Fast-Track Cardiac Anaesthesia Protocols: Is Quality Pushed to the Edge?

Abstract

Background: The quest for methods expediting rapid postoperative patient turnover has triggered implementation of various fast-track cardiac anaesthesia protocols. Using three different fast-track protocols in randomized controlled studies (RCT) conducted 2010-2016 we found minimal achievements in ventilation time together with actual and eligible length of stay in cardiac recovery unit. The comparable control group patients were evaluated in this retrospective post hoc analysis, for an association between above mentioned parameters and quality parameters, to assess whether the marginal gains have been at the expense of quality of recovery and patient comfort. Method: 90 control patients from three RCT with comparable demographic parameters and receiving standard department treatment were evaluated using time parameters and an objective/semi-objective Intensive Care Unit (ICU) score system (IDS score). Results: Ventilation time was statistical significant lower in latest study (C) than the early (A) and intermediate (B) studies (A=293, B=261, C=205 minutes; P=0.04). The IDS was lower at extubation and all time points in the early study compared to other studies (P< 0.001). The average IDS in latest study were the double of previous studies at the end of observations, and marginally above the acceptable score for discharge. The postoperative morphine requirement A=15.0, B=10.0 and C=26.5 mg; P=0.002) was statistical significant higher in the latest study compared to previous studies. Conclusion: The implementation of strict fast-track protocols resulting in shorter ventilation time did not convert to earlier eligibility to discharge from the ICU. However, the quality of recovery appears challenged.

Keywords: Cardiac anesthesia, fast-track protocols, quality of recovery, ventilation time

Introduction

The pursue for a more efficient use of resources together with earlier patient mobility secondary to increased patient turnover in cardiac surgery has resulted in a growing interest in intensive care unit (ICU) length of stay (LOS) as it is one of the main factors limiting operating room utilization. The requisite for a faster ICU turnover has led to an upward interest for fast-track cardiac anaesthesia protocols leading to earlier discharge from the ICU.[1,2]

Previous studies have demonstrated that the application of a fast-track protocol results in a decreased postoperative ventilation time with a reduced use of resources and costs.[3] Following, early extubation is usually considered one of the main steps in fast-track pathways.[4] and different protocols have been proposed.[5,6] However, the impact of the optimal extubation time on LOS after cardiac surgery is still debated[7] and the question of applicability, quality and safety is still open. Although a recent meta-analysis showed that fast-track protocols do not create more complications compared to standard anaesthesia and care.[8] Questions have been raised as to whether the method of anaesthesia or the characteristics of the recovery unit were decisive factors in fast-track protocols,[9] a major obstacle is that LOS is not a fully objective measure which may be contaminated by local policies and logistics.

Three randomised controlled trials (RCT) were conducted by same group of anaesthetists and surgeons in our institute during 2010-2016 with three different fast-track protocols implemented on demographically similar group of patients and equally treated control groups. Due to logistics, all patients usually stay overnight in our cardiac recovery unit (CRU) and to achieve a valid measure of LOS in CRU, the eligible time to discharge was established with a semi-objective ICU discharge scoring system (IDS) based on physiological parameters frequently named.
as performance indicators. The IDS, apart from estimate of eligible discharge time and objective measure of quality of recovery offer easy comparability within and between groups. The findings in the studies opened a discussion on whether the marginal gains had been at the expense of quality during recovery. We therefore conducted this study to investigate association between postoperative quality indicators, ventilation time and LOS in CRU, with the primary hypothesis that the quality of recovery may be challenged during the observation period.

**Method**

The review is based on the control groups from three RCTs from our institution during 2010-2016 handling fast-track protocols where the primary interventions were high epidural analgesia (study A), remifentanil (study B) and low dose sufentanil (study C). All studies had a comparable standard control group receiving sufentanil. During the overall study period, the department generally worked on faster extubation and early discharge from CRU in an attempt to facilitate patient turnover.

**Patients, inclusion, and exclusion**

All included patients were hospitalized one day prior to surgery and were randomly assigned to intervention or standard sufentanil. The inclusion criteria were age 60-80 years scheduled for CABG with/without aortic valve replacement. Study C also allowed mitral valve replacement. Exclusion criteria were arrhythmia, ejection fraction <30%, hypertension ≥180 mmHg, known pulmonary hypertension and diabetes mellitus together actual angina or recent myocardial infarction (within 30 days). Patients continued regular medical treatment until the morning of surgery, except platelet inhibitors and anticoagulant drugs which were paused at appropriate time before surgery as per Danish National guidelines. Premedication consisting of 5-10 mg diazepam and 2 g paracetamol (slow release) was administered 1-2 h before surgery.

