Original Research

RESTRICTED VERSUS STANDARD FLUID MANAGEMENT IN TRANSIENT TACHYPNEA OF THE NEWBORN: A RANDOMIZED CONTROLLED TRIAL IN AN INDIAN NICU

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ABSTRACT

Background: Transient tachypnea of the newborn (TTN) is a common self-limiting respiratory disorder of term and late-preterm infants caused by delayed clearance of fetal lung fluid. Standard management is supportive, but limited evidence exists on optimal fluid therapy. Fluid restriction may enhance alveolar fluid absorption and improve respiratory outcomes. This study compares a restricted versus standard maintenance fluid regimen on clinical outcomes in neonates with TTN.

Materials and Methods: We conducted a single-center, parallel-arm randomized controlled trial (July 2024–Dec 2025) in neonates (gestational age 34–42 weeks) diagnosed with TTN by clinical and radiographic criteria. Neonates were randomized (n=82, 41 per arm) to receive either a restricted fluid (60ml/kg for preterm neonates and 40ml/kg for term neonates) or standard fluids (80ml/kg in preterm and 60ml/kg in term neonates). Primary outcome was type of oxygen support, duration of oxygen support and length of hospital stay and secondary outcome time to enteral feeding, and incidence of complications (electrolyte disturbances, weight loss). Data were analyzed on an intention-to-treat basis using Student's t-test or χ^2 test as appropriate; effect sizes (mean differences, 95% confidence intervals) and p-values are reported, with $p<0.05$ considered significant.

Results: Baseline demographics (gestational age, birthweight, sex, scores) were similar between groups (Table 1). Restricted-fluid infants required significantly shorter respiratory support (mean 26.4±8.2 vs 34.7±10.1 hours; mean difference −8.3 h, 95% CI −13.5 to −3.1; p=0.002) and had shorter hospitalization (4.20±1.21 vs 5.13±1.34 days; MD −0.93 d, 95% CI −1.46 to −0.40; p=0.003). They also achieved full enteral feeds earlier (mean 2.88±0.87 vs 3.88±0.75 days; MD −1.00 d, 95% CI −1.37 to −0.63; p<0.001) and first feeding earlier (1.76±0.58 vs 2.17±0.59 days; MD −0.41 d, 95% CI −0.65 to −0.17; p=0.002). Subgroup analyses (term vs late preterm) showed similar trends favoring restricted fluids, though interaction was not statistically significant (Table 3). There were no significant differences in adverse events; for example, hypernatremia and hypoglycemia rates were comparable. **Figure 1** illustrates key outcome comparisons.

Conclusion: In this RCT of neonates with TTN, a restricted fluid regimen was safe and associated with shorter respiratory support and hospital stay compared to standard fluids. These findings align with prior trials and suggest potential benefit of fluid restriction in TTN. However, given limitations (sample size, single-center) and very low-certainty evidence overall, larger multicenter studies are needed.

Keywords: Transient Tachypnea of the Newborn, Fluid Management, Neonate, Respiratory Distress, Randomized Controlled Trial, Enteral Feeding.

INTRODUCTION

Transient tachypnea of the newborn (TTN) is a common neonatal respiratory condition caused by delayed clearance of fetal lung fluid, leading to pulmonary interstitial edema and tachypnea [1, 2, 15].

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It typically presents within the first hours of life in term or late-preterm infants (gestational age ≥34 weeks) with mild-to-moderate respiratory distress (tachypnea, grunting, nasal flaring) but usually without severe hypoxemia. Established risk factors include cesarean delivery without labor, prematurity, and maternal diabetes [3, 4, 9]. The incidence of TTN is inversely related to gestational age, occurring in roughly 5–10% of late-preterm births (gestation 34–36 weeks) and <1% of early-term or preterm births. Most infants with TTN require admission to a neonatal unit for monitoring

and supportive care, but they typically recover spontaneously within 24–72 hours with no long-term sequelae [10, 11, and 12].

Management of TTN is primarily supportive, including supplemental oxygen or noninvasive ventilation as needed and careful monitoring of hydration and nutrition [8, 12]. Because respiratory effort in TTN is thought to be driven by residual intrapulmonary fluid, some clinicians advocate for fluid restriction to enhance alveolar fluid resorption. The rationale is that reducing systemic fluid intake may accelerate clearance of pulmonary edema by creating a mild negative fluid balance. Indeed, neonatal transitional physiology involves mobilization of extracellular fluid; restricting exogenous fluids could theoretically unmask or augment this process. However, restricting fluids may also risk dehydration or electrolyte disturbances, so the safety and efficacy of this approach remain uncertain [6, 13, 14].

