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A Systematic Review of the Cost-Effectiveness of Long-Term Mechanical Circulatory Support

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ABSTRACT

Background: Mechanical circulatory support (MCS) is an option for the treatment of medically intractable end-stage heart failure. MCS therapy, however, is resource intensive. **Objective:** The purpose of this report was to systematically review the MCS cost-effectiveness literature as it pertains to the treatment of adult patients in end-stage heart failure. **Methods:** We conducted a systematic search and narrative review of available cost- effectiveness and cost-utility analyses of MCS in adult patients with end-stage heart failure. **Results:** Eleven studies analyzing the cost-effectiveness or cost-utility of MCS were identified. Seven studies focused on bridge to transplantation, three studies focused on destination therapy, and one study presented analyses of both strategies. Two articles evaluated the cost-effectiveness of the HeartMate II (Thoratec Corp., Pleasanton, CA). Incremental cost-effectiveness ratios between MCS and medical management ranged between $85,025 and $200,166 for bridge to transplantation and between $87,622 and $1,257,946 for destination therapy (2012 Canadian dollars per quality-adjusted life-year). Sensitivity analyses indicated that improvements in survival and quality of life and reductions in device and initial hospital-stay costs may improve the cost-effectiveness of MCS. **Conclusions:** Current studies suggest that MCS is likely not cost-effective with reference to generally accepted or explicitly stated thresholds. Refined patient selection, complication rates, achieved quality of life, and device/surgical costs, however, could modify the cost-effectiveness of MCS.

Keywords: cost-effectiveness, health technology assessment, heart-assist devices.

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Introduction

More than 4 million Americans are afflicted with heart failure, which is associated with significant morbidity and mortality. Approximately 10% of the patients have advanced or end-stage heart failure, with a 2-year survival probability of less than 10% [1]. Such patients may be offered mechanical circulatory support (MCS), which involves surgical implantation of a mechanical pump to augment or replace cardiac output. First-generation MCS devices were often large, connected to the heart in a paracorporeal fashion, and implemented pulsatile flow dynamics. Second-generation devices are relatively smaller, implement axially directed continuous-flow dynamics, and are implanted intracorporeally. Third-generation devices primarily differ from second-generation devices with respect to centrifugal, rather than axial, continuous-flow dynamics. Provision of MCS is resource intensive and includes medicosurgical management, intensive care unit requirements, hospital stays, and care after the index hospitalization, which may include readmission. Moreover, usage and indications continue to expand and patients will likely be considered for mechanical support earlier in their disease course. Therefore, to ensure efficient and responsible utilization of MCS, it becomes essential for health care managers, physicians, and decision makers to understand the cost-effectiveness of MCS, the circumstances under which cost-effectiveness may improve, and the potential impact of current and future technological developments on cost-effectiveness. We sought to describe these elements by conducting a systematic search and narrative review of the cost-effectiveness literature of MCS for adult patients in end-stage heart failure.

Methods

A health sciences librarian conducted a systematic search of the literature in the following databases: Ovid MEDLINE (1946–August 2014), Ovid Embase (1974–August 2014), the Cumulative Index to Nursing and Allied Health Literature (EBSCO, date of inception–

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August 2014), the Health Technology Assessment Database (Issue 3 of 4, July 2014 via Cochrane Library on Wiley), the NHS Economic Evaluation Database (Issue 3 of 4, July 2014 via Cochrane Library on Wiley), and the Tufts Cost Effectiveness Analysis registry. The searches combined subject headings (where appropriate) and keywords for the concepts of heart-assist devices and the various types of economic analyses. No language or publication type limits were applied to the searches. The Medline search strategy is documented in Appendix A in Supplemental Materials found at http://dx.doi.org/10.1016/j.jval.2014.12.020, and the full search history may be obtained from the authors on request. Reference lists were also reviewed for additional articles.

Inclusion criteria included formal economic evaluation (whereby incremental costs relative to health benefits of two or more strategies were determined) of ventricular assist device therapy in adult subjects published or translated in English, with at least one comparator of optimal medical management. A sample evaluation sheet is included as Supplemental Material found at http://dx.doi.org/10.1016/j.jval.2014.12.020. Two reviewers (A.J.N. and S.W.K.) applied selection criteria to the title and abstract of each citation, and subsequently obtained full-text articles for citations that could not be unequivocally excluded.

