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Protocol for project recovery after cardiac surgery: a single-center cohort study leveraging digital platform to characterise longitudinal patient-reported postoperative recovery patterns

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ABSTRACT

Introduction Improving postoperative patient recovery after cardiac surgery is a priority, but our current understanding of individual variations in recovery and factors associated with poor recovery is limited. We are using a health-information exchange platform to collect patient-reported outcome measures (PROMs) and wearable device data to phenotype recovery patterns in the 30-day period after cardiac surgery hospital discharge, to identify factors associated with these phenotypes and to investigate phenotype associations with clinical outcomes.

Methods and analysis We designed a prospective cohort study to enrol 200 patients undergoing valve, coronary artery bypass graft or aortic surgery at a tertiary centre in the USA. We are enrolling patients postoperatively after the intensive care unit discharge and delivering electronic surveys directly to patients every 3 days for 30 days after hospital discharge. We will conduct medical record reviews to collect patient demographics, comorbidity, operative details and hospital course using the Society of Thoracic Surgeons data definitions. We will use phone interview and medical record review data for adjudication of survival, readmission and complications. We will apply group-based trajectory modelling to the time-series PROM and device data to classify patients into distinct categories of recovery trajectories. We will evaluate whether certain recovery pattern predicts death or hospital readmissions, as well as whether clinical factors predict a patient having poor recovery trajectories. We will evaluate whether early recovery patterns predict the overall trajectory at the patient-level.

Ethics and dissemination The Yale Institutional Review Board approved this study. Following the description of the study procedure, we obtain written informed consent from all study participants. The consent form states that all personal information, survey response and any medical records are confidential, will not be shared and are stored in an encrypted database. We plan to publish our study findings in peer-reviewed journals.

Strengths and limitations of this study

- This study will assess the patients' perspective on recovery after cardiac surgery at a high frequency within the 30-day postoperative period with surveys and activity monitoring via a health information platform and wearable devices.
- Using longitudinal patient-reported outcome measure data, this study will define recovery patterns and factors associated with different recovery trajectories and guide the development interventions to improve recovery and support expansion of the study to additional sites.
- The study is single centre and the sample size is limited.

BACKGROUND

Improving postoperative patient recovery is a priority. Readmission rates in the postoperative period are high. Moreover, in the USA, the expansion of episode-based payments and performance measures is increasing interest in the post-acute experience of patients.[1 2] However, we generally lack systematically collected information on the experience of patients in the post-acute period, as few studies rigorously collect information using established patient-reported outcome measures (PROMs). We have, for example, little information about the variation of the trajectories of recovery and the factors most strongly associated with better outcomes.[3]

The assessment of the patient experience can provide important insights into the process of recovery that is not evident through clinical outcomes or intermittent clinical office visits. PROMs and wearable devices can provide complementary information by providing measurements of how the

patient's experience and functional status change over time.[4] Current digital platforms allow us to efficiently collect PROMs and wearable-generated data at high frequencies and with little cost and burden. These automated data collection approaches may minimise the bias introduced by clinician-directed patient interviews.[5] Such a platform is highly suited to obtain repeated measures to characterise a time-dependent process such as recovery.[6]

Cardiac surgery is an ideal area for the study of recovery. Many patients have good outcomes, but the limited existing evidence suggests a wide variation in the postoperative experience of these patients.[7] However, these patients' experience has been poorly studied, as most studies of recovery simply assess deaths and complications.

Characterising the recovery from the patients' perspective is important for many reasons. First, shared decision-making and informed consent should be guided not only by the risk of mortality and complications but also by the recovery experience. Understanding variations in recovery could enable the early identification of people who are struggling and require additional attention. Recovery data from the patients' perspective may enable remote monitoring after the procedure to selectively and pre-emptively intervene on those at high risk of poor recovery to improve outcomes. Characterisation of recovery can also be used to identify patient, surgeon, procedural and institutional factors that are associated with different patterns. With this information we can identify modifiable risk factors for poor recovery.

Thus, at this juncture, there are several notable gaps in knowledge. First, although recovery occurs over time, most studies of recovery included a small number of time-points, and the recovery trajectory phenotypes remains poorly defined.[3] Cohort-level average of recovery trajectories is a common way of reporting[3] and can indicate how patients recover on average,[7] but it obscures individual variation such as rapid early recovery, gradual recovery or initial recovery followed by a decline. Second, we have limited understanding of how recovery trajectories vary by patient factors, operation types, centre or surgeon characteristics, procedural processes and complications, which limit opportunities to identify high-risk patients pre-emptively and intervene.

