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Prevalence of Frailty and Reliability of Established Frailty Instruments in Adult Elective Colorectal Surgical Patients: a Prospective Cohort Study

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Abstract

Purpose: Large population studies now demonstrate that frailty is prevalent in all adult age groups. Limited data exist on the association between frailty and surgical outcome in younger patients. This study explores the agreement between frailty identification tools and their predictive value for frailty-associated outcomes in an adult surgical population.

Study Design: Prospective cohort single-centre study, conducted in surgical preassessment. The Clinical Frailty Scale(CFS), Accumulation Deficit(AD) and Frailty Phenotype(FP), frailty instruments were used for all patients and analysed for prevalence, agreement and relationship with outcomes.

Results: Frailty was assessed in 200 patients (91 male), mean(range) age 57(18-92) years. The prevalence of pre-frailty was 52-67% and that of frailty 2-32% depending on the instrument used. Agreement between the instruments was poor(kappa range 0.08-0.17). Outcome data were available on 160 patients. Only the frailty phenotype was significantly associated with adverse outcomes, odds ratio 6.1(1.5-24.5) for postoperative complications. The instruments studies had good sensitivity (CFS-90%, AD-96%, FP-97%) but poor specificity (CFS-12%, AD-13%, FP-18%) for the prediction of complications. All instruments were poorly predictive of adverse outcomes with likelihood ratios of CFS-1.03, AD-1.03 and FP-1.12.

Conclusions: This study showed a significant prevalence of pre-frailty and frailty in adult colorectal surgical patients of all ages. There was poor agreement between three established frailty scoring instruments. Our data do not support the use of current frailty scoring instruments in all adult colorectal surgical patients. However, the significant prevalence of pre-frailty and frailty across all age groups of surgical

patient justifies further research in this field.

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Key words: Frailty, Surgery, Colorectal

What is already known:

- There appears to be a relationship with severity of frailty and adverse surgical outcomes.
- There are various forms of frailty identification, with different philosophical approaches.
- Whilst frailty is associated with age, frailty (/ pre-frailty) can be present in younger populations.

Main messages:

- There is a significant number of surgical patients presenting with pre-frailty (52-67%) or frailty (2-32%).
- The three frailty identification instruments used in this study had a high sensitivity but low specificity for adverse postoperative outcomes.

Background

The term frailty describes a lack of physiological resilience.[1] Frail patients recover slowly from illness and insults such as surgery. Frailty is generally understood to relate to ageing, places a significant health burden on many older adults, and has been reported to be associated with adverse outcome in older patients undergoing various types of surgery.[2-4]

Elective colorectal surgery is associated with a significant risk of complications with postoperative morbidity rates of up to 35% reported in some studies. [5] Frailty is likely to contribute to the burden of postoperative complications in older surgical patients. [6] One study identified 43% of colorectal cancer patients as frail.[7] Whilst frailty is most common in the elderly, a significant population burden of frailty is reported in younger adults and may impact on surgical outcomes across all age groups. A large Canadian study reported a prevalence of frailty of between 1.8% and 11.6% in patients aged less than 65 years, depending on frailty instrument used and the age group studied.[8] A small study of emergency surgical admissions found a prevalence of frailty in patients aged under 65 of 16%, and was associated with a five-fold increased risk of postoperative mortality.[9] These studies examine mixed surgical populations. Colorectal surgery carries a significant risk of postoperative complications.

The identification of frailty in surgical patients brings its own challenges. A number of clinical scoring systems for the identification of frailty are available. The extent of agreement between these scores is variable.[10] The optimal scoring system for identifying surgical patients at risk of complications is unclear.

