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**The association between pre-admission frailty and care level at discharge in
Older adults undergoing Emergency Laparotomy.**

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Abstract

Introduction

Older adults undergoing emergency abdominal surgery have significantly poorer outcomes than younger adults. For those that survive, the level of care required upon discharge from hospital is unknown and such information could guide decision-making. The ELF Study (Emergency Laparotomy and Frailty) aimed to determine if pre-operative frailty in older adults was associated with increased dependence at the time of discharge.

Methods

The ELF study was a UK wide multicenter (n=49), prospective cohort study of 934 older patients (>65 years) undergoing emergency laparotomy during March-June 2017. The objective was to establish if pre-operative frailty increased care level at discharge, compared to pre-operative care. The analysis used a multi-level logistic regression adjusted for pre-admission: frailty; patient age; gender; and care-level.

Results

The mean patient age was 76.2 years (SD=6.83), with 57% female, 20.2% frail, and 37.4% of older adults had an increased care level at discharge. Increasing frailty was associated with increased discharge care level (and greater predictive power than age). The aOR for an increase in care level was 4.48 (95% CI 2.03-9.91) for apparently vulnerable patients (CFS 4); 5.94 (95% CI 2.54-13.90) for those mildly frail (CFS 5); and 7.88 (95% CI 2.97-20.79) for those moderately or severely frail, (CFS 6 and 7) compared to patients who were fit.

Conclusions

This is the first study to document that over 37% of older adults undergoing emergency laparotomy required increased care at discharge. Frailty scoring should be integrated into all acute surgical units to aid shared decision-making and treatment planning.

Study registration: (Black Country Research Committee: November 2016; 16/WM/0500) and was registered online (NCT02952430).

Introduction

Emergency abdominal surgery is performed acutely on a variety of pathologies with the common aim to prevent death and minimize life-changing complications^{1,2}. Older adults (65 years and above) account for nearly half of patients undergoing such emergency surgery and have the longest critical care and hospital stays, accompanied by the highest risk of morbidity and mortality³⁻⁵. With the older adult population predicted to expand significantly, there is an urgent clinical need to improve understanding of this high-risk and often overlooked surgical population^{1,6,7}. Indeed, maintaining independence is widely documented as a priority for older adults, but as a consequence of the focus on mortality, little is known about care provision after emergency laparotomy⁸⁻¹⁰. Improved understanding in this area will facilitate shared decision-making and allow treatment planning that respects the dignity of each individual patient¹¹.

Frailty is an objective measure of reduced functionality as a result of age-associated accumulation of physiological deficits in multiple systems and becomes increasingly prevalent with increasing age¹². Frailty results in diminished resilience to physiological insult (such as surgery), preventing or impairing recovery and return to baseline functional status. Poorer outcomes with frail patients is well accepted in the medical setting, including a higher risk of dying, longer hospital stay, higher re-admission rate and a requirement for increased level of care upon discharge. The introduction of frailty screening and the Comprehensive Geriatric Assessment (CGA) have led to improvements in survival alongside an ability to return to pre-admission residence¹³⁻¹⁵.

The concept of frailty is evolving in emergency surgery. Initial work prospectively assessed frailty in all older adult acute surgical admissions to three surgical units in the U.K.¹⁶. Using the Clinical Frailty Score (CFS), frailty was found in 28%, with the frail group spending longer in hospital (7.6 days versus 11.1) and more likely to die at both 30 and 90 days after admission¹⁷. This work led into a larger multi-centred cohort study (n=2,279 patients) where a linear dose response relationship between frailty (using the CFS) and 90-day mortality was reported¹⁸. However, only a small proportion of these patient populations underwent high-risk emergency surgery, with the remainder not requiring surgery, or being managed conservatively. The recent ELF study (Emergency Laparotomy and Frailty) was the first to prospectively assess the impact of frailty following emergency surgery in older adults^{19,20}. Using the CFS, 20% of older adults were found to be frail (CFS 5-7) with a higher risk of death at both 30 and 90 days after surgery.

Furthermore and independent of age, frail patients had longer hospital and critical care stays and a greater number of post-operative complications.

