Active Chest Tube Clearance After Cardiac Surgery Is Associated With Reduced Reexploration Rates

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Background. **Ineffective evacuation of intrathoracic fluid after cardiac surgery (retained blood syndrome [RBS]) might increase postoperative complications, morbidity, and mortality. Active tube clearance (ATC) technology using an intraluminal clearing apparatus aims at increasing chest tube drainage efficiency. This study evaluated whether ATC reduces RBS in an all-comers collective undergoing scheduled cardiac surgery with cardiopulmonary bypass and full or partial median sternotomy.**

Methods. **In this nonrandomized prospective trial, 581 consecutive patients undergoing scheduled cardiac surgery with median sternotomy between January 2016 and December 2016 were assigned to receive conventional chest tubes (control group) or a combination of conventional tubes and as many as two ATC devices (ATC group), depending on their operation date. Postoperative occurrence of RBS (one or more of the following: reexploration for bleeding or tamponade, pericardial drainage procedure, pleural drainage procedure) and other endpoints were compared. Propensity score matching was applied.**

Results. **In 222 ATC patients and 222 matched control patients, RBS occurrence did not differ between the groups (ATC 16%, control 22%; $p = 0.15$). However, reexploration rate for bleeding or tamponade was significantly reduced in the ATC group compared with the control group (4.1% versus 9.1%, respectively; $p = 0.015$). The mortality of RBS patients (21%) was higher compared with patients without RBS (3.9%, $p < 0.001$). Among the RBS components, only reexploration (odds ratio 16, 95% confidence interval: 5.8 to 43, $p < 0.001$) was relevant for inhospital mortality (ATC 6.8%, control 7.7%; $p = 0.71$).**

Conclusions. **Active tube clearance is associated with reduced reexploration rates in an all-comers collective undergoing cardiac surgery. Reexploration is the only RBS component relevant for mortality. The ATC effect does not translate into improved overall survival.**

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After cardiac surgical procedures, chest tubes are placed to evacuate blood or exudate from one or more thoracic cavities (retrosternal space, pericardium, right and left pleura). Inefficient clearance leads to intrathoracic fluid retention. Intrapericardially retained fluid can lead to cardiac tamponade and the need for reexploration [1]. Intrapleurally retained fluid can necessitate pleural drainage procedures. A major contributor to intrathoracic fluid retention is chest tube clogging [2]. Therefore, chest tubes are usually manually milked or stripped, generating short phases of excessively negative pressures in the chest tube and mobilizing blood clots. Chest tube stripping is controversial because it has been found to be not effective and even harmful in meta-analyses [3, 4].

Active chest tube clearance (ATC) technology is a new approach to increase chest tube patency: the ATC device (PleuraFlow' ClearFlow, Anaheim, CA) is made of a standard silicon chest tube with an intraluminal clearance apparatus (polytetrafluoroethylene guidewire with a clearance loop, magnetically connected to an external handle shuttle allowing for movement of the clearance apparatus without compromising sterility) [5, 6]. Active tube clearance aims to provide superior drainage patency compared with conventional chest tube manipulation.

To describe the target of ATC more precisely, the complications of inefficient chest tube clearance were summarized under the term "retained blood syndrome" (RBS) in the recent literature. Retained blood syndrome comprises any procedure to remove or drain blood, blood clot, or bloody fluid around the heart or the lungs

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(postoperative reexploration, pleural drainage procedure, pericardial drainage procedure) [7]. After cardiac surgery, RBS has been associated with increased inhospital mortality, length of admission, and need for postoperative intensive care [8]. This study aimed to evaluate whether ATC reduces RBS in an all-comers collective series undergoing scheduled cardiac surgery with cardiopulmonary bypass and full or partial median sternotomy.

Patients and Methods

Study Design

This was a prospective, controlled, single-center study with sequential design.

Study Population

All consecutive patients scheduled (elective or urgent) for cardiac surgical procedures with median full sternotomy or partial sternotomy in a single institution between January 2016 and December 2016 were prospectively included in the analysis. All patients included in the study were managed by the same surgery, anesthesia, and intensive care unit teams.

