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Clinical and Behavioral Impact of Pharmaceutical Care Services in Community Pharmacies in Puerto Rico

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Abstract

Background: Medication Therapy Management (MTM) is an area in which pharmacists have the opportunity to provide pharmaceutical care by working directly with the patients and their physicians to optimize the patient's pharmacological therapy. The objective of this research is to determine the relationship between MTM practices and changes in clinical markers of disease and behavioral attitudes of Puerto Rican patients at community pharmacies.

Methods: The study is a retrospective chart review design. A total of thirty-five patients participated in the first encounter, which consisted in an individualized clinic visit following a standardized MTM format. Follow-up was provided as appropriate for clinical evaluation. A trend analysis and paired t-test was planned to assess the impact of MTM interventions on blood pressure, lipid levels, and hemoglobin A1C with respect to baseline measurements. Adherence was assessed by calculating the medication possession ratio for all medication filled from the initial MTM clinic visit to the end of the study period.

Results: An average positive trend for clinical markers of de could be observed. Adherence in general improved from an average of MPR of 0.54 to an MPR of 0.63. However, the desired level for adherence was not reached in all patients.

Conclusion: Although recruitment was low this study showed an average improvement in clinical markers of disease and adherence of patients receiving MTM services in three community pharmacies in the metropolitan area of Puerto Rico. Due to the lack of statically significant data the results cannot be extrapolated to the general population. However, based on these preliminary findings, further research in this area is warranted.

Keywords: Medication Therapy Management (MTM); Pharmaceutical care; Community pharmacy

Background

Since the 1990's, the role of the community pharmacist as a drug-dispenser has evolved into a patient-centered health care provider. As the medication expert, the pharmacist can use his/her vast knowledge of pharmacodynamics, pharmacokinetics, compounding, and pharmacogenetics to formulate an individualized drug treatment with the ultimate goal of improving the patient's quality of life. This is called pharmaceutical care [1]. When providing pharmaceutical care, the pharmacist assumes responsibility for the patients' pharmacological therapy and provides adequate follow-up [1].

Medication Therapy Management (MTM) is an area in which pharmacists have the opportunity to provide pharmaceutical care by working directly with the patients and their physicians to optimize the patient's pharmacological therapy. According to the American Pharmacist Association, MTM services includes any activity that optimizes therapeutic outcomes for individual patients (such as medication therapy reviews, pharmacotherapy consults, anticoagulation management, immunization, health and wellness programs, and many other clinical services) with the purpose of health promotion, as well as, preventing, detecting, and solving medication related problems [2]. A study carried by Mitchell J Barnet et al. [3]. Barnet et al in 2009, demonstrated that MTM services have shifted from acute illness treatment consultations to chronic diseases management and education. This shift has not only provided better pharmaceutical care, but it has decreased costs to both the healthcare system and patient [4].

For example, Omran et al. [5] demonstrated that adding pharmacists to primary care teams for medication management of blood pressure in diabetes type 2 patients resulted in therapy

optimization [4]. Furthermore, in systemic interviews regarding collaborative agreements between pharmacist and physicians clinicians and patients, Lalonde et al. [6] found that both clinicians and patients highly appreciate pharmacists' intervention and is perceived as being more structured, systematic, effective and safer compared with the traditional approach, wherein physicians prescribe and adjust pharmacotherapy and pharmacists dispense medication [5].

In Puerto Rico, community pharmacists have the opportunity to offer MTM services to prevent and solve drug related problems, and sometimes be reimbursed for such services. Drug related problems vary from the drug's efficacy or toxicity to the patients' multi-factorial non-adherence which includes lack of understanding and lack of economic resources. Therefore, the success of MTM services can be measured by: (1) clinical outcomes, (2) behavioral outcomes, and (3) economical outcomes [6].

The University of Puerto Rico Medical Sciences Campus has carried out several studies on the role of the pharmacist in the community [7-10]. One notable example is the Programa S.I.M.P.L.E. This study demonstrated that the role of the community pharmacist as a facilitator

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and educator for the management of drug therapy problems in the elderly can improve medication understanding and adherence [9]. While it is evident that MTM services provide positive behavioral outcomes to the patients and providers, regional studies on clinical and economic outcomes are lacking. The objective of this research is to determine the relationship between MTM practices and changes in clinical markers of disease and behavioral attitudes of Puerto Rican patients at community pharmacies.

