Improving Patient-Reported Outcomes in Stroke Care using Remote Blood Pressure Monitoring and Telehealth

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Abstract

Background  Inequities in health care access leads to suboptimal medication adherence and blood pressure (BP) control. Informatics-based approaches may deliver equitable care and enhance self-management. Patient-reported outcomes (PROs) complement clinical measures to assess the impact of illness on patients’ well-being in poststroke care.

Objectives  The aim of this study was to determine the feasibility of incorporating PROs into Telehealth After Stroke Care (TASC) and to explore the effect of this team-based remote BP monitoring program on psychological distress and quality of life in an underserved urban setting.

Methods  Patients discharged home from a Comprehensive Stroke Center were randomized to TASC or usual care for 3 months. They were provided with a BP monitor and a tablet that wirelessly transmitted data to a cloud-based platform, which were integrated with the electronic health record. Participants who did not complete the tablet surveys were contacted via telephone or e-mail. We collected the Patient-Reported Outcomes Measurement Information System Managing Medications and Treatment (PROMIS-MMT), Patient Activation Measure (PAM), Neuro-QOL (Quality of Life in Neurological Disorders) Cognitive Function, Neuro-QOL Depression, and Patient Health Questionnaire-9 (PHQ-9). T-tests and linear regression were used to evaluate the differences in PRO change between the arms.

Results  Of the 50 participants, two-thirds were Hispanic or non-Hispanic Black individuals. Mechanisms of PRO submission for the arms included tablet (62 vs. 47%),
Background and Significance

Stroke is a serious and leading cause of disability in the world, and poststroke care is often fragmented. Blood pressure (BP) reduction is associated with decreased risk of stroke recurrence but remains poorly controlled in most survivors. Minority groups have a higher prevalence of uncontrolled BP and higher rates of stroke. Moreover, up to a third of stroke patients report poor adherence to antihypertensive medications. Black and Hispanic patients have less access to care and medications than White patients due to differences in health insurance coverage. Limited access contributes to challenges in poststroke management, leading to suboptimal medication adherence and BP control. The cumulative complexity model suggests that balanced patient workload and capacity improve outcomes when the patient-centered burden is addressed. These challenges are amplified among underserved minorities with an increased workload from life demands and reduced capacity poststroke with the further burden of illness through incurred physical and mental disabilities that affect access, utilization, and self-management. In addition to clinical measures, patient-reported outcomes (PROs) after stroke are underutilized but equally important in assessing the impact of illness because these measures are meaningful to patients. Effective strategies to improve access to care must activate engagement with PROs to improve patient-oriented outcomes, and ultimately develop patient-centered systems of care. A previous study demonstrated improved BP control in a general population, community-based setting with multidisciplinary chronic disease management provided by pharmacist-led teams and supported with telemonitoring.

In this clinical informatics application, we aimed to determine the feasibility of incorporating PROs into the flow of research data from TASC study participants to track any changes in depressive symptoms, quality of life, and patient activation. The feasibility of remote BP monitoring (RBPM) and the favorable impact of TASC on BP control has been previously published.

Methods

We developed Telehealth After Stroke Care (TASC), a team-based care model including telehealth visits with nurses, pharmacists, and physicians to transition patients from hospital discharge to recovery at home. In keeping with existing treatment guidelines, workflow processes were implemented by the multidisciplinary team and monitored data were built in with routine touch points. Patients were from the Columbia University Irving Medical Center (CUIMC) Comprehensive Stroke Center in the underserved area of Northern Manhattan, New York City, that serves a majority Hispanic low-income community. The participant enrollment process is described in detail in the published study protocol. Baseline BP and surveys were completed in person prior to hospital discharge. Participants were randomized to TASC intervention or usual care for postacute stroke care. All participants received wireless home BP monitoring devices and a tablet with built-in cellular connectivity that did not require Internet availability at home. The equipment wirelessly transmitted RBPM and survey data in real time to a cloud-based platform (eCareCoordinator, Philips, Amsterdam, the Netherlands) which was integrated with the electronic health record (EHR). This was to allow participants to transmit BP and PRO survey data remotely and complete telehealth video visits with the different members of the TASC team at specified time points after discharge. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliant applications supported telehealth visits. The TASC arm participants also received BP education in the form of tailored infographics developed with community participation and geared to promote BP control and self-efficacy.

