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RESEARCH ARTICLE

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Timing of Chest Tube Removal Following Adult Cardiac Surgery: A Cluster Randomized Controlled Trial

Ali Imad El-Akkawi[a]*, Ara Shwan Media[a]*, Niels Eykens Hjørnet[a], Dorthe Viemose Nielsen[a,b] and Ivy Susanne Modrau[a,b]

[a]Department of Cardiothoracic and Vascular Surgery, Aarhus University Hospital, Aarhus, Denmark; [b]Department of Clinical Medicine, Aarhus University Hospital, Aarhus, Denmark

ABSTRACT

Objectives: Early chest tube removal following cardiac surgery may be associated with an increased risk of pleural or pericardial effusions following cardiac surgery. This study compares the effects of two fast-track chest tube removal protocols regarding the risk of pleural or pericardial effusions, requirement of opioids, respiratory function, and postoperative complications.

Design: Prospective non-blinded cluster-randomized study with alternating chest tube removal protocol in adult patients undergoing elective cardiac surgery. Monthly changing allocation to scheduled chest tube removal on the day of surgery (Day 0) versus removal on the 1st postoperative day (Day 1) provided no air leakage and output < 200 mL within the last four hours.

Results: A total of 527 patients were included in the study from September 1st 2020 until October 29th 2021 and randomly allocated to chest tube removal at day 0 ($n = 255$), and day 1 ($n = 272$). More than every fourth patient required drainage for pleural effusion with no significant difference between the groups. Earlier removal of chest tubes did not reduce requirement of analgesics, improve early respiratory function, or reduce postoperative complications. The study was halted for futility after halfway interim analysis showed insufficient promise of any treatment benefit.

Conclusion: Fast-track protocols with chest tube removal within the first 24 h after cardiac surgery may be associated a high rate of pleural effusions.

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Cardiac surgery; chest tube; pleural effusion; analgesics; enhanced recovery after surgery; randomized controlled trial

Introduction

Following cardiac surgery, chest tubes are routinely placed in the mediastinum and, if needed, the pleural cavities in order to evacuate fluids and air, and to monitor post-operative bleeding [1]. However, no recognized criteria exist regarding the optimal timing or fluid output threshold for chest tube removal.

Previous studies have found an association between chest tubes regiments longer than 24 h and an increased need of analgesics postoperatively which may prolong postoperative recovery [2–4]. Conversely, premature chest tube discontinuation may increase the incidence of pleural and pericardial effusions requiring drainage with its inherent risks. Pleural and pericardial effusions may lead to respiratory and cardiac complications, prolonged recovery and hospital stay.

In a retrospective observational cohort study including 782 patients, the rate of effusions requiring drainage was reported significantly higher after chest tubes removal within 12 h as compared to chest tubes removal on the first postoperative day (POD) [5].

With the aim to accelerate recovery, fast-track protocols with chest tube removal within the first 24 h after cardiac surgery have been implemented at several institutions.

At our department, two fast-track chest tube removal protocols have been used over the last decade. Assuming patients would be earlier mobilized and in need of less postoperative opioids, an accelerated fast-track chest tube removal protocol was introduced in 2010. Chest tubes were removed at the earliest 10 hour after surgery in extubated and mobilized patients. Prior to 2010, chest tubes were not removed earlier than on the 1st POD. The same thresholds of fluid output of less than 200 mL during the last four hours and no evidence of air leakage were applied during both time periods. As the evidence behind our clinical practice is sparce, we aimed to compare effects of two fast-track chest tube removal protocols. We hypothesized that early removal of chest tubes on the day of surgery is related to an increased risk of postoperative effusions requiring drainage.

CONTACT Ara Shwan Media aramed@rm.dk Department of Cardiothoracic and Vascular Surgery, Aarhus University Hospital, Palle Juul-Jensens Blvd 99, 8200 Aarhus N, Denmark.
*Shared first co-authorship.

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Methods

Study design

This prospective cluster randomized controlled trial compared two fast-track chest tube removal protocols in adult patients undergoing cardiac surgery at the Department of Cardiothoracic and Vascular Surgery, Aarhus University Hospital, Skejby, Denmark. All patients undergoing elective cardiac surgery were eligible for participation in this trial. Exclusion criteria were 1) emergent surgery (<24h after admission), 2) procedures with expected prolonged stay in the intensive care unit, 3) aortic valve replacement through upper hemi-sternotomy, and 4) deviation of assigned drain protocol on request of the operating surgeon.

