Parameters affecting pleural drainage and a management strategy after Fontan operation

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Abstract

Background: Prolonged pleural drainage after the Fontan procedure is a common complication. Various protocols have been described, but there is no definitive consensus for the treatment of this complication. Materials and Methods: Our primary aim was to determine the effect of the protocol on the duration of drainage and hospital stay. Our secondary aim was to determine parameters affecting prolonged drainage after the Fontan procedure. Ninety two consecutive patients who underwent the Fontan operation retrospectively analyzed. A protocol-based postoperative management was adopted at July 2018. Patients operated before the protocol were defined as Group 1(n=48), and patients operated after the protocol were defined as Group 2(n=44). Results: The mean age was 5(IQR 4.0-6.9) years the mean body weight was 17.3 (IQR 15.1-21.8) kg.There were statistically significant differences between groups in terms of total drainage, duration of pleural drainage, prolonged drainage and, LOHS(p=0.05,p=0.04, p=0.04,p=0.04,respectively). In the multivariate analysis, the application of the protocol was observed to be the only factor for prolonged drainage (OR:2.46, 95% CI Lower-Upper:1.03-5.86,p=0.04). 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. After the changes in our medical management strategy, along with the decrease in total drainage and duration of pleural drainage, LOHS was also reduced, of course together with a reduction in the cost. Key Words: Fontan, pleural drainage, hospital stay, protocol

Introduction:

The Fontan procedure, currently, has been considered as the best choice for children with single ventricle physiology for separating the pulmonary and systemic circulations and establishing anear-normal systemic oxygen saturation (1). In the last decades, advances in surgical techniques and in postoperative patient careled to a decrease in postoperative mortality and morbidity (2,3). Prolonged intensive care unit (ICU) and lenght of hospital stays (LOHS) are frequently encountered. However, stil there is no consensus regarding the prevention and treatment of prolonged drainage. There have been several reported protocols to reduce prolonged pleural drainage and hospital stay (4-6). The use of a standardized treatment protocol could directly affect the length of hospital stay. However, the data on this subject was insufficient. For this purpose, we wanted to contribute to the literature by revealing the results of the modified Wisconsin protocol that we started to use in our clinic at July 2018. Our primary aim was to determine the effect of the protocol on the duration of drainage and hospital stay. Our secondary aim was to determine parameters affecting prolonged drainage after the Fontan procedure.

Materials and Methods

Patient Population:

With the approval of the institutional ethics committee, 92 consecutive patients who underwent the Fontan operation between January 2017 and December 2019 were retrospectively analyzed. A protocol-based postoperative management was adopted at July 2018. Patients operated before the protocol were defined as Group 1 (n = 48), and patients operated after the protocol were defined as Group 2 (n = 44). Patients who underwent hepatic re-routing and a single-stage Fontan procedure were also included in the study.

All patients underwent a cardiac catheterization before Fontan procedure. 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, ventricular end-diastolic pressure were calculated. In echocardiographic examination, ventricular functions, atrioventricular valve insufficiency, ventricular outflow tract obstruction were evaluated. Postoperative drainage output, chest tube duration, reinsertion of chest tube, mechanichal ventilation, ICU and LOHS and rehospitalization (within 30 days postoperatively) were recorded.

Definitions:

The length of hospital stay was defined as the time between the operation and the discharge of the patient. Re-hospitalization was defined as hospitalization within 30 days after the discharge of the patient postoperativelyfrom the hospital. Prolonged drainage was defined as chest tube duration more than a week. Cardiopulmonary resuscitation (CPR), need forextracorporeal membrane oxygenator (ECMO), atrioventricular(AV) block requiring permanent pacemaker (PM) implantation, diaphragm paralysis, neurological complication (persistent at discharge), acute renal failure (ARF) and unplanned reoperation were considered as MAE (7). Catheter interventions in the postoperative period were defined as reintervention. Hospital mortality was defined as mortality within the hospital or within the first 30 days postoperatively.

Surgical Technique: In our hospital, extracardiac (EC) Fontan procedure has been routinely performedfor end-stage palliation. An intra-extracardiac (IEC)Fontan operationwas performed only when standard extracardiac Fontan was not feasible, typically asin patients with isomerismand unusual systemic and pulmonary venous patterns. Procedures were performedunder normothermic or mild hypothermic cardiopulmonary bypass. Cardioplegic arrest was used only if concomittant intracardiac procedure was required. The pulmonary arteries were reconstructed as necessary, using xenograft pericardium, based on the cardiac catheterization and operative findings. The threshold for pulmonary artery reconstruction was very low.

