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EDITOR
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Dear Friends,

Season's Greetings !

Medicine, it is said, is an ever-changing science. With exponentially evolving research and expanding new clinical experience, there is a felt need to continually update our knowledge base. The current issue of IAP Neochap Bulletin is focused to present you important advancement on some of the issues in the field of neonatology. In India, approximately 3 lakh newborns die every year due to asphyxia. These asphyxiated newborn require skilled personnel and proficient resuscitation for better and improved outcome. Recently, The American Heart Association (AHA) and American Academy of Pediatrics (AAP) have published revised Neonatal Resuscitation guidelines (2010). Major guideline changes being, 3 initial questions instead of 4, skin color removed from primary clinical signs and replaced by pulse oximetry as means of judging oxygenations, targeted SpO2 values, use of room air or blended oxygen and air mixture for resuscitation, addition of "MRSOPA" pneumonic to ensure adequate ventilation and stronger endorsement of considering therapeutic hypothermia. In this issue of Neochap Bulletin, these new guidelines (2010) are presented in comparison to the previous (2005) guidelines to make it easier to understand and remember the recommendation changes. This may also serve as ready reckoner of the new guidelines.

Neonatal sepsis is the leading cause of mortality and morbidity in our country, and surely article on "Guidelines for Achieving & Maintaining an Aseptic Environment In NICU" will be helpful in improving knowledge and aseptic practices in the neonatal units.

There is increasing interest in the potential health benefits of Probiotics in all age groups and its use in neonates has been the topic of debate and research in recent years. The article on "Probiotics in Neonatal medicine" has addressed its efficacy and safety, favoring its use in preterm babies for prevention of NEC, though the dose and duration remains a matter of further research.

In an attempt to improve outcome, Neonatologist often are drawn to new and novel therapies and techniques. Author of next section described a relatively safer, less traumatic and claimed to be less painful technique for drainage of pneumothorax by Pigtail catheters which seems to have the potential to warrant a practice change. There has been always a quest to find new method of respiratory support for the small babies, and the article on "Heated High Flow Nasal Cannulae Yet another method of Non-Invasive Respiratory Support in Preterm Infants" comprehensively discussed utility of this device to provide a gentle kind of respiratory support. This device although is new to Indian market, appears to be another modality of noninvasive ventilation having a promising role in the near future, especially for smaller babies.

I am hopeful that you will find this issue practically useful and will enjoy reading.

Dr Naveen Bajaj
Guest Editor

Neonatal Resuscitation Guidelines 2010 An update

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The American Heart Association (AHA) and American Academy of Pediatrics (AAP) have published revised Neonatal Resuscitation guidelines 2010[1,2]. These guidelines are based on the evidence presented in the 2010 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science With Treatment Recommendations[2]. The major changes in 2010 guidelines in comparison to 2005 guidelines[3,4] are presented here:

Resuscitation Sequence	2005 Guidelines[3,4,5]	2010 Guidelines[1,2,6]	What's New?
Scope of NRP	Newly borns and neonates during first few weeks to months after birth.	Newly borns and neonates during first few weeks to months after birth.	Similar applicability.
Preparation for resuscitation	Concept of "Resuscitation Team" with a specified leader and an identified role for each member.	Along with concept of "Resuscitation Team", there is emphasis on teamwork, leadership, efficient communication and behavioral skills.	Behavioral skills and communication skills are important to the success of a neonatal resuscitation.
Equipment	Complete list of "Neonatal Resuscitation Supplies" and Equipment" is given.	In addition to "Neonatal Resuscitation Supplies and Equipment" list, the "NRP Quick Pre-resuscitation Checklist" is also provided.	More emphasis on checking the presence and function of resuscitation equipment and supplies in the same order as they are used in NRP flow diagram.
Assessment of need for resuscitation	**To ask 4 questions:** ✓ Term gestation? ✓ Amniotic fluid clear? ✓ Breathing or crying? ✓ Good muscle tone?	**To ask 3 questions:** ✓ Term gestation? ✓ Breathing or crying? ✓ Good muscle tone?	Assessment of need for resuscitation is based on 3 instead of 4 characteristics. Amniotic fluid clear or not is not a part of initial assessment.
If Answers to all the above questions is YES	**Routine Care** ✓ Provide warmth ✓ Clear airway, if necessary ✓ Dry ✓ Assess color	**Routine Care** ✓ Provide warmth ✓ Clear airway, if necessary ✓ Dry ✓ Ongoing evaluation	Ongoing evaluation of breathing, activity and color while the baby stays with the mother.
If Answers to any of above questions is NO	**Baby receives one or more of the 4 categories of action in sequence:** A. Initial steps B. Ventilation C. Chest compressions D. Administration of epinephrine and/or volume expansion	**Baby receives one or more of the 4 categories of action in sequence:** A. Initial steps B. Ventilation C. Chest compressions D. Administration of epinephrine and/or volume expansion	Same sequence Approximately 60 seconds are allotted for completing the initial steps, reevaluating and beginning ventilation, if required and termed as **"The Golden minute".**

Initial steps	✓ Provide warmth ✓ Position; Clear airway (as necessary) ✓ Dry, stimulate, reposition	✓ Provide warmth ✓ Clear airway if necessary ✓ Dry , stimulate	No routine suction. Suction only if : ✓ Obvious obstruction to spontaneous breathing ✓ Require PPV
Temperature control in VLBW (<1500 g) babies	They are at increased risk of hypothermia. Additional warming techniques like covering in plastic wrap without drying and then placing under radiant warmer in <28 weeks' gestation babies is recommended.	They are increased risk of hypothermia. Additional warming techniques like placing on exothermic mattress, covering in plastic wrap without drying and prewarming the delivery room to at least 26^0C in <28 weeks' gestation babies is recommended.	Preterms <28 weeks' gestation should be completely covered in a polythene wrap or bag up to their necks without drying immediately after birth and then should be placed under a radiant heater. Delivery room temperatures should be at least 26°C for these infants.
Neonates born through meconium stained amniotic fluid (MSAF)	No intrapartum suction.	No intrapartum suction.	
✓ **Vigorous baby**	Use a bulb syringe or large-bore suction catheter to clear secretions and meconium from the mouth and nose as needed and baby receives observational care.	Use a bulb syringe or large bore suction catheter to clear secretions and meconium from the mouth and nose as needed. This baby stays with his mother and receives routine care and ongoing evaluation.	Assessment of vigorous meconium stained babies can be done while they stay with the mother.
Non- Vigorous baby	Endotracheal suctioning	Endotracheal suctioning	Continue current practice of endotracheal suctioning of nonvigorous MSAF babies. However, if attempted intubation is prolonged/ unsuccessful or there is persistent bradycardia, give bag-mask ventilation.
Progression to next resuscitation step following initial steps	By simultaneous assessment of: **3 vital signs** ✓ Respiration ✓ Heart rate ✓ Color	By simultaneous assessment of: **2 vital signs** ✓ Respiration(Labored, unlabored, apnea, gasping) ✓ Heart rate	Color omitted as a signs of assessment of oxygenation or resuscitation efficacy as it is a poor indicator of oxyhemoglobin saturation during immediate neonatal period.
Heart rate assessment	Palpation of umbilical cord pulsation.	Auscultation of heart at the precordium is most accurate.	Precordium auscultation preferred than umbilical cord palpation for counting heart rate. When pulse is detectable,

			palpation of umbilical pulse provides rapid estimate of heart rate and is more accurate than palpation at other sites.
Use of Pulse oximeter	Pulse oximeter recommended for resuscitation of preterm babies (<32 weeks).	Use Pulse oximetry for both term and preterm in: ✓ Anticipated need for resuscitation ✓ Need for PPV for more than few breaths ✓ Persistent cyanosis ✓ Supplementary oxygen is being administered	Apply neonatal probe to right hand or wrist (measure pre-ductal saturations) of the baby before connecting it to machine, reliable reading can be obtained within 1-2 min. Target preductal SpO_2 ranges : 1 min - 60-65% 2 min - 65-70% 3 min - 70-75% 4 min - 75-80% 5 min - 80-85% 10 min - 85-95% (same for both term and preterm)
Assessment of Oxygen need and use of Supplementary Oxygen	✓ Based on color ✓ Supplementary (Free flow) oxygen to babies who are breathing but have central cyanosis.	Based on pulse oximetry. If labored breathing or persistent cyanosis: ✓ Clear airway ✓ SpO_2 monitoring ✓ Consider CPAP Attach a pulse oximetry probe to determine oxygenation, if levels are low and not increasing, provide supplemental oxygen.	Cyanosis can be normal for the first few minutes following birth and skin color is poor indicator of oxygen saturation. Hence, use pulse oximetry to assess oxygenation and titrate the percentage of inspired oxygen conc. so as achieve the target SpO_2 values as mentioned above.
Positive pressure ventilation (PPV) Indication for PPV	**Any 1 out of 3** ✓ Apnea or gasping ✓ Heart rate < 100/min ✓ Persistent central cyanosis despite administration of free-flow supplementary oxygen.	**Any 1 out of 3** ✓ Apnea or gasping ✓ Heart rate < 100/min ✓ SpO_2 below target values despite free-flow supplemental oxygen being increased to 100%.	Instead of color use SpO_2 to assess oxygenation and start PPV, if SpO_2 values are below the target range despite increasing delivered oxygen conc. to 100%.
PPV strategies ✓ **Inflation pressure**	Average initial peak inflation pressure of 30-40 cm of H_2O for term and 20-25 cm of H_2O for preterm babies is adequate.	Start with an inspiratory pressure of about 20 cm of H_2O which is usually effective in both term and preterm babies. Inflation pressure of ≥30-40 cm H_2O may be required in some term babies.	More emphasis on monitoring of inflation pressure. If pressure is not being monitored, use the minimal inflation required to achieve an increase in heart rate.

