Research Article
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Comparison of goal-directed and standard therapy for hemodynamic management in heart transplantation surgery

Abstract

Background: Significant numbers of patients who undergo major surgery experience postoperative problems, the majority of which are preventable. It has been demonstrated that goal-directed therapy, a method for guiding clinicians in administering fluids, vasopressors, and inotropes, reduces mortality and postoperative complications. However, heart transplant patients were not exclusively investigated. This study focused on patients having heart transplant surgery, which compared the effects of goal-directed versus traditional fluid management.

Methods: Goal-directed and standard therapy were examined on 74 patients who had received heart transplantation and were randomly divided into two groups. Using Lidco's CO, CI, SVV, and SVR to track progress toward treatment goals, two groups were compared in terms of fluid repositioning and the use of vasoactive medications. We also compared secondary outcomes like AKI, Cardiac dysrhythmia, CVA, ICU length of stay, and 30-day survival.

Results: Both groups had similar baseline characteristics. The goal-directed therapy group had less fluid repositioning. AKI, Cardiac dysrhythmia, CVA, ICU stay, and 30-day survival rates did not differ significantly between the groups; however, Conventional patients spent more time in the ICU.

Conclusion: Our data showed that the time spent in the intensive care unit after a heart transplant can be cut in half using GDT. Adverse events occurred in both groups with no statistically significant difference. Preoperative goal-directed therapy needs further well-designed and adequately powered studies.

Keywords: Heart transplantation, Goal-directed therapy, Anaesthesia.

Volume 15 Issue 1 - 2023

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Received: December 21, 2022 | **Published:** January 17, 2023

Background

Cardiovascular disease is the leading cause of mortality in both men and women in the United States, and its prevalence is increasing due to obesity and hypertension. Despite improvements in the management of patients with heart failure, the rate of hospitalisation and readmission in the hospital due to heart failure continues to rise. For some of these patients, heart transplantation is a potential option.[1] The prognosis of patients with congestive heart failure is generally poor, and the 5-year survival reported in studies is less than 30%. However, heart transplant surgery has advanced substantially during the past decade. Patients aged 30-59 years have the best survival because these patients do not have ischemic cardiomyopathy.[2] The therapy of choice for people with severe heart failure is heart transplantation, a surgical procedure in which a failing heart is replaced with a healthy donor heart. A heart transplant is chosen as a therapy option when, despite medicine or other operations and treatments, the cardiac issue persists and there is an insufficient improvement.[1] The first heart transplant surgery was performed in 1967 by Christine Barnard in South Africa. In this procedure, the heart of Reese Darwall, a 25-year-old woman killed in a car accident, was placed in the chest of a 53-year-old man named Louis Joshua Washkansky. A team of 30 people performed the first transplant in nine hours. Lewis died of a lung infection 18 days after surgery.[3] Heart transplantation did not gain widespread clinical acceptance until the 1990s when more effective and sophisticated immunosuppression was introduced. In the 1990 decade, the need for a transplanted heart and the number of donors increased, so the annual number of heart transplant surgeries have reached approximately 4000 cases worldwide, where 2200 cases are performed in the United States, and Iran's share is about 220 patients annually.[4] Today, Iran is one of the top ten countries in the world in the field of organ transplantation, including heart transplants.[5] In the early years following heart transplantation, survival at one and five years was poor. Still, with the advancement of surgical techniques and immunosuppressive drugs, the probability of increasing the survival of the transplant in the first and fifth years increased to more than 80% and 90%, respectively.[6] Cardiomyopathy, Ischemic Diseases, Valve Diseases, Congenital Heart Problems, Recurrent and Dangerous Arrhythmias, Amyloidosis, Previous Heart Transplant Failure, and Severe Heart Failure (Classes 3 and 4 in the NYHA classification) with a severe reduction in EF fraction to less than 20% are among the common indications of heart transplantation.[7] Stroke and dementia, cancer in the last four years, AIDS, active infections such as hepatitis and associated diseases such as insulin-dependent diabetes, kidney failure, lung disease, liver, pulmonary artery hypertension, addiction and obesity are contraindications to heart transplant surgery.

