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ORIGINAL RESEARCH

Budget Impact and Cost–Benefit Analyses of Sodium-Glucose Cotransporter-2 Inhibitors for Patients With Heart Failure in Thailand

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Purpose: To assess the budget impact and cost–benefit of incorporating sodium-glucose cotransporter-2 inhibitors (SGLT-2i) into the benefit package for patients with heart failure (HF) under the universal health coverage (UHC) in Thailand.

Patients and Methods: A budget impact analysis and cost–benefit model were developed using a five-year time horizon from the payer perspective. Dapagliflozin 10 mg daily or Empagliflozin 10 mg daily was considered as an additional treatment to standard of care (SoC) for patients with HF, under the UHC. Two analytical frameworks were applied: (1) only medicine cost and (2) medicine cost and cost of hospitalization for HF (HHF) and urinary tract infection (UTI) admission as the adverse event of SGLT-2i. The net budget impacts (NBI) were calculated along with the HHF cost reduction and benefit–cost ratio.

Results: The NBI in the first year in only medicine cost for dapagliflozin was 12,535 million Thai baht (THB) and that for empagliflozin was 13,265 million THB. The NBIs, when considering HHF and UTI admission costs, were 7661 and 7407 million THB in the first year. The prices of dapagliflozin and empagliflozin should be reduced by 57.13% and 52.07% to reach a budget impact of 500 million THB. The benefit–cost ratio was 0.396 for dapagliflozin and 0.456 for empagliflozin.

Conclusion: Incorporating SGLT-2i into the UHC would significantly impact the healthcare budget. Policymakers should consider this valuable evidence.

Keywords: budget impact, heart failure, reimbursement, sodium-glucose cotransporter-2 inhibitors, cost–benefit analysis

Introduction

Heart failure (HF) is a significant global health burden. The global prevalence of HF was approximately 1–3% among general adults or 64 million people worldwide. The 5-year mortality was 50–75% among patients with HF. There are three phenotypes of HF, including 1) heart failure with reduced ejection fraction (HFrEF), 2) heart failure with preserved ejection fraction (HFpEF), and 3) heart failure with mildly reduced ejection fraction (HFmrEF). Approximately, 60% of HF patients were HFrEF, 24% as HFmrEF, and 16% as HFpEF.[1]

The 2021 European Society of Cardiology (ESC) clinical treatment guideline[2,3] recommends the use of four main medication classes for HFrEF and HFmrEF, including beta-blockers, renin-angiotensin-aldosterone system (RAAS)

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blockers or angiotensin receptor/neprilysin inhibitors (ARNIs), mineralocorticoid receptor antagonists (MRAs), and sodium-glucose cotransporter-2 inhibitors (SGLT-2i). On the other hand, only SGLT-2i is recommended for HFpEF. Specifically, only dapagliflozin and empagliflozin for SGLT-2i are recommended for all phenotypes of HF.

Even though dapagliflozin and empagliflozin show their clinical benefits among patients with all phenotypes of HF, accessibility to the medications is still an issue, especially in low- and middle-income countries (LMICs) due to their current prices. Treatment of HF should be more emphasized in LMICs because evidence indicated that the mortality rate of HF among patients in LMICs is higher and more likely to fail to be prescribed guideline-directed medical therapy.[4,5] In Thailand, dapagliflozin and empagliflozin are currently not listed in the Thailand National List of Essential Medicines (NLEMs), resulting in limited access to the medicines to only patients who are under the Civil Servant Medical Benefits Scheme (CSMBS), which medicines could be reimbursed to the Thai government or patients who paid out-of-pocket. Recently, cost-effectiveness studies in Thailand have revealed that both dapagliflozin and empagliflozin were cost-effective for patients with HFrEF but not for patients with HFpEF or HFmrEF.[6,7] However, evidence on the budget impact and cost benefit of the medications in Thailand still needs to be included, which could lead to delayed decisions on whether dapagliflozin and empagliflozin could be reimbursed. Therefore, this study aimed to assess the budget impact and cost benefit of incorporating dapagliflozin and empagliflozin to be reimbursed for patients with HF under the universal health coverage (UHC) in Thailand.

Materials and Methods

Overall Description and Model Assumptions

A budget impact analysis (BIA) and cost–benefit analysis (CBA) model were conducted to estimate the financial consequence of incorporating SGLT-2i into the NLEMs for patients with HF over a five-year time horizon under the payer perspective. This study was approved by the Ethics Committee of the Faculty of Pharmacy, Chiang Mai University (006–2567-E).

