INPLASY PROTOCOL

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The ProtekDuo Dual Lumen Cannula as Temporary Acute Mechanical Support for Right Heart Failure: A Protocol for a Systematic Review

Brewer, JM[1]; Capoccia, M[2]; Maybauer, DM[3]; Lorusso, R[4]; Swol, J[5]; Maybauer, MO[6].

Review question / Objective: **Participants: Adult patients with right ventricular failure; Intervention: Right ventricular assist device with ProtekDuo cannula; Comparison: Control group of medical management or another type of RVAD (if available); Outcomes: Effectiveness of treatment in terms of survival and complications; Study design: Randomized controlled trials, prospective cohort studies, retrospective cohort studies, case series with >/=5 patientsProspective and retrospective cohort studies, case series of >/= 5 patients.**
Condition being studied: **Right ventricular failure.**
Information sources: **Databases: MEDLINE, Embase, Scopus.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 September 2022 and was last updated on 06 September 2022 (registration number INPLASY202290026).

INTRODUCTION

Review question / Objective: **Participants: Adult patients with right ventricular failure; Intervention: Right ventricular assist device with ProtekDuo cannula; Comparison: Control group of medical management or another type of RVAD (if available); Outcomes: Effectiveness of treatment in terms of survival and complications; Study design: Randomized controlled trials, prospective cohort studies, retrospective cohort studies, case series with >/=5 patientsProspective and retrospective cohort studies, case series of >/= 5 patients.**

Rationale: **Right ventricular failure (RVF) can occur acutely or chronically in association with a number of conditions who share the common pathophysiology of RV volume and/or pressure overload. The Acute RVF syndrome occurs when systemic congestion in combination with**

reduced cardiac output result in organ dysfunction or failure and is associated with a high in-hospital mortality rate that is independent of the underlying condition. Management of acute RVF begins with treatment of the underlying condition (e.g., coronary artery revascularization) and pharmacological intervention including diuretics for optimization of fluid status, inhaled pulmonary vasodilators for reduction of RV afterload, and vasopressors and inotropes if needed to maintain blood pressure and cardiac output. When these measures fail, escalation of treatment to mechanical circulatory support in the form of extracorporeal membrane oxygenation (ECMO) or right ventricular assist device (RVAD) is appropriate. RVADs can be inserted surgically via sternotomy or thoractomy or percutaneously through access of a large central vein. The ProtekDuo (LivaNova PLC, London, UK) is a percutaneous, single site, dual lumen cannula that when combined with a centrifugal extracorporeal circulatory support pump can be used as a temporary RVAD. Because of increasing interest and use of the ProtekDuo cannula, we will conduct a systematic review of the literature to determine the present level of evidence for its function as a temporary percutaneous RVAD as measured by survival and complications.

Condition being studied: Right ventricular failure.

METHODS

Search strategy: We will query MEDLINE, Embase, and Scopus databases using the following keywords and their variations: "ProtekDuo," "right ventricular assist device," and "ventricular assist device." We will exclude any animal or pediatric studies (<18 years) and articles not in the English language. We will assess all relevant studies and their reference lists to identify articles for inclusion. We will identify the total number of publications found. We will then screen for duplicate publications, conference abstracts, and impose automatic exclusion criteria (animal studies, age <18 years, and English language) and those studies will be discarded. Of the remaining publications, we will conduct a review at the title and abstract level and excluded publications that are deemed irrelevant by at least two reviewers, editorials, and non-research letters or brief communications. Of the remaining publications, further exclusion will be imposed at the full text level for case reports with less than five subjects, reviews, studies in which outcomes for patients with RVAD using ProtekDuo were co-analyzed with other percutaneous RVADs or configurations, studies in which the ProtekDuo was used for a purpose other than RVAD, and studies with data available in another publication. Prior to exclusion at this level, the reference lists will be reviewed and any relevant publications not found in the database search will be screened.
Selected studies will be reviewed in detail and data regarding survival and complications will be collected.

Participant or population: Adult patients with right ventricular failure.

Intervention: Right ventricular assist device with ProtekDuo cannula.

Comparator: Control group of medical management or another type of RVAD (if available)Control group if available.

Study designs to be included: Clinical randomized trials, controlled before-and-after studies, prospective and retrospective cohort studies, cross-sectional studies, case-control studies as well as case reports and case-series with >/=5 patients will be analysed.

Eligibility criteria: Exclusion criteria: animal studies, pediatric studies (age <18 years), clinical guidelines, reviews, book chapters, grey literature, editorials, letters to the editor, case reports/series with <5 patients, and conference abstracts.

Information sources: Databases: MEDLINE, Embase, Scopus.

Main outcome(s): The main outcomes will be survival and complications.

Additional outcome(s): Hemodynamic parameters, vasopressor-inotrope requirement, duration of mechanical support, conversion to surgical RVAD, use of oxygenator, ICU length of stay.

Data management: Citations from selected databases will be collated and stored in an Excel file.

Quality assessment / Risk of bias analysis: We will use the Oxford Centre for Evidence-Based Medicine levels of evidence (https://www.cebm.ox.ac.uk/resources/levels-of-evidence/oxford-centre-for-evidence-based-medicine-levels-of-evidence-march-2009) to assess the quality of evidence.
For studies with control groups, we will assess for bias on the following levels:
Random sequence generation (selection bias)
Allocation concealment (selection bias)
Blinding of participants and personnel (performance bias)
Blinding of outcome assessment (detection bias)
Incomplete outcome data (attrition bias)
Selective reporting (reporting bias)
Other bias.

Strategy of data synthesis: Due to the nature of publications currently available on the topic, which are predominantly small retrospective cohort studies and case reports/series, we will provide qualitative and descriptive synthesis of the findings from the included studies. The synthesis will be structured around target population characteristics, clinical indications for RVAD, duration of RVAD support, duration of ICU and hospital stay, reported survival, reported complications, and hemodynamic data including medication support.

Subgroup analysis: None planned.

Sensitivity analysis: None planned.

Language restriction: English.

Country(ies) involved: USA, UK, Germany, Netherlands.

Keywords: ProtekDuo cannula, right ventricular failure, right ventricular assist device, RVAD.

Dissemination plans: The results of this review will be published in a peer-reviewed journal.

Contributions of each author:
Author 1 - Joseph Brewer - Conceptualization, methodology, validation, data analysis, investigation, data curation, writing.
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Conflicts of interest: Prof. Dr. Lorusso is a consultant for Medtronic, Getinge and LivaNova and medical advisory board member for EUROSETS, all unrelated to this work; all honoraria to the university for research funding. The remaining authors declare that they have no competing interests.