

## Original Article

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# Comparison of median sternotomy and left anterior mini-incision for pulmonary valve replacement following primary tetralogy of Fallot repair

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**Abstract**

*Objective:* Pulmonary insufficiency requiring reintervention frequently occurs after primary tetralogy of Fallot repair. Repeat interventions present a challenge for both the surgeon and patient. We compare a minimally invasive, 5 cm left anterior mini-incision to redo median sternotomy for pulmonary valve replacement in tetralogy of Fallot patients. *Methods:* Following Internal Review Board approval, we conducted a single institution retrospective review of patients with tetralogy of Fallot who underwent pulmonary valve replacement via redo median sternotomy or left anterior mini-incision between 13 July, 2016 and 6 March, 2020. *Results:* Twenty-three patients underwent pulmonary valve replacement following primary tetralogy of Fallot repair between March 2016 and March 2020. Twelve patients received a redo-median sternotomy from March 2016 to August 2018. Left anterior mini-incision was first offered in August of 2018 and was chosen by all eleven patients thereafter. The two groups had similar baseline characteristics including preoperative pulmonary valve dysfunction. Early trends suggest a longer cardiopulmonary bypass time for patients who received left anterior mini-incisions. Other outcomes were comparable, including operative times, blood product requirements, residual pulmonary valve dysfunction, postoperative pain, narcotic requirements, ICU length of stay, total length of stay, and postoperative complications. *Conclusions:* In patients who have previously undergone primary repairs of tetralogy of Fallot, outcomes for pulmonary valve replacement via left anterior mini-incision are comparable to those via redo median sternotomy.

Minimally invasive adult cardiac surgery has resulted in reduced length of stay, less postoperative pain, earlier mobilisation, improved cosmesis, and avoidance of sternal precautions.<sup>1–3</sup> Despite these advances in adult cardiac surgery, unique characteristics of congenital cardiac surgery patients have prevented the expedient adoption of similar approaches.<sup>4</sup>

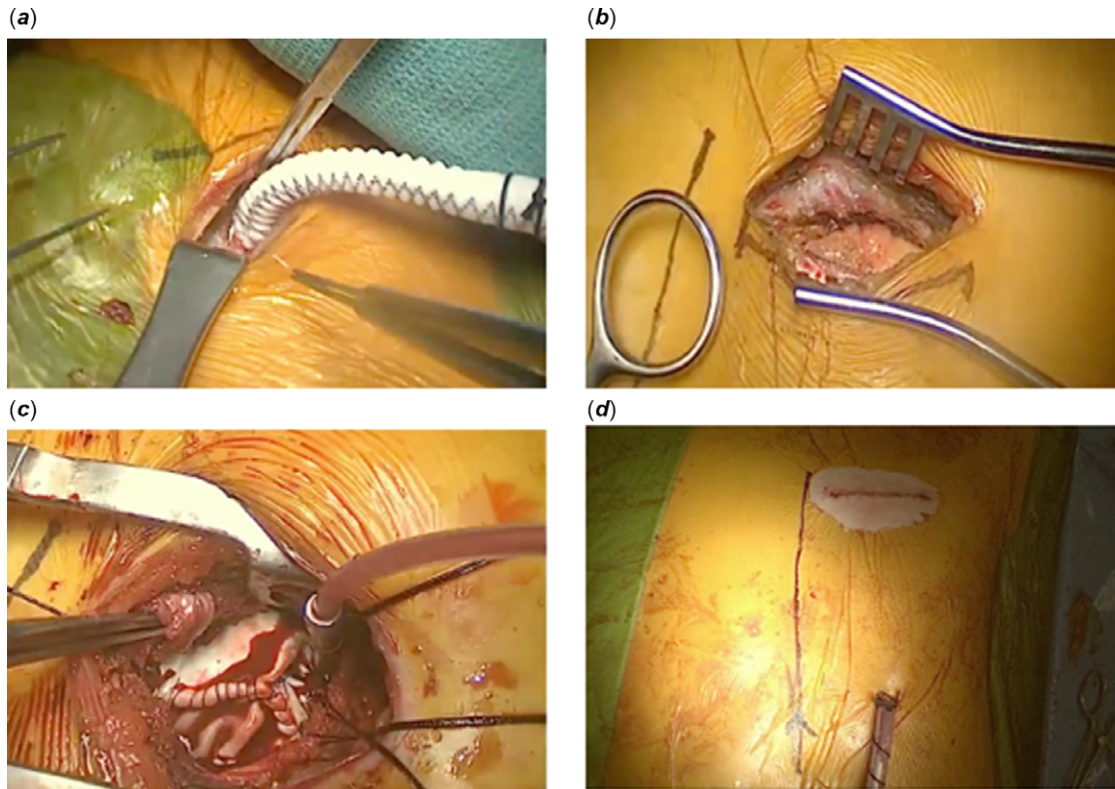
Improvements in surgical techniques and critical care practices for paediatric congenital cardiac patients have lowered mortality and led to a rise in the number of adult congenital cardiac patients.<sup>5–7</sup> As patients with CHD live longer, the likelihood for reintervention increases. Thus, the benefits of minimally invasive approaches could lead to improvements in the quality of life for this growing population.<sup>5,8</sup> Unique challenges in the paediatric population, such as patient size and available technology, have limited the use of minimally invasive approaches. Similarly, median sternotomy continues to be the standard approach for adult congenital cardiac patients, despite patients being larger.<sup>4</sup>

