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The Effect of a Novel Proactive First Day Prescription Counseling Program on Adherence to Select Cardiovascular Medications

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Conflicts of Interest: Jamie L. McConaha, Pharm.D., CGP is an assistant professor of pharmacy practice at Duquesne University Mylan School of Pharmacy in Pittsburgh, PA. Kevin Lynch, Pharm.D., BCPS, MBA, is a Medical Outcomes Specialist for Pfizer, Inc. Neither author declares any conflicts of interest of any kind in relation to this study.

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Keywords: medication adherence, patient counseling, community pharmacy

Abstract

Objective: *To determine the impact of a proactive first day prescription counseling program on medication adherence to new cardiovascular maintenance medications*

Design: *Cross-sectional study*

Setting: *Regional chain community pharmacy in Pittsburgh, Pennsylvania; August 2009 through November 2010*

Patients: *Data was collected from all patients aged 18-89 presenting with a new or transferred prescription or change in dosage within the study dates at four study locations*

Interventions: *Patients presenting with a new or transferred prescription or change in dosage were identified to receive pharmacist or student pharmacist counseling. Data from the counseling session was tracked weekly to determine if the program increased adherence to statins, ACEIs and/or ARBs.*

Main Outcome Measured: *Adherence to statins, ACEIs and/or ARBs was determined by differences in proportion of days covered (PDC) at six months and medication persistence to therapy.*

Results: *Analysis was conducted using IDNA[sm] software. Results of the 6,916 prescriptions included in the study revealed that persistence rates for statins was 32.5% (intervention) and 34.2% (control) ($p<0.001$); ACEI/ARBs persistence was 37.3% (intervention) and 43.2% (control) ($p<0.001$). PDC was nonsignificant with respect to statins; 43.2% (intervention) and 45.1% (control); and 50.2% (intervention) and 57.1% (control) ($p<0.001$) for the ACEI/ARBs.*

Conclusion: *Results from this study showed no improvement in adherence of statins or ACEIs/ARBs with the D1TC program versus control pharmacies, although several important limitations were identified. It is clear that a variety of methods and programs are needed to consistently improve adherence to maintenance medications.*

Introduction

Over 3.9 billion prescriptions are dispensed each year in the United States, primarily through retail pharmacies.[1,2] Pharmacist counseling is essential to optimize patient education and medication adherence and to prevent dangerous errors and adverse drug events. With the immense number of prescriptions dispensed through community pharmacy, pharmacists who work in this environment are in an optimal position to provide counseling to these patients. Pharmacist counseling is mandated by the US government via the Omnibus Reconciliation Act of 1990 (OBRA '90). This law stipulates that all Medicaid patients receive the offer to counsel when picking up a prescription. After the passing of this law, nearly all states responded by enacting and overseeing state-specific counseling regulations to all patients of the pharmacy, not just Medicaid patients. However, one study found that, due to the nature in which the offer to counsel was presented, 69% of patients refused the offer to counsel and therefore did not receive in-person pharmacist counseling when filling their initial prescription.[3] While OBRA '90 may appear antiquated with the advent of advanced pharmacist clinical counseling services such as mediation therapy management (MTM), it is still the reference point that requires that the offer to counsel be made. Many high-volume community pharmacies are more apt to comply with this regulation due to the lack of time or resources required for MTM-based discussions.

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Medication errors and poor medication adherence have been referred to as epidemics. Medication counseling and improved communication at retail pharmacies could help these issues. Therefore, one particular regional chain pharmacy ("the pharmacy") with stores located in Pennsylvania, Ohio and Maryland, has piloted a clinical counseling program entitled Day 1 Therapy Counseling (D1TC). The purpose of this counseling program is for the pharmacist to take a proactive approach in counseling all patients receiving new prescriptions. In this manner, the patient is not asked whether they would like to receive counseling, since this could result in patients refusing the counseling service. Instead, in the D1TC program, all patients receiving new prescriptions are moved to a private counseling area to receive counseling by the pharmacist or student pharmacist.