This current study reports the planned *A Priori* discharge findings from the ELF study and aimed to determine the level of care on discharge and the influence of frailty, for older adults undergoing emergency laparotomy.

Methods

Study design

The ELF Study was conducted as a UK multicenter, prospective cohort study of older patients (defined as 65 years and older) undergoing emergency laparotomy during 20th March to 19th June 2017 (12 weeks). The study was conceived, designed and led by two established research collaboratives: The North West Research Collaborative (NWRC – www.nwresearch.org) and The Older Persons Surgical Outcomes Collaboration (OPSOC – www.opsoc.eu). National health research ethics approved this study (Black Country Research Committee: November 2016; 16/WM/0500) and was registered online (NCT02952430). The protocol was consistent with STROBE and published¹⁹⁻²¹.

Inclusion criteria were consistent with the established U.K. National Emergency Laparotomy Audit [NELA; www.nela.org.uk/criteria]²². Patients were included if undergoing an expedited, urgent or emergency surgical abdominal procedure for gastrointestinal pathology (laparoscopic or open procedure) and/ or return to theatre for any major post-operative complication/dehiscence.

Measures

Demographic and clinical measures recorded on eligible participants pre-surgery included: age, gender; co-morbidities measured using the Charlson Co-morbidity Index; and polypharmacy (5 or more current medications). Care level was recorded on admission, and on discharge. Full details of scoring systems used are included in the protocol publication¹⁹.

Care level was recorded as an ordinal variable, with increasing dependence from: at home without carers; home with carers; residential home; nursing home; intermediate care; other (alive); other (dead). Residential level care was defined as individual care where service users can perform usual acts of daily living; washing dressing and toileting. Nursing care was defined as service users receiving assistance with nearly all tasks. Intermediate care varied depending on local provision and was defined as short-term care (either within an institution or individual's

home) which can be either withdrawn or modified and is designed to facilitate the transition from hospital to home²³. Patients recorded as other (alive) were deemed to be requiring the highest level of care as this encompassed those who remained in hospital at 30 days. Those recorded as other (dead) were those who died in hospital, and for the purpose of end analysis were assumed as an increased care requirement.

Objectives and Exposures

Primary objective: Increased care level was defined as a reduction of independence required at discharge from hospital, compared to pre-admission care level. A comparison was made between those that exhibited an increase level of care, versus those who were discharged with the same, or a reduced level of care.

Secondary objective: hospital stay length (herein described as time-till discharge) was assessed using a time to event analysis.

Pre-operative frailty was measured using the Clinical Frailty Score (CFS), developed by the Canadian Study of Health and Ageing¹⁷. This seven-point functional scale describes increasingly dependent living and is based on clinical judgment with a score of 1 to 3 being classified as non-frail, 4 as pre-frail and 5 to 7 as frail. The CFS has been validated and widely used in the emergency surgical population to assess frailty^{16,18,20,24}.

Anonymous data was entered into a specifically designed online multicenter secure electronic data capture system (REDCap, www.project-redcap.org) maintained by the North West Surgical Trials Centre (www.nwstc.org.uk). A minimum of 10% of key outcome variables were independently verified by secondary data entry in order to minimize missing and erroneous data.

Sample size justification

After accounting for loss to follow up, at least 500 patients were estimated to be recruited to this study, further details are published in our protocol¹⁹.

Data Analysis

Pre-admission and discharge care level was compared to those with an increased care level. A modified intention to treat analysis was adopted to include all patients where possible. Missing

care level at discharge were imputed if patients had died, or were still in hospital at four or more weeks, both, have been recorded as an increased care at discharge. Patients that had died before discharge were censored at this time, during the time-till-discharge analysis.

The primary analysis was performed using a multi-level logistic regression of increased level of care, associated with baseline frailty, adjusted for pre-operative patient: age; gender; and care level, and with each recruiting hospital was fitted as a random effect to account for hospital site variation. Crude, and adjusted odds ratio (aOR) with associated 95% CIs and p values were calculated. The intra-cluster correlation (ICC) coefficient was calculated for the within hospital correlation alongside the 95% confidence interval. A comparison of both age and frailty was undertaken by removing them sequentially in a step wise-approach and applying two likelihood ratio tests (LRT).

