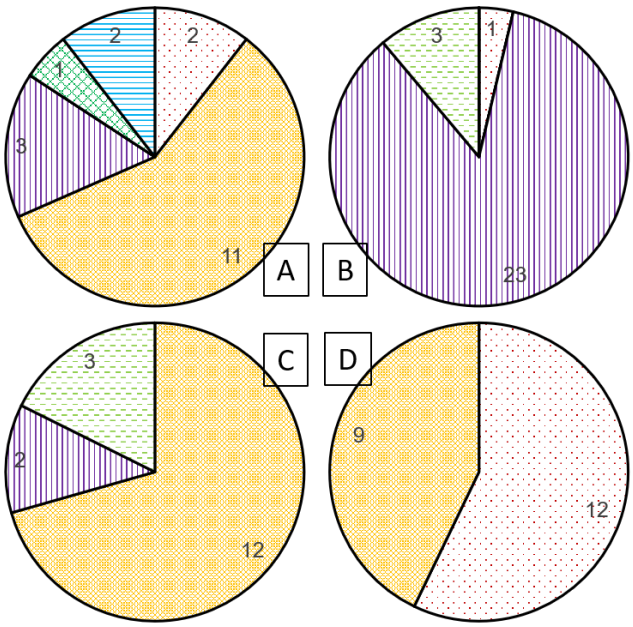
SUPPLEMENTAL CONTENT

Special Considerations for Durable Left Ventricular Assist Device Use in Small Patients

Advisory Groups

In November and December 2020, three two-hour Global Small Patient Advisory Board sessions were held virtually via WebEx (Milpitas, CA) videoconference. The sessions were sponsored by Abbott (Chicago, IL). Each was hosted and moderated by a pair of physicians – one surgeon and one cardiologist (all co-authors of this article) – with extensive interest in and experience treating small patients with durable mechanical circulatory support (MCS). In January 2021, a makeup session was held with one of the earlier co-moderator pairs hosting several physicians who missed earlier sessions to which they had been invited. A total of 29 physicians (including co-moderators) comprised the panels, representing 11 countries (12 x United States, 5 x Japan, 3 x Canada, 2 x Germany, Belgium, Italy, Saudi Arabia, Singapore, Spain, Turkey, United Kingdom); 21 are surgeons, 8 are cardiologists; 20 treat primarily adults, 6 treat primarily pediatric patients, and 3 treat a mix. All participants were selected for their established focus and experience treating pediatric and small adult patients with durable MCS, as the objective was to compile and compare expertise, not to orient or train. In addition to the panels, three Abbott facilitators representing Medical Affairs and Research and Development attended the sessions.

Prior to the sessions, the co-moderators collectively determined that discussion should focus upon special considerations for small MCS patients regarding patient candidacy and selection, surgical techniques for device implantation, and post-surgical patient management. A series of questions was devised to introduce talking points, and an online polling tool was used to capture attendee responses (Supplemental Figures 1-3). The same questions were used for all sessions, although in several instances time pressure resulted in skipping a question(s), resulting in incomplete responses. From meeting notes, the most common, critical themes were summarized and presented in the published manuscript.



A A female patient experiencing advanced heart failure symptoms presents to you for LVAD evaluation. She is 90 lb and has a BSA of 1.3 m^2. How do you assess if this patient is anatomically a candidate for an LVAD?

- LV volume
- LVEDD
- Chest cavity size
- No further assessment necessary; the patient is too small for an LVAD.
- No further assessment necessary; an LVAD is viable.
- Other

B Which test do you believe is the best to use when evaluating chest anatomy and device fit?