This program is currently being implemented in several store locations which have been identified as clinical sites. Implementation of this pilot program at certain stores has been aided with the help of a school of pharmacy faculty member and student pharmacists. The universal objectives of the D1TC program have been stated by the pharmacy to "improve customer service, customer loyalty, and therapy management." Within this program, customers beginning any new drug therapy (defined as a medication the patient has not received within the last six months or a transferred prescription from another pharmacy) or having a change in their medication dosage will be targeted to receive pharmacist or student pharmacist counseling on their prescription medication. Although all patients benefit from pharmacist counseling, this program is modeled to ensure that at the minimum, all patients receiving new prescription medications (as defined above) are identified to receive pharmacist or student pharmacist counseling, rather than the standard offer to counsel. While the D1TC program was developed to provide counseling on all new prescriptions, this pilot study focused on adherence with select cardiovascular medications, specifically statins, ACEIs, and ARBs, after receiving counseling as a result of this program. Day 1 Therapy interactions aim to educate the patient regarding the name of their medication, directions for use, indications, side effects, interactions, and any other unique properties of the therapy that may affect patient outcomes. By ensuring proper use of the medication, patient medication adherence, and thus, health outcomes, can be optimized.

Objective

The primary objective of this study was to determine the impact of the Day 1 Therapy Counseling (D1TC) program on medication adherence to new medications (as defined by the D1TC program), specifically statins, ACEIs, and ARBs.

Methods

Study Design

A prospective cross-sectional comparison of two locations of a regional chain grocery store pharmacy, with two similarly matched stores based on volume and demographics serving as control, were chosen to pilot the D1TC program in conjunction with a shared faculty member and experiential student pharmacists. Through this program, patients aged 18-89 with all new prescriptions, transfers, or changes in dosage were flagged to receive counseling by the pharmacist or student pharmacist between 8/2009 and 11/2010. Data collected from the counseling session included time spent counseling, medication accuracy, patient satisfaction, as well as any additional comments. This information was input into a computer tracking system immediately following each counseling encounter. The program was tracked weekly at the pharmacy corporate level to determine the percentage of prescriptions eligible for the program and those that actually received counseling services. Adherence data for statins, ACEI/ARBs was accessed retrospectively in November 2010, after the initial pilot phase of the program. The study was IRB approved, however patient consent was waived since pharmacist or student pharmacist counseling is a normal process of care.

As this was a pilot program, after conclusion of the study a Survey Monkey® questionnaire was sent to all fourteen locations of the pharmacy that had a D1TC program in place, not just the two intervention stores, to assess the pharmacy staff's perceived barriers with implementation of this program. The two intervention stores included in this research project were part of the total 14 stores that have a D1TC program in place, whereas the control stores were not. Results of this survey are addressed in the discussion section.

Site Selection

Two of the pharmacy locations in Pittsburgh, Pennsylvania which have piloted the D1TC program were chosen for inclusion in this study as the intervention group. These pharmacy locations were chosen for several factors: access to a shared clinical faculty member from the participating school of pharmacy, fourth-professional year experiential student pharmacists rotating through the site year-round, and the length of time that these locations have been involved in the D1TC program (since August 2009). The two pharmacy locations serving as the control group do not currently offer the D1TC program. The control locations were selected due to similar prescription volume, staffing, geographic location, and patient and pharmacist characteristics as the intervention pharmacies. Similar to the intervention stores, the control stores also have access to experiential student pharmacists. The pharmacists in the

control stores provided patient counseling as required by OBRA regulations, but did not have the proactive D1TC program in place, nor was data on length of counseling time, patient satisfaction, or medication accuracy tracked. Only prescription claims data were extracted to assess for medication adherence to the targeted medications.