A significant number of patients who have undergone major surgery have postoperative complications, many of which are preventable.[8] Identification of this group of patients may help find appropriate preventive measures.[9] Goal-directed therapy (GDT) utilises monitoring techniques to help guide clinicians with administering fluids, vasopressors, inotropes, or other treatments to patients in various clinical settings.GDT has been shown to reduce mortality and postoperative complications early, in the appropriate patient group, and with a well-defined protocol.[10,11] Heart transplantation is one of the world's riskiest surgeries, and the patient must wait a long time for the operation. In addition, the expenditures associated with this

endeavour are rather substantial. Therefore, it is preferable to take all necessary precautions to prevent complications and patient death during and after the operation (4). One of these precautious measures is using GDT to monitor the patient perioperatively. This method takes more factors into account compared to standard hemodynamic parameters (Blood Pressure-Spo2-Heart Rate) for Improving oxygen supply.[12] These parameters can include the following: Stroke Volume (SV), Cardiac Output (CO), Stroke Volume Variation (SVV) or Pulse Pressure Variation (PPV) and Cardiac Index (CI).

Shoemaker initially presented this strategy for enhancing oxygenation in 1980.[12] In his subsequent investigation, the researcher found that identifying patients at high risk for surgery with elevated hemodynamic parameters might minimise hospitalisation, morbidity, and mortality.[6] After surgery, tissue hypoxia can stimulate the systemic inflammatory response, which may not manifest clinically for several days. The GDT method employs flow-directed hemodynamic parameters to determine the use of inotropic fluids and drugs to maintain optimal circulation volume, blood supply and oxygen supply to the tissue.[12] Normal tissue blood flow decreases systemic inflammation, enhances organ function, and hence reduces surgical morbidity and death. Numerous RCT studies have demonstrated that GDT can improve outcomes in high-risk patients undergoing non-cardiac surgery. Due to the high risk of heart transplant surgery and the influence of hemodynamic circumstances on the better result, it appears reasonable to evaluate the effectiveness of this procedure in these situations.[13]

There is still no clear guideline about the preferred method for hemodynamic monitoring patients during organ transplantation. Anesthesiologists require a reliable tool for monitoring symptoms to determine Dosage, medication dose, and general management of patients. The primary objective of anesthesiologists during and after surgery is to achieve hemodynamic stability and ensure adequate perfusion and oxygen delivery for the patient. For hemodynamic control of patients, invasive and non-invasive monitoring techniques are used to facilitate the management of the patient's intravenous fluid requirements, and vasopressors and inotropes are used to maintain the patient's hemodynamic status.[14] Considering that previous studies have reported the positive effect of GDT in certain surgeries, and cardiac surgery is one of the high-risk surgeries, we decided to compare the outcome of heart transplant patients with standard monitoring methods and GDT to evaluate the effect of using the GDT method in reducing morbidity and mortality and improving outcome in these patients.

Methods

This study was performed as a randomised clinical trial. The study population was patients with heart disease referred to Imam Khomeini Hospital in Tehran in 2020-2021. The study sample was among patients who were candidates for heart transplantation due to heart failure. The sample size in each group was determined based on a similar study by Bastos et al. Based on the following formula in each group of 37 people. This study compared GDT and traditional fluid therapy in patients with heart failure in 2016. The rate of stay in ICU in the GDT group was 9.7 ± 19.9 and in the standard group was 9.7 ± 15.9.

$$A = \kappa nB \; and \; nB = \left(\frac{pA(1-pA)}{\kappa} + pB(1-pB) \right) \left(\frac{Z_{1-a} + Z_{1-b}}{pA - pB - \delta} \right)^2$$

nA=37

nB=37

margin=delta

kappa= 1

alpha=0.05

beta=0.20

Random blocking was employed to gather samples, and a table of random numbers determined the sequence of the codes. A questionnaire developed by the researcher is attached in the appendix.