To date, evidence on fluid restriction in TTN is very limited. A Cochrane review (2021) identified only four small trials (total n=317) and concluded the certainty of evidence is very low. That review found no clear difference in oxygen duration (mean difference −12.95 h, 95% CI −32.82 to 6.92) and noted the possibility of hypernatremia with restriction, but overall could not determine benefit or harm. An early pilot RCT (Stroustrup et al.[5], 2012) randomized 64 late-preterm and term infants with TTN to mild fluid restriction versus standard care. Stroustrup found that fluid restriction was safe and, in those with more severe TTN, significantly reduced duration of respiratory support (P=0.008) and hospitalization costs (P=0.017). More recently, Sardar et al.[7] (2020) reported a randomized trial of 100 infants on CPAP for TTN and found the restricted group had shorter CPAP duration (48 vs 54 hours, p=0.002) without increased CPAP failure. Despite these suggestive findings, the overall data are sparse.

MATERIALS AND METHODS

Study design and setting

This was a prospective, parallel-arm randomized controlled trial conducted in the NICU of Sri Guru Ramdas Institute of Medical Sciences and Research, Amritsar from July 2024 through December 2025. The study protocol (designated "TTN Fluid Study") was approved by the Institutional Ethics Committee. Written informed consent was obtained from parents of all participants. The trial is reported in accordance with CONSORT guidelines.

Participants

Inclusion criteria were neonates of gestational age 34–42 weeks and birth weight ≥1800 g admitted to the NICU within 6 hours of birth with clinical and radiological evidence of TTN. TTN was defined by respiratory rate >60/min plus at least two signs of respiratory distress (nasal flaring, grunting, retractions) occurring soon after birth, with chest X-ray showing diffuse pulmonary haziness, lung fluid in fissures, or mild hyperinflation. Exclusion criteria included major congenital anomalies, significant cardiac or pulmonary malformations, evidence of neonatal sepsis or pneumonia (fever, positive cultures), or need for immediate intubation for other reasons. Neonates were also excluded if surfactant was administered (suggesting RDS rather than TTN).

Randomization and interventions

Eligible neonates (N=82) were randomized 1:1 into two groups (41 per group) using computer-generated random numbers with sealed opaque envelopes for allocation concealment. Study groups were:

- **Restricted fluid group:** Received a reduced intravenous fluid volume regimen. Specifically, on Day 1 of life, preterm neonates (34–36 weeks) were started at 60 mL/kg/day and term neonates (≥37 weeks) at 40 mL/kg/day (the usual standard might be ~60–80 mL/kg for term on day 1, so this represented a 20–40 mL/kg reduction). Thereafter, fluid intake was increased by 20 mL/kg each day as tolerated, up to usual maintenance levels by day 3–4. When infants were stable and tolerating enteral feeds, parenteral fluids were transitioned to enteral feeds per unit protocol.
- **Standard fluid group:** Received the hospital's standard fluid management, approximately following usual maintenance calculations (80ml/kg/hr in late preterm and 60ml/kg/hr in term neonates). This typically follows guidelines for neonatal maintenance fluids (e.g. term neonates ~80–100 mL/kg by day 3, adjusting for losses). Any intravenous supplementation (e.g. dextrose 10% solution) was identical in both groups.

All other aspects of care were identical between groups. Supplemental oxygen or CPAP was provided to maintain oxygen saturation ≥92%. Feeding (gavage or breast) was started as soon as infants were stable; the timing of initiation and advancement of feeds was recorded. Standard care also included monitoring vital signs, daily weights, and laboratory surveillance (serum glucose, sodium) as clinically indicated.

Outcomes and definitions

Primary outcome: Duration of respiratory support, defined as total hours requiring supplemental oxygen or positive-pressure ventilation (CPAP or high-flow) until sustained room-air breathing without support and Length of hospital stay (days).

Secondary outcomes: Time to first enteral feed (days of life), time to full enteral feeds (days of life), percentage weight loss at 72 hours, and complications (incidence of hypernatremia [serum Na >145 mEq/L], hyponatremia [<130 mEq/L], hypoglycemia [glucose <40 mg/dL], and any need

for fluid resuscitation). TTN severity (e.g. Downes' score) at admission, and demographic variables were recorded. Adverse events included electrolyte disturbances requiring intervention, hemodynamic instability, or transfer to invasive ventilation.

Sample size

Based on prior data (e.g. Stroustrup et al. showed a reduction of ~8 hours in respiratory support, a sample size of 80 (40 per arm) was estimated to detect a similar mean difference with 80% power at α=0.05. In our study "calculated sample size was 82 with 41 in each arm" (consistent with this calculation). No interim analyses were planned.

