

The cost-effectiveness and budget impact of itopride hydrochloride for the treatment of functional dyspepsia in Vietnam

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Background

Functional dyspepsia (FD) is characterised by epigastric pain and burning with a significant negative impact on quality-of-life and productivity. In Asia, the prevalence of FD ranges from 8-23% (Inclusive of China, Japan, Korea, India and Taiwan) [1]. Prokinetic agents are widely used to treat FD in many Asian countries such as Vietnam. However, little is known with respect to cost-effectiveness and budget impact of these drugs as they are not approved for this indication in much of the Western world.

Itopride hydrochloride is a prokinetic agent which works through stimulating the gastrointestinal smooth muscles thereby promoting gastric emptying and has been shown to significantly improve symptoms in patients with FD. Clinical trial data has demonstrated that itopride hydrochloride is superior in terms of response rate when compared to placebo (itopride=56.7% vs placebo=41.2%, p=0.01) [2]. No severe adverse events (grade 3 to 4) were reported. Itopride hydrochloride has been available in Vietnam for many years however the cost-effectiveness of the drug has not been established.

There are four levels of public hospitals in Vietnam Central level hospitals (level 1), Provincial level hospitals (level 2), District level hospitals (Level 3) and Commune health stations (level 4) [3]. Itopride is current reimbursed the only prokinetic reimbursed for the treatment of functional dyspepsia in a hospital setting in Vietnam.

