

OUTCOMES RESEARCH

Shared medical appointments for patients with diabetes: Glycemic reduction in high-risk patients

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Introduction

Primary care providers offering diabetes care are often inundated with multiple patient comorbid conditions, end organ damage issues, and competitive tasks such as glycemic control and self-management education. In the United States, primary care providers are faced with the daunting task of caring for patients with diabetes in a typical 20-min visit to address multiple complaints (Chen, Farwell, & Jha, 2009). One study found that patients

Abstract

Purpose: To assess the impact on glycemic control (A1c, %) in a primary care urban Veterans Affairs (VA) shared medical appointments (SMAs).

Data sources: A retrospective pretest/posttest study included all patients who had attended ≥ 1 SMA from 4/06 to 12/10. A1cs 810 days pre- and postinitial SMA were obtained from 90-day time periods. A1c levels were averaged within patient in these 90-day intervals and data were aggregated based upon corresponding time intervals.

Conclusions: Of 1290 individuals seen in SMAs, 1288 (99.8%) had ≥ 1 A1c levels and 1170 (90.7%) individuals had ≥ 1 level collected both before and after attendance. The sample was predominantly (96%) male and middle aged or older (mean [± 1 SD] age of 62.6 + 9.09 years) with a mean Diabetes Severity Index 3.01 (2.34). There were significant A1c reductions ($\sim 1\%$) in A1c overall ($n = 1170$) and for patients with ≥ 1 measurement in the 180-day periods preceding and following their first SMA appointment ($n = 815$). Linear regression analysis showed a significant ($p < .001$) pre-SMA positive trend ($r^2 = 0.90$).

Implications for practice: Limitations notwithstanding (single site and design lacking a control group), the large number of patients demonstrates SMA clinical effectiveness in improving A1c for high-risk patients with diabetes.

with diabetes had more complaints than those patients without diabetes (mean 4.6 and 3.05), respectively (Beasley et al., 2004). Not surprisingly, it is difficult to address multiple complaints in one visit, creating gaps in meeting quality measures such as A1c, blood pressure, and lipids. To address these challenges, a variety of care models have been developed (Singh, 2005). The chronic care model (CCM) and the "planned visit" concept establishes a prepared proactive team to deliver chronic disease focused self-management skill development and

medication management in conjunction with the primary care provider's office visit (Bodenheimer, Wagner, & Grumbach, 2002; Coleman, Austin, Brach, & Wagner, 2009). Also inherent in the CCM is system redesign with use of innovative visits providing team care in the context of shared medical appointments (SMAs).

SMAs (also called group visits or cluster visits) combine a medical appointment with education and discussion to improve self-management of a chronic disease. On average 60–120 min, these visits often encompass an interprofessional team, and a group of patients who share a diagnosis or condition, for example, diabetes or heart failure. Originally conceptualized by E. Noffsinger (Noffsinger, 1996), participants receive education, participate in a facilitated, peer-supported group discussion, and interact with members of different professions. However, there are many variations related to types of patients, members of the interprofessional team, the actions performed during the visit (e.g., individualized medication management, educational content, and other features). The variation in design and delivery of SMAs have made comparisons more difficult (Burke & O'Grady, 2012; Edelman et al., 2010). Nevertheless, SMAs have demonstrated benefits, albeit inconsistently, in areas such as improvement in intermediate outcome measures, satisfaction, access to care, decreased long-term cost, and self-management skills (Burke & O'Grady, 2012; Edelman et al., 2010; Jaber, Braksmajer, & Trilling, 2006; Riley & Marshall, 2010). For example, Burke and O'Grady's recent systematic review (Burke & O'Grady, 2012) concluded that group visits had much potential in delivering effective care, but that more research was needed. Another major limitation of the data is lack of long-term follow-up. Most studies lasted less than 2 years. The 5-year study of Trento et al. (2004) involved 112 patients with diabetes and found stable A1c levels compared to controls (in which A1c increased) as well as benefits in problem solving ability, diabetes knowledge, and quality of life. Others have found improvements in blood pressure, use of primary care office visits, and quality of life (Cohen et al., 2011; Cohen, Hartley, Mavi, Vest, & Wilson, 2012; Due-Christensen, Zoffmann, Hommel, & Lau, 2012; Edelman et al., 2010; Guirguis et al., 2013; Jessee & Rutledge, 2012). Most studies have been relatively limited in size. In addition, most studies have been efficacy studies as opposed to implementation in practice.

