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Pharmaceutical consultation as a tool to improve health outcomes for patients with type 2 diabetes

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This study develops and evaluates a pharmaceutical consultation program (PCP) to improve treatment for Type 2 diabetes patients (T2DP) and reduce risk factors for diabetic complications with possible application in other chronic diseases. We recruited T2DP receiving conventional medical treatment but with fasting glycemia >140mg/dl and/or glycated hemoglobin >7%. The PCP includes strategies obtained from Dader's method, the PWDT (Pharmacist´s Workup of Drug Therapy method) model of pharmaceutical care, the SOAP (Subjective data, Objective data, Assessment, and Plan of care) method, and concepts based on a nursing care model. The PCP evaluated lifestyle, pharmacotherapy and monitoring it using laboratory tests, vital signs, and anthropometry. These procedures were repeated every 4 months for 1 year. Data obtained in each consultation were used to provide patient education focusing on healthy lifestyles and medications. Fifty patients completed the PCP. There were reductions in glycemia (P<0.0001), glycated hemoglobin (P=0.0022), cholesterolemia (P=0.0072), triacylglycerolemia (P=0.0204) and blood pressure (P<0.0001). Increased concordance with drug treatment and correction of drug-related problems contributed to improved treatment. We can therefore conclude that our PCP was suitable for improving health outcomes in T2DP by reducing risk factors for diabetic complications.

Uniterms: Pharmaceutical care. Type 2 diabetes/treatment. Type 2 diabetes/pharmaceutical care. Pharmaceutical consultation. Glycated hemoglobin. Diabetes education. Pharmacy.

Neste estudo, desenvolvemos e avaliamos um programa de consulta farmacêutica (PCF) visando melhorar o tratamento de pacientes diabéticos tipo 2 (PDT2) e reduzir os fatores de risco de complicações diabéticas com possibilidade de aplicação em outras doenças crônicas. Para alcançar este propósito, PDT2 recebendo tratamento médico convencional, apresentando glicemia de jejum > 140 mg/dl e/ou hemoglobina glicada >7% foram selecionados. O PCF inclui estratégias obtidas a partir do método de Dader, do modelo de cuidados farmacêuticos PWDT (Pharmacist´s Workup of Drug Therapy method), do método SOAP (Subjective data, Objective data, Assessment, and Plan of care) e conceitos baseados em um modelo de cuidados em enfermagem. O PCF avaliou o estilo de vida, farmacoterapia e seu monitoramento através de exames laboratoriais, sinais vitais e antropometria. Estes procedimentos foram repetidos a cada 4 meses durante 1 ano. Os dados obtidos em cada consulta possibilitaram oferecer educação focada no estilo de vida e uso de medicamentos. Para os 50 pacientes que concluiram o PCF houve redução da glicemia (P < 0.0001), hemoglobina glicada (P = 0.0022), colesterolemia (P = 0.0072), triacilgliceridemia (P= 0.0204) e pressão arterial (P < 0.0001). O aumento da concordância e a correção dos problemas relacionados a medicamentos contribuíram para melhoria do tratamento. Assim, podemos concluir que o PCF foi adequado para melhorar a saúde de PDT2 ao reduzir fatores de risco de complicações diabéticas.

Unitermos: Atenção farmacêutica. Diabetes tipo 2/tratamento. Diabetes tipo 2/cuidados farmacêuticos. Consulta farmacêutica. Hemoglobina glicada. Educação em diabetes. Farmácia.

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INTRODUCTION

Type 2 diabetes (T2D) has reached epidemic proportions in Brazil (Silva *et al*., 2004; Bahia *et al*., 2011). For this reason, we adopted T2D as a model of disease where the pharmacist could help improve standard medical care (Silva, Bazotte, 2011; Zubioli *et al*., 2011). In this context, the Dader method could provide adjustments for improving glycemic control (Fornos *et al*., 2006).

