CJC Open 4 (2022) 833–839

Original Article

Sternum-Sparing Left Ventricular Assist Device Insertion Reduces Perioperative Transfusions and Blood Loss: A Single-Centre Canadian Experience

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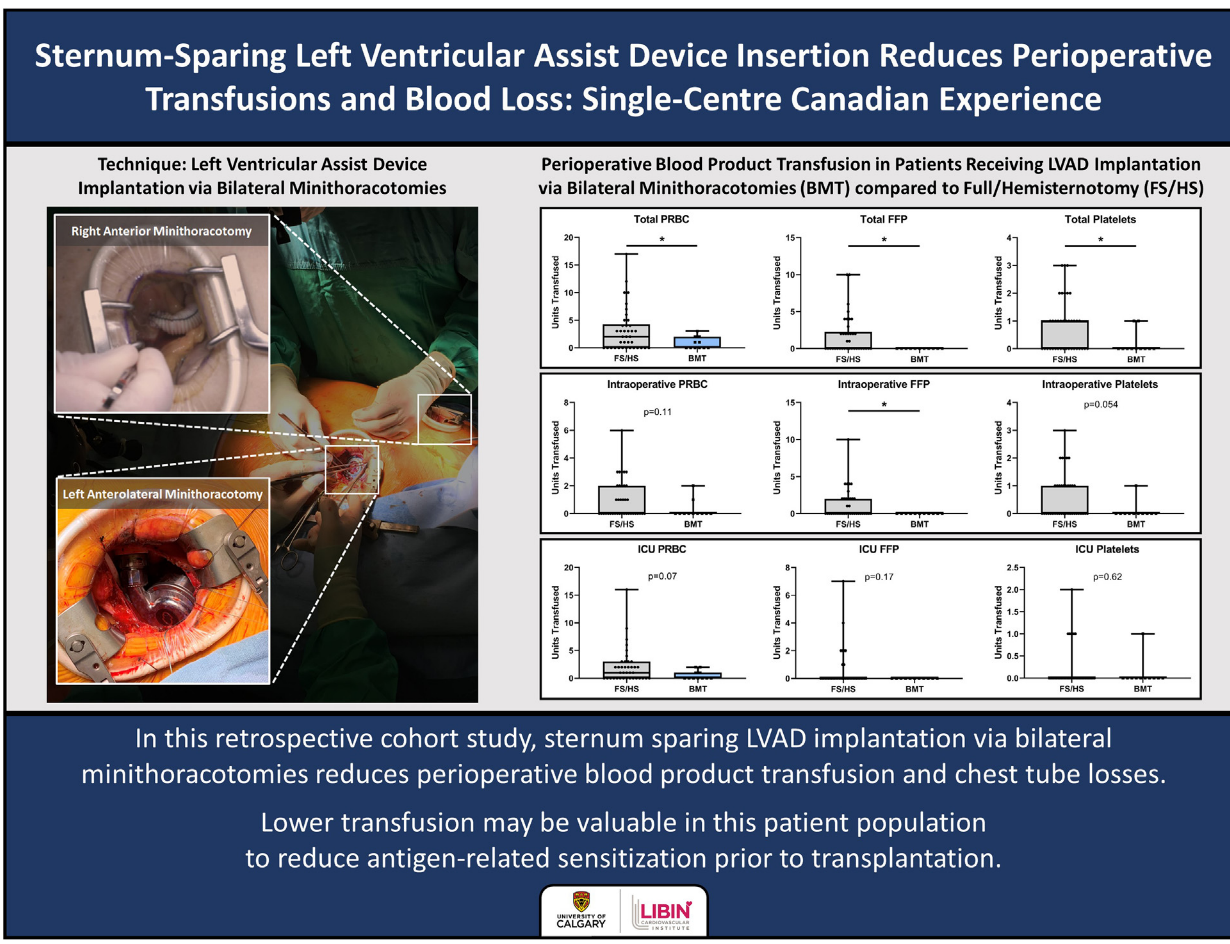

https://doi.org/10.1016/j.cjco.2022.06.002

ABSTRACT

Background: Left ventricular assist devices (LVADs) improve survival and quality of life, as either destination therapy or a bridge to transplantation. Although less-invasive hemisternotomy approaches for LVAD implantation are well studied, only a paucity of data is available in the literature on sternum-sparing bilateral minithoracotomy (BMT). Our centre has one of Canada's most extensive experiences with the BMT approach. Herein, we compared LVAD implantation via BMT with patients who received full median sternotomy or hemisternotomy.