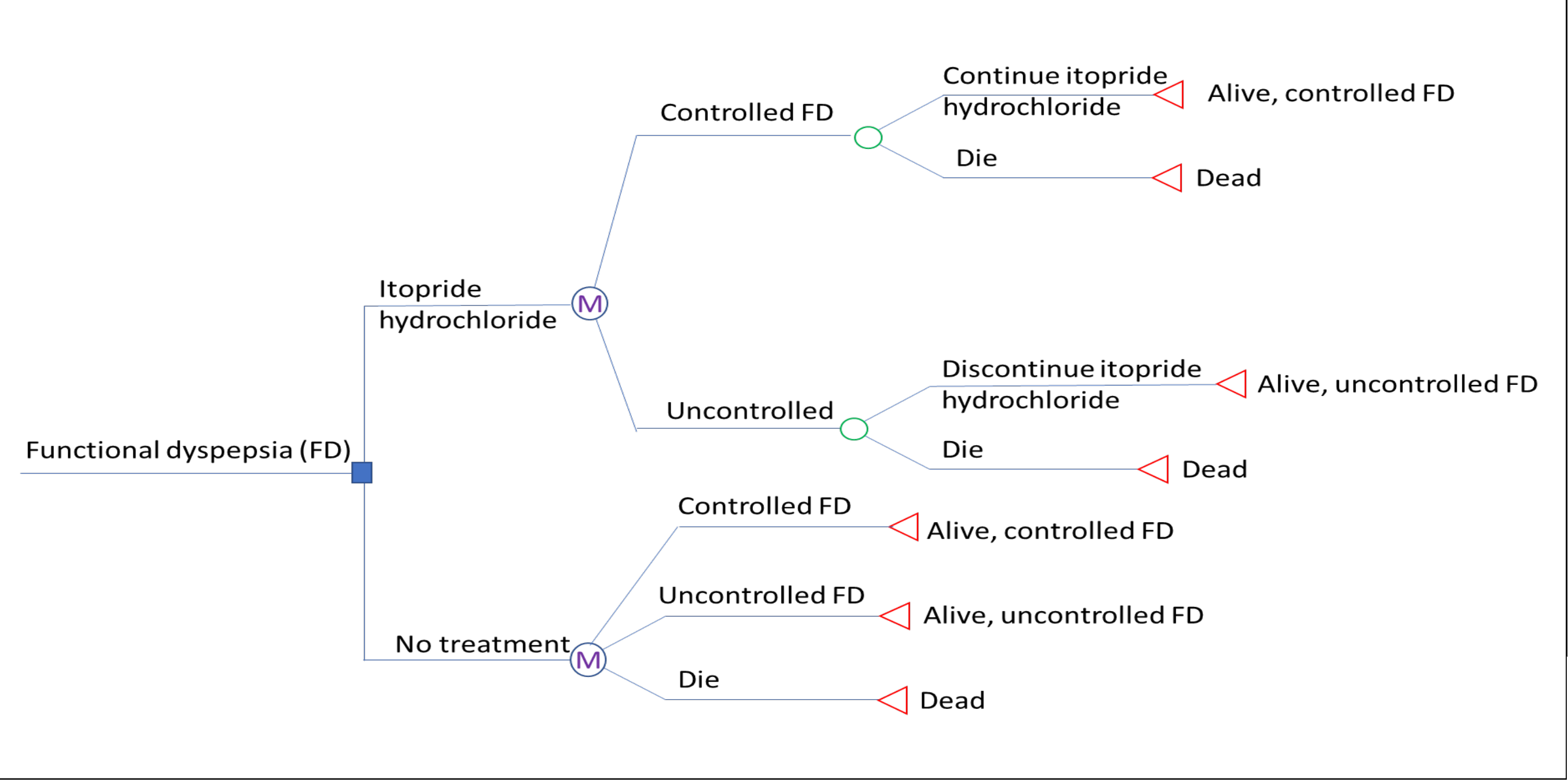
Objectives

This study sought to investigate the cost-effectiveness, uptake rate, and budget impact of reimbursing itopride in Vietnam for treatment naïve patients with newly diagnosed FD in level 3 and 4 hospitals.

Methods

For the Cost-effectiveness model: A 3-stage Markov model (health states: health states: controlled FD, uncontrolled FD, dead) with a 10-year time horizon using 8-week cycles was used to assess itopride versus no treatment (See figure 1).

Figure 1 Decision tree: health states



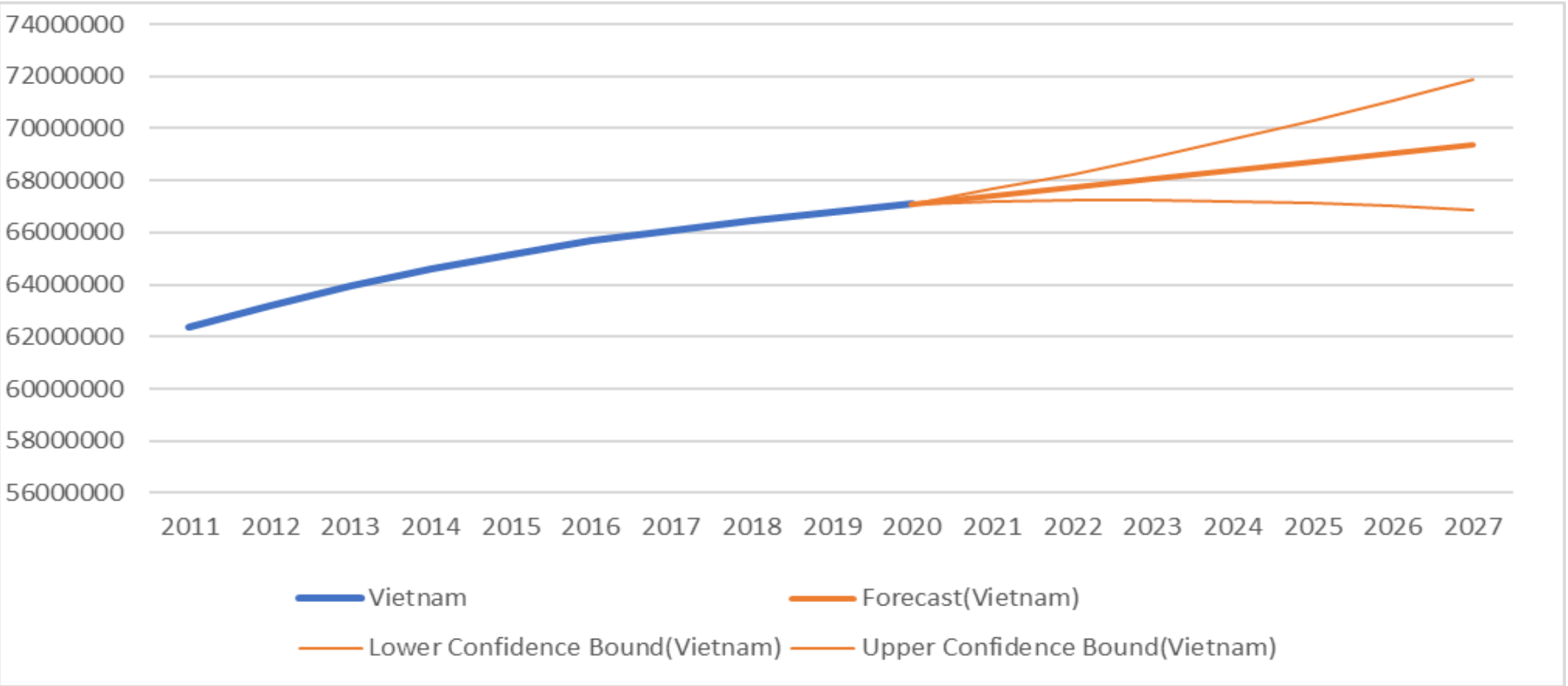
The cycle length was set to 8 weeks and the time horizon was ten years (65 cycles). Vietnamese specific costs and quality-of-life input were obtained from published sources and expert advice.