However, application of the Dader method is limited due to the fact that Brazil is a large country with people living in widely varying socioeconomic conditions (Angonesi, Sevalho, 2010). It is also difficult to develop a pharmaceutical consultation program (PCP) that provides quality care for all patients equally in Brazilian community pharmacies. Furthermore, it must be considered that although the fundamental goal of the community pharmacy is to provide suitable pharmaceutical care to each patient, Brazilian pharmacists are increasingly inundated with administrative responsibilities, leaving them less time to devote to direct patient care (Castro, De Castro, Correr, 2007). Our challenge, therefore, is to establish a new pharmacy community in our country where the pharmacist acts as a provider of health services helping to prevent disease and promote health. For this purpose, we developed and evaluated a PCP to improve T2DP treatment and reduce the risk factors for diabetes complications with the possibility of applying it to other chronic diseases.

Our PCP includes concepts from: 1) the Dader method of pharmacotherapy follow-up (Armando *et al*., 2005; Sabater-Hernández *et al*., 2010) which comprises a service offer followed by scheduling the first interview when the patient brings his medicine bag; 2) the SOAP plan (Subjective data, Objective data, Assessment, and Plan of care) which is characterized by clinical documentation for patient care (Weed, 1970). Described in detail by Santana, Petris, López-Chozas (2010), this procedure is very important as the documentation is a tool in treatment reformulation (Zierler-Brown *et al*., 2007); 3) The PWDT (Pharmacist´s Workup of Drug Therapy method) model of pharmaceutical care (Hepler, Strand, 1990; Hepler *et al*., 2002; Strand *et al*., 2004); and 4) The Nursing Care Consultation of São Paulo Federal University, São Paulo, Brazil (Leite de Barros, Michel, Lopes, 2002) modified and adapted for pharmaceutical care. Our pharmaceutical consultation program also includes strategies used in a previous study (Silva, Bazotte, 2011), communication based on face-to-face meetings, developing the pharmacist-patient relationship, and reinforcing lifestyle changes.

Thus, the purpose of this study was to develop and evaluate a PCP model to improve medical treatment by promoting a reduction in the risk of chronic complications in Brazilian T2DP.

PATIENTS AND METHODS

This intervention study was conducted in the Pharmacy School of Maringá State University, Maringá, Paraná State, southern Brazil which serves a wide socio-economic range of patients. Consultations occurred inside the pharmacy in a private room, exclusively dedicated to pharmaceutical care.

The study was conducted within the ethical standards established by the Declaration of Helsinki and approved by Maringá State University Ethics Committee (COPEP - CAAE 197/2006).

The impact of our pharmaceutical consultation model was evaluated by comparing each patient before (month 0) and during treatment (month 4, 8, and 12). In other words, each patient served as their own control.

Fifty of the 55 individuals starting the program (March/ 2010) completed the study (March/2011).

Inclusion and exclusion criteria

Eligibility criteria included: T2D receiving standard medical treatment with fasting glycemia ≥140 mg/dL and/or glycated hemoglobin >7.0%. Exclusion criteria were: pregnancy, other specific types of diabetes, and absence at first consultation.

Recruitment phase

Customers who visited the pharmacy school to acquire antidiabetic drugs and who declared a condition of medical treatment for Type 2 diabetes, were invited to participate in the study

During the recruitment phase (June/2009 – December 2009) 147 customers were invited to participate in this prospective study: 32 patients refused and a further 10 did not meet inclusion criteria. Reasons for refusing to participate were: avoid conflict with physician (15 patients), no time to attend the PCP (7 patients), claimed to know the problem well enough to waive participation in the study (8 patients), having professionals other than their physician involved in the treatment (20 patients).

After selection, three patients did not attend the first consultation and were excluded. Two patients left the PCP after starting: one alleging advanced cancer, the other marital conflicts.

First consultation

Study subjects were invited to bring their recent medical exams (clinical laboratory results, electrocardiogram, electroencephalogram, radiological exams etc.) to the first consultation.

Immediately after giving their written consent the first consultation started with a 40 step interview (summarized at the end of this section).

After interview the following anthropometric data and vital signs were measured: systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate, radial pulse, respiratory frequency, body temperature, body mass index (BMI), waist circumference (man), waist circumference (woman), waist/hip (man) and waist/hip (woman). For these parameters the following were considered normal values: <130 mm Hg, <80 mm Hg, 60-100 beats/min, 60-100 beats/min, 16-20 breaths/min, <37 °C, <25 kg/m², <94 cm, <80 cm, <0.90 and 0.85, respectively.