Methods: A single-centre retrospective review of data from Foothills Medical Centre (Calgary, Canada) was performed. Patients underwent LVAD insertion from 2012 to 2019, receiving either BMT (n = 11) or sternotomy (full median sternotomy or upper hemisternotomy with left minithoracotomy; n = 38). Intraoperative and early postoperative outcomes were assessed.

Results: Patients who received BMT had significantly fewer transfusions of red blood cells, fresh frozen plasma, and platelets. The BMT group had lower chest-tube output in the first 12 hours. No significant differences occurred in ventilation time, intensive care unit length of stay, mortality, stroke, or reoperation for bleeding.

Conclusions: Outcomes suggest that sternum-sparing LVAD implantation is a feasible alternative to sternotomy, leading to less postoperative blood loss and transfusion in the early postoperative period. Less transfusion is particularly valuable in this patient population, to reduce antigen-related sensitization prior to transplantation. Additional study is needed to assess potential benefits related to right heart function, postoperative mobility, and re-entry for transplantation.

RÉSUMÉ

Introduction : Les dispositifs d'assistance ventriculaire gauche (DAVG) contribuent à améliorer la survie et la qualité de vie, soit en traitement définitif ou en attente d'une transplantation. Bien que des approches d'hémisternotomie moins invasives lors de l'implantation d'un DAVG font l'objet d'un bon nombre d'études, seules de rares données sont disponibles dans la littérature sur la minithoracotomie bilatérale (MTB) sans ouverture du sternum. Notre centre possède l'une des expériences les plus approfondies au Canada de l'approche par MTB. Dans le présent article, nous avons comparé l'implantation du DAVG par MTB chez les patients qui avaient subi une sternotomie médiane complète ou une hémisternotomie.

Méthodes : Nous avons réalisé une revue rétrospective unicentrique des données du Foothills Medical Centre (Calgary, Canada). Les patients avaient subi l'insertion d'un DAVG de 2012 à 2019, soit par MTB (n = 11) ou par sternotomie (sternotomie médiane complète ou hémisternotomie supérieure associée à une minithoracotomie gauche ; n = 38). Nous avons évalué les résultats peropératoires et postopératoires précoces.

Résultats : Les patients qui avaient subi une MTB avaient eu significativement moins de transfusions de globules rouges, de plasma frais congelé et de plaquettes. Le groupe de MTB avait un plus faible débit du drain thoracique dans les 12 premières heures. Aucune différence significative dans la durée de ventilation, la durée du séjour aux soins intensifs, la mortalité, l'accident vasculaire cérébral ou la réopération en raison d'un saignement n'a été observée.

Conclusions : Les résultats montrent que l'implantation de DAVG sans ouverture du sternum est une alternative à la sternotomie, qui entraîne moins de pertes de sang postopératoires et de transfusions en phase postopératoire précoce. Un moins grand nombre de transfusions est particulièrement important au sein de cette population de patients afin de réduire la sensibilisation aux antigènes avant la transplantation. D'autres études sont nécessaires pour évaluer les avantages potentiels liés à la fonction du cœur droit, la mobilité après l'opération et la réadmission pour une transplantation.

The mortality rate for those on the waitlist for cardiac transplantation remains high despite attempts at expanding the donor pool and organ reconditioning.[1-3] Durable left ventricular assist devices (LVADs) effectively provide destination therapy, as well as a bridge to transplantation, while improving survival odds and quality of life.[4-7] LVADs are conventionally implanted via sternotomy.