Survey Instrument

Figure 1 illustrates the form used to collect data from the D1TC program counseling sessions. This form, which is stapled to all prescription bags containing medications that fit the criteria of the D1TC program, is a full-length sheet of paper that includes all pertinent information needed for the pharmacist or student pharmacist to conduct a counseling session with the patient when they return to pick up their prescription. The top of the paper indicates that the prescription is a D1TC program prescription. Below, prescription demographical information such as patient name, date of birth, and prescription number are listed. A separate box under the prescription identifiers contains the name of the new prescription (medication name, dose, and dosage form), directions for use, and prescriber name. This information is contained within a box to differentiate it from other information on the paper. At the bottom of the D1TC program sheet, the patient's active pharmacy profile information within the last 12 months is listed. This is pertinent to the success of incorporating the D1TC program into pharmacy workflow. By having access to all of the patient's current medications, the pharmacist or student pharmacist providing the counseling will not have to return to a computer to look up this information. The information included in this active profile section includes medication name, dose, dosage form, prescription number, first and last fill dates, quantity dispensed, and prescribing physician. Since this form only includes active profile information for the pharmacy filling the prescription, pharmacists and student pharmacists were trained to ask the patient about medications filled from other pharmacies as well as over-the-counter and herbal medications they might be taking, for purposes of a comprehensive and accurate counseling session. The last component of the D1TC program paper is a documentation box that is to be filled out by the person performing the counseling session. This documents the date of counseling, start and stop time of the counseling session (to quantify the number of minutes spent counseling), and the initials of the person providing the counseling. The person documenting the counseling session is also asked to indicate whether the correct medication was dispensed, if patient contact was made and whether it was a positive or negative encounter, and to add any additional comments that should be documented. While caregivers or spouses picking up a prescription could not be controlled for, the positive or negative patient experience was still documented for quality improvement measures.

Workflow

The standard process by which the D1TC program occurs during everyday workflow is as follows. During the NDC verification, or final check phase of dispensing, the computer system will indicate that the prescription meets criteria described above for inclusion into the D1TC program. The pharmacist at that station will then click the screen to print the D1TC program form which was described above. This form is stapled to the bag, which is then placed into the pick-up drawer until the patient returns for their prescription. When the patient returns to pick up their prescription, the cashier or technician will see the paper on the top of the bag indicating that this is a new prescription requiring counseling. All pharmacy staff has been trained in the proper dialogue to use with patients picking up prescriptions within this program. Rather than extending the offer to counsel (as required by OBRA '90), patients are told that the pharmacist wishes to speak to them, and asked to step to the consultation window. The pharmacist or student pharmacist then takes the D1TC program paper and provides counseling to the patient on their prescription. After the counseling session has concluded, the pharmacist or student pharmacist completes the documentation section of the paper. Data from these papers are then entered into the computer system to track the percentage of counseling opportunities that occurred and were acted upon.

Staffing and Hours

The current pilot of the D1TC program does not incorporate any additional pharmacist or student pharmacist staffing hours and occurs at designated stores during normal pharmacy operating hours. Currently, a non-staffing school of pharmacy faculty member and fourth-year experiential student pharmacists have aided in the implementation of this program at the intervention stores included in this study. The faculty member held a standardized training for each group of experiential student pharmacists prior to their rotation at the pharmacy locations. This training included an overview of the D1TC program, directions on how to input the data for tracking purposes, and a review of counseling points for the selected medication classes (statins, ACEIs, and ARBs). The staffing pharmacists at the stores were trained in the same way as the student pharmacists prior to implementation of the D1TC program. The faculty member rotated between the two intervention sites to aid in implementation of the D1TC program into the pharmacy daily workflow system. Due to the faculty member having academic obligations at the university as well as two pharmacy location sites, not every patient encounter was monitored; however, during time

spent at the stores, the faculty member oversaw student counseling sessions to ensure accuracy of information conveyed and that each completed interaction was properly documented. The faculty member also acted as a non-dispensing pharmacist to help ensure that an attempt was made to counsel on all new prescriptions during high-volume times in the pharmacy.

