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Effect of Needle Aspiration of Pneumothorax on Subsequent Chest Drain Insertion in Newborns
A Randomized Clinical Trial

Madeleine C. Murphy, MB, MRCPI; Christian Heiring, MD; Nicoletta Doglioni, MD, PhD; Daniele Trevisanuto, MD; Mats Blennow, MD, PhD; Kajsa Bohlin, MD, PhD; Gianluca Lista, MD, PhD; Ilaria Stucchi, MD; Colm P. F. O'Donnell, MB, PhD

IMPORTANCE Treatment options for a symptomatic pneumothorax in newborns include needle aspiration (NA) and chest drain (CD) insertion. There is little consensus as to the preferred treatment, reflecting a lack of evidence from clinical trials.

OBJECTIVE To investigate whether treating pneumothoraces diagnosed on chest radiography (CR) in newborns receiving respiratory support with NA results in fewer infants having CDs inserted within 6 hours of diagnosis.

DESIGN, SETTING, AND PARTICIPANTS This randomized clinical trial was conducted from October 7, 2013, to December 21, 2016. The setting was 5 tertiary European neonatal intensive care units. Infants receiving respiratory support (endotracheal ventilation, continuous positive airway pressure, or supplemental oxygen >40%) who had a pneumothorax on CR that clinicians deemed needed treatment were eligible for inclusion.

INTERVENTIONS Infants were randomly assigned (1:1) to drainage using NA or CD insertion, stratified by center and gestation at birth (<32 vs ≥32 weeks). Caregivers were not masked to group assignment. For NA, a needle was inserted between the ribs to aspirate air and was removed once air was no longer aspirated. A CD was inserted if clinicians deemed that the response was inadequate. For CD insertion, a drain was inserted between the ribs and was left in situ.

MAIN OUTCOMES AND MEASURES The primary outcome was whether a CD was inserted on the side of the pneumothorax within 6 hours of diagnosis.

RESULTS A total of 76 infants were randomly assigned, and 6 (4 assigned to NA and 2 to CD) were excluded because they met exclusion criteria at enrollment. Of the 70 remaining infants, 33 (16 male [48%]) were assigned to NA and 37 (22 male [59%]) to CD insertion. Their median (interquartile range [IQR]) gestational age was 31 (27-38) vs 31 (27-35) weeks, and their median (IQR) birth weight was 1385 (1110-3365) vs 1690 (1060-2025) g, respectively. Fewer infants assigned to NA had a CD inserted within 6 hours (55% [18 of 33] vs 100% [37 of 37]; relative risk, 0.55; 95% CI, 0.40-0.75) and during hospitalization (70% [23 of 33] vs 100% [37 of 37]; relative risk, 0.70, 95% CI, 0.56-0.87).

CONCLUSIONS AND RELEVANCE Needle aspiration reduced the rate of CD insertion in symptomatic newborns with pneumothorax on CR. It should be used as the initial method of draining radiologically confirmed pneumothorax in symptomatic infants.

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Author Affiliations: Department of Neonatology, National Maternity Hospital, Dublin, Ireland (Murphy, O'Donnell); School of Medicine, University College Dublin, Dublin, Ireland (Murphy, O'Donnell); National Children's Research Centre, Dublin, Ireland (Murphy, O'Donnell); Department of Neonatology, Rigshospitalet, Copenhagen, Denmark (Heiring); Department of Women's and Children's Health, Azienda Ospedaliera di Padova, University of Padova, Padova, Italy (Doglioni, Trevisanuto); Karolinska Institutet, University Hospital, Stockholm, Sweden (Blennow, Bohlin); Department of Neonatology, Ospedale dei Bambini "Vittore Buzzi," Milano, Italy (Lista, Stucchi).

Corresponding Author: Colm P. F. O'Donnell, MB, PhD, Department of Neonatology, National Maternity Hospital, Holles Street, Dublin 2, Dublin D02 YH21, Ireland (codonnell@nmh.ie).