Our previous pilot study (sample size $n = 44$, controls $n = 39$) indicated that veterans who participated in the Diabetes SMA had statistically significant improvements in A1c with a mean decrease of 1.4% ($p < .001$), a systolic blood pressure (SBP) mean decrease of 16.0 mmHg ($p < .001$), and mean drop of low density lipoprotein-calculated (LDL-c) of 14.8 mg/dL ($p = .022$) (Kirsh et al., 2007). The

purpose of this study was to determine if A1c decreased with participation in the SMA over a longer sustained time period with a larger number of participants involved.

Our current patient population continues to be patients with high risk for diabetes complications generally referred by an RN case manager or primary provider. We preferentially seek patients whose A1c is $>9\%$. Emphasis in the SMA is placed on controlling A1c as well as blood pressure and lipids. Our SMA provides group discussion, education, and individual medical evaluation for each patient. The group portion includes Socratic teaching, motivational interviewing, and patient peer support.

Our interprofessional team of clinicians consists of a Certified Diabetes Educator (either nurse practitioner [NP] or clinical pharmacy specialist), health psychologist, registered dietitian, and general internist. Pharmacy, NP, and nutrition learners rotate through the clinic as well as medical students and residents. For our SMA, patients are identified by a clinical registry as having high-risk status based on A1c, blood pressure, and lipids (Kern et al., 2008). In addition, patients may be referred by their primary care providers or RN care managers. The 90-min session starts with a discussion section facilitated by the health psychologist and dietician. Patients are given their own laboratory/blood pressure results and encouraged to examine barriers (and facilitators) of self-management. This occurs in the context of group support. After ~60, patients are pulled out individually for medication adjustment (Kirsh et al., 2009). We now describe our results in routine practice in >1000 patients over a 4.5-year period.

Research design and methods

Setting

The study was conducted at a primary care clinic at an urban tertiary care academic medical center in the Veterans Healthcare System. This clinic has employed a variety of strategies including performance measures and care redesign to improve the quality of diabetes care. For example, the VA has utilized a sophisticated electronic medical record for over a decade where providers access clinical reminders for multiple high-risk disease states, including diabetes, hyperlipidemia, and hypertension. Other system redesigns include adoption of the CCM and the patient-centered medical home model, which the VA calls Patient Aligned Care Teams (PACT). During the period of the study, the clinic provided care for 9500–11,000 patients including >2000 with diabetes.

Patient population: All participants were selected from patients receiving primary care at the Louis Stokes Cleveland VA Medical Center from April 2006 to December

Table 1 Demographics

	Patients with both pre- and post-A1c tests	Patients with pre-A1c tests only	Patients with post-A1c tests only	Patients with no A1c tests
Number	1170	104	14	2
Age (mean)	62.70	61.00	61.93	64.00
<40	7	4	1	0
41–50	60	13	0	0
51–60	359	30	4	0
61–70	520	35	6	2
71–80	172	12	2	0
80+	52	10	1	0
Gender				
Male	1127	99	12	2
Female	43	5	2	0
Race				
White	283	28	4	0
AA	721	62	7	2
Hispanic	6	0	0	0
Declined	25	1	0	0
Unknown	21	1	1	0
Other	8	12	2	0
Diabetes Severity Index				
0	163	35	3	0
1	180	25	3	1
2	237	14	6	0
3	169	15	1	1
4	139	7	1	0
5+	282	8	0	0

Table 2 Mean A1c levels score differences for patients with A1c values within the 180 days prior to or following the first SMA visit

