Original Article

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Budget Impact Analysis: A Difference between Theory and Practice

C. Sooksriwong[1] and F. Chanjaruporn [2]*

[1]Division of Social and Administrative Pharmacy, Department of Pharmacy, Faculty of Pharmacy, Mahidol University, 447 Sri-Ayudthaya Road, Payathai, Ratchathewi, Bangkok, Thailand
[2]Drug Control Division, Food and Drug Administration, Ministry of Public Health, Tiwanon Road, Muang, Nonthaburi, Thailand

Abstract

Budget impact analysis (BIA) has been increasingly considered as one important tool in the evaluation of health economics. At present, many countries require the pharmaceutical industry to submit the BIA study together with pharmacoeconomics evaluation as part of the drug registration or drug listing process. The objective of this study was to compare the difference in the budget impact analysis (BIA) result of pemetrexed calculating based on the theoretical BIA study with the actual result of the empirical study for the treatment of lung cancer. This was a cross-sectional research conducted from a payer's perspective used a teaching hospital's database in Bangkok, Thailand during the fiscal years 2005-2009 as the primary data source. Drug costs charged to the patients were included in the analysis. BIA was performed by taking into account the number of eligible patients and costs of drugs for each patient. Total drug expenditure of each patient was calculated and interpreted both in terms of entire cost and cost per patient. The results from the empirical study revealed an increasing trend of total drug expenditure for 17 non-small cell lung cancer (NSCLC) drugs. The average expenditure per patient for most drugs increased over the time. Pemetrexed expenditure rose from $259 to $2,170. In the theoretical BIA study, the hospital had to spend $11,881 for pemetrexed per one patient with NSCLC on average. The total cost of pemetrexed over the four years was $671,816. A difference in the result was clearly observed as the budget impact per patient in the theoretical BIA was constant while that of the empirical study increased over the time. In conclusions, other factors possibly cause an increase in drug expenditure in a BIA study should be taken into account. Evaluation of the hospital's drug policy should also be performed in order to control rising drug expenditure.

Key words: Budget impact analysis, pemetrexed, lung cancer, non-small cell, Thailand

***Corresponding author:** Department of Pharmacy, Faculty of Pharmacy, Mahidol University, 447 Sri-Ayudhaya Road, Bangkok 10400, Thailand.

INTRODUCTION

Budget impact analysis (BIA) has been increasingly considered as one important tool in the evaluation of health economics. At present, many countries require pharmaceutical industry to submit the BIA study together with pharmacoeconomics evaluation such as cost-effectiveness analysis, cost-utility analysis, etc as part of the drug registration or drug listing process. The objective of a BIA is to estimate the budgetary consequences of introducing new health intervention to the system context. It aims to forecast how a change in the mix of drugs and other therapies used to treat a specific health condition will have an effect on the expenditure (1). BIA has been employed to understand and predict the budgetary impact of the new options in order to evaluate the affordability issue. BIA not only accounts for the cost of the new intervention, but it accounts all costs in the healthcare system including the cost reduction of the current treatment strategy which is the main comparator of the new alternative (2). Therefore, BIA will be very useful for budgetary planning and forecasting. BIA is useful for many types of users. Health plan used BIA as a tool for making drug formulary decisions for managed care organizations (3-6). Some European countries, e.g. United Kingdom (UK), Germany, France, Italy, Sweden, Spain and the Netherlands, BIA is used for pharmaceutical reimbursement determination (7). In Canada, the drug programs require pharmaceutical manufacturers to submit economic evaluations and budget impact studies for new drugs (8). Australia is among the first countries to establish the guideline for BIA study for the reimbursement drug submission purpose. However, in conducting a BIA study, we have to set assumptions based on actual information to predict future financial consequences, thus, uncertainty is unavoidable and sometimes results of the study might not reflect the real situation. In this study, we aimed to compare the difference in the BIA result of one costly chemotherapy drug, pemetrexed, calculating based on the theoretical BIA study and the actual result of the empirical study carried out using a teaching hospital's data set during the fiscal years 2005-2006 for the treatment of lung cancer. We aimed our focus on pemetrexed because lung cancer is a leading cause of cancer and pemetrexed has recently been approved by the US Food and Drug Administration for the treatment of non-small cell lung cancer (NSCLC) which is a major type of lung cancer accounted for more than 80% of all lung cancer cases (9-11).