Assignment to Treatment Arms

The study was conducted in a sequential fashion. All patients undergoing surgery between January 2016 and June 2016 were assigned to the control group (conventional drainage tubes), and all patients who underwent surgery between July 2016 and December 2016 were assigned to the ATC group. The sequential design was chosen to maximize the ATC handling proficiency after implementation of the ATC management protocols in the intensive care unit during the study period.

Drainage Strategy

All patients underwent cardiac surgical procedures in the customary manner. Chest tube positioning was left to the discretion of the operating surgeon. Generally, a retrosternal drainage tube (24F) and a pericardial drainage tube (18F) were placed. Additional pleural drainage tubes (24F) were placed on the sides of mammary artery harvesting if the pleura was opened during preparation. In the ATC group, one or two 24F ATC devices were used as retrosternal or pleural drainage tubes, or both. For the remaining drainage sites, conventional chest tubes were used. The positions of the ATC devices were chosen by the operating surgeon. In the control group, conventional polyvinylchloride 24F chest tubes (Atrium Medical, Hudson, NH) were used.

Postoperative Drainage Management

Chest tubes were connected to suction (−20 cmH_2O). On postoperative day (POD) 2, chest tubes were removed if drainage volume was less than 300 mL during the past 12 hours or when only serous drainage loss was observed. If these criteria were not met, reevaluation was undertaken after 12 hours. Conventional chest tubes were milked at least once an hour. The ATC devices were cleared at least every 30 minutes, and more frequently if clotting was observed.

Perioperative Anticoagulation and Antiplatelet Therapy

Acetylsalicylic acid was not discontinued perioperatively, adenosine-diphosphate receptor antagonists were discontinued 5 days (clopidogrel, ticagrelor) or 7 days (prasugrel) preoperatively, respectively. Vitamin K antagonists or direct oral anticoagulants were discontinued 5 days preoperatively and bridged with low molecular weight heparin. Perioperatively, the patients received thromboprophylaxis with low molecular weight heparin. Vitamin K antagonists and direct oral anticoagulants were restarted on POD6. The protocol was similar in both groups.

Postoperative Monitoring for Bleeding and Pericardial and Pleural Effusions

Drainage volume was recorded hourly. When it exceeded 250 mL/h for more than 3 hours despite optimized procoagulatory therapy, normalization of platelet function, and plasmatic coagulation, reexploration for bleeding was performed. Transesophageal echocardiography or transthoracic echocardiography was performed in all patients with clinical signs of pericardial effusion or tamponade. Hemodynamically relevant pericardial effusions and tamponade were relieved using pericardiocentesis or reexploration.

Chest radiographs were obtained immediately postoperatively, after removal of the chest tubes, on POD6, and when clinical presentation warranted suspicion of pulmonary pathologies. Suspected pleural effusions were verified using pleural sonography. The volume of a pleural effusion was estimated as described previously [9]. Pleural effusions of less than 300 mL were usually managed conservatively (increase of diuretic medication), effusions of 300 to 500 mL were managed conservatively in asymptomatic patients and treated with a drainage procedure in symptomatic patients. Effusions of more than 500 mL were drained.

Endpoints

The primary endpoint of this study was RBS, defined as occurrence of at least one of these events: reexploration for bleeding or cardiac tamponade; pleural drainage procedure (thoracocentesis, new chest tube, thoracoscopy, or lateral thoracotomy); or pericardial drainage procedure (pericardiocentesis, pericardial fenestration) until hospital discharge. Secondary endpoints included the components of the primary endpoint, inhospital mortality, and transfusion requirements.

Ethics

The Local Ethics Committee approved the study. The study was conduced in accordance with the Declaration of Helsinki. Patients gave informed consent for inclusion in the study and analysis of their data for scientific purposes. The material used for the study was bought from ClearFlow (Anaheim, CA). The company had no influence on planning or conducting the study nor on interpretation of the results.

