Frailty in Older Patients undergoing Emergency Laparotomy: results from the observational ELF Study (Emergency Laparotomy and Frailty).

Kat L Parmar, Jennifer Law, Ben Carter, Jonathan Hewitt, Jemma M Boyle, Patrick Casey, Ishaan Maitra, Ian Farrell, Lyndsay Pearce and Susan J Moug* on behalf of the ELF Study Group.

Kat L Parmar: BSc, MBChB, MSc, PGCE, FRCSEng. Higher Surgical Trainee and Clinical Research Fellow, Manchester Cancer Research Centre, Wilmslow Road, Manchester M20 4GJ. klparmar@doctors.org.uk

Jennifer Law: BMBS, BMedSci, MSc. Higher Surgical Trainee and Clinical Research Fellow, Higher Surgical Trainee, University of Liverpool, Sherrington Building, Ashton Street, L69 3BX. jlaw1@nhs.net

Ben Carter: PhD, MSc. Senior Lecturer in Biostatistics Department of Biostatistics and Health Informatics, Institute of Psychiatry, Psychology & Neuroscience, King's College London, De Crespigny Park, London, UK, SE5 8AF. ben.carter@kcl.ac.uk

Jonathan Hewitt: MB BS, MSc, FRCPGlas PhD. Clinical Senior Lecturer, Department of Population Medicine, 5th floor, NeuaddMeirionnydd, Heath Park Campus, Cardiff University. CF64 2XX. Hewittj2@cardiff.ac.uk

Jemma M Boyle: MB ChB, PGCE, MRCS. Higher Surgical Trainee and Clinical Research Fellow, Royal College of Surgeons of England, 35-43 Lincoln's Inn Fields, London, WC2A 3PE. jboyle@rcseng.ac.uk

Patrick Casey: MB ChB, MRCS. Higher Surgical Trainee, Health Education North West, Three Piccadilly Place, Manchester, M1 3BN. Patrick.casey1@nhs.net

Ishaan Maitra: BSc (Hons), MB ChB, MRCS. Higher Surgical Trainee and Research Registrar, NorthWest Deanery, Lancashire Teaching Hospitals NHS Foundation Trust, Preston, PR2 9HT. ishann.maitra@googlemail.com

Ian Farrell:

Lyndsay Pearce: BMedSci, BMBS, FRCSEng. Locum Consultant Surgeon, Department of Surgery, Salford Royal NHS Foundation Trust, Stott Lane, Salford, M6 8HD. Lyndsay.pearce@srft.nhs.uk

***Corresponding Author:** Susan J Moug, BSc (Hons), MB ChB, PhD, FRCS. Consultant Surgeon and Honorary Clinical Associate Professor, Department of Surgery, Royal Alexandra Hospital, Paisley, Scotland, PA2 9PN. ++44 141 314 6965. susanmoug@nhs.net

Contributions.

LP and SJM conceived and designed the study. KLP, JL, JH, JB, PC, IM, IF and SJM coordinated the trial. KLP, JL, BC and SJM prepared the first draft of the manuscript and were responsible for the final manuscript. KLP, LP, JL, JB, PC, IM, IF and SJM developed the protocol. Patients were recruited by local investigators at each site. BC authored the statistical analysis plan and carried out the analysis. KLP, JL, BC JH, LP and SJM interpreted the data. All authors revised manuscript drafts, approved the final manuscript, and contributed intellectually important content. SJM is the guarantor of the paper and takes responsibility for the integrity of the work as a whole, from inception to published article.

ELF Study Group (contributing authors by site in alphabetical order).

