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Outcomes and Decision Making in High-Risk Lap and NoLap Patients: Clinical Frailty Score vs NELA Score

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ORIGINAL

Abstract

Introduction: High-risk emergency laparotomy patients are characterised as having a National Emergency Laparotomy Audit (NELA) mortality prediction of $\geq 5\%$, but this often underestimates risk. Frailty has been reported as an important factor in decision-making for laparotomy. Outcomes for patients who do not proceed to laparotomy (NoLap) are less reported, as are the reasons why this decision is made. Our aim was to explore the decision-making process for high-risk patients eligible for laparotomy and to investigate which factors heavily influenced the decision. We then analyzed outcomes in those who were managed with a laparotomy (Lap) versus those who were not (NoLap).

Methods: A prospective study over 6 months was conducted across two hospitals. Patients with NELA $\geq 5\%$ and aged ≥ 65 warranting laparotomy were included. Fisher's and Mann-Whitney U testing was used to compare Lap and NoLap outcomes. Multivariable regression analysis was used to determine which factors were associated with the decision for or against laparotomy. **Results:** A total of 62 patients were eligible for inclusion. NoLap patients had significantly higher NELA ($p < 0.001$), American Society of Anaesthesiologists (ASA) classification ($p = 0.008$) CFS ($p < 0.001$), and higher mortalities (< 0.001). ASA was the only predictor of mortality ($p = 0.04$). Only 32% of all cases had a full multidisciplinary team (intensivist, anaesthesiologist, and surgeon) involved in decision-making. CFS was the most specific and sensitive factor influencing decision-making ($p < 0.001$), but only NELA predicted morbidity ($p = 0.03$). **Conclusions:** High-risk NoLap patients have worse outcomes than their Lap counterparts. Although CFS is not currently included in the NELA calculation, it is a crucial variable used in laparotomy decision-making in high-risk patients.

Keywords

Emergency Laparotomy, NoLap, Frailty, NELA, Decision Making

Introduction

The National Emergency Laparotomy Audit (NELA) risk calculator score is the most frequently used calculation of mortality in the UK and defines 'high-risk' patients as those with a 30-day mortality of $\geq 5\%$. (1; 2; 3) High-risk patients account for approximately 10,000 emergency laparotomies per year, but many who fulfill the criteria for an emergency laparotomy do not proceed to surgery (2; 4). Such patients are categorised as 'NoLaps' (4). Following the recent focus of three large

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studies in Scotland, Denmark, and Australia, NELA has extended their audit from April 2024 to include these 'NoLap' patients (1; 3; 5; 6). A large UK multicentre study was recently published which offered significant insight into the importance of frailty and comorbidities in NoLap patients, but the decision-making process is still underrepresented in literature (7). Decision-making for or against laparotomy is an individualised complex process. NELA recommends a consultant-led multi-disciplinary meeting for all high-risk patients, but little is known about whether this happens in clinical practice, and indeed which factors carry the most weight in decision-making (1). The ELF Studies (Emergency Laparotomy and Frailty) showed that one-fifth of laparotomy patients are frail and that the measure of frailty independent of age is a reliable predictor of outcomes (8; 9). Frailty was also shown in a 2023 Danish study to be a factor much more prevalent in NoLap patients, but it is still not a formally recommended consideration in deciding whether to take patients for an emergency laparotomy (5). We compared Lap and NoLap patients with NELA scores $\geq 5\%$ who were also aged ≥ 65 in the hope of accounting for the NELA definition of 'high-risk' and 'the older patient'. Our primary aim was to explore the decision-making process for and against laparotomy to investigate which factors heavily influenced decision-making. We then sought to compare outcomes in Lap and NoLap patients. We hypothesised that NELA, age, and frailty would be significantly associated with the decision for laparotomy.

