Heliyon 9 (2023) e15741

Contents lists available at ScienceDirect

Heliyon

journal homepage: www.cell.com/heliyon

Research article

Feasibility and safety of ultra-fast track anesthesia for totally thoracoscopic closure of ventricular septal defect: A randomized controlled trial

Ningning Fang [a], Bingbing Ma [b,c], Kai Liu [b,c], Yuedong Hou [a,*], Zengshan Ma [b,c,**]

[a] Department of Anesthesia, Qilu Hospital, Cheeloo College of Medicine, Shandong University, No. 107 Wenhua Xilu Rd, Jinan, Shandong Province, PR China

[b] Department of Cardiac Surgery, Qilu Hospital, Cheeloo College of Medicine, Shandong University, No. 107 Wenhua Xilu Rd, Jinan, Shandong Province, PR China

[c] Institute of Thoracoscopy in Cardiac Surgery, Cheeloo College of Medicine, Shandong University, No. 107 Wenhua Xilu Rd, Jinan, Shandong Province, PR China

ARTICLE INFO

Keywords:
Thoracoscopy
Ventricular septal defect
Ultra-fast-track anesthetic
Extubation
Congenital heart disease

ABSTRACT

Objective: Ultra-fast channel anesthesia (UFTA) can reduce the dosage of opioid narcotic drugs, allow for a rapid postoperative extubation and reduce the harmful stress response during perioperative period. However, there has been limited information about the application of UFTA during thoracoscopic closure of ventricular septal defect (VSD). The aim of this study was to assess the feasibility and safety of UFTA technique in patients undergoing totally thoracoscopic closure of VSD.

Methods: Seventy-eight patients were randomly divided into study (UFTA) and control (standard general anesthesia) group. Totally thoracoscopic closure of VSD was performed in all patients. Extubation in the study and control group was attempted in the operating room and the intensive care unit, respectively.

Results: All patients in the study group were extubated in the operating room immediately after surgery, but 2 (6.1%) required reintubation. All the control group patients were extubated after a period of mechanical ventilation (3.0 ± 3.7 h vs 0 h in the study group, $p = 0.001$) in the intensive care unit. The intensive care and hospital stays in the study group were shorter than in the control group (4.3 ± 2.5 vs 13.4 ± 4.4 h, $p = 0.003$, and 5.8 ± 0.8 vs 6.5 ± 1.2 d, $p = 0.047$). The total costs for the treatment in the study group was lower than in the control group (5264 ± 514 vs 4662 ± 461 US dollars, $p = 0.02$).

Conclusions: UFTA and operating room extubation was feasible and safe in the majority of patients following totally thoracoscopic closure of VSD. This technique was associated with a shorter intensive care stay and lower overall costs for the surgical treatment.

* Corresponding author. Department of Anesthesia, Qilu Hospital, Cheeloo College of Medicine, Shandong University, No. 107 Wenhua Xilu Rd, Jinan, Shandong Province, PR China.

** Corresponding author. Department of Cardiac Surgery, Qilu Hospital, Cheeloo College of Medicine, Shandong University, No. 107 Wenhua Xilu Rd, Jinan, Shandong Province, PR China.

E-mail addresses: hou_yuedong@163.com (Y. Hou), zengshan.ma@sdu.edu.cn (Z. Ma).

https://doi.org/10.1016/j.heliyon.2023.e15741
Received 11 January 2023; Received in revised form 30 March 2023; Accepted 20 April 2023
Available online 25 April 2023

1. Introduction

High-dose opioid anesthesia during cardiac surgery has been the main anesthesia method for decades due to its ability to preserve hemodynamic stability and attenuate hormonal and metabolic response to surgical stress [1]. However, large doses of long-acting opioids required patients to be ventilated post-operatively for 12–24 h [2,3]. Increasing cost due to prolonged ventilation and ICU and hospital length of stay have influenced changes in this practice [4,5]. With the development and popularisation of enhanced recovery after surgery, the possibility of rapid recovery of spontaneous breathing and early tracheal catheter removal after an operation for cardiac surgery has attracted more attention. On the basis of fast-track cardiac anesthesia (extubation within 6 h after operation), ultra-fast-track anesthesia (UFTA) further optimises surgical and anesthesia procedures so as to allow for removal of the tracheal catheter immediately or within 1 h after an operation [6–8]. The core concept of UFTA is to reduce the dosage of opioid narcotic drugs and select appropriate sedative and analgesic drugs that will allow for a rapid postoperative extubation and reduce the length of duration of mechanical ventilation [9].

