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# Annals of Medicine and Surgery

journal homepage: www.elsevier.com/locate/amsu



Quality Improvement Study

# Patient reported outcomes in an elder-friendly surgical environment: Prospective, controlled before-after study

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A R T I C L E I N F O	A B S T R A C T
Keywords: Emergency surgery Elderly Patient reported outcomes Quality of life Nutrition ACE model	Introduction: The Acute Care for the Elderly (ACE) model has demonstrated clinical benefit, but there is little evidence regarding quality of life after discharge. The Elder-friendly Approaches to the Surgical Environment (EASE) study was conducted to assess implementation of an ACE unit on an acute surgical service. Improved clinical and economic outcomes have been demonstrated, but post-discharge patient reported outcomes have not yet been reported. <i>Methods</i> : Prospective, concurrently controlled, before-after study at two tertiary care hospitals in Alberta, Canada. The SF-12, EQ-5D, Canadian Malnutrition Screening Tool (CMST) and patient satisfaction were collected from elderly ( $\geq$ 65 years old) patients, 6 weeks and 6 months after discharge from an acute care surgical service. A difference-in-difference (DID) method was used to analyze between-site effects. <i>Results</i> : At six weeks, patient satisfaction was high at 68%–86%, with significant improvement Pre-to Post-EASE at the control site ( $p < 0.001$ ), but not the intervention site ( $p = 0.06$ ). For the intervention site, within-site adjusted pre-post effects were nonsignificant for all patient reported outcomes [EQ-Index Score $\beta$ coefficient (SE): 0.042 (0.022); EQ-Visual Analog Scale: 0.10 (2.14); SF-12 Physical Component Score: $-0.57$ (0.84); SF-12 Mental Component Score: $1.17$ (0.84); CMST Score: $-0.39$ (0.34)]. DID analyses were also non significant for all outcomes except for SF-12 Mental Component Score ( $p < 0.001$ ). <i>Conclusion</i> : The clinically and economically beneficial EASE interventions do not appear to compromise quality of life, risk for malnutrition, or patient satisfaction in the post-discharge period. Further research with larger sample size is needed with comparisons to pre-intervention and the early post-discharge period.

# 1. Introduction

The number of patients who present with an emergency surgical condition increases with age [1–3]. An older ( $\geq 65$  years old) emergent surgical population presents an increasingly difficult challenge due to the increased burden of pre-existing comorbidities, polypharmacy, frailty and decreased ability to tolerate acute physiological changes [4–6]. Due to this burden, consideration has been given to interventions for improving care for this older surgical patient population [7]. The

Acute Care for the Elderly (ACE) model had demonstrated clinical benefit for the inclusion of geriatrician care in specialized management of acutely ill older adult patients [8–10]. The majority of studies investigating ACE units pertain to medical wards, with limited evidence specifically for the surgical population, and methods to optimize care of older emergency surgery patients are needed [11].

Morbidity has significant consequences for the acute care older adult surgical population with repercussions on patients' long term health status, functional status, and ability to return to independent

https://doi.org/10.1016/j.amsu.2021.102368

Received 19 February 2021; Received in revised form 23 April 2021; Accepted 26 April 2021 Available online 29 April 2021

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living—thereby affecting overall quality of life (QOL) [12]. Older patients have reported significant distress and dissatisfaction with loss of function, independence and subsequent discharge to a higher level of care in comparison to on admission [13–15]. Similarly, older patients are at greater risk for malnutrition [16], which is associated with poorer postoperative clinical outcomes and with significant impact on longer-term functional outcomes [17,18].

Unfortunately, there is little evidence available with regards to patient reported outcomes in the older adult population after discharge from emergency surgery, as well as how these outcomes are affected by interventions such as ACE units [4,13,19,20]. From the limited evidence available in studies of older adults having elective surgery, the implementation of geriatrician consultation teams seem to have an equivocal impact on the functional outcomes of patients [20,21].

The Elder-friendly Approaches to the Surgical Environment (EASE) study was one of the largest studies conducted to assess the benefit of an ACE-style model of care in an emergency general surgical population. The EASE study demonstrated improved clinical and economic benefit [22,23]. Recognizing that surgery has significant implications for patients' nutrition and QOL, as a secondary outcome of the EASE study, we assessed post-discharge patient reported outcomes with the hypothesis that this integrated care will confer a benefit for QOL and patient satisfaction.