Widely-accepted frailty assessments include the Accumulation Deficit (AD) model, the Frailty Phenotype (FP) model, and the Clinical Frailty Scale (CFS).[11-13] The AD model uses the presence of co-morbidities, disabilities, clinical signs and symptoms to generate a frailty index.[11] The FP model (often known as the Fried model) rests on measurements in five domains: weight loss, mood, activities of daily living, functional gait speed and grip strength.[13] Both the AD and FP instruments can be time consuming to use in clinical practice. The Clinical Frailty Scale (CFS) is an estimate of the patient's fitness made by an experienced clinician or investigator. The patient is allocated to one of nine categories ranging from one (very fit) to eight (very severely frail) and nine (terminally ill). Its use for the rapid evaluation of frailty status is well described.[14-15] The classification of patients into frail, prefrail and not-frail categories arises from the FP model and has been shown to be a valid approach to characterising the frailty syndrome.[16] It has been mapped to other frailty instruments and is widely used in clinical practice.[17-19]

The objectives of this study were collect initial data on the prevalence and impact of frailty in all adult colorectal surgery patients (as opposed to only older patients); to assess the agreement between the CFS, AD and FP in this colorectal surgical population, and to determine the association between the three frailty instruments and post-operative complications.

Methods

Ethical approval was received from the West Midlands UK Research Ethics Committee (15/WM/0148). Data collection was performed adhering to the STROBE Statement and associated checklist. Adult elective colorectal (cancer and non-cancer) surgical patients were recruited in the surgical pre-assessment clinic at St James' University Hospital. Patients were eligible for the study if they were aged over 18 years, fluent in English or had an NHS translator present, and were attending the pre-assessment clinic prior to elective colorectal surgery. Patients were excluded if they were taking anti-Parkinsonian medication or anti-depressants as Parkinson's disease, depression and the effects of related medications impact on the assessment of frailty.[1] Clinical staff identified candidates for the study; the study was explained, and consent recorded by the investigators. Frailty assessments were performed by the investigators in the surgical pre-assessment clinic.

Full details of the frailty assessment instruments used in this study are given in the relevant methodology papers.[11-13] Patient characteristics were recorded from the clinical proforma routinely used for all patients attending the clinic. Frailty assessments were performed consecutively in the order of CFS, the AD model and finally the FP assessment. Assessments were timed and patients were classified as non-frail, pre-frail or frail according to each frailty assessment. For practical reasons, the CFS was timed using five-second increments. The CFS frailty score was measured first to ensure that it was based on the usual pre-assessment process and overall impression of the patient and was not influenced by the results of the AD and FP instruments. Surgical, ward and anaesthetic staff were blinded to the frailty

scores throughout the study, to avoid impacting on routine care.

Post-operative data were recorded from the patients' records for up to 30-days following their procedure. Data were collected on post-operative complications classified by Clavien-Dindo score,[20] postoperative mortality length of stay, and readmission within 30-days of surgery. The difference between observed and expected length of stay was calculated for each patient using local hospital data on median length of stay for each operation.

Analyses were performed using SPSS (IBM Statistical Package for the Social Sciences for Mac, Version 24.0, IBM Corp., Armonk, New York, USA). Correlations between frailty instruments were calculated and agreement was examined using the Kappa statistic. The differences between the frailty instruments were analysed using the chi-squared statistic. The differences in time taken to perform the AD and FP methods were analysed using a paired t-test. Assessments of frailty may take longer in more frail patients; we examined the correlation between the time taken to complete the FP and AD scores and the frailty scores themselves using Pearson's correlation coefficient. The differences between frailty scores by sex were analysed using the Mann Whitney-U test.

The associations between postoperative outcome and frailty as assessed by the different instruments were analysed. We combined pre-frail and frail categories for the analyses of the association between frailty and surgical outcomes. Analyses of contingency tables for frailty and surgical outcomes were used to examine the predictive values of the frailty instruments for surgical outcomes. Risk ratios and

likelihood ratios were used to test if the knowledge of a frailty score would materially change the expectations of a patient's post-operative recovery. A formal power calculation was not undertaken due to the lack of robust data on the association between frailty and outcome in non-elderly colorectal patients to inform such a calculation. We aimed to collect prevalence data on 200 patients over a six-month period starting July 2015. Follow-up data were collected on 160 patients over eight months at which point the study was closed for logistical reasons. A listwise deletion approach was adopted for analysis regarding outcomes.

Results

Two hundred patients (91 male) were recruited into the study. The mean(range) age of participants was 57(18-92) years, with 61% being less than 65 years of age. No patients withdrew from the study.

