Title: Post-Op Home Monitoring after Joint Replacement (POHM): a feasibility study

Short Title: POHM feasibility study

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Abstract:

Background

A prospective observational study of patients undergoing elective primary hip or knee replacements was conducted to examine the feasibility of a postoperative home monitoring (POHM) system as transitional care to support patients following their surgery in real-time.

Objective

Primary Outcome was the mean percentage of successful wireless transmission from home of blood pressure, heart rate, oxygen saturation, and pain scores until postop day 4 with a feasibility target of ≥ 90%.

Method

Patients with an expected length of stay ≤ 1 day; age 18-80 years; Revised Cardiac Risk Index ≤ Class 2; and care-takers willing to assist at home were eligible. Patient satisfaction as a secondary outcome was also obtained. Wireless monitoring equipment (Telus RPM) was obtained and a multi-disciplinary care team was formed.

Results

After Research Ethics Board approval, 54 patients completed the study: 21 males, 33 females. There were 9 total hips; 4 unipolar hips; 26 total knees; 15 hemi-knees. The mean transmission rate was 96.4% (SD 5.9%) [CI: 94.8% - 98.0%]. The median response to “I would recommend the Remote Monitoring System program to future patients” was 4.5 [IQR 4-5], 1 being “strongly disagree” and 5 “strongly agree”. At 30-days, there was no mortality or re-admission.
Conclusions

This is an evolving new paradigm for postoperative care and the first feasibility study on monitoring bio-metrics after primary hip or knee replacements. POHM combines current technology with real-time support by a multi-disciplinary transitional care team after discharge, facilitating post-surgical care with successful wireless transmission of vitals. The POHM implementation is therefore generalizable to other surgical discharges from hospitals.

Introduction

For a number of reasons including the impetus to increase surgical throughput, the median length of stay (LOS) for total hip replacements in Canada has been decreased from 6 days in 2006–2007 to 4 days in 2012–2013,\(^\text{[1,2]}\) and for total knee replacements from 5 days in 2006–2007 to 3 days in 2013–2014,\(^\text{[1,2]}\) Nevertheless, the Canadian Institute of Health Information (CIHI) “…data [on hip or knee arthroplasty] suggests that demand is rising at a rate that is outpacing the ability of health systems to keep up.”\(^\text{[3]}\)

The literature shows that within 30 days after surgical discharge, although most patients have no surgical "returns" such as emergency department (ED) visits or readmissions, 6.5% were readmitted and 18.7% returned to the ED within 30 days in Canada.\(^\text{[4]}\) In one study in the US after total knee replacements, the 30-day readmission rate was 5.6%.\(^\text{[5]}\) In another, the 30-day complication rate after hip or knee replacement was 2%, including myocardial infarctions (MI),
deep vein thrombosis (DVT), pulmonary embolism (PE), and death. It is important to note the corollary that 98% of those cases did not have complications, or that 95.4% were not readmitted in 30 days after hip or knee replacements. The statistics therefore support the concept of earlier discharge in spite of a small proportion of patients requiring readmissions after discharge.

Data from CIHI also show that 1.9%, 9.4%, 18.7% of post-surgical patients visited ED within 1, 7, & 30 days of discharge respectively (based on Ontario, Alberta, & Yukon data). Of the post-surgical patients who visited the ED within 7 days of discharge, 28.3% (8363/29552) were Canadian Triage and Acuity Scale (CTAS) IV/V and were non-life threatening or emergent, and therefore potentially preventable or manageable at home. In contrast, 24.4% & 47.2% of post-surgical visits to the ED were emergent or urgent (CTAS I, II, III), and repatriation of those patients to the hospital should be expeditious. The challenge is to decide which patients need to be repatriated expeditiously after discharge versus the ones with lesser complications to be managed at home. The Post-operative Home Monitoring (POHM) solution allows remote wireless transmission of blood pressure (BP), heart rate (HR), oxygen saturation (SpO2), and pain scores using a tablet, non-invasive blood pressure cuff (NIBP), and blue tooth saturation monitor. Through the monitoring, we hypothesize that patients could be wirelessly monitored at home and their concerns after discharge may be managed appropriately. This is a report of an outpatient hip and knee replacement pathway in our institution with post-operative home monitoring.
OBJECTIVES

To demonstrate feasibility of wireless home monitoring after elective primary hip or knee replacements with a primary feasibility target of ≥ 90% successful transmission of BP; HR; SpO2; and pain scores 4 times a day from home until post-op day (POD) 4. Secondary outcomes included patient satisfaction.