Inclusion criteria consisted of dilated cardiomyopathy, ischemic cardiomyopathy, fractional ejection less than 15%, NYHA class IV patients unresponsive to the medical therapies and congenital heart disease unresponsive to medication or surgery.

The study exclusion criteria were patients weighing less than 40 kg and more than 120 kg, aged less than ten years and refusing to participate.

This clinical trial study was conducted after approval by the Research Council and authorisation from the University Ethics Committee to compare the two GDT and standard methods in heart transplant patients at Imam Khomeini Hospital in Tehran in 2020 and 2021. The study samples were the patients who were candidates for heart transplantation due to heart failure and entered the study after meeting the inclusion criteria (Table 1).

Table 1 NYHA classification

New York Heart Association	ACC/AHA guidelines
I: No symptoms	A: No structural damage High risk for developing HF
II: Symptoms with substantial activity	B: Structural abnormality No symptoms
III: Symptoms with minimal activity	C: Structural abnormality Previous or current symptoms
IV: Symptoms at rest	D: Refractory symptoms

This study was conducted on 74 patients. In accordance with the procedure of the heart transplant team at Imam Khomeini Hospital, all patients got identical medicines during induction and throughout the operation. In both groups, anaesthesia was administered according to the procedure of the operating room. After induction, a central venous catheter was inserted in the right jugular vein for volume infusion, transfusion, vasoactive drugs, and an intra-arterial catheter for invasive monitoring. CVP does not directly indicate left ventricular filling pressure. Still, in a person with normal right ventricular function and normal pulmonary pressure, it can reflect an estimate of left ventricular pressure. In the case of CVP, the trend is more significant than the absolute value.

Considering that all heart transplant surgeries were performed in Imam Khomeini Hospital, the surgeon and the anesthesiologist were similar between the two groups. In the operating room, patients were monitored according to their group. Group A was monitored with standard Iran Saadat Co. patient monitoring devices, whereas group B was monitored with LiDCO devices. If the inotropic medicine was required, epinephrine was administered with a diastolic blood pressure of 80 mmHg, systolic blood pressure of 100 mmHg, and central venous CVP (pressure) of 10 cmH2O.

The LiDCO plus system combines both innovative and new displays, showing the heart waveforms with very high accuracy of cardiac output (Figure 1).

Figure 1

Hemodynamics of patients were recorded once before induction, after induction every fifteen minutes up to one hour (before and after the cardiopulmonary pump every fifteen minutes up to two hours). Also, after surgery in the intensive care unit at 1 o'clock, hemodynamics were recorded as 2, 3, 6, 12, and 24. These parameters included MAP, BP and CVP in the standard group and CVP, MAP, BP, CO, CI, SVR and SVV in the GDT group.

In the standard group, fluid therapy was used during surgery if the SBP dropped by more than 20% of baseline or MAP fell below 60 mmHg. If the patient's potassium exceeded 4 mmol/L, normal saline serum was used instead of Ringer for five minutes. Starting at a dose of 0.05 mcg/kg/min and increasing to 0.1 mcg/kg/min if needed, the pump was used immediately if the patient still did not respond to treatment. In the case of bradycardia, dopamine was not administered, but a pacemaker was used; the epinephrine infusion was started at 0.1 mcg/kg/min and increased to 0.2 mcg/kg/min if necessary. In case of no clinical response, norepinephrine infusion was started at a dose of 0.05 mcg/kg/min and increased to 0.1 mcg/kg/min if there was no response, and IABP was used if there was no response.

In the GDT group, three situations could occur:

1. If SBP fell below 20% baseline and SVV was <10%, and if CO and SVR were normal, 100 ml of fluid (Ringer serum with potassium less than 4 mmol / L) was administered. Then, if CO was normal and SVV was still <10%, and SBP did not increase, 100 ml of fluid was repeated; if CO was low, inotropic (epinephrine) at a dose of 0.05 mcg/kg /min was infused.
2. If SBP decreased to less than 20% baseline and SVV was <10% if CO decreased, and SVR was normal, the first 100 ml of fluid (Ringer serum with potassium less than 4 mmol / L) is administered. In case of no inotropic response, epinephrine 0.05 mcg/kg/min was infused.
3. If SBP was reduced to less than 20% baseline and CO and SVR were low, inotropic (epinephrine at a dose of 0.05 mcg/kg/min) was initially infused (Figure 2).