The results from the three frailty instruments are presented in Table 1. The prevalence of frailty ranged from 1.5% to 32% depending on the instrument used. There was a statistical difference in the prevalence of frailty and pre-frailty between the three frailty instruments ($P<0.001$). All three methods reported a relatively high prevalence of pre-frailty, ranging from 51.5% to 66.5%. There was no difference in the prevalence of pre-frailty and frailty between the sexes (CFS, AD and FP; $P=0.530$, $P=0.196$, $P=0.183$ respectively).

There was statistically significant moderate correlation between the three frailty instruments with R-values from 0.30 to 0.46. There was little agreement with the kappa statistic for pairwise comparisons ranging from 0.08 to 0.17. (Table 2)

Mean(SD) times for undertaking the assessments were CFS 7(3) sec, AD 224(108) sec, and FP 340(83) sec. The CFS was so much quicker than both AD and FP methods to perform that it was unnecessary to undertake formal statistical testing to confirm the differences. The AD instrument was quicker than the FP (paired t-test, $P<0.001$). The CFS and FP displayed weak positive correlations between time taken to perform the assessment and severity of frailty as measured by the same tool ($R=0.279$, $P<0.001$ and $R=0.154$, $P<0.001$ respectively). For the AD tool, there was

moderate correlation between the severity of frailty and the time taken for the assessment (R=0.549, P<0.001).

During the study, 160/200(80%) participants underwent surgery during the study. Thirty-six patients had not undergone surgery by the point the study had concluded, two were deemed medically unfit for surgery, one had surgery delayed allowing treatment of co-morbid disease, and one patient died prior to the surgery being performed. In the remaining cases the patient was awaiting surgery at the end of the study.

Eighteen(11%) of the 160 patients had one or more post-operative complications and 10(6%) patients were re-admitted within 30-days of surgery. Of the 18 patients with post-operative complications, six had Clavien-Dindo scores of 1, six scored 2 and six patients scored 3 (Table 3). The median(range) difference between actual and expected length of stay was 0(-2 to 21 days).

The FP was significantly associated with postoperative complications, risk ratio(95% CI) 6.1(1.5 - 24.5), readmission within 30 days of surgery 3.4(1.1 - 10.4), and extended length of stay 1.8(1.1 - 10.4). The Clinical Frailty Scale was significantly associated with extended length of stay 1.8(1.2 - 2.8). Other associations were not significant (Table 4).

The sensitivity, specificity, positive predictive value and negative predictive value of frailty for post-operative complications (Clavien-Dindo score of $\geq$1) and 30-day readmission and extended length of stay are reported in Table 4. The sensitivity of

the three instruments was high for all outcomes. However, many patients classified as pre-frail or frail did not suffer adverse outcomes, resulting in a high false-positive rate and low specificity with all three instruments. For post-operative complications, the sensitivity of the instruments ranged from 90% to 97%, whereas the specificity ranged from 12% to 18% depending on the frailty instrument used. For all surgical outcomes, positive predictive values ranged from 16% to 50%, and negative predictive values ranged from 69% to 94%.

The likelihood ratios for the CFS, AD and FP instruments were 1.02, 1.09, and 1.17 respectively for postoperative complications; 1.03, 1.03 and 1.12 respectively for 30-day readmission and 1.22, 1.14 and 1.23 respectively for extended length of stay. As the likelihood ratios are close to unity, classifying an individual as frail or pre-frail using any of the three instruments studied does not materially change the expectations of an adverse outcome for an individual.

Discussion

Pre-frailty is common in adult colorectal surgical patients of all ages, a consistent finding across three different frailty assessment instruments. This study aimed to identify the agreement between CFS, FP and AD assessments. There was imperfect agreement between the instruments as to which patients were classified as frail and pre-frail. There was a significant association between being classified as pre-frail or frail by the FP instrument and the adverse outcomes studied. The CFS was associated with extended length of stay but not with other outcomes. Being identified as pre-frail or frail had very good sensitivity for the identification of postoperative complications, but poor specificity. The high false-positive rate limits the postoperative predictive value of frailty assessments. The findings of this pilot study have implications for current clinical practice and for the design of future research

The burden of frailty in older patients presenting for colorectal surgery and its impact on outcome are well described.[7, 21-22] Large epidemiological studies demonstrate that frailty is common in older patients but affects all age groups. Data from the Canadian Heath Measures study showed a prevalence of frailty as assessed by the frailty phenotype ranging from 1.8% in the 18-34 age group to 11.6% in the 50-64 age group and 20.2% in people aged 65 years or older.[8] UK Biobank data on 493,737 people aged 37-73 years demonstrated a 3% prevalence of frailty and a 38% prevalence of pre-frailty.[23] Our finding of a high prevalence of pre-frailty in the adult colorectal surgical population of all ages is consistent with the results from the UK Biobank.

