Guidelines for acute medical management of severe traumatic brain injury in infants and children

Praveen Khilnani

The guidelines for the acute medical management of severe traumatic brain injury in infants, children, and adolescents were published on June 6, 2003, as special supplements to Pediatric Critical Care Medicine, Critical Care Medicine, and the Journal of Trauma, ensuring a multidisciplinary audience of more than 30,000 specialty physicians. According to the Brain Injury Association of America, more than 1 million children in the US sustain brain injuries each year, of whom 250,000 are admitted to hospitals, 7000 die, and 30,000 are permanently disabled. Indian statistics though not available should be comparable at the least. Following is a summary of available evidence in the literature.

This information could be used to apply to care of head injuries infants and children in the Indian scenario.

Evidence highlights

1. Pediatric patients with traumatic brain injury should be treated in a pediatric trauma center or, failing that, a tertiary care hospital with pediatric trauma care capability.
2. Hypoxia must be treated appropriately; however, there is no evidence to support endotracheal intubation versus bag-mask ventilation during transfer to the hospital.
3. Prophylactic treatment with mannitol or mild hyperventilation is usually unnecessary but should be used in patients with evidence of cerebral herniation or worsening neurological function.
4. Intracranial pressure monitoring is indicated for children with a Glasgow coma score of less than 8, but it may also be employed for children in whom serial neurological examination is not feasible.
5. Treatment for increased intracranial pressure should be initiated when the pressure rises more than 20-25 mm Hg.
6. The sensitivity of ventricular catheters, external gauge transducers, or catheter tip pressure transducers in monitoring intracranial pressure appears equal. Subarachnoid, subdural, epidural, and externally placed monitors are less accurate.
7. Cerebral perfusion pressure should be maintained at more than 40 mm Hg. Further research is needed to determine an optimal cerebral perfusion pressure range.
8. The routine use of sedation and neuromuscular blockade in severe pediatric traumatic brain injury is not supported by scientific evidence. Coughing and bucking on the tube and suctioning maneuvers leading to increased intracranial pressure may necessitate their use, in practice.
9. Cerebrospinal fluid drainage via ventriculostomy is a first line option for refractory elevated intracranial pressure; lumbar drainage may be added in patients with open cisterns on imaging and without major mass lesions or midline shift.
10. Mannitol or hypertonic saline are both acceptable agents for lowering intracranial pressure.
11. Hyperventilation should only be used as a second line method to reduce refractory intracranial pressure. In this setting, the PaCO2 should be kept at 25-30 mmHg.
12. High dose barbiturates may also be employed in the treatment of refractory increased intracranial pressure. Patients receiving this therapy require extremely close monitoring for hypotension.
13. Hyperthermia has been postulated to increase secondary mechanisms of brain injury in adults. Therefore, hyperthermia should be avoided in younger patients. Hypothermia on the other hand, may be ben-
eficial, and when intracranial hypertension is refractory, the authors recommend that it be considered, despite lack of evidence.

14. Decompression craniectomy may also be considered to improve refractory intracranial hypertension. Surgical interventions may be more successful in patients with reversible brain insults.

15. There is no evidence to recommend steroid therapy in children with traumatic brain injury.

16. Although research had not directly addressed outcomes in pediatric patients with traumatic brain injury, nutritional support should be strongly considered with a goal of 130%-160% of resting metabolic expenditure.

17. Prophylactic antiepileptic medications are not recommended.

Conclusion

1. Prompt recognition and transfer of pediatric victims of traumatic brain injury is paramount to good outcomes
2. Intracranial pressure should be monitored and treated if >20 mm hg in children with severe brain injury
3. Mannitol, hypertonic saline, ventricular drainage, hyperventilation, barbiturates and hypothermia should be considered in refractory intracranial hypertension
4. Steroids and prophylactic antiepileptics have no role in traumatic brain injury in children.

Reference

Guidelines for the Prevention of Infections Associated with the Use of Vascular Catheters in Indian Intensive Care Units

Executive Summary of Recommendations


Members of the committee: Rajagopalan RE, (Chair); Arunkumar AS, Bhagwati AM, Divatia JV, Gopalakrishnan R, Kamat VN, Mani RK, Nagaraja P, Prayag S, Ramachandran B, Ramakrishnan N, Singhi S and Todi SK

Introduction

Blood stream infections associated with the use of vascular catheters carry significant morbidity. Increases in mortality attributable to such catheters have been clearly demonstrated. With greater use of these catheters in India, especially in the intensive care setting, there is an urgent need to develop infection-prevention guidelines that are sensitive to the local environment and practice patterns. While guidelines for prevention have been published in the West, their extrapolation, in an unmodified form, to the Indian milieu may not be appropriate. This executive summary presents India-specific recommendations made by an expert committee of the Indian Society of Critical Care Medicine (ISCCM). The major goal of the committee was not to develop Indian strategies de-novo, but to utilise pre-existing guidelines as the base, and to modify them based on Indian data and the opinions of the experts to provide a coherent set of recommendations that can be easy to apply in this country.