✓ **PEEP**	No recommendation for PEEP.	PEEP likely to be beneficial for initial stabilization of apneic preterm infants requiring PPV and should be used.	PEEP should be used in preterm infants with suitable equipment (T-piece or flow inflating bags).
✓ **Indicators of adequate inflation pressure and ventilation**	Improvement in ✓ Heart rate ✓ Color ✓ Muscle tone	✓ Rising heart rate ✓ Rising SpO_2 ✓ Audible bilateral breath sounds	Rising heart rate most important indicator of successful PPV. Use SpO_2 along instead of color.
Initial oxygen concentration for resuscitation with PPV	**Term infants** ✓ Begin with 100% O_2. ✓ If resuscitation is initiated with room air and there is no improvement within 90 sec after birth, give supplemental O_2 up to 100%. ✓ In case non availability of O_2 start resuscitation with room air. **Preterm <32weeks** ✓ Start with O_2 conc. somewhere between 21-100% by using blender. ✓ For first few minutes SpO_2 of 70-80% is acceptable as long as heart rate and SpO_2 is increasing with ventilation, then adjust oxygen to target SpO_2 between 85-95%.	**Term infants** ✓ Best to begin with room air rather than 100% O_2. If despite effective ventilation there is no increase in heart rate or if oxygenation as guided by pulse oximetry remains unacceptable, use higher oxygen concentration of up to 100%. **Preterm <32weeks** ✓ Begin with O_2 conc. of 30% or 90% by using blender, then titrate O_2 conc. up or down to achieve target SpO_2.	Room air resuscitation preferred in term babies. Use blender and pulse oximeter for term babies also. In preterm start with O_2 conc. of 30% or 90% and then increase or decrease O_2 conc. so as to achieve saturation values as mentioned above. Insufficient evidence to define appropriate oxygen strategy for 32-37 weeks' gestation babies.
PPV Rates	40-60 breaths/min	40-60 breaths/min	No change
Ventilation corrective steps	Mentioned, but not in flow diagram ✓ Inadequate seal ✓ Blocked airways ✓ Not enough pressure	An additional step has been inserted in the flow diagram, involving a new pneumonic ("MR SOPA"), to ensure provision of adequate ventilation before initiating chest compressions.	**M**: Mask adjustment **R**: Reposition airway **S**: Suction mouth and nose **O**: Open mouth **P**: Pressure increase **A**: Airway alternative
CPAP during resuscitation	Consider if preterm baby is breathing spontaneously with a heart rate above 100/min, but has labored respirations, persistent cyanosis or a low SpO_2.	CPAP is beneficial, if baby is breathing spontaneously with a heart rate above 100/min, but has labored respirations, persistent cyanosis or a	Spontaneously breathing preterm infants who have respiratory distress may be supported with CPAP or intubation and mechanical ventilation as guided by

		low SpO_2, particularly if baby is preterm.	local expertise. No evidence to support or refute the use of CPAP in term baby.
Assisted ventilation devices	Effective ventilation can be achieved with self-inflating bag, a flow-inflating bag or a T-piece resuscitator.	Effective ventilation can be achieved with self-inflating bag, flow-inflating bag or T-piece resuscitator. Mouth-to-mask or tube-to mask ventilation can be used when bag-mask devices are not available.	Bag-mask ventilation is preferable to mouth-to-mask ventilation or tube-to mask ventilation.
Laryngeal Mask Airway (LMA)	LMA may be useful if bag-mask ventilation is unsuccessful and endotracheal intubation is unsuccessful or not feasible.	Considered as an alternative, if face mask ventilation is unsuccessful and endotracheal intubation is unsuccessful or not feasible for resuscitation of newborns weighing >2000 g or delivered at ≤34 weeks' gestation.	Limited evidence in newborns weighing <2000g or delivered at ≤34 weeks' gestation. Its use has not been evaluated in the setting of meconium stained amniotic fluid, during chest compressions, or for administration of medications.
Upper airway interface devices	Rounded cushioned or anatomical shaped mask can be used.	Conflicting evidence about ability to maintain seal with anatomical shaped mask compared to rounded mask. Nasal prongs are an alternative way of giving respiratory support.	Whichever interface is used, providers should ensure that they are skilled in using these interface devices.
Endotracheal intubation Indications	✓ Tracheal suctioning of nonvigorous MSAF babies ✓ Ineffective or prolonged bag-mask ventilation ✓ When chest compressions are performed ✓ When endotracheal administration of medications is desired ✓ For special resuscitation circumstances, such as congenital diaphragmatic hernia or ELBW (<1000 g) babies.	✓ Tracheal suctioning of nonvigorous MSAF babies ✓ Ineffective or prolonged bag-mask ventilation ✓ When chest compressions are performed ✓ For special resuscitation circumstances, such as congenital diaphragmatic hernia or ELBW (<1000g) babies.	Indications for endotracheal intubation are same except that there is de- emphasis on intubation for epinephrine administration.

Confirmation of endotracheal tube placement	Exhaled CO_2 detection is recommended method of confirmation of its placement except in low or absent cardiac output (cardiac arrest).	Exhaled CO_2 detection is recommended method of confirmation of its placement except in low or absent cardiac output (cardiac arrest).	No change
Chest compressions Indications	Heart rate < 60/min despite 30 sec of effective PPV.	Heart rate < 60/min despite 30 sec of effective PPV.	No change
Compression: ventilation ratio	3:1	3:1 .	Ratio is same, except if arrest is due to a clear cardiac etiology especially in babies who are beyond immediate newborn period, where higher ratio (e.g.15:2) may be used.
Technique	Thumb technique preferred than two finger.	Thumb technique preferred than two finger.	Thumb technique preferred even if umbilical access is desired.
Site **Depth**	Lower 1/3rd of sternum 1/3rd of AP diameter of chest	Lower 1/3rd of sternum 1/3rd of AP diameter of chest	
Reassessment of Heart rate	After 30 seconds of well-coordinated chest compressions and ventilation.	After 45 to 60 seconds of well-coordinated chest compressions and ventilation.	Once chest compressions are started, return of spontaneous circulation may take a minute or so, and there is delay of 45 seconds or longer before the coronary perfusion pressure returns to its previous value.
Medications **Epinephrine** ✓ **Indication**	Heart rate < 60/min after 30 sec of effective assisted ventilation and another 30 sec of coordinated chest compressions and ventilation.	Heart rate <60/ min after 30 sec of effective assisted ventilation (preferably after endotracheal intubation) and at least another 45 to 60 sec of coordinated chest compressions and effective ventilation.	Instead of 30 sec, wait at least 45-60 sec of coordinated chest compressions and effective ventilation before decision to administer epinephrine is made.
✓ **Intravenous dose** ✓ **Endotracheal dose**	0.1-0.3 ml/kg of 1:10000 0.3- 1 ml/kg, only if IV access not available.	0.1-0.3 ml/kg of 1:10000 0.5- 1 ml/kg, only if IV access not available.	Stronger emphasis on IV use and further de-emphasis on endotracheal use of epinephrine.
Volume expansion	Consider when blood loss is suspected and baby appears to be in shock and is not responding to resuscitation.	Consider when blood loss is suspected and baby appears to be in shock and is not responding to resuscitation.	No change

Naloxone	Use in case continued respiratory depression after positive pressure ventilation restored normal heart rate and color and there history of maternal narcotic administration within past 4 hours.	Administration of naloxone is not necessary as long as the baby can be adequately ventilated, it may be considered in a baby with continued respiratory depression when there is a history of maternal narcotic administration within the past 4 hours.	Not recommended as part of initial resuscitation in babies with respiratory depression in delivery room, focus needs to be on effective ventilation.
Type of Care	**3 levels of care** ✓ Routine care ✓ Observational care ✓ Post resuscitation care	**2 levels of care** ✓ Routine care ✓ Post resuscitation care	Observational care is removed from algorithm.
Post resuscitation Management Glucose	Infants who require significant resuscitation should be monitored and treated to maintain glucose in the normal range.	Intravenous glucose infusion should be considered as soon as practical after resuscitation, with the goal of avoiding hypoglycemia.	Due to the paucity of data, no specific target glucose concentration range can be recommended.
Therapeutic hypothermia	Avoid hyperthermia. Insufficient data to recommend routine use of modest systemic or selective cerebral hypothermia after resuscitation.	Therapeutic hypothermia recommended for infants born at ≥36 weeks gestation with evolving moderate to severe hypoxic-ischemic encephalopathy.	Therapeutic hypothermia should be implemented according to the studied protocols, which currently include commencement within 6 hrs following birth, continuation for 72 hrs, and slow rewarming over at least 4 hrs, in facilities with capabilities for multidisciplinary care and longitudinal follow-up.
Timing of Cord clamping	No recommendation.	Recommendation for delaying cord clamping for uncomplicated term and preterm births. **Term** Delay cord clamping for a minimum time ranging from 1 minute to until the cord stops pulsating after delivery. **Preterm** Delay cord clamping for a minimum time ranging from 30 seconds to 3 minutes after delivery.	Evidence of benefit to delaying umbilical cord clamping in both term and preterm babies, not requiring resuscitation. Insufficient evidence to support or refute a recommendation to delay cord clamping in babies requiring resuscitation.
Guidelines for Withholding Resuscitation	The guidelines must be interpreted according to current regional outcome. Generally withhold in:	The guidelines must be interpreted according to current regional outcome Generally withhold in :	No change in the guidelines. Assessment of morbidity and mortality risks should

	✓ Gestational age < 23weeks ✓ Birth weight <400 g ✓ Major chromosomal anomalies (e.g.Trisomy13) ✓ Anencephaly	✓ Gestational age < 23weeks ✓ Birth weight <400 g ✓ Major chromosomal anomalies (e.g. Trisomy13) ✓ Anencephaly	take into consideration available data, and may be augmented by use of published tools based on data from specific populations.
Guidelines for Discontinuation of Resuscitations	No detectable heart rate after 10 min of complete and adequate resuscitation.	No detectable heart rate after 10 min of complete and adequate resuscitation. Decision to continue resuscitation beyond 10 min with no heart rate should take many factors into consideration.	When heart rate is <60/min at birth and persists after > 10-15 min of adequate resuscitation, there is no sufficient evidence to guide decision as to whether withhold or continue resuscitation.
Structure of educational program to teach Resuscitation	Not mentioned	AHA/AAP NRP should adopt simulation, briefing-debriefing techniques in designing an educational program for acquisition and maintenance of skills necessary for effective neonatal resuscitation.	New recommendation for NRP teaching and training program.