Methods

The study is a retrospective chart review design to evaluate the impact of MTM services in community pharmacies of Puerto Rico. Three community pharmacies with established pharmacist-provided MTM services were selected for patient recruitment. All of the pharmacies chosen are located in the metropolitan area of Puerto Rico, and currently have contracts with various MTM payers in Puerto Rico.

From the pool of patients participating in the MTM clinics a convenience sample of 35 patients was selected for evaluation. Inclusion criteria included: age 18 years or older; regular patient of any of the 3 pharmacy-study site; documentation of least two of the following chronic conditions diagnosed: diabetes, hypertension, or dyslipidemia; use of 5 or more medications; participation in at least two MTM visits; and documentation of at least two hemoglobin A1C and/ or lipid panels measurements. Exclusion criteria included persons younger than 18 years of age, pregnant women, patients receiving palliative or terminal care, and patients receiving MTM services from another pharmacy.

Of the thirty-five patients selected, all participated in an initial encounter, which consisted in an individualized clinic visit following a standardized MTM format with focus on the four basic areas of medication indication, effectiveness, safety, and adherence. During the visit, the patients had each of their medications matched to their conditions and evaluated with respect to these four categories. For all MTM patients, the pharmacist assessed blood pressure and weight at each visit. Baseline laboratory values including, lipid panel and hemoglobin A1C, were also assessed for all patients at the first clinic visit with a plan to follow-up periodically thereafter as required for clinical monitoring of therapy. Any drug related problems identified were addressed with the patient and provider if appropriate. At each visit, patients were encouraged to adopt healthier lifestyles including adherence to medication.

For each patient a care plan was created, and follow up at 1-6 months was scheduled.

Clinical outcomes to measure included the following:

- Hypertensive patients: at least 3 BP readings (including baseline) at a minimum of two weeks apart

- Diabetic patients: at least 2 Hemoglobin A1c readings (including baseline) at a minimum of 3 months apart

- Dyslipidemia patients: at least 2 lipid panel readings (including baseline) at a minimum of 3 months apart

The average change in the clinical markers of disease was calculated based upon clinical information documented at follow-up encounters. A trend analysis and paired t-test was planned to assess the impact of MTM interventions on blood pressure, lipid levels, and hemoglobin A1C with respect to baseline measurements with a p value<0.05 considered significant. Adherence was assessed by calculating the medication possession ratio (MPR) 12 for all medication filled from the initial MTM clinic visit to the end of the study period. For this study, adherence was defined as a MPR of 0.8 or greater, and non-adherence was defined as a MPR of less than 0.8.

All of the statistical analyses were to be conducted using SAS 9.3 (SAS Institute Inc, Carry NC). The Microsoft® program Excel was used to determine and describe the socio-demographic variables and mathematical findings.

The University of Puerto Rico Medical Science Campus IRB committee approved this study. An informed consent sheet was created in both English and Spanish and submitted to the IRB. Although, the IRB determined that informed consent was not necessary for use in the study protocol itself, all patients did consent to their approval in participating of the MTM clinics, as it is standard procedure at the pharmacy sites. All records are stored in a secure archive located at the Pharmaceutical Care Office of one of the pharmacy sites.

Results

Out of 35 patients examined, 22 were lost to follow-up, thus making the sample size too small to provide adequate data for statistical analysis. Out of the remaining 13, two did not provide all the laboratory data required and were excluded. One patient only had one (resistant hypertension requiring the use of 4 antihypertensive medications) of the three disease states required and other chronic diseases not pertinent to the study. This patient was included only in the blood pressure and adherence analysis. Table 1 demonstrates the patient characteristics of the 11 patients that where included in the final analysis.

