Impact Assessment of Pharmacist-supervised Intervention on Health-related Quality of Life of Newly Diagnosed Diabetics: A Pre-post Design

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Abstract

Introduction: Diabetics face a series of challenges that affect all aspects of their daily life. Diabetes related complications adversely affect patient’s health-related quality of life (HRQoL). Knowledge and self-care skills of diabetics are corner stones to improve their HRQoL. Objective: To assess the impact of pharmacist-supervised intervention on HRQoL of newly diagnosed diabetics using an Audit of Diabetes-Dependent Quality of Life (ADDQoL) questionnaire. Materials and Methods: A pre-post comparison study was conducted among the control group (CG), test 1 group (T1G) and test 2 group (T2G) patients with three treatment arms to explore the impact of pharmacist-supervised intervention on HRQoL of newly diagnosed diabetics for 18 months. Patients’ HRQoL scores were determined using ADDQoL questionnaire at baseline, 3, 6, 9 and 12-months. T1G patients received pharmacist’s intervention whereas T2G patients received diabetic kit demonstration in addition to pharmacist’s intervention. CG patients were deprived of pharmacist intervention and diabetic kit demonstration, and only received care from attending physician/nurses. Non-parametric tests were used to find the differences in an average weighted impact scores (AWIS) among the groups before and after the intervention at \( P \leq 0.05 \). Results: Friedman test identified significant \( (P < 0.001) \) improvement in AWIS among the test groups’ patients. Differences in scores were significant between T1G and T2G at 6-months \( (P = 0.033) \), 9-months \( (P < 0.001) \) and 12-months \( (P < 0.001) \); between CG and T1G at 12-months \( (P < 0.001) \) and between CG and T2G at 9-months \( (P < 0.001) \) and 12-months \( (P < 0.0010) \) on Mann–Whitney U test. Conclusion: Pharmacist’s intervention improved AWIS of test groups’ diabetics. Diabetic kit demonstration strengthened the disease understanding and self-care skills of T2G patients. Disease and self-care awareness among diabetics should be increased in Nepali healthcare system by involving pharmacists for better patient’s related outcomes.

Keywords: Diabetes mellitus, health-related quality of life, intervention, Nepal, pharmacist

Introduction

Like any other chronic debilitating disease, people with diabetes face a series of challenges that affect all aspects of their daily life. Diabetes, if left untreated, may develop acute and chronic complications that adversely affect patients’ quality of life (QoL) and...
increase morbidity and mortality.[1-3] QoL is “a multidimensional construct referring to an individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns.”[4] Compared to QoL, “health-related quality of life (HRQoL) addresses life-specific domains related to health, which are influenced by physiological, psychosocial, sociological, economical, and spiritual factors.”[5] It is evident that the risk of developing depression is 2–3 times more common in people with diabetes than in their nondiabetic counterparts,[6] and hence this affects their physical and mental domains of QoL.[7] In addition, depression may provoke behavioral changes in patients so that an individual no longer complies with diet, exercise, and therapeutic regimens.[6]

Patients’ HRQoL can be improved by promoting patients’ care activities and supporting their life-specific domains.[8] Pharmacist’s intervention and care in chronic diseases can improve patients’ life-specific domains related to health.[9] Drug and disease-related counseling and education empower the knowledge and self-care skills of patients with diabetes to achieve a better QoL.[1-9] Few studies have highlighted the impact of pharmacist intervention on QoL of patients with chronic diseases, such as diabetes and hypertension, using various assessment tools.[9-14] But none of the studies have highlighted the impact of pharmacist intervention on HRQoL of newly diagnosed diabetics with different treatment arms using an Audit of Diabetes-dependent Quality of Life (ADDQoL) questionnaire. The ADDQoL is a diabetes-specific instrument to measure an individual’s perception of the impact of diabetes on their QoL. To measure the life-specific domains of patients with chronic diseases, such as diabetes, is still a challenge for health-care professionals in Nepal. At the same time, pharmacists’ roles in patients care are still not recognized in health-care system of Nepal, and studies are lacking emphasizing pharmacists’ involvement in patients care in the country. In addition to it, none of the studies have focused either on the impact of pharmacists’ intervention on life-specific domains of newly diagnosed diabetics or described how the extra demonstration of diabetic kit based on anatomical and physiological principle brought significant changes in life-specific domains related to health and improved HRQoL of patients with diabetes. Therefore, this study aimed to determine the impact of pharmacist-supervised intervention (PSI) on the HRQoL of newly diagnosed diabetics under three treatment arms using ADDQoL questionnaire in Nepal.

