Please note: These studies may involve findings that exceed the claims currently cleared by the FDA for the product. Bravida Medical is not intending to make performance claims about its product. The intent is to disseminate the scientific literature on these products. We encourage you to read these studies to understand the strengths and limitations of the data. For some claims, Bravida is seeking to broaden the indications with the FDA in the future using data, such as these studies, to provide the substantiation.

ADULT CARDIAC

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Use of Silver-Plated Dressings to Decrease CLABSIs in ECMO Patients Rose Richmond, <u>Megan Caffey</u>: Memorial Heramnn, Houston, USA

Abstract

Patients placed on Extracorporeal Membrane Oxygenation (ECMO) are at higher risk for infections including Catheter Associated Blood Stream Infections (CLABSIs) leading to increased morbidity and mortality. Multiple factors can lead to the increased risk of CLABSIs in ECMO patients including location of cannulas, emergency cannulation versus planned, length of cannulation, patient specific risk factors and maintenance of dressings. Nurses play a pivotal role in maintaining ECMO cannulation sites including dressing changes, sterility, and monitoring.

In July 2022 to August 2023, the hospital saw an increase in CLABSIs in ECMO patients. Nursing event analyses revealed inability to maintain occlusive dressings due to catheter locations, increased bleeding and patient factors. In August 2023, all nurses on the unit were trained in use of new dressings for ECMO cannulation sites. The new dressings were silver-plated and larger than previous chlorhexidine-embedded central line dressings. In September 2023, ECMO patients were transitioned to using silver-plated dressings at cannulation sites. Post-implementation (September 2023 to July 2024), only one patient was reported with a CLABSI. This patient was cannulated emergently with ongoing CPR and multiple risk factors and was reported to likely be a contaminated sample. The average number of ECMO patients seen by the unit from July 2022 to August 2023 was 2.16 versus during the silver-plated dressing trial period, the average ECMO patients was 3.20.

Despite the increased number of ECMO patients seen, there was decrease in the number of infections from 6 CLABSIs pre-implementation to 1 CLABSI post-implementation of silver-plated dressings.

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Utilization of ECMO Technologies in Normothermic Ex-vivo Perfusion Prolongation

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Abstract

Introduction: Normothermic ex-vivo heart perfusion (NEHP) prolongation is an exciting developing technology that continues to be limited to 6-10 hours of perfusion time. Utilization and optimization of ECMO technologies in the support of NEHP systems is paramount to perfusion prolongation.

Methods: Five juvenile sized pigs (51.8 ± 6.0 kg) were placed under general anesthesia prior to instrumentation. Hearts were recovered following standard heart procurement methods and cannulated on the backtable. On circuit, hearts were maintained in a Langendorff perfusion strategy with a fixed flow rate of 0.5-0.6 cc/g of cardiac tissue/min and managed with 22 kDa hemofiltration, electrolyte replacement, fixed rate vasoactive medications, and SF100 supplementation. Data collection included: Q30min hemodynamic monitoring, Q1h ABGs/VBGs, Q6h left atrial perfusion testing, and Q24h echocardiogram.

Results: All hearts successfully completed 48 hours of NEHP without meeting early termination criteria. Lactate average was 1.8 ± 0.6 mmol/L. Q24h echocardiogram demonstrated an average increase in interventricular septal wall diameter of $15.6\% \pm 24.4\%$ at 24hr and $24.9 \pm 20.0\%$ at 48hr time points. Left ventricular ejection fraction was measured and averaged; $62.4 \pm 4.6\%$ InVivo, $43.8 \pm 24.3\%$ at Hr0 of time on circuit, $25.2 \pm 14.7\%$ at Hr24, and $37.5\% \pm 14.6\%$ at Hr48.

Conclusion: The development of prolonged NEHP devices through optimization of ECMO technology allows for a myriad of improvements in the field of transplantation including temporal and geographic expansion of the donor pool, assessment and treatment of marginal organs, and individual gene therapy and immunomodulation of organs prior to implantation.