Analysis

Patients were included in the study analysis if they initiated a retail prescription for a statin, ACEI or ARB medication at any of the study locations between August 1, 2009 and November 30, 2010. These medications were selected based on their high prescription volume in these pharmacy locations. Following IRB approval, prescription claims for the identified medications were then extracted into a database for the period and were then uploaded to IDNA[sm], a web-based data analytic platform to create customized medication adherence analyses and reports using medical and pharmacy utilization data. Primary endpoints included differences in adherence metrics between the D1TC stores and controls, including proportion of days covered (PDC) at 6 months and medication persistence to therapy as measured by IDNA[sm]. PDC was calculated by taking the patient's total days supplied of the medication classes for the 180 day period following the index date of fill and dividing by 180. This method permitted adherence based on the entire 6 months and not on patients' persistence periods. Persistence was calculated as the number of days between the patient's index prescription until the end of 6 months or the date of discontinuation, whichever came first, with the application of a 15-day refill grace period. Medication persistence was evaluated at a class level; patients who switched medications within their index medication class but did not exceed a permissible gap were considered persistent. Descriptive statistics were used for demographical variables and chi square tests to compare D1TC stores with controls for persistence rates and PDC. Also noted in the discussion section of this report is a concurrent assessment of pharmacist's perceived barriers to implementation of the Day 1 Therapy Counseling program.

Results

There were over 78,434 patients with a prescription that met the Day 1 Therapy Counseling program criteria (a new prescription, transfer, or change in dosage). This total number included all prescriptions dispensed at the Day 1 pharmacies that met the D1TC program criteria and was not limited to the medication classes of statins, ACEI/ARBs. Of those 78,434 patients with a prescription meeting the program criteria, 40,671 (51.9%) received brief counseling by a pharmacist or student pharmacist on their prescription (average counseling time <2 minutes). This resulted in a counseling rate of 45.2 prescriptions per day per location. While 40,671 patients received counseling on their Day 1 prescription, only 6,916 of those prescriptions were for a statin, ACEI/ARB, and therefore were included in the study analysis. With concurrent utilization of medications from both classes, the therapy cohorts were 3,948 ACEI/ARB patients and 3,555 statin patients; mean age was 61.5 (18-89). The percentage of males was 54.3% (n=3752). (see table 1: baseline characteristics)

At 6 months post-index, persistence rates for statins for the D1TC stores were 32.5% and controls 34.2% ($p<0.001$), respectively. The persistence rates for ACEI/ARBs for the D1TC stores were 37.3% and controls were 43.2% ($p<0.001$), respectively. The PDC for statins at D1TC stores was 43.2% and control was 45.1%. (p=NS). The PDC for ACEI/ARBs at D1TC stores was 50.2% and control was 57.1% ($p<0.001$). (see table 2: persistence and PDC)

Discussion

This study sought to investigate the impact of a piloted proactive counseling program on patient adherence to the medication classes of statins and ACEI/ARBs. Previous internal surveys of this program revealed high patient satisfaction with this counseling approach; however, this was the first attempt to measure the impact on medication adherence with the initiation of a Day 1 Therapy Counseling program. Results from this study demonstrated better adherence rates, as measured by PDC and medication persistence, for the control stores versus those that had the D1TC intervention. While this result appears to contradict what current literature supports, there are several important factors that must be considered. First and foremost, the D1TC program revealed that there was only a brief amount of time spent in the counseling session (<2 minutes). Many studies have shown counseling interventions that successfully improve adherence generally involve a greater amount of time. McDonald et al. conducted a systematic review that showed most studies do not specify an optimal amount of counseling time that is required to see increases in medication adherence; however, they do point out that one study showed a minimum of a 20 minute initial consultation was needed to see an increase in short-term patient compliance with their medication regimen.[4] Other studies showed that a more involved pharmacist intervention to simplify the patient's medication dosing regimen resulted in greater adherence for patients with chronic conditions such as hypercholesterolemia or hypertension.[4] Lastly, many studies support the counseling technique of motivational interviewing to improve patient adherence. In this patient-centered approach, the pharmacist attempts to enhance the patient's own intrinsic motivation to change by exploring and resolving ambivalence.[5-6]

