Research Square

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Effect Sizes in Bronchiolitis children with Respiratory Distress: HFNC vs Nasal Oxygen Therapy—A Prospective Cohort Study

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Research Article

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Abstract

Background:

Currently, there are neither clinical features nor universally validated respiratory distress severity scores that are useful in all clinical settings, which can reliably distinguish bronchiolitis children needing high-flow nasal cannula (HFNC) therapy from those who can be managed with nasal oxygen. This clinical gap is due in part to limited data on the effect sizes of specific clinical features and that of respiratory severity scores in present predictive models.

Methods:

This prospective cohort study's aim was to evaluate the effect sizes of certain clinical parameters, the Respiratory Severity Score (RSS), and the Modified Comfort Score (MCS) in children with bronchiolitis receiving either HFNC or nasal oxygen therapy. A consecutive sample of sixty-eight children aged 1–36 months admitted to the Pediatric Intensive Care Unit (PICU) at Sri Ramachandra Children and Dental Hospital, Guntur, between September and December 2024 were studied. Data of demographic, and clinical characteristics, including respiratory severity scores (RSS and MCS) were collected at admission (0 hours) and at 6, 12, and 24 hours after starting oxygen therapy.

Results:

Bronchiolitis children started on HFNC had significantly lower oxygen saturation, higher respiratory and heart rates, and higher respiratory distress scores (RSS and MCS) at admission compared to those managed with nasal oxygen. Both groups showed progressive improvement in the parameters during the 24-hour observation period. The differences in the RSS and MCS between the two groups is not clinically significant by 6–12 hours after therapy, when the effect of baseline RSS was adjusted. The oxygen therapy method was not predicting the 6 hours SpO2, RR, and HR when their baseline values were controlled.

Conclusion:

This study highlights the need for developing reliable tools to predict the need for HFNC in specific group of bronchiolitis children. Shown effect sizes of this study provide preliminary data for future research aimed to develop predictive models with greater power and better generalisability. Further studies with large samples, RCT designs and with longer follow up of observations help delineate the characteristics at admission of bronchiolitis children which help development of better predictive tools.

Introduction

Bronchiolitis is among the most common causes of acute respiratory distress in infants and young children [1, 2]. Diagnosis is primarily clinical, based on history, physical examination, and pulse oximetry [3]. In resource-limited settings where pulse oximetry is unavailable, clinical signs such as increased respiratory rate, chest retractions, wheezing, and crackles are often used as surrogate markers of hypoxemia. An ideal assessment method for respiratory distress should offer a reliable, indirect measure of oxygenation status and guide oxygen therapy and prognostication. However, no universally accepted and validated scoring system currently fulfils these criteria [4–6].

Several respiratory distress scoring systems have been developed over time. Majority are difficult to apply consistently at the bedside due to subjectivity or the inclusion of components not readily measurable in all clinical settings. In practice, some children with bronchiolitis are managed with standard nasal oxygen, while others require escalation to HFNC therapy. However, clear clinical criteria or validated tools to guide this decision-making are lacking.

This study was aimed to evaluate and compare the clinical characteristics and severity scoring profiles (RSS and MCS) of children receiving HFNC versus nasal oxygen therapy. The goal was to quantify the effect sizes of distinguishing clinical features and assess the temporal trends in respiratory distress severity using established scoring systems. These exploratory findings may inform future studies which aim at the development of diagnostic, prognostic, or treatment-guiding tools.

Objectives

1. Compare the demographic and clinical characteristics of children receiving HFNC versus nasal oxygen therapy.
2. Evaluate the effect sizes of distinguishing clinical features between the two groups.
3. Assess the progression of Respiratory Severity Score (RSS) at 0, 6, 12, and 24 hours.
4. Assess the progression of Modified Comfort Score (MCS) at 0, 6, 12, and 24 hours.

Materials and Methods

Study Design: A prospective cohort study with descriptive and exploratory analysis.

Study Setting and Duration: The study was conducted at the Pediatric Intensive Care Unit (PICU) of Sri Ramachandra Children and Dental Hospital, Guntur, from September to December 2024.

Participants: A total of 68 children aged 1–36 months admitted with clinical features of bronchiolitis and respiratory distress were included.

Inclusion Criteria

Children aged 1 month to 36 months.

Diagnosis of bronchiolitis requiring either HFNC or standard nasal oxygen therapy.

Exclusion Criteria

Hemodynamic instability.

Pre-existing chronic respiratory diseases (e.g., asthma, bronchiectasis).

Multisystem or chronic comorbidities.

Data Collection and Procedures

Upon admission, demographic details and clinical history were obtained from caregivers. A thorough physical examination was performed, with particular attention to signs of respiratory distress such as tachypnoea, use of accessory muscles, wheezing, and other adventitious breath sounds. Oxygen saturation using pulse oximeter and respiratory rate (RR) and heart rate (HR), were recorded at baseline and at 6 hours. RSS and MCS were recorded at 0, 6, 12, and 24 hours.