METHODS

Approval from REB was obtained for a prospective observational study of patients undergoing elective primary hip or knee replacements with an expected LOS (length of stay) ≤ 1 day (same day discharge); age between 50 and 80 years; Revised Cardiac Risk Index (RCRI) ≤ Class 2; and care-takers to assist at home. As the study progressed, younger age group was found to present for primary hip or knee replacements which prompted a change in our age inclusion criterion from 18 to 80 and required additional REB supplemental approval. Exclusion criteria were ASA IV; Chronic Obstructive Pulmonary Disease (COPD) with Forced Expiratory Volume (FEV) 1 sec ≤ 1; Obstructive Sleep Apnea (OSA); patient or family reluctance to participate in early discharge; prior enrollment in POHM; and disease process that is unstable or undiagnosed. A sample size of 54 was sufficient to yield a one-sided 95% confidence interval estimate around our primary outcome measure (proportion of successful transmissions) with a lower bound exceeding the cut-point for feasibility of 90%, assuming a proportion of 95% successful transmissions. Consent was obtained in the Pre-Admission Unit (PAU) starting in March 2014 as per the Ottawa Hospital Research Institute (OHRI) Standard Operating Procedures (SOP). The choice of anesthetic was left at the discretion of the anesthesiologist assigned to the case. Surgical approach was as per standard practice of minimally invasive technique; direct anterior in the hip or sub-vastus in the
knee. Patients followed the standard post anesthetic recovery unit’s hip and knees replacement clinical pathways.

Prior to discharge on the same day of surgery, Telus RPM hardware with cellular connectivity to patient’s home; alerts to the research team smartphones; and data storage behind the hospital firewall was set up. A care path for primary hip or knee replacements was defined, with acetaminophen, celecoxib, opioid (tapentadol, tramadol, or hydromorphone), pregabalin, and anticoagulant (apixaban or rivaroxaban) prescribed on discharge unless otherwise contraindicated. Monitoring of BP, HR, SpO2, and pain scores was four times a day for four days post-operatively, transmitted to the hospital server behind the firewall. Specific alert protocols were set up within the Telus software and a primary responder from within the research team was designated to receive the alerts at all times. Otherwise, the primary responder would check the on-line monitoring dashboard once a day.

A patient questionnaire (Table 4) using a 5-point Likert scale, 1 – strongly disagree, 3 – neutral, and 5 – strong agree, was administered on the Telus hardware without any research personnel present at the end of each monitoring period. Patients were followed-up on POD 5 and by phone call on POD 30.

Descriptive statistics (mean and standard deviation or frequency and percentage) were used to describe pre-operative and pre-discharge characteristics of participants. Mean, standard deviation, and median transmission rates were used to describe the actual transmissions over the total daily possible transmissions. Mean and standard deviation were used to describe responses to the patient questionnaire.
We follow the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement in reporting our study.

RESULTS

The target sample size of 54 patients was achieved between April 2014 and September 2015. Patients’ demography and comorbidities are reported in Table 1. Patients’ eligibility, recruitment and participation in the study are shown in the flow diagram (Figure 1). Surgical procedures, type of anesthetics and medications received are reported in Table 2. The overall mean transmission rate was 96.4% (SD 5.9%) [CI: 94.8% - 98.0%], and the median transmission rate was 97.9% [IQR 97.8-98.8%] (Table 3). There were 6 alerts of BPs > 140; 7 of BPs < 90; 7 of HR > 120; 0 of HR < 50; and 1 of SpO2 88. “Unsatisfied with pain control” alerts were sent by patients on 7 occasions; and “Pain limiting movement” by 13. Apart from the courtesy phone call made on the evening of discharge, the median number of phone calls to patients during the 4 days of monitoring was 1.0 [IQR 1-3], with 11 and 21 patients with 0 or 1 phone call respectively; and 8 patients required 5 phone calls during the 4 days of monitoring.