While standard counseling points were reviewed with pharmacists and pharmacy students involved in the study, the brief counseling time did not allow for the aforementioned techniques to be employed. Also, although all pharmacy employees were trained on the proper dialogue for engaging patients to participate in the counseling session with the pharmacist, it was often noted that during peak times in the pharmacy, staff would resort to the OBRA-required method of asking the patient if they had questions for the pharmacist. When this occurred, the patient could more easily refuse pharmacist counseling. If the patient denied pharmacist counseling, their adherence data was still analyzed in the intervention cohort with that of patients who actually received D1TC counseling. In addition, the relatively lower number of prescriptions in the Day 1 Therapy group may have reduced statistical power to detect a change among the groups where no difference was observed. It is the belief that, in accordance with other adherence studies, should the patients in the intervention group be engaged in the counseling session for a longer period of time, a more positive impact on adherence would result.

At the completion of data analysis, a survey was sent to all pharmacies participating in the D1TC program, not just the study locations, to assess perceived barriers to implementation of the counseling program into daily workflow. A total number of 175 pharmacy staff, including pharmacists, technicians and student pharmacists/interns, was eligible to take the survey which was distributed via email. The survey was created using Survey Monkey® which allowed for anonymous collection of participant responses. A total of 38 responses were collected from the survey, resulting in a 21.7% response rate. Of those respondents, 28 identified themselves as pharmacists (73.7%), 4 were technicians (10.5%), and 6 were student pharmacists/interns (15.8%). The top barriers identified in the survey by all respondents included lack of time to counsel (50.7%), patients appearing uninterested in receiving counseling (41.6%), and inadequate staffing (41%).

Limitations

One potential limitation in this study was the relatively lower number of prescriptions in the intervention group as compared to control. The intervention store analysis included the 6,916 new prescriptions for statins, ACEI/ARBs that received counseling, whereas the control store analysis included all new prescriptions for statins, ACEIs, and ARBs filled within the study dates where either the offer to counsel or pharmacist counseling took place. It is also possible that other classes of medications, rather than the targeted medications, could have, by chance, had more consistent counseling. It is important to consider that the counseling of prescriptions through the D1TC program included all new prescriptions and was not limited to statins, ACEIs, or ARBs, although these were the medications selected for the purpose of this adherence study. Several other limitations existed in this study which could have affected the results such as the majority of counseling that occurred was performed by fourth-professional year student pharmacists (>89%). While all pharmacists and student pharmacists were trained in a standard and reproducible manner, specific and uniform counseling points were not consistently used. While most student pharmacists had acquired some community pharmacy experience by this point in their education, not all students had. Their medication knowledge was appropriate for a near-graduate of pharmacy school, however, for some, the art of counseling was still being learned. Additionally, the short duration that the student pharmacists spent at the pharmacy while on rotation (5 weeks) prevented them from developing the same rapport with the patient as the pharmacists who consistently worked there. Although it is unlikely that the students had a causal effect on reducing adherence rates, these potential limitations must be considered.

Conclusion

The results of this study show that the proactive D1TC program did not improve adherence rates as compared to control locations that did not have the program in place. Based on the findings of this pilot study, community pharmacists can work to improve medication adherence by tailoring the counseling session to the patient and addressing patient-related issues such as affordability, fear of adverse effects, motivation for change, and understanding of disease/medication. While this particular regional pharmacy has taken initial steps with the development of the D1TC program, improvements to this program may help to improve adherence rates. Future plans include re-assessment of the D1TC program on adherence rates utilizing additional pharmacist resources such as additional counseling time. Also, adherence data between patients in the D1TC program and those undergoing a full medication therapy management session will be compared.