**Materials and Methods**

**Study design**

A pre-post comparison study was conducted among the control group (CG), test 1 group (T1G), and test 2 group (T2G) patients with three treatment arms to explore the impact of PSI on HRQoL of newly diagnosed patients with diabetes at the Manipal Teaching Hospital, Pokhara, Nepal, for 18 months.[15] The study was approved by the Research and Ethics Committee (Ref. no. MEMG/NHRC/GA) of Manipal Teaching Hospital, Nepal.

**Study population**

Patients aged 16 years and older who visited the diabetic clinic of Manipal Teaching Hospital, and who were first time diagnosed with diabetes mellitus (DM) were enrolled in the study. Childbearing mother, mentally ill patients, and patients who did not complete their study follow-ups and who were unwilling to participate in the study were excluded. Patients were asked to give their written consent to participate in the study. However, parental consent was obtained in case of minors.

**Sample size and sampling technique**

Sample size was calculated by using Daniel’s finite population correction formula.[16] Approximately 9% of diabetes prevalence rate was taken as the calculation factor.[17,18] and a Z value 1.96 was set with 95% confidence interval and 5% margin of error.

$$n_0 = N Z^2 p (1-p)/d^2 (N-1) + Z^2 p(1-p)$$

where $n_0$ is the sample size with finite population correction, $N$ is the DM population size, $Z$ is the statistic for a level of confidence, $p$ is the expected prevalence (in proportion of one; if 10%, $p = 0.09$), and $d$ is the desired precision (in proportion of one; if 5%, $d = 0.05$). The calculated sample size was 125 patients. Approximately 30% dropout margin was expected[19,20] from this study as it was a follow-up, pre-post comparison study for the duration of 12 months. Therefore, 30% dropout margin was added to the calculated sample to achieve the final targeted sample size of 162 patients. A consecutive sampling method (based on time capsule frame) was followed to achieve 162 patients in over 6 months,[21] and each patient was followed for 1 year from their date of enrollment in the study. The patients were allocated in three parallel groups: CG ($n = 54$), T1G ($n = 54$), and T2G ($n = 54$) without disturbing the sequence of randomization (1:1:1).[22] Ten patients were excluded from the study because they did not complete their follow-ups and hence further study was carried out with 152 patients (CG [$n = 50$], T1G [$n = 51$], and T2G [$n = 51$]).[15,23]
Study tools
All the study tools and questionnaire were prepared in Nepali language due to language fluency and barriers to the English language among most of the patients that visited the diabetic clinic. Both the test group (T1G and T2G) patients were educated about diabetes by using various educational materials such as diabetes booklet, diabetes complication chart, and diabetic food chart. Patients from both the test groups received information pertaining to diabetes, such as diabetes and its risk factors, long-term and short-term complications of diabetes, importance of lifestyle and dietary modifications, and use of medications in diabetes, by the pharmacist. In addition to educational materials, test 2 group patients (T2G) received extra demonstration of diabetic kit, which was developed, especially for them, to explain about the anatomical and physiological relationship of diabetes and its impact on physiological system (T1G patients were deprived of the diabetic kit demonstration). The aim to use the diabetic kit only in T2G patients was to identify any significant change in patients’ weighted impact scores (WISs) and average weighted impact scores (AWISs) (indicating HRQoL) between T1G and T2G due to this extra demonstration of diabetic kit.[15,23]

ADDQoL questionnaire
An ADDQoL questionnaire was used to measure the HRQoL of diabetics.[24] It is a diabetes-specific instrument to measure an individual’s perception of the impact of diabetes on their QoL.[25] This instrument has a good reliability, internal, and external construct validity, and is recommended to be used to measure the HRQoL of patients with type 1 and type 2 DM.[26] The questionnaire was originally in English, which was translated into Nepali (native language) by professional experts. The questionnaire had two sections; the first section had two overview items (Statement I and Statement II) and the second section had 19 condition-specific domains (Statement 1 to 19) describing patient’s general and overall HRQoL, respectively. Each condition-specific domain had part (a) and part (b) statements that indicate the impact rating and the importance rating of the domain, respectively.[24]