Table 4 shows the patient responses to the questionnaire at the completion of the home monitoring. The median response to “I would recommend the Remote Monitoring System program to future patients” was 4.5 [IQR 4-5], 5 being “strongly agree”. (Figure 2). At the end of monitoring questionnaire, patients were given the chance to provide further comments (Table 5). There was no mortality in 30-day postoperative period.
Table 1  Patients demography

<table>
<thead>
<tr>
<th>Variable</th>
<th>n = 54</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>61.4 (SD 8.3)</td>
</tr>
<tr>
<td>Sex</td>
<td>F=33 (61%), M=21 (39%)</td>
</tr>
<tr>
<td>BMI</td>
<td>27.51 (SD 4.0)</td>
</tr>
<tr>
<td>ASA I</td>
<td>5 (9.3%)</td>
</tr>
<tr>
<td>II</td>
<td>40 (74.1%)</td>
</tr>
<tr>
<td>III</td>
<td>9 (16.7%)</td>
</tr>
<tr>
<td>IV</td>
<td>0</td>
</tr>
<tr>
<td>HBP on treatment</td>
<td>15 (27.8%)</td>
</tr>
<tr>
<td>Type II DM on treatment</td>
<td>3 (5.6%)</td>
</tr>
<tr>
<td>Hypercholesterolemia on treatment</td>
<td>14 (25.9%)</td>
</tr>
<tr>
<td>Pre-op NSAID</td>
<td>23 (43.4%)</td>
</tr>
<tr>
<td>Current Smoker</td>
<td>3 (5.8%)</td>
</tr>
</tbody>
</table>
Fig 1 Recruitment Diagram for POHM Part 1

Assessed for eligibility (n=104)

Enrollment (n=56)

- Not meeting inclusion criteria (n=3)
- Refused to contact for research (n=14)
- Refused Study participation (n=9)
- Equipment/Staff not available (n=10)
- Excluded (n=12)
  - withdrew consent (n=1)
  - Exclusion criteria identified (n=10)
  - Surg procedure cancelled (no longer eligible) (n=1)

POHM units sent home = 56

(n=56)
- Withdrawal at home (n=1)
- Late exclusion (OSA) found after inclusion (n=1)
- 54 to follow
- 1 refused 30 day FU-1 = 53

30 day Follow-Up done = 53
Table 2 Surgical procedures, type of anesthetics and medications received.

<table>
<thead>
<tr>
<th>Variable</th>
<th>n = 54 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Hip</td>
<td>9 (16.7%)</td>
</tr>
<tr>
<td>Unipolar Hip</td>
<td>4 (7.4%)</td>
</tr>
<tr>
<td>Total Knee</td>
<td>26 (48.1%)</td>
</tr>
<tr>
<td>Hemi Knee</td>
<td>15 (27.8%)</td>
</tr>
<tr>
<td>Anesthesia</td>
<td></td>
</tr>
<tr>
<td>spinal</td>
<td>50 (92.6%)</td>
</tr>
<tr>
<td>GA</td>
<td>4 (7.4%)</td>
</tr>
<tr>
<td>NSAID on discharge</td>
<td>40 (74.1%)</td>
</tr>
<tr>
<td>Tapentadol or Tramadol on discharge</td>
<td>14 (25.9%)</td>
</tr>
<tr>
<td>Acetaminophen on discharge</td>
<td>49 (90.7%)</td>
</tr>
<tr>
<td>Pregabalin on discharge</td>
<td>54 (100%)</td>
</tr>
<tr>
<td>Opioid on discharge</td>
<td>38 (71.7%)</td>
</tr>
<tr>
<td>Anticoagulant on discharge</td>
<td>51 (94.4%)</td>
</tr>
</tbody>
</table>
Table 3 Transmission rates in the first 4 days postoperatively.