#### 2. Methods

# 2.1. Study design and participants

The study protocol has been previously published [24]. In brief, the EASE study was a prospective, concurrently controlled, before-after study at two tertiary care hospitals in Alberta, Canada. The study population consisted of patients aged 65 years and older admitted to the acute care and emergency surgery services, who received acute surgical intervention. After a period of Pre-EASE data collection at both sites, the initiatives were implemented solely at one site (Intervention Site Post-EASE), while the other site acted as a time-matched control (Control Site Post-EASE). The EASE study received approval from the University of Alberta Research Ethics Board (Pro00047180) and the University of Calgary Conjoint Research Ethics Board (REB140729) and participants were consented before participating in post-discharge follow up. The EASE study has been registered with the Research Registry ClinicalTrials.gov, study identifier NCT02233153.

### 2.2. Data collection

Data were collected by trained study personnel by means of standardized case report forms, using medical records, as well as patient or surrogate interviews [25].

Patient reported outcomes were collected, in person or by telephone, as part of follow-up at six weeks (+/- four weeks) post-discharge and again at six months (+/- one month) post-discharge. Instruments included:

- 1. EQ-5D-3L instrument, a validated generic health related QOL assessment tool [26]. The EQ-5D is a health utility measure with a summative index (EQ-index) scored from 0 to 1 with 1 representing better QOL or full health. In the study we used the United States population validation study to calculate EQ-index [27]. In addition, a visual analog scale (EQ-VAS) score was used, ranging from 0 to 100 with 100 representing the best health possible.
- 2. RAND Short Form 12 (SF-12) survey, a commonly used generic health-status tool [28]. It assesses both physical and mental health (physical component score, PCS and mental component score, MSC, respectively), which follow a T distribution (mean 50, SD 10), normalized for the general United States population. Higher scores indicate better health status.

3. Canadian Nutrition Screening tool (CNST), is valid first-line assessment used to identify patients at risk for malnutrition [29]. The tool reports outcomes as a binary measure (proportion of patients at risk for malnourishment versus not).

A general 5-point Likert scale, Patient Satisfaction Question ('The medical care I have been receiving is just about perfect'), was also completed at six weeks [30].

#### 2.3. Statistical analysis

As lost to follow up (LTFU) data was likely to be high and would be missing not-at random we opted to not impute missing values. Analysis was performed with an intention-to-treat perspective. We calculated descriptive statistics for participant demographics, hospitalization details and patient reported outcomes. For the patient reported outcomes at 6 weeks, we calculated separate pre- and post-EASE comparisons within-site, using  $\chi^2$  tests for the CNST, and Student's T-tests for EQ-5D Index, EQ-VAS, SF-12 PCS and MSC scores. We also compared to provincial or national population norms. [31,32]. Previous research completed by the Canadian Malnutrition Task Force has reported the prevalence of malnutrition at 42.6% 30 days after discharge in a general previously hospitalized population using Subjective Global Assessment [33].

Adjusted within-site pre-versus post-EASE effects were estimated using a logistic regression or generalized linear regression. Effect modifiers were included in the initial model based on univariate statistical significance (p = 0.2) and kept in the final model if p = 0.05 or if the covariate was associated with confounding, based on a 10% or greater change in beta-coefficient within the model, irrespective of statistical significance. Pre-post effects were assessed for minimum clinically important differences (MCID). A minimum change in outcome score, a score that a patient would interpret as significant in QOL as assessed by EQ-5D index, of 0.03 was used [34]. The MCID for the EQ-VAS is reflected by a change in score of 10 points [34]. With regards to SF-12, a minimum clinically significant difference of change in PCS or MSC score of 3–5 points was used [8,35]. To our knowledge, an MCID for the CNST has not been established.

A difference-in-difference (DID) method was used to analyze the between-site effect of EASE on patient reported outcomes [36]. An interaction regression model, in which all participant data is included and the interaction term represents the interaction between site location (intervention = 1, control = 0) and the EASE initiatives (received EASE = 1, no initiatives = 0), was performed. The strategy for adjusting for confounding within these DID models was the same as described above.

Finally, change in patient report outcomes between six weeks and six months was calculated, and again assessed for MCIDs. All data analysis was performed using STATA statistical software, version 15 (StataCorp LP, Texas, USA).