The time from surgery until discharge from hospital was assessed visually using a Kaplan Meier plot, stratified by CFS, and the median time-till- discharge was calculated alongside the upper and lower quartiles. A crude and adjusted Cox's proportional hazards model was fitted with a random intercept for site, with pre-operative: CFS; age; sex; and care level, included. Baseline proportionality was assessed visually and with log-log plots, and crude and adjusted hazards ratios (HR) were estimated with 95% CI and p values. Statistical analyses were carried out using Stata 15 (StataCorp; www.stata.com).

Sensitivity analysis

Due to the heterogeneous nature of intermediate care, all patients with pre-admission residential and nursing care, who were discharged with intermediate care were removed from a sensitivity analysis. An unplanned sensitivity analysis (of the primary analysis) was carried out with the addition of the Charlson comorbidity Index, as an additional confounder to evaluate the impact of co-morbidity on the findings.

Results

A total of 956 patient records were entered into the ELF secure database from 49 surgical centers from England, Wales and Scotland. After removal of 22 ineligible and missing outcome data, 934 participants were included (Supplementary Figure 1). The mean patient age was 76.2 years old (SD=6.83), 57% (538/934) were female, and 66% (618/934) were ASA 3 or greater (Table 1).

The most common indication for surgery was intestinal obstruction (54%); the most often surgical procedure performed was adhesiolysis (25%) and the majority of surgery was performed by an open approach (87%). Pre-operatively 20.2% (189/934), of patients were defined as frail (CFS \geq 5) with frailty being present throughout all the age groups (Table 2). 30 and 90-day mortality were 14.6% and 19.5% respectively, with 50% having post-operative complications recorded.

Primary Objective

Pre-operatively 83% (776/934) of patients lived independently (at home without a carer) whilst a further 12.6% (118/934) lived at home with carer support. The remaining 4.4% were from a residential, nursing or intermediate care setting (Table 1). At the time of hospital discharge, 37.4% of all older adults had an increased level of care (n=349/934).

INSERT TABLE 1 HERE

The association between pre-admission care level, and care level at discharge were explored (Table 2). Of the 776 patients that underwent emergency surgery who were living at home without carers pre-operatively, 36% (278) required an increased level of care at discharge. Of the 118 patients that presented who were living at home with carers, 47% (55) required increased level of care. Of the 17 patients that came from a residential home, 9 (52.9%) had increased care and subsequently went to a nursing home.

There were 62 cases of patients who lived at home with (n=51) or without a carer (n=11) pre-admission, but needed intermediate care at discharge, these were imputed as having an increased level of care, since pre-admission care packages were inadequate. There were four patients with residential or nursing care pre-operatively, that were discharged with intermediate care, they were assumed to have an increased level of care at discharge, but were excluded in

a sensitivity analysis, to consider the impact on the assumption this was an assumed increase in care level.

INSERT TABLE 2 HERE

The distribution of patients that experienced an increased level of care, by age, frailty and pre-operative care level narratively suggested that both frailty and patient age was associated with increased care level (Table 3). Only 16.4% (9/55) patients that were described as very fit (CFS 1) required an increased level of care at discharge, this increased to 48.0% (95/199) for those pre-frail (vulnerable; CFS 4), and 53.4% (101/189) for those with frailty (CFS 5-7). Whereas, for patients aged 65-70, 26.4% (47/178) exhibited an increased care need, and this increased to 35.4% (163/461) and 47.1% (139/295) for those aged 70-80, and 80 years and older.

INSERT TABLE 3 HERE

Statistical Analysis

After fitting a crude logistic regression to model the association between increased care level at discharge and pre-operative: frailty; age; gender; and care level, there was strong evidence that increasing frailty and age were associated with an increasing odds of increased care level. For example, compared to very fit patients, those vulnerable had an odds ratio (OR) of 5.01 (95% CI 2.28 to 10.97; $p < 0.001$, Table 4), for needing an increased care level at discharge, and for those that were mildly and moderately frail had the greatest risk of increased care (Table 4). Similar findings were found for older patients, those aged 85-90 exhibited a crude OR = 2.99 (1.76 to 5.06; $p < 0.001$), compared to 65-69 years old.