Materials and Methods

Design

A prospective observational study was completed from two busy district general hospitals (DGHs) that conduct more than 200 emergency laparotomies annually in South East London. Approvals Ethical approval was not required, but local approval from the Clinical Audit Department was approved. **Inclusion and Exclusion Criteria**

The study took place over six months (between 01.10.2023 and 31.03.2024). Patients were included only if they were aged ≥ 65 and had a pre-operative NELA score of $\geq 5\%$. Patients were excluded if they were transferred to a tertiary center prior to a decision for or against laparotomy and if the primary reason for laparotomy was outside the NELA guidelines. Patients requiring an unplanned return to the theatre were excluded.

Data collection

Three clinicians independently screened on-call patient lists and theatre lists to ensure no eligible patients were missed. Variables included were split into groups of patient variables, pre-operative variables, decision-making variables, laparotomy variables, and outcomes. Patient variables included age, sex, American Association of Anaesthesiologists (ASA) classification, clinical frailty score (CFS), and a pre-operative package of care; Pre-operative variables included NELA score, pre-operative diagnosis, computed tomography (CT) scan, time to CT scan, seniority of CT scan reporting; Decision-making variables such as mini-MDT, present of anaesthetics/critical care at MDT, time from diagnosis to decision making for theatre, reason against laparotomy; Laparotomy variables include operative diagnosis, most senior operator, stoma formation, and relook laparotomy required; Outcomes included morbidity, Clavien-Dindo Classification of morbidity, ICU length of stay, length of stay, discharge destination, and mortality rates (10).

Statistical analysis

Statistical analysis was performed using PRISM 10 (Version 10.1.0 (264)). Abnormally distributed data was presented with median (interquartile ranges; (IQR)) and normally distributed data was presented with mean (standard deviation; (SD)). A p-value of 0.05 was taken as significant. Unpaired t-tests assessed the significance of normally distributed NoLap and Lap patients. Mann-Whitney U test was used for abnormally distributed variables respectively. Fisher's exact test was used to analyse categorical data groups. Multivariate regression analysis was used to determine factors predicting the decision for NoLap vs Lap.

Results

Demographics

There were 62 total patients who fulfilled inclusion criteria, who had a mean age of 80.1 years and 24% (24/62) were male. Study patient characteristics are summarised in Table 1. Patients in the NoLap group had higher ASA scores ($p=0.008$) and CFS ($p<0.001$). NoLap patients also had more support at home through a package of care (POC) ($p<0.001$). There was no difference in any pre-operative blood test except those in the NoLap group had a lower baseline Hb ($p=0.014$). The indication for surgery did not make any difference between Lap and NoLap patients. The NELA score was significantly higher in the NoLap patient group ($p<0.001$).

Table 1: Patient Demographics and Variables before Decision for and against Emergency Laparotomy.
Values are mean (SD), number (proportion) or median (IQR)

Variable	Total N=62	Laparotomy (Lap) N=38	No Laparotomy (NoLap) N=24	p-value
Demographics				
Age, years (SD)	80.1 (8.1)	77.5 (7.2)	83.1 (7.8)	0.007*
Male Gender (%)	34 (55)	20 (52.6)	14 (58.3)	0.285+
Deprivation index of postcode (SD)	5 (2.5)	5.4 (2.5)	4.4 (2.6)	0.094*
ASA	3.6 (0.6)	3.4 (0.6)	3.9 (0.4)	0.008*
2	1 (1.6)	1(2.6)	0	0.999+
3	24 (38.7)	20(52.6)	4(16.7)	0.007+
4	36 (58.1)	16 (42.1)	20 (83.3)	0.001+
5	1 (1.6)	1 (2.6)	0	0.999
Frailty				
Clinical Frailty Score (CFS)	4 (1.7)	3.7 (1.2)	6.3 (1.8)	<0.001*
Pre-admission package of care (POC)	15	2	13	<0.001
Once-Twice per day	2	0	2	0.146
Three Times per day	4	1	3	0.289
Four times per day or bedridden	9	1	8	0.001
Admission Laboratory Results, median (IQR)				
Hb	132 (114.8-149.3)	134 (121.8-154.5)	125 (100-138)	0.014*
Albumin	35.5 (31-42)	36 (31-43)	34.5 (32-39)	0.506*
CRP	62 (15.5-196.8)	54.5 (15.5-201.8)	82 (18-196)	0.748*
Lactate	2.2 (1.2-4.2)	2 (1.1-4.3)	2.5 (1.8-4.2)	0.345*
Creatinine	105 (74.8-170.8)	93.5 (72.8-136.5)	124 (83.8-232.2)	0.103*
eGFR	56 (27.8-70)	56 (35-70)	37 (22-63)	0.135*
Indication for Surgery				
Bowel Obstruction	29	19	10	0.606+
Ischaemia	7	4	3	>0.999+
Perforated Viscus	13	7	6	0.541+
Peritonitis	10	5	5	0.489+
Sigmoid Volvulus	3	3	0	0.277+
Pre Operative NELA Score, median (IQR)				
NELA (%)	21.5 (9.9-38.9)	12.7 (7.6-22.4)	35 (25.3-49.2)	<0.001*

