Original Article

Comparative Effect of High-Frequency Nasal Cannula and Noninvasive Ventilation on the Work of Breathing and Postoperative Pulmonary Complication after Pediatric Congenital Cardiac Surgery: A Prospective Randomized Controlled Trial

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ABSTRACT

Background: Various forms of commonly used noninvasive respiratory support strategies have considerable effect on diaphragmatic contractile function which can be evaluated using sonographic diaphragm activity parameters.

Objective: To compare the magnitude of respiratory workload decreased as assessed by thickening fraction of the diaphragm and longitudinal diaphragmatic strain while using high-flow nasal cannula (HFNC) and noninvasive ventilation (NIV) modes [nasal intermittent positive pressure ventilation (NIPPV) and bilevel positive airway pressure (BiPAP)] in pediatric patients after cardiothoracic surgery.

Methodology: This prospective randomized controlled trial was performed at a tertiary care surgical intensive care unit in postcardiac surgery patients aged between 1 and 48 months, who were randomly allocated into three groups: 1) HFNC (with flows at 2 L/kg/min), 2) NIPPV via RAMS cannula in PSV mode (pressure support 8 cmH_2O, PEEP 5 cmH_2O), and 3) BiPAP in nCPAP mode (CPAP of 5 cmH_2O). Measurements were recorded at baseline after extubation (R0) and subsequently every 12 hourly (R1, R2, R3, R4, R5) at 12, 24, 36, 48, and 60 hours respectively until therapy was discontinued.

Results: Sixty patients were included, with 20 patients each in the NIPPV group, HFNC group, and BiPAP group. Longitudinal strain at crura of diaphragm was lower in the BiPAP group as compared to HFNC group at R2-R4 [R2 (-4.27± -2.73 vs - 8.40± -6.40, $P = 0.031$), R3 (-5.32± -2.28 vs -8.44± -5.6, $P = 0.015$), and R4 (-3.8± -3.42 vs -12.4± -7.12, $P = 0.040$)]. PFR was higher in HFNC than NIPPV group at baseline and R1-R3[R0 (323 ± 114 vs 264 ± 80, $P = 0.008$), R1 (311 ± 114 vs 233 ± 66, $P = 0.022$), R2 (328 ± 116 vs 237 ± 4, $P = 0.002$), R3 (346 ± 112 vs 238 ± 54, $P = 0.001$)]. DTF and clinical parameters of increased work of breathing remain comparable between three groups. The rate of reintubation (within 48 hours of extubation or at ICU discharge) was 0.06% (1 in NIPPV, 1 in BiPAP, 2 in HFNC) and remain comparable between groups ($P = 1.0$).

Conclusion: BiPAP may provide better decrease in work of breathing compared to HFNC as reflected by lower crural diaphragmatic strain pattern. HFNC may provide better oxygenation compared to NIPPV group, as reflected by higher PFR ratio. Failure rate and safety profile are similar among different methods used.

Keywords: Diaphragmatic thickening fraction, extubation failure, high flow nasal oxygenation, noninvasive ventilation, pediatric cardiac surgery, postoperative pulmonary complications

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INTRODUCTION

Extubation failure after pediatric cardiac surgery is common with incidence varying from 6 to 22%.[1-4] It is associated with increased incidence of ventilator associated pneumonia (VAP), prolonged intensive care unit (ICU) stay, and increased morbidity and mortality.[1] To minimize this, postextubation elective noninvasive ventilation (NIV) in various forms such as NIPPV using RAMS cannula, HFNC, or BiPAP using infant flow LP nasal CPAP system is commonly used.

Different modes of NIV and levels of ventilatory support have considerable effect on the diaphragmatic contractile activity. Titration of the level of support provided by different NIV strategies could be directly monitored using sonographic diaphragm activity parameters such as diaphragmatic thickness, diaphragmatic thickening fraction (DTF), and its 2D longitudinal strain. Literature regarding comparative efficacy of different forms of NIV methods on the work of breathing and prevention of reintubation is scanty.

We hypothesized that due to differences in work principle and the compliance rate of different devices such as HFNC, NIPPV, and BiPAP, the respiratory workload of breathing and postoperative complication rate might vary. We conducted this study to compare the effect of three different NIV methods (HFNC, NIPPV, and BiPAP) on the work of breathing as reflected by diaphragm activity on ultrasound (primary outcome). Secondary outcome parameters included changes in respiratory rate, oxygenation (PF ratio), proportion of patients that require reintubation (48 hours postextubation/until discharge from ICU), incidence of respiratory complications, and correlation between strain and DTF as a measure of diaphragmatic function.