Participants randomized to the intervention arm were mailed wireless BP monitors and tablets in the week after discharge, while the control arm participants received these in time for the 3-month follow-up that concluded the study. For the follow-up, participants provided a final BP reading and completed PRO surveys on the tablets as part of the overall feasibility of implementing collection of PROs into the flow of research data for clinical care and the role of PRO findings in facilitating clinical care. All patients were provided a small compensation at study completion.

Data Integration

A bidirectional Health Level Seven (HL7) interface was built between the eCareCoordinator cloud-based platform and the Epic EHR environment. This HL7 interface was used for data integration to communicate patient information using the Transmission Control Protocol/Internet Protocol (TCP/IP) transports between the software platforms. This enabled...
data to be received in real time, 24/7, as the equipment transmitted the measurements to the cloud-based platform. The Epic EHR was configured to leverage flowsheets in Epic so that all measurements would appear in the chronological order with time stamps. To the end user or provider, these then appeared in a familiar format such as those in patient-entered flowsheets when engaged participants manually submit vitals through their patient portal for providers to review.

Multiple data sources were integrated to support the study procedures for the multidisciplinary care outcomes research as summarized in Fig. 1. All data, including BP readings and PRO surveys collected via tablet, were transferred in comma-separated value files and managed using REDCap electronic data capture tools and analyzed as participants completed the study.14

**Blood Pressure Control**

As previously described in the protocol, a goal of systolic BP less than 130 mm Hg defined optimal BP control.15 Wirelessly transmitted BP readings were recorded by eCareCoordinator where they were centrally monitored by Philips’ telehealth nurses and transmitted to Epic EHR flowsheets. Elevated BP readings triggered calls to participants and escalation to providers by the monitoring nurses. Providers could inform their treatment options by viewing call communication reports and BP data on Epic or on the provider-facing eCareCoordinator interface. Scheduled intervention telehealth visits were conducted by primary care nurse practitioner, pharmacy, and stroke physician providers to support transitions of care. Received participant data captured in Epic EHR was used to make medication adjustments, and further treatment decisions.

**Blood Pressure Medication Adherence**

Medication adherence to the BP regimen was evaluated as a binary measure, adherent or not, based on chart review and pharmacy fill data. Verification of dispense history with the outpatient pharmacy was completed or attempted.

**Patient-Reported Outcomes**

The National Institutes of Health developed health measure tools to systematically collect outcomes.16 Our study leveraged five measures to evaluate PROs at the time of consent (with direct interaction on paper at bedside prior to hospital discharge) and at 3 months (via tablet) in both the control and TASC arms. For the 3-month follow-up, a notification
appeared on the tablet screen through the patient facing application (eCareCompanion, Philips, the Netherlands) prompting participants to take measurements and surveys as shown in the screenshots in Fig. 2. Participants who did not complete the surveys independently were provided with additional support: they could receive coaching by phone on how to complete surveys on the tablet, give their responses verbally by phone, or send their responses in an e-mail.

The self-reported Patient-Reported Outcomes Measurement Information System Managing Medications and Treatment (PROMIS-MMT) short form v1.0 measured self-efficacy in the domain of managing chronic conditions. The Neuro-QOL (Quality of Life in Neurological Disorders) Cognitive Function short form v2.0 8a and Neuro-QOL Depression short form v1.0 8a were used to provide further insight as they have shown preliminary evidence of health-related quality of life among those with neurological diseases. The PROMIS-MMT instrument, Neuro-QOL cognitive function SF v2.0, and Neuro-QOL Depression SF v1.0 were scored using a scoring algorithm for REDCap provided by the HealthMeasures Scoring Service to produce standardized \(t\)-score estimates with a mean of 50 and a standard deviation of 10, where higher scores indicate higher levels of the target trait (e.g., better cognitive function, higher level of depression symptoms).