Data on the association between frailty and perioperative outcome in younger adults

are sparse. The association between frailty and perioperative outcome may not be constant across all ages in elective settings. Promising data from a recent multi-centre UK study identified that the CFS was predictive of mortality in emergent surgical admissions regardless of age [24]. Although frailty denotes a loss of physiological resilience, younger patients classified as frail may be better able to recover from surgery than their older peers (but less well than non-frail patients) in elective cases. It is likely that the acute disease and frailty status combined amplifies complication rates for emergent presentations and equalises the risk for younger and older frail patients, in comparison to the elective population in this study.

In the current study, all three instruments studied had ≥90% sensitivity for the prediction of postoperative complications. However, we also found a high false positive rate. Many patients identified as pre-or frail did not experience a postoperative complication. The frailty instruments studied had poor specificity for the identification of postoperative complications (12-18%). Consequently, all three instruments had likelihood ratios close to unity for the prediction of postoperative complications.

Whilst there were mild-to-moderate correlations between scores across the three instruments(R=0.30-0.46), agreement between the instruments was modest at best(K=0.08-0.17). This is consistent with findings in non-surgical patients. A study which used data from the English Longitudinal Study of Aging to compare 35 different scores and found substantial variation in the associations between the different scores and seven year all-cause mortality, cardiovascular disease, and cancer.[25] A review of instruments to detect frailty in community dwelling adults identified seven instruments examined in three studies and reported important

variation in the performance.[26] Most, if not all, instruments used to study frailty in surgical patients were first developed and validated in the community setting. It cannot be assumed that they are suitable for use in surgical patients. Different instruments use different constructs of frailty. The FP includes assessments of function (grip strength and walk speed) and brief questionnaire on leisure activity, depression and exhaustion.[13] The AD assumes the increased history of co-morbidities indicates increased frailty severity.[27] The CFS is based on a global assessment of frailty.[14-15] It is argued by some authors that the frailty phenotype best reflects the condition of frailty (as opposed to the accumulation deficit model reflecting a burden of aging and comorbid disease).[28] Proponents of the cumulative deficit approach to characterising frailty suggest that this approach gives an inclusive view of the changes associated with biological (as compared with chronological) aging.[11] The AD approach can be implemented using routinely collected clinical information and may be automated for use in electronic records.[29] A pragmatic approach should take into account both the ease of assessment and the strength of association with surgical outcome. Whilst this study identifies imperfect agreement in a single-centre, it cannot be assumed this is the case for all pre-assessment clinics. The weak kappa values identified in this study are of particular concern. Frailty is recognised in the International Classification of Disease(ICD)-10 as age-related physical debility, though there are arguments for frailty to be recognised in its own code in the new ICD-11. One barrier to this will stem from the significant disparity between available identification instruments. In order for frailty to be appropriately coded, operational definitions of frailty must have reasonable universal understanding. Poor agreement between operational definitions of **frailty further obscures a universally understood meaning of what it is to be frail. The poor**

agreement identified in this study is likely due to patients having a comorbid history, increasing the AD prevalence, without impacting on patients' physical performance and subsequent FP result. Additionally, it may be that whilst frailty is prevalent in an elective surgical population, one instrument may be more accurate in this group than the others. Without a clear gold-standard scoring system for frailty, it is difficult to identify which of the three is most accurate in this setting, and which of the three instruments would need further refinement before they could be accurately used in surgical pre-assessment. Further research into the optimal frailty assessments, supporting evidence for a gold-standard instrument, is welcomed.