Clinical laboratory tests

After the first consultation which lasted about 40-50 minutes, patients received instructions for the clinical laboratory tests. Venous blood was collected from overnight fasted patients and evaluated for blood glycated hemoglobin A1c (HbA1c), glucose, triacylglycerol, total cholesterol, and low and high density lipoprotein cholesterol (LDL-C and HDL-C). These tests were all repeated every four months. Patients also received copies of their lab test results tests, vital signs and anthropometric parameters with instructions to show them to their physician.

Target values for HbA1c, glycemia, triacylglycerol, total cholesterol, LDL-C, HDL-C (men) and HDL-C (women) were <7.0%, 70-130 mg/dL, <150 mg/dL, <200 mg/dL, <100 mg/dL, >40 mg/dL, and >50 mg/dL, respectively. These values were based on the Clinical Practice Recommendation position statement of the American Diabetes Association (2010) and World Health Organization recommendations (2012).

First evaluation

From the lab results and data obtained in the first consultation an initial evaluation of the health problems (controlled and not controlled) was made. If some aspect of the treatment was considered "not controlled", an appropriate pharmaceutical intervention was made. If the "not controlled" condition was related to drug related problems (DRPs), this condition was classified (indication, effectiveness, safety, and non-adherence) as a preliminary step in the pharmaceutical intervention (Cipolle, Strand, Morley, 2004). It was then possible to formulate a plan for each individual to achieve the goals for improving their T2D control. For this, patients received guidance about diet, physical activity, the correct use of drugs, and resolution of DRPs. They were also informed about the risks of suffering chronic complications as a consequence of inadequate disease control. During the consultation the pharmacist gave each patient a more holistic view of their treatment and reinforced the recommendations made by their physicians.

Second, third, and fourth evaluation

The second, third and fourth consultations were made 4, 8, and 12 months after the first consultation, where the pharmacist repeated the first consultation procedure (except for unchanged information from the first interview). All anthropometric and vital sign measurements were repeated to uncover the existence of new situations or the need for new interventions. From these consultations which lasted about 20-30 minutes together with the results from the lab tests, it was possible to retune the plan for each participant whenever necessary. Reformulations in treatment, particularly changes in dose and/or drug, were implemented by the physician.

Overview of the study design

Patient recruitment → patient selection → invitation to first pharmaceutical consultation → signing of written consent → first pharmaceutical consultation (interview and evaluation of anthropometric data and vital signs) → clinical laboratory tests → second pharmaceutical consultation (interview and evaluation of anthropometric data and vital signs) → clinical laboratory tests → third pharmaceutical consultation (interview and evaluation of anthropometric data and vital signs) → clinical laboratory tests → fourth pharmaceutical consultation (interview and evaluation of anthropometric data and vital signs) → clinical laboratory tests → final evaluation.

Statistical analysis

Statistical analysis was performed using GraphPad Prism version 6.0 software. Results were analyzed by ANOVA and are reported as means ± standard deviation (SD). A 95% level of confidence ($P<0.05$) was accepted for all comparisons.

Interview Schedule

1. Identification
1.1 Name: _____
1.2 Date: ___/___/___   1.3 Gender: _____
1.4 Date of birth: __/__/_
1.5 Marital status: _____
1.6 Place of Birth: _____
1.7 Phone number: _____
1.8. Place of Work: _____
1.9. Address and phone number: _____
1.10. Doctor (s) – responsible - Address and phone number: _____
1.11. Pharmacist responsible for the interview: _____
_____

2. Education: Illiterate ( ) – High school ( ) – Graduate ( ) – Post graduate ( ).
3. Profession: Current or prior (retired patient). Does the profession pose any risk to the patient's illness and/or drug therapy?
4. Family: Number and age of children. Does the patient live with their children or parents? Do you have someone with diabetes in your family? Who?
5. Social Interactions: Normal ( ) - Does not make friends easily ( ) – Prefers to be alone ( ) – Does not adapt easily to new situations or places ( ).
6. Housing Conditions: Urban area ( ) – Rural area ( ) Apartment ( ) – With basic sanitation ( ) Without basic sanitation ( ).
7. Ability to Make Decisions: Make decisions quickly ( ) – It is difficult to make decisions ( ) – Often seeks help from family and friends ( ) – Cannot make decisions ( ).
8. Spiritual Beliefs: Has spiritual beliefs ( ) – Has no spiritual beliefs ( ) – Seeks spiritual support in difficult times ( ).
9. Financial support: Private medical treatment ( ) – Private health insurance ( ) – Public health assistance ( ) - Receives financial help from family ( ).
10. Health care guidance: Physician ( ) – Pharmacist ( ) Nurse ( ) – Prefers that family members receive orientations ( ) – Receives little guidance ( ) – Prefers not to talk about it ( ).
11. Self care: Needs help with self care ( ) – Totally dependent ( ) – Totally independent ( ).
12. View of the treatment: Is optimistic about the treatment ( ) - Is not optimistic about the treatment ( ) – Discouraged ( ) – Does not accept the problem ( ) – Does not care ( ).
13. Hospitalization and surgery: a). Have you ever been admitted to hospital? b) When was your last hospital stay? c) Why were you hospitalized? d) What type of treatment? e) Did you undergo any surgery? f) What type of surgery?

