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COLLATERAL BENEFITS OF DIABETES SELF-MANAGEMENT ASSOCIATED WITH SELF-ADMINISTERED OUTPATIENT PARENTERAL ANTIMICROBIAL THERAPY

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Self-administered outpatient parenteral antimicrobial therapy (S-OPAT) is a self-care treatment modality in which patients requiring extended courses of intravenous antibiotics are trained to safely self-administer treatment via an indwelling catheter in their home. Many patients seen in the S-OPAT program have a diagnosis of diabetes and present with infections associated with poor glycemic control, including skin and soft-tissue infections and osteomyelitis. Given the degree of patient activation required to successfully complete the S-OPAT process, we hypothesized that participation in this self-care program may benefit patients in self-management of other chronic health conditions, such as diabetes. The study team included Anisha Ganguly (MPH candidate), Larry Brown (biostatistician), David Watkins, Dr. Kristin Alvarez, Dr. Deepak Agrawal, and Dr. Kavita Bhavan, founder and director of the Parkland S-OPAT clinic. We conducted a before-after retrospective analysis of diabetic patients receiving S-OPAT. HgbA1c, diabetes medication refill rates, and changes to diabetes medication regimen were compared in 6-month intervals prior to and following initiation of S-OPAT. A total number of 348 diabetic patients were identified, and 206 diabetic patients were included in the analysis. The mean HgbA1c decreased by 1.82 from the time period 6 months prior to and 6 months after initiation of S-OPAT ($p < 0.001$). Subgroup analysis showed an additional significant reduction in HgbA1c among insulin users ($p = 0.002$). There were no differences in refill rates of diabetes medications or changes in medication regimen pre- and post-initiation of S-OPAT ($p > 0.05$). Initiation of S-OPAT was associated with a significant reduction in HgbA1c among diabetic patients with similar findings among insulin users, a group requiring a higher level of self-care. The degree of patient engagement obtained through the S-OPAT model may have collateral benefits in improved self-management of other chronic diseases such as diabetes.

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BACKGROUND

Literature Review

Complex infections such as osteomyelitis or endocarditis require extended courses of intravenous (IV) antimicrobial treatment, often up to six weeks of therapy [1]. Patients may receive long-term IV antimicrobial treatment in one of three settings: the hospital, an outpatient clinic, or in the home. Given the prohibitive costs and significant inconvenience posed by prolonged hospital admission, patients most commonly receive extended course IV antimicrobial therapy through outpatient parenteral antimicrobial therapy (OPAT) [1], [2]. In the United States, OPAT is most often delivered either in a skilled nursing facility, an infusion center, or through home health services [1].

Self-administered outpatient parenteral antimicrobial therapy (S-OPAT) is a self-care treatment modality in which patients requiring extended courses of intravenous antibiotics are trained to self-administer treatment by gravity via indwelling catheter in their own homes. While S-OPAT is recognized as a safe and cost-effective treatment option in the European medical literature [3]–[6], S-OPAT remains under-utilized in the United States [7]. Parkland Hospital, an 862-bed safety-net hospital serving Dallas County, Texas, is currently the only major hospital system in the United States to offer S-OPAT as standard of care [8].

S-OPAT was initially introduced as a treatment option at Parkland for uninsured patients. Patients lacking insurance coverage for traditional OPAT are consigned to lengthy hospital stays that pose an inconvenience to patients and hospital systems alike. As an alternative to prolonged hospital admission, patients requiring extended courses of IV antimicrobial treatment are evaluated for candidacy for S-OPAT. Workflow for S-OPAT evaluation is illustrated in Figure 1. Potential S-OPAT patients undergo screening by Infectious Diseases physician consultation and nurse case manager psychosocial evaluation. Candidates for S-OPAT are then trained at the bedside with nurse-led teaching on how to safely administer IV antimicrobial therapy and maintain a peripherally inserted central catheter (PICC) line. Prior to discharge, patients are assessed for mastery of self-administration and PICC line maintenance via the teach-back method. Following discharge, patients return to clinic every week for follow-up and catheter line maintenance.