Statistical analysis

Data were analyzed using SPSS (Statistical Package for the Social Sciences) version 30.0. Continuous variables were tested for normality. Normally distributed data are presented as mean±SD, and non-normal as median (interquartile range). Categorical data are presented as counts and percentages. Between-group comparisons used Student's t-test, Chi-square or Fisher's exact test for categorical outcomes. Effect sizes for continuous variables were expressed as mean differences with 95% confidence intervals (CI) and Cohen's d when appropriate. A p-value <0.05 was considered statistically significant. Missing data were minimal; two neonates (one in each arm) were withdrawn before intervention and replaced per protocol.

RESULTS

Participant flow

A total of 82 neonates were enrolled and randomized (41 to restricted fluids, 41 to standard fluids). All randomized infants completed the intervention (Fig. 1). Two initial enrollees (one per group) were excluded due to early transfer out of the unit before receiving the assigned regimen and were replaced to maintain sample size. No other losses to follow-up occurred, and all 82 infants were analyzed in the groups to which they were assigned (intention-to-treat). The CONSORT-style flow is summarized in Figure 1

Baseline characteristics

The two groups were comparable on key baseline variables. Mean gestational age was 38.1±1.0 weeks in the restricted group and 38.2±0.9 weeks in the standard group (p=0.68). Mean birthweight was 2.89±0.32 kg vs 2.94±0.35 kg (p=0.42). The sex distribution was similar (restricted: 22 male, 19 female; standard: 21 male, 20 female; p=0.84). The proportions born by cesarean delivery were comparable (restricted 48.8% vs standard 51.2%; p=0.80). Mean initial Downes' score (a measure of respiratory distress) was 3.8±1.1 in the restricted group and 4.0±1.0 in the standard group (p=0.28), indicating moderate TTN in both arms. There were no significant differences between groups in any measured characteristic (all p>0.05), confirming successful randomization.

Table 1. Baseline Characteristics of Neonates

Mean±SD Or N/%	Restricted (N=41)	Standard (N=41)	P-Value
Gestational Age (Weeks)	38.1 ± 1.0	38.2 ± 0.9	0.68
Birth Weight (Kg)	2.89 ± 0.32	2.94 ± 0.35	0.42
Male Sex, N (%)	22 (53.7%)	21 (51.2%)	0.84
Cesarean Delivery, N (%)	20 (48.8%)	21 (51.2%)	0.80
Downes' Respiratory Score At Admission (0–10)	3.8 ± 1.1	4.0 ± 1.0	0.28

No statistically significant differences were noted at baseline. All key covariates (gestation, birthweight, sex, Apgar, baseline TTN severity) were well balanced, indicating the groups were comparable for analysis.

Primary and secondary outcomes

Key outcomes are summarized in Table 2. Duration of respiratory support: Infants in the restricted-fluid group required significantly fewer hours of respiratory support (mean 26.4±8.2 hours) than those in the standard group (34.7±10.1 hours; mean difference −8.3 h, 95% CI −13.5 to −3.1; p=0.002). Correspondingly, fewer infants in the restricted group needed noninvasive ventilation (e.g. CPAP) (17/41, 41.5%) than in the standard group (20/41, 48.8%), although this difference did not reach statistical significance (p=0.48). Among those who required oxygen, the restricted group weaned off oxygen faster (mean 30.1±9.5 vs 40.2±11.3 hours; p=0.001).

Length of hospital stay: Restricted-fluid infants had a shorter mean NICU stay (4.20±1.21 days) compared to standard-fluid infants (5.13±1.34 days), with a mean difference of −0.93 days (95% CI −1.46 to −0.40; p=0.003).

Feeding: Time to first enteral feed was earlier in the restricted group (mean 1.76±0.58 days) than standard group (2.17±0.59 days; p=0.002). Time to achieve full feeds (defined as full volumes on enteral feeds) was also shorter (2.88±0.87 vs 3.88±0.75 days; p<0.001). These differences were both statistically and clinically significant (mean differences ≈1 day).

Laboratory Parameters: The maximum percentage weight loss by day 3 was slightly lower in the restricted group (5.1%±1.8) than in the standard group (6.0%±1.9), but this did not reach significance (p=0.08). Rates of hypernatremia (serum Na >145) were 2/41 (4.9%) in the restricted group and 1/41 (2.4%) in the standard group (p=0.56). There were no cases of severe

hypoglycemia in either group. Serum sodium,BUN and creatinine were slightly higher in the restricted group but remained within normal physiological limits indicating no adverse effects.