14. Risk factors: Overweight ( ) – Smoking ( ) – Alcoholism ( ) - Illegal drugs ( ) – Other ( ):
15. Lifestyle
Shower: Every day ( ) – Every other day ( ) – Once a week ( ) - Once a month ( ).
Brushing teeth: Every day ( ) – Every other day ( ) – Once a week ( ) - Once a month ( ).
Recreational activities: Travel ( ) – TV ( ) – Reading ( ) – Other activities ( ). What?
Physical Activity (exercise): No ( ). Yes ( ). If yes which one(s)? How many times a week?
16. Sleep: At what time you usually sleep? At what time you wake up? How long do you sleep per night? Do you have insomnia? Is it difficult to fall asleep? Do you wake up several times during the night? Do you feel daytime sleepiness? Do you sleep during the day? Do you snore too much? Do you have any other problem with sleep?
17. Food ingestion: Do you follow a special diet? What kind? How many meals daily? Do you have a high intake of: fruit ( ) – Raw vegetables ( ) – Cooked vegetables ( ) – Red meat ( ) – Chicken ( ) – Fish ( ) – Juices ( ) – Coffee ( ) – Tea ( ) – Milk ( ) – Sweeteners ( ) – Vitamin supplements ( ) – Mineral supplements ( ).
18. Diseases of the digestive system: Normal ( ) - Peptic ulcer ( ) – Gastritis ( ) - Gastro esophageal reflux disease ( ) – Ulcerative colitis ( ) – Nausea ( ) – Vomiting ( ) – Hemorrhoids ( ) - Other abnormalities ( ). Which one (s)?
19. Fecal elimination: Normal ( ) – Pain or another difficulty during defecation ( ) - Fecal urgency ( ) – Fecal incontinence ( ) – Constipation ( ) – Diarrhea ( ). How often do you defecate per day?
20. Fluid ingestion: How much fluid do you consume each day? _____ Water ( ) – Soft drink ( ) – Beer ( ) – Other:
21. Kidney diseases: Kidney stone ( ), Renal failure ( ) – Hemodialysis ( ) – Other kidney diseases ( ). Which one (s)?
22. Urinary elimination: How often do you urinate each day? _____ Normal ( ) – Pollakiuria ( ) – Nocturia ( ) – Urinary urgency ( ) – Urinary incontinence ( ) – Decreased urine stream ( ) – Difficulty urinating ( ).
23. Cardiovascular diseases: Normal ( ) – Hypertension ( ) – Angina ( ) – Tachycardia ( ) - Bradycardia ( ) – Arrhythmia ( ) – Congestive heart failure ( ) – Heart attack ( ) - Other abnormalities ( ). Which one (s)?
24. Lung diseases: Absence ( ) – Dyspnea ( ) – Asthma ( ) – Pneumonia ( ) - Bronchitis ( ) – Chronic obstructive pulmonary disease ( ) - Other abnormalities ( ). Which one (s)?
25. Hepatic diseases: Absence ( ) – Steatosis ( ) – Ste-

