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A Cost-Effectiveness Analysis of Self-Monitoring Blood Glucose Practice in Type 2 Diabetes Mellitus Patients in a Teaching Hospital

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Abstract Self-monitoring blood glucose (SMBG) practice had been recognized as one of the important components in the management of patients with T2DM. It was found that this practice was associated with improved glycemic control and decreased risk of disease complications that lead to improvement in quality of life (QOL). In the era of rising healthcare costs and the increasing prevalence of T2DM, an economic evaluation of this practice is needed. Therefore, the main purpose of this study was to measure the cost-effectiveness of SMBG practice among T2DM patients by using the decision analytical model. An economic evaluation in the form of a cost-effectiveness analysis study was conducted among hospitalized T2DM patients in a teaching hospital. Data collection was conducted using a costing checklist and case report form. The costing analysis was conducted using a decision analytical model which involved theoretical model building and testing of primary data from a prospective cross-sectional study. A total of 100 patients participated in this study. The estimated mean for the total annual patients' cost for the patient not practicing SMBG and practicing SMBG was RM 76.82 (SD + RM2.43) and RM 609.83 (SD + RM 2.66), respectively. The cost difference was statistically (t [98] = -11.1, p=<0.05). The incremental cost-effectiveness ratio (ICER) was RM 10,165.19 per quality-adjusted life year (QALY). Sensitivity analysis showed that the probability of improvement in glycemic control with SMBG practice was the key parameter in this model. Therefore, the SMBG practice in T2DM patients was found to be cost-effective and should be advocated among T2DM patients. Despite its limitation in terms of the structural uncertainty, the finding from this study would provide valuable information to policymakers in the aspect of health care financing allocation. Future research by using complex cost modeling is recommended to explore other cost determinants for SMBG practice.

Keywords Cost-Effectiveness Analysis, Self-Monitoring Blood Glucose, Type 2 Diabetes Mellitus, Patients

1. Introduction

Self-monitoring of blood glucose (SMBG) practice has become an important tool for assessing and improving the quality of diabetes control. This is the only direct method by which a person with diabetes can be aware of their level of control of blood glucose. The practice is very beneficial when it is used by diabetes patients requiring considerable dose adjustment of insulin, and whose therapies place them at high risk of hypoglycemia. However, the practice is still

regarded as controversial, except for people using insulin, when it was used to provide feedback on the impact of lifestyle measures on blood glucose control, or as part of an overall educational package designed to enhance self-care.

The clinical practice guidelines in multiple countries for diabetes care encourage SMBG practice for diabetes patients to improve their glycaemia control [1-3]. Nevertheless, the specific protocols vary, particularly among non–insulin-using patients. In a developing country like Malaysia, the ministry of health has recommended SMBG to be carried out by patients on insulin therapy and recommended for those on the oral anti-diabetics agent. The frequency of SMBG should also depend on the glucose status, glucose goals and mode of treatment. Consequently, the prevalence of SMBG practice in Malaysia is still low as shown in a two-state study by Mastura et al. whereby the proportion of patients practicing SMBG was only 15.3% [4]. In comparison, the practice is more prevalent in patients with diabetes in developed countries [5-6].

The low prevalence of SMBG practice has raised the question of whether the patients suffering from diabetes have missed the opportunity to benefit from the practice. This is because Janssen et al. had reported that interventions using SMBG were found to be more effective in reducing HBA1C than interventions without self-monitoring [7]. The reduction in HBA1C was also found to be statistically significant and estimated at around 0.4% reduction. A higher frequency of SMBG is also associated with better glycemic control among T2DM patients who can adjust their regime, in which the risk of microvascular complications also decreased by 37% for every 1% decrease in HBA1C level [8]. Other than that, SMBG practice would also facilitate a better understanding and maintenance of self-care behaviors. Financially, Palmer et al. had found that in a cost modeling approach, the additional cost of SMBG will be partially offset by the reduction in the cost of complications [9]. Additionally, an analysis of SMBG cost-effectiveness, also found that the treatment cost was lower with SMBG use compared with non-SMBG use [10]. Therefore, with the rising healthcare cost, it is becoming ever more important to address many policy questions concerning the consequence of diabetes-related practice, which is now a disease of epidemic proportion. A cost-effectiveness study on SMBG practice will assist healthcare policymakers to determine whether or not it is cost-effective to be practiced for future diabetes management. The main aim of this study was to measure the cost-effectiveness of SMBG practice in a teaching hospital in Malaysia.

