

EFFECT OF FRAILTY ON THE POSTOPERATIVE OUTCOME IN PATIENTS
UNDERGOING OPEN HEART SURGERY¹Dr. Adeeb Arkan Fathullah, ²Dr. Merah Subhi Mohammed, ³Dr. Raid Hamid Zabar,
⁴Dr. Ahmed Moyed Hussein¹M.B.CH.B.-F.I.B.M.S- Senior of Anesthesia, Surgical Specialty Hospital Erbil Cardiac Center.²Specialist Cardiac Anesthetist- F.I.B.M.S.(Anesthesia)-CABMA & ICS-Iraqi Board Fellowship in Cardiac Anesthesia-
Ibn-Bitar Center for Cardiac Surgery and Cardiology-Baghdad-Iraq.³F.I.C.M.S.- Ibn-Bitar Center for Cardiac Surgery and Cardiology-Baghdad-Iraq.⁴Assistant Prof in Cardiology-Department of Medicine-College of Medicine-University of Nineveh.

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***Corresponding Author: Dr. Adeeb Arkan Fathullah**

M.B.CH.B.-F.I.B.M.S- Senior of Anesthesia, Surgical Specialty Hospital Erbil Cardiac Center.

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ABSTRACT

Background: Frailty is commonly reported to be associated with the outcomes of various surgeries. Over 50% of cardiac surgery surgeries carried out in senior patients. A considerable rate of those patients are frail. **Aim:** To compare the outcomes after open heart surgery in frailty test positive adult patients. **Patients and Methods:** The study was a prospective study with 60 adult patients who underwent open heart surgery, divided into a frail group (n=33) and a non-frail group (n=27) according to the FRAIL index. Patients were followed up for 30 days after surgery and their mortality, stay in intensive care unit and complications immediately after surgery were noted. **Results:** There was a higher proportion of the female gender in the frailty group (39.39%) than in the non-frail group (14.81%). There was significant difference between the Mean EF% in frail (49.21±11.91) and non-frail (54.96±7.54%) patients. The prevalence of hypertension and T2DM was higher in frail patients (72.73% and 48.48%) than in non-frail (25.93% and 22.22%) and was significantly higher for hypertension. In frail patients, the mortality rate was 18.18% while in non-frail patients, there was zero mortality. Results of multivariate analysis showed that the mean duration of stay in the intensive care unit was significantly associated with frailty (OR 8.42, 95%CI 1.27-68.91, p=0.023) and mean length of stay in the ICU was 2.7±1.46 days in frail patients versus 2.07±0.27 days in non-frail patients also significant. **Conclusions:** Elderly women are more likely to be frail than men and frail patients had lower ejection fractions compared to robust patients. Hypertension is a strong contributor to the onset of frailty. Furthermore, frail elderly patients who receive open-heart surgery have increased risk of death and longer stays in the intensive care unit (ICU) than non-frail patients.

KEYWORDS: Frailty, ICU stays, Open Heart Surgery, Mortality Rates.**INTRODUCTION**

Frailty is a term coined from the French word frêle (fragile) and is now recognised as a condition which is not exclusively of old age but is also common in younger people with chronic diseases or cognitive dysfunctions. It can be defined phenotypically as the age-related biological changes that manifest in the individual's body, including weight loss and diminished strength, and/or in terms of accumulations of clinical and psychosocial factors that make the individual more vulnerable.^[1,2] A

multidimensional definition of frailty is essential because it allows the recognition of the involvement of several factors in influencing physiological resilience. Consensus among geriatric societies defines frailty as a “multi-causal clinical syndrome” that reduces strength and increases vulnerability to poor outcomes. A pre-frail state is also identified as the condition wherein interventions can be targeted to prevent entering full frailty.^[3,4]

Epidemiological data shows that approximately 10% of elderly is frail and a recent study found 9.9% to be frail and 44% to be pre-frail.^[3] More prevalent in older adults especially in women and races such as blacks and Asians. Frailty is associated with increased co-morbidity, lower NYHA class, lower kidney function and more mobility constraints. The prevalence of frailty in cardiovascular diseases is in the range of 10-60%, and reaches 50% in elderly patients undergoing cardiac surgery. Treating frailty could reduce the death rate by 2-5%.^[5,6]

