TO EVALUATE THE INCIDENCE AND SEVERITY OF NASAL TRAUMA SECONDARY TO NASAL CPAP IN NEONATES ADMITTED TO A TERTIARY CARE NICU AND METHODS TO REDUCING SAME

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Medical and Research Publications

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Medical and Research Publications

First printing, 2023.
ISBN: 978-81-958535-8-8

Published by
Medical and Research Publications,
124SpencerRd,Stoke-on-TrentST42BE,
United Kingdom.

www.medicalandresearch.com
Email: info@medicalandresearch.com

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LIST OF ABBREVIATIONS

nCPAP =Nasal continuous positive airway pressure

VLBW= Very low birth weight

ELBW= Extreme low birth weight

RDS =Respiratory distress syndrome

CLD= Chronic lung disease

FRC=Functional residual capacity

V/Q= Ventilation-perfusion ratio

PVR =Pulmonary vascular resistance

PaCO2 = Partial pressure of carbon dioxide

PaO2= Partial pressure oxygen

IFD= Infant flow driver

NPUAP=US National Pressure Ulcer Advisory Panel

BW=Birth weight

GA=Gestational age

PT=Preterm

LPT=Late preterm

EPT= Extreme preterm

MAS=Meconium aspiration syndrome

TTNB=Transient tachypnoea of newborn

CHD=congenital heart disease

PPHN=Persistent pulmonary hypertension

CNSS= Coagulase-negative staphylococcus

INTRODUCTION

Continuous positive airway pressure (CPAP) is a simple, inexpensive and gentle mode of respiratory support in preterm very low birth weight (VLBW) infants. It helps by preventing the alveolar collapse and increasing the functional residual capacity of the Lungs. Since it results in less ventilator induced lung injury than mechanical Ventilation, it should theoretically reduce the incidence of chronic lung disease in VLBW infants. Various devices have been used for CPAP generation and delivery. Continuous positive airway pressure (CPAP), often thought to be the 'missing link' Between supplemental oxygen and mechanical ventilation, is gaining immense Popularity in neonatal intensive care units. Being technically simple, inexpensive and effective, it has become the primary mode of respiratory support in preterm very low birth weight (VLBW) infants**.**[1]

Physiological effects of CPAP in neonates include improved oxygenation, maintenance of lung volume, reduced upper airway resistance, regularisation of respiratory rate and a reduction in obstructive apnoea.[3] Preterm infants being extubated following a period of intermittent positive pressure ventilation via an endotracheal tube are at risk of developing respiratory failure as a result of apnea, respiratory acidosis and hypoxia. Nasal continuous positive airway pressure appears to stabilize the upper airway, improve lung function and reduce apnea and may therefore have a role in facilitating extubation[20].

Despite the many documented benefits of CPAP it is a form of respiratory support that has its complications and can be time consuming and tricky to administer effectively. For example, CPAP relies on maintaining constant pressure within the thorax, so the nasal prongs or masks distorting, the baby moving or simply the baby opening its mouth can cause sudden swings and loss of pressure.[3]

Continuous positive airway pressure (CPAP) administered by nasal devices (nCPAP) is widely used in the respiratory management of newborn infants. Although complications such as gastric distension and air leaks are well described, there is little documentation of nasal trauma, another common side effect.

Traumatic injuries to the nose are the most common complication of CPAP in neonates. Nasal trauma is a recognised complication of nCPAP but its extent has not been well described. Nasal prongs may rub and damage the internal aspects of the nasal septum whereas nasal masks are found to cause trauma or lacerations at the junction between the nasal septum and nasal philtrum. Both of these problems can be minimised by good nursing techniques.[3] Nasal trauma is a frequent complication of nCPAP, especially in preterm neonates, but long-term cosmetic sequelae are very rare. Nasal continuous positive airway pressure (nCPAP) frequently causes nasal trauma in neonates; erythema is most common, but erosion or necrosis occasionally occur. This study provides a description of nasal trauma and proposes a simple Staging system. We propose a standardised system to classify nasal trauma associated with nCPAP.[7] nCPAP. Nasal trauma was reported into three stages: (I) persistent erythema (II) superficial ulceration and (III) necrosis.[7] this could serve as a basis to develop strategies of prevention and treatment of this iatrogenic event. Should the incidence of nasal trauma become one of our NICU Quality Indicators? This is not a trivial problem - the occurrence of a significant erosion in a baby causes considerable angst amongst parents and health care providers as well as sometimes necessitates a switch to a less effective or more invasive system for respiratory support. Permanent scarring with the need for plastic surgery can occur.

Research and evidence have shown that iatrogenic injuries to the nose also occur with extended time on NCPAP. Research observing associations between the patient interface and nasal injury has shown duration of therapy to be the most significant risk factor. Immature skin and developing nasal structures place ELBW infants at increased risk for injury. The challenge for NICU caregivers is to maintaining the ELBW infant on NCPAP for extended periods without nasal injury. Appropriate protocols, practice guidelines, and staff education can decrease this injuries.[21]

No study from India has looked at incidence of nasal trauma from nCPAP, nIMV or nIPPV. This study is a step in this direction.

AIMS AND OBJECTIVES

1) To evaluate the incidence and severity of nasal trauma secondary to nasal cpap in neonates admitted to a tertiary care nicu.

2) To study methods of reducing nasal trauma in neonates undergoing nasal cpap.

REVIEW OF LITERATURE

CPAP refers to the application of positive pressure to the airway of a spontaneously breathing infant throughout the respiratory cycle.[1]

The first clinical use of CPAP was reported by Gregory et al in a landmark report in 1971. They described the use of CPAP via endotracheal tube or a head box in preterm Infants with respiratory distress syndrome (RDS). Shortly after this, Kattwinkel reported successful use of nasal prongs to provide CPAP in these infants. After the initial enthusiasm, it gradually fell out of favour in 1980s because of the advent of newer modes of ventilation (such as high frequency ventilation) and the perceived complications of CPAP (such as air leak). However, reports of significantly lower incidence of chronic lung disease (CLD) from Columbia University unit that used more CPAP (Hudson prongs) as compared to other North American Centers have led to a resurgence of interest in CPAP over the past 15 years.[1]

CPAP: HOW DOES IT WORK?

CPAP predominantly helps by preventing collapse of the alveoli with marginal stability.[1] This results in better recruitment of alveoli thus increasing the functional residual capacity (FRC). The physiologic effects of CPAP are represented in Figure1.[1]

COMPONENTS OF CPAP SYSTEM

The components of a CPAP system are:

1. Gas source: To provide continuous supply of warm humidified and blended gases i.e. air and oxygen.
2. Pressure generator: To create the positive pressure in the circuit.
3. Patient interface/delivery system: To connect the CPAP circuit to the infant's airway.

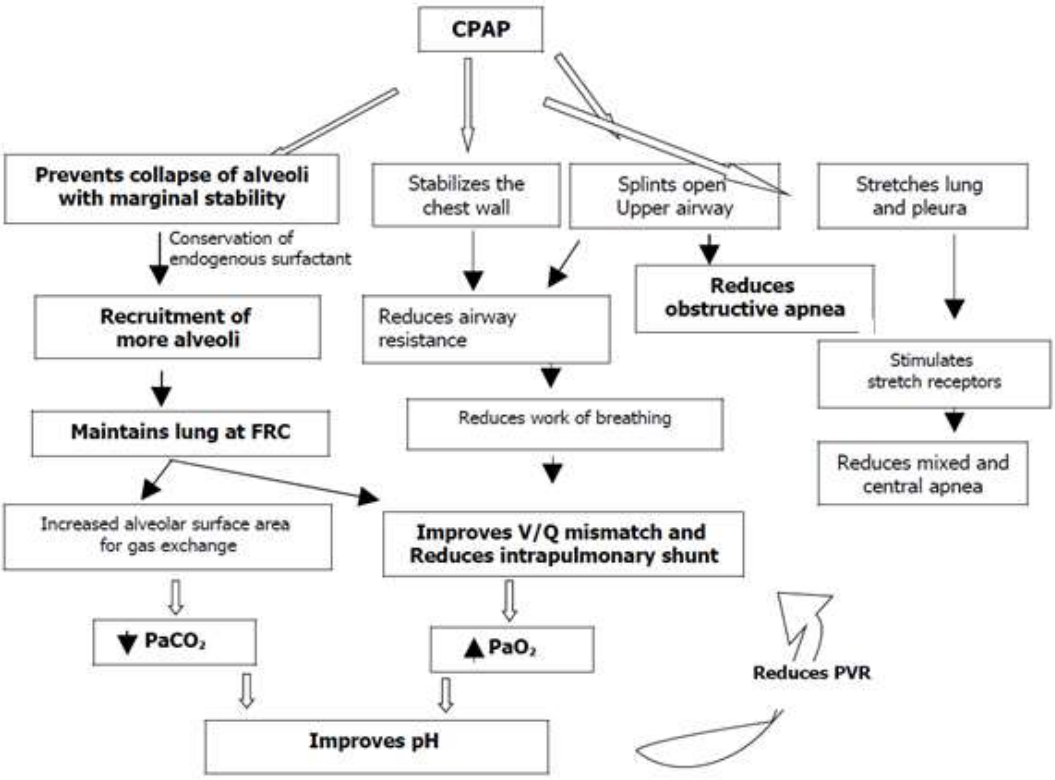


Figure1: Effects of CPAP

Effects of CPAP

(FRC, functional residual capacity; V/Q, ventilation-perfusion ratio; PVR, pulmonary vascular resistance; PaCO2 & PaO2, partial pressure of carbon-dioxide and oxygen respectively in the arterial blood).

The pressure sources of CPAP can be broadly grouped into:

1. Continuous flow devices
2. Variable flow devices

Bubble CPAP:

A typical bubble CPAP setup is shown in Panel 2. One has to remember that though classified as a continuous flow device, flow may still need to be adjusted to maintain continuous bubbling in the water chamber and thus the required level of CPAP.

Variable flow CPAP:

A typical example is the Infant flow driver (IFD). It uses the Bernoulli Effect via dual injector jets directed towards each nasal prong to maintain a constant pressure. If the infant requires more inspiratory flow, the Venturi action of the injector jets entrains additional flow. When the infant makes a spontaneous expiratory effort, there is a 'fluidic flip' that causes the flow to flip around and to leave the generator chamber via the expiratory limb (Coanda effect). So, unlike in the other methods of CPAP where the infant has to exhale against the incoming gas flow, the 'fluidic flip' of the variable flow devices assist his exhalation thus reducing the work of breathing.[1]

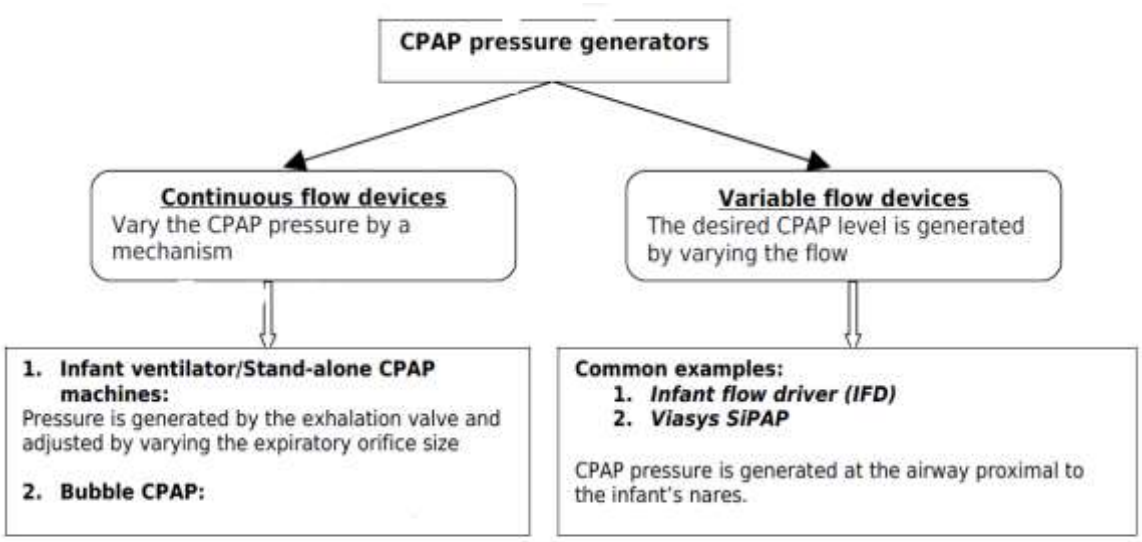


Figure2: Types of CPAP devices

We use continuous flow CPAP by both conventional ventilators and bubble CPAP device in our unit. The advantages and disadvantages of each of these methods are given in Table 2.[1]

Table 1: A comparison of CPAP devices used for pressure generation

Device	Examples	Approximate Cost (INR)	Advantages	Disadvantages	Remarks
Conventional ventilator derived CPAP	Bear Cub, Bird-VIP, Draeger Baby log, Newport, Sechrist, Siemens, SLE, etc.	5 – 10 lakhs	• No need of a separate equipment • Can be easily switched over to mechanical ventilation, if CPAP fails	• Expensive • Standard flow of 5-8L/min may be insufficient in the presence of high leak • Difficult to know if the set flow is sufficient or not (insufficient flow can lead to increased WOB)	Of practical utility in units having ventilators but not so in a small hospital/nursing home without a neonatal ventilator.
Stand-alone CPAP machines ('Indigenous CPAP')	Lectromedik, Meditrin, Phoenix, Shreeyash, Zeal	25,000 to 80,000	• Economical • Useful for small hospitals • Can have bubble CPAP option	• Most of them do not have proper blenders and/or pressure manometer	Though inexpensive, they have not been tested adequately; niggling issues observed during daily use
Bubble CPAP	Indian: Medserve, Meditrin Imported: Fisher & Paykel	50,000 to 80,000 1,60,000	• Simple and inexpensive • Oscillations produced by continuous bubbling might contribute to gas exchange (akin to HFV) • Can identify large leaks at the nares (bubbling stops)	• Flow has to be altered to ensure proper bubbling • It is difficult to detect high flow which can lead to over distension of the lungs	It seems unlikely that oscillations delivered at the nares are transmitted up to the alveoli; Still, the stand-alone option makes it an easy and cost effective proposition in developing countries
Variable flow devices	Arabella, IFD, Viasys SiPAP	3 lakhs	• Maintains more uniform pressure • Might decrease the WOB • Recruits lung volume more effectively	• Expensive • Requires more technical expertise	On theoretical grounds, this device scores more than the other two; However the prohibitive cost and the lack of evidence regarding its superiority preclude its widespread use

