**Evaluation of the effects of long-term of pharmacotherapeutic follow-up intervention on clinical and humanistic outcomes in diabetes mellitus patients**

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This study aimed to evaluate the long-term effects of pharmacotherapeutic follow-up on clinical parameters and the quality of life of a group of elderly patients. A longitudinal pilot study was carried out to examine 14 elderly patients with diabetes mellitus 12 months after they completed the pharmacotherapeutic follow-up in a popular Pharmacy in Aracaju-SE, Brazil. Glycosylated hemoglobin, blood pressure, blood glucose capillary level, body index mass and waist circumference and quality of life were measured. Glycosylated hemoglobin level was < 7% in 42.86% of the patients. In addition, baseline and post-reevaluation mean blood pressure values were statistically different (p < 0.05). The patients noticed improvement in all domains of quality of life, compared to baseline and reevaluation. Pharmacotherapeutic follow-up trained elderly patients to be capable of controlling their diabetes and this is important for maintaining their clinical parameters and quality of life.

**Key words:** Elderly, pharmacotherapeutic follow-up, diabetes mellitus, diabetes self-management education.

**INTRODUCTION**

Diabetes mellitus is a group of metabolic diseases characterized by hyperglycemia resulting from deficiencies in insulin secretion and/or its action; it is associated with complications, dysfunction, and the failure of various organs (American Diabetes Association (ADA), 2002). In 2000, 171 million people had diabetes worldwide; the number will reach 366 million in 2030, with the disease acquiring epidemic characteristics in several countries, particularly in developing countries that encounter barriers that make diagnosis and treatment difficult. In this scenario, Brazil will have approximately 11.3 million people with diabetes (Wild et al., 2004). The factors that
Contribute to the increasing incidence, prevalence and mortality rate of this disease include a sedentary lifestyle, improper eating habits, socio-behavioral changes and the accelerated rate of aging of the general population (BDS, 2005). Although diabetes can occur at any age, its prevalence significantly increases among the elderly population (Marcondes et al., 2005). Approximately 10% of people over 70 years of age have diabetes and thus, diabetes represents the fourth most common chronic condition for this group, greatly hindering the functional capacity, independence and quality of life for the elderly (Alves et al., 2007; Werneille et al., 2004).

Therefore, the need to improve the clinical management of diabetes and the quality of life of patients is an opportunity for pharmacists to be more involved in the treatment of this disease. In this context, in 1990, the “Pharmacotherapeutic Follow-up” (PF) was defined by Hepler and Strand (1990) and aimed at ensuring a convenient, safe and cost-effective use of pharmacotherapy that offers pharmaceutical guidance to patients, pharmacotherapeutic monitoring and health education (Hepler and Strand, 1990; Lyra Jr. et al., 2008).

Health education is defined as a set of values that promotes training and participation in the process of care (Auld et al., 1998). According to Lyra Jr. et al. (2007), the relationship between a pharmacist and a patient should be guided by ethical principles, mutual respect, confidentiality and above all, co-responsibility. Based on this, the pharmacist should try to establish a dialogue to understand the past and present morbid history of the patients and their needs; the pharmacist must use health education as an essential and effective tool for this in order to ensure good therapeutic results (Lyra Jr. et al., 2007).

In recent years, PF programs that use educational intervention for patients and health professionals have obtained positive results in the control of diabetes (Planas et al., 2009; Doucette et al., 2009; Kiel and McCord, 2005; Flores, 2005). For example, Al Mazroui et al. (2009) argued that educational intervention is as important as the clinical intervention because it provides the patients with better knowledge about drug therapy, diet and physical activity, allowing more effective self-monitoring of blood glucose to control diabetes (Al Mazroui et al., 2009; Speight and Bradley, 2001). McWhorter et al. (2002) confirmed that medicines reached the target goal established for glycosylated hemoglobin (HbA1c) level < 7% in patients who are oriented by a pharmacist about their illness.

On the other hand, a review by Cooper et al. (2001) about educational intervention promoted by many health professionals for chronic diseases such as diabetes shows that despite the improved metabolic levels reached in the first 6 months of monitoring, the levels revert 6 months after the education process. Therefore, the authors recommend continuous monitoring and reassessment of the program to measure the effects of educational intervention over time (Cooper et al., 2001; Funnell, 2009). Another review by Machado et al. (2007) points out the lack of studies evaluating the effect of long-term clinical and humanistic outcomes achieved by educational intervention promoted by pharmacists in the care of diabetes patients (Machado et al., 2007). Thus, the aim of this study was to evaluate the long-term effects of PF on the clinical and humanistic aspects of a group of elderly patients with diabetes mellitus.