LVAD implantation via bilateral minithoracotomy (BMT) is a less-invasive alternative, with early data suggesting reduced perioperative morbidity.[8-11] These reports suggest that, in addition to eliminating sternal complications, BMT facilitates earlier postoperative mobility and may reduce postoperative right ventricular dysfunction, mechanical ventilation time, and transfusions.[8,11-13] Recent studies demonstrate the safety of minimally invasive LVAD implantation and suggest that it can be performed in a cost-effective manner.[14-16]

Owing to the novelty of BMT, only limited data detail outcome differences between BMT and sternotomy approaches to LVAD implantation. Our group has growing experience with this operation, with both the HeartWare Ventricular Assist Device (Medtronic, Dublin, Ireland) and the HeartMate 3 (Abbott, Chicago, IL) devices.[10] Herein, we report on a retrospective consecutive cohort, comparing the intraoperative and early postoperative outcomes of sternum-sparing BMT LVAD implantation with full or hemisternotomy. Our study demonstrates that LVAD implantation via BMT reduces intraoperative and early postoperative transfusion requirements, along with postoperative chest-tube outputs. We aim to leverage these hypothesis-generating retrospective data to develop a prospective study for this minimally invasive, sternum-sparing approach to LVAD implantation.

Received for publication March 24, 2022. Accepted June 5, 2022.

Ethics Statement: The reported study has adhered to all relevant ethical guidelines. This study has been approved by the Conjoint Health Research Ethics Board at the University of Calgary.

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See page 838 for disclosure information.

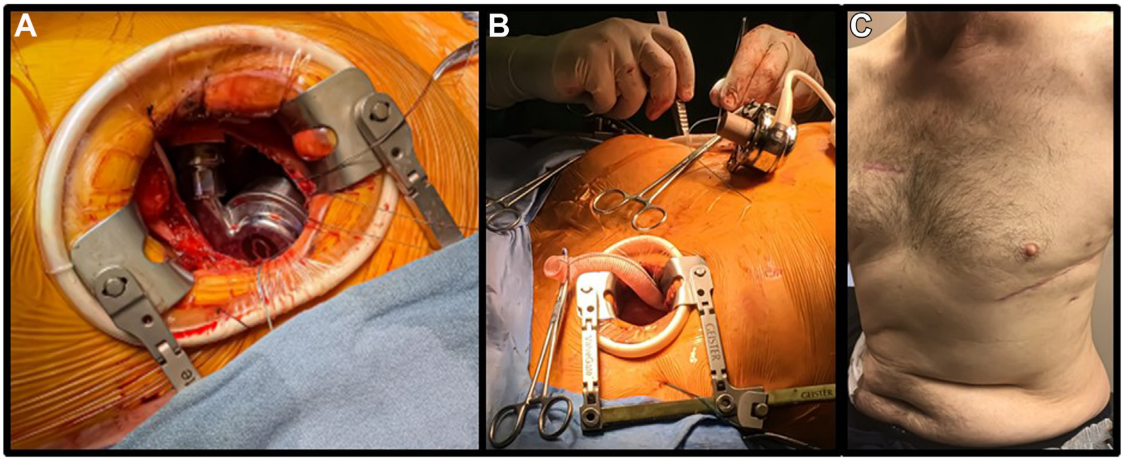

Figure 1. Sternum-sparing insertion of left ventricular assist device via bilateral minithoracotomies. (**A**) The device is implanted into the left ventricular apex through a left anterolateral minithoracotomy. (**B**) The outflow graft is tunneled within the pericardium and brought out through the right anterior minithoracotomy to be anastomosed to the ascending aorta. (**C**) Healed incisions at 6-week clinic follow-up.