Statistics

In this study, we prespecified the inclusion periods (6 months each for control group and ATC group). We conducted an exploratory statistical analysis using IBM SPSS Statistics 24 (IBM Corporation, Armonk, NY), GraphPad Prism 6 (GraphPad Software, La Jolla, CA), and R 3.1.2. Numeric parameters were analyzed as mean ± SD unless stated otherwise. Group comparisons were made using the χ^2 test for categoric variables, and Student's t test or Wilcoxon-Mann-Whitney U test for continuous variables, as appropriate. Statistical significance was assumed at p less than 0.05.

Covariates included in the propensity score matching were age, sex, body mass index, preoperative left ventricular ejection fraction, European System for Cardiac Operative Risk Evaluation II (EuroSCORE II), diabetes mellitus, weight of the intervention, preoperative activated partial thromboplastin time, preoperative international normalized ratio, and preoperative platelet count. Hereafter, nearest neighbor matching in a 1:1 fashion was performed. The maximum caliper between matched participants was set at 0.2. The baseline differences between the unmatched and matched groups were calculated as standardized differences.

Multivariate regression was conducted for the response "inhospital mortality" to quantify the relevance of previously described components of RBS for mortality in this study population. The RBS components were submitted to a binary logistic regression model. The model was tested for significance using the Omnibus test, the Nagelkerkes R^2 test to assess the goodness of fit, and Cohen's f test for the effect size.

Results

A total of 581 patients were included in the analysis, 222 patients in the ATC group and 359 in the control group because of different operating volumes in the first half and second half of 2016. The ATC patients were significantly older compared with control group patients (68 ± 9 years versus 66 ± 11, respectively; $p = 0.028$, standardized difference 0.24). The mean preoperative risk estimation using EuroSCORE II was 5.4% ± 8.0%, revealing a high-risk patient population. After propensity score matching, the baseline characteristics were well balanced between the groups (Table 1). Preoperative plasmatic coagulation and thrombocyte counts were regular in both groups (Table 1). All results described below refer to the matched study population. (For additional outcome data of the unmatched groups, see Supplemental Table 2.)

Procedural duration (ATC group 216 ± 65 minutes versus control group 211 ± 73, $p = 0.44$), cardiopulmonary bypass time (ATC 109 ± 45 minutes versus control 114 ± 58, $p = 0.25$), and cardioplegic arrest time (ATC 69 ± 29 minutes versus control 74 ± 35 minutes, $p = 0.72$) were comparable. A total of 363 ATC devices were applied in 222 patients (83 patients with one ATC device and 139 patients with two ATC devices). There was no malfunction requiring ATC device exchange. In 7 cases (1.9%) the cutaneous fixation of the ATC device had to be revised because of too tight fixation. Chest tubes remained in situ

Table 1. Baseline Characteristics

	Unmatched Study Population				Matched Study Population			
Characteristics	ATC (n = 222)	Control (n = 359)	p Value	Std. Diff.	ATC (n = 222)	Control (n = 222)	p Value	Std. Diff.
Age, years	68 ± 9	66 ± 11	0.028	0.24	68 ± 9	68 ± 10	0.90	0.026
Body mass index, kg/m^2	28 ± 5.3	28 ± 5.3	0.68	0.087	28 ± 5.3	28 ± 5.1	0.39	0.015
Female	47 (21)	92 (26)	0.22	0.048	47 (21)	59 (27)	0.18	0.049
Previous cardiac surgery	13 (5.9)	30 (8.4)	0.26	0.16	13 (5.9)	12 (5.4)	0.84	0.063
Weight of the intervention	149 (67)	194 (54)		0.38	149 (67)	144 (65)		0.017
Isolated CABG	22 (9.9)	75 (21)			22 (9.9)	25 (11)		
Isolated non-CABG	46 (21)	82 (23)	0.003		46 (21)	46 (21)	0.89	
Two procedures	5 (2.3)	8 (2.2)			5 (2.3)	7 (3.2)		
Three or more procedures								
Urgency of procedure			0.54	0.14			0.98	0.023
Elective	133 (60)	202 (56)			133 (60)	135 (61)		
Urgent	89 (40)	157 (64)			89 (40)	87 (39)		
EuroSCORE II	5.5 ± 8.3	5.3 ± 7.3	0.068	0.29	5.5 ± 8.3	5.6 ± 7.4	0.87	0.009
Preoperative INR	1.0 ± 0.1	1.0 ± 0.2	0.94	0.079	1.0 ± 0.1	1.0 ± 0.1	0.13	0.032
Preoperative aPTT, seconds	32 ± 10	33 ± 10	0.12	0.19	32 ± 10	33 ± 10	0.17	0.14
Preoperative platelet count, G/L	231 ± 72	234 ± 74	0.66	0.29	231 ± 72	233 ± 73	0.81	0.18

