Modelling the Cost Effectiveness and budget impact of Uterine botulinum toxin injections versus (EE707) conventional treatment in severe dysmenorrhoea: A France Perspective

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Background

Dysmenorrhea is all pelvic pain preceding or accompanying menstruation. Primary dysmenorrhea affects 60-91% of women, 16-29% of whom have a very severe form of dysmenorrhea[1]. Several longitudinal studies of young dysmenorrheic women have found that absenteeism rates range from 34% to 50% and that 10% to 30% of all working and student dysmenorrheic women lose one to two working days per month[2]. This represents an economic burden for the community[3] and an annual loss of 600 million work hours, or approximately $2 billion per year in the United States[4]. Faced with persistent pelvic pain, which considerably degrades the quality of life of patients. An innovative treatment, botulinum toxin (BoNT), is used in the Women's Health Research Center (CRSF) BoNT in addition to CT in the management of dysmenorrhea of uterine origin related to uterine hypercontractility[5]. Many studies have shown a significant improvement in pelvic pain and quality of life after receiving uterine injections of BoNT[6]. Beyond these promising results observed in patients with CT failure, this innovative treatment (BoNT) is costly, not reimbursed by the French Health Insurance (HI).

Study Objective

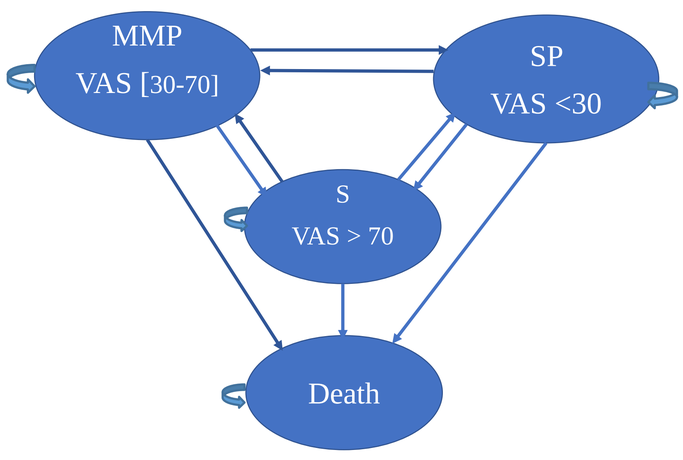
To assess the efficiency and budgetary impact of the combination of BoNT + CT (hormonal treatments + analgesics) compared with CT alone, in the severe dysmenorrhoea, from the French HI's perspective using a Markov model.

Methods

• We developed a Markov-type analytical decision model (fig 1) built and analysed with Microsoft Excel 2017, to assess efficiency of BoNT

• We defined four health states in the model to represent the evolution of the pathology. when: - VAS score < 30, pain is considered severe (SP); - VAS score between [30-70] pain is considered mild to moderate (MMP); -VAS score > 70 treatment is considered successful (S)- Death

Figure 1. Model structure



• Perspective: French HI ; The duration of the cycle was set at 6 months Total time Horizon of this study is 10 years

• We estimated transition probabilities between the main health states, costs and QALYs for each health state in the two groups BoNT + CT and CT alone by the data from patients in the cohort.

• Patients accrue costs and quality-adjusted life years (QALYs) at each passage in one health state until they die or the end of time horizon

• The average costs and efficiencies of the two groups were used to calculate ICER (ratio of the difference in average costs and the difference in average QALYs between the groups)

budgetary impact analysis results from the difference in expenditure between the different treatment scenarios (with and without BoNT), over a Time Horizon of five consecutive years

• Expenditure in each scenario was equal to the number of patients per year, multiplied by the average cost of each treatment

• Benefice Net was equal to the difference in expenditure per year between the two scenarios.

Results: Cost Utility

Table 1: Cost-utility analyses results at 1, 5 and 10 years.

Treatment	Mean Cost (€)	Mean (QALYs)	ICER (cost/ QALY gained)
1 Year (Base case)			
CT	3055,20	1,23	
BoNT + CT	1895,65	2,03	
Incremental	-1159,55	0,80	-1651,50
5 Years			
CT	10978,86	4,45	
BoNT + CT	7068,04	7,76	
Incremental	-1159,55	0,80	-1486,63
10 Years			
CT	18698,29	7,59	
BoNT + CT	12132,52	13,53	
Incremental	-6565,78	5,94	-1314,46

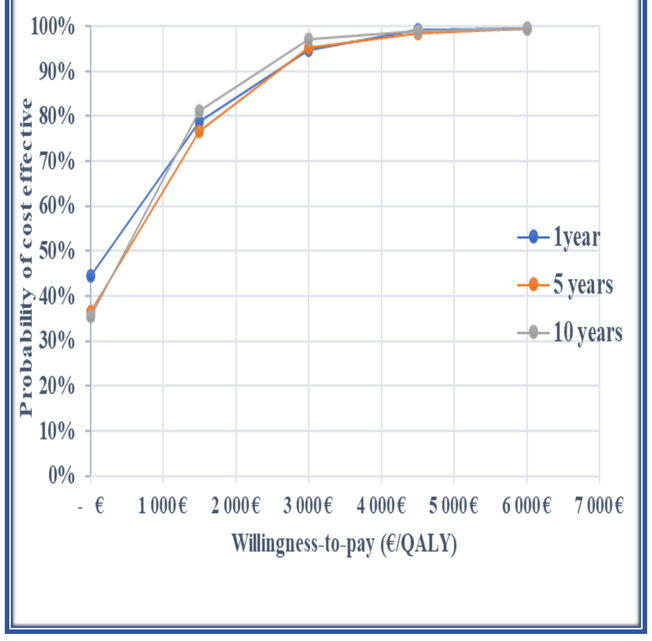
- Analyse at 1, 5 and 10 years show that the ICER for (BoNT + CT) below the efficiency threshold of €30,000/QALY
- (BoNT + CT) is associated with a reduction in pain and the consumption of care
- (BoNT + CT) is the most effective and economically dominant option whatever the Time Horizon

Results: Sensitivity Analyse

Table 2: Sensitivity analyses scenario

Scenario	ICER	Statut
Time horizon increased to:		
5 years	-1486,63€	Dominant
10 years	-1314,46€	Dominant
Discount rate increased to:		
Costs and effects discounted at 2,5 %	-1246,38€	Dominant
Costs and effects discounted at 6 %	-1249,57€	Dominant
GHS tarif increased to:		
10%	-1117,1€	Dominant
20%	-871,2 €	Dominant
30%	-684,7 €	Dominant

Fig 2 Cost effectiveness acceptability curve



- 95% of the model iterations favor the BoNT + CT strategy at a WTP of 3000 € /QALY

Results: Budget Impact

Fig 2 Potential budget Impact

Net impact varied from €98,091,098 to 112419, difference of € 14,328,79 over the 5-year for the administration of a 200 U dose of BoNT

Conclusions

• We found that a BoNT +CT strategy is cost-effective, is less expensive and more efficacy

• These results are explained by the fact that, in patients dysmenorrheic, BoNT can effectively reduce the pain and Improvement of QOL

• These results are consistent with our previous RWE study that used different data sources for capturing Improvement of QOL and reduction of health care consumption.

References

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