- 3D ECHO
- X-ray
- Cardiac CT
- Virtual Reality planning
- No testing
- Other

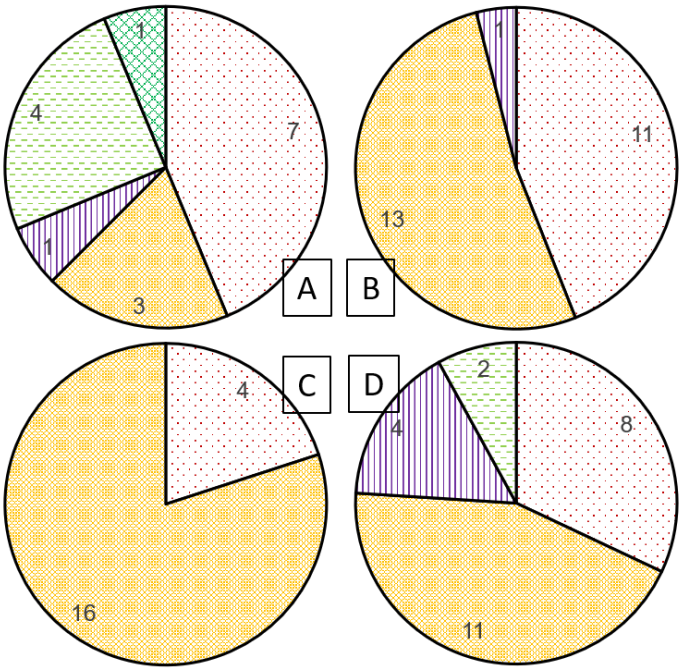
C A female patient with advanced heart failure symptoms presents to you for durable LVAD evaluation. She weighs 90 lb, has a BSA of 1.3 m^2, and her LVEDD is found to be 50 mm. What are your next steps?

- 3D ECHO
- Cardiac CT
- The patient is not eligible for an implanted LVAD.
- Other

D When selecting a device for a patient with a BSA ≤ 1.5 m^2, do you take into consideration short and/or long-term remodeling of the heart?

- Yes
- No

Supplemental Figure 1. Patient candidacy and selection survey questions and respondent answers. LVAD = left ventricular assist device, lb = pounds, BSA = body surface area, m = meter, LV = left ventricle, LVEDD = left ventricular end-diastolic diameter, ECHO = echocardiogram, CT = computed tomography image, mm = millimeter.



A When surgically placing a durable LVAD in a patient with a BSA ≤ 1.5 m^2, do you adjust your surgical approach?

- I do not adjust my approach for small patients, typically favoring sternotomy.
- I do not adjust my approach for small patients, typically favoring thoracotomy.
- I adjust my approach for small patients to a thoracotomy approach, typically favoring sternotomy.
- I adjust my approach for small patients to a sternotomy, typically favoring thoracotomy.
- Other

B When surgically placing a durable LVAD in a patient with a BSA ≤ 1.5 m^2, where do you place the device?

- Intrapericardial
- Extrapericardial
- Other

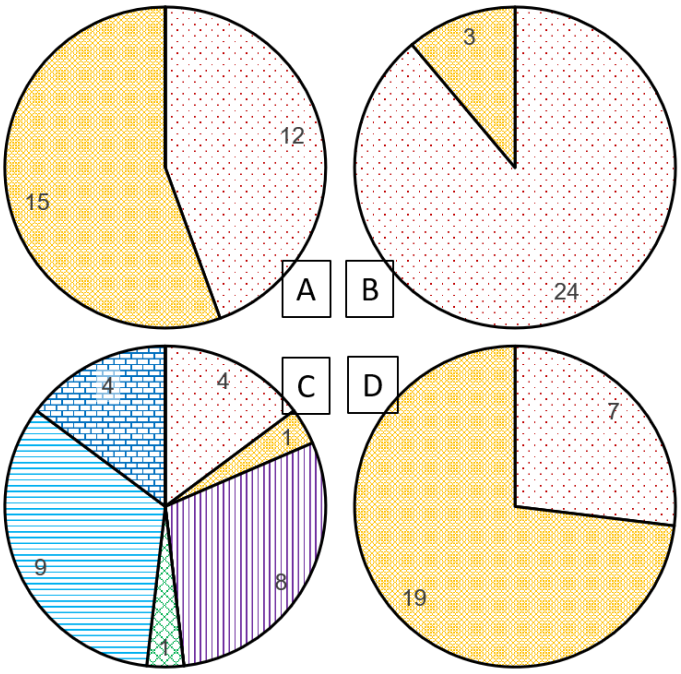
C When surgically placing a durable LVAD in a patient with a BSA ≤ 1.5 m^2, would you manage valvular pathology differently than in a larger patient?