Accordingly, our overall objective is to characterise short-term trajectories of patient recovery after cardiac surgery using PROMs and wearable data. We are conducting a prospective study to characterise trajectories of postoperative recovery in multiple domains after cardiac surgery. The specific aims of this study are to: (1) leverage a digital data platform to collect PROMs and wearable device data to bring forth the variable individual recovery trajectories, (2) describe distinct classes of recovery trajectories and clinical factors associated with the classes and (3) evaluate whether early postoperative recovery trajectory predicts later recovery trajectory. In addition, we will investigate optimal ways to manage missing data specific to these time-series data. This study is a step toward using this approach to prospectively monitor and pre-emptively identify patients at risk of poor recovery and facilitate intervention to reduce the risk of adverse events. The purpose of this study protocol summary is to describe a new approach to studying recovery in order to address the knowledge gap as well as to prespecify our approach.

METHODS

Design overview

This is a prospective cohort study of patients who are undergoing valve, coronary artery bypass graft (CABG) or aortic surgery at a tertiary centre in the USA. We chose the operations because they are the most common cardiac operations performed[8] while having different patient and operative characteristics, such as the use of deep hypothermic circulatory arrest, to potentially provide insights into the recovery pattern associated with such variations. Subgroup analysis will be conducted to evaluate whether there is a distinct patient experience by operation types. We are enrolling patients postoperatively after intensive care unit (ICU) discharge in order to ensure clinical stability, and we are electronically delivering surveys directly to patients every 3 days for 30 days after hospital discharge to study patient trajectories in multiple domains characterising recovery. The closing phone interview after 30 days, electronic medical record review and linkage to the Society of Thoracic Surgeons (STS) Database are used to confirm survival, readmission and complications. The closing interview asks about details of readmissions if they occurred, patients' overall satisfaction with the study and whether their experience was well captured by the summary of their PROM data. We will apply group-based trajectory modelling to the longitudinal PROM data to identify distinct categories of recovery trajectories in a data-driven fashion. We also identify predictors of protracted recovery trajectory and evaluate whether early recovery patterns (<10 days) predict the overall trajectory (30 days) at the patient-level. The Yale Institutional Review Board approved this study (IRB # 2000025689).

Patient population

This study began in January 2019 and is ongoing. The study is taking place at Yale New Haven Hospital, a tertiary centre in the USA, where over 1100 cardiac surgeries are performed annually. Inclusion criteria are patients of age 18 and older who are undergoing CABG, valve replacement or repair, or aortic operations. Exclusion criteria are those who undergo heart transplant, extracorporeal membrane oxygenation, adult congenital operations or ventricular assist device implantation, as these patient populations tend to have a longer course of ICU stay,[9] precluding the timely enrolment necessary to capture immediate postoperative recovery. We also excluded those who do not own a smartphone or a tablet or those who do not speak or read English, because the digital platform for PROM data collection relies on patients responding to surveys displayed on web browser via email or text,

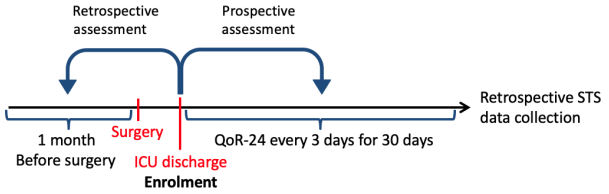

Figure 1 Timing of patient enrolment and PROM administration. The figure shows the timing of patient enrolment and PROM administration over the clinical course. Baseline function is assessed by retrospectively asking the patient about their state of health during 1 month prior to the operation. A 24-item quality of recovery questionnaire is administered every 3 days for 30 days following discharge from the ICU. ICU, intensive care unit; PROM, patient-reported outcome measure; QoR-24, 24-item quality of recovery; STS, Society of Thoracic Surgeons.

and the surveys were written in English language. We do not allow proxy for survey response and consequently excluded patients who were not able to respond by themselves as determined by the research assistant (RA).

In order to provide the sense of patient selection resulting from these criteria, we will compare patient characteristics of those who were approached and were and were not able to participate in the study for any reasons.

