



DEPARTMENT OF ANESTHESIOLOGY

JOURNAL CLUB

Thursday November 14, 2019
1800 HOURS

LOCATION:
AquaTerra, Henry Room
1 Johnson Street

PRESENTING ARTICLES:
Dr. Chris Haley and Dr. Sophie Breton

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SUGGESTED GUIDELINES FOR CRITICAL APPRAISAL OF PAPERS
ANESTHESIOLOGY JOURNAL CLUB
QUEEN'S UNIVERSITY
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Two presenters will be assigned to choose and present summaries of their papers. Ideally the two papers will represent similar topics but contrasting research methodologies. The focus remains on critical appraisal of the research and manuscript, more than on the actual contents of the article. Each presenter will then lead an open discussion about the article, based around the guidelines below. The object is to open up the appraisal to wide discussion involving all participants, who will be expected to contribute pending suspension of bar privileges.

GENERAL

1. Title of paper: Does it seem like an important problem? Does it reflect the purpose/results?
2. Authors, institution and country of origin

INTRODUCTION

1. What is the problem being addressed?
2. What is the current state of knowledge of the problem studied?
3. What is the hypothesis being tested?
4. How does testing the hypothesis help solve the stated problem?

METHODOLOGY

1. Study design:
 - a) Clinical trial vs. systematic review/meta-analysis
 - b) Prospective vs. retrospective
 - c) Observational vs. Experimental
 - d) Randomized or not
 - e) Blinded or not
2. Population studied:
 - a) Human, animal, other
 - b) Justification
 - c) Control groups: experimental vs. historical
 - d) Is the sample size/power calculated, and how?
 - e) Is the population similar to your own practice?
 - f) Single vs. multi-centre
3. Is the study ethically sound?
 - a) Clinical equipoise
 - b) Does treatment meet standard of care (esp controls)?
 - c) Appropriate consent and institutional ethics approval
4. Exclusions: what groups are excluded and why?
5. Experimental protocol
 - a) Is it designed to test the hypothesis?

- b) Is it detailed enough to be reproducible?
 - c) Is the methodology validated?
 - d) Are the drugs/equipment used detailed?
 - e) How does the randomization take place?
- 6. What are the primary endpoints?
- 7. Is power sufficient to justify secondary endpoints?
- 8. Is the protocol clinically relevant?
- 9. Data collection and analysis
- 10. Statistical analysis: Is it appropriate? Are results

RESULTS

- 1. Are the groups comparable?
- 2. Were any subjects/data eliminated?
- 3. Analyzed by intent to treat?
- 4. Are adequate details of results provided? - data, graphs, tables

DISCUSSION

- 1. What is the main conclusion of the study?
- 2. Do the results support this conclusion?
- 3. Do the results address the stated purpose/hypothesis of the study?
- 4. How do the authors explain the results obtained?
- 5. Are there any alternative interpretations to the data?
- 6. Are the results clinically as well statistically relevant?
- 7. How do the results compare with those of previous studies?
- 8. What do the results add to the existing literature?
- 9. What are the limitations of the methods or analysis used?
- 10. What are the unanswered questions for future work?

APPLICABILITY OF THE PAPER

- 1. Have you learned something important from reading this paper?
- 2. Will the results of this study alter your clinical practice?
- 3. Was the food and wine up to the high standards expected by self-respecting anesthesiologists?

Differences in Outcomes After Anesthesia-Related Adverse Events in Older and Younger Patients

Christopher W. Root • Yaakov Beilin • Patrick J. McCormick • Christopher J. Curatolo • Daniel Katz • Jaime B. Hyman

ABSTRACT

Because more older adults undergo surgical procedures, it is incumbent on us to learn how to provide them with the safest possible perioperative care. We conducted a retrospective cohort study at a large tertiary care center to determine whether outcomes after anesthesia-related adverse events differed between patients aged 65 years and older versus patients under age 65. One thousand four hundred twenty-four cases were referred to the Performance Improvement committee of the Department of Anesthesiology from the years 2007–2015. After exclusions of cases that were not anesthesia-related, could not be identified, or were duplicates, 747 cases with anesthesia-related adverse events were included in the study. Two hundred eighty-six were aged 65 years and older and 461 were under age 65. Anesthesia-related adverse events occurred more commonly in the postoperative period in older patients relative to younger patients (37.7% vs. 21.9%, $p = .001$), and older patients had a greater incidence of mortality compared with a propensity-matched group of younger patients (adjusted odds ratio 1.87 [1.14–3.12], $p < .05$). We concluded that older patients have a greater likelihood of mortality as a result of suffering an anesthesia-related adverse event and may benefit from increased vigilance in the postoperative period.

Keywords: geriatrics, patient safety, anesthesia

Introduction

As the population ages, perioperative medical providers must understand the complexities of providing care to older patients. Older patients are living longer, undergoing more surgeries,¹⁻³ and often present with multiple comorbidities. Older patients also have anatomical and physiologic changes that differ from the younger population which make the provision of safe anesthetic care more challenging.^{4,5} Indeed, older patients have been shown to suffer postoperative adverse events, including cerebrovascular accident, myocardial infarction, kidney injury, pneumonia,

unplanned intubation, and mortality at greater rates than younger adults.⁶ Furthermore, when complications occur, failure to rescue is more common in older adults, leading to an increased risk of mortality after the complication.⁷⁻⁹ To date, no previous study has reported on adverse events in the perioperative period which are specifically anesthesia-related in older patients.

In a previous study, we characterized anesthesia-related adverse events in patients of all ages including which organ systems were affected, the timing of the event in the perioperative period, the underlying cause of the event and whether it was preventable, and the ultimate outcome of the patient related to the adverse event.¹⁰ We undertook this secondary analysis of the data set to compare anesthesia-related adverse events between patients aged 65 years and older versus those under age 65.

Methods

This secondary analysis of our previous retrospective study⁷ was approved by the institutional review board at the Icahn School of Medicine at Mount Sinai, New York, NY. The requirement for written informed consent was waived.

At our institution, perioperative adverse events are reviewed by the Performance Improvement (PI) committee of the Department of Anesthesiology.

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The PI committee meets monthly in a closed session and consists of approximately 20 board-certified anesthesiologists representing all subspecialties as well as chief residents and the chief nurse anesthetist. In addition to adverse events reviewed because they met departmental criteria for review, for example, respiratory and cardiac arrest or neurologic injury, and those self-reported by anesthesiology personnel, the committee also reviews patient complaints, events referred through the hospital-wide electronic medical error reporting system, all mortalities within 48 hours of anesthetic care, and cases referred by other departmental PI committees.

Cases for review are first assigned to a member of the committee who performs a chart review, interviews the involved providers, and writes a detailed narrative and formal assessment of the adverse outcome. The case is then verbally presented to the PI committee. A detailed description of the case along with the committee's assessment and corrective action plan, if applicable, is recorded in the monthly minutes.

We performed a retrospective review of each anesthetic case presented to the anesthesiology department PI committee from 2007 to 2015. The review panel consisted of four anesthesiologists with subspecialties including pain (CC), obstetrics (YB), and neuroanesthesia (PM). One of the panelists is a former naval nuclear engineering officer with previous experience in critical incident study and root cause analysis (CC), and another panelist is board-certified in clinical informatics (PM).

Two authors were assigned to review each year of cases. The pairings were switched for subsequent years so that all possible reviewer combinations were achieved. Materials available for review included the PI committee report, the anesthetic record (CompuRecord, Philips, Andover, MA), and the institutional electronic health record (Epic Systems Corporation, Verona, WI). Using the Research Electronic Data Capture tool (REDCap; Vanderbilt University, Nashville, TN), data for each case were electronically entered by each reviewer.

Cases were excluded if the patient was unable to be identified, the case was a duplicate, no adverse event occurred, or the event was not anesthesia-related. An example of "no adverse event occurred" is a case referred to the committee because of a patient complaint; however, no complication occurred. The "not anesthesia related" exclusion applied to cases where both reviewers independently agreed that the complication was clearly not because of a decision or action by the anesthesia team, for example, a technical error by the surgeon.

Each study investigator reviewed the case and filled out the reporting template individually using a written taxonomy as guidance, which was jointly developed by all four investigators before starting the study. Investigators determined the underlying cause of the adverse event as adapted from Lagasse et al.¹¹ This process is more fully described in our previous publication.¹⁰ We regarded two underlying causes: "limitation of therapeutic standard" and "limitation of diagnostic standard" as nonmodifiable underlying causes, and therefore, the adverse event was deemed nonpreventable because either the patient and/or the surgical procedure was complex, and despite appropriate care, there was an adverse event. Investigators also classified the type of adverse event for each case using a classification scheme derived from the Anesthesia Quality Institute (AQI) Anesthesia Incident Reporting System (AIRS).¹² Adverse events categories included the following: neurologic, cardiac, respiratory, trauma, hematologic, and medication. Patient outcomes related to the event, including unplanned intensive care unit (ICU) admission, residual injury (defined as not returning to the patient's baseline level of health), all-cause death within 48 hours of the procedure, and death related to the adverse event at time of review, were recorded. Demographic and comorbidity data (in the form of administrative diagnosis codes) were retrieved from the electronic medical record.

