

EVALUATING THE USE OF A NEW BALANCED CRYSTALLOID SOLUTION (STEROFUNDIN) COMPARED TO RINGER'S LACTATE FOR PRIMING CARDIOPULMONARY BYPASS CIRCUITS

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ABSTRACT

Objectives: This study aims to evaluate the effects of using either Ringer's lactate (RL) or a newer balanced crystalloid solution called Sterofundin (SF) as the priming solution for the heart-lung machine during and immediately after single heart valve replacement surgery.

Methods: The study included 260 patients bifurcated into groups of SF and RL. A pulsatile roller pump and a membrane oxygenator were used for cardiopulmonary bypass. The circuit was primed either with 500 mL of the balanced 6% hydroxyethyl starch 130/0.4 plus 1000 mL of the RL or 1000 mL of balanced crystalloid solution SF.

Results: Significant differences were observed between SF and RL groups based on mean blood pressure, central venous pressure, cardiac index, mixed venous oxygen saturation, blood gas parameters, platelet count, and extubation hours.

Conclusion: Stable blood flow is key in heart bypass surgery. Fluid management is complex, and the ideal fluid type is debated. Colloids may help patients with weak hearts. Modern non-colloids are also safe. Research conflicts likely arise from study differences and researcher bias. This study suggests that both fluid types are useful, with colloids potentially better in certain cases. In addition, acetate solutions like SF were found to lower lactate levels. SF also maintains hemostasis, colloid oncotic pressure and reduced blood product requirement. Patient outcomes and intensive care unit stay were similarly affected by priming solutions.

Keywords: Cardiopulmonary bypass, Priming solutions, Single heart valve replacement, Colloids, Crystalloids.

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INTRODUCTION

Cardiac surgery has been regarded as one of the most important medical advances in the twentieth century. The first surgical procedures on these patients were performed using hypothermia and inflow occlusion [1]. The heart-lung machine was widely accepted and was used with an increasing frequency for open-heart surgery [2]. The standard equipment used in a heart-lung machine at present includes the main elements of the pump, oxygenator, venous reservoir, tubings, gas supply systems, different filters, bubble traps, as well as suckers and venting systems [3]. Before use, the machine has to be primed with a fluid solution so that adequate flow rates can rapidly be achieved upon initiation of cardiopulmonary bypass (CPB) without any risk of air embolism [4]. Priming solutions are solutions which are used to prepare the extracorporeal perfusion line in CPB applications [5].

Older age, more comorbidity, and emergency surgery lead to increased risk during cardiac surgery [5,6]. To maintain low morbidity and mortality in this population it is important to optimize all parts of their treatment. Fluid therapy in cardiac surgery offers challenges beyond other surgical specialties. The patient's underlying cardiac disease, the complexity of the surgical intervention (including cardiac arrest and hypothermia), and the pathophysiological impact of extra-corporeal circulation, all contribute to the need for critical reflection while instituting fluid treatment protocols.

Two types of solutions are commonly available: Crystalloids and colloids (albumins). Complex physiological and biochemical mechanisms are activated during cardiac surgery, especially when CPB is used: "The

period of the operation with the heart lung machine is equivalent to the first phase of clinically-controlled shock" [7].

Fluid volume replacement therapy in cardiac surgery generally is accepted to be of fundamental importance because intravascular volume deficits may result in inadequate cardiac output, microcirculation, and tissue oxygenation [8,9]. The physiology and pathophysiology of fluid compartments should be accounted for when a decision has to be made among different solutions [10].

Crystalloid solutions are cheap, easily available, and devoid of anaphylactic reaction but they reduce colloidal oncotic pressure significantly [11,12]. Albumin, a natural colloid which is responsible for 75–80% plasma oncotic pressure, is very costly and not easily available and also contains risk of anaphylactic reaction. Albumin maintains plasma oncotic pressure and prevents capillary leak of fluid resulting in improved organ functions [12,13]. Hydroxyethyl starch (HES/130/0.4) 6% is synthetic colloid produced from amylopectin. It was introduced in 1975 as a priming solution in cardiac surgery. It produces volume expansion with very less incident of anaphylactic reaction. HES may affect homeostasis by weakening thrombus formation and also associated with renal dysfunction [14,15].