Pneumothorax, a collection of air in the pleural space, can cause or exacerbate respiratory distress and may be life threatening. A symptomatic pneumothorax occurs in 0.05% to 1% of newborns and in 5% to 7% of infants weighing less than 1500 g.[1-4] Risk factors include respiratory distress syndrome, meconium aspiration, and pulmonary hypoplasia, and the incidence is increased in infants who are resuscitated at birth or are born by elective cesarean delivery before 39 weeks' gestation.[5-7] Mortality was higher among preterm infants who developed pneumothorax compared with well-matched control infants who did not.[8]

Treatment options for pneumothorax include expectant management, needle aspiration (NA),[9] and chest drain (CD) insertion. Needle aspiration (ie, removal of air through a needle that is inserted between the ribs and removed once air is no longer freely aspirated) is recommended as the first-line treatment of symptomatic spontaneous pneumothorax in adults[10] based on randomized studies[11-14] that compared it with CD insertion (ie, a catheter inserted between the ribs and left in situ). There is little consensus as to the preferred treatment in newborns. Some clinicians believe that NA may not provide definitive treatment and delay CD insertion, particularly in ventilated infants. Complications of CD insertion in newborns include thoracic organ injury[15] and breast deformities in adolescent girls.[16] Although many favor immediate insertion of a CD, the results of a retrospective cohort study[17] suggested that it is possible to treat a select group of ventilated neonates with pneumothorax expectantly. One randomized trial[18] that compared NA with CD insertion in 72 newborns indicated that aspiration may be safe and avoid the need for a CD. However, that study did not reflect widespread practice because the infants assigned to NA had a small-gauge catheter inserted that was left in situ (mean duration, 27.1 hours). A recent Cochrane review concluded that randomized clinical trials were needed comparing NA with CD insertion for pneumothorax in newborns.[19] For infants who are receiving respiratory support and who have a pneumothorax diagnosed on chest radiography (CR) that the treating clinician wants to drain, we aimed to determine whether NA reduces the rate of CD insertion within 6 hours of diagnosis.

Key Points

Question Among newborns receiving respiratory support, does treating pneumothoraces diagnosed on chest radiography with needle aspiration result in fewer infants having chest drains inserted within 6 hours of diagnosis?

Findings In this randomized clinical trial of 70 infants, fewer infants assigned to needle aspiration had a chest drain inserted within 6 hours.

Meaning Because needle aspiration reduced the rate of chest drain insertion, it should be used as the initial method of draining radiographically confirmed pneumothorax in symptomatic infants.

Methods

Study Design

From October 7, 2013, to December 21, 2016, we conducted the Needle or Drain (NORD) trial in the neonatal intensive care units at the following 5 tertiary European hospitals: National Maternity Hospital, Dublin, Ireland; Rigshospitalet, Copenhagen, Denmark; Azienda Ospedaliera di Padova, Padova, Italy; Karolinska Institutet, Stockholm, Sweden; and Ospedale dei Bambini "Vittore Buzzi," Milan, Italy. The study was approved by the research ethics committees at all participating centers before the first patient was enrolled (Supplement).

Participants

Infants were eligible for inclusion if they had a pneumothorax diagnosed on CR (clinical diagnosis alone was insufficient), were receiving respiratory support (endotracheal ventilation, continuous positive airway pressure, or supplemental oxygen >40% to keep oxygen saturation >90%), and the treating clinicians wanted to treat the pneumothorax. Infants were ineligible if they did not have respiratory distress or had significant pulmonary hypoplasia.

Treatment of pneumothorax is performed as an emergency procedure. Distress and time constraints associated with obtaining consent for research in emergency situations may compromise understanding and voluntariness, which are essential components of informed consent.[20] Because NA and CD insertion are well-recognized and widely used treatments for pneumothorax, the research ethics committees approved the use of a waiver of consent to enroll infants. We informed parents as soon as it was practical about the study and asked for their written permission to collect their infant's information. Parents were informed that they could withdraw their child from the study without explanation.