The Patient Activation Measure (PAM) was used to assess patient engagement in health care, including the ability to self-manage health care needs and confidence to seek attention from providers. The PAM was scored per its scoring manual into (1) a continuous patient activation score and (2) a patient activation level; our analysis reflects the score (1). A change of 4 or more points is considered clinically meaningful.

The Patient Health Questionnaire-9 (PHQ-9) assessed for a diagnosis of depression and severity of symptoms. PHQ-9 scores, which can range from 0 to 27, are interpreted using 5, 10, 15, and 20 as the cutoff points for mild, moderate, moderately severe, and severe levels of symptom burden. A change of 5 points is the minimal clinically meaningful change.

### Statistical Analysis
Change scores for the five PROs were evaluated for differences between study arms. For the PROMIS-MMT, PAM, and Neuro-QOL PROs, two-sample independent \(t\)-test was used to compare the change from baseline to 3 months between the study arms. Data normality was not assessed as survey data were reported in \(t\)-scores with normality assumption or ordinal variables with insufficient categories to provide a reasonable approximation of continuous data.

Change in PHQ-9 scores over the study period was transformed to clinically meaningful units of change (e.g., number of 5-point changes). Each 5-point reduction in PHQ-9 corresponded with a 1-point subtraction in this variable, and each 5-point increase corresponded with a 1-point addition. For example, a score that decreased from 15 to 9 was coded as \(-1\) and increase from 5 to 14 was coded as \(+2\). Simple linear regression was used to test whether assignment to the study arm was significantly associated with clinically meaningful change in PHQ-9 scores.

### Results
Of the 50 enrolled participants (25 in each arm), two-thirds were either Hispanic or non-Hispanic Black (80% in TASC vs. 72% in usual care) and \(\geq 54\%\) had less than high school education (52% in TASC vs. 56% in usual care). Participants...
25 participants completed the PRO surveys on the tablet independently, whereas only 6 were able to do so in the usual care arm at 3 months. PRO submission mechanism for the TASC and control arms included tablet (62 vs. 47%), phone (24 vs. 37%), tablet with staff coaching by telephone (10 vs. 16%), and e-mail (4 vs. 0%). Survey completion rates for each of the five tools and the mechanism of survey submission are described in –Table 1.

Baseline and 3-month scores for the five surveys are summarized in –Table 2. As rated by PROMIS-MMT, self-efficacy in medication adherence improved over the study period from baseline in all 50 participants. No significant differences across the study arms were found in PROMIS-MMT, PAM, Neuro-QOL cognitive function, or Neuro-QOL depression. Across the study arms, there were 12 participants with a baseline PHQ-9 score of 5 or greater (i.e., screened positive for depressive symptoms): 9 in the intervention arm and 3 in the control arm. Five (56%) of the nine intervention arm participants had clinically meaningful improvement with a score reduction of 5 or more points, compared with 0 (0%) in the control arm. Further, the PHQ-9 scores were transformed to clinically meaningful units of change (–Fig. 3). In simple linear regression, we found that depressive symptoms were nominally, but not significantly, lower in the TASC arm with an improvement in PHQ-9 compared with the control arm from baseline to 3 months as shown in –Table 3.

Table 1 Survey completion and mode of submission

<table>
<thead>
<tr>
<th>Survey, n (%)</th>
<th>TASC (n = 25)</th>
<th>Control (n = 25)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROMIS-MMT</td>
<td>20 (80%)</td>
<td>19 (76%)</td>
</tr>
<tr>
<td>PAM, Neuro-QOL cognitive function, Neuro-QOL depression, and PHQ-9</td>
<td>21 (84%)</td>
<td>19 (76%)</td>
</tr>
<tr>
<td>Mode, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tablet</td>
<td>13 (62%)</td>
<td>9 (47%)</td>
</tr>
<tr>
<td>Phone</td>
<td>5 (24%)</td>
<td>7 (37%)</td>
</tr>
<tr>
<td>Tablet + phone coaching</td>
<td>2 (10%)</td>
<td>3 (16%)</td>
</tr>
<tr>
<td>E-mail</td>
<td>1 (4%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

Abbreviations: Neuro-QOL, Quality of Life in Neurological Disorders; PAM, Patient Activation Measure, PHQ-9, Patient Health Questionnaire-9; PROMIS-MMT, Patient-Reported Outcomes Measurement Information System Managing Medications and Treatment.