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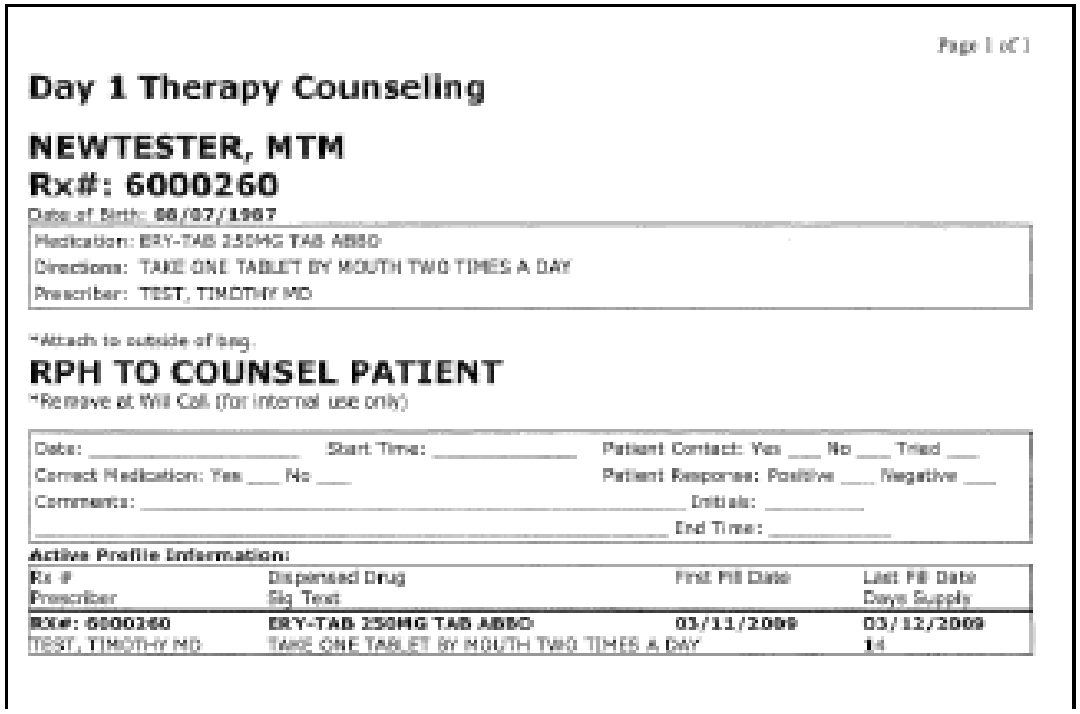
Figure 1. Day 1 Therapy Counseling Data Collection Form



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Day 1 Therapy Counseling

NEWTESTER, MTM
Rx#: 6000260

Date of Birth: 08/07/1967

Medication: ERY-TAB 250MG TAB ABBO
Directions: TAKE ONE TABLET BY MOUTH TWO TIMES A DAY
Prescriber: TEST, TIMOTHY MD

*Attach to outside of bag.

RPH TO COUNSEL PATIENT
*Remove at Will Call (for internal use only)

Date: _____ Start Time: _____ Patient Contact: Yes ___ No ___ Tried ___
Correct Medication: Yes ___ No ___ Patient Response: Positive ___ Negative ___
Comments: _____ Initials: _____
_____ End Time: _____

Active Profile Information:

Rx # / Prescriber	Dispensed Drug / Sig Text	First Fill Date	Last Fill Date / Days Supply
RX#: 6000260	**ERY-TAB 250MG TAB ABBO**	**03/11/2009**	**03/12/2009**
TEST, TIMOTHY MD	TAKE ONE TABLET BY MOUTH TWO TIMES A DAY		14