<table>
<thead>
<tr>
<th>Transmissions on Day of Sx (see *)</th>
<th>99.5% (SD 0.03%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transmissions on Post-op Day 1</td>
<td>98.3% (SD 0.06%)</td>
</tr>
<tr>
<td>Transmissions on Post-op Day 2</td>
<td>97.9% (SD 0.06%)</td>
</tr>
<tr>
<td>Transmissions on Post-op Day 3</td>
<td>97.8% (SD 0.06%)</td>
</tr>
<tr>
<td>Transmissions on Post-op Day 4</td>
<td>90.9% (SD 0.24%)</td>
</tr>
<tr>
<td>Transmission Per Day Overall (mean, SD)</td>
<td>96.4% (SD 5.9%) [CI: 94.8% - 98.0%]</td>
</tr>
</tbody>
</table>

* Day of Sx: 4 transmissions (BP, HR, SpO2, Pain)
POD 1 – 4: (BP, HR, SpO2, Pain) x 4 per day x 4 days
Total possible transmissions 68 per patient during study

Table 4 Patients satisfaction survey (Day 5 postop)

<table>
<thead>
<tr>
<th>Variable (1 – strongly disagree; 5 – strongly agree; not every patient answered every question)</th>
<th>Mean (Standard Deviation)</th>
</tr>
</thead>
</table>

171
172
173
174
175
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179
180
181
182
183
184
185
186
187
188
"The information provided, told me what to expect about the Remote Monitoring System at home." 4.57 (0.54) N = 51

"The instructions on how to set up and use the Remote Monitoring System were easy to understand." 4.61 (0.57) N = 51

"The Remote Monitoring System was difficult to use." 1.82 (0.87) N = 51

"I felt safe at home during the four days of monitoring" 4.33 (1.01) N = 51

"During the 4 day monitoring, the response by the Clinician was efficient." 4.46 (0.89) N = 50

"There was too much to manage at home including the Remote Monitoring System." 2.22 (1.19) N = 51

"The length of four days for the actual monitoring was just right" 4.14 (0.72) N = 51

"During the 4 day monitoring, I would have liked more feedback from the Clinician " 2.41 (1.1) N = 51

"I would recommend the Remote Monitoring System program to future patients" 4.36 (0.8) N = 50

Fig 2

Frequency of phone calls during the 4 days of monitoring, Part 1
### Table 5 Comments

<table>
<thead>
<tr>
<th>Study Patient</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td>Excellent wonderful</td>
</tr>
<tr>
<td>#2</td>
<td>Excellent, godsend</td>
</tr>
<tr>
<td>#10</td>
<td>Comforting-monitoring remotely triggered interaction when at home as he had event. He had event, low BP. He would like comment section at each evaluation time to express how one feels.</td>
</tr>
<tr>
<td>#26</td>
<td>Very good - reassuring that clinician sees the results entered BP monitor should have been demonstrated more with husband-(pt sleepy)</td>
</tr>
<tr>
<td>#40</td>
<td>very good. pain episode was managed, hard to remember the time but by Day 2 ok, Preop stressed and at discharge but having wife shown equip was good</td>
</tr>
<tr>
<td>#44</td>
<td>concerned how pills affect you. wonderful, very safe, good to check blood pressure</td>
</tr>
</tbody>
</table>

**DISCUSSION**

Our results demonstrate the feasibility of postoperative home monitoring at a transmission rate of > 96% supported by a response team. Early data transmission and clear communications...
between the patients and response team have led alteration in the postoperative course. This is
clearly demonstrated from patients comment; “I had a pain crisis on day 2 and this programme
allowed me to speak directly with [the nurse] and receive instructions and her rechecking on me I am
immensely grateful to her and her initiative. My only other recourse would have been a trip to
emergency and wait in line. This programme provides an indispensable safety net for major
surgery day patient well done.”