The ideal priming solution in cardiac surgery patients is a much-discussed issue. There is not only a debate whether colloids are advantageous for volume replacement as compared to crystalloids, in the majority of studies comparing crystalloids versus colloids; colloids are found to have better outcome. However, most colloids including human albumin are dissolved in saline consisting of un-

physiologic high concentration of sodium (154 mmol/L) and chloride (154 mmol/L) [16,17] and the use of considerable amounts of these colloids may be associated with the development of metabolic (hyperchloremic) acidosis as well as an untoward effect on coagulation due to platelet dysfunction. Elevated serum lactate level after cardiac surgery is an indicator of systemic hypo perfusion and tissue hypoxia.

There is a lack of prospective randomized studies with special regard to the cardiac surgical patient population. The present study aims at a preliminary comparison between two balanced crystalloid regimes – Sterofundin (SF) and Ringer acetate (Ringer’s lactate [RL]). Their effect on blood pH, lactates, and electrolytes was investigated.

METHODS

The present study was conducted in the Department of Cardiothoracic and Vascular Surgery at Fortis hospital, Mohali multispecialty tertiary care hospital. The study included 260 patients undergoing valve replacement during years 2015–2017.

Inclusion criteria

Patients weighing more than 40 kg who chose elective surgery and undergoing single valve replacement were included in this study.

Exclusion criteria

1. Emergency surgery
2. Left ventricular ejection fraction <55%
3. Preoperative renal dysfunction (serum creatinine>1.5 g/dL)
4. Bleeding diathesis
5. Patients with neurological disorder
6. Infective endocarditis
7. Left atrial clot
8. Patients with liver insufficiency
9. Patients with peripheral vascular diseases
10. Carotid diseases
11. Patients on preoperative dialysis.

Preparation of SF

Sodium chloride 6.80 g, potassium chloride 0.30 g, magnesium chloride hexahydrate 0.20 g, calcium chloride dihydrate 0.37 g, sodium acetate trihydrate 3.27 g, L-malic acid 0.67 g. electrolyte concentrations: mmol/L sodium 145.0, potassium 4.0, magnesium 1.0, calcium 2.5, chloride 127.0, acetate 24.0, malate 5.0.

The patients were randomly bifurcated with 130 patients in each group:
Group 1: RL as priming solution.
Group 2: SF as priming solution.

A pulsatile roller pump and a membrane oxygenator were used for CPB. The circuit was primed either with 500 mL of the balanced 6% HES 130/0.4 plus 1000 mL of the RL in group I or 500 mL of the conventional 6% HES 130/0.4 plus 1,000 mL of balanced crystalloid solution (SF) taking into consideration the baseline hemoglobin of the patient.

Statistical analysis

All the comparisons between groups were done using the Pearson Chi-square test, Student’s t-test, or Fisher’s exact test as appropriate.

RESULTS

In the present study, SF group had 59 males and 71 females while RL group had 69 males and 61 females (Fig. 1).

The distribution pattern of patients undergoing different procedures of cardiopulmonary bypass surgery is shown in Fig. 2.

Heart rate

A significant difference was observed in heart rate between SF and RL group during baseline, pre-bypass, and after CPB, but no significant difference was reported in after shifting of patients (Fig. 3).