**Hemodynamic monitoring and anaesthesia protocol**

All patients were perioperative monitored with continuous five-lead electrocardiogram, peripheral saturation and invasive hemodynamic monitoring with a pulmonary artery catheter (PAC) (744HF75, Edwards Life Sciences, Germany) and Vigilance monitor (Edwards Critical-care, Irvine, USA). Blood pressures (MAP), central venous pressure (CVP), continuous cardiac index (CI), mixed venous saturation (SvO₂) were obtained every minute and stored electronically for later analysis. All control group patients in the three studies received 1-2 µg/kg sufentanil intravenously within 1-2 min. The total dose of sufentanil before cardiopulmonary bypass (CPB) was intended to 3.0-3.5 µg/kg. Concomitant with initial opioid induction, propofol infusion (100-200 mg/h) was started together with a bolus dose of rocuronium (0.6 mg/kg) to facilitate tracheal intubation. Propofol was used for maintenance of anaesthesia and continued into the postoperative phase.

**Surgical procedure**

After median sternotomy, normothermic CPB was established using a closed system consisting of tubing with a surface modifying additive coating, an arterial filter with heparin coating, a hollow fibre membrane oxygenator with a surface modified additive coating and a venous cardiotomy reservoir. Before weaning from CPB, reperfusion of the heart was performed on an individual basis according to the patient’s general condition and cross-clamp time. At the end of surgery, all patients were transported to the CRU while still mechanically ventilated.

**Postoperative care**

The principal objective of these RCT’s was to assess the potential for earlier extubation and shorter CRU stay by using different anaesthesia protocols with focus on ventilation time together with eligible and actual LOS in CRU. In all studies, the awakening process started 1 h after arrival at the CRU, according to the department guidelines. Extubation was done when the patient was awake, pain free and satisfying the objective criteria; spontaneous respiratory rate 10-16/min, core temperature >36.0°C, pH between 7.34 and 7.45, PaO₂ >10 kPa with FiO₂ ≤40% and max PEEP 5 cm of H₂O, PaCO₂ <6 kPa, drain loss <100 ml/h in the last two consecutive hours together with stable haemodynamics (<20% change in CI/SvO₂/MAP the last hour).

Patients were assessed at least every hour using visual analogue score (VAS) (scale 1-10) for pain and received intravenous morphine 0.05 mg/kg if VAS was above 3-4 at rest or alfentanil 25 µg if rapid relief was needed. All patients received additional oral or intravenous paracetamol (1 g) every 6 h and intravenous 15-30 mg ketorolac to attenuate pain from chest tubes. The first dose of ketorolac (15 mg) was given 30 min before expected extubation and in cases with pain from chest tubes, a second dose was given 4-6 h later.

All other aspects of postoperative patient management were at the discretion of the attending anaesthesiologist and as per the department guidelines concerning the administration of intravenous fluids, vasoactive drugs, or pacemaker treatment to obtain the following goals: CI >2.0 L/min/m², SvO₂ >60%, MAP 60-90 mmHg, heart rate 60-80 beats/min and diuresis >1 ml/kg/h. Any use of pharmacological support, transfusions of blood products and use of opioids were recorded until discharge.

**Predefined outcome variables**

The primary outcome variables were ventilation time, eligible and actual time to discharge from CRU together with quality during recovery. Ventilation time was defined as the time from arrival at the CRU until extubation. The LOS in the CRU was defined as the time from arrival
until discharge to the general ward. The eligible time and quality were assessed using individual variables of the IDS [Figure 1] by the attending nurse, where higher IDS values reflected lower quality. Patients were scored 30 min after extubation and every hour until discharge or until the next morning at 08:00, whichever came first, except in study A where the patients were scored at fixed times, 2, 4, 6 h after extubation and before discharge.

The variables and ratings in the IDS are slightly modified from the scoring system made for general surgery by the Danish Society of Anaesthesia and Intensive Care by adding extended hemodynamic and bleeding parameters. The variables consist of five semi-objective variables (sedation, respiration, nausea, pain and motor function) and seven objective variables (peripheral saturation, diuresis, arterial blood pressure, heart rate, cardiac index, temperature and postoperative drainage). Patients were considered eligible to discharge from the CRU after a 3-h steady and continuous IDS ≤4 and with no single variable scoring 3 or 4.