Methods

Surgical technique: LVAD implantation via BMT

Our operative technique has been outlined previously and is further detailed in Figure 1 and Video 1 (view video online).[10] Cardiopulmonary bypass is achieved by femoral arterial (19F arterial cannula; Medtronic, Dublin, Ireland) and venous (25F multi-sideport venous cannula; Medtronic) cannulation under transesophageal echocardiographic guidance. Two surgeons collaborate, simultaneously each performing one of the thoracotomy incisions. A 5-cm right anterior minithoracotomy is made in the second intercostal space to access the ascending aorta; and an 8-cm left anterolateral minithoratomy is made in the sixth intercostal space, to approach the cardiac apex. After left and right pericardiotomies are performed, retraction sutures are placed to expose the cardiac apex and the aorta. Cardiopulmonary bypass is initiated, followed by securing of the LVAD sewing cuff to the apex using a running prolene suture line. Apical coring is then performed, enabling examination of the left ventricular cavity. Trabeculations are identified, and any laminated clot is removed. The device is then attached to the apical sewing cuff, and the driveline is tunneled to the right upper quadrant exit site. The outflow graft is brought through the pericardium to the right-sided incision. The outflow graft is then cut to length and anastomosed to the proximal ascending aorta using a side-biting clamp. The clamp is removed, cardiopulmonary bypass is weaned, and the device speed is gradually increased.

Patient data

Data were obtained from a retrospective consecutive cohort from October 2012 to October 2019, consisting of 11 patients who received BMTs and 41 patients who received either full median sternotomy (FS; 28 patients) or upper hemisternotomy and left-sided thoracotomy (HS; 10 patients). Intraoperative and intensive care unit (ICU) data were pulled from the MetaVision Database and manual review of patient charts. All patients received their LVAD as a bridge-to-transplantation.

Patients were included if they were aged over 18 years and had undergone LVAD implantation at our centre. Patients were excluded if they were on temporary mechanical circulatory support (extracorporeal membrane oxygenation, temporary biventricular assist device, or temporary LVAD) prior to durable LVAD implantation. This exclusion was performed because emergent clinical status and coagulopathy would confound postoperative bleeding outcomes, and many of these patients had a sternotomy already. Patients that received aortic cross-clamping during sternotomy-based LVAD implantation were excluded to maintain procedural similarity between groups, as the BMT group did not contain any patients receiving aortic cross-clamping. Five patients in the FS/HS group received concomitant tricuspid valve repair or closure of a patent foramen ovale, which was performed on a beating heart while the patient was on cardiopulmonary bypass. None of these patients had had previous cardiac surgery. Coronary artery disease, diabetes mellitus, smoking, hypertension, dyslipidemia, prior implantable cardioverter defibrillator (ICD) implantation, valvular disease, chronic kidney disease, and chronic lung disease were noted for each patient, as these comorbidities were identifiable in the available databases and play a key role in the consideration of each patient for LVAD implantation.

Outcomes: intraoperative and ICU

Transfusion data were reported during operative and ICU time periods as intraoperative, ICU, and total. Transfusion of packed red blood cells, fresh frozen plasma, and platelets was quantified using database and chart review.

Other intraoperative outcomes included cardiopulmonary bypass time and cross-clamp time. ICU-exclusive outcomes included cardiovascular ICU length of stay, invasive ventilation time, crystalloid transfusion, and total chest-tube

Table 1. Patient characteristics

Variable	BMT (n = 11)	FS/HS (n = 38)	P
Age, y	61 (57, 64)	56 (46, 61)	0.02
Female	1 (9)	9 (24)	0.42
Body mass index, kg/m^2	25.7 (24.0, 31.2)	26.4 (23.3, 32.8)	0.78
Indication for LVAD			0.49
Ischemic heart disease	7 (64)	17 (45)	
Nonischemic cardiomyopathy	3 (27)	18 (47)	
Mixed cardiomyopathy	1 (9)	3 (8)	
INTERMACS			0.24
2	2 (18)	1 (3)	
3	8 (73)	33 (87)	
4	1 (9)	3 (8)	
5	0 (0)	1 (3)	
Ejection fraction, %	22.7 (16.7, 25.7)	17.1 (11.9, 30.3)	0.34
Comorbidities			
Coronary artery disease	8 (73)	22 (58)	0.49
Diabetes mellitus type II	4 (36)	13 (34)	> 0.99
Diabetes mellitus type I	0 (0)	1 (3)	> 0.99
Smoking	3 (27)	19 (50)	0.30
Hypertension	2 (18)	15 (39)	0.29
Dyslipidemia	2 (18)	12 (32)	0.47
Prior ICD implantation	6 (55)	28 (74)	0.28
Severe valvular disease	0 (0)	4 (11)	0.56
Chronic kidney disease	2 (18)	2 (5)	0.17
Chronic lung disease	0 (0)	3 (8)	0.34
Bloodwork			
Hemoglobin, g/L	124 (105, 137)	114 (102, 127)	0.21
Platelets, 10^3 per μL	194 (121, 250)	190 (163, 240)	0.42
Prothrombin time, INR	1.1 (1.0, 1.2)	1.1 (1.1, 1.3)	0.21
eGFR, mL/min per 1.73 m^2	70 (53, 79)	66 (52, 78)	0.96