Pulmonary valve replacement following primary tetralogy of Fallot repair is commonly performed through a redo median sternotomy.<sup>9</sup> At our institution, we innovated a novel approach using a 5 cm left anterior mini-incision for pulmonary valve replacement in this patient population.<sup>9,10</sup> Here, we provide an interim analysis of outcomes for tetralogy of Fallot patients receiving left anterior mini-incision for pulmonary valve replacement and compare them to those of patients receiving redo median sternotomy.

**Materials and methods**

Internal Review Board approval was obtained for a retrospective chart review of patients undergoing pulmonary valve replacement following primary tetralogy of Fallot repair between March 2016 and March 2020. Beginning in August 2018, the left anterior mini-incision approach was developed by the senior authors and offered as an alternative to median sternotomy for all patients undergoing pulmonary valve replacement. No patient selection criteria were applied during this

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**Figure 1.** (a) End-side cannulation of right common femoral artery. (b) 5 cm dissection through the third interspace. (c) Visualization of the RVOT. (d) Closure of 5 cm incision in layers.

time. Given both options, all families chose to proceed with the left anterior mini-incision. As previously described, this approach involves peripheral femoral-femoral cardiopulmonary bypass via a 6 mm end-to-side Dacron graft on the artery, direct venous cannulation and exposure of the right ventricular outflow tract through a 5 cm incision in the left third interspace (Fig 1a–d).<sup>10,11</sup> Transesophageal echocardiogram (TEE) confirms the absence of an atrial septal defect and the final repair is completed on a beating heart.<sup>9,11</sup> To augment drainage for improved visualisation, a single-stage venous cannula in the left subclavian vein was added, only as needed.

Twelve patients underwent redo median sternotomy between March 2016 and August 2018. Left anterior mini-incision was introduced in August of 2018 and was offered preoperatively to all patients undergoing evaluation for pulmonary valve replacement thereafter. It was chosen unanimously by eleven patients with prior tetralogy of Fallot repair undergoing pulmonary valve replacement from August 2018 to March 2020.

A chart review was conducted to collect preoperative, intraoperative, and postoperative variables. Preoperative variables included age, race, body mass index, and baseline degree of pulmonary valve insufficiency. Intraoperative variables included cardiopulmonary bypass time, operative time, blood product utilisation, need for conversion to a median sternotomy, and surgical complications. Postoperative variables included degree of pulmonary valve insufficiency, pain scores on postoperative day 1, 3, and at discharge; total required opioids on postoperative day 1, 3, and at discharge; ICU length of stay, total hospital length of stay, complications, and time to most recent follow-up. Pain scores were obtained using retrospective chart review of the Numeric Rating Scale.<sup>12</sup> The reported score was calculated by averaging the

reported pain over a 24-h period (0700 to 0700) wherein the denominator was the number of times a patient reported their pain score for the given period. Opioids received were calculated as morphine equivalents by weight over 24 hours (0700 to 0700).<sup>13</sup> Opioids required at discharge refers to the amount provided by the discharging physician based on the patient's pain medication requirement at time of discharge.

