A randomized trial of early versus delayed mediastinal drain removal after cardiac surgery using silastic and conventional tubes

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Abstract

OBJECTIVES: Mediastinal drainage following cardiac surgery with traditional large-bore plastic tubes can be painful and cumbersome. This study was designed to determine whether prolonged drainage (5 days) with a silastic tube decreased the incidence of significant pericardial effusion and tamponade following aortic or valvular surgery.

METHODS: One hundred and fifty patients undergoing valvular or aortic surgery in a tertiary cardiac surgery institution were randomized to receive a conventional mediastinal tube plus a silastic Blake drain (n = 75), or two conventional tubes (n = 75). Conventional drains were removed on postoperative day (POD) 1, while Blake drains were removed on POD 5. The primary end-point was the combined incidence of significant pericardial effusion (≥15 mm) or tamponade through POD 5. Secondary end-points included total mediastinal drainage, postoperative atrial fibrillation (AF) and pain.

RESULTS: Analysis was performed for 67 patients in the Blake group and 73 in the conventional group. There was no difference between the two groups in the combined end-point of significant effusion or tamponade (7.4 vs 8.3%, P = 0.74), or in the incidence of AF (47 vs 46%, P = 0.89). Mean 24-h drainage was greater in the Blake group than in the conventional group (749 ± 444 ml vs 645 ± 618 ml, P < 0.01). Overall incidence of significant pericardial effusion at 30 days was 12.1% (n = 17), with 5% (n = 7) requiring drainage. The Blake group had a numerically lower incidence of effusion requiring drainage at POD 30 (3.0 vs 6.8%, P = 0.44). Postoperative pain was similar between groups.

CONCLUSIONS: In patients undergoing ascending aortic or valvular surgery, prolonged drainage with silastic tubes is safe and does not increase postoperative pain. There was no difference between the Blake and conventional drains with regard to significant pericardial effusion or tamponade in this cohort; however, this conclusion is limited by the low overall incidence of the primary outcome in this cohort.

Keywords: Postoperative care • Aorta/aortic • Bleeding • Mediastinum • Heart valve

INTRODUCTION

The incidence of pericardial effusion after cardiac surgical procedures is estimated to be between 1 and 85%, depending on the method and criteria used for assessment [1, 2]. In patients undergoing aortic and/or valvular surgery, the incidences of significant pericardial effusion and delayed cardiac tamponade have been reported to be as high as 30 and 15%, respectively [1, 3, 4]. Significant pericardial effusion and delayed cardiac tamponade are associated with significant morbidity, resulting in the need for surgical reintervention, an increased incidence of atrial fibrillation (AF), prolonged hospitalization and rehospitalization.

Mediastinal drainage after cardiac surgical procedures is traditionally achieved using large-bore (28–36 Fr) plastic chest tubes for the first 24 h after surgery or until drainage is minimal. Prolonged retention of conventional drains is rarely practised and is perceived to be inconvenient. Owing to rigidity and large diameter, these drains can cause significant pain and are associated with increased use of analgesic agents. Moreover, they may limit self-ambulation early after surgery because of discomfort from the tubes as well as bulky thoracic fluid-collecting systems.

Blake drains (Ethicon, USA) are soft silastic tubes with four lateral channels and a solid core centre. Suction is exerted over the entire length of the tubed portion of the drain. Non-collapsible tubing and long drainage channels theoretically make them resistant to occlusion by thrombi and capable of draining large fluid volumes. Their size and flexibility may result in less patient discomfort and allow prolonged drainage with conversion from the usual thoracic fluid-collecting system to a small
bulb favouring self-ambulation. Furthermore, there is evidence to suggest that Blake drains are more effective and are associated with a decreased incidence of pericardial effusion, tamponade and postoperative AF [5]. At present, few studies have addressed the safety and efficacy of Blake drains after cardiac surgery.

The objective of the present study was to assess the optimal drainage method in patients undergoing ascending aortic or valvular surgery. The incidence of postoperative pericardial effusion and tamponade in patients with a Blake drain was compared with those with only conventional drains. We hypothesized that the use of Blake drains would be associated with a reduction in significant postoperative pericardial effusion and tamponade.