MATERIAL AND METHODS

This prospective randomized controlled trial was performed in a tertiary care cardiac surgical intensive care unit between March 2021 and June 2022. After obtaining ethical clearance from the institute's ethics committee and informed consent from the parents, 60 pediatric patients aged 1–48 months who underwent uneventful elective cardiac surgery were enrolled in the study. Neonates, patients with preoperative respiratory compromise or, need of mechanical ventilation and emergency surgery, and patients with diaphragmatic palsy were excluded. Patients were randomized into three groups using computer-generated random number and allocated into either of the three groups using opaque sealed envelopes method by ICU technical staff as 1) HFNC (AIRVO 2 Fisher and Paykel Healthcare; Auckland, New Zealand) with flows 1 L/kg/min, and increased by 0.5 L/kg/min up to a maximum of 2 L/kg/min, 2) NIPPV via RAMS cannula (Neotech, Valencia, CA) in PSV mode (pressure support 8 cmH_2O, PEEP 5 cmH_2O), and 3) BiPAP (Care Fusion, California, USA) in nCPAP mode of 5 cmH_2O were used. FiO2 was titrated to achieve SpO2 92–96% for corrective repair surgeries and 85–90% for palliative repair.

All ultrasound measurements of DTF and strain were performed during quiet regular breathing in semirecumbent position and recorded in cine movies with the average of five cycles. For DTF, a linear array transducer (2.5–8 MHz) of GE Vivid E95 echocardiography machine (General Electric Healthcare, Horten, Norway) was placed between midclavicular and anterior axillary lines, in the subcostal area, and directed medially, cranially, and dorsally on the right hemidiaphragm which was identified as a three-layered structure (nonechogenic central layer bordered by two echogenic layers, the peritoneum and the diaphragmatic pleura) in the B mode imaging. DTF was calculated using M mode [DTF = thickness at end inspiration- thickness at end expiration/thickness at end expiration] by reviewers blinded to the mode of support [Figure 1]. Diaphragmatic strain was measured using a phased array transducer (1.6–6 MHz) of GE Vivid E95 echocardiography machine (General Electric Healthcare, Horten, Norway). The probe was positioned on the abdominal wall just below the right costal margin around the midclavicular line at the right hemidiaphragm. The peritoneum, mid-diaphragm, and pleural border were considered equivalent to the epicardial, mid-myocardial, and endocardial lines according to the manual of the analytical

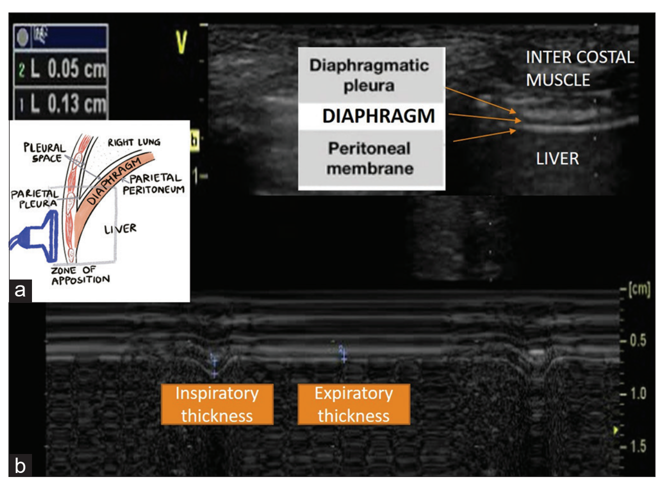

Figure 1: (a) Schematic diagram showing probe position at right costal margin to delineate anatomical structures; (b) assessment of diaphragmatic thickening fraction using M mode

software devised for cardiac motion as a region of interest. The right diaphragm was divided into three segments: the dome position (the highest point of the diaphragm) in the middle; the zone of apposition (the cylindrical region of the diaphragm that opposes the rib cage), and the crura of the diaphragm [Figure 2]. A negative value indicated active shortening of the muscle, while positive value indicated passive stretching of the corresponding segment of the diaphragm.

Baseline measurements of DTF and 2D longitudinal strain were performed at 30 minutes after endotracheal extubation before the application of NIV mode (R0). As per standard practice of the institute, all patients received nebulization with salbutamol and ipratropium bromide immediately after extubation. Respiratory support strategy was applied after recording the baseline measurements of DTF and 2D longitudinal strain. The measurements were repeated every 12 hourly after baseline value (R1, R2, R3, R4, R5) until the therapy was tapered to conventional oxygen therapy with nasal prongs. All ultrasound measurements were obtained by an experienced senior intensivist in the ICU who was not a part of the study. Data analysis was performed by a third party not involved in the study. Changes in respiratory rate and oxygenation (PF ratio) over same time points; proportion of patients that require reintubation till 48 hours postextubation and until discharge from ICU; and the incidence of respiratory complications such as atelectasis, collapse, pneumothorax, abdominal distension, feed intolerance, etc., were noted using clinical parameters, chest X ray, and lung ultrasound.