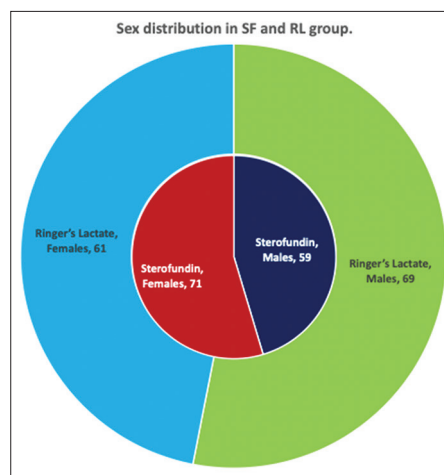


Fig. 1: Pie charts representing sex distribution in the present study. Each group had 130 patients which Sterofundin group had 59 males and 71 females while the Ringer’s lactate group had 69 males and 61 females

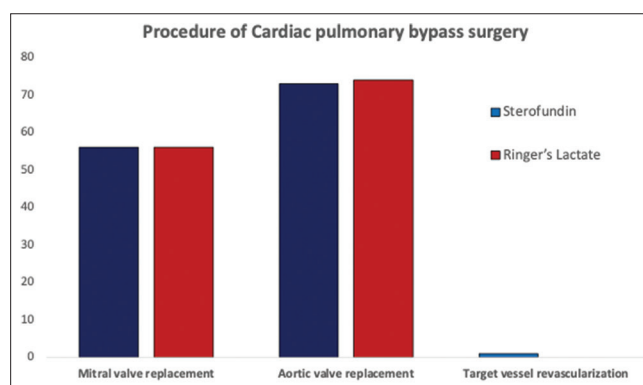


Fig. 2: Bar graphs exhibiting distribution of patients concerning procedure of cardiac pulmonary bypass surgery. In Sterofundin group 56 patients undergoes Mitral valve replacement, 73 have Aortic valve replacement surgery and only 1 patient undergoes target vessel revascularization. In Ringer’s lactate group, 56 patients have mitral valve replacement, and 74 have aortic valve replacement surgery

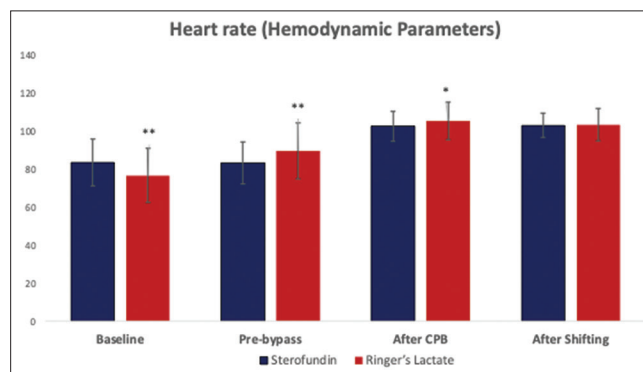


Fig. 3: Bar graphs representing the heart rate of patients during baseline, pre-bypass, and after cardiopulmonary bypass. *Represents p<0.05 while **represents p<0.01

Mean blood pressures

A significant difference existed in mean blood pressure between SF and RL groups during baseline, at the time of CPB, after CPB, and after

shifting. However, no significant difference was observed in mean blood pressure between SF and RL group pre-bypass (Fig. 4).

Table 1 represents the different parameters which play an important role in calculating risks for cardiac surgery patients were recorded in both groups. It was observed that central venous pressure (CVP) was significantly different at the time of pre-bypass, after CPB, and after shifting. The cardiac index significantly differed at the baseline, pre-bypass and after CPB. On comparing mixed venous oxygen saturation a significant difference was observed between SF and RL as priming solution at the lowest temperature from the venous line and right atrium after the bypass is over. Interestingly, no significant difference was found in prothrombin, international normalized ratio, activated clotting time and serum sodium levels between SF and RL groups.

We observed that the requirement of packed red blood cells is higher in patients of RL group as compared to SF group patients. Whereas, the requirement of fresh frozen plasma is higher in patients of the SF group (Table 2).