atohepatitis ( ) - Hepatitis ( ) – Cirrhosis ( ) – Other abnormalities ( ) - Which one (s)?
26. Hematological diseases: Absence ( ) – Anemia ( ) – Abnormal coagulation ( ) – Leukocytosis or leucopenia ( ) – Other abnormalities ( ) – Which one (s)?
27. Neurological diseases: Absence ( ) – Hemorrhagic or ischemic stroke ( ) – Headache ( ) – Seizure disorder ( ) – Migraine ( ) – Memory loss ( ) – Dizziness ( ) – Drowsiness ( ) – Syncope ( ) – Other abnormalities ( ) – Which one (s)?
28. Psychiatric diseases: Depression ( ) – Psychosis ( ) – Mania ( ) - Other abnormalities ( ) – Which one (s)?
29. Other endocrinal diseases: Hypothyroidism ( ) – Hyperthyroidism ( ) – Other endocrinopaty ( ) – Which one (s)?
30. Other diseases/symptoms: Pain ( ) – Fatigue ( ) – Weakness ( ) – Other disease(s) ( ). Which one (s)?
31. Physical examination to identify main health problems.
<u>Head:</u> Normal ( ) – Dandruff ( ) - Scalp lesions ( ) – Hair loss ( ) – Other abnormalities ( ). Which one (s)?
<u>Eyes:</u> Normal ( ) – Cataract ( ) - Blurred vision ( ) – Abnormal secretions ( ) – Other abnormalities ( ). Which one (s)?
<u>Nose:</u> Normal ( ) – Allergy ( ) – Nasal obstruction ( ) – Epistaxis ( ) – Rhinitis ( ) – Other abnormalities ( ). Which one (s)?
<u>Mouth:</u> Normal ( ) – Caries ( ) – Gingivitis ( ) – Missing teeth ( ) – Denture ( ) - Other abnormalities ( ). Which one (s)?
<u>Ears:</u> Normal ( ) – Decreased acuity ( ) – Tinnitus ( ) – Inflammatory or infectious processes ( ) - Labyrinthitis ( ) – Other abnormalities ( ). Which one (s)?
<u>Neck:</u> Normal ( ) – Thyroid nodules ( ) – Enlarged thyroid – Other abnormalities ( ). Which one(s)?
<u>Upper limb:</u> Normal ( ) Paresis or plegia ( ) – Lesions ( ) – Pain ( ) – Paresthesia ( ) – Other injuries ( ). Which one (s)?
<u>Abdomen:</u> Normal ( ) – Pain ( ) – Flatulence or bowel sounds ( ) – Other abnormalities ( ). Which (s)?
<u>Lower limb:</u> Normal ( ) – Edema ( ) – Pain ( ) – Paresthesia ( ) – Loss of sensitivity ( ) – Paresis ( ) – Plegia ( ) – Lesions ( ) – Other injuries ( ). Which one (s)?
<u>Feet:</u> Normal ( ) – Loss of sensitivity ( ) – Pain ( ) – Paresthesia ( ) – Lesions ( ) – Ulcers ( ) – Corns and calluses ( ) – Deformities ( ) – Edema ( ) – Amputation ( ) – Other abnormalities ( ) Which one (s)?
<u>Skin:</u> Normal ( ) – Age spots ( ) – Skin lesions: dermatitis, vitiligo, psoriasis, acne, infections, eruption ( ) – Dry skin ( ) - Excess hair ( ) - Edema ( ) – Allergic reactions ( ) – Eczema ( ) – lesions ( ) – Rash ( ) – Pale skin ( ) – Other injuries ( ). Which one (s)?