Finally, the pair of reviewers assigned to each case met in person to merge their case assessments using the REDCap double data entry tool. The tool provided a work list of cases with disparate reviewer responses, which were reviewed by the two investigators. A verbal agreement was reached on those items to produce a final, merged record. If agreement was unable to be reached, a group consensus was sought by discussion with the other two investigators.

After exclusions, the final data set was divided into two groups for comparison, aged less than 65 years and age 65 years and older.

Statistical Analysis

Data are presented as mean (SD), median (quartile 1–quartile 3), and count (percent). For comparisons between age groups, the chi-squared test was used for categorical variables and the Wilcoxon rank-sum test for continuous variables, with $p < .05$ considered significant. To account for differences in patient populations, propensity-matched scoring was performed on the data set. Patients were matched on the following variables: sex, body mass index, ASA

classification, presence of hypertension, diabetes, congestive heart failure (CHF), arrhythmia, valvular disease, peripheral vascular disease, neurologic disease, renal failure, hepatic failure, cancer, coagulopathy, Charlson comorbidity index, specialty category, and total anesthesia time. These variables were chosen because they have been associated with poor outcomes after perioperative complications or in the case of specialty category because they may represent a similar group of patients or procedures.¹³⁻²⁶ After matching, a total of 210 matched pairs were included for further analysis. Differences between groups in outcomes (unplanned ICU admission, failure to return to baseline health, all-cause mortality within 48 hours of the anesthetic, and mortality related to the adverse event) found in univariate analysis were entered into a multivariable logistic regression analysis to assess for independence. We then performed sensitivity analyses by examining models of interaction terms and assessing different age cutoffs. All calculations were performed using R version 3.3.2 (R Foundation for Statistical Computing, Vienna, Austria). The R package *medicalrisk* version 1.2 was used to determine Charlson comorbidity index values.²⁷

Results

Of 551,394 anesthetics during the years 2007–2015, 144,353 (26.2%) were performed in patients aged 65 years and older and 407,041 (73.8%) occurred in those less than 65 years old. Overall during the study period, 1,424 records were referred to the PI committee for review (0.26%), and after exclusions, 747 were included in the final study; 286 (38.3%) were aged 65 years and older and 461 (61.7%) were younger than 65 years (Figure 1). Older patients were over-represented in the data set, as 26.2% of all anesthetics were performed in older patients but 38.3% of the anesthesia-related events occurred in this group, $p < .00001$.

There were significant differences in the demographics and general state of health between the two patient groups. A higher percentage of patients aged 65 years and older had an American Society of Anesthesiologists' physical status (ASA-PS) score >2 (91.3% vs. 63.3%, $p < .001$). Older patients were also more often inpatient (92.0% vs. 82.6%, $p < .001$) and had hypertension (79.7% vs. 42.7% $p < .001$), diabetes (27.3% vs. 16.7% $p < .001$), CHF (28.0% vs. 14.3%, $p < .001$), and pulmonary disease (28.3% vs. 18.0% $p < .001$). The proportion of cases classified as emergent was similar between groups (17.8% vs.

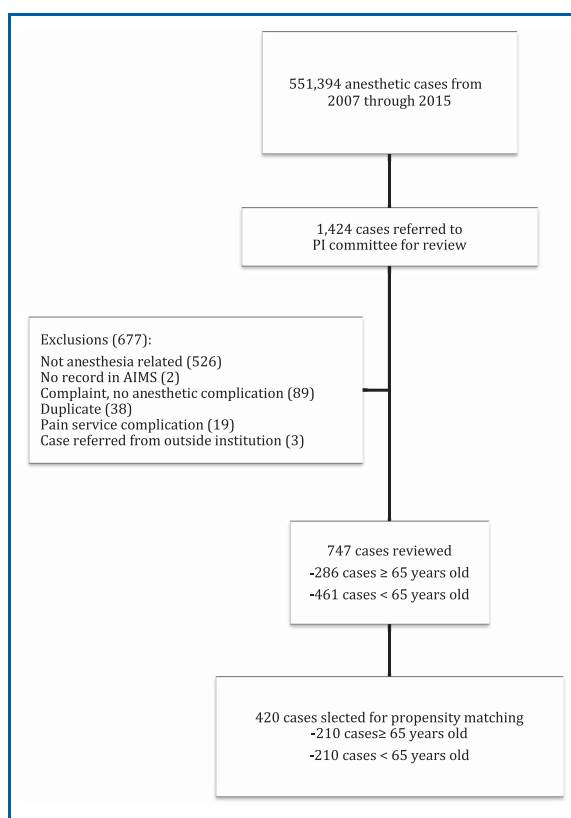


Figure 1. Flow chart of case selection. Most cases excluded were because two reviewers independently agreed that the adverse event was unrelated to anesthetic management. PI = Performance Improvement; AIMS = Anesthesia Information Management System.

18.4%, $p = .83$), (see Table 1, Supplemental Digital Content 1, <http://links.lww.com/JHQ/A90>).

Propensity matching was used in an effort to control for the significant differences in baseline characteristics. The 24 specialty categories were constructed into 5 groups based on the general type of patient characteristics and anesthesia care provided.

There were no obstetric cases in patients older than 65 years in our original data set; thus, these cases were excluded from the propensity matching. There were no significant differences in the underlying characteristics or comorbidities between the two groups in the propensity-matched population, (Table 1).

In the original data set of 747 anesthesia-related adverse events, respiratory events ($n = 245$, 32.8%) were the most commonly reported adverse event category, followed by cardiac ($n = 179$, 24.0%),

Table 1. Characteristics of the Propensity-Matched Population Stratified by Age (n = 420)

	<65	≥65	<i>p</i>
N (%)	210 (100)	210 (100)	
Specialty category group			
Cardiac, thoracic, cardiology (%)	49 (23.3)	57 (27.1)	.432
Dental, ENT, OMFS (%)	15 (7.1)	16 (7.6)	1
GI, pulmonology, psychiatry, IR, radiology, ophthalmology, pain (%)	22 (10.5)	22 (10.5)	1
General/colorectal, gynecology, plastics, urology, transplant, vascular (%)	93 (44.3)	82 (39.0)	.322
Neurosurgery, orthopedics, spine (%)	33 (15.7)	36 (17.1)	.792
OB (%)	0 (0)	0 (0)	1
Female gender (%)	102 (48.6)	92 (43.8)	.378
BMI (median [IQR])	28.95 [23.28–34.10]	26.56 [23.82–31.30]	.161
ASA-PS score (%)			.902
1	5 (2.4)	3 (1.4)	
2	21 (10.0)	22 (10.5)	
3	92 (43.8)	95 (45.2)	
4	81 (38.6)	82 (39.0)	
5	11 (5.2)	8 (3.8)	
Length of anesthesia (mins) (median [IQR])	257.00 [143.25–393.25]	265.00 [175.00–396.25]	.322
Emergency status (%)	44 (21.0)	40 (19.0)	.714
Inpatient	182 (86.7)	189 (90)	.362
Hypertension (%)	148 (70.5)	154 (73.3)	.587
Diabetes (%)	53 (25.2)	59 (28.1)	.581
CHF (%)	51 (24.3)	49 (23.3)	.909
Pulmonary disease (%)	50 (23.8)	53 (25.2)	.821
Arrhythmia (%)	69 (32.9)	73 (34.8)	.757
Valvular disease 1 (%)	30 (14.3)	29 (13.8)	1
Pulmonary circulation disease (%)	18 (8.6)	21 (10.0)	.737
Peripheral vascular disease (%)	22 (10.5)	28 (13.3)	.451
Paralysis (%)	7 (3.3)	7 (3.3)	1
Neurological disorders (%)	24 (11.4)	25 (11.9)	1
Hypothyroid (%)	13 (6.2)	15 (7.1)	.845

Table 1. Characteristics of the Propensity-Matched Population Stratified by Age (n = 420)
(Continued)

	<65	≥65	<i>p</i>
Renal failure (%)	53 (25.2)	48 (22.9)	.648
Liver disease (%)	25 (11.9)	23 (11.0)	.878
Peptic ulcer disease (%)	3 (1.4)	2 (1.0)	1
Cancer (%)	44 (21.0)	46 (21.9)	.905
Rheumatoid arthritis (%)	3 (1.4)	4 (1.9)	1
Psychiatric disease (%)	22 (10.5)	27 (12.9)	.543

ASA-PS = American Society of Anesthesiologists Physical Status Score; BMI = body mass index; CHF = congestive heart failure; ENT = ear, nose and throat surgery; GYN = gynecological surgery; IR = interventional radiology; OB = obstetrics; OMF = oral and maxillofacial surgery.

traumatic injuries (n = 125, 16.7%), neurologic events (n = 110, 14.7%), medication errors (n = 68, 9.1%), and hematologic complications (n = 21, 2.8%).

