at 75% in the base case (and 65% for low adherence (LA) scenario) for NMES and 55% for both OA and CPAP.
- Compared to no treatment, NMES added 0.268 QALYs and \$17,445 in cost (no CV benefit scenario), or 0.536 QALYs and \$7,481 in cost (CV benefit scenario), resulting in corresponding ICERs of **\$57,844** and **\$15,436** per QALY gained (Fig. 2.A) for respective CV benefit scenarios.
- Compared to OA, NMES was cost-effective at ICERs of \$73,301 and \$40,078 per QALY gained (no CV benefit and CV benefit scenario; see Fig. 2.B).
- Compared to CPAP, NMES was cost-effective for the No CV benefit scenario (\$66,335 per QALY gained). Where CV benefit was considered, NMES was or was not cost-effective dependent on CPAP CV risk reduction effectiveness (Fig. 2.C).

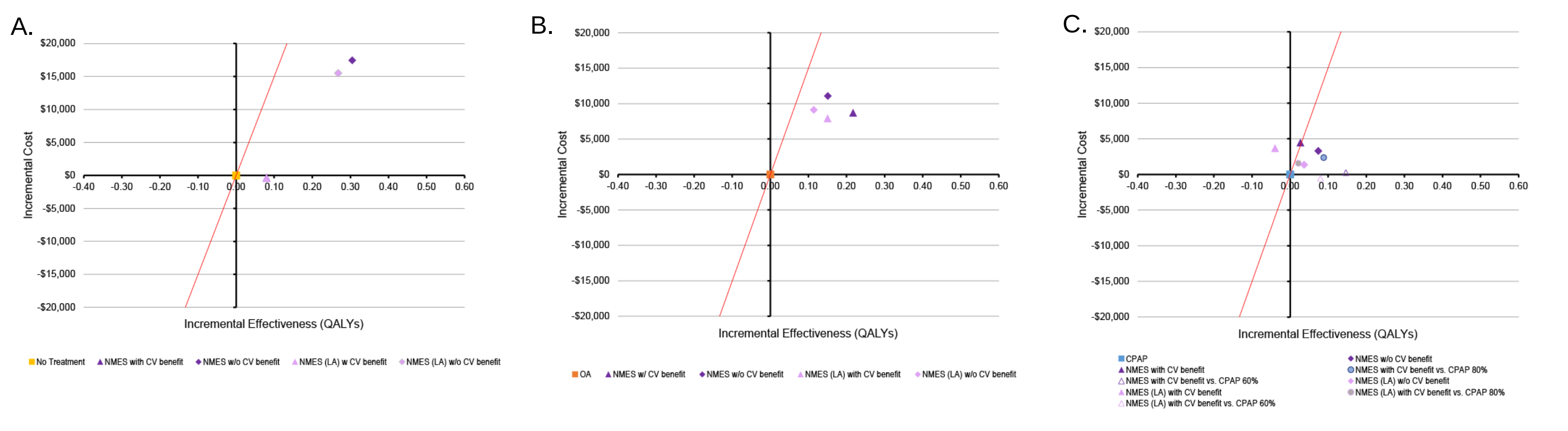


Figure 2. Lifetime Cost-Effectiveness Estimates for NMES vs. No Treatment (A.), NMES vs. OA (B.), and NMES vs. CPAP (C.)

- For the No CV benefit scenario, NMES was the preferred strategy (Fig. 3.A). For the CV benefit scenario, CPAP was preferred if patients were assumed to be adherent for the full night, while NMES was preferred if lower CPAP nightly compliance was assumed (Fig. 3.B).