Based on the mean difference of DTF 10% and equivalence margin of 1%, with alpha level of 0.05 and power of study 80%, the required sample size was 18 subjects in each group.[5] Using the normal standard deviation of longitudinal strain of diaphragm, i.e. 40.3 ± 9% the mean difference of strain to be 9%, with same alpha level and power of study, the required sample size was 20 per group.[6] So total 60 patients were included in the study.

Data are presented as Mean ± SD or median [interquartile range (IQR)] or frequencies (percentages) as appropriate. The normalcy of the data was checked using Shapiro–Wilk test. One-way ANOVA test with Bonferroni correction for multiple comparisons and Kruskal–Wallis test were used to compare means of normally distributed and skewed data, respectively, among three groups. Fisher's exact test was applied to find association between categorical variables and study groups. Repeated measures ANOVA was used to compare means of normally distributed variable at different time points with Bonferroni correction as *post hoc* test for multiple comparisons. All analyses were performed using SPSS version 22.0 (Statistical Packages for the Social Sciences, Chicago, IL).[7] Two-tailed P value ≤ 0.05 was considered statistically significant.

RESULTS

Total 80 patients were screened for the study. Of these, 67 patients met the inclusion criteria. Among these, 3 patients did not give consent and 4 patients were excluded from the study (2 patients did not tolerate BiPAP, 1 patient withdrew consent, and 1 had emergency surgery) [Figure 3]. Out of total 60 patients included in the study, 20 patients each received NIPPV using RAM'S cannula (NIPPV group); HFNC (HFNC group), and BiPAP (BiPAP group).

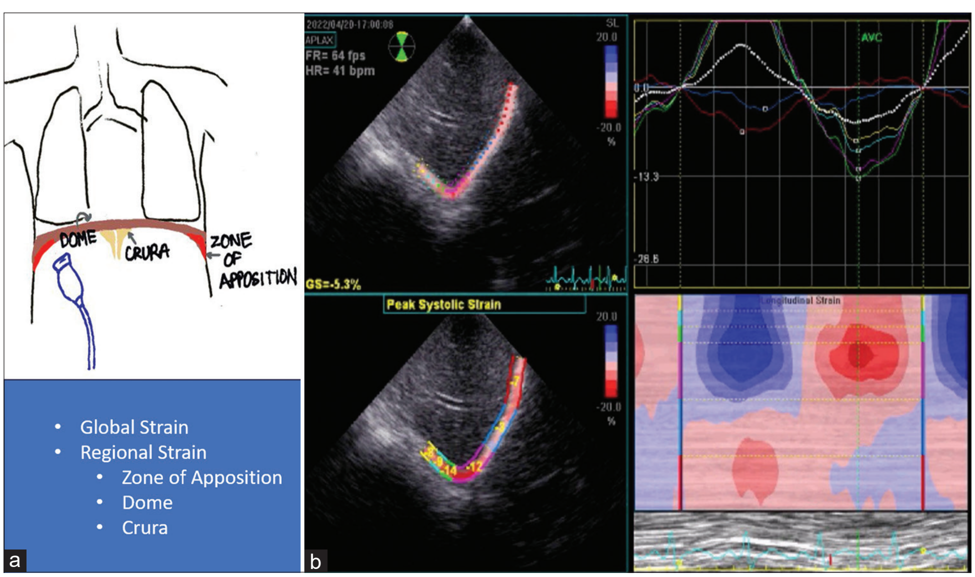

Figure 2: (a) Schematic diagram illustrates the different parts of the diaphragm, (b) diaphragmatic strain measurement using a phased-array transducer positioned just below the right costal margin around the midclavicular line at the right hemidiaphragm