(WOB, work of breathing; HFV, high frequency ventilation; IFD, infant flow driver)

Table 2: Advantages and disadvantages of common CPAP delivery systems

Delivery system	Advantages	Disadvantages	Remarks
Nasal prongs (single/binasal) Example: • Argyle • Hudson • IFD prongs	• Simple device • Lower resistance leads to greater transmission of pressure • Mouth leak acts like a 'pop-off' mechanism	• Relatively difficult to fix • Risk of trauma to nasal septum and turbinates • Leak through mouth means end expiration pressure is variable	Studies have shown that they are more effective than nasopharyngeal prongs (in post-extubation setting)[8]
Nasopharyngeal prongs (e.g. using a cut endotracheal tube)	• Easy availability • Economical • More secure fixation	• More easily blocked by secretions • Likely to get kinked	Though more economical and easily available, they are found to be inferior to

Devices used for CPAP delivery (Patient interface)

Various devices used for CPAP delivery include:

1. Nasal prongs (single/double or binasal)
2. Long (or) nasopharyngeal prongs
3. Nasal cannulas
4. Nasal masks (Figure 3).

Face mask, endotracheal, and head box are no longer used for CPAP delivery in neonates. Endotracheal CPAP is not recommended because it has been found to increase the work of breathing (infant has to breathe 'through a straw').[1]

In our unit, we use short bi-nasal prongs for delivering CPAP (both ventilator and bubble CPAP).

INDICATIONS FOR CPAP

Common indications

1. Respiratory distress syndrome (RDS)
2. Apnea of prematurity (especially obstructive apnea)
3. Post-extubation in preterm VLBW infants
4. Transient tachypnea of newborn (TTNB)/delayed adaptation

Other indications

1. Pneumonia
2. Meconium aspiration/ other aspiration syndromes
3. Pulmonary edema/pulmonary hemorrhage
4. Laryngomalacia/ tracheomalacia/ bronchomalacia

Practically, CPAP is very useful in preterm (<35 weeks') infants with respiratory distress/failure of any etiology. Some of these indications have been briefly described below[1]:

1. **RDS:** The most common indication for CPAP is mild to moderate RDS. It helps in this condition by preventing collapse of alveoli with marginal stability. The recruitment of

more alveoli helps to increase the FRC thus helping in better oxygenation (Figure 1). Numerous studies have proved its efficacy in reducing the need for mechanical ventilation and probably the incidence of chronic lung disease in infants with RDS.

CPAP and surfactant: The beneficial effect of CPAP in preterm infants (<29 to 30 weeks') could probably be enhanced by administering surfactant. In this approach, if respiratory distress progresses even after initiating CPAP, the baby is intubated, given surfactant, and then extubated and put back on CPAP again. Known as INSURE (Intubation-Surfactant-Extubation), this approach might further reduce the need for subsequent ventilation and improve the outcome in extreme preterm infants. However, clinical trials have not shown any reduction in the incidence of CLD so far. More studies are needed to confirm or refute its possible beneficial effects. We do not routinely employ INSURE technique at present.

2. **Apnea of prematurity:** The mechanism by which CPAP helps in apnea of prematurity has been explained before (Figure 1). It is typically used when clinically significant episodes persist despite optimal methylxanthine therapy.

3. **Post-extubation in VLBW infants:** CPAP reduces the incidence of apnea, respiratory acidosis, and increased oxygen requirement in VLBW infants extubated after a brief period of mechanical ventilation.

4. **Delayed adaptation/TTNB:** In these conditions associated with excess lung fluid, CPAP helps by maintaining the lung expansion. Though useful in premature infants, term and near-term neonates with TTNB often do not tolerate this mode of respiratory support.

5. **Pneumonia:** CPAP can be tried in stable infants with mild to moderate respiratory distress due to pneumonia. It helps in this condition by maintaining the lung expansion preventing any collapse due to fluids and secretions.

6. **Meconium aspiration syndrome:** Use of CPAP is a contentious issue in this condition as most of the infants would already have hyper expanded lung fields and CPAP might further aggravate it. Moreover, these term infants are unlikely to tolerate CPAP well. It is only indicated in a rare infant with predominant Collapse/atelectasis (preferably proven by chest X-ray).

We use CPAP predominantly in preterm infants (<35 weeks' and birth weight <1800g) with respiratory distress, apnea of prematurity, delayed adaptation, and pneumonia; also we extubated VLBW infants to CPAP routinely. We occasionally use CPAP in near term and term infants with transient tachypnea and pneumonia.

CONTRAINDICATIONS OF CPAP[1]

The important contraindications for CPAP include:

1. Progressive respiratory failure with PaCO2 levels >60 mmHg and/or inability to maintain oxygenation (PaO2 <50 mmHg)
2. Certain congenital malformations of the airway (choanal atresia, cleft palate, Tracheo esophageal fistula, congenital diaphragmatic hernia, etc.)
3. Severe cardiovascular instability (hypotension)
4. Poor respiratory drive (frequent apnea and bradycardia) that is not improved by CPAP.

GUIDELINES FOR CPAP THERAPY

When to initiate CPAP?

The timing of initiation of CPAP in preterm infants with respiratory distress needs further elaboration.

Early CPAP: It is important to note that CPAP helps mainly by preventing the alveolar collapse in infants with surfactant deficiency. Once atelectasis and collapse have occurred, CPAP might not help much. Therefore, all preterm infants (<35 weeks') with any sign of respiratory distress (tachypnea/chest in-drawing/grunting) should be started immediately on CPAP.[1]

Prophylactic CPAP: Extending this logic, some have advocated use of prophylactic CPAP (before the onset of respiratory distress) in preterm VLBW infants as majority of them would eventually develop respiratory distress. However, there is no evidence for any additional benefit with this approach; indeed, there are concerns regarding increased adverse effects such as intraventricular hemorrhage. Hence, prophylactic CPAP is NOT recommended at present.[1]

The most difficult aspect of using nasal CPAP is the positioning and fixation of the patient interface. The optimal technique of fixation depends on the type of delivery system used; the exact technique used does not matter as long as the device is secure and not traumatizing.[1]

Short binasal prongs: It is important to choose the appropriate sized prong that snugly fits in the nasal cavity to avoid a significant leak. However, to avoid causing any injury, it should be fixed straight and not pressed hard against the nasal septum. Use of a modified cap (made from adult cotton socks) and tapes to secure the binasal prongs shown in Figure.[1]

Steps of initiation and nursing care before and during CPAP

PROTOCOL FOR CPAP THERAPY

Protocol for CPAP therapy in the three most common clinical indications is given in Table 3.

MONITORING WHILE ON CPAP

The following parameters need to be monitored while the infant is on CPAP:

1. Continuous monitoring of respiratory rate, heart rate, SpO2
2. Serial monitoring of

a. Severity of respiratory distress by using Downe's or Silverman score

b. Arterial blood gases (ABGs)

c. Perfusion - CFT, BP, peripheral pulses, urine output

d. Abdominal girth

The **target** saturation and blood gases during CPAP therapy are: **SpO2 - 90-93%;**

PaO2 – 50 to 70 mmHg; PaCO2 – 45 to 50 mmHg.

Steps of Initiation and Nursing Care during CPAP

A. How bubble CPAP was set up in our study.

1. Connect the air and oxygen tubing (pressurized gases from either central manifold or from compressor and oxygen cylinder respectively)
2. Attach both to the air-oxygen blender
3. set the flow using flow meter (usually at 5-8 L/min)
4. Set up the inspiratory limb:

a. From the flow meter to the humidifier and

b. From the humidifier to the patient end (e.g. nasal cannulas); fill water in the humidifier and humidify the gases to 34-370C.

5. Set up the expiratory limb - from the patient end to a chamber filled with sterile water. Immerse it under the water up to the required depth (which is determined by the intended pressure - e.g. to deliver 5 cm H20, immerse up to 5 cm mark in the tube).
6. Attach a pressure manometer at the patient end
7. Set required pressure and FiO2, low pressure alarm and apnea alarm
8. Occlude the patient end of the ventilator circuit with your palm and observe if:

a. Bubbling occurs in the water chamber - If there are no bubbles, look for any leak in the circuit; if no leak is found, increase the flow by 1 L/min and recheck.

b. The set pressure is delivered (see the manometer reading) - If it is less than the set pressure, look for any leaks in the circuit/around the cannula. If no leak is found, increase the flow and recheck.

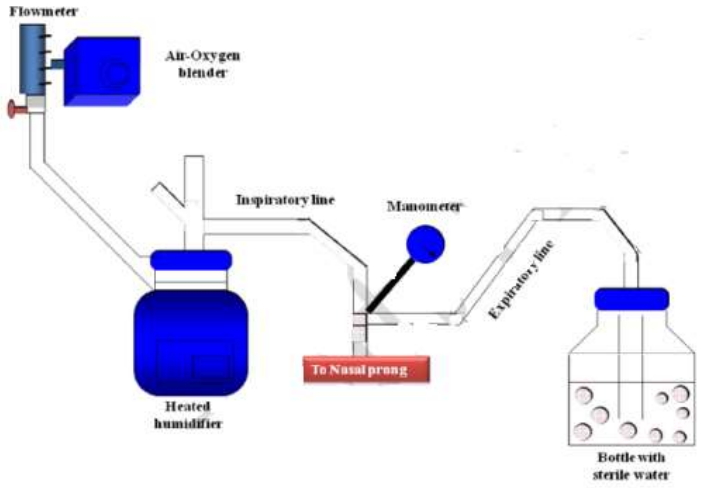


Figure 3 : How to set up bubble CPAP.

B. Initiation of CPAP

1. Place a roll under infants' shoulder to slightly extend the neck

2. Application of prongs:

- Choose the correct size prong (the prongs should fill the nasal opening without stretching the skin)
- Apply a thin strip of Tegaderm/comb fill on overlying skin of septum.
- Place the prongs with the curve downwards and fix as shown in Figure 4.

3. Attach the patient end of the ventilator circuit to the cannula.

4. Attach a pulse-oximeter to the infant.

C. Nursing Care

1. Monitor the infant frequently; observe if the baby is comfortable

2. Pass an orogastric tube. Keep the proximal end of tube open. If the infant is being fed while on CPAP, close the tube for half an hour after giving feeds and keep it open for the next 90 minutes (if fed 2hourly).