The patients were divided into two cohorts based upon the initial approach selected, redo median sternotomy, or left anterior mini-incision, and intention to treat analysis was used. The median and interquartile range for each variable were calculated. Groups were compared using Mann–Whitney U analysis for quantitative data and Fischer Exact tests for ordinal. Critical U values from the Mann–Whitney U analysis were transformed to corresponding p values. Continuous variables are presented as (redo median sternotomy median (interquartile range), left anterior mini-incision median (interquartile range), p) in the results section.

## Results

Twenty-three patients underwent pulmonary valve replacement between 13 July, 2016 and 6 March, 2020 following primary tetralogy of Fallot repair. Eleven of these were performed from a left anterior mini-incision and twelve were via redo median sternotomy. Two patients required conversion to a median sternotomy due to inadequate exposure of their right ventricular outflow tract. One had an extensive surgical history including prior Waterston shunt via right thoracotomy and two prior sternotomies from their repair and a subsequent pulmonary valve replacement, placement of a sternal bar for pectus excavatum, and a previously unstable chest with sternal non-union. Collectively, this resulted in a

**Table 1.** Comparison of baseline characteristics for patients undergoing median sternotomy or left anterior mini-incision for pulmonary valve replacement.

	Redo MS	LAMI	p-value
Age (years)	14.5 (11.5–45)	15 (13–24.5)	0.66
Race	White: 6	White: 10	0.14
	Black: 4	Black: 1	
	Asian: 1	Asian: 0	
	Native American: 1	Native American: 0	
BMI (kg/m <sup>2</sup> )	23.7 (20.0–26.6)	20.9 (18.5–30.4)	0.64
Degree of pulmonary valve insufficiency	Moderate: 3	Moderate: 2	1.0
	Mod/Severe: 1	Mod/Severe: 0	
	Severe: 8	Severe: 9	

Data is listed as the median followed by the interquartile range (IQR) in parenthesis

BMI = body mass index; CPB = cardiopulmonary bypass; LAMI = left anterior median incision; LOS = hospital length of stay; ME = morphine equivalents; MS = median sternotomy

densely adherent infundibular patch which complicated dissection. The second converted patient had mesocardia, and the pulmonary valve could not be lateralised to the required exposure. These converted patients' data were reported with the left anterior mini-incision cohort. A single left anterior mini-incision patient developed a perivalvular leak and required a redo PVR on postoperative day 1. The groups were similar, with no differences in their preoperative characteristics nor baseline pulmonary valve insufficiency (Table 1).

Early trends show a longer cardiopulmonary bypass time (159 minutes (137–168), 119 minutes (71–137),  $p = 0.04$ ) with comparable operative time (320 minutes (290–402), 291 minutes (230–318),  $p = 0.13$ ) for patients undergoing left anterior mini-incision compared to redo median sternotomy. There were no intraoperative complications or mortalities in either group. Postoperative residual degree of pulmonary valve insufficiency was comparable between groups and is shown in Table 2. There were no significant differences between the groups in the median number of days spent in the ICU following surgery (1.5 days (1–2), 2 days (1–3),  $p = 0.25$ ) or in the total number of days spent in the hospital (5 days (3.8–5), 5 days (3.5–7.5),  $p = 0.64$ ) after the operation. Postoperative pain, represented by morphine equivalents and patient reported pain scores on postoperative day 1, 3, and at discharge also did not differ between groups as is shown in Table 2. There were no thromboembolic complications or arrests in either group.

## Discussion

In our interim analysis comparing a 5 cm left anterior mini-incision to redo median sternotomy for pulmonary valve replacement, left anterior mini-incision was shown to be largely comparable to redo median sternotomy. Minimally invasive approaches have previously been associated with longer cardiopulmonary bypass times. This relates to the early peripheral bypass strategy utilised by a majority of minimally invasive techniques.<sup>2,14</sup> In our early analysis, trends suggest that left anterior mini-incision patients may have longer cardiopulmonary bypass times with comparable operative times when compared to redo median sternotomy. There were no postoperative complications in either group, and the quality of valve replacement was not compromised by the minimally invasive approach.