The immune and endocrine dysfunction and metabolic imbalances associated with frailty are related to processes including apoptosis and mitochondrial dysfunction. This condition has a negative impact on the regulation of energy metabolism which results in metabolic deficiencies, nutritional risks and sarcopenia (loss of muscle mass and strength). Inflammatory processes compound frailty in chronic cardiovascular diseases by stimulating catabolic processes and diverting amino acids for repair processes.^[7] Furthermore, inflammatory markers such as C-reactive protein are raised by chronic diseases and surgery, which increase inflammation and result in a further decline in frailty—both directly by the degradation of proteins and indirectly by the effects of inflammation on metabolism.^[7,8]

The Subjective 'end-of-the-bed' test is based on clinical judgement, visual assessment and is limited by variation in the appearance of frailty.^[8]

Fried's Frailty Phenotype includes three or more physical traits such as weakness and unintentional weight loss but does not include psychosocial measures.^[8,9]

The Frailty Index of Accumulative Deficits (FI-CD) is based on the ratio of co-morbidity to indicate frailty, but can be difficult to use clinically.^[9,10]

The Frailty Index Comprehensive Geriatric Assessment (FI-CGA) consists of 52 components, shows a high correlation with FI-CD, and has predictive value for a variety of clinical areas.^[9]

The Edmonton Frail Scale (EFS) rates frailty on nine factors and severity into five categories.^[10,11]

The FRAIL Index, one of the proposals of IANA, assesses five components and assigns the person to the frail group if he/she has three or more.^[11]

The validated Canadian Clinical Frailty Scale (CFS) is a clinical judgment and a scoring system that provides an assessment of frailty risk.^[9]

The gait speed and grip strength are individual parameters that have been shown to be good predictors

of the frailty syndrome, and good screening parameters for frailty.^[10]

Frailty and Cardiac Interventions brings a fresh perspective to the growing importance of frailty in cardiac interventions. Frailty is a strong predictor of mortality and hospital outcomes in older patients undergoing cardiac surgery.^[9]

TAVI is a less surgical procedure for high-risk patients suffering from serious aortic stenosis. The association between frailty and complications in the periprocedural period was absent, but frailty was associated with 1-year mortality. Frailty also is a good predictor of late death with other health issues. In cardiac device therapy, there is a lack of frailty assessments, and there have been proposals to include frailty assessments when considering patients for LVAD. A higher number of comorbidities and greater mortality (28% vs. 6% in non-frail).^[12,13] are present in PCI in frail patients. Frailty has emerged as a key measure in cardiac surgery to inform patient management and decision making, especially for TAVR and mitral surgery. Physical activity interventions and treating sarcopenia and other treatable causes of frailty are key focuses of management strategies that have benefits in reducing markers of frailty and improving health outcomes overall.^[14] The current study aimed to evaluate postoperative outcome for adult patients having frailty test positive undergoing open-heart surgery and to optimize their postoperative conditions.

PATIENTS AND METHODS

Study Design and Settings

This study is a prospective single observational study included 60 adult patients who were undergoing open-heart surgery in Iraqi center for heart disease/ Baghdad medical city from June 2020 to February 2021. The council of Medical specializations in Iraq has approved the study protocol.

Inclusion criteria.

In the case of carotid Doppler, the adult (equal or older than 50 years old).

□ Open-heart surgery

While those with redo (heart) surgery, psychiatric disorder & medications, previous brain surgery and trauma, hepatic failure, and renal failure, were excluded from the study.

Study sampled groups: The study groups consisted of two groups: Group F (the frail) and Group N (non-frail) based on frailty score.

The Fatigue, Resistance, Ambulation, Illness, Loss of Weight (FRAIL) Index used for frailty score in the present study.

The score only takes minutes in the ward and covers the following points.

