



Extubation in operating room versus early extubation in ICU after open-heart surgery in patients with CHDs

Original Article

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Corresponding author:
J. G. Kwak; Email: switch.surgeon@gmail.com

Chan Hyeong Kim¹ , Jae Hong Lee¹ , Hye Won Kwon¹ , Sungkyu Cho¹,
Woong-Han Kim¹ , Sang-Hwan Ji² , Young-Eun Jang² , Jin-Tae Kim² and
Jae Gun Kwak¹

¹Department of Thoracic and Cardiovascular Surgery, Seoul National University Hospital, Seoul, Republic of Korea and ²Department of Anesthesia and Pain medicine, Seoul National University Hospital, Seoul, Republic of Korea

Abstract

Backgrounds and Objectives: The “Fast track” protocol is an early extubation strategy to reduce ventilator-associated complications and induce early recovery after open-heart surgery. This study compared clinical outcomes between operating room extubation and ICU extubation after open-heart surgery in patients with CHD. **Methods:** We retrospectively reviewed 215 patients who underwent open-heart surgery for CHDs under the scheduled “Fast track” protocol between September 2016 and April 2022. The clinical endpoints were post-operative complications, including bleeding, respiratory and neurological complications, and hospital/ICU stays. **Results:** The patients were divided into operating room extubation (group O, n = 124) and ICU extubation (group I, n=91) groups. The most frequently performed procedures were patch closures of the atrial septal (107/215, 49.8%) and ventricular septal (89/215, 41.4%) defects. There were no significant differences in major post-operative complications or ICU and hospital stay duration between the two groups; however, patients in group I showed longer mechanical ventilatory support (0.0 min vs. 59.0 min (interquartile range: 17.0–169.0), p < 0.001). Patients in Group O showed higher initial lactate levels (3.2 ± 1.7 mg/dL versus 2.5 ± 2.0 mg/dL, p = 0.007) and more frequently used additional sedatives and opioid analgesics (33.1% versus 19.8%, p = 0.031). **Conclusions:** Extubation in the operating room was not beneficial for patients during post-operative ICU or hospital stay. Early extubation in the ICU resulted in more stable hemodynamics in the immediate post-operative period and required less use of sedatives and analgesics.

After open-heart surgery for patients with CHD, conventional post-operative care in the ICU focuses on stabilising the patient’s hemodynamic status while maintaining an endotracheal tube in situ for mechanical respiratory support. “Fast track” protocol is defined as an early extubation strategy compared to conventional post-operative management and has been proposed as a part of an enhanced recovery after surgery programme to initiate post-operative rehabilitation earlier, induce early recovery, and shorten hospital stays after open-heart surgery.^{1–7}

The fast-track protocol has the advantage of reducing mechanical ventilation duration, thereby decreasing ventilator-associated respiratory complications and positive pressure ventilation-associated hemodynamic compromise.^{4,5,7,8} In addition, the fast-track protocol was reported to shorten the length of ICU stay, leading to fewer psychological problems, such as delirium and depression, and ultimately reducing hospital stays and socio-economic costs.^{5–11}

However, it has been noted that too early extubation leads to respiratory failure and re-intubation, which portends prolonged ventilatory support and hemodynamic compromise after open-heart surgery. In paediatric patients, more sedatives and analgesics must be used to calm agitated patients after extubation, which can lead to neurological complications such as neurodevelopmental disorders.^{12,13}

This study aimed to identify the optimal timing of extubation in the fast-track protocol and to compare the clinical outcomes of extubation in the operating room with extubation in the ICU, after open-heart surgery, in patients with CHD.

Material and method

Patient characteristics

This retrospective single-center cohort study enrolled 230 patients who underwent open-heart surgery for CHD under the fast-track protocol between September 2016 and April 2022, and 215 (93.5%) patients completed the fast-track protocol. Causes for exclusion from the planned

fast-track protocol were patient's unexpected deep sedative status not allowing early extubation ($n = 5$), delayed ventilator weaning due to unclear mental status with agitation ($n = 3$), unexpectedly prolonged operating times and late ICU admission ($n = 2$), and significant post-operative bleeding ($n = 2$). Other causes included transient pulmonary hypertension, respiratory distress during ventilator weaning, and accidental extubation and re-intubation immediately after ICU admission in one patient each. Among the 215 patients, 124 were extubated immediately after surgery in the operating room (operating room extubation group, group O), and 91 were extubated in the ICU (early ICU extubation group, group I).

