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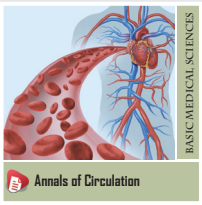

CLINICAL GROUP

AC ANNALS OF Circulation OPEN ACCESS JOURNAL

ISSN: 2641-2985 DOI: https://dx.doi.org/10.17352/ac

Research Article

Objective Lessons from a Chylothorax Protocol: Identifying Specific Mediators of Chest Tube Duration

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Received: 28 September, 2024
Accepted: 01 August, 2025
Published: 02 August, 2025

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Abstract

Background: Chylothorax after pediatric cardiothoracic surgery is associated with increased morbidity and resource utilization. There is limited data on optimal management of chylothorax, as well as the effectiveness of individual components of previously reported management protocols. A chylothorax clinical management protocol was implemented at Advocate Children's Hospital as a quality improvement initiative with the primary objective of determining the association of protocol implementation with chest tube duration. Secondary objectives were to determine the association of individual protocol elements with chest tube duration.

Methods: The clinical management protocol was developed by a multidisciplinary work group after reviewing internal practice patterns as well as published data. Patient data was compared 21 months before and 21 months after implementation of the protocol in April 2019. Data collected included patient demographics, chest tube duration, and medical and dietary interventions such as the use of steroids and low low-fat diet. Outcomes analyzed included death, surgery, duration of chest tube, and hospital length of stay.

Results: A total of 15 and 27 patients were analyzed before and after protocol implementation, respectively. There was no significant difference in demographic data. Protocol adherence was 96%. Methylprednisolone was used exclusively after protocol implementation. Patients tended to receive lower maximum doses of furosemide and chlorothiazide after protocol implementation. Multivariable analysis showed that the duration of chest tube after the onset of chylous output decreased by 3 days after protocol implementation. A cutoff of 10 mL/kg per 24 hours of chest tube output was shown to predict high volume chest tube output above the median.

Conclusion: A chylothorax management protocol was associated with a 3-day decrease in chest tube output in pediatric cardiac patients. Review of the protocol components demonstrates that a 5-day course of steroids may be beneficial, while a low-fat diet may not. This initiative demonstrates how a quality improvement initiative can be successfully utilized in the clinical setting and provide not only protocol-level data but also component-specific data.

Introduction

Chylothorax, while infrequent, is associated with increased morbidity and resource utilization when present [1-4]. Often noted after cardiothoracic surgery, chylothorax may be secondary to mechanical injury to the lymphatic system, increased venous pressures impairing lymphatic drainage, or inflammation with subsequent lymphatic leak. Risk factors such as specific congenital malformations of the heart, cardiac physiologies, cardiac surgeries, and comorbidities have been identified [1,5-9].

As the overall incidence of chylothorax is low and varies by institution, there are limited data regarding optimal management of chylothorax. To further complicate this, chylothorax of various etiologies may respond differently to similar management, thus the sample size of each subset of chylothorax is even lower. Various clinical management protocols have been described. While many of these have been associated with a decrease in chest tube duration and hospital length of stay, specific components of the protocol mediating these improvements have not been delineated [10-12].

A similar clinical management protocol was established

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and implemented at Advocate Children's Hospital. The primary objective of the quality improvement initiative was to determine the association of protocol implementation with chest tube duration. Secondary objectives of this quality improvement initiative were to determine the association of individual protocol elements with chest tube duration.

Methods

Study design

This was a single-center, retrospective study designed to assess the change in chest tube duration in pediatric patients with chylothorax before and after the implementation of a clinical management protocol. This study was reviewed by the institutional review board and is in concordance with the Helsinki Declaration.

Protocol development

A chylothorax work group was assembled from a multidisciplinary group of team members to develop a clinical management protocol for pediatric patients with chylothorax. This was open to all who participate in the care of these patients in the pediatric cardiac intensive care unit at Advocate Children's Hospital and included attending physicians, advanced practice providers, and registered dietitians.

