Use of Mobile Technology to Improve Acute Care Utilization in Sickle Cell Disease

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Inclusive Dates of Project: 06/15/2019 – 11/30/2018

Federal Project Officer: Derrick Wyatt

Acknowledgement of Agency Support: AHRQ

Grant Award Number: R21 HS23989

ABSTRACT

Purpose: We aimed to determine if the use of a mobile app with remote monitoring would improve: acute care utilization for patients with sickle cell disease (SCD), compliance to treatment plan, and follow appointments. Scope: There are approximately 100,000 patients with SCD in the United States with estimates of 2.4 billion dollars in healthcare costs annually. Patients with SCD notably have pain and are commonly treated in the day hospital in an attempt to avoid hospitalization. A large number, however, return to the day hospital or emergency room for pain and ultimately become hospitalized. Methods: We randomized patients presenting to the day hospital to either standard of care (SOC) or to use a self-developed mobile application (SMART app), which allowed daily remote monitoring of pain scores and bi-directional texting. Primary outcomes included 30-day acute care utilization rates and secondary outcomes included number of patients returning for follow up appointment. Results: We enrolled 59 patients from the day hospital (54% male, mean age 31 ± 6.9 years). As compared to SOC we found patients using SMART were significantly more likely to return for their scheduled 12-day follow up visit (24% vs. 50%, p=0.02) and more returned for their 30-day visit (34% vs. 50%, p=0.11). Importantly, 30-day re-utilization was significantly higher for patient in SOC (55% vs. 23%, p=0.04). Overall, we found the use of SMART led to communication by text, an increased likelihood to return for follow up visits, and ultimately, a significant decrease in acute care utilization.

Key Words: Sickle cell disease, mobile health, pain, remote monitoring

PURPOSE

Our long-term goal is to develop a mobile health based service that will ***help chronic disease patients and their medical providers monitor and manage medical treatments to improve health outcomes***. The specific goal of this R21 project was to perform a ***pilot study*** implementing an acute care model using the SMART app to test a mobile-based personal health record service in order to help decrease acute care utilization following visits to the Day Hospital for pain.

Aim 1: **Determine acute care utilization for patients given SMART vs. usual care following treatment at our Day Hospital.**

Aim 2: **Document compliance using SMART to the treatment plan specified by the provider team for medications and follow up appointments.**

SCOPE

Sickle Cell Disease (SCD) is an inherited blood disorder that primarily affects people of African descent. One in 396 African Americans in the United States (US) has SCD, and one in 14 carry the trait.[1] Although medical treatment for SCD has improved dramatically, median survival for all patients with SCD is 61 years[2], significantly lower than for African-Americans without SCD. In SCD, red blood cells (RBCs) become adherent and dehydrated, as well as sickle-shaped when deoxygenated, causing them to clump together and stick to blood vessel walls.[3] These processes decrease blood flow and lead to frequent vaso-occlusive painful episodes and chronic organ damage.[4] Vaso-occlusion is responsible for debilitating SCD complications, including renal and pulmonary disease, aseptic necrosis of bone, retinopathy, and stroke.[5]

SCD is very costly. SCD-related problems result in a disproportionately high use of healthcare resources, as indexed by number of ED visits, hospitalizations, and days hospitalized each year.[6, 7] The combined financial impact of both emergency department and hospital utilization charges for SCD has been estimated at $2.4 billion annually.[8] Potentially preventable readmissions from all diagnoses, including SCD crisis, is likely to cost Medicare alone an estimated $12 billion per year.[9] With approximately 100,000 patients with SCD in the US, the financial burden of this chronic disease is striking. The disease is an economic burden to patients and their families, many of whom are already socially and economically disadvantaged. Of the adult patients cared for at the Duke Comprehensive Sickle Cell Center, 60% are on disability.[10]

SCD Day Hospital: an alternative used to help decrease acute care utilization in ED and Hospitals. Emergency departments, despite their frequent use, are not the most appropriate venue to manage acute, recurrent pain in a SCD patient, given the need for patient-specific therapy, close monitoring and careful opioid dose titration. An acute care medical facility dedicated to providing SCD patients effective and rapid painful episode management has been shown to reduce hospitalizations and related costs [11].