Fast track protocol

The "fast track" protocol has been used regularly at our centre since November 2016. This study defined "fast track" as early extubation within 6 h post-operatively, including on-table extubation in the operating room. Initially, a fast-track was planned for non-neonatal patients with simple congenital cardiac anomalies requiring relatively short cardiopulmonary bypass and aortic cross-clamp times, such as atrial septal defect or ventricular septal defect, without significant pulmonary hypertension or left ventricular dysfunction.

For induction of anaesthesia, atropine, sodium thiopental, midazolam, rocuronium, and fentanyl were administered depending on the patient's age and body weight. Maintenance drugs included remifentanyl, rocuronium, midazolam, and sevoflurane, the concentrations of which were adjusted according to the bispectral index (Medtronic Korea, Seoul, Korea) or patient state index (MASIMO Korea, Seoul, Korea). Additional bolus doses of rocuronium and midazolam were administered when cardiopulmonary bypass was initiated. Continuous rocuronium/midazolam administration was discontinued when cardiopulmonary bypass was discontinued, and remifentanyl was tapered to a half-dose. At the end of the operation, sevoflurane was discontinued, and neostigmine or sugammadex was administered as a neuromuscular blockade reversal agent according to response to train-of-four stimulation that measures degree of neuromuscular blockade. Adequate reversal of neuromuscular blockade was confirmed by observation of T4/T1 ratio $\geq 90\%$ in response to train-of-four stimulation. When patients' self-respiration and consciousness were restored after reversal of neuromuscular blocker, extubation was performed in the operating room. When adequate spontaneous respiration and clear obey-commands were not achieved, even after reversal of neuromuscular block, the patients were transferred to ICU with an endotracheal tube in place. When patients presented with improved consciousness and spontaneous respiration without apnoea in ICU, extubation was performed. For optimal pain control after extubation, the anaesthesiologists used regional nerve blocks under ultrasound guidance, such as bilateral paravertebral and erector spinae blocks, in the operating room just before extubation or transfer to ICU.

If not extubated in the operating room, patients were sedated lightly, before extubation in ICU, with a low dose of remifentanyl (0.02–0.05mcg/kg/min), which does not cause respiratory depression. Additionally, non-opioid painkillers (intravenous acetaminophen or NSAIDs) were administered regularly (3 to 4 times a day). The ventilator mode was started in a synchronised intermittent mandatory ventilation–pressure control mode and then changed to a pressure support ventilation mode when self-respiration was restored. If the blood gas profile was tolerable after pressure support was tapered to 6–8mmHg, and if no respiratory distress symptom/

sign occurred, remifentanyl was discontinued and extubation was performed 30 minutes later. Depending on the ventilator fraction of the oxygen, a nasal cannula or high-flow nasal cannula was applied after extubation. If self-respiration was restored but consciousness was not clear, a flumazenil (0.02mg/kg) injection was tried, on the basis of a probability that this was a side-effect of midazolam.

Clinical endpoints

The clinical endpoints in this study were immediate post-operative complications during ICU stay. The amount of red blood cell transfused, duration of drainage tube placement, re-operation rate due to post-operative bleeding, and change in hematocrit level on the day of surgery were reviewed to analyse bleeding complications. Regarding respiratory issues, post-operative pneumonia events, re-intubation after early extubation, duration of mechanical ventilation support, and additional use of sedatives and opioid analgesics were analysed. "Additional use of sedatives and opioid analgesics" was defined as the bolus administration of benzodiazepine (midazolam) and opioid analgesics (fentanyl or pethidine) or restarting remifentanyl after it had been stopped to calm the patient's agitation following extubation, in addition to scheduled administration of regular analgesics (acetaminophen, ibuprofen, or ketorolac). The change in lactic acid levels on the day of surgery was analysed as an indicator of hemodynamic status. Cerebrovascular attacks, seizures, and consultations with the neuropsychiatry department for post-operative delirium were analysed as neurological issues. We thought that the ICU stay, total hospital stay after surgery, transfer to the general ward on the day of surgery, and rate of readmission to the ICU could represent the cost of hospitalisation. These factors were compared and analysed between the two groups. Discharge criteria were: all drain tubes had been removed; post-operative work-ups (echocardiography, cardiac computed tomography, or magnetic resonance imaging, tailored to surgery) had been completed; and medication had been adjusted in consultation with the cardiologists.