Intervention

On a monthly basis, we alternated between two fast-track chest tube removal protocols, with chest tube removal scheduled at the day of surgery (Day 0 protocol) in odd months and chest tube removal scheduled at day one after surgery (Day 1 protocol) in even months.

Criteria for chest tube removal applied regardless of protocol: Chest tube output had to be less than 200 mL within the last four hours without evidence of air leakage and all patients had to be mobilized prior to chest tube removal. Participants were allocated to chest tubes removal at the earliest ten hours after surgery (Day 0 protocol), and chest tubes removal at the earliest on the morning of the first postoperative day (Day 1 protocol) provided no and fluid output of less than 200 mL within the last four hours and no evidence of air leakage.

With the exception of the timing of chest tube removals, the same criteria for chest tube removal applied regardless of allocation. Allocation was inevitably known to participants and care providers while outcome adjudicators were blinded.

Approval

In accordance with Danish law, this study was approved as a quality control study by the hospital management as two chest tube removal protocols that have been routinely practiced at our institution were compared. A waiver of the requirement for informed patient consent was granted by the Central Denmark Region Committee on Biomedical Research Ethics (1-10-72-1-20/28 February 2020).

Outcomes

The primary endpoint was the rate of pleural or pericardial drainage within first 30 postoperative days. On clinical indication, i.e. patients with 1) reduced respiratory capacity with requirement of supplementary oxygen or experiencing dyspnea during rest or activity and 2) with an estimated pleural effusion >500 mL, the pleural cavity was drained [6]. Drainage of pericardial effusions was performed only if deemed hemodynamically significant and clinically limiting.

Secondary endpoints were carefully chosen taking into account previous research, safety considerations, and clinical assumption – these were:

- Chest tube outcomes (duration of chest tube treatment and total fluid output)
- Intensive Care Unit (ICU) outcomes (ICU length of stay, duration of mechanical ventilation, partial pressure of oxygen at first mobilization, oxygen saturation of first morning after surgery duration of oxygen treatment)
- Postoperative complications (new onset of atrial fibrillation, kidney injury, infections)
- Requirement of opioids within the first 24 hours after surgery and on the first postoperative day respectively reported as total oral morphine equivalent daily dose (OMEDD) [7].

Data were registered and managed using REDCap (Research Electronic Data Capture) data capture tools hosted at Central Denmark Region [8]. Perioperative variables were registered prospectively and retrieved from the electronic patient journal and electronic ICU patient files. Participants were followed for 30 days after surgery in order to gather complete information regarding postoperative requirement of chest drainage, infections, renal function, and analgesics at discharge. Peak creatinine levels within 30 days were compared to baseline, and kidney injury was defined using Acute Kidney Injury Network (AKIN) classification [9]. Data regarding demographics and comorbidities were extracted from the Western Denmark Heart Registry which employs the EuroSCORE II definitions [10, 11].

Statistical analysis

Our sample size calculation was based on the following assumptions: Incidence of drainage for pleural/pericardial effusion is reduced from 20% (removal 10 h after surgery) to 13% (removal on the morning of 1st POD), significance level of 0.05 and 90% power [5].

We planned to enroll 1200 patients over a period of 18 months based on the assumption that 90% of patients undergoing open cardiac surgery at our institution would be enrolled. An interim analysis was planned when 50% of the sample size was reached. In case of the interim analysis showing insufficient promise of treatment benefit, the study would be stopped for futility.

Continuous variables are presented as mean ± standard deviation when distributed close to normal as assessed by quantile–quantile plots, otherwise as median (interquartile range). Intergroup comparisons were performed with the Fisher's exact test or Chi^2 test for categorical outcomes, as appropriate. Continuous outcomes were compared using t-test or Wilcoxon–Mann–Whitney test, as appropriate. Two-sided p-values below 0.05 were considered statistically significant. All statistical analyses were done using STATA IC version 15 (STATA Corp., College Station, TX, USA).

Results

A total of 743 patients were assessed for eligibility from September 1st 2020 to October 29th 2021 with inclusion of 527 patients. Participants were randomly allocated to treatment arms according to the time of surgery in odd or even months, resulting in 255 patients in Day 0 group, and 272 patients in Day 1 group. The progress through the phases of this cluster randomized controlled trial are illustrated in the CONSORT flow (Figure 1). Patient demographics and procedural characteristics were well balanced between the groups (Table 1). The study was discontinued prematurely after inclusion of 527 patients as per protocol interim analysis showed no promise of treatment benefit between the groups. Study outcomes are presented in Table 2.