There were significant differences in the distribution of adverse events between younger and older patients (Figure 2A) ($p < .0001$). Cardiac events represented a larger portion of adverse events in older patients (34.3% vs. 17.6% $p < .0001$) in the unmatched data set. More specifically, cardiac arrest accounted for 23.1% of adverse events in older patients versus 12.6% of adverse events in younger patients, $p < .001$. Within the propensity-matched data set, the distribution of types of adverse events was not significantly different based on age $p = .18$ (Figure 2B). A complete list of adverse events for both age groups is included in Supplemental Digital Content 2 (see Appendix A, <http://links.lww.com/JHQ/A91>).

The percentage of events considered preventable was not different between older or younger patients (40.9% vs. 44.0% $p = .40$). The timing of the adverse events was different between older and younger patients in both the unmatched data set and in the propensity-matched data set ($p = .001$). Events in younger patients occurred more frequently during the preincision period, whereas older patients experienced more adverse events in the postoperative period (Figure 3).

The reviewers classified each event as being attributable to either a system or human cause. Overall, system causes accounted for 73.8% of all adverse events. There was not a significant difference noted in the proportion of events attributed to system causes between older and younger patients (76.9%

vs. 71.8%, $p = .14$) (Table 2). An age-stratified table of adverse events by underlying cause is available in Supplemental Digital Content 3 (see Appendix B, <http://links.lww.com/JHQ/A92>).

Univariate logistic regression results from the unmatched data set can be found in (see Table 2, Supplemental Digital Content 4, <http://links.lww.com/JHQ/A93>). Multivariable logistic regression analysis revealed that age more than 65 years was independently associated with failure to return to baseline after the event, all-cause 48-hour mortality, and overall mortality as a result of the adverse event. Emergency surgery was associated with all-cause death within 48 hours and mortality related to the event. An ASA-PS score >2 was also an independent predictor of all three of these outcomes (see Table 3, Supplemental Digital Content 5, <http://links.lww.com/JHQ/A94>).

In the propensity-matched data set, age more than 65 years remained a significant predictor of mortality related to the adverse event but not failure to return to baseline or all-cause death within 48 hours. Increasing ASA-PS scores above 2 remained predictive of failure to return to baseline, all-cause death within 48 hours, and mortality related to the adverse event. Emergency surgery predicted both all-cause death within 48 hours and mortality related to the adverse event (Table 3).

As part of the sensitivity analysis, the logistic regressions were run using different age cutoffs. Age more than 55 years was independently predictive of overall mortality as a result of an adverse event; age more than 75 was independently predictive of failure to return to baseline, death within 48 hours, and overall mortality as a result of the event (see Table 4,

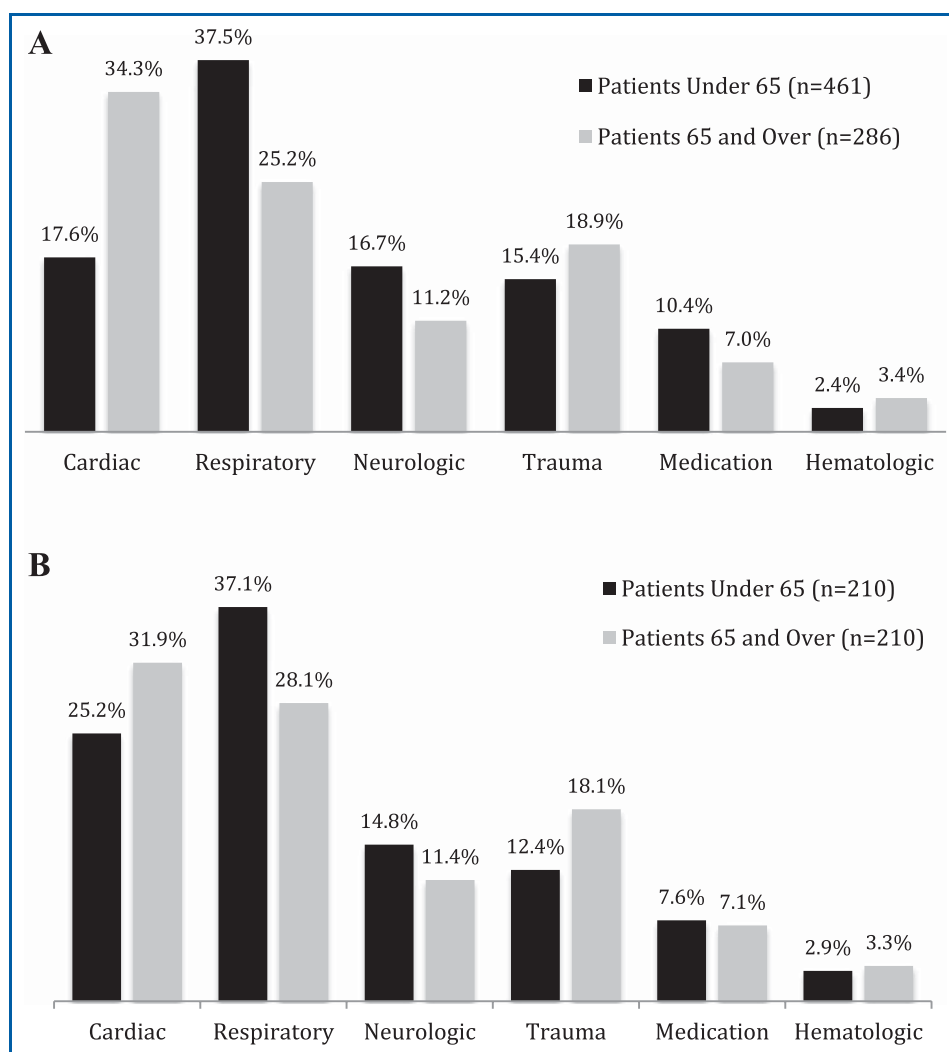


Figure 2. A, Adverse event type by age ($n = 747$). Cardiac events were more common in patients aged 65 years and older and respiratory events were more common in patients less than 65 years old. $p < .001$. B, Adverse event types in the propensity-matched population ($n = 420$) were not significantly different based on age. $p = .18$.

Supplemental Digital Content 6, <http://links.lww.com/JHQ/A95>). When the population is constrained to patients between 55 and 75 years old, or 60–70 years old, age more than 65 years ceases to be predictive of adverse outcomes, which may indicate that the effect is more concentrated at the extremes of the older population (see Table 5, Supplemental Digital Content 7, <http://links.lww.com/JHQ/A96>).

Limitations

This study has several limitations. It is a single institution study, and the distribution of adverse events may be different in other practice settings. Minor adverse events that occurred during the study period but were not significant enough to be

reported to the PI committee would not have been included in the study. It is also possible that significant adverse events occurred over the study period were not reported to the PI committee. The decisions to exclude cases are to some extent subjective. Excluding cases for being “not anesthesia related” has been performed in previous studies of adverse events. Previous studies have used screening by a single anesthesiologist to determine whether a case required further review.^{28–30} Our study design required two anesthesiologists to independently review each case to help strengthen the quality of the data reviewed. Furthermore, our sample was too small to make significant conclusions about specific subtypes of adverse events beyond the six broad adverse event categories discussed here. In addition,

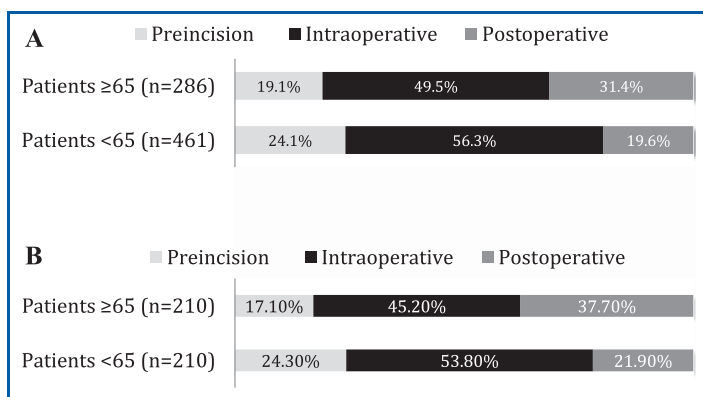


Figure 3. A, Timing of adverse events in unmatched patient population (n = 747). B, Timing of adverse events in propensity-matched population (n = 420). Preincision = induction, intubation, and positioning. Intraoperative = from procedure start to procedure finish. Postoperative = emergence, extubation, transport, postanesthesia care unit, intensive care unit/inpatient floor/home. Patients less than 65 years old had more preincision adverse events and patients older than 65 years had more postoperative adverse events. $p = .001$.

any comparison of populations is vulnerable to omitted variable bias. Although our propensity models attempt to control for nonage differences within the groups, we are only able to control for a limited number of factors; thus, it is possible that omitted variables (e.g., measures of frailty, baseline cognitive function, laboratory results, and other unmeasured characteristics) impacted our observed results.