3. Do regular but gentle nasal suction to clear the mucus 4 hourly or as and when required.

4. Clean the nasal cannula and check its patency once per shift.

5. Change the infant's position regularly every 2-4 hours and check the skin condition frequently for redness and sores.

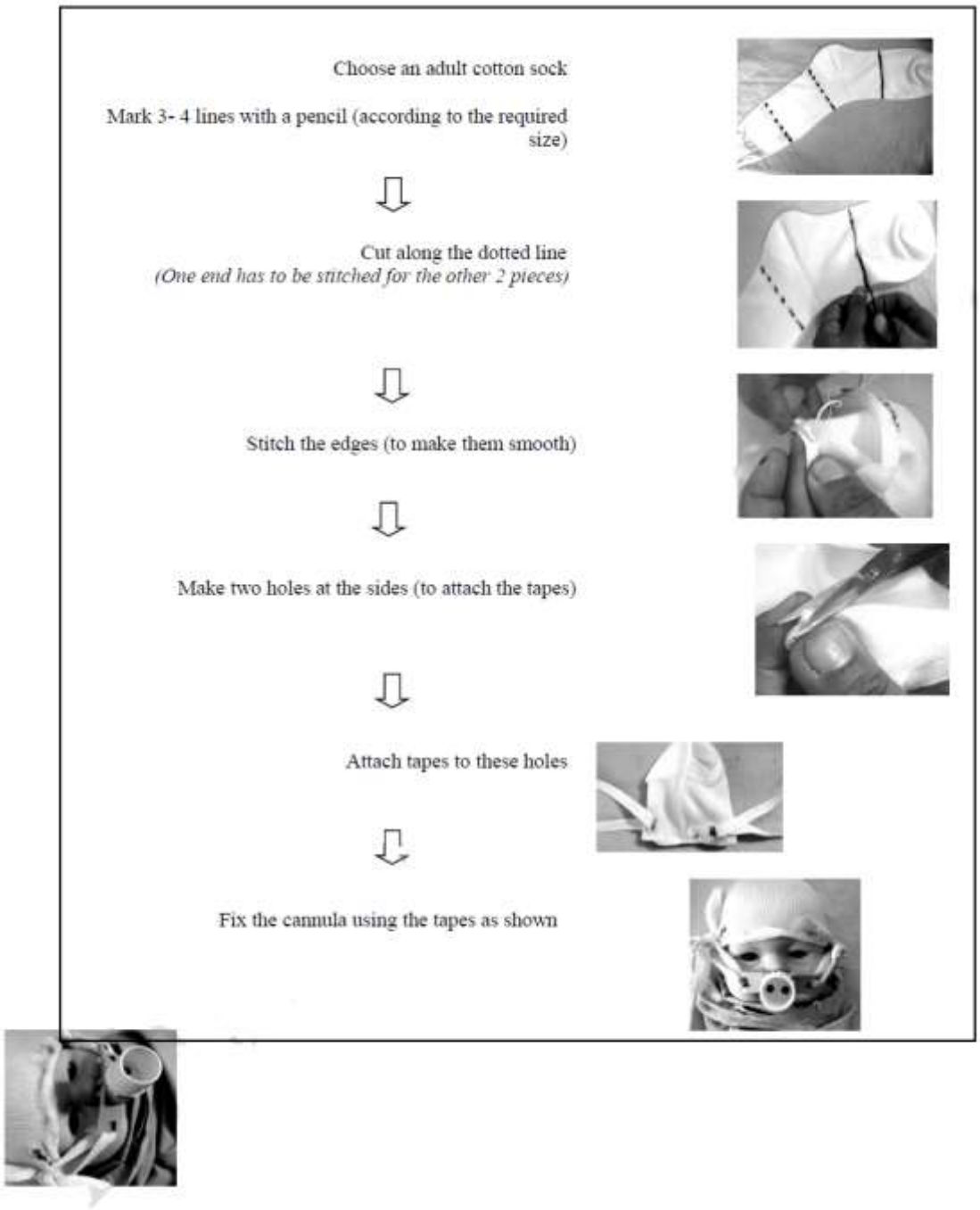


Figure 4: STEPS IN FIXATION OF NASAL CANNULA

Table 3 Protocol for CPAP therapy in the three common neonatal conditions

	Indications		
	RDS **Apnea of prematurity** **Post extubation**	**Apnea of prematurity**	**Post extubation**
How to initiate CPAP? Pressure FiO_2	• Start at 5cm H_2O • 0.5 (titrate based on SpO_2)	• Start at 4cm H_2O • 0.21-0.4 (as decided by SpO_2)	• Start at 4-5cm H_2O • 0.05 to 0.1 above the pre-extubation FiO_2
What to do if there is no improvement? Pressure FiO_2	• Increase in steps of 1-2cm H_2O to reach a maximum of 7-8 cm H_2O • Increase in steps of 0.05 (if oxygenation is still compromised) up to a maximum of 0.8	• Increase up to 5cm H_2O (further increase is not warranted usually in this condition - may lead to hyperinflation) • FiO_2 increase does not help much	• Increased in steps of 1-2cm H_2O to reach a maximum of 7-8cm H_2O • Increase in steps of 0.05 to a maximum of 0.8
Failure of CPAP	Worsening respiratory distress (as indicated by Silverman scoring) and/or hypoxemia (PaO_2 <50mmHg) / hypercarbia ($PaCO_2$ >60mmHg) despite CPAP pressure of 7-8 cm H_2O and FiO_2 of 0.8	Recurrent episodes of apnea requiring PPV *(Likely to occur in infants with*	Same as for RDS *(Likely to occur in ELBW*

	(Likely to occur in infants with severe RDS, associated sepsis, and in ELBW infants who have not received ANS)	*central apnea's sepsis)*	*infants and in sepsis / pneumonia, PDA, metabolic acidosis, and collapse)*
Weaning from CPAP • When to wean • How to wean	• When there is no respiratory distress and SpO_2 / blood gases are normal • Reduce FiO_2 in steps of 0.05 to 0.4, then decrease pressure in steps of 1-2cm H_2O until 3-4 cm H_2O (infants clinical condition will guide the speed of weaning)	• No episodes of apnea/desaturation / bradycardia for atleast 12-24 has hrs • Same as for RDS	• Same as for RDS

Complication: Traumatic injuries to the nose are the most common complication of CPAP in neonates. Nasal prongs may rub and damage the internal aspects of the nasal septum whereas nasal masks are found to cause trauma or lacerations at the Junction between the nasal septum and nasal philtrum. Both of these problems can be minimised by good nursing techniques. Other complications include a two to three fold increase in the risk of pneumothorax, gaseous distension of the stomach and difficulties identifying when a baby is 'failing' on CPAP and requires more intensive intervention.[3]

Nasal trauma:

The nasal trauma was caused by nasal prongs and has been reported as 20%.A recent randomised control study by Yong et al[6] found a higher incidence of nasal trauma due to CPAP and also found that that there was no significant difference in nasal trauma between prongs and mask. The nasal injuries reported in the literature range from redness, erythema, crusting and excoriation to scaling. The common sites for injuries are the base of the septum, where it meets the philtrum, caused by the mask, and the medial aspect of the septum, caused by the prongs. Duration of nCPAP is a definite risk factor for nasal trauma. Birth weight, gestation and type of nasal device are not significant.[5]

The major underlying mechanism of nasal injury related to NCPAP appears to be the pressure generated on the columella by the prongs. Etiology is similar to the pressure sores. Pressure sores are best defined as soft-tissue injury resulting from unrelieved pressure over a bony prominence. There is maxillary spine behind the columella and its surface is very small. NCPAP device causes the pressure on this area. Increased pressure on the columella

causes diminished circulation of blood flow. This subsequently impairs tissue perfusion and leads to ischemia along with tissue damage. Persistent erythema, dermal injury, edema, indu-ration and finally an ulcer can occur. Relieving the pressure is the key to healing and more importantly, the key to prevention.[10]

The local pressure of CPAP devices to the nasal area tends to develop decubitus lesions in the newborn due to its cutaneous vulnerability and anatomical factors such as end-vascularisation of the columella and nostril. Nasal trauma represent a source of discomfort for patients, possible site of infection and a risk of long term functional or cosmetic sequelae. Robertson et al first reported a rate of 20% for Nasal trauma due to continuous positive airway pressure in neonates nasal deformities secondary to nCPAP in very low birth weight infant. Yong et al have studied the effect of mask versus cannula in the development of nasal trauma and found no statistically significant difference between these two devices (29% vs. 35%, respectively). Other studies comparing different nCPAP systems reported this complication as a secondary outcome. Furthermore, nomenclature of these nasal lesions is highly variable including nasal trauma, injury, breakdown, blanching, bleeding or necrosis· respectively.

Incidence and severity of trauma were inversely correlated with gestational age and birth weight. The risk of nasal trauma was greater in neonates <32 weeks of gestational age, weighing <1500 g at birth, treated >5 days by nCPAP, or staying >14 days in the NICU. Most cases of nasal trauma (90%) appeared during the first 6 days of nCPAP. Nasal trauma occurred rarely after several weeks of treatment. The immaturity of the skin could be implicated in the pathogenesis of such trauma. Cosmetic or functional sequelae of nasal trauma due to nCPAP have been reported with an unforeseeable need for surgery. Another possible complication of nCPAP trauma is nosocomial infections·[7]Kopelman AE, Holbert D, Use of oxygen cannulas in extremely low birth weight infants is associated with mucosal trauma and bleeding, and possibly with coagulase-negative staphylococcal sepsis reported, CNSS occurred less often in infants treated with oxyhoods than those on OC or CPAP (1 of 13, 8%, vs. 10 of 44, 23%), but the difference was not significant[26].

Another study showed that lesions were observed in all newborns, which were classified as: mild (79.6%), moderate (19.7%) and severe (0.7%). The conclusion is that the use of prongs for more than two days represents a risk factor for the lesions to develop. Research classifies nasal injuries caused by the use of prongs in three stages: mild, moderate and severe. The mild stage is described as redness or nasal hyperemia; the moderate presents bleeding injuries and the severe stage refers to injuries with necrosis, found a 25% frequency of nasal lesions caused by the use of CPAP with prongs; an absolute precision of 7% and 5% of significance level were considered.[11]

Nasal lesions caused in newborns due to misuse of prongs vary from simple hyperemia of the nasal mucosa, bleeding, formation of crusts, and necrosis up to total destruction of the anterior part of the septum (columella) and nasal septum.

There is currently no recognised classification available to describe the severity of nasal trauma secondary to nCPAP in neonates. We therefore classified trauma based on the standardised classification of the decubitus lesions from the US National Pressure Ulcer Advisory Panel (NPUAP).[7]

► Stage I: erythema not blanching, on an otherwise intact skin.
► Stage II: superficial ulcer or erosion, with partial thickness skin loss.
► Stage III: necrosis, with full thickness skin loss.
When a patient presented a nasal trauma evolving through different
Stages, only the most severe stage was considered.[7]

Prongs are classified in three types: Hudson®, Argyle® Sherwood and Inca Ackrad®, while the ideal size for each newborn depends on his(er) current weight. The Hudson® type presents the following sizes: 0, 1, 2, 3, 4 and 5, which correspond to the following weights: less than 1000g, between 1000g and 1500g, between 1500 and 2000g, between 2000 and 3000g and above 3000g. The sizes for the Argyle® Sherwood type are: extra small, small and large and the sizes for the Inca Ackrad® type are: 7.5 and 9 for newborns below 700g, 10.5 for newborns between 701g and 1000g, 12 for newborns between 1001g and 1300g, and 15 for newborns above 1300 gm. Some researchers consider that the ideal prong is the one not so large to the point it distends the nostrils and not so small to the point it lets extra

space between the prong and nostrils. As for its positioning, a well-positioned prong is that which does not deform the newborn's face and its bridge does not touch the nasal septum and does not allow the device to move inside the nostrils. Thus, prongs' inappropriate size and fixation are harmful factors that determine the formation of lesions, especially prongs smaller than they are supposed to be because they do not properly fit into the newborns' nostrils, causing friction between the devices and the nostrils and also encouraging air leakage.[11]Rego 2002 showed that Argyle prongs were more likely to cause nasal hyperaemia when compared with Hudson prongs.[27] Buettiker 2004 showed no significant difference in the rates of nasal trauma between the NCPAP devices investigated.[28]

When the cap is larger than the newborn's head, it causes the tube to move and consequently it presses the prongs into the nostrils. Hence, it is advisable to ensure adequate cap sizes better suited to newborns' heads so that pressure on the nostrils is minimal. In the absence of caps, bandages were fixed around the head with patches with the same function: immobilizing the prongs. Formation of nasal lesions is related to health professionals inappropriately fixing the prongs into the newborns' nostrils. They introduce the entire prongs stems into the nostrils so that the bridge of this device is in direct contact with the columella. Additionally, it is possible the prongs, smaller that the ideal size, cause the device to move inside the nostrils, clamping the septum. Prongs were inserted beyond the recommended millimeters, the bridge touched the columella and septum so as to produce sufficient pressure to the CPAP system and impede air leakage. This practice probably encouraged early nasal lesions. The literature indicates that resistance to the device is inversely proportional to its radius, that is, the larger the prong (larger diameter/radius) the lower the resistance and, consequently, the better the pressure. Prongs with the correct diameter reduce air leakage and prevent harm in the nasal tissues. The traction exerted by the tube weight jointly with the device is responsible for 25% of nasal lesions.[11]

The trauma resulted from the shape of the prong, which was reported not to be anatomical and the base not allowing for projection of the columella beyond the alar rim. The prongs were perpendicular to the base, not converging as the baby’s nasal passages do and the base of the prongs were closest together where the columella was widest. It was suggested that a curved design with tapering prongs would be more suitable. Other recommendations to avoid nasal trauma include ensuring appropriate fit of the prongs, tying the hats to the

prongs more horizontally to prevent upward pull on the nose and supporting the weight of the tubing. In addition, the nose should be rested for half an hour every 4–6 hours, although such a policy may be impractical in a CPAP-dependent infant.[14] The skin should be cleaned with sterile water and nasal prongs should be cleaned as per the manufacturers' instructions (with distilled water) every 4 to 6 hours. It is very important to periodically inspect nasal mucosa for hyperaemia, columella and alae nasi for blanching at least 4 hourly. If the prongs are required for more than 3 to 4 days it may be prudent to change them and sterilize by putting in glutaraldehyde solution before reapplication.[15]

Aiming to alleviate and prevent lesions, nostrils are protected by adhesive tapes, such as common patches, hypoallergenic tapes and hydrocolloid dressings, used to avoid direct friction between the prongs and the columella and septum. Common dressings in form of patches (cut into strips and adhered to the columella) and in form of a pig snout, which covers both the columella and the nostrils edge.[11]

The silicon gel application may reduce the incidence and the severity of nasal injury in preterm infants on nasal CPAP.[10]. Traditionally, static devices such as gel pads and mattress overlays are used to reduce pressure and support surfaces. A silicon dressing can also be used to manage pressure ulcers. Silicon gel sheeting is a soft and flexible material. It reduces the pressure on columella, distributes pressure around the nares and reduces friction between device and skin. Silicon gel sheet can prevent trauma to the surrounding skin.[10] Do not cover an injured septum with hydrocolloid shields. The increased moisture can actually promote further breakdown of the septum. Hydrocolloids can be applied around the opening of the nares cautiously if there is difficulty maintaining a seal; however, it must be changed every 12 hours so the septum can be monitored.22,27 The hydrocolloid will not protect the septum from breakdown.[25]

The hydrocolloid is currently the most reported material used as a preventive measure, especially in the international literature. Even though lesions are still observed with its use, they are presented in a smaller proportion. This fact makes clear that cost-benefit issues should be revaluated in the use of prongs.[11]

Care of the Nose and Face. [8, 9]

Skin Care Policy for Infants Nursed on CPAP

Every hour check visually:

· The generator should be positioned correctly.

· The nose should not be squashed or pushed upwards.

· The eyes should be clearly visible.

· Tapes should not be too tight and should certainly not cause indentation, pitting or ocular oedema.