METHOD

This study was a cross-sectional research conducted from a payer's perspective. A teaching hospital's database was used as the primary data source. The database consisted of the information on the drug utilization profile for lung cancer patients who visited the hospital during the fiscal years 2005-2009 (1 October 2004 to 30 September 2009). Drug costs charged to the patients were included in the calculation. Cost of pemetrexed was calculated using its unit price of $1,485 multiplied by the number of patients.

In the theoretical BIA study, the baseline data was set at the fiscal year 2005 as pemetrexed was first introduced in early of the fiscal year 2006. The number of lung cancer patients was estimated based on the actual number of patients in 2005 and assumed incidence rate of lung cancer patients at 2.25%. The number of NSCLC patients was estimated to be 85% of lung cancer patients. The proportion of eligible patients was assumed at 9.4% based on the hospital actual data and the uptake rate of pemetrexed was set at 50, 70, 100 and 100 percent for the years 2006-2009. As the recommended dose of pemetrexed is 500 mg/m^2 for 4 cycles (11-13), One eligible patient assumed to have the body surface area of 1.7 m^2 (14) would consume 8 vials of pemetrexed 500 mg/20 ml. Thus the total cost of pemetrexed per patient per year was estimated at $11,881.

In the empirical study, retrospective data during 2005-2009 from the hospital database was used as primary source. Drug utilization data of all lung cancer patients were retrieved. Impact on drug expenditure and drug utilization was monitored and analyzed using Microsoft Office Excel 2007 and Microsoft Office Access 2007. Budget impact analysis was performed by taking into account the number of patients with lung cancer and costs of drugs for each patient. Total drug expenditure of each patient was calculated and interpreted both in terms of entire cost and cost per patient (1). Common descriptive statistic such as percentage, arithmetic mean and standard deviation were used to interpret the demographic data of the patients, the utilization of drugs and the costs. Expenditure and costs in this study were displayed in US dollar ($). ($1=30 Thai Baht)(15)

RESULTS

During 2005-2009, four new drugs were introduced into the hospital's formulary. Erlotinib, pemetrexed and bevacizumab entered in 2006 and cetuximab joined the group in 2009. From the empirical study, result revealed an increasing trend of total drug expenditure for 17 NSCLC drugs during the study period except in 2009 especially for the new ones. In 2005, the total expenditure for all drugs used for the treatment of NSCLC was $1,854,821. The number increased to $2,513,039, $2,628,440, $3,383,168 and $3,423,008 in 2006, 2007, 2008 and 2009 respectively. With specific focus on pemetrexed, an increasing trend was also found. After the introduction of pemetrexed in the early 2006, its expenditure increased from $170,884 to $1,031,986 during four years with the total expenditure of $2,098,093. (Table 1)

For the treatment of lung cancer, the study found an increasing trend as well. It was found that all drugs expenditure and NSCLC drugs expenditure per patient continuously increased over the time. NSCLC drugs accounted for 60%-70% of the total drug expenditure. (Table 2)

Focusing on four new NSCLC drugs, identical trend was observed for three drugs except gefitinib. The average expenditure per patient for most drugs increased over the time. With an exception for gefitinib, pemetrexed expenditure rose from $259 to $2,170 within four-year time. Erlotinib expenditure also increased from $314 in 2006 to almost ten times or $2,812 Baht in 2009. Moreover, bevacizumab expenditure had an increase from $8 in 2006 to $347 in 2009. (Table 3)

From the theoretical BIA study, the number of patients started at 575 in 2005 and rose to 629 in 2009. The total cost of pemetrexed was $671,816 over the four years. On average, the hospital had to spend $11,881 for pemetrexed per one patient with NSCLC. (Table 4)

According to these two BIA studies, it can be observed that there is a difference in the result. Table 5 and Figure 1 illustrate the gap of these two methodologies.