Table 2 TASC study patient-reported outcomes survey results

<table>
<thead>
<tr>
<th></th>
<th>TASC</th>
<th>Control</th>
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</thead>
<tbody>
<tr>
<td>PROMIS-MMT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (M ± SD)</td>
<td>43.1 ± 8.1</td>
<td>43.1 ± 8.7</td>
<td>&gt;0.10</td>
</tr>
<tr>
<td>Delta, CI</td>
<td>1.9 (–1.1 to 5.0)</td>
<td>2.6 (–2.1 to 7.1)</td>
<td></td>
</tr>
<tr>
<td>3 mo (M ± SD)</td>
<td>45.0 ± 9.6</td>
<td>45.7 ± 11.0</td>
<td></td>
</tr>
<tr>
<td>Neuro-QOL cognitive function</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (M ± SD)</td>
<td>48.5 ± 10.7</td>
<td>51.0 ± 10.4</td>
<td>&gt;0.10</td>
</tr>
<tr>
<td>Delta, CI</td>
<td>0.6 (–6.5 to 7.8)</td>
<td>–0.6 (–6.2 to 5.0)</td>
<td></td>
</tr>
<tr>
<td>3 mo (M ± SD)</td>
<td>49.2 ± 13.8</td>
<td>50.3 ± 10.5</td>
<td></td>
</tr>
<tr>
<td>Neuro-QOL depression</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline (M ± SD)</td>
<td>46.9 ± 7.2</td>
<td>44.9 ± 5.5</td>
<td>&gt;0.10</td>
</tr>
<tr>
<td>Delta, CI</td>
<td>–2.0 (–7.6 to 3.6)</td>
<td>–1.3 (–5.0 to 2.4)</td>
<td></td>
</tr>
<tr>
<td>3 mo (M ± SD)</td>
<td>45.0 ± 10.0</td>
<td>43.6 ± 5.5</td>
<td></td>
</tr>
<tr>
<td>PHQ-9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>4.9 ± 4.7</td>
<td>2.4 ± 2.0</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>3 mo</td>
<td>2.7 ± 3.6</td>
<td>4.0 ± 4.1</td>
<td></td>
</tr>
<tr>
<td>Delta, CI</td>
<td>–2.24 (–4.80 to 0.32)</td>
<td>1.53 (–0.50 to 3.55)</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; Neuro-QOL, Quality of Life in Neurological Disorders; PAM, Patient Activation Measure, PHQ-9, Patient Health Questionnaire-9; PROMIS-MMT, Patient-Reported Outcomes Measurement Information System Managing Medications and Treatment; TASC, Telehealth After Stroke Care.
Both cohorts of participants had similar pill burdens at discharge (TASC: 9 vs. control: 8). In the TASC group, providers (including primary care nurse practitioners, pharmacists, and stroke providers) made twice the number of medication initiations, modifications, and discontinuations after patient discharge compared with the control group with most changes made to BP medications. There was no significant difference between the intervention and control group regarding BP medication adherence among 37 participants (n = 21 in the TASC group and n = 16 in the usual care group) with available data. Similar proportions of participants adhered to prescribed medication in the TASC (67%) and usual care (63%) groups (p = 0.79). Six study participants (12%) had recorded history of antidepressant use. Additionally, four (67%) participants were started on antidepressants during the study, and four (67%) were referred to a mental health specialist for further evaluation during the 3 months. Five participants maintained the same number of antidepressant medications at the end of the study as at the beginning. Four of the subjects who had the same number of medications filled their antidepressants consistently, and one lacked pharmacy fill data to ascertain adherence.