☐ Fatigue: over past month fatigue felt most of time (yes=1, no=0)
Yes = 1, No = 0 (Resistance: difficulty in climbing flight of stairs)

☐ Ambulation: unable to walk 1 block (yes = 1, no = 0)

☐ Illnesses: have any of these disease: hypertension, diabetes, cancer (other than a minor skin cancer), chronic lung disease, heart attack, congestive heart failure, angina, asthma, arthritis, stroke, and kidney disease (five or greater = 1, fewer than 5 = 0)
Yes = 1; No = 0 (on top of the previous year)

☐ Weight loss (more than 5% compared to last year): yes = 1; no = 0
Frailness was defined as having a score of ≥ 3 .

A written consent obtained for each patient. Each patient's history reported prior to recruitment and a physical examination done. In the theatre, vital signs were taken which included BP, SPO2 and ECG connected. Two wide bore cannula were inserted and all patients were pre oxygenated prior to induction. All patients were pre medicated with metoclopramide and omeprazole and invasive BP (arterial line) and central venous line inserted.

All patients received midazolam 0.1 mg/kg, ketamin 2 mg/kg, fentanyl 2-5 μ g/kg and rocuronium 1 mg/kg at induction of anesthesia. After this, maintenance of anesthesia was performed using propofol and/or remifentanyl and/or sevoflurane and adjusted based on hemodynamic parameters. Additional dose of muscle relaxant was given at cross clamp and rewarming time. All patients were transferred to ICU postoperatively and follow up done for them.

Evaluation of results: Major outcome referred to rate of postoperative mortality (<30 days) and major morbidity such as permanent stroke, postoperative renal failure, prolonged ventilation (>24 hours), deep sternal wound infection, reoperation for bleeding, and reoperation for cardiac reason from any surgical complications. Postoperative mortality was defined as death either in hospital, before discharge the patient, or within 30 days of procedure wherever the place. Postoperative events and complications are not infections, which can occur in the hospital, or after discharge within 30 days of the procedure as defined by Society of Thoracic Surgeons (STS).^[15]

All the data were recorded in Microsoft excel and analyzed by using Statistical package for Social Sciences (SPSS) software, version 24.0. The difference between the mean values of the variables were reported with standard deviation (SD) and the frequency and percentage of categorical were reported. Correlation of persons involved to analyze the relation between frailty score with other continuous variables. Chi square test used to find the significant association of frailty test with the study outcomes. If p value is less than or equal to 0.05, then it is considered to be significant.

RESULTS

Demographic Characteristics of the Patients

The means for age of the patients (with and without frailty) was 61.3 ± 8.1 years and 58.63 ± 5.92 years respectively with insignificant difference; and the mean weight of the patients (with and without frailty) was 67.6 ± 11.3 kg and 67.5 ± 10.7 kg respectively, with insignificant difference. However, there a significant difference between the patients with and without frailty, with a higher number of females' patients with frailty (39.39%) compared with those without frailty (14.81%) as shown in table (1).

Table 1: Demographic characteristics of the patients.

Variables		With frailty (n=33)	Without frailty (n=27)	P-value
Age, years	Mean±SD	61.3±8.1	58.63±5.92	0.157*
	Range	50-78	50-73	
Sex	Male	20(60.61%)	23(85.19%)	0.036**
	Female	13(39.39%)	4(14.81%)	
Weight, kg	Mean±SD	75.64±11.1	81.63±14.85	0.084*
	Range	46-95	43-112	
*Independent t-test for two means; **Chi square test				

Clinical Characteristics of the Patients

Out of six included clinical factors, three factors showed significant association with frailty. The mean EF in frail patients was $49.21 \pm 11.91\%$ which was lower than that of non-frail patients ($54.96 \pm 7.54\%$) with a significant difference. There were significant difference in the prevalence of hypertension among frail patients representing (69.7% vs. 33.33%) among non-frail

patients. Lastly, mortality (18.18%) was lower in the non-frail group than in the frail group (0) and difference between them was significant. A higher proportion of frail patients had DM than did non-frail patients (51.52% vs. 37.04%), but this was not statistically significant. The values of bypass time were lower and values of HB were higher in non-frail group than in frail group but these differences were not significant as indicated in table (2).

