DOI: 10.1111/jocs.14691

ORIGINAL ARTICLE

JOURNAL OF CARDIAC SURGERY WILEY

Parameters affecting pleural drainage and management strategy after Fontan operation

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Abstract

Background: Prolonged pleural drainage is a common complication after undergoing the Fontan procedure. Although various protocols have been described, there is no definitive consensus for how to treat this complication.

Materials and Methods: Our primary aim was to determine the effect of the management strategy protocol on the duration of drainage and length of hospital stay. Our secondary aim was to determine the parameters affecting the need for prolonged drainage after the Fontan procedure. Ninety-two consecutive patients who underwent the Fontan procedure were retrospectively analyzed. A protocol-based postoperative management strategy was adopted in July 2018. Group 1 (n = 48) consisted of patients that underwent the procedure before the protocol was implemented. Group 2 (n = 44) consisted of patients that underwent the procedure after the protocol was implemented.

Results: The mean age was 5 years (interquartile range [IQR], 4.0-6.9); the mean body weight was 17.3 kg (IQR, 15.1-21.8). Statistically significant differences were found between the groups in terms of total drainage, duration of pleural drainage, prolonged drainage, and length of hospital stays (LOHS) ($P = .05$, $P = .04$, $P = .04$, $P = .04$, respectively). The multivariate analysis results showed that the application of the protocol was the only factor impacting prolonged drainage (OR, 2.46, 95% CI lower-upper: 1.03-5.86, $P = .04$).

Conclusion: Standardization and strict application of the medical treatment within a specific protocol without being affected by doctor-, nurse-, or patient-based factors increases the success rate of this procedure. After implementing the changes in the medical management strategy, total drainage and duration of pleural drainage and LOHS decreased, and the costs associated with these factors also decreased.

KEYWORDS

Fontan procedure, hospital stay, pleural drainage, protocol

Accepted as an oral presentation at the 19th National Pediatric Cardiology and Cardiac Surgery Congress.

1 | INTRODUCTION

Currently, the Fontan procedure is considered to be the best choice for separating the pulmonary and systemic circulatory systems and establishing near-normal systemic oxygen saturation in children with a single ventricle defect.[1] In the last several decades, advances in surgical techniques and postoperative patient care have led to a decrease in postoperative mortality and morbidity.[2,3] Prolonged intensive care unit (ICU) stays and length of hospital stays (LOHS) are frequently encountered. However, there is still no consensus regarding the prevention and treatment of prolonged drainage. Several protocols have been reported to reduce prolonged pleural drainage and hospital stays.[4-6]

Although the use of a standardized treatment protocol could directly affect the LOHS, there is a limited amount of data on this subject. Thus, we wanted to contribute to the literature by revealing the results of implementing the modified Wisconsin protocol that we began using in our clinic in July 2018. Our primary aim was to determine the effect of the protocol on the duration of drainage and the LOHS. Our secondary aim was to determine the parameters affecting prolonged drainage after the Fontan procedure.

2 | MATERIALS AND METHODS

2.1 | Patient population

With the approval of the Istanbul Mehmet Akif Ersoy Training and Research Hospital institutional ethics committee, 92 consecutive patients who underwent the Fontan procedure between January 2017 and December 2019 were retrospectively analyzed. A protocol-based postoperative management strategy was adopted in July 2018. That strategy was adapted from the Wisconsin protocol reported by Cava et al[4] and modified by Pike et al.[6] Group 1 (n = 48) consisted of patients that underwent the Fontan procedure before the protocol was implemented. Group 2 (n = 44) consisted of patients that underwent the Fontan procedure after the protocol was implemented. A total of 48 Fontan procedures were performed between January 2017, when the study began, and July 2018, when we started using the protocol. Before the study was terminated in 2019, 44 Fontan procedures had been performed. All the patients undergoing the Fontan procedure after July 2018 were included in the protocol. Patients who underwent hepatic re-routing and a single-stage Fontan procedure were also included in the study.