Randomization and Masking

Infants were randomly assigned (1:1) to NA or CD insertion. Randomization was stratified by center and gestational age (GA) at birth (<32 vs ≥32 weeks). We generated the group assignment schedule at National Maternity Hospital in blocks of 4 using a random number table. Group assignment was written on cards and placed in sequentially numbered, sealed, opaque envelopes. Neither caregivers nor outcome assessors were masked to group assignment.

Procedures

Needle Aspiration

A needle (butterfly needle or cannula) was attached via a 3-way tap to a syringe and inserted into the second intercostal space in the midclavicular line. The needle was inserted perpendicular to the chest, the tap was opened to the syringe, and air was aspirated. When the syringe was full, the tap was opened to the atmosphere, and the air was expelled. These steps were repeated until air was no longer aspirated freely, and the needle was then removed. Needle aspiration was performed once only. If the clinician deemed that there was insufficient improvement, a CD was inserted. It was not mandatory to obtain a CR before CD insertion because we did not want to delay treatment that clinicians believed was necessary in participants who were very ill.

CD Insertion

Chest drains were inserted in the fifth intercostal space in the midaxillary line. A drain with a trocar or a pigtail drain was used. Trocar drains were inserted after superficial infiltration of the area with 1% lidocaine hydrochloride. An incision was made in the skin, and a forceps was used to bluntly dissect through the tissue to the pleura. The drain was then inserted, connected to an underwater seal, and secured. A CR was obtained to confirm the position. For pigtail drain insertion, a needle and syringe were assembled and inserted perpendicular to the chest. The syringe was removed, and the soft end of the J-wire was advanced through the needle. When the guide wire had passed through the chest wall, the needle was removed. The dilator was then advanced over the wire and thereafter removed. The pigtail drain was fed over the J-wire and advanced, and the J-wire was removed. The catheter was secured and connected to drainage, and the position was confirmed with a CR.

Outcomes

The primary outcome was whether a CD was inserted for treatment of a pneumothorax within 6 hours of diagnosis. Chest drain insertion during hospitalization was a secondary outcome. Other prespecified secondary outcomes were as follows: (1) number of CDs inserted, (2) duration of CD in situ, (3) duration of endotracheal ventilation, (4) duration of respiratory support, (5) pleural effusion related to CD, (6) proven nosocomial infection related to CD, (7) positive blood cultures during stay, (8) duration of hospital stay, (9) survival without bronchopulmonary dysplasia (defined as oxygen treatment at day 28 of life), (10) survival without long-term lung disease (defined as oxygen treatment at 36 weeks' corrected GA), and (11) death before hospital discharge.

Statistical Analysis

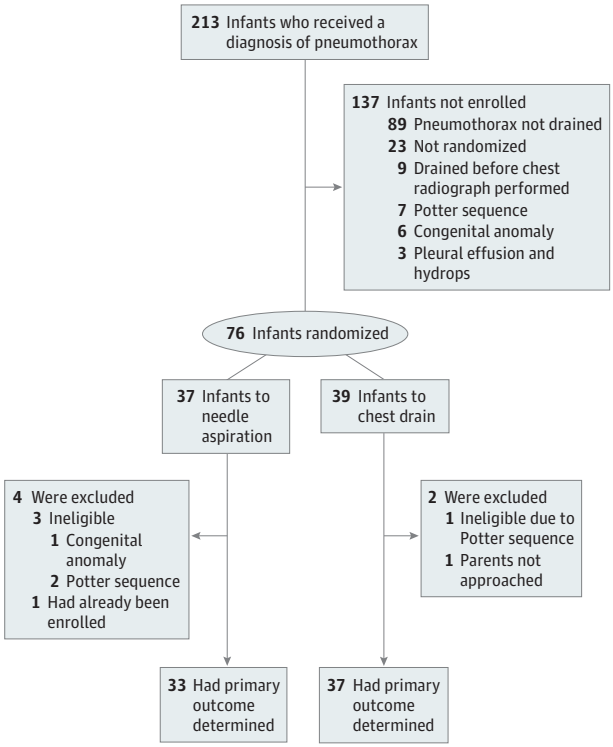
To demonstrate a reduction in the rate of CD insertion within 6 hours from 100% to 80% (relative and absolute reduction of 20%) using NA with a 2-tailed type I error rate of .05 and 80% power, we estimated that we would need to recruit 70 infants. Statistical significance was set at $P < .05$. We analyzed data using statistical software (SPSS, version 20; IBM). Continuous data were described using the mean (SD) when normally distributed and the median (IQR) when the distribution was skewed and were compared using parametric tests. Dichotomous data were expressed as proportions and compared using nonparametric tests.