Site	Contributors
Addenbrooke's Hospital	Bryony Ross; Julia Oleksiewicz; Nicola Fearnhead
Blackpool Victoria Hospital	Christopher Jump; Jemma Boyle; Alex Shaw; Jonathan Barker
Bristol Royal Infirmary	Jane Hughes; Jonathan Randall; Isileli Tonga; James Kynaston; Matthew Boal
Countess of Chester Hospital	Nicola Eardley; Elizabeth Kane; Harriet Reader; Sunanda Roy Mahapatra; Michael Garner-Jones
Croydon University Hospital	Jessica Juliana Tan; Said Mohamed
Doncaster Royal Infirmary	Rina George; Ed Whiteman
East Cheshire NHS Trust	Kamran Malik; Christopher J Smart; Monica Bogdan
East Lancashire Hospitals (Blackburn)	Madhu Parna Chaudhury; Videha Sharma; Daren Subar
Furness General Hospital (Barrow)	Panna Patel; Sok-Moi Chok; Evelyn Lim
Glan Clywd Hospital	Vedamurthy Adhiyaman; Glesni Davies
Glasgow Royal Infirmary	Ellen Ross; Rudra Maitra; Colin W Steele; Campbell Roxburgh
Gloucestershire Royal Hospital	Shelly Griffiths; Natalie Blencowe; Emily N Kirkham
Lorn and Islands Hospital (Oban)	John S Abraham; Kirsty Griffiths
Maidstone and Tunbridge Wells NHS Trust	Yasser Abdulaal; Muhammad RafaihIqbal; Munir Tarazi
Manchester Royal Infirmary	James Hill; Azam Khan; Ian Farrell
Mid Essex / Broomfield	Gemma Conn; Jugal Patel; Hyder Reddy
Mid Yorkshire NHS Hospitals	Janahan Sarveswaran; Lakshmanan Arunachalam; Afaq Malik
Milton Keynes University Hospital NHS Foundation Trust	Luca Ponchietti; Krystian Pawelec; Yan Mei Goh; Parveen Vitish-Sharma; Ahmed Saad
Musgrove Park (Taunton)	Edward Smyth; Amy Crees; Louise Merker; Nahida

	Bashir
Newport	Gethin Williams; Jennifer Hayes; Kelly Walters; Rhiannon Harries; Rahulpreet Singh
Ninewells Hospital (Dundee)	Nikola A Henderson; Francesco M Polignano
Queen Alexandra Hospital (Portsmouth)	Ben Knight; Louise Adler; Alexandra Kenchington
Queen Elizabeth Hospital (Birmingham)	Yan Li Goh; Ilaria Dicurzio
Queen Elizabeth University Hospital (Glasgow)	Ahmed Alani; Katrina Knight; Patrick MacGoey; Guat Shi Ng
Royal Albert Edward Infirmary (Wigan)	Naomi Mackenzie; Ishaan Maitra
Royal Alexandra Hospital (Paisley)	Kelly Ong ; Susan Moug
Royal Berkshire Hospital (Reading)	Daniel McGrath; Emanuele Gammeri; Guillame Lafaurie
Royal Bolton Hospital	Gemma Faulkner; Gabriele Di Benedetto; Julia McGovern; Bharathi Subramanian
Royal Devon and Exeter Hospital NHS	Sunil Kumar Narang; Jennifer Nowers; Neil J Smart; Ian R Daniels
Royal Free Hospital (Hampstead site)	Massimo Varcada; Tanzeela Gala
Royal Glamorgan Hospital	Julie Cornish; Zoe Barber
Royal Infirmary of Edinburgh	Stephen O'Neill; Richard McGregor; Andrew G Robertson; Simon Paterson-Brown
Royal Lancaster Infirmary	Thomas Raymond
Royal London Hospital	Mohamed A Thaha; William J English; Cillian T Forde; Heidi Paine; Alpa Morowala
Royal Preston Hospital	Ravindra Date; Patrick Casey; Thomas Bolton; Xuan Gleaves; Joshua Fasuyi
Royal Surrey County Hospital, Guildford	Sanja Durakovic; Matt Dunstan; Sophie Allen; Angela Riga
Salford Royal NHS Foundation Trust	Jonathan Epstein; Lyndsay Pearce; Emily Gaines; Anthony Howe; Halima Choonara

