A method for chest drainage after pediatric cardiac surgery: A prospective randomized trial

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Objectives: The purposes of this study were to evaluate the clinical safety and efficacy of 10F, 15F, and 19F Blake drains (Ethicon, Sommerville, NJ) in a pediatric population after cardiac surgery and to compare their clinical effect with that of conventional chest drains.

Methods: From January 2002 through December 2004, a prospective randomized trial was conducted on 189 patients who underwent surgical intervention for congenital heart disease at our institution. Statistical analyses were conducted to test the null hypothesis that there was no difference in the incidence of pericardial or pleural effusion requiring drainage. Secondary end points included total volume of drainage, drain size, and time to drain removal.

Results: Ninety-eight patients (group A) received Blake drains, and 91 patients (group B) received conventional chest drains. There were no statistically significant difference in age, weight at the time of surgical intervention, open- and closed-heart procedures, and number of drains applied. Statistically significant differences were detected in the frequency of pericardial effusion (group A: 1.1% vs group B: 4.8%, $P < .01$), pleural effusion (group A: 1.1% vs group B: 5.3%, $P < .01$), size of the drain (group A: 12.37 French $\pm$ 1.72 French vs group B: 16.81 French $\pm$ 0.70 French, $P < .001$), and time to removal (group A: 43.75 $\pm$ 20.76 hours vs group B: 55.62 $\pm$ 26.48 hours, $P < .001$).

Conclusions: Blake drains are safer and more efficient than conventional chest tubes in pediatric populations after cardiac surgery. In comparison with conventional chest tubes, they showed fewer occurrences of effusions and the same amount of fluid drained but smaller size and earlier removal.

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Drainage and decompression of the pericardial spaces, pleural spaces, or both is necessary after cardiac surgery. The conventional method of evacuating fluid, air, or both from the mediastinum and pleural spaces is through insertion of multiple large-bore semirigid tubes connected to a closed underwater sealed drainage system. Preliminary reports suggest that small silastic drains might be superior to the conventional chest tube in terms of patient tolerability, post-operative pain, earlier ambulation, and improved pulmonary toilet.^{1,2} Non-well-defined consensus exists about chest drains in neonate and infant populations after cardiac surgery. The introduction of Blake drains (Ethicon, Sommerville, NJ) in this setting is not new; however, there has been reluctance concerning their routine use by congenital heart surgeons because of the unknown effectiveness of the system. To validate this device in neonatal and pediatric populations after cardiac surgery, we designed a prospective randomized study to compare the clinical safety and efficacy of small and soft silastic drains (Blake drains, Ethicon; Figure 1) versus the conventional chest tube (Tyco Healthcare, Mansfield, Ma). The Blake drains are white, radiopaque silicone drains with 4 channels along the sides and a solid core

Figure 1. Blake drain: a section view.

center. Silicone Blake drains are small-bore, round, flexible fluted drains that exert constant suction over the entire length of the fluted portion of the drain. With noncollapsible tubing and long channels for drainage, they are theoretically resistant to occlusion with thrombus. At present, there has been no available study addressing the safety and efficacy of these drains in pediatric cardiac surgery.

Material and Methods

Study Population

Eligibility for enrollment in the study was extended to all babies who underwent open- or closed-heart surgery over a period of 3 years at the San Vincenzo Hospital of Taormina. No exclusion criteria were individualized. Study approval was obtained by the local ethics committee on November 15, 2001. All parents provided written informed consent before study enrollment. During the study period, 98 patients (group A: median age, 2 months; median weight, 4.1 kg [500 g-17 kg]) received size 10F, 15F, and 19F Hubless Blake drains, and 91 patients (group B: median age, 3 months; median weight, 4 kg [600 g-14 kg]) received conventional drains. One hundred twenty-four patients underwent open-heart surgery during cardiopulmonary bypass (group A, 64 patients; group B, 60 patients), and 65 patients underwent closed-heart surgery (group A, 34 patients; group B, 31 patients).