All children were initially placed on nasal oxygen in the Emergency Room and then transferred to the PICU. Based on clinical assessment and decision about the need for a type of oxygen therapy by the attending paediatrician, children were started on HFNC therapy or nasal oxygen. In children where caregivers declined HFNC therapy, standard nasal oxygen therapy was continued.

Respiratory distress Assessment Tools used in the evaluation of children:

Respiratory Severity Score (RSS)

The RSS quantifies respiratory distress using clinical parameters such as RR, accessory muscle use, adventitious lung sounds, and oxygen saturation. Each parameter is given a score by the observer as stipulated in the RSS. Basing on the summed score patients are categorised into respiratory distress severity categories [7].

Modified Comfort Score (MCS)

The MCS assesses patient comfort and distress in relation to respiratory symptoms. Parameters include level of consciousness, facial expression, mean arterial pressure, heart rate, and movement [8].

Both RSS and MCS were evaluated in each child at 0, 6, 12, and 24 hours by trained Pediatric staff.

Statistical analysis:

Univariate descriptive analysis is done to describe quantitative characteristics with the mean or medians and 95% confidence intervals and qualitative characteristics by frequencies, percents (proportions) and 95% confidence intervals.

Comparison of the quantitative characteristics of the two groups is done with t-tests if the data distributions are parametric and if the data distributions are not normal despite logarithmic transformation, Mann-Whitney U test is done.

To compare more than two groups with repeated measures with non-parametric data, the Friedman test is used, ANCOVA and Repeated measures ANOVA are used as required by the data. The RSS and MCS scores at 0, 6, 12, and 24 hours for the HFNC and Nasal O2 groups are analyzed to observe patterns and trends.

Qualitative dichotomous characteristics of the two groups are compared with Fisher's exact test.

Statistical significance is decided by a P-value of less than 0.05. Furthermore, the size of the effect sizes of observations is assessed using proper statistical methods.

Statistical analysis of data is done with statistical softwares MedCalc® (Version 23.1.7), JASP® (Version 0.19.3), jamovi® (version 2.6.44), and Epi-Info® (7.2.6.0).

AI tools are not employed in data analysis, drafting, or editing the manuscript. Only for checking errors in English grammar, Grammarly: A Grammar App is used.

Results

Demographic characteristics of HFNC and Nasal Oxygen groups:

The median age of children (p = 0.0964) and sex distribution (p = 0.433) of children are not significantly different between the HFNC and nasal oxygen group of children (Table 1 supplementary & Table 3 supplementary, and Table 4 supplementary & Table 5 supplementary).

Clinical characteristics of HFNC and Nasal Oxygen groups:

The HFNC and nasal oxygen groups are not significantly differing from each other in relation to weight (p = 0.1777), fever (p = 0.613), and breathing difficulty (p = 0.169), and cough was present in 100% of subjects in both groups, as can be observed from Table 1 Supplementary, Table 3 supplementary, Table 4 supplementary, and Table 5 supplementary.

At admission (0 hours) HFNC group compared to nasal oxygen group was having lesser median SpO2 (91.0% vs 92.0%, p = 0.0022; Rank-Biserial Correlation: -0.451), higher mean respiratory rate (70.8 vs 61.3, p = 0.0024; Cohen’s d: 0.811), and higher mean heart rate (153.2 vs 143.3, p = 0.0192; Cohen’s d: 0.615) as observed from the table 1 supplementary and table 4 supplementary.

Mean respiratory rate (45.3 vs 41.0, p = 0.0166; Cohen’s d: 0.630) and mean heart rate (112.3 vs 105.3, p = 0.0037, Cohen’s d: 0.771) at 6 hours after therapy were significantly higher in HFNC group in

comparison to that of nasal oxygen group, as observed in Table 4 supplementary, though the median spo2 at 6 hours was not significantly differing between the two groups (99.0% vs 99.0%, p = 0.3232; Rank-Biserial Correlation: -0.142, 95% CI -0.410 to 0.148), as observed from the table 1 supplementary and table 4 supplementary.

Comparison of Respiratory distress assessment scores between HFNC and Nasal Oxygen groups:

The HFNC group had a significantly higher median RSS than nasal oxygen group at 0 hours (8.00 vs. 6.00, P < 0.0001; with a large effect size - Rank-Biserial Correlation: 0.631). This difference persisted at 6 hours (median 3.00 vs. 1.00, P < 0.0001; with a medium effect size - Rank-Biserial Correlation: 0.468) and at 12 hours (median 1.00 vs. 0.00, P = 0.045; with a small effect size (Rank-Biserial Correlation: 0.276). No significant difference was found at 24 hours (median 0.0 vs 0.0, P = 0.300; Rank-Biserial Correlation: 0.129) as seen in table 1 & table 2 supplementary.