METHODS

Study design

This is a randomized controlled trial conducted at a single centre. The study protocol was approved by the institutional review board of the Montreal Heart Institute (MHI) and registered with clinicaltrials.gov (NCT00684125). The enrolment period was from August 2008 until May 2010. Consecutive patients from 18 to 90 years of age undergoing cardiac valvular or ascending aortic surgery were eligible for randomization. The only exclusion criteria were emergency surgery and lack of availability for follow-up at the MHI. Annually at the MHI, ~100 ascending aortic and 600 valvular surgeries are performed. Of the 300 patients who were screened and met these criteria, 150 underwent randomization. Further exclusions were the result of patients already being enrolled in another research protocol and patient refusal.

Sample-size calculations were made assuming a combined incidence of tamponade or pericardial effusion of 20%, as we have found upon review of our institution’s outcomes over the preceding 2 years (unpublished data), and as has been shown in the literature [2–4]. We hypothesized a 75% relative reduction for the composite end-point in the group undergoing prolonged mediastinal drainage using a Blake drain (from 20 to 5%). Targeting a P-value of 0.05 and a power of 80%, we estimated that 150 patients would have to be randomized to test the hypothesis.

Patients were randomized at the time of surgery into one of two groups, using a computer-generated algorithm. Group A (Blake group) received one conventional tube and one Blake tube at the end of surgery, while Group B (conventional group) received two conventional tubes. Conventional drainage consisted of 28- or 32-Fr Argyle tubes. The Blake tubes consisted of 19-Fr silastic drains (Ethicon, Johnson & Johnson; Somerville, NJ, USA). In the Blake group, the conventional tube was placed in the pericardiac space and the Blake drain was placed on the diaphragmatic surface. In the conventional group, both conventional tubes were placed in the pericardiac space. The pericardium was left open in both groups. All conventional tubes were removed 24 h after surgery or when drainage was decreased. Blake tubes were transferred from pleurevac drainage to bulb suction after 24 h and removed on postoperative day (POD) 5.

Surgical technique

The surgical technique was similar in both groups. Heparin was administered to achieve activated clotting times of 450 s. Cardiopulmonary bypass (CPB) was implemented using standard cannulation techniques and moderate hypothermia (32–34°C). The CPB circuit was equipped with a membrane oxygenator (Monolyth; Sorin BioMedica, Inc., Richmond Hill, ON, Canada) and primed with a crystalloid solution. Myocardial protection techniques were at the discretion of the surgeon, however, intermittent antegrade sanguineous tepid cardioplegia was used in the majority of cases. When possible, autologous blood was removed before initiation of CPB and reinfused after cessation of CPB. All patients received 1 g of tranexamic acid intravenously at induction, 500 mg in the pump prime and 400 mg/h while on pump. Biological or mechanical valves were implanted according to clinical indication.

Postoperative anticoagulation

In patients who received a mechanical valve, intravenous heparin and oral warfarin were started 48 h after surgery. Heparin was discontinued once a therapeutic INR was achieved. Patients receiving a bioprosthesis were not systematically anticoagulated. Patients who developed atrial fibrillation lasting more than 48 h, or with paroxysms recurring over 48 h, were anticoagulated in a similar manner, using heparin as a bridge until the INR was therapeutic.

Follow-up

Clinical follow-up was performed daily after surgery until hospital discharge and on POD 30. Recorded parameters included volume of mediastinal drainage in the first 24 h, total volume of mediastinal drainage, time of drain removal after surgery and re-exploration for bleeding. Other parameters included presence or absence of postoperative cardiac tamponade (>24 h), pericardial effusion on POD 5, subjective thoracic pain intensity according to visual scale method, cardiac rhythm according to continuous telemetry and daily electrocardiography, and drain-associated infection or other drain-related adverse events.