Procedural Details

Three drains were placed through separate stab incisions in all patients who underwent open-heart surgery. One drain was positioned anteriorly in the mediastinal space, and 2 others were inserted in the right and left pleurae. In the case of closed-heart surgery, a single chest drain was located in the mediastinum or the pleura. Drains were secured to the skin with 4-0 silk sutures and connected to a Pleurevac device with special connectors supplied by the company. In both groups a conventional underwater low-pressure suction (20 cm H₂O) was used, which was only disconnected for a short period of time (5-10 minutes) during transfer of the patient from the operating room to the intensive care unit and

TABLE 1. End points of the study

	Blake drain (n = 98)	Conventional drain (n = 91)	P value
Pleural effusion	2 (2%)	10 (10.9%)	.01
Pericardial effusion	2 (2%)	9 (9.8%)	.01
Size of drain (F)	12.37 ± 1.72	16.81 ± 0.70	<.001
Time to removal (h)	43.75 ± 20.76	55.62 ± 26.48	<.001
Volume of drainage (mL)	43.71 ± 29.69	54.07 ± 38.01	.03

Data are presented as absolute frequency, percentage of relative frequency, and mean value ± standard deviation, as shown.

from the intensive care unit to the ward. All patients were treated with continuous morphine infusion (10-50 $\mu\text{g} \cdot \text{kg}^{-1} \cdot \text{h}^{-1}$). Chest drainage was recorded hourly. Bleeding of less than 1 mL/kg for more than 6 hours, chest radiography, and transthoracic echocardiography were considered standard criteria for drain removal. Routine chest radiography was performed after removal.

Randomization

The patients were randomly allocated to receive either a Blake drain or a conventional drain before surgical intervention was started. The allocation was communicated to the surgeons after weaning from cardiopulmonary bypass. All the intraoperative surgical team was blinded to the allocation process. During the study period, no violation of the protocol occurred.

Primary and Secondary Outcome Measures

In this study we tested the null hypothesis that there was no difference in the incidence of pericardial or pleural effusion requiring drainage. The primary end point was considered the reduction of complications between the 2 devices. Secondary end points were identified as total volume of drainage, drain size, and time to drain removal. Additional analysis was carried out to better understand the clinical effect of these devices. The population was divided by weight into 3 different groups (<3 kg, 3-6 kg, and >6 kg).

Statistics

Data are reported as means and standard deviations. The χ^2 test was used to compare categorical variables. Assumption of normal distribution for continuous variables was tested with the Kolmogorov-Smirnov test. Nonnormally distributed variables were compared by using the Mann-Whitney test and the Kruskal-Wallis test and multiple comparisons. *P* values were calculated by using the 2-sided test.

Results

No patients were excluded from the study. There were no statistically significant differences in age, sex, number of drains, and use of cardiopulmonary bypass between the 2 groups. In Group A 2 neonates were maintained on extracorporeal membrane oxygenation for 24 hours and 6 days, respectively, and 3 patients underwent delayed sternal closure for hemodynamic instability. Nine of the patients who

TABLE 2. Frequency of complications in 3 classes of weight

	Class of weight			<i>P</i> value
	≤3 (57 patients)	3.1-6.0 (89 patients)	>6 (53 patients)	
Pleural effusion				
Blake drain	0/30	2/42 (4.7%)	0/25	.35
Conventional drain	3/27 (11%)	3/47 (6.3%)	4/28 (14.2%)	.49
Pericardial effusion				
Blake drain	1/30 (3.3%)	1/42 (2.3%)	0/25	.69
Conventional drain	2/27 (7.4%)	4/47 (8.5%)	3/28 (10.7%)	.92

Data are presented as absolute frequency and percentage of relative frequency, as shown.

underwent closed-heart surgery weighed less than 2 kg. Effusion requiring additional treatment was recorded as a complication. Intervention was made only when both clinical criteria, instrumental criteria, or both were satisfied (ie, suspicion of cardiac tamponade or compression on echocardiography or atelectasia on X-ray or computed tomographic scanning for both pleura). The overall frequency of complications was 4% (4/98) in group A and 20% (19/91) in group B. Table 1 shows the statistical difference between the 2 groups. In the cases of additional drainage positioning, the mean volume of supplemental pericardial effusion was 12 ± 1 mL (range, 7-21 mL), whereas the mean volume of pleural effusion was 15 ± 7 mL (range, 12-27 mL). In group B 8 of 10 patients had both pericardial and pleural effusion. All 8 patients underwent open-heart surgery during cardiopulmonary bypass. In 7 cases additional drains were positioned after removal of the first drain. In group A only 1 patient had both complications. All 3 patients underwent open-heart surgery during cardiopulmonary bypass. Two of the 3 patients received additional drainage after previous drains were removed. The median time of additional drain removal was 2 days. Additional analysis was carried out, dividing the population by weight into 3 differ-

ent groups. In this subset we observed that more than 60% of adverse events (pleural effusion and pericardial effusion) occurred in the patient group weighing less than 6 kg (Table 2). No differences were observed between the 2 groups in terms of time to removal and volume of drainage (Table 3); vice versa, there was a highly statistically significant difference in the size of drains for all 3 classes of weight ($P < .001$; Table 3).