Validation of ADDQoL questionnaire
Linguistic validation (LV) of the questionnaire was done before using it in the study. According to LV process guidelines, two forward and two backward translators, one forward translation reconciler (FT-rec), one clinical reviewer, one psychiatrist reviewer, and one final proofreader were involved in the process of translation and reviewing of the questionnaire. Nepali version of the ADDQoL questionnaire was used to conduct the cognitive debriefing (CD) interview with selected CD group of patients with diabetes as per CD interview guidelines.[24] The data were entered in the Statistical Package for the Social Sciences (SPSS) software, version 16.0 (SPSS Inc., Chicago, IL, USA), and Cronbach α test for reliability was calculated. The internal consistency for the ADDQoL questionnaire was 0.81.

Scoring of ADDQoL questionnaire
The scoring of the questionnaire was done as per the criteria laid by the original author of the questionnaire. In the first section, overview item I (one) was scored from −3 to +3 (−3, −2, −1, 0, 1, 2, and 3) and overview item II (two) was scored from −3 to +1 (−3, −2, −1, 0, and 1). In the second section, part (a) scored from −3 to +1 (−3, −2, −1, 0, and 1) and part (b) scored from 0 to 3 (0, 1, 2, and 3). A WIS for each domain and an AWIS were calculated by the formula recommended by the author in the questionnaire guidelines. The maximum possible negative and positive impact scores of diabetes were −9 and +3, respectively. More negative scores (in negative direction) indicate poor HRQoL and less

| Table 1: Distribution chart of intervention and reinforcement program in control and test groups of patients with diabetes mellitus |
|---|
| Phases | Materials used for intervention |
| Intervention phase | | |
| Phase I (baseline) | CG | T1G | T2G |
| 1 | × | × | × | × | ✓ | ✓ | × | ✓ | ✓ |
| Phase II (3 months) | × | × | × | × | ✓ | ✓ | × | ✓ | ✓ |
| Phase III (6 months) | × | × | × | × | ✓ | ✓ | × | ✓ | ✓ |
| Reinforcement phase | | |
| Phase IV (9 months) | × | × | × | × | ✓ | ✓ | × | ✓ | ✓ |
| Phase V (12 months) | × | × | × | × | ✓ | ✓ | × | ✓ | ✓ |

CG = control group, T1G = test 1 group, T2G = test 2 group

Intervention materials are represented by 1 (diabetes information booklet), 2 (diabetic food chart), 3 (diabetes complication chart), and 4 (diabetic kit). Tick (✓) and cross (×) denotes that the mentioned interventional material was used and not used in that group of patients, respectively
negative scores (in positive direction) indicate better HRQoL of diabetics.[24]

**Pharmacist intervention to patients with diabetes**

Patients with diabetes received intervention from pharmacist in two phases: intervention phase (Phases I to III) and reinforcement phase (Phases IV and V). Patients from the CG received only their usual care from physicians/nurses and kept away from pharmacist interventions (Treatment arm 1). However, patients from the test groups (T1G and T2G) received PSI using various educational materials and counseling aids related to diabetes and its management [Table 1]. They also received counseling on insulin administration technique by using insulin pen or insulin syringe (if on insulin as therapy) and use of glucometer for self-monitoring of blood glucose at home to improve their self-care skills. To improve patients’ compliance to medication(s), medication envelops were used to dispense the prescribed medicine(s) to the patients (Treatment arm 2). However, in addition to educational materials, T2G patients received extra demonstration of diabetic kit (Treatment arm 3).