The interventions of interest were dapagliflozin 10 mg once daily and empagliflozin 10 mg once daily as additional treatments to the current standard of care (SoC), which were beta-blockers, MRAs, and RAAS blockers/ARNIs. We adopted a comparative budget impact framework for the International Society of Pharmacoeconomics and Outcomes Research (ISPOR).[8,9]

Several assumptions were made about the budget impact and cost–benefit analysis model. First, dapagliflozin and empagliflozin could be used as an additional treatment to SoC, not as a replacement for the current SoC. This assumption was in line with the current clinical practice guidelines, which recommend using dapagliflozin or empagliflozin as one main class for patients with any phenotypes of HF. Second, we applied the "choose-one" policy, meaning that either dapagliflozin or empagliflozin could be selected to be listed in the NLEMs. This assumption was based on the actual health technology assessment practice in Thailand, where healthcare policymakers usually decide to list one medication of a medication class to be listed for reimbursement. Third, the costs of SoC among patients receiving and not receiving the SGLT-2i were assumed to be the same. Last, the effects of SGLT-2i on hospitalization for HF (HHF) and adverse drug events as urinary tract infection (UTI) were considered for cost–benefit analysis. This assumption was made based on cardiologists' recommendations to reflect the most important clinical factors for both the efficacy and safety of SGLT-2i.

Inputs

A pragmatic literature review was performed to determine inputs for the budget impact and cost–benefit analyses. During the review process for data selection, we considered studies from Thai context when available. However, if there is no Thai study, data from Asia or international countries could be considered hierarchically. The clinical efficacy of dapagliflozin and empagliflozin was derived from the landmark studies.[10–13]

Epidemiological Data

The total population in Thailand was derived from the 2023 Thai Public Health Statistical Report, which is approximately 71.8 million people,[14] while the prevalence of patients with HF in Thailand was 2.0%,[15] resulting in the number of

current HF patients was 1.44 million people. In addition, the annual incidence rate of HF in Thailand was about 332 cases per 100,000 population,[16] resulting in the estimated number of new cases of HF being 237,715 cases annually. The proportion of patients with HFrEF was 40.0%.[17] Because this study aimed to estimate the budget impact and cost–benefit analysis for patients under the UHC, the estimated 70% of patients who were under the UHC was applied. The annual death rate of patients with HF was derived from a previous Thai study.[18] In addition, the 100% uptake rate was assumed to reflect the maximum budget impact and cost–benefit of the medicines among patients with HF under the UHC. The details of the epidemiological inputs are presented in Table 1.

Clinical Efficacy and Adverse Events

The clinical efficacy of dapagliflozin on HHF, the number of UTI adverse events, and hazard ratios of cardiovascular death were derived from the DAPA-HF study[10] for HFrEF and the DELIVER study[11] for HFmrEF, and HFpEF. Similarly, those of empagliflozin were derived from the EMPEROR-reduced[12] for HFrEF, and the EMPEROR-preserved[13] for HFmrEF and HFpEF. The rate of cardiovascular death without the use of SGLT-2i was 17.7%,[18] while the annual rate of HHF without SGLT-2i was 19.0%.[19] The details of the clinical efficacy and adverse inputs are presented in Table 1.

Cost

Median purchasing prices of dapagliflozin and empagliflozin were retrieved from the Drug and Medical Supply Information Center (DMSIC), Ministry of Public Health.[20,21] The current median price of dapagliflozin 10 mg was

Table 1 Epidemiological, Clinical, and Cost Inputs

Inputs	Value	References
Total number of population	71,839,464	[14]
Prevalence of HF	2.0%	[15]
Incidence of HF	332 per 100,000 population	[16]
The proportion of patients with HFrEF	40.0%	[17]
Cardiovascular death without SGLT-2i	17.70%	[18]
The hazard ratio of cardiovascular death in patients with HFrEF receiving dapagliflozin	0.82	[10]
The hazard ratio of cardiovascular death in patients with HFmrEF and HFpEF receiving dapagliflozin	0.88	[11]
The hazard ratio of cardiovascular death in patients with HFrEF receiving empagliflozin	0.92	[12]
The hazard ratio of cardiovascular death in patients with HFmrEF and HFpEF receiving empagliflozin	0.91	[13]
The rate of non-cardiovascular death	7.13%	Age-specific Mortality Rate in Thailand
The rate of HF hospitalization without SGLT-2i	19.0%	[19]
The hazard ratio of HF hospitalization among patients with HFrEF receiving dapagliflozin	0.70 (0.59–0.83)	[10]
The hazard ratio of HF hospitalization among patients with HFmrEF and HFpEF receiving dapagliflozin	0.77 (0.67–0.89)	[11]
The hazard ratio of HF hospitalization among patients with HFrEF receiving empagliflozin	0.69 (0.59–0.81)	[12]
The hazard ratio of HF hospitalization among patients with HFmrEF and HFpEF receiving empagliflozin	0.71 (0.60–0.83)	[13]
The rate of UTI admission in dapagliflozin	0.465%	[10]
The rate of UTI admission in empagliflozin	1.020%	[12]
The current price of 10 mg dapagliflozin (Thai baht/tablet)	37.70	DMSIC [20]
The current price of 10 mg empagliflozin (Thai baht/tablet)	40.43	DMSIC [21]
Cost of HF hospitalization (Thai baht/hospitalization)	127,284	[22]
Cost of UTI admission (Thai baht/admission)	20,570	[6]