In accordance with the protocol, median time until chest tube removal was significantly shorter, and median chest tube output significantly lower in Day 0 group compared to the Day 1 group. The rate of patients requiring drainage of the pleural or pericardial cavity was comparable between the two groups (30.6% Day 0 vs. 30.0% Day1, $p = 0.882$).

We observed no statistically significant differences in the requirements of opioids or in any other postoperative clinical endpoints between the two groups.

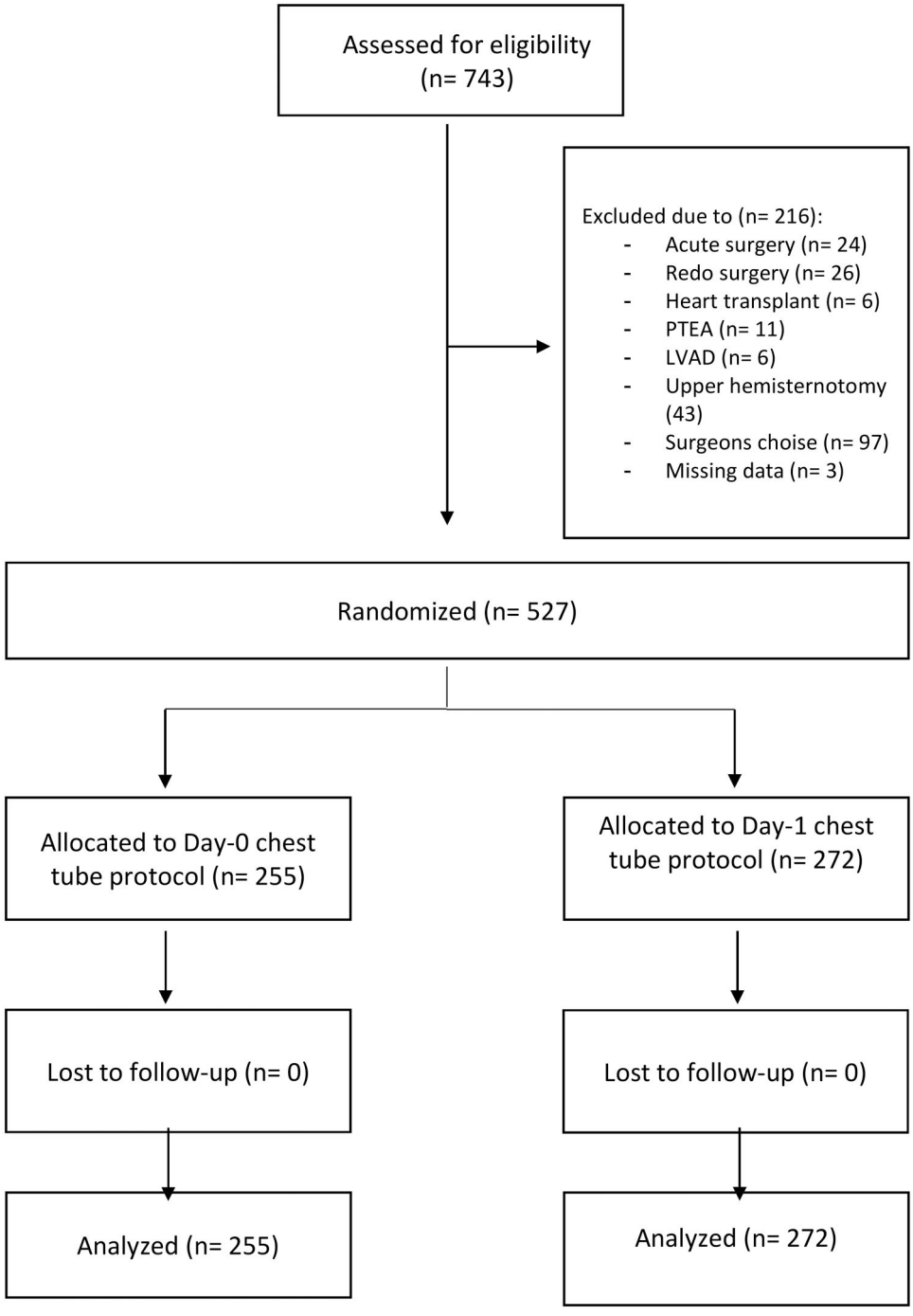

Figure 1. CONSORT flow diagram.