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Guidelines for Achieving & Maintaining an Aseptic Environment in NICU

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Neonatal infection is a significant cause of morbidity and mortality. This leads to long hospital stay, increased cost, increased the risk of neurodevelopmental delay in babies. The nosocomial sepsis rates are as high as 25 to 30%. Hence, "Prevention of infection is more cost effective than treating infections in neonates"

The asepsis routines must be introduced strictly and should be consistently followed for best results. Many practices may not be evidence based, but most of them have been proven to play a major role in reduction of the rate of the neonatal sepsis.

Every hospital should establish its own detailed policies for asepsis. The policies should include, guidelines for entry into the baby care area, policy regarding visitors, environmental factors and design issues, a thorough knowledge of the disinfectants, housekeeping routines and the safe disposal of bio-medical waste.

Guidelines for entry into the baby care area

- Remove shoes, socks, woolens, watch, bangles, and rings. Roll up the full sleeves up to elbow.
- Put on new slippers, wash hands with soap and water for 2 min (6 steps of hand washing).
- Put on sterile half sleeve gown.

Policy regarding visitors (1)

- Ordinarily parents should be allowed entry into NICU. However, in special situations guardian or other care givers may be allowed entry.
- Mothers are welcome at any time; they can come every 2 to 3 hours to the baby care area.
- Fathers should be allowed at the time of admission, after stabilizing, and daily for 1-2 hour.
- Parents should be guided and supervised about proper hand washing technique.

  Personnel with active infection (respiratory, mucocutaneous or gastrointestinal) should not be allowed entry into the baby care area

Environmental factors and design issues (2,3)

- **Space:** Each infant space should be 120 sq feet, excluding sinks and aisles. Each baby should have an aisle of 3 feet.
- **Ventilation:** A minimum of 6 air changes/hr is required with 2 changes being of outside air. The ventilation air delivered in NICU should be filtered with at least 90 % efficiency. Fresh air inlet should be located at least 25 feet from the exhaust outlets. ventilation. Overcrowding should be avoided.

Disinfectants and germicides:

- One should be aware of the different disinfectants and their uses.
- The preparation method should be strictly followed as per the manufacturer guidelines
- The required contact time should be always adhered to for optimal asepsis benefits
- The general guidelines and the details of the commonly available disinfectants and germicides are mentioned with indications in the Annexure I. These may be adapted based on the availability and the infection control policy of the hospital

Strict housekeeping routines for disinfection (4)

- There should be written policy guidelines (in the form of a manual) for cleaning of floors, walls, articles, equipment and fumigation of the unit.
- Cleaning should be performed in the in following order – patient areas, accessory areas and then adjacent halls. Always wet mop the floors, dust should not be dispersed into the air. Refer to annexure II.
- The equipments are important environment of baby and an important source of infection. The details of the asepsis routines for the equipment is mentioned in Annexure III

Other basics of Asepsis:

- Handling of neonates should be minimized. Staff should hand wash between infants as well as upon entering and leaving the nursery
- Separate spirit and betadine swab containers, stethoscope, tape measure and thermometer should be kept for each baby.
- Change intravenous sets daily. Feeding tubes as long as baby can keep. Change the burette set every 24 hour or as per policy of your unit.
- Do not keep FOMITES e.g. files, X-ray films, pens etc. on the baby cot.
- Change antiseptic solution in SUCTION BOTTLES and water in humidification chambers daily. Sterilize the bottles/chambers using 2% glutaraldehyde for 4 to 6 hours.
- Never use stock IV fluids. There should be separate IV fluid bottle for each baby.
- Label the bottle with date and time of opening. After seal is removed, first clean with spirit swabs, then use Betadine soaked sterile cotton to cover the stopper of the bottle.
- Use syrups within 1 week of opening, write the opening date.
- Antibiotics vials to be changed after 24 hrs. e.g. injections Ampicillin and Cefotaxime.
- Use separate IV line for giving antibiotics (do not open the IV fluid line for giving injections).

Annexure 1: A list of disinfectants and germicides used in NICU

Name	Indication of use	Directions for use any special precautions if any
Detergents : Help in cleaning debris, and hence enhance the action of the disinfectants		
SOAP/ WATER	O_2 Hood, Feeding utensils, Swab containers, Buckets	wash in soap and water, boil the feeding utensils for 20 minutes
IOPREP (10% iodine)	Pre and post surgical skin care	One step cleaning of the soiled hands with disinfection
Alcohols : No action on spores, Isopropyl alcohol is preferred as it is less volatile, more bactericidal and has better fat solubility		
BACILLOCID (2%) (Propan 1, 2, & Glutaral)	Walls ,Incubators and Warmers (When ideal)	Prepare as per the instruction & put off the AC at the time of spray (5 ml concentrate is sufficient to disinfect 1sqm), Keep surfaces wet for 30 min.
MEDICAL SPIRIT (Ethyl , isopropyl alcohol 70%)	Skin preparation, Laryngoscope blades, Tapes, Stethoscopes	Do not use to clean incubators and warmers
STERILLIUM 1 & 2- propanolol, ethyl-hexadechyle dimethyl ammonium ethyl sulfate	Hand disinfection (not visibly soiled)	Rub 2-3ml on hands for 30 sec and allow it to dry for disinfection of hands
MICROSHIELD HANDGEL	Hand disinfection (not visibly soiled)	Rub 2-3ml on hands for 30 sec and allow it to dry for disinfection of hands
Aldehydes : Are bactericidal, sporicidal, fungicidal and virucidal. Unlike the alcohol do not damage the rubber/ glass/ masks, sharp instruments and polyethene tubing. The gas generated is toxic/ irritant/ carcinogenic, that may have a residual effect.		
CIDEX (2%/2.25%) (Glutaraldehyde)	Oxygen/ Suction tubing, Face mask and Ambu bag reservoir, Ventilator Circuits	Clean with soap /water before inserting in the CIDEX, Once active the solution remains active for 14 days For sterilization : 4-6 hours, For disinfection : 15-20 minutes
KORSOLEX (10%) 1, 6 dihydroxy, 2,5 dioxyhexane, glutaraldehyde	Oxygen/ Suction tubing, Face mask and Ambu bag reservoir, Ventilator Circuits	Dissolve 1 part in 9 parts of water, once active the solution remains active for 14 days. For sterilization : 4-6 hours, For disinfection : 15-20 minutes

ANNEXURE II : House Keeping Routines

Name	Disinfection Method	Frequency and other considerations
Floors	Wet mopping with Phenol 3%, Lysol 5% , CLEAN-A-SEPT, ECOSHIELD	No dry sweeping or dusting Clean once in shift Do not use 2% gluteraldehyde
Walls	2% Bacillocid, Clean-a-sept, Ecoshield	Once in each shift
Fans	Clean with soap and water	Once a week
Window AC	Surface and filters to be washed with soap and water	One a week
Refrigerator	Defrosted and clean with soap and water	Once a week
Buckets	Soap and water	Daily in the morning shift
Sinks	Detergents (vim or surf)	Daily in the morning shift or as required
Dustbin	Wash daily with soap and water	Polythene should be changed daily or whenever full.
Needles and sharp objects	Discard in polar bleach in a needle proof container	Daily
Waste and soiled linens	Closed bins should be available, bin must be closed and emptied at regular intervals Plastic bags should be used in the bins , they are discarded as per the waste disposal policy	As required

Source : Essential newborn nursing for small hospitals.. Teaching aids on newborn care: Deorari AK (Ed), 2nd Edition, 1988, New Delhi

Minimum Supplies to be made available for the Housekeeping in NICU:

1. *The surface disinfectant for cleaning the work surfaces, equipment etc of like Bacillocid, Sodium Dichloroisocynurate*
2. *The Soap water for cleaning: dustbins, sinks, refrigerators and window AC's.*
3. *The phenols like Cresol or Lysol for cleaning of the floors.*

Phenols : Active against wide range of organisms, affectivity against gram negative organisms like pseudomonas poor. Lysol and cresol are superior to phenyl as not inactivated by the presence of organic matter. All these are toxic to humans and carcinogenic		
Phenyl ((Carbolic acid), Lysol (5%) Cresol	Cleaning floors	Every shift
Chlorhexadine MICROSHIELD HAND WASH (4%) MICROSHIELD HAND RUB (0.5% + 70% Eth Alcohol) BD PERSIST PLUS (1% + 75% ethanol)	Hand Wash Hand disinfection of clean hands	After hand wash before touching the baby 4 % May also be used for skin preparation
Halogens : Iodine is active against bacteria and moderate action against the spores, May cause hypothyroidism when applied over large surface area in a very small baby		
Betadine (Povidone Iodine (7.5%) Microshield PVP-S (10%)	Surgical Hand wash & Skin Preparation Skin preparation	Use with alcohol for better action, Wipe off extra application Use with caution in extremely preterm babies
Sodium hypochlorite (Bleach)	Sharps/needles and disposables	Keep the solution covered, change it every 24 hours.
Others		
NaDCC Sodium Dichloroisocyanurate	Disinfection of the work surfaces, cupboards, floors Infected linens Utensils. Glassware, rubber tubes	Available as CLEA-N-SEPT Tabs 1 TAB in 2 liters of water Contact time of 1 hour
ECOSHIELD Complex formulation of stabilized hydrogen peroxide 11% w/v with o.o1% w/v silver nitrate solution	Aerial disinfection Terminal cleaning (5%)	Make 20 % solution by adding 200ml in 800ml water for 1000cu ft space, Fogging duration may be 20 min at lowest setting Fogging machine mounted at 2 ft height Angle of fogger is 45, AC is put on after 1 hour of fogging Close time 1 hour Take 250 ml in 5 liter solution and make 5 %, mop liberally all surfaces , walls and floor