All the patients underwent cardiac catheterization before the Fontan procedure. The mean pulmonary artery pressure (mPAP), pulmonary vascular resistance (PVR), transpulmonic gradient (TPG), McGoon and Nakata indexes, right pulmonary artery and left pulmonary artery *z*-scores, and ventricular end-diastolic pressure were calculated. Echocardiography was used to evaluate ventricular function, atrioventricular (AV) valve insufficiency, and ventricular outflow tract obstruction. Postoperative drainage output, chest tube duration, reinsertion of the chest tube, mechanical ventilation, ICU stay, LOHS, and rehospitalization (within 30 days postoperatively) were recorded.

2.2 | Definitions

LOHS was defined as the time between the patient's procedure and discharge. Rehospitalization was defined as hospitalization within 30 days after the patient was postoperatively discharged from the hospital. Prolonged drainage was defined as the use of a chest tube for more than 1 week. Cardiopulmonary resuscitation (CPR), need for an extracorporeal membrane oxygenator (ECMO), an AV block requiring permanent pacemaker (PM) implantation, diaphragm paralysis, neurological complications (persistent at discharge), acute renal failure (ARF), and unplanned reoperation were considered as major adverse events (MAEs).[7] Catheter interventions in the postoperative period were defined as a reintervention. Hospital mortality was defined as mortality within the hospital or within the first 30 days postoperatively.

2.3 | Surgical technique

In our hospital, the extracardiac (EC) Fontan procedure is routinely performed for end-stage palliation. An intra-extracardiac (IEC) Fontan procedure is only performed when standard EC Fontan is not feasible, typically in patients with isomerism and unusual systemic and pulmonary venous patterns. The procedures were performed under normothermic or mild hypothermic cardiopulmonary bypass. Cardioplegic arrest was used only if a concomitant intracardiac procedure was required. The pulmonary arteries were reconstructed as necessary, using a xenograft pericardium, based on the cardiac catheterization and operative findings. The threshold for pulmonary artery reconstruction was very low.

At our clinic, fenestration is not performed routinely except in high-risk patients (in case of AV valve regurgitation and in cases with high PVR, end-diastolic pressure, and late Fontan patients). Four-millimeter fenestrations were performed in patients with central venous pressure (CVP) > 16 mm Hg and a TPG > 12 mm Hg at the end of the Fontan procedure.

2.4 | Protocol

We adopted the Fontan protocol inspired by the Wisconsin protocol, which was previously reported by Cava et al[4] and modified by Pike et al[6] (Table 1).

The protocol we use at our hospital differs from the Wisconsin and modified Wisconsin protocols, as follows:

We do not use warfarin due to our concerns about patient compliance after discharge. Instead, we initiated heparin infusion at the postoperative 6th hour. On the postoperative 1st day, subcutaneous enoxaparin was initiated. Aspirin is initiated during discharge. We prefer using lisinopril instead of enapril, and we routinely use sildenafil. If the drainage continues, fat is withdrawn from the diet except for medium-chain triglycerides, and total parenteral nutrition is initiated if necessary. We use catheter angiography for diagnosis and treatment if the drainage period exceeds 14 days.

TABLE 1 Istanbul Mehmet Akif Ersoy Training and Research Hospital, Fontan protocol (modified Wisconsin protocol)

1. Postoperative 6th hour, heparin initiated (infusion rate of 15 U/kg/h) if there was no bleeding (ceased at postoperative 1st day).
2. Postoperative 1st day enoxaparin (1 mg/kg/d) initiated (single dose/d, ceased at discharge).
3. Postoperative 1st day intravenous (iv) furosemide (1 mg/kg/d) initiated (switched to perioral (po) furosemide [1 mg/kg/d, two divided doses] after the drains were removed).
4. Lisinopril 0.1 mg/kg/d (po, single dose).
5. Spironolactone 1 mg/kg/d (po, two divided doses).
6. Aspirin 5 mg/kg/d (po, single dose).
7. Sildenafil 3 mg/kg/d (po, three doses).
8. 0.5 L/min nasal oxygen supply until the drains were removed.
9. Fluid restriction (80% of daily fluid requirement).
10. Low-fat diet (30% of daily calories from fat).
11. Chest tubes were removed when drainage decreased to 2 ml/kg/d.
12. If the need for drainage exceeded 1 wk, fat was withdrawn from the diet except for medium-chain triglycerides.
13. If drainage continued, oral feeding was ceased and total parenteral nutrition was initiated.
14. Catheter angiography was used to detect and correct the residual pathologies if the need for ongoing drainage exceeds 14 d or if it was necessary to create a transcatheter fenestration in the case of high Fontan pressure without a residual pathology.

