**Original Article**

**Peritoneal Dialysis for the Prevention of Fluid Overload in Infants after Cardiac Surgery - A Systematic Review and Meta-analysis**

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**ABSTRACT.** The objective is to compare peritoneal dialysis with standard care therapy for the prevention of fluid overload in infants after cardiac surgery. We searched published literature through the major database up to December 2017. Randomized controlled trials (RCTs), quasi-randomized trials, and observational studies were included in the study. The primary outcome measures were as follows: all-cause mortality and duration of hospitalization. Of the 392-citation retrieved, full text of 7 was finally assessed for eligibility. Of these, a total of five studies (RCTs = 3, and observational studies = 2) were included. There was no significant difference between the prophylactic PD and the standard therapy group for any of the primary outcomes. The present systematic review shows that prophylactic PD is not beneficial compared to standard care in infants postcardiac surgery for congenital heart disease. The GRADE evidence generated was of “very low quality.”

**Introduction**

Congenital heart disease (CHD) is defined as “a gross structural abnormality of the heart or intrathoracic great vessels that is actually or potentially of functional significance.” Incidence of CHD varies from 4 to 50 per 1000 live births in various studies. Of these, 25% of the neonates require immediate surgical intervention whereas many others require it during later part of infancy.

In the postoperative period, fluid overload is an important risk factor for morbidity and mortality in these groups of children. Fluid overload in postoperative period is attributed to acute kidney injury, capillary leak, or hemo-dilution. To overcome this fluid overload and acute kidney injury, various treatment modalities have been implicated which include diuretics, passive peritoneal drainage, and early (prophylactic) renal replacement therapy (RRT).
In infants, peritoneal dialysis (PD) is the preferred mode of RRT in view of small intravascular volume. However, there is insufficient evidence available in these groups of infants and the results of the randomized controlled trials (RCTs) have been conflicting. This systematic review was carried out to synthesize the evidence regarding the effect of prophylactic PD on fluid overload in postcardiac surgery infants.

**Objective**

Our objective is to compare prophylactic peritoneal dialysis with standard care therapy (peritoneal drainage and/or diuretics) for the prevention of fluid overload in infants after cardiac surgery.

**Methods**

**Types of studies**

RCTs, quasi RCT’s and nonrandomized controlled studies were considered for the analysis.

**Types of participants**

Children with age <1 year with CHD who underwent cardiac surgery were included. Patients with preexisting kidney disease, interventions combining drug therapy with PD, without any control group were excluded from the study as those with preexisting genitourinary abnormality, serum creatinine >1 mg/dL, active urinary tract infections, requiring >72 h of nephrotoxic medications, premature neonates <37 weeks gestation and weight <2 kg, urine output <0.5 mL/kg/H over 24 h in the 48 h before procedure, abdominal defects, chromosomal abnormalities, preoperative extracorporeal life support (ECLS), planned PD catheter (PDC) not placed and the patient dying or requiring a second operation.

**Types of intervention**

The type of intervention is the prophylactic use of PD for the prevention of fluid overload in postoperative period of infants with CHD undergoing cardiac surgery.

**Types of comparison/control**

The type of comparator/control is the use of passive drainage (no prophylactic PD) or diuretics or both (passive drainage and diuretics).

**Types of outcome measures**

**Primary outcomes**

1. All-cause mortality
2. Duration of hospitalization

**Secondary outcomes**

1. Proportion of infants with 10% fluid overload
2. Duration of mechanical ventilation/time to extubation
3. Time to achieve negative fluid balance
4. Adverse events

**Definitions**

Percentage fluid overload is defined as cumulative fluid balance that is expressed as percentage and a cutoff of ≥10% has been associated with increased mortality in critically ill patients. Fluid overload percentage is calculated by the following formula:

\[
\% \text{ fluid overload} = \frac{\text{Total fluid in - Total fluid out}}{\text{Admission weight}} \times 100.
\]

A deficit in fluid volume is known as negative fluid balance.

**Data extraction (selection and coding)**

Data extraction was done by using a pilot tested data extraction form. The first two authors independently extracted data including author, type of population, exposure/intervention (PD or diuretic infusion), results (outcome measures, effect, significance), and sources of funding/support. Any disagreement in the extracted data was resolved through discussion with the third author.

**Risk of bias (quality) assessment**

Two review authors independently assessed the methodological quality of the selected trials by using Cochrane methodological quality assessment forms. The handbook has seven criteria, which include – random sequence
generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and any other bias. Any disagreements between the two review authors were resolved through discussion with the third author.

