The Use of Ultrafiltration in High-Risk Post-operative Coronary Artery Bypass Grafting Patients.

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Abstract

Abstract: Background: Fluid overload (FO) and acute kidney injury (AKI) after CABG surgery are due to multiple perioperative etiologies associated with high failure to rescue rates (FTR) and associated with poor outcomes [1-,3]. Diuretics, fluid restriction, ultrafiltration (UF) and renal replacement therapies are the treatment modalities implemented as monotherapy or in combination to address this severe complication. There is limited data on the use of simplified UF therapy as a fluid management strategy in post-operative cardiac surgery patients. **Methods:** A retrospective review of our post operative isolated CABG patients was done from Jan 1 st, 2020 to July 31 st, 2021. Those subjected to a simplified UF protocol incorporating Goal Directed Therapy (GDT) to treat fluid overload and/or acute kidney injury were evaluated for 30-day survival and readmission rates. **Results:** A total of 254 isolated CABG procedures were performed during this period. Ultrafiltration was used in 17 (6.7%) patients. The 30-day mortality for the entire CABG cohort was 5/254 (2.0%) patients and in the UF group 0/17 (0%). The mean age of UF therapy patients was 65.8 years (Range 41-89). The mean Society of Thoracic Surgeons STS mortality score of UF patients was 5.7% (Range 0.6-50.0). The 30-day survival for the 17 patients placed on UF therapy was 100% and their readmission rate was 2/17 (11.7%). **Conclusions:** The use of ultrafiltration in this patient population with relatively high STS scores provided a safe and effective modality to manage fluid balance but further studies are needed.

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Running Title: Ultrafiltration after Cardiac Surgery.

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(247 words)

Introduction

Coronary artery bypass grafting (CABG) surgery for coronary artery disease (CAD) remains the most common cardiac surgery performed in the USA and Canada[4]. The increased age of patients along with risk factors for CAD (i.e., hypertension (HTN), diabetes mellitus (DM), obesity and chronic kidney disease (CKD) increase the perioperative risk for acute kidney injury (AKI) and subsequent fluid overloaded (FO) states. The incidence of post operative AKI after cardiac surgery has been reviewed and reported as high as 40%.[5] Understandably, the two most common chronic risk factors for heart disease (i.e., HTN and DM) are also the leading causes for chronic kidney disease in the USA[6]. Pre, intra and post operative factors for AKI include but are not limited to baseline preoperative heart failure states, baseline renal function, intraoperative intravenous fluid over or under hydration, and or decreased renal excretion[7-9]. Other perioperative risk factors for AKI include dye contrast from cardiac angiography and the systemic inflammatory response syndrome (SIRS) due to surgery. More concerning, is the relatively high failure to rescue (FTR) rate reported for post cardiac surgery AKI[3]. Although the STS mortality risk score is the most common indicator used to differentiate low, medium, and high-risk cardiac surgical patients, it fails to predict and capture other well-known high mortality risk factors including uncontrolled DM (i.e., HgbA1c level)[10], nutritional status (i.e., albumin level) and decompensated heart failure (i.e., BNP levels). According to the most recent 2019 STS results, the average in-hospital and 30-day mortality rates for CABG are 1.8% and 2.2%, respectively[7]. Excess fluid overload in the perioperative phase of care has also been associated with increase morbidity and mortality[6]. Modified Ultrafiltration (MUF) techniques have been used for decades in the operating room to remove fluid but the use of simplified UF in the post operative cardiac surgery period has not been fully investigated. Enhanced Recovery after Surgery (ERAS) recommends using goal directed therapy (GDT) to avoid excess perioperative salt and water intravenous infusions and maintenance of euvolemia[11, 12]. Simplified ultrafiltration therapy with its low extracorporeal volume can be used to accomplish this task safely by removing isotonic plasma water in the post-operative period.

The current data evaluates a simplified UF technology for the removal of isotonic plasma water in high-risk post operative cardiac surgery patients. No randomized controlled trial data has yet been published on this subject. Results presented in this paper show safety and applicability of this technology in post cardiac surgery care.

Patients and Methods

Patient Selection

This project was undertaken as a quality improvement initiative at Baylor Scott & White Health, Temple, Texas. A retrospective analysis of patient records was performed and the need for formal evaluation was waived by our local IRB.

A retrospective review, from Jan 1st 2020 to July 31st 2021, of all isolated CABG patients from our institution was conducted. All patients who underwent simplified UF using Aquadex (Nuwellis, MN. USA) during their hospital course were included in this analysis. Charts were reviewed using the electronic medical records (Epic Systems, WI. USA) and patient's demographics were extracted and shown in Table 1 and 2. The exclusion criteria were ages <18 years. The institution has adopted the cardiac enhanced recovery after surgery (ERAS) protocols for all our cardiac surgery patients. Hemodynamic monitoring (i.e., CVP, SvO2, CI, SVR) for goal directed therapy was performed using the HemoSphere advanced monitoring platform (Edwards Lifesciences, Irvine Ca).

