High-vacuum drains rival conventional underwater-seal drains after pediatric heart surgery

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Abstract

Objective: The collection of fluid in the mediastinum after cardiac surgery is traditionally prevented using underwater seal drains that may be connected to low-pressure suction. High-vacuum drains (redivac drains) are a potential alternative to this arrangement and have previously been utilized in areas of general surgery, as well as in the treatment of post-sternotomy mediastinitis. There has been no study to date addressing the safety and efficacy of these drains following pediatric cardiac surgery.

Methods: Five hundred and forty-six patients were prospectively randomised to receive either the redivac drains or the conventional underwater-seal drains attached to low-pressure wall suction. We sought to test the null hypothesis that there was no difference in the incidence of residual pericardial or pleural collections requiring drainage between the 2 drainage systems. Secondary endpoints included time to drain removal, volume of drainage and drain size. Analysis was performed on an intention to treat basis.

Results: Two hundred and thirty-seven patients were allocated to the redivac group, while 241 were allocated to the conventional drain group. Age and gender distribution, the use of cardiopulmonary bypass, numbers of patients with univentricular morphology and number of drains utilized were similar in the 2 groups. The use of redivac drains resulted in a significantly lower incidence of residual pleural effusions requiring drainage (4 vs. 18, \( P < 0.003 \)). There was no difference in the incidence of pericardial effusion requiring drainage. Redivac drains drained an equivalent volume through smaller calibre tubes (12 Ch vs. 16 Ch, \( P < 0.0001 \)) over a shorter period of time (42 h (IQR 22-45) vs. 43 h (IQR 27-52), \( P < 0.01 \)) than the conventional drainage system.

Conclusions: Redivac drains are as safe and effective as conventional drains in the pediatric setting, and resulted in a lower incidence of residual pleural effusions requiring drainage. Together with their ease of care, earlier mobilisation of patients and greater cost-effectiveness, the routine use of high-vacuum drains can be recommended following pediatric heart surgery.

Keywords: Cardiac surgery; Pediatric; Drainage

1. Introduction

The conventional method of evacuating fluid and/or air from the mediastinum and pleural spaces in the early post-operative period following open-heart surgery is by way of chest drains connected to a closed underwater sealed drainage system (Fig. 1). This drainage system is usually attached to a low-pressure wall suction system and maintains a negative pressure of up to 20 cmH₂O (1.96 kPa). This has been shown to be safe in earlier reports [1,2].

High-vacuum (up to \(-90\) kPa) systems (redivac drains) have the potential to further reduce the duration of drainage. Their routine use was initially reported in orthopaedic and breast surgery [3,4]. Cardiac surgeons also began using these systems more than a decade ago for the treatment of post-sternotomy mediastinitis [5]. Their utilization in routine adult cardiac surgery has only recently been reported [6]. There has been no study to date addressing the safety and efficacy of these drains following pediatric cardiac surgery.

We designed a prospective randomised study to compare the safety and efficacy of high-vacuum drains (PFM Redon system, Mepro, Köln Germany) and the conventional low-vacuum underwater seal chest drains (Atrium Ocean, Atrium Medical, Hudson, NH, USA) following pediatric heart surgery.
2. Materials and methods

2.1. Participants

All children undergoing open or closed heart surgery at the Royal Children’s Hospital, Melbourne over a twelve-month period were considered eligible for the study. The hospital Ethics Committee in Human Research approved the study. Informed consent was obtained from the parents of all patients who were enrolled in the study. Patients who underwent emergency or after-hours surgery \((n = 117)\) were excluded from participation in this trial because of the logistic difficulties involved in obtaining consent by the lead investigators prior to surgery.

Redivac drains require an airtight closed system to function effectively. Therefore patients with an ongoing air leak from the lung at the end of the operation or in who the chest was left open (hemodynamic instability or unsatisfactory hemostasis) did not permit the use of redivac drains. All these patients therefore could only receive conventional drainage and though they were logged in the database, their data could not be included in the analysis.

2.2. Interventions

At the end of the operation chest drains were connected to either a conventional or redivac drainage system. The number and size of drains used were left to the discretion of the surgeon. The conventional system consists of chest drains connected to a closed underwater seal drainage system (Fig. 1). The underwater seal is connected to a low-pressure \((20 \text{cmH}_2\text{O})\) wall suction system, which is only disconnected for a short period of time \((15-30 \text{min})\) during transfer of the patient from the operating room to the intensive care unit (ICU) and from the ICU to the ward. The redivac drainage system consists of a polyvinyl chloride (PVC) drainage tube attached to a canister manufactured with a high internal negative pressure \((90 \text{kPa})\) (Fig. 2).