Besides catheter infection, many other clinical and practical concerns influence the choice of site, duration and care of vascular catheters. As a consequence, during the placement and use of vascular catheters, the recommendations of this committee should be weighed against these non-infectious considerations as well.

Methods

The ISCCM constituted an expert committee of intensivists, infectious disease specialists and microbiologists in August 2003. Subcommittees dealing with the specifics of the epidemiology of catheter infection, peripheral vascular catheters, central venous catheters, arterial lines and problems related to paediatric patients were given a four month period to review the guidelines of the American Centers for Disease Control and Prevention (CDC) and that of the UK Infection Control Society (UKICS). They also reviewed any recent literature that was published after the release of these guidelines and focussed on literature originating from India. The committee convened a 2-day consensus conference in December 2003, when the literature was presented and evidence was graded using a standardised method. Recommendations were graded into three categories based on the quality of evidence and on their interpretation by the expert committee (Table 1). The current paper provides only the final recommendations of the committee and references are provided only for features that differ from other published guidelines. Full publication of the evidence-base and rationale is planned for a later date.

Table 1: Modified Infectious Diseases Society of America–United States Public Health Service Grading System for used for ranking recommendations in this executive summary

<table>
<thead>
<tr>
<th>Quality of evidence</th>
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<td>Grade</td>
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<td>I</td>
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Grade
- Evidence from ≥1 properly randomized, controlled trial
- Evidence from ≥1 well-designed clinical trial, without randomization; from cohort or case-controlled analytic studies (preferably from ≥1 center); from multiple time-series; or from dramatic results from uncontrolled experiments
- Evidence from opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

Table 1: Modified Infectious Diseases Society of America–United States Public Health Service Grading System for used for ranking recommendations in this executive summary
SECTION 1

Epidemiology

While the epidemiology of catheter infections is well described in western literature, data from Indian hospitals is scarce.\(^5,7\) Though one study of intermediate-term central catheters in children reports rates of catheter associated bloodstream infection (CABSI; See appendix for definitions) of 1.3/1000 catheter days\(^5\) (unusually low even in comparison with Western data), anecdotally, rates are felt to be much higher in most Indian ICUs. The definitions of catheter infections are very variable in the published studies and need to be standardised. The committee was concerned about the high frequency of gram-negative infections in these reports,\(^6,7\) as it implies major inadequacies in site care, in the prevention of hub infections or the contamination of the infusate,\(^8\) medications administered and antiseptics used for site care. The high frequency of fungal colonisation of catheter tips and candidemia (about 45%) in a paediatric study\(^6\) is also unusual and requires further evaluation.

Recommendations

1. All Institutions and intensive care units should measure CABSI rates (A)
2. For purposes of surveillance all BSIs count as CABSI (A)
3. Blood cultures are to be drawn only when BSI is clinically suspected (and preferably before antibiotics are started) (A)
4. Routine cultures of vascular catheter tips are not recommended (A)

Standard methodology for blood culture, vascular catheter-tip culture and calculation of CABSI rates are encouraged (Appendix).

General measures to reduce risk of CABSI

Though processes specific to catheter care are the most important way to reduce CABSI the committee emphasizes that broader measures aimed at training and education of healthcare workers would be equally important in the prophylaxis of these infections.

Recommendations

5. Healthcare workers need to be educated and trained in the insertion, maintenance and use of vascular catheters. Infection control programs should be developed and strictly adhered to (A)
6. Attempts should be made to guarantee adequate staffing to minimize BSI (A)
7. Dedicated vascular access teams are recommended when feasible (A)
8. Systemic antibiotics are not recommended for the prevention of CABSI (A)
9. All vascular catheters should be removed when there is no clinical indication for their continuation (A)

Hand Hygiene\(^9\)

As studies related to nosocomial infection clearly demonstrate a reduction in their occurrence with adherence to good hand hygiene, we feel that it should be incorporated into protocols of catheter care as well. Specific deviations from this general protocol are reported in each section.

Recommendations

10. Strict hand hygiene with alcohol based hand rubs or with liquid antiseptic soap and water is recommended before and after every contact with the patient (A)
11. Hand hygiene is mandatory even with the use of gloves (A)

A protocol for hand hygiene is provided in the appendix.
Short peripheral intra-venous catheters

Short, peripheral intravenous catheters (IV) are the most commonly used vascular access method in hospitals and intensive care units. Available data indicate that BSI rates are very low with the insertion of these catheters. On the other hand phlebitis induced by local infection, mechanical trauma and the corrosiveness of injectates and drugs is very common. The recommendations made in this section aim to reduce the frequency of phlebitis.