### Statistical analyses

The analysis of all obtained data was done off-line after the completion of the study. Normality of data was checked by D’Agostino-Pearson test for normal distribution. Data are expressed as mean ± SD for normally distributed data or median [interquartile range] for non-normally distributed variables, or number and percentage. Inter-group comparisons and continuous data were analysed by an independent samples t-test, two-way ANOVA, Mann-Whitney or Kruskal-Wallis-test according to normality and categorical data with a χ²-test. Analyses were performed with MedCalc® software version 18.5 (Mariakerke, Belgium). A probability value of <0.05 was used to define statistical significance.

### Results

Patients in the three studies were fully comparable in relevant demographic parameters and perioperative variables, except age where patients included in study A seemed marginally older than the other studies. Additionally, patients in study A and C had more combined surgery than in study B [Table 1].

There was no statistical significant difference in absolute or in per kg per operative administered sufentanil, but when including anesthesia time, there was a small difference in sufentanyl expressed as µg/kg/h (study A ≠ study B; Table 1). Postoperative Morphine requirement, both total and per kg, was statistical significant higher in study C compared to the previous studies [Table 2].

Ventilation time showed statistically significant differences between groups. Patients in study C were extubated earlier (205 min) as compared to study A (293 min) and B (261 min), respectively [Table 2]. The minimal differences in LOS in CRU were not statistically significant. The patients in study group A became eligible to discharge later than those in study B and C, but the difference was not statistically significant. Although no differences were observed in eligible time to discharge, there were some differences in overall IDS throughout the studies.

Figure 2 demonstrates the fraction of individual scores after extubation and average values throughout the observations period. The data showed some differences in hemodynamic factors (blood pressure + heart rate + cardiac output) being A: 0.16, B: 0.32 and C: 0.33 after extubation and A: 0.20, B: 0.30 and C: 0.33 during the observation time. Likewise a difference was found in awake/respiratory state (sedation + respiration + saturation) being 0.45, 0.21 and 0.09 after extubation and 0.34, 0.15 and 0.07 during the observation period in the three studies, respectively.

IDS in study A group was lower in all common time points (0.5, 2, 4 and 6 h after extubation and at the end of the observation period [Figure 3]). Additionally, the average IDS in study B and C at the time of extubation were approximately 6.5 compared to study A patient 3.5. The difference in the average scores persisted for 4 h, after which the scores improved more in study B patients compared to the patients in study C. The IDSs at the end showed similar trends where
study A patients had lowest scores, while patients in study C had the highest scores [Figure 3], which was marginally above the acceptable figure for eligibility to discharge of <4. At common time points after extubation, the patients in study C showed scores ≥2 in all the individual parameters of IDS, except in sedation, respiration, saturation and BP [Table 3].

Discussion

This is the review of the experienced quality during recovery in patients from the control groups of three RCTs handling FTCA principles in a single institution 2010-2016, where all control patients received standard anesthetic treatment. The primary finding was that ventilation time was decreased statistically significant in the observation period but without effect on eligible or actual discharge from CRU. A possible explanation could be that patients in later studies received less peroperative sufentanil per hour, but these patients received significantly more post-operative morphine; leaving room for other explanations. Furthermore, the overall amount of peroperative sufentanil was not statistically significant. The standard administration of up to 3.5 µg/kg of sufentanil before CPB indicates that most patients received sufentanil early and the difference in µg/kg/h is due to anesthesia times which were marginally, but not statistically different. Similarly, the shorter ventilation can also be explained by the fact that the fast-track protocols increasingly focus on early discharge from the CRU which is technically dependent on extubation. Despite the fact that ventilation time has no impact on LOS in CRU, extubation is still prioritized to achieve shorter eligible time to discharge, while simultaneously stabilizing patient’s other physiological parameters. This is reflected in the patients in study B and C, where patients are extubated earlier and with substantial higher scores compared to patients in study A, but with the notion that sedation and respiration parameters were lower.

IDS increased over time and in study B and C were higher from extubation until the discharge compared to study A and the later studies (study B and C) the patients had higher pain scores, lower diuresis, and higher drainage especially at the time of discharge, reflect suboptimal recovery.