Echocardiograms were reviewed by experienced cardiologists blinded to group allocation. Pericardial effusions were qualified as anterior, lateral, posterior or circumferential. The maximum measured effusion was used for data analysis, with an effusion ≥15 mm in one or more locations considered significant. Patients were considered to have cardiac tamponade if they presented postoperatively with symptoms and signs of tamponade, had significant pericardial effusion, and required surgical reintervention.

Patients completed a daily thoracic pain-intensity questionnaire using a visual scale (0–10) method. Questions included: (i) Average pain experienced with activity over the last 24 h; (ii) greatest pain experienced with activity over the last 24 h; (iii) pain at rest at the time of questionnaire completion; and (iv) pain with activity at the time of questionnaire completion.

Primary and secondary end-points

The primary composite end-point was significant pericardial effusion or cardiac tamponade requiring surgical intervention through POD 5. Secondary end-points were (i) total volume of mediastinal drainage, (ii) incidence of postoperative atrial fibrillation, (iii) drain-related adverse events and (iv) degree of postoperative pain.
Statistical analysis

Statistical analysis was performed using SPSS version 18. Univariate and multivariate analyses were performed to compare preoperative patient characteristics, postoperative outcomes and risk factors for postoperative effusion. Comparisons were made using $\chi^2$, Fisher’s exact or Student’s t-tests when appropriate. Pain data were compared by analysis of variance. P-values < 0.05 were considered significant.

RESULTS

Over a 21-month period, 150 patients were randomized to either the Blake group ($n = 75$) or conventional group ($n = 75$). Sixty-seven patients remained for analysis in the Blake group; 6 were excluded for early mortality and 2 for breach of protocol. In the conventional group, 73 patients were analysed; 2 were excluded due to early mortality.

There was no difference between the two groups in preoperative patient characteristics, including age, gender or weight. Preoperative use of warfarin was 10.5% in the Blake group and in 11.0% in the conventional group ($P = 0.93$), while the history of previous cardiac surgery was 10.7 and 13.2%, respectively ($P = 0.23$). See Table 1 for a complete list of preoperative characteristics.

Tables 2 and 3 summarize intraoperative and postoperative data, respectively. There was no significant difference in the types of interventions performed in each group, although the Blake group tended to have more complex procedures. CPB times were similar between groups, however, aortic cross-clamp was longer in the Blake group (82 ± 35 vs 68 ± 29 min, $P = 0.02$). There was no difference in blood loss or the use of postoperative warfarin. The rate of transfusion and intensive care unit and hospital length of stay were similar between the groups.

Volume of postoperative drainage was greater in the Blake group, both at 24 h (749 ± 444 ml vs 645 ± 618 ml, $P < 0.01$) and total drainage (1013 ± 630 ml vs 716 ± 702 ml, $P = 0.01$). The Blake tubes drained an average of 313 ± 294 ml after the first 24 h. AF developed in 46.3% of patients in the Blake group and 45.2% in the conventional group, with no statistically significant difference between the groups ($P = 0.90$). After excluding all patients with preoperative AF ($n = 21$), there remained no difference between the groups (35.6 vs 45.5%, $P = 0.28$). Four patients in each group required early reintervention (Day 0–1) for bleeding or tamponade, while none required reintervention for tamponade on Days 2–5 in either group. Indication for bleeding reintervention was decided by the surgeon and dependent on