Abbreviations: THB, Thai baht; HF, heart failure; HFmrEF, heart failure with mildly reduced ejection fraction; HFpE, heart failure with preserved ejection fraction; HFrEF, heart failure with reduced ejection fraction; SGLT-2i, sodium-glucose cotransporter-2 inhibitors; SoC, standard of care; UTI, urinary tract infection.

37.70 Thai baht (THB) per tablet, while that of empagliflozin 10 mg was 40.43 THB per tablet. Given that both medicines were in oral form and self-administered, costs associated with medicine administration and potential medicine waste due to oversupply or non-adherence were assumed to be negligible and excluded from the analysis.

The cost of HHF was derived from a previous Thai study[22] which reported the cost of HHF as 127,284 THB per hospitalization. The cost of UTI admission was 20,570 THB per admission, derived from another Thai study.[6] The calculation of event costs involved multiplying the incidence of each event by its corresponding treatment cost. The details of the cost inputs are presented in Table 1.

Data Analysis

Budget Impact Analysis

Two analytical frameworks were used as base-case analyses to estimate the budget impact of the use of dapagliflozin or empagliflozin for patients with HF under UHC. Framework 1, only the medication cost was considered with the assumption of a 100% uptake rate. Framework 2, including the medication cost, HHF cost, and UTI admission cost, were considered with the assumption of a 100% uptake rate. The net budget impacts (NBI) were calculated using the following equation:

$$\text{NBI} = \text{Total cost of adding dapagliflozin (or empagliflozin) to SoC} - \text{Total cost of SoC}$$

Where total cost of adding dapagliflozin (or empagliflozin) to SoC consists of medication cost, HHF cost, and UTI admission cost occurred in SGLT-2i arm, while total cost of SoC consists of medication cost, HHF cost, and UTI admission cost occurred in SoC arm. Because the intervention was the addition of dapagliflozin (or empagliflozin) to SoC, the medication cost of SoC was assumed to be equal for both interventions and comparator.

NBI was calculated for all patients with HF, patients with HFrEF, and HFmrEF and HFpEF.

A series of sensitivity analyses was performed. First, we varied the assumption of a 100% uptake rate to 50%, 75%, and 90%, respectively. Second, we assumed the reduction of the medicine prices by 10%, 20%, and 30%. Last, a threshold analysis was performed to determine the reduced prices for the budget impact of 500 million THB.

Cost–Benefit Analysis

The cost–benefit analysis was also performed. HHF cost for patients treated with the SGLT-2i in addition to SoC was calculated as well as the HHF cost for patients treated with SoC. The monetary benefit of the SGLT-2i was defined as the cost-savings from HHF, which were calculated by the differences of HHF cost among patients treated with dapagliflozin or empagliflozin and SoC. The medication cost of the SGLT-2i was also calculated. The benefit–cost ratio was calculated by dividing the cost-saving from HHF with the medication cost.

Results

Budget Impact Analysis

Framework 1: Only the Medication Cost Was Considered

According to the assumptions that 70% of patients were under the UHC and a 100% uptake, the estimated number of the target population for SoC was 881,108 patients in Year 1, while the numbers for dapagliflozin and empagliflozin were 910,983 and 898,950 in Year 1, respectively (Figure 1). The overall estimated numbers of target patients are presented in Table 2.

According to the assumption that the cost of SoC was the same among interventions, the budget impact was solely from the estimated total budget for each medicine. The NBI of dapagliflozin for all patients with HF was 12,535 million THB in Year 1, while that of empagliflozin was 13,265 million THB. The details of NBI for each analysis are presented in Table 2.

