COST-EFFECTIVENESS OF BUDESONIDE IN MICROSCOPIC COLITIS PATIENTS IN THE CZECH REPUBLIC

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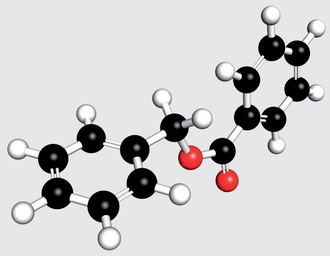

Objectives

Budesonide is an anti-inflammatory drug (corticosteroid hormone) and is an effective treatment of microscopic colitis. It increases probability of achieving short-term clinical remission as well as maintaining long-term remission, according to recent clinical evidence. There is no reimbursed treatment for patients in the Czech Republic. The aim of the analysis was to compare costs and effectiveness of budesonide in comparison with placebo in adult patients with microscopic colitis. The analysis was conducted from the perspective of the public healthcare payer in the Czech Republic.

Methods

Health-economic model

To assess the cost-utility of Budesonide, a Markov model was developed. The analysis was focused on adult patients with active and histologically proven microscopic colitis (either collagenous or lymphocytic) to initiate and maintain clinical remission.
Budesonide was compared to placebo as there is none currently reimbursed alternative in the Czech Republic. Primary endpoint of the analysis was incremental cost-effectiveness ratio (ICER) measured in terms of costs per quality-adjusted life year (QALY). All costs and outcomes were discounted at 3 % as required by national authority in the Czech Republic.
A Markov model was developed in Microsoft Excel using an eight-week cycle length with the following structure of health states:

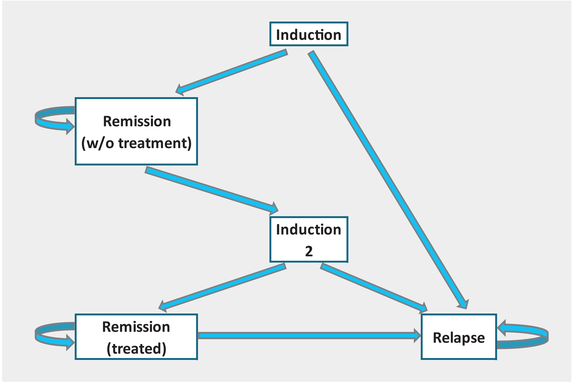

Figure 1: HE model - health states

Efficacy

Transition probabilities between the individual states are modelled based on relevant clinical data. Induction of remission probability is derived from network meta-analysis [1] merging 5 clinical trials that examined efficacy and safety of budesonide in patients with active microscopic colitis. Probability of maintaining the remission is adopted from [2] – clinical trial aimed on outcomes of long-term budesonide therapy for maintenance of clinical remission. Difference in probability of maintaining remission for the first cycle and all subsequent cycles is assumed.
Mortality is assumed equal to general population as increased risk of death for microscopic colitis patients was not proven in clinical trials.
Transition probabilities for one 8-week cycle are shown separately for budesonide and placebo in transition matrices below:

Budesonide	Induction	Remission w/o treatment (1)	Remission w/o treatment (2+)	Induction 2	Remission treated (1)	Remission treated (2+)	Relapse
Induction	0.00	0.80	0.00	0.00	0.00	0.00	0.20
Remission w/o treatment (1)	0.00	0.00	0.39	0.61	0.00	0.00	0.00
Remission w/o treatment (2+)	0.00	0.00	0.95	0.05	0.00	0.00	0.00
Induction 2	0.00	0.00	0.00	0.00	0.80	0.00	0.20
Remission treated (1)	0.00	0.00	0.00	0.00	0.00	0.78	0.22
Remission treated (2+)	0.00	0.00	0.00	0.00	0.00	0.97	0.03
Relapse	0.00	0.00	0.00	0.00	0.00	0.00	1.00

Table 1: Transition probabilities (budesonide)