Diabetic kit consisted of two glass tubings that were filled with two different types of liquid preparations such as blood. These glass tubes were considered as the blood vessels of human physiological system through which blood flows in different organ systems. One glass tube was filled with low-viscosity liquid without sugar particles (tube 1) and another glass tube was filled with high-viscosity liquid with high sugar particles (tube 2). Tube 1 showed good fluidity pattern from one end to another end of the glass tube without any obstruction in flow (in nondiabetic patients as blood is free from high concentration of sugar), whereas tube 2 with high-viscosity liquid showed slow fluidity pattern with obstruction in flow from one end to another end of the glass tube (in patients with diabetes as blood contains high sugar level). This flow pattern of liquid was linked with the flow of blood in different organs of human physiological system. T2G patients were explained

![Figure 1: Theoretical framework. *MCC = Medication Counseling Center](image-url)
about how the viscosity of blood gets changed due to high sugar level in blood (in diabetes) and affects its flow in different organs (e.g., heart, brain, and kidney), leading to various short-term and long-term diabetes complications. Patients were also explained how they could control diabetes complications by managing their blood glucose level following pharmacological and non-pharmacological measures in their life [Figure 1].

Moreover, T2G patients were educated about the location of different organs in human body and blood supply in these organs through blood vessels using a chart of human anatomy with circulatory system. More focus was given to those organs that are mainly affected due to diabetes such as heart, kidney, brain, eyes, and nerves with special attention on pancreas and its role in diabetes. Knowledge about the use of antidiabetic medications in diabetes management and medication compliance among T2G patients was enhanced using daily medication calendar and antidiabetic medicine calendar. As diabetes is a chronic disease in which patients require continuous support from health-care professionals, patients were reinforced with the diabetes-related information during their reinforcement phases [Table 1]. Patients' HRQoL was evaluated using ADDQoL questionnaire before and after disseminating the PSI at baseline, 3, 6, 9, and 12 months, respectively.15,23

Statistical analysis
The patients' HRQoL scores were entered in SPSS software, version 22.0, and descriptive analysis was done as per the requirement for data analysis. Data were tested for its distribution pattern on Kolmogorov–Smirnov test, which was found skewed at P < 0.05 significance level. Non-parametric tests, such as Friedman test and Mann–Whitney U test, were used to find the differences between dependent and independent variables within and between the groups before and after the interventions, respectively. Pre- and post-comparison within the groups was done using the Wilcoxon signed-rank test. Post hoc analysis with Wilcoxon signed-rank test was used at P ≤ 0.005 after Bonferroni adjustment to identify in which follow-up the significant differences occurred in the group. All the analyses were performed at P ≤ 0.05 significance level.

Results
Demography of patients with diabetes
The mean age (in years) and body mass index of the study patients were 49.14 (12.56) years and 27.60 (3.54) kg/m², respectively. Majority of the patients (n = 106, 65.43%) were male. Approximately 40.7% patients were unemployed, businessman (25.9%), employed (18.5%), pensioner (13.6%), and students (1.2%). Only 30.9% patients were either primary educated or secondary educated, and 24% and 14.2% patients were noneducated and tertiary educated, respectively. Approximately 92% patients were nonvegetarian. No alcohol and smoking habits were found in 42.6% and 57.4% patients, respectively. However, 16.7% and 17.9% patients were found to consume alcohol and smoke every day and only 24.1% and 6.8% patients were occasional alcoholic

| Table 2: General quality of life scores of control and test groups (T1G and T2G) patients with diabetes at baseline and follow-ups |
|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| **Statement I:** my present quality of life |
| Groups (FUs) | CG (Median score (IQR)) | T1G (Median score (IQR)) | T2G (Median score (IQR)) |
| Baseline | −1 ([−1]–[0]) | −1 ([−1]–[0]) | −1 ([−1]–[−1]) |
| 3 months (first FU) | −1 ([−2]–[−1]) | −1 ([−2]–[−1]) | −2 ([−2]–[−1]) |
| 6 months (second FU) | 1.5 ([−2]–[−1]) | −1 ([−2]–[−1]) | −2 ([−2]–[−1]) |
| 9 months (third FU) | −2 ([−2]–[−1]) | −2 ([−2]–[−1]) | −1 ([−2]–[−1]) |
| 12 months (forth FU) | −2 ([−2]–[−2]) | −2 ([−2]–[−1]) | −1 ([−2]–[−1]) |
| **Statement II:** quality of life without diabetes |
| Baseline | −2 ([−2]–[−1]) | −2 ([−2]–[−1]) | −2 ([−2]–[−1]) |
| 3 months (first FU) | −1 ([−1]–[−1]) | −1 ([−2]–[−1]) | −1 ([−2]–[−1]) |
| 6 months (second FU) | −1 ([−2]–[−1]) | −2 ([−2]–[−1]) | −2 ([−2]–[−1]) |
| 9 months (third FU) | −1 ([−2]–[−1]) | −2 ([−2]–[−1]) | −2 ([−2]–[−1]) |
| 12 months (forth FU) | −1 ([−2]–[−1]) | −2 ([−2]–[−1]) | −2 ([−2]–[−1]) |