Postoperative recovery constitutes a diverse process that concludes in return of patient status to baseline[15,16] and

### Table 1: Pre- and peroperative demographic and treatment factors

| Factor                  | Study A      | Study B      | Study C      | P       | Differences |
|-------------------------|--------------|--------------|--------------|---------|-------------|
| Age (years)             | 71 (68-75)   | 68 (64-75)   | 67 (58-73)   | 0.020   | A≠C         |
| Female sex              | 9 (30.0)     | 3 (10.0)     | 9 (30.0)     | 0.107*  |             |
| BMI                     | 26.7 (23.5-29.0) | 27.4 (24.5-30.0) | 27.5 (24.7-29.5) | 0.494  |             |
| CABG                    | 11           | 21           | 17           | 0.001*  | B ≠A/C      |
| Valve                   | 8            | 9            | 2            |         |             |
| Combined                | 11           |              | 11           |         |             |
| Anaesthesia time (min)  | 235 (216-272) | 265 (220-301) | 274 (224-308) | 0.079  |             |
| ECC time (min)          | 85 (61-111)  | 91 (69-114)  | 97 (81-131)  | 0.056   |             |
| CC time (min)           | 49 (37-73)   | 52 (40-76)   | 67 (54-93)   | 0.055   |             |
| EuroSCORE (modified)    | 4 (3-5)      | 4 (2-4)      | 3 (2-5)      | 0.205   |             |
| Sufentanil total (µg)   | 330 (300-400) | 300 (250-400) | 320 (250-405) | 0.456  |             |
| Sufentanil (µg/kg)      | 4.22 (3.45-5.17) | 3.63 (3.05-4.44) | 3.95 (3.00-4.93) | 0.160  |             |
| Sufentanil (µg/kg/h)    | 1.13 (0.86-1.30) | 0.81 (0.68-1.07) | 0.92 (0.68 1.21) | 0.033  | A≠ B        |

Modified EuroSCORE is the total EuroSCORE minus the procedure factors. Statistics *) χ² test, all others Kruskall-Wallis test

### Table 2: Postoperative ventilation time, actual discharge time and eligible discharge type together with postoperative morphine administration, medical support and postoperative drainage of control patients in three studies

| Factor                  | Study A      | Study B      | Study C      | P       | Differences |
|-------------------------|--------------|--------------|--------------|---------|-------------|
| Ventilation time (min)  | 293 (229-360) | 261 (216-372) | 205 (139-279) | 0.004   | A ≠ B ≠ C   |
| ICU discharge (h)       | 21.6 (19.3-23.4) | 21.2 (19.5-23.1) | 20.4 (18.5-22.0) | 0.206  |             |
| Eligible discharge (h)  | 13.9 (10.8-19.5) | 11.4 (8.4-14.6) | 11.1 (7.0-13.4) | 0.082  |             |
| Morphine total (mg)     | 15.0 (9.0-26.5) | 10.0 (4.0-20.0) | 26.5 (10.3-40.0) | 0.002   | C≠ A/B      |
| Morphine (mg/kg)        | 0.20 (0.10-0.31) | 0.15 (0.05-0.25) | 0.34 (0.14-0.46) | 0.002   | C≠ A/B      |
| Morphine (µg/kg/h)      | 9.1 (4.6-12.3) | 7.2 (3.5-11.4) | 15.1 (7.8-20.7) | 0.004   | C≠ A/B      |
| Constrictors [no (%)]   | 4 (13.3)     | 14 (46.7)    | 11 (36.7)    | 0.018   | A ≠ B/C     |
| Inotropes [no (%)]      | 4 (13.3)     | 2 (6.7)      | 2 (6.7)      | 0.578   |             |
| Vasodilators [no (%)]   | 21 (70.0)    | 10 (33.3)    | 7 (23.3)     | < 0.001 | A ≠ B/C     |
| Overall medical support | 23 (76.7)    | 22 (73.3)    | 16 (53.3)    | 0.112   |             |
| Postoperative drainage (ml) | 418 (300-760) | 445 (375-720) | 425 (300-656) | 0.746   |             |

Statistics Kruskall-Vallis test
has been assessed by various recovery assessment tools by addressing physical,[17-19] psychological,[20] functional,[21] and more recently, cognitive domains. In case of postoperative cardiac surgical patients, normalization of patient status before discharge from CRU may ensure, that the patient will be without risk of physiological derangements in the wards. The IDS model is based on scoring of performance indicators and one of the specially made recovery assessment tools,[21,22] which allows identification of suboptimal recovery at both individual and group levels, and when implemented in real time helps in targeted interventions specific to individual patients as well as facilitates optimal resource rationalization. The observation of suboptimal recovery in study B and C cannot be overlooked with the argument that IDS model is developed on the principle of normalization of physiologic and physiologic indicators to the population standard threshold values and not to the patient’s own immediate preoperative values, due to the fact that the sufficiently wide range of vital parameter values used for classification in IDS, avoid the probable subjective bias resulting from response shift.