The average change in the clinical markers of disease was calculated, between the first and second encounter, and the following results were observed:
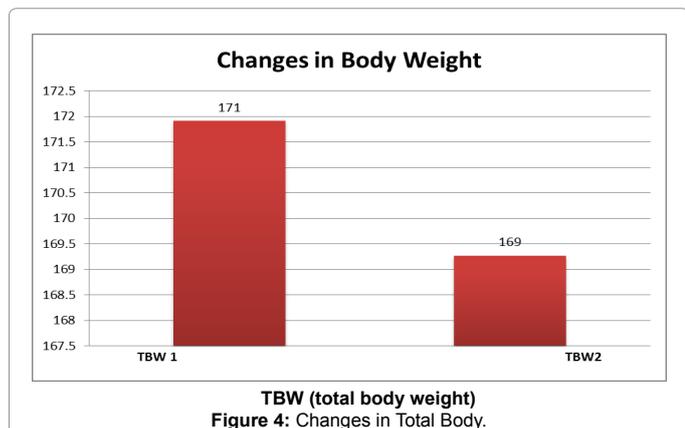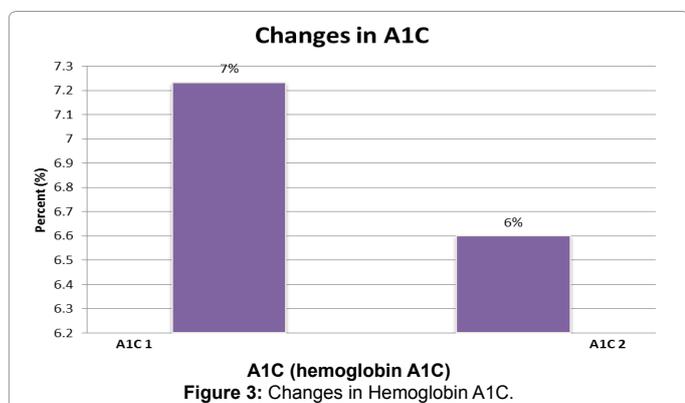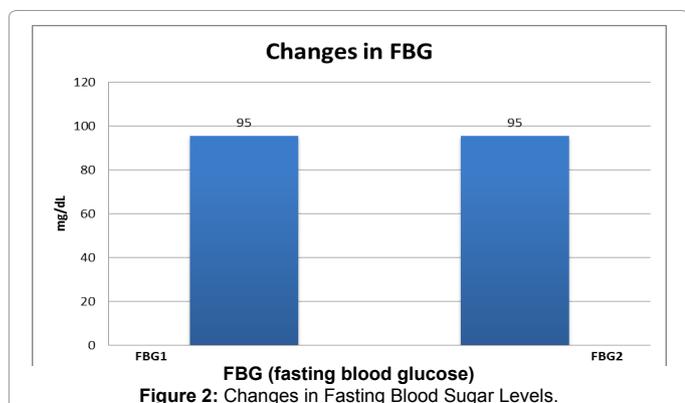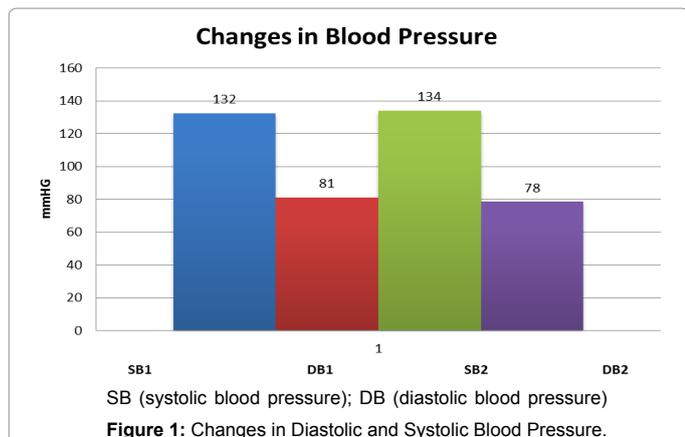
- An increase of 2% in diastolic blood pressure
- A 2.6% decrease in systolic blood pressure
- No change in fasting blood glucose levels
- 1% decrease in total body weight
- A 3.7% increase in total cholesterol
- A 19% decrease in low density cholesterol
- A 31% increase in high density cholesterol
- An 85% decrease in triglycerides
- A decrease of 0.6% in hemoglobin A1C

Figures 1-8 depict the changes observed in the variables measured.