At least four hourly check physically:

- The hat should be checked for tightness and correct fit regularly – it should not be too tight or too loose or rub against the infant's skin.
- Prongs/Mask should be removed from the nose to allow rest from the pressure on it, more often if the infant's condition dictates.
- The nose should be inspected for signs of redness, skin breakdown, bruising, Indentation, altered shape and bleeding. Any alteration in appearance should be documented.
- Prongs/Mask should be checked to ensure that they are clean and patent prior to being replaced on the infant.
- The ears should be inspected to ensure that they are not creased or folded. They should also be inspected for signs of skin breakdown, redness, bruising, swelling, discharge or bleeding. Any alteration in appearance should be documented.
-

Remember:

- Prongs/Mask should be removed by loosening of the tapes rather than pulling them straight off the infants face.
- Regular mouth care should be performed.
- Suctioning should NOT be routine but as dictated by the infant.
- It is important that documentation is completed when the nose is checked and any changes noted.

If there are changes to the nose or surrounding area:

1. Check that all of the above have been followed – that the hat/mask/prongs are the correct size and are clean and patent. That there is no error with the set-up of the CPAP. Document and recheck in 1-2 hours depending on severity**.**

2. Recheck – have there been any changes? Has it improved or deteriorated? If improved, document and continue to recheck regularly, minimum of every four hours. If deteriorated, inform nurse in charge and medical staff, document.

3. Try increasing time off to relieve pressure, consider facial oxygen if needed. Consider using vapotherm if available or alternating mask and prongs. Consider a dressing or treatment to the affected area. Document any changes in care.

4. Consider intubation and CPAP or ventilation. Inform tissue viability nurse and plastic surgeons. Complete an incident form. Document any changes in care. [8, 9]

Many strategies have been applied to reduce the incidence of this complication including meticulous securing and positioning, regular inspection of the septum and nose, use of hydrocolloid dressings and alternating between nasal prongs and mask for the CPAP interface. Prevention should be possible but cases continue to occur.

Several questions may be posed regarding this complication. I would be interested to hear from you.

1. What are the best preventive strategies? If you have had success in preventing nasal trauma, what is the key?
2. Is the enthusiastic embrace of High Flow in part to minimize the risk of this complication?
3. How much discomfort do babies on NCPAP endure?
4. How do families regard these lesions?

Should the occurrence of nasal erosion be considered a "medical error" or just a recognized complication of NCPAP? Might use of the term "just a complication" imply that it is not manageable or preventable? At least, we need to think of this condition as a preventable hospital acquired condition. This is the same category as bed sores in the adult population. It is no more a complication of CPAP use than bed sores are a complication of using beds.

CPAP has been well established as the first line therapy in the management of respiratory distress in preterm VLBW infants. It helps by preventing alveolar collapse, maintaining airway stability and stabilizing the chest wall. Various devices, both for pressure generation and for delivery of CPAP, are available for use in neonates. The advantages and disadvantages of each device, method of fixation of short binasal prongs, and a protocol for initiation of CPAP have been discussed.

Although experts affirm it is unlikely that the incidence of nasal lesions is reduced to zero despite prevention measures, risk factors can and should be minimized through the employment of correct device and technique. The nursing team has to be constantly committed to adequate set up, to maintaining the system and especially to keeping surveillance on the newborns. Trainings and educational programs are strategies that can improve care to newborns in CPAP with prongs, so as to make this practice safe and avoid complications as a consequence of its use.

MATERIALS AND METHODS

A. STUDY HYPOTHESIS:

Known risk factor for nasal trauma:

1) Lower GA

2) Lower birth weight

3) Sepsis

4) Early Age of onset of CPAP

5) Longer the duration

6) More pressure

7) More flow

8) Frequent displacement

9) Absent protective measure like silicon gel

10) Smaller size prongs

B. AIMS AND OBJECTIVES:

1) To evaluate the incidence and severity of nasal trauma secondary to nasal cpap in neonates admitted to a tertiary care nicu.

2) To study methods of reducing nasal trauma in neonates undergoing nasal cpap.

C. DESIGN: Prospective observational study

D. PLACE OF STUDY: NEONATAL DIVISION
MANIPAL HOSPITAL
OLD AIRPORT ROAD.
RUSTAM BAGH, BANGALORE

The study protocol was approved by the hospital's Research Scientific and Ethics committee. Parental informed consent was taken from all eligible infants.

E. PERIOD OF STUDY: June 2011 to December 2012

F. SAMPLE SIZE: 50 Neonates.

G. STUDY POPULATION: In this study we included all the neonates treated with nasal CPAP in Manipal hospital, which is a tertiary level neonatal unit and a referral centre. Newborn infants fulfilling the following selection criteria were enrolled in the study.

H. SELECTION CRITERIA:

a) INCLUSION CRITERIA: All neonates treated with nCPAP more than 24 hrs were included in the study.

b) EXCLUSION CRITERIA: Neonates who received of nCPAP treatment duration<24 hr, pre-existing nasal lesions secondary to nasotracheal intubation, upper airway malformations or patients referred from other centres after more than 24 h of nCPAP treatment were excluded from our study.

I. METHOD OF EVALUATION:

All Neonates satisfying inclusion criteria were prospectively observed daily for the following feature of nasal trauma:

1 .Persistent erythema

2 .Superficial ulceration

3. Necrosis

4. Other evidence of injury

When a patient was observed to have different stages of trauma, only the most severe stage was considered.

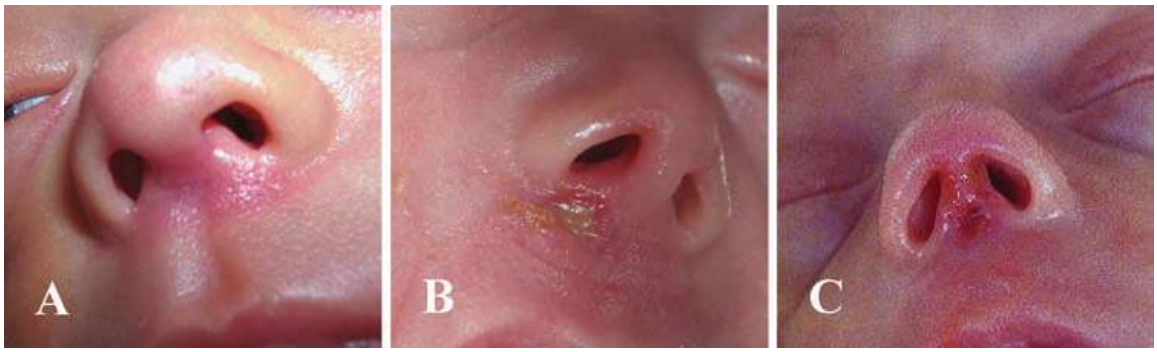


Fig.5 Classification of nasal trauma. (A) Stage I (non-blanching erythema), (B) stage II (superficial erosion), (C) stage III (necrosis of full thickness of skin).

Informed consent was taken for all infants included in the study, the size of prong, age of onset of CPAP and the duration of CPAP were recorded. If the neonate failed depronging or if put back on CPAP, the baby reentered the study and duration of CPAP continued till the neonate was off CPAP.Care of the nostrils during CPAP such as application of muprocin ointment, plasters, silicon gel etc.were recorded.

Applications and modalities of nCPAP:

Standard policy in our NICU is to promote the routine use of nCPAP soon after birth for all newborns with respiratory distress of various aetiologies, post extubation, reintubation for worsening. Pressure of 5 cm H2O is maintained and oxygen is adjusted to keep SpO2 >90 %. Endotracheal intubation and mechanical ventilation are considered when nCPAP is not sufficient to achieve a satisfactory SpO2 while breathing 80–100% O2 and lower the PaCO2 <65 mm Hg, or to relieve marked retractions or frequent apnoeas. Weaning nCPAP is considered when the tachypnoea and retractions become minimal or have disappeared, and when there is no longer need for supplemental oxygen. Nasal CPAP is reintroduced when the infant has tachypnoea >70/min, deep retractions or frequent episodes of apnoea and bradycardia. Throughout the study period, the same nCPAP system was used (**SLE 2000 Ventilator Driver /Baby log 8000/ Fisher and Paykel Bubble CPAP MR 730/incubator, Drager Medical AG&Co**., HWA flow sensor) and driver was set up according to the manufacturer's instructions (SLE Ltd, Berlin- Germany). Nasal prongs (**Hudson Prong**) size was adapted to the nose and nostrils and they were fixed to a fitted hat with Velcro moustaches. Infants were positioned supine or on their sides. Nursing care of all infants under nCPAP including, an ointment (**MUPIROCIN**) was applied with massages and a **silicon Gel film** (**COMB FILL**) was placed between pressure points and nCPAP devices. Nurses and medical staff were trained for careful observation of the nose every 30–60 min during nCPAP treatment, which was removed every 2–4 h to allow closer local inspection.

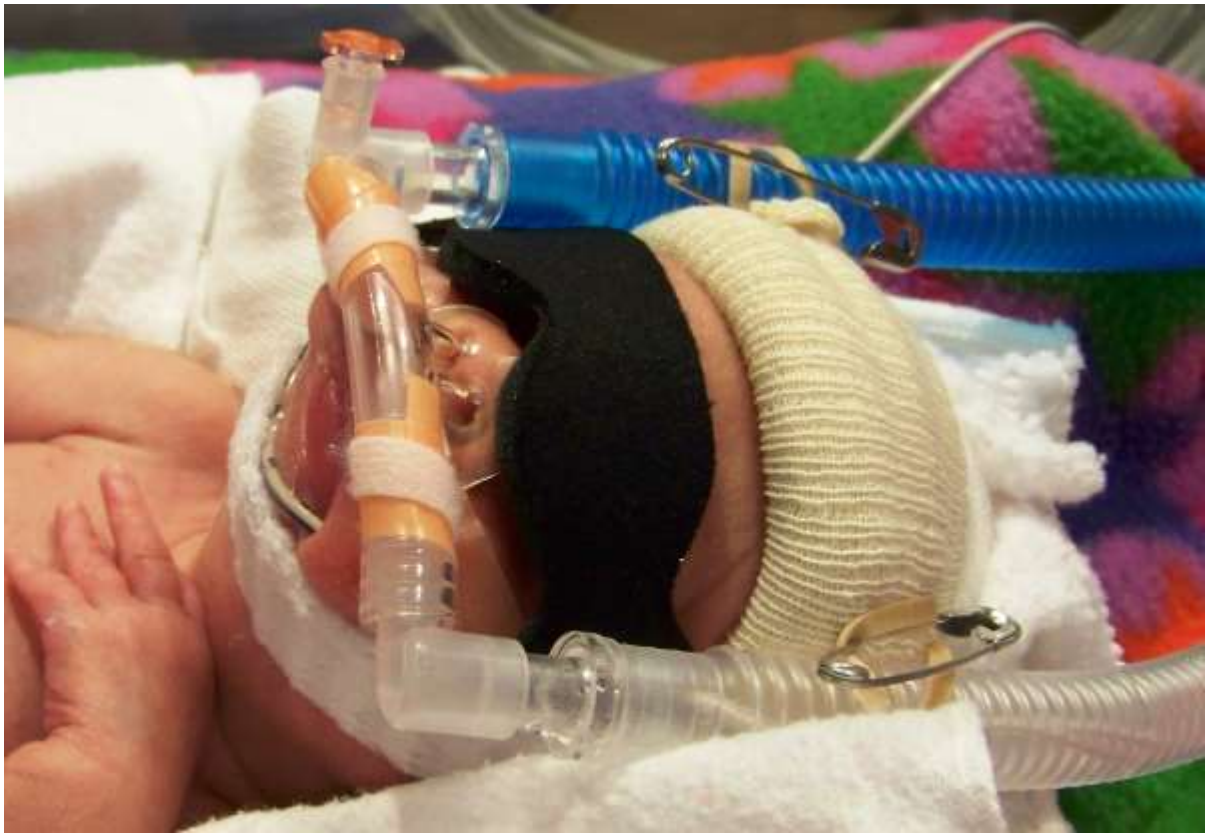


Fig.6: Premature infant with the Hudson prongs in place. Notice the bridge of the prongs do not touch the nasal septum and are supported by the Velcro mustache. In addition, the infant's hat is snug and the corrugated tubing is secured with the safety pins and rubber band.