Discussion

The main findings of this study were that as compared to patients less than 65 years old, those aged 65 years and older suffered anesthesia-related adverse events more commonly in the postoperative period and were more likely to die as a result of an adverse event. In addition, approximately 40% of adverse events were preventable regardless of age.

Previous large database studies have shown that age independently predicts a composite of major adverse outcomes, length of stay, and mortality in the perioperative period.^{3,7,25,31-34} One of the largest studies, a retrospective cohort study using the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database from 2005 to 2008 included 165,600 patients

and found that within the first 30 days after non-emergency general surgery, older adults had higher rates of surgical site infections, venous thromboembolism, cerebrovascular accident, myocardial infarction, kidney injury, urinary tract infection, pneumonia, prolonged mechanical ventilation, unplanned intubation, and return to the operating room.⁶ Furthermore, once a complication occurred, older patients were significantly less likely to survive the event (i.e., failure to rescue) relative to younger patients, especially in the cohort more than 80 years old. Although advances in surgical techniques and systems improvements have led to decreases in mortality for patients of all ages, older adults who suffer a postoperative complication have a much higher risk of mortality than younger patients across studies, and failure to rescue has been identified as a key driver of the wide variability in mortality for older adults who suffer a complication across different institutions.^{8,9,33,35,36} This makes anticipating, preventing, and, importantly, responding to complications particularly important in older adults.

Compared with previous studies, this study is unique, in that we focused specifically on anesthesia-related adverse events. We found that among patients who suffered anesthesia-related adverse events, older patients had a decreased

Table 2. Events by Primary Cause Stratified by Age

	Total (n = 747)	Age <65 (n = 461)	Age ≥65 (n = 286)	p
Primary cause				.14
System	551 (73.8%)	331 (71.8%)	220 (76.9%)	
Human	196 (26.2%)	130 (28.2%)	66 (23.1%)	

Table 3. Adjusted Odds Ratio for Outcomes Through Multivariable Logistic Regression on a Propensity-Matched Subgroup

Patient characteristic (n = 420)	Return to baseline (n = 245)			Death within 48 hours (n = 115)			Overall mortality as a result of adverse event (n = 76)		
	AOR	95% CI	p	AOR	95% CI	p	AOR	95% CI	p
Age ≥65	0.73	0.48–1.11	0.143	1.76	1.00–3.16	0.054	1.87	1.14–3.12	0.014
ASA-PS Score 3	0.40	0.15–0.91	0.040	4.29	0.80–79.62	0.169	7.54	1.49–137.79	0.053
ASA-PS Score 4	0.20	0.07–0.48	0.001	18.13	3.50–334.14	0.006	29.82	5.88–545.78	0.001
ASA-PS Score 5	0.05	0.01–0.23	<0.001	44.17	5.99–939.01	0.001	131.40	16.28–3,019.85	<0.001
Emergency	0.62	0.35–1.11	0.108	2.96	1.53–5.71	0.001	2.48	1.34–4.61	0.004
Hypertension	0.98	0.59–1.63	0.934	0.61	0.31–1.20	0.148	0.66	0.36–1.22	0.179
Diabetes	0.82	0.50–1.34	0.431	1.27	0.64–2.49	0.498	1.38	0.77–2.46	0.276
Congestive Heart Failure	0.95	0.56–1.62	0.847	0.88	0.43–1.74	0.715	1.10	0.60–2.00	0.758
Pulm disease	1.09	0.67–1.78	0.741	0.38	0.17–0.78	0.012	0.63	0.34–1.14	0.132

AOR = adjusted odds ratio; ASA-PS = American Society of Anesthesiologists Physical Status Score, for ASA-PS score, a score of 2 was used as the reference; Pulm = pulmonary.

likelihood of returning to their baseline level of health, and after propensity matching for pre-existing comorbidities and type of surgery, age remained an independent predictor of mortality as a result of the adverse event. Older adults have a lower functional reserve in all organ systems to varying degrees. This limited physiologic reserve may not be apparent at baseline but may become evident during acute processes such as illness or surgery and may in part explain the greater incidence of mortality as a result of an anesthesia-related adverse event in our study, as well as failure to rescue after perioperative complications in general.

The older patients in our unmatched data set suffered more cardiac adverse events, likely explained by the burden of pre-existing comorbidities in the older population as the propensity-matched sample did not show a difference between groups in adverse event type. Cardiovascular adverse events were found to be the most common perioperative adverse event in older patients by a prior group of investigators.³⁷ In another study, increasing age was independently associated with an increased risk of major adverse cardiovascular events (MACE) after noncardiac surgery.³⁸ Older patients have also been shown to have a higher risk of cardiac arrest compared with younger patients,³³ and older age is associated with lower survival after perioperative

cardiac arrest.³⁹ In general, greater than 60% of in-hospital cardiac arrests may be avoidable, especially those that happen in noncritical care areas as it has been demonstrated that survival after cardiac arrest is improved if the arrest occurs in critical care areas.⁴⁰ Given the greater number of cardiac arrests in older patients relative to other adverse events and that they occurred in the postoperative period, careful consideration should be given to the postoperative disposition of older patients with multiple comorbidities and may warrant consideration for ICU admission relative to younger patients.

We expected that anesthesia-related adverse events would not be preventable in older patients, given their higher burden of co-morbidities and decreased functional reserve. Approximately 40% of anesthesia-related adverse events in this data set were determined to be preventable, and this did not differ between older versus younger patients, suggesting that there is room for improvement in patient safety for all age groups.

Conclusions

Our data suggest that there are significant differences in the timing and outcomes of anesthesia-related adverse events between older and younger patients, most notably that older patients have

a higher likelihood of mortality as a result of suffering an anesthesia-related adverse event. Approximately 40% of anesthesia-related adverse events were preventable in both older and younger patients, and future efforts should be made to reduce the incidence of these preventable events.

Implications

Older patients may benefit from a longer period of heightened vigilance in the PACU and postoperative period, as this is the time period when they were most susceptible to anesthesia-related adverse events in our study. Further studies using larger samples from multiple centers are needed to more precisely determine the significance of the differences seen here.

Author's Biographies

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Patient activation intervention to facilitate participation in recovery after total knee replacement (MIME): a cluster randomised cross-over trial

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ABSTRACT

Background Patient participation in care is a fundamental element of safe and high-quality healthcare with the potential to enhance health outcomes and improve patient satisfaction.

Objectives To test the efficacy of a clinician-facilitated, bedside multimedia (*MyStay*) intervention designed to support patient participation in their recovery after total knee replacement surgery. The primary outcome was patients' reported worst pain intensity on postoperative day 3. Secondary outcomes were patient activation, length of hospital stay, knee function and satisfaction with care.

Methods Unmasked, cluster randomised, four-period cross-over trial with a simultaneous process evaluation within a large private, not-for-profit, metropolitan teaching hospital. Statistical analyses used linear mixed models with random effects for wards, cohorts within wards and patients within cohorts and fixed effects for treatment and period.

Results 241 patients were recruited between March 2014 and June 2015. Patients were admitted to intervention (104) or control (137) clusters. Intervention group patients reported significantly lower mean pain intensity scores on postoperative day 3 (6.1 vs 7.1, 95% CI –1.94 to –0.08, $p=0.04$). The percentages of patients who reported severe pain (score ≥ 7) were 43.7% and 64.2% in the intervention and control groups, respectively (χ^2 9.89, $p=0.002$; generalised linear mixed model Wald test, $p=0.05$). Intervention group patients on average stayed in hospital one less day (5.3 vs 6.3, 95% CI 0.05 to 1.94, $p=0.04$), reported higher activation (45.1% vs 27.1% at level 4 activation) ($p=0.04$) and higher overall satisfaction with care (9.3 vs 8.6, 95% CI 1.09 to 0.219, $p=0.01$), and were more likely to refer family or friends to the health service (9.3 vs 8.7, 95% CI 1.07 to 0.13, $p=0.02$).

Conclusion The clinician-facilitated, *MyStay* bedside multimedia intervention enhanced patients' activation and participation in their care after surgery; pain intensity and length of stay in hospital were reduced and patients were more satisfied with their care.

Trial registration ACTRN12614000340639 (<http://www.anzctr.org.au/default.aspx>).

INTRODUCTION

Patient participation is recognised worldwide as a key element of quality healthcare.^{1–3} It is associated with positive outcomes for patients with chronic illness,^{4–6} but benefits of patient participation in acute care contexts remain less well described. In high acuity environments, barriers to participation include the brevity of interactions⁷ with multiple clinicians,^{8–9} patients' symptom burden,^{9–11} acuity,^{9–11} perceived knowledge related to their condition,^{8–12–13} level of confidence^{14–16} and preference for participation.^{17–19} Yet overcoming these barriers will likely enhance recovery and patient experience overall.^{14–20}

The early postoperative period after total knee replacement surgery (TKR) involves a complex balance between recovery, rehabilitation and prevention of complications. TKR is performed to treat end-stage arthritis when other treatment methods have not improved patient symptoms.²¹ Achieving maximum benefit from this surgery is dependent on correct insertion and fixation of the prosthesis, restoration of alignment of the knee²² and early mobilisation of the knee joint to maximise range of movement.^{23–24} Although a relatively common and successful procedure, TKR is considered one of the most painful,²⁵ particularly in the early postoperative period.²⁶ Patient participation in pain management, mobilisation and exercises may enhance recovery and prevent complications; however, activating patients to participate and work with the multidisciplinary team in order to benefit

from the healthcare available to them^{16 27} is complex in acute environments. Simply equipping patients with information about ideal recovery without structured facilitation by clinicians is not sufficient.²⁸ Innovative strategies are needed to assist patients to participate effectively in their care to the extent that is possible and preferred. Multimedia technology offers a potential platform for facilitating patient–clinician interactions because of its low burden, continuous availability and ease of use. There is evidence that multimedia plays an important role in preoperative delivery of information for patients undergoing surgery,^{29–31} but not for their postoperative recovery.