**Strategy for data synthesis**

The data from various studies were pooled and expressed as mean difference (MD) with 95% confidence interval (CI) in case of continuous data and risk ratio (RR) with 95% CI in case of categorical data. $P < 0.05$ was considered statistically significant. The assessment of heterogeneity was done by $I^2$ statistics. If there was a high level heterogeneity (>50%), we explored the cause. A fixed-effects model was initially conducted. If significant heterogeneity existed between trials, potential sources of heterogeneity were considered and where appropriate a random effects model was used. Review Manager version 5.2 was used for all the analyses. Where data were provided as median with range or interquartile range (IQR), these were converted to mean and standard deviation as per standard methods described recently.

**Search methods for identification of studies**

Cochrane Central Register of Controlled Trials (CENTRAL), PubMed/MEDLINE, Google Scholar, Cochrane renal group were searched from 1970 to December 2017. Following search strategy was applied: Peritoneal dialysis (PD) AND prevention OR prophylaxis OR controlled AND infants OR neonates OR children.

**Publication bias**

This was looked for by construction of the inverted funnel plot as suggest by Egger et al.

**Grade of evidence**

For assessment of the quality of evidence we used GRADE Profiler software (version 3.2, McMaster University and Evidence Prime Inc, Canada). The software uses five parameters for rating the quality of evidence. The parameters used were - limitations to design of RCTs, inconsistency of results or unexplained heterogeneity, indirectness of evidence, imprecision of results, and publication bias. The rating was done as – no, serious, and very serious limitation.

**Results**

Of 392 citations retrieved, full text of 16 articles was assessed. Of these, a total of three RCTs and two nonrandomized studies were included in qualitative synthesis. The three RCTs were open-label studies with moderate-to-high risk of bias. The detailed flow of the studies is shown in Figure 1. All of the studies were conducted in cardiac intensive care unit (CICU) of USA ($n = 4$) and Canada ($n = 1$). Most of the participants were <6 months of age and had critical CHD. The characteristics of the included studies are shown in Table 1. There were three comparisons of prophylactic PD versus standard care (PD vs. passive drainage, PD vs. furosemide, and PD vs. passive drainage plus furosemide) as follows.

**Prophylactic peritoneal dialysis versus passive drainage**

A total of three studies (2 RCTs, and 1 observational study) reported these outcomes.

**Primary outcomes**

1. All-cause mortality: Two RCTs with 42 participants reported this outcome, and the pooled data showed no difference in mortality among PD group compared to supportive therapy group (RR 3.26; 95% CI: 0.37 to 29.01) (Figure 2). One observational study with 84 participants reported this outcome, and the pooled data showed no difference in mortality among PD group compared to supportive therapy group (RR 2.00; 95% CI: 0.54 to 7.47).

2. Duration of hospitalization: One RCT with 22 participants reported this outcome, and the pooled data showed no difference between the two groups (MD −7.30; 95% CI:
Another observational study with 84 participants reported this outcome, and the pooled data showed no difference between the two groups (MD $-0.98; 95\% \text{ CI}: -5.49 \text{ to } 3.53$).

Secondary outcomes
1. Proportions of patients with 10\% fluid overload: This outcome was not reported by any of the studies.
2. Duration of mechanical ventilation/time to extubation (d): One RCT with 22 participants reported this outcome, and the pooled data showed no difference between the two groups (MD 1.5; 95\% CI: $-2.26 \text{ to } 5.26$). One observational study with 84 participants reported this outcome (4) and the pooled data showed no difference between the two groups (MD $-0.88; 95\% \text{ CI}: -2.3 \text{ to } 0.54$).
3. Time to negative fluid balance: One RCT with 22 participants reported this outcome, and the pooled data showed no difference between the two groups (MD 0.03; 95\% CI: $-0.72 \text{ to } 0.78$). One observational study with 84 participants reported this outcome, and the pooled data showed a significantly shorter duration in the PD group (MD $-0.91; 95\% \text{ CI}: -1.24 \text{ to } -0.58$).
4. Adverse events: Two studies reported the adverse events. One RCT with 22 participants reported four serious adverse events only in the PD group, of which, three required cardiopulmonary resuscitation followed by ECLS and one died. One observational study with 84 participants reported three adverse events only in the PD group (one major and 2 minor) in the form of bloody effluent in the catheter, replacement of catheter, and omental evisceration requiring partial omentectomy followed by secondary closure of the abdominal wall.

Prophylactic peritoneal dialysis (versus furosemide)
One RCT with 73 participants reported the outcomes.