The blood gas parameters differed significantly in base excess between SF and RL groups during baseline, post-heparin, CPB, post-protamine,

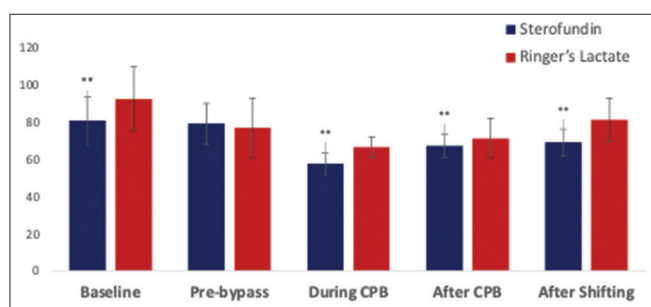


Fig. 4: Bar graphs representing the mean blood pressures. **Represents $p < 0.01$

Table 1: Comparison of central venous pressure, cardiac index, mixed venous oxygen saturation, prothrombin time, INR, activated clotting time, and serum sodium levels between SF and RL groups

Comparison parameters	Time	Sterofundin (n=130)	Ringer's lactate (n=130)
Central venous pressure/ pulmonary arterial pressures	Baseline	5.25±1.31	4.98±1.33
	Pre-bypass	12.77±2.48**	5.7±1.5
	After CPB	15.93±2.96**	7.81±1.5
	After shifting	6.27±3.05*	6.9±1.67
Cardiac index	Baseline	3.33±0.72**	4.19±0.63
	Pre-bypass	3.97±0.78**	4.16±0.77
	After CPB	4.42±0.765**	3.58±1.03
	After shifting	4.06±0.86	4.05±0.99
Comparison of mixed venous oxygen saturation in SF and RL group	Before bypass from RA	71.04±5.24	69.9±4.38
	On bypass at the lowest temperature from venous line	71.75±4.76**	68.25±5.05
	After bypass is over	74.20±4.8**	71.92±4.95
Prothrombin time (anticoagulation profile)	Baseline	13.50±1.22	13.3±1.46
	1 st POD	15.96±1.98	15.78±1.27
	2 nd POD	17.96±1.62	17.70±1.40
INR (anticoagulation profile)	Baseline	1.11±1.07	1.11±0.19
	1 st POD	1.40±0.26	1.40±0.25
	2 nd POD	1.35±0.30	1.35±0.22
Activated clotting time (anticoagulation profile)	Baseline	104.47±13.7	104.37±23.83
	After heparin	358.1±106.41	358.19±93.03
	During CPB	605±165.73	605.34±114.51
	After protamine	140±24.4	140.13±55.91
	6 h after shifting	124.6±13.91	124.5±16.7
	1 st POD	120.62±14.95	120.6±15.51
Serum sodium level	Baseline	138.4±4.2	137.5±4.6
	1 st POD	141.01±6.6	141.16±4.47
	2 nd POD	139.0±4.3	138.33±3.96

SF: Sterofundin, RL: Ringer's lactate, INR: International Normalized Ratio, POD: Post-operative delirium, CPB: Cardiopulmonary bypass. *Represents $p < 0.05$ and **Represents $p < 0.01$

in surgical intensive care unit (SICU), 1st post-operative delirium (POD) and 2nd POD (Fig. 5). Significant difference was reported in bicarbonate level between SF and RL group during post-heparin, in SICU, 1st POD and 2nd POD (Fig. 6). Fig. 7 represents serum potassium level between SF and RL groups Significant difference was found during post-heparin, CPB, post-protamine and in SICU.

While comparing the blood gas parameters (pH and lactate), a significant difference was observed in serum pH levels in SF and RL groups during baseline, post-heparin, CPB, post-protamine, in SICU, 1st POD, and 2nd POD. In the case of serum lactate levels during CPB, post-protamine, and during 2nd post-operative day significant difference was reported. We found a significant difference in platelets count in two groups at the time of intraoperatively, 1st POD and 2nd POD (Table 3).