Annexure III: Equipment disinfection[5]:

Name	Disinfection method	Frequency and other considerations
Cots and Mattresses	Clean daily with soap and water. If change of baby → clean with NaDCC / ECOSHIELD/ Bacillocid 2%	As required
Baby linen and blanket cover	Wash and autoclave	Use autoclaved linen each time
Feeding utensils (Paladay, spoon katories)	Wash with soap/ water & and boil for 10 min	Before each use
Procedure sets, cotton Gauze, Cheattle Forceps	Autoclave	As required, Forceps every 72 hrs if unused
Thermometer (Separate for each baby)	Clean with alcohol from bulb to base. Store in the case with dry sterile cotton	Daily
Stethoscope, measuring tape, thermometer, BP cuffs, probes of radiant warmer/incubator pulse oximeter	Clean with spirit swab. Do not clean the display screen with alcohol	Daily
Laryngoscope	Clean with 70% alcohol swabs thoroughly daily and after each use. CIDEX for sterilization	After every use. Sterilize weekly once
Syringe Pumps, Phototherapy machines, Pulse Oximeters , Weighing Machine	Clean with wet clean cloth. If blood stained , use soap and water	Daily in morning shift, if possible , in each shift
Oxygen hood	Wash with soap and water; dry with clean linen	Daily in the morning shift
Face mask, Resuscitation bag and reservoirs,	Clean with soap and water, immerse in CIDEX 2% for 20 min, rinse in distilled/running water, dry and wrap with autoclaved linen. For sterilization: Immerse for 4-6 hours.	Daily and after each use. Sterilize weekly once
Oxygen tubing, tubing of the suction machine	Clean with detergent soap and water after dismantling. Immerse in gluteraldehyde for 4-6 hours. Rinse in distilled water. Dry , wrap in autoclaved linen and put a date	Daily
Radiant Warmer and incubator	Clean with soap water daily, if occupied. If not occupied, clean with 2 % Bacillocid	Daily

Source : Essential newborn nursing for small hospitals.. Teaching aids on newborn care: Deorari AK (Ed), 2nd Edition, 1988, New Delhi

SAFE DISPOSAL OF HOSPITAL WASTE

- Proper disposal of hospital waste is important to keep the environment clean. The waste should be disposed off in a proper way. All health professionals should be well conversant with their local hospital policies for waste disposal which may vary from place to place.
- The different color drums with different color polythene for different type of waste, to be disposed off in a different way. (refer to Annexure IV)

ANNEXURE IV : Safe disposal of Hospital Waste

COLOUR OF DRUMS/POLYTHENES	DISPOSALS RECOMMENDED	Ultimate disposal method adopted
Black drums / Bags	Leftover food, fruits feeds, vegetables, waste paper, packing material, empty box, bags etc. Empty vials of medicines. This waste is disposed off by routine municipal council committee machinery.	Dumping
Yellow drums / Bags	Infected non-plastic waste e.g. human anatomical waste, blood, body fluids, placenta etc. This type of waste requires incineration.	Incineration
. Blue drums / Bags	Infected plastic waste such as used disposable syringes. Patients IV set, BT set, and ET tube, catheter, urine bag etc. should be first dipped in 1% bleaching powder and cut into pieces and disposed in blue bag	This waste will be autoclaved to make it non-infectious. This is then shredded and disposed off.
Puncture Proof containers	First destroy the needle in the needle destroyer). Used sharps, blade and broken glass should be discarded in puncture proof containers before discarding.	This waste will be autoclaved to make it non-infectious. This is then shredded and disposed off.

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Probiotics in Neonatal Medicine

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Probiotics in the form of fermented milk have been ingested by humans for thousands of years in the belief that they have health benefits. In the early 20th century, the Russian immunologist Elie Metchnikoff proposed that lactic acid bacilli may have beneficial health effects and attributed his own longevity to regular probiotic ingestion. The proposed health benefits of probiotics have undergone increasingly rigorous scientific evaluation in recent years, and there is now strong evidence for their use in treating and preventing some human diseases (1). Pharmaceutical market is flooded with variety of probiotic combinations which are used routinely at all age groups for variety of ailments. The current write-up aims at giving evidence base on use of probiotics in neonates.

Intestinal microbiota : The intestine of a fetus is sterile. Within hours of birth, bacteria ingested during the birthing process rapidly colonize the gut. The gastrointestinal tract soon contains about 10 times as many bacteria as there are cells in the body(2). This complex ecosystem comprising of commensal bacteria is termed as 'microbiota'. Once established, around 18th to 24th month of life, an individual's microbiota tends to be stable throughout the lifetime. It includes 400 to 1,000 bacterial species. Approximately 97% of the species are anaerobic and 3% are facultative anaerobes. Number of bacteria within intestine goes on increasing from proximal to distal gut. The stomach is practically sterile; proximal small intestine contains up to 104 bacteria/mL and the colon contains highest numbers, nearly 1012 bacteria per gram of feces.(3).

Factors which influence development and composition of this microbiota are mode of birth, postnatal environment, diet and use of antibiotics. In infant born by vaginal delivery the gut is colonized by the vaginal and fecal flora of the mother. On the other hand, infants born by caesarian section are colonized by environmental bacteria. Natural breastfeeding provides microbiota predominant in (> 90%) bifidobacteria and lactobacilli which are thought to confer protection from infection and allergy. Infants who are artificially fed tend to have complex flora with no one bacterial genus showing a numerical predominance.(1;4;5). Premature neonates are at risk of poor intestinal probiotic colonization due to poor enteral feeding accompanied by the absence of the benefits of breast milk, frequent antibiotic exposure and the neonatal intensive care unit (NICU) environment(6). It is hypothesized that probiotics act to down-regulate pathogenic organisms and protect against intestinal inflammation. Bacterial translocation from the gastrointestinal tract is an important pathway initiating late-onset sepsis and necrotizing enterocolitis in very low-birth-weight infants. (7) Probiotics can decrease intestinal bacterial colonization and translocation in premature infants. In an interesting probiotic supplementation study in VLBW babies, Klebsiella pneumoniae, Escherichia coli and Enterococcus faecium were common colonization bacteria in the babies who did not receive probiotic. (8)

Probiotics administered during the establishment of the infant's intestinal microbiota becomes part of the host's definitive microbiota. Administration of probiotics later in life alters microbiota only transiently unless the probiotic supplement is continued for a long period of time. (3;5).

Probiotics

Probiotics are live microbial preparations, when consumed orally, colonize the intestine and provide benefit to the host (9).

Some criteria used to define a microorganism as probiotic are:(10)

- Human origin
- Nonpathogenic
- Resistance to enteric processing
- Stability to acid and biliary secretion
- Adherence to the epithelial cell
- Capacity to persist in the gastrointestinal tract
- Capacity to influence local metabolic activity

The major bacterial microorganisms regarded as probiotic are those of the genera lactobacillus and bifidobacterium, in addition to escherichia, enterococcus and bacillus. The fungus saccaromyces boulardii has also been considered to be probiotic however it is not human derived(2).

Prebiotics are substances such as furcto-oligosaccharides which, when ingested, are not digested in the gut but they selectively stimulate growth of a bacterium or group of bacteria (e.g.: bifidobacteria) when they reach the colon, bringing health benefits to the host. Common commercial preparations contain combination of probiotic and prebiotic (referred to as symbiotic).

Mode of action of probiotics.

Probiotic microorganisms positively change the intestinal flora, inhibit the growth of pathogenic bacteria, promote adequate digestion, stimulate the local immune function and increase resistance to infection.(3)

1. Change in intraluminal pH - Lactobacilli and bifidobacteria produce organic compounds from fermentation of carbohydrates, with formation of lactic acid, hydrogen peroxide and acetic acid. Increased acidity in the intestine inhibits the proliferation of pathogenic bacteria (11)
2. Production of substances with antimicrobial activity - Bacteria regarded as probiotic also produce substances known as bacteriocins, metabolically active proteins, which help destroy undesirable microorganisms. Several bacteriocins have already been described, including a low molecular weight substance, reuterin, produced by L. reuteri. Both lactobacilli and bifidobacteria are able to produce these elements. Also interesting is that Lactobacillus rhamnosus GG, in addition to producing bacteriocins, also produces a biosurfactant, which helps its own survival.(11)
3. Competition for nutrients - One of the limiting factors for bacterial growth in the intestinal lumen is the availability of nutrients. Increase in the number of lactobacilli and bifidobacteria in large intestine do not allow proliferation of pathogenic bacteria(3;11)
4. Competition for intestinal receptors for adherence – Probiotic bacteria have capacity to adhere to specific receptors found in the intestinal mucosa. Receptor attachment prevents them from elimination by peristalsis and prevents pathogenic bacteria such as Salmonella typhimurium, Yersinia enterocolitica and Escherichia coli from producing their enteropathogenic effect (5;11). Lactobacillus plantarum synthesizes adhesins for intestinal receptors that contain mannose. Therefore, they compete with Escherichia coli, to bind to the receptors in order to exert its pathogenic activity.(12)
5. Immunomodulatory effect - The intestine is the largest lymphoid organ in the human body. Macrophages dispersed in the lamina propria and epidthelium or organized into well defined structures, play a key role in

antigenic presentation and development of immune response to microorganisms and dietary proteins. The immune effects of probiotics that have been observed include increase in gamma-interferon in patients with cow's milk allergy and atopic dermatitis, probably due to the deviation of immune response to a TH1 profile.(13) Thus, the presence of these agents in the gastrointestinal tract can help with the development of a tolerogenic response.

6. Recovery of intestinal permeability: Some lactobacilli may have some effect on the expression of the mucin gene, stimulating the production of mucus in the intestinal mucosa and contributing to the efficiency of the barrier function of the intestinal mucosa.(14)
7. Gastrointestinal tract protein synthesis: Both lactobacilli and bifidobacteria are capable to induce the synthesis of proteins with allergenic potential in the gastrointestinal tract. This process can contribute to the reduction of protein allergenicity, minimizing the risk for food allergy.