Group	<i>n</i>	Mean (± 1 SD) pretreatment	Mean (± 1 SD) posttreatment	Difference
≥ 1 A1c measurements 180 days pre and post	815	9.30 \pm 2.10	8.24 \pm 1.73	1.06, $p < .001$
≥ 2 A1c measurements 180 days pre and post	121	9.30 \pm 1.96	8.21 \pm 1.30	1.09, $p < .001$
≥ 2 A1c measurements 180 days pre and 1 post	332	9.26 \pm 1.92	8.37 \pm 1.64	0.89, $p < .001$
1 A1c measurement 180 days pre and ≥ 2 measurements post	294	9.51 \pm 2.19	8.46 \pm 1.57	1.05, $p < .001$

2010. Over time, selection criteria for participation have evolved. At the initiation of SMAs, the targeted patients included those with type 2 diabetes enrolled in the primary care clinic at the highest risk for cardiovascular morbidity (i.e., did not meet diabetes performance measure targets or had one or more of the following: A1c > 9%, SBP > 160 mmHg initially). When the number of such patients was lowered, we lowered the threshold for participation to >140 mmHg and LDL-c > 130 mg/dL). The A1c target threshold for identification of potential patients from our clinical registry has remained unchanged. Now separate SMAs exist for hypertension and hyperlipidemia and our focus for the diabetes SMA is primarily glycemic control.

Measures

The primary outcome measure of effectiveness was A1c. Disease severity was measured using the Diabetes Severity Index (Young et al., 2008). This index is a useful tool for prediction of mortality and hospitalization risk. Each level of the continuous score is associated with a 1.34-fold (95% CI = 1.28, 1.41) greater risk of death and risk of hospitalization. Therefore, our mean Diabetes Severity Index score of 3.01 indicated a 4.03-fold risk of hospitalization and mortality. We also obtained mean A1c for all patients with diabetes at the Cleveland VA Medical Center-Wade Park Division for fiscal years (FY) 2005–2012. Data were extracted from the hospitals' electronic record and the registry.

Study design

This was a retrospective pretest/posttest A1c naturalistic study including all patients who had attended at least one diabetes SMA was the article focus. The patients served as their own controls.

Statistics

Analysis of the data was conducted using Excel and SPSS (Version 17). Data were obtained from 90-day time periods prior to and following the first SMA visit. If a patient had more than one measurement in a 90-day interval, the average of all A1c levels collected during the interval was used. A1c levels obtained within 24 h of the first SMA appointment were considered to be Pre-SMA data (baseline). Post-SMA data points were calculated as time from first SMA appointment. Data from all patients were then aggregated based upon corresponding time intervals. This approach was designed to account for the variation in both number of recorded data points overall and the number of data points over a particular time period. Each aggregated time period was checked for conformity to the normal distribution. Analysis of variance (ANOVA) and linear regression models were developed. This research was reviewed and approved by the Institutional Review Board at the Louis Stokes Cleveland Veterans Affairs Medical Center.

Results

There were 1290 individuals seen in SMAs during the course of the study (Table 1). One thousand two hundred eighty-eight (99.8%) had at least one A1c level, and 1170 (90.7%) individuals had at least one A1c level collected both before and after attendance at an SMA for the first time. The sample was predominantly (96%) male, middle aged or older mean (± 1 SD) age of 62.6 (± 9.09) years, and African American. The mean (± 1 SD) Diabetes Severity Index was ± 3.01 .

We first conducted an independent samples *t*-test using aggregate data for the entire period—up to 810 days pre- and post-SMA attendance for all patients who had at least one A1c pre- and post-SMA ($n = 1170$). This showed significant reduction in A1c levels ($\Delta = 0.54$, $p < 0.001$), between subjects pre- and post-SMA. We then conducted paired *t*-tests for patients who had at least one A1c measurement in the 180-day period preceding and the 180-day period following their first SMA appointment ($n = 815$). Because most patients were identified for participation based on high levels of A1c, we conducted subgroup analyses with patients who had two or more A1c