Statistical analysis

Statistical analyses were performed using the IBM SPSS statistical software version 28.0 (IBM Inc., Armonk, NY, USA). Continuous variables were presented as the mean \pm standard deviation for normally distributed data or median with interquartile range for not normally distributed data. Categorical variables were presented as numbers and percentages. Categorical and continuous variables were compared using the chi-square test or Fisher's exact test and Student's t-test or Mann–Whitney U test, respectively.

Ethics statement

This study protocol was reviewed by the Institutional Review Board and approved as a minimal risk retrospective study (approval number:2206-040-1331), and individual consent was waived based on the institutional guidelines for obtaining consent.

Results

Patients' characteristics/ operative profile

The pre-operative characteristics and operative data are shown in Table 1. There were no significant differences between the two groups. The median ventilatory support time in group I was 59.0 (interquartile range 17.0–169.0) min. In group I, 61 (67.0%) patients were extubated within 2 h after the operation, and 35 (38.5%) were extubated within 30 min.

Table 1. Post-operative change in haematocrit and lactate after fast track

Variables	OR extubation (n = 124)	ICU extubation (n = 91)	p-value
Haematocrit (POCT, %)			
initial	34.7 ± 3.3	34.1 ± 3.8	0.239
1-hour	32.5 ± 3.9	32.6 ± 4.2	0.946
3-hour	31.3 ± 3.0	31.0 ± 3.8	0.665
6-hour	30.4 ± 3.4	29.6 ± 4.1	0.230
lowest	30.1 ± 3.7	29.4 ± 4.1	0.181
Haematocrit (CBC, %)			
initial	35.1 ± 2.7	34.8 ± 3.3	0.510
3-hour	32.4 ± 2.8	34.1 ± 4.1	0.068
6-hour	30.5 ± 3.2	30.3 ± 3.9	0.771
lowest	30.1 ± 3.3	30.1 ± 3.6	0.911
Lactate (POCT, mg/dL)			
initial	3.2 ± 1.7	2.5 ± 2.0	0.007
1 h	3.2 ± 2.0	3.4 ± 2.2	0.614
3 h	2.5 ± 1.9	2.9 ± 2.0	0.138
6 h	2.3 ± 1.8	2.3 ± 2.0	0.952
highest	3.5 ± 1.9	3.6 ± 2.2	0.721

CBC = complete blood count; ICU = intensive care unit; OR = operating room; POCT = point-of-care test.

*Values are presented as mean ± standard deviation or n (%).

The median age at the operation seemed to be older in group O (38.0 [interquartile range:18.9 ~ 67.6] months old) than in group I (22.9 [interquartile range:13.9 ~ 59.2] months old), but there was no significant difference ($p = 0.230$). The median body weight at the operation was 13.4 (interquartile range:10.3 ~ 18.5) kg in group O and 12.3 (interquartile range:9.1 ~ 19.3) kg in group I ($p = 0.539$). Mean cardiopulmonary bypass time and aortic cross-clamp time were 95.1 ± 28.5 min and 58.1 ± 21.8 min in group O and 100.0 ± 40.4 min and 61.2 ± 31.7 min in group I, respectively, with no significant difference ($p = 0.371$ and 0.390 respectively) (Supplementary Table S1).

The most frequently performed procedures were patch closures of atrial septal defect (107/215, 49.8%) and ventricular septal defect (89/215, 41.4%). Eight patients had a history of undergoing previous cardiac surgery. There were no significant differences in operative procedures between the two groups. Forty-seven (37.9%) patients in group O and 34 (37.4%) in group I underwent multiple cardiac procedures with no significant difference ($p = 0.936$) (Supplementary Table S2).