The median MCS scores at 0 hours in HFNC group (23.0) compared to that of nasal oxygen group (20.0) was significantly more (p = 0.009; with a medium effect size - Rank-Biserial Correlation: 0.386), and at 6 hours the median MCS in HFNC group was 14.0 compared to that of nasal oxygen group (13.0) that was significant (p = 0.024; Rank-Biserial Correlation: 0.323, a medium effect size). The median MCS scores at 12 hours was not significantly differing between the two groups (8.0 vs 8.0, p = 0.490; Rank-Biserial Correlation: 0.073, 95% CI -0.215 to 0.350) and at 24 hours was also not differing between the two groups (7.0 vs 7.0, p = 0.128; Rank-Biserial Correlation: 0.134, 95% CI -0.156 to 0.403), as observed in table 1 & table 2 supplementary.

Temporal pattern of RSS within each oxygen group (Friedman test):

Over time (0 hours, 6 hours, 12 hours, and 24 hours) both groups showed a significant improvement in their Respiratory Severity Scores (RSS) as can be seen in Table 6 Supplementary & Table 7 Supplementary, and Figs. 1 & 2.

Temporal pattern of MCS within each oxygen group (Friedman test):

Over time (0 hours, 6 hours, 12 hours, and 24 hours) both groups showed a significant improvement in their Modified Comfort Scores (MCS) as can be seen in Table 8 Supplementary & Table 9 Supplementary, and Figs. 3 & 4.

Effects of time, oxygen therapy: HFNC vs. nasal oxygen, and their interaction on RSS by Repeated measures ANOVA (Table 7):

There was a significant time effect on RSS over time [F (2.514,165.942) = 980.64, P < 0.001; partial η2 = 0.937, a large effect]. HFNC and Nasal oxygen groups were having overall significant difference in RSS

[(F (1,66) = 18.63, P < 0.001; partial η2 = 0.220, medium]. A significant interaction was found between the groups and RSS scores over time, RSS trajectories over time differ by oxygen group [F (2.514,165.942) = 7.70, P < 0.001; partial η2 = 0.104]. HFNC group shows a relatively steeper early decline in RSS, compared to relatively gradual decrease in RSS in Nasal Oxygen group (interaction effect), as seen in Fig. 5.

Effects of time, oxygen therapy: HFNC vs. nasal oxygen, and their interaction on MCS by Repeated measures ANOVA (Table 8):

There was a significant time effect on MCS over time [F (1.718,113.381) = 1579.54, P < 0.001; partial η2 = 0.960, a large effect]. HFNC and Nasal oxygen groups were having overall significant difference in MCS [(F (1,66) = 8.96, 0.004; partial η2 = 0.120, moderate effect]. The interaction between the oxygen groups and time was having significant influence on MCS scores over time: MCS trajectories over time differ between oxygen groups [F (1.718,113.381) = 5.09, P = 0.011; partial η2 = 0.072, small effect]. HFNC group shows a relatively steeper early decline in MCS, compared to relatively gradual decrease in MCS in Nasal Oxygen group (interaction effect), as seen in Fig. 6.

Vital signs and respiratory distress scores showed measurable differences between the HFNC and nasal oxygen groups from admission through the first six hours of therapy, based on observations, without adjusting for baseline values.

To know whether it is the baseline value or type of oxygen therapy or both that will have an influence on an outcome at 6 hours, after controlling for the baseline value of the characteristic ANCOVA analysis was done.

As shown in Table 2, the model adjusting baseline SpO2 (SpO2 at 0 hours) predicted 7.2% (R^2-adjusted) variance of SpO2 at 6 hours (F [1, 65] = 6.119, P = 0.016), and the type of oxygen support did not have significant effect (F [1, 65] = 0.00792, P = 0.929), when the SpO2 at 0 hours is controlled.

Table 3 shows the analysis that evaluates the impact of oxygen support type on respiratory rate (RR) at 6 hours, adjusting for baseline RR. The goal is to find whether HFNC offers a statistically significant advantage over NASAL O_2 in reducing RR. Baseline RR was a strong predictor of RR at 6 hours (F [1, 65] ≈ 59.568, P < 0.001). However, the type of oxygen support did not significantly influence RR after adjustment (F [1, 65] ≈ 0.121, P = 0.729). The model explains ~ 52% of the variability in RR at 6 hours.

After controlling for baseline HR (HR at 0 hours) it significantly predicted HR at 6 hours [F (1,65) ≈ 70.259, P < 0.001), but the type of oxygen support (HFNC Vs. Nasal O_2) did not have a significant effect on HR at 6 hours [F (1,65) ≈ 3.079, P = 0.084). Overall model is significant statistically [F (2, 65) ≈ 44.402, P < 0.001), with adjusted effect size (R^2) that is strong = 0.5644 (Table 4).