Neonatal uses of Probiotics

Probiotics are used in pediatric and adult population for prevention and treatment of diarrhea and allergic disorders. In the neonate use of probiotics was restricted by the fact that they are 'live microorganisms' and neonate is immune deficient. Good quality randomized clinical trials during the last decade have brought out clinical indications and safety of use of probiotics in neonate.

Prevention of NEC

Necrotizing enterocolitis (NEC) is the most commonly occurring gastrointestinal emergency in preterm infants. Some reports estimate a 10% incidence among infants weighing <1500 g, with mortality approaching 30%. Approximately 25% of survivors experience long-term sequelae.(9) The causes of this intestinal catastrophe are complex, but common factors associated with the disease are prematurity, immaturity of the intestinal tract (impaired motility, impaired barrier function), intestinal ischaemia, microbial colonization with pathogenic organisms and enteral feeding. The premature infant may be exposed to many antibiotics, which alter intestinal microflora to facilitate colonization by more pathogenic organisms. Certain changes in flora activate the inflammatory cascade, leading to high expressions of pro-inflammatory mediators. A combination of all these events culminates in the manifestations of NEC.

Several randomized controlled trials in last 2 decade have evaluated probiotics in neonate.(15-24) An updated meta-analysis of 11 RCTs comprising of 2176 neonates has been published recently in Pediatrics. (25)The meta-analysis gives some clear answers as to use of probiotics in VLBW neonates.

Preterm VLBW neonates receiving Probiotic showed 65% reduction in the incidence of NEC RR: 0.35 [95% confidence interval (CI): 0.23–0.55]; P <0.00001) The numbers needed to treat (NNT) with probiotics to prevent 1 case of NEC was 25 (95% CI: 17–34). TSA results showed evidence to support at least 30% reduction in the incidence of NEC (alpha= 0.05; power: 80%). Further there was 58% reduction in all cause mortality (RR: 0.42 [95% CI: 0.29–0.62]; P <0.00001 in babies in probiotic group. The NNT to prevent 1 death from all causes by treatment with probiotics was 20 (95% CI: 14 –34). Meta analysis did not show any significant difference in the risk for culture positive sepsis between the two groups (RR: 0.98 [95% CI: 0.81–1.18] P 0.80). Time required to reach full enteral feeds was less in babies who received probiotic preparations (weighted mean difference: - 5.03 days [95% CI: - 5.62 to - 4.44]; P < 0 .0001).

The authors have concluded, "The dramatic effect sizes, tight confidence intervals, extremely low P values, and overall evidence indicate that additional placebo-controlled trials are unnecessary if a suitable probiotic product is available. Given the totality of the evidence, withholding probiotic preparation in an eligible baby is now almost unethical "(25) Previously the authors of a Cochrane review article recommended probiotics for infants of >1000 g birth weight but also recommended more research in smaller infants (26;27). However, in a subsequent trial,(22) probiotics reduced death or NEC in infants with a birth weight of 500 to 750 g.

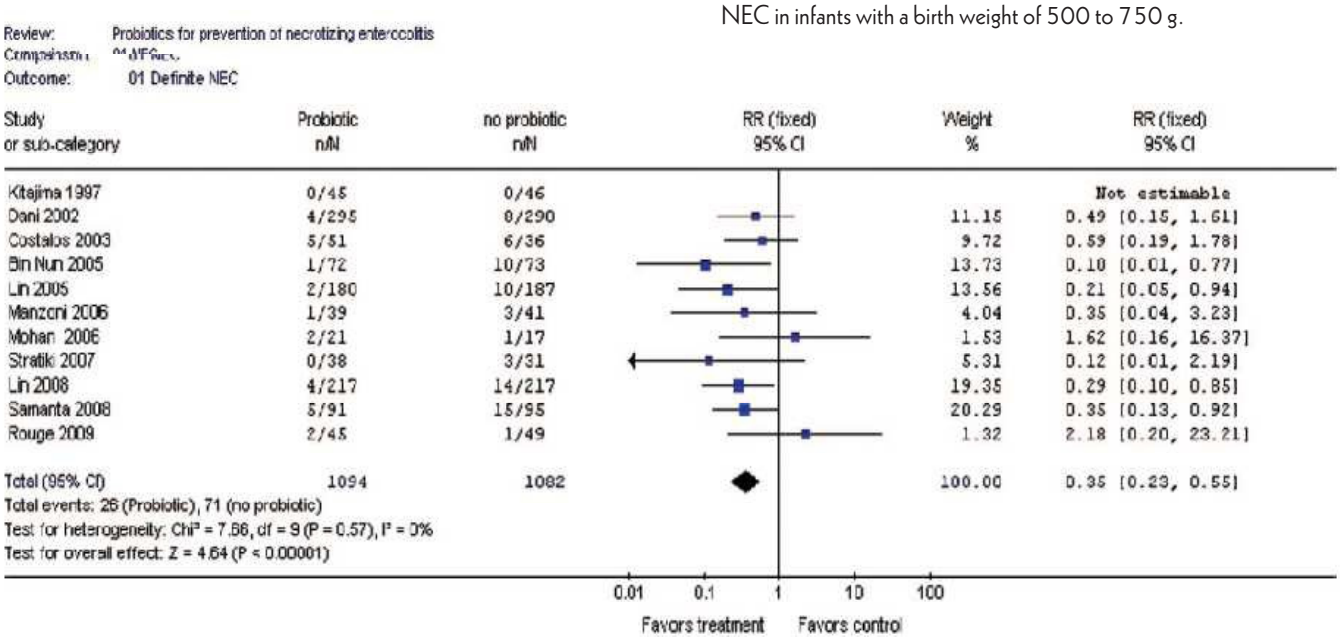

Fig 1.: Forest plot – Probiotics for prevention of Necrotizing Enterocolitis (NEC) In a time sequential cumulative metanalysis done by Tarnow-mordi et. al. it is evident that evidence is getting stronger and stronger after year 2005 and it is highly improbable that any further studies done on this topic will revert these findings. (28) Fig.

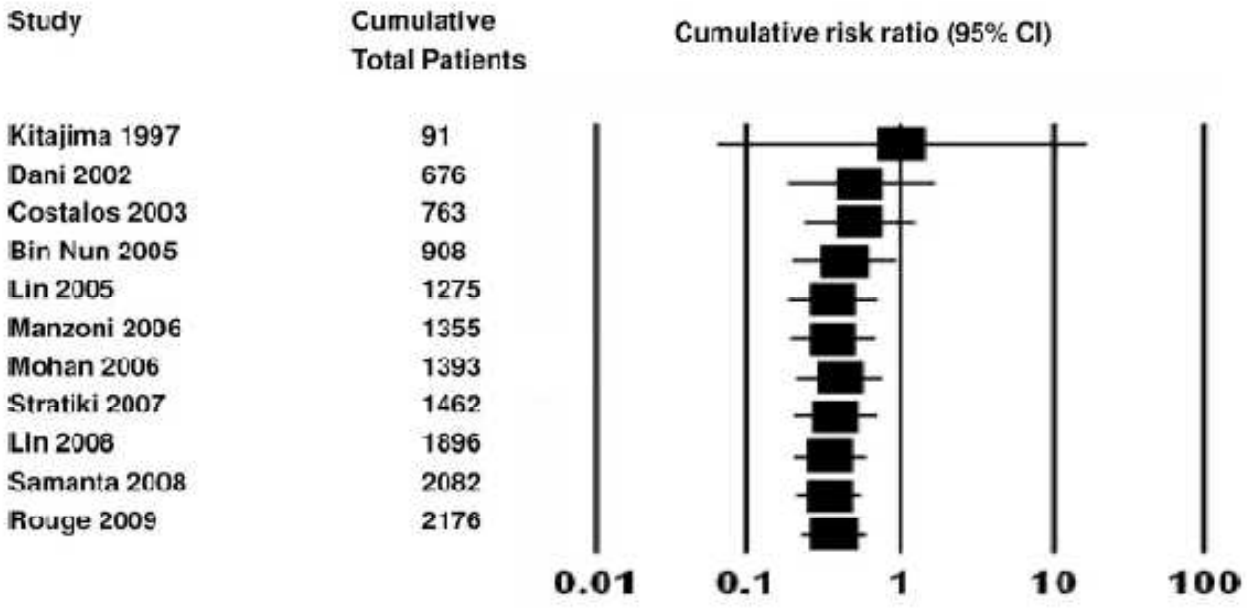

Fig.2 Cumulative meta-analysis of probiotics trials by Tarnow Mordi et. al (28)

Is more evidence needed before introducing this inexpensive, apparently safe and effective treatment? The authors comment that "the evidence that probiotics reduce mortality
rates is as conclusive as that for surfactant for respiratory distress syndrome, cooling for hypoxic ischemic encephalopathy, or antenatal corticosteroids for threatened preterm labor." The authors conclude that "parents of all infants who met eligibility criteria from earlier studies be offered probiotics after adequate quality control of reconstituted product."(28)

There is wide variation in the probiotic strains, dosage, duration, practicalities of administration among various trials. However now it can be safely said that probiotics "in general" are beneficial in this high-risk population. Further trials should not use placebo control but should compare different species, dosages etc. to find out unanswered questions(25).

Probiotics in other Gastrointestinal problems

Infant colic is a very common problem seen in early infancy. In an RCT efficacy of Lactobacillus reuteri on infantile colic and its relationship to the gut microbiota was studied. The study demonstrated that, there was significant reduction in daily crying time in infants receiving probiotics by day 7. During the study, there was a significant increase in fecal lactobacilli (P=.002) and a reduction in fecal Escherichia coli and ammonia in the L reuteri group only (P=.001). There were no differences in weight gain, stooling frequency, or incidence of constipation or regurgitation between groups, and no adverse events related to the supplementation were observed.(29). However more studies are required to make this as a general recommendation for treatment of infant colic.