Continuous variables are represented as median (interquartile range); categorical variables are represented as n (%).

BMT, bilateral minithoracotomy; eGFR, estimated glomerular filtration rate; FS/HS, full sternotomy / hemisternotomy; ICD, implantable cardioverter defibrillator; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; IQR, interquartile range; LVAD, left ventricular assist device.

output. Invasive ventilation time was obtained from the Metavision Database, calculated as the postoperative time in the ICU prior to extubation during which the patient was connected to a ventilator. Perioperative mortality, perioperative nonfatal stroke, postoperative bleeding requiring transfusion, and reoperation for mediastinal bleeding were reported.

Statistical analysis

All statistical analysis was performed on GraphPad Prism (GraphPad, San Diego, CA). Binary or categorical variables were analyzed using a χ^2 test. Continuous or discrete variables were displayed as median with interquartile range and analyzed using a Mann-Whitney test. Statistical significance was deemed to be $P < 0.05$.

Results

Patient characteristics

Table 1 shows patient demographic data. All results are expressed as BMT vs sternotomy (FS/HS). The BMT group was older (61 vs 56 years; $P = 0.025$). Otherwise, no significant differences were present regarding gender, indication, **Int**eragency **R**egistry for **M**echanically **A**ssisted **C**irculatory **S**upport (INTERMACS) profile, past medical history, or preoperative lab test results. The majority of patients in both groups had an INTERMACS profile 3. Supplemental Figure S1 shows the number of cases performed per year over the study period.

Transfusion

Along with serving as a metric for postoperative bleeding, quantification of transfusions is of particular importance in this patient population, as blood products risk further immunosensitizing a patient who is waiting for cardiac transplantation. Table 2 shows total transfusions of packed red blood cells, fresh frozen plasma, and platelets provided to treatment groups from the start of the operation to the end of ICU stay. Figure 2 separates units of each product transfused into intraoperative and ICU transfusions, with individual patient data displayed.

No differences between groups were present in ICU and operative packed red blood cell transfusions. However, a significant difference was seen in total transfusions during this timeframe (0 vs 2 units; $P = 0.03$). Intraoperative transfusions of fresh frozen plasma were significantly lower in the BMT group ($P = 0.01$ and $P = 0.04$, respectively). Total transfusions of fresh frozen plasma (0 vs 1 unit; $P < 0.01$) and platelets (0 vs 1 unit; $P = 0.03$) were significantly less in the BMT group.

Figure 2 shows that intraoperative transfusions drove differences seen in total fresh frozen plasma and total platelet transfusion; the significant difference in total packed red blood cell transfusion was likely driven by a combination of intraoperative and ICU transfusions, which were not significant on their own.

Supplemental Figures S1 and S2 respectively depict the number of cases per year and the median number of transfusions per year. These data demonstrate a likely era effect, which may need to be considered when interpreting results. The number of transfusions per patient in the FS/HS group decreased over time, with a higher number occurring before the introduction of BMT into our program.