### Table 1: Preoperative patient characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Blake ($n = 67$)</th>
<th>Conventional ($n = 73$)</th>
<th>$P$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years) (mean ± SD)</td>
<td>64.3 ± 9.9</td>
<td>62.5 ± 12.3</td>
<td>0.35</td>
</tr>
<tr>
<td>Male (%)</td>
<td>71.6</td>
<td>67.1</td>
<td>0.56</td>
</tr>
<tr>
<td>Weight (kg) (mean ± SD)</td>
<td>80.0 ± 12.9</td>
<td>80.3 ± 14.4</td>
<td>0.89</td>
</tr>
<tr>
<td>New York Heart Association functional class (mean ± SD)</td>
<td>2.2 ± 0.8</td>
<td>2.4 ± 0.8</td>
<td>0.54</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>38.8</td>
<td>37.0</td>
<td>0.82</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>10.5</td>
<td>12.3</td>
<td>0.73</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease (%)</td>
<td>1.5</td>
<td>0</td>
<td>0.48</td>
</tr>
<tr>
<td>Coronary artery disease (%)</td>
<td>41.8</td>
<td>37.0</td>
<td>0.56</td>
</tr>
<tr>
<td>Warfarin (%)</td>
<td>10.5</td>
<td>11.0</td>
<td>0.92</td>
</tr>
<tr>
<td>Previous cardiac surgery (%)</td>
<td>7.5</td>
<td>13.7</td>
<td>0.23</td>
</tr>
<tr>
<td>Preoperative chronic renal failure (%)</td>
<td>4.5</td>
<td>1.4</td>
<td>0.35</td>
</tr>
<tr>
<td>Preoperative aspirin (%)</td>
<td>13.4</td>
<td>11.0</td>
<td>0.80</td>
</tr>
</tbody>
</table>

### Table 2: Intraoperative characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Blake ($n = 67$)</th>
<th>Conventional ($n = 73$)</th>
<th>$P$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Valve</td>
<td>26.7</td>
<td>40.8</td>
<td>0.79</td>
</tr>
<tr>
<td>Valve + cardiopulmonary bypass</td>
<td>32.0</td>
<td>30.3</td>
<td>0.59</td>
</tr>
<tr>
<td>Double valve or valve + ascending aorta</td>
<td>30.7</td>
<td>18.4</td>
<td>0.40</td>
</tr>
<tr>
<td>Ascending aorta</td>
<td>2.7</td>
<td>7.9</td>
<td>0.93</td>
</tr>
<tr>
<td>Aortic root</td>
<td>8.0</td>
<td>2.6</td>
<td>0.70</td>
</tr>
<tr>
<td>Mechanical valve</td>
<td>32.8</td>
<td>31.5</td>
<td>0.87</td>
</tr>
<tr>
<td>Redo surgery (%)</td>
<td>7.5</td>
<td>13.7</td>
<td>0.23</td>
</tr>
<tr>
<td>Aortic cross-clamp (min) (mean ± SD)</td>
<td>81.8 ± 35.4</td>
<td>67.6 ± 28.5</td>
<td>0.02</td>
</tr>
<tr>
<td>Cardiopulmonary bypass time (min) (mean ± SD)</td>
<td>106.5 ± 41.8</td>
<td>95.9 ± 34.0</td>
<td>0.21</td>
</tr>
<tr>
<td>Operative time (min) (mean ± SD)</td>
<td>194.3 ± 58.2</td>
<td>190.8 ± 57.3</td>
<td>0.69</td>
</tr>
<tr>
<td>Blood loss (ml) [median (IQR)]</td>
<td>400 (300–550)</td>
<td>400 (300–600)</td>
<td>0.69</td>
</tr>
</tbody>
</table>

IQR: interquartile range.
both chest tube output and haemodynamic factors. No patient in either group developed a deep or superficial sternal wound infection.

**Postoperative effusion**

Evidence of at least minimal pericardial effusion with echocardiography on POD 5 was present in 56.7% of patients in the Blake group and 57.5% of patients in the conventional group (\( P = 0.92 \)). Significant effusions were present in five (7.2%) individuals in the Blake group and six (8.2%) in the conventional group (\( P = 0.87 \)). At 30 days, the incidence of effusion diagnosed by echocardiography was similar between the two groups (Blake = 10.4% vs conventional = 13.7%, \( P = 0.55 \)). There was a numerically higher incidence of effusion requiring drainage at 30 days in the conventional group (\( n = 5, 6.9\% \)) compared with the Blake group (\( n = 2, 3.0\% \)), although the difference did not reach statistical significance (\( P = 0.44 \)) (Fig. 1).