The study aimed to test whether the *MyStay* intervention, a clinician-facilitated multimedia programme designed to inform and assist patients to participate daily in their acute postoperative recovery, improved their recovery in terms of reduced pain intensity, reduced length of hospital stay, improved activation and function, and satisfaction with care received.

METHODS

Trial design and participants

The Multimedia Intervention for Managing patient Experience (MIME) study was an unmasked, cluster randomised, four-period cross-over trial and simultaneous process evaluation conducted in three acute, inpatient orthopaedic wards of a large private, not-for-profit, metropolitan teaching hospital in Melbourne, Australia. Wards rather than patients were randomised to minimise ‘contamination’ through any exchange of information between patients. Because the intervention was clinician-facilitated and delivered on portable devices, blinding was not feasible. The duration of each period ranged from 12 to 16 weeks and was determined by the number of participants required in each cohort. Patient-level data were collected to measure outcomes (figure 1). For pragmatic reasons, namely to minimise the resources required to coordinate the study simultaneously over several sites, a cluster randomised cross-over trial, with ‘washout’ intervals between the periods and cohorts, was favoured in contrast to a cluster randomised trial run simultaneously at several sites or a stepped-wedge design. The cross-over design also allowed for adjustment, if required, for any trend in pain management over the life of the trial. The full trial protocol, including sample size calculation, has been published previously.³²

Patients were included if they were adults (aged >18 years) and had an elective admission for primary, unilateral, TKR surgery and excluded if they were cognitively impaired or lacked proficiency in English language such that it would interfere with informed consent or ability to complete questionnaires. Most patients (79.6%) attended a standardised preoperative education session at the hospital 1 to 2 weeks prior to surgery and received information on how a TKR was

performed, the possible risks and what to expect in the postoperative period.

Primary outcome

The primary outcome was patients’ reported worst (dynamic) pain intensity score measured using the 11-point Numerical Rating Scale³³ (NRS) on day 3 after surgery (where day 0 refers to the day of surgery). Patients were asked to choose a whole number between 0 and 10 that best described their worst pain in the previous 24 hours where 0 equated to ‘no pain’ and 10 equated to ‘worst possible pain’. With two wards and 30 patients in each period within a ward, the trial was powered³² to detect a difference of 1.65 or more in mean pain intensity scores (a third ward was included to retain all consented patients).

A multimodal analgesic regime that included paracetamol, non-steroidal anti-inflammatory drugs (NSAIDs), long-acting opioids and short-acting opioids (for breakthrough pain) was recommended for all patients.

Secondary outcomes

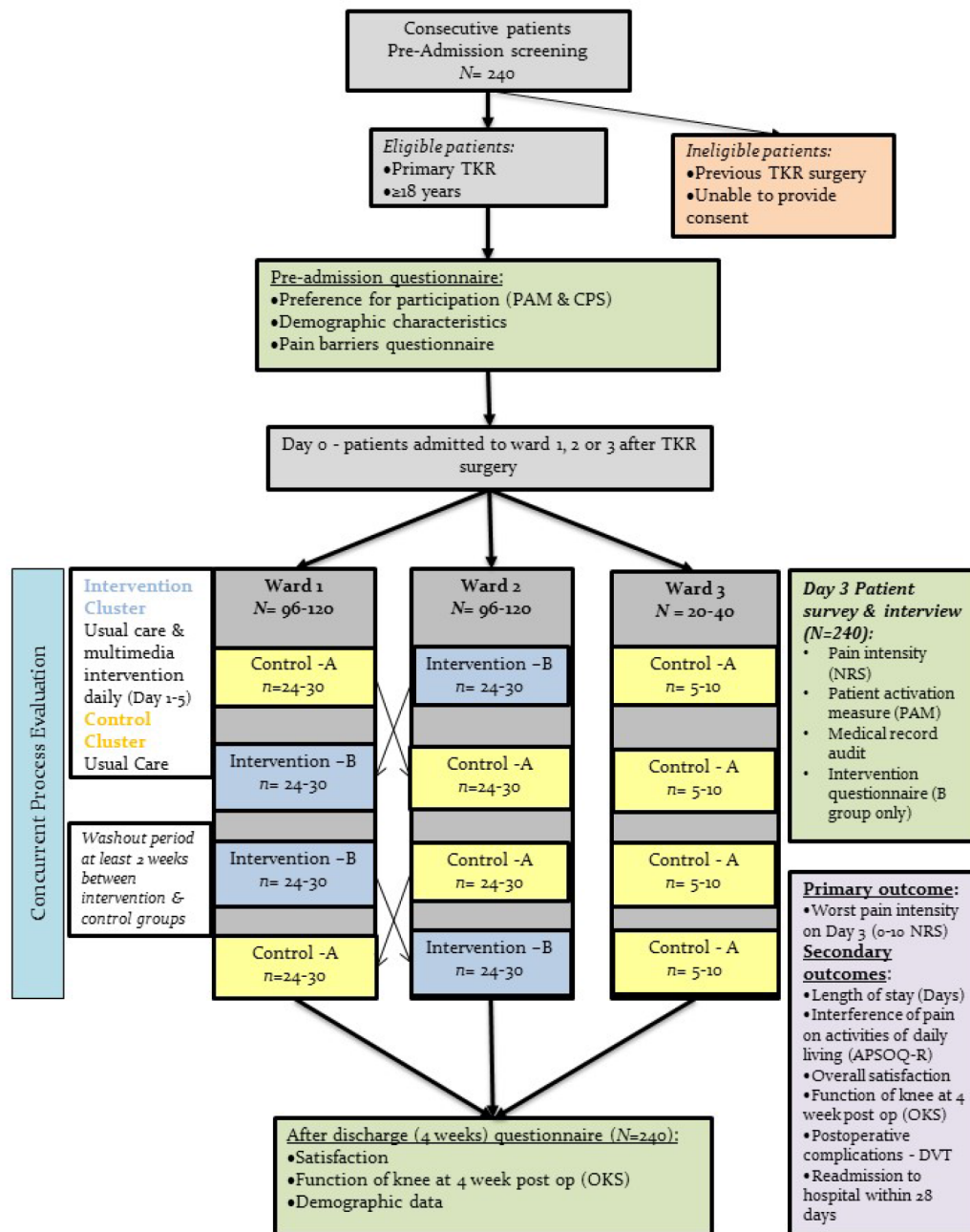
Secondary outcomes were interference of pain on activities of daily living measured by items in the American Pain Society Patient Outcome Questionnaire—Revised (APSOQ-R)³⁴ on day 3, length of hospital stay (days), function and pain following TKR surgery measured using the Oxford Knee Score (OKS)^{35 36} 4 weeks after discharge from acute care, overall satisfaction and NET promoter score³⁷ measured 4 weeks after discharge from acute care, incidence of deep vein thrombosis (DVT) within 28 days and incidence of readmission to study hospital within 28 days.

Concurrent process evaluation

Process evaluation was used to assess the conduct of the trial and explore whether the intervention had the intended effect of providing patients with the capability and opportunity to participate in care related to their goals of recovery. The overall objectives of the process evaluation were to determine if there were any differences in patient activation (Patient Activation Measure,³⁸ PAM) between intervention and control group patients and, whether patient outcomes related to pain intensity may have been attributed to differences in available (prescribed) and/or administered analgesics between groups.

Randomisation

Two wards (clusters) were randomly assigned (by the trial statistician) to a sequence of control (A) and intervention (B) periods prior to recruitment of patients and commencement of the trial. A third ward, used as an ‘overflow ward’ for consented patients who could not be accommodated in the first two wards, received the control condition in each period. At the time of patient recruitment, it was not known to which cluster



*Legend

A – Intervention cluster

B – Control cluster

TKR – Total Knee Replacement

Figure 1 Study design. APSOQ-R, American Pain Society Patient Outcome Questionnaire—Revised; CPS, Control Preference Scale; DVT, deep vein thrombosis; NRS, Numerical Rating Scale; OKS, Oxford Knee Score.

or period individual patients would be allocated. Allocation of patients to clusters occurred via usual hospital processes of ward allocation post-surgery and was largely dependent on bed availability at the time of surgery. Patient allocation to wards is undertaken centrally by a discrete hospital service and was in no

way related to this research project or any persons involved or aware of this research.