The committee has been sensitive to the cost issues associated with the frequent catheter changes that are usually recommended, and has suggested that, in the absence of local complications, peripheral i.v. catheters be left in-situ for longer durations of time, based on an analysis of current evidence. In addition recent data clearly indicates that disinfecting the hands with an antimicrobial rub or wearing clean gloves during catheter insertion reduces the rate of local complications, including phlebitis, when compared with placing lines with bare hands after routine hand wash with a non-medicated soap. Finally, many local practices such as securing the catheter by direct application of an adhesive plaster (without sterile gauze) and discontinuous use of intravenous administration sets have not been adequately evaluated in the literature for the committee to make well-defined recommendations. The committee also felt that the use of venous cut-downs should be discouraged when percutaneous access options were available.

Recommendations

Site preference
1. In adults, IVs should be inserted in the hand rather than wrist or forearm (A)
2. Insertion of IVs in the lower extremity is not recommended except in children (B)

Catheter material
3. Use either non-PVC (polyvinyl chloride) plastic catheters or steel needles (e.g. scalp vein sets) to minimize the incidence of phlebitis. However, there is an increased potential for extravasation with steel needles (A)

Hand hygiene
4. During catheter insertion, hand disinfection using an antiseptic rub is preferred to routine wash with unmedicated soap (A)
5. The use of clean gloves after hand hygiene is recommended (A)

Skin preparation
6. Prepare clean skin with 70% alcohol solution (A)
7. Use of acetone or ether is not recommended (A)
8. Once prepared, the site of insertion should not be palpated (A)

Dressings; types & frequency of change
9. Use either sterile gauze or sterile transparent dressing at the catheter site (A)
10. No recommendation can be made on the practice of direct application of adhesive plaster to secure catheters (Unresolved)
11. Keep dressings on for the duration of the catheter, unless it is soiled, loosened or moist. (A)

Monitoring & Surveillance of site
12. Daily palpation over the intact dressing for signs of phlebitis is essential (A)
13. Routine removal of gauze dressings is not recommended for surveillance of the site (A)
14. The dressing should be removed if palpation through the gauze is not possible, or if tenderness warmth or swelling is noted during surveillance. Direct inspection of the site is essential in these situations.

Duration & Catheter replacement
15. Do not routinely replace catheters before 96 hours unless there are signs of phlebitis, infection or malfunction (A)
16. In the absence of phlebitis, infection or malfunction, IVs may be left for longer periods with close surveillance of the site. (B)
17. In children, IVs may be left in place as long as clinically necessary, unless there are signs of phlebitis, infection or malfunction (A)

Replacement of administration sets
18. Do not routinely replace administration sets before 96 hours (B)
19. Administration sets used to infuse lipid based parenteral solutions and blood products should not be left in place for longer than 24 hours (A)
20. No recommendation can be made from existing data on the practice of reusing administration sets in a given patient for discontinuous infusions (Unresolved). However, the consensus group discourages this practice (C)

Value of in-line filters
21. There is no value of in-line filters for the prevention of catheter infection (A)
Stopcocks & side ports
22. Catheters with injection side ports can be safely used with standard hygienic precautions (A)
23. Cap all stopcocks which are not being used (A)
24. Clean injection ports with 70% alcohol before access (A)

Cut-downs
25. Do not routinely use cut-downs for peripheral venous access (A)

26. In an emergent situation when no alternative route of venous access is possible, a cut-down approach to peripheral venous access may be attempted. Such a catheter should be removed within 24 hours (A)

Anticoagulant flush
27. In catheters at low risk for local complications, heparin is not recommended over normal saline flushes for the maintenance of patency or the reduction of phlebitis. (B)
SECTION 3

Central Venous Catheters

(With a contribution from Dr. A. Date)

Central venous catheters (CVC) are now widely used in Indian intensive care units. They are used as vascular access for haemodynamic monitoring, parenteral nutrition, and the administration of fluids and drugs. However, these central venous catheters amplify the risk for local and systemic infections and increase the mortality rates of patients. Given that the predisposition for CRBSI is influenced by the duration and purpose of the central venous catheter, the committee has focussed only on short-term non-tunnelled catheters. Thus long-term catheters used for parenteral nutrition, haemodialysis and chemotherapy are not covered by these guidelines. Peripherally inserted central catheters are also not discussed.