Post-operative bleeding

Changes in haematocrit levels after surgery were investigated using complete blood count and point-of-care tests. (Table 1) The two groups showed no significant differences in the initial haematocrit and 1-, 3-, and 6-h haematocrit by point-of-care test and the initial, 3- and 6-h haematocrit by complete blood count. Both groups had the lowest haematocrit 6 h after surgery (30.4% [point-of-care test] and 30.5% [complete blood count] in group O vs. 29.6% [point-of-care test] and 30.3% [complete blood count] in group I).

One bleeding re-operation was performed in each group (0.8% in group O and 1.1% in group I, $p = 0.825$). Sixteen (12.9%)

patients in group O and 17 (18.7%) in group I required red blood cell transfusion in the ICU ($p = 0.246$). Packed red blood cells were transfused when there was clinically significant post-operative bleeding accompanied by haemodynamic instability, or when Hb was lower than our centre's criteria (8mg/dL for simple CHDs, 10mg/dL for complex or cyanotic CHDs). The mean chest tube removal time was 3.0 ± 1.0 days after the operation in group O and 3.1 ± 1.1 days in group I ($p = 0.713$). There were no significant differences in the three indices between the two groups. (Table 2)

Respiratory and haemodynamic issues

Changes in lactate levels after surgery were investigated using point-of-care test immediately, 1-, 3-, and 6-h after the operation. The initial lactate level was significantly higher in group O (3.2 ± 1.7 mg/dL versus 2.5 ± 2.0 mg/dL, $p = 0.007$); however, there were no significant differences in 1-, 3-, and 6-h lactate levels between the two groups. (Table 1)

Re-intubation was required only in group O (two [1.6%] patients), but the difference was not statistically significant ($p = 0.509$) compared to group I. Post-operative pneumonia occurred in two (1.6%) patients in group O and one (1.1%) in group I with no statistical significance ($p = 0.615$). Additional administration of sedatives and opioid analgesics was significantly higher ($p = 0.031$) in group O (41 patients, 33.1%) than in group I (18 patients, 19.8%). (Table 2)

Neurological complications and hospital stay

Post-operative delirium occurred in two (1.6%) patients in group O and two (2.2%) in group I. Neurological complications, including cerebrovascular stroke events and post-operative seizures,

Table 2. Post-operative major complications after fast track

Variables	OR extubation (n = 124)	ICU extubation (n = 91)	p-value
Bleeding complications			
Bleeding re-operation (n, %)	1 (0.8%)	1 (1.1%)	0.825
RBC transfusion (n, %)	16 (12.9%)	17 (18.7%)	0.246
Duration of chest tube placement(day)	3.0 ± 1.0	3.1 ± 1.1	0.713
Respiratory complications			
Re-intubation (n, %)	2 (1.6%)	0 (0.0%)	0.509
Post-operative pneumonia (n, %)	2 (1.6%)	1 (1.1%)	0.615
Additional Sedatives/Opioids (n, %)	41 (33.1%)	18 (19.8%)	0.031
Delirium	2 (1.6%)	2 (2.2%)	0.566
Neurologic complications			
Median ICU stay (hour)(IQR)	8.0 (6.2-21.9)	9.7 (6.3-22.8)	0.821
Median hospital stay (day)(IQR)	6 (5-7)	6 (5-7)	0.281
General ward transfer at OP day	76 (61.3%)	44 (48.4%)	0.059
ICU readmission	0 (0.0%)	2 (2.2%)	0.178

ICU = intensive care unit; IQR = interquartile range; OR = operating room; OP = operation; RBC = red blood cells.

*Values are presented as mean ± standard deviation or n (%).

occurred in two (1.6%) patients in group O and one (1.1%) in group I. The two groups showed no significant differences in the ratio of post-operative delirium to neurological issues. (Table 2)

The median duration of ICU stay was 8.0 (interquartile range 6.2–21.9) h in group O and 9.7 (interquartile range 6.3–22.8) h in group I ($p = 0.821$). The median post-operative hospital stay was 6.0 (interquartile range 5.0–7.0) days in group O and 6.0 (interquartile range 5.0–7.0) days in group I ($p = 0.281$). A slightly higher number of patients in group O (76 patients, 61.3%) were transferred to the general ward on the day of surgery than those in group I (44 patients, 48.4%, $p = 0.059$). (Table 2)