Placebo	Induction	Remission w/o treatment (1)	Remission w/o treatment (2+)	Induction 2	Remission treated (1)	Remission treated (2+)	Relapse
Induction	0.00	0.26	0.00	0.00	0.00	0.00	0.74
Remission w/o treatment (1)	0.00	0.00	0.39	0.61	0.00	0.00	0.00
Remission w/o treatment (2+)	0.00	0.00	0.95	0.05	0.00	0.00	0.00
Induction 2	0.00	0.00	0.00	0.00	0.26	0.00	0.74
Remission treated (1)	0.00	0.00	0.00	0.00	0.00	0.39	0.61
Remission treated (2+)	0.00	0.00	0.00	0.00	0.00	0.95	0.05
Relapse	0.00	0.00	0.00	0.00	0.00	0.00	1.00

Table 2: Transition probabilities (placebo)

Quality of life

Utilities are based on publication [3] that documented a change in the quality of life in patients after six weeks of induction budesonide treatment versus placebo. Quality of life was measured using the GIQLI index.

GIQLI		Budesonide	LB (95% CI)	UB (95% CI)
Total score	Begining	67	32	102
	End	92	47	137
Symptoms	Begining	36	24	48
	End	51	36	66
Emotional functioning	Begining	10	5.5	14.5
	End	14.6	9.8	19.4
Physical functioning	Begining	16.5	12	22
	End	21.1	14.8	27.4
Social functioning	Begining	15.3	12.8	17.8
	End	16.5	13.7	19.3

Table 3: GIQLI

GIQLI values were subsequently mapped to standardized SF-6D using algorithm proposed in [4]. This approach leads to utilities 0.67 for patient with active disease and 0.77 for patient in clinical remission.

Costs

All costs relevant from health care payer are included. Drug costs, management costs, and adverse events costs specific for the Czech healthcare system are assumed as following (March 2018) [1] [2]:

	Daily dose	Drug cost per day	Drug cost per cycle
Budesonid (induction)	9 mg	2.95 EUR	165.01 EUR
Budesonide (maintenance)	6 mg	1.96 EUR	110.00 EUR
Placebo	-	0.00 EUR	0.00 EUR

Table 4: Drug costs

Study drug costs of budesonide per induction/maintenance 8-week cycle are 165 EUR and 110 EUR respectively versus zero study drug costs in comparator arm (placebo).
Management costs reach 9.9 EUR per cycle in patient with active disease and 1.4 EUR per cycle for patient in remission. Costs related to adverse events are negligible in both arms (0.35 EUR per cycle in budesonide arm vs. 0.27 EUR per cycle in comparator arm).

Results

In the base case scenario, the incremental cost-effectiveness ratio (ICER) of budesonide compared to placebo reached 7 591 EUR/QALY. QALYs gained on treatment were 0.98 whereas patients on placebo gained only 0.92 over 1.5 year time horizon. Presented ICER lies well below willingness to pay threshold (47 000 EUR/QALY) and therefore budesonide is highly cost-effective intervention.
The probabilistic sensitivity analysis showed that 88 % of iterations are located below the willingness to pay threshold.

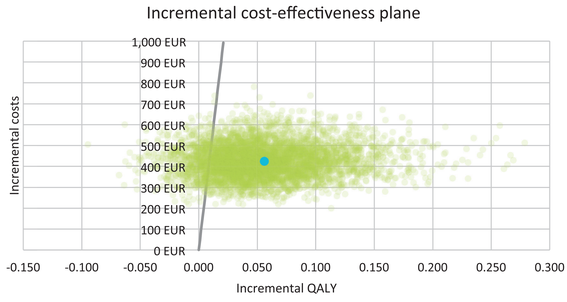

Figure 2: Cost-effectiveness plane

Conclusion

Based on the results of recent clinical evidence budesonide provides substantial benefit for microscopic colitis patients. Results indicate budesonide treatment is also highly cost-effective with ICER well below willingness to pay threshold in the Czech Republic.

References

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