* Mann-Whitney U test. † Fisher's Exact Test

Reasons for NoLap

The most prevalent decision given for patients not proceeding to a laparotomy was frailty (Figure 1). Only one case did not have any documentation of a reason against laparotomy. Post-operative Outcomes The majority of NoLap patients died during their admission (71%) compared to only 29% of Lap patients (11/38). Of the seven NoLap survivors, five were discharged from hospital with an increased POC or palliative therapy. Overall hospital and ICU LOS were significantly higher in Lap patients ($p<0.001$) likely due to an increased mortality and lower ceilings of care in the NoLap group.

Predictors of Outcomes Mortality

On univariate analysis, NELA and CFS were not associated significantly with mortality (Table 2).
Morbidity

Of the Lap patients, 25 developed a post-operative morbidity. One NoLap patient developed pneumonia, which was not included in our morbidity analysis. NELA score was predictive of the development of morbidity ($p<0.05$), but no factors predicted the severity of the morbidity by Clavien-Dindo Classification (CDC) as shown in Table 2.

Decision-Making

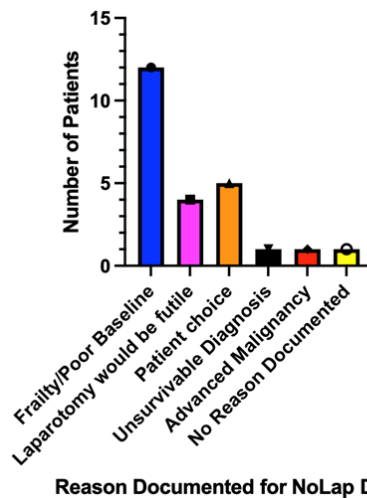


Figure 1. Reasons Given to Justify Conservative Management in The NoLap Group

Table 2: Univariate regression analysis for pre-operative predictors of mortality and morbidity

Variable	Mortality	Morbidity	Clavien-Dindo Severity
	<i>P value</i>	<i>P value</i>	<i>P value</i>
Age	0.786	0.514	0.268
ASA	0.044	0.413	0.718
CFS	0.500	0.420	0.377
POC on Admission	0.329	0.830	0.241
NELA	0.098	0.030	0.538
eGFR	0.766	0.530	0.151
Deprivation Index	0.453	0.464	0.155
Albumin	0.272	0.336	0.108
Creatinine	0.574	0.433	0.554
CRP	0.082	0.897	0.613
Hb	0.115	0.183	0.756
Lactate	0.066	0.249	0.291

P value of <0.05 was taken as statistically significant

On multivariate regression analysis when adjusting for confounders, age, ASA, CFS and Pre-admission POC were associated with the decision for NoLap. Despite the classification of 'high-risk' patients being based on NELA, this was not a statistically significant predictor for decision-making in this cohort of patients (Table 3).

ROC curves were generated to evaluate the performance of CFS and NELA score in decision making for NoLaps. For CFS, the AUC was 0.877. (95% CI:0.5-0.7). The NELA ROC demonstrated an AUC of 0.613 (95% CI: 0.8-0.9). The AUC demonstrated that CFS was more accurate in predicting decision making for NoLap management than NELA, shown in Figure 2.