Although their analysis was mainly on chronic disease management, in a Pan-Canadian Study on
Remote Patient Monitoring (RPM) in 2014, acute care was considered and was thought to be
the most complex in RPM initiatives, at Level 5\(^7\). In their risk stratification framework, RPM
deployment should ensure that technological complexity, patient acuity, and risk of
hospitalization (re-hospitalization in our case) are aligned. A patient profile with moderate to
high risk of (re)hospitalization should be known to one or more services to ensure multi-
disciplinary case management. We concur with the conclusion and having a multidisciplinary
team; our care model involved surgery, anesthesia, acute pain service, and nursing.

The importance of the POHM does not rely only on the availability of software and hardware
but on the infrastructure to support the home monitoring, including patient safety, secured
transmissions, and team response while maintaining privacy. Potential data security and privacy
breaches are an increasing concern in mobile medicine.\(^8,9\) One study identified potential data
security and privacy breaches in 95.63%, 17,193/17,979 of mobile iOS apps.\(^10\) In our project,
patient confidentiality and data security were built into the design from the beginning, starting
with the hospital firewall for data repository and with the use of protected institutional emails.
We believe that is paramount and, since the study completion, we have continued the project in
partnership with the Ontario Telehealth Network which has a data infrastructure in compliance with the provincial Office of the Information and Privacy Commissioner of Ontario.

In addition, the designation of a primary responder at the originating hospital, whereupon the patient’s surgical and anesthetic history is immediately available whenever alerts are received. The protocols for alerts include algorithms to allow an escalation of severity. The immediate transmission of alerts to the primary responder’s smartphone allows the primary responder not to be tied to a monitor but able to carry out other duties during the monitoring period. In addition, as demonstrated in our feasibility study, most of the patients in fact only required 0 or 1 phone call over the 4 days apart from the initial courtesy call on the day of discharge.

Nevertheless, there were 8/54 patients who required 5 phone calls over the 4 days for support and management. With an escalating alert algorithm, it allows the primary responder to focus on the patients who require more attention at home after discharge.

There have been studies on post-surgical RPM. All studies but one were on the monitoring of activity level at home using mobile devices such as smartphones. The one study that monitored bio signs at home was on 20 patients after liver transplants. We present here the first feasibility results on post-op home monitoring of bio signs after primary hip or knee replacements.

There are limitations to the current study. It was a prospective observational trial without interventions. The primary outcome was collected based on actual digital transmissions to the hospital server as an objective count. The patient questionnaire administered at the end of the monitoring period was done on the POHM hardware at a patient’s home without any
researchers being present. It is unlikely a bias would have influenced a patient’s responses. The actual data on 30-day mortality and any other adverse events were collected by the research team by phone call and being a numerical count, was objective and unbiased. We believe therefore that the feasibility and reliability of POHM was demonstrated without bias.

Any surgical population, with low surgical readmission or ED visit rates would be excellent candidates for EDc and POHM. In other surgical specialties, initiatives, such as Early Recovery after Surgery (ERAS), have been implemented to achieve earlier discharge. With the advent of minimally invasive surgery, improved anesthetic techniques and postoperative pain management modalities, earlier post-surgical discharge is increasingly possible and appropriate; POHM is therefore generalizable to other surgical populations.

Our study demonstrates that a wireless system is feasible in monitoring patients at home after surgery. Combining real-time interactive support by the healthcare team and the rapidly evolving monitoring technologies such as wearables, post-operative home monitoring system holds great promise for even more advanced monitoring at home. The automated system with escalating alerts is a monitoring system with built-in intelligence and allows the primary responder to monitor patients without being tied to a monitor. We believe POHM is a new paradigm of transitional care for surgical recovery in the post-acute care period.
Conflict of Interest

None

Acknowledgements

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