Prevention of infections

Various studies have shown that probiotic may prevent growth of certain pathogenic bacteria and fungi. In vitro studies showed certain strains of lactobacilli have strong inhibitory properties against candida species.(30). In a PICU setting when probiotic was used for prevention of nosocomial infection it was shown to be not effective in reducing sepsis, in fact there was a trend towards increase in sepsis.(31) The meta-analysis by Deshpande et. al. shows that probiotics do not reduce or increase incidence of culture positive neonatal sepsis (25). Based on current knowledge probiotics cannot be recommended for prevention of nosocomial sepsis in newborns.

Studies for prevention of preterm delivery

Occurrence of preterm delivery has been linked to abnormal vaginal bacterial flora. Women who reported habitual intake of probiotic dairy products had a reduced risk of spontaneous preterm delivery. (32) Further studies are underway to give clear answer to this common problem.(33)

Atopic Dermatitis

The prevalence of atopic dermatitis (AD) has risen over the past decades, especially in western societies. According to the revised hygiene hypothesis this increase is caused by a changed intestinal colonization pattern during infancy, which has an impact on the immune system. Manipulating the intestinal microflora with pro-, pre- or synbiotics is an innovative way to prevent or treat AD.

In a randomized controlled trial, 112 pregnant women with a family history of allergic diseases received probiotic supplement or placebo, starting at 4-8 wks before delivery and continuing until 6 months after delivery. Infants were exclusively breast-fed during the first 3 months, and were subsequently fed with breastmilk or cow's milk formula from 4 to 6 months of age. The prevalence of eczema at 1 yr in the probiotic group was significantly lower than in the placebo group (18.2% vs. 40.0%, p=0.048). However, there was no difference in serum total IgE level or the sensitization against food allergens between the two groups. (34) In another similar study, Supplementation with Lactobacillus GG during pregnancy and early infancy neither reduced the incidence of atopic dermatitis nor altered the severity of atopic dermatitis but was associated with an increased rate of recurrent episodes of wheezing bronchitis.(35) Mixture of probiotics and prebiotics may have a role in treatment of IgE associated Atopic Dermatitis.(36)

In an RCT on 171 mother-infant pairs, infants of atopic mothers, when

exclusively breastfed over 2.5 months, had a higher risk of sensitization at the age of 12 months. This risk could be reduced by the use of probiotics during pregnancy and lactation.(37)

Thus studies evaluating use of probiotics have shown varied results. Meta analysis by Lee et. al (2008) evaluated 10 RCTs (6 prevention studies (n = 1581) and 4 treatment trials (n = 299)). It showed significant reduction in Pediatric Atopic Dermatitis severity score (PAD score) for prevention studies. (38). Recent meta analysis of randomized controlled trials on prevention or treatment of AD or food allergy does not support routine use of pro, pre or synbiotics.(39;40)

Cochrane review on probiotic supplementation to reduce infant allergy, published in 2007 showed significant reduction in infant eczema (typical RR 0.82, 95% CI 0.70, 0.95) with use of probiotics. However, there was significant and substantial heterogeneity between studies. When the analysis was restricted to studies reporting atopic eczema (confirmed by skin prick test or specific IgE), the findings were no longer significant (typical RR 0.80, 95% CI 0.62, 1.02). Authors concluded, currently there is insufficient evidence to recommend the addition of probiotics to infant feeds for prevention of allergic disease or food hypersensitivity. Further studies were recommended. (41)

Safety of probiotic use in neonate

A fragile preterm VLBW receiving a live microbial supplement is at risk of development of infection from the probiotic itself. There have been occasional case reports of sepsis caused by the probiotic bacterium(42). However various RCTs and long term use in certain units have shown that usage of these probiotics is safe.(6;25;43)

Long term benefit studies

Oral probiotics given to Preterm VLBW infants at 1 week after birth to reduce the incidence of NEC did not affect growth and neurodevelopmental and sensory outcomes at 3 years corrected age(44). It is critical that authors of all trials in this subject report long-term neurodevelopmental outcomes, however we have to remember that definite NEC, which can be prevented by using probiotic is associated with higher risk for long-term NDI in preterm VLBW neonates.(25)

Which probiotic preparation to use?

It is argued that the probiotics available in the market may not have live organisms and they may not colonize the gut. However recent RCT in neonate comparing killed Lactobacillus acidophilus supplementation with living Lactobacillus acidophilus showed similar benefits in terms of reduction in incidence of NEC and gut colonization(45). It is proposed that liberation of substances (bacteriocidins) from the dead probiotics may be responsible for beneficial effects of killed probiotic supplement. (45). Studies carried out in neonates have used more than 10 different probiotic preparations. Further studies are necessary to find the best probiotic preparation to use in neonates.(25)

Probiotics in infant milk substitutes

Probiotic added formula preparations; Hypoallergic formulas (protein hydrolysate containing) are available in international market. These formula preparations have been shown to increase gut colonization with probiotic bacteria, but these did not persist in the bowel once probiotic administration had ceased (46). Cutaneous electrogastrography (EGG) and ultrasound gastric emptying (GE) studies showed that feeding preterm infants with a formula supplemented with prebiotics or probiotics may stimulate gastric emptying ,mimicking the effect of breast milk(47). However, overall studies have failed to demonstrate advantage over formulas without them(41;48).

Some of the common food items are also being manufactured with added probiotics in them eg. probiotic ice cream etc. with the view that they are beneficial.

Conclusion

Current evidence strongly suggests that probiotic use in preterm VLBW infants, reduces risk of definite NEC and all cause mortality by more than 50% and it also improves time required to reach full feeds, without causing any significant side effects. However further studies are required to define which species are best to use?, at what dose?, and for how long? (54). The opinion in medical fraternity is divided at this stage, over routine use of probiotics in VLBW infants. Some experts have warranted cautious approach for the use (49-53), while others have questioned whether it is ethical to not administer probiotics when there is already enough evidence (25;28). Clearly, this is an evolving therapy which needs periodic recommendations and position statements from peak professional bodies such as, National Neonatology Forum and Neonatology Chapter of IAP. This simple inexpensive therapy has great potential to improve neonatal 'intact' survival. Regarding role of probiotics in prevention or treatment of infant allergy and infant colic, currently there is insufficient evidence to draw any conclusions.

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Pigtail catheters for draining pneumothoraces

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Introduction

The incidence of pneumothorax is highest in the neonatal period as compared to any other time in life (Hidir & Omer, 2008). According to the same authors, the incidence of pneumothorax is 1-2% of all neonates while the incidence of clinically significant pneumothorax is much less at 0.07%. However the incidence rises sharply in neonates with respiratory distress syndrome where it can reach 5-20% (Hidir & Omer, 2008) while other studies have described that the incidence of pneumothorax in neonates ventilated for respiratory distress syndrome is as high as 35% (Tarnow-Mordi, Narang, & Wilkinson, 1985). However with the introduction of surfactant therapy the incidence of pneumothorax has been reported as 4% (de Boer, Jones, Ward, & Baume, 1993). There is increased risk of chronic lung disease, intraventricular haemorrhage and death following neonatal pneumothorax (Powers & Clemens, 1993) (Hill, Perlman, & Volpe, 1992).

It is also important to note that the treatment of neonatal pneumothorax is in itself associated with several complications like lung perforation, cardiac tamponade, phrenic nerve injury leading to diaphragmatic palsy and stomach perforation (Jung, Nelson, Jenkins, & WA., 1991), (MacDonald & Chou, 1986).

In a search for catheters which are less traumatic there have been reports of different smaller calibre catheters being used (Rowe, O'Neill, Grosfeld, Fonkalsrud, & Coran, 1995). One article describes the use of umbilical venous catheters for draining neonatal pneumothoraces (Arda, Gurakan, & Aliefendou, 2002).

In this article the author describes the recent use of "modified pigtail catheters" for pneumothoraces in neonates and explains why it might be simpler and safer as compared to the traditional trocar based chest drains.

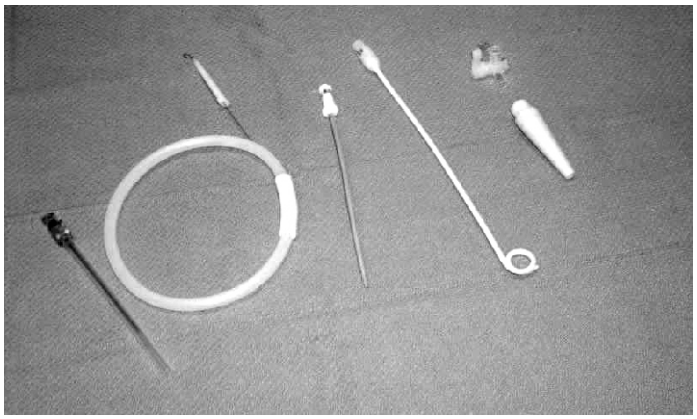
The pigtail catheter

The use of the pigtail catheter for non-traumatic drainage of air from the pleural cavity was described over 20 years ago (Lawless, Orr, & Killian, 1989). This article described the use of the pigtail catheter as a simple, safe and non-traumatic method in the treatment of pneumothoraces. These authors used an 8.5 French radiopaque polyurethane catheter and the catheter was inserted using the modified Seldinger technique.

Figure 1

The entire set is available as a pack. The catheter size varies between 5-12 Fr and it may be prudent to consider using the larger catheters in bigger sized babies and in situations like chylothorax where the draining fluid is more viscous.

Equipment



The technique of insertion

The first steps are positing of the neonate and preparation of a sterile field. The neonate should be positioned with the affected side up. Although the exact site for placement of the catheter varies based on the clinical indication, the usual site of placement is the 4th intercostal space in the midclavicular line. It is necessary as in many neonatal procedures to clean and drape the site of insertion. Analgesia is also important and depending on unit policies local anaesthesia or systemic opioid analgesics or both can be used. It is the author's practice to use both local and systemic analgesia during placement of the pigtail catheter.