INSERT TABLE 4 HERE

After adjusting for each of the other mediating and confounding effects, both patient age and frailty remained strongly associated with increased odds of greater dependency at discharge. The adjusted OR (aOR) was seen as 1.79 (95% CI 1.11 to 2.88; $p = 0.016$); 2.58 (95% CI 1.49 to 4.46; $p = 0.001$); and 4.12 (95% CI 1.74 to 9.79; $p = 0.001$), for patients aged 80-84, 85-89, and 90 or older years old respectively. There was also an approximately linear increase in odds of increased care level from patients with poorer frailty status. The aOR was 4.48 (95% CI 2.03 to

9.91; $p < 0.001$) for those that were vulnerable (CFS 4); 5.94 (95% CI 2.54 to 13.90; $p < 0.001$) for those mildly frail; 7.88 (95% CI 2.97 to 20.93; $p < 0.001$) for those moderately or severely frail (CFS 6 and 7). Neither pre-operative care level, or gender offered any association with increased care level at discharge. The intra-cluster correlation (ICC) for the adjusted analysis accounting for the within-hospital correlation was 0.01 (95% CI 0.001 to 0.166). Frailty was found to offer more explanatory power than age after removing each in a likelihood ratio test (LRT), however, both independently were found to be important predictors of increased care level.

The linear comparison of CFS with increased level of care is shown in Figure 1, and exhibited a strong, linear association between patients aggregated at CFS, and the proportion with an increased level of care ($r = 0.92$, $p = 0.002$). After carrying out both sensitivity analyses there were no changes in the findings due to the potentially unclear care level of those patients recorded with intermediate care at discharge, or due to co-morbidity.

INSERT FIGURE 1 HERE

Secondary Objective

Within ELF the crude length of hospital stay using a zero inflated negative binomial regression was reported, this method did not account for censoring (for example death) or the multi-level structure of the data. We found that the median time-till discharge (in days [Q1, Q3]) doubled from those patients that were fit from 10 (6 to 17), to those vulnerable 19 (12, 31); mildly frail 21 (12, 36); and moderately or severely frail 22 (12, 47). Within this study we have reported the time-till-discharge using a Kaplan Meier plot, stratified by frailty (Figure 2) and multi-level Cox Proportional hazards model. Compared to those patients that were very fit, those vulnerable, mildly, and moderately frail all exhibited a longer hospital stay post-surgery. The adjusted Hazard Ratio (aHR) was estimated as 0.50 (95% CI 0.36 to 0.70; $p < 0.001$) for those vulnerable; aHR = 0.52 (95% CI 0.36 to 0.77; $p = 0.001$) for the mildly frail; aHR = 0.55 (95% CI 0.34 to 0.88; $p = 0.013$) for the moderately and severely frail. This was consistent with a longer median time till discharge for the vulnerable patients of approximately double the number of days in hospital, compared to patients that were very fit. Neither, patient age, sex, or pre-admission level of care exhibited any evidence of an association with the time till discharge, after accounting for censoring (eg death). There was no suggested evidence of a lack of proportionality in the baseline hazard assumption observed from the Kaplan Meier plot or log-log plot.

INSERT FIGURE 2 HERE

INSERT TABLE 5 HERE

Discussion

Key findings

This was the first study to prospectively document the discharge destination and the influence of frailty in older adults undergoing emergency laparotomy. Although the vast majority of patients lived independently at home prior to their surgery, over a third required an increased level of care at the time of their discharge, making it essential that discharge destination should be included in the pre-operative decision-making process. With increasing frailty strongly associated with an increased care level, frailty scoring should be integrated into all acute surgical units to aid decision-making and guide individual discharge treatment planning.