Outcomes in Decision-Making

The MDT involved in decision-making consisted of intensivists and anaesthetists. Intensivists were involved in 48% (30/62) of cases compared to 45% of anaesthetists, but only 37% involved both. This occurred more frequently in the Lap cases in all domains (Table 4). There was no difference in time from diagnosis to decision in either group.

NELA Standard of Care

NELA Standard of Care was assessed throughout. Computerised Tomography (CT)s were performed in all the patients proceeding to laparotomy compared to 92% of the NoLap patients (22/24). All were reported by a radiology consultant and only one of the Lap group CTs was not

Variable	Univariate Linear regression	Adjusted Multivariate Regression Model	
	P value	Estimate (95% CI)	P value
Age	0.003	0.7 (0.5-0.8)	0.005
ASA	0.010	0.0 (0.0-0.7)	0.050
CFS	<0.001	0.1 (0.0-0.3)	0.008
POC on Admission	<0.001	17.3 (1.7-49)	0.042
NELA	<0.001	0.9 (0.8-1)	0.193
eGFR	0.097	1 (0.9-1.1)	0.473
Deprivation Index	0.176		
Albumin	0.288		
Creatinine	0.218		
CRP	0.887		
Hb	0.116		
Lactate	0.959		

*Variables with $p < 0.1$ were included in the multivariate regression model

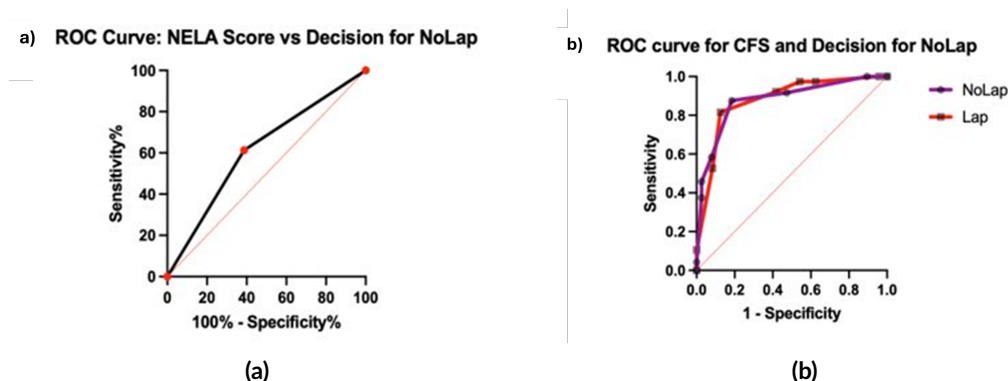


Figure 2. ROC for a) NELA, and b) CFS for Decision Making for NoLap patients

Decision Making Variables	Total N=62	Lap N=38	NoLap N=24	p-value
Time from Diagnosis to Decision Making (hours)	5 (2-18.5)	5 (2-30.3)	4.6 (3.3-9.3)	0.934*
Clinicians Involved				
All	23 (37)	18	5	0.018+
Surgeons	62 (100)	62	62	-
Anaesthetists	28 (45)	24	4	<0.001+
Intensivists	30 (48)	26	4	< 0.001+

performed prior to the decision for surgery (Table 5). Documentation of pre-operative NELA scores was done in 81% (50/62) of all patients but was done significantly more in the Lap group ($p=0.045$). There was no difference in the time between review and decision. Of the Lap patients, 89% received ICU care, compared to 33.3% their NoLap counterparts ($p < 0.001$). All NoLap patients had a ceiling of care documented, and those not admitted to ICU were for 'ward-based care' only following diagnosis.