Note: Adapted by the Wisconsin protocol, which was previously reported by Cava et al and modified by Pike et al.

2.5 | Statistical analyses

Statistical analyses were performed using SPSS software. Categorical variables are presented as frequency and percentage; the parametric continuous data are presented as mean ± standard deviation and the nonparametric continuous data are presented as median and interquartile ranges. For group comparisons, the independent samples *t* test was used for the parametric continuous variables, the Mann-Whitney *U* test was used for the nonparametric continuous data, and Pearson's χ^2 test was used for categorical data. To determine the predictive risk factors related to the dependent variable, univariate and multivariate analyses were performed. The factors having $P < .15$ in the univariate analysis were included in the multivariate logistic regression model. Independent risk factors were determined in the multivariate analyses. The Wald test was utilized to determine model appropriateness. In all the analyses, $P < .05$ was defined as statistically significant.

3 | RESULTS

3.1 | Demographic and preoperative hemodynamic parameters

Between January 2017 and December 2019, the Fontan procedure was performed on 92 patients. The mean age was 5 years (IQR, 4.0-6.9); the mean body weight was 17.3 kg (IQR, 15.1–21.8). Thirty-nine (42.4%) of the patients were male. Fifty-three (57.6%) of the patients were female. None of the patients had ventricular dysfunction. Except for the primary palliation method, no statistically significant difference was found between the groups in terms of demographic data and the hemodynamic and echocardiographic parameters (Table 2).

3.2 | Operative data

Fenestration was only performed in three (3.3%) patients during the procedure. There was no statistically significant difference between the groups in terms of cardiopulmonary bypass time (CPB) time, fenestration rate, and aortic cross-clamp (ACC) time ($P = .19$, $P = .51$, $P = .31$, respectively). Forty-five (48.9%) patients underwent an additional concomitant procedure. Twenty-two (23.9%) patients had pulmonary artery patch arterioplasty, 20 (21.7%) underwent repair of an AV valve, and one (1%) underwent repair of an aortic valve. Ventricular outflow tract obstruction repair was performed in two (2.2%) patients.

3.3 | Postoperative data

3.3.1 | Drainage and LOHS

Although both Group 1 and Group 2 had similar hemodynamic and preoperative features and fenestration rates, the total drain output, duration of pleural drainage, prolonged drainage, and LOHS were lower in Group 2 ($P = .05$, $P = .04$, $P = .04$, $P = .04$, respectively). Although the mean total drain output was 111 mL/kg (IQR, 56-171) in Group 1, it was 85 mL/kg (IQR, 60-104) in Group 2 ($P = .05$). The mean duration of pleural drainage was 10 days in Group 1 and 7.8 days in Group 2 ($P = .04$). Prolonged drainage was observed in 35 (72.9%) patients in Group 1 and 23 (52.3%) patients in Group 2 ($P = .04$); the duration of drainage was 15 days (IQR, 11-21) in Group 1 and 12 days (IQR,8-19) in Group 2 ($P = .04$). No statistically significant difference was observed between the groups in terms of the incidence of chest tube reinsertion ($P = .84$) (Table 3).

3.4 | Mortality and morbidity

Catheter angiography was performed in seven (7.6%) patients during the postoperative period. Diagnostic angiography was performed in three (3.2%) patients, and the remaining four patients underwent transcatheter fenestration. A statistically significant difference was found between the groups in terms of reintervention ($P = .04$). In Group 2, four (9%) patients had transcatheter fenestration; in all four, the drainage was reduced and the patients were discharged. No patients in Group 1 had transcatheter fenestration (Table 2). Reoperation was performed in 13 (14.1%) patients. Reoperations were performed for bleeding, cardiac tamponade, and Fontan takedown. No statistically significant difference was found between the groups in terms of the need for reoperation ($P = .61$) (Table 2).