Results

Study Findings

A total of 213 infants were assessed for eligibility (**Figure**). Of the 76 infants randomized, 6 were excluded after randomization. Final analysis was performed on the remaining 70 infants (26 at National Maternity Hospital, 16 at Rigshospitalet, 14 at Azienda Ospedaliera di Padova, 8 at Karolinska Institutet, and 6 at Ospedale dei Bambini "Vittore Buzzi") using a modified intent-to-treat principle.

Figure. Diagram of the Trial Profile of Infants Who Received a Diagnosis of Pneumothorax at Participating Centers



Thirty-three infants were randomized to NA and 37 to CD insertion. The groups were well matched for demographic variables (**Table 1**).

Fewer infants randomized to NA had a CD inserted within 6 hours (number needed to treat [NNT], 2) and during hospitalization (NNT, 3) (**Table 2**). There were no statistically significant differences in any of the other secondary outcomes measured (**Table 3**).

Nine infants died before hospital discharge (median [IQR] GA, 26 [24-27] weeks and median [IQR] birth weight, 600 [590-1030] g). More infants assigned to NA died (7 of 33 [21%] vs 2 of 37 [5%]); however, the difference in mortality between the groups was not statistically significant. Five infants died of respiratory failure within 48 hours of study entry, 3 assigned to NA (all of whom had CDs inserted) and 2 assigned to CD. Four infants assigned to NA died of causes apparently unrelated to the intervention days to months later (systemic thrombosis on day 6, disseminated intravascular coagulation at 7 weeks, cardiac failure at 8 weeks, and congenital surfactant protein B deficiency at 8 months). Six of the 7 infants assigned to NA who died had a CD inserted (median [IQR], 1.8 [0.5-2.6] hours, with the longest interval being 4.5 hours); the remaining infant died at 8 weeks.

The proportion of infants assigned to NA who had a CD inserted within 6 hours did not differ across centers. These included 6 of 12 at National Maternity Hospital, 4 of 7 at Rigshospitalet, 6 of 8 at Azienda Ospedaliera di Padova, 1 of 4 at Karolinska Institutet, and 1 of 2 at Ospedale dei Bambini "Vittore Buzzi."

Among infants less than 32 weeks' GA, 17 infants were assigned to NA and 22 infants to CD insertion. Fewer infants assigned to NA had a CD inserted within 6 hours (12 of 17 [71%] vs 22 of 22 [100%]). Among infants at 32 weeks' GA or older, 16 infants were assigned to NA and 15 infants to CD insertion. Fewer infants assigned to NA had a CD inserted within 6 hours (6 of 16 [38%] vs 15 of 15 [100%]) and during hospitalization (9 of 16 [56%] vs 15 of 15 [100%]).

Overall, there was no difference between the groups in the proportion of infants who were ventilated at study entry. However, fewer infants at 32 weeks' GA or older who were assigned to NA were ever ventilated during hospitalization compared with those who were assigned to CD insertion (5 of 16 [31%] vs 11 of 15 [73%]).