Values are mean ± SD or n (%).

aPTT = activated partial thromboplastin time; ATC = active chest tube clearance; CABG = coronary artery bypass graft surgery; EuroSCORE = European System for Cardiac Risk Evaluation; INR = international normalized ratio; Std. Diff. = standardized difference.

for 1.8 ± 3.6 days in the ATC group and 1.6 ± 1.0 days in the control group ($p = 0.29$). Total chest tube drainage volumes were similar in cavities drained with ATC devices or conventional chest tubes (Fig 1, Supplemental Table 1).

Retained blood syndrome occurred in 16% of ATC patients and 22% of control patients ($p = 0.15$). The components of RBS did not differ between the groups (Table 2) except for a significantly reduced rate of reexploration for bleeding or tamponade in the ATC group (4.1%, versus control group 9.9%; $p = 0.015$). Reexplorations were performed after a median of 14 hours (interquartile range [IQR]: 9 to 28) postoperatively in ATC patients and 13 hours (IQR: 6.5 to 22) postoperatively in control patients ($p = 0.38$). During reexploration, active bleeding was found in 4 of 9 ATC patients (44%) and in 17 of 22 control patients (77%, $p = 0.10$). The intraoperative findings are shown in Supplemental Table 3. Pleural (4.5%; median timing POD6, IQR: 4 to 7) or pericardial drainage (2.7%, $p = 0.33$; median timing POD7, IQR: 5 to 10) procedures occurred similarly in both groups. Of note, if stratified for the intraoperative drainage strategy, the prevalence of thoracocenteses in hemithoraces that were drained with an ATC device (10%) did not differ significantly from hemithoraces that were drained with a conventional chest tube (13%, $p = 0.31$). Hemithoraces with intact pleura and no intraoperative chest tube placement had the lowest prevalence of postoperative pleural drainage procedures (5.5%; Fig 2). If postoperative pleural drainage was necessary, the median drainage volumes from hemithoraces previously drained with ATC devices (1,350 mL, IQR: 825 to 2510 mL) or conventional chest tubes (1,400 mL, IQR: 850 to 1736 mL) were similar (Fig 3). Transfusion of blood products occurred similarly in both groups (Table 2). Inhospital mortality (ATC 6.8% versus control 7.7%, $p = 0.71$) was slightly higher than predicted by EuroSCORE II.

There was no difference between patients who received one versus two ATC devices in terms of RBS (15% versus 17%, $p = 0.77$), reexploration for bleeding or tamponade (3.6% versus 4.3%, $p = 0.21$), or mortality (7.6% versus 6.5%, $p = 0.97$). There was also no difference between patients who received only ATC devices (n = 85) compared with patients who received a combination of ATC devices and conventional chest tubes (n = 137) in terms of RBS (17% versus 16%, $p = 0.35$), reexploration for bleeding or tamponade (3.6% versus 4.8%, $p = 0.94$), or mortality (7.0% versus 6.0%, $p = 0.88$).

A subgroup analysis for rates of reexploration due to bleeding or tamponade depending on the procedural categories showed that the main difference between the ATC group and control group occurred in patients who underwent isolated coronary artery bypass graft surgery (ATC 0.7% versus control 5.6%, $p = 0.015$; Table 3).