TABLE 2 Patient demographics and hemodynamic parameters

Variables, mean ± SD/median (IQR)/n (%)	All patients (n: 92)	Group I (n: 48)	Group II (n: 44)	*P-value*
Age	5.0 (4.0-6.9)	5.0 (4.0-6.5)	4.9 (4.0-7.0)	.81
Weight	17.3 (15.1-21.8)	16.8 (14.9-20.7)	17.5 (16.0-22.2)	.17
BSA	0.7 (0.6-0.8)	0.7 (0.6-0.8)	0.7 (0.7-0.8)	.11
Gender				.57
Male	39 (42.4)	19 (39.6)	20 (45.5)	
Fontan timing				.36
Primary	9 (9.8)	6 (12.5)	3 (6.8)	
Staged	83 (90.2)	42 (87.5)	41 (93.2)	
Primary diagnosis				.43
TA	25 (27.2)	16 (33.3)	9 (20.5)	
DILV	18 (19.6)	12 (25.0)	6 (13.6)	
U-AVSD	16 (17.3)	6 (12.5)	10 (22.7)	
Mitral atresia	4 (4.3)	2 (4.2)	2 (4.5)	
HLHS	2 (2.2)	2 (4.2)	0	
IVS-PA	8 (8.7)	3 (6.3)	5 (11.4)	
DORV	12 (13)	5 (10.5)	7 (15.9)	
c-TGA	5 (5.4)	1 (2.1)	4 (9.1)	
Ebstein's anomaly	2 (2.2)	1 (2.1)	1 (2.3)	
Ventricle type				.80
Right ventricle	26 (28.3)	13 (27.1)	13 (29.5)	
Left ventricle	61 (66.3)	33 (68.8)	28 (63.6)	
Non-biventricular type	5 (5.4)	2 (84.2)	3 (6.8)	
Initial palliation type to adjust pulmonary blood flow				.03*
No palliation	40 (43.5)	24 (50.0)	16 (36.4)	
Shunt	27 (29.3)	10 (20.8)	17 (38.6)	
Pulmonary artery banding	18 (19.6)	12 (25.0)	6 (13.6)	
Norwood procedure	2 (2.2)	2 (4.2)	0	
PDA stenting	4 (4.3)	0	4 (9.1)	
Hybrid Norwood procedure	1 (1.1)	0	1 (82.3)	
Hemodynamic parameters				
mPAP	12 (10-13)	12 (10-14)	11 (10-13)	.28
PVR	1.8 ± 1.0	2.0 ± 1.0	1.7 ± 1.0	.15
TPG	5.0 (4.0-6.0)	5.0 (4.0-6.0)	4.5 (4.0-7.0)	.63
McGoon index	2.2 ± 0.6	2.1 ± 0.5	2.2 ± 0.6	.70
Nakata index	245 (199-334)	245 (210-318)	241 (176-406)	.80
Atrioventricular valve regurgitation	20 (21.7)	10 (20.8)	10 (22.7)	.83
Rhythm				.58
Sinus	87 (94.6)	46 (95.8)	41 (93.2)	
Pacemaker existence	5 (5.4)	2 (4.2)	3 (6.8)	
Ventricular outflow tract obstruction	2 (2.2)	0	2 (4.5)	.14
Aristotle comprehensive score	11 (11-11)	11 (11-11)	11 (11-12)	.56
Pulmonary artery distortion	22 (23.9)	10 (20.8)	12 (27.3)	.47

Abbreviations: BSA, body surface area; c-TGA, corrected transposition of great arteries; DILV, double inlet left ventricle; DORV, double outlet right ventricle; HLHS, hypoplastic left heart syndrome; IQR, interquartile range; IVS-PA, intact ventricular septum-pulmonary atresia; mPAP, mean pulmonary artery pressure; PDA, patent ductus arteriosus; PVR, pulmonary vascular resistance; TA, tricuspid atresia; TPG, transpulmonic gradient; U-AVSD, unbalance atrioventricular septal defect.
*Statically signifficant.