This team conducted a chart review of internal practice patterns of patients with chylothorax to establish a general sense of current clinical management practices. Next, published data regarding chylothorax were reviewed by the group. This group then developed a clinical management protocol based on a combination of currently published data and general internal practice patterns.

The resulting protocol was then presented to the cardiac intensivists and cardiothoracic surgeons at division meetings. Concerns regarding the protocol were obtained, and the protocol was revised per divisional feedback. The final protocol is demonstrated in the supplemental files. Briefly, the protocol began with laboratory assessment of chest tube fluid to demonstrate a formal diagnosis of chylothorax. Next, patients with chylous chest tube output were divided into high volume and low volume groups using a cutoff of 20 ml/kg per 24 hours based on previously published protocols. Next, algorithms for both dietary and medical interventions were outlined for each arm. Finally, reassessment of output and timing for the transition from one arm of the protocol to the other was determined.

A final protocol was then disseminated and implemented in April of 2019. Members from the chylothorax work group monitored patients with chylothorax and made sure that care teams were reminded of the clinical management protocol and had a copy of this protocol. Care teams were also reminded that the clinical management protocol was a suggestion, and that deviation from the protocol based on individual patient need was acceptable.

The working group decided, a priori, that data would then be reviewed in January of 2021, such that 21 months of data would be available.

Data review

Patient data was collected 21 months after protocol initiation. Patients with chylothorax in the 21 months preceding the protocol were also identified as controls. An electronic data collection tool was utilized to collect data on patients before and after the protocol.

Age at the time of onset of chylous output, the cardiac diagnosis, presence of a genetic anomaly, and type of cardiac surgery performed were collected. Chest tube fluid characteristics, including the triglyceride count and the volume of drainage in the first 24 hours, were collected. The central venous pressure at the time of the onset of chylous output was collected. Data were collected for the following medical interventions: methylprednisolone, octreotide, maximum chlorothiazide dose during chylous output, and maximum furosemide dose during chylous output. Data were collected for the following dietary interventions: feeding change to low-fat diet, duration of feeding change, and institution and duration of nothing per os. The following hospitalization characteristics were collected: chest tube duration, hospital length of stay, and inpatient mortality.

Data was compared between those cared for before and after the implementation of the protocol. Descriptive variables are described as absolute frequency and percentage, and continuous variables are described as median and range. Descriptive variables were compared using a Fisher's exact test, while continuous variables were compared using a Mann-Whitney U test.

Linear regression analyses were conducted to model chest tube duration from the onset of chylous output. The regression analyses were conducted using a backward approach.

Next, a Spearman correlation analysis was conducted to determine the relationship between chylothorax volume in the first 24 hours with chest tube duration. Next, a receiver operator curve analysis was done to determine an optimal cutoff for volume of chylothorax in the first 24 hours with a binary outcome of having chest tube duration greater than the median.

Statistical analyses were conducted using SPSS Version 23.0. A p-value of less than 0.05 was considered statistically significant. Any use of the word "significant" or "significantly" refers to statistical significance unless explicitly stated otherwise.

Results

Overall cohort

A total of 15 patients had chylothorax in the 21 months prior to protocol implementation, and a total of 27 patients had chylothorax in the 21 months after protocol implementation. Median age for all patients was 3 months. Trisomy 21 and isomerism were the most frequently noted genetic anomalies. Trisomy 21 was noted in 9 (21%) patients, while isomerism

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was noted in 6 (14%) patients. The most common congenital malformation of the heart was a common atrioventricular junction noted in 13 (31%) patients (9 atrioventricular septal defect and 4 atrioventricular septal defect with tetralogy of Fallot). The second most common congenital malformation of the heart was hypoplastic left heart syndrome and coarctation of the aorta, both of which were present in 6 (14%) patients. The most frequent surgical procedure in this cohort was a superior cavopulmonary anastomosis (Glenn procedure), which was done in 8 (19%) of patients.

Protocol adherence, defined as having met over 80% of the protocol's suggestions, was 96% after its implementation. Of note, in those who were managed per the protocol, 3 (11%) required no specific intervention after an initial 24-hour period of observation.