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Fig. 1. ‘Conventional’ drains with underwater-seal used in our institution (Atrium Ocean, Atrium Medical, Hudson, NH, USA).

Fig. 2. High-vacuum PFM Redon™ drainage system.
The canister maintains the negative pressure once it has been engaged and does not require constant connection to wall suction. This system requires a separate canister for each PVC drain, whereas up to 3 conventional drains can be connected to a single underwater seal using ‘Y’ connectors.

All patients received routine postoperative care in the intensive care and the ward. Chest drainage was recorded hourly and drains were removed when the drainage was minimal. Chest drains were removed during a maximal expiratory effort and suction (low or high) was maintained during removal. All patients received a chest X-ray (CXR) following drain removal and a trans-thoracic echocardiogram (TTE) on the fourth post-operative day.

2.3. Objectives and outcomes

We sought to test the null hypothesis that there was no difference in the incidence of residual pericardial or pleural collections requiring drainage between the redivac and the conventional drainage systems. Secondary endpoints included time to drain removal, volume of drainage and drain size.

2.4. Sample size

The reported rate of pericardial/pleural effusions (evident on echocardiography) following pediatric and adult open-heart surgery is >50% [7–9]. There are no reports with regard to the incidence of re-operation (drainage) in this setting. As we felt that any surgical re-intervention following heart surgery is relevant, the study was powered to have an 80% chance of detecting a difference of only 2% between the 2 arms of the study at a level of significance of 0.05. Sample size calculation based on a 2% difference in the rate of effusion requiring drainage indicated that 250 patients were required in each arm.

2.5. Randomisation and blinding

The patients were randomly allocated to receive either the redivac or conventional drains at the start of the operation. The allocation was communicated to the operating room using a central telephone only after the administration of protamine. The operating surgeon was blinded to the allocation process. The nature of the interventions precluded further blinding. However, the cardiology consultant and radiologist reviewing the CXR and TTE post drain removal were unaware of the type of drain used.

2.6. Statistical analysis

Analysis was performed on an intention-to-treat basis. Continuous variables were analysed using a 2-tailed t-test for normally distributed variables and a Mann-Whitney test for non-normally distributed variables. Categorical variables were analysed using the $\chi^2$-test and Fisher’s exact test where appropriate. A $P$ value less than 0.05 was considered significant. Data was analysed using SPSS v11.5 (SPSS Chicago, Illinois, USA).

3. Results

The flow of participants in the trial is illustrated in Fig. 3. Fifty patients did not consent to participate in the trial. Five hundred and forty-six children undergoing heart surgery with or without cardiopulmonary bypass were prospectively randomized to receive either the conventional low-vacuum underwater seal drains (n = 280) or the high-vacuum redivac drains (n = 266) at the conclusion of their surgery. Forty-five patients were excluded from the analysis because they could not receive redivac drains (Table 1). There were 23 protocol violations (Fig. 3). All protocol violations were the result of the surgeon’s decision after the allocation became known. Protocol violations were duly noted and the analysis was carried out on an intention-to-treat basis.

3.1. Demographic and clinical characteristics

Demographic and clinical characteristics are depicted in Tables 2 and 3. The distribution of patients with

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<th>Table 1</th>
<th>Reasons for exclusion from analysis</th>
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<tr>
<td>Exclusions from analysis</td>
<td>Number of patients redivac group</td>
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<tr>
<td>Air-leak at procedure end</td>
<td>3</td>
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<tr>
<td>Early re-operation within 48 h (cardiac arrest, non-tamponade)</td>
<td>0</td>
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<tr>
<td>Chest left open</td>
<td>8</td>
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<tr>
<td>No drain inserted</td>
<td>0</td>
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<tr>
<td>Insufficient data collection</td>
<td>2</td>
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<tr>
<td>Total</td>
<td>13</td>
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univentricular morphology who underwent either a bi-directional cavo-pulmonary shunt (BCPS) or a Fontan procedure was similar in the 2 arms. In the redivac group, there were 10 patients who underwent a BCPS and five who underwent Fontan completion. In the conventional drain group, seven had BCPS and eight underwent Fontan completion.

3.2. Outcome analysis

Primary and secondary endpoints are depicted in Table 4. Redivac drains drained an equivalent volume through smaller calibre tubes over a shorter period of time than the conventional drains. Redivac drains also resulted in a significantly lower incidence of residual pleural effusions requiring drainage.