TABLE 3 Operative findings

Variables, median (IQR)/n (%)	All patients (n: 92)	Group I (n: 48)	Group II (n: 44)	*P-value*
Main surgical procedure				.93
Fontan	88 (95.7)	46 (95.8)	42 (95.5)	
Hepatic re-routing	4 (4.3)	2 (4.2)	2 (4.5)	
Fontan type				.03*
Extracardiac	88 (95.7)	48 (100.0)	40 (90.9)	
Intra-extracardiac	4 (4.3)	0	4 (9.1)	
Fenestration	3 (3.3)	1 (2.1)	2 (4.5)	.51
Hypothermia	35 (35-36)	35 (34-36)	35 (35-35)	.27
CPB time	97 (72-131)	105 (74-126)	86 (69-132)	.19
Aortic cross-clamp time	40 (17-73)	23 (17-69)	50 (18-90)	.31
Surgery in beating heart	48 (46.7)	23 (47.9)	25 (56.8)	.15

Abbreviations: CPB, cardiopulmonary bypass; IQR, interquartile range
*Statically signifficant.

One (1.1%) patient in Group 1 and two (2.2%) patients in Group 2 underwent reoperation, and fenestrations were performed. In the two (2.2%) patients who underwent reoperation for suspicion of cardiac tamponade, fenestration was performed because the Fontan pressure was greater than 16 mm Hg.

The overall hospital mortality was 5.4%. There was no statistically significant difference between the groups in terms of mortality and MAE ($P = .58$ and $P = .43$, respectively) (Table 4).

3.5 | Parameters affecting drainage

In the multivariate analysis, the application of the protocol was observed to be the only factor that reduced drainage (OR, 2.46; 95% CI lower and upper, 1.03–5.86; $P = .04$) (Table 5).

4 | CONCLUSIONS

Our protocol-based postoperative management strategy was adapted from the Wisconsin protocol reported by Cava et al[4] and modified by Pike et al.[6] We began using the modified Wisconsin protocol in July 2018. Before that time, we did not have a standard treatment protocol. After July 2018, factors, such as more clinical experience and better patient selection, might have had an impact on the results. Moreover, while only a small number of IEC Fontan procedures were performed, this might have caused heterogeneity. We have recently performed fenestration to the prolonged pleural drainage patients with a lower threshold. Accordingly, in our protocol group much more fenestrations were performed. But these fenestrations had been performed only in case of prolonged drainage and this had not affected the prolonged drainage incidence. However, we had been performing the fenestration with a lower threshold, that might have affected the total drainage time. This study aimed to examine the effect of implementing a standardized treatment protocol early on after the Fontan procedure on prolonged drainage and LOHS. Our main findings were that the use of a standardized treatment protocol after the Fontan procedure reduced the total drainage amount, decreased the duration of pleural drainage and the need for prolonged drainage, and shortened the LOHS.

Various protocols that were previously used to reduce total drainage and the duration of pleural drainage have been reported in the literature. First, Cava et al[4] published their protocols to reduce pleural drainage. After initiating the protocol, they reported that the duration of pleural drainage and LOHS decreased in the protocol group.[4] Sunstrom et al published the PORTLAND protocol, which includes peripheral vasodilation, oxygen, fluid restriction, a modified surgical technique, low-fat diet, anticoagulation, and diuretic therapy without ventilation.[7] In the PORTLAND protocol, routine fenestration is recommended in addition to the medical treatment. They also reported that the LOHS was shortened and the total drainage was reduced.[7] Pike et al[6] published their own postoperative medical management strategies referring to it as the Modified Wisconsin protocol. This protocol was a modified version of the protocol reported by Cava et al.[4] That study reported that the duration of pleural drainage, prolonged drainage, and LOHS were decreased.[6] Although operative data (CPB and ACC times) were not considered, all these studies reported that a standardized treatment protocol improved the outcomes. In our study, we found no difference in terms of the preoperative and intraoperative variables and the need to perform fenestration. The total drainage and LOHS were decreased by implementing a standardized treatment protocol. Total drainage (111 vs 85 mL/kg), LOHS (15 vs 12 days), duration of pleural drainage (10 vs 7.8 days), and incidence of prolonged drainage (35 vs 23) were all lower in the protocol group (Group 2).