**Pain**

Average pain over consecutive 24-h periods decreased consistently in both groups, with no statistically significant difference between the groups (\( P = 0.22 \)) (Fig. 2). On POD 1, average pain in the Blake group was 3.8 ± 1.8, compared with 4.3 ± 2.0 in the conventional group (\( P = 0.47 \)). On POD 5, average pain was 3.0 ± 1.5 and 2.7 ± 1.3 in the Blake and conventional groups, respectively (\( P = 0.52 \)). Maximal pain in the preceding 24-h period followed a similar trend, with a mean rating of 6.5 ± 2.1 in the Blake group and 6.7 ± 2.7 in the conventional group on POD 1 (\( P = 0.86 \)) (Fig. 2). This decreased to 4.7 ± 2.1 and 4.7 ± 2.2 on POD 5 (\( P = 0.97 \)). Results for questions 3 and 4, indicating pain at rest and with activity at the time of questionnaire completion, are shown in Fig. 2.

**Overall patient cohort**

The overall incidence of tamponade requiring reintervention was 5.7% (\( n = 8 \)), and the incidence of significant effusion at 5 days was 7.9% (\( n = 11 \)). Five percent (\( n = 7 \)) had a significant effusion or drainage at 30 days. Risk factors for significant effusion at 30 days included increased perioperative blood loss (hazard ratio [HR] 1.1, 95% confidence interval [CI] 1.03–1.14) and early reintervention for haemostasis (HR 5.1, 95% CI 1.1–23.5). Redo surgery and anticoagulation, both preoperative and postoperative, tended to be associated with effusion at 30 days, although these values did not reach statistical significance. The results of the univariate analysis are summarized in Table 4.

**DISCUSSION**

We have presented the results of a randomized comparison of conventional mediastinal drainage vs prolonged drainage with a silastic Blake drain following ascending aortic or valvular surgery. The incidence of significant pericardial effusion or tamponade at 5 days was similar between the Blake group (7.5%) and the conventional group (8.2%). Although there was a numerical advantage in the Blake group for effusion requiring drainage at 30 days, this difference did not reach statistical significance (3.0 vs...
6.9%; \( P = 0.44 \). Owing to the low incidence of the primary outcome in both groups, our study may have been underpowered to demonstrate an advantage with the Blake drains. The sample-size calculation was based on an incidence of effusion or tamponade of 20%, as suggested by the literature [1, 3, 4]. Reports of outcomes with Blake drains in cardiac surgery have shown mixed results, although all studies have demonstrated that they can be safely used in this context. Frankel et al. retrospectively studied 1110 patients who received conventional (n = 556) or Blake (n = 554) tubes following CABG surgery [6]. This report helped establish the safety of silastic drains in the context of cardiac surgery and reported decreased postoperative hospital length of stay in the Blake group. The authors suggested that the shorter length of stay was a consequence of greater ease of ambulation with the Blake drain. Randomized comparisons by Roberts et al. [7] and Bjessmo et al. [8] also found the Blake to be non-inferior to conventional drains following cardiac surgery. Sakopoulos et al. reported similar findings [9]. Ege et al. randomized 202 patients undergoing CABG surgery to receive either two Blake or two conventional drains. They found that patients in the Blake group had significantly increased postoperative drainage and a decreased volume of pericardial effusion [5]. In all of the aforementioned studies, Blake drains were removed 24–48 h postoperatively, corresponding to the removal of the conventional chest tubes in the control group. Our protocol differed in this regard, with the Blake drains remaining in place until just before echocardiographic control on POD 5. Eryilmaz et al. [10], using Redon drains, showed that prolonged drainage of the posterior pericardial space effectively decreased the incidence of postoperative pericardial effusion and late tamponade. We sought to accrue the added benefit of prolonged mediastinal drainage, without a cumbersome fluid-collecting system. However, the results of the primary outcome in this study do not support this hypothesis.

Total mediastinal drainage was greater in the Blake group, although the clinical significance of this finding is unclear. Neither group experienced any drain-related adverse events. In several studies, Blake drains were associated with a decreased rate of AF [5, 10]. In our study, there was no difference in the incidence of AF between the two groups, which may be explained by differences in monitoring. All patients in our institution are followed with wireless telemetry until discharge, improving our ability to diagnose asymptomatic AF compared with practices that may differ in other hospitals.