In both groups, patients were transferred to the intensive care unit intubated and underwent mechanical ventilation with SIMV Mode. Patient wakening was performed based on normal neuromuscular strength and stability of the patient's hemodynamic condition (normal heart pumping and normal circulatory system). If the patient woke up and the patient's respiratory effort returned, the ventilator mode was adjusted to PSV.

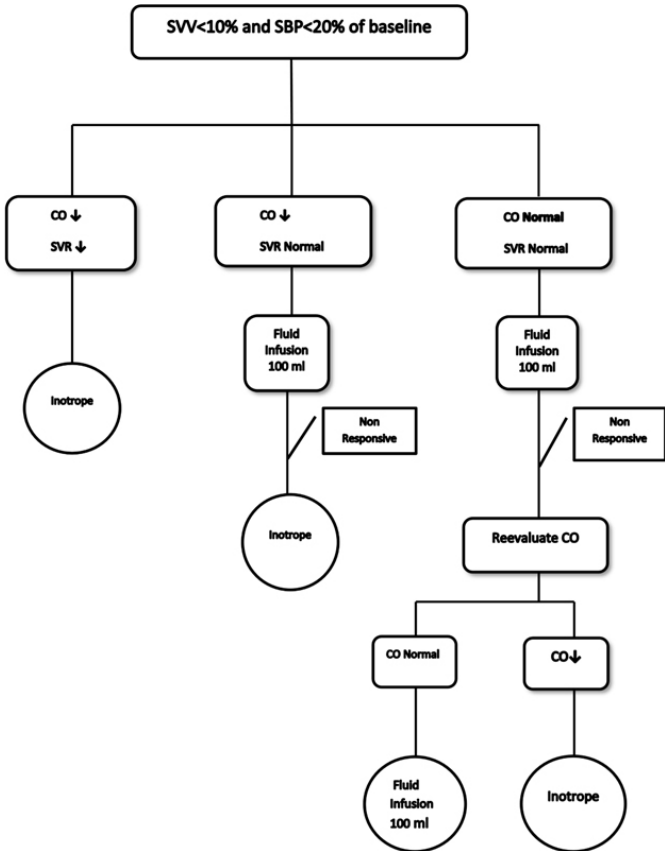

Figure 2

Criteria for patient extubation and weaning from a mechanical ventilator were as follows: The patient should have been fully awake with normal neuromuscular strength, should be hemodynamically stable with no arrhythmia, PH: 7.35-7.45, Po2> 100 mmHg, PaCo2: 35-45 (within physiological range); also, urine output should be more than 1 cc/kg/h.

After extubation, the patient was checked every 2 hours for probable extubation failure.

If the patient had an Intra-Aortic Balloon Pump (IABP) receiving a high dose of inotropes, cardiac output was less than 4 litres per minute (MAP <60 mmHg) and the patient had no respiratory effort, the SIMV mode was still maintained, and if the patient regained consciousness and the aforementioned conditions resolved, the PSV mode was used, and weaning process was initiated.

Criteria for discharge from the intensive care unit included the following:

The patient's hemodynamic condition must have been stable, the patient should be awake, and out of bed, the patient's inotropic drug must have been discontinued, the immunosuppressive drug (tacrolimus) should be well tolerated with an adjusted dose, and the patient should be in good condition in terms of neurological and clinical function.

The device used for group B for post-surgery management by the GDT method was a LiDCO device made in England. The hemodynamic

parameters recorded by this device included CI, CO, SVV, SVR, MAP, and CVP. These parameters were recorded before induction, after induction, and before the start of the pulmonary heart pump at intervals of every 15 minutes in 4 shifts and after the pulmonary heart pump at intervals of every 15 minutes up to a maximum of 8 shifts. The GDT group was also monitored with the LiDCO device in the intensive care unit for 24 hours after the operation.