METHODOLOGY

Study design and location

We conducted a longitudinal and prospective study with an intervention divided into 3 stages. In this study, we describe the results obtained in the 3rd evaluation, which was a continuation from a previous study that describes the 1st and the 2nd ones (Balisa-Rocha et al., 2012). The study was conducted in a Popular Pharmacy in Brazil, a community pharmacy, located at Estância Street, Aracaju-SE, Brazil. The Popular Pharmacy was launched by the Federal Government to augment the acquisition of essential medicines by the low-income population of Brazil. At present, there are 423 Popular Pharmacies in Brazil and the PF is planned as one of the main guidelines for the care setting (BRASIL, 2005). This study was approved by the Ethics Committee in Research from the University Hospital at Universidade Federal de Sergipe, under protocol No. 0137.0.107.000-07.

Patients

All patients (n = 34) who attended the Popular Pharmacy of the PF from January to November, 2009 were invited for the 3rd evaluation (November, 2010). These patients were elderly patients between 60 and 75 years of age and included men and women diagnosed with diabetes. The study population was recruited over a period of approximately 2 months through telephone contact. All patients signed an informed consent document in accordance with Resolution CNS No. 196/96.

Data collection

One year after the end of the program (3rd evaluation), individual consultations were scheduled within 1 month, each lasting 40 to 60 min. The period for reassessing the clinical and humanistic results was 1 year, which doubled the amount of time suggested by Cooper et al. (2001) during which the parameters evaluated after the educational intervention declined. During the consultations, sociodemographic and pharmacotherapeutic data (that is, the number of medicines, specifically for hypoglycemia) and clinical data equivalent to data obtained during the PF one year later (that is, HbA1c level, blood glucose level, blood pressure (BP), body index mass (BMI) and waist circumference (WC)) were obtained (ADA, 2013a; BDS, 2013; Lipschitz, 1994; WHO, 1998).

In addition, to assess the humanistic outcomes, quality of life was evaluated in all 3 stages of the study by using the same generic tool, the Portuguese version of the Medical Outcomes Studies 36-Item Short Form (SF36™), used in the PF in 2009 (Ciconelli et al., 1999). This instrument has 8 domains that measure physical capacity, pain, general health, vitality, social, physical and emotional
emotional aspects and mental health. Each domain was transformed into a scale from 0 to 100 where lower scores represent a better quality of life.

Pharmaceutical and educational intervention

During the PF (January to November, 2009), educational interventions were performed through oral and written instructions, including folders and slides (Balisa-Rocha et al., 2012). The intervention was based on the previous experience and reality of the patients, and involved dialogue and co-responsibility in the process of health care and decision making (ADA, 2013b; Roter et al., 2001; Freire, 1983). The patients were oriented about diabetes and its complications, proper dosage, medication side effects and storage, changes in lifestyle-particularly with regard to diet and physical exercise and the importance of managing the signs and symptoms of diabetes through self-monitoring (Al Mazroui et al., 2009; ADA, 1996). The educational intervention was reinforced by the pharmacist during each visit. In addition, changes in drug therapy were discussed with patients and their physicians when necessary, and suggestions were made according the American Diabetes Association (ADA) (1996). For the 3rd evaluation (November, 2010), the educational intervention was reinforced through oral and written instructions.

Statistical analysis

Data were collected and entered twice in a BioEstat® version 5.0 database. The frequency, means and standard deviations were obtained. Changes in clinical and humanistic outcomes pre- and post-intervention and during reevaluation were analyzed using bivariate Friedman’s test for dependent samples. A p value less than 0.05 was considered statistically significant, with a confidence interval of 95%.

