INTRODUCTION

Diabetes mellitus is a metabolic disorder characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both. According to the Diabetes atlas 2006 published by the International Diabetes Federation, the number of people with diabetes in India is currently around 40.9 million is expected to rise to 69.9 million by 2025. Diabetes and other chronic non-communicable diseases (NCDs) are significant public health challenges in the 21st century. It is estimated that 3.8 million deaths were attributable to diabetes in 2007, equivalent to 6% of all deaths globally. India has the largest population of diabetes patients when compared to any other country, diabetes deaths accounts for 9.7%.

In India the prevalence of diabetes is increasing. Diabetes once viewed as a rich man’s disease but this idea is wrong. The reasons for prevalence of diabetes are changing lifestyle, sedentary occupations, and irregular food habits. There have been corresponding changes in semi-urban environments also. So this leads to increase morbidity and mortality of non communicable diseases (NCDs). Therefore prevention is the best strategy. Quality of life is an important health outcome in its own right, representing the ultimate goal of all health interventions. People with diabetes have a poor quality of life than people with no chronic illness. The goals of chronic care are ‘not to cure but to enhance functional status, minimize distressing symptoms, prolong life’ through secondary prevention and enhance quality of life. Quality of life (QOL) measurements are increasingly recognized as important in the assessment of chronic diseases and in evaluating medical outcomes.

Several studies have reported the positive impact of clinical pharmacists provided patient education intervention counseling on glyemic control and quality of life outcomes in diabetic populations.

MATERIALS AND METHODS

A prospective educational interventional hospital based study was carried out in the medicine outpatient and inpatients department of Adichunchanagiri Hospital & Research Center. Ethical clearance was obtained from the institutional ethical committee of the hospital. Patients consent was obtained and randomized into control and intervention group by simple randomization technique.

A patient data collection form was prepared to collect the demographic details of the enrolled patients. A total of three follow-ups were made from baseline, with an interval of one month in each follow-up. Educational materials and counseling was given to the intervention group and at last follow-up to control group by the clinical pharmacist.

A WHO-Brief QOL was used to assess the patient QOL; prior permission was obtained from the WHO to use the questionnaire. Based on the patient preference the questionnaire was given in English or Kannada. The questionnaire consists of 26 items, divided into 4 domains. The questionnaire was administered at each follow up to both the groups. The four domain scores denote an individual’s perception of quality of life in each particular domain. Domain scores are scaled in a positive direction (i.e. higher scores denote higher quality of life). The mean score of items within each domain is used to calculate the domain score. Mean scores are then multiplied by 4 in order to make domain scores comparable with the scores used in the WHOQOL-100. The obtained scores are added within each domain and thus become the raw score and then it will be converted into transform score where finally it will be compared with the WHO QOL-100 score scale.

A validated questionnaire was used in order to assess the subject’s score of Knowledge, Attitude and Practice concerning diabetes management. Both in English and Kannada languages were used based on patient understanding. Prior permission was taken from the MediMedia USA, Inc., publishers of P&T Journal to use the questionnaire for the study. The questionnaire was administered at baseline and final follow up to know the influence of education by pharmacist. The questionnaire contains 25 questions out of which 18 were Knowledge based questions, 4 questions were designed to assess the attitude and 3 questions to assess the actual practice of management of diabetes. The various topics covered in the questionnaire were knowledge related issues such as the diabetes symptoms.

Medication adherence behavior was assessed at each follow up for both the groups by using a 4 item scale and license agreement was
made before incorporating into the study. Scoring was given based on the scheme of “Yes” = 0 and “No” = 1. Blood glucose was done for both groups using a SD Check gluco-meter at each follow-up.

Statistical software such as SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data.

RESULTS

One hundred thirteen patients were enrolled into the study after considering the inclusion and exclusion criteria. Out of which one hundred patients completed the study (i.e., three follow-up of one-month interval each) fifty-two patients in intervention group and forty-eight patients in control group. Thirteen patients were dropped out (due to not completing the follow up), in which five patients in intervention group and eight patients in control group. Thirteen dropouts may be because of left the place, negligence, illiteracy, dependent on others, economic status, age factor and duration of diabetes. The detailed demographic details of the enrolled patients are depicted in the table 1

Medication adherence of the patients

Significant improvement was observed in all the follow ups in intervention group but variation in the control group. Comparative evaluation was made between the groups made where there was no significant (P > 0.05) but in the second and final follow up there was strong significant (P > 0.05). Figure 1 shows the change in the scores between the groups.