- Yes
- No

D When surgically placing the HeartMate 3 LVAD in a patient with a BSA ≤ 1.5 m^2, how do you address the extra driveline intraoperatively?

- Loop the driveline internally.
- Abdominal counter incision.
- No change in technique. The driveline is longer externally.
- Other.

Supplemental Figure 2. Surgical techniques and device implantation survey questions and respondent answers. LVAD = left ventricular assist device, BSA = body surface area, m = meter.



A How do you run the speed (rpm) when coming off cardiopulmonary bypass after implanting a HeartMate 3 LVAD in a patient with a BSA ≤ 1.5 m^2?

- No change. We base speed on ECHO for all patients.
- Slower. Initially, we generally run the speed lower on small patients.
- Faster. Initially, we generally run the speed faster on small patients.

B Post-operatively, how do you manage blood pressure in HeartMate 3 LVAD patients with a BSA ≤ 1.5 m^2?

- No change. We manage them the same as all our LVAD patients.
- We use a special protocol for small patients.

C For a patient with a BSA ≤ 1.5 m^2 and implanted with an LVAD, which early postoperative adverse event are you most worried about, given the patient's small size?

- Stroke
- Bleeding
- Right heart failure
- Infection
- Arrhythmia
- Low-flow alarm
- None
- Other

D Do you have any Quality of Life concerns for patients with a BSA ≤ 1.5 m^2 and implanted with an LVAD?

- Yes
- No

Supplemental Figure 3. Post-surgical patient management survey questions and respondent answers. Rpm = revolutions per minute, LVAD = left ventricular assist device, BSA = body surface area, m = meters, ECHO = echocardiogram.

Discussion/Surgical Techniques and Device Implantation/Driveline

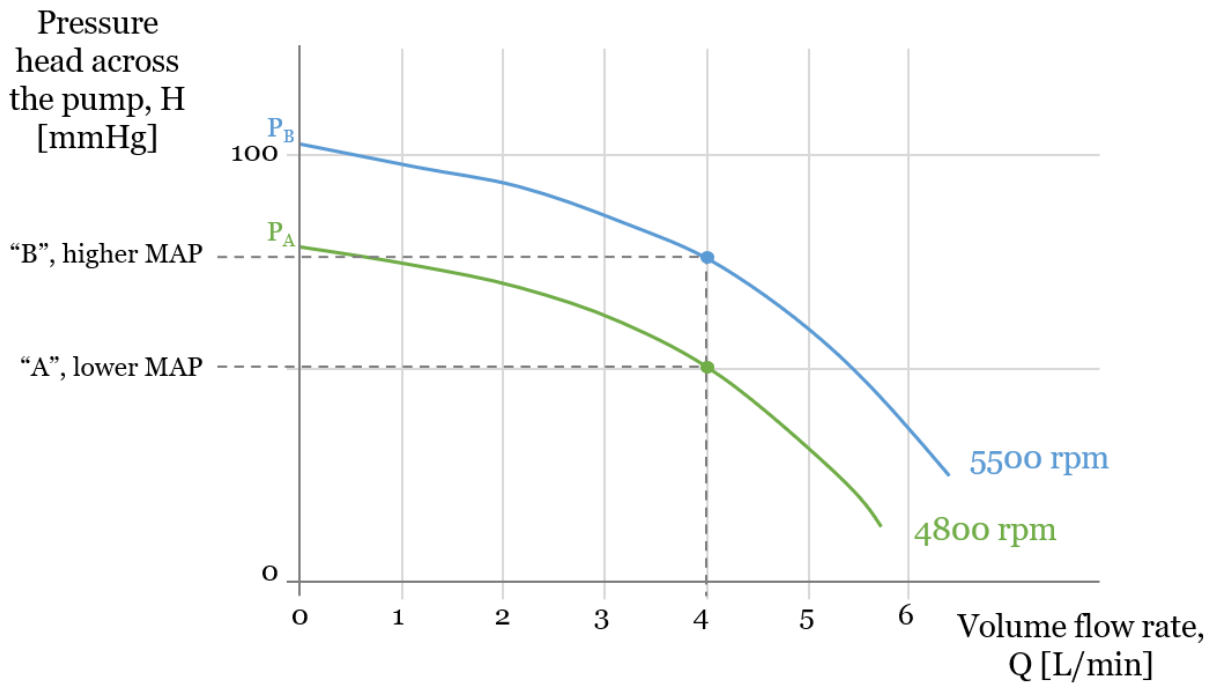
Immobilization of the LVAD percutaneous driveline is required to promote healing and avert infection. Factors such as the relatively heavy in-line connector in the close vicinity of the driveline exteriorization site may confound immobilization and healing. During the advisory meetings, Dr. Morales suggested a palliating surgical approach, described here.