The volume of air removed with NA was recorded for 31 of 33 infants. A median (IQR) of 35 (20-45) mL was removed; the volume aspirated was similar whether or not a CD was subsequently inserted. The method used was recorded for 30 infants. There was no difference in whether a CD was inserted if a butterfly needle or a cannula was used (14 of 25 [56%] vs 3 of 5 [60%]).

Both pigtail drains and trocars were used during the study. The choice of CD varied across centers: pigtail drains were predominantly used at National Maternity Hospital and Karolinska Institutet, whereas trocar drains were predominantly used at Rigshospitalet, Azienda Ospedaliera di Padova, and Ospedale dei Bambini "Vittore Buzzi."

Table 1. Infant Characteristics at Study Entry[a]

Variable	Needle Aspiration (n = 33)	Chest Drain (n = 37)
GA, median (IQR), wk	31 (27-38)	31 (27-35)
GA <32 wk, No. (%)	17 (52)	22 (59)
Birth weight, median (IQR), g	1385 (1110-3365)	1690 (1060-2025)
Male sex, No. (%)	16 (48)	22 (59)
Multiple births, No. (%)	11 (33)	6 (16)
Antenatal (GA <32 wk) corticosteroid exposure, No./total No. (%)	17/17 (100)	19/22 (86)
Endotracheal ventilation at study entry, No. (%)	14 (42)	17 (46)
GA <32 wk, No./total No. (%)	12/17 (71)	12/22 (55)
GA ≥32 wk, No./total No. (%)	2/16 (13)	5/15 (33)
CPAP at study entry, No. (%)	16 (48)	20 (54)
Oxygen concentration, mean (SD), %	53 (22)	48 (24)

Abbreviations: CPAP, continuous positive airway pressure; GA, gestational age; IQR, interquartile range.

[a] Median (IQR) compared by independent-samples median test. No. (%) compared by Fisher exact test. Mean (SD) compared by independent-samples *t* test.

Exploratory Outcome

There was no difference between the groups in the proportion of infants ventilated at study entry (14 of 33 [42%] vs 17 of 37 [46%]; relative risk [RR], 0.92; 95% CI, 0.54-1.57). However, fewer infants randomized to NA were ventilated during hospitalization compared with those randomized to CD (19 of 33 [58%] vs 30 of 37 [81%]; RR, 0.71; 95% CI, 0.51-0.99).

Of the 33 infants assigned to NA, 14 (42%) were ventilated at study entry, and 19 (58%) were not. More infants who were ventilated had a CD inserted within 6 hours compared with those who were not ventilated (11 of 14 [79%] vs 7 of 19 [37%]; RR, 2.13; 95% CI, 1.11-4.08).

Of the 18 infants randomly assigned to NA who had a CD inserted, 12 had a follow-up CR before its insertion. For the 6 infants who did not have a follow-up CR, CDs were inserted within 1 hour for 4 infants and at 3 and 4.5 hours for the remaining 2 infants.

Five infants assigned to NA had CDs inserted more than 6 hours after the initial diagnosis; these were inserted from 7.5 to 21 hours. All infants showed significant improvement on CRs obtained after NA. All 5 infants subsequently had clinical deterioration, a repeat CR was obtained, and a CD was inserted because of reaccumulation of the pneumothorax.

Fifteen of the 33 infants assigned to NA did not have a CD inserted within 6 hours (GA range, 23-41 weeks and birth weight range, 590-4610 g). Three of the 15 (20%) were ventilated at study entry.