The finding that, the IDS of over 6.5 in study B and C at the time of extubation [Figure 3] appears predominantly influenced by higher pain reports and
unstable hemodynamics. It can partly be explained by the lower sufentanil blood level following the lower perioperative sufentanil/kg/h and partly by a less aggressive administration of opioids in the pre-extubation period to avoid further delay. While adequate analgesia offers improved hemodynamics, immunologic and hemostatic modulation, it can partly be explained by the lower sufentanil blood level following the lower perioperative sufentanil/kg/h and partly by a less aggressive administration of opioids in the pre-extubation period to avoid further delay. While adequate analgesia offers improved hemodynamics, immunologic and hemostatic modulation, it can partly be explained by the lower sufentanil blood level following the lower perioperative sufentanil/kg/h and partly by a less aggressive administration of opioids in the pre-extubation period to avoid further delay. While adequate analgesia offers improved hemodynamics, immunologic and hemostatic modulation,

earlier extubation, shorter hospital stay and overall patient satisfaction, absence of adequate analgesia may expose the patients to development of chronic pain pathologies like post-sternotomy pain syndrome. As the patients express recovery as a return to previous “normality” in their various daily roles, and the quality of their recovery is defined by the level of “normality”, they attained and the process they experienced to reach their goal. Higher IDS secondary to presence of pain may be reported as poor quality of recovery. However, as per recently published data, it has been postulated that the older the patients, the lower their reported maximum pain levels. Therefore, as patients in study B and C were relatively younger, the higher pain reporting may correlate with the inherent characteristics of age-related pain acceptance, tolerance, and reporting. However, these patients simultaneously had higher IDS in hemodynamic parameters which may be a reflection of pain. So, irrespective of assumption of age-related bias towards pain reporting, adequate analgesia still remains a priority as significant acute postoperative pain is associated with poorer long-term nociceptive recovery.

The observation that patients in the newer studies had higher pain and unstable hemodynamic parameters during the stay in CRU and at the time of discharge, supports the statement that the QR may have declined, and pain may expose the patients for risk of readmissions and long-term chronic pain syndrome. As in all the three studies, we have concluded that the interventions, that is, high thoracic epidural, remifentanil and low-dose sufentanil offer no clinically significant gain in context to discharge from recovery, implementation of fast-track protocols may result in larger long-term consequences as compared with clinically non-significant short-term achievements. Although it has been concluded in the retrospective meta-analysis that there is no increased risk of adverse outcomes in patients undergoing fast-track, the focus in the meta-analysis was primarily on mortality, myocardial infarction, stroke and renal failure and therefore the issues of experienced quality during recovery and long-term consequences of fast-track protocols need further investigation.

Limitations of the study

Despite that all three studies focused on fast-track potentials and the control groups received the department standard anesthetic treatment, the time span cannot exclude minor different approaches to general patient handling. Important observations in the study are that study B and C had a higher number of young patients and that study C had a lower number of valve cases. However, they are all standard cases with similar postoperative treatment, which should diminish any impact on results.

Although, all patients with preoperative arrhythmias were excluded from the study, an increased incidence of unstable hemodynamics. It can partly be explained by the lower sufentanil blood level following the lower perioperative sufentanil/kg/h and partly by a less aggressive administration of opioids in the pre-extubation period to avoid further delay. While adequate analgesia offers improved hemodynamics, immunologic and hemostatic modulation, earlier extubation, shorter hospital stay and overall patient satisfaction, absence of adequate analgesia may expose the patients to development of chronic pain pathologies like post-sternotomy pain syndrome. As the patients express recovery as a return to previous “normality” in their various daily roles, and the quality of their recovery is defined by the level of “normality”, they attained and the process they experienced to reach their goal. Higher IDS secondary to presence of pain may be reported as poor quality of recovery. However, as per recently published data, it has been postulated that the older the patients, the lower their reported maximum pain levels. Therefore, as patients in study B and C were relatively younger, the higher pain reporting may correlate with the inherent characteristics of age-related

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postoperative rhythm disturbances in study C may still be a possibility as mitral valve patients were included. However, no such incidence was noted during the study.

The data on readmissions and postoperative events including physiological and biochemical markers of cardiac, respiratory and renal function may enlighten whether there are any immediate consequences of discharging the patients with high IDS in wards. However, the number of patients was too little as no serious postoperative events or readmissions were found in the control groups of the three studies.

Conclusion

Although the patients were extubated earlier, we could not demonstrate the effect on eligibility to discharge from CRU and the data indicate that quality of recovery is challenged after the strict implementation of fast-track protocols.

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Conflicts of interest

There are no conflicts of interest.

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