Importantly, the 14- and 30-day re-hospitalization rates have been reported are as high as 28.4% and 41%, respectively.[12] Acute care visits to the ED and day hospital also highlight the high healthcare utilization by patients with SCD. Analysis of visits at Duke recently found patients seen in the ED had a 50% hospital admission rate, and of those discharged from the ED, 33% returned to the ED within 30 days. Furthermore, of 208 Day Hospital visits for pain, while only 12% were admitted to the in-patient service, 61.5% were re-admitted to the Day Hospital within 30 days. Interestingly, this does not include patients who were subsequently seen in the ED or hospitalized and therefore represents an underestimate of 30-day healthcare utilization in this group.

Health IT Intervention: Sickle cell Mobile Application to Record symptoms via Technology (SMART)

Need for SMART technology. Currently, daily symptoms and patient-reported outcomes are most commonly monitored in SCD care through paper diaries or surveys during visits, which have are associated with poor compliance and unreliable data [13]. In contrast, electronic diaries have been associated with improved compliance and reduced data entry errors [14]. One group has successfully implemented an electronic diary in a pediatric SCD population, showing that children aged 10-17 were able to monitor their pain and symptoms daily using a smartphone.[15]

SMART (Figure 1) is an instrument initially developed to help physicians educate their patients about self-monitoring and self-management, clarify the risks and the benefits of adherence to treatment plans and tailor each patient's treatment to their clinical condition. Patients are engaged in their health education by monitoring their own medication and symptoms. The SMART service will assist patients and providers in the decision-making process for starting treatment, continuing treatment, and assessing clinical response.

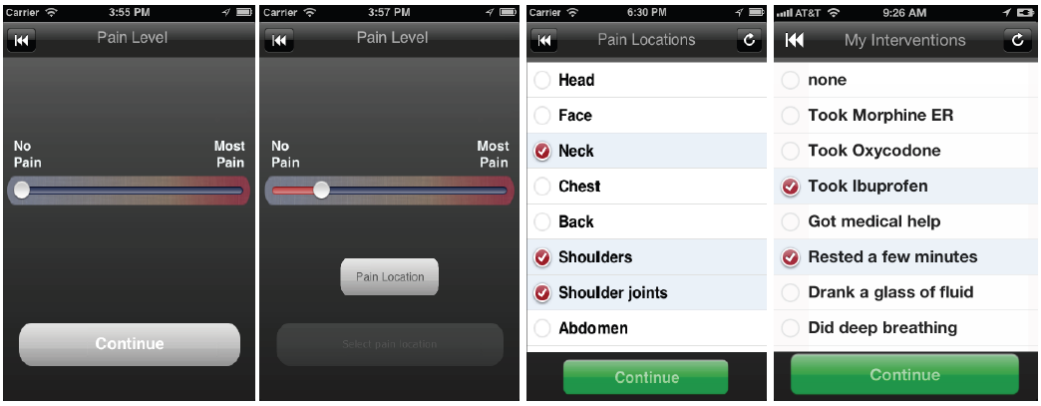


Figure 1. SMART symptom and intervention monitoring.

Medication compliance

A high medication non-compliance rate has been well documented in SCD.[16-18] This is extremely important when acute care utilization is also high. Therefore, promoting the proper use of HU and a pain medication plan is critical. HU is currently only one of two FDA-approved pharmaceutical therapy for SCD; it works by reactivating expression of fetal hemoglobin (HgbF) and increases the number of normally shaped RBCs in circulation.[19, 20] HU, which was approved for use in SCD in 1998, has been shown to improve SCD outcomes, quality of life (QOL)[21] and may improve survival.[22] Patients taking HU experience fewer pain crises, recurrences of acute chest syndrome, and strokes;[23] HU is also associated with decreased frequency and duration of hospital admissions in both adults[24] and children.[25] Although the importance of compliance seems obvious, patients with SCD have clear evidence of non-compliance [18]**.** This highlights the need to utilize novel technology to remind patients to stay compliant and also send notices to providers when patients are not following the recommended regimen.

