Inappropriate restrictions on life saving technology

Stephen Westaby, David Taggart

When a patient dies it is of considerable consolation to relatives if they can be reassured that everything possible and appropriate was done. For many acute heart failure patients in the UK, this approach cannot be taken with honesty. This is because the NHS will not fund circulatory support equipment to treat cardiogenic shock in the majority of cardiac tertiary centres. Affected are 2% of 40 000 cardiac surgical patients who fail to separate from cardiopulmonary bypass and around 5% of 25 000 myocardial infarction patients who progress to cardiogenic shock. These disparate groups suffer ischaemia followed by reperfusion injury, then lethal but potentially recoverable myocardial stunning. Young patients with myocarditis or postpartum cardiomyopathy may experience a similar fate through an inflammatory process. Chronic heart failure patients suffer bouts of decompensation from which they can be rescued. At a conservative estimate these categories account for between 2000 and 3000 patients per annum in the UK.

Whereas myocardial stunning and most episodes of myocarditis will resolve over days or weeks, the immediate vicious cycle around 5% of 25 000 myocardial infarction patients who progress to cardiogenic shock. These disparate groups suffer ischaemia followed by reperfusion injury, then lethal but potentially recoverable myocardial stunning. Young patients with myocarditis or postpartum cardiomyopathy may experience a similar fate through an inflammatory process. Chronic heart failure patients suffer bouts of decompensation from which they can be rescued. At a conservative estimate these categories account for between 2000 and 3000 patients per annum in the UK.

Full recovery of contractile function after ischaemia or myocarditis takes between 7 and 28 days. This partly explains failure of the innovative but shorter-term percutaneously inserted Impella and TandemHeart LVADs to improve survival. Evidence for the effectiveness of circulatory support is indisputable. In contemporary series ECMO or temporary implantable LVADs rescue around 50% of post-infarction cardiogenic shock patients and 60% or more who cannot be separated from cardiopulmonary bypass.

Department of Cardiothoracic Surgery, John Radcliffe Hospital, Oxford, UK

Correspondence to Professor Stephen Westaby, Department of Cardiothoracic Surgery, John Radcliffe Hospital, Headington, Oxford OX3 9DU, UK, swestaby@ahf.org.uk

Heart August 2012 Vol 98 No 15 1117

Heart: first published as 10.1136/heartjnl-2011-301365 on 25 May 2012. Downloaded from http://heart.bmj.com/ on July 4, 2022 by guest. Protected by copyright.
Mechanical Assisted Circulatory Support (USA), showed immediately life-threatening shock to account for 42% of implants reported in 2009. Those who required only left ventricular support (the vast majority) manifest 50% survival at 6 months. For biventricular support (LVAD + RVAD), survival fell to 35%. Prognosis was poor for isolated right ventricular support and use of a total artificial heart. Notably the Registry encompassed only those who received Food and Drug Administration approved pumps before 2009. It did not include patients who received the ‘Levitronix Centrimag’ pump which has improved outcomes throughout Europe and is now widely used in the USA. We have used this pump electively to increase the safety of very high risk cardiac surgery. In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on temporary circulatory support, concluding: ‘limited evidence on the safety and efficacy of short-term circulatory support with LVADs as a bridge to cardiac transplantation or recovery appears adequate to support the use of this procedure provided that the normal arrangements are in place for audit and clinical governance’. While transplantation is in decline, much new evidence supports the use of circulatory support pending functional recovery or as a bridge to a long-term LVAD. Nevertheless the National Specialist Commissioning Group fund devices only in a few centres, intentionally constraining their use to transplant candidates or respiratory ECMO patients. During the swine flu epidemic the designated UK ECMO centres were unable to address this additional workload and their cardiac surgery came to a halt. We believe that provision of this simple intervention remains inadequate and that the Commissioning Group’s standpoint that only specialised centres can manage ECMO is inaccurate and inappropriate.

Though NICE made reference to several categories of shock patient, the NHS continues to withhold circulatory support equipment from most tertiary cardiac centres, even those who perform surgery on infants and children. This is incomprehensible when more than half of patients who die after cardiac surgery or post-infarction shock could survive with appropriate treatment. Furthermore, it is potentially punitive to individual surgeons in a system which publishes their mortality rates. If relatively inexpensive temporary LVADs had been made available in UK cardiac surgical centres since the NICE guidelines, we estimate that at least 5000 lives could have been saved in the intervening 5 years. Meanwhile the deprivation/publication paradox may understandably contribute to risk averse behaviour in surgeons to the disadvantage of sicker patients who should benefit most from cardiac surgery.