Recruitment

Recruitment takes place postoperatively after the patient has left the ICU for the step-down or floor unit (figure 1). We chose to enrol patients postoperatively, as opposed to preoperatively, because postoperative enrolment allows for enrolment of patients who undergo surgery under non-elective settings. Recruitment after transfer from the ICU setting ensures clinical stability. A RA visits the patient and after confirming the patient is eligible to participate and following the description of the study procedure, obtains written informed consent (online supplementary material S1) from all study participants. The informed consent form states that all personal information, survey response and any medical records are confidential, will not be shared and will be stored in an encrypted database.

We iteratively refined the enrolment process to minimise the onboarding time, which includes obtaining informed consent and sign-up process directed by the RA on a tablet device to enter patients' name and email address or phone number and takes approximately 10–15 min.

PROM instrument and administration

We use 24-item quality of recovery (QoR-24) to characterise patients' postoperative recovery in various domains. The questionnaire consists of 24 items that were developed and validated in inpatient and outpatient surgical populations in terms of convergent validity with visual analogue scale, construct validity compared with length of hospital stay and sex-based difference, along with good internal consistency and test–retest reliability.[10–13] We chose QoR-24 among five other PROMs developed specifically to measure postoperative recovery. QoR-24 possessed many qualities advantageous for the purpose of our study, including the robust validation of psychometric property, extensive use cases in various surgical populations, ability for self-administration and the ease of interpreting item-wise scores (online supplementary tables 1 and 2). The instrument was previously adapted into a mobile format and was successfully used to administer the survey daily for 14 days.[11 12] We added three items to QoR-24 to capture the self-reported time patients went to sleep, the time they awakened and their global perception of how much they have 'recovered' in a 0%–100% scale. The resulting 27-item questionnaire takes 2–4 min to complete, making its frequent administration feasible (online supplementary material S2). Among the published studies in cardiac surgery, this study will have the highest number of PROM data points collected in the first postoperative month.[3]

Digital data platform

We are delivering surveys on the day of enrolment and every 3 days for 30 days. This method provides detailed longitudinal data across multiple domains of recovery (figure 2). To facilitate data organisation and scheduled survey delivery, we use Hugo (Me2Health, Guilford Connecticut, USA) a patient-centred health data sharing platform, which has a customisable survey delivery function and reminder feature to facilitate data collection. Hugo platform allows for automated delivery of surveys without researchers having to directly contact patients, which facilitates high-frequency data collection. Additionally, it imports data from connected wearable devices to facilitate centralisation of patient health data. The patients retain access to their own data in a cloud-based account. Hugo does not fall under the covered entity that Health Insurance Portability and Accountability Act (HIPAA) regulates, but employs all the security measures that would be required by HIPAA had it been a covered entity.

Identifying common reasons for low response rate

Recognising that the survey response will be incomplete for some participants, we have conducted a phone interview with the first 22 patients to learn reasons for low responses and identify strategies to minimise the barriers toward survey response for subsequent participants. In the first 22 patients, we identified 5 with a response rate of <50% and conducted recorded phone interviews. Our interview guide (online supplementary material S3) contained questions to elucidate technical barriers, differential preferences for engagement and/or any other issues precluding survey completion. We also asked whether the length of the questionnaire or types of questions asked made it difficult to complete the survey. Two members of the research team (CB and MM) evaluated the interview recordings to identify common reasons for low response rate. This suggested the potential importance of reminder to maintain patient engagement. We modified the protocol to contact all participants

