



Original article

Custodiol versus blood cardioplegia in pediatric cardiac surgery, two-center study

Ebtehal A. Qulisy^a, Anas Fakiha^a, Ragab S. Debis^a, Ahmed A. Jamjoom^b,
Ahmed A. Elassal^{a,c}, Osman O. Al-Radi^{a,b,*}

^a Abdullah Bakhsh Children's Heart Center, Department of Surgery, Faculty of Medicine, King Abdulaziz University, Jeddah, Saudi Arabia

^b Division of Cardiovascular Surgery, The Cardiovascular Department, King Faisal Specialist Hospital, Jeddah, Saudi Arabia

^c Cardiothoracic Surgery Department, Faculty of Medicine, Zagazig University, Zagazig, Egypt

Received 2 April 2016; revised 27 April 2016; accepted 4 May 2016

Available online 16 June 2016

Abstract

Background: Cold blood cardioplegia is widely used as a method of myocardial protection in pediatric cardiac surgery. Operative interruption to administer cardioplegia and need for repeated administration and occasional direct coronary ostial cannulation are considered a drawbacks of this technique. Custodiol, a crystalloid solution, has been used in children as an alternative cardioplegia solution with the potential advantage of single dose administration with equivalent myocardial protection. We sought to compare the outcomes of cold blood cardioplegia versus Custodiol cardioplegia in pediatric cardiac surgery.

Methods: A retrospective cohort study was performed between November 1st, 2013 and June 30th, 2014. All children who underwent heart surgery at two institutions with the use of cardiopulmonary bypass and cardioplegia were included. Patients were identified from a prospective database and additional data were collected from operative report and electronic and paper charts. Continuous data were represented as median and interquartile range, and tested with Wilcoxon rank-sum test. Categorical data were represented as proportions, and tested with Pearson test. A composite endpoint of all cause death, Low Cardiac Output Syndrome (LCOS), Acute Kidney Injury (AKI), and significant arrhythmia was analyzed with a multiple logistic regression model adjusted for complexity using the Risk Adjustment of Congenital Heart Surgery -1 (RACHS-1) categories. A p-value of less than 0.05 was considered to be significant.

Results: Blood cardioplegia was administered in 88 (57.1%) patients, and Custodiol cardioplegia was administered in 66 (42.9%) patients according to surgeon's preference. In the risk adjusted comparison of the composite outcome of all-cause death, LCOS, AKI and significant arrhythmia, Custodiol cardioplegia was found to be an independent predictor of an adverse outcome, OR 3.17 (95% CI 1.41–7.14, P-value = 0.0054).

Conclusions: Custodial cardioplegia is associated with less optimal myocardial protection and higher adverse outcomes compared to cold blood cardioplegia in children undergoing cardiac surgery. A randomized comparison is warranted.

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Abbreviations: AKI, Acute Kidney Injury; HTK, Histidine-Tryptophan-Ketoglutarate; LCOS, Low Cardiac Output Syndrome; MV, Mechanical Ventilation; RACHS-1, Risk Adjustment in Congenital Cardiac Surgery – Version 1.

* Corresponding author. Department of Surgery, King Abdulaziz University Hospital, P.O. Box 80215, Building 10 Room 1027, Jeddah 21589, Saudi Arabia.

E-mail address: oradi@kau.edu.sa (O.O. Al-Radi).

Peer review under responsibility of The Egyptian Society of Cardio-thoracic Surgery.

<http://dx.doi.org/10.1016/j.jescts.2016.05.001>

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Ultra-mini abstract: In a retrospective multicenter study, 88 children received blood cardioplegia, and 66 received Custodiol cardioplegia. In a risk adjusted comparison of the composite outcome of all-cause death, morbidity and significant arrhythmia, Custodiol cardioplegia was found to be an independent predictor of an adverse outcome, OR 3.17 (95% CI 1.41–7.14, *P*-value = 0.0054).