In terms of sodium bicarbonate levels and SICU days, no significant difference was observed in both groups. However, while comparing extubation hours, a highly significant difference was reported between SF and RL groups (Table 4).

DISCUSSION

The present study was designed to compare two crystalloids as an intraoperative fluid regime. Cardiac surgery impacts fluid homeostasis more than other surgical interventions. The primary objective was to compare the RL with a new balanced crystalloid solution known as - SF.

It was observed that male patients are at a higher risk during coronary artery bypass graft procedures [15,18]. By replacing the intraoperative fluid, no significant difference was observed [19]. The study of various post-operative parameters was important to decide between the two fluids. In this regard, serum urea levels and creatinine levels were measured. No significant difference was observed between the SF and RL group indicating normal renal function while using either of the fluids [20]. Our findings reported a noteworthy difference in time of extubation in RL and SF groups while no statistically relevant observation was recorded on patients stay in SICU by using different

Table 2: PRBC and FFP requirement in SF and RL group

PRBC and FFP requirements	Sterofundin (n=130)	Ringer's lactate (n=130)
PRBC (blood product requirements)		
Baseline	15	28
1 st POD	7	19
2 nd POD	7	15
FFP (blood product requirements)		
Baseline	27	19
1 st POD	15	14
2 nd POD	16	4

SF: Sterofundin, RL: Ringer's lactate, POD: Post-operative delirium, FFP: Fresh frozen plasma, PRBC: Packed red blood cell

Table 3: Comparison between DF and RL groups based on blood gas parameters (pH and lactate) and platelet count

Blood parameters	Time	Sterofundin	Ringer's Lactate
pH (blood gas parameters)	Baseline	7.39±0.03*	7.40±0.04
	Post-heparin	7.38±0.03*	7.37±0.04
	CPB	7.38±0.03**	7.34±0.49
	Post-protamine	7.39±0.04**	7.32±0.05
	In SICU	7.34±0.05**	7.29±0.04
Lactate (blood gas parameters)	1 st POD	7.36±0.05**	7.32±0.04
	Baseline	1.17±0.46	1.14±0.49
	Post-heparin	3.15±0.77	3.06±0.96
	CPB	4.64±1.12**	5.13±1.29
	Post-protamine	8.27±1.78**	10.98±3.11
Platelets count	In SICU	9.31±1.96	9.43±3.10
	1 st POD	7.55±2.02	7.85±2.77
	Intraoperatively	241.91±43.86**	195.80±46.72
	1 st POD	204.37±47.29**	159.07±45.03
	2 nd POD	223.80±47.04**	185.34±52.97

SF: Sterofundin, RL: Ringer's lactate, POD: Post-operative delirium, SICU: Surgical intensive care unit, CPB: Cardiopulmonary bypass. *represents p<0.05 and **represents p-value <0.01

Table 4: Comparison of sodium bicarbonate levels, hours of extubation, and SICU days between SF and RL groups

Comparison parameters	Sterofundin	Ringer's lactate
Sodium bicarbonate	90.11±25.55	89.58±15.77
Extubation hours	12.66±2.92**	13.8±3.37
SICU days	2.42±0.52	2.43±0.54

SICU: Surgical intensive care unit, SF: Sterofundin, RL: Ringer's lactate. **represents p-value <0.01

priming solution [20,21]. Other important factors such as prothrombin time, INR, and activating clotting time did not exhibit any significant difference, implying the use of SF in place of RL. Similar results were presented by Kuitunen *et al.* [14]. The level of lactate was measured higher in the RL group during CPB, post-protamine period, in SICU, and in the 1st POD. Interestingly lactate levels were high during baseline and 2nd POD in the SF group. Although the acetate level increased significantly during the operation in the SF group, it decreased to the normal range at the end of the operation. In contrast, Isosu *et al.* [22] also found its usefulness in patients with liver dysfunction and compared it with RL solution. No significant blood product requirements were presented by patients of either group.