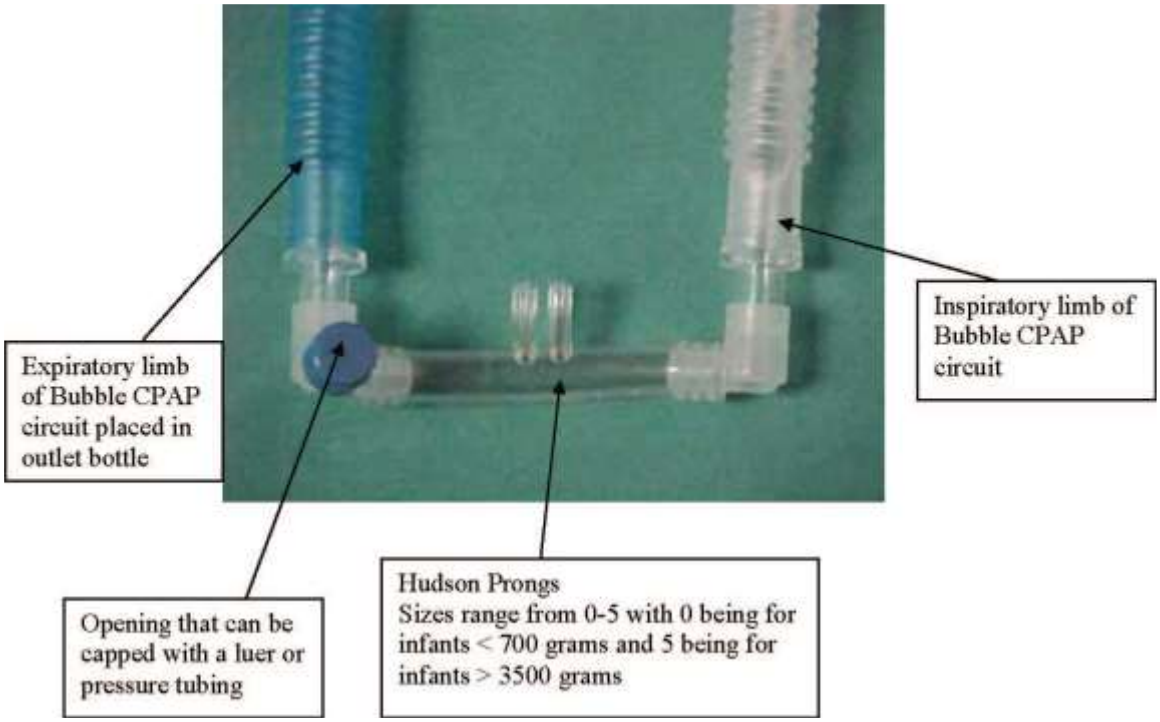


Fig.7 Hudson prongs attached to corrugated tubing to make up the bubble CPAP circuit.

J. STATISTICAL ANALYSIS:

Statistical Methods: Descriptive and inferential statistical analysis was carried out in the present study. Results on continuous measurements are presented on Mean □ SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance was assessed at 5 % level of significance. The following assumption on data is made,

Assumptions: 1. Dependent variables should be normally distributed, 2. Samples drawn from the population should be random, Cases of the samples should be independent

Chi-square/ Fisher Exact test was used to find the significance of study parameters on categorical scale between two or more groups. Logistic regression analysis was performed to find the significance of predictors of Nasal trauma.

1. Chi-Square Test: The chi-square test for independence is used to determine the relationship between two variables of a sample. In this context independence means that the two factors are not related. In the chi-square test for independence the degree of freedom is equal to the number of columns in the table minus one multiplied by the number of rows in the table minus one

$\chi^2 = \frac{\sum (Oi - Ei)^2}{Ei}$, Where Oi is observed frequency and Ei is Expected frequency.

With (n-1) df

The Assumptions of Chi-square test

The chi square test, when used with the standard approximation that a chi-square distribution is applicable, has the following assumptions:

- Random sample – A random sampling of the data from a fixed distribution or population.
- Sample size (whole table) – A sample with a sufficiently large size is assumed. If a chi square test is conducted on a sample with a smaller size, then the chi square test will yield an inaccurate inference. The researcher, by using chi square test on small samples, might end up committing a Type II error.
- Expected Cell Count – Adequate expected cell counts. Some require 5 or more, and others require 10 or more. A common rule is 5 or more in all cells of a 2-by-2 table, and 5 or more in 80% of cells in larger tables, but no cells with zero expected count. When this assumption is not met, Fisher Exact test or Yates' correction is applied.

2. Fisher Exact Test: The Fisher Exact Test looks at a contingency table which displays how different treatments have produced different outcomes. Its null hypothesis is that treatments do not affect outcomes-- that the two are independent. Reject the null hypothesis (i.e., conclude treatment affects outcome) if *p* is "small".

The usual approach to contingency tables is to apply the $\square^2$ statistic to each cell of the table. One should probably use the $\square^2$ approach, unless you have a special reason. The most common reason to avoid $\square^2$ is because you have small expectation values.

	Class1	Class2	Total
Sample1	a	b	a+b
Sample2	c	d	c+d
Total	a+c	b+d	n

2x2 Fisher Exact Test statistic= $\sum p = \frac{(a+b)!(c+d)!(a+c)!(b+d)!}{n!} \frac{1}{\sum a!b!c!d!}$

Fisher Exact test (rxc tables)

Let there exist two such variables X and Y, with $m$and $n$observed states, respectively. Now form an m x n matrix in which the entries aij represent the number of observations in which x = i and y=j. Calculate the row and column sums Ri and Cj, respectively, and the total sum of

$$N = \sum_i R_i = \sum_j C_j$$

the matrix. Then calculate the conditional probability of getting the actual matrix given the particular row and column sums, given by...

$$P_{\text{cutoff}} = \frac{(R_1!\, R_2! \cdots R_m!)\,(C_1!\, C_2! \cdots C_n!)}{N! \prod_{i,j} a_{i\,j}!},$$

Which is a multivariate generalization of the hypergeometric probability function.

3. Multivariate Logistic mode:

Multivariate Logistic Regression analysis The dependent variable in logistic regression is usually dichotomous, that is, the dependent variable can take the value 1 with a probability of success q, or the value 0 with probability of failure 1-q. This type of variable is called a Bernoulli (or binary) variable. Although not as common and not discussed in this treatment, applications of logistic regression have also been extended to cases where the dependent variable is of more than two cases, known as multinomial or polytomous [Tabachnick and Fidell (1996) use the term polychotomous]. As mentioned previously, the independent or predictor variables in logistic regression can take any form. That is, logistic regression makes no assumption about the distribution of the independent

variables. They do not have to be normally distributed, linearly related or of equal variance within each group. The relationship between the predictor and response variables is not a linear function in logistic regression; instead, the logistic regression function is used, which is the logit transformation of q:

$$\theta = \frac{e^{(\alpha+\beta_1 x_1+\beta_2 x_2+\ldots+\beta_i x_i)}}{1+e^{(\alpha+\beta_1 x_1+\beta_2 x_2+\ldots+\beta_i x_i)}}$$

Where e = the constant of the equation and, 1+e = the coefficient of the predictor variables. An alternative form of the logistic regression equation is:

$$\mathbf{logit}\left[\theta(\mathbf{x})\right] = \mathbf{log}\left[\frac{\theta(x)}{1-\theta(x)}\right] = \alpha + \beta_1 x_1 + \beta_2 x_2 + \ldots + \beta_i x_i$$

The goal of logistic regression is to correctly predict the category of outcome for individual cases using the most parsimonious model. To accomplish this goal, a model is created that includes all predictor variables that are useful in predicting the response variable. Several different options are available during model creation. Variables can be entered into the model in the order specified by the researcher or logistic regression can test the fit of the model after each coefficient is added or deleted, called stepwise regression.[28-32]

4. Significant figures:

+ Suggestive significance (P value: 0.05<P<0.10)

* Moderately significant (P value: 0.01<P □ 0.05)

** Strongly significant (P value: P□0.01)

Statistical software: The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1 ,Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc**.**

RESULTS

***Study design**: A Comparative two group study*

Table 4: Incidence of Nasal trauma in patients studied.

Nasal Trauma	**Number of patients**	**%**
No	36	72.0
Yes	14	28.0
Total	50	100.0

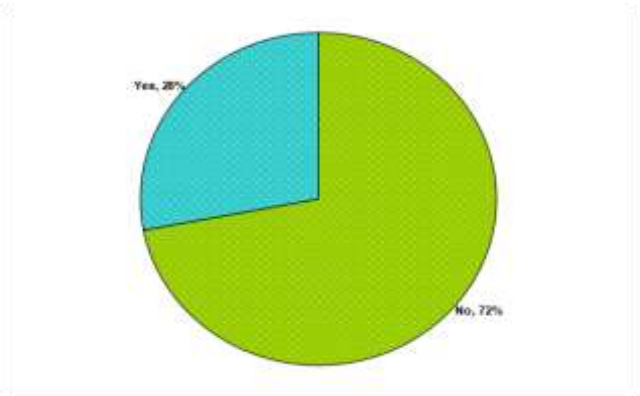


FIG.8 Incidence of nasal trauma

Among the 50 patients included, 14(28 %) developed nasal trauma.

Table 5: Incidence of Nasal trauma according to gestational age.

GA	***Total number of patients***	***Number of patients with Nasal trauma***	***% of nasal trauma***
EPT	*4*	*1*	*25.00*
LPT	*9*	*1*	*11.11*
PT	*26*	*7*	*26.92*
T	*11*	*5*	*45.45*
Total	*50*	*14*	*28.00*

P=0.454

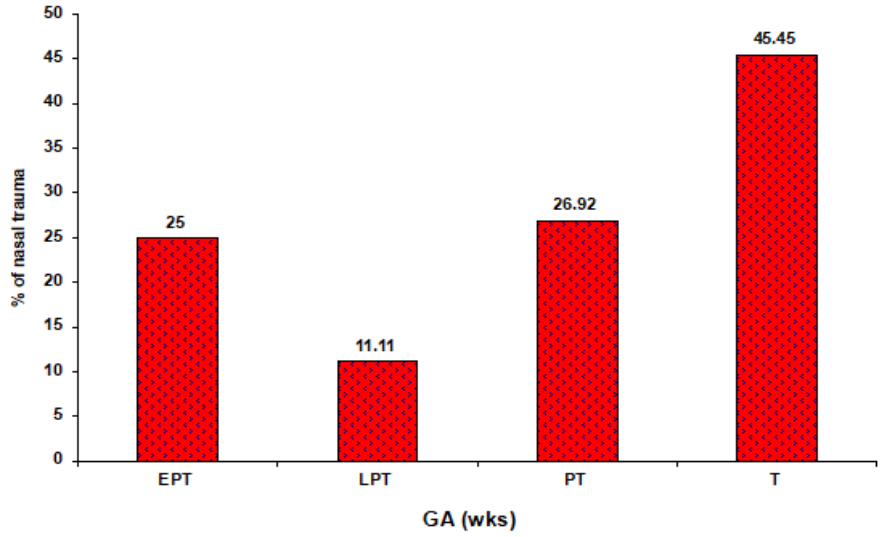


FIG.9

Table 6: Incidence of Nasal trauma according to Birth weight (Gms).

Birth weight (gms)	***Total number of patients***	***Number of patients with Nasal trauma***	***% of nasal trauma***
<1000	*4*	*2*	*50.00*
1000-2500	*33*	*7*	*21.21*
≥2500	*13*	*5*	*38.46*
Total	*50*	*14*	*28.00*

P=0.370

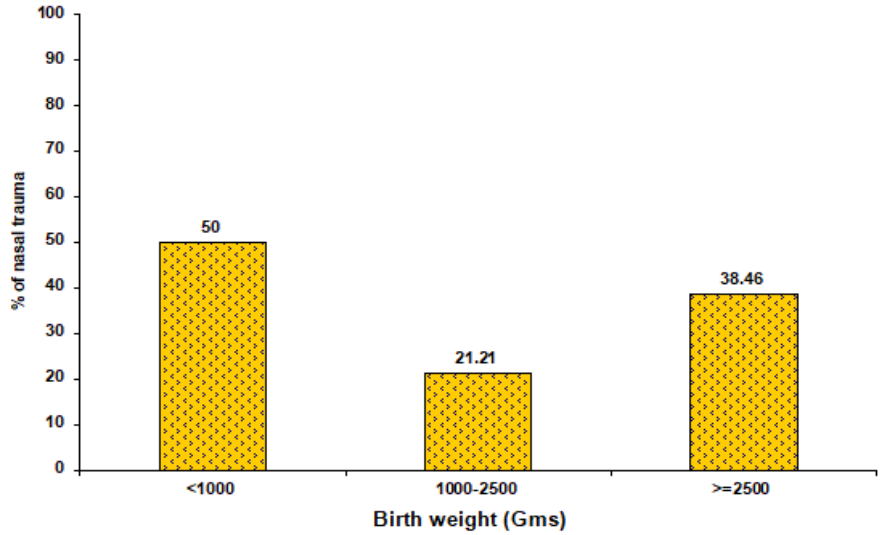


FIG.10: Frequency of nasal trauma due to nCPAP was greater in infants weighing <1000 gm (50%) than compared to infants of birth weight of more than 2500 gm (38 %). A similar distribution was not found when comparing the frequency in different Gestational age categories. Nasal trauma due to nCPAP developed in 25% of the patients<28 weeks of gestation(EPT) and in 11.11% of those 28-33+6 weeks of gestation(PT), compared to 26.92% of those ≥33-36+6 weeks of gestation and 45.45 % of term(≥37) neonates. Multivariate Logistic Regression analyses confirmed that birth weight inversely correlated with the severity of nasal trauma, but statistically not significant (P 0.853).

Table 7: Incidence of Nasal trauma according to Gender.