Table (2): Clinical characteristics of the study population.

Variables		With frailty (n=33)	Without frailty (n=27)	P-value
Bypass time, min	Mean±SD	98.3±33.64	89.56±24.93	0.267*
	Range	40-180	49-150	
EF, %	Mean±SD	49.21±11.91	54.96±7.54	0.034*
	Range	25-68	42-65	
Hb, g/dl	Mean±SD	12.83±1.52	13.23±1.22	0.180*
	Range	10.7 – 16.5	10.1-16	
S. creatinine	Mean±SD	1.02±0.26	0.93±0.21	0.189*
	Range	0.6-1.4	0.7-1.5	
Comorbidities	HTN	23(69.7%)	9(33.33%)	0.005**
	DM	17(51.52%)	10(37.04%)	0.262**
	TIA	2(6.06%)	0(0%)	0.132**
	Others	1(3.03%)	1(3.7%)	0.823**
Outcome	Survived	27(81.82%)	27(100%)	0.020**
	Died	6(18.18%)	0(0%)	

*Independent t-test for two means; **Chi square test

Association of the frailty with the outcome

Univariate and multivariate logistic regression were performed to investigate the relationship of distinct demographic and clinical characteristics (including frailty) and the patients' outcome. Patients were divided into two groups for these analyses: survivors (favorable) and those who died or spent a long time in the intensive care unit (unfavorable). Each continuous variable was categorized into two categories using a proper cut off values. Four factors were found to be statistically significant in univariate analysis affecting the outcomes of the patient. The majority of patients with unfavorable outcome (77.78%) had EF ≤ 50% compared to the majority of patients with favorable outcome who had EF > 50% (39.22%) (OR= 5.42, 95%CI=1.02-28.79,

p=0.045). Likewise, patients with unfavorable outcome (88.89%) had a lower level of Hb as 47.06% of patients with favorable outcome had Hb level ≤13 g/dl (OR= 9.0, 95% CI= 1.05-77.29, p=0.045). Furthermore, (22.22%) of patients with unfavorable outcome were suffering from TIA compared with none of patients with favorable outcome with this comorbidity (OR= 8.3, 95%CI= 1.33-82.7, p= 0.001). Finally, (47.06%) of patients with favorable outcome were frail while (100%) of patients with unfavorable outcome were frail (OR=2.12, 95%CI=1.59-2.84, p= 0.003). Table (3) shows that females, HTN and DM were more common among the patients with unfavorable outcomes than favorable outcomes but the differences were not significant.

Table (3): Univariate Analysis.

Variables		Discharged well (n=51)	Prolonged ICU stay or died (n=9)	P-value*	OR(95%CI)
Age, years	≤60	30(58.82%)	6(66.67%)	0.658	1.0
	>60	21(41.18%)	3(33.33%)		0.71(0.16-3.18)
Gender	Male	39(76.47%)	4(44.44%)	0.061	1.0
	Female	12(23.53%)	5(55.56%)		4.06(0.94-17.59)
Weight, kg	≤75	17(33.3%)	4(44.44%)	0.522	1.0
	>75	34(66.67%)	5(55.56%)		0.62(0.15-2.63)
Bypass time, min	≤95	31(60.78%)	4(44.44%)	0.36	1.0
	>95	20(39.22%)	5(55.56%)		1.94(0.46-8.09)
EF, %	>50	31(60.78%)	2(22.22%)	0.047	1.0
	≤ 50	20(39.22%)	7(77.78%)		5.42(1.02-28.79)
Hb, g/dl	>13	27(52.94%)	1(11.11%)	0.045	1.0
	≤ 13	24(47.06%)	8(88.89%)		9.0(1.05-77.29)
S. creatinine	≤1	18(35.29%)	5(55.56%)	0.257	1.0
	> 1	33(64.71%)	4(44.44%)		0.44(0.11-1.83)
Comorbidities	No	16(31.37%)	3(33.33%)	0.907	1.0
	HTN	26(50.98%)	6(66.67%)	0.390	0.91(0.20-4.13)
	DM	22(43.14%)	5(55.56%)	0.493	1.65(0.4-6.86)
	TIA	0(0.0%)	2(22.22%)	0.001	8.3(1.33-82.7)
	Others	2(1.96%)	0(0.0%)	0.762	3.17(0.81-14.82)
Frailty	No	27(52.94%)	0(0.0%)	0.003	1.0
	Yes	24(47.06%)	9(100%)		2.12(1.59-2.84)