Patients with RBS had a higher inhospital mortality compared with patients without RBS (21% versus 3.9%; OR 6.7, 95% confidence interval [CI]: 3.2 to 14, $p < 0.001$). The RBS was equally relevant for mortality in both groups

Table 2. Postoperative Outcomes

Outcome	ATC (n = 222)	Control (n = 222)	*p* Value
Inhospital mortality	15 (6.8)	17 (7.7)	0.71
Retained blood syndrome	36 (16)	48 (22)	0.15
Rethoracotomy for bleeding or tamponade	9 (4.1)	22 (9.9)	
Bleeding	1	10	0.015
Tamponade	8	12	
Pleural drainage procedure	30 (14)	32 (14)	
Thoracocentesis	28	30	0.82
Chest tube	2	2	
Pericardial drainage procedure	10 (4.5)	6 (2.7)	0.33
Puncture	4 (1.8)	1 (0.5)	0.37
Operation/fenestration	6 (2.7)	5 (2.3)	0.74
Transfusion, units			
Red blood cells	2.7 ± 6.6	2.7 ± 6.0	0.84
Platelets	0.27 ± 1.5	0.6 ± 1.7	0.73
Fresh frozen plasma	1.2 ± 4.7	1.2 ± 3.9	0.91

Values are mean ± SD or n (%).

ATC = active chest tube clearance.

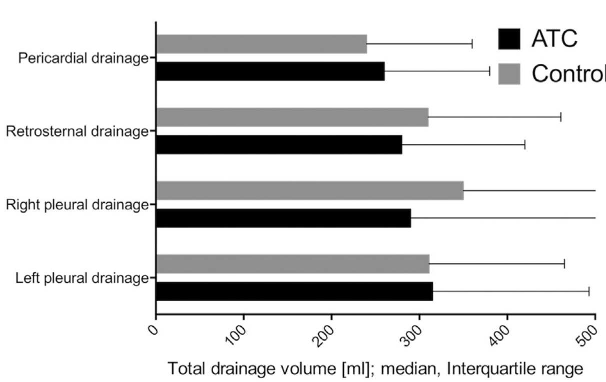

Fig 1. Drainage volume loss: active chest tube clearance (ATC) group (black bars) and control group (gray bars).

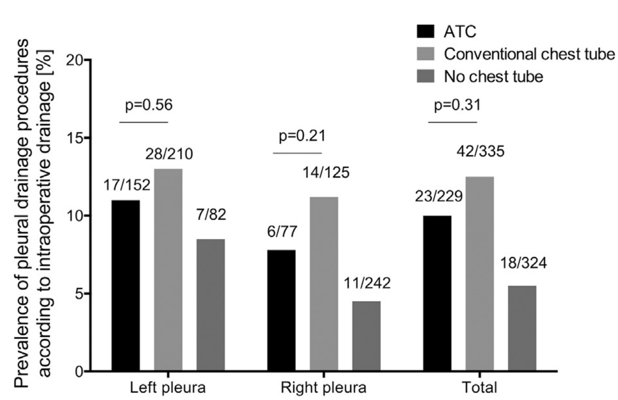

Fig 2. Prevalence of postoperative thoracocenteses stratified according to intraoperative drainage placement strategy: active chest tube clearance (ATC) technology (black bars); conventional chest tube (lighter gray bars); and no chest tube (darker gray bars).

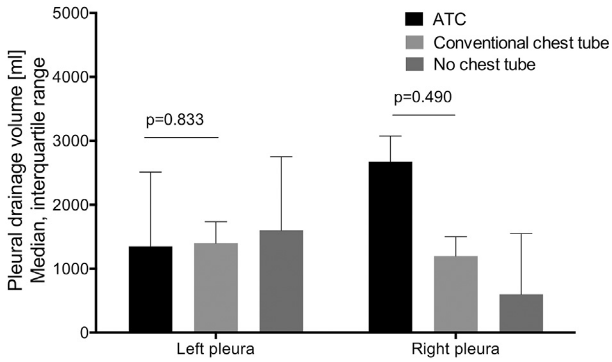

Fig 3. Total pleural fluid volume removed by postoperative thoracocentesis or new chest tubes according to intraoperative drainage placement strategy: active chest tube clearance (ATC) technology (black bars); conventional chest tube (lighter gray bars); and no chest tube (darker gray bars).

