

ORIGINAL ARTICLE**Health Economic Evaluation of Home and Hospital-Based Care in T2D Patients on Insulin Therapy****Ali Janati¹, Mohamad Ali Sarabchian², Bahram Mohaghegh^{3*}, NaserAghmohamadzadeh², Hesam Seyedin⁴, Masumeh Gholizadeh¹, Edris Hasanpoor¹****OPEN ACCESS**

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ABSTRACT

BACKGROUND: *Type 2 Diabetes is a main concern of public health in contemporary world with remarkable mortality, delayed complications and health costs. Governments are obliged to improve the quality of health care and consider appropriate strategies to reduce the costs. An alternative strategy for hospital services is care at home. Therefore, this study was aimed to evaluate the cost-effectiveness of home-based and hospital-based diabetes care.*

METHODS: *A quasi-experimental, pre-test and post-test design was conducted in Northwest Iran. Sixty subjects who were eligible insulin-treatment type 2 diabetes mellitus were randomly assigned into two equal groups to receive home-based or conventional hospital-based care. Data on glycosylated hemoglobin (HbA1c), hypoglycemia episodes, time needed to achieve glycemic control level, diabetes treatment satisfaction, diabetes knowledge and costs during three months were collected.*

RESULTS: *The cost of home-based care in insulin therapy diabetes was 61% less compared with the hospital-based methods. The former strategy was cost-effective in terms of reduction in HbA1C and the time needed to achieve glycemic control. The patients in home care group were more satisfied and knowledgeable.*

CONCLUSIONS: *The care at home approach for type 2 diabetic patients can be introduced and supported as a cost-effective care method in the country.*

KEYWORDS: *Cost-effectiveness, type 2 diabetes, insulin therapy, home care, hospital care*

INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) is a globally rising chronic disease (1). This metabolic disorder causes serious damages to vital organs such as eyes, kidneys and nerves in the long term. Its complications are among the main causes of mortality and morbidity in the world. During 2005 to 2030, the diabetes-related deaths are projected to be doubled in the world (2). The World Health Organization report in

2014 shows that 347 million people in the world had diabetes of whom 4.581 million were living in Iran with a 8.6% prevalence (3).

This metabolic disease imposes a significant cost of 12% of the health expenditures (i.e.1330 USD per person) in the world. It is 11% in Iran (4).

Diabetes as a chronic disease has no definite cure but providing good metabolic control could prevent or delay its complications (5). Thus, health systems and professionals should be prepared to detect and manage the disease and its sequelae. Also, a new role of home-based care is needed to be delegated to patients with chronic diseases management (6).

The demand for home health care has gined increasing currency in recent years. Aging population and the push for more efficient delivery of hospital services have fueled this growing demand. Therefore, an alternative strategy to expensive hospital-based care is home and community-based care because of their cost containment (7). As evidence is needed to provide information for efficiency and effectiveness of hospital or home-based care, this research was designed to compare these two strategies in terms of their cost effectiveness for control of type 2 diabetes mellitus.

In Iran, a national program for prevention and control of type 2 diabetes was designed in 1996 (8). The diabetes care was integrated in three levels of the Iranian health system. Early detection and treatment of diabetes are usually made at the first level (i.e. rural and urban health centers) by general physicians and allied health staff. All diabetic patients recognized in health centers are referred to district diabetes clinics located in general hospitals as the second level to early detection and control of complications. In these clinics, patients are visited by internists (or endocrinologist) and get care by nurses and nutritionist staff. Patients needing more specific treatments are referred to the diabetes centers foun in the provincial hospitals, which manage diabetes complications and provide educational support.

MATERIAL AND METHODS

Study Design: This research was a quasi-experimental, pre-test and post-test study conducted in 2013. The setting was a diabetes clinic in an Iranian teaching hospital. The study population were patients with type-2 diabetes getting care from a diabetes clinic in Tabriz, Iran. The subjects included diabetics who needed to change oral anti-diabetic therapy to insulin injection according to the internal specialists' orders. The diabetics with co-morbid conditions such as acute infections, thromboembolic diseases, getting glucocorticosteroids and recent surgery or trauma were excluded. The eligible subjects were randomly assigned into two equal groups to receive home-based or conventional hospital-based care.

The patients within the intervention group received home care and frequent follow-up of nurse visits and consultations at home. The control group patients received routine care, including inpatient services in hospital and subsequently monthly visits to the diabetes clinic. *Figure 1* illustrates a flowchart of the two approaches in this study.

Sample size: To calculate the sample size, an estimate of the mean and variance of HbA1c from a similar study was used (9). Therefore, the total sample size with the attrition rate of 20% was calculated to be 60 patients (N= 60).

The measure: HbA1c was used to assess cost-effectiveness of two employed strategies. It is an index of overall glycemic exposure and risk for long-term complications of diabetes mellitus (10). This test is performed to approximate metabolic control over the previous 2-3 months and to help treatment decisions (11).