A broader Vietnamese societal perspective is taken in this cost-effectiveness analysis with a discount rate of 5%. Input was where possible retrieved from the literature. literature. Additionally, interviews with key opinion leaders with extensive experience in treating functional dyspepsia in Vietnam were performed as a supplement to the literature review.

For this analysis, a threshold of 3 x GDP (=approx. VND140.1M) per capita in Vietnam per QALY was used. One-way sensitivity analyses were performed by varying the input variables with +/- 10% and probabilistic sensitivity analysis were performed to assess the impact of uncertainty of the input variables on the cost-effectiveness.

For the Budget Impact Model: A budget impact model was developed in Microsoft Excel in accordance with the ISPOR good practice guidelines. Population estimates (see figure 2) and uptake rates were ascertained through prevalence data available in the literature, estimates of diagnosed vs undiagnosed patients, and patient spread between different level hospitals. The budget impact was examined over 5-years by capturing treatment costs, health resource utilisation, societal costs and savings from funding itopride for patients in the target population.

Figure 2 - BIM Model flow



The baseline study population included in the model was from prevalence data reported in the Talley et al 2008 study on FD and was estimated to be 10,162,675. The number of patients who will receive prokinetic treatment is based on the assumption that 55% will be diagnosed, and of that 30% of those who are diagnosed with FD and who will go on to seek treatment. The number of patients with FD who could go on to access prokinetic treatment at Level 3 + 4 hospitals is 20% of the prokinetic treatment patient population. This figure was extrapolated from Vietnam population estimates inclusive natural mortality and population growth.

Results

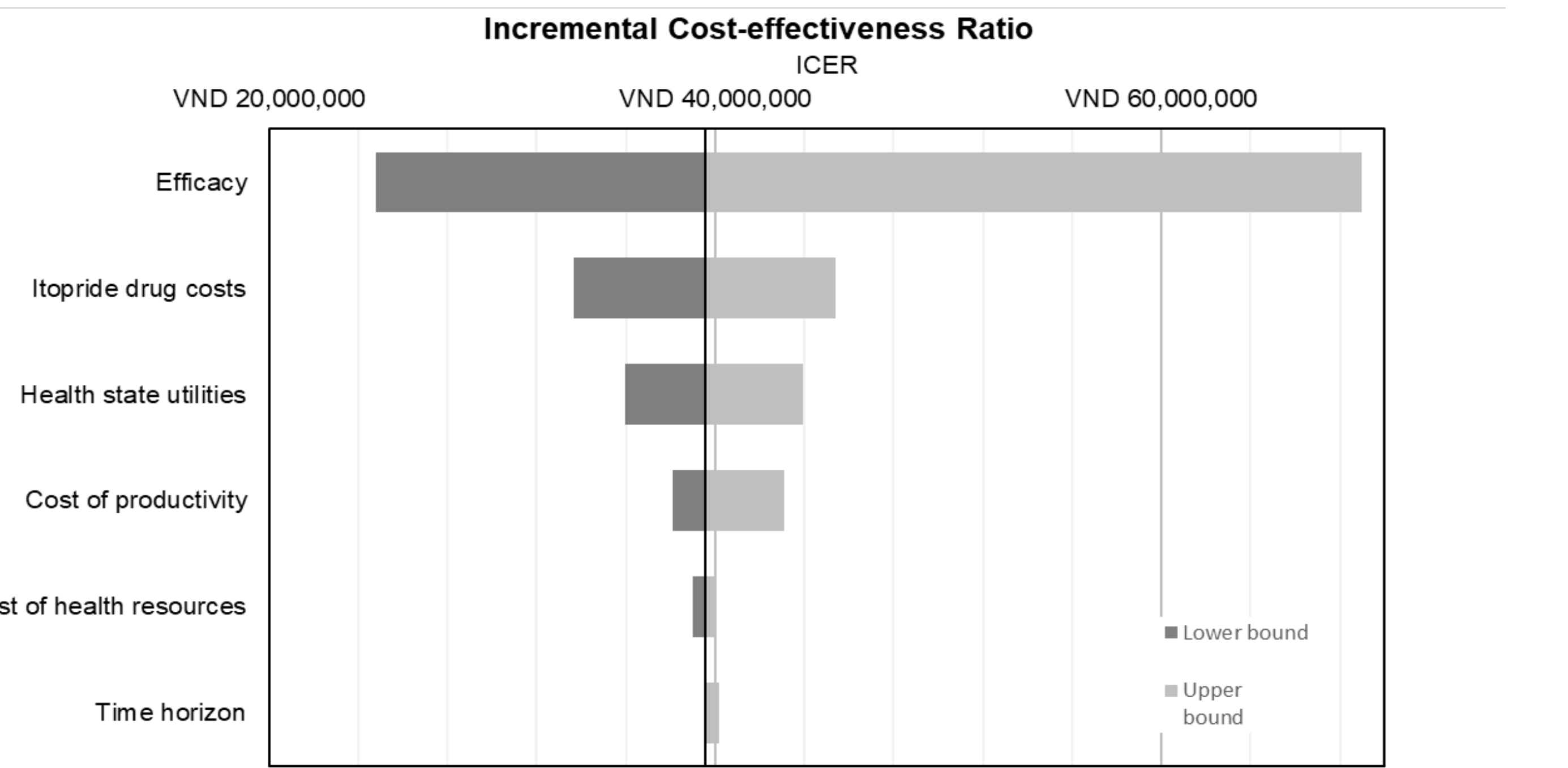
CEA results: The incremental cost effectiveness ratio (ICER) per life-year gained for itopride vs current standard of care was VND32.2M. The ICER per quality-adjusted-life-year (QALY) was estimated to be VND49.8M.