Comparison of patients before and after protocol implementation

Demographic data did not differ between the two groups by univariate analyses. This includes age, frequency of genetic anomaly, cardiac diagnosis, and surgery. Those after the protocol tended to have higher chest tube fluid triglyceride levels (Table 1).

With regard to management of chylothorax, those after protocol implementation were more likely to receive methylprednisolone and received a lower maximum daily dose of furosemide by univariable analyses (Table 2).

Duration of chest tubes after onset of chylothorax, and time from onset of chylothorax to discharge did not differ between the two groups by univariable analysis. Time from onset of chylothorax to formula change was greater in the protocol group, and time from surgery to discharge was lower in the protocol group (Table 3).

Table 4 outlines median chest tube duration in the before and after protocol groups concerning methylprednisolone, nothing per os, and thoracic duct ligation. There was a significant increase in chest tube duration with nothing per os and thoracic duct ligation, but not methylprednisolone use.

Table 1: Comparison of characteristics of chylous output before and after the protocol.

	Before protocol (*n* = 15)	After protocol (*n* = 27)	*p* -value
Age at onset of chylous drainage (months)	4.0 (0.0 to 39.0)	3.0 (0.0 to 243.0)	0.45
Syndrome or chromosomal abnormality	8 (53.3)	15 (55.6)	0.89
Onset of chylous drainage after surgery (days)	2.0 (0.0 to 59.0)	2.0 (1.0 to 26.0)	0.93
Chest tube fluid triglycerides	216.0 (58.0 to 783.0)	355.0 (150.0 to 1000.0)	0.01
Volume of drainage in first 24 hours of chylous drainage (ml/kg)	11.1 (4.0 to 88.0)	12.7 (2.3 to 200.0)	0.70
Central venous pressure when chylous drainage first noted	10.5 (4.0 to 17.0)	10.0 (7.0 to 13.0)	0.61

Table 2: Univariate analyses comparing medical, dietary, and surgical interventions between the two groups.

	Before protocol (*n* = 15)	After protocol (*n* = 27)	*p* - value
Methylprednisolone	0 (0.0)	14 (51.9)	< 0.01
Days of methylprednisolone	--	5.0 (3.0 to 12.0)	--
Maximum chlorothiazide dose while chest tubes in place (mg/kg/day)	9.0 (4.2 to 14.0)	7.8 (3.3 to 26.0)	0.31
Maximum furosemide dose while chest tubes in place (mg/kg/day)	6.1 (2.0 to 9.6)	3.5 (1.2 to 10.0)	0.01
Maximum spironolactone dose while chest tubes in place (mg/kg/day)	--	1.5 (1.0 to 2.0)	--
Octreotide	1 (6.7)	0 (0.0)	0.17
Change in formula	14 (93.3)	20 (74.1)	0.12
Time from onset of chylous drainage to formula change (days)	0.0 (0.0 to 21.0)	1.0 (0.0 to 27.0)	0.08
Made nothing per os due to chylothorax	1 (6.7)	4 (14.8)	0.43
Thoracic duct ligation	2 (13.3)	2 (7.4)	0.53

Table 3: Comparison of admission characteristics before and after protocol.

	Before protocol (*n* = 15)	After protocol (*n* = 27)	*p* - value
Duration of chest tubes after onset of chylothorax (days)	4.0 (1.0 to 42.0)	3.0 (1.0 to 19.0)	0.25
Time from onset of chylothorax to formula change (days)	0.0 (0.0 to 21.0)	1.0 (0.0 to 27.0)	< 0.01
Time from onset of chylothorax to discharge (days)	11.0 (5.0 to 96.0)	12.0 (4.0 to 128.0)	0.75
Time from surgery to discharge (days)	22.0 (6.0 to 100.0)	13.0 (5.0 to 139.0)	< 0.01

Table 4: Univariate median and range of the chest tube duration after chylous drainage noted in patients with specific interventions.