A satisfaction measuring questionnaire with 20-items and five Likert scale was developed by researchers reviewing some diabetes treatment satisfaction tools (12,13). The participants' knowledge relating to the insulin injection, self-monitoring, hypoglycemia and complications was examined by employing a researcher-designed questionnaire with 15 closed-ended questions.

Three internists confirmed the validity of the questionnaire.

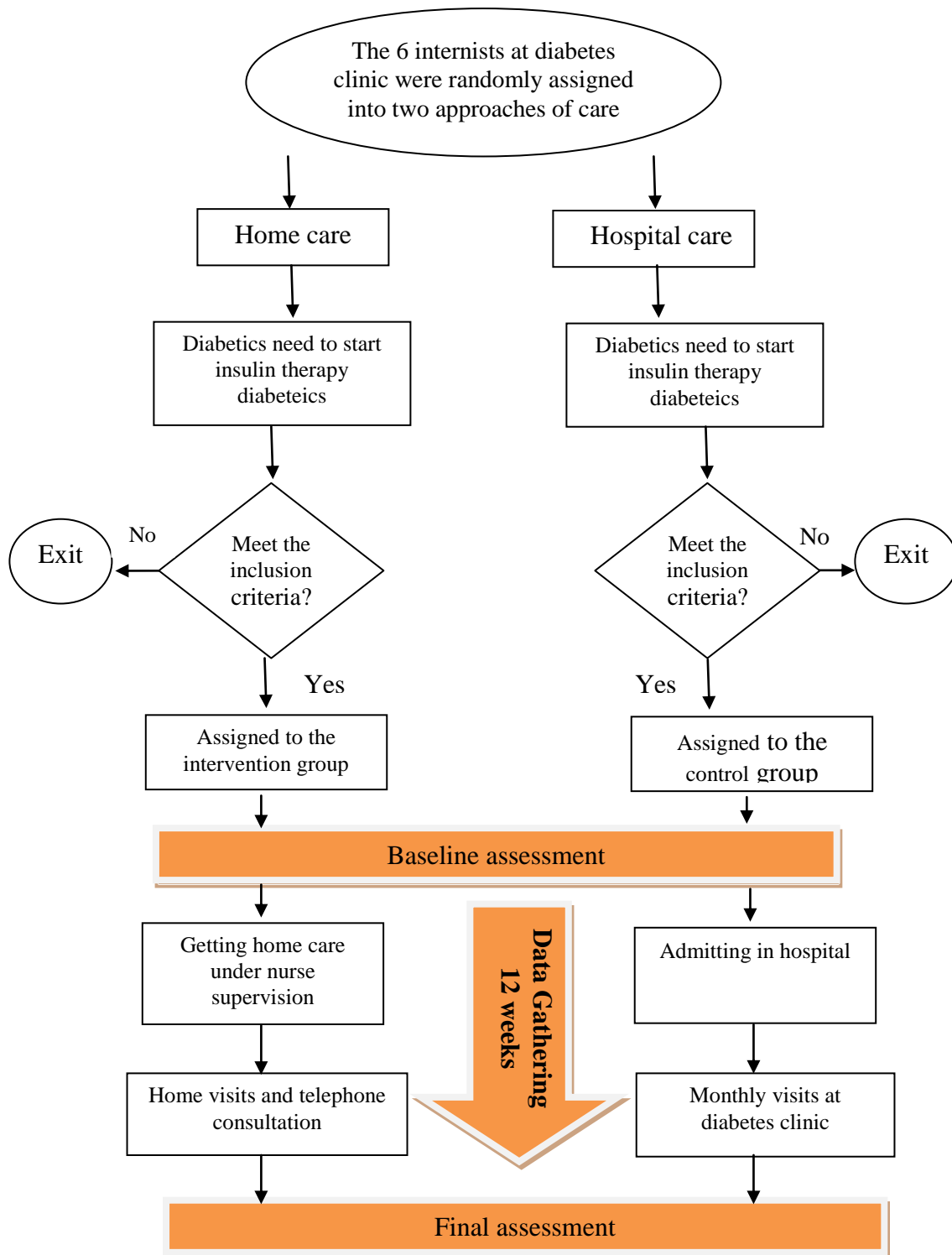


Figure 1: the Flowchart of home and hospital care approaches

Besides, two process metrics, including hypoglycemia episodes and time needed to achieve the glycemic control were measured during a three-month period. The diagnosis of hypoglycemia was based on personal experience of patients with at least one physical symptom (e.g. shakiness and fast heartbeat) as well as psychological (e.g. anxiety) and neuroglycopenic (e.g. confusion) states. The index of the time needed to achieve the glycemic control was compared with the target level of blood glucose (FBG=70-130 mg/dl or blood glucose 2 hours after meal <180 mg/dl).