Blood glucose levels

The mean fasting blood glucose levels at baseline of control group patients was 138.50mg/dl and that of intervention group was 151.13mg/dl. Post prandial blood glucose at baseline in control group was found to be 200.42mg/dl and in intervention group was 219.69mg/dl. At the last follow up a significant reduction in mean blood glucose in intervention but not in control group as shown in figure 2 and 3.

Knowledge, Attitude and Practice of the patients

A significant improvement was observed in intervention group compared to control group and their mean score are shown in table 2.
DISCUSSION

QOL is increasingly viewed as a therapeutic outcome and is gradually gaining the same level of importance as clinical or physiological outcome parameters. QOL in this context refers to health – related problems, including the impact of disease and treatment on functioning, health beliefs and subjective well-being. A number of studies suggest that, pharmacists can play an important role in improving the health and quality of life in patients with chronic illnesses. Diabetes is one such chronic disease where patients report a lower quality of life than the general population.10, 11, 12.

Assessment of medication adherence

Pharmacist provided educational influence was assessed on medication adherence behavior by MMAS-4 scale. At baseline most of the patients in both control and intervention group suggest that the patients were non-adherent to their treatment. The scores of the patients at final follow up in intervention group showed significant improvement, this may be due to education influence of pharmacist on disease and medication. Similar results were observed in the study conducted by Morisky et al.13, 14, 15.

Assessment of Knowledge, attitude and practice

Patients' knowledge, attitude and beliefs have been shown to affect their medication taking behavior. Medication adherence is essential to achieve better therapeutic outcomes in chronic and asymptomatic diseases like diabetes mellitus. An understanding of the cause of diabetes and the changes in habits required to control blood glucose also helps to improve treatment outcomes. At baseline only a few patients in either group were aware about the signs, symptoms, complications and management of diabetes and the dietary and lifestyle modifications essential to control blood glucose levels. At the final follow-up, the test group, who had received extensive education regarding their disease management, medication importance, dietary and lifestyle modifications necessary to control their disease, showed a significant improvement in KAP score. Though the patients in the control group did show a slight increase in score, this was not significant as showed in intervention group and this may be due to repeatedly follow up provoked the group to ask questions to doctors or friends etc.

Assessment of Quality of life

WHO- Bref QOL questionnaire was administered to measure the quality of life of the enrolled patients. An increase in the QOL score indicates an improvement in QOL. Although it is a generic instrument, studies have demonstrated its sensitivity in patients with diabetes. A gradual improvement in the overall quality of life scores was observed in the test group patients where as in control group patients, change in the overall scores was non-significant.

The overall QOL of both the intervention and control groups were similar (P value > 0.05) at the base line. However a non significant improvement in the overall QOL was observed in the first and second follow up but a significant improvement was observed in final follow up. In the 3 follow up there was significant improvement in the QOL (P value < 0.05) when compared with baseline whereas in control group there was no improvement in all the three-follow ups. This was due to the fact that patient education influenced in proper glyemic control, which has reduced the diabetic symptoms that improved the patients’ enjoyment in day-to-day life activities.

Domain 1 (Physical health)

Domain 1 consists of activities of daily living, dependence on medicinal substances and medical aids, energy and fatigue, mobility, pain and discomfort, sleep and rest, work capacity. Comparative analysis was made between the groups in the Domain 1 at baseline and first follow-up there was statistically insignificant. But in second follow up there was moderately significant (P value: 0.01<0.033≤ 0.05) and in third follow up strongly significant (P value: <0.001≤0.01) was observed. This could be attributed to the fact that an increased understanding of their disease management, improved adherence and thus resulted in improvement of their Quality of Life.

Domain 2 (Psychological)

Domain 2 consists of bodily image and appearance, negative feelings, positive feelings, self-esteem, spirituality/religion/personal beliefs, thinking, learning, memory and concentration. Comparative analysis was made between the groups in the Domain 2 at baseline and first follow-up there was no significant, but in second follow up there was moderately significant (P value: 0.01<0.047 ≤ 0.05) and in third follow up strongly significant (P value: <0.001≤0.01) was observed. The improvement seen in the intervention group patients could be due to the impact of education about their disease and life style modifications. It is probable that the pharmacist provided education helped the patients to understand their condition and about their disease state and thus improved Quality of life.