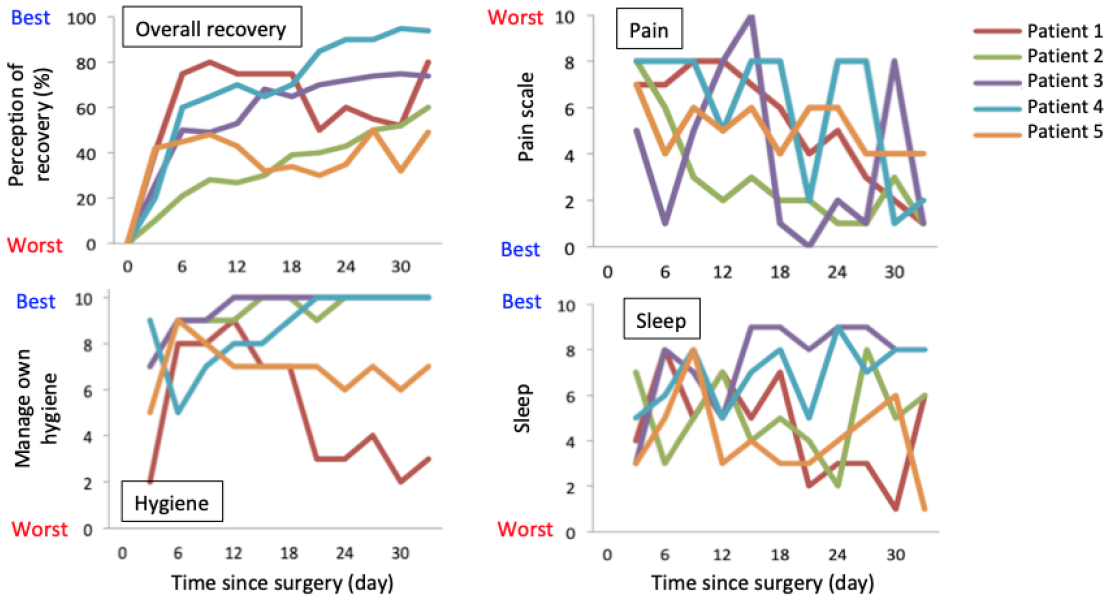

Figure 2 Sample trajectories of recovery in five patients. The figures display trajectories of recovery in different domains in five patients. Each colour corresponds to the same patient. Overall recovery is the patient's perception of overall recovery in 0%–100% scale. Pain in surgical site is reported in 0–10-point scale, with 10 representing the worst pain. Being able to take care of own hygiene is reported in 0–10-point scale, with 10 representing complete independence in managing own hygiene. Patient's perception of sleep quality is reported in 0–10-point scale, with 10 being the best sleep.

approximately 10 days after enrolment. We will continue to conduct this phone interview for patients with low response rate and describe engagement and barriers to participation in the final cohort. Survey response rate and time spent to complete each survey will be reported descriptively to evaluate the degree of patient engagement. This approach likely allows us to identify patients who either did not respond or completed the survey in an unrealistically short time that may not represent a meaningful response.

Additional clinical data and adjudication of hospitalisation and survival

Additionally, we are using the STS Adult Cardiac Surgery Database data specifications to retrospectively collect clinically relevant data in this patient population. Pre-specified candidate predictors in this database will be used to identify clinical predictors of recovery trajectories (table 1). The STS database contains patient demographics, comorbidities, presenting clinical status, operative details and postoperative mortality and morbidity up to 30 days after the time of operation.[14] These data are routinely collected at Yale New Haven Hospital. At our programme, 30-day mortality rates for isolated aortic valve replacement and isolated CABG are stable around 1%, with 30-day readmission rate of about 10%, which are slightly lower than the national average.

We will determine mortality and hospital readmissions by several approaches: review of hospital records, review of cardiac surgery clinic notes and conducting closing phone interviews with the patient or contact person previously identified.

Patient involvement

Prior to launching the study, we interviewed five patients both in preoperative and postoperative settings to evaluate whether the frequency of survey delivery and PROM instrument were likely to adequately capture their experience of recovery. All patients agreed that the frequency of questionnaire administration and the length of the PROM instrument were reasonable and provided face validity that the questionnaire captured aspects of recovery that were important to the patients. Additionally, this article is authored with a patient who participated in the study to reflect his perspective on the study design and experience in responding to the surveys.

Sample size

The study sample target is 200 patients. Adequate sample size for studies using group-based trajectory modelling depends on the dataset's representativeness of the population of interest.[15] Therefore, the concept of statistical power traditionally used for sample size calculation does not apply to latent class analyses. We may generate a larger simulation dataset from the measured patient trajectory data to perform a split-sample testing, evaluating whether trajectories generated from the derivation sample would allow for satisfactory categorisation of the testing dataset. Additionally, the study setting is scalable to increase the sample size by increasing the enrolment period, should a larger sample size become necessary.