(ATC group OR 5.4, 95% CI: 1.8 to 16; control group OR 8.3, 95% CI: 2.9 to 24, $p = 0.52$). Multivariate analysis revealed that only reexploration for bleeding or tamponade (OR 16, 95% CI: 5.8 to 43, $p < 0.001$) was an independent predictor of inhospital mortality (Table 4).

Comment

The main finding of this prospective, controlled study is that RBS was not reduced by the use of as many as two ATC devices in an all-comers collective of patients undergoing scheduled cardiac surgery with full or partial median sternotomy. We assume that the possible effect of ATC mainly acts in the immediate perioperative period (ie, when the ATC device is in place). Formation of postoperative pleural or pericardial effusions is multifactorial, and perioperatively retained fluid might not be the most relevant aspect. However, rates of reexploration for bleeding or tamponade were significantly reduced. The number needed to treat for prevention of one reexploration was 17. Logistic regression revealed that RBS accounted for only 16% of the variance of mortality. Among all RBS components, only reexploration was a significant predictor of inhospital mortality. That is contradictory to a study by Balzer and associates [8] who showed relevance of several RBS components. However,

Table 3. Subgroup Analysis for Rethoracotomy Due to Bleeding or Tamponade

Subgroup	ATC (n = 222)	Control (n = 222)	p Value
Isolated CABG	1/149 (0.7)	8/144 (5.6)	0.015
Isolated non-CABG	4/22 (18)	5/25 (20)	0.87
Two procedures	4/46 (8.7)	8/46 (17)	0.22
Three or more procedures	0/5	1/7 (14)	0.38

Values are n/N (%).

ATC = active chest tube clearance; CABG = coronary artery bypass graft surgery.

Table 4. Multivariate Regression for Components of Retained Blood Syndrome as Predictors of Inhospital Mortality[a]

Variable	Coefficient	p Value	OR (95% CI)
Reexploration for bleeding/tamponade	2.76	<0.001	16 (5.8–43)
Pleural drainage procedure	0.16	0.75	1.2 (0.43–3.2)
Pericardial drainage procedure	-0.85	0.28	0.43 (0.10–2.0)

[a] Mortality $R^2 = 0.16$ (Nagelkerke), namely, 16% of inhospital mortality is explained by retained blood syndrome.

CI = confidence interval; OR = odds ratio.

our data are in accordance with Tauriainen and colleagues [10] who showed that postoperative interventions associated with RBS only increased early mortality if a rethoracotomy was necessary. Our data confirm the detrimental relevance of reexplorations for postoperative mortality that has been studied extensively in the past [11, 12]. Another aspect is that patients with postoperative bleeding or cardiac tamponade substantially tie up nursing resources on the intensive care unit. That might have negative secondary effects in the intensive care unit work environment [13]. Interestingly, the most relevant reduction of reexploration occurred in patients undergoing isolated coronary artery bypass graft surgery. Reduction of reexplorations using ATC has previously only been shown after implantation of left ventricular assist devices [14].

From a technical point of view, this study imposes two new concepts: first, we placed ATC devices in the pleural cavity; and second, it is the first study to investigate the use of as many as two ATC devices per patient. We observed no malfunction of the kinked ATC device in the pleural cavity, suggesting it to be a suitable device for this application. Our data further suggest that using one ATC device might be sufficient, as the use of a second ATC device did not increase the effect on relevant outcome parameters. Accordingly, there was no difference in outcomes between patients who received only ATC devices compared with patients who received a combination of ATC devices and conventional chest tubes. Interestingly, we observed equal or even slightly reduced chest tube drainage volumes in the ATC group, confirming previous data by Sirch and colleagues [15].