For the 11 patients evaluated, the medication possession ratio (in

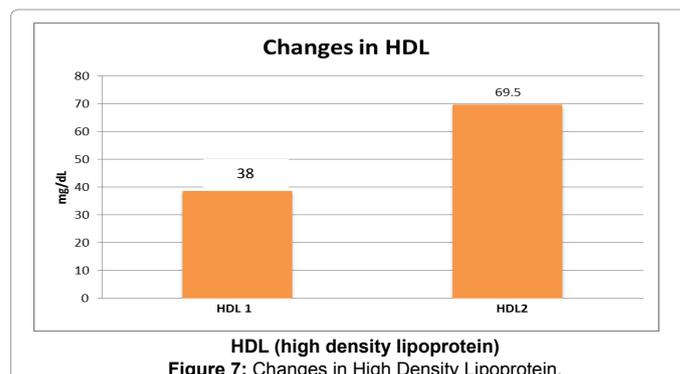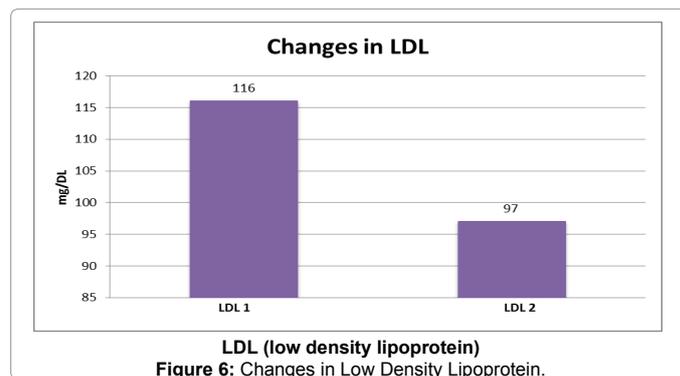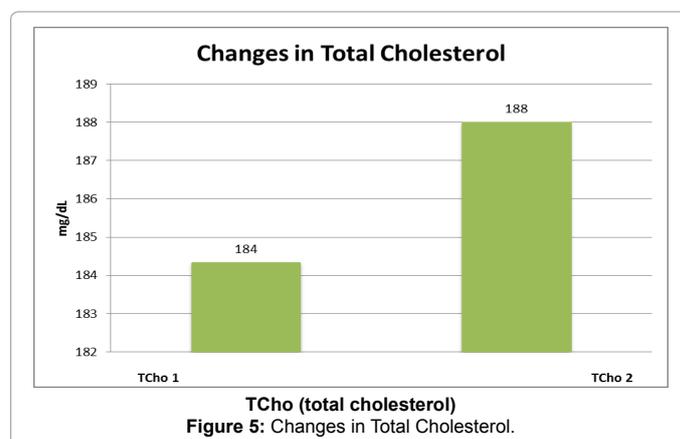| Characteristic	# Patients	Range or %
Average age in years	70.1	59-83
Male patients	6	54.6%
Female patients	5	45.4%
Patients with diabetes	7	63.3%
Patients with dyslipidemia	10	90.9%
Patients with hypertension	11	100%
Patients with two of the following conditions: Diabetes, dyslipidemia, and hypertension	3	27%
Patients with all three of the following conditions: Diabetes, dyslipidemia, and hypertension	7	63.3%

Table 1: Patient Demographics.

Figure 1: Changes in Diastolic and Systolic Blood Pressure.

SB (systolic blood pressure); DB (diastolic blood pressure)

FBG (fasting blood glucose)
Figure 2: Changes in Fasting Blood Sugar Levels.

A1C (hemoglobin A1C)
Figure 3: Changes in Hemoglobin A1C.