Domain 3 (Social relationships)

Domain 3 consists of personal relationships, social support, and sexual activity. Comparative analysis was made between the groups in the Domain 3 at baseline, first follow up and second follow up showed statistically insignificant. But in final follow up strongly significant (P value: ≤0.01<0.001) was observed. This may be due to the fact that social relationship is influenced by the patient’s disease and depends on each individual’s reaction.

Domain 4 (Environment)

Domain 3 consists of financial resources, freedom, physical safety and security, Health and social care: accessibility and quality, home environment, opportunities for acquiring new information and skills, participation in and opportunities for recreation/leisure activities, physical environment (pollution / noise / traffic / climate), transport. Comparative analysis showed baseline, first follow up insignificant but at second follow up moderately significant (P value: 0.01<0.085 ≤ 0.05) and in final follow up strongly significant (P value: 0.011≤0.01) was observed.

Table 2: Shows the total average mean KAP score in both the groups

<table>
<thead>
<tr>
<th>KAP Score</th>
<th>Intervention group (n=52)</th>
<th>Control group (n=48)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>5.28±1.8</td>
<td>6.05±2.53</td>
</tr>
<tr>
<td>Final follow up</td>
<td>8.99±3.375</td>
<td>6.59±2.40</td>
</tr>
</tbody>
</table>

Table 3: Total QOL and subscale scores of QOL in the Control group (n=48)

<table>
<thead>
<tr>
<th>QOL scores</th>
<th>Base line</th>
<th>First follow-up</th>
<th>Second follow-up</th>
<th>Third follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domain 1</td>
<td>42.75±7.93</td>
<td>40.62±6.93</td>
<td>40.75±7.95</td>
<td>40.17±7.24</td>
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<tr>
<td>Domain 2</td>
<td>42.79±7.01</td>
<td>42.25±6.15</td>
<td>41.7±6.79</td>
<td>39.17±6.56</td>
</tr>
<tr>
<td>Domain 3</td>
<td>34.65±10.55</td>
<td>33.17±13.07</td>
<td>32.77±12.92</td>
<td>30.15±11.28</td>
</tr>
<tr>
<td>Domain 4</td>
<td>42.9±9.76</td>
<td>40.42±7.11</td>
<td>40.3±8.73</td>
<td>40.02±6.7</td>
</tr>
</tbody>
</table>
Table 4: Total QOL and subscale scores of QOL in Intervention group (n=52)

<table>
<thead>
<tr>
<th>QOL scores</th>
<th>Base line</th>
<th>First follow-up</th>
<th>Second follow-up</th>
<th>Third follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domain 1</td>
<td>41.06±7.31</td>
<td>41.67±6.18</td>
<td>44.06±7.46</td>
<td>45.96±5.54</td>
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<tr>
<td>Domain 2</td>
<td>41.54±7.44</td>
<td>41.21±6.27</td>
<td>44.42±6.59</td>
<td>46.19±5.18</td>
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<tr>
<td>Domain 3</td>
<td>34.40±10.43</td>
<td>34.12±10.44</td>
<td>36.00±10.64</td>
<td>37.94±11.31</td>
</tr>
<tr>
<td>Domain 4</td>
<td>41.31±7.92</td>
<td>41.58±6.83</td>
<td>43.37±5.85</td>
<td>44.21±4.8</td>
</tr>
<tr>
<td>Total quality of life score</td>
<td>39.58±8.83</td>
<td>39.65±8.23</td>
<td>41.77±8.88</td>
<td>43.57±7.92</td>
</tr>
</tbody>
</table>

CONCLUSION

This study confirms that improvement in knowledge of the disease and its management, improves medication adherence, which in turn has a positive impact on Quality of Life of diabetes patients. Hence we can conclude that there is a positive impact of clinical pharmacist provided education and counseling for improving the health outcomes like QOL, KAP in diabetes mellitus patients.
Fig. 6: Shows the Domain 3 score at each level in both the groups

Fig. 8: Pearson correlation of Total QOL with Blood glucose in intervention group

Fig. 9: Pearson correlation of QOL with Blood glucose in control group
ACKNOWLEDGEMENT

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REFERENCES