METHODS

Aim 1: Determine acute care utilization for patients given SMART vs usual care following treatment at our Day Hospital.

Study Design: We prospectively enrolled patients with SCD presenting for a Day Hospital visit and followed them to determine the need for another acute care visit within 30 days. An acute care visit was defined as a visit to the ED or day hospital for VOC, or hospital admission with a primary diagnosis of VOC.

Day hospital description. The Sickle Cell Day Hospital is a facility within Duke Medical Center dedicated to acute and short-term management of uncomplicated painful episodes. It receives patients with any type of Sickle Cell Disease presenting with a pain episode of acute onset (within prior 24 hours) and not responding to management at home and /or to oral pain medication

Inclusion criteria. Documented SCD (any type including type SS, SC, or HgbS-beta^0 thalassemia), age 18 years old or older, seen during an acute care visit at our Day Hospital.

Exclusion criteria. Patients incapable of giving informed consent. Patients with greater than 20 acute care visits within the past year and patients on chronic RBC transfusions (scheduled transfusions). Patients admitted to the hospital from the day hospital were also excluded.

Intervention and control group. Patients enrolled were alternately assigned to each group to ensure randomization and equal numbers of patients to each arm. All patients were given a return appointment within

12 days of Day Hospital visit. The control group were given standard of care, including a printed plan for medications to be taken, phone number to call for questions or issues, and the return date for visit.

SMART Overview. SMART, a mobile phone-based self-monitoring service to enhance outpatient treatment in chronic illness was used to help reduce acute care utilization rates for patients given SMART following acute care visits at the Sickle Cell Day Hospital. SMART allowed monitoring with a particular emphasis on pain measures, co-symptoms, and related interventions aided by provider daily monitoring and support guided by patient report via SMART to provide a Sickle Cell Disease Information interchange (SCDi) service. Instead of using their current routine of triaging phone messages daily, assessing patients' need for intervention, providers will instead monitor patients' entries via SMART daily. Our current clinicians, a nurse practitioner or medical doctor, reviewed data generated from patients' reports, as well as patient phone calls. Data entered daily by patients were viewable by our clinicians. Clinician from our provider team viewed electronic records and communicated with patients electronically by push notification, text messaging, secure email, or via the app.

Aim 2: **Document compliance using SMART to the treatment plan specified by the provider team for medications and follow up appointments.**

Follow-up SOC. Our institution guidelines assigned a clinic nurse to call patients and make direct contact at least 72 hours before scheduled appointments.

Pattern of pain interventions post-acute care discharge. Patients are typically discharged home from the Day Hospital if there is 30-50% improvement of pain symptoms and the patient and provider feel that the patient is ready to return home. Upon discharge, patients were asked to: 1) Rest for the remainder of the day; 2) Take medication as previously prescribed for 'breakthrough' pain; and 3) Increase fluid intake throughout the day, among other recommendations. SMART documented patients' pattern of interventions reported through SMART during the post-acute care discharge period.

Intervention and control group. Patients assigned to the intervention group were given the pre-programmed SMART with the medication plan as outlined in the discharge instructions and an appointment within 12 days. These included SCD-related medications, including HU, folic acid, non-narcotic and narcotic pain medications. Patients were asked to log entries each time they take their medications and were reminded by SMART to take their medications based on their advised schedule. Follow up appointment time and date were also programmed into SMART, and reminders were given to the patient 3 days prior and on the day of appointment. Compliance was confirmed by pill count of all medications at the 30-day visit.

The control group was given standard of care discharge instructions and an appointment within 12 days of Day Hospital visit. Standard of care includes a printed plan for medications to be taken, a phone number to call for questions or issues, and the return date for the outpatient visit. Patients also were asked to bring all of their medications to their 30-day visit.

The SCDi Web portal interface enabled the SCDi program coordinators to manage patient information and study progress. The SCDi website enabled the coordinators to set up each patient with their registered iPhone device and application.