Multimedia intervention

The bedside multimedia intervention known as ‘MyStay Total Knee Replacement’ (referred to as

MyStay) was developed through consultation with patients, surgeons, physiotherapists and nurses and review of best available evidence and existing clinical pathways (detailed description of *MyStay* development—online supplementary material 1). *MyStay* was presented in a chapter-based format that combined text, sound, graphics and animation and packaged for iPad presentation. It was designed to be both clinician-facilitated and patient self-directed, that is, to be facilitated by clinicians during patient–clinician interactions but also used independently by patients as a stand-alone programme. *MyStay* had two interacting components: (1) information tailored to each day of recovery to enhance patients' understanding of the goals of recovery and their role in their own recovery, and (2) opportunity for patients to achieve their recovery goals through clinician facilitation.

It was expected that *MyStay* would facilitate interactions between patients and clinicians about daily goals and plans of care for each day of recovery and provide an opening for patients to discuss their pain management. Nurses in particular were asked to incorporate the intervention at the beginning-of-shift patient assessments by assisting their patients to navigate through the programme, clarify any uncertainties and plan their management together. Physiotherapists were asked to incorporate the exercise animations into physiotherapy sessions. Application of *MyStay* commenced on day 1 after TKR surgery.

Comparator

During control periods, throughout and following a wash-out period of 2 weeks, iPads containing *MyStay* were removed and patients received usual care based on the hospital standard care pathway (online supplementary material 2).

Data collection

Data were collected at three time points: pre-admission, day 3 postoperatively and 4 weeks following discharge from acute care (table 1).

On day 3, all patients (intervention and control) completed a self-reported questionnaire and participated in a semistructured interview. Concurrent medication chart and medical record audits elicited the type and quantity of analgesics prescribed and administered in the previous 24 hours corresponding to the primary outcome measure of worst (dynamic) pain intensity.

Analgesics were prescribed either as fixed or *pro re nata* (PRN). Fixed analgesics were administered at set intervals and were not modifiable unless there was a contraindication to their administration; PRN analgesics were administered in response to 'breakthrough' pain (ie, pain that breaks through a fixed analgesic regimen) or in preparation for activities that may exacerbate pain such as physiotherapy or mobilisation.

According to the existing clinical care pathway in all wards, patients were deemed 'eligible for discharge'

Table 1 Measurements and tools used according to data collection periods

Data collection period	Outcome	Measurement
Pre-admission	<ul style="list-style-type: none"> ▶ Activation ▶ Baseline characteristics ▶ Patient perceived barriers to management of pain 	<ul style="list-style-type: none"> ▶ Patient Activation Measure (PAM)³⁸ ▶ Age, sex, cultural background, employment status ▶ Pain Barriers Questionnaire⁴⁰
Day 3 after surgery	<ul style="list-style-type: none"> ▶ Pain intensity ▶ Pain quality ▶ Pain treatment—analgesic management ▶ Activation 	<ul style="list-style-type: none"> ▶ Numerical Rating Scale 0–10 where 0 is no pain and 3 is worse possible pain³³ ▶ American Pain Society Outcome Questionnaire—Revised version³⁴ ▶ Medical record audit of fixed and PRN analgesics prescribed and administered in 24 hours prior to pain intensity measurement ▶ PAM³⁸
4 weeks after discharge	<ul style="list-style-type: none"> ▶ Activation ▶ Pain and function of knee after surgery ▶ Overall satisfaction with care ▶ Postoperative complications 	<ul style="list-style-type: none"> ▶ PAM³⁸ ▶ Oxford Knee Score Questionnaire⁵⁵ ▶ Global satisfaction questions ▶ Net Promoter Score³⁷ ▶ Incidence of DVT ▶ Readmission to study hospital

DVT, deep vein thrombosis; PRN, *pro re nata*.

from acute care when assessed as medically stable, tolerating diet and fluids, walking independently, could safely ascend and descend stairs with the use of a walking aid, demonstrated confidence in attending home exercise programmes and were comfortable with a pain medication regime.

Follow-up questionnaires were administered 4 weeks after discharge via mail.

Statistical analyses

Quantitative data were analysed using GenStat (V.17) and analyses were independently validated using SPSS V.23. Statistical significance was claimed at p value <0.05 . Descriptive statistics were used to characterise the study population and any differences between treatment groups and environmental characteristics. For the primary endpoint of pain intensity, a linear mixed model analysis, using the restricted maximum likelihood (REML) method,³⁹ was used to calculate the F-test to enable comparison of the means of the groups (intervention vs usual care). The model included random effects for wards, cohorts within wards and patients within cohorts, and fixed effects for period and treatment (control vs intervention). If the period effect was not significant, it was deleted from the mixed model. Other outcome measures such as length of stay (LOS), pain and function following TKR, overall satisfaction, NET promoter,

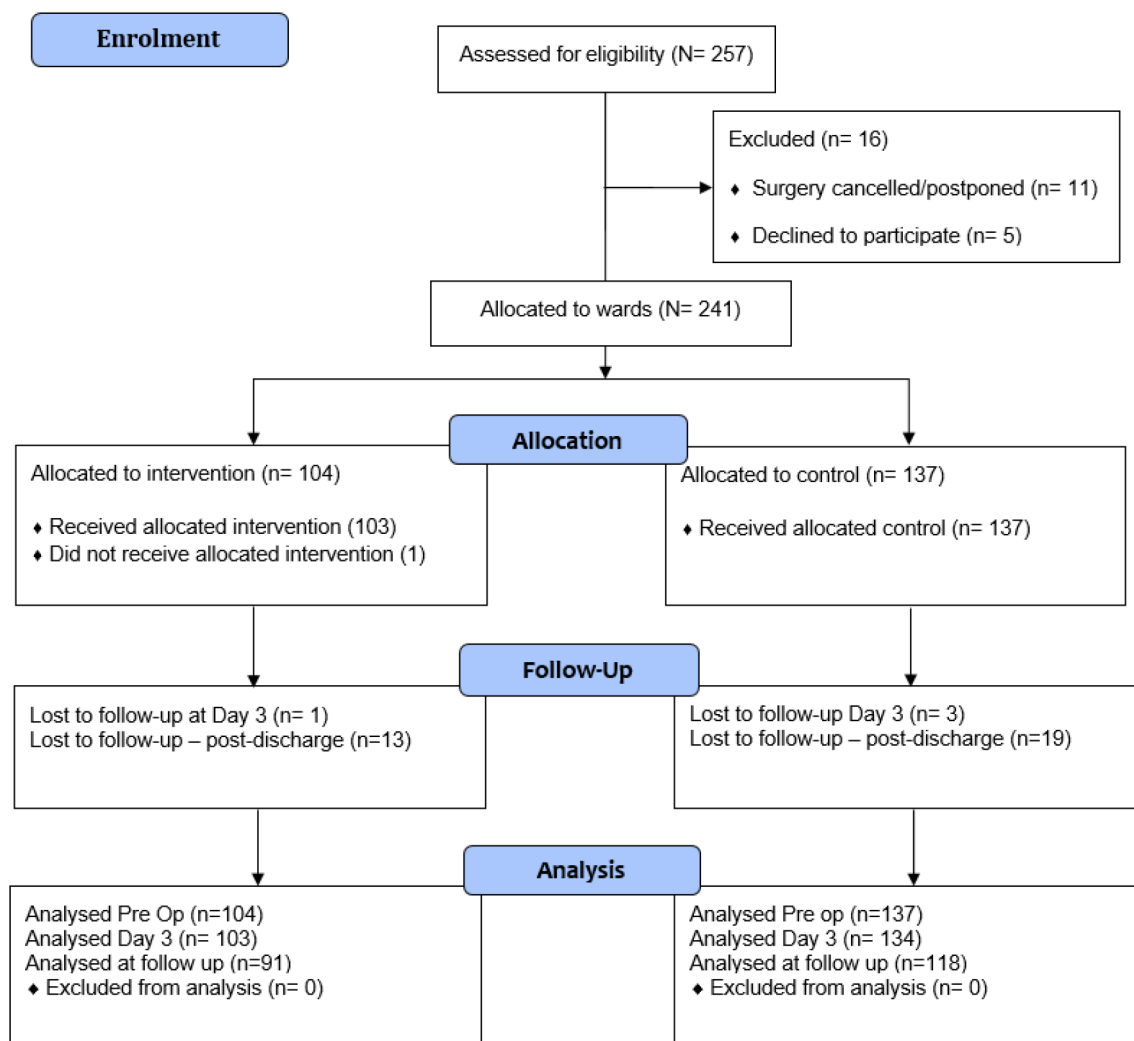


Figure 2 Trial profile.

patient activation, incidence of DVTs and readmission to study hospital were compared between the groups and analyses used a linear mixed model approach and analogous methods developed for binary and categorical data. Analysis was according to intention to treat.