Given overall similar perioperative outcomes for left anterior mini-incision and redo median sternotomy in this patient population, technical considerations of each approach, patient preference, and limitations of the left anterior mini-incision should serve as a guide in determining which approach is best for a given patient.

Redo median sternotomy presents unique challenges. Following the first sternotomy, adhesions form between the mediastinal structures and the sternum. This distorts the underlying anatomy, which necessitates extensive and careful dissection prior to the start of any operation. The increased technical difficulty of a redo sternotomy is associated with increased bypass time, cardiac and aortic injuries, and increased blood transfusion requirements when compared with an initial sternotomy.<sup>15–17</sup> It is also well established that increasing age, a phenomenon of the current congenital cardiac population, is an independent risk factor for sternal non-union.<sup>18</sup> In patients with a prior sternotomy, we have found that the left anterior mini-incision is appropriate for a majority of individuals requiring intervention near the pulmonary artery. In such cases, the right ventricular outflow tract is often positioned anteriorly and can be accessed through a 5 cm incision which requires less dissection than redo median sternotomy to achieve a safe exposure and complete the repair.<sup>9,10</sup>

Beyond the technical advantages of the left anterior mini-incision, patients tend to prefer a minimally invasive approach over redo median sternotomy. All eleven patients offered the mini-incision chose the procedure and expressed a preference for a smaller incision despite this representing an additional incision from their prior sternotomy. Additionally, patients receiving a median sternotomy require sternal precautions which limits their activity for 6 weeks. Patients who receive a left anterior mini-incision, however, can avoid these restrictions. This allows resumption of activities as tolerated and is the primary advantage of a minimally invasive approach.<sup>19</sup> This is particularly important in the congenital cardiac population where patients tend to be younger and more active than their adult cardiac surgery counterparts. The median patient in our cohort was 15 years old, underscoring the importance of considering the impact of sternal precautions on postoperative quality of life in the congenital population. Based on our experience, patients seem to view the left anterior mini-incision as appealing. And while prior studies have shown a reduction in pain with minimally invasive strategies, our study shows no

**Table 2.** Comparison of outcomes for patients undergoing median sternotomy or left anterior mini-incision for pulmonary valve replacement.

	Redo MS	LAMI	p-value
CPB time (minutes)	119 (71–137)	159 (137–168)	0.04
Operative time (minutes)	291 (230–318)	320 (290–402)	0.13
Blood products (Units)	0 (0–1.75)	0 (0–1)	1.0
Degree of pulmonary valve insufficiency	None: 4	None: 2	0.86
	Trace: 5	Trace: 5	
	Trace/Mild: 1	Trace/Mild: 1	
	Mild: 2	Mild: 3	
Pain score POD 1	3.25 (2.05–5.13)	3.8 (2.85–4.8)	0.76
Pain score POD 3	1 (0–2.2)	2.8 (0–3.78)	0.33
Pain score at discharge	0.25 (0–1.43)	1.5 (0–4.15)	0.38
ME POD 1	17.5 (9.38–46.9)	51.8 (30.6–78.8)	0.07
ME POD 3	0 (0–20.5)	15 (0–32.5)	0.34
ME at discharge	0 (0–0)	0 (0–11.3)	0.32
Length of ICU stay (days)	1.5 (1–2)	2 (1–3)	0.25
LOS (days)	5 (3.8–5)	5 (3.5–7.5)	0.64
Follow-up (months)	41 (27–46)	14 (7–28)	0.03

Data is listed as the median followed by the interquartile range (IQR) in parenthesis

BMI = body mass index; CPB = cardiopulmonary bypass; LAMI = left anterior median incision; LOS = hospital length of stay; ME = morphine equivalents; MS = median sternotomy

difference, potentially owing to small sample size and the inclusion of converted mini-incision patients who received both thoracotomy and sternotomy.<sup>1,3</sup>