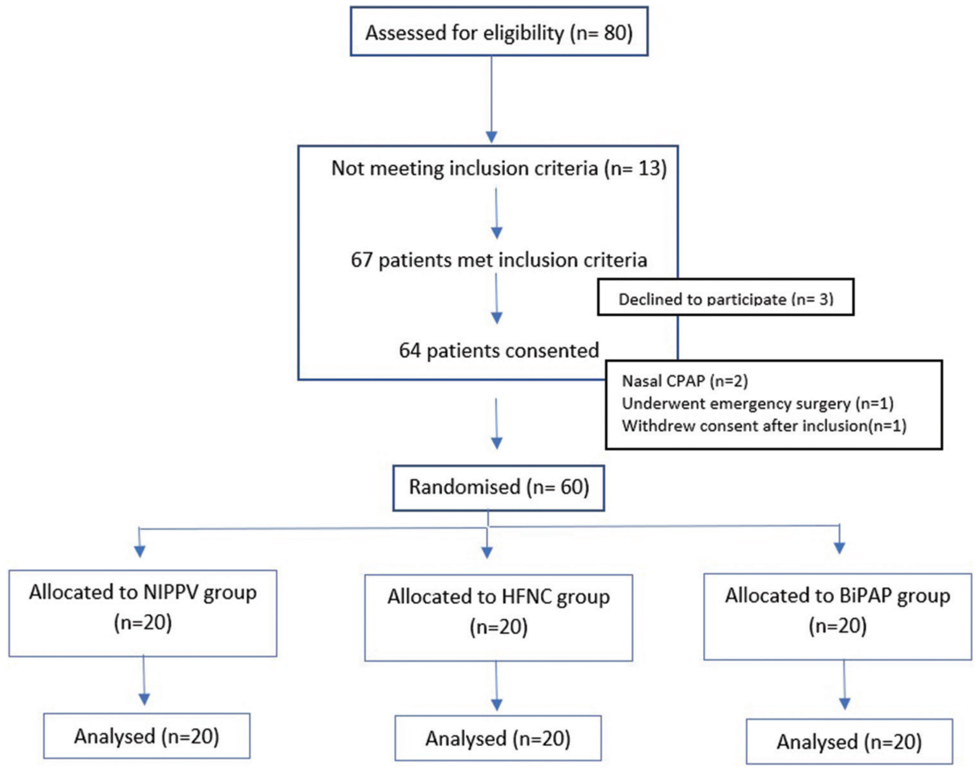

Figure 3: Consort diagram depicting subject enrolment in the study

Patient demographic and perioperative variables were comparable between three groups [Table 1].

Baseline DTF was higher in the HFNC group than the BiPAP group (43.4 ± 9.5% vs 31 ± 12.3%, *P* = 0.009) [Figure 4]. It remains comparable between all three groups at all time points during study period.

Longitudinal strain for crura (STC) of diaphragm was significantly lower in the BiPAP group as compared to HFNC group at R2 to R4 [R2 (-4.27± -2.73 vs - 8.40± -6.4, *P* = 0.031), R3 (-5.32± -2.28 vs -8.44± -5.6, *P* = 0.015), and R4 (-3.8± -3.42 vs -12.4± -7.12, *P* = 0.040)] [Figure 5]. It remained comparable between NIPPV vs BiPAP group, HFNC vs NIPPV group and at the rest of time points between BiPAP vs HFNC group. Strain of zone of apposition (STZ), dome of diaphragm (STD), and whole diaphragm (STT) was also comparable between and within all the three groups at all time points [Figure 5].

PF ratio was significantly higher in the HFNC group as compared to the NIPPV group at baseline (R0) and from R1 to R3 [R0 (323 ± 114 vs 264 ± 80, *P* = 0.008), R1 (311 ± 114 vs 233 ± 66, *P* = 0.022), R2 (328 ± 116 vs 237 ± 47, *P* = 0.002), and R3 (346 ± 112 vs 238 ± 54, *P* = 0.001)]. Similar results were found on comparison of HFNC with BIPAP group at R3 (346 ± 112 vs 296 ± 17, *P* = 0.036). It remains comparable between NIPPV vs BIPAP group and at the rest of the time points between HFNC vs BIPAP group and NIPPV vs BIPAP group [Figure 4]. $PaCO_2$ remain comparable between and within all the three groups at all time points. Respiratory rate was significantly lower in the HFNC as compared to the BIPAP group at R3 (28.4 ± 6.4 vs 35.4 ± 8.4, *P* = 0.032). It remains comparable between NIPPV vs HFNC, NIPPV vs BIPAP, and at rest of the time points between HFNC vs BIPAP group [Figure 4].

Four (6.7%) patients required reintubation which was comparable among all three groups (*P* = 1.000). Six (28%) patients in NIPPV group, four (21%) in HFNC, and six (30%) in BiPAP group developed nasal injury from the interface. One (4.8%) patient in the NIPPV group had feed intolerance, while 2 (9.7%) had excessive leak from and around the NIPPV interface applied for ventilation [Table 2].

DISCUSSION

Results of our study suggested better respiratory workload reduction with use of BiPAP than the HFNC, reflected by lower strain values of the diaphragm. HFNC use resulted in higher PF ratio than NIPPV and reduction in respiratory rate when compared to BiPAP. All the modalities were comparable in preventing reintubation and other complications, when applied prophylactically for the prevention of extubation failure.