Primary outcomes
1. All-cause mortality: There was no significant difference between the two groups (RR 0.26; 95\% CI: 0.03 to 2.38) (Figure 4).
2. Duration of hospitalization (d): There was no significant difference between the two
Table 1. Characteristics of included studies.

| Study ID   | Setting, Country                  | Participants                                                                 | Intervention                                                                 | Outcomes measured                                                                 | Comments                                                                 |
|------------|-----------------------------------|-------------------------------------------------------------------------------|----------------------------------------------------------------------------|----------------------------------------------------------------------------------|------------------------------------------------------------------------|
| Riley 2014 | Single center, (Cardiovascular ICU), USA | Number: 20 (PD = 10; Standard care = 10). Age: <90 days. Inclusion criterion: Undergoing CPB surgery for correction of CHD. Exclusion criterion: genitourinary abnormality; pre-operative SCr >1 mg/dL; active urinary tract infection; requiring >72 h continuous use of nephrotoxic medications; prior ECMO; prior surgery requiring CPB, prior RRT; enrollment in another study | Intervention group: treated with PD as a part of standard treatment. Control group: a PDC was placed but never used to provide PD | Difference in urinary output between the two groups and difference in the level of biomarkers of renal injury post cardiac surgery | Open-label trial. Blinding and allocation concealment not clear. Small sample size |
| Sasser     | Single center, (Pediatric cardiac ICU), USA | Number: 52 (PD = 25; Furosemide = 27). Age: <75 days. Inclusion criterion: PDC placement during primary cardiac procedure. Exclusion criterion: preoperative RRT, ECMO initiation within 6 h of CICU admission, or lack of informed consent | Intervention group: Standard PD protocol within 6 h of admission to ICU. Control group: Patients were managed with passive peritoneal drainage and diuretics | Difference in cumulative fluid balance, indices of disease severity, and clinical outcomes and Plasma IL-6 and IL-8 in both groups | Before and after cohort study, small sample size |
| Ryerson 2015 | Single center, (Pediatric cardiac ICU), Canada | Number: 22 (PD = 10; Standard care = 12). Age: <30 days. Inclusion criteria: Neonates undergoing Norwood procedure. Exclusion criteria: Prematurity, oliguria over 24 h in the 48 h before Norwood procedure, abdominal defects, chromosomal abnormality, preoperative cardio-pulmonary resuscitation or preoperative ECLS | Intervention group: PDC placement with or without prophylactic PD. Control group: Standard care without PDC insertion | Time until the first POD of fluid balance, time to achieve lactate ≤2 mmol/L, maximum ionotropic score on day 2 to 5, time to sternal closure, time to first extubation, modified clinical outcome score, or hospital length of stay, adverse events (death, need for CPR and ECLS) | Open-label trial with block randomization. Blinding not done |
| Study | Design | Setting | Number | Inclusion Criteria | Exclusion Criteria | Intervention Group | Control Group | Outcomes | Study Type |
|-------|--------|---------|--------|-------------------|-------------------|-------------------|--------------|---------|------------|
| Kwiatkowski 2015<sup>4</sup> | Single center (CICU), USA | Number: 84 (PD = 42; Standard care = 42) | Age: <6 months | Inclusion criteria: case -infants <3 months undergoing any CPB, infant <6 months undergoing transplant or <4 months undergoing TOF or DORV repair | Exclusion criteria: control-infants with uncommon surgeries whose control could not match, infant died on the day of surgery or started on ECMO | Intervention group: PDC placement with or without prophylactic PD | Control group: Standard care without PDC insertion, with diuretics | Difference in the negative fluid balance on post OP day 1 to 3, time to negative fluid balance, time to extubation, ionotropic score, days to sternal closure | Retrospective case matched study |
| Kwiatkowski 2017<sup>20</sup> | Single centre (cardiac ICU), USA | Number: 73 (PD = 41; Furosemide = 32). | Age: Infants aged <6 months | Inclusion criterion: Infants aged <6 months undergoing cardiac surgery with CPB | Exclusion criterion: Preexisting kidney disease (eGFR <60 mL/min/1.73 m²), not undergoing CPB or if a PDC was not placed as planned if the patient died or required a second operation or ECLS within the first POD | Intervention group = Received prophylactic PD | Control group = Received furosemide | Incidence of negative fluid balance on POD 1, the incidence of fluid overload, duration of mechanical ventilation, ICU stay, electrolyte abnormalities and repletion doses, duration of inotropic support and mortality | Open-label trial. Block randomization. Allocation concealment done. Blinding not done |

PD: Peritoneal dialysis, CPB: Cardiopulmonary bypass, CHD: Congenital heart disease, SCr: Serum creatinine, ECMO: Extracorporeal membrane oxygenation, CICU: Cardiac intensive care unit, ECLS: Extracorporeal life support, PDC: Peritoneal dialysis catheter, TOF: Tetralogy of Fallot, DORV: Double outlet right ventricle, eGFR: estimated glomerular filtration rate, ICU: Intensive care unit, PDC: PD catheter.
groups (MD −2.78; 95% CI: −8.5 to 2.94) (Figure 5).

