Independent Risk Factors for Fast-Track Failure Using a Predefined Fast-Track Protocol in Preselected Cardiac Surgery Patients

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Objectisves: **The purpose of this study was to identify the independent risk factors for fast-track failure (FTF) in cardiac surgery patients.**

Design: **A retrospective analysis.**

Setting: **A university-affiliated heart center.**

Participants: **In a 2-year period, 1,704 consecutive preselected patients undergoing elective cardiac surgery were treated according to the local fast-track protocol in the postanesthetic care unit (PACU), bypassing the intensive care unit (ICU).**

Measurements and Results: **Independent risk factors for FTF in the univariate regression analysis were tested in a multivariate regression analysis. FTF was defined as any transfer of the preselected patient to the ICU. FTF was primary when the patient was transferred directly from the postanesthetic care unit to the ICU and secondary when the patient was transferred from the intermediate care unit or ward to the ICU. FTF rate was 11.6% for primary and 5.6% for secondary FTF. In the multivariate regression analysis, age >70 years, female sex, prolonged surgery, and prolonged cross-clamp time could be defined as independent risk factors for FTF.**

Conclusions: **In a preselected patient population, fast-track treatment could be done with a low FTF rate. Independent risk factors for FTF are age, female sex, prolonged surgery, and prolonged cross-clamp time.**

KEY WORDS: fast track, cardiac surgery, fast-track protocol, fast-track failure, intensive care unit, cardiac anesthesia, postoperative ventilation

FAST-TRACK (FT) ANESTHESIA in cardiac surgery is considered a standard of care in current practice.[1] A numbers of studies have demonstrated that there are no differences in mortality and morbidity rates between FT anesthesia and conventional anesthesia,[2,3] with the benefit of reduced costs of healthcare.[4,5]

Fast-track failure (FTF) rates reported in the literature vary from 15.6% to 45.5% in mixed-age populations,[6,7] depending on the definition of FTF and the patient population (ie, comorbidities and type of surgery). Most of the studies focused on coronary artery bypass grafting (CABG) procedures.[8] In an attempt to work out a standardized protocol for both patient selection and FT process, many studies have evaluated the variables for successful and failed FT treatment in the whole patient population.[3,6,7,9]

The aim of this study was 2-fold: To evaluate the rates of FTF and to identify independent risk factors for FTF in preselected FT patients undergoing elective cardiac surgery.

MATERIALS AND METHODS

This retrospective observational study was performed in a single center and was approved by the local medical ethics committee (registration number: 322-10-08112010). In all, 1,704 consecutive patients who underwent cardiac surgery and FT treatment in a dedicated postanesthetic care unit (PACU) from January 2007 to December 2008 were included in this study.

Patients were admitted to the PACU if they were hemodynamically stable with or without low-dose vasopressor and/or inotropic support (continuous infusion of $<0.1\mu g/kg/min$ of norepinephrine and/or <0.05 μg/kg/min of epinephrine), without excessive bleeding (defined as bleeding that did not affect the hemodynamic stability and that was easy to control), and with a core temperature of at least 36°C. Transfusion requirement was not an exclusion criterion, per se, if the patient was stable hemodynamically and no clinical signs of bleeding were present before transfer to the PACU. Both elective and urgent surgeries were included in the protocol, whereas emergency surgeries were excluded. The decision for FT treatment of the specific patient was made cooperatively at the end of the surgery by the cardiac anesthesiologist and the cardiac surgeon. If one or both declined, the patient was transferred to the intensive care unit (ICU; Table 1).

Fast-Track Protocol

The patients were treated according to the Leipzig FT protocol published previously.[10] Criteria for extubation were fully awake and alert patients with completely (clinically) recovered motor power, no neurologic deficit, hemodynamically stable, bleeding <100 mL/h, core temperature $\geq 36°C$, acceptable blood gases on $F_IO_2 < 0.5$, sufficient tidal volume on ventilator support (pressure support (PS) 8 cmH_2O and positive end-expiratory pressure 5 cmH_2O), normal lactate, mixed venous oxygen saturation (SvO_2), electrocardiogram, and chest x-ray (Table 2). The PACU operated daily Monday to Friday from 10 AM to 6:30 PM.