The time taken for an assessment is an important consideration for its implementation into practice. The CFS was quick to perform yet had poor association with outcomes. This may reflect the fact the CFS was originally designed to summarise the output of a comprehensive geriatric assessment rather than to be used as a tool in its own right. It has evolved with an expansion of the scale from seven to nine points and its seemingly intuitive format has made it attractive as a tool for rapid assessment.[14-15] However, some guidelines point out that it was not originally designed as an assessment instrument and should not be used for this purpose.[30] The AD was quicker to perform than the FP but again in this study had limited power to predict outcome. The FP was consistent in its time to complete and had the highest likelihood ratios for the prediction of adverse outcomes. Our data suggest that the FP is best of the instruments studied for the identification of frailty across all age groups. However, it is more time consuming to use than other instruments and requires the use of a handgrip dynamometer which incurs addition

equipment costs. The likelihood ratio of 1.12 for the FP tool, whilst better than that for the other two instruments, suggests that it is a relatively weak tool for predicting outcome and does not support its routine use. Studies to refine this approach for use in surgical patients may be of value. The cut-off values originate in non-surgical settings and may not be applicable to the analysis of risk in the perioperative setting.[19]

There are a number of limitations of the current study. This was a single centre study reflecting the surgical population and practice in a one surgical unit. Frailty instruments were studied in a fixed order. This was done to reflect the use of the CFS in other studies by ensuring that assessment based on a global impression of the patient was not influenced by the more detailed FP and AD instruments. It brought with it the risk that the CFS could itself bias the other assessments. This was mitigated by the structured nature of the FP and AD instruments, but bias cannot be excluded. Resource constraints limited patient follow-up so that not all patients could be followed to surgery, death, or an explicitly documented decision not to operate. We collapsed 'pre-frail' and 'frail' into one group to investigate the associations between frailty and surgical outcomes. This approach allowed the examination of the frailty instruments for the binary classification of patients for the purpose of preoperative risk stratification but involved the loss of some information. **The frailty instruments adopted in this study were intended to identify frailty in older adult populations, and it may be that these tools need further revisions to become more accurate at identifying the prevalence of a true frail presentation and a stronger representation of their relationship with adverse surgical outcomes. However, this study provides valuable pilot data for further**

research into the use of these instruments in younger populations.

Conclusions

In summary, we studied three frailty assessment instruments, all of which demonstrated a significant prevalence of pre-frailty but a low prevalence of frailty in the adult colorectal surgical population at all ages. Data suggest that pre-frailty is present in all age groups, consistent with population-wide data from large studies. We found a lower prevalence of frailty than has been reported in the general population. This may reflect the selection of patients for surgery. We did not find pre-frailty/frailty to be strongly predictive of surgical complications. This may reflect the fact that we studied all adult age groups or it may be that pre-frailty is less predictive of adverse outcome in younger patients. The three instruments were inconsistent in identifying frailty. The purpose of identifying frailty in the pre-assessment clinic is to inform decision making and to allow appropriate modifications to perioperative care. Labelling a patient as pre-frail or frail has implications for the patient, the care pathway and resource use. Our data do not support screening for frailty across all adult patients undergoing colorectal surgery but do imply that larger studies would be of value to compare the performance of frailty scoring instruments in adult patients and to calibrate cut-off points for the prediction of postoperative outcomes.

List of Abbreviations

AD	Accumulation deficit
FP	Frailty phenotype
CFS	Clinical frailty scale

Declarations

Ethics approval and consent to participate:

Ethical approval was received from the West Midlands Edgbaston UK Research Ethics Committee (15/WM/0148). Informed written consent was obtained from all participants, and were all deemed to have capacity my healthcare.

Consent for publication:

Not applicable.