Despite our observed unanimous patient preference for the left anterior mini-incision, and the overall similar outcomes, there are limitations to this approach. The first limitation is a reduction in the size of the operative field of view, a salient factor in paediatric patients where the surgical field is already small. This reduced operative view necessitates a near bloodless field to maintain adequate visualisation which may require additional venous drainage from the left subclavian.<sup>9,10</sup> Our practice is to obtain such venous access percutaneously. Increased patient size can also compound this effect. To help facilitate an adequate workspace, peripheral cannulation strategies are employed. Ultrasound is utilised to evaluate patency and size of the femoral vessels prior to making the mini-incision. The risk of distal limb ischaemia is reduced in paediatric patients by establishing the arterial circuit through a 6 mm end-to-side Dacron graft with the femoral artery. Postoperatively, the graft is removed, and the artery is repaired with bovine pericardium. Lastly, the left anterior mini-incision leaves redo patients with a second, albeit smaller, scar. Preoperatively this point is discussed with patients, and in our experience, they seem to care more about the size and location of the planned incision rather than whether it is within the prior scar.

In this series, two patients required conversion from thoracotomy to sternotomy. This underscores the importance of appropriate patient selection, which is expected to mitigate the risk of conversion compared to this cohort where the procedure was offered without exclusion criteria. Based on these findings, we now consider two or more prior sternotomies and mesocardia as well as dextrocardia to be contraindications for the left anterior mini-incision. These situations lead to poor exposure secondary to

dense adhesions and anatomic constraints, respectively. Early trends also indicate that patients with a body mass index above 30 have increased likelihood of conversion and are counselled accordingly. Since these early cases, we now perform preoperative CT for all patients being considered for the mini-incision, a process that can also be of value for patients undergoing redo sternotomy. CT scans help ensure that the pulmonary valve is accessible through a minimally invasive approach and demonstrate which intercostal space should be accessed to perform the mini-incision. Placement is confirmed in the operating room with transthoracic echocardiogram. Additional data may reveal more factors relevant to patient selection and help lower conversion rates.

We believe that the single left anterior median incision patient requiring redo PVR due to a perivalvular leak did so because of sewing into a fenestrated muscle bar and feel that visualisation was not an issue, though this cannot be definitively stated. Perivalvular leaks are not uncommon during valvular intervention. Surprising, however, was the fact that the leak was not detected during the post-bypass TEE, which we routinely perform in the operating room. Thus, rather than repairing the leak during the initial intervention, the patient returned to the operating room the next day. They recovered well, and we have had no such complications since.

The small sample size limits our power of detection for statistical significance in this interim analysis comparing pulmonary valve replacement outcomes for patients undergoing left anterior mini-incision and median sternotomy. Still, while early trends suggest longer bypass times, outcomes between the two groups are otherwise comparable. We believe that public reporting of early results and an open discussion of minimally invasive outcomes in congenital cardiac surgery are essential. It ensures that the balance of risks and benefits continues to favour patients by facilitating a public review of innovative approaches for low-volume

operations. This is critical to ensuring patient safety and accelerating the surgeon's learning curve. The retrospective nature, along with unanimous patient preference for left anterior mini-incision since it was offered, resulted in longer follow-up for the sternotomy cohort. Attention should be given to the durability of repair in left anterior mini-incision patients as their follow-up increases. Future prospective studies should specifically address patient satisfaction with the overall procedure experience via survey data, whether they would make the same decision again, and if their preference is based on perceptions about cosmesis or anticipated postoperative pain.

In conclusion, our experience demonstrates a strong patient preference for minimally invasive approaches to pulmonary valve replacement, despite prior sternotomy, and similar outcomes with slightly longer bypass times for the mini-incision group. The key benefit conferred by the left anterior mini-incision is avoidance of sternal precautions in appropriately selected patients. Additionally, patients express a desire for a smaller incision and scar. The costs and benefits to the patient and surgeon should be considered carefully. Left anterior mini-incision should continue to be offered to patients while comparable outcomes are achieved. Ongoing reporting of these outcomes will promote patient safety and surgeon education. As the left anterior mini-incision cohort expands and their duration of follow-up is increased, we anticipate additional insights into patient selection, a lower conversation rate, and advancements in operative technique.

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**Conflicts of interest.** None.

**Ethical standards.** The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national guidelines on human experimentation and with the Helsinki Declaration of 1975, revised in 2008, and has been approved by the institutional review board of our institution.

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