Southmead (North Bristol)	Ffion Dewi; Joanne Bennett; Emile King; Kathryn McCarthy
Swansea	Greg Taylor; Dean Harris; Hari Nageswaran; Amy Stimpson
Tameside Hospital	Kamran Siddiqui; Lay In Lim
University Hospital Crosshouse, Kilmarnock	Christopher Ray; Laura Smith; Gillian McColl
University Hospital of South Manchester	Mohammed Rahman; Aaron Kler; Abhi Sharma; Kat Parmar
University Hospital of Wales (Cardiff)	Neil Patel; Perry Crofts; Claudio Baldari; Rhys Thomas; Michael Stechman
Western General Hospital (Edinburgh)	Roland Aldridge; James O'Kelly; Graeme Wilson
Weston General Hospital	Nicholas Gallegos
Whiston	Ramya Kalaiselvan; Rajasundaram Rajaganeshan
William Harvey Hospital (East Kent	Aliya Mackenzie; Prashant Naik; Kaushiki Singh; Harinath Gandraspulli
Wirral University Teaching Hospital	Jeremy Wilson; Kate Hancorn; Amir Khawaja; Felix Nicholas; Thomas Marks
Wrexham	Cameron Abbott; Susan Chandler

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Transparency declaration

The corresponding author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

What this paper adds

This is the first study to assess the influence of frailty in the older adult undergoing emergency laparotomy, finding frailty to be both prevalent and more predictive of post-operative mortality and morbidity than age. These findings support routine frailty scoring to: aid prediction of older adult outcomes in the emergency surgery setting; potentially improve patient surgeon interaction and understanding and to allow evaluation of novel and targeted

Section 1: What is already known on this subject

- Frailty has been shown in medical and elective surgical settings to be predictive of older adult (≥65 years) outcomes leading to the development of the role of geriatric-surgeon multi-disciplinary teams that have improved short-term outcomes.

- Frailty has not been assessed in older adults undergoing emergency laparotomy, despite this population accounting for the majority of adults undergoing emergency surgery in the U.K. and carrying the highest risk of 30-day mortality.

Abstract

Objectives To document the prevalence of frailty in older adults undergoing emergency laparotomy and to explore the relationship of frailty to post-operative morbidity and mortality.

Design Observational study.

Setting Multi-center (n=49) U.K. acute general surgical units.

Participants Nine hundred and thirty-seven older adults (65 years and older) admitted as a surgical emergency requiring emergency laparotomy between March and June 2017. Exclusion criteria followed that of the U.K. National Emergency Laparotomy Audit (NELA).

Intervention Pre-operative frailty score using the Clinical Frailty Score (CFS): ranging from 1 to 7 with CFS 1-4 defined as non-frail; CFS 5-7 as frail.

Main outcome measures Prevalence of frailty and mortality at 90 days post-operative with comparison to pre-operative frailty score. Secondary outcomes included 30-day mortality and morbidity, length of critical care and overall hospital stay.

Results Frailty was present in 20% of participants with an overall mortality for older adults undergoing emergency surgery of 19.5% at 90 days. After adjusting for age and sex, the risk of 90-day mortality for frail older adults was directly associated with frailty: CFS 5 had aOR of 3.18 (95%CI 1.24 to 8.14) and CFS 6/7 aOR 6.10 (95%CI 2.26 to 16.45) compared to the non-frail group (CFS 1). Similar findings were found for 30-day mortality. Frailty was also associated

with a significantly increased risk of complications, length of critical care stay and overall hospital stay.

Conclusions Frailty is prevalent in the older adult undergoing emergency surgery and places the frail older adult at significantly greater risk of post-operative mortality and morbidity, irrespective of their age. Frailty scoring should be integrated into routine practice to aid decision-making with older patients and allow development of novel post-operative strategies to improve outcomes in this high-risk population.