Intraoperative, perioperative, and reoperative outcomes

Tables 3 and 4 outline intraoperative and postoperative data. Cardiopulmonary bypass times were similar between the 2 groups (71 vs 69 minutes; $P = 0.85$). In the sternotomy group, 3 patients required cross-clamping that was not necessitated by a concomitant procedure, and 5 patients required a concomitant cardiac procedure that did not necessitate cross-clamping (3 tricuspid valve repairs and 2

Table 2. Transfusion outcomes

Parameter	BMT (n = 11)	FS/HS (n = 38)	P
Total PRBC transfusion units	0 (0, 2)	2 (0, 4)	0.048
Total FFP transfusion units	0 (0, 0)	0 (0, 2)	0.01
Total platelet transfusion units	0 (0, 0)	1 (0, 1)	0.04
ICU crystalloid infusion, L	8 (4, 15)	10 (7, 13)	0.71

Data are represented as median (interquartile range), unless otherwise indicated.

FFP, fresh frozen plasma; ICU, intensive care unit; PRBC, packed red blood cell.

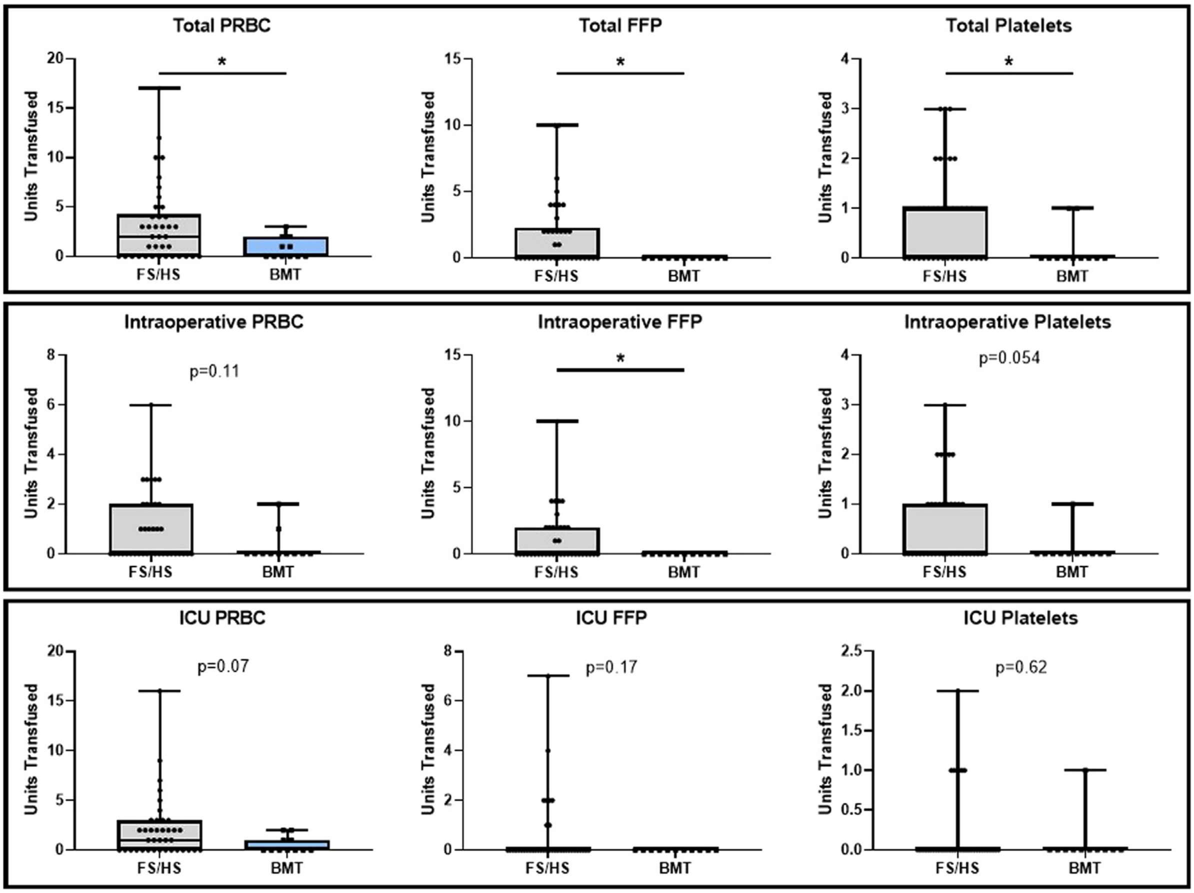

Figure 2. Comparison of perioperative transfusions in sternotomy and bilateral minithoracotomy (BMT) groups. Transfusions are represented as total, intraoperative, and intensive care unit (ICU). **Box and whisker plot** depicts median, interquartile ranges, and full range. Statistical analysis was performed using the Mann-Whitney test. $*P < 0.05$. FFP, fresh frozen plasma; FS/HS, full sternotomy or hemisternotomy; PRBC, packed red blood cells.

patent foramen ovale closures); but no significant differences occurred in either of these parameters ($P = 0.59$ and $P = 0.32$, respectively). Perioperative mortality and nonfatal stroke from the time of operation to the end of ICU stay did not differ between groups ($P > 0.99$ and $P = 0.17$, respectively). The cause of perioperative mortality in the 3 patients in the FS/HS group was stroke.

ICU-related outcomes

Table 4 shows ICU-related outcomes, and patient-to-patient variability within each treatment group. The BMT group demonstrated a significant reduction in chest-tube output at 12 hours. No differences were present in ICU length of stay or invasive ventilation time with BMT. Total hospital length of stay in the FS/HS and BMT groups was 47 days (interquartile range: 35.5-73) and 55 days (interquartile range: 38-75), respectively.

Discussion

