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ORIGINAL ARTICLE

Rebalancing thoraco-abdominal method does not increase immediate pain assessed by Neonatal Infant Pain Scale: a randomized clinical trial

O método reequilíbrio tóraco-abdominal não aumenta a dor avaliada pela Neonatal Infant Pain Scale: estudo clínico randomizado

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Abstract

Objective: To compare in neonates with transitory tachypnea if chest rebalancing thoraco-abdominal method (RTA) increased immediate pain. *Methods*: This was a randomized controlled clinical trial. Forty-nine neonates with transitory tachypnea and aged < 72 hours were included to receive either conventional physiotherapy (CP) or RTA method. Participants received usual care and one 15-minute session of chest physiotherapy. Neonatal Infant Pain Scale (NIPS), peripheral oxygen saturation, heart rate, respiratory rate, axillary temperature before and after chest physiotherapy were recorded. Kruskal-Wallis ANOVA and Mc Nemar test were used to compare differences between measures. The relative risk (RR) for pain after interventions was calculated using a Poisson regression model (robust estimation). A significance level of 5% ($p < 0.05$) was adopted for all analyses. *Results*: RTA was not associated to pain. After chest physiotherapy, NIPS reduced (2 versus 3, $p < 0.001$) and number of neonates with pain reduced (10.2% versus 28.6%, $p = 0.02$). RR for pain after chest physiotherapy in comparison to before was 0.3 (95% CI 0.15-0.41; $p = 0.02$); respiratory frequency decreased after chest physiotherapy (58 versus 70, $p < 0.001$) and peripheral oxygen saturation increased (98% versus 96%, $p < 0.001$). *Conclusion*: In neonates with transitory tachypnea, in the first 72 hours of life, RTA did not influence pain evaluation, chest physiotherapy was safe and reduced immediate pain.

Keywords: neonate; physiotherapy specialties; pain assessment; respiratory care.

Resumo

Objetivo: Comparar em recém-nascidos com taquipneia transitória se o método reequilíbrio tóraco-abdominal (RTA) aumentou a dor imediatamente após. *Métodos*: Estudo de ensaio clínico randomizado. Quarenta e nove recém-nascidos com diagnóstico de taquipneia transitória com menos de 72 horas de vida, foram incluídos para receber fisioterapia respiratória. Os participantes receberam os cuidados usuais e uma sessão de fisioterapia convencional ou do método reequilíbrio tóraco-abdominal. Foram registradas a escala NIPS (*Neonatal Infant Pain Scale*), a saturação periférica de oxigênio, a frequência cardíaca, a frequência respiratória e a temperatura axilar antes e depois da

fisioterapia. Para as comparações entre as medidas, foram utilizados o teste de ANOVA de Kruskal-Wallis e o teste de McNemar. O risco relativo de dor após os procedimentos foi calculado usando o modelo de regressão de Poisson (estimação robusta). Foi considerado o nível de significância de 5% para todas as análises ($p < 0,05$). *Resultados*: O método RTA não foi associado a dor. Após a fisioterapia respiratória, a escala NIPS reduziu (2 versus 3, $p < 0,001$) e a proporção de recém-nascidos com dor também reduziu (10,2% versus 28,6%, $p = 0,02$). O risco relativo de dor após a fisioterapia respiratória em comparação a antes, foi de 0,3 (IC 95% 0,15-0,41; $p = 0,02$), a frequência respiratória diminuiu (58 versus 70, $p < 0,001$) e a saturação periférica de oxigênio aumentou (98% versus 96%, $p < 0,001$). *Conclusão*: Em recém-nascidos com taquipneia transitória nas primeiras 72 horas de vida, o método RTA não influenciou a avaliação da dor, a fisioterapia respiratória foi segura e reduziu a dor imediatamente após.

Palavras-chave: recém-nascido; modalidades de fisioterapia; dor; cuidado respiratório.

Introduction

Pain is a “bad sensorial and emotional experience” [1]. In the neonate, pain has been studied for a long time. At first, it was believed that the neonate was unable to localize and interpret pain, though pain pathways, cortical, subcortical centers and neurotransmissors were functionally present. Many neonates were not treated with analgesics during painful procedures due to this thinking. It is surprising that neonate nociceptives fibers density is superior to adults. Some pain pathways are myelinated by the 30th gestational week and this process is completed by the 37th gestational week [2]. Even if some pathways were not completely myelinated, the shorter distance the impulse needs to travel in the neonate seems to offset the slower conduction associated to uncomplete myelination [2].