If improvement in depressive symptoms occurs in the absence of the full pharmacological effect of antidepressants, then the effects of close contact and engagement should be further examined. In that effort, we explored if there was an independent effect of engagement in the program by the number of BP readings taken by participants, and an improvement in depressive symptoms reported in PHQ-9 surveys without antidepressant use at baseline. We evaluated the number of home BP reading submissions in relation to improvement in PHQ-9 for those with depressive symptoms but not on antidepressants at baseline (n = 5). They submitted an average of 151.2 readings during the follow-up period. This is greater than the average of everyone else who submitted at least one reading (average of 56.3 among 32 other participants) and greater than that the average restricting to the intervention group (average of 84.6 among 16 other TASC arm participants). Further, the average number of readings submitted in this group of 5 was greater than the number of readings submitted by all but one other participant in the complete cohort.

With respect to the feasibility of managing multiple data sources, the only meaningful deviation from the plan was that BP and PRO data were not exported directly from Epic into REDCap but rather transferred in a .csv file. Export from Epic was possible but involved procedural delays that were incompatible with the study timeline.

**Discussion**

We found that the majority of participants in the TASC intervention group completed the 3-month follow-up PRO...
surveys via tablet independently; almost half did so in the control group. Some participants successfully completed the surveys when coached by phone on using the tablet to do so. The remaining participants provided their responses by telephone or e-mail. The informatics implication is that it is feasible to collect PROs in this manner provided that additional support is available from research staff or a caregiver for the participants who need it.

Data integration from multiple sources supported the feasibility of incorporating and reporting PROs as part of the TASC feasibility pilot trial. Notably, data quality imported from the EHR has previously been noted to be highly inconsistent.\textsuperscript{23} In our study, directly transmitting PROs via a tablet device to a centralized cloud-based platform integrated with the EHR as a defined clinical information system facilitated data management and subsequent analyses for research outcome measures. It also reduced time and effort spent on manual data entry.

Although there was no difference in medication adherence by patients between the two arms, twice the number of medication interventions were made by providers in the TASC arm compared with usual care. This suggests that the health information exchange (HIE) facilitated focused interprofessional team efforts. Enhanced collaboration through touch point calls between primary care, pharmacists, and stroke specialists reduced therapeutic inertia. This has previously been noted in rural settings for chronic care to improve clinical outcomes.\textsuperscript{24,25} but has not been studied among an underserved urban stroke population.

We found leveraging technology may be feasible among postacute stroke patients while adding valuable feedback in patient-oriented outcomes. Clinical information systems have previously been integrated in an effort to improve quality of acute stroke care delivery through Mobile Stroke Units staffed by multidisciplinary teams.\textsuperscript{26} Postacute stroke, care transitions are subject to a fragmented health care system with limited provider support, particularly among those from underserved communities.\textsuperscript{27} However, the importance of incorporating PRO assessment into routine poststroke care has been increasingly recognized for recovery.\textsuperscript{28} Poststroke factors that influence patient well-being should be systematically addressed with team-based care to build patient-centered systems that improve long-term health outcomes. In the postacute stage, illness-related burden includes depressive symptoms and cognitive changes that occur among more than a third of stroke patients.\textsuperscript{29,30} In fact, mental health domains may play a greater role in the road to recovery than physical disabilities, and patient well-being must be considered in clinical decision-making.

Comparable survey scores across study arms suggest that all study arms yield lower completion rates. As noted in a recent mixed methods study, primary care patients responded favorably to the use of CDS tools with greater promise of engagement when visual displays include more detailed recommendations set to clinician priorities.\textsuperscript{31} Interestingly, we observed clinically meaningful improvements in PHQ-9 score among stroke patients in the TASC group but not in the control group, implying that in a properly powered study, we might find that participants receiving the frequent telemonitoring and team engagement of the TASC intervention are less likely to be depressed. Such a finding would have important clinical implications. As an example, among patients with chronic heart failure, telemonitoring at home has been found to improve patient’s perception of their quality of life and assisted them to sustain self-care behaviors leading to fewer hospitalizations.\textsuperscript{32}

Given that antidepressants require time and concerted effort to improve clinically significant depressive symptoms, the full clinical effect of the medication dose changes or new initiatives is unclear within the study timeframe.\textsuperscript{33} Additionally, we acknowledge the racial disparities in underreporting depressive symptoms among minorities such as in our patient population. This may be due to cultural differences in openly sharing depressive symptoms and the lack of an evaluation of perceptions of emotional vulnerability in the current tools.\textsuperscript{34,35} Therefore, even small changes in reported depressive symptoms such as in our study merit investigation. Moreover, differences were noted in PHQ-9 and not Neuro-QoL Depression. This observation enhances the importance of leveraging multiple surveys to accurately assess PROs and incorporate training to identify the need for treatment even with subclinical PHQ-9 scores.