32. Pharmacological profile:
a) What drugs are you currently using to treat diabetes? If you don't remember please bring them to the next consultation.
b) What drugs are you currently using to treat other diseases? If you don't remember please bring them to the next consultation.
c) What unprescribed drugs are you currently using? If you don't remember please bring them to the next consultation.
d) Do you use herbal teas or other alternative medicines or practices? Which one (s). How?
e) Have you presented allergic reactions to medications? What drugs?
f) Who administers your medications?
Observations: a) for prescribed drugs include: brand name, generic name, pharmaceutical form, dose and treatment schedule and times, and verify whether the drug is on the national list of essential drugs (RENAME, 2008); b) treatment regimen noted as: 1 (after breakfast) + 1 (after lunch) + 1 (after dinner). If there was absence of drug administration "1" is replaced by "0". Additionally, if the patient forgot the information about his medication, he was reminded to bring the drugs and/or the prescription to the next consultation.
33. Medication guidance: Physician ( ) – Pharmacist ( ) – Nurse ( ) – Prefers that family members receive guidance ( ) – Receives little guidance ( ).
34. Drug side effects: Did you present symptoms indicating drug adverse reactions. If yes: before starting the treatment ( ). After starting the treatment ( ). What did you feel? When? Which drug (s)? Which dose (s)?
35. Drug interactions: Did you present symptoms indicating drug interactions. If yes: before starting the treatment ( ) – After starting the treatment ( ). What did you feel? When? Which drug (s)? Which dose (s)?
36. Drug compliance: Yes ( ). No ( ). If no: Why? When? Which drug (s)? Which dose (s)?
37. Drug related problem: Yes ( ). No ( ). If yes: Which one (s)?
a) Classification: Indication ( ), Effectiveness ( ), Safety ( ) and Non adherence ( ).
38. Pharmacist's opinion on patient's appearance: Good (G) or Bad (B): Clothing ( ) - Hair ( ) – Nails ( ) – Oral care ( ) – Body care ( ).
39. Final question: is there anything else you would like us to know?
40. Pharmacist's opinion about the patient's health problem: controlled (C) or not controlled (NC). If NC: What is (are) not controlled? What is the appropriate pharmaceutical intervention?

RESULTS

The patients (25 men and 25 women) had a mean age of 58.6 ± 7.8 (mean $\pm$ SD) years (range 36-75 years). Additionally, 64% of the patients had ≥ 5 years of diagnosis with time of diagnosis: 11.2 ± 8.4 (mean $\pm$ SD) years, ranging from 2 to 38 years. Interestingly, 48% had private health insurance and 52% used the public health system.

The physician (68%) and the pharmacist (44%) were the most sought after professional for guidance on health and drug problems, respectively. In addition, 50% of the T2DP had not received guidance on drug use before starting the study.

The main abnormalities detected from interviews, and anthropometric data and vital sign evaluation were hypertension (76%), overweight or obesity (48%), tachycardia (48%), skin age spots (22%), lower limb edema and pain (22%), upper limb pain (20%), flatulence or bowel sounds (18%), lower limb lesions (18%), upper limb edema and lesions (16%), kidney stones (16%), migraine (14%), gastritis (14%), abdominal pain (12%), foot pain (12%), cataract (12%), upper limb paresthesia (10%), blurred vision (10%), thyroid complaints (10%), gastro esophageal reflux (8%), eye discharge (8%), constipation (6%), diarrhea (6%), sinusitis (6%), labyrinthitis (6%), foot deformities (4%), paresthesia in the feet (4%), foot edema (4%), renal failure (4%), peptic ulcer (4%), hemorrhoids (4%), and tinnitus (4%).

Concerning hospitalization 52% patients were hospitalized in the last 7 years. However the majority of hospitalizations (44%) were not related with the diabetes.

Sleep was not satisfactory for 54% T2DP: insomnia (2%), sleep medication (6%), sleeping difficulty (18%), waking up several times in the night (16%), sleeping during the day (8%), and sleepiness (4%).

Changes in lifestyle were detected. For example, regular physical activity increased from 30% (month 0) to 64% (month 12). From these results the percentage of patients engaged in the nutritional education process increased from 14% (month 0) to 76% (month 12).

Oral antidiabetic drugs were used in mono (32%) or combined (68%) therapy. Metformine was present in all combined antidiabetic drug treatments. Metformine (isolated or combined) was used by 44 patients (88%), gliclazide by 11 (22%), glimepiride by 8 (16%), glibenclamide by 7 (14%), clorpropamide by 1 (2%), vildagliptine by 3 (6%), sitagliptine by 1 (2%), and rosiglitazone by 1 (2%).

Regimens for oral antidiabetic drugs were: a) once a day: metformine (n=1), gliclazide (n=9), glibenclamide (n=1), glimepiride (n=7), vildagliptine (n=1); b) twice a day metformine (n=25), gliclazide (n=2), glibenclamide (n=5), glimepiride (n=1), clorpropamide (n=1), vildaglipitine (n=2), sitagliptine (n=1), rosiglitazone (n=1); c) three times a day: metformine (n=18), glibenclamide (n=1).