RESULTS

Fourteen of the 34 patients (41.17%) recruited for the 3rd evaluation in November, 2010, 22 months after the start of the program, attended the consultations. Regarding the use of medications, the polypharmacy phenomenon was identified in 12 (85.71%) patients. Table 2 shows the sociodemographic features and the pharmacotherapeutic profile of the participants. The mean values obtained for HbA1c, systolic blood pressure (SBP) and diastolic blood pressure (DBP) significantly improved in relation to the 1st and 2nd evaluations, that is before and after the pharmaceutical intervention (p < 0.05), as shown in Table 3. In addition, in the 2nd evaluation, 10 (71.42%) patients presented HbA1c level < 7% and 13 (92.85%) patients presented HbA1c level < 8%. In the 3rd evaluation, 6 (42.86%) of the patients achieved HbA1c level < 7% and 12 (85.71%) of the patients achieved HbA1c level < 8%. Blood pressure values also reduced over the sessions of the program and remained stable during the 3rd evaluation (p < 0.05). In addition, in the 2nd evaluation, capillary blood glucose values achieved the targets recommended by the literature (American Diabetes Association, 2005). It is noteworthy that during the 3rd evaluation, blood glucose values were significant (p < 0.05) compared to those at the 1st evaluation (not statistically significant). The SF-36 scores changed significantly (p < 0.05) between the 1st and 2nd evaluations after the pharmaceutical intervention in the fields “pain” and “vitality,” as shown in Table 4. Although there were no statistically significant differences in the other parameters, their averages increased from the 1st to 3rd evaluations.

Table 1. The 3 stages of development of the longitudinal and prospective study with an intervention, 2009 - 2010.

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>Period</th>
<th>Phase of study</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st</td>
<td>January, 2009</td>
<td>Beginning of the pharmacotherapeutic follow-up</td>
</tr>
<tr>
<td>2nd</td>
<td>November, 2009</td>
<td>Final of the pharmacotherapeutic follow-up</td>
</tr>
<tr>
<td>3rd</td>
<td>November, 2010</td>
<td>Evaluation performed 12 months after the pharmacotherapeutic follow-up</td>
</tr>
</tbody>
</table>

Table 2. Sociodemographic and pharmacotherapeutic profiles of the elderly patients (n = 14) treated at the Popular Pharmacy in Aracaju-SE, Brazil during the 3rd assessment in November, 2010.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)*</td>
<td>64.28 (2.63)*</td>
</tr>
<tr>
<td>Gender</td>
<td>N (%)</td>
</tr>
<tr>
<td>Women</td>
<td>7 (50)</td>
</tr>
<tr>
<td>Men</td>
<td>7 (50)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>10 (71.43)</td>
</tr>
<tr>
<td>Single</td>
<td>2 (14.28)</td>
</tr>
<tr>
<td>Divorced</td>
<td>2 (14.28)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
</tr>
<tr>
<td>Elementary school</td>
<td>9 (64.28)</td>
</tr>
<tr>
<td>Middle school</td>
<td>4 (28.57)</td>
</tr>
<tr>
<td>High school</td>
<td>1 (7.14)</td>
</tr>
<tr>
<td>Quantity of drugs</td>
<td>6.57 (2.28)*</td>
</tr>
<tr>
<td>Hypoglycemic drugs</td>
<td>1.93 (0.8)*</td>
</tr>
</tbody>
</table>
Table 3. Clinical parameters in the 1st, 2nd, and 3rd evaluations of elderly patients (n = 14) at the Popular Pharmacy in Aracaju-SE, Brazil in November 2010.

<table>
<thead>
<tr>
<th>Statistical indicator</th>
<th>1st evaluation</th>
<th>2nd evaluation</th>
<th>3rd evaluation</th>
<th>P*</th>
<th>P*</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP (mmHg)</td>
<td>150.35</td>
<td>134</td>
<td>131.5</td>
<td>&lt;0.05*</td>
<td>&lt;0.05*</td>
<td>nss</td>
</tr>
<tr>
<td>DBP (mmHg)</td>
<td>86.57</td>
<td>78.21</td>
<td>78.85</td>
<td>&lt;0.05*</td>
<td>nss</td>
<td>nss</td>
</tr>
<tr>
<td>Capillary glycemia</td>
<td>200.64</td>
<td>167.92</td>
<td>140.43</td>
<td>nss</td>
<td>&lt;0.05*</td>
<td>nss</td>
</tr>
<tr>
<td>BMI</td>
<td>28.61</td>
<td>29.13</td>
<td>29.49</td>
<td>nss</td>
<td>nss</td>
<td>nss</td>
</tr>
<tr>
<td>HbA1C</td>
<td>8.59</td>
<td>6.94</td>
<td>6.92</td>
<td>&lt;0.05*</td>
<td>nss</td>
<td>nss</td>
</tr>
<tr>
<td>WC (women)</td>
<td>104.43</td>
<td>102.86</td>
<td>104.57</td>
<td>nss</td>
<td>nss</td>
<td>nss</td>
</tr>
<tr>
<td>WC (men)</td>
<td>97.62</td>
<td>96.5</td>
<td>96.81</td>
<td>nss</td>
<td>nss</td>
<td>nss</td>
</tr>
</tbody>
</table>

*Statistical significance: p < 0.05. nss: not statistically significant.