FU = follow-up, CG = control group, T1G = test 1 group, T2G = test 2 group

†Less negative scores indicate better quality of life

−3 (extremely bad) to +3 (excellent), +2 (very good), +1 (good), 0 (neither good nor bad), −1 (bad), −2 (very bad), −3 (very much better) to +1 (worse), −2 (much better), −1 (a little better), and 0 (the same)
Table 3: Impact scores, importance scores, and weighted impact scores of the patients of control and test groups at the baseline and follow-up

| Life domains                        | FU       | CG       | T1G      | T2G      |
|------------------------------------|----------|----------|----------|----------|
|                                   | a B c*   | a B c*   | a B c*   | a B c*   |
| Leisure activities                 |          |          |          |          |
| BL                                 | -2       | 2        | -4       | -2       |
|                                   | (-2) (-1)| (2) (-2) | (-1.23) (-2)| (-2) (-1)| (2) (-2) | (-4) (-2)| (-2) (-1)| (2) (-2) | (-4) (-2)|
| 4th FU                             | -2       | -2       | -4       | -1       |
|                                   | (-2) (-1)| (2) (-2) | (-4) (-2)| (-2) (-1)| (2) (-2) | (-4) (-3)| (-1) (-1)| (2) (-2) | (-4) (-2)|
| Physically can do                  |          |          |          |          |
| BL                                 | -1.67 (0.47) | 1.91 (0.73) | -1.67 (0.47) | -1.43 (0.53) | 2.17 (0.54) | -2.91 (1.35) | -1.43 (0.49) | 2.13 (0.47) | -3.00 (1.13) |
|                                   | -2       | 2        | -2       | -1       |
|                                   | (-2) (-1)| (2) (-2) | (-2) (-1)| (-2) (-1)| (2) (-2.25) | (-4) (-2)| (-2) (-1)| (2) (-2) | (-4) (-2)|
| 4th FU                             | -2       | -2       | -4       | -1       |
|                                   | (-2) (-1)| (2) (-2) | (-4) (-2)| (-2) (-2)| (2) (-2) | (-4) (-3)| (-1) (-1)| (2) (-2) | (-2) (-2)|
| Family life                        |          |          |          |          |
| BL                                 | -1.33 (0.51) | 2.19 (0.39) | -1.33 (0.51) | -1.41 (0.49) | 2.24 (0.47) | -3.15 (1.13) | -1.17 (0.50) | 2.15 (0.49) | -2.56 (1.19) |
|                                   | -1       | 2        | -1       | -1       |
|                                   | (-2) (-1)| (2) (-2) | (-2) (-1)| (-2) (-1)| (2) (-3) | (-4) (-2)| (-1) (-1)| (2) (-2) | (-3) (-2)|
| 4th FU                             | -1       | 2        | -3       | -2       |
|                                   | (-2) (-1)| (2) (-3) | (-4) (-2)| (-2) (-1)| (2) (-2) | (-4) (-3)| (-1) (-1)| (2) (-2) | (-2) (-2)|
| Friendship and social life         |          |          |          |          |
| BL                                 | -1.17 (0.37) | 2.00 (0.61) | -1.17 (0.37) | -1.30 (0.46) | 2.02 (0.41) | -2.65 (1.16) | -1.15 (0.35) | 2.00 (0.77) | -2.37 (0.87) |
|                                   | -1       | 2        | -1       | -1       |
|                                   | (-1) (-1)| (2) (-2) | (-1) (-1)| (-2) (-1)| (2) (-2) | (-4) (-2)| (-1) (-1)| (2) (-2) | (-3) (-2)|
| 4th FU                             | -2       | -2       | -4       | -1       |
|                                   | (-2) (-1)| (2) (-2) | (-4) (-2)| (-2) (-1)| (2) (-2) | (-4) (-2)| (-1) (-1)| (2) (-2) | (-2) (-2)|