The benefits of the sternum-sparing BMT approach for LVAD implantation are currently not well defined. Most contemporary literature combines upper HS, together with BMT, to assess minimally invasive outcomes.[14,17] BMT is a different operation. It avoids sternotomy, which may offer distinct benefits. Our study exclusively frames BMT as the treatment group in comparison to sternotomy-based approaches, as control. Herein, we outline our sternum-sparing LVAD implantation via BMT and provide a video of the technique (Video 1, view video online). By assessing BMT as a distinctly different procedure, our analysis is novel, and it indicates the safety of this approach, with its potential benefit of reduced transfusion requirements.[18]

Our study demonstrates that BMT LVAD implantation reduces perioperative transfusion requirements. Reductions in fresh frozen plasma and platelet transfusions were driven by the intraoperative setting, and reduction of packed red blood cell transfusion was evident when intraoperative and ICU data were combined. These findings add to those of prior studies that show a trend of less transfusion, but they lack statistical significance.[13,18] Transfusion-related benefits are particularly valuable in this patient population to reduce the probability and degree of antigen-related sensitization prior to transplantation.[19,20]

Although median chest-tube output was only reduced from 575 cc in the FS/HS group to 460 cc in the BMT group, a signal for reduced chest-tube output in the early postoperative period at 12 hours may contribute to decreased transfusion,

Table 3. Operative data

Variable	BMT (n = 11)	FS/HS (n = 38)	P
Median cardiopulmonary bypass time, min	71 (61, 83)	67 (52, 86)	0.85
Median cross-clamp time, min	0 (0,0)	0 (0,0)	> 0.99
Concomitant procedure	0	5 (13)	0.57
Implanted device			0.24
HeartMate II	0	7	
HeartWare Ventricular Assist Device	7	23	
HeartMate III	4	8	

Continuous variables are represented as median (interquartile range); values for categorical variables are n (%). Concomitant procedures included tricuspid valve repair and patent foramen ovale closure.

BMT, bilateral minithoracotomy; FS/HS, full sternotomy or hemisternotomy.

and provide hemodynamic benefits. Another purported benefit of BMT is improved right ventricular function and safer transplant through virgin sternotomy.[8,10-12,21,22] Preserving the pericardium in BMT has been hypothesized to protect right ventricular function by providing a pressure barrier. Equally plausible is that decreasing transfusions in the perioperative period reduces right ventricular fluid overload and transient immune-related changes in pulmonary hemodynamics that may cause right ventricular dysfunction.