Since its establishment in 2009, the Parkland S-OPAT program has shifted care from hospital to home for more than 2,000 patients, saving Parkland Health and Hospital System an estimated $10 million per year [8]. S-OPAT patients have demonstrated lower readmission rates than healthcare-administered OPAT (H-OPAT) patients and report high levels of patient satisfaction [7], [9], [10]. Given that S-OPAT has been shown to have better clinical outcomes than H-OPAT, it has been speculated that patient engagement through S-OPAT bedside teaching may yield improved self-care behaviors.

OPAT patients often present for treatment of infection with complex pre-existing co-morbidities [11], [12]. Diabetic patients in particular commonly utilize OPAT for cellulitis and osteomyelitis associated with poor glycemic control [13], [14]. Diabetes self-management interventions have demonstrated quantifiable improvement in terms of glycemic control [15], [16]. Furthermore, it has been previously shown that treatment of acute illness may improve glycemic control among diabetic patients [17]. Given the demonstrated efficacy of S-OPAT as a self-care intervention, we considered if S-OPAT could be associated with positive diabetes outcomes beyond the patients' primary diagnosis of infection. We sought to examine the association of S-OPAT as a self-care intervention on glycemic control and diabetes self-management.

Public Health Significance

Understanding the cross-cutting role of patient engagement across management of different diseases will support the field of public health by developing treatment interventions that impact multiple aspects of patient care at once. This project will examine the value of S-OPAT teaching that extends beyond the realm of infectious diseases into management of a serious, common co-morbidity, diabetes. If an association with diabetes self-management is demonstrated among S-OPAT patients, this could signal a translatable tool for patient engagement that could be applied in a variety of patient self-care domains. The potential for patient engagement through the S-OPAT model could introduce significant cost savings and likely improve patient-centered outcomes through increased self-care interventions.

Hypothesis, Research Question, Specific Aims or Objectives

Given the degree of patient engagement demanded by the S-OPAT program, we hypothesized that S-OPAT may benefit patients in other self-care domains. Given the prevalence of diabetic patients requiring S-OPAT for infections related to poor glycemic control, we plan to determine if patient engagement through self-administration of IV antibiotics is associated with improved diabetes outcomes.

METHODS

Study Design

We conducted a before-after retrospective analysis of diabetic patients receiving S-OPAT. The database used is comprised of data collected from the Parkland Electronic Medical Record (EMR) by the S-OPAT clinic for quality improvement purposes. Diabetic patients were defined from the total S-OPAT cohort as patients with an HgbA1c >6.7 or with a known ICD-10 code diagnosis of diabetes. Outcomes were compared between the 6 month-period prior to and the 6-month period following initiation of S-OPAT. Outcomes of diabetes self-management included HgbA1c, diabetes medication adherence as measured by proportion of days covered (PDC), and changes made to diabetes medication regimen. The numerator of the PDC calculation was the number of days of medication filled and the denominator was the time the medication order was active on the medication list and not transferred out of the study institution's pharmacy. Decreases and increases in doses were accounted for in the calculation for oral medications as well as time spent in the hospital. Patients needed to have the same drug class active in the pre and post time frames for a comparison of PDC within a therapeutic class to be calculated.

Study Setting

The study setting was the Parkland Hospital S-OPAT Clinic.

Study Subjects

Inclusion criteria was all patients discharged from Parkland Hospital with IV antibiotics to the S-OPAT program between the study pilot period from 2009 to 2013. Only adult patients are eligible to participate in the program. These patients are identified from service log books maintained in the hospital.

Sample Size Calculation and/or Study Power

Our sample size of known 944 S-OPAT patients achieved 87% power to detect a mean of paired differences of -0.5 in Hgb A1c with an estimated standard deviation of differences of 5.0 and with a significance level (alpha) of 0.05 using a two-sided paired t-test.

Data Collection

Data used in this study is derived from a database comprised of electronic medical records from Parkland EPIC system and medication refills data from Parkland CERNER data. Kavita Bhavan, MD, MHS is the owner of this data and granted permission for Anisha Ganguly to use and analyze de-identified data from the Parkland S-OPAT database.