Gender	***Total number of patients***	***Number of patients with Nasal trauma***	***% of nasal trauma***
Female	*14*	*2*	*14.29*
Male	*36*	*12*	*33.33*
Total	*50*	*14*	*28.00*

P=0.295

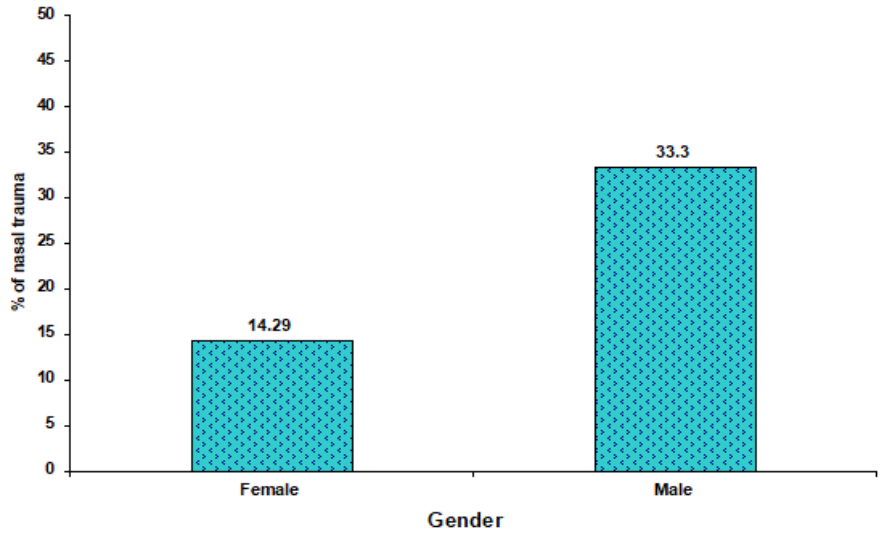
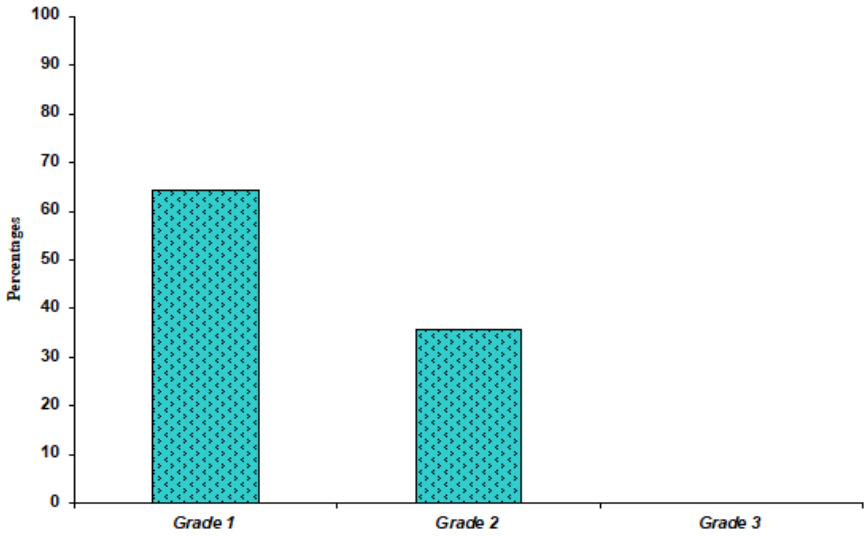


FIG.11: Incidence of Nasal trauma more in the male babies (33.33 %) compared to female babies (14.29%), but the difference is not statistically significant (P=0.295).

Table 8: Incidence of nasal trauma according to nasal Trauma grade.

Nasal Trauma grade	***With Nasal Trauma***
Grade 1	*9(64.3%)*
Grade 2	*5(35.7%)*
Grade 3	*0 (0%)*
Total	*14(100%)*

FIG.12: According to the standardised classification of the decubitus lesions from the US



National Pressure Ulcer Advisory Panel (NPUAP), nasal trauma grading was done, 9 (64.3%) cases had stage I nasal trauma, 5 (35.7%) of stage II and none of the babies had stage III trauma.

Table 9: Incidence of Nasal trauma according to Clinical features.

Clinical features	***Total number of patients***	***Number of patients with Nasal trauma***	***%of nasal trauma***	***P value***
1.MAS	*5*	*3*	*60.00*	*0.110*
2.RDS	*23*	*2*	*8.70*	*0.0393+*
3.SEPSIS	*10*	*8*	*80.00*	*0.002***
4.TTNB	*6*	*0*	*0.00*	*-*
5.VACTER/TEF/CHD	*1*	*0*	*0.00*	*-*
6.CLD/CRF/APNOEA	*1*	*0*	*0.00*	*-*
7.MCDA TWIN/TTTS/IDM	*2*	*0*	*0.00*	*-*
8.PPHN/PDA/PNEUMO TX	*1*	*1*	*100.00*	*0.023**
Total	*50*	*14*	*28.00*	*-*

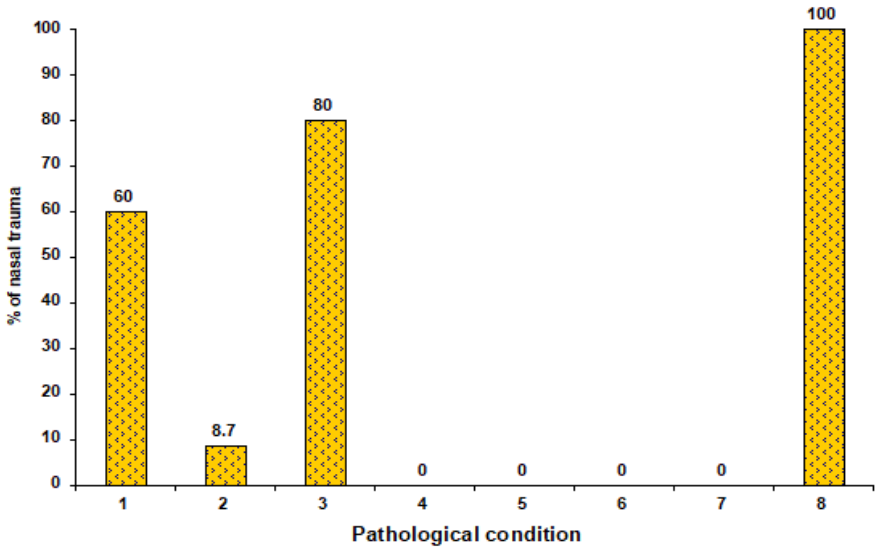


FIG.13: Incidence of nasal trauma was more in babies who had sepsis (80%) compare to other pathological condition. statistical model showed strong significance (P 0.002).

Table 10: Incidence of Nasal trauma according to Age of onset of CPAP in days.

Age of onset in days	***Total number of patients***	***Number of patients with Nasal trauma***	***% of nasal trauma***
1-2	*30*	*7*	*23.33*
2-5	*9*	*3*	*33.33*
6-10	*4*	*2*	*50.00*
>10	*7*	*2*	*28.57*
Total	*50*	*14*	*28.00*

P=0.658

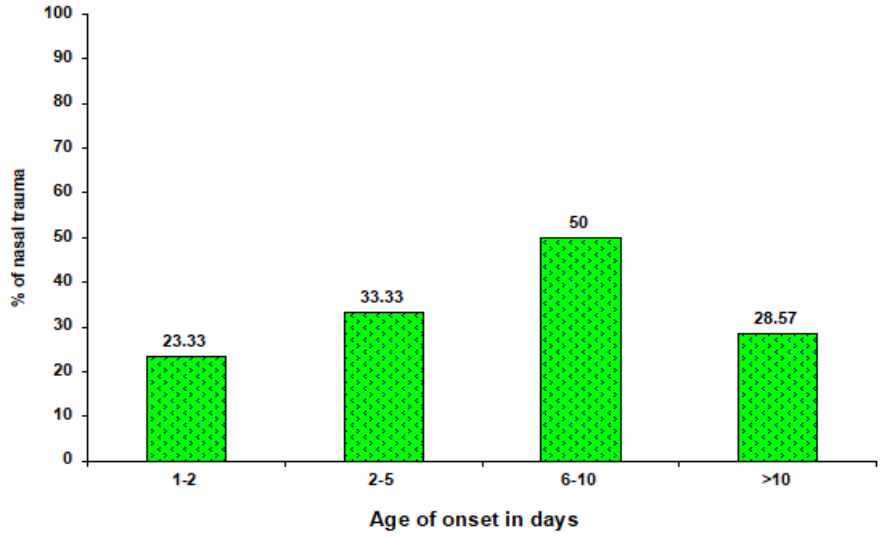


FIG.14: Incidence of nasal trauma was observed to be more in babies who was kept on CPAP at 6-10 days of age (50 %), compared to those babies who required CPAP >10 days (28.57%) and <6 days (33.33%) but statistical model does not show any significance(P=0.658).

Table 11: Incidence of Nasal trauma according to Total duration of CPAP in days.

Total duration	***Total number of patients***	***Number of patients with Nasal trauma***	***% of nasal trauma***
1-5	*39*	*6*	*15.38*
6-10	*7*	*6*	*85.71*
>10	*4*	*2*	*50.00*
Total	*50*	*14*	*28.00*

*P<0.001***

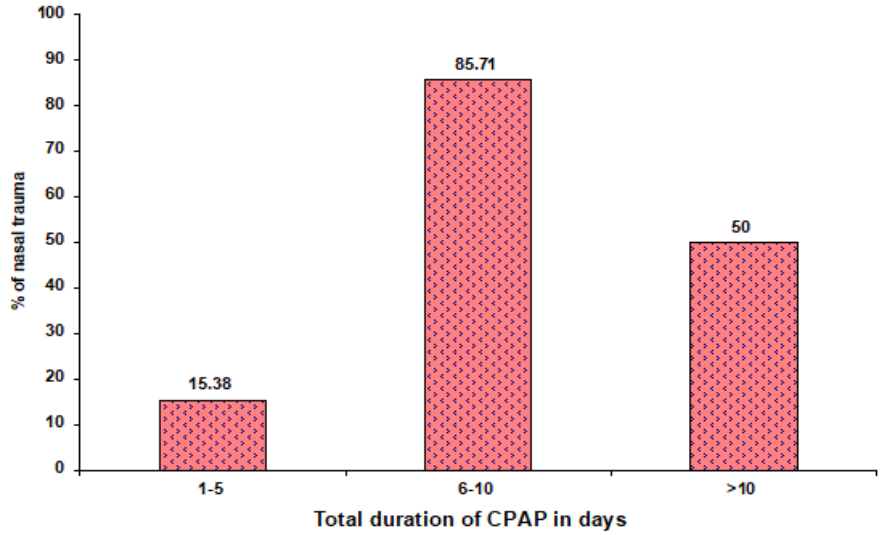


FIG.15: Incidence of nasal trauma was observed to be more in babies who were kept on CPAP more than 5 days (85.71 %), and difference was statistically significant(P<0.001).

Table 12: Incidence of Nasal trauma according to Ventilation CPAP in days.

Ventilation CPAP	***Total number of patients***	***Number of patients with Nasal trauma***	***% of nasal trauma***
Nil	*5*	*0*	*0.00*
1-2	*19*	*3*	*15.79*
3-5	*17*	*4*	*23.53*
>5	*9*	*7*	*77.78*
Total	*50*	*14*	*28.00*

*P=0.004***

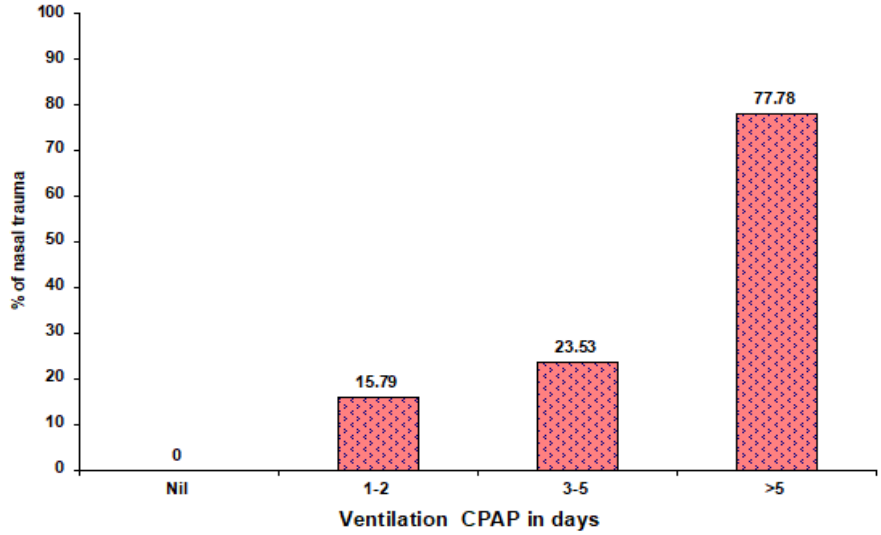


FIG.16

Table 13: Incidence of Nasal trauma according to Bubble CPAP in days.