All patients were transferred to the intermediate care unit (IMC) once a bed was available and the following criteria were fulfilled: Patients were awake and alert, had no neurologic deficit, had a pain score (visual analog scale) between 2 and 4,

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Table 1. Inclusion Criteria for FT and PACU

Hemodynamically stable ± low-dose inotropic support
No excessive bleeding
Core temperature ≥36°C
Elective or urgent surgeries (not emergency surgeries)
Clinical judgment and communication between anesthesiologist and the surgeon

Abbreviations: FT, fast track; PACU, postanesthesia care unit

were hemodynamically stable and without vasopressor and/or inotropic support, had acceptable blood gas analysis (PaO_2 >90 mmHg and $PaCO_2$ <46 mmHg, SaO_2 >96% on oxygen flow 2-6 L/min), had no significant bleeding (<50 mL/h), had urinary output >0.5 mL/kg/h, and had normal serum lactate, SvO_2, cardiac enzymes, and chest x-ray (Table 3).

IMC patients were discharged to the ordinary ward when they had a stable rhythm and were able to mobilize independently. The staff in the IMC unit was aware of which patients underwent FT treatment, whereas staff on the nursing ward were not.

In this study, FT was considered successful if patients were discharged from the hospital without admission to the ICU or readmission to the IMC during their primary stay in the hospital.

Definition of Fast-Track Failure

FTF was defined as any unplanned transfer of the preselected FT patient to the ICU. Patients transferred from the PACU directly to the ICU were defined as primary FTF, whereas patients transferred from either the IMC or ward to the ICU were defined as secondary FTF.

Statistical Analysis

Data are displayed throughout the article as median and interquartile range for all non-normally distributed continuous variables and mean and SD for normally distributed values.

A univariate logistic regression analysis using variables known in the literature as risk factors for FTF was performed (ie, age, sex, EuroSCORE, surgery time, aortic cross-clamp time, cardiopulmonary bypass time, preoperative ejection fraction, number of reoperations, impaired renal function, history of chronic obstructive pulmonary disease (COPD), diabetes, peripheral vascular disease, previous myocardial infarction, pulmonary hypertension, neurologic comorbidities, and urgent surgery).[6] Parameters found to be significant in the univariate analysis were used to perform a multivariate logistic regression model to identify independent risk factors for FTF. The primary events of interest were FTF and readmission to a higher dependency area during a patient's stay in the hospital.

The odds ratio and p values were calculated for each variable. A $p < 0.05$ was considered statistically significant. Analysis was performed using the statistical analysis software SPSS version 16.0 for Windows (SPSS, Chicago, IL, USA).

Table 2. Criteria for Extuabation

Full consciousness, no neurologic deficit
Hemodynamically stable
Core temperature ≥36°C
Arterial blood gas: PO_2 ≥100 mmHg, PCO_2 ≤40 mmHg on F_iO_2 <0.5
Respiratory parameters: sufficient tidal volume on ventilator support (P.S. 8 cmH_2O and PEEP 5 cmH_2O)
Bleeding: <100mL/h
Normal serum lactate
Normal SvO_2
No new ECG and CXR changes

Abbreviations: CXR, chest x-ray; ECG, electrocardiogram; PEEP, positive end-expiratory pressure SvO_2, central venous oxygen saturation

Table 3. Criteria for Transfer of Patients From PACU to IMC

Fully awake and alert, no neurologic deficit
Hemodynamically stable, without inotropic support
Acceptable blood gas analysis (PaO_2 >90 mmHg and $PaCO_2$ <46 mmHg, SpO_2 >96% on O_2 flow 2-6 L/min)
Urinary output >0.5 mL/kg/h.
No significant bleeding (<50 mL/h)
Normal serum lactate, normal SvO_2, cardiac enzymes, and CXR

Abbreviations: CXR, chest x-ray; IMC, intermediate care; PACU, postanesthesia care unit; SvO_2, central venous oxygen saturation

RESULTS

Overall, 1,917 patients were admitted to the PACU between January 2007 and December 2008. Of these patients, 1,704 were treated using the FT concept; 213 patients were excluded as they were admitted to the PACU only for a short time until an ICU bed was available. The demographic and operative data are shown in Table 4.