Data Analysis

Patient demographics are presented using proportions, median and interquartile ranges. Paired t-tests were used to assess the statistical significance of any change in indicators of diabetes, medication adherence rates, and medication changes within 6 months before and after initiation of OPAT. Excel and SPSS were used for analysis.

Human Subjects, Animal Subjects, or Safety Considerations

The student has undergone CITI training for human subject research. A de-identified data set of patients was collected from the electronic medical record of the self-administered OPAT patients. Other data was gathered from pharmacy, telephone survey and chart review. All HIPPAA regulations were followed. The de-identified data are maintained only in UT Southwestern and Parkland secure, HIPAA-compliant servers. Published results of the study will be published only in aggregate form that will not identify individual patients either overtly or through statistical identification.

RESULTS

One-hundred and ninety-five patients were identified using ICD-9 codes and 153 patients identified using prior HgbA1c value greater than 6.7. The total number of 348 patients was identified for inclusion in the Diabetes S-OPAT cohort. Demographics of diabetic S-OPAT patients are given in Table 1. Diabetic S-OPAT patients were more likely to be male, between the ages 45 and 64, Hispanic, unfunded, and received S-OPAT for osteomyelitis. There were 142 (41%) patients excluded in the change in diabetes management analysis due to lack of valid HgbA1c 6 months prior or 6 months after OPAT visit. The mean HgbA1c decreased by 1.82 in the 6 months prior to the 6 months after initiation of S-OPAT ($p < 0.001$). All HgbA1c values represented relative to initiation of S-OPAT are shown in Figure 2. Subgroup analysis ($N = 49$) showed a similar statistically significant reduction in HgbA1c of 0.99 among insulin users ($p = 0.002$). There were no statistically significant differences in medication refill rates as represented by PDC ($N = 48$) nor changes to medication regimen ($N = 40$) in the 6 months prior to and the 6 months after initiation of S-OPAT. Only patients with valid PDC or medication regimen in both the 6 month prior and 6 months after OPAT visit are included in the paired analysis.

CONCLUSION

This retrospective before-after study shows a near 2-point reduction in Hg A1C for patients with diabetes in the 6 month time frame prior to and after initiation of home IV antimicrobial therapy in the S-OPAT program. This significant drop in HgbA1c is likely a result of multiple factors including self-management of diabetes by improved medication compliance, diet and exercise. This observation is only an association derived from analysis of retrospective data. Findings of improved glycemic control were not attributable to medication refill rates or adjustments in medication regimen since these patients were excluded.

While it is possible that serum glucose levels improved after treatment of an infection, this does not fully explain the significant decrease in HgbA1c. First, while hyperglycemic has been described in the setting of infection, the increase in glucose associated with infection is mainly described in critically ill patients with sepsis, and is not representative of our stable patient population managed in the outpatient setting [18], [19]. Second, an increase in glucose is transient and rapidly improves with resolution of infection and our patients had sustained increases in glucose levels, as demonstrated by the long-term indicator of HgbA1c [19]. Third, the association between hyperglycemia and infection is best understood as a forward cause-and-effect relationship in which hyperglycemia predisposes to infection, rather than the other way around [19] [20].

The benefits of patient engagement in management of chronic diseases has been well recognized and described. Gruman et al, in 2010, proposed an 'engagement behavior framework' compiled from literature review and interviews of stakeholders [21]. They concluded that patients must make informed choices about their physicians, coordinate communication among providers and manage chronic diseases on their own, where not doing so risks preventable illness, suboptimal outcomes and wasted resources. In this regard, an engaged patient is an informed, activated patient who has the knowledge, skills, motivation and confidence to manage his or her health. Studies have shown that higher activated patients are more likely to adhere to medical regimens, to engage in regular exercise, and maintain a healthy diet and weight [22]–[24].