Bubble CPAP	***Total number of patients***	***No. of Pt with nasal trauma***	***% of nasal trauma***
Nil	*42*	*13*	*30.95*
1-2	*3*	*0*	*0.00*
3-5	*3*	*1*	*33.33*
>5	*2*	*0*	*0.00*
Total	*50*	*14*	*28.00*

P=0.812

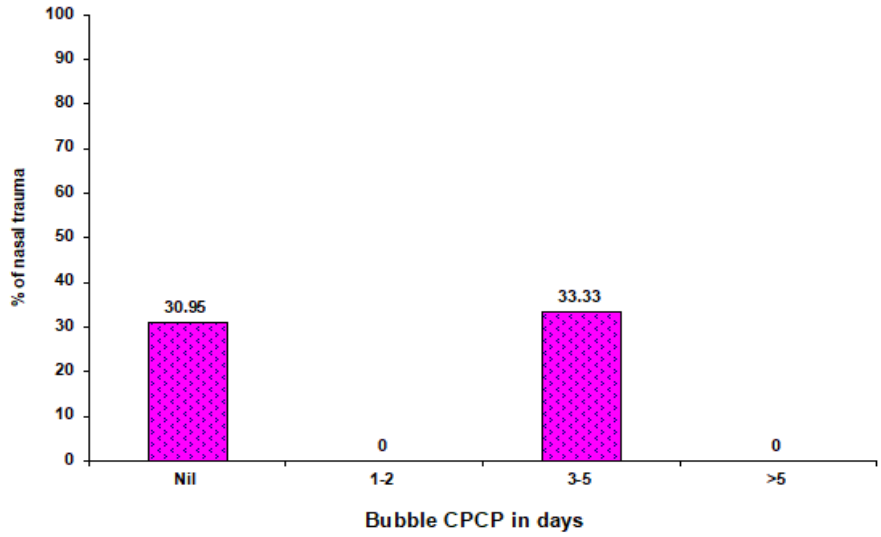


FIG.17

Table 14: Association of incidence of Nasal trauma in patients with Ventilator CPAP And Bubble CPAP

Nasal trauma	**Ventilator CPAP**	**Bubble CPAP**
No	31(68.9%)	7(87.5%)
Yes	14(31.1%)	1(12.5%)
Total	45(100.0%)	8(100.0%)

*Incidence of nasal trauma is significantly more associated with Ventilator CPAP with P<0.001***

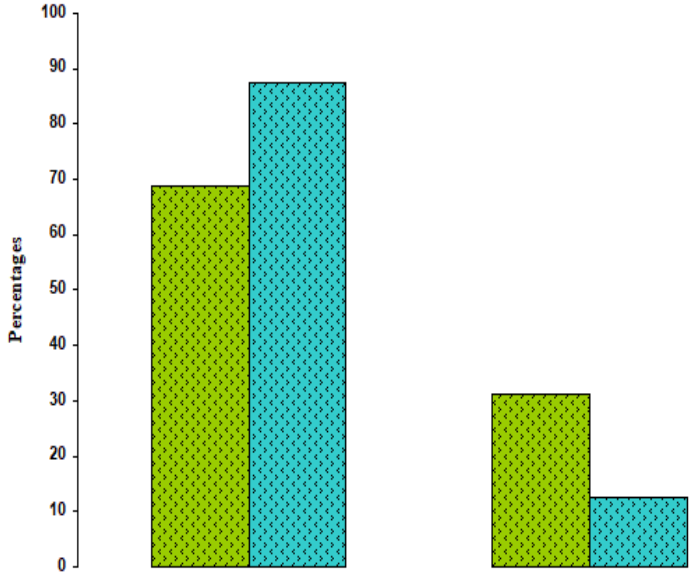
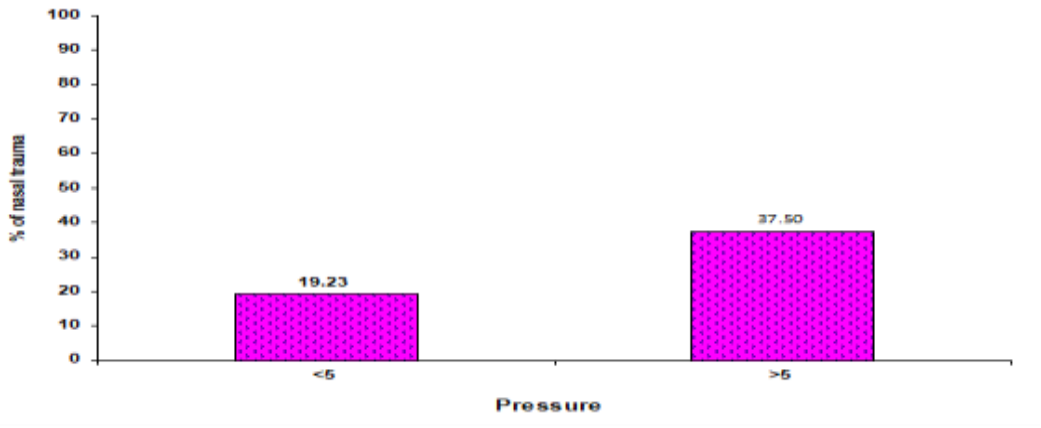


*FIG.18: Incidence of nasal trauma was observed to be more in babies who were kept on ventilator CPAP more than 5 days (77.71 %), and difference was statistically significant (P=0.004), where as this difference was not found with bubble CPAP (P=0.812).correlation study suggestive of ventilation CPAP is significantly associated with presence of nasal trauma with p<0.001**compare to bubble CPAP.*

Table 15: Incidence of Nasal trauma according to Pressure.

Pressure(cm H_2O)	***Total number of patients***	***Number of patients with Nasal trauma***	***% of nasal trauma***
<5	*26*	*5*	*19.23*
>5	*24*	*9*	*37.50*
Total	*50*	*14*	*28.00*



P=0.211

FIG.19

Incidence of nasal trauma was found more in CPAP setting of pressure >5 ***cm*** H_2O *(37.50 %), but statistically not significant (p 0.211).*

Table 16: Incidence of Nasal trauma according to Flow.

Flow (L/minute)	***Total number of patients***	***Number of patients with Nasal trauma***	***% of nasal trauma***
1-5	*9*	*0*	*0.00*
5-8	*29*	*9*	*31.03*
>8	*12*	*5*	*41.67*
Total	*50*	*14*	*28.00*

P=0.084+

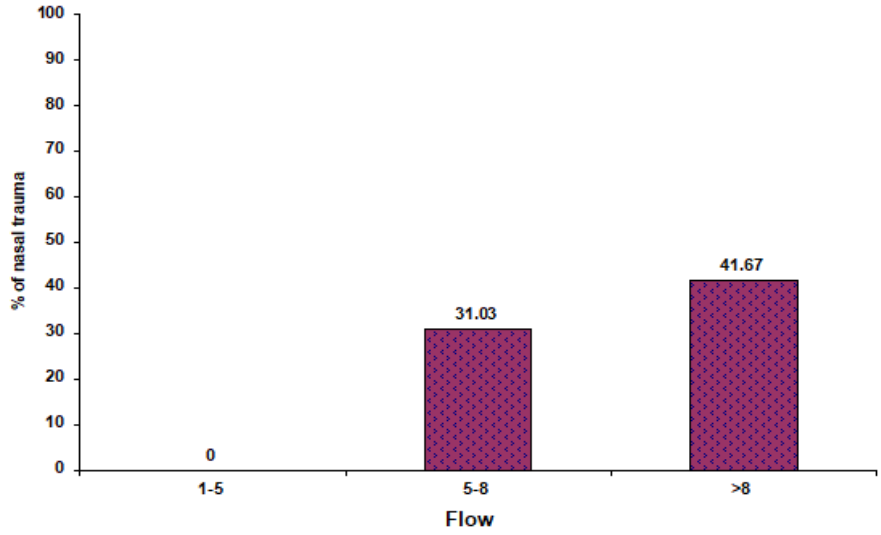


FIG.20: Incidence of nasal trauma was found more in CPAP setting of flow >8 L/minute (41.67%), but statistically not significant (p 0.084).

Table 17: Incidence of Nasal trauma according to Number of times prong change.

Number of times prong change	***Without Nasal Trauma (n=36)***	***With Nasal Trauma (n=14)***	***Total (n=50)***
No	*32(88.9%)*	*6(42.9%)*	*38(76%)*
Yes	*4(11.1%)*	*8(57.1%)*	*12(24%)*
• *1*	*1(2.8%)*	*5(35.7%)*	*6(12%)*
• *2*	*1(2.8%)*	*2(14.3%)*	*3(6%)*
• *3*	*2(5.6%)*	*0(0%)*	*2(4%)*
• *4*	*0(0%)*	*1(7.1%)*	*1(2%)*

*P=0.002***

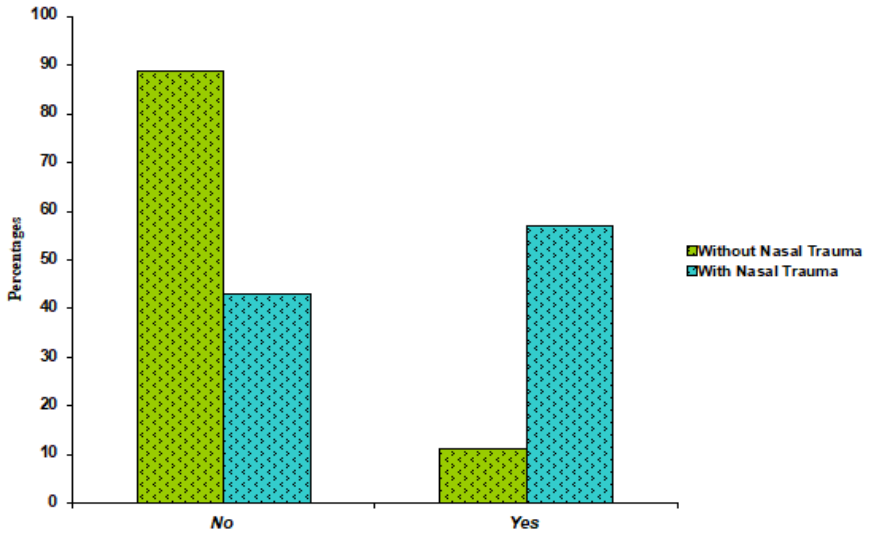


FIG.21: Incidence of nasal trauma was found more in cases where prongs were changed more frequently (57.1%) compared to those in whom prongs were changed infrequently. (42.9%). Difference was statistically significant (p 0.002).

Table 18: Incidence of Nasal trauma according to frequency of displacement.

frequency Displacement	***Total number of patients***	***Number of patients with Nasal trauma***	***% of nasal trauma***
Frequency	*17*	*9*	*52.94*
Infrequent	*33*	*5*	*15.15*
Total	*50*	*14*	*28.00*

*P=0.008***

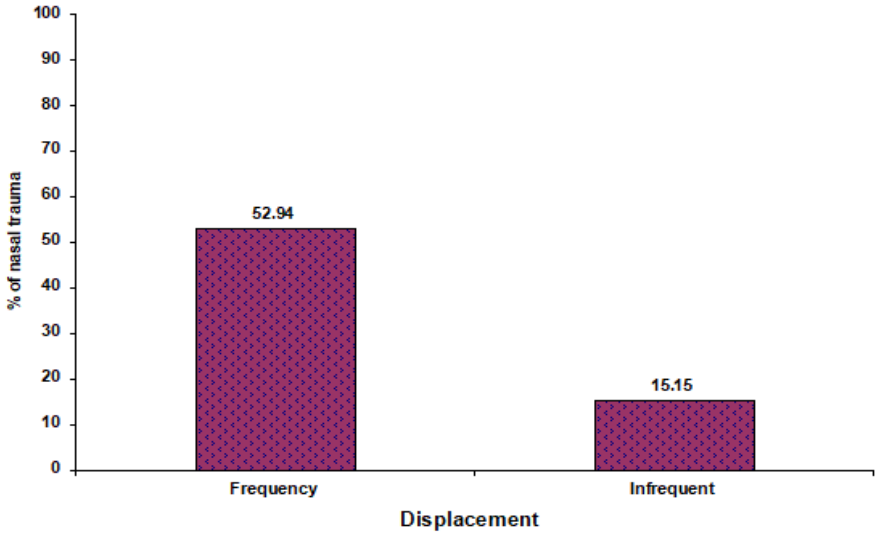


FIG.22: Incidence of nasal trauma was observed to be more in babies where frequent displacement of prongs observed (52.94%), and difference was statistically significant (p 0.008).

Table 19: Incidence of Nasal trauma after application of silicon gel.

Comb fill	***Total number of patients***	***Number of patients with Nasal trauma***	***% of nasal trauma***
No	*8*	*3*	*37.50*
Yes	*42*	*11*	*26.19*
Total	*50*	*14*	*28.00*

P=0.670

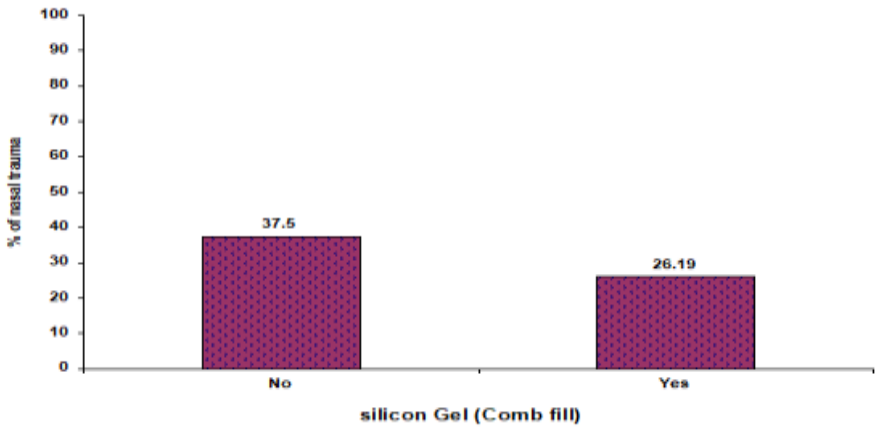


FIG.23: Incidence of nasal trauma was found less in babies, were protective measure like silicon gel was used (26.19 %) compared to babies where it was not used (37.50 %). Difference was not statistically significant (p 0.670).

Table 20: Prong Size in No.

Prong Size	***Without Nasal Trauma (n=36)***	***With Nasal Trauma (n=14)***	***Total (n=50)***
0	*21(58.3%)*	*5(35.7%)*	*26(52%)*
1	*11(30.6%)*	*7(50%)*	*18(36%)*
2	*3(8.3%)*	*2(14.3%)*	*5(10%)*

P=0.315

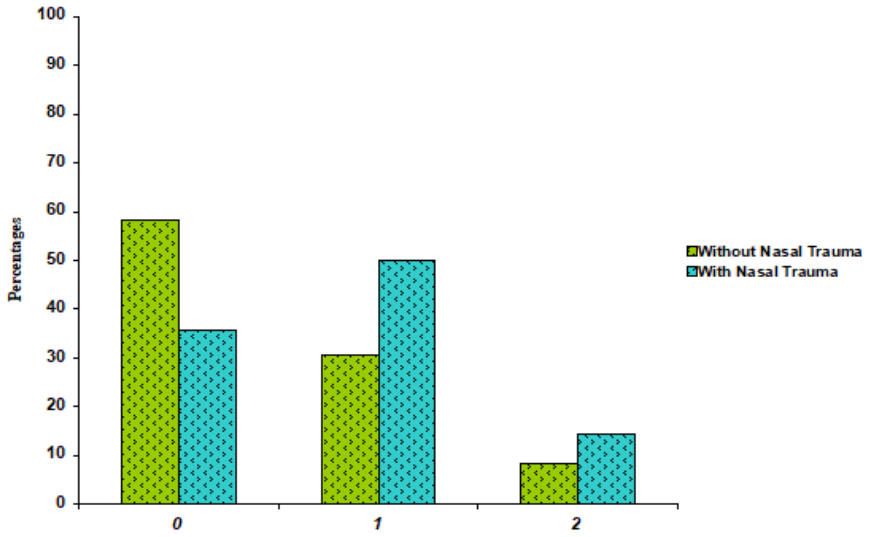


FIG.24: Incidence of nasal trauma with '0' size prong's (35.7%) was less compared to '1'size prong's (50%). Prong's size contribution to nasal trauma was not statistically significant (p 0.315).