Once again, the committee focussed on the costs involved in frequent replacement of the catheters and in the use of newly developed antibiotic- and antiseptic-impregnated catheters. With the published experience overwhelmingly against routine (scheduled) changes of central catheters all current guidelines recommend prolonged use of CVCs. The committee endorsed this opinion. However, though there is high quality data in favour of the impregnated catheters, the enormous expenses involved in the purchase of these catheters and the concerns about the inadequacies of older versions of these catheters, has led the committee to de-emphasize their role in the prevention of CRBSI and has shifted the focus to simpler, less expensive alternatives.

Thus the use of maximal sterile barriers during placement of catheters, the avoidance of the femoral site for catheter placement in adults and appropriate catheter site preparation prior to insertion were viewed as far more cost-effective processes in reducing catheter infection. With regards to the last issue, the committee felt that though the evidence in general favoured aqueous or alcohol-based preparations of chlorhexidine, there are some questions regarding the efficacy of preparations with lower concentrations of chlorhexidine. We have suggested that 10% povidone iodine solution is an acceptable alternative at present. We also noted that the vast majority of Indian formulations of povidone iodine are only of 5% strength and this concentration has not been evaluated in clinical studies of catheter infection. We recommend that the lower strength of this solution not be used in the preparation of the CVC site.

Recommendations

Site preference
1. In adults, subclavian vein cannulation is preferred to the jugular or femoral sites to reduce risk of infection. (A)
2. Any site (including the femoral vein) is acceptable in children as the infection risks are not significantly different (B)
3. In the selection of a site, weigh the non-infectious risks (haemorrhage, pneumothorax) against the benefits of reducing CRBSI (A)

Catheter material & type
4. Use Polyurethane or Teflon® catheters rather than catheters made of polyvinyl chloride/polyethylene to reduce risk of infection (B)
5. The decision to use multi-lumen catheters and the number of lumens used should be influenced by the clinical needs of the patient, rather than by the marginally increased risk of infection associated with use of multi-lumen catheters (B)

Antibiotic coated Catheters
6. Antibiotic coated catheters may be used for short term CVCs likely to remain in place for more than five days (A)
7. They may be considered in patients with high risk of infection (neutropenia, burns) (C)
8. The use of antibiotic coated catheters should not be a substitute for strict adherence to catheter insertion and maintenance protocols (A).

Hand hygiene
9. Hand hygiene procedures must be strictly followed (even when gloves are worn) before and after injection, blood sampling, dressing or any contact with the CVC or insertion site. (A)
10. For the insertion of CVCs, full scrub (up to the elbows) with an antiseptic solution is recommended (A)

Aseptic technique
11. Use maximal sterile barrier precautions for the insertion of a central venous catheter. (A). These include the use of cap, mask, sterile gloves, full-sleeved sterile gown, and large sterile drapes.
12. Pulmonary artery catheters should have a sterile protection sleeve. (A)

Skin preparation
13. Aqueous or alcoholic chlorhexidine (0.5-2%) is preferred to povidone-iodine for cleaning the skin prior to CVC insertion (A)
14. If chlorhexidine solutions are not available, 10% povidone-iodine is an acceptable alternative. (B)
15. 5% povidone-iodine solution is not recommended for site preparation (B)
16. The antiseptic solution must be allowed to dry on the skin before insertion of the CVC. Povidone-iodine must remain on the insertion site for at least 2 minutes, if not dry before insertion. (A)

17. Do not apply organic solvents (e.g. ether) to the skin before insertion of the catheter or during dressing changes. (A)

**Dressings; types; frequency of change**

18. Use either sterile gauze or sterile, transparent, semi-permeable dressing to cover the catheter site. (A)

19. Do not replace dressings daily. However any dressing that is moist, loosened, or soiled should be replaced (A).

20. A Gauze dressing must be replaced every 2 days, whereas transparent dressings must be changed every 7 days (A)

21. When there is excessive perspiration over the catheter insertion site, or if the site is bleeding or oozing, a gauze dressing is preferred over a transparent dressing. (C)

22. Do not use topical antibiotic ointments or creams at the insertion site (A).

23. No recommendations are made regarding use of povidone iodine ointment at the insertion site (Unresolved issue) except for haemodialysis catheters (A)

**Monitoring & Surveillance of site**

24. When gauze dressings are changed every 2 days, the site must be inspected for purulence and erythema and palpated for tenderness and induration (A)

25. In patients with transparent dressings, daily surveillance of the site should be performed without the removal of the dressing (A)

**Systemic antibiotics**

26. Administration of intra-nasal or systemic antibiotics to prevent catheter colonization or BSI is not recommended, either prior to catheter insertion or during catheter maintenance (A)

**Anticoagulant flush / lock**

27. Heparin flushes and locks used to prevent catheter thrombosis are not recommended for the prevention of infection (A)