Currently, we know that neonates submitted to severe and prolonged pain may have a higher morbidity and moreover, the lack of a behavioral response does not assure that there is no pain. At our knowledge, painful experiences during the neonatal period may be related to pain feedback in the future [3].

Pain evaluation in the infant is a challenge. The Neonatal Infant Pain Scale (NIPS scale) was validated in 1993. This scale evaluates facial expression, cry, members movimentation, respiratory pattern and wakefulness. It has been widely applied in the neonate and varies from 0 to 7. Pain is present when the scale ponctuation is ≥ 4 [4].

During hospitalization, neonates are submitted to many procedures that are necessary for clinical recovery, some of them potentially painful. It is estimated that half of neonates under hospitalization have pain during the first week of life [5].

Transitory tachypnea of the neonate is caused by a delayed pulmonary liquid clearance, resulting in the presence of fetal liquid in the neonate lungs and leading to an increase in the interstitial compartment. This condition causes a respiratory distress that regress spontaneously in most cases. In some cases, the neonate requires respiratory support [6,7].

Chest physiotherapy (CPT) has been part of respiratory care in neonatal units for a long time. Initial studies enrolled small samples and had the objectives to show physiotherapy efficacy, particularly in removing airway secretions [8,9]. Literature regarding CPT in the neonate is still scarce and the validation of physiotherapy techniques is necessary. Recent studies evaluated CPT effects in infants and neonates with acute viral bronchiolitis and suggested that slow expiration techniques in this situation caused a relief in moderate patients and no harmful side effects [10,11]. Rebalancing thoracoabdominal method (RTA) is a CPT method based on muscle tonus, length, and strength normalization through inspiratory and expiratory balance. This method has been practiced in neonatal units. A clinical trial that included preterm infants suggested that RTA reduced respiratory rate and respiratory distress and did not change neonate behavior [12].

Few studies evaluated pain after CPT in the neonate. A recent study suggested that preterm neonates not submitted to ventilatory support presented more pain immediately after CPT and this was stabilized after 15 minutes [13]. A systematic review suggested that airway suctioning, and chest compressions caused pain in neonates. However, because of methodological differences between studies, the authors concluded that more studies using adequate

designs are needed to evaluate if physiotherapy techniques really cause pain in the neonate [14].

Therefore, the research question for this study was: does RTA cause immediate pain in the neonate with transitory tachypnea?

Methods

Study design

This was a two-armed randomized controlled clinical trial conducted at a private university-affiliated tertiary hospital in Teresópolis, Rio de Janeiro, Brazil. The study was approved by the UNIFESO Research Ethics Committee (CAAE: 45519415.1.0000.5247) and the study protocol was registered online at the Brazilian Clinical Trials Register -ReBec (RBR 2FFV9G). This study is reported in accordance with the CONSORT guidelines [15].

Study population and sample size

A sample of 49 neonates with transitory tachypnea was recruited to receive a conventional protocol (CP) of CPT or RTA method. Sample was calculated considering a 54% difference and a 6% frequency, a statistical power of 80% and setting alpha at 5%.

Between September 2015 and October 2016, neonates with transitory tachypnea were approached consecutively. Inclusion criteria were: age < 72 hours with respiratory distress due to a diagnosis of transitory tachypnea of the neonate. Exclusion criteria were congenital malformations, pneumothorax, use of analgesics or sedatives, 5th minute Apgar < 7.

Blinding and randomization

The statistician was blinded to treatment allocation. The allocation was conducted by an independent researcher. A simple randomization was made by draw. When a neonate was included, an independent researcher made the raffle and decided the intervention.

Outcome measures

The primary outcome was pain after the CPT session defined as a NIPS scale evaluation ≥ 4. All neonates were evaluated in a calm ambient, during a 5-minute period immediately after the intervention, by the same physiotherapist. Heart rate, respiratory rate, peripheral oxygen saturation, axillary temperature, were assessed before and after the intervention.

Procedures

Usual nursing and medical care were provided to all participants. All neonates with respiratory distress were submitted to a 15-minute CPT session, performed by the same physiotherapist, shortly after birth. One of the following two methods was applied: the conventional protocol (CP) consisted of manual passive expiratory therapy, chest expiratory vibration, chest expiratory compression, chest vibration or prolonged slow expiration [16]; The rebalancing thoraco-abdominal (RTA) method protocol consisted of inferior abdominal support, thoraco-abdominal support, ileo-costal support, and inspiratory aid [12]. Airway aspiration was applied only when considered necessary, by the physiotherapist. All neonates were in the supine position.

