

Written for study purposes and generalized for Clinical Use here with italicized comments by the author to answer Frequently Asked Questions.

PROTOCOL TITLE:

Abdominal Support for CPAP Belly

1.0 Objectives

- 1.1 Hypothesis: If a neonate supported on CPAP has abdominal wall support, then gaseous distension can be minimized in the bowel preserving abdominal wall integrity and optimizing respiratory course.

2.0 Background

- 2.1 Clinically, neonates experience gaseous abdominal distension due to CPAP. Air in the abdomen can over distend the bowel, weaken the abdominal wall musculature by overstressing it and inhibit respiration by pressing up on the diaphragm. The abdominal wall is important in postural support of respiration, digestion, and elimination and if supported may optimize functions including breathing, motor control and address concerns including constipation.
- 2.2 In past efforts to use abdominal wall support clinically, infants with weak abdomens have been observed to have improvement in comfort, abdominal muscle tone and integration with the thoracic cage, and ability to stool. It has been used while still on CPAP and decreased gaseous distension and maintained level of respiratory support, rather than escalation sometimes seen when infants have abdominal distension significant enough to inhibit respiration.
- 2.3 Jaile and colleagues published in 1992 in regard to benign gaseous distension in premature infants on CPAP. They found it was common in infants less than 1000 grams occurring 82% of the time. While they found it was not correlated with serious morbidity at the time, discussion continues as to the consequences of this distension as represented in an editorial piece by Dr. Kim in 2018 voicing concerns for inhibition of respiration and effects on bowel wall development and dysmotility. This clinician adds the concerns for musculoskeletal development as the muscles of the abdominal wall, as well as the bowel, are premature When they are overstretched and weakened in this process it has unknown long-term effects to chest wall and motor development. Massery outlines the role of the chest wall in development. While Koo 2015 describes the relationship between diaphragm dysfunction and loss of abdominal wall integrity, this clinician has seen post-CPAP abdominal diastasis representing decreased abdominal wall integrity in premature infants.

Stabilization of the rib cage and abdominal wall has been used to optimize respiratory function when the abdominal wall is compromised by SCI, as described by West 2012. And an elastic band has been used in the premature population as described in Brunherotti 2013 to improve oxygen saturations.

Dr. Kim shared his concerns. He called for creative solutions to address the concerns of CPAP belly. This is one potential answer.

Case reports, McGill 2022, describing this intervention were peer reviewed and accepted for publication by the Journal of Neonatal-Perinatal Medicine.

3.0 Inclusion and Exclusion Criteria

- 3.1 Inclusion Criteria: Babies born less than 32 weeks who are at least 7 days old advancing on enteral feeds and established spontaneous stooling.

(You can use abdominal support at any point to rehabilitate after CPAP is discontinued. This protocol was written for expanding this practice to prevention and habilitation rather than rehabilitation. Tolerating feeds and stooling represents establishing typical GI function and each unit may develop a different parameter to meet that criteria for safety.)

- 3.2 Infant currently receiving CPAP therapy.

(Different centers are using different forms of non-invasive ventilation. While gaseous distension is also seen with these different forms of positive pressure ventilation, this clinician has only explored use on BCPAP thus far)

- 3.3 Infant is tolerating at least 140mL/kg based on birthweight for at least 48 hours.
(My center has since decreased this to 120ml/kg and each center may have a different definition of full enteral feeds or advancing enteral feeds with which they are comfortable with for establishing GI function)

- 3.4 There are no skin integrity concerns (skin has been evaluated by provider).

- 3.5 Infant has been voiding and stooling appropriately.

- 3.6 No concerns for abdominal pathology (NEC, obstruction, infectious ileus, etc.)

- 3.7 Parents have given consent to use band.

(This is taken from a study protocol. While clinical use does not necessitate consent necessarily, I recommend having and documenting discussion of its use with the family. This is simply good practice, in my opinion, for any placement of something on a child's body and I do the same for splints and casts, etc.)

- 3.8 Exclusion Criteria: Infants who have experienced GI (gastrointestinal) insult including spontaneous ileal perforation, necrotizing enterocolitis or undergone GI surgery or have concerns for GI compromise, inability to stool spontaneously i.e., Hirschsprung's or other GI concerns. Infants with

hydrocephalus as norms are established as a ratio to head circumference.
Genetic anomalies.

(This, again, was for study purposes. An abundance of caution is advised when considering surgical and other past pathological conditions. Arguments can be made for later use as surgery can weaken the abdominal wall. I always have this discussion with Neonatology and Surgery. Use, in this circumstance in my experience, has been limited and much after healing and re-establishment of GI function.)

4.0 Procedures Involved

- 4.1 Infants on admission will be measured for abdominal and head circumferences and these measurements will continue to be taken one time a week for head circumference as is current practice and nightly for abdominal circumference which is an added but not experimental practice. Abdominal wall to head circumference ratios to establish if girth is in normal range as established in Setruk 2020. Monitor level of respiratory support.
- A group of belly band superusers is being trained including Respiratory therapy as this is a smaller group and consistently present at care times for infants on CPAP on every shift who can guide and ensure proper fit. Training includes an in person teaching session with a PT or OT, sample abdominal support and doll to demonstrate proper position and fit and provide opportunities for questions. Many bedside staff are familiar with its use clinically and superusers are intended to be an extra layer of support for checking proper fit.