Introduction

Emergency abdominal surgery is performed in every acute U.K. hospital for a wide range of pathologies with the common aim to prevent death and minimise life-altering complications. The majority of these emergency laparotomies are performed on older adults (65 years and older) that when compared to younger adults, have the highest post-operative mortality and morbidity, the highest utilisation of intensive care resources and subsequently, the longest hospital stays [1-5]. This older adult population has different clinical needs from younger adults as a consequence of a higher prevalence of multi-morbidity, cognitive impairment, polypharmacy and frailty, yet little work has been performed to improve understanding of this high-risk group undergoing emergency surgery [1,6,7]. Furthermore the clinical application of widely used prognostic tools to guide decision-making are potentially limited as many were developed from younger, healthier and frequently, elective patient cohorts [8-13]. With the population ageing it is clear that there is an urgent clinical need to develop accurate risk assessment tools that could allow targeted peri-operative strategies for this expanding complex group of health service users [1,15-18].

Frailty is an objective measure of increased vulnerability and decreased physiological reserve, resulting from the age-associated accumulation of deficits in multiple physiologic systems [19]. It results in decreased resilience to any physiological insult such as surgery, preventing recovery or return to the pre-existing functional level. In the medical setting where much of the frailty work has focused, routine frailty assessment on older adult admissions accompanied by interventions to modify frailty such as the multi-disciplinary, multi-

dimensional Comprehensive Geriatric Assessment (CGA), have led to improved survival and an ability to return to their pre-admission residence [20,21]. In relation to surgery, two recent meta-analyses assessed the influence of frailty in older adults admitted to general surgical units with the presence of frailty (ranging from 0.5 % to 67.2%) leading to significant increases in 30-day mortality, complications and hospital stay [22,23]. Although promising, the inclusion of lower risk elective surgical patients and/or those admitted as an emergency but managed non-operatively, mean the prevalence of frailty and its' influence on post-operative outcomes in the high-risk emergency laparotomy setting remains unclear.

The primary aims of the Emergency Laparotomy and Frailty (ELF) Study were to determine the prevalence and influence of frailty on 90-day mortality in older adults undergoing emergency laparotomy. The influence of frailty on post-operative outcomes including 30-day mortality, morbidity and length of stay were also explored as secondary aims.

Methods

From March to June 2017 (3 months' duration) all older patients (defined as 65 years and older, Office for National Statistics) [14] undergoing emergency laparotomy at forty-nine registered sites in the U.K. were screened for inclusion into the ELF Study. This multi-centred prospective cohort 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).

Ethical approval was obtained from National Health Service Research Ethics Committee (Black Country Research Committee: November 2016; 16/WM/0500). The study was registered centrally with the Health Research Authority (England), the NHS Research Scotland Permissions Co-ordinating Centre (Scotland) and the Health and Care Research Permissions Service (Wales). The ELF study was registered online at www.clinicaltrials.gov (NCT02952430).

Site recruitment

Participation from sites across the U.K. was invited using presentations at the National Research Collaborative meeting and the use of social media with 56 surgical centres from England, Scotland and Wales registering. Completed anonymous datasets were entered into a specifically designed online secure electronic database (REDCap, www.project-redcap.org) developed and maintained by the North West Surgical Trials Centre (www.nwstc.org.uk).

Patients

The full protocol was developed then published in October 2017 according to STROBE Guidelines [24,25]. Inclusion criteria were consistent with the established U.K. National Emergency Laparotomy Audit [NELA; www.nela.org.uk/criteria] [1]. In general, older patients were included if undergoing an expedited, urgent or emergency surgical abdominal procedure for gastrointestinal pathology (laparoscopic or open procedure) and/ or returning to theatre for any major post-operative complication/dehiscence. Patients were excluded if no frailty score was recorded or if undergoing: elective surgery; diagnostic laparotomy/ laparoscopy with no further procedure performed; surgery for appendiceal, biliary, oesophageal, splenic, nephric, hepatic, urological or gynaecological pathology unless in addition to another gastrointestinal pathology requiring surgical intervention; hernia repair not requiring bowel resection and laparotomy/ laparoscopy performed due to blunt/penetrating trauma.

Data Collection

Pre-operatively, each older adult had the following recorded: age and gender; number of co-morbidities (allowing calculation of Charlson Co-morbidity index, CCI and multi-morbidity ≥2 chronic co-morbidities) [9]; independence status (selected from: home - no carers; home with carers; residential home; nursing home, intermediate care, other) and polypharmacy (5 or more current medications). ASA grade (American Society of Anaesthesiologists Grade) [11] and P-POSSUM score were calculated as both are routinely collected as part of the NELA

[12,13]. The indication for surgery was documented and in theatre, the actual surgery performed was recorded.