Serum sodium and potassium levels were within the normal range during baseline, the 1st POD, and 2nd POD. However, significant differences in serum potassium and pH were observed between the two groups during post-heparin administration, CPB, post-protamine administration, and in the SICU.

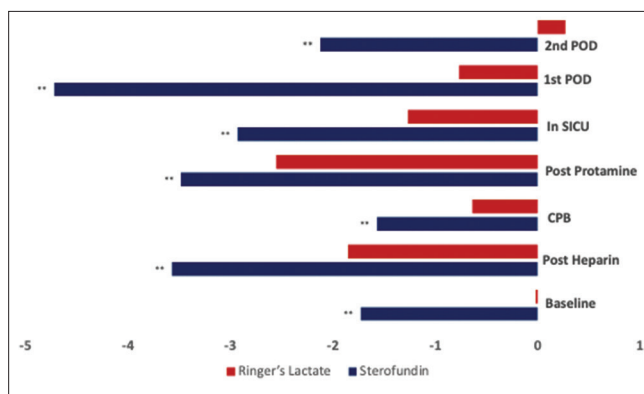


Fig. 5: Bar graphs representing base excess (blood gas parameters) between Sterofundin and Ringer's lactate groups. **Represents p<0.01

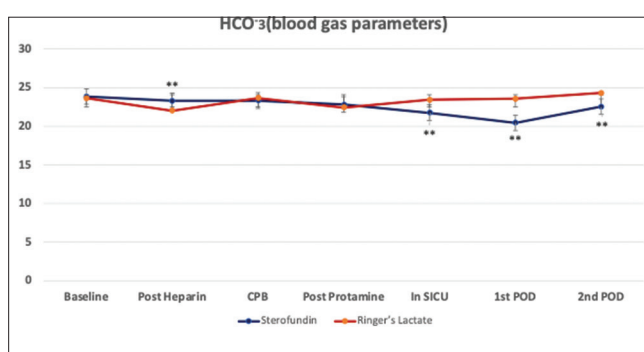


Fig 6: Line chart representing bicarbonate levels at different time points between Sterofundin and Ringer's lactate groups. **Represents p<0.01

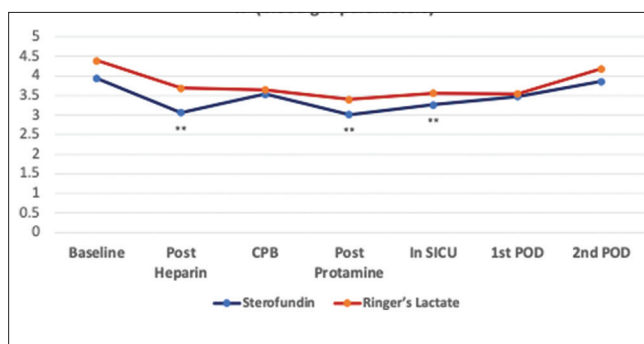


Fig. 7: Line graphs representing serum potassium levels between Sterofundin and Ringer's lactate groups. **Represents p<0.01

Previous research by McCague *et al.* [23] reported no pH changes after trauma resuscitation using acetated Ringer's solutions. The mild acidosis noted by Barak *et al.* in the SF group could be attributed to red blood cell transfusion. It is well-established that acid-base balance is significantly influenced by intraoperative hypothermia and hypotension.

When sodium bicarbonate was administered during CPB, no significant difference was found between the SF and RL groups. While, a significant difference in bicarbonate levels was observed between the SF and RL groups during post-heparin, in the SICU, and on the 1st and 2nd POD. In addition, a significant difference in blood sugar levels was noted between the SF and RL groups during baseline and the 2nd POD. No such difference was seen on the 1st POD. These findings align with Rajan *et al.*, who reported comparable baseline values for pH, bicarbonate,

sodium, potassium, lactate, and glucose between RL and SF groups. Intraoperative pH was similar except at 8 h, where the RL group showed a significantly lower pH. Lactate levels were significantly elevated in the RL group at 2, 4, 6, and 8 h, while bicarbonate levels remained comparable. No significant differences in sodium, potassium, or chloride levels were observed intraoperatively. Group B exhibited significantly higher glucose levels at 2 h, but levels were comparable to the SF group at other time points.