Workflow:

- Nurses will measure and chart abdominal circumference every evening when obtaining the daily weight. ***(Each unit has a different baseline of taking and using abdominal circumference already)***
- Nurse, therapist and provider team will discuss whether a patient qualifies for a BellyBand during rounds.
- If a patient qualifies, PT or OT will apply BellyBand.
- PT and OT will plot AC (abdominal circumference): HC (head circumference) ratio on normative curves to track for data collection.
- PT and OT will keep running excel document of patients with Belly Bands (see data below).
- PT and OT will provide new bands as needed for growth determined by band no longer being correct width for trunk length measured from Xiphoid process to center of line between ASISs.
- Nurses will open band at each care-time (every 3-6 hours) to assess skin and abdomen - this is typical interval currently assessed in the NICU.
(Some are concerned about covering the abdomen, however, the neonatologists I

work with noted, that if the infant is swaddled or prone the abdomen is not being continuously visualized and having a band on and opening it at care time is the same interval for assessment that would happen if they were not wearing it.)

- Nurses will open LDA and chart skin integrity and wear schedule in EPIC.
- Parents and nurses fill out Likert scale at least weekly for each infant after Belly Band is applied.

Data Collection:

- Variables to collect for each patient to use in Case Series:
 - Infant name, DOB, MRN
 - Race, Gender
 - Birth GA, Birth weight
 - Admission respiratory support
 - Date/PMA of Belly Band Application
 - AC
 - HC
 - AC:HC Ratio
 - Weight and Length
 - PEEP
 - FiO2 range
 - Day of life achieved full feeds = 140ml/kg
 - PMA on CPAP
 - Days of total CPAP
 - PMA successfully off CPAP
 - PMA successfully off all respiratory support
 - PMA first oral feeding
 - PMA full oral feeding/time to full oral feeding
 - PMA at discharge/length of stay
 - Feeding tolerance issues during course
 - Inguinal or umbilical hernia present
 - Stooling frequency
 - Emesis/reflux frequency
 - Home with G-tube or oxygen
 - Skin break-down or concern
 - Feeding tolerance/comfort per parents or nursing via Likert Scale (past feedback has been most significant for feeling their infant is more comfortable during wear)
 - Z-score change from birth to discharge
- Goal to collaborate with other centers in the future for possible multi-center RCT
(This was a goal of speaking at NANT 2023 and collaboration is underway for a multi-center QI project – feel free to reach out if you would like support in studying this at your center)

Abdominal support will remain in place continuously other than skin checks for duration of CPAP treatment, weaning period will include 6 hours on/6 hours off for

first 48 hours off CPAP and until circumference normalizes . During treatment interval skin will be checked every care time by bedside RN and charted in LDA.

A case control study was considered but given this intervention has been used with success in this unit before, staff interviewed felt it would be difficult ethically not to treat. As this is a new intervention, all infants prior to use of this intervention at this facility and in other NICUs are comparisons. ***(This is specific to my unit and is part of why collaboration is key. Use in other centers is how to establish the generalizability of this intervention.)***

- 4.2 EPIC notes, and flowsheet values, x-rays and pictures to be used in illustrating response of patients to abdominal wall support may be used from medical chart as well as normative graphs.

5.0 Data Management and Confidentiality

- 5.1 Patient information will be maintained in EPIC with consents including access of PHI from parents, identifiers removed for publications or outside use. Information in Excel sheet will be kept in SharePoint to maintain confidentiality. Information will be kept for 5 years after completion of study and then discarded following proper institutional policies for disposal of paper and electronic records.
- 5.2 Data Analysis by CNS and/or Statistician to establish efficacy of treatment. This will include descriptive graphs of ratios to look for trends of ability to maintain normal girth ratios.
- 5.3 For comparison past patients of similar demographics who underwent routine care/did not receive any intervention could be compiled through retrospective chart review.
- 5.4 NA

6.0 Risks to Subjects

- 6.1 As applied has minimal but possible risk of skin injury, application instruction to include not having temperature probes under support band. Intention is not to apply at less than existing abdominal girth and therefore compression of the abdomen is not a goal. It is possible but minimized by detailed instruction in application, including to lay on and fasten not tighten or squeeze an infant in to the band. The purpose is support of

muscles underlying, not compression. Minimal but possible risk of loss of data, minimized by storage plan.

6.2 NA

7.0 Potential Benefits to Subjects

7.1 Potential benefits include prevention of gaseous abdominal distension and consequences of such including need for increased respiratory support and escalation of care which can include intubation, septic work up and exposure to radiation for x-rays to work up abdominal distension. (Priyadarshi 2020) Optimization of respiratory support and decreased time on respiratory support which could also decrease length of stay as timely weaning facilitates progression towards oral feeding and subsequent NICU discharge. Past patients have had decreased time between first and full feeds and discharged prior to term which is a decrease in length of stay for these infants born 28 weeks or less.

8.0 Describe how the results of this study will be shared (e.g. journal article, academic paper, conference presentation).

Hope to submit to journal for publication (*have already published case study paper*) and/or for conference presentation.

9.0 Recruitment and Consent Process

9.1 Will discuss with parents during first week of admission in patient room. Consent will be reviewed with parents by PI or co-investigator.

9.2 Consent attached, brochure may also be used for less technical language.

9.3 NA

9.4 NA

9.5 NA

10.0 Waiver or Alteration of Informed Consent and HIPAA Authorization

Please provide non-human research waiver for retrospective chart reviews of patients who did and did not receive intervention in the past for comparison.

References:

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(A more extensive reference list is at the end of the article.)