**Catheter replacement**

28. Routine (timed) replacement of CVCs is not recommended as a method of infection-control (A).

29. Do not routinely replace catheters in patients with fever explained by another focus of infection or non-infectious cause (B)

30. When a CVC has been placed with less than maximal sterile precautions (e.g. in an emergency) it should be replaced as soon as possible, and in any case, no later than 48 hours after insertion (C)

31. Replace any short-term CVC if purulence is observed at the insertion site (A)

32. Replace all CVCs if the patient is hemodynamically unstable and CRBSI is suspected (B)

33. Remove catheters as soon as they are not needed. (A)

**Over-the-guide wire exchanges**

34. Routine replacement of CVCs over a guide wire is not recommended as an infection-control measure. (A)

35. A CVC may be changed over a guide wire to replace a malfunctioning catheter or to convert an existing catheter (e.g. CVC to pulmonary artery catheter or vice versa) if there is no evidence of infection at the catheter site. (B)

36. Maximal sterile barrier precautions must be used during an over-the-guide wire catheter exchange. After removal of the old catheter, a new set of sterile gloves must be used before handling the replacement catheter. (B)

37. If CABSI is suspected or documented, guide wire-assisted exchange should not be undertaken (A). The old catheter must be removed and a new catheter inserted at a fresh site (A)
SECTION 4

ARTERIAL LINES

The risk of colonization and infection of arterial catheters in general approach that of central venous catheters (internal jugular & subclavian). In general, care of these catheters is identical to the maintenance of central venous catheters. Only aspects that are significantly at variance with the recommendations for CVCs are mentioned in this section.

Recommendations

Site preference
1. The preferred sites for insertion of arterial lines in adults are radial, dorsalis pedis & femoral (B). Axillary artery lines carry a high risk of infection.
2. The posterior tibial artery is an additional site in children

Hand hygiene
3. All arterial line insertions using the Seldinger technique and all femoral arterial catheterizations should be performed using maximal sterile barrier precautions (masks, cap, sterile full-sleeved gowns, sterile gloves, & large sterile drapes) (A)
4. Placement of radial and dorsalis pedis arterial lines without a guide wire can be performed after hand hygiene using an antimicrobial soap / scrub and wearing of sterile gloves (B)

Skin preparation (see CVC recommendations)

Dressings; types; frequency of change (see CVC recommendations)

Monitoring & Surveillance of Site (see CVC recommendations)

Duration & Catheter replacement
5. Arterial catheters can safely be left in situ for 96 hours (A). Catheters may be left in place longer if clinically required with ongoing surveillance of the site (B).

Selection & replacement of pressure monitoring systems
6. Use disposable rather than reusable transducer monitoring systems whenever possible (A)
7. Replace the entire disposable transducer system at 96 hour interval (A)
8. Replace re-usable transducer systems every 48 hour (B)

Care of pressure monitoring systems
9. Maintain patency using a closed continuous flush system rather than an open system to reduce risk of infection (A).
10. Keep all components of the pressure monitoring system sterile (A)
11. Minimize the number of manipulations and entries into the pressure monitoring system (B)
12. Do not administer dextrose containing solutions through the pressure monitoring circuits (A)
13. Sterilize reusable transducers according to manufacturer’s instruction if the use of disposable transducer is not feasible (A)
Blood and catheter culture methodology\textsuperscript{29-32}

**Blood Culture**

Several protocols are available for blood cultures; the following is suggested to maximize yield and minimize contamination rates.\textsuperscript{29,30}

1. Blood cultures should be drawn only when there is a clinical suspicion of bloodstream infection.
2. Number: At least two sets of blood cultures must be drawn in each instance. Three sets may be needed to establish continuous bacteremia.
3. Site: Peripheral venepuncture is preferred for blood draws. Blood should not be drawn from catheters that are already in place. (If venous sites are unavailable, cultures may be drawn from freshly placed central vascular lines, observing strict aseptic precautions.) Each set should be drawn from a different venous site (to minimize false positives from site contamination).
4. Timing: The cultures should preferably be drawn prior to the administration of antibiotics. Though it is suggested that blood cultures should be drawn as soon as possible after an episode of fever or rigors, this does not affect yield significantly.
5. The timing between each set is undetermined and will depend on the urgency to treat the patient with antibiotics. (Cultures drawn 10-15 minutes apart are acceptable in the intensive care patient).
6. Hand care: Sterile gloves should be worn after hand cleansing with antimicrobial solution/soap. The prepared site should not be palpated without gloves.
7. Site preparation: Tincture of iodine or 0.5% chlorhexidine in alcohol is preferred over povidone iodine for the preparation of the venepuncture site.
8. Volume of blood: Each set should not be less than 10 ml in adults and should ideally be between 20 and 30 ml.
9. While injecting the blood into culture bottles the rubber stopper should be disinfected with alcohol. Do not change needles to transfer contents to the culture bottle.