The four essential steps in placing the catheter are:

1. Insertion of the needle into the pleural space
2. Introduction of wire through the needle
3. Dilating the site of the needle entry on the skin
4. Introducing the pigtail catheter

The needle is inserted in the above the rib in the 4th intercostal space to avoid damage to the neurovascular bundle. A 10 ml syringe is attached to the syringe. The needle is advanced and accompanied by withdrawal of the syringe plunger. When air or fluid is drained the needle is secured in position with one hand and the syringe is then removed.

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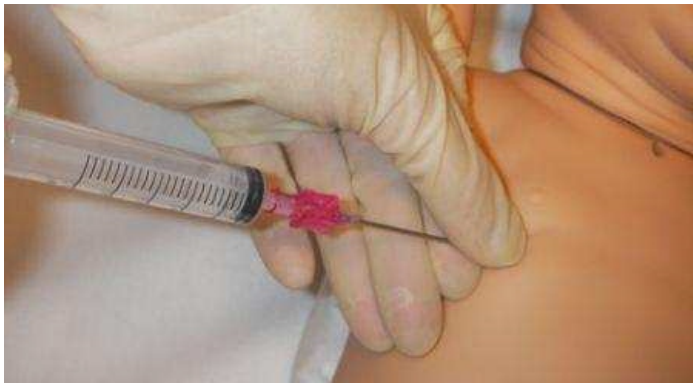
The next step is to attach the guidewire sleeve to the hub of the needle and to advance the guidewire through the needle. Guidewires have a marking and when this marking has been reached at the hub of the needle, it should not be introduced further. Once the guidewire is in the pleural cavity, it should advance easily and smoothly. Do not force the guidewire in. This is likely to cause false passages and more importantly lead to trauma to the underlying structures.



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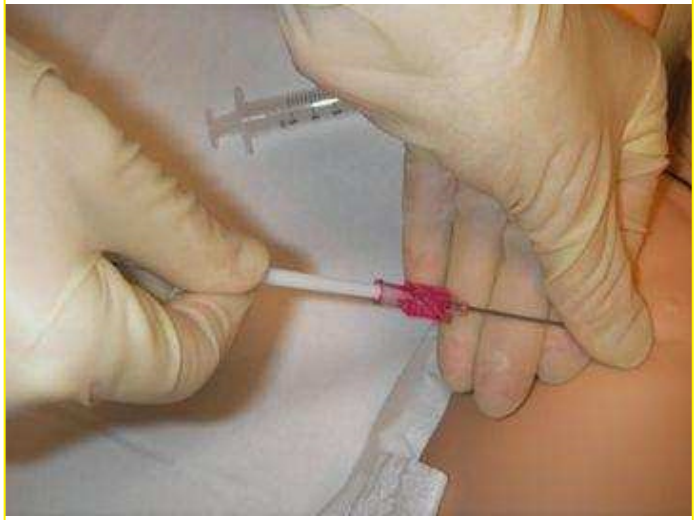
In the next step, the needle is withdrawn while holding the wire in place. The wire is perhaps the most important equipment in the whole procedure. It is necessary to keep it in place till the pigtail is in situ. The wire should be held steady and it should not advance or withdraw.

Next the dilator is passed over the wire. It may be necessary to make small incision in the skin using a scalpel to facilitate the entry of the dilator into the pleural space. The dilator should be introduced through the skin for not more than 1 cm. The dilator is then withdrawn over the wire. Note that the wire still remains in exactly the same position.



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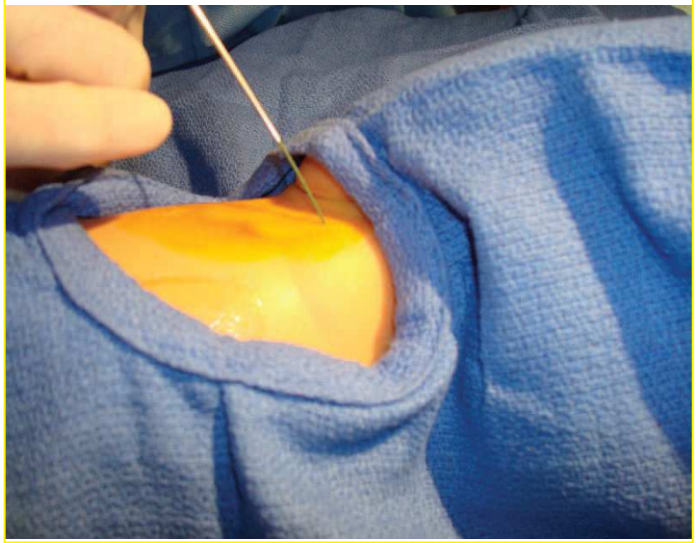
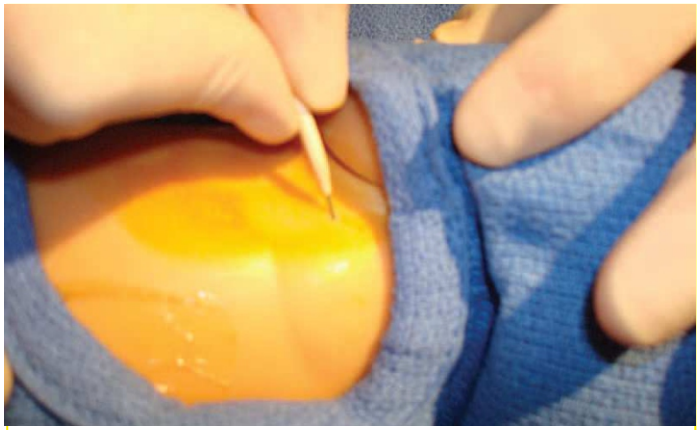
The pigtail catheter is now introduced over the wire till all the portholes are inside the baby. The wire can then be removed.

Copied from (Cates, 2009)

It is helpful to make sure that the catheter is in situ by palpating the thorax around the site of insertion. Rarely the catheter has been inserted into the subcutaneous tissue and can be easily detected by palpation.

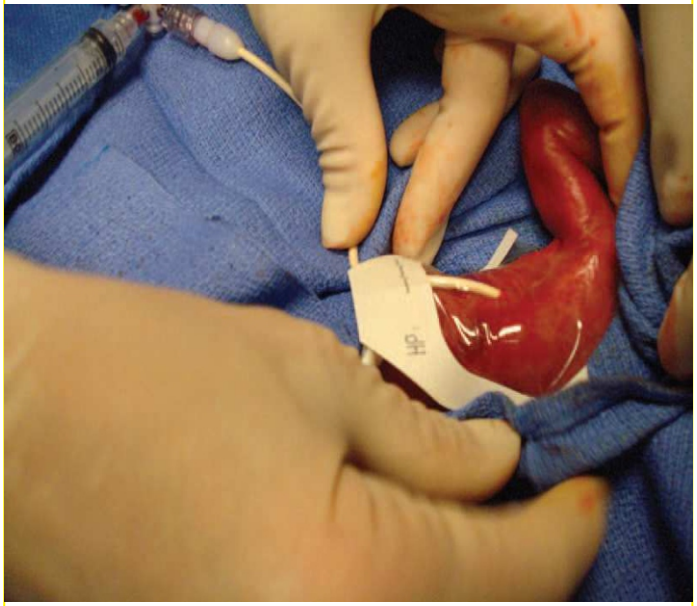
The catheter needs to be secured in position. This can involve a placing a suture on the skin and tying it around the catheter. Sometimes a suture is not used. Regardless of whether the suture is used or not, the catheter is then secured in position by using a clear dressing like tegaderm





Copied from (Cates, 2009)

Finally the catheter is connected via the adapter to either a flutter valve device or to an underwater seal.



Discussion

Pneumothorax is a common condition in neonatal medicine although only a small proportion of neonates with pneumothorax are symptomatic (Hidir & Omer, 2008). Even among those who are symptomatic, the pneumothorax may resolve with expectant management.

However in a small minority of infants the pneumothorax will need insertion of a catheter. The pigtail catheter has been proposed as a safe, simple, non-traumatic way of treating a pneumothorax (Cates, 2009) (Jung, Nelson, Jenkins, & WA., 1991).

The studies comparing the effectiveness of the pigtail catheter and the traditional chest drains have concluded that the pigtail catheter is at least as effective as the traditional chest drain in the treatment of pneumothoraces in neonates (Lawless, Orr, & Killian, 1989). Studies in animals have also confirmed that the pigtail catheter is effective in the treatment of pneumothorax (Valtolina & Adamantos, 2009). Furthermore in studies done in adult patients the small bore catheters have been found to be useful in pleural effusions, chylothorax and empyaema (Caffarotti, Armi, & Cusumano, 2011). There are no reports to indicate that the pigtail catheter is less efficacious. On the basis of the current evidence the use of small bore catheters

inserted using the Seldinger technique are as efficient as the traditional chest drains.

One major advantage of the small bore catheters is the ease of insertion. Indeed several studies have supported this view (Cates, 2009) (Jung, Nelson, Jenkins, & WA., 1991) (Lawless, Orr, & Killian, 1989) (Valtolina & Adamantos, 2009). The author is not aware of any journal article or report favouring the large bore catheter for ease of insertion. Thus it is reasonable to conclude at this point that small bore catheters offer an advantage over the large bore catheters in terms of ease of insertion.

The next issue is regarding the safety of the small bore catheters as compared to the large bore catheters. Small bore catheters have been reported to have caused organ perforation because of aberrant placement. This includes perforation of stomach, lung, heart, great vessels and stomach (Henry, Arnold, & Harvey, 2003).

Another study described that though there were few complications related to insertion of the small bore catheter, there was a high incidence of dislodged and blocked chest catheters (Davies, Merchant, & McGown, 2008). It must be noted that this study was conducted on adult patients. Also of note is the fact that in over 65% of cases the indication for the chest drain was malignant effusion or chest empyaema. As both these conditions are associated with drainage of a more viscous fluid, the complication of blockage is more likely in this setting.