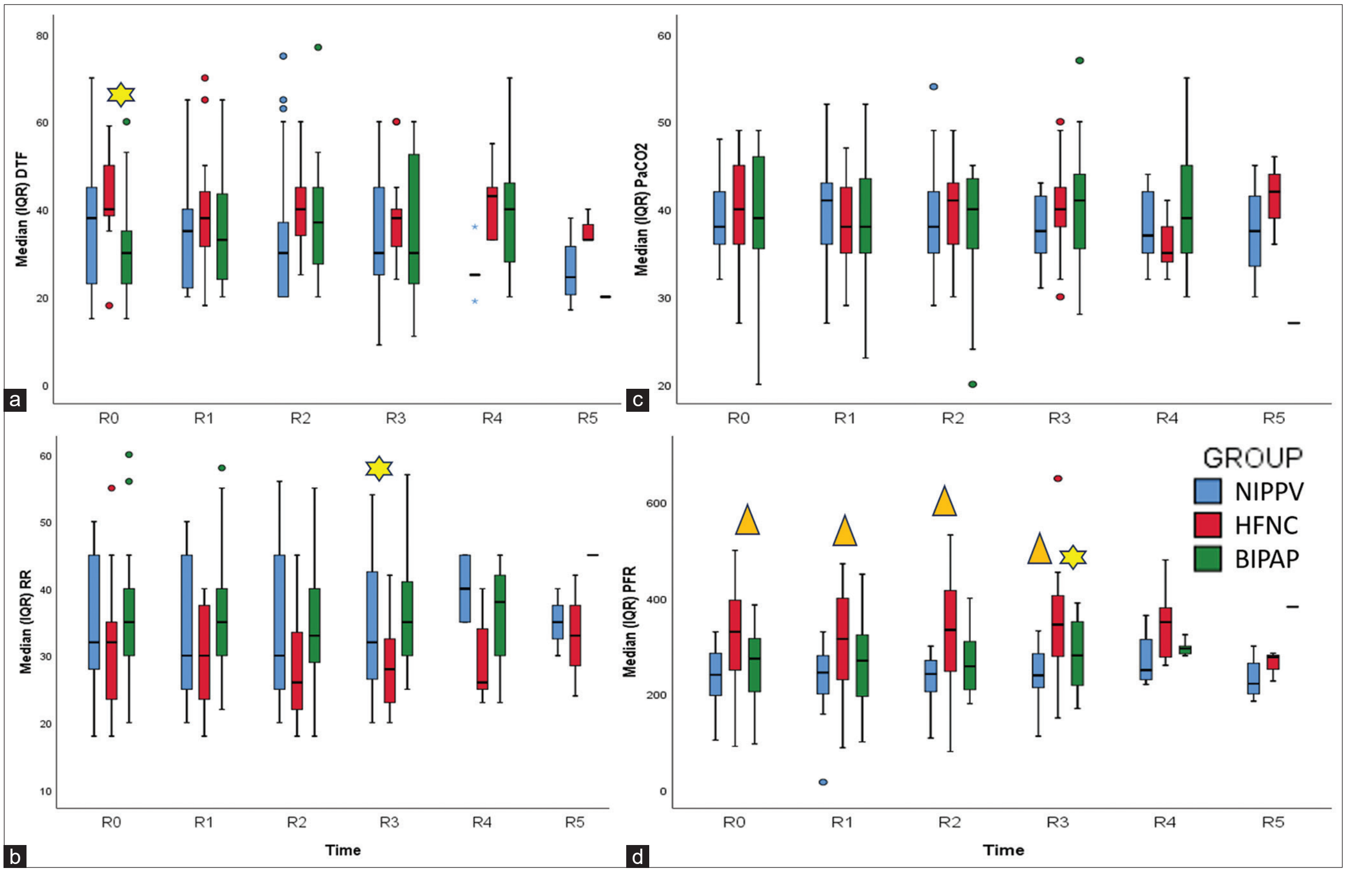

Figure 4: Box–Whisker plot showing comparison of (a) DTF; (b) respiratory rate; (c) PaCO2; (d) PF ratio at different time points. * showing significance between HFNC and BiPAP groups; ^ showing significance between HFNC and NIPPV groups. [Repeated measure ANOVA test was used for within group analysis, one-way ANOVA test for between group analysis, and multiple pairwise comparison using Bonferroni correction, *P* value < 0.05 considered significant. (DTF-diaphragmatic thickening fraction; PFR = PaO2/FiO2 ratio; $PaCO_2$- arterial carbon dioxide in mmHg; R0, R1, R2, R3, R4, and R5-readings at 0, 12, 24, 36, 48, 60 hours respectively after application of different NIV methods)]