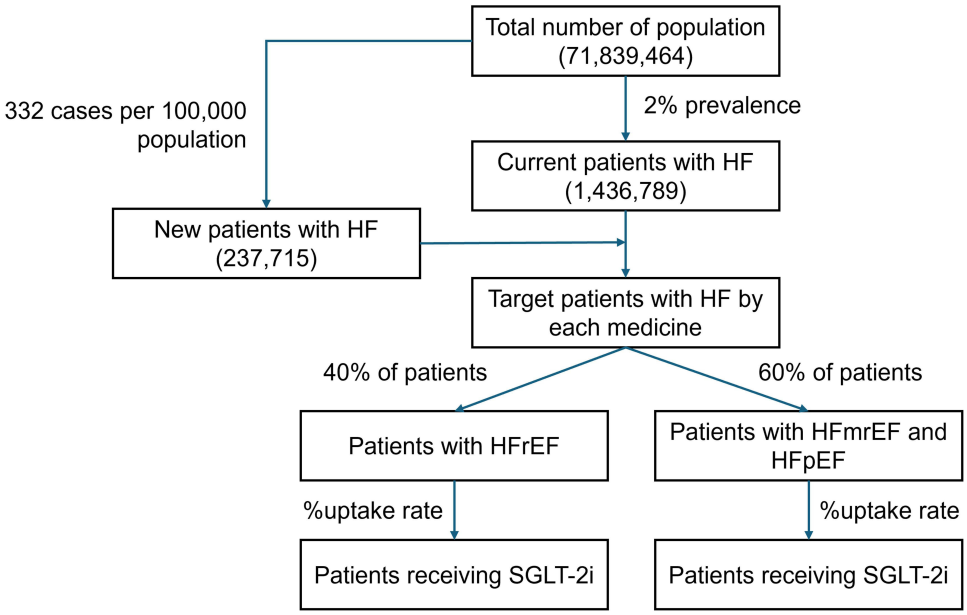

Figure 1 Budget Impact and Cost–Benefit Analyses Model.
Abbreviations: HF, heart failure; HFmrEF, heart failure with mildly reduced ejection fraction; HFpEF, heart failure with mildly preserved ejection fraction; HFrEF, heart failure with reduced ejection fraction; SGLT-2i; sodium-glucose cotransporter-2 inhibitors.

The budget impact of dapagliflozin for Year 1, when the %uptake varied to 50%, 75%, and 90%, was 6,165 million THB, 9,324 million THB, and 11,245 million THB, respectively. Those of empagliflozin were 6.567 million THB, 9,899 million THB, and 11,915 million THB, respectively.

When the price reductions were 10%, 20%, and 30%, the NBI of dapagliflozin in Year 1 were 11,282 million THB, 10,028 million THB, and 8,774 million THB, respectively. The NBIs of empagliflozin in Year 1 were 11,939 million THB, 10,612 million THB, and 9,286 million THB, respectively.

Framework 2: The Medication Cost, HHF Cost, and UTI Admission Cost Were Considered

The details of medication cost, HHF cost, and UTI admission cost are presented in Table 3. The NBI of dapagliflozin for all patients with HF was approximately 7,661 million THB for Year 1, while that for patients with HFrEF, and HFmrEF and HFpEF were 2,694 million THB and 4,967 million THB, respectively. The NBI of empagliflozin for all patients with

Table 2 Budget Impact Analysis (Framework 1: Base-Case)

Description	Year 1	Year 2	Year 3	Year 4	Year 5	Average
The estimated number of the target population						
Dapagliflozin	881,108	787,412	716,981	664,038	624,241	Not applicable
Empagliflozin	910,983	814,111	741,292	686,553	645,407	Not applicable
SoC	898,950	803,357	731,500	677,485	636,882	Not applicable
Net Budget Impact (THB)						
Dapagliflozin for all	12,535,586,387	11,202,571,007	10,200,543,347	9,447,319,154	8,881,120,529	10,453,428,085
Dapagliflozin for HFrEF	5,014,234,555	4,481,028,403	4,080,217,339	3,778,927,662	3,552,448,211	4,181,371,234
Dapagliflozin for HFmrEF and HFpEF	7,521,351,832	6,721,542,604	6,120,326,008	5,668,391,492	5,328,672,317	6,272,056,851
Empagliflozin for all	13,265,760,584	11,855,099,580	10,794,705,703	9,997,607,626	9,398,429,002	11,062,320,499
Empagliflozin for HFrEF	5,306,304,234	4,742,039,832	4,317,882,281	3,999,043,051	3,759,371,601	4,424,928,200
Empagliflozin for HFmrEF and HFpEF	7,959,456,350	7,113,059,748	6,476,823,422	5,998,564,576	5,639,057,401	6,637,392,299

Abbreviations: THB, Thai baht; HF, heart failure; HFmrEF, heart failure with mildly reduced ejection fraction; HFpEF, heart failure with preserved ejection fraction; HFrEF, heart failure with reduced ejection fraction; SoC, standard of care.