Some authors have also raised concerns about the need for training junior doctors involved in performing the procedure as lack of familiarity, suboptimal patient position and poor imaging have contributed to serious harm occurring to patients (Maskell, Medford, & Gleeson, 2010). This article has described the complications of chest tube insertion following the widespread use of small bore catheters in the UK. This article does not compare the safety of larger bore catheters with the small bore catheters.

Horsley et al have described that the serious organ injury which was seen with the trocar based catheters is rarely seen with the small bore catheters (Horsley, Jones, White, & Henry, 2006).

It is the author' opinion that chest drain insertion in neonates is a major procedure and should only be performed by personnel competent in the procedure. Because of the multiples types of chest drains, there is a need to train the personnel in the type of chest drain which is used on a particular unit. Even when the trocar based chest tubes are used, it would be appropriate to use blunt dissection to open the thorax and not to go for a blind chest drain insertion with the trocar.

Summary

Neonatal pneumothorax is a condition associated with serious morbidity and mortality. The treatment of pneumothorax using a chest tube is itself associated with serious complications. The use of a small bore catheter is definitely advantageous in terms of ease of placement and efficacy of treatment. Despite the absence of high quality evidence regarding safety of small bore catheters as compared to the trocar based catheters, it seems prudent to assume that using the smaller calibre catheter with a fine needle is likely to cause fewer traumas. Why go for a blind shove with a trocar when a smaller catheter placed under control can serve the same purpose?

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Heated High Flow Nasal Cannulae Yet another method of Non-Invasive Respiratory Support in Preterm Infants

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What are the common non-invasive methods of respiratory support in premature infants?

There are a variety of non-invasive ways in which respiratory support can be provided to preterm infants with apnoea or parenchymal lung disease. These include nasal cannula, nasal continuous positive airways pressure (CPAP) and nasal intermittent positive pressure ventilation (NIPPV).

Nasal cannulae typically provide unheated, non-humidified and unblended oxygen (i.e., 100% oxygen) at flow rate of ≤ 1 L/min via two short and thin tubes (usually < 1 cm in length) that sit just inside the nostrils without occluding them. Although they may provide some positive end expiratory pressure (PEEP) these low flow nasal cannulae (LFNC) are commonly used in convalescing preterm infants, often with chronic lung disease as a source of oxygen and have not been thought to provide significant support to the infant's pulmonary function.1

Nasal CPAP involves administration of blended, humidified and heated oxygen typically via short binasal prongs that snugly fit into the infant's nostrils with minimal leakage. The pressure delivered by the circuit for nasal CPAP is measured and regulated directly. It is widely used in premature and term newborns and provides an effective, safe alternative to endotracheal intubation, reduce extubation failure, treat apnoea and respiratory distress syndrome and, by minimising duration of mechanical ventilation, may reduce chronic lung disease.2,3

NIPPV involves nasal CPAP with superimposed ventilator delivered inflations, to a set peak pressure and at a set rate. NIPPV may be delivered by nasal mask or prongs and some devices attempt to synchronise inflations with the infant's inspiration. There is evidence that NIPPV reduces the rate of extubation failure in preterm infants. There is some evidence for using NIPPV in the treatment of apnoea, but this is inconclusive. There is limited observational evidence that NIPPV may be used as a primary mode of ventilation.4

What is High Flow Nasal Cannulae (HFNC) system?

HFNC have been used to refer to the administration of oxygen or blended oxygen and air to newborn infants via nasal cannulae at flow rates higher than with LFNC. High flow rates have been shown to provide PEEP and the method has emerged more recently as a kinder, gentler CPAP.1,5

How is high flow delivery provided?

Principle

Medical gases are essentially anhydrous (without water) and require artificial humidification, depending on the flow rate used. Low flow gas can be delivered without humidification. As the delivered gas flow rate increases, however, humidification becomes more important because lack of humidification results in drying of the upper airways from "excess" gas (that which is not inspired into the lower airways during the respiratory cycle). This in turn results in mucosal irritation, nasal obstruction, bleeding and increases the risk of nosocomial infection. Heating of the delivered gas is inevitable to maintain humidification as unheated gas can not be adequately humidified even if it passes through humidifier. Thus high flow delivery system involves delivering heated, humidified gas at flow rate higher that 1 L/min.

Set up (Fig 1)

1. Air/Oxygen mixture(a) enters the humidifier(b) through tubing(c), where it gets heated to a set temperature of 370C and humidified to 44mg/L. Gas flow can be adjusted using a flow meter(d).
2. Water for injection bag (e) connected to the humidifier through tubing (f) helps to provide sterile source of water for humidification.
3. Humidification circuit equipment (Fisher & Paykel™) includes:

- Humidifier chamber (b)
- Pressure relief valve (g) which is usually set to a limit of 45 cm water. The valve has been designed to minimize the risk of excessive pressure being delivered to the infant in the event that the cannula prongs seal around the patient's nares while the mouth is closed.
- Extension tube (h) from humidifier base to nasal cannula. This contains Heater wire adaptor and helps to heat the gas mixture in the tubing.
- Temperature probe (I) placed close to the patient end of the tubing helps to maintain temperature of gas in the tubing through servo-control.
- Fisher and Paykel Optiflow™ nasal cannula with tubing delivers (J) humidified high flow directly into the nares.
- Size of Fisher & Paykel Optiflow® nasal Cannula (Fig 2) depends on size of infant's nares. In premature infants prongs with outer diameter of 2.4 mm are recommended.7
- The maximum flow rate allowed is dependant on the size of nasal prongs and is 6L/min in premature infants. Flow rate is adjusted in steps of 1, in a manner similar to adjusting PEEP in a CPAP device. Delivered pressure is proportional to flow, although it is not equivalent to flow rate. What this means is that flow rate of 5L/min provides higher PEEP compared to flow of 3L/min. It does not mean that flow of 5L/min provide PEEP of 5 cm/H2O nor does flow of 3L/min provide PEEP of 3 cm H2O.

Fig 1

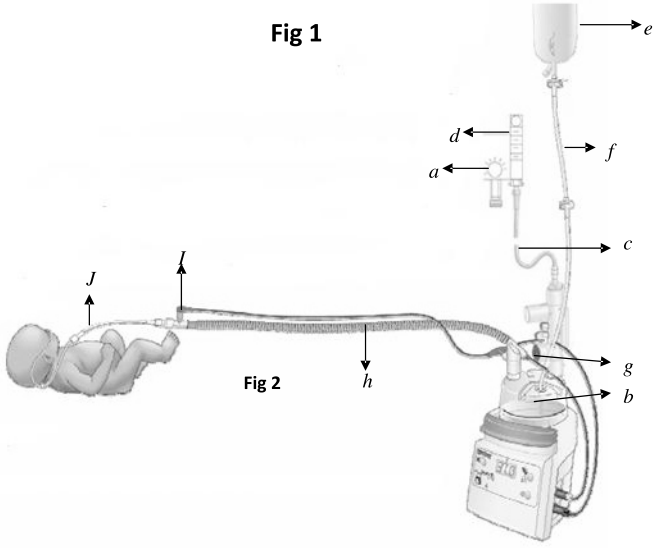

Fig 2

What are the various available HFNC devices?

Vapotherm (Stevensville, MD) and Fisher and Paykel Healthcare (Irvine, CA) manufacture high-flow nasal cannula devices that deliver breathing gases heated to near body temperature and highly saturated with water vapour, through small nasal cannulae at relatively high flow rates (1–8 L/minute).

How is HFNC different from nasal CPAP?

With nasal CPAP, the infant breathes from a pressurised circuit and it is possible to measure and regulate the pressure applied to pharynx. Safety valves ensure that the delivered pressure does not exceed the set level.

With HFNC, the calibre of tubing delivering the gas is significantly smaller, and consequently the resistance to flow and pressure in the circuit is much higher. Hence the pressure delivered to the airway can not be determined directly from the pressure in the circuit.,6 Flow rate and body weight determine the delivered pharyngeal pressure. Circuit flow is adjusted according to clinical effect and, although a pressure relief valve is often used, the circuit pressure is not routinely measured.8

What are the potential advantages of HFNC?

HFNC seems an attractive approach that would conceivably avoid trauma to the nose by using smaller, lighter and less bulky nasal cannula compared with the binasal prongs of CPAP. This is associated with less trauma to the nasal septum and distortion of the nares and enables easier parental interaction, kangaroo care and feeding, while improving the comfort of the infant.5

What are the potential disadvantages of HFNC?

High flow rates may generate excessive and variable PEEP. Excess PEEP is generated when the mouth is closed and tightly fitting cannulae are used.9 On the other hand almost entire PEEP may be lost when mouth is open.

Pressure generated at a given flow depends on infant's weight.8 It is conceivable that an adequate PEEP may not be generated in larger, more mature infants.

There have been concerns about contamination of the units used for administering HFNC with gram negative organisms including Ralstonia.10 One case has been reported associating HFNC with pneumocephalus, pneumo-orbitis and scalp emphysema.11 Other possible risks include gastric distension or perforation.

What is the current evidence for HFNC use?

Nair et al, in a prospective study compared HFNC versus nasal CPAP for preterm infants soon after birth for treatment or prophylaxis of RDS and showed that rates of respiratory failure (and consequent need for intubation) were similar between the 2 groups.12 For infants extubated following mechanical ventilation, Campbell et al found a significantly higher rate of reintubation in infants treated with HFNC.13 The most recent Cochrane metanalysis14 concluded that there is insufficient evidence to establish the safety or effectiveness of HFNC in comparison to nasal CPAP as a form of respiratory support in preterm infants and that HFNC used following extubation may be associated with a higher rate of reintubation than nasal CPAP.

Key Points : HFNC is emerging as a novel mode of non-invasive ventilation in preterm infants and is gentler on infants than the currently available modalities such as nasal CPAP and NIPPV.

Presently, there is insufficient evidence regarding the safety and efficacy of HFNC, although it seems to be at least as effective if not more than CPAP in premature babies with Respiratory Distress Syndrome.

Further randomised studies are required before its use can be widely advocated.

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