Table 5 shows that the type of oxygen support did not significantly predict RSS at 6 hours [F (1,65) ≈ 0.370, P = 0.545) after controlling baseline RSS. The baseline RSS was the main predictor of RSS at 6 hours [F (1, 65) = 29.638, p < 0.001). The overall model's adjusted effect size (R^2) is moderate = 0.4019.

After controlling baseline MCS (MCS at 0 hours) the type of oxygen support did not significantly predict MCS at 6 hours [F (1, 65) ≈ 0.374, p = 0.543). The baseline MCS was the main predictor of RSS at 6 hours [F (1,65) ≈ 40.011, p < 0.0 01). Overall model has an adjusted effect size (R^2) that is moderate = 0.4076 (Table 6).

Discussion

Oxygen therapy is the mainstay for children with bronchiolitis requiring admission, but not all patients need the same method of oxygen therapy. Some respond to nasal oxygen, while others require higher levels of support such as HFNC [9] or positive pressure ventilation.

Earlier studies on bronchiolitis have used respiratory distress severity scores to predict either the need for a specific oxygen therapy or the likelihood of therapy failure. In the study by Nikhil Rajavanshi et al., the Bronchiolitis Severity Score (BSS) outperformed the Respiratory Distress Assessment Instrument (RDAI) in predicting bronchiolitis severity. However, neither score is reliable enough for management decisions without clinical judgement [4]. A study compared three scoring systems for predicting respiratory support needs: WBSS (sensitivity 85.71%, specificity 80.77%, cutoff > 3), KRS (sensitivity 75.71%, specificity 92.31%, cutoff > 3), and GRSS (sensitivity 93.75%, specificity 88.24%, cutoff > 3.8) [10]. In a disease like bronchiolitis, the predictive powers are not safe enough to rely on any one of the three scoring systems for clinical management. Some researchers have evaluated clinical scores and indicators to predict HFNC failure [11].

Summary of this study:

This study evaluated and compared the effectiveness of High Flow Nasal Cannula (HFNC) and nasal oxygen therapy in children by analyzing demographic, clinical, and physiological outcomes over time. The results show that while initial differences existed between the two groups—such as lower oxygen saturation and higher respiratory and heart rates in the HFNC group at admission—these differences were mostly attributed to baseline patient characteristics rather than the type of oxygen therapy administered.

Both HFNC and nasal oxygen groups showed significant improvement in respiratory distress, as measured by Respiratory Severity Score (RSS) and Modified Comfort Score, (MCS) over the course of 24 hours. Early on, the HFNC group showed steeper reductions in RSS and MCS, showing a rapid first response, but by 24 hours, scores between the two groups converged with no significant difference.

Repeated measures analysis confirmed these patterns, showing considerable time effects for both RSS and MCS, and medium overall differences between therapy types. However, after controlling baseline values using ANCOVA, the type of oxygen therapy (HFNC vs. nasal oxygen) did not significantly influence oxygen saturation, respiratory rate, heart rate, or distress and comfort scores at 6 hours; baseline measurements were the primary predictors of patient status at follow-up.

In brief, while HFNC may offer a rapid early improvement for children with greater initial severity, both oxygen therapies ultimately led to similar clinical outcomes by 24 hours. The study highlights the importance of considering baseline clinical condition in interpreting therapeutic effects, suggesting that initial patient status, rather than oxygen delivery method, is the key determinant of short-term progress in this population.

Currently, there are no validated indicators to accurately predict the need for high-flow nasal cannula (HFNC) or nasal oxygen therapy in pediatric bronchiolitis patients or predict the outcomes of such therapy. The difficulty in establishing the predictive power of various respiratory distress assessment methods may be due to several factors like: 1) lack of a simple, non-invasive biological reference standard to evaluate the scoring systems, 2) the scoring systems often include subjective measures or ones that are difficult to apply in some clinical settings, 3) challenges in applying the reference method of oxygen deficit at the same time of using the scoring methods in a child, and 4) limited availability of evidence on the effect sizes of predictive signs or scores in subgroups of bronchiolitis patients needing different oxygen supports.

Before evaluating the predictive efficacy of any method, it is important to understand the effect sizes of individual clinical features or groups of features. These must be assessed separately in children needing nasal oxygen and those needing high-flow nasal cannula (HFNC). Parameters with larger effect sizes can be further investigated for their predictive or diagnostic value, while those with negligible effect sizes may be excluded, thus leading to the identification and establishment of clinically useful models of respiratory distress assessment. A model may show a high predictive power (e.g., high R^2), but if the effect sizes of the predictors are small, it may show that the model may not be useful for clinical practice.

However, such studies are few or done with small number of children [12]. This observational study explored certain clinical features, RSS and MCS scores, in children with bronchiolitis for the differences and size of those differences in the groups who needed HFNC and nasal oxygen therapy, from admission to 24 hours after a therapy was started.

Strength of this study

This exploratory study provides the effect sizes of certain characteristics, and two respiratory distress scoring systems in a consecutive sample of 68 bronchiolitis children during real-time clinical management.