The current study provides hypothesis-generating data, and demonstrates a potential therapeutic signal for BMT that may justify future prospective study. Limitations to our study include the era effect, as results from the FS/HS group are from a longer time period than those from the BMT group. Although this study may indicate a potential therapeutic option, era effects need to be addressed in further prospective studies. As shown in Supplemental Figure S1, FS/HS LVAD implantations peaked in 2015, whereas BMT cases rose from 2016 to 2019. Another potential era effect may come from the fact that the HeartMate II was used in the FS/HS group, which may potentially require additional transfusions given the requirement of a diaphragmatic incision and formation of a pump pocket. Although our data demonstrate acceptable results with the BMT approach, Supplemental Figure S2 demonstrates that an era effect was likely present, as transfusion rates decreased in the FS/HS group when the BMT program was initiated at our centre. Additionally, transfusion targets may have varied over time, given the release of new data supporting restrictive transfusion strategies.[23] Also, 5 patients in the FS/HS group required concomitant tricuspid valve repair or patent foramen ovale closure, which adds extra suture lines to the procedure.

Table 4. Postoperative outcomes

Variable	BMT (n = 11)	FS/HS (n = 38)	P
Perioperative mortality	0 (0)	3 (7.9)	> 0.99
Perioperative nonfatal stroke	0 (0)	8 (21)	0.17
Reoperation for mediastinal bleed	0 (0)	5 (13)	0.57
CVICU length of stay, d	4.2 (3.1, 11.1)	5.9 (3.8, 8,0)	0.80
Invasive vent time, h	11.2 (8.7, 42.5)	17.6 (9.0, 29.1)	0.86
Chest-tube output at 12 h, cc	460 (340, 570)	575 (430, 935)	0.03

Values for categorical variables are n (%); continuous variables are represented as median (interquartile range).

BMT, bilateral minithoracotomy; CVICU, cardiovascular intensive care unit; FS/HS, full sternotomy or hemisternotomy.

Given the limitations inherent to a retrospective design, we aim to employ a prospective cohort study to re-examine intraoperative and ICU outcomes, while also focusing on cardiac function and patient-reported outcomes measures. This future study will provide a complete echocardiography dataset to better explore purported benefits related to cardiac function. Quality-of-life metrics may also show benefit with sternum-sparing procedures because the need for postoperative sternal precautions is eliminated, and patients may participate in physiotherapy and rehabilitation earlier. Given that thoracotomy approaches are known to be painful, prospective pain scores would also help evaluate our program's ability to control postoperative pain while patients are in the hospital.[24] We use erector spinae catheters for postoperative pain management. Our institute has developed the appropriate infrastructure to examine pain, quality of life, and physical function, which are of importance from the patient perspective.[25-27]

Overall, our study supports the feasibility of LVAD implantation via BMT, and highlights a potential benefit of less transfusion in the early postoperative period. These findings should be interpreted in the context of recent reports that the HM III SWIFT trial (Implantation of the HeartMate 3 in Subjects with Heart Failure using Surgical Techniques Other Than Full Median Sternotomy) was terminated due to excessive adverse events in the minimally invasive arm of the study. This outcome suggests that further prospective study is needed to fully elucidate the safety and potential benefits of this technique.

Conclusions

Sternum-sparing LVAD implantation via BMT is a feasible alternative to sternotomy or hemisternotomy approaches. The sternum-sparing approach demonstrated significantly decreased transfusion rates. A prospective study is needed to evaluate this technique in more detail and address the era effects inherent to this retrospective study.

Acknowledgements

We thank Sean Elliott, RN, BN (MSc Student; Data Access Analyst for eCritical TRACER, Alberta Health Services) for aiding our team with data collection from the MetaVision Database.

We thank Eunice Caouette, BSc Pharm for her help in optimizing the image quality in Figure 1.

Funding Sources

The authors have no funding sources to declare.

Disclosures

The authors have no conflicts of interest to disclose.

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Supplementary Material

To access the supplementary material accompanying this article, visit *CJC Open* at https://www.cjcopen.ca/ and at https://doi.org/10.1016/j.cjco.2022.06.002.