OR: odds ratio, EF: ejection fraction; *Chi square test

Similar results were found using multiple analysis, except for Hb. Each of EF (OR= 18.26, 95%CI=1.55-214.15, $p= 0.021$), the presence of TIA (OR= 10.6,

95%CI=1.14-146.43, $p= 0.036$) and frailty (OR= 9.42, 95%CI= 1.33-71.27, $p=0.012$) remained significantly associated with patients' outcome, as shown in table (4).

Table (4): Multivariate analysis.

Variables		P-value*	OR(95%C)
Gender	Male	0.052	1.0
	Female		10.79(0.98-118.25)
EF, %	>50	0.021	1.0
	≤ 50		18.26(1.55-214.15)
Hb, g/dl	>13	0.155	1.0
	≤ 13		5.3(0.53-52.59)
TIA	No	0.036	1.0
	Yes		10.6(1.41-146.43)
Frailty	No	0.012	1.0
	Yes		9.42(1.33-71.27)

*Chi square test

Correlation of Frailty Score with other Variables

There was good correlation between the Frailty Score and other variables. Pearson's correlation was used to explore the possible correlation between frailty score and other variables. Table (5) shows a positive significant correlation between the Frailty score with the age ($r=0.378$, $p= 0.03$).

Table (5): Correlation of frailty score with other variables in frail patients.

Variable	Coefficient	p-value
Age	0.378	0.030
Weight	-0.1221	0.217
Bypass time	0.302	0.088
EF	0.304	0.085
Hb	0.193	0.282
S. creatinine	-0.003	0.988
ICU stay	0.319	0.105

Perioperative Complications

After exclusion of died patients, the mean ICU stay in frailty group was 2.7 ± 1.46 days which was significantly longer than that of non-frailty group (2.07 ± 0.27 days). As shown in table (6), three patients in frailty group required IABP intervention during operation, and one patient had CVA post operation, while there was no significant difference with non-frailty group, as none of them had the same complications.

Table (6): Perioperative complications.

Variables		With frailty (n=33)	Without frailty (n=27)	P-value
ICU stay, days	Mean±SD	2.7±1.46	2.07±0.27	0.032*
	Range	2-8	2-3	
Need for IABP	No	30(90.91%)	27(100%)	0.108*
	Yes	3(9.09%)	0(0%)	
CVA	No	32(96.97%)	27(100%)	0.362*
	Yes	1(3.03%)	0(0%)	

*Independent t-test for two means; **Chi square test

DISCUSSION

In our study aimed to evaluate postoperative outcome for adult patients having frailty test positive undergoing open-heart surgery. The outcome of the study indicated that females were more likely to be frail than males. This result is in agreement with almost all previous studies in this context. A cross-sectional study by Zhang et al.^[16] identified 1126 geriatric Chinese patients to be studied for frailty. In females, the incidence of frailty was higher than in males (8.8% v. 5.4%). The other study indicated that women living in the community aged over 65 years

were more likely to be frail and to have a higher frailty burden than men of the same age.^[17]

In our study, robust patients had higher weight than frail patients did although the difference was not significant. There is some question about frailty and BMI. In a study include 3055 community-dwelling males and females aged ≥ 65 year from the English Longitudinal Study of Ageing gave a U-shaped relation between BMI and frailty where those with higher and lower BMIs had higher scores of frailty.^[18]