Communication with patients**.** Providers used the Web portal's message center to seamlessly send text messages to their patients. These messages included reminding patients to take their medications if not compliant, adhere to pain medication plans when symptoms of pain increase, and to utilize non-pharmacologic techniques for pain management.

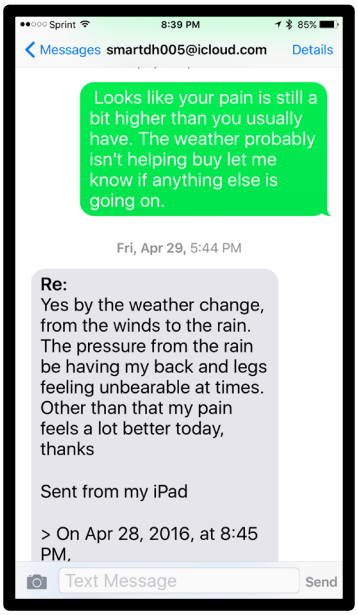
RESULTS

A total of 72 patients were approached for the study and 67 patients were enrolled (93% enrollment to screening), indicating interest by patients to participate in the study. Patients not included in analysis included 3 patients subsequently admitted to the hospital directly from the day hospital and 5 patients which were enrolled from Foundation for SCD Research (FSCDR) in Ft. Lauderdale. Due to technical issues, patients

enrolled from FSCDR had data inconsistencies, with symptoms entered only on day of enrollment and no follow up texting. The remaining 59 patients discharged from the day hospital were included in analysis (54% male, mean age 31 ± 6.9 years), with 29 patients randomized to SOC and 30 patients randomized to the SMART intervention.

Aim 1: **Determine acute care utilization for patients given SMART vs usual care following treatment at our Day Hospital.**

Patients discharged from the day hospital were followed for 30 days and all returns to the ED, day hospital, or hospital were recorded. Patients given SMART returned less often, with acute care utilization significantly higher for patient randomized to SOC (55% vs. 23%, p=0.04). Interestingly, re-utilization was delayed for those using SMART. Re-utilization of care was found in seven patients using SMART, which included five visits to the day hospital with one subsequently hospitalized, and two emergency room visits, each also requiring hospitalization for pain crisis. Patients using SMART presented for acute care visits between 10-24 days post discharge from the day hospital. This is in contrast to the 16 patients randomized to the SOC who re-utilized care, including a range of 1-26 days.



Only three patients did not make any entries into SMART, with the remaining 27 patients on average entering 0.47 entries per day over the 30 days. Patient entries were predominately pain scores, however, additional co-existing symptoms recorded included: fatigue, headache, nausea, and itching. In addition to symptoms recordings by the patient, all patients with SMART were texted by the medical team at least twice (range 2-20 times per 30 days). Most patients (n=19, 63%) returned texts to the medical team. Texting resulted in reminders for appointments, questions about pain following discharge from day hospital, and general questions about health (Figure 2).

Aim 2: **Document compliance using SMART to the treatment plan specified by the provider team for medications and follow up appointments.**

Medication Compliance

Medication compliance was found to be extremely difficult to assess throughout the study. Despite being reminded to bring their pill bottles, patients consistently did not bring their medications. Furthermore, although patients used the SMART app to record symptoms, medications taken were much less often recorded. Only 20% of patients randomized to the SMART intervention recorded medication administration on >5 days and 47% making at least one entry through the 30 day follow up period. Overall, patients used the app infrequently (3.7 times per 30 days, SD 6.8). Patients making at least 5 entries, however, had an average of 15.5 entries (SD 7.4) and is similar to compliance from our previous studies.

Due to difficulty in assessing pill counts at the 30 day visit for those that returned and the infrequent recordings within the app for medication compliance, we were unable to assess differences between SOC and SMART intervention. Although patients were given the SMART app preprogrammed with their specific medications and shown how to use the app, patients expressed lack of interest and time for this aspect of the app. Upon return of the iPads with SMART, patient responses included: the ‘pop-ups’ for medication reminders, which occurred up to three times per day, were too frequent; there was no ability to snooze the medication reminder; and patients were most often forgetful of recording their medications.