There is no consensus regarding the use of a fenestrated Fontan, and the decision to create fenestrations has been associated with institutional clinical experience and personal preferences. Toncu et al[8] in their meta-analysis, suggest performing the fenestration on high-risk Fontan patients or to the patients' whose intraoperative hemodynamic

TABLE 4 Postoperative outcomes

Variables, median (IQR)/n (%)	All patients (n: 92)	Group I (n: 48)	Group II (n: 44)	*P-value*
Drainage amount				
Total	90 (54-132)	111 (56-171)	85 (60-104)	.05*
Right-chest tube	51 (26-85)	64 (26-109)	48 (25-61)	.08
Left-chest tube	23 (13-45)	25 (11-51)	24 (14-33)	.48
Mediastinal tube	13 (8-24)	10 (7-17)	17 (9-24)	.09
Type of drainage fluid				.14
Serous	90 (97.8)	48 (100.0)	42 (95.5)	
Chylous	2 (2.2)	0	2 (4.5)	
Duration of drainage tube existence	8 (6-12)	10.5 (6-14)	7,8 (6-11)	.04*
Prolonged drainage tube existence	57 (62)	35 (72.9)	23 (52.3)	.04*
Reimplantation of drainage tube due to pleural effusion	7 (7.6)	4 (8.3)	3 (6.8)	.84
TPN needing	4 (4.3)	2 (4.2)	2 (4.5)	.93
Pleurodesis needing	2 (2.2)	1 (2.1)	1 (2.3)	.95
Delayed sternal closure	2 (2.2)	0	2 (4.5)	.14
Peritoneal dialysis need	3 (3.3)	1 (2.1)	2 (4.5)	.51
Respiratory troubles				.84
Pulmonary complication	11 (12.0)	5 (10.4)	6 (13.6)	
Re-intubation due to atelectasis	2 (2.2)	1 (2.1)	1 (2.3)	
Tracheostomy needing	1 (1.1)	0	1 (2.3)	
Arrhythmia				.55
Transient atrioventricular block	3 (3.3)	2 (4.2)	1 (2.3)	
JET	1 (1.1)	1 (2.1)	0	
Infection				.30
Sepsis	4 (4.3)	1 (2.1)	3 (6.8)	
Mediastinitis	1 (1.1)	0	1 (2.3)	
Sternal detachment	3 (3.3)	0	3 (6.8)	.07
CPR need	2 (2.2)	1 (2.1)	1 (2.3)	.95
ECMO need	1 (1.1)	1 (2.1)	0	.34
Neurological complication	1 (1.1)	0	1 (2.3)	.29
Diaphragm paralysis	3 (3.3)	2 (4.2)	1 (2.3)	.61
MAE	20 (21.7)	12 (25.0)	8 (18.2)	.43
In-hospital mortality	5 (5.4)	2 (4.2)	3 (6.8)	.58
Readmission to the hospital	8 (8.7)	4 (8.3)	4 (9.1)	.90
Reintervention				.04*
For fenestration	4 (4.3)	0	4 (9.1)	
Diagnostic	3 (3.3)	1 (2.1)	2 (4.5)	
Reoperation				.61
For fenestration	3 (3.3)	1 (2.1)	2 (4.5)	
Bleeding revision	6 (6.5)	4 (8.3)	2 (4.5)	
Pericardial effusion/ tamponade	3 (3.3)	1 (2.1)	2 (4.5)	
Fontan takedown	1 (1.1)	1 (2.1)	0	
Ventilation time	6 (4-15)	6 (4-16)	6 (4-12)	.67
Length of ICU stay	3.5 (2.0-5.0)	3 (2-5)	4 (2-6)	.34
Length of hospital stay	13 (9-20)	15 (11-21)	12 (8-19)	.04*