Secondary outcomes
1. Proportions of patients with 10% fluid overload: This was significant lesser by 78% in the PD group (RR 0.22; 95% CI: 0.07 to 0.67)
2. Duration of mechanical ventilation (d): There was no significant difference between the two groups (MD −1.00; 95% CI: −2.17 to 0.17)
3. Time to negative fluid balance (d): There was no significant difference between the two groups (MD −0.28; 95% CI: −0.6 to 0.04)
4. Adverse events: Only two minor adverse events in the PD group noted.

Prophylactic peritoneal dialysis versus passive drainage and furosemide
A single-observational study with 52 participants reported the outcomes.21
Primary outcomes
1. All-cause mortality: There was no significant difference between the two groups (RR 3.24; 95% CI: 0.36 to 29.15) (Figure 6)
2. Duration of hospitalization (d): This outcome was not reported.

Secondary outcomes
1. Proportions of patients with 10% fluid overload: This outcome was not reported
2. Duration of mechanical ventilation: There was no significant difference between the two groups (MD –1.84; 95% CI: –3.73 to 0.05)
3. Time to negative fluid balance: The study described in figure that PD group had lesser time to negative fluid balance than the control group
4. Adverse events: peritonitis, hyperglycemia, catheter leak, hypokalemia, hemoperitoneum, chyloperitoneum, hypoglycemia, hypophosphatemia, and omentum herniation occurred in both groups without any significant difference.

Publication bias
As there were few trials, we could not construct funnel plot to denote any chance of publication is there or not.

Grade of Evidence
We constructed the GRADE table mainly for the primary outcomes as most of the secondary outcomes were reported by single studies which inherently generate “very low” quality evidence. The grade evidence generated for primary outcomes was also of “very low” quality (Tables 2-4).

Discussion
Summary of evidence
A detailed literature search retrieved five studies which were included in the present systematic review. The result indicates that prophylactic PD compared to standard care (either passive drainage or diuretics or both) in infants postcardiac surgery for CHD neither decreases all-cause mortality nor decreases the duration of hospitalization. The result is not significant (RR 3.24; 95% CI: 0.36 to 29.15) as per the funnel plot (Figure 6).
Table 2. Peritoneal dialysis compared to passive drainage for fluid overload in postcardiac surgery infants.

| Patient or population: | Patients with fluid overload in postcardiac surgery infants |
|------------------------|------------------------------------------------------------|
| Settings:              | Hospital                                                   |
| Intervention:          | Peritoneal dialysis                                        |
| Comparison:            | Passive drainage                                           |

| Outcomes                             | Illustrative comparative risks* (95% CI) | Relative effect (95% CI) | No of Participants (studies) | Quality of the evidence (GRADE) |
|--------------------------------------|-----------------------------------------|--------------------------|-----------------------------|--------------------------------|
| All cause mortality                  | Assumed risk Passive drainage 0 per 1000 | Corresponding risk Peritoneal dialysis 100 per 1000 (37 to 1000) | RR 3.26 (0.37 to 29.01) | 42 (2 studies) | ☭✭✭✭ very low$^{1,2}$ |
| Duration of hospitalization (d)      | The mean duration in the control groups was 21.4 d | The mean duration in the intervention groups was 7.3 d lower (21.14 d lower to 6.54 d higher) | 22 (1 study) | ☭✭✭✭ very low$^{1,2}$ |

$^{1}$The 95% CI includes no effect.
$^{2}$The studies lack allocation concealment or it was inadequate, and they were open label.

*The basis for the assumed risk (e.g., the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: Confidence interval, RR: Risk ratio.

GRADE Working Group grades of evidence.

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.
Table 3. Peritoneal dialysis compared to furosemide for fluid overload in postcardiac surgery infants.