Table 4. SF-36 scores related to quality-of-life parameters in the 1st, 2nd, and 3rd evaluations of elderly patients (n = 14) in Aracaju-SE, Brazil in November, 2010.

<table>
<thead>
<tr>
<th>Statistical indicator</th>
<th>1st evaluation</th>
<th>2nd evaluation</th>
<th>3rd evaluation</th>
<th>P*</th>
<th>P*</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional capacity</td>
<td>69.6</td>
<td>70.6</td>
<td>81</td>
<td>nss</td>
<td>nss</td>
<td>nss</td>
</tr>
<tr>
<td>Physical aspects</td>
<td>58.3</td>
<td>61.6</td>
<td>73.3</td>
<td>nss</td>
<td>nss</td>
<td>nss</td>
</tr>
<tr>
<td>Pain</td>
<td>48.9</td>
<td>67.7</td>
<td>61.3</td>
<td>&lt;0.05*</td>
<td>nss</td>
<td>nss</td>
</tr>
<tr>
<td>General health</td>
<td>66</td>
<td>76.0</td>
<td>75.8</td>
<td>nss</td>
<td>nss</td>
<td>nss</td>
</tr>
<tr>
<td>Vitality</td>
<td>68</td>
<td>80.6</td>
<td>77.6</td>
<td>&lt;0.05*</td>
<td>nss</td>
<td>nss</td>
</tr>
<tr>
<td>Social aspects</td>
<td>75.8</td>
<td>85.8</td>
<td>90</td>
<td>nss</td>
<td>nss</td>
<td>nss</td>
</tr>
<tr>
<td>Emotional aspects</td>
<td>59.9</td>
<td>86.6</td>
<td>75.5</td>
<td>nss</td>
<td>nss</td>
<td>nss</td>
</tr>
<tr>
<td>Mental health</td>
<td>69.8</td>
<td>81.8</td>
<td>79.7</td>
<td>nss</td>
<td>nss</td>
<td>nss</td>
</tr>
</tbody>
</table>

*Statistical significance: p < 0.05. nss: not statistically significant.

DISCUSSION

The sociodemographic characteristics and use of polypharmacy presented by the elderly patients are concordant with the data reported in the literature (Wermeille et al., 2005; Al Mazroui et al., 2009; Rosa et al., 2003). Polypharmacy, which is the use of 5 or more drugs simultaneously, increases the risk of adverse events that result in hospitalization, such as hypoglycemia (Picone et al., 2008; Jyrkka et al., 2009). In Europe, 20% of the elderly patients are attended to in clinics and other 20% are admitted in geriatric hospitals owing to adverse reactions caused by drugs (Laroche et al., 2006). Thus, the pharmacist must ensure that the patient is aware of the risks of polypharmacy, handle the medicine schedule and report to physicians about possible drug interactions and therapeutic duplicity.

The results obtained in this study suggest that pharmaceutical intervention generates clinically relevant improvement because several patients with hypertension and diabetes concomitantly were able to achieve and maintain clinical goals recommended by the literature (130/80 mmHg) (Balisa-Rocha et al., 2012; Wild et al., 2004). Patients exhibited significant reductions in mean SBP (18 mmHg) and DBP (12 mmHg) after the educational intervention; similar results were obtained by Lyra Jr. et al. (2008). According to the UK Prospective Diabetes Study (UKPDS), a difference of 10/5 mmHg reduces the risks of stroke, microvascular complications and diabetes-related mortality by 44, 37 and 32%, respectively (UKPDS, 1998).

In the 3rd assessment, even after 1 year of pharmaceutical educational intervention, HbA1c level had changed but not significantly. Similarly, Al Mazroui et al. (2009) showed that 45.4% of patients from the group who received pharmaceutical intervention achieved the target HbA1c levels (< 7%) (Al Mazroui et al., 2009).

Nevertheless, a decrement of at least 0.5% in HbA1c
levels leads to estimated 18.5 and 10.5% reductions in microvascular complications and diabetes-related mortality, respectively (UKPDS, 1998). Although the results suggest these parameters were improved and maintained, it is necessary to periodically strengthen the educational process to account for the possibility of other interferences related to the natural aspects of the disease or external factors such as diet and sedentary lifestyle; the goal of this is to avoid any reduction in the effectiveness of the long-term intervention (ADA, 2013b).