Post-operatively, each patient was followed up for 90 days to record the primary outcome of mortality at 90 days. For the first 30-days post-operative, mortality was also recorded in addition to: post-operative complications; length of critical care stay (level 2 High Dependency Unit, HDU and level 1 Intensive Care Unit, ICU); overall length of hospital stay and readmission to hospital.

Frailty Scoring

Frailty was assessed pre-operatively using the Clinical Frailty Score (CFS) developed by the Canadian Study of Health and Ageing (CSHA) [26; Appendix 1]. This 7-point progressive score was developed within an older adult population and is based on clinical judgment with a score of 1 to 4 being classified as non-frail and 5 to 7 as frail. The CFS has been found to be a valid and reproducible score in addition to being easy to understand and simple to apply. OPSOC has used the CFS previously to assess frailty in the emergency surgical population [27].

Data Completion and Validation

Regular emails to each registered site and twitter (@ELFstudy) were used to motivate data collection and update ELF Collaborators. To ensure accurate data collection, data validation was performed on 25% data fields for 10% cases at each site after study completion.

Statistical analysis

Sample size justification from previous publication: To detect a 10% difference in post-operative Day 90 mortality between frail and non-frail patients (7.5% versus 17.5%), a sample size of 480 was required to maintain 80% power and 5% significance [27].

The primary analysis was performed using a multi-level logistic regression of 90-day mortality by frailty, adjusted for age (65–74, and >75 years old) and gender. Each recruiting hospital was fitted as random effects to account for site variation. A secondary analysis of the primary outcome was carried out by presenting the crude OR, and adjusted OR with associated 95% CIs and p values. Length of stay was analysed with a zero inflated negative binomial regression, and presented as the mean increased length of stay (in whole day integers) with associated 95% CI. We carried out an exploratory analysis to investigate the distribution of day 90 mortality, within age and frailty to determine if our findings could be explained in part by patient age. All statistical analysis was carried out using Stata 14 (StataCorp; www.stata.com).

Results

Patients and Procedure

A total of 956 older adults undergoing emergency surgery were recruited with nineteen patients excluded, leaving 937 patients in the final analysis (Supplementary Figure 1).

Table 1 displays the pre-operative patient characteristics by frailty score. Overall frailty (CFS 5,6 and 7) was present in 20% of older adults undergoing emergency surgery. The mean age of the patients was 76.22 years (SD 6.82; range 65 – 99) with over a third (38%) aged 80 or older. Eighty-nine percent of older adults reported co-morbidity; 54% poly-pharmacy and the majority (83%) were admitted from home with no carers in place. Pre-operative ASA was 3 or more in 66% of cases.

The commonest indication for surgery and actual surgery performed were intestinal obstruction (54%) and adhesiolysis (25%) performed by an open approach (87%), in keeping with the NELA 3rd report (Supplementary Table 1) [1]. Fifty percent of patients had a post-operative complication with the median length of overall hospital stay being 3 days (IQR 1-6) and 13.7% (123/ 899) were re-admitted to hospital within 30 days of discharge.

Frailty and 90-day Post-operative Mortality

Overall day 90 mortality was 19.5% and was directly associated with frailty: the highest frailty scores (CFS 6 and 7) had the highest risk of 90-day mortality (OR 5.89, 95% CI 2.19 to 15.86; p=0.001) compared to CFS 1 (very fit) (Table 2). After accounting for patient age and sex, the adjusted odds ratio (aOR) of day 90 mortality for patients who were mildly frail (CFS 5) and moderately/ severely frail (CFS 6/7) was aOR of 3.18 (95%CI 1.24 to 8.14; p=0.016) and 6.10 (95%CI 2.26 to 16.45; p<0.001) respectively compared to CFS 1 (very fit).