#### 3. Results

A total 684 participants were included in the EASE Study. At the control site 216 participants (55%) died or were LTFU at six weeks, while 99 participants (34%) died or were LTFU at the interventions site (Fig. 1). Another 64 participants (10%) (control site n = 37, intervention site n = 27) were LTFU or died between six week and six months. The LTFU was statistically significantly greater at the control site (p < 0.001), with more LTFU Pre-EASE compared to Post-EASE, within both sites (control site p = 0.005, intervention site p = 0.01). Those who were LTFU were statistically significantly older [mean (SE) difference: 2 (0.58) years, p < 0.001], had a higher Charlson Comorbidity Index [Median (IQR): 1 (0–2) vs. 0 (0–1), p < 0.0001], had longer lengths of stay [Median (IQR): 9 (5–17) vs. 7 (5–12), p < 0.001], and were more frequently discharged to another hospital, assisted living, or a skilled nursing facility (12% vs. 9%, p < 0.001) compared to those who

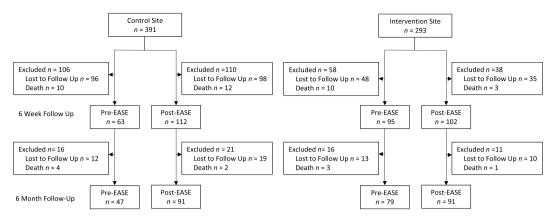


Fig. 1. Study design flow diagram.

completed follow up.

A total of 372 participants were included in the analysis of QOL. The mean age (SD) of patients was 74.6 (7.1) years, 189 (n = 51%) were female, and comorbidities at admission were similarly distributed between the two groups (Table 1). Frailty was consistent between sites, as well as Pre- to Post-EASE, with those being vulnerable or frail ranging from 21 to 35%. Patient satisfaction was high at 68– to 86%, with

#### Table 1

6 Week demographics.

SE         E           63         n           5         7           977         (40)           (62)         5           4         2           911         (40)           (29)         1           133)         1           8)         1           55)         6	EASE n = 112 73.2 66.04) 67 (51) 28.0 5.17) 0 (0-1) 51 (46) 17 (15) 13 (12) 12 (11) 5 (5)	EASE n = 95 76.2 (7.84) 48 (50) 26.6 (5.61) 0 (0-2) 29 (31) 20 (21) 21 (22) 11 (12)	Post- EASE n = 102 74.6 (7.41) 47 (46) 27.2 (5.94) 0.5 (0-1) 43 (42)* 22 (22)* 10 (10)* 14 (14)*
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4     2       91)     (!       9-1)     0       (40)     5       (29)     1       13)     1       3)     1       5)     6	28.0 5.17) (0-1) 51 (46) (7 (15) (13 (12) (2 (11) 5 (5)	26.6 (5.61) 0 (0-2) 29 (31) 20 (21) 21 (22) 11 (12)	27.2 (5.94) 0.5 (0–1) 43 (42)* 22 (22)* 10 (10)* 14 (14)*
91)     (!       )-1)     0       (40)     5       (29)     1       13)     1       3)     1       5)     6	5.17) ) (0–1) 51 (46) 17 (15) 13 (12) 12 (11) 5 (5)	(5.61) 0 (0–2) 29 (31) 20 (21) 21 (22) 11 (12)	(5.94) 0.5 (0-1) 43 (42)* 22 (22)* 10 (10)* 14 (14)*
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(29) 1 13) 1 3) 1 5) 6	17 (15) 13 (12) 12 (11) 5 (5)	20 (21) 21 (22) 11 (12)	22 (22)* 10 (10)* 14 (14)*
13) 1 3) 1 5) 6	13 (12) 12 (11) 5 (5)	21 (22) 11 (12)	10 (10)* 14 (14)*
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5) 6	5 (5)		
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13) 1			7 (7)*
	13 (12)	7 (7)	6 (6)*
5–11) 7	7	9 (6–14)	6 (4–10)
			*
(76) 9	91 (82)	61 (64)	81 (79)*
			11 (11)*
			8 (8)*
1) 0	) (0)	2 (2)	2 (2)*
(70) 8	38 (79)	62 (65)	76 (75)
			14 (14)
			11 (11)
5) 2	2 (2)		0 (0)
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(17) 5	57 (51)*	33 (35)	52 (51)
			35 (34)
			8 (8)
			7 (7)
			0 (0)
	(76)         (77)           (13)         (13)           (13)         (13)           (14)         (17)           (17)         (17)           (17)         (17)           (5)         (2)           (51)         (3)	$\begin{array}{ccccccc} 5-11) & 7 & (4-12.5) \\ (76) & 91 (82) \\ (13) & 17 (15) \\ 0) & 3 (0) \\ (13) & 0 & (0) \\ (13) & 17 (15) \\ (14) & 0 & (0) \\ (17) & 88 (79) \\ (17) & 14 (13) \\ (17) & 14 (13) \\ (17) & 14 (13) \\ (17) & 57 & (51)^* \\ (51) & 38 (34)^* \\ (51) & 38 (34)^* \\ (51) & 5 & (5)^* \\ (23) & 7 & (6)^* \end{array}$	5-11)       7       9 (6-14)         (4-12.5)       91 (82)       61 (64)         (13)       17 (15)       19 (20)         (30)       13 (14)         (4)       0 (0)       2 (2)         (70)       88 (79)       62 (65)         (17)       14 (13)       20 (21)         (3)       8 (7)       9 (9)         (5)       2 (2)       2 (2)         (17)       57 (51)*       33 (35)         (51)       38 (34)*       48 (51)         (5)       5 (5)*       5 (5)         (23)       7 (6)*       6 (6)