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Table 3 Budget Impact Analysis (Framework 2: Base-Case)

Description	Year 1	Year 2	Year 3	Year 4	Year 5	Average
Medication costs						
Dapagliflozin for HFrEF	5,014,234,555	4,481,028,403	4,080,217,339	3,778,927,662	3,552,448,211	4,181,371,234
Dapagliflozin for HFmrEF and HFpEF	7,521,351,832	6,721,542,604	6,120,326,008	5,668,391,492	5,328,672,317	6,272,056,851
Empagliflozin for HFrEF	5,306,304,234	4,742,039,832	4,317,882,281	3,999,043,051	3,759,371,601	4,424,928,200
Empagliflozin for HFmrEF and HFpEF	7,959,456,350	7,113,059,748	6,476,823,422	5,998,564,576	5,639,057,401	6,637,392,299
HHF costs						
Dapagliflozin for HFrEF	6,168,731,771	5,512,758,124	5,019,662,733	4,649,002,928	4,370,377,952	5,144,106,701
Dapagliflozin for HFmrEF and HFpEF	10,178,407,422	9,096,050,904	8,282,443,509	7,670,854,831	7,211,123,621	8,487,776,057
Empagliflozin for HFrEF	6,000,287,325	5,362,225,806	4,882,594,963	4,522,056,458	4,251,039,664	5,003,640,843
Empagliflozin for HFmrEF and HFpEF	9,261,313,045	8,276,478,962	7,536,179,182	6,979,695,837	6,561,387,307	7,723,010,867
SoC for HFrEF	8,523,467,519	7,617,094,818	6,935,774,459	6,423,625,945	6,038,643,907	7,107,721,330
SoC for HFmrEF and HFpEF	12,785,201,279	11,425,642,228	10,403,661,689	9,635,438,918	9,057,965,861	10,661,581,995
UTI admission costs						
UTI admission cost for dapagliflozin	87,047,383	77,790,895	70,832,794	65,602,388	61,670,693	72,588,831
UTI admission cost for empagliflozin	188,586,494	168,532,490	153,457,896	142,126,323	133,608,380	157,262,317
Net Budget Impact (THB)						
Dapagliflozin for HFrEF	7,661,104,164	6,846,433,884	6,234,046,234	5,773,714,438	5,427,683,027	6,388,596,349
Dapagliflozin for HFmrEF and HFpEF	2,694,317,759	2,407,808,066	2,192,438,730	2,030,545,600	1,908,850,534	2,246,792,138
Dapagliflozin for all HF	4,966,786,405	4,438,625,818	4,041,607,504	3,743,168,838	3,518,832,493	4,141,804,212
Empagliflozin for HFrEF	7,407,278,650	6,619,599,793	6,027,501,596	5,582,421,381	5,247,854,584	6,176,931,201
Empagliflozin for HFmrEF and HFpEF	2,858,558,637	2,554,583,816	2,326,085,943	2,154,324,092	2,025,210,709	2,383,752,640
Empagliflozin for all HF	4,548,720,013	4,065,015,977	3,701,415,653	3,428,097,289	3,222,643,875	3,793,178,561

Abbreviations: THB, Thai baht; HF, heart failure; HFmrEF, heart failure with mildly reduced ejection fraction; HFpEF, heart failure with preserved ejection fraction; HFrEF, heart failure with reduced ejection fraction; SoC, standard of care; UTI, urinary tract infection.

HF was approximately 7,407 million THB, while that for patients with HFrEF and HFmrEF and HFpEF were 2,858 million THB and 4,548 million THB, respectively (Table 3).

The budget impacts of dapagliflozin for Year 1, when the %uptake varied to 50%, 75%, and 90%, were 3,773 million THB, 5,703 million THB, and 6,874 million THB, respectively. Those of empagliflozin were 3,669 million THB, 5,529 million THB, and 6,654 million THB, respectively.

When the price reductions were 10%, 20%, and 30%, the NBI of dapagliflozin in Year 1 were 6,407 million THB, 5,153 million THB, and 3,900 million THB, respectively. The NBIs of empagliflozin in Year 1 were 6,080 million THB, 4,754 million THB, and 3,427 million THB, respectively.

The price reductions that could reduce the budget impact to below the ceiling of 500 million THB were 57.13% for dapagliflozin and 52.07% for empagliflozin (Figure 2).