Insulin was used by 18% of T2DP. The regimen was: a) NPH: once a day (n=3), twice a day (n=1); b) Regular: twice a day (n=1); b) NPH + Regular: once a day (n=1); c) glargine: once a day (n=2), twice a day (n=1). We also observed that insulin was used on its own (n=1) or combined with metformine (n=4), clorpropamide (n=1), gliclazide (n=1), glimepiride (n=1), or vildagliptine (n=1).

Antihypertensive, lipid lowering, antiplatelet, and over the counter drugs were used by 31 (62%), 11 (22%), 8 (16%), and 18 (36%) patients, respectively.

Prescribed and non-prescribed pharmaceutical drugs included the following: acetylsalicylic acid, alendronate, aminophylline, amoxillin, alprazolam, amitriptyline, amlodipine, atenolol, bezafibrate, bromazepam, budesodine, butylscopolamine, carbamazepine, cyclobenzaprine, clonazepam, cloxazolan, captopril, celoxib, cilostazol, clortalidone, clopidogrel, condroitin, diclofenac, diltiazem, dimenidrate, domperidone, enalapril, eplerenone, spironolactone, folic acid, formoterol, hydrochlorothiazide, indapamide, fenitoin, ferrous sulfate, furosemide, ginkgo biloba, lorazepam, levofloxacin, losartan, meloxicam, methyldopa, naproxen, nitrofurantoin, nitroglycerin, nifedipine, omeprazole, paroxetine, pentoxifylline, predinisolone, propranolol, ramipril, rosuvastatin, sibutramine, sidenafil, simvastatin, valsartan, thyroxine, and ziprasidone.

Table I shows improvements for glycemia ($P<0.0001$), HbA1c ($P=0.0022$), total cholesterol ($P=0.0072$), HDL ($p=0.0042$), triacylglycerol ($P=0.0204$), SBP, and DBP. In the specific case of SBP ($P<0.0001$) and DBP ($P<0.0001$) the reduction occurred 4 months after starting the PCP. However, BMI and waist circumference remained unchanged.

DISCUSSION

The role of pharmaceutical care in improving patient health outcomes is well established (Brooks, Rihani, Derus, 2007; Lyra, Marcellini, Pelá, 2008; Al Mazroui *et al.*, 2009). However, there is a need for a pharmaceutical care model suitable for applying in Brazil where the health care system is very different to countries where the main pharmaceutical care methods have been developed (Obreli-Neto, Cuman, 2010; Correr *et al.*, 2009a,b; Correr *et al.*, 2011).

For this reason our PCP incorporates concepts from several well established patient care methods (Armando *et al.*, 2005; Weed, 1970; Leite de Barros, Michel, Lopes, 2002; Hepler, Strand, 1990). Selecting the best aspects of

TABLE I - Profiles of the patients before (month 0) and 4, 8, and 12 months after starting the pharmaceutical care program (PCP)

Parameters	month 0	month 4	month 8	month 12	P values #	P values §	P values *
GLY	183.4±7.3	164.8±7.4	158.7±7.2	143.9±5.5	0.0769	0.0182	<0.0001
HbA1c	9.6±0.3	8.8±0.33	8.5±0.3	8.15±0.3	0.1082	0.0288	0.0022
TC	220.0±5.6	213.1±6.9	208.9±5.9	196.3±6.1	0.4428	0.1837	0.0072
HDL-C	35.6±1.4	38.57±1.7	39.35±1.3	41.57±1.4	0.1829	0.0539	0.0042
LDL-C	130.4±4.7	129.5±6.4	128.2±4.4	118.1±4.9	0.9185	0.7395	0.0743
TG	209.1±15.5	213.3±18.8	192.6±22.4	161.0±12.7	0.8622	0.5475	0.0204
SBP	157.0±3.2	133.4±3.4	130.7±2.2	126.6±1.3	<0.0001	<0.0001	<0.0001
DBP	107.6±2.7	93.7±2.7	89.9±2.0	85.73±1.2	0.0004	<0.0001	<0.0001
HR	115.0±3.2	108.3±6.5	104.8±7.1	99.0±6.2	0.3692	0.2110	0.0379
RP	117.4±3.5	109.1±8.0	105.7±8.0	99.4±6.8	0.3664	0.2040	0.0361
RF	21.6±0.63	19.3±0.44	18.2±0.61	18.1±0.6	0.0047	0.0004	0.0002
BMI > 25	31.1±0.65	30.8±0.7	30.7±0.7	30.5±0.7	0.7827	0.7411	0.5611
BMI > 30	33.6±0.63	33.4±0.72	33.3±0.7	33.1±0.7	0.8315	0.7662	0.6108
W/H	0.99±0.008	0.99±0.008	0.98±0.008	0.98±0.008	0.8129	0.8683	0.3723

