Title: Passive Peritoneal Drainage versus Pleural Drainage after Pediatric Cardiac Surgery

Running Head: Passive PD in Pediatric Cardiac Surgery

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Abstract

Background: In some centers, passive peritoneal drainage is utilized as alternative means of fluid removal in infants recovering from cardiac surgery. Based on our prior retrospective studies, we hypothesized that patients with peritoneal drainage would more efficiently attain negative fluid balance postoperatively as compared to similar patients with pleural drainage.

Methods: An IRB-approved prospective randomized study of children undergoing repair of Tetralogy of Fallot (TOF) or atrioventricular septal defect (AVSD) was performed between 9/2011-6/2013. Consented patients were randomized to intraoperative placement of peritoneal catheter or right pleural tube. The primary outcome measure was fluid balance at 48 hours postoperatively. Variables were compared using t-tests or Fisher exact tests as appropriate.

Results: We enrolled 24 patients (14 TOF, 10 AVSD), with 12 patients in each study group. There was a non-significant trend toward more negative mean fluid balance at 48 hours in patients with peritoneal drainage, −41±53 mL/kg versus −9±40 mL/kg, P=0.10. On subset analysis, mean fluid balance at 48 hours was significantly more negative in AVSD patients with peritoneal drainage as compared to AVSD patients with pleural tubes, −82±51 mL/kg versus −1±38 mL/kg, respectively, P=0.02. In contrast, fluid balance at 48 hours in patients with TOF was not significantly different between study groups.

Conclusions: Passive peritoneal drainage may more effectively facilitate negative fluid balance when compared to pleural drainage after pediatric cardiac surgery, though this benefit is likely not universal but rather dependent on the patient's underlying physiology**.**

Abstract Word Count: 238 words

Introduction

Fluid overload frequently complicates recovery from pediatric cardiac surgery [1] and has been associated with adverse outcomes such as acute kidney injury, prolonged intensive care stay, and in-hospital mortality [1-4]. In some centers, peritoneal drainage catheters are used as adjuncts to traditional methods of mitigating postoperative fluid overload in this patient population [4-9]. These catheters are typically placed intraoperatively and are allowed to drain passively to gravity, acting as an additional means of removing unwanted extravascular fluid. Several centers have further utilized these catheters for peritoneal dialysis when necessary [4-5, 10-12]. We have previously reported retrospective data examining the effects of passive peritoneal drainage in infants undergoing repair of complete atrioventricular septal defects (AVSD) [13] and children undergoing Fontan palliation [14]. In both of these studies, fluid balance in patients with peritoneal drainage was significantly more negative at 48 hours postoperatively as compared to patients with only traditional mediastinal and pleural tubes. Moreover, in both studies, no mechanical complication occurred in any of the patients with peritoneal catheters and vasoactive medication requirements did not differ between patients with and without peritoneal drainage. In other words, patients with peritoneal drainage were able to tolerate greater fluid removal during the same time period without compromised hemodynamic stability.

These studies were limited by their retrospective design and the lack of randomization for surgeon and disease severity. To address these limitations, we designed a randomized prospective trial aimed at determining the effect of passive peritoneal drainage on postoperative fluid balance. We hypothesized that patients with passive peritoneal drainage will more effectively achieve negative fluid balance as compared to pleural drainage after surgery for congenital heart disease.

Patients and Methods

This was a prospective randomized controlled study approved by the Institutional Review Boards at Wayne State University and the Detroit Medical Center between September 2011 and June 2013.

Patient Population

To limit study homogeneity, only patients less than two years of age undergoing definitive repair of classic Tetralogy of Fallot (TOF) (or TOF-like double outlet right ventricle with ventricular septal defect) and complete AVSD at Children's Hospital of Michigan were eligible. These lesions were chosen because patients with these lesions typically undergo surgical procedures of similar complexity at similar ages. Children with more complex forms of TOF and complete AVSD (e.g. Tetralogy of Fallot with major aortopulmonary collaterals, unbalanced AVSD) were excluded, as were children undergoing palliative shunt or banding procedures.

Parents of patients were approached for informed consent at preoperative evaluation by one of the study investigators. Enrolled patients were block randomized by lesion to receive either a peritoneal catheter or right pleural tube in addition to the prerequisite mediastinal tube. A randomization scheme was generated using six random permutated blocks of four and a table of random numbers. The principal investigator and surgeons were blinded to the randomization scheme.