Abbreviations: CPR, cardiopulmonary resuscitation; ECMO, extracorporeal membrane oxygenator; ICU, intensive care unit; IQR, interquartile range; JET, junctional ectopic tachycardia; MAE, major adverse event; TPN, total parenteral nutrition.
*Statically signifficant.

parameters reveals a high risk. Also Bouhout et al[9] emphasized that the fenestration may lead to a shorter drainage time but has no effect on early mortality and long-term results, in this respect they recommend the fenestration only for high-risk patients. Regardless of the anatomical subtype, we adopted the nonfenestrated EC Fontan policy, and we preferred to fenestrate only the high-risk patients (pathologies with AV valve regurgitation and those with high PVR, high-end diastolic pressure, and late Fontan patients).

In a study investigating the parameters affecting drainage after EC Fontan, Gupta et al[10] showed that preoperative low oxygen saturation level, long CPB duration, small conduit size, and postoperative infection were risk factors for prolonged drainage. Salvin et al[11] reported that age, PVR, preoperative CVP, postoperative CVP, postoperative left atrial pressure, CPB duration, high-volume resuscitation, and a high inotropic score were associated with prolonged recovery. Some studies have reported that right ventricular morphology, hypoplastic left heart syndrome, and not performing fenestration are related to prolonged drainage and prolonged LOHS.[12,13] It was thought that early extubation was associated with decreased drainage time and a shorter hospital stay.[14] It has also been reported that the drainage period was shorter for the IEC Fontan procedure than the EC Fontan procedure.[15] In our study, the absence of a standardized treatment protocol was determined as a risk factor for prolonged drainage.

The findings in our study are comparable to those reported for other Fontan management protocols.[4-6] Our study was conducted over a period of 3 years. Moreover, it was conducted using two demographically similar groups that were homogeneous in terms of the hemodynamic and preoperative parameters. These features make the study's findings more valuable. The routine use of the protocol eliminated confusion about drain removal. The decrease in the length of the time required to use the drain caused concerns about increasing the rate of rehospitalization due to pleural effusions during follow-ups. However, we found no difference between the groups in terms of chest tube reinsertion. We did not routinely use nasal oxygen, sildenafil, a low-fat diet, or fluid restriction until 6 weeks after discharge, but only in selected patients. Now, we are using these routinely. Another innovation in our medical management strategy was to increase the doses of furosemide according to the protocol. This decreased the incidence of pleural effusions and shortened the LOHS after the Fontan procedure.

TABLE 5 Univariate and multivariate analysis for prolonged drainage duration

Univariate		Variables		*P*-value
		No-applied protocol		.04
		Norwood type palliation		.11
		CPB duration		.14
Multivariate	**Variables**	**OR**	**95% CI lower and upper**	***P*-value**
	No-applied protocol	2.46	1.03-5.86	.04

Abbreviation: CPB, cardiopulmonary bypass.

Prolonged pleural drainage after the Fontan procedure is a common complication that can sometimes require reoperation and reintervention. Standardization and strict application of the medical treatment within a specific protocol, without being affected by doctor-, nurse-, or patient-based factors, increases its chances of success. After changing our medical management strategy, in addition to the decrease in the total drainage and duration of pleural drainage, the LOHS was shortened, and the costs associated with these factors also decreased.

5 | STUDY LIMITATIONS

This study has some limitations. The single-center and retrospective study design is the most important limitation. We began using the modified Wisconsin protocol in July 2018. Before that time, we did not have a standard treatment protocol. After implementing the protocol, factors, such as increased clinical experience and better patient selection, might have had an impact on the results. Furthermore, although only a small number of IEC Fontan procedures were performed, they might have caused heterogeneity. Thus, studies with a more homogeneous and larger sample of patients are needed.

CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

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How to cite this article: Ergün S, Yildiz O, Ayyıldız P, et al. Parameters affecting pleural drainage and management strategy after Fontan operation. *J Card Surg*. 2020;35:1556–1562. https://doi.org/10.1111/jocs.14691