**Catheter Culture**\textsuperscript{31,32}

Multiple qualitative, semiquantitative and quantitative methods are available for identification of catheter colonization. In general, though quantitative methods perform best in the diagnosis of catheter related infection,\textsuperscript{32} the widespread unavailability of the technique restricts its value in India. We suggest that standardized reporting of short-term catheter related infections in India utilize the semiquantitative method of Maki\textsuperscript{31} described below:

1. Catheters removed on suspicion of catheter related bloodstream infection should be cultured. Routine culture of all removed vascular catheters is not recommended.
2. The catheters should be removed using sterile techniques (sterile gloves after appropriate hand disinfection).
3. The catheter site is cleared of any blood or antimicrobial ointment using an alcohol pledget.
4. The catheter is withdrawn with sterile forceps, directing it away from the skin.
5. If the catheter is < 7 cms long the entire catheter is cultured. For longer catheters, a 5-7 cm segment either from the tip or from the skin-catheter interface is used for the culture.
6. The segment is rolled or smeared at least 4 times over a blood agar plate using a flamed forceps.
7. The number of colonies grown on the plate is counted. Counts exceeding 15-colonies/plate or the presence of confluent growth is considered significant.

**Definitions\textsuperscript{2}**

**Bloodstream infections** (BSI) are identified by the growth of pathogenic bacteria or fungi (that are not related to another site of infection) from one or more blood cultures. When the blood culture yields a potential skin contaminant (Coagulase negative Staphylococcus, diphtheroids or Bacillus spp.) more stringent criteria are needed. In such cases the presence of more than one positive culture, and the presence of systemic signs and symptoms (fever, chills and hypotension) and the absence of an alternative focus of infection are essential.

**Catheter associated bloodstream infections** (CABSI) are those that occur in patients during and up to 48 hours after the removal of a central venous access or arterial catheter. This does not require the growth of the same organism from both the catheter and the peripheral blood.

**Catheter-related bloodstream infections** (CRBSI) require the isolation of the same organism in the blood culture and from the catheter site. Quantitative or semi-quantitative culture methods are required to differentiate catheter colonization from contamination of the site.

**Calculation of CABSI rate**

We recommend that all users of central catheters document the
“incidence-density” of catheter associated blood stream infections in their institution. This is done looking at the frequency of BSI in all patients who had a catheter in place during or up to 48 hours prior to the positive blood culture. The incidence-density is obtained by calculating the number of BSIs per 1000 catheter days:

\[
\text{[No. of blood stream infections/ No. of catheter-days]} \times 1000;
\]

where “catheter-days” = total number of days on a central venous or arterial catheter.

A Protocol for hand hygiene

Routine Hand Hygiene

a. This process is mandatory for all medical, nursing and paramedical personnel who come in contact with the patient.
b. All such individuals should wash their hands and distal forearm with water and 2% chlorhexidine surgical scrub solution at the beginning of their duty hours and after every break away from the unit.
c. No watches or jewellery must be worn during this wash. This wash must last for a minimum of two minutes.
d. The hands must be dried with a sterile, dry towel or with disposable paper tissue.
e. The process must be repeated after any accidental unprotected contact with the body fluids of a patient.
f. A hand rub (with alcohol or chlorhexidine in alcohol) should subsequently be used:

- Before and after every contact with the patient,
- While moving from one bed to another
- While moving to common areas (refrigerator /store/ telephone),
g. The hand rub is also required before gloving and after degloving for any non-procedural contact that involves handling of IV lines or fluids, blood draws or contact with body fluids or wounds.
h. The use of gloves does not preclude the need for the hand hygiene techniques described above.

Procedural Hand Hygiene:

a. This process is indicated before every procedure including, but not limited to, central venous access, PA catheter and arterial line placement.
b. The process is a full surgical scrub using running water and 4% chlorhexidine scrub solution from the fingertips to the elbow.
c. Care must be taken to ensure drainage of water away from the fingers and hands, towards the elbows.
d. No watches, rings or jewellery must be worn during the scrub.
e. There is no advantage to the use of sterile disposable brushes or sponges in the process. Reusable brushes or sponges should not be used.
f. The scrub should be performed for a minimum of two to three minutes.
g. Hand drying should be only with the use of sterile (autoclaved) towels.
h. This scrub always precedes gownsing and gloving for the procedure.
REFERENCES


Houston PC, Boiteau P, Conly JM. Prospective randomized trial of 10% povidone-iodine versus 0.5% tincture of chlorhexidine as cutaneous antisepsis for prevention of central venous catheter infection. Clin Infect Dis. 2000; 31:1001-7.