Frailty and Secondary Outcomes

Overall 30-day mortality was 14.6% (137/ 937) and a similar association with frailty was seen for 30-day mortality as for 90-day mortality: CFS 5 aOR 9.79 (95%CI 2.23 to 42.91; p=0.002) and for CFS 6/7 aOR 10.40 (95%CI 2.24 to 48.18; p=0.003) [Table 2]. Furthermore frailty was associated with a significantly increased risk of post-operative complications: CFS 5 aOR 4.56 (95% CI 2.17 to 9.60; p=0.001) and CFS 6/7 aOR 3.92 (95%CI 0.35 to 4.19; p=0.001) compared to those older adults scoring CFS 1.

There was a significant association between an increased length of hospital stay and stay in ICU in frail patients (Table 2). For overall length of hospital stay: CFS 5 aOR 1.44 (95% CI 1.10 to 1.89; p=0.008) and CFS 6/7 aOR 1.62 (1.19 to 2.20; p=0.002) compared to adult scoring CFS 1. For ICU length of stay: CFS 5 aOR of 2.15 95%CI 1.15 to 3.96; p=0.02) and CFS 6/7 aOR 4.18 (95% CI 2.11 to 8.03; p<0.001) compared to CFS 1. In the context of median number of days, frail patients stayed in hospital post-operatively for 3 days (IQR 1-6) versus non-frail of 3 days (IQR

1-5) and in ICU for 2 days (IQR 1-4) versus 1 day (IQR 0-3) for non-frail. There was no association with frailty to the length of time in HDU or to 30-day re-admission.

Frailty, by Age mortality distribution

Tables 3A and 3B show that frailty is distributed throughout the range of ages and not restricted to the very old age patient groups (85+). Observation of this distribution shows that patients with a poorer frailty score had a higher mortality rate. The marginal 90-day mortality rates were increased from 11.1% to 50% for CFS of 1 to 7 and the marginal mortality rate for increased patient age was 15.9% to 25.3% for patients aged 65-70, compared to those aged 85-90 (Table 3A). Similar results were found for the Day 30 mortality showing that frailty results in a wider distribution of predicted mortality than age (Table 3B). In addition when compared to P-POSSUM, it can be seen that frailty stratifies the older adult into a greater number of prognostic groups and also allows risk-prediction of 30-day morbidity through the range of scoring, whilst P-POSSUM does not [Table 4].

Discussion

This study is the first to prospectively document the prevalence of frailty in older adults undergoing emergency surgery, finding frailty present in a fifth of patients that places them at significantly greater risk of 30- and 90-day mortality. In addition, the frail older adult carries a higher risk of developing post-operative complications with longer stays in intensive care and in hospital overall. With frailty found to be independent of age, this work supports integration of frailty scoring to all older adults admitted as a surgical emergency to guide peri-operative strategies for this high-risk complex population.

Strengths and weaknesses of the study

There are several strengths to this work. First, it focused solely on a large population of older patients undergoing emergency laparotomy improving understanding of this overlooked group that carry the highest risk for post-operative death. Second, the data was collected prospectively and was multi-centred minimising geographical bias that could occur with local or regional studies. Third, validation of a proportion of each site's data optimised data completion. Fourth, the Clinical Frailty Score (CFS) appears to be simple to use with only a small percentage of frailty scores not entered despite the substantial over-recruitment to this study.

The authors cannot exclude selection bias where a local recruiter may have not contributed a consecutive series of older patients undergoing emergency laparotomy. This is likely to reflect the pragmatic nature of this work with many of these patients having multiple urgent health

professional inputs and investigations to optimise their care that could mean frailty scoring was missed.