Greene et al measured patient activation based on a "Patient Activation Measure" score calculated based on a questionnaire that patients filled themselves [25]. The study included 25,047 patients and in a multivariate model showed that patients with higher activation score had significantly better clinical outcomes including control of systolic blood pressure, cholesterol, diabetes, emergency room visits and hospitalizations. Notably, patients with higher activation had HgbA1c lower by 1.9 points compared to patients with low activation. In this study, patients with lower socioeconomic status had lower activation scores and supporting activation amongst these group of patients was identified as a particularly promising approach to improve health related outcomes. The patients in our hospital were mostly indigent without health insurance and supports the assertion of the authors.

Methods to promote patient activation have focused on developing patient education tools, teaching patients specific skills, how to ask questions and navigate the health care system. Programs have also been developed to teach providers to tailor support to the individual's level of activation, encouraging small achievable steps for patients with low activation and more challenging behavior modifications for patients with higher activation [26]–[28]. Our S-OPAT program incorporates all of these approaches. Patients were taught at an appropriate literacy level and the process was repeated using the teach-back method until competency was achieved. Patients had access to both written material and teaching video which could be accessed by scanning the QR code on the back of an antibiotic bag with their smartphone, taking them to a video on YouTube. Teaching was reinforced and individual performance was encouraged and affirmed at weekly clinic visits for PICC line maintenance and laboratory test monitoring. We believe the successful completion of small tasks, positive clinical outcomes and encouragement contribute to patient activation and increased motivation and to better manage their other medical problems.

The potential collateral benefit of improvement in diabetes among patients self-administering intravenous antibiotics is a testament to the importance of patient engagement in management of chronic diseases. Importantly, it has been shown in one study that the benefits of patient activation are sustained for a longer time intervals [29]. Hibbard et al tested the hypothesis that once people gain knowledge, skill, and confidence, they retain those assets and use them to manage other health condition –"just like learning to ride a bike or learning to swim, the skills are enduring" [29]. In the study, the authors determined patient activation scores of 4,865 patients with chronic conditions 4 years after the initial assessment and reported that the mean activation scores overall remained unchanged.

However, patients who initially had low activation scores showed a substantial improvement in activation after 4 years.

For our study we chose diabetes to study the collateral benefits of patient activation since it is very prevalent in patients needing OPAT. Diabetes requires a significant engagement in self-care behaviors for successful management. The American Diabetes Association standards for diabetes self-management utilizes patient empowerment models that incorporate behavioral and psychosocial strategies for improving both clinical and quality of life outcomes [30]. It is likely that similar improved outcomes in our patient population would also be seen in other chronic conditions such as hypertension or screening behavior.

The limitations of our study include the inherent restrictions of a retrospective study design. Specifically, we show only an association between drop in HgbA1c and S-OPAT. We did not measure patient activation scores or self-behavior. We attempted to control for other causes of decrease in HgbA1c but a cause and effect can only be established by a prospective study. We believe our study provides preliminary data for such a study, which is much needed as the attention shifts to patient-centered care and patient engagement as the cornerstone of chronic disease management. Self-management disease specific programs such as S-OPAT, where patients gain knowledge, confidence and motivation by performing focused activities may be one way to improve patient engagement.

TABLES

Table 1: Demographics of S-OPAT Patients with Diabetes

Demographic Category	Demographic attribute	n (%)
Gender	Male	220 (63.2%)
	Female	128 (36.8%)
Age (years)	16-24	1 (0.3%)
	25-44	75 (21.6%)
	45-64	222 (63.8%)
	65+	50 (14.4%)
Race	Hispanic	197 (56.6%)
	White Non-Hispanic	58 (16.7%)
	Black Non-Hispanic	79 (22.7%)
	Other	14 (4.0%)
Preferred language	English	208 (59.8%)
	Spanish	132 (37.9%)
	Other	8 (2.3%)
Insurance status	Unfunded	213 (61.2%)
	Commercial	24 (6.9%)
	Medicaid	36 (10.3%)
	Medicare	75 (21.6%)
Diagnosed infection	Bone and joint	168 (48.3%)
	Bacteremia	48 (13.8%)
	Skin and soft tissue	33 (9.5%)
	CNS	8 (2.3%)
	Abdominal	7 (2.0%)
	Genitourinary	49 (14.1%)
	Pulmonary	12 (3.4%)
	Other	23 (6.6%)