Mean (SD) unless indicated.

<sup>†</sup>n (%).

# median (IQR).

\* $p \le 0.05$ , compared to within site pre-EASE group.

significant improvement in patient satisfaction Pre-to Post-EASE at the control site (p < 0.001), but not at the intervention site (P = 0.06).

#### 3.1. EQ-index

The mean (SD) six-week post discharge EQ-index score Pre-EASE was 0.82 (0.18) at the intervention site and 0.83 (0.18) at the control site, with no significant change Post-EASE at either site (Table 2). At both sites, both Pre- and Post-EASE, the EQ-Index was statistically and clinically significantly higher than the older Alberta population norm (all p < 0.01). Within-site adjusted pre-post effects were not statistically significantly different but did reach MCID (0.03) at both sites (adjusted pre-post effect = 0.042 at both sites). Between-site DID was not statistically significant (p = 0.45). Comparing six weeks to six months, only the mean [SD] change over time at the control site Pre-EASE met MCID (0.05 [0.027]), but this difference did not reach statistical significance (Fig. 2).

#### 3.2. EQ-VAS

The mean (SD) six-week EQ-VAS score Pre-EASE was 77.2 (15.8) at the intervention site and 74.5 (16.8) at the control site, with no significant change Post-EASE (Table 2). Compared to the older Alberta population norm, control site Post-EASE, as well as intervention site Pre-and Post-EASE EQ-VAS were clinically and statistically significantly better (all p < 0.02). Within-site adjusted pre-post effects were statistically and clinically non-significant at both sites, as was the between-site DID (p =0.15). Comparing six weeks to six months, only the mean change over time at the control site Post-EASE significantly decreased (4.56 [1.8] points, p = 0.01, Fig. 2).

# 3.3. SF-12 PCS

The mean (SD) Pre-EASE PCS score was 38.9 (5.38) at the intervention site and 40.2 (7.04) at the control site, with no significant change Post-EASE (Table 2). Compared to the elderly Canadian population norm, at both sites, both Pre- and Post-EASE, the PCS scores were clinically and statistically lower (all p < 0.001). Within-site adjusted pre-post effects were statistically and clinically non-significant at both sites, as was the between-site DID (p = 0.9). Comparing six weeks to six months, only the control-site Post-EASE mean change in PCS was significantly increased (1.52 [7.04] p = 0.02, Fig. 2).

# 3.4. SF-12 MCS

At the intervention site, the mean (SD) six-week MCS score was 50.0 (6.12) Pre-EASE, with no significant change Post-EASE (Table 2). At the control site the six-week MCS score was 55.6 (6.88) Pre-EASE and

#### Table 2

#### 6 Week QOL outcomes.

	Control Site			Intervention Site			
	Pre-EASE	Post-EASE	Adjusted Pre-Post Effect	Pre-EASE	Post-EASE	Adjusted Pre-Post Effect	
	n = 63	n = 112	$\beta$ coefficient (SE)	n = 95	n=102	$\beta$ coefficient (SE)	Difference of Difference
EQ-5D Index	0.83 (0.18)	0.87 (0.13)	0.042 (0.024)	0.82 (0.18)	0.85 (0.17)	0.042 (0.022)	p = 0.45
EQ-5D Visual Analog Scale	74.5 (16.8)	79.4 (16.5)	2.99 (2.58)	77.2 (15.8)	76.6 (15.0)	0.10 (2.14)	p = 0.15
SF-12 Physical Component Score	40.2 (7.04)	40.1 (4.88)	-0.82 (0.94)	38.9 (5.38)	39.0 (5.86)	-0.57 (0.84)	p = 0.9
SF-12 Mental Component Score	55.6 (6.88)	50.8 (4.83)*	-4.21 (0.87)*	50.0 (6.12)	50.9 (5.86)	1.17 (0.84)	p < 0.001
Malnutrition Screening Tool <sup>a</sup>	39 (62)	42 (52)*	-0.98 (0.37)*	34 (36)	28 (27)	-0.39 (0.34)	p = 0.23

Mean (SD) unless indicated.