2. Materials and Methods

2.1. Study Design

This study was an economic evaluation study, which involved building a model using theories and testing the model using the primary data from a prospective cross-sectional study in the year 2014 in terms of the cost and effectiveness of SMBG practice.

2.2. Study Population

In the prospective cross-sectional study, the purposive sampling technique was used to gather the sample patients who had fulfilled the eligibility criteria to complete the study interview. The sample population was patients with T2DM diagnosis who attended the endocrine medical specialist clinic in a teaching hospital from February 2014 to July 2015. The sampling units were those who did not practice SMBG and those who practiced SMBG during the study period. SMBG practice was defined as the process of pricking one's finger with a lancet device to obtain a small amount of blood sample, applying a drop of blood onto a reagent strip, and determining the glucose concentration by inserting the strip into a reflectance photometer for an automated reading [11]. Only adult patients aged 18 years old and above were included in the study. The data were collected using a Patient Costing Checklist consisting of three sections; Section 1: Sociodemographic Data; Section II: Cost Data; Section III: Laboratory Investigation Results.

2.3. Collection

The data were collected through interviewing patients and by examining their respective medical records. Only one research team member was involved with the interviews. The information from the interviews and medical records was recorded inside the Patient Costing Checklist. The outcome of interest, which was the HBA1C blood level, was obtained from the laboratory information system of the hospital. After an interval period of six months from the interviews, follow-up HBA1C levels were again obtained from the laboratory information system. A six-month interval was selected because of the assumption that patients in the study location have received the standard treatment and management as recommended in Malaysia's Clinical Practice Guideline (CPG). In the guideline, the recommended practice for the investigation of HBA1C level for patients with T2DM was between three to six months, depending on their blood glucose control status [3]. The patients' SMBG practice was recorded as yes or no during the interview. Their answers categorized them into the appropriate SMBG practice group during data analysis. The patients were given a written consent form prior to the interview. This study had received ethical approval from UKM Research Ethics Committee prior to the conduct of the study. [UKM 1.5.3.5/FF-2014-031]

2.4. Data and Cost Analysis

Demographic and clinical data were analyzed using

Statistical Package for the Social Science (SPSS) software. The chi-square test of independence was carried out to detect any difference between patients in the 'no SMBG' group and the 'with SMBG' group according to their demographic factors. An independent sample T-test was performed to compare the mean age, while the Mann-U Whitney test was performed to compare the median HBA1C level at baseline between the two groups. The Wilcoxon signed-rank test was used to understand any difference between the levels of HBA1C at baseline and at the follow-up period of the study.

The cost analysis was done using the patients' perspective. The cost data were log-transformed to obtain the normal distribution before calculating the mean and standard deviation values. The cost was obtained through the face-to-face interview using the patient cost checklist form during the outpatient clinic visits, in which two components of patients' costs were calculated. These costs were the direct cost, which was derived from the out-of-pocket cost and SMBG practice cost, and also the indirect cost, which referred to patients' loss of productivity cost.

2.4.1. Direct Costs

These were the out-of-pocket (OOP) costs which include the transportation costs paid by patients. It was the two-way cost spent by the patients to travel from their houses to the clinic, which was standardized based on the 2013 taxi fare schedule [12].

2.4.2. Indirect Costs

Time cost included the waiting time from the time patients arrived until the time patients went home and were standardized to one-day loss of work productivity using the human capital approach. The assumption was set as patients had to work for five days a week and four weeks per month. Therefore, one day salary would be equal to their one month salary divided by 20. The housewife was assumed to have the minimum salary of a housemaid at RM 700.00 per month, which was the market recommended salary for a housemaid in the year 2013[13]. As for patients who claimed to be unemployed or without fixed income, they were assumed to receive aid from the welfare department of RM 300.00 per month based on the financial assistance scheme for poor families scheduled by Department of Community Welfare [14].

2.4.3. SMBG Cost

The SMBG practice costs covered three components, which were the costs of glucometer, glucose test strips and lancets. These costs were estimated for one year of usage and were self-reported by patients. The cost of the glucometer was expected to have a life span of 5 years and was discounted at 5 percent. The cost of glucose test strips was for 1 year of usage. The cost of lancets was also calculated for 1 year of usage.

2.4.4. Cost-effectiveness Analysis (CEA) Model & Variables Definition

The cost-effectiveness analysis was measured using the decision tree analytic model. In this present study, the problem statement was, which of the practice strategy is more cost-effective in improving the glycemic control of T2DM patients; by not practicing SMBG ('no SMBG' group) or by practicing SMBG ('with SMBG' group)?