In our clinic, fenestration has notbeen performed routinely except in high-risk patients (in case of atrioventricular valve regurgitation and those with high PVR, end-diastolic pressure and delayed patients). Four milimetres fenestrations were performed in patients with central venous pressure (CVP) higher than 16 mmHg and transpulmonic gradient (TPG) more than 12 mmHg at the end of the Fontan procedure. In addition, in patients with a CVPvalue between 14-16 mmHg, fenestration was not performed, instead the right atrium and Fontan tube were brought together by a purse stich to be used for opening a fenestration via transcatheter route if required. This region was also marked with radio-opaque pacemaker wires to guide the possible transcatheterintervention (Figure 1-4).

Protocol:

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

Istanbul Mehmet Akif Ersoy Training and Research Hospital, Fontan protocol (Modified Wisconsin protocol)

Postoperative 6^{th}hour, heparin initiated (infusion rate of 15 U/kg/hour) if there was no bleeding (ceased at postoperative 1

The protocol we use differs from Wisconsin and modified Wisconsin protocols:

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

Statistical analyses

Statistical analyses were performed using SPSS software. Categorical variables were defined as frequency and percentage, while parametric continuous data as mean±standard deviation, non-parametric continuous data as median and interquartile ranges. For group comparisons, Independent sample T test was used for parametric continuous variables; whereas, Mann Whitney U test for non-parametric continuous data, Pearson Chi-Square test for categorical data. In order to determine predictive risk factors related to the dependent variable, univariate and multivariate analyses were performed. The factors having a p value < 0.15 in the univariate analysis included multivariate logistic regression model. Independent risk factors were determined in the multivariate analyses. Wald test was utilized for model appropriateness. p value < 0.05 was defined as a statistical significance in all analyses.

Results:

Demographic and preoperative hemodynamic parameters

Between January 2017 and December 2019, Fontan operation was performed in 92 patients. The mean age was 5 (IQR 4.0-6.9) years, the mean body weight was 17.3 (IQR 15.1-21.8) kg. Thirty nine (42.4%) of the patients were male. None of the patients had ventricular dysfunction. Except the primary palliation method, no statistically significant difference was found between the groups in terms of demographic data, hemodynamic and echocardiographic parameters (Table 1).

Operative data:

Fenestration was performed in only three (3.3%) patients during the operation. There was no statistically significant difference between the groups in terms of cardiopulmonary bypass time (CPB) time, fenestration and aortic cross clemp (ACC) time ($p = 0.19$, $p = 0.51$, $p = 0.31$, respectively). Forty five (48.9%) patients underwent an additional concomittant procedure. Twenty two (23.9%) patients had pulmonary artery patch arterioplasty, 20 (21.7%) patients underwent repair of an atrioventricular valve and one (1%) patient repair of an aortic valve. Ventricular outflow tract obstruction repair were performed in two (2.2%) patients.

Postoperative data:

Drainage and hospital stay:

While both groups had similar haemodynamic and peroperative features and fenestration rates, in Group 2; total drain output, duration of pleural drainage, prolonged drainage and LOHS were lower (p=0.05, p=0.04, p=0.04, p=0.04, respectively). While the mean total drain output was 111 (IQR 56-171) ml / kg in Group 1, it was 85 (IQR 60-104) in Group 2 (p=0.05). The mean duration of pleural drainage was 10 days in Group 1 and 7.8 days in Group 2 (p=0.04). Prolonged drainage was observed in 35 (72.9%) patients in Group 1 and in 23 (52.3%) patients in Group 2 (p=0.04). While it was 15 (IQR 11-21) days in Group 1, it was 12 (IQR 8-19) days in Group 2 (p=0.04). There was no statistically significant difference between the groups in terms of the incidence of chest tube reinsertion (p=0.84) (Table 2).

Mortality and morbidity:

Catheter angiography was performed in seven (7.6%) patients at the postoperative period. Diagnostic angiography was performed in three (3.2%) patients, and the remaining four patients underwent transcatheter fenestration. There was statistically significant difference between groups in terms of reintervention (p=0.04). In Group 2, four (9%) patients had transcatheter fenestration, whereas in Group 1, no patient had transcatheter fenestration (Table 2). These four (9%) patients drainage was reduced and they were discharged.

Reoperation was performed in 13 (14.1%) patients. Reoperations were performed for bleeding, cardiac tamponade and Fontan takedown. There was no statistically significant difference between groups in terms of reoperation (p=0.61) (Table 2). One (1.1%) patient in Group 1 and two (2.2%) patients in Group 2 were reoperated and fenestrations were performed. In two (2.2%) patients who were reoperated for suspicion of cardiac tamponade fanestration was performed because of Fontan pressure was measured above 16 mmHg.