Data are means ± standard deviation (50 patients). P values were obtained after comparing month 0 with month 4 (#), month 0 with month 8 (§), and month 0 with month 12 (*). Key: GLY (glycemia – mg/dL), HbA1c (glycated hemoglobin A1c - %), TC (total cholesterol - mg/dL), HDL-C (high density lipoprotein cholesterol - mg/dL), LDL-C (low density lipoprotein cholesterol - mg/dL), TG (triacylglycerol - mg/dL), SBP (systolic blood pressure - mmHg), DBP (diastolic blood pressure - mmHg), HR (heart rate - beats/min), RP (radial pulse - beats/min), RF (respiratory frequency - breaths/min), BMI (body mass index - kg/m²), W/H (waist/hip).

each method resulted in the PCP described in this paper. The contribution made by each strategy cannot be evaluated, but results showed that providing diabetes education and reinforcing lifestyle changes can help patients optimize metabolic control in a country where only 0.2% of T2DP simultaneously reach targets for glycemia, lipidemia, and blood pressure (Gomes *et al.*, 2006). Additional details on the contribution by each method can be found in Zubioli (2011).

The main limitation of our PCP is the time needed (40-50 min) in the first consultation to obtain all the required information. But, the availability of this information for other professionals, particularly the physician, could be important by supplying relevant clinical data which is difficult to acquire in a regular medical consultation. In accordance with this statement, of the 50 T2DP who concluded the study, more than 350 abnormalities and/or diseases were able to be detected, about 7 per patient.

The success of our PCP in promoting a reduction in chronic complication risks in Brazilian T2DP is summarized the Table I. Similar results were obtained when male (n= 25) and female (n= 25) or optimist (n=29) and non-optimist (n=21) patients were compared (results not shown).

Improvements in fasting glycemia, HbA1c, triacylglycerol, total cholesterol, HDL-C, SBP and DBP show the importance of monitoring not only glycemia but also blood pressure and lipid profile to obtain a reduction in cardiovascular risks, the main cause of death in T2D (Azambuja *et al.*, 2008; Kothari *et al.*, 2002).

The DCCT (1993) and UKPDS (1998) studies demonstrated a clear reduction in the chronic complications associated with a 1.0% reduction in HbA1c levels in Type 1 and Type 2 diabetes patients, respectively. The reduction in HbA1c obtained in this study, i.e., 1.45% is very relevant and suggests that our PCP together with the medical treatment represents a suitable approach for T2DP.

Changes in lifestyle certainly contributed to these improvements. At the start of the PCP 30% of the patients were engaged in regular physical activity, but due to constant reinforcement of lifestyle changes by the pharmacist, this percentage increased to 64%. Improvement in regular physical activity is a benefit, even without weight loss, because it will prevent weight gain, abdominal obesity, and insulin resistance favoring better glycemic control and decreasing cardiovascular risk (Clifford *et al.*, 2005; Castro *et al.*, 2006; Coleman *et al.*, 2007). Additionally, 14% of the patients were engaged in the nutritional education process when the PCP started, but due to continuous encouragement from the pharmacist towards nutritional changes, this percentage increased to 76%.

In contrast, BMI and waist circumference remained

unchanged after one year of follow up (Table I). For this reason future studies must include new strategies based on reducing body weight by 5 to 10%, as this represents a significant improvement in metabolic control, blood pressure levels, and a reduction in diabetes related mortality (Ahrens, Hower, Best, 2003).

Evaluation of our PCP needs to take in to account several methodological limitations: potential selection bias, the possibility of behavior changes by the patients simply because they are being studied (Lindenmeyer *et al*., 2006), the limited number of patients etc. However, despite these limitations our PCP is suitable for application and may be used in the private community pharmacy chain and could also be adapted for the public health system and for other chronic diseases.

CONCLUSION

The PCP developed in this study was suitable for improving health outcomes in T2DP by reducing the risk factors for diabetes complications.

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