Strengths and weaknesses in relation to other studies

The largest prospective multi-centred U.K. study (n=324) using the CFS found frailty in 28% of older adults admitted to emergency surgical units resulting a longer length of stay and greater risk of mortality at 30 and 90 days [27]. However, with only 31% of these older adults undergoing surgery of which a third were classified as minor or intermediate, definite conclusions from this work on the influence of frailty on high-risk emergency laparotomy outcomes are limited. Other groups focused completely on older patients undergoing emergency surgery and despite using different frailty scores, all found poorer outcomes, including 30-day mortality, in frail older adults. However, both publications are single centred, small in number (<250) and have differing definitions of emergency surgery, unlike the clearly defined NELA criteria applied in this current work [28,29]. The largest study comes from over 35 000 patients collected as part of the National Surgical Quality Improvement Program (NSQIP) [30]. Using an 11-point frailty score on patients aged at least 60 years undergoing emergency laparotomy, this group found that as frailty increased, poorer post-operative outcomes including morbidity and 30-day mortality significantly increased, findings that are in keeping with our results. However our current work has several strengths over the larger NSQIP publication; it is prospective with a clear definition of emergency laparotomy, powered for its' primary outcome and uses an established frailty score.

Clinicians have long been interested in prognostic scores with many being available including the well known APACHE II, Charlson Age-Cormobidity Index, ASA and P-POSSUM. All have their limitations including: predicting mortality only (APACHE II, ASA); multiple variables making calculation labour intensive (APACHE II); not validated in older adult populations (Charlson, ASA) or require intra-operative details to complete score (P-POSSUM) [8-13]. Indeed, NELA have acknowledged and circumvented such limitations by using P-POSSUM to define a high-risk patient to trigger specific process pathways rather than determine prognosis [1,16]. The Clinical Frailty Score in comparison predicts both morbidity and mortality, is straightforward to calculate, is validated in older adult surgical populations and can be determined pre-operatively.

Meaning of the study: possible explanations and implications for clinicians and policymakers

One potential intervention for the frail older adult undergoing emergency laparotomy is early geriatrician involvement to perform a Comprehensive Geriatric Assessment (CGA) [1, 16]. The multi-disciplinary approach of the CGA (physiotherapy, nutrition, pharmacy, occupational health as examples) has been used in many acute medical settings with a recent Cochrane meta-analysis concluding there was high evidence a CGA performed on admission increased the likelihood that older adults will be alive and in their own homes at 3 to 12 months follow-up [31,32]. In the trauma emergency setting, achieving orthogeriatrics input in 88% of cases within first 72 hours in hospital has resulted in improved outcomes in hip fracture care [33]. In

contrast, despite the 2nd NELA report recommending early geriatrician input to optimize older patient outcomes after emergency laparotomy, their 3rd report stated only 19% of older adults had received such input, despite 97% of contributing hospitals having access to on-site specialist geriatric services [1].

One potential reason for this disparity is that recovery from high-risk abdominal surgery presents a different set of post-operative complications from orthopaedics, where early recognition of such complications by an experienced surgeon allows prompt initiation of treatment including when an urgent return to theatre is needed. However, such a surgeon is unlikely to be trained specifically in management of the older adult, creating an opportunity for targeted training within both surgical and geriatric curriculums to allow multidisciplinary peri-operative care in a modified surgical CGA [7, 34]. Development of a surgical CGA could optimise the high-risk surgical older adult addressing their individual complex and multi-dimensional needs rather than the traditional single organ approach.

Decision-making in emergency surgery can be complex which is why clinicians developed prognostic scores to guide them in addition to improving communication between different specialties, but this is potentially at the expense of the patient as few are easy to understand [35]. Frailty is a concept that many patients will already be aware of which may lead to improved engagement with the patient and their next of kin when discussing not only their operative risks of dying, but of having significant life-altering complications and a prolonged

and difficult recovery in hospital. Establishing realistic treatment goals as part of that shared decision-making can be time-limited and within emotive circumstances making it paramount that the patient and their family gain all the relevant information [36-38]. To aid such decision-making, future work should focus on long-term outcomes for those older frail adults that survive in particular loss of independence, diminished quality of life and place of discharge.

Conclusion

Frailty is present in 20% of older adults undergoing emergency surgery, placing them at significantly higher risk of post-operative mortality and morbidity when compared to non-frail adults. These findings support the integration of frailty assessment of older adults prior to undergoing emergency surgery and clarify the clinical need for the development of novel post-operative strategies to improve short and long-term outcomes for this expanding complex group of health service users.