**Patient or population:** Patients with fluid overload in postcardiac surgery infants

**Settings:** Hospital

**Intervention:** Peritoneal dialysis

**Comparison:** Furosemide

| Outcomes                        | Illustrative comparative risks* (95% CI) | Relative effect (95% CI) | No. of Participants (studies) | Quality of the evidence (GRADE) |
|---------------------------------|----------------------------------------|--------------------------|------------------------------|--------------------------------|
|                                 | Assumed risk Furosemide                | Corresponding risk       |                              |                                |
|                                 |                                        | Peritoneal dialysis      |                              |                                |
| All cause mortality             | 94 per 1000                            | 24 per 1000 (3 to 223)   | RR 0.26 (0.03 to 2.38)       | 73 (1 study)                   |
|                                 |                                        |                          |                              | ⊕⊕⊕⊕                            | very low,1,2,3                   |
| Duration of hospitalization (d) | The mean duration in the control group was 15.06 d | The mean duration in the intervention group was 2.78 d lower (8.5 d lower to 2.94 d higher) | 73 (1 study) | ⊕⊕⊕⊕ | very low,1,2,3 |

1 Open label study
2 Single study lacking generalizability
3 The 95% CI includes no effect

*The basis for the assumed risk (e.g., the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: Confidence interval, RR: Risk ratio.

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.
Table 4. Peritoneal dialysis compared to passive drainage and furosemide for fluid overload in postcardiac surgery infants.

**Patient or population:** patients with fluid overload in postcardiac surgery infants

**Settings:** Hospital

**Intervention:** Peritoneal dialysis

**Comparison:** Passive drainage and furosemide

| Outcomes               | Assumed risk Passive drainage and furosemide | Corresponding risk Peritoneal dialysis | Relative effect (95% CI) | No. of Participants (studies) | Quality of the evidence (GRADE) |
|------------------------|---------------------------------------------|--------------------------------------|--------------------------|------------------------------|--------------------------------|
| All cause mortality    | 37 per 1000                                 | 120 per 1000 (13 to 1000)            | RR 3.24 (0.36 to 29.15)  | 52 (1 study)                 | ⊕⊕⊕⊕ |

1Observational nature with high risk of bias
2Single study lacking generalizability
3The 95% CI includes no effect

*The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: Confidence interval, RR: Risk ratio.

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.
hospitalization. Regarding the secondary outcomes, proportion of infants with 10% fluid overload was lesser as reported by a RCT. Other outcomes like time to achieve negative fluid balance, duration of mechanical ventilation/time to extubation, and adverse events were not significantly different between the two groups when data from RCTs were considered. Only, time to achieve negative fluid balance was significantly lesser in the prophylactic PD group when data from observational studies were considered. Adverse events were common in the prophylactic PD group though it was not significantly different from the standard care group.

Studies have shown that positive fluid positive balance is associated with higher morbidity (prolonged ventilation and prolonged hospital stay) and increased mortality independent of illness severity. A fluid overload between 10% and 20% has been determined as clinically significant threshold for adverse outcomes in children with critical illness. A number of interventions such as diuretic use, theophylline fluid restriction, early use of RRT, etc. has been tried to achieve a negative fluid balance but with variable success. A recent trial comparing furosemide with peritoneal dialysis in infants undergoing cardiopulmonary bypass found that furosemide group had three times odds of 10% fluid overload, more likely to have prolonged ventilator use, longer duration of inotrope use and higher electrolyte abnormality score as compared to PD group. However, in this unblinded trial the authors had given lower furosemide dosage and also the study was not powered to determine difference in clinical outcome. Another randomized controlled trial on use of PD after Norwood palliations reported no significant clinical outcomes associated with PD, but found more adverse effect in PD group. They reported four patients in the PD group have one or more serious adverse events. However, three of the patients in the PD group had cardiac arrest before the initiation of PD and this group had worse preoperative cardiac function and lactate levels. Another limitation was a small sample size in this study.

**Strengths and Limitations**

The major strengths of the present systematic review are: it is the first systematic review conducted to show the clinical utility of PD for prevention of fluid overload in infants undergoing cardiac surgery, and the use of GRADE evidence to further strengthen the recommendations. Potential limitations include: inclusion of few eligible trials with small sample size, inclusion of studies from high income countries only, and very low grade evidence generated (due to potential biases in the included study). Further adequately powered randomized multi-center clinical trials with the inclusion of novel biomarkers of AKI and determining the cost-effectiveness of interventions are required before any firm recommendations can be made.

**Conclusions**

The present systematic review shows that prophylactic of PD is not beneficial compared to standard care in infants postcardiac surgery for CHD. As the GRADE evidence generated was of “very low quality,” good quality RCTs with larger sample size are needed before any firm recommendations are made.

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