The information about the effect sizes from this study helps design further studies that aim to find the predictive ability of characteristics or the scoring systems.

Limitations of the study

Small sample size especially in one group and dissimilar sample sizes of the two groups may cause some uncertainties. There is a likelihood of reduced power in identification of some effect sizes. Better

reference indicators of respiratory function, like arterial blood gases, at similar time points of measurement of characteristics of respiratory distress are not studied to avoid unnecessary invasive measurements in children without invasive ventilation. This is an exploratory observational study in a single referral center.

Conclusions

Baseline (at admission and before starting therapy) characteristics like SpO2, R.R, H.R, RSS and MCS scores have greater influence over the change in subsequent time point values (6, 12, and hours) of the parameters, in both HFNC and Nasal oxygen groups.

The type of oxygen therapy is having lesser effect on the values of RSS and MCS at 6, 12, and 24 hours, compared to baseline respiratory distress severity.

There is a small interaction between temporal trend of RSS and MCS scores and type of oxygen therapy.

Further research studies with large samples and longer follow-up may clarify the advantages of oxygen delivery method.

Declarations

The parent(s)/legal guardian(s) of all participants provided informed consent for participation in this study. I confirm that ethics committee approval for this study was obtained, and details are with our institution.

Ethical approval:

This study was approved by our institutional ethics committee.

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Tables

Tables are available in the Supplementary Files section.