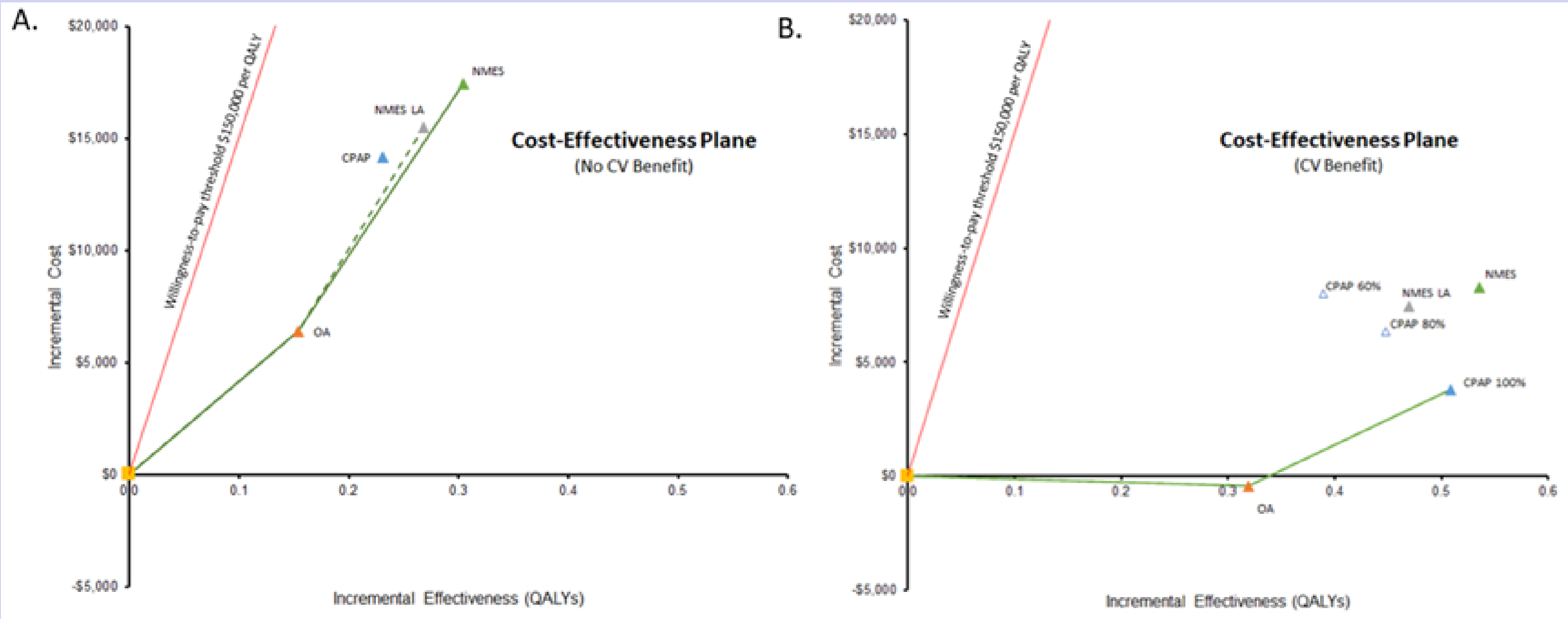


Figure 3. Lifetime cost-effectiveness estimates for NMES, OA, and CPAP vs. No Treatment, base case (A.) and exploratory analysis with consideration of potential therapy-associated cardiovascular benefit (B.) Legend: LA: low adherence.

- Depending on long-term adherence assumptions, either NMES or CPAP were found to be the preferred treatment option among the four evaluated therapies, with NMES becoming more attractive with younger age and assuming CPAP was not used for the full night in all patients (Figure 4).

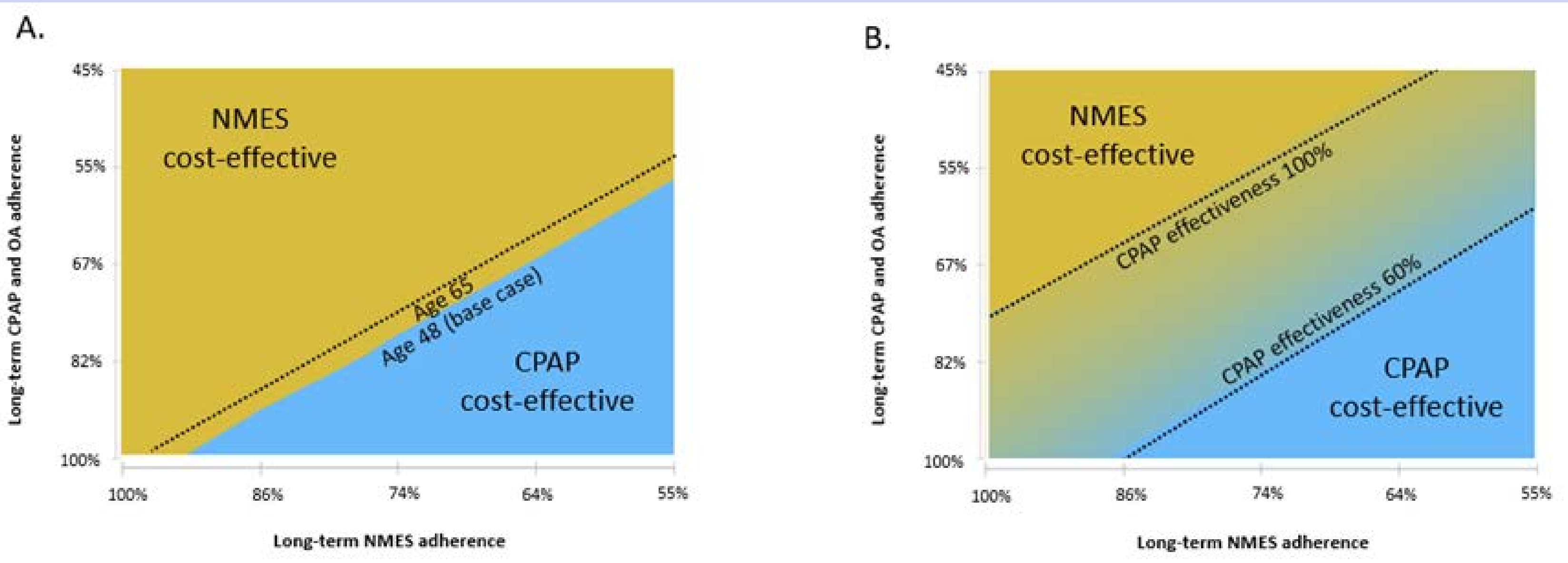


Figure 4. Two-way sensitivity analysis of the effect of variation in long-term CPAP/OA adherence vs. NMES adherence on cost-effectiveness. Male cohort, No cardiovascular benefit scenario (A.) and Male cohort, Cardiovascular benefit scenario (B.)

CONCLUSION

- NMES – a non-invasive daytime treatment whose clinical effect is independent of night-time usage – might be a cost-effective treatment option for patients with mild OSA and may be preferred over CPAP or OA depending on adherence and cost assumptions.