The decision to perform simple UF in the post-operative period was made by the attending cardiothoracic surgeons in collaboration with the CVICU intensivists using our division's protocol as summarized in Table 3.

Ultrafiltration Technique

Various modes of venous access were used including the previously placed intra-operative ARROW MAC with ARROWg+ard Blue Technology 9F catheter (Teleflex, USA, Fig 1), a peripheral dual lumen extended length catheter (dELC) 6F/16Ga (Nuwellis, MN US, Fig 2) or a standard central venous 14Ga or 16Ga hemodialysis (HD) catheter (not shown). The approximate time from UF request placed to initiation of fluid removal is typically 15 to 60 minutes once venous access is in place. Elective nephrology consultations were submitted, and emergent consultations were reserved for patients who met indications for hemodialysis. All diuretics were discontinued once UF was in progress. Most patients were anticoagulated with 400 to 600 Units Heparin per hour or Argatroban (to maintain PTT 40-50 secs) if heparin induced thrombocytopenia was suspected. The UF rates of fluid removal varied from 100cc to 500/cc per hour at the discretion of the surgeon, CVICU intensivist and ICU team using clinical, hemodynamic and biomarkers to guide GDT. Intermittent CVP readings were recorded from the central venous access line and goal directed therapy was utilized with the HemoSphere advanced monitoring platform (Edwards Lifesciences, Irvine Ca). The goal of UF was to target a net negative 1-2L /day until CVP was <12, O2 requirements were decreased, patient returned to baseline weight and or regained adequate renal function to become diuretic responsive.

Statistical Methods

This was a retrospective study. Descriptive statistics were used including sample size, mean, standard deviation, median, minimum, and maximum for continuous variables and frequency and percent for categorical variables.

Results

A total of 254 isolated CABG procedures were performed during the study period from Jan 1st 2020 to July 31st 2021. A total of 5 (2.0%) patients died. Simplified ultrafiltration was used in 17 (6.7%) isolated CABG patients during the post-operative period according to the institutional protocol described in Table 3. The mean age of the patients placed on UF therapy was 65.8 years (Range 41-89), preoperative HTN and DM were diagnosed in 88.2% and 76.5%, respectively. The mean UF cohort STS mortality score was 5.7% (Range 0.6-50.0). The 30-day readmission rate for patients in the UF group was 2/17 (11.7%). For this high-risk isolated CABG group, 30-day survival for the 17 patients placed on UF therapy was 100% (Table 2.)

Comments

Acute kidney injury in post operative cardiac surgery patients is seen in up to 40% of patients with 1% requiring hemodialysis long term and is associated with increased morbidity and mortality (M&M)[7,8]. Fluid overload in post operative cardiac surgery patients is also associated with increased M&M[1,9]. This peri-operative "temporary kidney injury state" during post cardiac surgery has been studied extensively and is associated with increased need for resources, increased length of stay, urgent renal consultations, and a relatively higher failure to rescue (FTR) rate when compared to other complications[2-4,9]. The current options available for the treatment of AKI with or without fluid overload in post operative cardiac surgery patients are limited and include escalating diuretics, continuous renal replacement therapy (CRRT), simple ultrafiltration technology (to remove isotonic plasma) and hemodialysis, each with their associated risks and benefits. Modified ultrafiltration (MUF) was developed over the last two decades and used intraoperatively while on the cardiopulmonary bypass circuit to remove excess fluid in both adult and pediatric cardiac surgery patients. Simplified ultrafiltration technology using an extracorporeal circuit has been in clinical use for more than a decade and its efficiency has been extensively studied in heart failure clinical trials (i.e., UNLOAD, AVOID-HF, EUPHORIA)[13]. More recently, US clinical trials and the Food and Drug Administration approval were granted for the treatment of fluid overload in the pediatric population weighing [?]20 Kg. CRRT is the mode of choice over conventional hemodialysis for post operative cardiac surgery patients due to improved hemodynamic tolerance[14].

Adult cardiac surgery patients mostly present acutely after many years of chronic medical conditions and modifiable risk factors including HTN, DM, obesity, hyperlipidemia, physical inactivity, and smoking. HTN and DM were seen in 88% and 76% of our 17 UF patients, respectively. The long-term deleterious effect of HTN and DM on renal function is underestimated in patients with cardiovascular diseases since both chronic diseases are found in most patients requiring hemodialysis. The term cardiorenal syndrome also describes the inter-organ pathophysiological relationships in the setting of fluid overload[15,16]. Mortality scoring systems and online calculators are used more frequently to risk stratify and predict outcomes of surgery. These scoring systems provide a guide and underscore the various phases of care, multi-disciplinary knowledge, available skills, hospital structure, processes, available equipment, staffing ratios and complexity that is inherent in cardiac surgery.