Thoracoscopic closure of congenital heart defects, such as atrial septal defect (ASD), has emerged as an alternative to conventional cardiac surgery to treat congenital heart diseases in children and young adults [10–13]. Compared with conventional surgery through sternotomy, thoracoscopic closure of ASD was associated with a shorter-postoperative recovery time [14,15]. Recently, totally thoracoscopic closure of ventricular septal defect (VSD) without robotically assisted surgical system has also been reported [16]. General anesthesia is required for thoracoscopic closures of ASD or VSD, and extubation was conducted in the intensive care unit in the majority of the previously reported cases [10–16]. Prolonged extubation has brought some problems to patients, such as unexpected tracheal tube prolapse, pulmonary hypertension crisis induced by sputum aspiration, additional sedative and analgesic drugs, and ventilator-associated pneumonia [17]. Although UFTA can achieve immediate extubation after surgery, there has been limited information about the application of UFTA during thoracoscopic closures of congenital cardiac defect. The aim of this study was to investigate the feasibility and safety of UFTA in patients undergoing totally thoracoscopic closure of VSD.

2. Patients and methods

2.1. Ethics

This single-centre, randomised controlled study was prospectively registered with the Chinese Clinical Trial Registry (ChiCTR2200059987, chictr. org.cn/index.aspx). The trial was approved by the ethics committees of Qilu Hospital of Shandong University (Approval No.2021277). This trial conformed to the Consolidated Standards of Reporting Trials (CONSORT) guideline. Written informed consent was obtained from the guardian of each child who participated in this study. The trial was conducted in accordance with the principles of the Declaration of Helsinki and the Good Clinical Practice guidelines of the International Conference on Harmonisation.

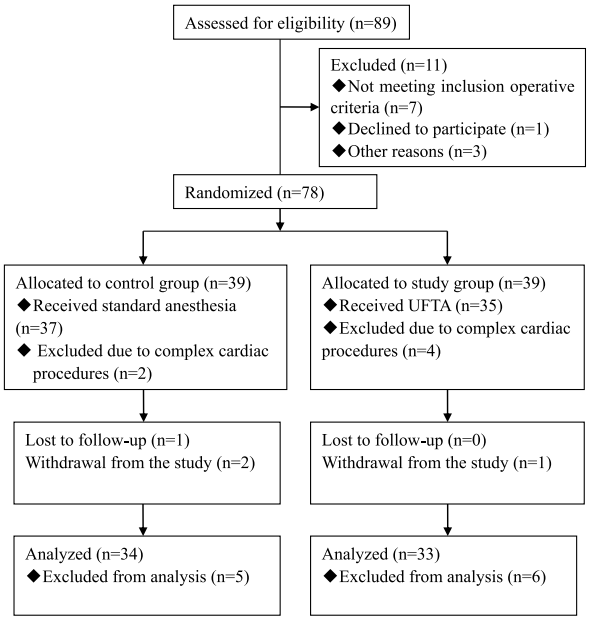

Fig. 1. Flow chart of randomization. UFTA: ultra-fast track anesthesia.

2.2. Patient selection

Between May 2022 and August 2022, 89 patients with VSD were screened for totally thoracoscopic closure. A total of 78 (36 males, mean age 10.2 ± 4.5 years, range 3–19 years) met the selection criteria outlined below, and were recruited to this study (Fig. 1). For thoracoscopic VSD closure all the following selection criteria must be met: a) membranous or perimembranous VSD of any size; b) age >2 years old with a body weight of >14 kg. Exclusion criteria are any one of the following: a) supracristal or muscular VSD; b) pulmonary arterial systolic pressure (measured by echocardiography) ≥ 60 mm Hg; c) a history of lung disease, right chest surgery, or adhesions of the right pleural membrane; d) concurrent cardiovascular disease or chronic illnesses; e) ventricular dysfunction (New York Heart Association function class III or IV; f) smaller children (<2 years old and/or body weight <15 kg), mainly because the sizes of the femoral blood vessels were too small to be cannulated for cardiopulmonary bypass (CPB).