Discussion

In this randomized clinical trial, NA reduced the rate of CD insertion in symptomatic newborns with pneumothoraces. Infants had to have a pneumothorax diagnosed on CR to be eligible for enrollment. Although transillumination of the chest may be helpful in detecting a pneumothorax acutely, its diagnostic accuracy and reliability are uncertain. While ultrasonography is becoming increasingly popular for diagnosing pneumothoraces,[21,22] it was not widely used at the time of study design. The requirement for CR diagnosis did not adversely affect enrollment because few infants were treated for

Table 2. Enrolled Infants Who Had a Chest Drain Inserted

Variable	No./Total No. (%)		Relative Risk (95% CI)
	Needle Aspiration	Chest Drain	
Chest drain within 6 h[a]	18/33 (55)	37/37 (100)	0.55 (0.40-0.75)
GA <32 wk	12/17 (71)	22/22 (100)	0.71 (0.52-0.96)
GA ≥32 wk	6/16 (38)	15/15 (100)	0.38 (0.20-0.71)
Chest drain during hospitalization	23/33 (70)	37/37 (100)	0.70 (0.56-0.87)
GA <32 wk	14/17 (82)	22/22 (100)	0.82 (0.66-1.03)
GA ≥32 wk	9/16 (56)	15/15 (100)	0.56 (0.37-0.87)

Abbreviation: GA, gestational age.

[a] Primary outcome.

Table 3. Other Secondary Outcomes[a]

Variable	Needle Aspiration (n = 33)	Chest Drain (n = 37)	Relative Risk (95% CI)	Absolute Difference (95% CI)
No. of chest drains inserted, median (IQR)	1 (0 to 2)	1 (1 to 2)	NA	0 (−1 to 0)
Duration of chest drain in situ, median (IQR), h	49 (0 to 96)	60 (44 to 108)	NA	−11 (−48 to 0)
Duration of endotracheal ventilation, median (IQR), d	2 (0 to 6)	2 (1 to 5)	NA	0 (−2 to 1)
Duration of respiratory support, median (IQR), d	5 (3 to 12)	6 (3 to 40)	NA	−1 (−5 to 1)
Pleural effusion related to chest drain, No. (%)	0	1 (3)	NA	NA
Proven nosocomial infection related to chest drain, No. (%)	0	1 (3)	NA	NA
Positive blood cultures during stay, No. (%)	2 (6)	3 (8)	0.75 (0.13 to 4.20)	NA
Duration of hospital stay, median (IQR), d	12 (4 to 40)	31 (18 to 67)	NA	−19 (−33 to −6)
Survival without BPD, No./total No. (%)	3/17 (18)	9/22 (41)	1.39 (0.92 to 2.10)	NA
Survival without chronic lung disease, No./total No. (%)	4/17 (24)	11/22 (50)	1.52 (0.93 to 2.50)	NA
Death before hospital discharge, No. (%)	7 (21)	2 (5)	3.92 (0.87 to 17.58)	NA
Exploratory Outcome				
Endotracheal ventilation during stay, No./total No. (%)	19/33 (58)	30/37 (81)	0.71 (0.51 to 0.99)	NA
GA <32 wk	14/17 (82)	19/22 (86)	0.95 (0.72 to 1.26)	NA
GA ≥32 wk	5/16 (31)	11/15 (73)	0.43 (0.19 to 0.94)	NA

Abbreviations: BPD, bronchopulmonary dysplasia; GA, gestational age; IQR, interquartile range; NA, not applicable.

[a] Median (IQR) compared by independent-samples median test. No. (%) compared by Fisher exact test.

a pneumothorax before confirmation with a CR at participating centers during the study period.

We found statistically significant and clinically important effects of NA. For many infants, it had a lasting effect and did not merely delay definitive treatment. The NNT to avoid CD insertion within 6 hours was 2; the NNT to avoid CD insertion during hospitalization was 3. This is an impressive treatment effect for a procedure that can be carried out easily and with fewer reported adverse effects compared with CDs.

Preterm infants and those who are ventilated are important subgroups to consider. Five of 17 (29%) infants less than 32 weeks' GA assigned to NA did not have a CD inserted within 6 hours. Three of 14 (21%) infants assigned to NA who were ventilated at study entry did not have a CD inserted within 6 hours.