However, this model calculation was based on the effectiveness of SMBG practice by using the quality-adjusted-life- years (QALY) value for the outcome, and not the level of HBA1C directly. The conversion to QALY involves three steps. Firstly, patients' QALYs were assigned at baseline based on the diagnosis of T2DM and associated co-morbidity [7]. Then, the HBA1C level in the follow-up period was deducted from their respective level at baseline, giving a reduction or incremental value in percentage. The resulted percentage was converted as a loss of 0.03 QALYs for every 1% increase in the HBA1C level and vice versa [15]. In the third step, the outcome QALYs were calculated as baseline QALYs plus the converted QALYs, which was calculated in the second step (Figure 1).

$$QALY_{fup} = QALY_{base} + (\pm\, QALY_{conv})$$

$$QALY_{conv} = \frac{\pm 1\%^{HbA1c}}{-0.03_{QALY}}$$

Whereby,
$QALY_{base}$ = QALY value at baseline (based on literature)
$QALY_{fup}$ = Calculated QALY at follow-up
$QALY_{conv}$ = Converted QALY value
+1%HbA1c = Incremental 1% of HbA1c level
-0.03QALY = Disutility value of 0.03 QALY

Figure 1. Formula for calculation of the QALYs outcome

2.4.5. Model Pathway Probabilities

The model construction was done based on theoretical examples. The parameters of importance were imputed into the models [16].

(a) Probability of SMBG practice category

The evaluated strategies based on respondents' data shown for the probabilities for 'no SMBG' and 'with SMBG' were 0.48 and 0.52, respectively.

(b) Probability of improvement in the glycemic control

The main target in the management of T2DM patients was to control the blood glucose level [3]. This was based on respondents' data. The probabilities of improvement among the 'no SMBG' and 'with SMBG' groups were 0.30 and 0.37 respectively.

(c) Cost incurred in each SMBG practice group categorized by the probability of practice and glycemic control improvement

The costs incurred or borne by patients were the self-reported data available from the previous study to differentiate patients' expenditures on the SMBG practice.

(d) QALYs in each SMBG practice group categorized by the probability of practice and glycemic control improvement

The QALYs were chosen as a proxy for the rates of glycemic control improvement to ensure comparability with other published studies of the SMBG cost-effectiveness in T2DM patients. QALY was well recognized as the economic measure that combines the effects of health interventions on mortality and morbidity into a single index [17]. QALYs for those in the 'no SMBG' group were 0.74 among those who showed improvement in glycemic control and 0.73 for those in the 'with SMBG' group. A similar QALYs value was observed among patients who had no improvement in glycemic control, which was 0.81.

Subsequently, the cost-effectiveness analysis of SMBG practice inside the model was calculated. This was done by weighting each pathway utility value or costs by its respective probability and then summing across all pathways. This calculation method was based on Bayesian statistics as mentioned by Drummond et al. utilized for decision analytical model [18].

2.4.6. Sensitivity Analysis

A one-way sensitivity analysis was performed to test which parameters have the greatest influence on the model's results. All variables imputed as parameters for the model were tested using maximum and minimum value to assess the impact on the base-case results of altering single parameter value separately [16]. This was also done to check the internal validity and explore the parameters of uncertainty in the model. The key parameter was subsequently assessed in detail to demonstrate the relationship between the input value and the model's result in the threshold analysis.

Table 1. Respondents Characteristics

Variable	SMBG practice group Freq n, (%)		p-value
	No SMBG	With SMBG	
Age (years) Median+IQR	56.8 (12.7)	58.1 (11.5)	0.603
Gender			
Male	21 (44.0)	21 (40.0)	0.553
Female	27 (56.0)	31 (60.0)	
Ethnicity			
Malay	27 (56.2)	26 (50.0)	
Chinese	11 (22.9)	16 (30.8)	0.733
Indian	9 (18.8)	9 (17.3)	
Others	1 (2.1)	1 (1.9)	
Occupation			
Unemployed	6 (12.5)	2 (3.8)	
Self-employed	3 (6.3)	8 (15.4)	
Housewife	17 (35.4)	19 (36.5)	
Private sector	10 (20.8)	5 (9.6)	0.062
Education sector	3 (6.3)	0 (0.0)	
Pensioner	5 (10.4)	12 (23.1)	
Others	4 (8.3)	6 (11.5)	
Comorbidity			
None	4 (8.3)	9 (17.3)	
Hypertension	15 (31.2)	13 (25.0)	0.252
Dyslipidemia	2 (4.2)	6 (11.5)	
Both	27 (56.2)	24 (46.2)	
Treatment modalities			
Lifestyle modification	2 (4.2)	4 (7.7)	
Oral anti-diabetic agent	14 (29.2)	12 (23.1)	0.456
Insulin therapy	11 (22.9)	18 (34.6)	
Combination of oral and insulin therapy	21 (43.8)	18 (34.6)	
HbA1c reading [%] Median (+1QR)			
Baseline			
Follow-up in 6 months	8.1 (3.3)	7.7 (3.8)	0.442
Improved HBA1c level at 6-month follow-upa	8.1 (2.7)	7.9 (2.7)	
No	31 (64.6)	28 (53.8)	0.275
Yes	17 (35.4)	24 (46.2)	