Figure 2. Patients Participating in D1TC program

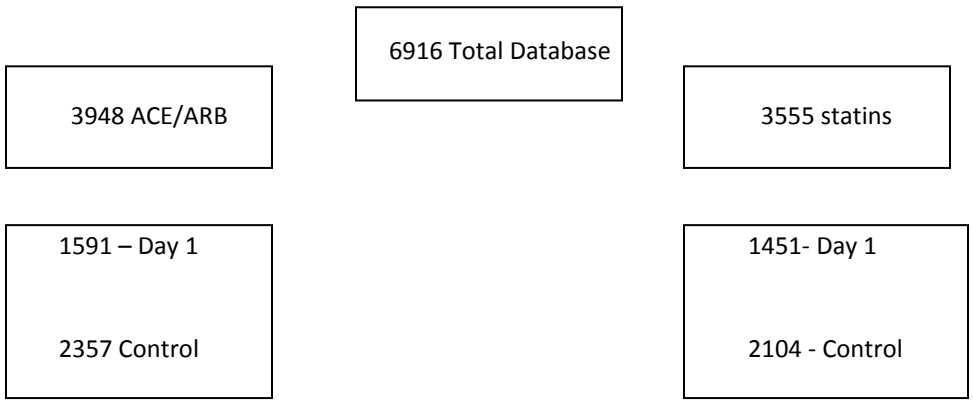

Figure 3. Six Month Persistence

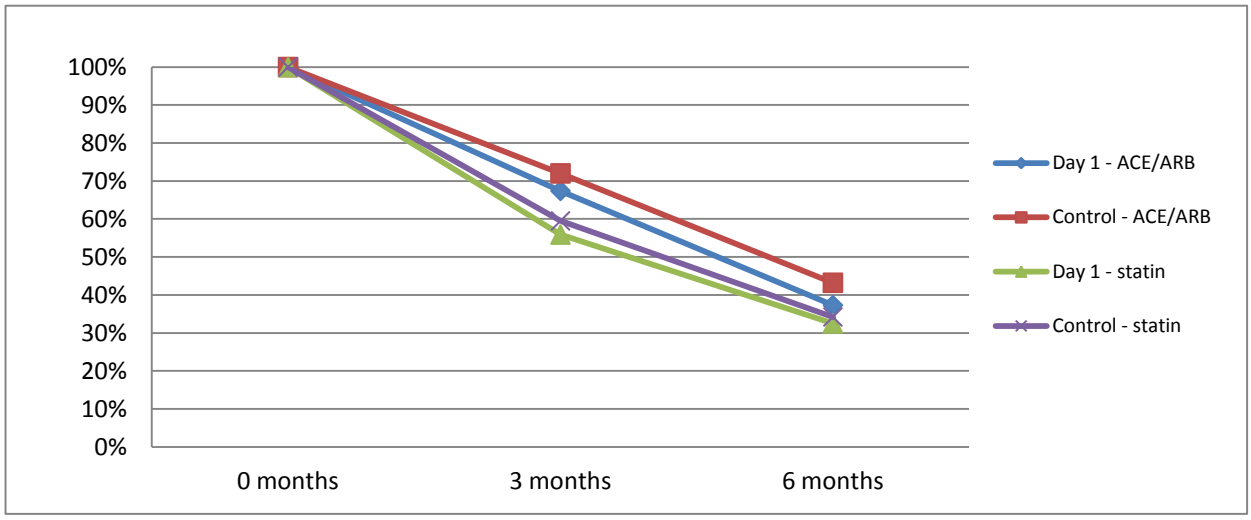

Table 1. Baseline Characteristics

Characteristic	Statins (N=3555)	ACEI/ARBs (N=3948)
Age		
Mean ±SD (min, max)	62.8 ±12.8 (18, 89)	61.8± 15.1 (18,89)
Gender N(%)		
Male	1977 (55.6%)	2159 (54.7%)

Table 2. Persistence and PDC

	Intervention Stores	Control Stores
Statin		
Persistence	32.5% (p < 0.001)	34.2%
PDC	43.2% (NS)	45.1%
ACEI/ ARBs		
Persistence	37.3% (p < 0.001)	43.2%
PDC	50.2% (p < 0.001)	57.1%