Respiratory rate (breath per minute), heart rate (beat per minute), peripheral oxygen saturation (%), axillary temperature (°C) and NIPS scale evaluation were assessed before and after CPT. The following data were also collected: gestational age (days), birth weight (grams), sex, age (hours), oxygen/ventilatory support (none; supplementary oxygen; non-invasive ventilation; invasive ventilation).

Statistical analysis

Statistical analysis was performed using Stata 13.0 program (StataCorp, LC). Data did not follow a normal distribution and were presented as medians, interquartile range (IQR) and 95% confidence intervals (95% CI). The Kruskal-Wallis ANOVA was used to test the continuous variables. The McNemar test was

used to compare categorical variables. Spearman correlation coefficient was applied to measure correlation between measures before and after intervention. The relative risk (RR) for pain after CPT in comparison to before, was calculated using a Poisson regression (robust estimation). A significance level of 5% ($p < 0.05$) was adopted for all statistical analyses.

Results

Flow of participants

During the study period, 1,660 patients were born at the reference hospital, and 49 had transitory tachypnea of the neonate diagnosis. Figure 1 presents the flowchart of enrolment of the research participants.

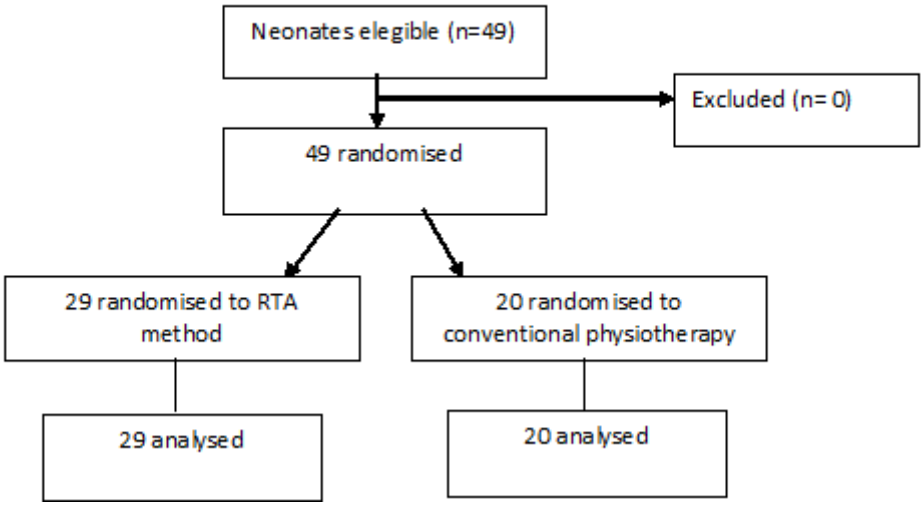


Figure 1 - *CONSORT flow diagram*

Baseline characteristics of participants

Median birth weight was 2,980 g (IQR 2,510-3,340) and gestational age was 266 days (IQR 255-275). Median age was 4 hours (IQR 2-10) and 51% were male sex. Eleven (22.5%) neonates were not using respiratory support, 34 (69.4%) were using supplementary oxygen, 3 (6.1%) were using non-invasive ventilation and 1 (2.0%) was on invasive ventilation. Table I shows baseline comparisons between RTA method and CP groups. There were no appreciable

differences between the two groups with respect to gender, birth weight, gestational age, age, respiratory and heart rate, peripheral oxygen saturation and axillary temperature.

Table I - *Baseline parameters and demographic characteristics between RTA method and CP groups, Rio de Janeiro, Brazil, 2020 (n = 49)*

	RTA method (n=29		CP (n=20)		
	Median	IQR	Median	IQR	p value
Demographic characteristics					
Male, %, 95% CI	51.7	38.9-76.4	45.0	23.0-68.4	0.64
Birth weight, g	2,990	2,510-	2,850	2,500-	0.48
Gestational age, days	266	3,505	268	3,172	0.21
Age, h	6	258-280	3	250-273	0.15
		2,5-15,0		2,0-6,0	
Baseline parameters					
Respiratory rate, bpm	74	68-76	67	65-70	0.07
Heart rate, *bpm*	138	129-148	136	131-142	0.67
Peripheral oxygen saturation, %	97	95-98	95	93-97	0.16
Axillary temperature, °C	36.3	35.8-36.6	36.4	36.1-36.7	0.23

g = grams; h = hours; bpm = breaths per minute; bpm = beats per minute; °Celsius = Celsius degree. *p value associated to Mc Nemar or Kruskal-Wallis

Overall effects of chest physiotherapy

Physiological parameters and NIPS were compared for all the sample before and after CPT (Table II). We observed an increase of peripheral oxygen saturation, a reduction in respiratory rate and NIPS scale after CPT.