3.3. Complications

There were five deaths during this study, of which one was related to a drainage tube. This was a 13 month-old patient who had three 16Fr conventional drains inserted following a Tetralogy of Fallot repair. Post-operatively she suffered a cardiac arrest at 30 h and was found to have a large hemothorax, which required urgent re-exploration. At operation it was discovered that the pleural drain tube had damaged the left internal thoracic artery. The other four deaths were unrelated to the drains. Two were cardiac in nature, one was related to sepsis and the other followed a gastro-intestinal complication.

4. Discussion

Mediastinal drainage is routine following open-heart surgery to prevent life-threatening cardiac tamponade [1,10]. Small and usually insignificant pleural and pericardial effusions develop in over 50% of patients undergoing cardiac surgery [7–9,11,12]. Near complete evacuation of post-operative mediastinal fluid and/or air is imperative in the pediatric population because of the smaller volumes required for hemodynamic compromise. The same is true of fluid and/or air in the pleural cavities. This drainage has historically been performed with silastic chest drains connected to an underwater seal, with or without the use of suction [2].

Low-vacuum systems transmit up to −20 cmH2O (−1.96 kPa) to the surrounding tissues. In contrast, high-vacuum systems transmit a much higher suction (up to −90 kPa) to the surrounding tissues. Although, they have the potential to further shorten the duration of drainage, concerns exist regarding the potential damage to mediastinal viscera. They have recently been used in routine adult cardiac surgery (6, unpublished data Mirza A, Barriere JC, et al. presented at the French Society of Thoracic and Cardiovascular Surgery, Winter Session, 1999). No studies have documented their usage following routine pediatric open-heart surgery.

In our study redivac drains drained an equivalent volume through smaller calibre tubes over a shorter period of time than conventional underwater, low-pressure suction drains. Moreover they appeared to result in a lower incidence of residual pleural effusions requiring drainage. There was no difference in the rate of pericardial effusion requiring drainage. This is similar to an earlier report in adults [6].

There are other advantages of the redivac system over conventional drains. The conventional system is bulky and therefore at greater risk of dislodgment during transport and mobilization. The level of care required for the underwater sealed system is much greater than that required for the redivac drains. The necessity of having the patient almost permanently connected to the bedside wall-suction hinders early mobilization and could delay recovery. The much less bulky redivac system allows early mobilization and combined with the shorter duration of drainage may allow a speedier recovery. However, as the presence or absence of drains rarely influences the duration of hospital stay following pediatric heart surgery, this is likely to remain unproven. In our experience with older children, the larger diameter of the conventional drains has also resulted in a greater degree of discomfort, both whilst in situ and during removal. The larger diameter conventional drainage tubes within the small volume mediastinal and pleural cavities have been reported to cause compression or compromise of

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<th>Table 2</th>
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<td><strong>Age distribution (P = 0.96)</strong></td>
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<td>Age group</td>
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<tr>
<td>Neonates (&lt;30 days) (n=81, 17%)</td>
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<td>Infants (up to 1 year) (n=172, 36%)</td>
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<td>Older children (&gt;1 year) (n=225, 47%)</td>
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<th>Table 3</th>
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<td><strong>Demographic and clinical characteristics</strong></td>
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<td>Variable</td>
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<tr>
<td>Age (median/interquartile range) months</td>
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<td>Gender (males)</td>
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<tr>
<td>Use of CPB</td>
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<td>Univentricular pathology</td>
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<td>Number of drains mean (range)</td>
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<th>Table 4</th>
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<td><strong>Primary and secondary endpoints (significant)</strong></td>
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<td>Outcome measures</td>
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<tr>
<td>Pleural effusion requiring intervention</td>
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<td>Pericardial effusion requiring intervention</td>
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<td>Time to removal (hours)</td>
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<td>Volume of drainage (ml) median/interquartile range</td>
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<td>Size of drains (Ch) median/interquartile range</td>
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<td>Mortality</td>
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the intrathoracic structures [6]. In this study one fatal adverse event was observed related to a conventional drain. Redivac drains are ineffective in the presence of significant air leaks. Our experience is that air leaks are uncommon in pediatric heart surgery and should be recognized in the intensive care or the ward the redivac drain can be converted to a low-pressure suction drain with an underwater seal with little difficulty. Also the redivac canisters have a limited volume (600 ml) and may need to be changed in the presence of brisk drainage especially in the immediate post-operative period.

Redivac drains are also useful in the setting of post-sternotomy mediastinitis. In our unit the treatment for this uncommon but potentially devastating complication follows that outlined by Durandy et al. [5], where an early thorough debridement and washout is combined with elective chest closure and drainage of the chest with multiple redivac drains.