Cost–Benefit Analysis

Cost-Saving From HHF

Based on the differences in HHF rate among SoC, dapagliflozin, and empagliflozin, the total HHF costs for patients with HFrEF receiving SoC in Year 1 was 8,523 million THB, while those for patients with HFrEF receiving dapagliflozin and empagliflozin were 6,168 million THB, and 6,000 million THB, respectively. These resulted in cost-savings of HHF costs among patients with HFrEF for dapagliflozin as 2,354 million THB and 2,523 million THB for empagliflozin. The HHF costs for patients with HFmrEF and HFpEF receiving SoC in Year 1 were 12,785 million THB. In comparison, those for patients receiving dapagliflozin and empagliflozin were 10,178 million THB and 9,261 million THB, respectively. These resulted in the cost saving of HHF among patients with HFmrEF and HFpEF for dapagliflozin,

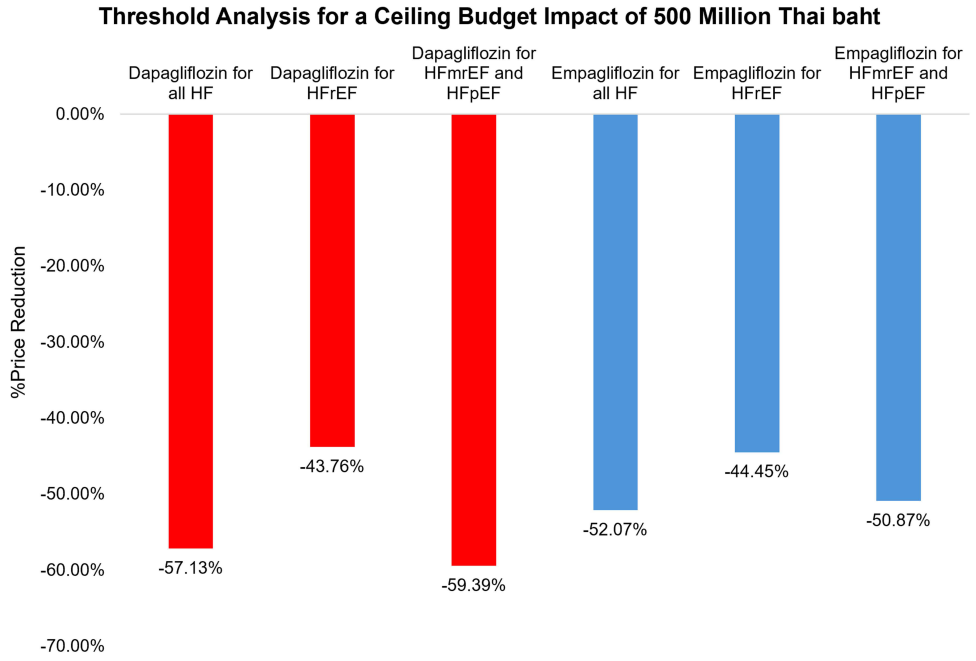

Figure 2 Price reductions for a ceiling budget impact of 500 million Thai baht.
Abbreviations: HF, heart failure; HFmrEF, heart failure with mildly reduced ejection fraction; HFpEF, heart failure with mildly preserved ejection fraction; HFrEF, heart failure with reduced ejection fraction.

which was 2,606 million THB and 3,524 million THB for empagliflozin. Overall, the HHF cost savings of dapagliflozin and empagliflozin were 4,961 million THB and 6,047 million THB, respectively (Table 4).

Benefit–Cost Ratio

To comprehensively illustrate the net financial benefit gained per unit of currency invested, a benefit–cost ratio was calculated. The benefit–cost ratio of dapagliflozin in Year 1 for all HF was 0.396, while that for patients with HFrEF and HFmrEF and HFpEF were 0.470 and 0.347, respectively. Similarly, the benefit–cost ratio of empagliflozin in Year 1 for all HF, HFrEF, and HFmrEF and HFpEF were 0.456, 0.476, and 0.443, respectively (Figure 3).

Table 4 HHF Cost Savings for Dapagliflozin and Empagliflozin

Cost	Year 1	Year 2	Year 3	Year 4	Year 5
HHF cost					
Dapagliflozin for HFrEF	6,168,731,771	5,512,758,124	5,019,662,733	4,649,002,928	4,370,377,952
Dapagliflozin for HFmrEF and HFpEF	10,178,407,422	9,096,050,904	8,282,443,509	7,670,854,831	7,211,123,621
Empagliflozin for HFrEF	6,000,287,325	5,362,225,806	4,882,594,963	4,522,056,458	4,251,039,664
Empagliflozin for HFmrEF and HFpEF	9,261,313,045	8,276,478,962	7,536,179,182	6,979,695,837	6,561,387,307
SoC for HFrEF	8,523,467,519	7,617,094,818	6,935,774,459	6,423,625,945	6,038,643,907
SoC for HFmrEF and HFpEF	12,785,201,279	11,425,642,228	10,403,661,689	9,635,438,918	9,057,965,861
Cost-savings from HHF					
Dapagliflozin for HFrEF	2,354,735,749	2,104,336,695	1,916,111,726	1,774,623,018	1,668,265,955
Dapagliflozin for HFmrEF and HFpEF	2,606,793,857	2,329,591,324	2,121,218,180	1,964,584,087	1,846,842,240
Dapagliflozin for all HF	4,961,529,606	4,433,928,019	4,037,329,906	3,739,207,105	3,515,108,195
Empagliflozin for HFrEF	2,523,180,194	2,254,869,012	2,053,179,496	1,901,569,487	1,787,604,244
Empagliflozin for HFmrEF and HFpEF	3,523,888,234	3,149,163,266	2,867,482,507	2,655,743,081	2,496,578,554
Empagliflozin for all HF	6,047,068,428	5,404,032,277	4,920,662,003	4,557,312,568	4,284,182,797