IQR= Interquartile Range, *p value of <0.05 taken as level of significance

3. Results

A total of 100 samples were analyzed for the study outcome. 48 patients were under the 'no SMBG' practice group, while the other 52 patients were under the 'with SMBG' practice group. The median HBA1C level at baseline and six months later were similar for the 'no SMBG' group, which was 8.1% (65 mmol/mol), whereby the median HBA1C level was 7.7% (61 mmol/mol) and increased to 7.9% (63 mmol/mol) at follow-up for the 'with SMBG' group. The respondents' characteristics were summarized in Table 1.

The rate of improved glycemic control was 35.4% for the 'no SMBG' group and 46.2% for the 'with SMBG' group based on HBA1c reading at baseline and 6-months follow-up. However, the chi-square test of independence showed that the difference in the rates was not significant (p=0.275) as stated in Table 1. The Wilcoxon signed-rank test showed that the observed HBA1C level after six months showed a statistically significant difference for both the 'no SMBG' group (Z= -0.603, p=<0.05) and also the 'with SMBG' group (Z= -0.628, p=<0.05).

3.1. Cost for Patients with 'no SMBG' and 'with SMBG'

The costs for patients in the 'no SMBG' group and the 'with SMBG' group were based on patients' perspectives. The costs included time cost and out-of-pocket expenditures. Consultation and medication costs were not included in the calculation given only 9% of the patients paid for these costs, while the rest of the patients were either paid for by third-party payers or subsidized by the government. For the 'no SMBG' group, the indirect cost was RM63.55 (2.78) and OOP was RM8.51 (1.38). Meanwhile, for the 'with SMBG' group, the indirect cost was RM73.75 (2.92), OOP was RM8.91 (1.48) and the cost for the practice of SMBG was RM398.11 (3.98). The mean total annual patient cost for the SMBG practice groups was a combination of the total patients' costs and the cost of SMBG practice. This means that patients in the 'no SMBG' group would not incur any cost for SMBG practice. The estimated mean for the total annual patients' cost for the 'no SMBG' group was RM 76.82 (SD + RM2.43). Meanwhile, for the 'with SMBG' group, the mean total annual patient cost was RM 609.83 (SD + RM 2.66). The difference between both groups was statistically significant based on the t-test t (98) = -11.1, p=<0.05 (95%CI=-1.1, -0.74).

3.2. CEA Results for Patients in 'no SMBG' and 'with SMBG' Groups

Patients in the 'no SMBG' group incurred less cost compared to the 'with SMBG' group. The incremental cost of RM 275.35 for the 'with SMBG' group had resulted in 0.03 QALYs gained. The incremental cost-effectiveness ratio (ICER) of the 'with SMBG' practice was RM 10,165.19. Therefore, even though 'with SMBG' practice was more expensive, it was more effective than 'no SMBG' practice.

One-way sensitivity analysis had revealed that the key parameter for the model was the probability of the patients whose glycemic control improved with SMBG practice, whereby the incremental cost-effectiveness for the practice varied around 22% to 59% from the baseline ICER.

4. Discussion

The prospective study to populate the cost model found that the difference in HBA1C level between patients in the 'no SMBG' group and the 'with SMBG' group was not statistically significant (p=0.111). This finding contradicted the result of a randomized control trial in 2013, where it was found that SMBG practice was associated with improved glycemic control in T2DM patients in Malaysian public primary care clinics, whereby the proportion of patients who reached the HBA1C level of equal or less than 7% was about 14% and 32.1% in the control and intervention group, respectively. The same study also concluded that the improvement might be due to the encouragement of self-care in the intervention group of SMBG practice [19]. Therefore, in terms of the contrasting result, the reason could be due to the different study designs and the operational definition of SMBG practice in both studies. In the previous study, patients were given structured instruction including the timing of SMBG and education on how to adjust their medications. However, in the present study, the patients were observed in their natural environment without any intervention or education, either in the SMBG practice or their treatment. Thus, a different result between these two studies was not unexpected.