RESULTS

Patient recruitment

Between 12 March 2014 and 10 June 2015, of the 257 eligible patients, 241 were recruited (figure 2) either via the hospital pre-admission clinic (79.6%) or via mail-out invitations (20.4%). There was no significant difference in allocation to intervention or control cohorts for patients recruited via either method.

Recruitment ended when the number of participants required for statistical power was reached. Follow-up data collection was completed in September 2015. Data validation and cleaning was conducted by the trial statistician, blinded to groups.

Loss to follow-up

Figure 2 outlines the flow of patients through the trial. One patient, allocated to an intervention period, did not receive the intervention because of a cerebrovascular accident in the early postoperative period. After discharge, 86.7% patients returned follow-up questionnaires.

Baseline data

The baseline characteristics of patients are presented in table 2. The mean age of participants was 65.3 (SD 9.8) years in the intervention group and 67.4 (SD 8.7) years in the control group ($p=0.20$). There were slightly more women (55.2%) than men (44.8%) in the sample overall, and the proportion of men was lower in the intervention group (38.5%) than the control group (49.6%), but this difference was not significant ($p=0.09$). Key demographic characteristics were balanced between study periods.

Baseline assessments

The Pain Barriers Questionnaire (BQ)⁴⁰ and PAM⁴¹ were completed prior to admission by all patients.

Table 2 Baseline characteristics of the intention-to-treat population

Characteristics	Intervention group (n=104)	Control group (n=137)
	Mean (SD)	Mean (SD)
Age (years)	65.25 (9.77)	67.42 (8.7)
Sex	n (%)	n (%)
Male	40 (38.5%)	68 (49.6%)
Female	64 (61.5%)	69 (50.4%)
Living arrangements		
Living communally	88 (84.6%)	109 (79.6%)
Living alone	16 (15.4%)	28 (20.4%)
Marital status		
Partnered	84 (80.8%)	106 (77.4%)
Not partnered	10 (9.6%)	18 (11.6%)
Widowed	10 (9.6%)	13 (9.5%)
Country of birth		
Australia	76 (73.1%)	101 (73.7%)
UK	11 (10.6%)	10 (7.3%)
Other	8 (7.7%)	11 (8.0%)
Europe	6 (5.8%)	10 (7.3%)
Asia	2 (1.9%)	3 (2.2%)
New Zealand	1 (1.0%)	2 (1.5%)
Language spoken at home (primary)		
English	102 (98.0%)	130 (96.3%)
Italian	1 (1.0%)	2 (1.5%)
Mandarin	0 (0%)	1 (0.7%)
Greek	0 (0%)	1 (0.7%)
Other	1 (1.0%)	3 (2.2%)
Employment status pre-admission		
Retired	52 (50.0%)	76 (55.5%)
Full time	24 (23.1%)	28 (20.4%)
Part time/casual	16 (15.4%)	25 (18.2%)
Unemployed	7 (6.7%)	3 (2.2%)
Other	5 (4.8%)	5 (3.6%)
Recruitment method		
Pre-admission clinic	79 (76%)	113 (82.5%)
Mail-out	25 (24%)	24 (17.5%)

There were no significant between-group differences in the characteristics at baseline. Age was compared using the t-test; other variables compared using the χ^2 test of association.

There were no significant differences in the mean scores for the BQ between groups (intervention group $M=16.1$ vs control group $M=15.6$, $t=0.71$, $p=0.48$). Pre-admission, patients in both groups were found to have a high level of activation (levels 3 and 4) according to the PAM, indicating an understanding of their role in maintaining their health and perceived capability to fulfil that role (intervention group 79% vs control group 74%, $p=0.09$).

Primary outcome

The mean worst pain scores, measured on day 3 using the NRS, were 6.05 (SEM 0.33) (intervention group) and 7.05 (SEM 0.28) (control group) (mean difference

(I-C) = -1.01 , 95% CI -1.94 to -0.08 , $p=0.04$). The period effect was not significant ($p=0.61$) and the estimated components of variance were 0.05, 0.14 and 5.56 for wards, cohorts within wards and patients within cohorts, respectively. The percentages of patients with severe pain (score ≥ 7) were 43.7% intervention group versus 64.2% control group ($p=0.002$; generalised linear mixed model Wald test, $p=0.049$). In an unplanned, supplementary analysis that excluded all 41 patients in the overflow ward, the mean worst pain scores were 6.03 (SEM 0.38) (intervention group) and 6.96 (SEM 0.39) (control group) (mean difference 95% CI -2.13 to 0.27 , $p=0.10$).

In an additional unplanned analysis adjusted for administered PRN oxycodone (Endone), inclusion of the oxycodone covariate in the REML analysis was almost statistically significant ($p=0.05$) and a 1 mg increase in dose was associated with a 0.03 increase in day-3 reported pain (NRS). The difference in the adjusted means of the treatment arms remained significant: mean difference (95% CI -2.06 to -0.25 , $p=0.02$). There was no evidence of an interaction between the oxycodone covariate and the treatment ($p=0.41$).

Secondary outcomes

Secondary outcome analyses (APSOQ-R) are presented in online supplementary material 3. Patients in the intervention group perceived that they had received more pain relief in the previous 24 hours ($M=7.67$ vs $M=7.07$, 95% CI -0.003 to 1.194 , $p=0.05$). Significantly more patients in the intervention group than the control group reported using deep breathing as a method to relieve pain (82.2% vs 68%, $\chi^2=5.53$, $p=0.02$).

There was a significant reduction in LOS for the intervention group; intervention group 5.29 days vs control group 6.29 days (95% CI -0.05 to -1.94 , $p=0.04$). One patient in the intervention group was discharged prior to day 3; this patient was sent to in-hospital rehabilitation on day 2 following surgery. None of the control group patients were discharged from acute care prior to day 3.

There was no difference between groups in terms of those discharged directly home compared with a rehabilitation facility. Most patients (86.3%) were discharged to in-patient rehabilitation. In addition, there was no difference between patients discharged home versus rehabilitation in terms of acute care length of stay.

Patient activation

There was no significant difference in activation between groups when measured at baseline ($\chi^2=6.41$, $p=0.09$). On day 3, a significantly higher proportion of patients in the intervention group reported level 4 activation (45.1% vs 27.1%, $\chi^2=8.47$, $p=0.04$). The number of control group patients with activation

Table 3 Prescribed fixed and PRN analgesics by group

Analgesic (fixed)	Prescribed		P value
	Control	Intervention	
	n (%)*	n (%)	
NSAIDs			
Ibuprofen	18 (13.1%)	15 (14.4%)	0.77
Celecoxib	19 (13.9%)	16 (15.4%)	0.74
Naproxen	8 (5.8%)	12 (11.5%)	0.11
Meloxicam	32 (23.4%)	27 (26.0%)	0.64
Paracetamol	97 (70.8%)	84 (80.8%)	0.08
Pregabalin	72 (52.6%)	64 (61.5%)	0.16
Oxycodone SR	38 (27.7%)	31 (29.8%)	0.73
Oxycodone– naloxone	66 (48.2%)	37 (35.6%)	0.05
Analgesic (PRN)			
Morphine	62 (45.3%)	48 (46.2%)	0.89
Oxycodone	131 (95.6%)	101 (97.1%)	0.54
Tramadol	62 (45.3%)	35 (33.7%)	0.07

*Number of prescriptions in each group. Percentages are across the groups within an analgesic.

NSAID, non-steroidal anti-inflammatory drug; PRN, *pro re nata*; SR, sustained release.

scores at level 3 or 4 reduced from 74% at baseline to 53% on day 3. Activation in the intervention group patients also declined but not to the same degree; from 79% patients at level 3 or 4 at baseline to 64% on day 3.

Four weeks after discharge from acute care, patients' activation levels returned to those at pre-admission. For the intervention group, 82% indicated level 3 or 4 activation versus 74% control group patients on follow-up. There was no significant difference between groups in patient activation measured at follow-up ($p=0.56$).

Analgesic management

In relation to processes of care, the prescription and administration of both fixed and PRN analgesics for the 24 hours preceding the day 3 pain score were extracted from all patients' charts. There was no significant difference between groups in terms of prescribed regular and PRN analgesics. Tables 3 and 4 outline prescribed and administered fixed and PRN analgesics by treatment group, respectively. There were no differences in prescriptions for paracetamol, NSAIDs, adjuvant medicines or opioids between groups. Overall, 5.8% of patients indicated an allergy to NSAIDs and were excluded from these analyses.