Analytical approach: group-based trajectory modelling

The resulting dataset is a complex time-series data, with each patient having 10 data points (1 every 3 days) at different postoperative times for each item. A practical

Table 1 Candidate predictors of recovery trajectory

Demographic	Comorbidity	Operative factors	Postoperative factors
Age	Diabetes	Cardiopulmonary bypass time	Length of ICU stay
Sex	Prior stroke	Cross clamp time	Length of hospital stay
Race	Congestive heart failure	Operation type	Surgical site infection
Insurance status	Chronic kidney disease	Non-elective status	Prolonged ventilation
BMI	Dialysis	Transfusion requirement	Transfusion requirement
	Prior MI	Minimally invasive approach	Stroke
	Prior cardiac surgery		Reoperation for any reasons
	Ejection fraction		Death
	Arrhythmias		Readmission
	Prior PCI		Pneumonia
	Cardiogenic shock		
	Hypertension		
	Dyslipidaemia		
	Smoking status		
	Chronic lung disease		
	Endocarditis		
	Pneumonia		
	Peripheral artery disease		
	Immunocompromised		
	Mechanical circulatory support use		
	Valvular disease severity		

BMI, body mass index; ICU, intensive care unit; MI, myocardial infarction; PCI, percutaneous coronary intervention.

approach to dimension reduction is group-based trajectory modelling, which is a type of latent class analysis that groups similar patient trajectories according to a number of features derived from the time-series data.[16 17] This approach allows for dimension reduction of the complex time-series data into several distinct classes of recovery trajectories. These trajectories can be labelled according to the observed clinical phenotype of trajectories, for example, 'fast recovery', 'average recovery', or 'protracted recovery'. This data-driven categorisation enables additional regression modelling to identify predictors of patients belonging to a certain class of recovery path.

The dataset will be classified into distinct categories of trajectories at domain level, using group-based trajectory modelling.[16 17] Traj package on R[18] or Proc Traj package on SAS (version 9.4),[15] performs trajectory modelling by first extracting 24 features of patient-level trajectory, selecting a subset of features that describes the overall trajectory and identifying optimal number of classes to group the trajectories based on the longitudinal k-means method. The 24 features include range, mean change per unit time and slope of the linear model (table 2), which have been demonstrated to discriminate between stable–unstable, increasing–decreasing, linear–non-linear and monotonic–non-monotonic patterns of trajectories.[18] K-means method partitions the time-series data into k groups such that the mean squared error distance of each data point from the assigned cluster is minimised.[19] The optimal number of clusters is determined by the minimisation of Bayesian information criterion, which signifies the balance between model's complexity and the ability to describe the dataset. This process yields distinct classes of patient trajectories in a data-driven fashion. Trajectories will be identified separately for the five domains and one global recovery measure.

With the characterisation of trajectories, we will then fit multinomial logistic regression models using clinical variables outlined in table 1, including patient demographics, comorbidity and postoperative event, such as complications and ICU readmissions, to identify predictors of patients belonging to each trajectory class. As some variables interact with each other, such as history of chronic lung disease increasing the risk of postoperative pneumonia, which likely impacts the recovery experience, we plan to stratify the cohort with and without the index complications defined by the STS (prolonged ventilation, renal failure, sternal wound infection, pneumonia, stroke, all-cause reoperation). Further analyses on interaction and mediation effects likely require a larger sample size and are of interest in the future.

Analytical approach: missing data

Because missing data are inevitable in longitudinal PROMs, there is a need employ an appropriate handling

Table 2 Twenty-four features of trajectory used in group-based trajectory model

N	Features
1	Range
2	Mean-over-time
3	SD
4	Coefficient of variation
5	Change
6	Mean change per unit time
7	Change relative to the first score
8	Change relative to the mean over time
9	Slope of the linear model
10	Proportion of variance explained by the linear model
11	Maximum of the first differences
12	SD of the first differences
13	SD of the first differences per time unit
14	Mean of the absolute first differences
15	Maximum of the absolute first differences
16	Ratio of the maximum absolute difference to the mean-over-time
17	Ratio of the maximum absolute first difference to the slope
18	Ratio of the SD of the first differences to the slope
19	Mean of the second differences
20	Mean of the absolute second differences
21	Maximum of the absolute second differences
22	Ratio of the maximum absolute second difference to the mean-over-time
23	Ratio of the maximum absolute second difference to mean absolute first difference
24	Ratio of the mean absolute second difference to the mean absolute first difference

SD, standard deviation.

of missing data. Multiple imputation prior to latent class analysis may yield a less biased estimate of the resulting trajectories. An alternative approach used in group-based trajectory models assumes the data are missing at random (MAR) and generates the maximum likelihood of the model parameters.[20] MAR is valid when the response attrition is independent of the group membership. However, patient attrition is oftentimes dependent on clinical characteristics and likely related to the class of trajectory itself. An extension of the model allows for modelling of attrition across trajectory groups,[21] permitting dropout probability to vary as a function of covariates or observed outcomes prior to dropout and yields a more robust estimate of the probability of group membership. As such, we will perform sensitivity analysis to compare the trajectories generated via raw data versus data preprocessed with multiple imputation versus trajectories generated via trajectory model accounting for response attrition.