Table 1 – CEA Results

	QALY	Costs	ICER
Base case	0.65	VND 32.2M	VND 49.77M
Without productivity	0.65	VND 41.4M	VND 63.5M
Without healthcare costs	0.65	VND 34.9M	VND 52.4M
Discount rate 3%	0.71	VND 35.2M	VND 49.76M
5-year time horizon	0.38	VND 18.8M	VND49.82M

The time horizon and cost of health resources had the least influence on the ICER as varying the time horizon with +/- 2 years resulted in an ICER from VND 39.63M to VND 40.19M and varying the cost of the health resources +/-10% resulted in an ICER between VND 39,01M to VND 40,19M (see Figure 3).

Figure 3 – One-way sensitivity analyses.



More than 80% of the simulations in the probabilistic sensitivity analysis were cost-effective at the 1xGDP (VND64.1M) threshold. Over 5 years, the health care spending was increased by 2.3% from VND1.80T to VND1.84T with an estimated increase of 13.7% patients being treated for FD.

BIM results:

Presented are 4 scenarios 1) Current scenario: itopride not reimbursed for level 3+4 hospitals; 2) Alternative scenario 1: itopride reimbursed for level 3+4 hospitals and a flat market uptake; 3) Alternative scenario 2: itopride reimbursed for level 3+4 hospitals and a somewhat liberal market uptake; 4) Alternative scenario 3: itopride reimbursed for level 3+4 hospitals and high/increasing market uptake.

The financial implications takes into account both drug costs and costs/savings to the healthcare system. Budget impact of each alternative scenario can be found in table 2. The net costs are estimated to be between VND 363,836M (Alternative scenario 1) and VND 365,034M (Alternative scenario 3) in 2023, gradually growing to VND 371,351M (Alternative scenario 1) and VND 385,163M (Alternative scenario 3) in 2027.

Table 2 - BIM results from 3 scenarios

	2022	2023	2024	2025	2026	2027	Total 5 years (2023-2027)
Current scenario							
Patients treated with itopride	151,931	152,656	153,380	154,104	154,829	155,553	770,521
Costs (VND)	354,357M	356,046M	357,736M	359,425M	361,114M	362,804M	1,797,125M
Alternative scenario 1							
Patients treated with itopride	170,091	172,422	174,768	175,593	176,418	177,244	876,444
Costs (VND)	361,513M	363,836M	366,164M	367,893M	369,623M	371,352M	1,838,868M
Alternative scenario 2							
Patients treated with itopride	170,091	172,422	176,295	184,802	193,382	195,836	922,737
Costs (VND)	361,513M	363,836M	366,766M	371,523M	376,308M	378,679M	1,857,111M
Increase in spending	7,156M	7,789M	9,031M	12,098M	15,193M	15,875M	59,986M
Alternative scenario 3							
Patients treated with itopride	170,091	175,463	182,024	190,079	200,008	212,291	959,865
Costs (VND)	361,513M	365,034M	369,024M	373,602M	378,919M	385,163M	1,871,743M

Conclusion

This study shows that itopride hydrochloride is a very cost-effective treatment for functional dyspepsia in Vietnam with the ICER (VND49.8M/QALY). More than 91.3% of the simulations in the probabilistic sensitivity analysis were cost-effective at the 3xGDP VND192.2M) threshold.

Furthermore, the broadening of the reimbursement of itopride to include level 3+4 hospitals would be cost-effective, and provide benefit for between 13.7% (105,923) to 24.6% (89,343) more patients at only 3.3% (VND 41,742M) to 4.2% (VND 74,617M) additional costs over five years. As such itopride is deemed to represent great benefit for patients suffering from functional dyspepsia in Vietnam.

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