The selected patients were randomly divided into study (UFTA) and control group (standard anesthesia, Fig. 1). The randomization was conducted by a computer randomization program. The general characteristics of the study and control group patients are listed in Table 1.

2.3. Anesthesia management

All of the patients received intravenous (I.V.) fluids upon arrival in the operation room. Next, they were given routine monitoring that included mask oxygen, electrocardiogram, percutaneous oxygen saturation (SPO_2), temperature in the operation room. Preoperative IV penehyclidine hydrochloride was given at a dose of 0.01 mg/kg. In the study group, the following medications were used intravenously for induction of general anesthesia: midazolam (0.04 mg/kg), propofol (1.5–2.0 mg/kg), fentanyl (3–5 μg/kg), and vecuronium (0.1–0.15 mg/kg) [18]. Maintenance of general anesthesia was achieved with continuous infusion of remifentanil (0.3–0.8 μg/kg/min) [18]. The patients received inhalation of 2%–3% sevoflurane after tracheal intubation. During cardiopulmonary bypass, propofol was intravenously infused at a rate of 2–7 mg/kg/h to maintain deep anesthesia. In the study group, the following medications were used intravenously for induction of general anesthesia: Thiopental (5.0 mg/kg), fentanyl (3–5 μg/kg), pancuronium (100 μg/kg). After tracheal intubation, the patients received inhalation of 1.5%–2.5% isoflurane. Fentanyl (5–10 μg/kg) was added at the beginning of the operation and CPB.

A single-lumen (for patients with a body weight <30 kg) or double-lumen tube (DLT) was placed to allow for single-lung ventilation. The size of DLT is used according to the following height/gender standards: female<1.6 m, 35 Fr; Women>1.6 m, 37 Fr; Male<1.7 m, 39 Fr; Male>1.7 m, 41Fr. After tracheal intubation, the invasive arterial pressure, central venous pressure, end-expiratory carbon dioxide, and urine volume monitoring were conducted for all of them. The respiratory parameters are set as follows: tidal volume 10 ml/kg, ventilation frequency 18–30 times/min, respiratory ratio 1.0:1.5. Respiratory parameters are adjusted according to blood gas analysis. The depth of anesthesia was monitored according to the bispectral index. The bispectral index was maintained between 40 and 60 throughout the operation. At the end of the surgery, neostigmine and atropine was intravenously administered to antagonise the effects of muscle relaxants used in the surgery.

2.4. Surgical techniques

Totally thoracoscopic VSD closure was performed without the aid of a robotic surgical system, using the methods that we have recently described [13,16]. The patient was positioned in a 20° to 30° left lateral decubitus position, with the right upper arm slightly abduction fixed. A F10–F18 catheter was inserted to the right femoral artery to introduce a guide wire, which was guided by insertion of bipolar drains from the femoral artery feeding vessel and femoral vein, respectively, to establish cardiopulmonary bypass (CPB). After the start of CPB, the superior and inferior vena cava were sequentially blocked. The ascending aorta was blocked by aortic blocking forceps and perfused anterogradely with cold St Thomas cardioplegic solution to achieve cardiac arrest. The right atrium was opened from a site parallel to the atrioventricular annulus, and the tricuspid valves were pulled apart to expose the VSD. Direct suture

Table 1
Comparison of baseline and operational data between the study and control group.