DISCUSSION

In the theoretical study, the cost of pemetrexed per patient per year was constant; where as in reality it increased by year. One reason could be used to explain this situation was due to the differences in the method used. Theoretical study assumed constant body surface area and fixed the cost of pemetrexed for each eligible patient so the cost per patient was constant. On the other hand, the empirical study calculated the cost per patient by dividing the total cost of all lung cancer patients by the number of lung cancer patients which differed from time to time. Thus, the cost of pemetrexed per patient was not constant. An increase in the cost per patient in the empirical study could be due to the increasing growth rate of cancer patients worldwide including Thailand. This might also possibly be due to the inflation so that the expenditure increased over the time. From this situation, it might be concluded that in theory an increase in the cost of new drug could be a result of an increase in the number of patient. However, in reality, there are other factors we should take into account.

Table 1. Expense of 17 NSCLC drugs in 2005-2009 ($)

Drug Name	2005	2006	2007	2008	2009	Total
Erlotinib		207,544	837,160	1,482,069	1,337,324	3,864,096
Gefitinib	321,666	1,249,796	480,205	389,975	300,307	2,741,948
Pemetrexed		170,884	253,674	641,549	1,031,986	2,098,093
Paclitaxel	593,074	294,961	306,916	226,924	207,426	1,629,300
Gemcitabine	339,166	228,740	327,967	337,803	194,047	1,427,724
Docetaxel	336,394	183,752	276,945	181,936	92,971	1,071,999
Vinorelbine	125,120	70,540	72,472	36,131	33,769	338,032
Bevacizumab		5,070	0	36,005	164,968	206,043
Carboplatin	67,860	36,890	23,998	25,011	20,475	174,234
Irinotecan	37,514	40,430	20,360	18,656	0	116,959
Etoposide	18,384	9,499	10,137	2,819	3,997	44,835
Ifosfamide	10,826	9,833	10,836	2,062	853	34,410
Cetuximab					32,242	32,242
Cisplatin	4,425	4,686	7,378	2,052	2,326	20,866
Vincristine	225	260	393	177	316	1,372
Mitomycin	147	155	0	0	0	301
Vinblastine	21	0	0	0	0	21
Total	**1,854,821**	**2,513,039**	**2,628,440**	**3,383,168**	**3,423,008**	**13,802,476**

NSCLC = non-small cell lung cancer

Table 2. Budget impact for the treatment of lung cancer in 2005-2009 ($)

	2005	2006	2007	2008	2009
Number of lung cancer patients	575	660	650	605	476
All NSCLC drugs expenditure	1,854,821	2,513,039	2,628,440	3,383,168	3,423,008
Average all NSCLC drugs expenditure/patient	3,226	3,808	4,044	5,592	7,197
All drugs expenditure	3,068,668	4,262,981	4,529,901	5,559,840	4,912,784
Average all drugs expenditure/patient	5,337	6,459	6,969	9,190	10,329

NSCLC = non-small cell lung cancer

Table 3. Budget impact of 4 NSCLC drugs in 2005-2009 ($)

Average expenditure/ patient	2005	2006	2007	2008	2009
Pemetrexed	0	259	390	1,060	2,170
Bevacizumab	0	8	0	60	347
Gefitinib	559	1,894	739	645	631
Erlotinib	0	314	1,288	2,450	2,812

NSCLC = non-small cell lung cancer

Table 4. Result for the theoretical BIA study

Data	Fiscal Year				
	2005 (Baseline)	**2006**	**2007**	**2008**	**2009**
Numbers of lung cancer patients	575	588	601	615	629
Numbers of NSCLC patients		500	511	522	534
Numbers of patients likely to be treated with pemetrexed		24	34	50	50
Total cost of pemetrexed		285,133	403,938	594,027	594,027
Average cost/patient/year			11,881		

NSCLC = non-small cell lung cancer

Table 5. Result differences resulting from different BIA methodology

Average expenditure/patient ($)	**2006**	**2007**	**2008**	**2009**
Empirical study (all expenditure/patient)	6,459	6,969	9,190	10,329
Empirical study (pemetrexed expenditure/patient)	8,834	8,063	9,591	10,053
Theoretical BIA	11,881	11,881	11,881	11,881