levels either pre-SMA or post-SMA levels. Reductions in mean A1c were comparable in all four analyses, ranging from 0.88 to 1.09, suggesting that the observed A1c reduction was not simply regression to the mean (Table 2) (Linden, Adams, & Roberts, 2006). We tested for regression discontinuity to assess the possibility that test levels were changing simply as a function of time, and not as a result of the implementation of SMAs (Linden et al., 2006). Linear regression analysis of the pre-SMA A1c levels showed a significant ($p < .001$) pretreatment trend but in the increasing, rather than decreasing, direction and the association was substantial ($r^2 = 0.90$), suggesting a strong probability of A1c scores continuing to increase over time unless intervened upon (see Figure 1). This increase was seen over the nine average 90-day pretreatment data points, which were normally distributed, giving the trend a total time span of approximately 810 days prior to being seen in the SMA clinic. Given the strength of the association, the linear regression of pretreatment A1c levels was used to predict A1c levels for the 90-day intervals following initial SMA. Pretreatment predicted scores for posttreatment periods were all outside the 95% confidence interval of the observed posttreatment scores, indicating at least a significant difference in intercept (Table 3). It is notable that of the 19 possible difference scores between the 20 consecutive time periods that were measured, only one period showed a significant decrease in A1c levels: the period during which we began implementing SMAs. In addition to the lower starting level, the slope of the regression line based on post-SMA data was lower than that based on pre-SMA data (-0.1 vs. $+1.2$, per 1000 days, $p < .05$). Finally, we examined for secular trends in glycemic control for all patients with diabetes at the Cleveland VA Medical Center-Wade Park Division from which patients attending SMAs were drawn. There was little change in mean A1c: 7.6%, 7.5%, 7.5%, 7.6%, 7.5%, 7.4%, 7.4% for FY 2005, FY 2006, FY 2007, FY 2008, FY 2009, FY 2010, FY 2011, and FY 2012, respectively. These findings suggest a main effect for SMA implementation.

Linear regressions of posttreatment A1c levels stratified by Diabetes Severity Index score suggested relatively little disease severity affect (at least among patients willing to come to SMAs). Slopes of the regression lines for individuals with a more severe disease (Diabetes Severity Index ≥ 3) showed A1c levels, which continued to decline over the entire course of the study, while those with less complex cases showed a slight increase in A1c levels over the course of the post-SMA measurement period.

We looked at the relationship between the number of SMA appointments attended (which varied between 1 and 17 for the overall sample) and A1c results. Overall, there was not a significant relationship between the number