Characteristics	Study (n = 33)	Control (n = 34)	P value
Age (years)	10.2 ± 4.5	9.9 ± 4.7	0.119
Male	19 (57.6%)	17 (50.0%)	0.651
Body weight (kg)	30.4 ± 10.6	29.6 ± 9.8	0.265
Mean femoral vein diameter (mm)	8.5 ± 1.2	8.4 ± 1.1	0.361
Mean right femoral artery diameter (mm)	12.1 ± 2.2	12.0 ± 1.9	0.329
Perimembranous VSD	10 (30.3%)	9 (26.5%)	0.791
Membranous VSD	23 (69.7%)	25 (73.5%)	0.791
Tricuspid regurgitation	2 (6.1%)	2 (5.9%)	1.000
Total operation time (min)	76 ± 9	78 ± 7	0.124
CPB (min)	42 ± 4	43 ± 6	0.461
Aortic crossclamp time (min)	32 ± 4	31 ± 4	0.329
Blood transfusion during operation	7 (21.2%)	8 (23.5%)	0.084

No statistical significant differences between groups. Reported as Mean ± SD. Categorical variables reported as: n (%).VSD, ventricular septal defect; CPB: cardiopulmonary bypass.

(4-0proline) was used for closure for ventricular septal defects smaller than 6 mm. Ventricular septal defects above 6 mm require a bovine patch to repair.

De-airing was performed via the perfusion needle at the root of the aorta and open aortic blocking forceps when the repair of VSD was completed. Transesophageal echocardiography was performed to confirm the integrity of the VSD closure. Finally, the catheters in the right femoral vein, femoral artery or the right internal jugular vein were removed, and a closed chest drain was placed at the entrance of the thoracoscope.

2.5. Perioperative management and cost analysis

UFTA was conducted in the study group patients, using the methods that we have recently reported [18]. Extubation in the control group was performed in the surgical intensive care unit. With the study group, extubation was attempted in the operating room if all the following criteria were met: 1) Patients were able to respond to verbal commands of the medical staff on eye opening, cough and swallowing; 2) Resumption of spontaneous respiration with SpO_2 >95%; 3) Stable blood pressure and heart rate with no arrhythmia; 4) Body temperature >36.5 °C; 5) No signs of active bleeding; 6) Blood gas: pH > 7.30; PaO_2 >60–70 mmHg; $PaCO_2$ <45 mmHg, FiO_2 <0.5. Patients who did not meet the above criteria within 20 min of the surgery were transferred to the intensive care unit for monitoring and extubation.

Extubation in the study group was attempted in the operation room. With control group, extubation in the operation room was also attempted if the criteria for immediate extubation were met. Patients were subsequently monitored in the cardiac surgical intensive care unit overnight, and were discharged to the wards if all the following criteria were met: 1) The capillary refills rapidly; 2) the pulse is strong; 3) the arterial blood pressure is within the normal range; 4) the blood gas index is good; 5) the extremities are warm. Bedside chest X-ray was routinely performed in the intensive care unit to exclude complications in the lungs. After discharge, patients were followed-up in our hospital clinics monthly in the first 3 months following the operation. The integrity of ventricular septum was assessed by transthoracic echocardiography before discharge and 3 months after surgery.

The overall costs to each patient were retrieved from the hospital finance department at the time of discharge. The charges to each patient were comprised of pre- and post-operational laboratory tests, medications, thoracoscopic surgery, duration of intensive care monitoring, and length of hospital stays. The charges for thoracoscopic surgery were session based with little variations between patients. The pre- and post-operational tests and medications were also similar between patients, except in those who developed post-operative complications for which additional medications or tests may be required. Therefore, the differences in total costs were largely related to the complexity and duration of treatment and monitoring in the intensive care unit, as well as the length of hospital stays.

3. Outcomes

The primary outcome was the immediate extubation rate of patients in the operating room.

To assess the feasibility and safety of UFTA technique in patients undergoing totally thoracoscopic closure of VSD, Secondary outcomes included respiratory complications and costs of hospitalization. The secondary outcome measures also comprised the mean mechanical ventilation time, the intensive care stays, the hospital stays, the total operation time, CPB time, aortic clamp time and volume of chest drains. We also documented the cases of perioperative mortality and major postoperative bleeding that requiring surgical revision.

3.1. Statistical analysis

We calculated sample sizes (two-tailed tests, alpha 0.05, 80% power) with parametric methods to compare the mean differences between groups and expanded the results by 16% to adjust for possible non-parametric analyses. We defined 20% difference in immediate extubation rate as clinically significant. For primary outcome measures, the results reported by Xingrong Song and colleagues [6]were used to approximate the immediate extubation rate. The minimum sample size for nonparametric between two-group comparisons was calculated as 24 per group.