The schedule of diabetes care: The patients in the home-based group received visits and consultations by a team consisting of nurses and endocrinologists. The intervention was focused on encouraging participants to engage in activities that protect and promote health such as modifying behavior, and change in diet, medication and blood glucose monitoring. The cases received three personal home-visits (first day of the experiment and two with monthly intervals) and ten follow-up phone calls (twice in the first week and eight at weeks 2, 3, 4, 6, 8, 10 and 12) provided by a nurse. Home visits and calls averaged 45 and 14 minutes each, respectively. Five telephone consultations led by medical specialists were performed per case.

The patients in the control group received regular services based on a conventional programme of diabetes control in Iran. They had insulin injection therapy in hospital, to control their glucose levels, and monthly physician appointment in diabetes clinics.

Data gathering: Data gathering was performed by a paper data sheet for recording the background characteristics (age, gender and the literacy level of subjects) and the indices showing the quality of diabetes care during the 3-month period of the study (the frequency of hypoglycemia episodes and time needed to achieve the glycemic control).

Two indexes including, HbA1c and patients' diabetes knowledge were measured twice at the beginning and end of the study (after three months). Also, patients' satisfaction was assessed with two approaches.

Individual table-sheets were used to register the direct costs of diabetes care for patients. The costs in the conventional approach included charges of outpatient care (i.e. physician visits, lab tests, medications and allied health care) and inpatient hospitalization. The costs calculated for the intervention group were the outpatient care, home visits, telephone consultations and endocrinologists consultations. The main non-medical cost for both groups was the travel costs.

Statistical analysis: Descriptive statistics was used to summarize the characteristics of participants. Parametric and nonparametric tests were used according to Kolmogorov-Smirnov test for normality. Paired and independent t-tests were performed to verify the pre-post differences within the groups and differences between groups. We used the Mann-Whitney U or Wilcoxon test for data which were not normally distributed. Also, analysis of covariance (ANCOVA) was used to compare quantitative variables between the two groups when adjusting for another covariate was needed.

Ethical approval: Ethical approval was obtained from the Local Research Ethics Committee of the Tabriz University of Medical Sciences. A written informed consent was taken before randomization of subjects into home-based and hospital-based group. Informed consent was obtained from all individual participants for whom identifying information is included in this article.

RESULTS

Due to the attrition of five participants, data of 55 subjects were analyzed. The mean age of patients in the two groups of home-based and hospital-based were 53.15 ± 8.25 and 58.41 ± 13.68 , respectively. The ratio of males in home-based participants (15 of 26; 58%) and hospital-based group (10 out of 29; 34%) was not similar ($P < 0.05$). Also, illiterate participants were more prevalent in hospital-based groups (69% vs. 46%) ($P < 0.05$), but the mean weight in home-based group (71.52 ± 11.66 kg) was not significantly different from hospital-based one (71.41 ± 13.68 kg) ($P < 0.05$).

This study was also found that the mean HbA1c dropped significantly in the home-based group (paired t test: $t = 8.80$, $df = 23$, $P < 0.001$), but it did not change in the hospital-based group (paired t test: $t = -0.72$, $df = 25$, $P < 0.47$). Also, the majority of the home-based patients experienced

at least once hypoglycemia event whereas this experience was very rare in the alternative group (53.8% vs. 3.4%) ($p < 0.001$). More details regarding the diabetes knowledge, satisfaction level and time needed to achieve glycemic control could be found in Table 1.

Table 1: Comparing the characteristics between the two study groups.

Variables	Home-based (n=26)	Hospital-based (n=29)	P-value
Diabetes Knowledge			<0.001[†]
Before	45.38±12.65	45.93±10.67	
After	83.07±10.19	47.65±10.07	
P-value	<0.001 [§]	0.47 [§]	
Patient satisfaction score	85.24±10.23	68.20±13.29	0.001 [¥]
The time needed to achieve glycemic control	7 (1)	9 (15)	0.014 [‡]

- Variables with normal numeric scales are reported as Mean (standard deviation)
- Variables with non-normal numeric scales are reported as Median (interquartile range (IQR)).

[†]ANCOVA Test, [§]Paired t-test, [¥]Independent Sample T-Test, [‡] Mann-Whitney U test

Table 2 indicates that the average costs for diabetes care in the three-month period were significantly difference between the intervention and control groups ($t=13.42$; $p < 0.001$). It is worth mentioning that the strategy of home-based care was dominant over hospital-based care in terms of less cost to reduce a unit of HbA1c in diabetic

patients. This study also shows that to achieve prevention, an additional hypoglycemia in diabetics 106.93 US Dollar is needed. This cost needs to be compared with the Iranian threshold of cost-effectiveness values for diabetes management.