Discussion

Fast track was introduced as a part of the enhanced recovery after surgery programme and applied to cardiac surgery for CHDs, and its range of application is currently expanding from simple CHDs such as atrial septal defect and ventricular septal defect to complex CHDs such as functional single ventricle, re-operation cases, and even CHDs in neonatal patients.^{14–17}

Our early experiences with the fast-track protocol for patients who underwent open-heart surgery revealed that patients with similar disease entities enrolled in the fast-track protocol showed significantly shorter ICU stays than those not enrolled with similar disease entities.¹⁸ In contrast to the situation in some North American countries, a shorter ICU stay did not significantly reduce the actual hospital costs in our previous study. We assumed this was due to the unique national insurance system in Korea. As our fast-track protocol has stabilised, we have extended it to patients with simpler congenital cardiac diseases and those with slightly more complex diseases, such as re-operative cases or single ventricle patients. However, we noticed that patients extubated on the operating room table frequently exhibited respiratory difficulty, apnoea, severe agitation, or delirium after transfer to the ICU. These patients were also more likely to show elevated lactate levels in the immediate post-operative period, although they

stabilised over time. Therefore, this study attempted to clarify whether operating room extubation was clinically superior to early ICU extubation.

The present study revealed similar post-operative clinical courses in terms of the incidence of post-operative bleeding, respiratory complications, and neurological concerns, regardless of the timing of extubation: on-table extubation in the operating room or slightly delayed extubation in the ICU within 6 h, mostly within 2 h (67%) after surgery. However, patients extubated in the operating room had significantly higher initial lactate levels, a key indicator of tissue perfusion and oxygenation. Robin L Kloth and Victor C Baum reported similar trends in a study for paediatric patients who underwent cardiac surgery. In this study, patients extubated in operating room showed higher carbon dioxide levels and were more likely to develop respiratory acidosis on blood gas analysis immediately after transfer to ICU, in comparison to patients who had been transferred with an endotracheal tube in place.¹⁹ These results imply that transferring extubated patients to ICU after open-heart surgery may result in decreased systemic perfusion and oxygenation. Additionally, the on-table extubation group required more sedatives and opioid analgesics to calm down and reduce agitation after extubation. Elevated lactate levels and increased use of sedatives were two factors expected to increase the risk of respiratory failure and re-intubation; however, there was no significant difference, even though all re-intubation cases in the study cohort (2/215, 0.9%) occurred in the operating room extubation group.

Extubation in the operating room immediately after surgery did not reduce the length of ICU or hospital stay. In addition, there was no significant difference in the transfer rate to the general ward between the two groups on the day of surgery. In the entire cohort, patients transferred to the general ward on the day of operation (120/215, 55.8%) showed a significantly shorter length of post-operative hospital stay (5.9 ± 1.3 days versus 7.4 ± 3.7 days, $p < 0.001$). This means that transfer to the ward on the day of surgery is a more important factor in the overall hospital stay than extubation in the operating room.

This study has some limitations. First, this was a retrospective observational study conducted at a single institution. Second, most patients had simple CHDs, such as atrial septal and ventricular septal defects. There were only two cases of bidirectional cavopulmonary shunt or Fontan-type procedure in which positive pressure ventilation may adversely affect the post-operative course and benefit from early extubation. Third, extubation in the operating room and the timing of transfer to the general ward on the day of surgery were not entirely determined by clinical or medical factors. Operating room extubation was periodically abandoned due to a busy operating room schedule, and transfer to the general ward was delayed by other unforeseen events, such as quarantine due to a viral infection or patient's familial concerns. These factors may have affected the proportions of patients in each group.

In conclusion, extubation in either the ICU or operating room did not increase the incidence of post-operative complications. Despite longer mechanical ventilator support, early ICU extubation was not inferior to operating room extubation in terms of ICU and hospital stays. Patients extubated in the operating room had significantly higher initial lactate levels and required more sedatives and opioid analgesics. Early ICU extubation under close observation can provide a margin of safety with the same post-operative complications and length of hospital stay as operating room extubation.

Supplementary material. The supplementary material for this article can be found at <https://doi.org/10.1017/S1047951123003839>.

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