The overall hospital mortality was 5.4%. There were no statistically significant difference between the groups in terms of mortality and MAE (p=0.58, p=0.43 respectively) (Table 3).

Parameters affecting drainage: In the multivariate analysis, the application of the protocol was observed to be the only factor for reduced drainage (OR: 2.46, 95% CI Lower and Upper: 1.03-5.86, p= 0.04) (Table 4).

Comment:

In this study, the aim was to examine the effect of application of a standardized treatment protocolearly on after the Fontan procedure, on prolonged drainage and LOHS. Our main findings included that the use of a standardized treatment protocol reduced the total drainage amount, duration of pleural drainage, prolonged drainage and LOHS after the Fontan procedure.

Various protocols that were previously used to reduce total drainage and the duration of pleural drainage have been reported in the literature. First, Cava and colleagues published their protocols to reduce pleural drainage. After the initiation of the protocol they reported that the duration of pleural drainage and LOHS shortened in the protocol group (4). Sunstrom et al, published another protocol called PORTLAND protocol which includes peripheral vasodilation, oxygen, fluid restriction, a modifiedsurgical technique, low-fat diet, anticoagulation anddiuretic therapywithout ventilation. In this protocol, routine fenestration was recommended in addition to the medical treatment. They alsoreported in their study that, the LOHS and the total drainagewas shortened (7). Pike et al, published their own postoperative medical management strategies under the name of Modified Wisconsin protocol. This protocol was a modified version of the protocol reported by Cava et al. In this study, it was reported that theduration 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 there were no difference in terms of preoperative and intraoperative variables and performing fenestration. The total drainage and LOHS were reduced by application of 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.

There has been no consensus regarding the use of a fenestrated Fontan and the decision of fenestration has been associated with institutional experience and personal preferences. Regardless of the anatomical subtype, we adopted the non-fenestrated EC Fontan policy and preferred to fenestrate only the high-risk patients (pathologies withatrioventricular valve regurgitation and those with high PVR, high end diastolic pressure and delayed patients). A standardized treatment protocol together with selective use of fenestration did provide a hospital stay below average and with the marking method used during surgery, transcatheter fenestration opening was possible without a need for surgery.

In a study where parameters affecting drainage after EC Fontan were investigated, Gupta et al. showed that preoperative low oxygen saturation level, long CPB duration, small conduit size and postoperative infection were risk factors for prolonged drainage (8). In their study, Salvin et al. reported that age, PVR, preoperative CVP, postoperative CVP, postoperative left atrial pressure, CPB duration, high volume resuscitation and high inotropic score were associated with prolonged recovery (9). There are publications reporting that right ventricular morphology, HLHS and not to perform fanestration related to prolonged drainage and prolonged LOHS (10,11). It was thought that early extubation was associated with shorter drainage time and hospital stay (12). There were also articles reporting that IEC Fontan procedure was related with shorter drainage period than the EC Fontan procedure (13). In our study, absence of a standardized treatment protocol wasdetermined as a risk factor for prolonged drainage.

The findings in this study were comparable to other Fontan management protocols (4-6). Our study was conducted in aperiod of 3 years. The study was conducted between two demographically similar groups which were homogeneous in terms of hemodynamic and peroperative parameters. These features make the study more valuable. The routine use of the protocol, eliminated the confusions about drain removal. The shortening of the stay of the drain caused concerns of increase in rate of re-hospitalization due to pleural effusions during follow-ups. However, there was no difference between groups regarding chest tube reinsertion. We were not routinely using nasal oxygen, sildenafil, low-fat diet until 6 weeks after the discharge and fluid restriction, but only in selected patients. We are using now routinely. Another innovation in our medical management strategy was to increase the doses of furosemide used according to protocol. These reduced the incidence of pleural effusions and LOHS after the Fontan procedure.

Conclusion

Prolonged pleural drainage after the Fontan procedure is a common complication that might sometimes require re-operation and re-intervention. 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. After the changes in our medical management strategy, along with the decrease in total drainage and duration of pleural drainage, LOHS was also reduced, of course together with a reduction in the cost.

Limitations:

The single center and retrospective study design was our most important limitation. We started using the modified Wisconsin protocol in July 2018. In the previous period, we did not have a standard treatment protocol. Factors such as increased experience and better patient selection after this period might also have an impact on the results. In addition, although the number was small, performing IEC Fontan might cause heterogeneity. We believe that studies with more homogeneous and larger sample of patients are needed.

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Figures and Legends

Figure 1: Right atrium-Fontan tube junction marked with radio-opaque pacemaker wire,

Figure 2 and 3: Transcatheter fenestration was performed and a stent was placed

Figure 4: Stent placed into the marked area

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