RESULTS

Between January and May 2019, we have enrolled 22 patients who completed the 30-day follow-up. In this cohort, median age was 58.5 years (IQR 53.5–67.0) and 7 (32%) were women. There were nine (41%) mitral valve repair cases and six isolated or concomitant CABG (27%).

Barriers to completing surveys

Of the 22 patients enrolled, 3 (14%) did not complete any surveys, 19 (86%) completed at least 3 surveys and 17 patients (77%) completed at least 6 of 11 delivered surveys (>50% of delivered surveys). Of the five patients who completed less than half of the surveys, we successfully contacted four, and one could not be reached after five attempts. All four reported that the major barriers precluding survey completion were their clinical conditions: two described readmissions as an overwhelming event that made them feel continuing survey participation challenging and two described not feeling well in general, which precluded participation. All four patients noted that text or email reminders might have been helpful to sustain participation. Based on these responses, we modified the protocol to contact all participants approximately 10 days after enrolment to improve engagement and resolve any patient-specific issues in completing the surveys.

Clinical outcomes

There were no deaths during follow-up. Two (9%) patients experienced at least one hospital readmission. Figure 2 depicts the breadth in recovery trajectories in pain, sleep, ability to take care of own hygiene and perception of overall recovery in five patients with complete response.

DISCUSSION

This study will provide time-series data on short-term recovery after cardiac surgery using PROM instruments complemented by clinical records obtained via the STS Database and electronic health records. This study will provide one of the highest density of postoperative PROM data in existing cardiac surgery literature,[3] and it will characterise the variability in individual recovery processes with a high temporal resolution. This study will be important in closing knowledge gaps around patient-level variations in trajectories because prior studies have mostly focused on changes in PROM scores at a limited number of time points[3] or reporting group-level aggregate of longitudinal recovery data.[7 22] Because recovery is an individual, variable and time-dependent process, we designed our data collection and analytical approach to capture such features important to recovery.

This study has the potential to make a variety of contributions toward improving post-acute phase of care. First, we will be able to develop a preliminary nomogram of postoperative recovery for each domain and overall perception of recovery, which would be instrumental for patients and clinicians to gauge the breadth of possible

recovery trajectories to facilitate informed shared decision-making. Second, identifying predictors of accelerated or protracted recovery, as classified by group-based trajectory model, may allow for individualised prediction of the postoperative recovery course to better inform the patients and family members. Third, early detection of recovery signals related to adverse events, such as mortality and readmission, may eventually facilitate pre-emptive intervention and focused monitoring of patients at an elevated risk for such events. Our design of the longitudinal PROM data collection allows for incremental update of such prediction as patients progress through the phase of recovery.

There are many challenges to the successful acquisition of patient measurements during recovery: efficient administration of PROMs in a way that does not require prohibitive amount of resources, minimising selection bias originating from barriers to survey completion, handling of missing data that inevitably occurs in PROMs and summarising the complex data in a way that is interpretable to surgeons and patients.[23] Additionally, the use of wearables and device data requires active patient participation in periodically charging the device, wearing them correctly and reliably syncing the device to the server for data uploads. Moreover, there is a need to provide value to the patients for providing their recovery profile, such as giving them access to their health data in a meaningful way.

The resulting data collection, analytical and output platforms have the potential of being implemented in the clinical setting where an integration of incrementally increasing PROM and clinical data provides the near-real time estimate of individual patient risk of adverse postoperative events. Such a model may allow for triggering of pre-emptive clinical intervention. An output may assimilate a form of clinical dashboard within the electronic health record system, which may be monitored at a centralised location where a trained clinician reviews high-risk cases filtered by the algorithm to further evaluate whether the patient condition warrants an intervention. Together, this workflow has a tremendous potential to improve post-acute phase of care following surgery.

Lessons learned from the initial experience

Through this first group of enrolled patients, we learnt that most of the patients approached were willing to participate and consented to the study. By streamlining the enrolment process, the enrolment time shortened from over 1 hour on the first patient to approximately 10–15 min for the current enrolment. The overall response rate is acceptable, with 77% of the participants completing more than half of the delivered surveys independently without any intervention by researchers. Challenging recovery course, including readmissions may have interfered with patient engagement. While this would have resulted in an under-representation of those with protracted recovery or with complications, our preliminary data show we were able to capture variations in the trajectories of recovery.