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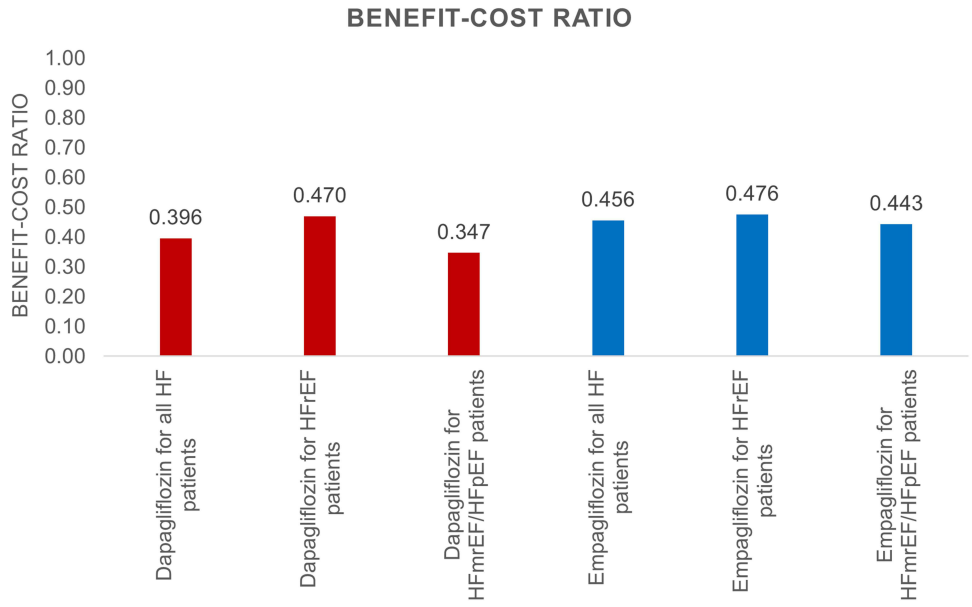

Figure 3 Benefit–cost ratio.
Abbreviations: HFmrEF, heart failure with mildly reduced ejection fraction; HFpEF, heart failure with mildly preserved ejection fraction; HFrEF, heart failure with reduced ejection fraction.

Discussion

This study revealed the budget impact and cost benefit of incorporating dapagliflozin and empagliflozin to be reimbursed for patients with HF under the UHC in Thailand. We found that incorporating the medicines for reimbursement for patients with HF under UHC had a substantial budget impact on the healthcare payer at the current prices. Considering the HHF cost and the UTI admission cost, the NBI was approximately 4.96 billion THB for dapagliflozin and 4.55 billion THB for empagliflozin in the first year of incorporating either of them. This increase is primarily attributed to the high drug acquisition costs associated with SGLT-2i, which significantly outweigh the potential cost-savings resulting from reduced hospitalization rates. These findings could support the healthcare policies that aim to provide safe, effective, and affordable healthcare interventions and services for all Thai citizens in a timely manner.

The subgroup analyses indicate that the NBI varied depending on the type of heart failure. The impact was more pronounced in patients with HFmrEF and HFpEF than HFrEF. This disparity can be attributed to the higher prevalence of HFmrEF and HFpEF and the differential efficacy of SGLT-2i in these patient subgroups.

A threshold analysis exploring medicine price reductions demonstrated that prices of dapagliflozin and empagliflozin should be decreased by approximately 50% to have an NBI of 500 million THB in Year 1. The ceiling NBI is assumed to provide general insights for policymakers because there is no explicit NBI ceiling for budget impact analysis in Thailand. These findings underscore the significant financial challenge of incorporating SGLT-2i for reimbursement in patients under the UHC at their current prices.

Furthermore, the analysis of HHF cost revealed that while the inclusion of medicine led to cost savings due to reduced hospitalization rates, these savings were insufficient to offset the high medicine acquisition costs. The benefit–cost ratio analysis further emphasized this point, indicating that the financial benefits of reduced hospitalizations did not outweigh the prices of SGLT-2i.