TBW (total body weight)
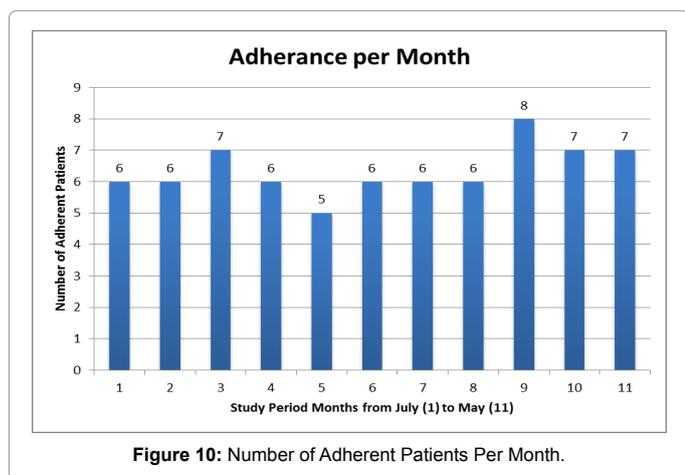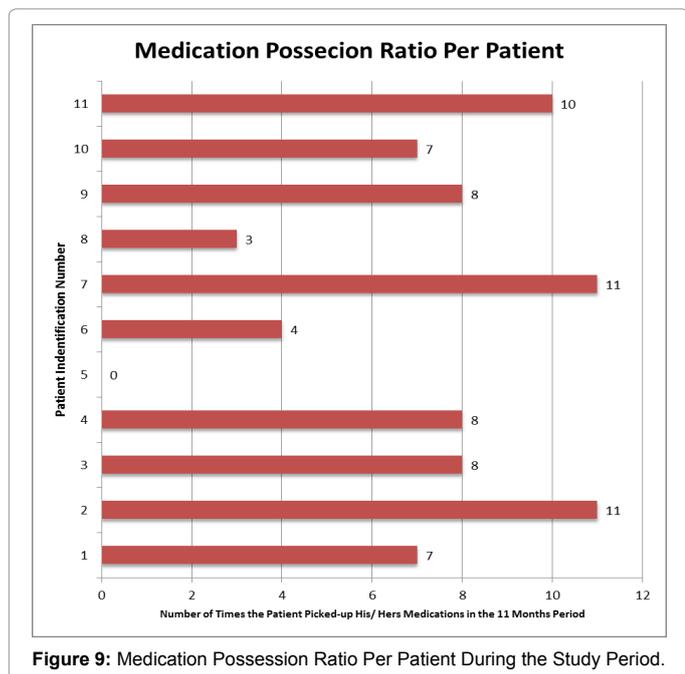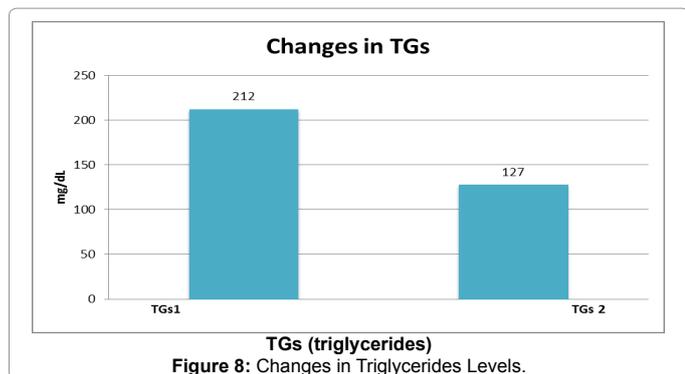**Figure 4:** Changes in Total Body.

months) for the study period was calculated. The average medication possession ratio was 63.18% with 0% being the lowest MPR to 100% being the highest. Three patients had a MPR greater than 0.8, while the other eight remained below the desired adherence mark. Adherence in general improved from an average of MPR of 0.54 in July to an MPR of 0.63 in May. However, the desired level for adherence was not reached in all patients. Figures 9 and 10 demonstrate the MPR calculated per patient and adherence per month during the study period, respectively.

Discussion

Our study had a number of limitations. The primary limitation was lack of laboratory values for follow-up. Most of the participants visited the clinic at least three times, but forgot or did not have labs available. Thus a more comprehensive analysis could not be realized. Also the number of patients that were part of the final group was too small to carry out any statically significant analysis. In addition, the fact that the variables were averaged and compared using only the first and

TCho (total cholesterol)
Figure 5: Changes in Total Cholesterol.

LDL (low density lipoprotein)
Figure 6: Changes in Low Density Lipoprotein.

HDL (high density lipoprotein)
Figure 7: Changes in High Density Lipoprotein.

Figure 8: Changes in Triglycerides Levels.

Figure 9: Medication Possession Ratio Per Patient During the Study Period.

Figure 10: Number of Adherent Patients Per Month.

second encounter can produce a large margin of error. Measurements of adherence could be influenced by the fact that patients could have picked up their medications at other pharmacies. Also the medication possession ratio may not always be an indicative of whether patients are (or are not) taking their medications as prescribed.

However, our study is consistent with other studies that demonstrate the positive impact of pharmaceutical care services in clinical markers of disease as well as adherence 5-11. Although the study was unable to product any statistically significant results, the positive trends in some outcomes demonstrates the need for further research in this area. A larger number of participants, a longer period of time and more rigorous data collection may provide better analysis of pharmaceutical care services in Puerto Rico and their effect on patient outcomes.

Conclusion

Although recruitment was low this study showed an average improvement in clinical markers of disease and adherence of patients receiving MTM services in three community pharmacies in the metropolitan area of Puerto Rico. Due to the lack of statically significant data the results cannot be extrapolated to the general population. However, based on these preliminary findings, further research in this area is warranted.

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