Continuous data were analyzed with a Student *t*-test for normally distributed values and a Mann-Whitney *U* test for non-normally distributed values and presented as mean ± standard deviation. A one-way ANOVA followed by Tukey post hoc tests were performed to determine the statistical difference between multiple groups with one variable and normally distribution. To compare multiple groups with more than one variable, two-way ANOVA followed by Tukey or Sidak post hoc tests was used. Categorical variables were compared by Chi-square or Fisher's exact test. P value < 0.05 was considered statistically significant. All statistical analysis was performed with SPSS v13.0 software package (Version 13.0, Chicago, USA).

4. Results

4.1. General findings

After randomization, 6 patients from the study and control group were excluded due to complex cardiac procedures (Fig. 1): presence of another cardiac defect in addition to VSD (n = 3); unsuccessful single lung ventilation due to pulmonary hypertension (n = 2); and reversion to standard VSD repair via sternotomy due to femoral artery deformity (n = 1). After discharge, 4 patients lost to the

follow-up or withdrawal from the study for non-medically related reasons. In the end, 33 of the study and 34 of the control group patients completed the study. There was no statistically significant difference in age, sex, body weight, and the types of VSD between the study and the control group ($p > 0.05$, Table 1).

4.2. Operational data

VSD closure was successful in all patients. There was no perioperative mortality and no major postoperative bleeding that requiring surgical revision. There was no statistically significant difference in the total operation time, CPB time, aortic clamp time, or volume of chest drains between the two groups ($p > 0.05$, Table 1). The mean mechanical ventilation time and the intensive care stays in the control group was longer than in the study group ($p = 0.001$ and 0.003, respectively), whereas the hospital stays were slightly longer ($p = 0.047$, Table 2).

4.3. Extubation, respiratory complications and costs of hospitalization

None of the patient in the control group met the operating room extubation criteria. These patients were extubated after a period of mechanical ventilation (3.0 ± 3.7 h, Table 2) in the surgical intensive care unit. All study group me the extubation criteria, and operating extubation was successful in 31 (93.9%). In 2 patients (6.1%), re-intubation was performed in the operating room within 15 min of the initial extubation. One re-intubation was due to a decline in consciousness level in the operating room shortly after extubation, and the other was due to arrhythmia and reduction in blood pressure shortly after extubation. Both patients were observed in the intensive care unit, and extubation was successfully completed 3 h after the intensive care unit admission.

In the control group, 1 patient experienced atelectasis and another had lung infection following the surgery. Both patients had full recovery after respiratory physiotherapy or intravenous antibiotics treatment. There were no respiratory or other complications in the study group. There were no significant differences in the arterial Lac, PaO_2, and $PaCO_2$ values in the study and control groups (Table 3).

The total costs of the hospitalization to the study group patients, including surgery, intensive care treatment and treatment in the wards, were higher than in the control group ($p = 0.022$, Table 2).

5. Discussion

Several previous studies have reported factors that may influence the feasibility or safety of UFTA in patients undergoing cardiac surgeries. In patients who were treated with coronary bypass grafting, pre-existing renal failure, diabetes mellitus, cardiac reoperation and preoperative unstable hemodynamics were associated with an increased risk of extubation failure in the operating room [19]. Prolonged total operation time was also associated with the risk of extubation failure [19,20]. Totally thoracoscopic ASD or VSD closures are minimally invasive cardiac surgeries. In experienced centers, the total operation times are usually less than 2 h, and the CPB time less than 1 h [16,21]. Most patients undergoing thoracoscopic procedures for congenital heart defects are young, and are generally free of severe respiratory or cardiovascular dysfunction, or other co-morbidities that may increase the risk of extubation failure. In the present study, operating room extubation was successfully achieved in 93.9% of the patients, and in only 6.1% that re-intubation was required due to decline in consciousness level, or unstable hemodynamics as a result of cardiac arrhythmia. These results suggest that UFTA and operating room extubation is feasible in the vast majority of the patients undergoing totally thoracoscopic closure of VSD.