Evidence from clinical practice guidelines,[2,3] the landmark studies,[10–13] previous Thai CEA studies,[6,7] and our budget impact and cost–benefit analyses illustrate the overall clinical and economic benefits of the SGLT-2i among patients with HFrEF over patients with HFmrEF and HFpEF. In a situation where the National Health Security Office (NHSO), the responsible institution for patients under the UHC, has a limited budget for reimbursement, the reimbursement of SGLT-2i for patients with HFrEF should be a priority over the reimbursement for patients with HFmrEF or HFpEF.

Exploring alternative reimbursement strategies might be considered when the budget is limited to enhance the affordability and accessibility of SGLT-2i for patients with HF in Thailand. Managed entry agreements might be an option to reduce the risk of spending substantial budgets with minimal clinical benefits for high-cost medicines.[23]

One important piece of evidence that could be considered for policy decisions is patient-reported outcomes, such as patients' health-related quality of life. A recent systematic review and meta-analysis of the effect of SGLT-2i on patients' health-related quality of life showed that SGLT-2i could significantly improve the Kansas City Cardiomyopathy Questionnaire-Overall Summary Score (KCCQ-OSS) by 2.05 points. In addition, SGLT-2i could significantly improve the KCCQ-OSS by at least 5.00 points as the relative risk of 1.14 (95% confidence interval; 1.02–1.28). This indicates the benefit of SGLT-2i on patient-reported outcomes.[24] Policymakers should consider patients' health-related quality of life as a factor for decision-making. However, such evidence is limited in Thailand, so we could not assess this additional benefit in our study.

Several limitations of this study should be acknowledged. First, input parameters mainly relied on clinical data from landmark studies that were conducted in predominantly Caucasian populations. It might not fully reflect the real-world effectiveness of SGLT-2i in the Thai population. Second, the budget impact and cost–benefit model did not account for potential long-term benefits of SGLT-2i, such as improved health-related quality of life and reduced cardiovascular mortality, which could provide a broader view of the clinical and economic benefits of the medicines. Third, the assumption of a 100% uptake rate of SGLT-2i among eligible patients may not be achievable in real-world practice due to other related factors on drug access. The % uptake rates were used to reflect the maximum budget impact that NHSO could encounter. However, sensitivity analyses were performed by varying the %uptake rate to better reflect the potential budget impact in practice. Fourth, we used HHF cost from a previous cost-effectiveness study, which did not provide the cost elements. Thus, we could not assess which cost elements affect the overall HHF cost. Finally, the analytical models in this study did not include other potential costs, such as the need for additional medications or laboratory tests.

This study provides valuable insights into the budgetary impact of incorporating SGLT-2i for reimbursement among patients with HF under the UHC in Thailand. The findings highlight the need for careful consideration of medicine prices and the development of strategies to mitigate the financial burden associated with these medicines. The NHSO might consider price negotiation strategies or managed entry agreements with pharmaceutical companies to reduce the price of SGLT-2i. In addition, further research is also warranted to assess the long-term clinical and economic impacts of SGLT-2i in the Thai population.

Conclusion

In conclusion, this budget impact analysis demonstrates that incorporating SGLT-2i for reimbursement for patients with HF under the UHC in Thailand would result in a substantial increase in the healthcare budget. The magnitude of this impact underscores the need for careful consideration of medicine prices and the exploration of strategies to mitigate the financial burden associated with these medicines. The reimbursement for SGLT-2i for patients with HFrEF should be considered over patients with HFmrEF or HFpEF when the budget is limited.

Abbreviations

ARNIs, angiotensin receptor/neprilysin inhibitors; BIA, budget impact analysis; CBA, cost–benefit analysis; CSMBS, the Civil Servant Medical Benefits Scheme; DMSIC, the Drug and Medical Supply Information Center; ESC, the European Society of Cardiology; HF, heart failure; HFmrEF, heart failure with mildly reduced ejection fraction; HFpEF, heart failure with preserved ejection fraction; HFrEF, heart failure with reduced ejection fraction; HHF, hospitalization for heart failure; ISPOR, the International Society of Pharmacoeconomics and Outcomes Research; KCCQ-OSS, the Kansas City Cardiomyopathy Questionnaire-Overall Summary Score; LMICs, low- and middle-income countries; MRAs, mineralocorticoid receptor antagonists; NBI, net budget impacts; NHSO, the National Health Security Office; NLEM, the Thailand National List of Essential Medicines; RAAS, renin-angiotensin-aldosterone system; SGLT-2i, sodium-glucose cotransporter-2 inhibitors; SoC, standard of care; THB, Thai baht; UHC, universal health coverage; UTI, urinary tract infection.

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