| Close personal relationship        |          |          |          |          |
| BL                                 | -0.80 (0.59) | 2.09 (0.59) | -0.80 (0.59) | -0.94 (0.65) | 2.13 (0.64) | -2.28 (1.30) | -0.59 (0.59) | 2.09 (0.52) | -1.35 (1.43) |
|                                   | -1       | 2        | -1       | -1       |
|                                   | (-1) (0)| (2) (-2) | (-1) (0)| (-1) (-1)| (2) (-2.25) | (-3) (-2)| (-1) (0)| (2) (-2) | (-0) (-2)|
| 4th FU                             | -1       | 2        | -2       | -2       |
|                                   | (-1) (-1)| (2) (-3) | (-3) (-0)| (-1) (0)| (2) (-3) | (-3) (-0)| (-1) (0)| (2) (-3) | (-0) (-2)|
| Feelings/worries about the BL future |          |          |          |          |
| BL                                 | -1.48 (0.50) | 1.93 (0.54) | -2.83 (1.12) | -1.63 (0.48) | 1.98 (0.30) | -3.22 (1.02) | -1.37 (0.48) | 2.09 (0.44) | -2.83 (1) |
|                                   | -1       | -3       | -2       | -2       |
|                                   | (-2) (-1)| (2) (-2) | (-4) (-2)| (-2) (-1)| (2) (-2) | (-4) (-2)| (-2) (-1)| (2) (-2) | (-4) (-2)|
| 4th FU                             | -2       | -2       | -4       | -1       |
|                                   | (-2) (-1)| (2) (-2) | (-4) (-2)| (-2) (-2)| (2) (-2) | (-4) (-2)| (-1) (-1)| (2) (-2) | (-2) (-2)|
| Life domains                        | FU      | CG       | T1G      | T2G      |
|-----------------------------------|---------|----------|----------|----------|
|                                   | a       | b        | c*       | a        | b        | c*       | a        | b        | c*       |
| Financial situation               | BL      | -1.83 (0.42) | 2.30 (0.46) | -4.20 (1.26) | -1.57 (0.49) | 2.15 (0.35) | -3.35 (1.11) | -1.50 (0.50) | 2.13 (0.33) | -3.19 (1.16) |
|                                   | 4th FU  | -1.86 (0.35) | 2.14 (0.35) | -3.98 (1) | -1.94 (0.50) | 1.82 (0.55) | -3.41 (1.09) | -1.20 (0.53) | 2 (0.29) | -2.39 (1.06) |
|                                   | BL      | -1.33 (0.47) | 2 (0.33) | -2.69 (1.09) | -1.26 (0.44) | 2.06 (0.30) | -2.61 (1.08) | -1.07 (0.42) | 2 (0.27) | -2.19 (0.99) |
|                                   | 4th FU  | -1.20 (0.49) | 2.04 (0.19) | -2.46 (1.09) | -1.16 (0.50) | 2.08 (0.52) | -2.39 (1) | -0.98 (0.14) | 2.02 (0.14) | -1.98 (0.31) |
| Living conditions                 | BL      | -1.39 (0.49) | 1.96 (0.75) | -2.87 (1.30) | -1.22 (0.57) | 1.98 (0.81) | -2.54 (1.51) | -1.30 (0.46) | 2.17 (0.57) | -2.81 (1.23) |
|                                   | 4th FU  | -1.78 (0.58) | 2.16 (0.42) | -3.90 (1.66) | -1.61 (0.69) | 1.57 (0.53) | -2.43 (1.38) | -1.41 (0.49) | 2 (0.36) | -2.79 (0.99) |
| Freedom to eat                    | BL      | -1.19 (0.39) | 2.02 (0.62) | -2.43 (1.17) | -1.22 (0.42) | 2.06 (0.56) | -2.48 (1) | -1.19 (0.39) | 1.94 (0.68) | -2.30 (1.09) |
|                                   | 4th FU  | -1.94 (0.47) | 2.38 (0.49) | -4.66 (1.72) | -1.61 (0.69) | 1.61 (0.49) | -2.51 (1.40) | -1.55 (0.50) | 2.16 (0.36) | -3.31 (1.14) |
| Freedom to drink                  | BL      | -2       | -4       | -2       | -2       | -2       | -2       | -2       | -2       | -2       |
|                                   | 4th FU  | -2       | -4       | -2       | -2       | -2       | -2       | -2       | -2       | -2       |