Availability of data and material:

The datasets generated and analysed during the current study are available from the corresponding author on reasonable request

Competing interests:

The authors declare no competing interests

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Authors' contributions:

TDM, DB and SJH were responsible for the study design

TDM and OB recruited patients

TDM and OB performed data cleaning and preliminary analyses

TDM, DB and SJH performed the final data analysis as presented in this paper

TDM, DB and SJH wrote the manuscript

All authors commented on the manuscript leading to the final submitted version

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Tables

Table 1: The number(percentage) of non-frail pre-frail and frail patients in the study population (n=200)

Assessment method		Non-frail	Pre-frail	Frail
CFS		64 (32%)	133 (67%)	3 (2%)
AD		31 (16%)	105 (53%)	64 (32%)
FP		86 (43%)	103 (52%)	11 (6%)
CFS	Male	31 (16%)	59 (25%)	1 (1%)
	Female	33 (17%)	74 (37%)	2 (1%)
AD	Male	16 (8%)	50 (25%)	25 (13%)
	Female	15 (8%)	55 (28%)	39 (20%)
FP	Male	43 (22%)	45 (23%)	3 (2%)
	Female	43 (22%)	58 (29%)	8 (4%)

The number(percentage) of pre-frail and frail patients in the study population (n=200), as defined by the clinical frailty scale (CFS), accumulation deficit (AD) and frailty phenotype (FP). Data are shown for the population as a whole and divided by sex. Some rows do not sum to 100% due to rounding.

Table 2: Correlation and agreement between the Clinical Frailty Scale, Accumulation Deficit and Frailty Phenotype instruments

Instruments compared	Statistic test	Result	P value
Clinical Frailty Scale and Accumulation Deficit	Correlation	R = 0.41	<0.001
	Kappa	K = 0.08	0.06
Clinical Frailty Scale and Frailty Phenotype	Correlation	R = 0.28	<0.001
	Kappa	K = 0.17	<0.005
Accumulation Deficit and Frailty Phenotype	Correlation	R = 0.46	<0.001
	Kappa	K = 0.16	<0.001

Correlation and Kappa analyses between the Clinical Frailty Scale, Accumulation Deficit and Frailty Phenotype instruments in 200 elective colorectal surgery patients

Table 3: Post-operative complications (Clavien-Dindo > 1 and causes of 30-day readmission in 160 patients

Outcome measure		
Post-operative complications during index admission. (n=18 patients)	Wound infection	4
	Hypotension/Early sepsis	2
	Hospital acquired pneumonia	2
	Persistent pyrexia/ other infective sign warranting empiric treatment	2
	Surgical site bleeding	2
	Protracted Ileus/delayed return of bowel function	2
	Severe pain delaying mobilisation and recovery	2
	Anastomotic Leak	1
	Small bowel obstruction	1
Readmission within 30 days of surgery (n=10 patients)	Bowel obstruction	2
	Anastomotic leak	1
	Incisional hernia	1
	GI bleeding	1
	Wound infection	1
	Pancreatitis	1
	Admission under another clinical service	3

Post-operative complications (Clavien-Dindo $\geq$ 1 and causes of readmission within 30 days of surgery in 160 elective colorectal surgery patients.

Table 4: Risk ratios and predictive value of three frailty instruments for adverse outcome following surgery.

Post-operative complications (Clavien-Dindo $\geq$ 1)					
Instrument	Risk ratio (Confidence Interval)	PPV(%)	NPV(%)	Sensitivity(%)	Specificity(%)
CFS	1.2 (0.5 - 2.8)	32	72	90	12
AD	3.2 (0.3 - 32.2)	17	94	96	13
FP	6.1 (1.5 - 24.5)	47	89	97	18
Re-admission within 30 days					
Instrument	Risk ratio (Confidence Interval)	PPV(%)	NPV(%)	Sensitivity(%)	Specificity(%)
CFS	1.4 (0.5 - 3.7)	32	75	92	11
AD	1.3 (0.3 - 5.2)	16	88	92	10

FP	3.4 (1.1 - 10.4)	47	81	96	14
Extended Length of Stay					
Instrument	Risk ratio (Confidence Interval)	PPV(%)	NPV(%)	Sensitivity(%)	Specificity(%)
CFS	1.8 (1.2 - 2.8)	36	80	82	33
AD	1.5 (0.3 - 5.2)	17	89	80	30
FP	1.8 (1.1 - 10.4)	50	69	80	35

The associations between and predictive value of the Accumulation Deficit model (AD) and Frailty Phenotype (FP) for post-operative complications, 30-day readmission and an extended length of stay in 160 elective colorectal surgery patients. PPV; positive predictive value, NPV; negative predictive value. In this table, the 'frail' and 'pre-frail' states are collapsed into frail.