<sup>a</sup> n (%).

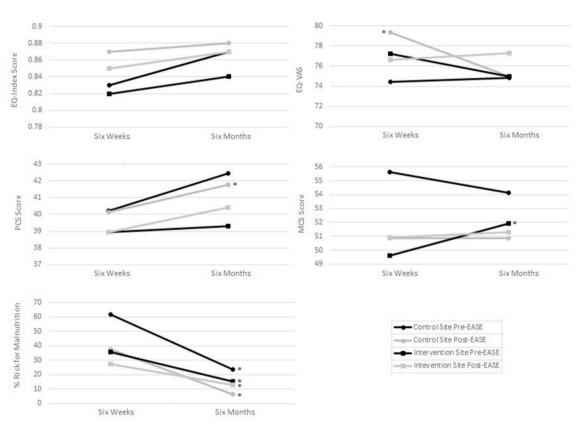


Fig. 2. Change in patient reported outcomes over time.

significantly lower Post-EASE (50.8 [4.83], p < 0.001). Compared to the older Canadian population norm, control site Post-EASE, as well as intervention site Pre-and Post-EASE MSC scores were clinically and statistically significantly lower (all p < 0.02). Adjusted within-intervention site pre-post effect was neither statistically nor clinically significant. The adjusted within-control site pre-post effect was both statistically and clinically lower ( $\beta$  coefficient (SE) –4.21 (0.87), p < 0.001), and the between-site DID was also statistically significant (p < 0.001). Comparing six weeks to six months, only the intervention site mean change during Pre-EASE statistically significantly increased (2.03 [6.76], p = 0.01).

# 3.5. CNST

At the intervention site, 36% (n = 34) were at risk for malnutrition Pre-EASE at six weeks, and 27% (n = 28) Post-EASE at 6 weeks (no statistically significant difference; Table 2). At the control site, 62% (n = 39) were at risk for malnutrition Pre-EASE, with 52% (n = 42) at risk for malnutrition Post-EASE (p = 0.002). The intervention site Post-EASE malnutrition risk prevalence was significantly lower than the Canadian Malnutrition Task Force reported prevalence (p = 0.008), while the control site Pre-EASE risk for malnutrition prevalence was significantly higher (p = 0.001). Adjusted within-control site pre-post effect reached statistical significance (p = 0.007), but within-intervention site pre-post effect did not (p = 0.24) nor did the between-site DID (p = 0.23). Comparing six weeks to six months, there was a statistically significant improvement in malnutrition risk over time at both sites, both Pre- and Post-EASE (all p < 0.01, Fig. 2).

## 4. Discussion

We implemented the Elder-friendly Approaches to the Surgical Environment (EASE) initiatives in a population of older adults undergoing emergency surgery. Our study found that the EASE intervention did not appear to compromise post-discharge QOL or risk of malnutrition. QOL measurements at six-weeks were maintained up to 6 months post-discharge and were above average Alberta normative values in both sites. There were statistically significant difference-in-difference improvements in mental health, comparing the EASE intervention to no intervention, due to stable mental health at the intervention site, and a significantly worsening of mental health at the control site. Patient satisfaction at six weeks remained high at the intervention site, and significantly improved Pre-EASE to Post-EASE at the control site. In combination with the EASE interventions demonstrating the clinical and economic benefits, the stable QOL outcomes and patient satisfaction provides further support for elder-friendly surgical care [22,23].

There is a paucity of studies on optimizing recovery after surgery in older adults for comparison, and those that do exist are in elective procedure populations [37]. Overall, our results are similar to elective surgical interventions: pre-operative comprehensive geriatric assessments have been shown to reduce post-operative adverse outcomes, but have not shown improvements on QOL [20,38]. Other multidisciplinary team approaches have had positive results in functional or dispositional outcomes, with no data for QOL [39–41].