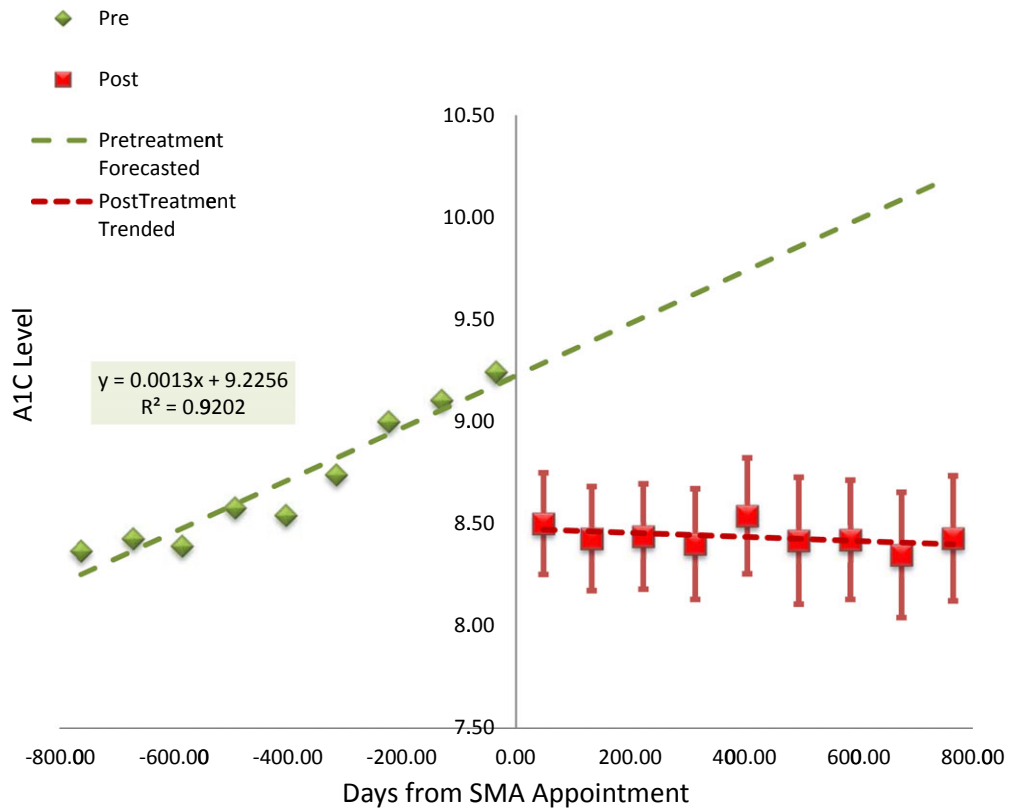


Figure 1 Overall sample regression.

Table 3 Mean (± 1 SD) A1c scores across 90-day intervals pre- and posttreatment

Time from initial SMA appointment	Pretreatment		Posttreatment		Pretreatment forecasted	95% CI for posttreatment
	Mean	<i>n</i>	Mean	<i>n</i>		
± 90 days	9.24 \pm 2.21	903	8.50 \pm 1.80	567	9.28	8.25–8.75
± 180 days	9.11 \pm 1.95	464	8.43 \pm 1.83	559	9.39	8.17–8.68
± 270 days	9.00 \pm 1.99	489	8.44 \pm 1.76	506	9.51	8.18–8.70
± 360 days	8.74 \pm 2.04	431	8.40 \pm 1.86	509	9.63	8.13–8.67
± 450 days	8.54 \pm 1.84	386	8.54 \pm 1.88	477	9.75	8.26–8.82
± 540 days	8.58 \pm 1.99	399	8.42 \pm 1.95	430	9.87	8.11–8.73
± 630 days	8.39 \pm 1.82	336	8.42 \pm 1.81	419	9.98	8.13–8.71
± 720 days	8.43 \pm 1.87	358	8.35 \pm 1.77	359	10.10	8.04–8.66
± 810 days	8.37 \pm 1.94	340	8.43 \pm 1.69	330	10.22	8.12–8.74

Note. Pretreatment days are before start of SMAs, posttreatment days are from start of SMAs.

of SMA appointments and difference between average pre- and post-A1c scores ($r = -0.01$). However, there was a difference between the trending of the posttest scores in individuals with fewer SMA appointments. Figure 2 shows a difference between individuals with three or less SMA appointments ($n = 208$) and individuals with four or more SMA appointments ($n = 267$). Individuals in the three or less SMA group showed an average increase of

0.6% in their A1c over 1000 days, while individuals with four or more SMAs showed an average decrease of 0.4% over the same time period.

Discussion

The maintenance of SMAs for >4 years (and still continuing) indicates the long-term sustainability of SMAs in