In the 3rd evaluation, some patients had HbA1c levels higher than the recommended levels (≤ 7%). However, patients who present complications in advanced stages or other clinical conditions that reduce the quality of life may have slightly higher HbA1c levels as a treatment goal. In Brazil, HbA1c level ≤ 8% is considered acceptable for the elderly and other patients in whom the risks of more intensive glycemic control are greater than the potential benefits of tight control (BDS, 2013).

In this study, educational intervention aimed to persuade patients about the need for self-care and health co-responsibility as well as the active role of referring to physicians and pharmacists when they have problems. The self-management of glycemic control should keep patients cognizant about the possibility of the loss of control of clinical parameters; they should be able to identify symptoms and prevent complications and squeals (ADA, 2013b). Therefore, the need to strengthen the educational process in order to stimulate the self-care of patients and conscious improvement of these parameters is necessary.

The body mass index (BMI) and waist circumference (WC) parameters did not differ significantly before and after educational intervention as well as in the 3rd assessment. This can be explained by the fact that the elderly are less involved in physical activities and the reduction of weight gain than younger patients. Thus, the need to include other health professionals such as doctors, nutritionists, and physical trainers in the support team for the continuous care of elderly people is necessary (ADA, 2013a; Guimarães and Ciolac, 2004; Ahrens et al., 2003).

Regarding the assessment of quality of life, our results are similar to those obtained by Elnour et al. (2008) and Al Mazroui et al. (2009). The presence of diabetes is a factor that can influence the quality of life because patients with this chronic condition use more medicines than healthy ones do, have higher blood pressure, higher rates of cardiovascular complications, worse self-perception of real quality of life, lower scores on physical scales and functional capacity of the SF-36 and higher mortality (Martinez-Casteano et al., 2004). Grincenkov et al. (2011) assessed the quality of life of hemodialysis patients and found that elderly patients with diabetes have the worst results and need to understand the limitations and perspectives of the treatment process (Grincenkov et al., 2011). Thus, it is necessary to consider the living conditions and health of the elderly with diabetes; considering these may allow the creation of proposals for specific educational intervention, promoting wellness in this age group.

**ADVANTAGES AND LIMITATIONS**

This study has some advantages and limitations. The advantages are the positive impact of pharmaceutical intervention on most clinical and humanistic parameters even after 12 months without communication with a pharmacist. In addition, the educational intervention combined the optimization of the use of medicines, self-monitoring of the disease, diet information and physical activity, and included the patient in the care process such that they could attend to their own needs; therefore, the intervention was effective in the treatment of diabetes.

The reduced sample size and the absences of patients (58.82%) were considerably high in this study; this may have influenced the statistical analysis. The limited time window (1 month) for performing the reassessment could be a reason for the small number of recruited patients, because many were available to participate in this study on a later date.

The percentage of patients with HbA1c level < 7% in the 2nd evaluation (the end of the Pharmaceutical Care Program) was 71.42%; in the 3rd assessment, this rate dropped to 42.86%. This fact may indicate that the PF period (10 months) was too short to ensure the sustainability of the educational, clinical and humanistic benefits demonstrated in this study.

The pharmaceutical educational intervention can also be a factor to be re-evaluated by researchers. According to the National Standards for Self-Management Education DM (Funnell et al., 2008), diabetes education is effective for improving clinical outcomes and the quality of life of patients. However, the need for continuous support to sustain the progress made by the participants of the educational program was discussed. It is important to emphasize that for diabetes to be a chronic condition, the disease requires continuous monitoring by physicians and other health professionals with new appointments every 3 months (Funnell, 2009; BDS, 2013). This frequency may also be necessary for the care of patients participating in the PF.

In conclusion, PF trains elderly patients to be capable of controlling their diabetes and this is important for maintaining their clinical parameters and quality of life long term. In this study, we observed that the PF contributed to maintaining the levels of BP after 12 months. Moreover, in the 3rd evaluation, HbA1c level and quality of life were similar to those at the 2nd evaluation, suggesting that the program contributed to developing the self-management of diabetes in some patients.
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ABBREVIATIONS

PF, Pharmacotherapeutic follow-up; HbA1c, glycosylated hemoglobin; BP, blood pressure; BMI, body index mass; WC, waist circumference; SF36®, medical outcomes studies 36-item short form; SBP, systolic blood pressure; DBP, diastolic blood pressure.

Conflict of interest

Authors reported none.

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