During quiet breathing, diaphragmatic contraction has several effects: the central dome lowers because of contraction of the muscle fibers of the zone of apposition, leading to a decrease in pleural pressure while the muscle fibers of the costal part of the diaphragm lift the lower rib cage causing forward and outward (bucket-handle) movements. Diaphragmatic contraction is frequently measured sonographically, as DTF to estimate the work of breathing in various clinical setting. In a randomized cross-over study, on patients with respiratory failure, Sklar *et al*.[8] observed no difference in DTF between HFNC and NIV, but high-flow therapy significantly decreased respiratory rate and minute ventilation, conferring additional physiological benefits. Laverdure *et al*.[9] found comparable DTF with the use of HFNC and BiPAP but significantly lower DTF value in both HFNC and BiPAP groups as compared to standard oxygen therapy group. In the index study also, DTF remains comparable between all three groups except at the baseline. This has been attributed to the ability of DTF to assess only regional function of the diaphragm, i.e., only in the zone of apposition.[10]

Longitudinal strain could be a better modality to assess diaphragmatic deformation as it is neither unidimensional nor angle dependent. Lower strain values on NIV suggest greater workload reduction by providing greater respiratory support and hence less diaphragm deformation. Ye *et al*.[11] showed that the strain in the zone of apposition (-10 ± 4.58) was significantly higher than in the crura (-7.42 ± 5.10) during forced breathing in spontaneously breathing patients. Vivier *et al*.[12] observed decrease in diaphragmatic inspiratory thickening with increasing pressure support and therefore decreased muscular workload.

In the index study, strain for crura of diaphragm was significantly lower in the BiPAP group as compared to HFNC at 24, 36, and 48 hours. The strain of zone of apposition, dome of diaphragm, and the whole diaphragm showed trends toward lower values with BiPAP, than in other groups at majority of the time points. The difference in finding could be related to difference in the pattern of breathing (spontaneous breathing vs positive pressure ventilation) and regional differences in function of different

Table 1: Demographic data and perioperative variables

Variables		NIPPV (*n*=20)	HFNC (*n*=20)	BiPAP (*n*=20)	*P*
BSA (m^2)		0.38±0.06	0.40±0.05	0.39±0.07	0.506
Weight (kg)		8.8±4.8	9.5±3.5	8±3.62	0.505
Age (months)		16.43±13.8	16.26±8.2	15.2±11.9	0.941
Gender	Male	15 (75%)	12 (57%)	13 (65%)	0.456
	Female	5 (25%)	8 (43%)	7 (35%)	
RACHS Category	Category 1	3 (15%)	0	1 (5%)	0.116
	Category 2	15 (75%)	17 (89%)	16 (80%)	0.406
	Category 3	2 (10%)	3 (11%)	3 (15%)	0.888
Diagnosis	ASD	1	2	2	
	VSD	7	3	8	
	PDA	3	2	1	
	COA	3	0	0	
	TAPVC	0	4	2	
	TOF	3	7	4	
	EBSTEIN	1	0	2	
	OTHERS	AML Prolapse-1 Tricuspid Atresia-(BD Glenn)- 1	AML Prolapse-1 TOF-Pulmonary Atresia-1	Supravalvular Aortic Stenosis-1	
Comorbidities		Downs Syndrome 2 (9.5%)	DI-GEORGE Syndrome 1 (5.2%)	Downs Syndrome 1 (5%)	1.0
CPB time (minutes)		109±50.7	137±48.6	112±22	0.096
AXC time (minutes)		72.5±44.9	94.7±41.2	81.3±22	0.183
MV duration (hours)		34.1±26	48.1±30.7	41.6±21.7	0.258
Duration of sedation (hours)		24±19.5	35.7±26	27.9±15.1	0.208
Steroid use before extubation		10/20 (47.6%)	12/20 (63%)	10/20 (50%)	0.813
Muscle relaxant use on MV		1/20 (4.7%)	3/20 (15.7%)	3/20 (15%)	0.540
Surgical complications		Sternal instability 1 Seizures 1 (9.5%)	Acute Kidney Injury 1 Paralytic ileus 1 Reperfusion pulmonary edema 1 (15%)	Massive bleed 3 (15%)	0.802

(RACHS- Risk assessment for congenital heart surgery, BSA- Body surface area, ASD- Atrial septal defect, VSD- Ventricular septal defect, AML-Anterior mitral leaflet, TAPVC- Total anomalous pulmonary venous connection, TOF- Tetralogy of Fallot, PDA- Patent ductus arteriosus, COA- Coarctation of aorta, BD Glenn- Bidirectional Glenn; CPB- Cardiopulmonary bypass, AXC- Aortic cross-clamp duration, MV- Mechanical ventilation. Data was compared using Fisher's exact test, and P value<0.05 was considered significant.