Table 5 shows the results of the univariate analysis for the prediction of either primary or secondary FTF. The primary FTF rate was 11.6% compared with 5.6% for secondary. Univariate analysis revealed age, sex, EuroSCORE, surgery duration, aortic cross-clamp time, and diabetes as significant risk factors for primary FTF. For secondary FTF, renal impairment, COPD, peripheral vascular disease, previous myocardial infarction, and bypass time were shown to be the significant risk factors.

After performing a multivariate analysis for all patients (Table 6), age >70 years, surgery duration, aortic cross-clamp time, and female sex were found to be independent risk factors for primary FTF. In comparison, independent risk factors for secondary FTF were duration of surgery, COPD, renal impairment, and diabetes.

In-hospital mortality for all FT patients was 0.9% (n = 17), of which 29% (n = 5) were primary FTF and 70% (n = 12) were secondary FTF. All secondary FTF patients were transferred from the IMC to the ICU. None of patients in the successful FT group died. On the other hand, almost 6% (n = 17) of the patients from the FTF group died. This difference was statistically significant ($p < 0.00001$).

The average ICU length of stay (LOS) for FTF patients was 66.2 ± 125 hours. The average IMC LOS for FTF patients was 53.7 ± 71 hours compared with 32.6 ± 32 hours for successful FT patients ($p < 0.05$). Average hospital LOS for FTF patients was significantly longer than that for successful FT patients (17.4 ± 17.2 *v* 9.9 ± 3.8 days, $p < 0.05$).

DISCUSSION

In this study, primary FTF occurred in 11.6% of patients and secondary FTF in 5.6%. Age >70 years, female sex, and lengthy surgery (>3 hours) and cross-clamp times (>65 minutes) were

Table 4. Demographic and Operative Data

	All patients (%) N = 1,704
Age (y), mean	63 ± 13
Female sex	586 (34.4)
Creatinine >130 μmol/L	55 (3.2)
Chronic renal failure	50 (2.9)
COPD	128 (7.5)
PVD	92 (5.2)
Diabetes	409 (24)
IDDM	162 (9.5)
Pulmonary hypertension	34 (2)
Neurologic disorders	135 (7.9)
Past MI	91 (5.4)
Previous stroke	82 (4.8)
Previous cardiac surgery	44 (2.6)
Ejection fraction (%)	62 ± 11
Log EuroSCORE	5.12 ± 5.45
Urgent surgery	96 (5.6)
Procedure duration (min)	177 ± 49
Bypass time (min)	103 ±79
Cross-clamp time (min)	65 ± 28
CABG	490 (28.8)
OPCAB	31 (1.8)
MVR	515 (30.2)
AVR	368 (21.6)
MVR + tricuspid valve repair/replacement	25 (1.5)
Ascending aorta replacement	80 (4.7)
CABG + AVR	78 (4.6)
CABG + MVR	15 (0.9)
Miscellaneous*	102 (6)

Abbreviations: AVR, aortic valve repair/replacement; CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; IDDM, insulin-dependent diabetes mellitus; MI, myocardial infarction; MVR, Mitral valve repair/replacement; OPCAB, off-pump coronary artery bypass; PVD, peripheral vascular disease

*Includes heart tumors, congenital heart defect surgeries, and other combined valve procedures.

Table 5. Univariate Analysis for All Patients

	Primary FTF 198 (11.6%)		Secondary FTF 96 (5.6%)	
Patients (n)	OR	p Value	OR	p Value
Age per 10 y	1.406	**<0.01**	1.386	**<0.01**
Female sex	1.509	**<0.01**	1.107	0.644
Creatinine >130 μmol/L	1.955	0.053	2.407	0.052
Chronic renal failure	0.838	0.711	3.980	**<0.01**
COPD	1.353	0.247	2.187	**0.014**
PVD	1.387	0.276	2.313	**0.019**
Diabetes	1.396	**0.046**	2.452	**<0.01**
IDDM	1.362	0.189	2.505	**<0.01**
Pulmonary hypertension	1.315	0.576	2.428	0.106
Neurologic disorders	1.441	0.144	1.126	0.757
Past MI	1.537	0.143	2.091	**0.047**
Past stroke	1.059	0.868	1.101	0.839
Previous cardiac surgery	1.207	0.673	0.391	0.356
Ejection fraction/10%	1.027	0.705	0.972	0.766
Log EuroSCORE/10-point increase	1.484	**<0.01**	1.298	0.088
Urgent surgery	1.567	0.115	0.558	0.330
Surgery duration (h)	1.382	**<0.01**	1.343	**<0.01**
Bypass time (h)	1.056	0.176	1.098	**0.026**
Cross-clamp time (h)	1.672	**<0.01**	1.590	**0.038**

NOTE. Bold indicates statistical significance.