	No	Yes	*p* - value
Methylprednisolone	3.0 (1.0 to 42.0)	3.5 (1.0 to 19.0)	0.73
Nothing per os	3.0 (1.0 to 22.0)	17.0 (5.0 to 42.0)	< 0.01
Ductal ligation	3.0 (1.0 to 22.0)	14.0 (3.0 to 42.0)	< 0.01

Univariate analyses for chylothorax volume and chest tube duration

A Spearman correlation demonstrated a correlation coefficient of 0.36 (p = 0.02). Thus, a weak but significant correlation was noted. Area under the curve analyses to determine the utility of chylothorax volume and requiring greater than the median chest tube duration demonstrated that chylothorax volume had an area under the curve of 0.61, but that this was not statistically significant (p = 0.22).

Regression analyses for chest tube duration and time to discharge after onset of chylothorax

Multivariable regression demonstrated that the following were significantly associated with chest tube duration: octreotide was associated with a 26.8-day increase, nothing per os was associated with an 8.5-day increase, and the protocol was associated with a 3.3-day decrease (Table 5).

Multivariable regression demonstrated that the following were significantly associated with time from onset of

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chylothorax to discharge: octreotide was associated with a 35.8-day increase, nothing per os a 40.2-day increase, and every 1ml/kg volume of drainage in the first 24 hours a 0.3-day increase (Table 5).

It is important to note that there was a strong collinearity between methylprednisolone use and the protocol. All of the methylprednisolone use occurred after implementation of the protocol. Delineating the effect of methylprednisolone was not truly possible.

Table 5: Variables significantly associated with changes in chest tube duration or time to discharge by multivariable analyses.

	Duration of chest tubes after onset of chylous output (days)		Time from onset of chylous drainage to discharge (days)	
	Beta-coefficient	*p* - value	Beta-coefficient	*p* - value
Octreotide	26.8	< 0.01	35.8	0.03
Nothing per os	8.5	< 0.01	40.2	< 0.01
After protocol	-3.3	0.03		
Volume of drainage in first 24 hours			0.3	< 0.01
Days of onset after surgery			0.4	0.04

Discussion

This initiative demonstrated that a protocol did help decrease chest tube duration. Individual components of the protocol were not found to be significantly associated with decreased chest tube duration, although this was likely secondary to a low sample size and the presence of collinearity among some interventions and the protocol itself.

The implementation of a protocol may have been associated with a decrease in chest tube duration for a few reasons. First, the protocol recommended a 24-hour period during which output could simply be observed and allow for some chylothoraces to resolve without intervention. Second, the protocol prioritized formula change and steroids versus nothing per os and parenteral nutrition. By preventing the use of a nothing per os strategy for lower volume chylothoraces, this may have also contributed to a decrease in chest tube duration.

The effect of specific aspects of the protocol was assessed. After adjusting for initial chylothorax volume and triglyceride volume, octreotide and nothing per os were associated with significant increases in chest tube duration and time to discharge. The initial volume of output was only associated with an increase in the time to discharge, but not chest tube duration. Day of chylothorax onset after surgery was also associated with an increase in time to discharge. Methylprednisolone trended towards significance in the regression analyses, but its use only occurred after the protocol was implemented. Thus, collinearity limited the statistical power to delineate the precise effect of methylprednisolone. A majority of patients in both arms were switched to low-fat formula, and so the regression analyses were unlikely to detect a small or moderate effect size, although a large effect size should have been detected.

Also importantly, the data provided insight into the impact of the amount of chylous output in the first 24 hours on chest tube duration. The oft-used cutoff of 20ml/kg of chest tube output may not be the most objective. The correlation analysis, the receiver operator curve analysis, and the multivariable regression analysis demonstrate that use of any such cutoff may not be particularly useful with respect to trying to modulate chest tube duration in a significant way.

The internal review of the data from the first review of the protocol led to revisions to be made to the clinical management protocol. In brief, the volume-based divergence was reduced to 10 mL/kg in the first 24 hours due to the results discussed above. The use of steroids and low-fat formula was retained in the revised protocol as they trended towards significance in chest tube duration from the multivariable regression analysis. Future reviews of data with future iterations of the protocol will help lend additional insight into specific elements of the protocol and allow for future modifications.

Previous studies have shown the beneficial effect of steroids, somatostatin analogues, and pleurodesis [1,13,14]. There is almost no data that has demonstrated the efficacy of a low-fat diet or nothing per os.