Table 2: Comparison of pulmonary complications

Complications	NIPPV (*n*=20)	HFNC (*n*=20)	BiPAP (*n*=20)	*P*
Reintubation	2 (10%)	1 (5%)	1 (5%)	1.00
Change Of Mode	0	1 (5%)	0	0.316
VAP/SEPSIS	1 (5%)	0	0	1.00
CXR Changes	(10%)	(25%)	(20%)	0.377
• Collapse	2	4	3	
• Pleural Effusion	0	0	1	
• Atelectasis	0	1	0	
Clinical Signs of Increased WOB	4 (20%)	5 (25%)	4 (20%)	0.856
Persistent O_2 Requirement	1	0	1	1.000
Feed Intolerance	1	0	0	1.000
Nasal Injury	6 (30%)	4 (20%)	6 (30%)	0.816
Excessive Leak	2	0	0	0.322

VAP- ventilator associated pneumonia; WOB – work of breathing; PL-pleural effusion; *P* value from Fisher's exact Chi-square test
*P**<0.05

parts of diaphragm due to different embryological origins with *in vivo* differences in thickness.[13]

HFNC allows washout of the nasopharyngeal dead space, thereby improving the efficiency of ventilation and enhancement of oxygen delivery. Corley *et al*.[14] found improvement in PF ratio tidal volume and reduction in the respiratory rate with HFNC as compared to low-flow oxygen therapy. Azevedo *et al*.[15] found improvement in PF ratio and decreased respiratory rate after beginning of both HFNC or NIPPV therapy, but no difference between these two groups. Lavizzari *et al*.[16] reported that HFNC flows of 2–7 L/min generated PEEPs of 2–4 cm H_2O in preterm infants when their mouths were closed. With the standard recommended flows of 2 L/kg/min, HFNC resulted in mean airway pressures of 3–6 cm H_2O in of pediatric patients.[17,18] Our finding of higher PF ratio with HFNC is in consistence with the previous reports. Singh *et al*.[19] found that in preterm infants, the RAM cannula system consistently delivered lower intraoral pressure (effective CPAP) with a mean difference of 2.45 cmH_2O than Hudson prongs. Our observation was similar with the RAMS, Neotech cannula where excessive leak was noted in two patients resulting in unreliable the delivery of positive pressure. Despite difference in strain values, clinical parameters for work of breathing remain comparable between the three groups, may be due to the fact that strain being a sensitive measure could detect subclinical impairment in function, before patient becomes symptomatic. Nonconsistence of changes in the longitudinal strain and PF ratio beyond 36 hours could be related to reduction in the number of participants (75%) beyond this time.

The expected incidence for extubation failure varies between 6 and 22%.[1-4] In the current study, the overall