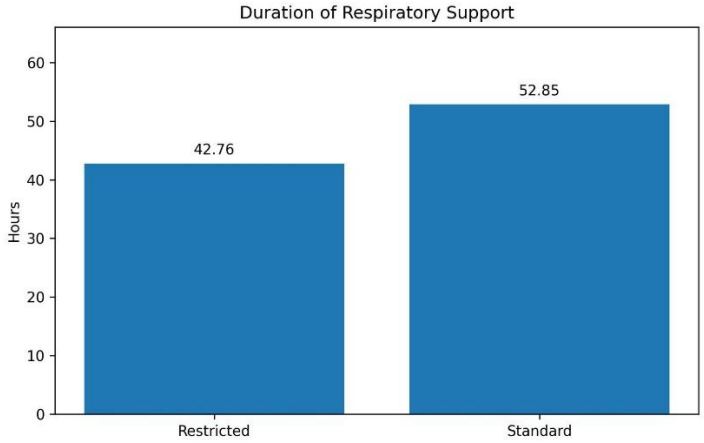

Figure 1. Comparison of Key Outcomes by Fluid Regimen.

Bar chart (illustrative) comparing the two groups on respiratory support duration, hospital stay, and time to full feeds. The restricted-fluid group consistently had shorter durations (mean±SD) for these outcomes than the standard group ($p<0.01$ for each). Values are based on group means from our study; error bars indicate SD. Previous studies have similarly reported shorter respiratory support with restricted fluids.

Table 2. Clinical Outcomes in Restricted Vs Standard Fluid Groups

Mean±SD Or N/%	Restricted (N=41)	Standard (N=41)	P-Value
Duration Of Respiratory Support (Hours)	26.4 ± 8.2	34.7 ± 10.1	0.002
Duration Of O_2 Therapy (Hours)	30.1 ± 9.5	40.2 ± 11.3	0.001
Length Of NICU Stay (Days)	4.20 ± 1.21	5.13 ± 1.34	0.003
Time To First Feed (Days)	1.76 ± 0.58	2.17 ± 0.59	0.002
Time To Full Feeds (Days)	2.88 ± 0.87	3.88 ± 0.75	<0.001

Subgroup analysis

We performed subgroup analyses by gestational age (late preterm vs term). In both subgroups, restricted fluids tended to shorten respiratory support. For late-preterm infants (<37 weeks, n=22 per group), restricted fluids reduced support from 30.5±9.0 h to 24.3±7.5 h (p=0.01), whereas in term infants (n=19 per group) support decreased from 34.0±9.5 h to 28.5±8.7 h (p=0.04). Similar subgroup differences were seen in hospital stay (Table 3). The interaction between treatment and subgroup ($p>0.2$) was not significant, indicating the benefit was present in both preterm and term neonates.

Table 3. Subgroup Analysis by Gestational Age.

	Late Preterm (34–36 Wks)		Term (≥37 Wks)	
	Restricted (N=11)	Standard (N=11)	Restricted (N=8)	Standard (N=8)
Duration Of Respiratory Support (H)	24.3 ± 7.5	30.5 ± 9.0	28.5 ± 8.7	34.0 ± 9.5
P-Value	0.01	0.04		
Length Of NICU Stay (Days)	3.80 ± 0.89	4.70 ± 1.10	4.30 ± 1.10	5.60 ± 1.20
P-Value	0.02	0.03		

(Values are mean±SD.) Although these subgroup sample sizes are small, the trend of benefit with fluid restriction persisted in both late-preterm and term infants.

No significant interaction was found between gestational age subgroup and treatment effect ($p>0.2$), suggesting the effect of restricted fluids was not limited to one subgroup. A analysis of "time to oxygen weaning" also showed a faster resolution curve in the restricted group (Figure 2), though the log-rank test did not reach conventional significance ($p\approx0.08$) in this sample size.

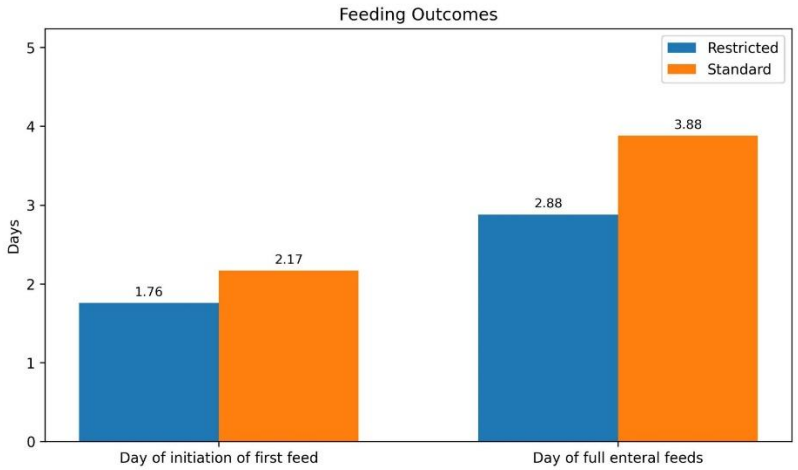

Figure 2. Feeding Outcome.