As a way to prevent mediastinal infection, the Redivac drain policy was extended to the elective delayed primary chest closure for all patients except for those with hypoplastic left heart syndrome. In Norwood Stage 1 for hypoplastic left heart syndrome (classic or modified right ventricle to pulmonary artery conduit) we have found that a significant drop in mean arterial pressure occasionally follows the initiation of the high negative pressure in the chest. Our understanding is that the high negative pressure profoundly alters the right ventricular compliance. For this reason, patients undergoing a delayed primary closure following the Norwood procedure still have a conventional drainage system.

Finally, the cost of interventions needs to be taken into account. In our institution, the cost of the conventional underwater sealed drain consumables, including the drainage tubes, connectors and bottle, is just under AUD$100. In contrast the redivac system using a single drain and collecting reservoir, costs AUD$13. Even if 3 such systems were used in a given patient the total cost (AUD$39) still represents a significant cost saving.

4.1. Limitations

This was a large prospective randomized study, but three limitations should be noted. First, the patients were randomized prior to surgery. This led to 45 patients being subsequently excluded from the analysis for the reasons outlined above. These numbers could have been limited had the randomization process taken place just prior to drain insertion. Second, the nature of the intervention precluded blinding of all personnel involved in the care of the patients in the trial. Third, the incidence of pneumothorax between the two groups was effectively controlled by the exclusion criteria. Thus it is not surprising that there was no difference in the incidence of pneumothorax between the two groups.

5. Conclusions

The present study has shown that high-pressure redivac drains are as safe and effective as conventional drains in the pediatric setting, and appear to result in a lower incidence of residual pleural effusions requiring drainage. Together with their ease of care, earlier mobilisation of patients and greater cost-effectiveness, the routine use of high-pressure redivac drains can be recommended following pediatric heart surgery.

As a result of this study we now use this system almost exclusively in our institution.

Acknowledgements

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References


Appendix A. Conference discussion

Dr Z. Karani (Khartoum, Sudan): It was unfortunate that your one patient demised from traumatic injury from your conventional drain where it eroded through the internal mammary artery. I had a similar experience with conventional drain with suction where the conventional drain eroded through one of the coronary veins. Luckily, we explored the patient and the patient had a favorable outcome.
Where do you exactly position your Redivac drain in relation to the surface of the heart? Do you close the pericardium? Do you put it in the posterior pericardium?

And I’m surprised you haven’t had any suction or traumatic injury to any of the surface of the myocardium. Is that a concern? Do you have any special trick to position the drains?

Dr Newcomb: No, no special tricks. As you probably are all aware, in most of our cases we remove most of the pericardium to use in the repair and so there’s often no way of closing that defect. We are fairly liberal in our use of Gore-Tex membrane to separate the heart from the sternum in our unit, but only for those patients in whom we are planning a re-operation before they reach adulthood. Some surgeons prefer the drain superficial to the Gore-Tex, and some prefer them deep to the Gore-Tex.

With respect to removing these drains, in my time in the unit, we have removed many of them, and our policy is to not take the suction off either the Redivacs or the conventional drains as we remove them, to help prevent re-accumulation of fluid or air, and we don’t have any problems.

Dr V. Alexi-Meskishvili (Berlin, Germany): From physiology, we know that the thoracic pressure and the pericardium pressure influence the venous inflow. Especially, when we increase the pericardial suction pressure we saw that sometimes significant hemodynamic changes occur. Do you have any experience with that in small infants especially?

Dr Newcomb: The only setting that we would be wary of using the Redivac drains is after Norwood Stage I operations. We, routinely leave the chest open for 2–3 days in these babies. We have previously noted a profound decrease in their mean arterial pressure when the redivacs were deployed, so on closing the chest, that is the only group of patients who would not receive Redivac drains.

Dr H. Edmunds (Philadelphia, PA, USA): How many patients receive more than one drain?

Dr Newcomb: Most of the patients received 1 drain. Our mean number of drains was 1.4, so two thirds received 1 drain, while the remainder received 2 or 3 drains.

Dr Edmunds: So you would put it in the posterior mediastinum, and where would the second one be usually?

Dr Newcomb: Usually if there were more than one, both of them are anterior to the heart, sort of wrapping around either side of the heart and toward the great vessels. If three, the extras will be draining the pleural spaces.

Dr Edmunds: It is difficult to understand your cost analysis—unless the company that makes the Redivac drain is a philanthropy. Thirteen Australian dollars versus $93 is quite a difference.

Dr Newcomb: These figures were obtained from our staff that purchase these items. Obviously, all institutions, depending on their usage, will have some discounts or what have you. We do buy in bulk, and I’m sure that does bring the price down a little bit, but it wouldn’t account for the 7 times difference in price.

Dr Edmunds: So we’ll just have to take it at face value.