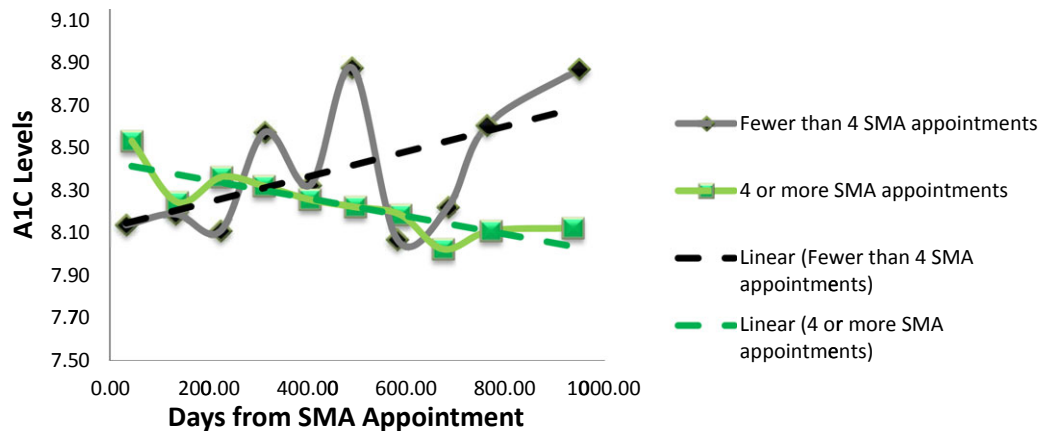


Figure 2 A1c score trends posttreatment by number of SMA appointments.

Veterans Health Affairs (VHA), a finding that may apply to other healthcare organizations with capitated models of reimbursement. In addition, the current study involving >1000 patients, making it one of the largest, strongly suggests the clinical effectiveness of SMAs in reducing A1c levels over 9% in patients with diabetes. Although the magnitude of the A1c reduction over a relatively short time interval was comparable to many other self-management focused interventions, the magnitude of the A1c reduction was more modest over a longer time period. Nevertheless, more striking was the difference in A1c slopes before and after the intervention. This interruption of the steady deterioration in glycemic control shown so clearly in the UKPDS analyses was also consistent with the results observed by Trento et al. in their 5-year study. In Trento's randomized trial (Trento et al., 2004), there was no reduction in A1c, but only a change in the slope of A1c levels. It is also of note that there did not appear to be significant differences in the effectiveness of SMAs for patients with more complex clinical presentations.

Conclusions from our study are limited by several factors. First, this study involves a single site, and the results reflect only those veterans participating in an SMA in an inner city midwestern outpatient clinic. Therefore, generalizability beyond the population of veterans who share a similar demographic background, medicine formulary, and ancillary healthcare resources, may be limited.

However, the finding of implementation of SMAs in multiple VA medical centers as well as in the private section and the results similar to other studies suggest the relevance. Second, this study was a pretest/posttest design and lacked a specific control group. Two of the

major threats to validity of the findings in this design are secular trends and regression to the mean. We did not observe a significant secular trend in A1c levels, though serial cross-sections do not take into account in- and out-migration from the diabetes population. We specifically sought evidence for regression to the mean, but found little difference in A1c reduction related to the number of A1c levels that individual patients had pre- and postattendance at SMAs. Third, the number and timing of A1c measurements varied widely. This mirrors actual practice and would be reflected in the results of current diabetes quality-of-care measures. Patients were receiving routine care before and after they began to participate in SMAs. Nevertheless, the (apparent) regression discontinuity strongly suggests an effect occurring at the time of the first SMA visit. Finally, we lack the necessary data to clarify the mechanism by which SMAs are effective.

Why SMAs are effective remains somewhat speculative. Particular emphasis is placed on medication adherence and titration during the SMAs. The discussion on barriers to treatment, troubleshooting those barriers, and supporting continued adherence with medication are the key emphasis of the meetings and are likely contributors to the success of the intervention. However, there was not a clear dose-response phenomenon associated with the SMA. Although A1c reductions tended to be larger in patients who attended more than one SMA compared to those who attended only once, the magnitude and significance of these differences was inconsistent at best. This is likely a function several factors. First, individuals were not selected at random for follow-up SMA appointments so that the design for participation precluded assessment for dose effect. Second, we did not have data on medication use, so that

we cannot quantify an effect from a medication change at that time, such as starting insulin to reduce A1c quickly perhaps in only one or two visits. Similarly, we cannot examine mechanisms such as changes in medication adherence related to participation in SMAs. However, SMAs are a complex social intervention characterized by multiple interactions among clinicians, patients, and their conditions. The inherent variability of the sample and the number of interactions may preclude overall dose effect in the population as a whole. However, these limitations notwithstanding, this study represents a naturalistic implementation of SMAs in a real-world setting and supports the effectiveness and sustainability of diabetes SMAs based on the CCM.

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