Operative protocol

Prior to incision, all patients received methylprednisolone 30mg/kg. Cardiopulmonary bypass was performed using a Terumo System One heart lung machine with a roller arterial pump (Terumo Cardiovascular Systems, Ann Arbor, MI, USA) and a Jostra HCU-30 heater cooler unit (Maquet Cardiopulmonary, Solna, Sweden). Zero balanced ultra-filtration was done after cross

clamp removal and a twenty minute period of modified ultra-filtration was initiated after termination of cardiopulmonary bypass.

For the patients randomized to peritoneal drainage, catheters (Kendall Quinton, 37cm, Tyco Healthcare Group, Mansfield, MA, USA) were placed in the subxyphoid area leaving the cuff outside the skin to facilitate removal. An opening was made in the peritoneum and the catheter was usually introduced into the left upper quadrant of the peritoneal cavity (if not constrained by anatomical factors to go into the right upper quadrant) where it drained freely by gravity without interference by the omentum. For the patients randomized to receive pleural drainage, a right pleural tube, sized appropriately for the patient's BSA, was placed which was attached to suction. All patients underwent intraoperative placements of mediastinal tubes, sized appropriately for the patient's BSA.

Postoperative care was at the discretion of the intensive care unit (ICU) team. All patients received 750-1000 mL/m^2/ day of 5% dextrose solution with 0.2% sodium chloride for daily maintenance fluid and electrolyte requirements; packed red blood cells were transfused to keep hematocrit > 30%; fresh frozen plasma and platelets as needed to reverse postoperative coagulopathy; and 5% albumin boluses to maintain hemodynamic stability as determined by the ICU team. Additionally, as per our institutional protocol, 5% albumin or fresh frozen plasma, depending on coagulation studies, was used to replace chest tube and peritoneal drainage each hour at a ratio of 1:1 mL during the first postoperative night. The rationale behind this practice is to maximize cardiac with adequate systemic ventricular preload by preventing excessive negative fluid balance in the immediate postoperative period, which is usually the period of greatest hemodynamic lability. Furosemide therapy was initiated in all patients on the morning of postoperative day 1, and some patients received additional intermittent boluses of intravenous furosemide (1 mg/kg) and chlorothiazide (2 mg/kg) during the study period.

All patients arrived at the pediatric intensive care unit nasotracheally intubated and receiving positive pressure ventilation, which is standard practice at our institution for patients undergoing cardiopulmonary bypass. All patients were managed using synchronized intermittent mandatory ventilation. Patients were extubated from ventilator support when they were breathing comfortably with good gas exchange on the following settings: respiratory rate ≤ 5 breaths per minute, pressure support ≤ 10 cm H_2O, positive end-expiratory pressure ≤ 5 cmH_2O, and fraction of inspired oxygen concentration ≤ 0.4.

Data Collection

Demographic, intraoperative, and postoperative data were recorded prospectively for all patients. Postoperative fluid data was recorded for the first 72 hours. Hemodynamic stability was assessed using the vasoactive inotrope score (VIS), which is calculated as follows using doses in µg/kg/min: dopamine + dobutamine + 100 × epinephrine + 10 × milrinone + 10,000 vasopressin + 100 × norepinephrine [15]. Respiratory system function was quantitated using the ventilation index (VI): RR × (PIP – PEEP) × $PaCO_2$ / 1000, where RR is respiratory rate set on ventilator, PIP is peak inspiratory pressure, and PEEP is positive end-expiratory pressure [16]. Outcomes such as duration of mechanical ventilation, duration of vasopressor use, duration of tube drainage, ICU length of stay, and need for additional tubes were also recorded.

Statistical analysis

The primary outcome of the study was the fluid balance at 48 hours. Sample size calculation was estimated before the initiation of the study based on the effect size in our previous data on patients with AVSD [13]. The null hypothesis is that the 48 hour-fluid balance means for the two groups are equal. The criterion for significance (alpha) has been set at 0.050. The test is 2-tailed, which means that an effect in either direction will be interpreted. Sample sizes of 12 per

group would achieve 83% power. Of note, the ICU team was unaware of our primary outcome variable. Secondary outcomes analyzed included fluid balance at 24 and 72 hours postoperatively; duration of mechanical ventilation, vasoactive medications, and intensive care unit length-of-stay; need for additional passive drainage tubes or catheters; and complications related to tube or catheter placement. Descriptive statistics were used to summarize demographics and outcome measures. These include means with standard deviations for normally-distributed continuous variables, median with ranges for skewed continuous variables, or frequencies and percentages for categorical variables. Groups were compared using t-tests, Mann-Whitney U tests or chi-squared tests as appropriate. SPSS version 21.0 (IBM Inc., Chicago IL 2012) was used for statistical analysis. All tests are two-tailed test. P-value < 0.05 was considered statistically significant.