Abbreviations: CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; FTF, fast-track failure; IDDM, insulin-dependent diabetes mellitus; MI, myocardial infarction; OPCAB, off-pump coronary artery bypass; OR, odds ratio; PVD, peripheral vascular disease

found to be independent risk factors for primary FTF, whereas COPD, diabetes, renal impairment, and duration of surgery were identified as risk factors for secondary FTF. The FT failure rate in this study was lower than that found in other studies.

The rates of FTF reported in the literature vary from 15.6% to 45.5% in mixed-age populations.[6,7] This can be explained by the different definitions of FTF and by patient selection. Based on different organizational structures of each hospital, a number of different local FT protocols exist, resulting in various definitions of a successful FT concept. A common definition of a successful FT is extubation within 6 hours postsurgery and ICU LOS <24 hours.[11] Successful FT should lead to reduction of ICU stay and economic benefits for the hospital compared with conventional treatment.

A meta-analysis of 25 prospective studies showed that there was limited evidence of cost reduction from early extubation.[12] Only one study described cost effectiveness in early extubated patients.[8] Reduction of ICU LOS played a major role in cost reduction, and therefore FT protocols in dedicated PACUs were designed to bypass the ICU completely.[6,10]

In this study, successful FT treatment was defined as transfer of the patient to the IMC within the open hours of the PACU (8.5 hours), completely bypassing the ICU, and transfer of the patient to the ordinary ward during the following postoperative days until discharge from hospital without readmission to the ICU. The authors chose this definition because this FT protocol has been shown previously to be safe[10] and cost effective.[5]

One study[9] reported a slightly higher FTF rate of 16% in patients transferred from the PACU to the ward on the day of surgery; however, in contrast to the present study, follow-up was not complete. Many patients were discharged to peripheral hospitals on postoperative day 3. The authors of that study mentioned the lack of further information.

A comparable FTF of 15.6% also has been reported. The LOS in an FT unit within the ICU was <48 hours. It was reported that extubation of the FT patients mainly was nurse-driven, and the decision of weaning from mechanical ventilation was made by the cardiothoracic team. Anesthesiologists or intensivists were only involved if respiratory problems occurred.[6] In contrast, the PACU in the present study was

Table 6. Independent Risk Factors After Multivariate Analysis for Primary FTF Patients

Parameters	p Value	OR
Age >70 y	<0.01*	2.2
Surgery duration	<0.01*	1.4/h >3 h
Cross-clamp time	<0.01*	1.5/h >65 min
Female sex	<0.01*	1.5

Abbreviations: FTF, fast-track failure; OR, odds ratio

*p < 0.05.

managed by 1 anesthesiologist and 1 anesthetic nurse who cared for a maximum of 3 patients at a time. Only 57% of patients in the previously mentioned study could be extubated within 8 hours. According to the FT criteria of the present study, this would reflect an FTF rate of 43%. Another study[3] reported an FTF rate of 11% in an FT unit, but did not report extubation times. Another surgical group reported an FTF rate of 36% in a study of 229 cardiac patients; their definition of FT was transfer of the patient from the ICU to the IMC unit on the same day as surgery.

A study with much higher FTF rates[7] used extubation times within 10 hours, LOS in the ICU <24 hours, and total hospital LOS <6 days. Readmission rate to the ICU, defined as secondary FTF, was 5.6% in the present study, similar to previous reports, which showed 3.1%[6] and 3.3%, respectively.[3]

In the present study, independent risk factors for FTF (ie, age, female sex, surgery and clamp time) were found to be completely different from those reported previously (ie, left ventricular function, acute coronary syndrome within 30 days of surgery, reoperations, extracardiac arteriopathy, preoperative intra-aortic balloon pump, raised serum creatinine, surgical urgency, and complex surgery).[6]

The main explanation for this discrepancy was that, in the present study, the final decision to transfer the preselected patients to the PACU was made at the end of the surgery, whereas the previous study included all patients except those who required dialysis for renal insufficiency, patients with cardiothoracic trauma, and those who were admitted directly to the ICU because of bed availability.

