Continuous flow ventricular assist devices for bridge to transplantation
Australian Safety and Efficacy Register of New Interventional Procedures - Surgical (ASERNIP-S)

Record Status
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Citation

Authors' conclusions
The clinical burden of congestive heart failure continues to mount worldwide, in Australia and New Zealand, donor heart shortage continues to weigh heavily on the survival of end stage heart failure patients. In order to keep patients alive while waiting for a suitable donor heart, LVADs have been increasingly utilised for long-term support. Pneumatic P-LVADs in particular have been shown to be an effective bridge to transplantation. The REMATCH destination therapy trial demonstrated the significant survival benefits of LVAD support in patients with end stage heart failure; however, this randomised trial also highlighted that patients under LVAD support experience significantly higher rates of complications and adverse events compared to medical therapy. Therefore although P-LVAD support is effective, clinicians are still concerned with the risks of mechanical failure or other complications.

As LVADs begin to play a more prominent role as a bridge to transplantation and destination therapy, researchers have attempted to improve on current designs and to address the shortfalls of current LVADs. A new generation of LVADs that produce continuous flow instead of pulsatile flow has emerged as an alternative to P-LVADs. C-LVADs are substantially smaller and lighter than current P-LVADs and have less moving parts. These characteristics confers some theoretical advantage compared to P-LVADs as less mechanical movement may translate to lower rates of mechanical failure and its smaller size requires less incisions, hence less risk for infections.

The evidence base currently available on C-LVADs is limited to comparative studies and often low quality case series studies. A total of 17 comparative studies (Level III intervention evidence) were retrieved for inclusion in this report. The evidence retrieved was quite supportive of the capabilities of C-LVADs. Haemodynamic improvements during C-LVAD support were generally comparable to P-LVADs. However, one study showed that P-LVADs appear to excel in certain haemodynamic parameters, such as mean arterial pressure and ventricular stroke work index. One study demonstrated that C-LVAD support resulted in significant improvements in LVEDD, LVEDV, LVESV, LVESD and LVEF, and the outcomes were comparable to P-LVADs patients. However, some studies with longer follow-up indicated that although C-LVAD support results in significant structural improvements, P-LVADs appear to confer significantly better improvements in LV size, LV mass and LVEF. This implies that reverse ventricular remodelling is more prevalent in patients who receive P-LVAD support. The reason for this is not known and warrants further investigation. Exercise performance appears to be similar for both P-LVAD and C-LVAD patients (Vo2, duration of exercise, respiratory exchange ratio, pump flow), but peak exercise pump flow was significantly greater in P-LVAD supported patients.

When organ function parameters are considered, two studies with follow-up ranging from three to six months reported that measures of renal function (GFR, creatinine clearance) improved significantly post-implantation and was comparable to P-LVAD. In contrast, a third study (follow-up: 15 months) noted that only P-LVAD recipients achieved significant improvements in measures of renal and hepatic function while C-LVAD recipients did not experience significant improvements in these measures. Meanwhile, patient survival was demonstrated to be similar for both types of LVADs in six of the included studies. Long-term Kaplan Meier estimates revealed that patient survival rates remain similar up to 5 years post-implantation.

One of the purported advantages of C-LVAD support was lower infection rates due to the fact that smaller incisions are required during implantation. Two studies supported this view, with significantly lower device, pocket, wound and driveline infections. In addition, antibody use was significantly shorter in duration and the lower rate of positive bacterial culture provides further support that infection rates are lower for C-LVAD recipients compared to P-LVAD recipients. However, one study noted that C-LVAD recipients had significantly higher interleukin-6 and anaphylatoxin

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C5a levels compared to P-LVAD patients (other inflammatory measures were comparable [TNFα, PNM EL, C3a]), but the reason for this is not known and may be related to the biocompatibility of materials used to construct the C-LVAD pump. The incidence of severe bleeding and need for blood/platelet transfusion was significantly lower for C-LVAD patients. Biochemical markers of brain injury (S100B, NSE) returned to baseline values within one day post implantation for C-LVAD patients. Neurologic assessments showed that there were no neurological deficits for C-LVAD patients compared to two cases for the P-LVAD group. Examination of cognitive P300 evoked potentials showed that C-LVAD recipients experienced significant improvements post-implantation that were comparable to P-LVAD recipients. This indicates that the use of C-LVAD does not result in neurological injury or impair neurological function. One of the major questions related to the use of C-LVADs is whether continuous flow has any detrimental effects toward physiological function. One of the included studies highlighted that C-LVAD support appears to impair vascular reactivity. Another study highlighted that vascular pulsatility is markedly reduced during C-LVAD support. These results indicate that long-term C-LVAD support might lead to vascular stiffening and may have long-term implications to health. However, at this point of time high quality long-term clinical data concerning these issues remains scarce. The overall consensus from the retrieved evidence suggests that C-LVADs are capable of matching the performance of P-LVADs. There are some clear advantages that support the use of C-LVADs as well, such as the lower infection rates and bleeding complications. However, it is important to recognise that all of the studies retrieved had relatively small patient numbers, and the scarcity of long-term data leaves many questions unanswered. The mechanical reliability of C-LVADs was not adequately investigated in the studies retrieved, physiological effects of long-term continuous flow remain ambiguous and issues of pump biocompatibility were not addressed in detail. Randomised-controlled trials are required before the medical community can elucidate the advantages and potential safety issues of C-LVAD support relative to P-LVAD.

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