One of the most attractive features of the Blake drain is the relatively soft silicone material, which has been shown to result in significantly less associated pain [6, 11, 12]. In our study, patients in both groups had a conventional tube in place for the first 24 h following surgery. After this period, only the Blake group remained with a chest tube in place. Despite this, there was no difference in postoperative pain as measured by the visual scale method. This clearly demonstrates that Blake tubes cause only minimal, if any, discomfort. In light of these results, we have adopted the selective use of Blake drains to complement conventional tubes in the context of complex surgery and anticipated anticoagulation because of low associated morbidity and a perceived, although not statistically significant, benefit.

Finally, we aimed to identify the risk factors for postoperative effusion in this patient population. Perioperative blood loss and

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**Table 4: Risk factors for pericardial effusion at 30 days**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>HR</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative warfarin</td>
<td>3.1</td>
<td>0.9–11.3</td>
<td>0.08</td>
</tr>
<tr>
<td>Redo surgery</td>
<td>3.1</td>
<td>0.9–11.3</td>
<td>0.08</td>
</tr>
<tr>
<td>Perioperative blood loss</td>
<td>1.1</td>
<td>1.03–1.04</td>
<td>&lt;0.02</td>
</tr>
<tr>
<td>Re-exploration</td>
<td>5.1</td>
<td>1.1–23.5</td>
<td>&lt;0.04</td>
</tr>
<tr>
<td>Postoperative anticoagulation</td>
<td>2.8</td>
<td>0.97–8.1</td>
<td>0.06</td>
</tr>
</tbody>
</table>

CI: confidence interval; HR: hazard ratio.

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**Figure 2:** Results of pain survey according to question. Mean scores in each group are represented. X-axis = postoperative day. Y-axis = pain on a scale of 1–10. Analysis of variance showed no significant difference in response to any question. Pain ‘at rest’ and ‘with activity’ = at the time the survey was completed.
mediastinal re-exploration were associated with significant effusion, while redo surgery and pre- and postoperative anticoagulation showed a trend towards significance. However, it is important to note the wide confidence intervals associated with each risk factor. This may be due to the very low incidence of the primary outcome and precludes any definitive conclusions.

Limitations
This study was intended to evaluate the use of Blake drains in the setting of valvular and ascending aortic surgery. Although this may limit extrapolation to patients undergoing CABG surgery, we believe that it is important to focus the investigation on a more high-risk population who stands to gain the most from a superior drainage device. Another possible criticism is the decision to use both rigid and Blake drains in the treatment group for the first 24 h, making it impossible to single out the effect that the Blake drain would have if used alone. We chose this compromise with the intention of beneﬁtting from the known reliability of conventional tubes in the early postoperative period and the potential advantage of prolonged mediastinal drainage with the Blake tube. In doing so, it is possible that some advantages of the Blake tubes were masked, such as a lower incidence of postoperative AF and signiﬁcantly reduced postoperative pain. We appreciate that some surgeons now use Blake drains alone following cardiac surgery; however, our goal was to evaluate Blake drains as currently used in our institution and to address a drainage protocol that has not been previously studied in a randomized trial. Additionally, although the differences in drain location, with the conventional tube in the anterior mediastinum and the Blake drain on the diaphragmatic surface, may be a confounding factor, we chose to maintain our institution’s current practice with regard to conventional tube placement to isolate the effect of adding the Blake drain. Finally, the overall low incidence of the primary end-point limits our ability to draw definitive conclusions and increases the possibility of type II error.

CONCLUSION
In conclusion, prolonged mediastinal drainage with a Blake drain is a safe addition to the care of patients undergoing cardiac valvular or ascending aortic surgery. It does not increase postoperative pain, or the incidence of drain-related adverse events. We found no clear clinical advantage associated with the Blake drain; however, this conclusion is limited by the low overall incidence of significant pericardial effusion and tamponade in this cohort.

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