That is somewhat contradictory to the purpose of ATC of removing intrathoracic fluid more efficiently. Milking of drainages has been shown to result in higher drainage volumes without reducing bleeding complications or rethoracotomies [16]. We hypothesize that the bleeding rate is not a constant but a dynamic process and can be influenced by the drainage technology used. The milking or stripping of conventional chest tubes induces negative pressure as great as −400 mm Hg. That could dislodge fresh microvascular blood clots, reinducing bleeding [3]. Other manipulation methods for chest tubes may also cause rapid changes of intrathoracic pressure and thus be harmful in this respect [3, 17]. On the contrary, ATC acts

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without changing intrathoracic pressure. We speculate that this mechanism is particularly relevant in small vessel stumps (eg, the distal part of mammary artery branches) with freshly formed blood clots. Bleedings of this kind occur in the preparation areas of internal mammary arteries or from small bypass graft side branches, thereby explaining the particular effect of ATC in coronary artery bypass graft procedures in our analysis. Another potential mechanism for reduced bleeding after ATC is that more effective removal of blood from the wound area leads to elimination of thrombolysins embracing suture lines and maintaining bleeding [5]. The hypothesis that ATC might reduce bleeding is supported by the finding that among patients who underwent reexploration, active bleeding was observed in 44% of patients with ATC and 77% of patients with conventional chest tubes ($p = 0.10$), indicating a trend toward reduced bleeding activity in ATC patients.

Economic justification analyses for implementing a new technology like ATC are just beginning to be explored in this field. One can either directly measure the potential economic benefit, or one can estimate it based on a few assumptions combined with the measured outcomes. That allows estimating if implementing a new technology is expected to be cost justified, neutral, or cost prohibitive [18]. We conducted a basic cost justification analysis in which we utilized the measured number needed to treat (n = 17) for prevention of one reexploration combined with the estimated cost of a reexploration in conjunction with the costs per unit of ATC. The incremental cost of reexploration after coronary artery bypass graft surgery has been described as ranging from 6.290€ to 23.780€ ($7,748 to $28,000) [5, 19, 20]. Assuming a cost per ATC unit of 300€ ($369), the incremental cost for 17 patients (one ATC device per patient) would be 5.100€ ($6,282). Therefore, incremental savings of 1.190€ to 18.680€ ($1,466 to $23,008) per 17 patients, or 70€ to 1.098€ ($86 to $1,352) per patient can be estimated. That suggests this technology would be cost justified even if a very low incremental cost for reexplorations is assumed. Because the incremental costs of postoperative complications differ substantially in different countries, more detailed and site-specific studies are needed to go beyond the estimate of costs to the direct measurement of costs saved.

Study Limitations

This is a nonrandomized study, and the baseline characteristics and patient numbers in the ATC group and control group differed. We therefore applied propensity score matching, resulting in comparable group characteristics. Nevertheless, imbalances of unknown confounders between the groups cannot be excluded. Another limitation might result from ATC handling. The ATC device was cleared at least every 30 minutes, and more often if clotting or excessive bleeding was observed. Previous papers have described clearance intervals of 15 minutes during the first 8 postoperative hours [14, 15]. The clearance intervals might further influence the ATC effect on the primary endpoint of RBS. However, there are no data on dose-effect relationships of ATC available until now. Furthermore, our study includes different locations and numbers of ATC devices per patient, in each case individually chosen by the treating surgeon. That adds to the explorative character of the study and disables robust conclusions about the optimal number and position of ATC devices after cardiac surgery.

Conclusion

Active tube clearance technology compared with conventional chest tubes is a low-risk intervention associated with reduced reexploration rates after cardiac surgery. The use of two versus one ATC device does not increase ATC efficiency. Overall, RBS is not reduced. The relevance of RBS for mortality is only caused by reexplorations. The ATC effect does not translate into improved overall survival.

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