### Table 1 Mechanical blood pumps currently used for the treatment of cardiogenic shock

<table>
<thead>
<tr>
<th>Device type</th>
<th>Pump name</th>
<th>Approximate duration of support</th>
<th>Approximate device cost per intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percutaneous ECMO</td>
<td>Biomedicus Maquet Rotaflow Levitronix Centrimag Impella</td>
<td>Days (3–28)</td>
<td>£6000–10 000</td>
</tr>
<tr>
<td>Percutaneous LVAD</td>
<td>Tandem heart Ablomed BVS 5000 Thoratec PVAD/RVAD Berlin excor</td>
<td>Days (3–7)</td>
<td>£10 000–15 000</td>
</tr>
<tr>
<td>Temporary pulsatile VAD</td>
<td>Levitronix centrimag</td>
<td>Weeks (1–26)</td>
<td>£20 000–25 000</td>
</tr>
<tr>
<td>Temporary rotary VAD*</td>
<td>Heartmate XVE Micromed deBakey Jarvik 2000 Berlin excor Heartmate II Heartware (HVAD) Berlin incor Terumo Duraheart SynCardia</td>
<td>Weeks (1–12) Months (3–24) Years (so far up to 8 years)</td>
<td>£60 000–80 000</td>
</tr>
<tr>
<td>Long-term pulsatile LVAD</td>
<td><strong>Total artificial heart</strong></td>
<td>Months (bridge to transplant only)</td>
<td>£100 000</td>
</tr>
</tbody>
</table>

*Rotary refers to axial or centrifugal continuous pumping mechanisms which provide non-pulsatile blood flow.

ECMO, extracorporeal membrane oxygenation; VAD, ventricular assist device (LVAD or RVAD).

Figure 1 Transport of a cardiogenic shock patient on extracorporeal membrane oxygenation (courtesy of Prof. C Schmidt, University of Regensburg, Germany).
Provision of circulatory support now has precedent in law. Article 2 of the European Convention on Human Rights defines ‘the right to life and a positive duty on medical staff and organisations to preserve life and palliate distressing symptoms’. This ruling is pivotal when reaching decisions about life threatening illness. The General Medical Council has issued guidelines for end of life care which clearly apply to heart failure patients. These state that ‘the terminally ill must be offered high quality treatment to support them to live as well as possible until death’ and that ‘you should not withhold a treatment if doing so would involve significant risk for the patient and the only justification is resource constraints’ (Point 39, page 27). The presumption therefore exists that all reasonable steps will be taken to prolong life if the treatment is based on contemporary evidence. Failure to treat a potentially recoverable patient could now be deemed neglectful or frankly negligent. Putting this into context, our first viral myocarditis ‘bridge to recovery’ patient (who benefitted from a charitably funded LVAD) has already survived for 15 years with normal left ventricular function.

In summary, the intra aortic balloon pump (IABP) must no longer be regarded as the ‘ceiling’ for shock treatment in contemporary UK practice. Evidence based circulatory support for heart failure should be regarded as equivalent to haemodialysis for renal impairment. If the UK is to meet the aspirations of ‘world class healthcare outcomes’ proposed in the recent White Paper, ‘Equity and excellence: liberating the NHS’, then systems of care must keep pace with advances in technology. All tertiary cardiac centres must have the capacity to deal with cardiogenic shock and have access to the necessary equipment. Towards this goal a UK bioengineering group is working to develop more affordable circulatory support devices. Meanwhile the nationwide project to provide primary percutaneous angioplasty networks for myocardial infarction should now establish appropriate ‘hub and spoke’ shock centres in cardiac surgical units. In 2008 the cost to the NHS of providing terminal care to cancer patients (27% of the 470,000 annual UK deaths) was £1.8 billion. A tiny fraction of this ongoing could restore normal life to many of the patients who die annually from acute heart failure.

Contributors Both authors made a significant contribution to the content of the paper.

Competing interests None.

Provenance and peer review Not commissioned; externally peer reviewed.

Published Online First 25 May 2012

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