Discussion

In 1875, underwater seal drainage was introduced by Playfair. The following year, Hewett described the use of the first closed drainage system.³ Because of the serosanguineous nature of the fluid drained after cardiac operations, it has been standard teaching that drainage of the mediastinum is best accomplished with rigid, large-bore chest tubes. Increasing technologic advances have provided clinicians with a variety of commercially available chest drainage systems. Different complications have been widely reported with the use of large chest tubes, such as dysrhythmia caused by cardiac irritation,⁴ injury to the intercostal nerves,⁴ parietal pleural or lung parenchymal damage,⁴ erosion into major intrathoracic vessels,⁵ and cardiac tamponade.⁶ Fur-

TABLE 3. Comparison of patients from 3 different classes of weight

	Class of weight			<i>P</i> value
	≤3	3.1-6.0	>6	
Time to removal (h)				
Blake drain	34.62 ± 17.62	44.92 ± 20.64	54.20 ± 20.67	.004
Conventional drain	43.52 ± 21.02	56.19 ± 20.70	65.76 ± 35.03	.01
<i>P</i> value	.10	.01	.20	
Size of drain (F)				
Blake drain	11.03 ± 1.45	12.38 ± 1.23	14.19 ± 1.33	.001
Conventional drain	16.30 ± 0.56	16.67 ± 0.47	17.48 ± 0.65	.001
<i>P</i> value	.001	.001	.001	
Volume of drainage (mL)				
Blake drain	31.07 ± 26.51	48.85 ± 32.84	49.43 ± 20.66	.02
Conventional drain	40.13 ± 39.13	51.00 ± 29.76	72.16 ± 43.84	.01
<i>P</i> value	.33	.75	.03	

Data are presented as mean values ± standard deviation.

ther thrombus formation might compromise their function, and the conventional stripping of the chest tubes to prevent thrombus formation has been associated with injury to adjacent structures.⁷ This trend was confirmed in a single-institution study⁸ in which the authors conclude that the silastic drain can be used with the same efficacy and safety of conventional tubes because of similar outcome. The reported incidence of pericardial effusion, pleural effusion, or both after both adult and pediatric cardiac surgery is about 50%.⁹⁻¹¹ In 1998, Gundry and colleagues¹² from Loma Linda first reported the use of Blake drains in 57 children after a minimally invasive approach for congenital heart disease, but no clear information about the performance of these drains was reported. In 2005, Kejriwal and associates¹³ published their experience with 37 patients (mean age, 65 years; range, 18-81 years) in whom a single Blake drain was used after thoracic surgery. They concluded that the use of a Blake drain might be safe and effective in draining both fluid and air, although an additional tube might be necessary for persistent leak. In our series we observed just 1 case with such a problem, which occurred in a 14-month-old child, but no additional drain was used.

Our study represents the first experience in an unselected neonatal and pediatric cohort of patients in whom such a device has been used after cardiac surgery. This study confirms how nowadays the current practice in pediatric cardiac surgery faces neonates and infants. This subgroup of patients remains always the most delicate population toward whom a lot of new devices are currently addressed to minimize risks and procedural complications. In our experience the Blake drain can be used with efficacy because of the fact that it demonstrates drainage of an equivalent volume of fluid through smaller-caliber tubes over a shorter period of time than with conventional chest tubes. Blake drains do not require an airtight closed system to function effectively. For this reason, they were used also in patients with an ongoing air leak from the lung or when it was necessary to delay sternal closure. We can conclude that the Blake drain in neonates and infants after cardiac surgery is safe and efficient, mainly because of the reduction in drain

size. This is possible because the most important mechanism of action is obtained by means of capillarity. Even if we can speculate that use of smaller chest tubes, kept in for a shorter period of time, results in minimized discomfort for the patient, we recommend further studies focused on this aspect.

This study clearly demonstrates how important it is to look to technology to optimize critical care in such an important population. We are also persuaded that the Blake drain represents a real improvement, particularly for neonatal cardiac surgery.

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