Frailty has previously been categorized and analysed as a binary concept (simply frail or not), but evidence is emerging that frailty has a linear relationship with post-operative outcomes. A recent study on all emergency surgical admissions (including mainly non-operatively managed patients) found that 90-day mortality incrementally increased with each increase in the Clinical Frailty Score¹⁸. Findings from this current study support this linear relationship of frailty to post-operative outcomes, but this time report the risk of increased care on discharge and length of hospital stay. In particular, the vulnerable patient group (CFS 4) or the so-called pre-frail group carries a higher risk of independence loss alongside longer hospital stays than the fitter older adults of CFs 1-3. Therefore, classifying CFS 4 as non-frail risks overlooking and under-estimating outcomes for these high-risk patients.

Poorer outcomes have been consistently reported with increasing age^{1,20,25-28}. Indeed, results from this study found that age had a similar linear relationship to increased level of care on discharge from hospital found with frailty. However, frailty had greater predictive power and was associated with increases in length of hospital stay reflecting the difficult and prolonged recovery frail patients can have. With greater prognostic stratification, these results highlight that post-operative outcomes from emergency laparotomy cannot be determined by a patient's age.

Concurrent literature

In the surgical setting, frailty was traditionally not considered, but recently, several studies have shown the impact of poorer frailty on short and long term clinical outcomes with the focus being

on mortality^{16,20,25,29-33}. In contrast, there is no published work in relation to frailty and level of care after emergency abdominal surgery. Early evidence does exist in other surgical populations³⁴⁻³⁷. For example McRae et al (2016) recruited 110 patients from vascular surgical patients in Australia and detected frail patients had a longer length of stay and were discharged to a higher level of care³⁴. Supporting these findings, one large study of 1418 older patients from both general medical and orthopedic surgical wards found there was an increase of discharge to residential care in those that were frail.

With it being well established that independent living and return to baseline functional status is an important consideration for an older person, the results from this study provide the first step in improving understanding and addressing an expressed clinical need¹¹. Indeed, the need for strategies specifically for older patients undergoing emergency surgery has been highlighted by both NELA and the High-Risk Surgical Patient working group^{1,7}.

Strengths and limitations

This study included a large UK population from 49 hospitals that was representative of the NELA Audit, showing external validity towards the UK health care model. However, it should be acknowledged that different care pathways exist worldwide and that the conclusions drawn from this work may not be applicable in a different healthcare setting. The data management and validation plan maximised data completion, reduced missing data, and reduced bias. Last, the Clinical Frailty Score appeared to be a simple to use tool, consistently scored by differing members of clinical multidisciplinary teams.

Implications of clinical practice and research

From a surgical perspective, identification of the frail patient would allow development of targeted strategies developed and supported by frailty specialists. This multi-disciplinary approach would involve the surgical, anaesthetic and critical care teams working alongside frailty specialists to implement a CGA that was adapted for frail older adult surgical patients^{25,26}. Future randomised controlled trials are needed to evaluate the clinical and cost effectiveness of post-operative physiotherapy led mobility interventions to increase mobility and reduce frailty, mortality and subsequently improve independence and quality of life. From a patient perspective, frailty is an easy to understand concept unlike many of the other currently used prognostic scores. It is possible that frailty scoring would allow each patient and their next of kin

to have improved understanding of their entire peri-operative course, leading to individualised treatment pathways that achieve their personal needs and wishes⁷⁻¹¹.

Conclusions

Maintaining independence is a priority for an older adult. Irrespective of pre-admission place of residence, frailty was strongly associated with an increased level of care on discharge and prolonged hospital length of stay in older adults undergoing emergency laparotomy. There is need to integrate frailty scoring into acute surgical care to allow improved decision-making and the development of targeted strategies to improve short and long-term quality of life.

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Authors contributions:

Conceived the project (LP, SM); Developed the protocol (BC, JH, JL, KP, LP, SM); led the study (KP, SM), Collected the data (JB, KP, JL, KP, IM, PC, SM), Carried out the analysis (BC), Interpreted the findings (BC, JL, JH, LP, SM), drafted the manuscript (BC, JL, JH, LP, SM), all authors approved the manuscript. SM was the Chief Investigator of the ELF study and was the guarantor of this study. All authors have read and approve the manuscript.

Competing interests:

None of the authors have any conflicts of interest (BC, JB, JL, JH, IM, KP, LP, PC, SM)

Ethics approval and consent to participate

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