Between groups A and B, factors such as length of ventilation (hours), hospitalisation time in an intensive care unit (days), general hospitalisation time (day), the dose of inotropic drug and frequency required to change the dose of the inotropic drug and serum therapy (millilitres) were compared. In addition, critical organ damage, including Cerebral Vascular Accident (CVA), Acute Kidney Injury (AKI according to KDIGO criterion), need for hemodialysis, and ventricular and atrial fibrillation was documented. Patients' 1-month follow-up survival report is also included in the article.

To collect information, researchers used a questionnaire (data form). Blinding was done only for a specialist examining the study's primary outcome. Therefore, the study was one-sided blind, and there was no possibility of blinding the other side (i.e. the anesthesiologist in the operating room).

At the end of the study, the data were entered into SPSS software version 25 and analysed. In descriptive statistics, central indices and dispersion were calculated for quantitative data (mean, standard deviation). In statistical data analysis, due to the small amount of statistical data, if the data were normal, an independent t-test was used to assess the effect of treatment in the two groups, and chi-square was used for qualitative variables.

Results

In this study, 74 individuals were evaluated; 26(70.3%) of the patients in both groups were male, while 11(29.7%) were female. The average age of the study sample was around 41.5 in both GDT and standard groups. Although the standard group had a significantly higher weight (p=0.044) than the GDT group (78.9 Vs 72.7 respectively), BMI in both groups was roughly the same. Other clinical variables can be seen in Table 2. ICU stay was expressed in days and was higher in the standard group(p=0.015).In contrast, there was not a statistically meaningful difference between mechanical ventilation time and hospital stay in the two groups; however, the standard group experienced a longer time.

Table 2

Variables	Standard Group Average(±SD)	GDT Group Average(±SD)	T	P
Age(Years)	41.4 (9.8)	42.3 (10.8)	0.384	0.702
Weight(Kg)	78.9 (14.8)	72.7 (10.8)	2.047	0.044
BMI	23.2 (2.6)	24.1 (2.9)	-1.363	0.177
ICU stay (Days)	5.4 (1.3)	4.5 (1.8)	2.485	0.015
Mechanical ventilation (Hours)	9.4 (2.2)	9.0 (7.0)	0.335	0.739
Hospital stay (days)	14.7 (7.3)	12.2 (9.1)	1.313	0.193
Inotropes required dose (Mcg/Kg/Min.)	0.126 (0.06)	0.119 (0.06)	0.488	0.627
Inotropes change (Times)	1.3 (1.1)	1.3 (1.6)	0.083	0.934
Average volume used(ml)	4075.7 (406.5)	3497.3 (569.5)	5.028	<0.001

Again, the required dose for inotropes was slightly higher in the standard group and was not statistically different. The urgency to change in inotropes' dose or drug was the same in both groups. The amount of fluid administered was significantly lower in the GDT group(<0.001).

This study investigated neurological complications including CVA and renal complications and cardiac dysrhythmias including AF and VF, but no difference was observed between the two groups (Table 3).

Table 3

Complications	Standard Group persons (Percentage)	GDT Group persons (Percentage)	All persons (Percentage)
AF	6 (28.6)	6 (20.0)	12 (24.4)
AKI	6 (28.6)	5 (25.0)	11 (26.8)
hemodialysis	0	2 (10)	2 (4.9)
CVA	4 (19)	3 (15)	7 (17.1)
VF	4 (19)	6 (30)	10 (24.4)
All	20 (100)	22 (100)	42 (100)
			P=0.548

Mean Arterial Pressure (MAP) at certain hours was recorded in both groups. According to explained protocol, the average set times for pre-induction MAP, pre-CPB MAP, post-CPB MAP, and ICU MAP were significantly higher in the standard group (P<0.05). Similarly, Pre-induction and pre-CPB CVP were substantially lower in the GDT group (P<0.05). However, post-CPB CVP were the same in both groups, and ICU CVP was higher in the GDT group (p<0.05) (Table 4).