CG = control group, T1G = test 1 group, T2G = test 2 group, BL = baseline, FU = follow-up

*Weighted impact score = impact rating (-3 to +1) × importance rating (0–3) = -9 (maximum negative impact of DM) to +3 (maximum positive impact of DM). #Scores are presented in mean (standard deviation) and median interquartile range (IQR)

a (impact scoring) = -3 (greatest) to +1 (least), b (importance scoring) = 0 (least) to +3 (most), c (weighted impact scoring) = -9 to +3
and smoker, and 16.7% and 17.9% were former alcoholic and smoker, respectively.

**General quality of life scores of the patients of control and test groups at baseline and follow-ups**

The CG and the test group (T1G and T2G) patients were examined for their general quality of life (GQoL) scores at baseline and during follow-ups by using the ADDQoL questionnaire [Table 2], and data were analyzed by descriptive statistics.

**Impact, importance, and weighted impact scores of the patients of control and test groups**

The HRQoL of patients can be explained by exploring their life-specific domain impact scores, importance scores, and WISs at baseline. PSI improved the patients’ life-specific domains in test groups than CG in their subsequent follow-up compared to baseline [Table 3].

**Average weighted impact scores of the patients of control and test groups at baseline and follow-ups**

The impact of diabetes on patients’ life-specific domains was found greater at 3 months than at baseline as indicated by the increasing trend for negative scores, which replicates the patients’ HRQoL more in unhealthy states. The greater impact of diabetes at first follow-up was held true once patients get diagnosed with diabetes that affected their life-specific domains in real life, which they did not experience before the diagnosis of diabetes. Pharmacist intervention had shown improvement in patient’s life-specific domains in subsequent follow-ups.
after 3 months with considerable improvement in patients’ AWIS at the fourth follow-up than the baseline. The AWIS was found greater (in positive direction) among T2G patients than T1G patients. However, CG patients had the highest impact of diabetes as shown by the highest negative AWIS [Table 4].

**Comparison of patients’ average weighted impact scores at baseline and follow-ups within test groups**

Patients’ AWISs were used to compare the changes in the HRQoL of the patients in both test groups by using the Friedman test. There were significant improvements in the HRQoL of patients due to PSI, but it was more nourished at the fourth follow-up than at the baseline in both test group patients [Table 5].

*Post hoc* analysis with the Wilcoxon signed-rank test was used to examine where the significant differences occurred in each group after Bonferroni adjustment [Table 6].

**Comparison of average weighted impact scores between test groups and control and test groups patients**

The differences in patients’ AWISs between the test groups and control and test group patients were compared by using the Mann–Whitney *U* test. The significant differences between the groups are presented in Table 7.

**Discussion**

Depression among diabetics is more common due to the psychological distress associated with restricted physical activity and inability to fulfill role obligation. Pharmacist-provided counseling and education can improve patient’s social, physical, psychological, and role functioning to a greater extent by clearing their doubts and through better management of the disease and hence improve patient’s HRQoL outcomes.

PSIs improved patients’ GQoL and life-specific domains of test group (T1G and T2G) patients compared to CG patients. However, an extra demonstration of diabetic kit to T2G patients brought a significant improvement in their GQoL and life-specific domains compared to T1G patients.