Table 2: Incremental Cost-effectiveness Ratios of different strategies among study groups

Group	Total cost (SD) (USD)/per person	Outcome	Incremental cost (US \$)	Incremental effectiveness	ICER*
HbA1c					
Home-based	45.88 (7.54)		-	-	Dominant
Before		11.40(2.37)			
After		7.30 (1.42)			
Hospital-based	116.46 (27.17)		70.58	4.13	Dominated
Before		10.58(1.80)			
After		10.65(1.82)			
Hypoglycemia episodes					
Home-based	45.88 (7.54)	14 (53.8)	-	-	-
Hospital-based	116.46 (27.17)	1 (3.4)	70.58	0.66	106.93
Satisfaction score					
Home-based	45.88 (7.54)	85.24(10.23)	-	-	Dominant
Hospital-based	116.46 (27.17)	68.20(13.29)	70.58	17.04	Dominated
Time needed to achieve glycemic control **					
Home-based	45.88 (7.54)	7 (1)	-	-	Dominant
Hospital-based	116.46 (27.17)	9 (15)	70.58	4.48	Dominated

- Variables with normal numeric scales are reported as Mean (standard deviation)
- Variables with non-normal numeric scales are reported as Median (interquartile range (IQR)).
- Variables with categorical scales are reported as n (%).

*Incremental Cost-effectiveness Ratios

DISCUSSION

The findings showed that the mean costs of diabetes care could be reduced by 61% at home-based strategy. This finding, regardless of the different diseases being studied, was congruent with some studies (12,13) and inconsistent with others (14), in terms of predominant cost-saving strategy.

Comparing the effects of home- and hospital-based care revealed that the home-based method had more effect on improving clinical and non-clinical outcomes. The interventional cases experienced a mean of 37% reduction in their HbA1c levels (from 11.4 to 7.3) after three months. Such a finding came in agreement with several studies that reported a significant decrease in HbA1c of diabetics getting a nurse-led home diabetes management program compared with the control group (15-18). This reduction in HbA1c level could result in reducing the development of severe complications in diabetics (19). It is suggested that nurse visits and telephone counseling in home-based strategy could develop individual self-management for diabetes control (20). In some forms of interventions that diabetes education and counseling or phone calls follow-up were made by nurses, different results were reported. For example, Gallegos et al. reported a significant decrease in HbA1c in the experimental group (21), but with a nurse-coaching strategy undertaken by Whittemore et al. the HbA1c levels improved in both the control and the intervention groups (22).

It seems frequent medical staff contacts with patients in the home-based strategy, comparing with the usual strategy could positively affect HbA1c level (23). The central role of nurses as an impressive factor to improve health outcome in patients with chronic diseases has been reported by Sutherland et al. (24).

In this study, the diabetes knowledge and awareness of the intervention subjects was significantly improved. Consistent with findings of Zareban et al., the improvement was concurrent with falling in HbA1c levels (25). Comparing the mean time (in days) to achieve the optimum level

of blood glucose in patients was statistically similar in the two groups; but, almost four and a half days shorter in the intervention than control group. The home-care strategy was dominant over the conventional strategy in terms of less cost, but more effect on reducing the time (days) needed to achieve the glycemic control in diabetics.

The participants in the experimental group reported more hypoglycemic episode than the control group. This is in contrast with a study has been done by Piette et al. (26). These results should be taken with caution, since the use of a self-reporting approach for data collection constitutes a potential source of bias in the form of underestimating the true numbers of hypoglycemia episodes especially in usual care subjects due to lack of any scheduled supervision by health staff.

Finally, the participants in the experimental care demonstrated more satisfaction than the usual care which is inconsistent with a study done by Navicharearn et al. (16). It can be concluded that home-based model of diabetes care generates better outcomes at lower costs than conventional care, that encourages integration of home health care into the usual program of diabetes prevention and control.

It seems that the home-based approach by reinforcing the team work through nurses' home visits and phone calls plus physicians' phone counseling has potentially positive effects on diabetes control in adults with insulin-treated diabetes type 2 that in turn could prevent or delay the complications. Further research is needed to clarify the optimum number of home visits and nurse or physician phone counseling needed to achieve the maximum outcomes in diabetics and to investigate the long term consequences of home care compared with the usual care.

The limitations of this study include the following issues:

- Patients who received the intervention had higher literacy levels at baseline than the control subjects. This would have resulted in an overestimation of the increased diabetes knowledge at the end of the study.

- Due to limited resources, the time to follow the participants up was not continued after three months. Two measures of diabetes control estimates (i.e. time needed to achieve the glycaemic control and hypoglycaemic episodes) were based on self-reports, i.e., their direct measures by health staff were not available to validate data.
- The mean value of HbA1c level at baseline was almost similar among the experimental and the control groups, indicating the strength of the finding that the remarkable reduction of noted index in the home-care was true.

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