The other finding in the present study was that the EF ratio was significantly lower in frail patients than in robust patients. Few studies directly reported relation between ejection fraction and frailty, while the majority of the available studies focused on the association between CVDs and frailty. The risk of cardiovascular-related mortality was greater than other risk factors in patients with peripheral artery disease^[19] when frailty was reported as a predictor. In one study, 2825 older people, without heart failure at baseline over 11 years, were followed up. New heart failure^[20] was 30% more likely in those who were frail.^[20]

In contrast, a large retrospective cohort analysis including 788785 elderly Japanese patients suffering from heart failure reported that the prevalence of frailty was 38.3% in patients with reduced EF while it was 61.7% in those with preserved EF.^[21] The different findings between studies could be connected with the various variables that affect the EF. Ejection fraction is highly variable and varies with many other comorbidities (eg, hypertension, diabetes mellitus and atrial fibrillation) present in the elderly population that are associated with this condition. These comorbidities may lead to systematic microvascular inflammation, which adversely affects the adjacent cardiomyocytes, and lead to impaired myocardial energetics and decreased nutritional status.^[22]

Both DM and HTN found to be more frequent in frail patient and HTN showed significant association while DM showed insignificant association. In accordance with these results are several studies worldwide. In study cover 5086 men aged ≥ 65 years, the frail patients had higher ratio of comorbidity including cancer, hypertension, obstructive pulmonary disease, diabetes mellitus and osteoporosis compared to their pre-frail and robust counterparts.^[23] In a cohort study by Aprahamian et al.^[24], distribution of hypertension among non-frail, pre-frail, and frail patients were 52%, 73%, and 83%. However, a cross-sectional study by Gijón-Conde et al.^[25] implicated among 1047 individuals aged ≥ 60 years, mean systolic BP was significantly lower by 1.5 mm Hg for each frailty score. In another study using cohort data from Canada and Korea, frailty was associated with a U-shaped BP curve^[26], which implies that hypo and hypertension were connected to frailty. This variation among different studies in the link between blood pressure and frailty is attributed to many factors, the most important of which are using of antihypertensive drugs, demographic variation in the study population and the presence of other comorbidities. On the other hand, DM may contribute to frailty through the diabetes-related complications that can lead to physical inactivity, impaired muscular performance and functional impairment^[27], which are characteristics of frailty.

The most interesting finding in the present study was that frailty was significantly associated with the worse outcome in the patients undergoing open-heart surgery in

univariate and multivariate analyses (OR= 9.42, 95%CI=1.33-71.27). This implies that frail patients about 9-fold higher risk of mortality or prolonged ICU stay compared with non-frail patients. A Canadian study explained mortality effect of frailty post cardiac surgery, this study figured out patients who regarded frail pose a 1.5-fold higher risk mortality compared to not frail patients.^[28] Another study showed a significant association between frailty and increased mortality rates (OR, 3.68; 95% CI, 1.21-11.19).^[29] Ad et al.^[30] recruited 166 elderly patients ≥ 65 years' old who underwent valve and/or coronary artery bypass graft surgery (CABG). Among those were 39 frail patients. The most important findings were that frail patients had longer median ICU stays (54 vs. 28 h, $p = 0.003$), longer median length of hospital stay (8 vs. 5 days, $p < 0.001$), and higher complications rate (54% vs 32% $p = 0.011$).

In the present study, frailty score was significantly correlated with the age ($r = 0.378$, $p = 0.03$). Age is a well-known risk factors of frailty^[31], and this fact was reported in many previous studies.^[32,33] The influence of ageing on frail syndrome is related to the decline in the physiological reserve with ageing.^[34] However, not all older people are frail suggesting that the onset of frailty requires other reasons for augmenting this condition than normative process of ageing.^[35]

CONCLUSIONS

Frailty is more common in older women than in males; this could be because of hormone imbalances. Elderly feeble people have a much lower ejection fraction than their robust counterparts. Comorbidities (DM and HTN), especially in those with HTN, are strongly linked to frailty in older individuals. Compared to non-frail patients, elderly frail patients undergoing open-heart surgery will be more likely to die or require a longer stay in the intensive care unit.

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