Figures

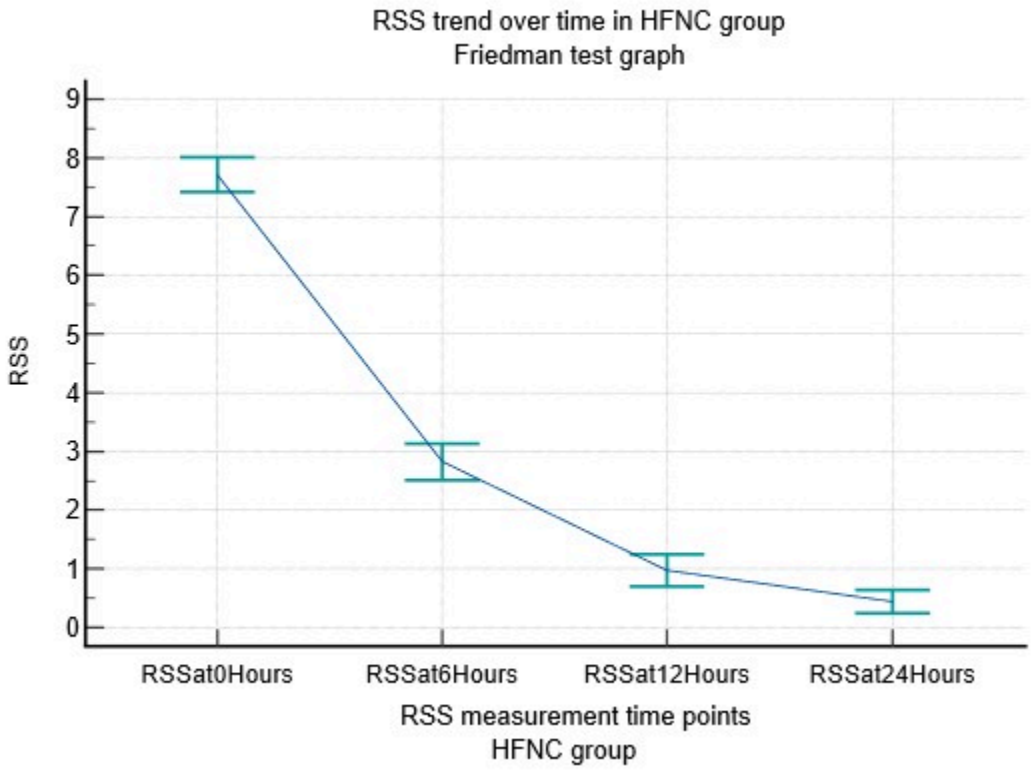


Figure 1

RSS trend over time in HFNC group

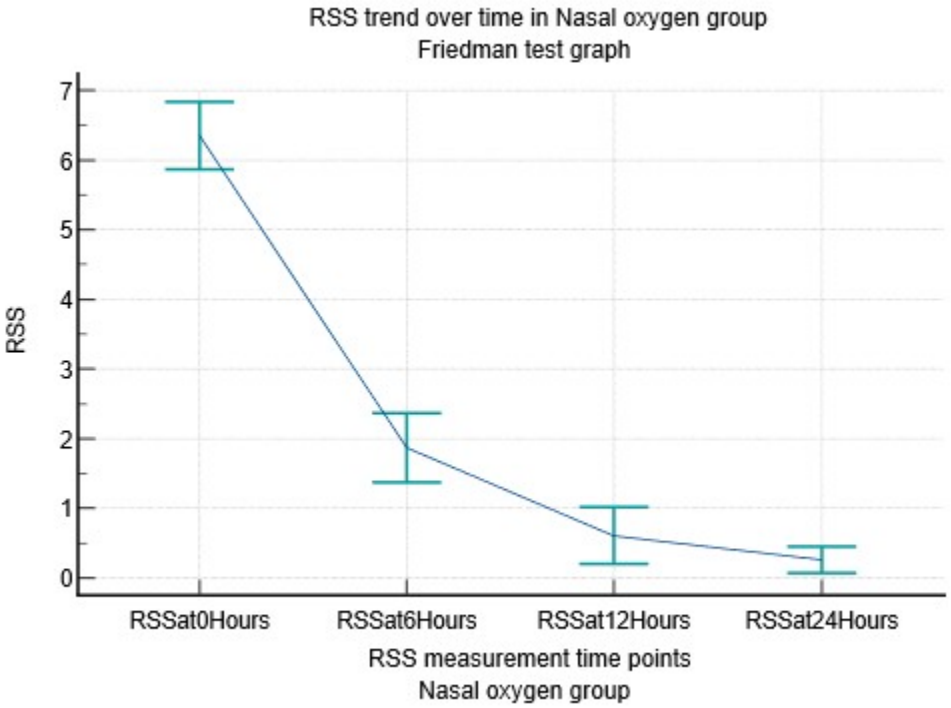


Figure 2

RSS trend over time in Nasal oxygen group

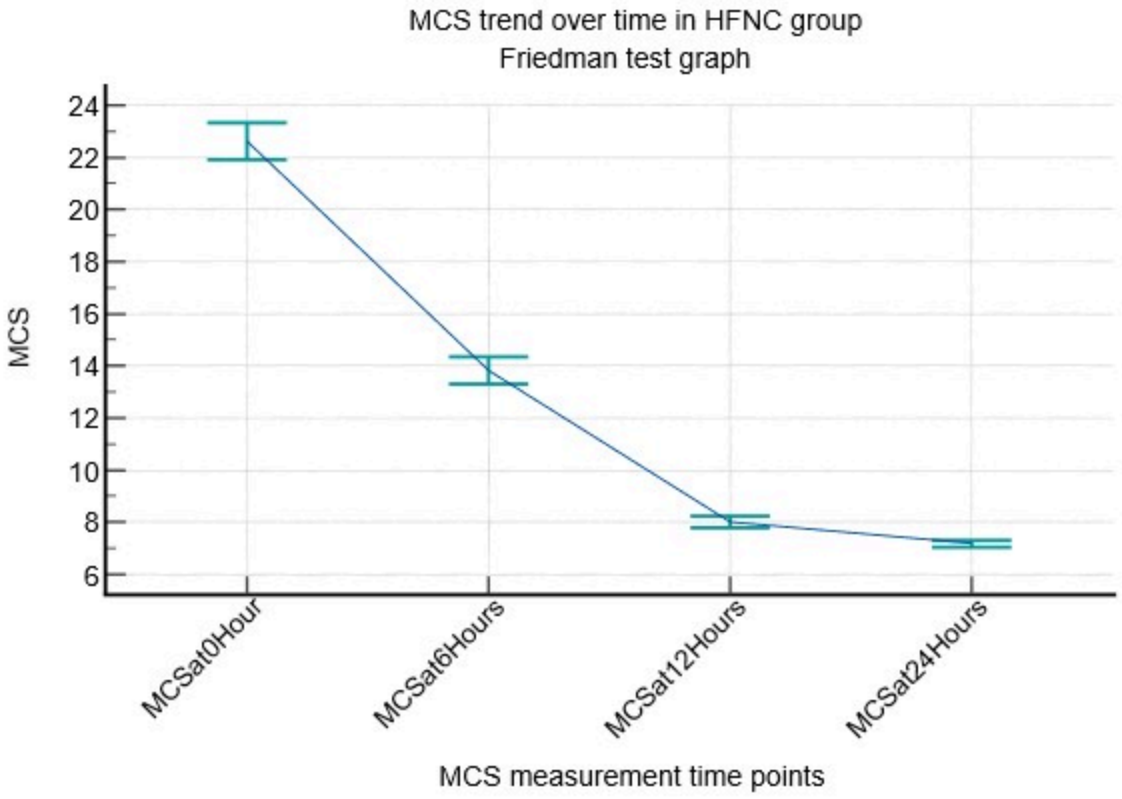


Figure 3