Table 1. Demographics, and procedural characteristics of the study population.

	Day 0 Group		Day 1 Group		
	(*n* = 255)		(*n* = 272)		P-value
Demographics					
Age, (years)	66.4	± 9.5	65.9	± 9.3	0.477
Sex, male (%)	211	82.8 %	233	85.7 %	0.358
Body Mass Index (kg/m2)	27.2	± 3.9	27.4	± 4.5	0.741
Comorbidities					
Preoperative LVEF <35 %	9	3.6 %	11	4.2 %	0.727
Diabetes Mellitus	35	14.6 %	36	14.4 %	0.939
Chronic Obstructive Pulmonary Disease	26	10.8 %	21	8.4 %	0.361
Peripheral Artery Disease	9	3.8 %	14	5.6 %	0.333
Preoperative eGFR (mL/min/1.73m2)	90	(IQR = 18)	90	(IQR = 19)	0.477
EUROscore II	4	(IQR = 3)	4	(IQR = 3)	0.851
Procedural characteristics					
Type of surgery					0.100
- CABG, isolated	152	59.6 %	156	57.4 %	
- JOPCAB	26	10.2 %	46	16.9 %	
- Valve replacement, isolated	60	23.5 %	48	17.4 %	
- CABG + Valve replacement	13	5.1 %	14	5.2 %	
- Other	4	1.6 %	8	2.9 %	
Operative variables					
Surgery duration, (mins)	186	(IQR = 81)	185	(IQR = 93)	0.996
Cardiopulmonary bypass duration, (mins)	87	(IQR = 47)	90	(IQR = 52)	0.469
Aortic cross clamp duration, mins	64	± 32	66	± 33	0.511

Data are mean ± standard deviation, median (interquartile range), or n (%). Abbr.: CABG = Coronary Artery Bypass Grafting, JOPCAB = Off Pump Coronary Artery Bypass Grafting through lower J-sternotomy, ECC (ExtraCorporeal Circulation), LVEF (Left Ventricle Ejection Fraction), eGFR (estimated Glomerular Filtration Rate),

Table 2. Outcomes

	Day 0 Group		Day 1 Group		
	(*n* = 255)		(*n* = 272)		P-value
Chest tube, drain output, and drainage					
Chest tube, time (h)	17.5	(IQR = 18)	21.7	(IQR = 20)	<0.001
Chest tube, total output (mL)	385	(IQR = 360)	465	(IQR = 405)	<0.001
Drainage, Total (%)	78	30.7 %	81	30.1 %	0.882
Drainage, Pleural Effusions (%)	72	28.2 %	76	27.9 %	0.940
Once	52	20.4 %	57	21.0 %	
Twice	15	5.9 %	13	4.8 %	
Three or more	5	2.0 %	6	2.2 %	
Drainage, Pericardiocentesis (%)	4	1.6 %	1	0.4 %	0.203
Drainage, Pneumothorax (%)	8	3.1 %	4	1.5 %	0.249
ICU outcomes					
ICU stay, (nights)					
=1	241	94.5 %	250	92.3 %	0.299
≥2	14	5.5 %	21	7.8 %	
Duration of Mechanical Ventilation, (h)	8.6	(IQR = 3.6)	8.4	(IQR = 4.5)	0.921
PaO2 at First Mobilization, (kPa)	11.1	± 2.5	10.9	± 1.8	0.170
Nasal O2 Morning, (L/min)	2.2	± 1.3	2.2	± 1.2	0.904
Need for Supplemental Oxygen, (days)	3	(IQR = 2)	3	(IQR = 3)	0.542
Clinical outcomes					
New Onset of Atrial Fibrillation, (%)	98	38.9 %	93	35.0 %	0.355
Kidney Injury ≥ AKIN stage I, (%)	75	29.4 %	90	33.1 %	0.363
Infections	55	21.6 %	52	19.5 %	0.554
- DSWI	7	2.8 %	5	1.8 %	
- SSWI	8	3.1 %	6	2.2 %	
- Other	40	15.7 %	41	15.1%	
Analgesics					
Opioids first 24 h postop.					
OMEDD, 24h. (mg)	75	(IQR = 71)	83	(IQR = 68)	0.152
Opioids first postop. day					
OMEDD, Day 1 (mg)	69	(IQR = 63)	76	(IQR = 65)	0.267
Analgesics at discharge					
Requiring Opioids, (%)	139	54.5 %	146	53.7 %	0.848