Table 21: Univariate and Multivariate analysis to predict the Nasal trauma in patients studied

Variables	Univariate analysis			Multivariate analysis	
	Nasal trauma		P value	OR	P value
	No (n=36)	Yes (n=14)			
1.Lower GA	11(30.6 %)	2(14.3%)	0.303	0.05	0.079+
2.BW <2500 gms	24(66.7 %)	9(64.3%)	1.000	0.82	0.853
3.Sepsis	6(16.7%)	9(64.3%)	0.002**	19.18	0.017*
4.Less age of onset(<=1)	20(55.6 %)	6(42.9%)	0.420	1.06	0.962
5.More total duration(>=3)	18(50%)	11(78.6 %)	0.066+	-	-
6.More Vent CPAP>=3	15(41.7 %)	11(78.6 %)	0.019*	-	-
7.Bubble CPCP	7(19.4%)	1(7.1%)	0.414	0.22	0.362
8.More pressure (>5)	15(41.7 %)	9(64.3%)	0.151	4.51	0.185
9.More flow >8	7(19.4%)	5(35.7%)	0.278	1.34	0.781
10.frequent displacement	8(22.2%)	9(64.3%)	0.008**	4.77	0.110
11.Silicone gel	5(13.9%)	3(21.4%)	0.670	2.39	0.474
12.Small (0) size prong	21(58.3 %)	5(35.7%)	0.151	0.23	0.223

Cut –off values are based on Median.

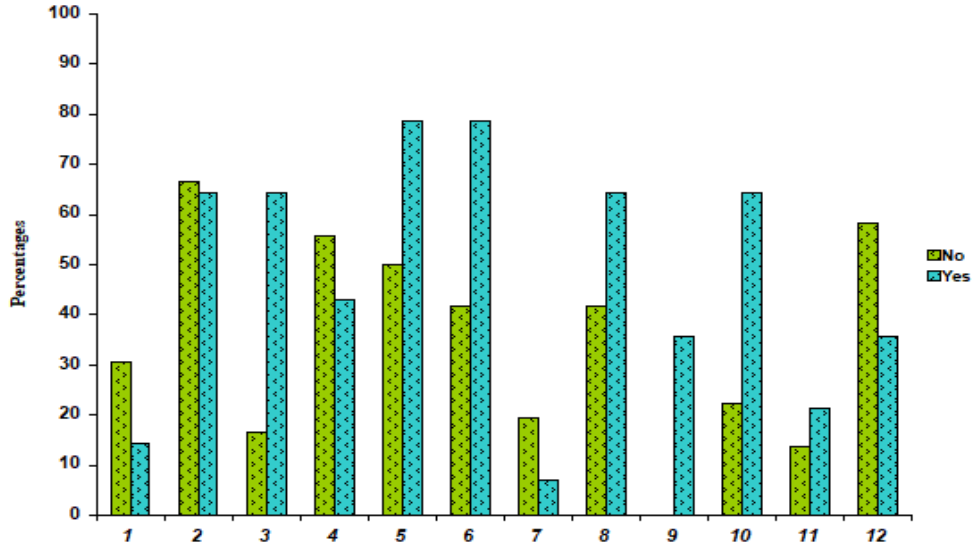


FIG.25: Logistic regression analysis was performed to find the significance of predictors of Nasal trauma. Incidence of nasal trauma were observed to be more in babies with

1) Sepsis (OR 19.18, p 0.017)

2) Total duration of CPAP >5 days

3) Ventilator CPAP compared with bubble CPAP

4) Pressure >5 (OR 4.51)

5) Flow >8 (OR 1.34)

6) Frequent displacement (OR 4.77) and

7) CPAP without protective gel (OR 2.39).

DISCUSSION

Nasal trauma secondary to nCPAP is an adverse event with potential short or long-term consequences. Little data is available in the literature on this topic, with reported incidence ranging from 20% to 60%. Comparisons between published studies are difficult because of highly variable descriptions and definitions of nasal trauma, which differs in severity from limited local redness to full necrosis. We propose a standardised classification of the decubitus lesions from the US National Pressure Ulcer Advisory Panel (NPUAP) which includes three stages.

Among the 50 patients included our results showed that nasal trauma secondary to nCPAP was 28% in the study population. According to the US NPUAP, 9 (64.3%) cases had stage I nasal trauma, 5 (35.7%) of stage II and none of the babies had stage III trauma and required surgical treatment. (Table 4-8).

Robertson et al first reported a rate of 20% for Nasal trauma due to continuous positive airway pressure in neonate's secondary to nCPAP in very low birth weight infant.[4]

Buettiker, et al. reported 16 cases with nasal injury (1 severe, 8 moderate and 7 mild injury) in 40 patients (40 %) on different type of NCPAP systems.[28]

In our study, Cut-offs for risk comparisons by gestational age and birth weight were a prior chosen based on existing categories of newborn infants in outcome studies. For the purpose of this study we have used the following terminologies for gestational age (GA), <28 week was categorised as EPT and GA between 28-33+6 was classified as PT and >33-33+6 weeks was called late preterm and >37 wks called as term gestation. Frequency of nasal trauma due to nCPAP was greater in infants weighing <1000 gm (50%) than compared to infants of birth weight of more than 2500 gm (38 %). A similar distribution was not found when comparing the frequency in different Gestational age categories. Nasal trauma due to nCPAP developed in 25% of the patients<28 weeks of gestation(EPT) and in 11.11% of those 28-33+6 weeks of gestation(PT), compared to 26.92% of those ≥33-36+6 weeks of gestation and 45.45 % of term(≥37) neonates. Multivariate Logistic Regression analyses confirmed that birth weight inversely correlated with the severity of nasal trauma,

but statistically not significant (P 0.853) (Table 5-6). There was no significant difference in the incidence of nasal trauma in different GA categories.

Table (10) shows the timing of the onset of the nasal trauma in the course of nCPAP treatment. Incidence of nasal trauma was observed to be more in babies who were kept on CPAP at 6-10 days of age (50 %), compared to those babies who required CPAP >10 days (28.57%) and <6 days (33.33%) but statistical model did not show any significance(P=0.658).Nasal trauma occurred rarely after several weeks of treatment. The immaturity of skin could be implicated in the pathogenesis of such trauma.

Table(11) shows the Incidence of nasal trauma based on total duration of CPAP used incidence was more in babies who were kept on CPAP more than 5 days (85.71 %), and difference was statistically significant(P<0.001).The simple logical thought like mechanical trauma could be implicated in the pathogenesis of such trauma.

Céline Fischer reported, that Frequency and severity of nasal trauma increased with lower gestational age (>90% in neonates <28 weeks of gestational age), lower birth weight, longer duration of nCPAP and longer NICU stay but same results were not reproducible in our study.[7]

Table (9) shows the Incidence of nasal trauma was more in babies who had sepsis (80%) compared to other pathological conditions. statistical analysis showed strong significance (P 0.002).colonization of bacteria possibly with coagulase-negative staphylococcus, hemodynamic instability like blanching could be implicated in the pathogenesis of such trauma. The study “Use of oxygen cannulas in extremely low birth weight infants is associated with mucosal trauma and bleeding”by Kopelman AE, Holbert D showed that CNSS occurred less often in infants treated with oxyhoods than those on OC or CPAP (1 of 13, 8%, vs. 10 of 44, 23%), but the difference was not significant.[26]

Table (12,13,14) shows the Incidence of nasal trauma was observed to be more in babies who were kept on ventilator CPAP more than 5 days (77.71 %), and difference was statistically significant (P=0.004).where as this difference was not found with bubble CPAP (P=0.812).correlation study suggested that ventilation CPAP is significantly associated with higher risk of nasal trauma with p<0.001**compared to bubble

CPAP.Early deprong to the bubble CPAP from ventilator CPAP might help to reduce incidence of nasal trauma. It is not clear which NCPAP device is least likely to cause nasal trauma. , limited randomised cross-over (Ahluwalia 1998)[20] and non-randomised (Kavvadia 2000) clinical studies found no significant difference in short-term physiological parameters when comparing the Infant Flow system with single prong NCPAP.

Table (15) shows the Incidence of nasal trauma was found more in CPAP setting of pressure >5 cm H_2O (37.50 %), but statistically not significant (p 0.211). Table (13) shows the Incidence of nasal trauma was found more in CPAP setting of flow >8 L/minute (41.67%), but statistically not significant (p 0.084). Increased pressure on the columella causes diminished circulation of blood flow. This subsequently impairs tissue perfusion and leads to ischemia along with tissue damage. Persistent erythema, dermal injury, edema, indurations and finally an ulcer can occur. Relieving the pressure is the key to healing and more importantly, the key to prevention. Further studies are required to know the exact cut off at which the risk of nasal trauma increase in relationship with pressure and flow of CPAP .so, that appropriate preventive measures can be taken at the earliest.
Table (17) shows the Incidence of nasal trauma was found more in cases where prongs were changed more frequently (57.1%) compared to those in whom prongs were changed infrequently. (42.9%).Difference was statistically significant (p 0.002). Table (18) shows the Incidence of nasal trauma was observed to be more in babies where frequent displacement of prongs (>4-5 times/day) observed (52.94%), and difference was statistically significant (p 0.008). The requirement of frequent change and frequent displacement of prong might also associated with longer duration of CPAP as well as increase handling associate with more mechanical trauma and infection during changing prong could be implicated in the pathogenesis of such trauma. Identifying factors that may contribute to agitation and then correcting them will facilitate comfort level of the infant. Calming techniques can be used such as swaddling, containment, nesting, or offering a pacifier. Aspirating air from the infant's stomach and positioning the infant prone may also increase the infant's comfort by decreasing abdominal distension and diaphragmatic pressure. Lastly, the nurse can calm the infant by declaring "hands off." At times, slowly settle, especially as they learn to adjust to the CPAP.

NCPAP interfaces have the potential to cause nasal excoriation and scarring if inappropriately applied or infrequently monitored (Loftus 1994; Robertson[4] 1996).

Table (20) shows the Incidence of nasal trauma with '0' size prong's (35.7%) was less compared to '1'size prong's (50%). Prong's size contribution to nasal trauma was not statistically significant (p 0.315). The requirement of smaller prong size associated in smaller baby's is likely to be less displacement of prong as well as less local pressure necrosis.

Table (19) shows the Incidence of nasal trauma was found less in babies, were protective measure like silicon gel was used (26.19 %) compared to babies where it was not used (37.50 %).Difference was not statistically significant (p 0.670). It reduces the pressure on columella, distributes pressure around the nares and reduces friction between device and skin. Silicon gel sheet can prevent trauma to the surrounding skin. Silicon gel application may reduce the incidence and severity of nasal injury in preterm infants on nasal CPAP. Similar results were reported by randomised studies done by Ayla, Tonguc and turker (2008).

Logistic regression analysis was performed to find the significance of predictors of Nasal trauma (Table 21).Incidence of nasal trauma were observed to be more in babies with

1) Sepsis (OR 19.18, p 0.017)
2) Total duration of CPAP >5 days
3) Ventilator CPAP compared with bubble CPAP
4) Frequent displacement (OR 4.77) and

There were no significant differences in other clinically important outcomes like pressure and without protective gel through the odd's ratio is implying that those babies on CPAP >5 cmH_2O have 4.5 times more risk of development of nasal trauma than babies with CPAP of pressure <5 cmH_2O.

This inspection was external and not instrumented, so it is possible that isolated internal trauma of the nostrils was missed.

The nursing team has to be constantly committed to adequate set up, to maintain the system and especially to keep surveillance on the newborns. Trainings and educational programs are strategies that can improve care to newborns in CPAP with prongs, so as to make this practice safe and avoid complications as a consequence of its use.

Further research in preterm infants requiring NCPAP for respiratory support is required to focus on defining the nasal trauma and preventive methods.

Further studies in this line of research are needed so as to develop new devices and fixation methods that can reduce nasal trauma. Attention should also be directed at determining which device is least traumatic to the infant nose, particularly in very low birth weight infants.

CONCLUSION

From our study it can be concluded that:

1) Nasal trauma secondary to nCPAP is, accounting 28% in the study population. Most often limited to a non-blanching erythema appearing early in the course of the treatment.

2) Risk factors for nasal traumas are:

1) Sepsis
2) Total duration of CPAP >5 days
3) Ventilator CPAP compared with bubble CPAP
4) Pressure >5 cmH_2O
5) Frequent displacement and
6) CPAP without protective gel.

3) Common recommendations for prevention of nasal trauma due to nCPAP in neonates include careful local monitoring and avoidance of pressure, friction and moisture. The application of silicone gel may reduce the incidence and severity of nasal injury in preterm infants on nasal CPAP.

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