The difference between the groups in mortality before hospital discharge was not statistically significant. We do not believe that the 7 deaths that occurred among infants in the NA group were attributable to the intervention or to either a lack of or delay in CD insertion. There was a suggestion of increased survival without chronic lung disease among preterm infants randomized to CD; while this suggestion might reflect increased mortality in the NA group, it may likely be a chance finding because our sample size was small and the study was not adequately powered.

We found a strong association between ventilation and CD insertion. Ventilated infants randomized to NA were more likely to have a CD inserted. Although similar proportions of infants in both groups were ventilated at study entry, more infants assigned to CD insertion were subsequently ventilated. This outcome may partly reflect some clinicians' preferences or beliefs that ventilated infants with pneumothorax should have a CD and that infants with a CD should be ventilated. While our results highlight the association between CD insertion and ventilation, our small, unmasked study was not stratified according to whether participants were ventilated at study entry and cannot determine a causal relationship. However, we speculate that avoiding CD insertion may reduce ventilation. This outcome may have implications for cost, resource consumption, and duration of stay. We recommend that future studies of treatments for pneumothorax should stratify randomization by type of respiratory support at study entry.

Our study was unusual in that half of the infants were randomly assigned to the primary outcome. However, we believe that this protocol was reasonable because CD insertion for a symptomatic pneumothorax was a well-accepted treatment at all participating centers and in most neonatal intensive care units internationally at the time of study design. Avoiding CD insertion is a clinically meaningful outcome because rare but devastating adverse events have been reported with this procedure.[15,16] We enrolled infants using a waiver of consent. We could not have completed this study if prospective consent had been required and believe that this approach was acceptable to parents and caregivers.

Strengths and Limitations

To our knowledge, our study is the first to examine NA and immediate CD insertion for treatment of symptomatic pneumothoraces in newborns. A strength of this study is that it was a trial of an emergency treatment of a rare event in a unique population. The infants enrolled were appropriately sick. Its multicenter design increases the generalizability of our findings.

The principal weakness of our study is that clinicians were not masked to group assignment, introducing the risk of performance bias. Also, we did not specify criteria for CD insertion in those randomized to NA. Given the likely wide variation in any single measure of illness severity (eg, signs of respiratory distress, mode of respiratory support, distending pressures, oxygen requirement, and pneumothorax size on CR) among participants at study entry, we could not satisfactorily define when we designed the study an inadequate response to NA that would be applicable to all participants that would prompt CD insertion. Therefore, if the clinician deemed the response to NA to be inadequate, a CD was inserted. This process may have introduced potential for bias in deciding whether or not to insert a CD in this unmasked study. We suspect that this process may have been the case for infants who were ventilated and that bias may have led to more CDs being inserted, potentially underestimating the effect of NA. Furthermore, when designing the study, we did not mandate that participants assigned to NA should have a CR obtained after the procedure to check for resolution of the pneumothorax. We did not want to delay treatment (CD insertion) that clinicians believed was necessary for infants who were very ill. Also, we did not want participants to have CRs that they might not otherwise have received. Furthermore, for participants who had a satisfactory clinical response to NA, we did not want to increase the likelihood of CD insertion by identifying residual air on CR that they might not otherwise have had. In addition, our small sample size rendered the study underpowered to measure differences between the groups in rare but clinically important outcomes (eg, thoracic organ injury). Because neither the type of needle nor the CD type was randomly assigned, it is not possible to draw conclusions about the relative merits of any of the devices used.

Conclusions

Needle aspiration significantly reduced the rate of CD insertion in symptomatic newborns with pneumothorax on CR. It should be used as the initial method of draining radiologically confirmed pneumothorax in symptomatic infants.

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Study concept and design: O'Donnell.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Murphy, O'Donnell.
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