Results

Patient enrollment is illustrated in Figure 1. During the study period, 36 eligible children underwent surgical repair and 24 were enrolled and completed the study. Of note, two additional patients were enrolled but were noted intraoperatively to have transitional AVSD's and therefore excluded from the study. Anthropometric and perioperative data including intraoperative fluid balance were not statistically different between patients with and without peritoneal drainage, outlined in Table 1.

Postoperative fluid and diuretic management during the first 48 hours are summarized in Table 2. Passive fluid drainage (i.e. mediastinal plus peritoneal or pleural) was significantly greater in patients with peritoneal catheters, primarily due to greater peritoneal drainage in these patients as compared to pleural drainage in the other cohort of patients. Accordingly, replacement fluid administered as per our ICU protocol during this time period was greater in patients with peritoneal catheters, and this difference in replacement fluid resulted in significantly greater total

fluid administration in these patients during the first 48 postoperative hours. Despite receiving

this greater amount of fluid, patients with peritoneal drainage tended to be more negative in

regards to postoperative fluid balance at 48 hours (P=0.10). This trend could not be attributed

to differences in resuscitative needs, urine output or diuretic use. Postoperative fluid balance

over time is graphed in Figure 2. Between 48 and 72 hours, mean postoperative fluid balance

continued to become more negative in patients with peritoneal catheters and these patients

were significantly more negative at 72 hours than patients with pleural catheters (P=0.04).

Mean cumulative urine output and passive drain output over time are provided in Figure 3A and

3B, respectively, demonstrating that the differences in the observed patterns of fluid balance

over time were primarily due to differences in passive drain output and not urine output.

Ventilator support, hemodynamic data and renal function are listed in Table 3 and postoperative

outcomes are provided in Table 4; no significant differences were observed. Two patients with

right pleural tubes required left pleural tubes placed postoperatively, while one patient with to

peritoneal drainage catheter placement in the study. One patient with complete AVSD who

received intraoperative placement of a peritoneal catheter developed fever and a distended

abdomen on postoperative 4, which was after an unremarkable initial postoperative course and

discharge from the intensive care unit. Abdominal x-ray demonstrated free air and surgical

exploration was performed, during which a small colonic perforation was discovered near the

area of the peritoneal purse string suture placed to secure the peritoneal catheter. This

perforation was primarily repaired in two layers. The patient recovered and was discharged

home after a prolonged hospital stay (20 days) for intravenous antibiotic therapy.

Post-hoc, we analyzed fluid balance in patients with AVSD and TOF as separate cohorts. In

patients with AVSD (N=10, 5 in each group), mean postoperative fluid balance at 48 hours was

significantly more negative in the infants with peritoneal catheters, −82 ± 51mL/kg versus −1±38

mL/kg, *P*=0.02. In contrast, fluid balance in patients with TOF (*N*=14, 7 in each group) who received peritoneal catheters was statistically similar to their counterparts who received pleural tubes, −12±30 mL/kg versus −14±43 mL/kg, *P*=0.90. Boxplots illustrating medians and ranges for postoperative fluid balance at 48 hours in each of the groups are provided in Figure 4A and 4B.

Comments

To our knowledge, this is the first prospective randomized controlled study to study the impact of passive PD following surgery for congenital heart disease. Though there was a trend toward a greater degree of negative fluid balance at 48 hours in patients with peritoneal drainage, this difference did not reach statistical significance, which differs from what we reported previously in our retrospective studies of patients undergoing complete repair of AVSD [13] and Fontan palliation [14]. Neither of these studies however contained patients undergoing definitive repair of TOF, and our power analysis for the current study was based on our observed differences in our retrospective study of only patients with complete AVSD [13]. We chose not to focus this prospective study solely on complete AVSD because (A) it is our standard practice to place peritoneal catheters in patients undergoing repair of TOF yet we had never formal studied it, and (B) the study would have taken considerably longer to complete had we restricted enrollment to just one lesion. Further, we hypothesized that patients with TOF and complete AVSD who are both prone to postoperative right heart dysfunction would similarly be at risk for the accumulation of ascites. Based on our *post-hoc* sub-analyses however, the potential beneficial effect of peritoneal drainage on fluid balance seemed to be restricted to patients with complete AVSD. We speculate that mean pulmonary pressures were possibly higher in these patients due to their propensity for postoperative pulmonary hypertension, which consequently favored generation of extravascular ascites more so than pleural fluid. A follow-up study focused on only complete AVSD is therefore necessary.