The authors did not exclude patients because of preoperative low ejection fraction; however, inotropic support at the end of the procedure, more likely to be used in patients with reduced ejection fraction, was included in this FT protocol criteria. One study[9] also concluded that left ventricular dysfunction was a significant preoperative predictor for FTF, although the logistic EuroSCORE in that study was 2.9 compared with 5.1 in the present study.

In the present study, female sex was an independent risk factor for FTF. A possible explanation is the fact that women with ischemic heart disease have different pathology, risk factors, severity, and mortality than men.[13] It has been concluded previously that sex was not an independent risk factor for perioperative morbidity, mortality, or excessive ICU LOS after adjustment for other risk factors.[14] On the other hand, more recent studies supported the results of the present study. One group of researchers[15] found a sex difference when comparing patient outcomes after isolated coronary artery bypass, which was worse in women. They suggested that women present at an older age, with multiple comorbidities and a more acute presentation, possibly predisposing them to a higher incidence of mortality. These results were the same as those proposed in another study[16] regarding postoperative morbidity, but not mortality. This delayed presentation theory was supported by other recent studies, albeit in cardiology rather than in cardiac surgery settings.[17,18] Many studies that were analyzed previously[19] reached the same conclusion; women react differently from men due to gender-determined differences in anatomy, physiology, and immune response.

Some of the identified risk factors (ie, age >70 years, surgical duration, and renal impairment) were similar to those determined in a study by the Cleveland Clinic group,[20] although the endpoints of that study were morbidity and mortality. This raises the possibility of preoperative (EuroSCORE) or postoperative scores in helping to triage eligible patients. It also suggests that the same variables indicating risk for FTF overlap those of morbidity and mortality; in other words, patients with poor reserve fare poorly.

Age >70 years was found to be an independent factor for FTF in this study, in line with a previous study.[5] It has been concluded that age, per se, should not be a determining factor in the decision of FT management; instead, type of surgery (other than isolated CABG) and accompanying noncardiac complications such as cerebrovascular accident, renal failure, bleeding, and infection should be determining factors.[7] FT management for elderly patients undergoing isolated CABG has been recommended.[7] This differs from the present study, as the authors included a wide variety of cardiac surgeries. One study[21] examined the effect of age on patient outcome in more complicated surgeries (triple-valve disease) and concluded that other comorbidities rather than older age should be a limiting factor for complicated procedures. In that study, age did not affect overall mortality, perhaps due to the average age of study patients (67.2 years). As age is a nonmodifiable risk factor, experts recommended focusing on modifiable risk factors and meticulous preoperative preparation to improve the outcome in this age group.[22]

As previously published,[5,9] the Leipzig Heart Center has an FT protocol that bypasses ICU admission completely; patients are admitted to the PACU instead. Another study[9] also admitted patients directly to the PACU, but because of major differences both in patient preselection and the inclusion and exclusion criteria, it is difficult to compare these studies with the present study. The Leipzig Heart Center is operated entirely by anesthesia staff trained in methods of early extubation. Moreover, the hours of operation for the PACU in the Leipzig Heart Center are from 10 AM to 6:30 PM. This means that extubation should take place within 7 hours of surgery, followed by post-extubation observation for at least 90 minutes, or the patient cannot be transferred to a lower level of care (IMC, in this case). Because of this organizational protocol, in the present study FTF was defined as failure to extubate within 7 hours post-surgery and therefore transfer of the patient to the ICU. Finally, the authors did not use thoracic epidural analgesia, but used intravenous analgesics instead. The use of neuraxial block in FT management is outside the scope of this study.

Limitations

The limitation of this study was its retrospective design; this may have an impact because of recent developments in perioperative management. FTF rates were much lower than in the literature, perhaps because of selection bias. The data set

was collected for patients who underwent cardiac surgery in 2007 and 2008. Throughout this period, no major changes were introduced in the department regarding patient preselection and FT protocol. The authors believe, therefore, that the data are still valid and reflect the real-life scenario.

CONCLUSION

This study demonstrated that preselection of patients for FT treatment reduced the number of independent risk factors for FTF and ensured a high success rate.

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