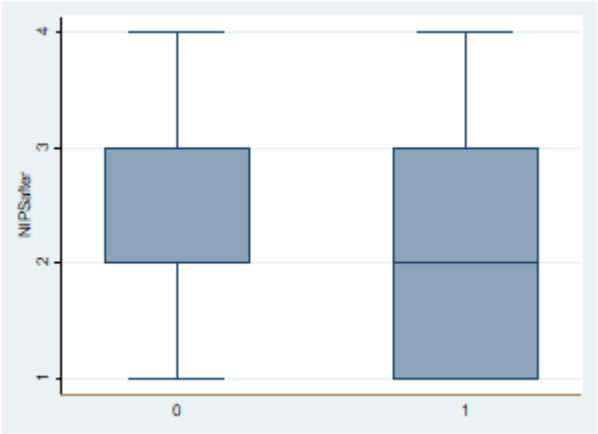
Table II - *Physiological parameters and Neonatal Infant Pain Scale (NIPS scale) before and after CPT in neonates aged < 72h with transitory tachypnea, Rio de Janeiro, Brazil, 2020 (n = 49*

Physiological parameters	Before CPT (n=49)		After CPT (n=49)		*
	Median	IQR	Median	IQR	p value
Respiratory rate, bpm	70	66-75	58	55-65	< 0.001
Heart rate, *bpm*	137	130-145	136	128-146	0.46
Peripheral oxygen saturation, %	96	94-98	98	96-99	0.003
Axillary temperature, °C	36,3	36-37	36,2	36-37	0.45
NIPS	3	3-4	2	2-3	< 0.001

bpm = breaths per minute; bpm = beats per minute; °C = Celsius degree; NIPS = Neonatal Infant Pain Scale; *p = value associated to Kruskal Wallis ANOVA

A 18.4% reduction in the proportion of neonates with pain was observed after CPT (28.6% vs 10.2%; p = 0.02). The correlation between NIPS scale before and after the intervention was weak (Spearman 0,21; p value = 0.12). Among neonates with pain after CPT, two received no respiratory support and three were receiving supplementary oxygen.

We observed no differences (p value 0.35) in NIPS median after CPT according to CPT method (Graph 1).



Graph 1 - *Box plots comparisons of NIPS after CP (0) and RTA method (1), Rio de Janeiro, Brazil, 2020 (n = 49)*

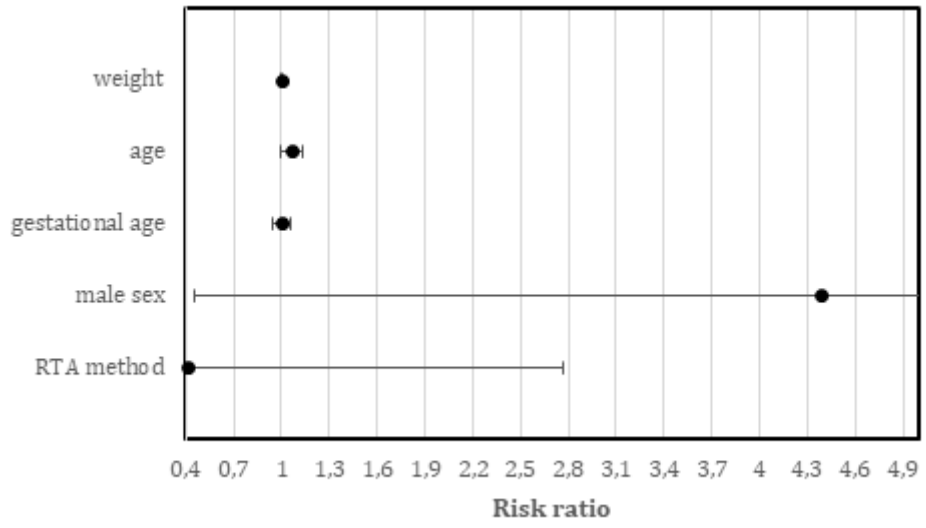
After CPT, overall relative risk for pain decreased and RTA method had no influence on pain, compared to CP (Table 3).