Although there were no significant differences in PROs between study arms, there was trend in improved depression scores among those in the TASC arm at three months compared to those in the control arm.\textsuperscript{10} Flexibility in utilizing various surveys and submission portal options may be needed to collect meaningful data for clinical improvements.

Limitations

Considering the small sample size, between-group differences in patient-centered outcome measures should be interpreted cautiously. However, the approach was found feasible and an adequately powered trial utilizing this informatics application will be planned. Further, due to the limited sample, it is possible that the trend in improved depression scores among the TASC patients may be due to more patients with baseline depression in the TASC group compared with the usual care group. Additionally, we acknowledge that medication fill data are a limited method of documenting medication adherence with other more reliable methods that may be employed in the future to gauge true completeness.

As a limitation of our study design, we cannot evaluate the extent to which the usability of the tablets and survey interface influenced participants’ ability to complete the PRO surveys independently. Systems that are less well designed might yield lower independent completion rates.
Conversely, additional digital support such as video tutorials might reduce the number of participants who need assistance. Further research is needed to address this gap tailored by digital skills assessment among participants.

**Conclusion**

Enhancing postacute stroke care with wireless technology and home BP telemonitoring integrated into EHR is a promising informatics-based approach to improving hypertension control and self-management in an underserved setting. Our findings suggest the feasibility of incorporating PROs and support the concept of self-management through an interactive web-based platform. The team-based RBPM intervention showed a statistically significant improvement in PHQ-9, and trends toward improved PROMIS scores. Further, data flows from multiple sources can be integrated to improve clinical research. Patients equipped with tailored support and appropriate resources can actively engage in poststroke care to mitigate health care inequities.

**Clinical Relevance Statement**

Integrated telehealth platforms that communicate remotely monitored patient data through wireless BP devices and collect PROs into EHR can be successfully leveraged to support a multidisciplinary telehealth intervention and, ultimately, improve patient-oriented outcomes.

**Multiple-Choice Questions**

1. What additional supports can aid successful completion of PROs?
   a. Text alerts
   b. Phone coaching
   c. Handheld devices
   d. None of the above
   **Correct Answer:** The correct answer is option b. Phone coaching can aid successful completion of PROs and is to be considered for feasibility.

2. How did data flow into the EHR in this study?
   a. From REDCap
   b. From the cloud platform (eCareCompanion) through HL7 interface
   c. Directly from the tablet and BP monitor
   d. Entered into the EHR by the participants
   **Correct Answer:** The correct answer is option b. Data were communicated through HL7 interface between the cloud-based platform and EHR.

3. Which of the following statements is supported by the findings of this study?
   a. There were no measurable trends in PROs between study arms.
   b. There was a significant difference in PROs at study completion.
   c. There was a trend toward improvement in the intervention arm.
   d. There was a significant difference in PROs at study enrollment.
   **Correct Answer:** The correct answer is option c. There was a trend toward improvement in the intervention arm at study completion in depressive symptoms among those more engaged in the interactive platform.

4. When creating an integrated web-based platform for clinical use, which of the following should be considered to improve clinical outcomes?
   a. Timely health information exchange.
   b. Workflow for providers.
   c. Ease of use of devices for participants.
   d. All of the above
   **Correct Answer:** The correct answer is option d. All the of the above need to be considered when supporting a multidisciplinary team to provide clinical care for optimal patient engagement with an integrated web-based platform linked to EHR.

**Protection of Human and Animal Subjects**

The study was performed in compliance with the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects and was reviewed by the TASC Institutional Review Board.

**Conflict of Interest**
None declared.

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