The most commonly prescribed and administered PRN strong opioid was oxycodone (Endone) with most patients (96.3%) receiving at least one dose during the 24-hour audit period (table 4). Endone was administered as an oral tablet and the total administered dose over 24 hours ranged from 2.5 to 30 mg. There was a difference between treatment groups in the mean

Table 4 Administered fixed and PRN analgesics by group

Analgesic (fixed)	Administered (mg)		
	Control	Intervention	P value
	M (SD)*	M (SD)	
NSAIDs			
Ibuprofen	966.7 (330.8)	1040.0 (364.1)	0.55
Celecoxib	173.7 (56.2)	206.2 (85.4)	0.19
Naproxen	718.7 (338.2)	526.5 (400.6)	0.40
Meloxicam	13.1 (3.7)	11.0 (6.0)	0.10
Paracetamol	3236.1 (933.4)	3250.0 (1008.6)	0.92
Pregabalin	158.3 (82.8)	162.1 (58.1)	0.76
Oxycodone SR	22.4 (13.6)	25.8 (14.5)	0.32
Oxycodone– naloxone	19.9 (11.0)	20.5 (7.8)	0.77
Analgesic (PRN)			
Morphine	1.49 (4.1)	1.25 (3.1)	0.74
Oxycodone	10.8 (12.0)	16.1 (12.9)	<0.001
Tramadol	64.7 (97.3)	61.2 (99.67)	0.86

*Zero doses (prescribed but not administered) are excluded from calculation of the mean in milligrams (M) and SD.

NSAID, non-steroidal anti-inflammatory drug; PRN, *pro re nata*; SR, sustained release.

daily amount (mg) of oxycodone administered PRN (intervention group $M=16.1$ vs control group 10.8 , $t=3.23$, $p=0.001$) (table 4). While the interaction between treatment groups and subgroups of patients categorised by pain score (0–3, 4–6 and 7–10) was not significant ($p=0.29$), there was a trend ($p=0.002$) for oxycodone administered PRN to increase across the pain groups and a significant difference between the treatments was noticed in the highest (7–10) pain group: intervention ($M=21.2$, $SD=13.5$ mg) and control ($M=11.9$, $SD=12.9$ mg) groups ($p=0.004$).

Patient follow-up

Intervention group patients had a mean OKS of 19.9 and control group patients 21.3 four weeks post-surgery; this difference was not significant (95% CI -5.78 to 2.80 , $p=0.44$).

Intervention group patients reported higher mean satisfaction with care received of 9.26 versus 8.58 control group patients (95% CI 1.09 to 0.219 , $p=0.01$). Intervention group patients were also more likely to 'recommend the health service to a family or friend' (NET promoter score) with a mean score of 9.27 versus 8.67 (95% CI 0.13 to 1.07 , $p=0.02$). The intervention group also had a higher percentage of promoters (81.3%) compared with the control group (66.9%) ($\chi^2[2, N=209]=8.80$, $p=0.01$).

Eight (3.3%) patients developed a DVT while inpatients or presented to the study hospital within 28 days of discharge. Of these, six patients were in the intervention group and two were in the control group ($p=0.06$). Six (2.5%) patients were readmitted to hospital within 28 days of discharge from hospital for

any reason; three in the intervention and three in the control group ($p=0.73$).

DISCUSSION

Our results show that the *MyStay* intervention, designed to enhance patient participation, was effective in reducing patients' reported pain intensity on day 3 after TKR surgery when compared with standard care. Although patients in both groups reported high levels of dynamic pain on day 3 following surgery (suggesting that pain management overall was suboptimal),⁴² intervention group patients reported lower worst pain scores indicating that they experienced lower levels of dynamic pain. Patients who received the intervention also had a lower length of stay in acute care, higher overall satisfaction with the care they had received, and were more likely to recommend the health service for similar surgery to family and friends. There were no observed differences in interference of pain on activities of daily living (APSOQ-R), knee pain and functioning (OKS) 4 weeks after discharge, incidence of DVTs or readmission to the study hospital.

The clinical significance of these results is the evidence of the impact of patient participation on patient-reported and organisational outcomes in acute care environments. Prior to this study, interventions designed to facilitate patient participation in acute care had failed to show effects other than higher patient satisfaction.^{43–46}

While the significant reduction (1.01) in mean pain scores may seem small, it corresponds to a 'medium' effect size (Cohen's d) of 0.42 and it is approximately one-third of the IQR of the observed scores and is therefore of clinical relevance. Furthermore, whereas 64% of control patients had a day-3 score ≥ 7 , with *MyStay* 44% of patients had a day-3 score ≥ 7 . In some patient populations, '7' is regarded as the cut-off for severe pain⁴⁷ so the *MyStay* intervention produced a non-trivial reduction in the percentage of patients experiencing severe pain. Patients in the intervention group received significantly higher amounts of PRN oxycodone. While that may explain the lower reported worse pain intensity scores, unplanned post hoc analyses failed to show a significant interaction between PRN oxycodone dose and treatment group. Patients receiving *MyStay* were also more likely to use non-pharmacological methods to manage pain. We need a better understanding of the ways in which patient participation affects pain experience and patients' influence on the care they receive. We can conclude, however, that the *MyStay* intervention as a treatment policy has a clinically important effect on the occurrence of severe pain.

Reasons for differences in acute LOS can be multidimensional and may depend on the age and demographic characteristics of the patient population, readiness of the patient for discharge and the availability of beds in rehabilitation facilities.⁴⁸ The

observed reduction in LOS may not be reproducible in the future where the LOS in acute care is continually decreasing through enhanced recovery pathways.^{49 50} Although enhanced recovery pathways are commonly used internationally, they are not widely used in Australia to date.^{51 52} On average, data from 2016 to 2017 indicate that patients following TKR in Australia spend 4.7 days (range, 3.6–8.3 days) in hospital.⁵³ There were no changes to the Care Pathways or TKR practice by the surgeons during the study period. The reduction in hospital LOS observed in this study suggests that a relatively low-cost, clinician-facilitated *MyStay* multimedia intervention at the bedside that provided patients with the necessary information and the opportunity to engage with clinicians increased patients' engagement in mobility and exercise to maximise function and knee flexion, and hence 'readiness for discharge'. The findings provide 'proof of concept' that patient participation can improve outcomes other than patient satisfaction alone and the benefits of patient participation may extend to rehabilitation or home if patients are discharged early.

Further evidence suggesting that *MyStay* was effective in engaging patients in their recovery were findings relating to the activation scores and satisfaction with care. Prior to admission, the majority of patients had relatively high activation scores indicating that they felt they had the necessary skills and knowledge to care for themselves. There was no difference between intervention (79% at level 3 or 4) and control groups (74% at level 3 or 4) prior to admission to hospital. On day 3 after surgery, although there was a reduction in the proportion of patients at level 3 and 4 activation in both groups, this reduction was most marked in control group patients. There was a 20% decrease in the number of control group patients with level 3 or 4 activation compared with baseline, and the difference between intervention and control group patients at this level was significant. Patient activation measures returned to baseline measures for both groups 4 weeks after surgery. These findings highlight the impact of acute illness and acute care environments on patients' perceived ability to manage their healthcare needs and the need for, and potential effectiveness of, interventions to moderate these impacts.

Patients exposed to the intervention had a significantly higher overall satisfaction with their acute care experience and a higher NET promoter score. Although there are well-known limitations in the measurement of patient satisfaction,^{25–27} the consistency of higher satisfaction with other patient-reported outcomes such as the NET promoter score³⁷ and lower reported pain intensity supports an interpretation of an intervention effect on satisfaction.

Failure to obtain an OKS preoperatively meant that we could not evaluate differences in changes

in knee function at follow-up. Further limitations may include the lack of blinding of the intervention among ward nurses, patients and data collectors and could have introduced bias. Blinding in this type of intervention was not possible because the iPads were visible and patients would often refer to the *MyStay*. To mitigate the risk of bias, validated outcome questionnaires were used. Data collectors extracting medical record audit data and the statistician who conducted the analysis were blinded to group. A robust research methodology was used to overcome the limitations associated with conducting a single-site study⁵⁴; however, the generalisability of our findings to other health service settings needs further investigation. The inclusion in the analyses of data gathered from consented patients allocated to the overflow ward, which itself received a fixed sequence consisting of the control condition in all four periods, could be criticised for being susceptible to an unknown allocation bias; however, in a supplementary analysis of the primary endpoint, which excluded these patients, the observed effect was similar in magnitude, but given the 17% reduction in the total sample size, it was no longer statistically significant at the conventional 5% level.

Creating an opportunity for patient participation without placing additional burden on clinicians and patients in this context was considered critical because implementing a shared tool has the risk of adding to the burden of care rather than facilitating it. Time spent orientating patients to the technology was approximately 5 to 10 min initially (day 1), then 2 to 5 min per day with individual patients. It is concluded, therefore, that the *MyStay* intervention can be incorporated into everyday routine care despite the acuity of the environment, and the time required for clinicians to apply (not facilitate) the programme is low and feasible. The *MyStay* programme provides patients with an alternative and complementary source of information related to their recovery that is usually highly reliant on clinicians and often limited to 'what is important now' rather than what the patient wants or needs to know.

Our findings contribute to the evolving understanding of the role of patient participation in acute care environments and the use of multimedia technology as a tool for facilitating patient-clinician interactions. We have shown that a simple and easily implementable intervention such as *MyStay* facilitated patient participation in their care after surgery and improved outcomes. These findings would be strengthened by replication in other acute healthcare settings; however, our findings support the use of facilitated patient engagement interventions in post-operative recovery after TKR.

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