Coronary artery bypass grafting surgery is the most common open heart surgery procedure performed for the treatment of coronary artery disease and its outcomes are used as a quality indicator for the hospitals[4]. Since AKI has been reported to occur in up to 40% of patients undergoing cardiac surgery and has the highest failure to rescue rates of post cardiac surgery complications, more incite is needed to improve this quality metric[3,7,8].

The care of these patients has evolved with the application of newer monitoring technology, devices, artificial intelligence, and processes to improve overall outcomes. Implementation of a cardiac Enhanced Recovery after Surgery (ERAS) protocol is one example of process improvement using goal directed therapy with emphasis on avoidance of excess sodium and water overload. Although prevention of fluid overload intra-operatively is preferable, it is still seen as a common denominator in post cardiac surgery patient's complications. Fortunately, most cardiac ICUs in the immediate post-operative setting is equipped with hemodynamic monitoring, critical care expertise and protocols to care for any possible complication. Due to the high FTR rates for AKI, close monitoring of these patients is essential for improved survival.

Our entire CABG population (254 patients, which included the COVID-19 pandemic) had a mean STS mortality score of 2.5 $\pm$ 6.61% whereas, the subset (17 patients) that underwent UF therapy had a mean STS score of 5.7 $\pm$ 11.55%. Despite the higher mortality STS score for the UF group, there was a favorable survival outcome (100%). In addition to the mortality benefits, real time advantage of UF therapy (Table 4) include: quick set up (15 to 30 minutes) any time of day, night, weekend or holiday; no immediate need for renal consultation unless RRT is needed; use of existing venous access placed intra-operatively during the initial CABG procedure or a new peripheral cannula can be placed (see Figure 1 and 2), the set-up is very simple relative to other RRT devices and is done by the ICU bedside nurse with no additional nursing staff. The volume to be removed is adjustable (hour to hour as needed) and the machine records the amount of fluid removed every hour thereby improving ICU nursing labor efficiency without the need for volume calculations. The total extracorporeal blood is approximately 35cc within the circuit limiting blood loss if UF is discontinued. Of note, this study period included the COVID-19 pandemic period and the use of Aquadex UF system freed up CRRT/HD resources for other critical care patients since no increased nursing staff was needed to perform UF.

This small retrospective pilot study shows the safety of using this UF technology to remove excess isotonic plasma water from patients in a highly monitored setting in the post-operative phase of cardiac surgery care with great outcomes. A larger multi-institutional study including long term follow up of high-risk patient populations is warranted.

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Table 1.

Demographics of 17 Isolated Coronary Artery Bypass Grafting Surgery patients subjected to Post Operative Simple Ultrafiltration.

Age (yrs)	Gender	HTN	DM	Pre-op Cr (mg/dL)	Post-Op Cr (mg/dL)	STS Score (%)	EF (%)
41	Female	No	Yes	1.06	1.99	1.3	16
42	Female	Yes	Yes	1.74	2.37	2.6	47
43	Male	Yes	Yes	4.72	6.33	3.1	46
52	Male	Yes	Yes	6.15	8.73	3.13	43
53	Female	Yes	Yes	1.18	2.29	1.02	63
59	Male	Yes	Yes	3.16	3.91	2.21	62
65	Female	Yes	Yes	0.73	1.71	4.23	27
68	Male	Yes	Yes	2.25	1.63	1.69	65
68	Male	Yes	No	1.98	3.81	1.35	49
70	Male	Yes	No	1.3	1.65	1.86	25
72	Female	Yes	No	0.9	1.21	2.82	60
75	Male	Yes	Yes	1.08	4.71	0.56	52
77	Male	Yes	Yes	2.83	5.45	6.8	33
78	Male	Yes	Yes	1.21	3.52	50	9
83	Male	No	Yes	1.8	1.79	5.7	5
84	Male	Yes	No	1	1.6	3.25	65
89	Male	Yes	Yes	1.37	2.28	5.41	30

HTN: Hypertension, DM: Diabetes Mellitus, EF: Ejection Fraction, Cr: Creatinine, STS: Society of Thoracic Surgeons

Table 2.