MCS trend over time in HFNC group

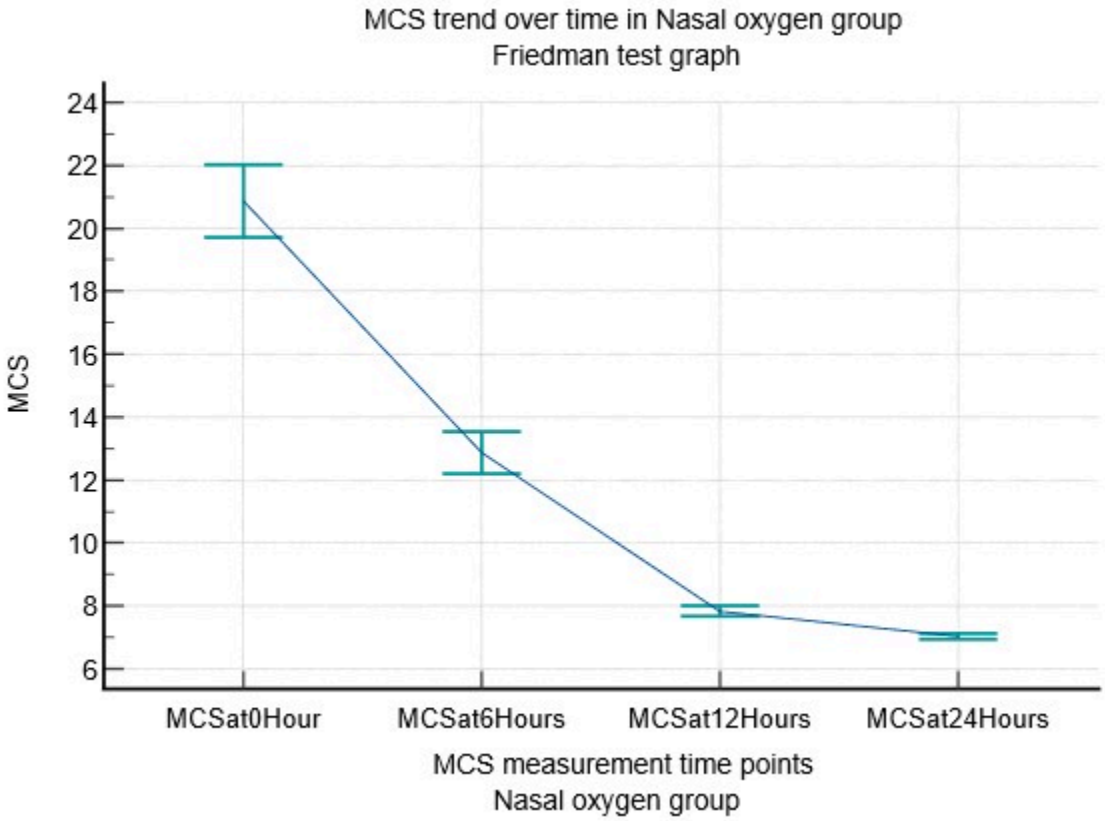


Figure 4

MCS trend over time in Nasal oxygen group

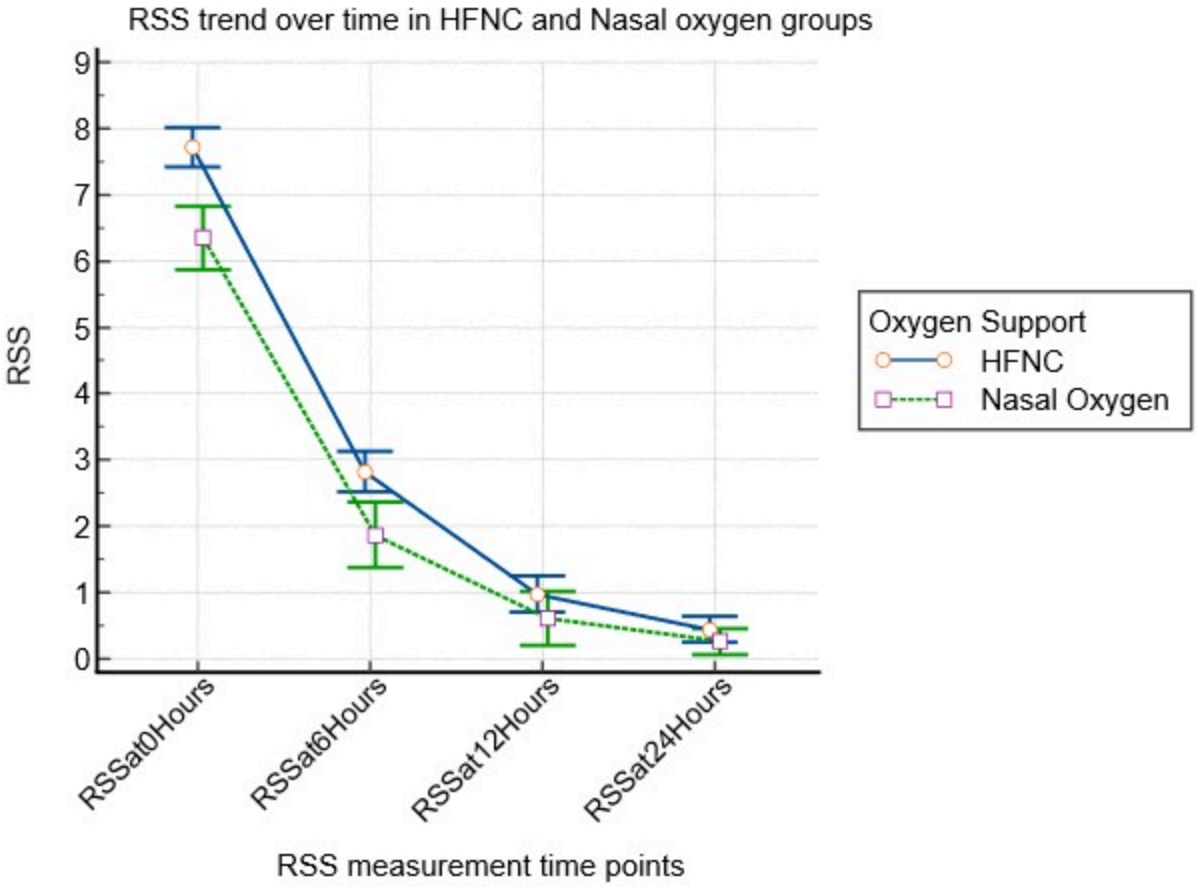


Figure 5

RSS changing pattern comparison over time in HFNC and Nasal oxygen groups