Although the risks and benefits of UFTA and operating room extubation are still a matter of debate, there are some obvious reasons that favor the implementation of early extubation following cardiac surgery. First, successful operating room extubation after cardiac surgery may reduce the need for intensive care stay and lower overall surgical costs [22]. Nurse and intensive care dependency may also be reduced, the risk of airway and lung trauma may be diminished, and cardiac output may be improved by spontaneous breathing [19]. In the present randomized and controlled study, the length of intensive care stays in patients of the UFTA group was significantly shorter than in patients of the control group. The hospital stays, and the mean time interval between hospital discharge and resumption of work or schooling in the UFTA group were also shorter than in the control group. In addition, the total costs for the hospital stays and treatment in the UFTA group were lower than in the control group. As in our hospital there were little variations in the costs of the thoracoscopic surgery per se, or pre- or post-operational tests, examinations of medications between patients, the lower costs in the

Table 2
Comparison of postoperative hospitalisations between the study and control group.

Characteristics	Study (n = 33)	Control (n = 34)	P value
Mechanical ventilation time (h)	0	3 ± 3.7	0.001
Intensive care stays (h)	4.3 ± 2.5	13.4 ± 4.4	0.003
total hospital stays (d)	5.8 ± 0.8	6.5 ± 1.2	0.047
Respiratory complications	0	2 (5.7%)	0.492
Time returning to work or schooling (d)	15 ± 4	22 ± 5	0.047
Total costs of the surgery* (US $)	4662 ± 461	5264 ± 514	0.022

The mechanical ventilation time, intensive care stays, total hospital stays, time returning to work or schooling and total costs of the surgery in Study Group were all significant lower. *Fees were charged and paid in local currency. They are converted to US dollars for the purpose of this study.

Table 3
Comparison of arterial Lac, PaO_2, and $PaCO_2$ on the1nd hour after extubation between the study and control group.

Characteristics	Study (n = 33)	Control (n = 34)	P value
Lac (mmol/L)	1.31 ± 0.06	1.86 ± 0.14	0.189
PaO_2 (kPa)	18.40 ± 1.14	19.42 ± 1.37	0.681
$PaCO_2$ (kPa)	6.58 ± 0.54	5.92 ± 0.34	0.347

Comparison of the arterial Lac, PaO_2, and $PaCO_2$ on the1nd hour after extubation between the study and control group. There was no statistically significant difference between groups.
Lac, lactic acid; PaO_2, arterial oxygen partial pressure; $PaCO_2$, arterial partial pressure of carbon dioxide.

UFTA group was largely due to reduced intensive care stays and monitoring, and to a lesser extent, a shortened hospital stay. These results suggest that UFTA and operating room extubation reduce intensive care dependency, and may shorten hospital stays and reduce the overall costs for the treatment.

Although this study adopts a random design, there are some limitations due to the single center and small sample. The results of this study needs to be interpreted in the context that this was a relatively small clinical trial. Two control group patients experienced atelectasis or lung infection, and none of the study group patients suffered from respiratory complications. However, there was probably not sufficient statistical power to draw a conclusion on the post-operative respiratory complications between the UFTA and control groups. In addition, hospital stays and time intervals between discharge and resumption of work or schooling may be influenced by a number of physical, social factors and measurement bias caused by single blindness. In the future, larger sample data will be needed to verify the experimental results.

In conclusion, this randomized and controlled study has demonstrated that UFTA and operating room extubation can be safely performed in the vast majority of patients undergone totally thoracoscopic closure of VSD. The UFTA and early extubation techniques are associated with a shorter intensive care stay and lower costs for the treatment. The benefits of UFTA and operating room extubation on hospital stays and post-operative recovery need to be further investigated.

Author contribution statement

Ningning Fang; Bingbing Ma: Performed the experiments; Analyzed and interpreted the data; Wrote the paper.
Kai Liu: Contributed reagents, materials, analysis tools or data.
Yuedong Hou; Zengshan Ma: Conceived and designed the experiments.

Funding statement

Ningning Fang was supported by the special funds for comfortable medical anesthesia optimization of Shandong Provincial Medical Association [YXH2020ZX022].

Data availability statement

Data included in article/supplementary material/referenced in article.

Declaration of interest's statement

The authors declare no conflict of interest.

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