The current data indicate that steroids may be beneficial, as this was routinely done after the implementation of the protocol, resulting in an overall lower duration of chest tubes. As nobody received steroids before the protocol, it is hard to directly compare. A previous study demonstrated that steroids were associated with a decrease in intensive care unit length of stay, hospital length of stay, billed charges, and decreased need for surgical intervention [1]. Steroids likely help in the setting of systemic inflammation, which can lead to lymphatic leak.

Somatostatin analogues did not demonstrate improvement in chest tube duration, although the current study is not designed to determine efficacy. There is usually a temporal delay associated with somatostatin analogues as they are generally started for chylothorax after a failed response to initial medical and dietary therapies. Thus, an increase in chest tube duration associated with somatostatin analogues may simply represent this human behavior. The evidence for somatostatin use is lacking. Previous case series have demonstrated benefit but often lack a control arm [13,15,16]. Another single-center study showed that octreotide use did not bestow a significant benefit in outcome compared to nothing per os alone [XX]. A large database study demonstrated that octreotide was associated with decreased intensive care unit length of stay, decreased total hospital length of stay, decreased bill charges, but not a decrease in surgical intervention [1].

Low-fat diets and nothing per os do not seem to be particularly associated with any improvement. While low-fat diets have become a part of chylothorax management for many, there is no data to demonstrate that low-fat diets or nothing per os are beneficial. Studies, particularly in those with congenital heart disease, have not been done randomizing patients with chylothorax to a low-fat diet or normal-fat diet and comparing the two groups [10,17,18]. Data for low-fat

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diets comes from case reports and retrospective reviews, which cannot differentiate the effect of time versus the effect of the low-fat diet. The most robust data comes from a database study, which demonstrates no apparent benefit from a low-fat diet [1]. While the current study also did not randomize patients, nearly 20% fewer patients were transitioned to a low-fat diet after the introduction of the protocol, yet chest tube duration still decreased. Thus, the current study appears to demonstrate that low-fat diets may be of limited benefit. Previous studies looking at chyle composition after dietary changes have shown no change or no clinically significant change with low-fat diet, medium chain triglyceride diet, or total parenteral nutrition [17,19]. A meta-analysis of adult studies demonstrated that dietary change did not impact the need for surgical intervention for chylothorax [20].

Pleurodesis is utilized in some cases. In the current study, it was associated with increased chest tube duration and length of stay, which is similar to some previously published studies [1]. This, like somatostatin analogues, may be because there is a delayed use of pleurodesis only after other interventions are attempted first. Other studies have demonstrated the benefits of earlier pleurodesis, although this benefit may be limited to those with higher chest tube output, which the current study demonstrates to be around 10 ml/kg in the first 24 hours.

The data generated by this qualitive improvement insight is beneficial in a few ways: 1) they add objective data to the current body of literature, specifically regrading cutoffs for low and high volume chylothorax; 2) they add objective data of how individual elements of the protocol impacted chest tube duration and hospital length of stay; 3) they offer an example of how iterative review of data from quality improvement initiatives can help mold future iterations of clinical management protocols.

These data, however, are not without their limitations. This is a single-center quality improvement project that limits its sample size and generalizability. With regards to sample size, it is difficult to do subset analyses and identify patients in whom the effect of various interventions may differ from that of the entire group. Chylothorax may occur due to mechanical injury, high venous pressure, systemic inflammation, or underlying lymphatic anomalies. Due to the small number of patients, subset analyses were not possible to help determine the effect of intervention by suspected etiology. With regards to generalizability, uncaptured differences in management may impact generalizability to patients cared for at other centers. This, however, is unlikely to be a major limitation.

Conclusion

A chylothorax management protocol was associated with a 3-day decrease in chest tube output in pediatric cardiac patients. Review of the protocol components demonstrates that a 5-day course of steroids may be beneficial, while a low-fat diet may not. This initiative demonstrates how a quality improvement initiative can be successfully utilized in the clinical setting and provide not only protocol-level data but also component-specific data.

(Supplemental Tables)

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