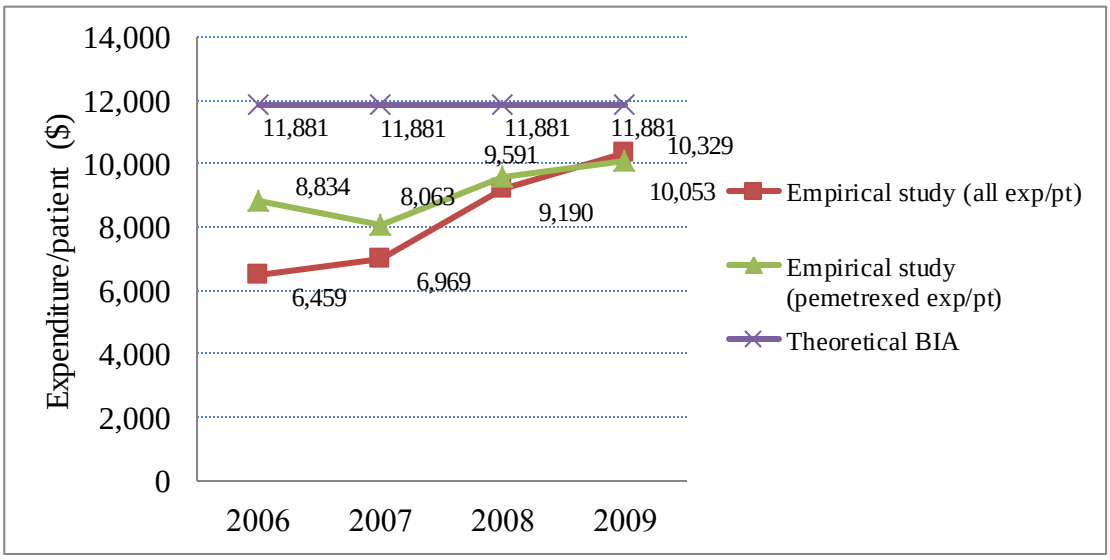

Figure 1. The gap of the two methodologies

Besides the above issue, results revealed that the empirical study yielded less amount of expenditure than the theoretical BIA. This could be explained by looking at the issue of body surface area (BSA) calculation in the theoretical study which might contribute to the increase. If we assumed that a Thai patient has less BSA, the dose would be less thus reduced the cost of pemetrexed as a consequence.

Although result from the empirical study showed less budget impact comparing to the theoretical one, an increase in the expenditure over the time was observed. This raises an important concern in terms of practical issue. In the real world, an introduction of a new drug does not only affect its expenditure, but it also has an effect on the total expenditure through an increase in other drugs expenditure. It was true that an introduction of pemetrexed caused an increase in the total drug expenditure. However, the increase in the years followed might not solely be a result of pemetrexed. It might possibly cause by an increase of other cancer lung drugs. Possible reasons might be due to the fact that the physicians were encouraged to prescribe more new drugs by many promotional campaigns from the drug companies. Moreover, as this hospital is a very huge teaching hospital, it was likely that lots of patients had severe cancer thus they needed advanced new drugs recently launched.

Besides, possible explanation of the increase might be due to irrational use of medicines. The increase in the total drug expenditure in the empirical study might cause by over utilization. These results suggested the hospital to emphasize on the evaluation of the use of medicines. The hospital should consider this evidence in order to identify if there are irrational use and off-label use. Moreover, there is also a need to pay more attention on the appropriateness of the practice guideline for the treatment of lung cancer. It would also be useful to establish tougher eligible criteria of use. Hence the unnecessary treatment and burden of costs will be controllable.

CONCLUSION

This study showed that there was a difference between theoretical BIA and empirical study. Results revealed that the budget impact per patient calculated in the theoretical BIA was constant while that of the empirical study increased over the time. This evidence suggests taking into account other factors which might cause an increase in drug expenditure when carrying a BIA study. Results also suggest evaluating the hospital's drug policy to better control escalating drug expenditure.

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We declare that we have no conflict of interest.

ETHICAL CONSIDERATION

This study was approved by the Ethical Clearance Committee on Human Rights Related to Researches Involving Human Subjects of the Faculty of Medicine, Ramathibodi Hospital, Mahidol University.

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