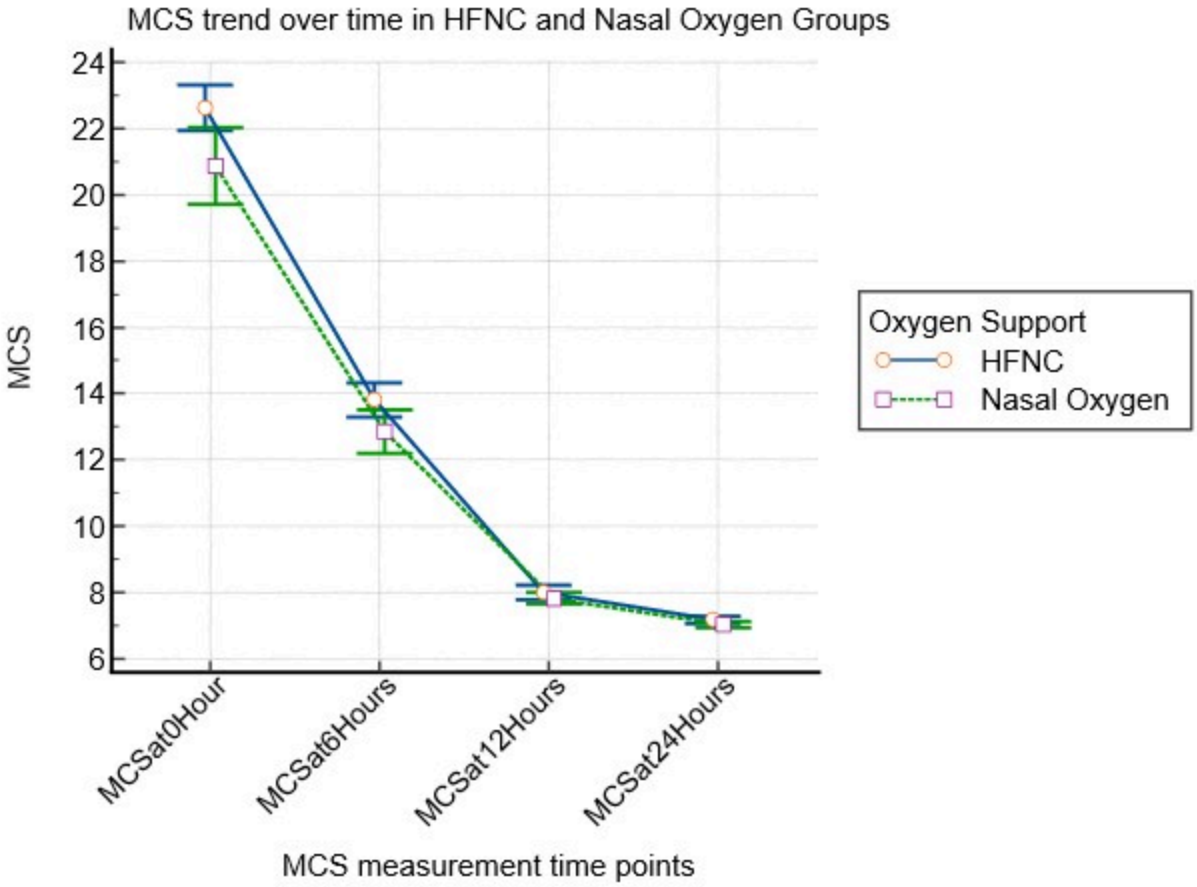


Figure 6

MCS changing pattern comparison over time in HFNC and Nasal oxygen groups

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- 2Bronchiolitisstudymainandsupplementarytableswithgraphs.docx