In the prospective study data collection, there was a possibility of information bias as patients had to recall information on the cost involved in SMBG practice, especially in terms of the equipment bought in the period of more than one year from the time of the interview. The consultation cost and medication cost were not incorporated into the calculation due to the reason that 94% of patients were either subsidized or covered by other payment mechanisms that did not require them to use OOP payments. This is supported by findings by recent study by Essam et al. [20] that found almost half of the T2DM patents were subsidized by the government and one-third paid through insurance provider.

Moreover, the reported income cannot be correctly proven as true as it was not taken from the patients' pay slips during the study interview. The limitation is further compounded in terms of indirect cost calculation, which became quite difficult since about 8% of the patients claimed that they were not working and 36% were housewives with no salary. Therefore, to overcome the

variation, using the human capital approach, the housewives were assumed to have the minimum salary of a housemaid in the year 2013 and patients who claimed that they were not working were assumed to have a salary which is at the same rate as those who receive aids from the welfare department of RM 300.00 per month based on the financial assistance scheme for poor families schedules by the welfare department. Thus, this study might have underestimated the true cost of SMBG practice. Nonetheless, it was still considered valid because the study was based on the patients themselves, and they would have to estimate the real-life cost of the practice.

In terms of the cost-effectiveness of the SMBG practice, the ICER of RM 10,165.19 per QALY was calculated from this model. The cost-effectiveness threshold was recommended to be lower than 1 to 3 times GDP per capita for developing countries by the World Health Organization for the intervention to be deemed cost-effective [21]. Because the ICER value from this study was lower when compared to GDP per capita for the year 2014 in Malaysia [22] therefore, the SMBG practice was cost-effective. This finding echoed the previous finding in several studies in other countries such as Switzerland [23], Canada [24] and Russia [25]. Nonetheless, despite the value of ICER suggesting that this practice was cost-effective, the result from this analysis should be taken with caution taking into consideration existing study limitations, especially concerning the decision tree analytical model. In the context of the present study, it is known that the decision tree model time was not explicitly defined. Therefore, economic evaluations that are time-dependent could be difficult to test. The Markov modeling may solve this problem, but a more complex model and a larger cohort size are needed and the study should be extended. Additionally, with regards to the QALY value used in this model, it was derived based on literature findings from the previous study by [7] in different geographical areas that the present study. Hence, this study may not reflect the true nature of the value in the QALY outcome. However, the conversion method from the HBA1C level changes as an outcome of this study ensures that the outcome has been standardized in terms of changing rates to make the SMBG practice model still valid to be used as a predictor in a study population. Furthermore, with regards to sensitivity analysis, the one-way sensitivity analysis approach could provide flexibility in choosing the parameter choice and was quite insightful. Nevertheless, one-way sensitivity analysis by itself is criticized as inadequate with several related problems. Firstly, the incremental cost and effectiveness depend on multiple parameters, not just one. Secondly, the interaction between particular factors may imply that the total effect is quite different from the simple sum of individual contributions. Other than that, the cost-effectiveness ratio is a ratio of two uncertain numbers with the result that the uncertainty in the ratio may be substantially larger than either of its element [26]. Health economists had suggested a complementary Probabilistic Sensitivity Analysis (PSA) to overcome these limitations. However, this more complex type of sensitivity analysis is out of the scope of this cost modeling study. The strength of this study was in proposing a preliminary theoretical probability model to assess the cost-effectiveness of SMBG practice in a small sample of T2DM patients. The costing analysis from the patient's perspective could provide additional information on health expenditure for T2DM patients because the earlier studies had focused on the provider perspective in Malaysia [27, 28]. The finding of this study could assist policymakers in proposing policy related to strategies in improving QOL of T2DM patients, for example by giving targeted subsidy in self-care practice related to this disease. At the country financing level, future studies might consider adding the taxation system factor into the model. A study in Indonesia that had successfully examined the impact of taxation of unhealthy sugary food to reduce its consumption is one such example [29]. In the future, the proposed theoretical model from the present study could be used as a basis to examine the impact of reducing tax on SMBG related equipment on QOL of T2DM in the future.

In conclusion, the SMBG practice will indeed require more cost, but it is for a good cause, the reason being that the extra cost would lead to a better quality of life in T2DM patients. Admittedly, a much larger scale study might dispute this, as pointed out by Simon et al. [30]. Nonetheless, the contrasting finding implied that the subject of the SMBG practice among patients warranted further exploration to fill in the knowledge gap that emerged from different studies across the world.

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