Patients’ perceptions about their present QoL were found to be good initially, and they felt that their GQoL could be “much better” without diabetes.[27,28] A slightly negative perception of the present QoL of the patients might be due to their unexpected diagnosis of diabetes. Patient’s response to HRQoL domains may differ according to their characteristics, study location, and diabetes perception. In terms of overall HRQoL, patients from the three groups had given more
importance to 10 life-specific domains of 19 domains [Table 3]. Studies also highlighted more importance to work/employment, close personal relationship, financial situation, and family life among the diabetic population. Moreover, “financial situation,” “leisure activities,” and “physically can do” were the highest negative weighted impact domains in diabetes. Furthermore, “financial situation” and “family life” were considered as the most important, and “working life” as the least important domain by the patients. A study from Slovakia highlighted “family life” and “personal relationship” as the most important, and “freedom to drink” as the least important QoL domain in the study population. Being a chronic disease, diabetes needs regular care and use of antidiabetic medications that exert a heavy financial burden on diabetics, and therefore diabetics considered “financial situation” as the most important life-specific domain, whereas they considered “working life” as the least important domain, which could be due to more illiteracy and unemployment among the people in the country.

A greater negative WIS (mean WIS) were observed at 3 months for 10 life-specific domains of 19 domains [Table 3] with the highest negative WISs for the “physically can do” and “freedom to drink” domains in the patients from the three groups. Similarly, UK-based studies found the highest negative impact of diabetes for the “feelings/worries about the future” and “interrupt do” domains, and the “freedom to eat as I wish” domain among the studied diabetes population, which indicated major impact of dietary restriction on QoL. The highest negative impact of diabetes was also noted for the “feelings about future,” “freedom to eat,” and “self-confidence” domains in one study from Taiwan. However, a US-based study indicated the negative impact of diabetes on the overall QoL of diabetics. The impact of diabetes on the life-specific domains of patients with diabetes drove their GQoL toward a “bad” position in their consecutive follow-ups. A study from Durham, UAE, also highlighted the possibility of a negative perception for the physical and psychological well-being domains of HRQoL in newly diagnosed patients with diabetes.

PSI significantly improved patients’ HRQoL in this study. However, empowerment-based psychosocial intervention significantly improved patients’ psychological and social aspects of QoL whereas therapeutic educational program was an effective instrument to improve overall QoL of diabetics at 3 months and 1 year in one study conducted in France. Pharmacist counseling and education improved not only patient’s AWIS (lower AWIS indicates better HRQoL and low impact of diabetes) in test groups at the fourth follow-up compared to baseline but also their GQoL in subsequent follow-ups, which shows that patients’ GQoL walks parallel with the overall HRQoL of patients. This could be justified from one randomized control trial conducted in UK stating the impact of an immediate DAFNE (dose adjustment for normal eating) training program in a significant improvement for dietary freedom among patients with diabetes after 1 year that improved their present QoL. The improvement in patients’ overall HRQoL and GQoL was much better among T2G than T1G patients due to extra demonstration of diabetic kit, which motivated T2G patients more for better self-care management of diabetes and hence better improvement in their HRQoL. However, overall HRQoL and GQoL of CG patients were more negatively impacted with highest AWIS compared to test groups at 12 months.

Limitations of the study: Like any other research study, this study also had a few limitations. Patients with diabetes were selected from only one hospital of the Kaski district in western Nepal, and hence the study findings may not be able to generalize the entire diabetic population of the country. Study also had few expected biasness at different stages of the study. A repeat measurement bias was expected as the same self-administered questionnaire was given to the participants. To limit this biasness, however, patients were asked to complete the questionnaires in the presence of researcher. Patient selection biasness was resolved by allocating the patients in different groups without disturbing the sequence randomization. However, an external moderator was appointed to moderate the complete study process to overcome the self-biasness (researcher biasness).

Conclusion

Patients from test groups improved WIS and AWIS of their life-specific domains due to PSI and also improved their HRQoL. Extra demonstration of diabetic kit brought a significant improvement in HRQoL of T2G patients compared to that of T1G patients. At the same time, CG patients who received doctor’s and nurse’s directive care showed insignificant improvement in their life-specific domains and found their life-specific domains in an acceptable state compared to the test groups (T1G and T2G). The significant improvement in the HRQoL of the patients indicated the benefits of PSI in patient care in diabetics. Therefore, disease and
self-care awareness program among diabetics should be increased in Nepali health-care system by involving qualified pharmacists to achieve better patient-related outcomes.

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Conflicts of interest
There are no conflicts of interest.

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