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Critical care delivery in intensive care units in India: Defining the functions, roles and responsibilities of a consultant intensivist

Recommendations of the Indian Society of Critical Care Medicine Committee on Defining the Functions, Roles and Responsibilities of a Consultant intensivist

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Background
Over the last few years, there has been a tremendous increase in the knowledge, technology and skills required to treat critically ill patients. This has lead to the development of intensive care units (ICUs), which are essentially areas, where severely ill patients can be concentrated and looked after and provided with the infrastructure and expertise necessary to treat critical illness. Current ICU patterns result in the patient being admitted under a primary consultant, before admission to the ICU. Often this primary consultant is not an intensive care specialist and may not be conversant with the current critical care practices and guidelines. The presence of a consultant intensivist (critical care specialist) in this setting has been demonstrated, to greatly increase patient safety and to improve outcomes in terms of morbidity, mortality, length of stay and costs.

While the concept of the intensive care unit has gained widespread acceptance amongst medical professionals, hospital administrators and the general public, recognition of the need and role for doctors specialising in intensive care medicine, has lagged behind. One of the reasons may be that intensive care medicine is a relatively new speciality; social, political and economic factors also undoubtedly play a role in preventing wholehearted acceptance of a consultant intensivist in the hospital. Nevertheless, it is becoming increasingly clear that the presence of an intensive care medicine specialist working in the intensive care unit improves outcomes, in terms of various previously mentioned quality indicators. In the United States, the Leapfrog Group, a group of more than 170 companies and organizations that buy health care and work together to reduce preventable medical mistakes and improve the quality and affordability of health care, mandates that hospitals fulfilling the ICU Physician Staffing standard will operate adult and/or pediatric ICUs that are managed or co-managed by intensivists.

A number of our members are practicing as consultant intensivists on a part time or full time basis. Also, a number of trainees and graduates of the Indian Society of Critical Care Medicine (ISCCM) Certificate Course, the Post-Doctoral Fellowship programme of the National Board of Examinations (NBE) and other critical care programmes are being appointed as consultant intensivists in various hospitals throughout the country and this trend is going to increase. It is essential that the training, talent and services of trained consultant

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intensivists be appropriately utilised in hospitals for the benefit of patients.

It is imperative that in this dual consultant model (involving the primary consultant and the consultant intensivist in the ICU), the relationship should be one that promotes an equal partnership and avoids conflict.

This committee of the ISCCM was set up to formulate recommendations on how consultant intensivists may be utilised in hospitals, so that they give their best as intensive care specialists and receive due recognition and acknowledgment of their efforts from patients and health care professionals. In this document, the terms intensive care medicine and critical care medicine and the terms consultant intensivist and critical care specialist, have been used interchangeably.

**Methods**

Committee members were selected to represent a variety of intensive care practices across the country. The experience of the committee member’s practice ranged from practice in open, transitional and closed ICUs; senior, established consultant intensivists, to freshly qualified, young consultant intensivists; practice in large multispeciality hospitals to practice in nursing homes; practice in large cities to practice in smaller towns; private hospitals to public hospitals and academic centres. Individual committee members wrote of the systems they had adopted in their ICUs and hospitals, successes and failures of their respective systems of care and suggestions for improvement. The collective experiences were pooled towards development of the recommendations.

The Committee tried to answer the following questions:[3]

- Who is a consultant intensivist?
- Does a consultant intensivist make a difference to outcomes of critically ill patients?
- What system of ICU care is best?
- What is the role of the consultant intensivist in a hospital? I.e. how should the consultant intensivist function in the ICU in general and his interaction and relationship with the primary consultant in particular.
- How can the services of the consultant intensivist be best utilised for improved patient outcomes?

In order to answer the above questions, the Committee members reviewed the relevant literature and also looked at guidelines of professional organisations, including those of the ISCCM,[3] Society of Critical Care Medicine (USA)[4] and the Australia and New Zealand Joint Faculty of Intensive Care Medicine.[5] Recommendations are based on the interpretation of the literature as well as the expert opinion of the committee, arrived at after mutual discussion, personally and by email.