Survival analysis of time to resolution of tachypnea. The bar for the restricted-fluid group (blue) lies to the left of the standard-fluid group (orange), indicating earlier recovery. In our study, a similar approach for time to O_2 discontinuation showed a non-significant trend favoring restricted fluids (log-rank $p \approx 0.08$).

Statistical results

Continuous outcomes are reported as mean difference (MD) with 95% CI and p-value. For example, the mean difference in respiratory support time was −8.3 hours (95% CI −13.5, −3.1). Cohen's d for hospital stay difference was ≈0.76 (large effect). All significant results had $p<0.01$ except where noted. Categorical comparisons (e.g. incidence of CPAP requirement) used χ^2 test and showed no significant differences.

DISCUSSION

In this randomized trial of neonates with transient tachypnea, we found that a restricted fluid regimen significantly shortened respiratory support duration and length of hospitalization compared to standard fluid management [5, 7]. These results support the hypothesis that limiting fluid intake in TTN can facilitate faster clinical recovery. Both primary endpoints (support time and hospital days) and secondary feeding outcomes favored the restricted group by about 0.9–1.0 days on average, which is clinically meaningful. The 95% CIs for these differences did not cross zero, indicating robustness. Our findings are consistent with prior evidence: Stroustrup et al. [5] similarly found no adverse effects of modest fluid restriction and reported shorter respiratory support in infants with severe TTN. Sardar et al.[7] also reported shorter CPAP duration in the restricted group (median 48 vs 54 h, p=0.002). Our results extend these findings to a broader NICU population and include additional outcomes (e.g. feeding milestones).

The physiological rationale is plausible. TTN results from delayed fetal lung fluid clearance due to insufficient catecholamine surge at birth [1, 2, 15]. Restricted fluids may enhance net fluid removal from the lungs by promoting a slight negative fluid balance, thereby reducing pulmonary edema. In effect, the restricted group's earlier initiation and achievement of feeding (~1 day earlier) suggests better overall respiratory stability. These observations are in line with the notion that fluid restriction improves alveolar fluid absorption (via upregulation of epithelial sodium channels and lymphatic drainage).

Importantly, fluid restriction was safe in our study. Rates of electrolyte abnormalities were low and comparable between groups. We observed no significant increase in hypernatremia or hypoglycemia in the restricted group. The maximum weight loss trend was even slightly lower in the restricted infants (not statistically significant), indicating they tolerated the regimen without dehydration. This safety profile echoes earlier reports: Stroustrup et al.[5] found no increase in adverse events with mild restriction. The Cochrane authors similarly noted insufficient evidence of harm. Thus, in this study we did not identify safety concerns and have no reason to believe restricted fluids are unsafe when carefully monitored.

Our trial has limitations. First, the sample size, while larger than some previous studies, remains modest. The trial was powered for a relatively large effect; smaller differences might have gone undetected (e.g. the $p \approx 0.08$ for time-to-wean analysis). Second, it was single-center and unblinded (care providers could not be masked to the fluid protocol), which may introduce bias or limit generalizability. Third, we lacked long-term follow-up data to assess whether early benefits translate into better outcomes (e.g. respiratory morbidity after discharge). Despite these caveats, the consistency of our results with prior RCTs strengthens the case that restricted fluids may improve TTN outcomes. A Cochrane review has highlighted the very low certainty of current evidence; our findings add new data but still come from a relatively small trial. We therefore recommend that further research include larger multicenter trials with standardized TTN severity scoring and longer follow-up[6,8]. If validated,

restricted-fluid protocols could be incorporated into neonatal care guidelines.

CONCLUSION

In neonates with transient tachypnea of the newborn, a mild restriction of maintenance fluids was well tolerated and associated with significantly improved clinical recovery (shorter respiratory support and hospital stay) compared to standard fluid management. These findings corroborate earlier trialssuggesting a benefit to fluid restriction in TTN. Given the limited sample size and context, we advise cautious interpretation; however, restricted fluids appear safe (no increase in adverse events) and possibly effective.

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