Table 4

Variables	St	GDT	p
Pre-induction MAP	87.51(13.78)	76.75(15.75)	0.003
Pre-CPB MAP	78.44(11.88)	68.39(11.56)	0.0001
Post-CPB MAP	83.39(10.44)	75.36(13.40)	0.018
ICU MAP	84.32(9.72)	78.68(10.08)	0.022
Pre-induction CVP	13.70(6.07)	9.62(5.93)	0.005
Pre-CPB CVP	11.16(4.69)	9.10(5.82)	0.032
Post-CPB CVP	10.21(4.58)	10.84(5.26)	0.390
ICU CVP	9.91(4.49)	14.21(4.06)	0.0001

The rate of blood product transfusion was recorded in the two groups. The only difference was the rate of platelet transfusion, which was significantly higher in the GDT group (p = 0.027) (Table 5).

Table 5

Variables	St	GDT	p
PRBC	0.86(1.45)	1.27(1.53)	0.248
FFP	0.67(1.73)	4.75(1.29)	0.18
PLT	0.67(1.73)	2.27(3.92)	0.027

Thirty-day survival was followed in patients of the two groups, but no significant difference was observed between the two groups (Table 6).

Table 6

30-days survival	St Number (percentage)	GDT Number (percentage)	All
Yes	35 (94.6)	31 (83.8)	66 (89.2)
No	2 (5.4)	6 (16.2)	8 (10.8)
Total	37 (100)	37 (100)	72 (100)
			Exact Fisher=0.261

Discussion

Cardiovascular disease is the leading cause of death in both men and women in the United States, and its prevalence is increasing due to increased obesity and high blood pressure. Despite advances in managing patients with heart failure, hospitalisation and readmission rates for heart failure remain high. For some of these patients, heart transplantation is a potential option. The prognosis for patients with congestive heart failure is generally poor; the 5-year survival reported in studies is less than 30%. The choice of heart transplant as a treatment option is made when taking medication, or other surgeries and procedures have been done, but the heart condition is still persistent and has not improved enough. The main goal of anesthesiologists is to achieve hemodynamic stability and ensure adequate perfusion and oxygen delivery to the patient during and after surgery. Invasive and non-invasive monitoring techniques are used to control patients' hemodynamics. Control of the patient's intravenous fluid requirements is estimated, and vasopressors and inotropes are used to maintain the patient's hemodynamic status.

Since heart transplant surgery is a major and complex operation and despite the high vulnerability of patients who are candidates for this type, choosing the preferred method for managing their anaesthesia is very important. Considering that previous studies have reported the positive effect of GDT in some surgeries, we decided to compare the outcome of a heart transplant with two standard monitoring methods and GDT to evaluate the effect of using the GDT method in reducing morbidity and mortality and improving outcome in heart transplant patients.

The duration of ventilation did not differ between the two groups in our study, but this variable was lower in the other three studies in the GDT group.[15-17] In our study, it was observed that the duration of hospitalisation in the intensive care unit was shorter in the GDT group (P-value: 0.015). In five other studies,[15,16,18-20] the duration of hospitalisation in the GDT method was shorter, which is in line with our study. GDT reduces the problems caused by excessive fluid therapy and thus reduces the patient's stay in the hospital. However, despite lesser fluid in the GDT group, Bastos's study showed no difference in in-hospital stay of both groups.[21]

In the present study, the amount of fluid used in the standard group was higher. The Bastos study[21] observed this on the first day after surgery. Naturally, fluid therapy is more targeted using parameters such as CO and SVV and prevents volume overload in the patient. In the Smetkin study,[19] more colloids were utilised in the GDT group. No difference was observed in the Grocott study.[22]

Studies have shown that balanced fluid therapy can improve patient outcomes. Excess fluid therapy has many side effects (31). There was no difference between the two groups in our study regarding the side effects. In Vecino's study, also, there was no difference between the two groups. In our study, although fluid therapy was higher in the standard group, the documented side effects were not significantly different in the two groups, contrary to most previous studies.[17,20,23-26] This consequence may be due to the side effects we studied in our research. For example, in our study, pulmonary complications were not studied.