Table III - *Pain evaluation comparisons between CP (n = 20) or RTA method (n = 29) before and after CPT and risk for pain. Rio de Janeiro, Brazil, 2020 (n = 49)*

Outcome measures	Before			After		
	RTA value method	CP	P	RTA value method	CP	P*
Neonates with pain, n (%)	9 (31,0)	5 (25,0)	0.64	2 (6,8)	3 (15,0)	0.35
NIPS, median (IQR)	3 (3-4)	3 (3-3,5)	0.92	2 (1-3)	3 (2-3)	0.01
Risk for pain, RR (95% CI)						
Overall (after/before)	0,3 (0.15-0.41)					0.02
RTA method (after RTA/CP)	0,4 (0.08-2.55)					0.36

RR = relative risk. *p = value associated to Mc Nemar, Kruskal-Wallis or Poisson regression

Risk factors for pain after CPT and associated factors were calculated. Birth weight (RR 1,0; 95% CI 0.99-1.00; p value 0.49), gestational age (RR 1,0; 95% CI 0.95-1.06; p value = 0.78), male sex (RR 4,3; 95% CI 0.45-42.49; p value = 0.20) were not associated to pain, as observed in Figure 2. Age was considered not associated to pain, as its RR was near the null value and 95% CI included the null value (RR 1,06; 95% CI 1.00-1.13; p value = 0.04).



RTA method = Rebalancing Thoraco-abdominal method

Figure 2 - *Forest plot of relative risk for pain after chest physiotherapy and factors (n = 49)*

Discussion

The results of this study show that RTA method did not increase the risk for pain in neonates with transitory tachypnea. RTA intervention was associated to a lower NIPS evaluation. CPT reduced risk of pain, NIPS evaluation and the proportion of neonates with pain. Reduced respiratory frequency and enhanced peripheral oxygen saturation was observed after CPT. It is important to evaluate whether these benefits are of clinical importance. It seems that a respiratory rate reduction has a clear clinical importance. A 18.4% reduction of pain also seems to have a strong clinical impact, as less neonates had pain after CPT.

This study also showed that neonate characteristics had no influence in pain after CPT. Most of neonates were ≥ 7 months gestational age, birthweight > 2,500 g, not intubated and aged less than 24 hours. Also, neonates were not routinely aspirated. These characteristics are important as it has been suggested in other study that preterm neonates after CPT and airway aspiration, had more pain. In that scenario both procedures were applied to neonates, and it is difficult to assure that pain was caused by CPT, airway aspiration or both. CPT was considered by those authors as a painful stimulus [16].

In the present study, physiological parameters suggested a better clinical condition after CPT, as respiratory rate decreased, and peripheral oxygen

saturation increased. We must emphasize that all neonates were treated before and after CPT in the same and calm ambient and this can have influenced results. A previous study comparing clinical parameters after CPT in preterm neonates showed an immediate increase in heart rate and pain scales with posterior return to baseline in 15 minutes [12]. Also, Nicolau *et al.* [17] suggested that physiological parameters did not correlate with pain and should not be used alone to measure pain.

Reduced NIPS scale after CPT, independent to the physiotherapy method, revealed that CPT seems to be safe in neonates with transitory tachypnea. We must emphasize that in the present study, the magnitude of this effect was high as both RR and 95% IC were far from the benefit thresholds. Noteworthy, pain scale was applied immediately after the intervention, in the peak moment for pain assessment. It has been previously suggested that in preterm neonates, immediately after CPT and after airway aspiration, pain evaluation was worse [12,16]. Also, it has been suggested that there is no sufficient evidence to recommend one pain evaluation scale over another [12].

The familiarity with a scoring seems to be very important for pain assessment [18]. Pain scores are necessary as pain cannot be directly measured in neonates and behavioral items are very informative of pain, such as calmness, alertness, and facial tension [19]. We must emphasize that in the present study, all neonates were in supine position and in a calm ambient. Also, airway suction was not routine. So, this does not seem to have influenced the results. Prone position is comfortable to the neonate, and it has been suggested as part of non-pharmacological pain treatment [18,20].

The present study has strengths and limitations. The same observer evaluated neonates before and after CPT and this evaluation was not blinded. We had no loss of follow-up, as all neonates included received the interventions and contributed to outcome measures. Although groups were not balanced, randomization worked, as groups were comparable at baseline parameters, demographic characteristics, and initial pain assessment.

Conclusion

The results of this study indicate that RTA does not influence pain and CPT applied in a calm ambient reduced NIPS immediate evaluation in neonates with transitory tachypnea, was effective on reducing respiratory frequency and enhanced peripheral oxygen saturation. Therefore, CP and RTA can safely be integrated to other clinical practices in neonatal units.

What was already known on this topic: CPT is widely practiced in neonatal units. The existing evidence suggested that neonates present a higher pain scale evaluation immediately after CPT, but few studies explored RTA method.

What this study adds: In neonates with transitory tachypnea, CPT was associated to a decrease in pain and RTA was well tolerated and did not cause an increase in NIPS evaluation.

Conflicts of interest
The authors declare no conflicts of interest.

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