Follow up appointment compliance

Patients randomized to the SMART app intervention received appointment reminders and were more likely to return as scheduled. As compared to SOC, we found patients using SMART were significantly more likely to return for their 12-day follow up visit (24% vs. 50%, p=0.02) and more frequently returned for their 30-day visit (34% vs. 50%, p=0.11). Patients stated at completion they were appreciative of the ‘pop-up’ reminder for their appointment.

DISCUSSION

Our pilot study found that patients benefited significantly from using the SMART app platform with medical review of symptoms and texting for patient communication. Patients using SMART had significantly less acute care utilization and were more likely to return for follow up visits. The use of a simple technology solution such as a mobile app to record symptoms, allowed symptoms such as pain to be reviewed remotely. Daily review of pain scores remotely provided the medical team with the ability to text specific patients believed to be at risk due to increasing pain. To aid in follow up, SMART also included the ability to have a reminder for an appointment 'pop-up'. Technology reminders also led to patients being more likely to return as scheduled for their appointment as compared to SOC.

Limitations

There were a few limitations to our study. Due to slower than anticipated enrollment, we expanded to an additional day hospital site, FSCDR. Finalized contract with Duke, data usage agreement and IRB approval delayed beginning enrollment at FSCDR, however, we were surprised to have technology issues following our success at Duke. Expansion to FSCDR included providing devices, education to the staff, and follow up calls to the clinic. Issues found include: 1) consistent Wi-Fi access at FSCDR; 2) devices were hardened for security by Duke, limiting ease of technical support by local FSCDR staff; and 3) lack of immediate technology support for questions. Although Wi-Fi is not required to record data, it is required for data to upload. FSCDR reported that several patients did not have Wi-Fi and therefore unable to monitor data remotely. It was also reported that username and passwords occasionally 'reset' and it was difficult to update on the Duke security hardened device. Finally, although there were numerous patients to enroll, the lack of consistent technology support led to delays and missed opportunities to enroll. For future studies, we have modified the app to become native to each patients' phone, therefore utilizing cellular service and avoiding security issues.

We also are unable to confirm all outside acute care visits to facilities not in our electronic medical records (EMR). Although we do have remote access to many hospitals in our area, we believe the lack of access to outside EMR is consistent in both SOC and SMART arms. Our newer version of the SMART app now has geo-fencing capabilities to potentially passively record when patients arrive in any acute care setting and we will explore this in future studies.

Although we found compliance to follow up appointments improved for patients using SMART, we were unable to evaluate medication compliance. We believe that using pill counts for medication compliance in a 30-day study is difficult in this population. Furthermore, the study emphasized assisting them in pain monitoring and management, with most patients stating they did not find the technology prompts for medications as useful. Studies have found variable use for technology to improve medication compliance, and refining the platform such as including gamification, badges and less 'pop-ups' may help patients become more adherent.

CONCLUSION

We are excited to find our pilot study show a benefit for patients using SMART. Mobile apps such as SMART allow patients to provide real-time data of their symptoms and potential risk for complications. We will continue to modify our mobile app to focus on remote symptom management and communication, with a focus on funding for larger multi-institutional studies.

SIGNIFICANCE/IMPLICATIONS

There are very few studies evaluating mobile health apps in SCD. We are the first to report success in a randomized controlled study of using a mobile app in SCD, a chronic disease with notably high health care utilization. We are optimistic that the ongoing efforts to improve the mobile health platform will provide patients with improved access to care, better decision making by medical providers, and ultimately an improved quality of life. Future studies will focus on these goals and will leverage our findings to improve the care of patients with SCD.

PUBLICATIONS

Narine K, Chang J, Jonassaint J, et al. Use of Mobile Technology to Monitor Pain and Reduce Outpatient, Emergency Department (ED), and Hospital Visits for Sickle Cell Pain Crisis [abstract]. American Society of Hematology 2016 Dec 4-6; Atlanta, GA. Blood 2016 128:2390.

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