NELA standard of care	Total N=62	Laparotomy (Lap) N=38	No Laparotomy (NoLap) N=24	p-value
Computerised tomography (CT)	60	38 (100)	22 (92)	0.146+
Before decision	59	37	22	>0.999+
Reported by consultant	60	38	22	0.002+
NELA Risk Documented	50 (81)	34 (89)	16 (66)	0.045+
MDT Done and Documented	46 (74)	31	15	0.137+
Admission to surgeon review time (hrs.mins)	2.1 (0.5-3.4)	2.1 (0.5-3.3)	2.1 (0.6-4.8)	0.608*
Time from surgeon review to decision	5 (2-18.5)	4.6 (3.9-9.3)	5 (2-30.3)	0.943*
Admitted to critical care following decision	42	34 (89)	8	< 0.001+

* Mann-Whitney U test. † Fisher's Exact Test

Discussion

This prospective study concerns decision-making in emergency laparotomy including NoLap patients in England. Our findings are like a large prospective study conducted in Scotland analysing NoLap and Lap patients (4). NoLap patients made up 39% of our total cohort and displayed higher mortality rates than Lap patients. NoLap patients were significantly older, frailer, and of higher anaesthetic risk. Of the Lap patients, 65.8% developed a post-operative morbidity. NELA was the only variable statistically significant in predicting mortality but did not predict morbidity and was not statistically significant in decision-making. No other factors predicted mortality or the severity of morbidity.

NELA guidelines recommend a consultant surgeon, anaesthetist, and intensivist be involved in the decision-making process of all those with NELA $\geq 5\%$ (1). Unfortunately, in only 37% of our cases, all three members of this team were involved. This suggests that the decision for laparotomy remains unilaterally guided by surgeons which may reflect the high morbidity seen in the Lap group. Anaesthetics and intensivists were more likely to be involved in the decision-making for, rather than against laparotomy which is comparable to McIlveen et al and re-enforces the significance in this study of surgeons prompting the MDT discussion (4).

The decision to operate or not is complex and life-changing for the patient. Pre-operative risk stratification calculations like The Portsmouth Physiological and Operative Severity Score for the enumeration of Mortality and Morbidity (P-POSSUM) and NELA provide figures based on the clinical status of the patient to aid decision-making (11; 1). However, frailty is not included in these despite several other studies suggesting frailty as an independent predictor of poor outcomes after laparotomy.(4; 8; 12; 13; 14) A multicentre UK study of all older emergency laparotomy patients conducted by Parmar et al, identified an increased risk in both 30 and 90-day morbidity and mortality with an increased CFS, but low-risk patients were also included in this cohort, and NoLaps were not assessed (8). In our experience, frailty carried a huge weight in decision-making within our MDT. In both Lap and NoLap decision-making, it is crucial to have a 'best interests' meaningful discussion with the patient, family members, and carers to allow the patient to make the most informed decision. Patients included in our study were all already deemed high risk with their age and NELA score, but including frailty in the discussion facilitated the expectation management. This is reflected in our results: five of our 24 NoLap patients chose not to proceed with a laparotomy. Although we were unable to show a relationship between CFS and outcomes, frailty was shown to be the critical factor in deciding whether to proceed with a laparotomy or not. We feel this study is important as it increases the awareness of using CFS in older patients eligible for emergency laparotomy. Price et al recently suggested CFS be used in conjunction with NELA score (5). We support these findings with our study to offer the most pragmatic approach in decision-making for emergency laparotomy in high-risk patients.

This study has a few limitations. Although the prospective nature of this study reduces selection bias, results are less reliable with only 62 patients eligible for inclusion. It is also important to account for any potential missed information even in prospective studies. For example, patients may have been discussed with anaesthetics and intensivists for the decision to operate, but it was not documented at the time. Although NELA recommends a cut of 5% for high-risk patients, other studies have suggested further stratification by NELA score to illustrate differences in outcomes. We did not differentiate between high-risk patients and 'extremely high risk' patients as other literature has previously (2).

Conclusion

In conclusion, this prospective study describes decision-making and outcomes in Lap and NoLap patients specifically of an older, high-risk nature. Deciding whether to offer emergency laparotomy to high-risk patients is complex and multifactorial. Although risk stratification measures provide insight into post-operative mortality, clinical frailty score is not incorporated into this. We have shown that frailty is significantly different in Lap and NoLap patients and suggest that CFS is used

in conjunction with NELA in decision making.

Conflict Of Interest

Author declare no conflict of interest and no funding for this study.

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