Our practice of replacing passive fluid drainage during the first post-operative night likely also confounded our results. This practice is implemented to prevent excessive negative fluid balance until bedside clinicians are comfortable with a patient's postoperative stability. In many cases however, it was not discontinued until morning rounds on postoperative day 1 when it could have likely been discontinued much earlier. In follow-up studies, more definitive criteria for postoperative replacement fluid discontinuation should be instituted.

In our analysis of secondary outcomes, we observed increasingly negative fluid balance in patients with peritoneal drainage as compared to minimal change in fluid balance in patients with pleural drainage. For infants recovering from pediatric cardiac surgery, consistent removal of excess fluid without compromising hemodynamic stability is a common goal, and this goal seemed to occur more readily in patients with peritoneal drainage. Other postoperative outcomes were not statistically different between groups, though absolute values, especially in regards to hospital length of stay, tended to favor patients with peritoneal catheters. This study was not powered to detect differences in these outcomes, and we further speculate that a somewhat larger study focused on complete AVSD would show statistically significant improvements. Though not routine, placement of peritoneal catheters is not uncommon [4-9] and thus, a multicenter trial is feasible.

The one case of colonic perforation by the peritoneal catheter was a preventable complication that resulted in a prolonged hospital length-of-stay for this patient. In our prior retrospective studies, there were no complications in 43 patients who underwent Fontan palliation and 36 patients undergoing repair of complete AVSD. In fact, this was the first and only serious complication attributable to intraoperative peritoneal catheter placement during the 15 years that we have used this technique. Colonic perforation should be viewed as a serious but

exceedingly rare complication of intraoperative peritoneal catheter placement that incidentally occurred during our study period.

Our study is limited by its single center nature and focused patient population and thus may not be generalizable to other centers or lesions. The study however was performed prospectively and appropriately randomized, and patients were otherwise similar demographically and clinically. In conclusion, peritoneal drainage may be more effective than traditional pleural drainage in facilitating negative fluid balance in some patients recovering from pediatric surgery. We believe our study provides important data that supports further research aimed at determining optimal candidates for peritoneal drainage in this patient population.

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Tables

Table 1. Demographic and Perioperative Data

Variable	Peritoneal (n=12)	Pleural (n=12)	P-value
TOF	7 (58%)	7 (58%)	1.00
AVSD	5 (42%)	5 (42%)	1.00
Age (days)	194 (105)	206 (104)	0.81
Weight	6.8 (1.7)	6.2 (1.3)	0.37
Female	8 (67%)	3 (25%)	0.10
Trisomy 21	5 (42%)	6 (50%)	1.00
Cardiopulmonary bypass (min)	173 (36)	177 (42)	0.81
Aortic Cross Clamp (min)	123 (32)	124 (23)	0.94
Intraoperative Balance (mL/kg)	-39 (73)	-28 (51)	0.66
Transannular patch	3 (25%)	6 (50%)	0.40
Surgeon 1	7 (58%)	5 (42%)	0.68

[a]Data: mean (standard deviation) for continuous variables and n (%) for categorical variables; statistical significance: *P*<0.05

Table 2. Fluid and Diuretic Data for the First 48 Postoperative Hours

Variable	Peritoneal (n=12)	Pleural (n=12)	P-value
Total Fluid Input (mL/kg)	226 (56)	182 (34)	0.03*
Resuscitation (mL/kg)	42 (27)	38 (23)	0.74
Replacement (mL/kg)	72 (35)	17 (9)	<0.01
Urine Output (mL/kg)	136 (47)	138 (31)	0.92
Passive Fluid Drainage[a]	130 (59)	53 (21)	<0.01*
Mediastinal (mL/kg)	29 (30)	16 (7)	0.17
Peritoneal / Pleural (mL/kg)	107 (52)	37 (18)	<0.01*
Fluid balance (mL/kg)	-41 (53)	-9 (40)	0.10
Cumulative furosemide (mg/kg)	5.6 (2)	5.2 (2)	0.70
Cumulative chlorothiazide (mg/kg)	0 (0 - 6)	0 (0 - 4)	0.61