Demographics, Baseline Characteristics and STS Scores.	**Table 2.**
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	UF
N=17	**No UF**

N=237	**p-value [1]**		
Age (years)			0.357
Mean ± SD (N)	65.8 ± 15.19 (17)	63.8 ± 10.56 (237)	
Median (Min, Max)	68.0 (41.0, 89.0)	65.0 (24.0, 84.0)	
Gender			0.555
Male	70.6% (12/17)	77.2% (183/237)	
Female	29.4% (5/17)	22.8% (54/237)	
Hypertension			0.730
Yes	88.2% (15/17)	89.0% (211/237)	
No	11.8% (2/17)	10.1% (24/237)	
Not Reported	0.0% (0/17)	0.8% (2/237)	
Diabetes			0.098
Yes	76.5% (13/17)	49.4% (117/237)	
No	23.5% (4/17)	49.8% (118/237)	
Not Reported	0.0% (0/17)	0.8% (2/237)	
30 Day Mortality			>0.999
Yes	0.0% (0/17)	2.1% (5/237)	
No	100.0% (17/17)	97.9% (232/237)	
Last Creatinine (mg/dL)			<0.001
Mean ± SD (N)	2.0 ± 1.47 (17)	1.3 ± 1.05 (234)	
Median (Min, Max)	1.4 (0.7, 6.2)	1.0 (0.6, 9.5)	
Post-Op Creatinine (mg/dL)			<0.001
Mean ± SD (N)	3.2 ± 2.06 (17)	1.7 ± 1.60 (235)	
Median (Min, Max)	2.3 (1.2, 8.7)	1.2 (0.7, 11.2)	
STS (%)			<0.001
Mean ± SD (N)	5.7 ± 11.55 (17)	2.2 ± 6.08 (235)	
Median (Min, Max)	2.8 (0.6, 50.0)	1.1 (0.1, 80.0)	
EF (%)			0.066
Mean ± SD (N)	41.0 ± 19.80 (17)	50.4 ± 13.25 (234)	
Median (Min, Max)	46.0 (5.0, 65.0)	53.0 (13.0, 75.0)	
[1] Two-sided normal approximation Wilcoxon Mann-Whitney test was used for continuous variables and Fisher's Exact test was used for categorical variables.	[1] Two-sided normal approximation Wilcoxon Mann-Whitney test was used for continuous variables and Fisher's Exact test was used for categorical variables.	[1] Two-sided normal approximation Wilcoxon Mann-Whitney test was used for continuous variables and Fisher's Exact test was used for categorical variables.	[1] Two-sided normal approximation Wilcoxon Mann-Whitney test was used for continuous variables and Fisher's Exact test was used for categorical variables.

Table 3. Criteria for use of Ultrafiltration in Post operative CABG patients.

Indications Post-operative CABG patients with a poor diuretic response and/or any of the following:	**Contraindications**
AKI of any stage with net positive fluid balance Fluid overload > 5% increase in body weight relative to pre-operative body weight Net > 3 Liter positive fluid status with high oxygen requirements	Indication for hemodialysis is met

Indications Post-operative CABG patients with a poor diuretic response and/or any of the following:	**Contraindications**
Respiratory failure, pulmonary edema on chest x-ray and high oxygen requirement with elevated central venous pressure (CVP). No indications for hemodialysis (i.e., no acidosis, no hyperkalemia) May be used interchangeably with hemodialysis (i.e., for clearance) and UF for fluid removal	

Table 4. Practical Real-World Differences for In-patient Resources.

	Ultra -Filtration (Aquadex)	Renal Replacement Therapy/CVVHD
Nurse staffing	Same/ No Change	Increased
Venous Access	Peripheral/Central	Central
Immediate need for Renal Consult	No	Yes
Earliest time from request to start of Fluid removal	Within minutes (15-60 mins)	Within hours (3 to 48 hours)
Ease of use /set-up	Simple	Complex
Dialysate Fluid	None	Yes
Treatment Location	Ambulatory/Stepdown/ICU	ICU/Monitored/HD unit

Figure 1. Standard intra-operative ARROW MAC with ARROWg+ard Blue Technology 9F catheter (Teleflex, USA).

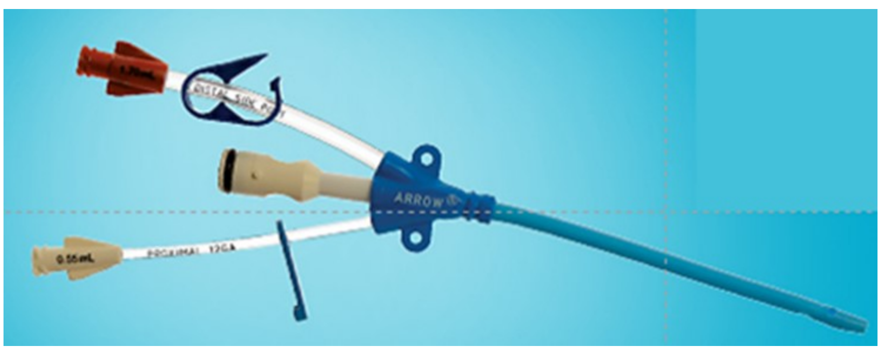

Figure 2. A peripheral dual lumen extended length catheter (dELC) 6F/16G (Nuwellis, MN, USA).