Where the weight of a proximate driveline connector is a concern, a supported exteriorization can be created during the LVAD implantation procedure. Through a left upper quadrant incision, dissection down to the fascia around the rectus abdominis is opened. A tunnel is made from the medial aspect of the rectus abdominis muscle above the posterior abdominal fascia into the mediastinum. A 24 French chest tube is inserted and the driveline trocar is placed into the chest tube and passed into this incision. The driveline is atraumatically passed under the entire preserved abdominis rectus and out the most leftward aspect of the incision. The wound is closed in layers with no velour exposed. This technique results in increased support of the driveline, quick healing since there is no trauma to the muscle or hematoma, and reduced risk of ascending

driveline infection since the infection pathway would have to go through the healthy, non-traumatized fascia and muscle of the rectus abdominis.

Discussion/Post-Surgical Patient Management/Blood Pressure Management/LVAD Speed

Most panelists approach blood pressure management no differently for small adult patients than for others in terms of measurement technique and target, but the risk of device low-flow alarms due to hypertension-related device flow reduction is higher for small patients. For the HeartMate 3™ Left-Ventricular Assist Device (Abbott, Chicago, IL), experience to date with relatively low stroke rates merits consideration that the tradeoff between hypertension-related risks (e.g., hemorrhagic stroke) and the complications of excessive reduction in blood pressure (e.g. presyncope and nausea) might be optimized at a somewhat higher mean arterial pressure (MAP) than with older commercial devices. If for a given patient this is medically advisable, there are motivating factors to run the device at a higher speed. For example, for a device that can be safely operated at a mean arterial pressure (MAP) of 90 to 100 mmHg rather than 65 to 75 mmHg, narrow control of MAP can be avoided and the device can be run at a higher speed to achieve the same flow (Supplemental Figure 4).



Supplemental Figure 4. HeartMate 3 characteristics illustrate an example of the effect of afterload on pump speed selection, all factors kept equal except those discussed. If a low afterload is maintained ("A"), a relatively low speed of 4800 rpm is required to achieve a flow rate of 4 L/min with HeartMate 3. If the afterload is increased ("B"), a higher speed of 5500 rpm is required to achieve the same flow, with the potential advantages that "shutoff" pressure increases from P_A to P_B, outside of the normal arterial pressure range. Maintaining patient MAP centrally within the normal range may avert symptoms associated with low MAP, such as pre-syncope, provided opposing risks are considered. HeartMate 3 = HeartMate 3 Left Ventricular Assist Device; MAP = mean arterial pressure; mmHg = millimeters of mercury; L/min = liters per minute; rpm = rotations per minute.