[a]Passive fluid drainage represents mediastinal plus pleural or peritoneal drainage
[b]Data: mean (standard deviation) for normally-distributed continuous variables, median (range) for skewed continuous variables, and n (%) for categorical variables; statistical significance: $P<0.05$

Table 3. Postoperative Cardiopulmonary and Renal data

Postoperative variable	Peritoneal (n=12)	Pleural (n=12)	P-value
Ventilation Index @ 0 hours	13 (4)	15 (4)	0.29
Ventilation Index @ 48 hours	0 (0-14.4)	0 (0-26)	0.60
Vasoactive Infusion Score @0 hours	10 (2)	11 (3)	0.48
Vasoactive Infusion Score @ 48hours	7.5 (0-14.5)	5 (0-27.5)	0.98
CVP (mmhg) @ 0hrs	12 (3)	12 (3)	1.00
CVP (mmhg) @48hrs	10 (2)	11 (4)	0.30
Peak lactate (mg/dL)	2.5 (1)	2.7 (0.9)	0.40
Creatinine, ICU admit (mg/dL)	0.42 (0.1)	0.45 (0.2)	0.50
Creatinine, POD-2 (ml/min)	0.40 (0.1)	0.45 (0.1)	0.33
BUN, ICU admit (mg/dL)	10 (3)	10 (4)	0.70
BUN, POD-2 (mg/dL)	15 (3)	17 (8)	0.52

[a]POD: postoperative day; BUN: blood urea nitrogen

[b]Data: mean (standard deviation) for normally-distributed continuous variables, median (range) for skewed continuous variables, and n (%) for categorical variables; statistical significance: *P*<0.05

Table 4. Outcome Data

Outcome	Peritoneal (n=12)	Pleural (n=12)	P-value
Mechanical ventilation (days)	2.1 (1)	2.1 (1.3)	0.91
Vasoactive medications (days)	2.9 (1.2)	3.3 (1.7)	0.47
Catheters / tubes (days)	3.9 (2.7-4.8)	4.1 (1.8-13)	0.99
Hospital stay (days)	6.8 (4.7-12.8)	8.3 (2.9-38.8)	0.20
Additional catheters / tubes	1 (8%)	2 (17%)	1.00
Mortality	0	0	1.00

[a]Data: mean (standard deviation) for normally-distributed continuous variables, median (range) for skewed continuous variables, and n (%) for categorical variables; statistical significance: *P*<0.05

Figure Legends

Figure 1: Flow chart for subject entry into the Peritoneal versus Pleural Drainage study.

Figure 2: Mean ± standard error for cumulative fluid balance over time in patients with peritoneal (solid line) and pleural (dashed line) drainage over the first 72 postoperative hours. Mean fluid balance became increasingly more negative over time in patients with peritoneal catheters and was significantly more negative at 72 hours as compared to patients with pleural tubes, *P*=0.04.

Figure 3: Mean ± standard error for (A) cumulative urine output and (B) passive drain output in patients with peritoneal catheters (black) and right pleural tubes (grey) over the first 72 hours. Urine output was remarkably similar over time while passive drain output was consistently greater in patients with peritoneal catheters at each time point.

Figure 4: Postoperative fluid balances at 48 hours in patients with atrioventricular septal defects (AVSD) and Tetralogy of Fallot (TOF). Fluid balance in patients with AVSD (*N*=10, 5 in each group) was significantly more negative in those infants with peritoneal catheters as compared to pleural tubes, while fluid balance in patients with TOF (*N*=14, 7 in each group) was similar in both groups.

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                                   ├───────▶│ 12 Excluded                              │
                                   │        │  ♦ Not meeting inclusion criteria (n=2)  │
                                   │        │  ♦ Declined to participate (n=6)         │
                                   │        │  ♦ Guardian unable to consent (n= 4)     │
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                    │        24 Randomized            │
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12 Allocated to Peritoneal Drain	12 Allocated to Right Pleural Tube
7 Tetralogy of Fallot 5 Atrioventricular Septal Defect	6 Tetralogy of Fallot 1 Double Outlet Right Ventricle with VSD 5 Atrioventricular Septal Defect
1 required additional right pleural tube	2 required additional left pleural tubes 0 required additional peritoneal drain