Siriraj Health Policy Unit
หน่วยวิจัยเพื่อขับเคลื่อนนโยบายสุขภาพ

Mahidol University
Faculty of Medicine Siriraj Hospital

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Original Research

Botulinum Toxin Type A For The Treatment Of Patients With Post-stroke Focal Spasticity In Thailand: A Cost-utility Analysis

Hadnorntun P[1],Prawjaeng J[1], **Leelahavarong P[1]**, Tanvijit P[2], Chueluecha C[3], Jintakul N[3], Saringcarinkul T[4], Srinonprasert V[1], Kumthornthip W[2]

[1]Siriraj Health Policy Unit, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand, [2]Department of Rehabilitation Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand,[3] Department of Rehabilitation Medicine, Faculty of Medicine, Thammasat University, Pathum Thani, Thailand, [4]Department of Rehabilitation Medicine, Neurological Institute of Thailand, Bangkok, Thailand

INTRODUCTION

- About 20-40% of stroke survival will develop spasticity, Spasticity affects both active and passive functions resulting in pain and discomfort for the patient (1).
- Botulinum toxin-A (BoNT-A) is injected directly into the targeted muscle bundles for reducing muscle spasticity.
- BoNT-A is expensive and has not yet been included in Thailand's National List of Essential Medicines (NLEM).

OBJECTIVE

- This study aims to evaluate the cost-utility of BoNT-A as an add-on to standard of care (SoC) for treating patient with upper (UL) and lower limb (LL) post-stroke spasticity (PS).

METHODS

Study Design and Participants

- A Markov model **(Figure 1)** with a 3-month cycle length were constructed using a societal perspective to estimate relevant costs and health outcomes for a lifetime horizon, with a 3% annual discount(2).
- The patient characteristic in this cohort is patients aged 55 years with post-stroke focal UL or LL spasticity and having a Modified Ashworth Scale (MAS) score ≥ 1. For assessing treatment response, using a minimum 1-level reduction in MAS or goal achievement, achieving the predefined treatment goal according to the International Classification of Functioning, Disability, and Health (ICF) dimension.

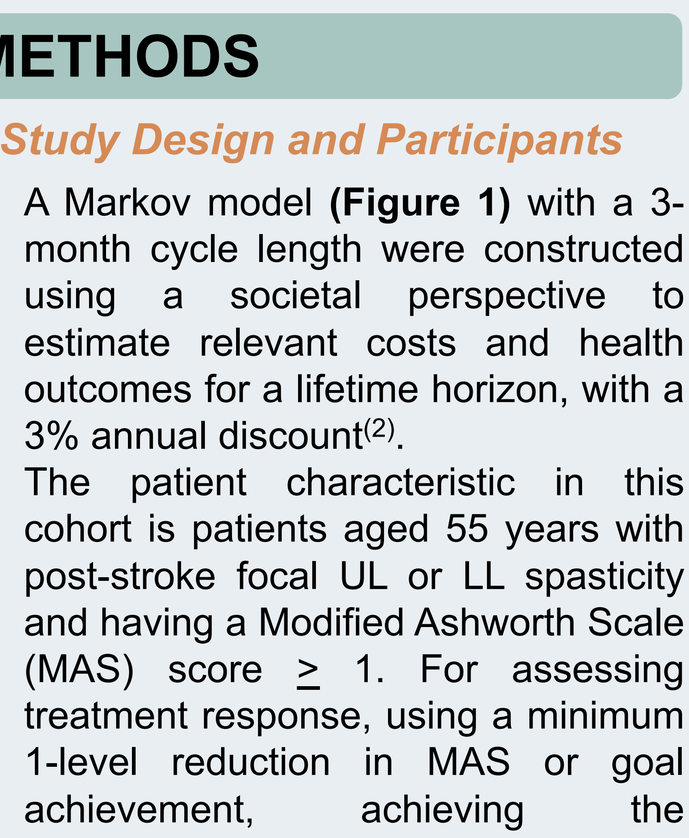

Figure 1. A Markov Model

Treatment Options

- Abobotulinum toxin A (Abo), Onabotulinum toxin A (Ona), or Prabobotulinum toxin A (Pra) combined with SoC were compared to the SoC alone.

Model Inputs

- Direct medical cost was determined using a generalized linear model based on a five-year retrospective treatment cost from a tertiary hospital.
- Data on direct non-medical cost, utility, and transitional probabilities were primarily obtained from three tertiary hospitals.
- A network meta-analysis was employed to estimate the treatment efficacy in terms of its impact on reducing MAS score by ≥ 1 grade *or* achieving the designated goal.

Analyses

- Lifetime cost, quality-adjusted life years (QALYs) and an incremental cost-effectiveness ratio (ICER) were calculated and compared to the cost-effectiveness threshold of 160,000 THB (US $4,597, where 1 USD = 34.81 THB in 2023) per QALY gained (2).
- The robustness of the findings was assessed using deterministic and probabilistic sensitivity analyses.

RESULTS

- The combination of Abo and SoC yielded the highest QALYs gained in UL and LL spasticity (0.013 and 0.011), followed by Ona (0.010 and 0.006) and Pra (0.008 in UL), respectively. The additional costs for treating UL and LL were highest for Ona (2,683 THB and 3,407 THB), followed by Abo and Pra. The ICER for treating UL with Abo, Ona, and Pra ranged from 167,211 to 270,079 THB per QALY. For LL treatment, Abo and Ona had an ICER ranging from 253,274 to 543,746 THB per QALY **(Table 1)**.