Here, we found a significant difference exists in heart rate between SF and RL group during baseline, pre-bypass, and after CPB. However, there does not exist a significant difference in heart rate between SF and RL groups after shifting of patients. Similarly, a significant difference exists in mean blood pressure between SF and RL group during baseline, at the time of CPB, after CPB, and after shifting. However, there does not exist a significant difference in mean blood pressure between SF and RL group pre-bypass. Here, also Rajan *et al.* [24] made the comparison of intraoperative hemodynamics revealed a significantly high HR in Group SF at 4, 6, and 8 h with comparable MAP throughout the study period. A significant difference in base excess between SF and RL groups during baseline, post-heparin, CPB, post-protamine, in SICU, 1st POD, and 2nd POD. Similarly, in the study of Sharma *et al.* the pH, bicarbonates, and base excess remained more stable and recovered faster to the normal range earlier with the infusion of SF than RL. We found a significant difference in platelet count in the two groups at the time of intraoperatively, 1st POD and 2nd POD, platelet count in the SF group was higher than RL group. In line with this Patel *et al.* found that patients receiving crystalloid (RL) had lower levels of platelets postoperatively 1st day but were not associated with increase blood loss as compared to albumin as priming solution. There is no significant effect on venous oxygen saturation before bypass from the radial artery using SF or RL as a priming solution. However, there exists a significant difference between SF and RL as priming solution on venous oxygen saturation during bypass and after bypass is over. In line with this Bishnoi *et al.* found that Group RL showed lower mean PaO₂ and saturation% values than SF but the values were within the normal range [25]. A significant difference exists in CVP/pulmonary arterial pressure between SF and RL group during pre-bypass, after CPB and after shifting. Here, we observed a low CVP in RL group as compared to SF group. In line with this Sharma *et al.* also observed relatively low CVP was observed throughout surgery in RL Group [26].

CONCLUSION

Maintaining stable blood flow during heart bypass surgery is vital for preventing complications. Effective fluid management, based on understanding the fluid distribution and the patient's condition, is crucial. The ideal fluid for volume replacement is debated, but colloids like albumin may benefit patients with weak hearts who might not tolerate large volumes of crystalloids.

While there's no single best fluid, modern non-colloid options are safe and effective. Conflicting research on fluid choice and patient outcomes likely stems from variations in study methods. The emotional debate often sees researchers favoring the type of fluid they study.

The present study concludes that both crystalloids and colloids have their place, but colloids may be superior in some situations. We also observed while comparison between RL and SF, where acetate-based solutions such as SF reduced lactate levels. SF is a better priming solution as it maintains hemostasis, colloid oncotic pressure and reduced blood product requirement. RL will not hamper hemostasis and renal function in lower doses and is better than crystalloid as it maintains negative fluid balance. Patient outcome and intensive care unit stay were similarly affected by priming solutions.

AUTHOR CREDIT STATEMENT

Gurpreet Singh Oberoi: Data collection, experiment design, data analysis, writing and formulating manuscript, Guneet Sharma: Formatting, proofreading Writing of Manuscript, Manbir Singh: Data

visualization, preparation of materials, Rajwinder Kaur: Experiment guidance, Procedure evaluation, Proofreading, analysis of Manuscript, Data collection, and visualization.

CONFLICTS OF INTEREST

All the Authors declare that there are no conflicts of interest.

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CONSENT

Written consent was taken from all the patients under study.

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Author Query???

AQ1: Kinly provide location