To sustain patient engagement through challenging recovery course, we implemented a protocol for an RA to call the patient around 10 days after enrolment to troubleshoot any issues and re-emphasise the importance of their participation. By the protocol, the RA making this call does not act in clinical capacity and does not provide clinical evaluation or advise, which is an important boundary for this call to not act as an intervention to alter recovery course. We believe that once the survey becomes part of clinical workflow with clinicians monitoring and responding to the PROM response, patient response rate would improve further.

We modified the enrolment protocol to reduce the enrolment time, because to some patients, the complexity and prolonged time spent for enrolment discouraged sign-ups. Initial protocol for enrolment required patients to download an app and register. This resulted in a wide range of time spent for enrolment between 15 min and 90 min, with longer enrolment owing to technical challenges. These challenges include patients forgetting the password for the app download, having to reset the password and not having immediate email access to check account confirmation emails. Because our cardiac surgery patient population tended to be older, these technical challenges may have been pronounced. By not including the app download and allowing for the RA to enrol the patient via an online form with their permission, the enrolment time shortened significantly to 10–15 min.

Examining the initial individual data on recovery, there were wide variations in the trajectories of recovery even among only five patients. The variation suggests that the instrument we used was sensitive to capturing such differences. We also noted variations in improvement over time across different domains of recovery, where overall perception of recovery seemed to have a steady improvement pattern, while pain varied between consecutive measurements in some patients.

Limitations

There are several limitations to this study. First, the single-centre tertiary care setting limits the sample size and applicability of the findings to patients cared for in different settings. A multi-centre study following the current study would address this limitation and evaluate whether the findings at our centre are comparable to findings in other centres. Additionally, group-based trajectory modelling will classify patients into distinct trajectories based on similar recovery patterns, and this analytical approach may allow for generalisation of the variations in the trajectories as long as our sample represents the breadth of the possible variation in recovery.

Another limitation is the exclusion of patients who cannot participate for various reasons. The use of digital platform is advantageous in reducing the resource intensity for data collection, but leads to exclusion of patients who do not own mobile devices, which likely affects older

patients disproportionately. As the number of adults using mobile devices is increasing,[24] we believe this will become less of a limitation over time. Initiating this study now despite this limitation is important to establish a platform that may become the standard of postoperative care when the vast majority of patient population own digital devices in a predictably near future. Those who cannot participate due to lack of interest or technological barrier represent an important population that may be distinct in characteristics and risk profiles. While acknowledging the selection bias originating from this inclusion threshold, we believe there is a need to initiate collection of patient-centred outcome measures in the proposed approach, in order to further engage hospitals and programmes for a broader implementation of this approach in the context of extremely limited evidence base. We plan on minimising the non-participation for the lack of interest by intermittent phone check-ins to sustain interests and identify barriers to inform strategies to increase engagement. While recognising that clinical implementation of this protocol would preclude the use of incentives, in following studies, we may consider other forms of incentives to participate, if this population is indeed distinct and large in proportion. Additionally, when the PROM data are integrated into routine clinical care, patient engagement will likely increase substantially because they will be more inspired to share these data if they are used by their clinicians.

Finally, postoperative enrolment and retrospective assessment of preoperative health status, as opposed to preoperative enrolment, may introduce recall bias. We decided on postoperative enrolment, because preoperative enrolment precluded standardised enrolment of patients operated on under non-elective settings. Given the retrospective assessment of baseline health status takes place on the first postoperative survey, we believe the recall bias is minimised owing to the temporal proximity.

CONCLUSION

This study will generate highly granular, longitudinal PROM data to characterise individual trajectories of patient recovery after cardiac surgery. Digital data sharing platforms promise to minimise the patient and researcher burden in administering and completing PROMs, allowing for characterisation of granular progression of patients' state of health over time in the postoperative period. Implementation of such study is complex but feasible, and it will serve as an important platform to facilitate clinical use of PROM data to improve the overall patient recovery.

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Contributors MM, HMK, SD and AG developed the study and research questions. MM and HMK developed analytical strategy with inputs from BJM, GL and YZ. SC, CB and ES guided in refining the enrolment strategy and interpretation of the phone interview responses. LAG provided patients' perspective on the study protocol and interpretation of the preliminary results. All authors developed and approved the final manuscript before submission.

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