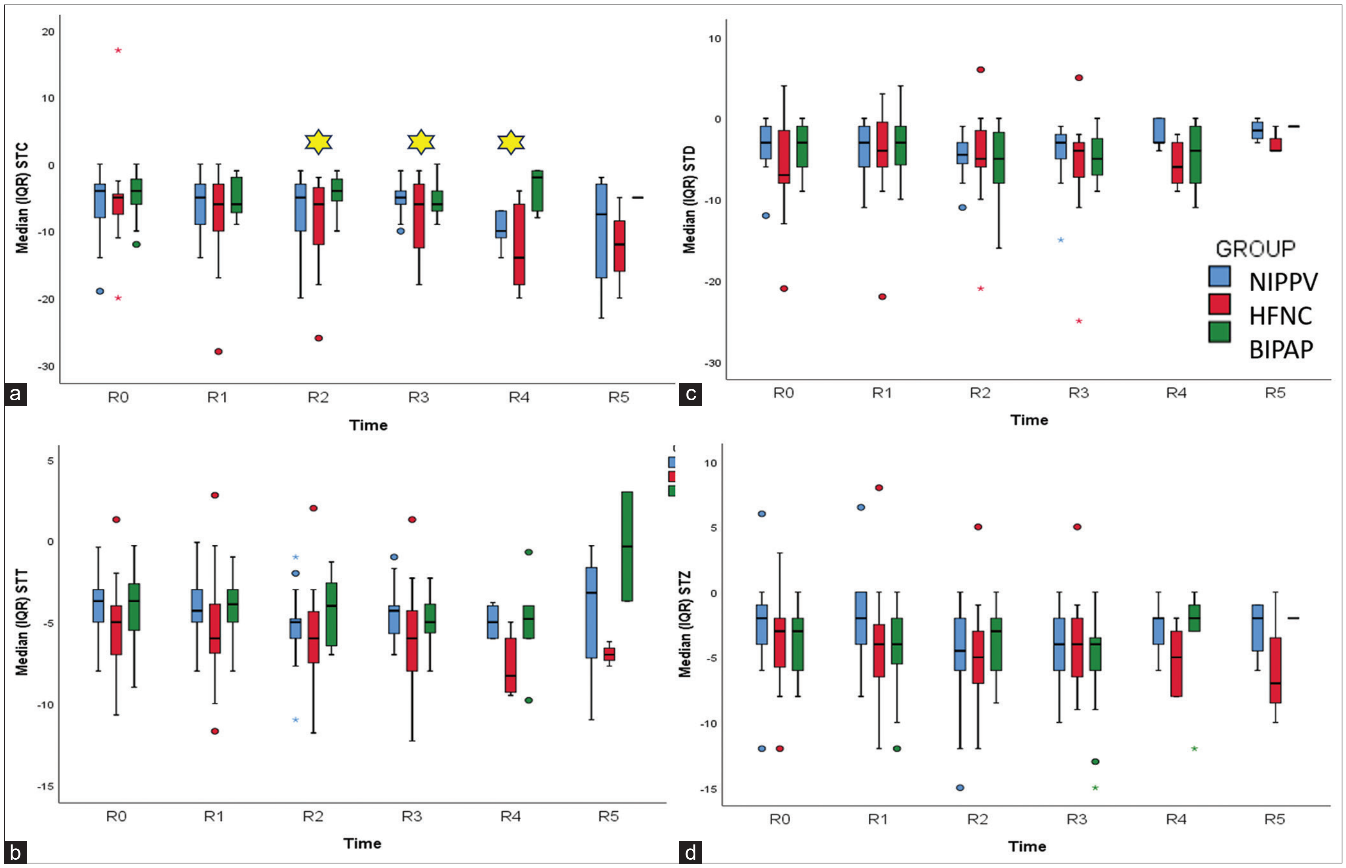

Figure 5: Box–Whisker plot comparing: (a) STC-Longitudinal strain for crura (b) STT-strain of whole diaphragm; (c) STD-strain of dome of diaphragm; (d) STZ-Strain of zone of apposition, at different time points. * showing significance between HFNC and BiPAP groups. [Repeated measure ANOVA test was used for within group analysis, one-way ANOVA test for between group analysis, and multiple pairwise comparison using Bonferroni correction, *P* value < 0.05 considered significant. (R0, R1, R2, R3, R4, and R5-readings at 0, 12, 24, 36, 48, 60 hours respectively after application of different NIV methods)]

rate of reintubation was 4% with no difference amongst all three modalities which could be attributed to the prophylactic use of the respiratory support strategies in all subjects. Stéphan *et al*.[20] reported comparable incidence of reintubation rate between HFNC and BiPAP groups. Frat *et al*.[21] found comparable incidence between HFNC, NIPPV, and standard oxygen therapy. Zhao *et al*.[22] also found no difference between HFNC and NIPPV. However, Shioji *et al*.[23] demonstrated significantly lower reintubation in the HFNC vs NIV group within 48 hrs and within 28 days of extubation. They suggested that HFNC helped in washing out nasopharyngeal dead space, while the CPAP of 10 cm H_2O increases the dead space which might have caused the differences in rate of reintubation among the two groups.

Nasal injury in 26% of the patients found in our study is similar to the incidence reported by previous studies in neonates, i.e. 25–72%.[24,25] Fischer *et al*.[26] demonstrated that the majority had only erythema (88.3%) or superficial ulceration (11%), and only very few patients developed necrosis (0.7%), which is similar to our study finding of no necrosis in any subject.

There were several limitations in the study such as it was a single-center study with small sample size, though ours was highest among existing literature. Software utilized for strain assessment was built for myocardium, and the results may not represent the maximum deformation of the diaphragm in an entire inspiratory phase. BiPAP group was intended to be used with the conventional P high, P low setting; however, the patients did not tolerate the BiPhasic mode, and we had to shift to the CPAP mode. This may have contributed to a change in results. Lastly, we did not perform cost benefit analysis and impact on the overall outcome.

However, this study gives an insight into the physiological level of respiratory support provided by various noninvasive ventilation modalities that are currently in use. From clinical point of view, our current finding may act as guide in choosing NIV mode in different spectrum of patients.

Further large-scale research is needed to establish the efficacy of these devices in different population subsets.

CONCLUSION

BiPAP may provide better decrease in work of breathing compared to HFNC as reflected by lower crural diaphragmatic strain pattern, while HFNC may provide better oxygenation compared to NIPPV group, as reflected by higher PF ratio. Failure rate and safety profile in terms of pulmonary complications and compliance to the devices are similar among different modes NIV used.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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