One reviewer (A.J.N.) used a standardized form to extract and record relevant information, which was subsequently verified by a second reviewer (S.W.K.). Recorded information included objective, population, setting, comparators, device generation, analysis type, perspective, time horizon, discounting, outcomes data, health-related quality of life, resource data source, costing data source, model details, decision model, sensitivity analysis approach, base-case results, sensitivity analysis findings, and conclusion. Costs were converted to a common currency and year (2012 Canadian dollars), accounting for currency conversion and consumer price index [2]. Study quality was assessed by two reviewers (S.W.K. and A.J.N.) independently, using an adapted checklist [3]. Qualitative synthesis was conducted, with a focus on the identification of model variables and parameters that modified results and cost-effectiveness conclusions between and within studies.

Results

The systematic literature search revealed 569 citations, of which 33 underwent further scrutiny (Fig. 1). Ultimately, 11 country-specific cost-effectiveness analyses of MCS were identified. Three studies addressed destination therapy [4–6], seven studies addressed bridge to transplantation [7–13], and one study incorporated analyses of both strategies [14]. Study and model details are provided in Table 1. Eight publications were deemed to be of high quality, one of moderate quality, and one of low quality (Table 2). A study evaluating both destination and bridge to transplantation published in Danish, but the English translation was incomplete and did not depict tables and figures; the lack of data precluded summarization and quality assessment, and the study was excluded [13]. No study concluded that MCS was a cost-effective option for patients in end-stage heart failure when compared with medical management (Fig. 2). One study, using second- and third-generation MCS devices, concluded that the cost-effectiveness of MCS is approaching that approved by the British National Health Service for end-of-life therapies [11]. Another study, using second- and third-generation MCS devices, concluded that on the balance of probabilities MCS may be cost-effective in comparison to direct heart transplantation for patients with the greatest degree of hemodynamic compromise [10].

Bridge to Transplantation

Clegg et al. [7] estimated the cost-effectiveness of first-generation MCS as a bridge to transplantation for patients in end-stage heart failure, compared with medical bridge to transplantation. Base-case incremental cost-effectiveness ratio (ICER) for MCS as a bridge to transplantation compared with medical bridging was $150,440/quality-adjusted life-year (QALY) gained. The model was sensitive to the survival benefit and costs of MCS (e.g., assessment, implantation, and device). When combined device and operative MCS costs were below $115,294—compared with the estimated base-case cost of $195,910—the ICER reached a stated

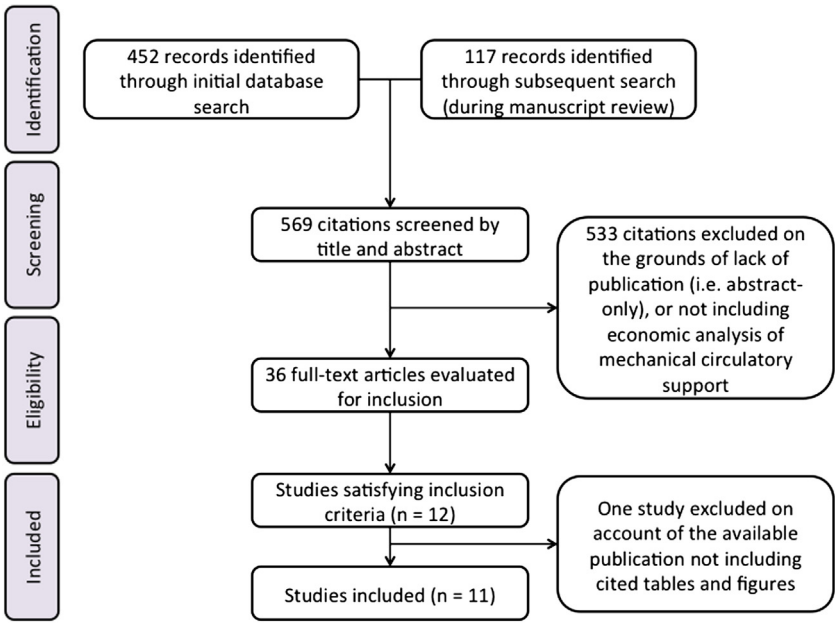

Fig. 1 – PRISMA diagram depicting systematic review strategy. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

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