Excessive fluid therapy can cause pleural effusion and pulmonary oedema. Also, increasing the volume of extravascular fluid in the lungs reduces oxygen exchange. In addition, excessive fluid therapy can increase the kidneys' interstitial fluid due to decreased blood flow in the ischemic renal vessels (33,32). Excess fluid therapy also reduces liver function. Reduces coagulation and delays wound healing. It can also lead to increased intra-abdominal pressure and consequent gastrointestinal oedema. None of the above items was investigated in our study. Excess fluid therapy, in addition to the above, can lead to myocardial oedema and pericardial effusion and ultimately to a decrease in the contractile strength of the heart (32). In our study, atrial and ventricular fibrillation was examined, and no difference was seen between the two groups. Excessive fluid therapy can also lead to cerebral oedema (32). However, in our study, CVA has studied which four cases in the standard group and three patients in the GDT group were seen; this difference was not statistically significant. The incidence of this complication was no more than in similar studies.

In the present study, the dose and frequency of changes in the amount of inotropes (epinephrine) did not differ between the two groups. In the other two studies, it was observed that the duration of inotropic dependence was shorter in the GDT group.[15,16] However, in the Smetkin study,[19] the inotropic dose was higher in the GDT group. Maintaining cardiac output was compensated by inotropy instead of increasing fluid intake, and ultimately patients' outcomes were better, and hospital stays were reported to be shorter. In Bastos's study,[21] the dose of inotropic (dobutamine) was the same in both groups. In our study, the number of blood products received was also recorded and evaluated, which showed a significant difference only in the case of platelets. Platelet administration was higher in the GDT group. In the Bastos study,[21] only one patient in the GDT group received a PRBC unit.

In the present study, the one-month survival rate was evaluated, but no significant difference was seen between the two groups. There was no difference in some studies, [21,22] but in the study of Rhodes et al.,[27] The three-year survival rate was better in the GDT group. In addition, Cecconi[24] and FEDORA trial[17] reported lower mortality in GDT patients. Unlike Rhodes's study,[27] short-term survival (30 days) was studied in our study and others. Perhaps due to differences in follow-up time, this insignificant difference is observed.

Conclusion

In the present study, two methods of GDT and standard procedures for hemodynamic management and fluid therapy in heart transplant surgery in Imam Khomeini Hospital were compared to suggest a suitable method to reduce complications and increase survival and benefit for fluid therapy and hemodynamic management in these patients. It was concluded that the choice of the GDT method for managing postoperative fluid therapy could be an excellent solution to maintain the patient's optimal condition because, for example, the amount of hospitalisation in the intensive care unit was reduced by this method. This consequence can have many benefits, such as reduced complications from a prolonged stay in the ICU (such as delirium and nosocomial infections), resulting in reduced treatment costs and a shorter waiting list for this type of surgery. Advanced monitoring with the Lidco device can be an excellent guide for on-site fluid therapy. Given the criteria for SVR, CO, CI, and SVV, a safer choice can be made between fluid therapy or inotropic administration.

In this study, the extent and severity of some complications, such as pulmonary complications and wound infection, were not evaluated, which might have concealed some of the GDT effects on patients' outcomes. It is suggested that in future double-blind studies, larger sample size and longer duration be used to evaluate all complications, especially pulmonary complications, wound infection, metabolic complications, the analysis of arterial blood gases, and other cardiac complications.

Citation: Benisy R, Saberi K, Saberi H, et al. Comparison of goal-directed and standard therapy for hemodynamic management in heart transplantation surgery. *J Anesth Crit Care Open Access*. 2023;15(1):4–9. DOI: 10.15406/jaccoa.2023.15.00543

Acknowledgments

None.

Conflicts of Interest

None.

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