Table 2: Diabetes Self-Management Outcomes

Outcome (mean value per patient)	6 months prior	6 months after	Paired t-test p-value
HgbA1c (n=206)	9.69 ± 2.33	7.87 ± 1.95	<0.001
HgbA1c ***Insulin users only*** **(n=49)**	9.55 ± 2.09	8.56 ± 2.37	0.002
Average proportion of days covered ***Oral hypoglycemic agents*** **(n=48)**	46.6%	54.5%	0.07
Use of any diabetes medication (n=40)	46.6%	52.5%	0.17

FIGURES

Figure 1

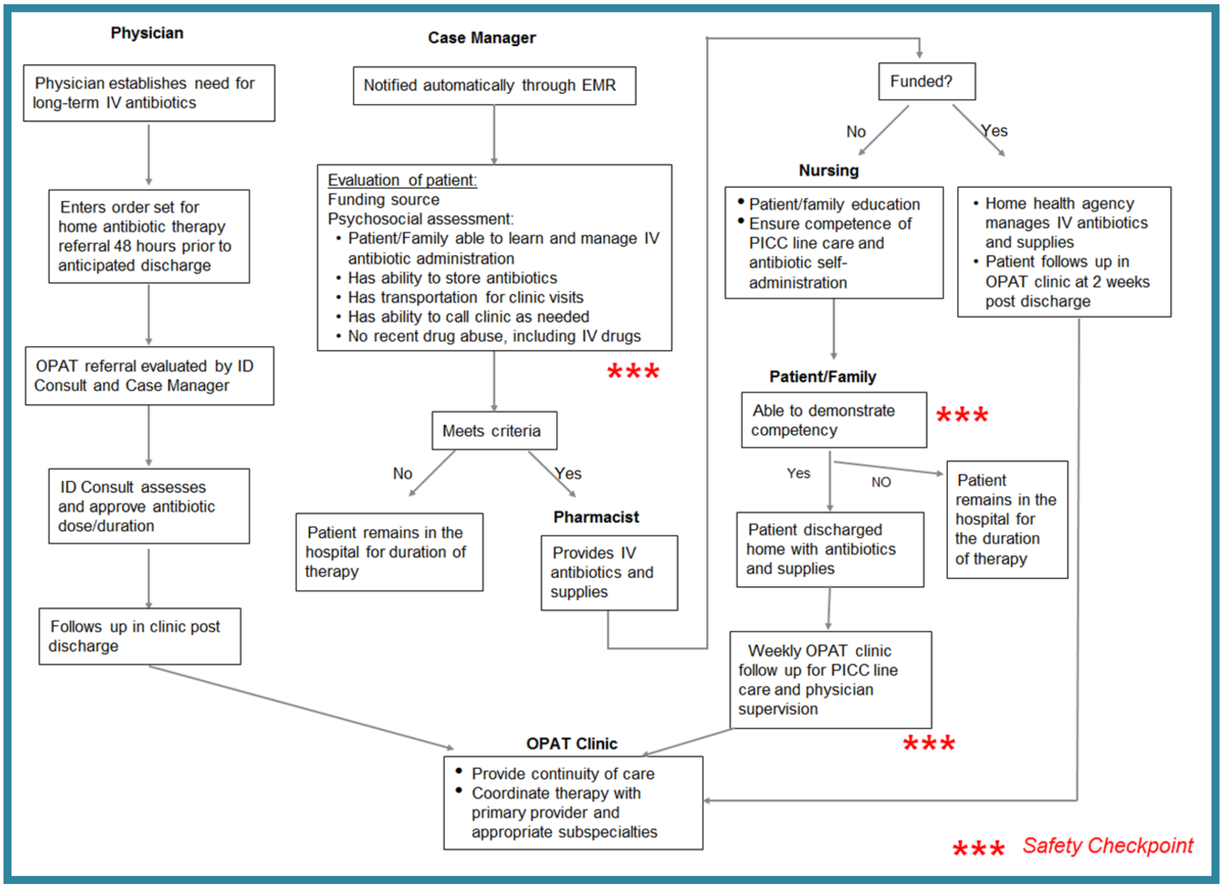
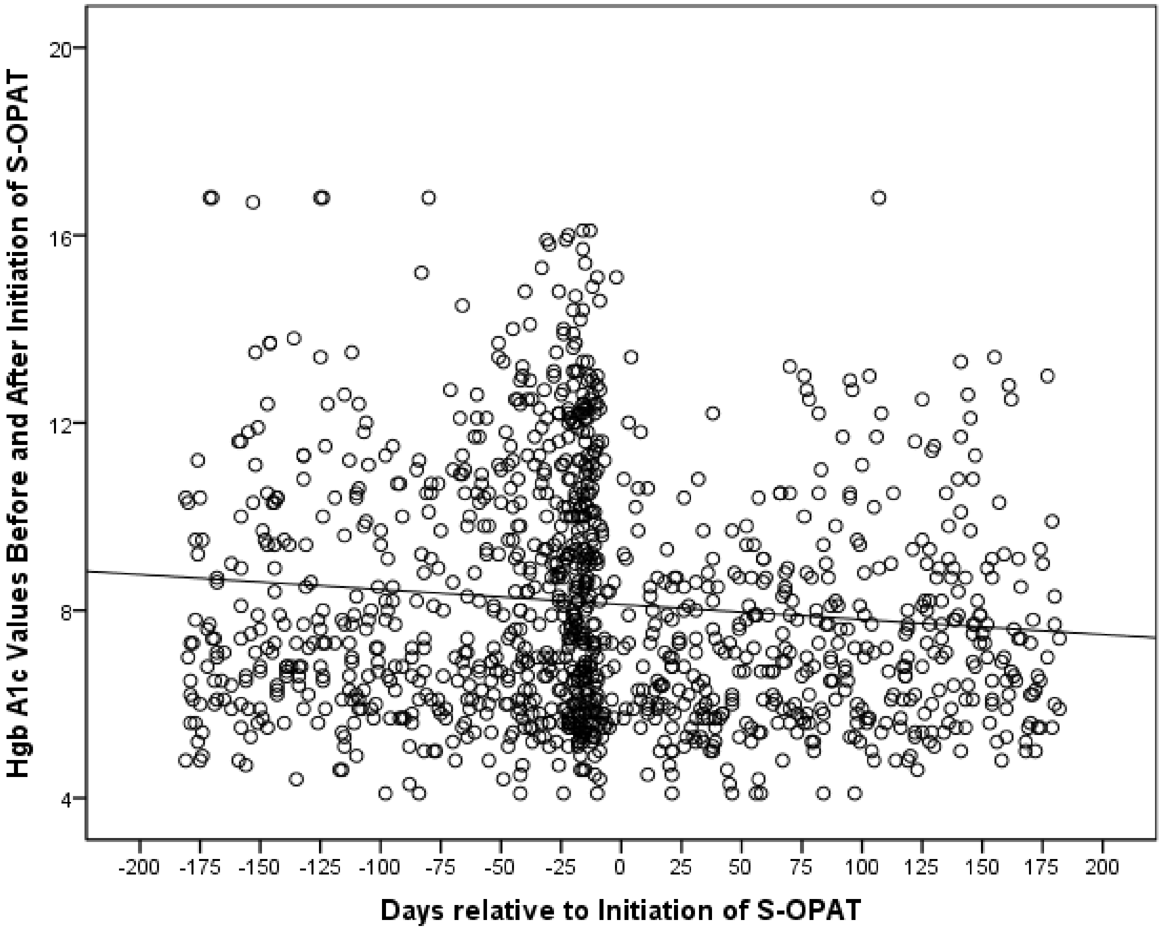


Figure 2


Hgb A1c Values Before and After Initiation of S-OPAT
20
16
12
8
4
-200
-175
-150
-125
-100
-75
-50
-25
0
25
50
75
100
125
150
175
200
Days relative to Initiation of S-OPAT

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