Keywords: Cardiopulmonary bypass; Congenital heart disease; Custodiol; Cardioplegia; Pediatric; Cardiac surgery

1. Introduction

Cardioplegia, a solution used to stop the heart, is an essential tool for cardiac surgery. In conjunction with cardiopulmonary bypass it provides a motionless bloodless protected heart for the surgeon to repair any intra-cardiac or extra-cardiac defect. This is achieved by arresting the heart and minimizing myocardial metabolism during the ischemic time. After placing the patient on cardiopulmonary bypass, the cardioplegia solution is infused in the clamped proximal ascending aorta exclusively supplying the coronary arteries perfusing the myocardium. The ideal cardioplegia solution should provide excellent myocardial protection, cause minimal systemic electrolyte imbalance, and be effective for prolonged periods of time to minimize repeated administration. In a survey of congenital heart surgeons, Kotani et al. identified that there is no agreement between surgeons about the ideal cardioplegia solution [1]. The main types of cardioplegia used are blood based cardioplegia and crystalloid based cardioplegia. Recently, there has been growing interest in the use of a more simplified solution that offers simplified perfusion technique, prolonged ischemic tolerance and minimized disruption during surgery. The Histidine-Tryptophan-Ketoglutarate solution, known as HTK Custodiol (Essential Pharmaceuticals, LLC, Newton, PA, and MACURE PHARMA ApS, Copenhagen, Denmark) has emerged as an option [2]. The goal of this study was to compare the safety and efficacy of Custodiol cardioplegia versus blood cardioplegia.

2. Methods

A multi-centered, retrospective review was conducted at two institutions. The participating institutions were Abdullah Bakhsh Children's Heart Center, King Abdulaziz University, Jeddah, Saudi Arabia and the division of cardiovascular surgery, King Faisal Specialist Hospital, Jeddah, Saudi Arabia. The study protocol was approved by the research ethics boards at both institutions. All children (1 day–18 years of age) who underwent congenital heart surgery with the use of cardiopulmonary bypass and cardioplegia between November 2013 and June 2014 at one of the two participating institutions were included. Patients were divided into two groups on the basis of the cardioplegia solution used. In the Blood group, cardioplegia was given in the standard ratio of (4:1) four parts of blood from the cardiopulmonary bypass circuit, and one part potassium-rich crystalloid ($K = 60$ ml eq/L) named Plegisol (Hospira, Inc, Lake Forest, IL). The initial dose was 30 ml/kg body weight, and subsequent doses were 20 ml/kg given every 20 min. Temperature was reduced to 10–15 °C, while maintaining a perfusion pressure of 100–125 mmHg. In contrast, the Custodiol group was given Custodiol solution at 4–8 °C perfused for 5 min. The dose was 40 ml/kg body weight, with a minimum of 5 min of perfusion time.

All available electronic and paper patient charts as well as the perfusion record, the anesthetic chart, the intensive care record and the operative reports were examined. All cause death was defined as death during the index admission from any cause and regardless of length of stay. Low Cardiac Output Syndrome (LCOS) was defined as the use of more than 0.7 mic/kg/min of Milrinone and/or more than 0.05 mic/kg/min of Epinephrine for more than 5 days. The length of Mechanical Ventilation (MV) was defined as time of mechanical ventilation using endotracheal intubation in hours, re-intubation episodes and subsequent ventilation time was added. Acute Kidney Injury (AKI) was defined as postoperative increase in serum creatinine of more than double the preoperative baseline at any point up to hospital discharge. Significant arrhythmia was defined as any sustained cardiac arrhythmia requiring pharmacologic intervention or cooling of body temperature. Length of ICU stay in days and length hospital stay in days were also reported.

2.1. Statistical analysis

Variable distribution was checked for normality. Continuous data were represented as median and interquartile range, while categorical data were represented as frequencies and proportions. Differences between two groups were analyzed using non

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