Sensitivity Analyses

- The PSA demonstrated that no BoNT-A had a chance of being cost-effective at the ceiling threshold. The Abo was more likely to be cost-effective if the ceiling threshold were set higher than 400,000 THB/QALY gained for UL **(Figure 2A)** and 300,000 THB/QALY gained for LL **(Figure 2B)**.
- The one-way sensitivity results were sensitive to the responder's utility.

Table 1. Lifetime cost, quality-adjusted life year (QALY) and incremental cost-effectiveness ratio (ICER)

Base case [a]	Treatment options			
	SoC	Ona + SoC	Abo + SoC	Pra + SoC
Upper limb				
Lifetime costs (THB)[b]	76,612	79,295	78,754	78,344
QALYs[b]	3.356	3.367	3.370	3.364
Incremental costs		2,683	2,142	1,732
Incremental QALYs		0.010	0.013	0.008
ICER (THB/QALY gained)		**270,079**	**167,211**	**223,865**
Lower limb				
Lifetime costs (THB)[b]	76,612	80,019	79,270	
QALYs[b]	3.356	3.363	3.367	
Incremental costs		3,407	2,658	
Incremental QALYs		0.006	0.011	
ICER (THB/QALY gained)		**543,746**	**253,274**	

[a]Base case patient aged 55 years with 1-year stroke duration and the average values were obtained using a probabilistic model with 5,000 iterations.
[b]Cost and outcomes are discounted by 3% annually.

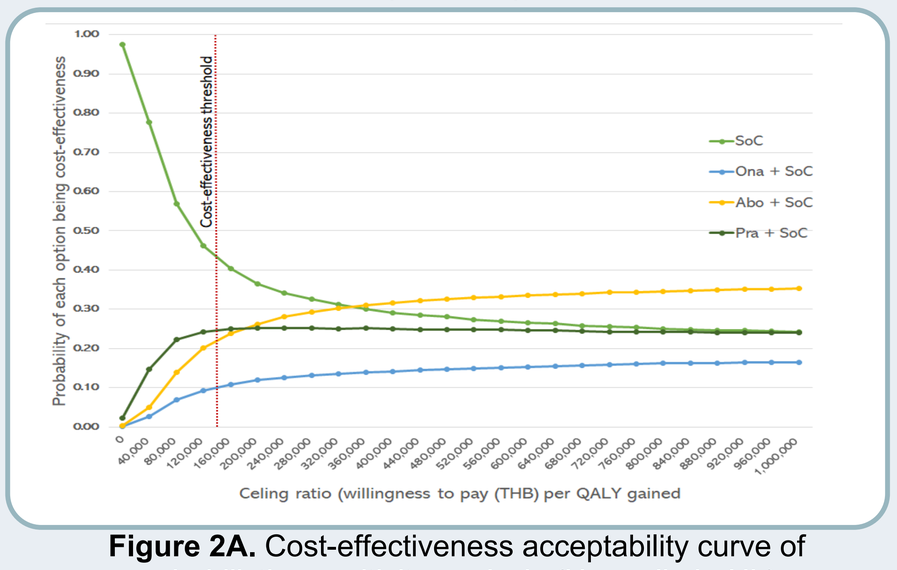

Figure 2A. Cost-effectiveness acceptability curve of probabilistic sensitivity analysis (Upper limb: UL).

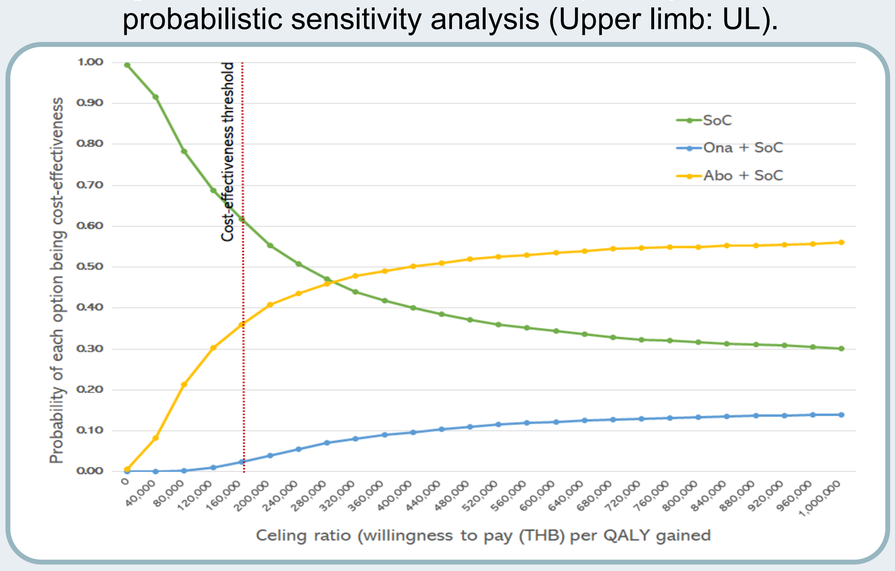

Figure 2B. Cost-effectiveness acceptability curve of probabilistic sensitivity analysis (Lower limb: LL).

CONCLUSIONS

Combining BoNT-A with SoC effectively decreased spasticity and improved quality of life in PS patients, but its cost-effectiveness in Thailand necessitates price negotiations for inclusion in the pharmaceutical reimbursement list.

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