Data are mean ± standard deviation, median (interquartile range), or n (%). Abbr.: H (hours), ML (milliliters), L/MIN (liter per minute), ICU (Intensive Care Unit), DSWI (Deep sternal wound infections), SSWI (Superficial sternal wound infections), OMEDD (Oral morphine equivalent daily dose), MG (milligram), IQR (interquartile range)

Discussion

This cluster randomized controlled trial investigated two fast-track chest tube removal protocols following cardiac surgery. Nearly one third of all patients required pleural- or pericardial drainage with no difference between the groups. We found no differences between groups regarding

requirement of opioids, early respiratory function, or postoperative complications. Our results indicate no beneficial clinical effect of chest tube removal on the day of surgery compared with removal on the first postoperative day. Our findings raise caution that fast-track chest tube removal may be associated with high rates of pleural effusions, requiring drainage.

This study is unique due to the fact that all eligible patients undergoing elective cardiac surgery were included, and no patients were excluded after randomization. To our knowledge, this is the first randomized trial comparing two fast-track protocols with chest tube removal within 24 h of cardiac surgery.

Previous literature offers sparce evidence and contradictory results whether chest tube removal within 24 h of cardiac surgery reduces postoperative pain or increases the risk of pleura or pericardial effusions.

Two small-scale randomized trials have compared chest tube removal within or after 24 h postoperative after coronary artery bypass surgery [3, 4]. These studies reported lower pain scores [3], and a lower demand for analgesics [4] in patients with chest tube removal within 24 h There was no significant difference in the rate of pleural effusions between the groups in the two studies [3, 4].

Two observational studies [5, 12] confirmed significantly decreased pain scores or requirement of analgesics in the groups with shorter duration of chest tubes. However, both studies demonstrated an association between shorter duration of chest tubes, and an increased need of pleural- or pericardial drainage after cardiac surgery.

A third large retrospective study including 468 patients found no significant difference in the use of opioids, and comparable patient-reported pain scores [13], when comparing chest tube removal on day one with day two postoperatively.

Furthermore, a large prospective observational study including 484 patients reported a significantly higher risk of late cardiac tamponade requiring reintervention (8.8% vs. 3.6%) when chest tubes were removed on the 1st POD as compared to 2nd POD, although no differences in drainage of pleural effusions was found [14].

In our study, around 30% of patients in both groups required pleural drainage following cardiac surgery. This rate of required pleural drainage is higher than previously published rates which were below 20% [2, 5, 12, 15]. Our result may be related to the fact that both drainage protocols in this study are fast-track with intended chest tube removal within 24 h. Another possible explanation for the high rate of pleural drainage in our study may be the lowered threshold for drainage based on the association of pleural effusions with adverse outcomes after cardiac surgery [16].

Only a few patients in our study required pericardiocentesis while this was significantly higher in the study by Khan et al. [14]. The full explanation for these large variations across studies remains unknown.

Several limitations to this study need to be acknowledged. Per protocol, our study was discontinued when interim analysis that showed no promise of treatment benefit between the two fast-track regimes regarding pleural effusion requiring drainage to justify a continuation of the trial. The early stop for reasons of futility may increase the risk of a type-two error.

Another limitation was the mean difference in drainage time which was only four hours, although statistically significant. However, the prolonged time with chest tube in the day 0 group with intended chest tube removal after ten hours was dictated by clinical needs. Finally, the fact that it was not possible to blind neither personnel nor patients to the study intervention might possibly imply bias. We performed blinded outcome assessment and omitted patient-reported outcomes measures to limit this bias.

Conclusion

In this cluster randomized controlled trial comparing two fast-track chest tube removal protocols following cardiac surgery, we found no significant differences in the need of drainage of the pleural cavity or requirement of analgesics. A high rate of effusions requiring drainage was found in both groups and no clinical benefit of shorter duration protocol could be shown. We suggest further randomized studies comparing fast-track with prolonged chest tube removal protocols.

Disclosure statement

The authors have no competing interests to declare.

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ORCID

Ivy Susanne Modrau http://orcid.org/0000-0002-2812-6591

Data availability statement

Individual-level de-identified patient data that support the findings of this study, statistical analysis plan and informed consent form are available upon reasonable request from the corresponding author. Data sharing with other researchers requires approval by the Danish Data Protection Agency.

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