Unfortunately, it was not feasible to complete patient reported surveys before admission or during the early post-operative recovery phase, due to the emergency nature of the participants' surgeries. This eliminated our ability to quantify participants' pre-operative QOL and malnutrition risk, assess the immediate post-surgical impact of EASE on patient reported outcomes, and put these post-discharge measures in context. Trajectories of patient-centered outcomes have been rarely described after surgery, but could be expected to follow the trajectory of overall recovery, with an immediate post-surgical deterioration phase followed by an improving rehabilitation phase, and back to or exceeding the pre-operative state in a matter of weeks to months [42]. In elective surgical populations, physical QOL has been reported to decrease 30-days post-surgery, with no change to mental QOL, although early post-surgical QOL change scores have been shown to vary greatly by specialty. [43,44]. This suggests that early assessment of patient reported outcomes (up to four weeks after surgery) may reflect peri- and post-operative management, and our initial assessment at six weeks post-discharge may have missed the window of opportunity to capture patient reported outcomes that reflect the enhanced recovery impacts of EASE. In absence of this pre-surgery comparison, we compared our post-discharge patient reported outcomes with population normative values to support the interpretation of our results [31,32].

The interpretation of our results is further limited by the fact that patient reported outcomes were secondary to the overall objective of the EASE study and therefore the sample size may not be sufficiently large to properly power our analyses. This is further exacerbated by the high LTFU that appears to be non-random. Another limitation in the analysis is the higher rate of death in the control site (5.4 vs. 2.1%) which could result in a falsely elevated QOL scores in the control site, since deaths could have been included in the EQ-5D calculation as 0 values. This approach is somewhat underestimating the program outcomes not allowing all the difference to be seen.

# 5. Conclusions

We have previously shown that EASE interventions are clinically and economically effective, so irrespective of patient reported outcomes, there may be utility in implementing ACE-style units into post-surgical care from the health system perspective [22,23]. Further investigations are necessary to assess the impact of ACE-style models of care on QOL outcomes in the surgical context.

### **Ethical Approval**

The EASE study received approval from the University of Alberta Research Ethics Board (Pro00047180) and the University of Calgary Conjoint Research Ethics Board (REB140729) and participants were consented before participating in postdischarge follow up.

# Source of funding

RGK received financial support from Alberta Innovates and Alberta

Health Services by holding a Partnership for Research and Innovation in the Health System (PRIHS) research award and a CIHR Project Grant for the submitted work for the submitted work; no financial relationships with any organization that might have an interest in the submitted work; no other relationships or activities that could appear to have influenced the submitted work.

#### Authors contribution

RGK drafted the original study concept, all authors contributed to the study design, and RGK, JHL and LMW oversaw the implementation of the study protocol. Outcomes analysis was performed by a BSB and LMW and was supported by AO. The initial draft of this manuscript was written by BSB and LMW, with support from RGK and AO. All authors contributed to the editing of the manuscript and approved the final submitted draft.

# Consent

The EASE study received approval from the University of Alberta Research Ethics Board (Pro00047180) and the University of Calgary Conjoint Research Ethics Board (REB140729) and participants were consented before participating in postdischarge follow up.

# **Registration of Research Studies**

- 1. Name of the registry: ClinicalTrials.gov
- 2. Unique Identifying number or registration ID: NCT02233153.

3. Hyperlink to your specific registration (must be publicly accessible and will be checked): https://clinicaltrials.gov/ct2/show/NC T02233153

#### Guarantor

Rachel G Khadaroo.

#### Provenance and peer review

This article was not commissioned and was externally peer-reviewed.

# Declaration of competing interest

The authors have no conflicts of interest to report.

#### Acknowledgements

The authors would like to acknowledge Saad Salim, Hanhmi Huynh, Ashley Wanamaker, Carrie Le, Jenelle Pederson, Justin Lowes, and Shelly Jun for their contributions to data collection for this study. We would like to acknowledge Alberta Innovates, the Surgery & Seniors Health Strategic Clinical Networks, the University of Alberta Hospital Geriatricians and the Geriatric Assessment Team, and the Acute Care and Emergency Surgery Services, Alberta Health Services for providing support for the EASE project.

This study was supported by Alberta Innovates and Alberta Health Services with a Partnership for Research and Innovation in the Health System (PRIHS) grant (Dr. Khadaroo) and Canadian Institute of Health Research (CIHR) grant (Dr. Khadaroo); no financial relationships with any organization that might have an interest in the submitted work; no other relationships or activities that could appear to have influenced the submitted work.

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