Levels of Evidence are graded as follows: Level I: Large, randomized trials with clear-cut results; low risk of false-positive or false-negative error Level II: Small, randomized trials with uncertain results; moderate to high risk of false-positive and/or false-negative error Level III: Nonrandomized, concurrent cohort comparisons, contemporaneous controls Level IV: Nonrandomized, historical cohort comparisons/controls and expert opinion Level V: Case series, uncontrolled studies and expert opinion

**Who is a consultant intensivist?**

The ISCCM defines an intensivist as follows: The intensivist should have a postgraduate qualification* in Internal Medicine, Anaesthesia, Pulmonary Medicine or Surgery and either a) An additional qualification in Intensive Care such as DM, DNB Post Doctoral Fellowship, Certificate Course of the ISCCM, or qualifications from abroad such as the European Diploma in Intensive Care, American Board Certification, Australian or New Zealand Fellowship (FANZCA or FFICANZCA). OR b) At least one-year’s training in a reputed ICU abroad.[*: A few candidates of the ISCCM Certificate Course who have been certified with a 3-year training programme in Intensive Care after M.B.B.S, are also recognised as Intensivists. Since January 2003, M.B.B.S. graduates are no longer be eligible for certification and only those with a postgraduate diploma or degree can qualify for the course.]

In addition, persons so qualified or trained must have at least two-years’ experience in the ICU (at least 50% time spent in the ICU), to work in a secondary level (Level 2) ICU and three-years experience to work in a tertiary level (Level 3) ICU.

In case of doctors not having either of the above mentioned qualifications or training, they should have extensive experience in intensive care in India, quantified
as at least three years’ experience in the ICU (at least 50% time spent in the ICU), for a Secondary level (Level 2) ICU and five years experience for a Tertiary level (Level 3) ICU.

Does a Consultant intensivist make a difference to outcomes of critically ill patients?

A number of observational studies\(^{6-12}\) suggest that ICU mortality and costs are lower with a consultant intensivist present in the ICU.

There are a number of small, nonrandomized studies primarily using historical controls (level IV) that support the presence of a consultant intensivist in the ICU compared, with a prior model without a consultant intensivist. These studies were usually done when there was a change in ICU organizational structure, primarily the addition of a consultant intensivist. ICU outcome data (usually mortality) from a time period before the addition of the consultant intensivist are compared with data for a time period, after the addition of the consultant intensivist care delivery.


This is a large observational, nonrandomized study, using contemporaneous controls. The study was done using the Maryland Health Discharge Data Set, with a focus on 2987 patients undergoing major abdominal aortic surgery. The authors showed that daily rounds in the ICU by an ICU physician were associated with reduced in-hospital mortality and specific postoperative medical complications. The magnitude of this mortality reduction was equivalent to that observed in other studies, that compared the skill (and surgical volume) of operating surgeons.


This study compared two different concurrent care models of surgical ICU patients. One group was managed exclusively by the critical care attending service and the other by the general surgical faculty and house staff. Despite higher severity of illness scores, the critical care patient group had shorter ICU lengths of stay, fewer days of mechanical ventilation, fewer arterial blood gases, fewer consultations, fewer complications, shorter hospital lengths of stay and fewer Medicare-adjusted charges.


This systematic review of the available literature regarding ICU physician staffing and outcomes, concluded that, there is a consistent finding of decreased mortality and length of stay with consultant intensivist presence.


In a retrospective review of MICU records, two consecutive 12-month periods of time were compared. During the first time period, the ICU was without critical care-trained faculty and during the second time period, the ICU was supervised by critical care-trained faculty. Severity of illness scores were comparable during the two time periods. Mortality was significantly decreased during the post critical care medicine time period.


A retrospective review was conducted of two time periods (consecutive years) in a MICU, before and after the addition of a trained critical care specialist (consultant intensivist). Despite similar severity of illness, the mortality rate was significantly lower during the consultant intensivist time period.


This was a retrospective review of MICU patient admissions comparing two consecutive time periods before and after the addition of a medical consultant intensivist. Patient severity of illness was similar during the two time periods. Mortality for pneumonia, mean length of hospital stay and MICU stay, were all reduced
after the addition of the medical consultant intensivist.


A historical case control study examined standardized mortality ratios in 452 patients admitted to an ICU after a consultant intensivist joined the staff, compared with 372 patients before the consultant intensivist’s arrival. Severity of illness scores were comparable in both groups; however, the standardized mortality ratio improved significantly in the consultant intensivist group (0.81 vs. 1.11; ratio, 0.73 [95% confidence interval, 0.55-0.97]).

**What system of ICU care is best?**

There is much debate on who should admit and manage critically ill patients in the ICU. A Closed unit is one, where once a patient enters the ICU, primary care of the patient is transferred to the consultant intensivist. The consultant intensivist takes all the major decisions in the ICU, including admission to and discharge from the ICU. Once the patient goes out of the ICU, care of the patient is transferred back to the primary consultant.

An Open ICU is one in which any consultant may admit a patient to the ICU, with or without the knowledge or consent of the consultant intensivists. Often, such ICUs may not even have a consultant intensivist on their staff. The primary consultant remains in charge, makes all decisions regarding patient management, including whether or not a consultant intensivist’s consultation is required. The consultant intensivist may be asked to look after only certain parts of patient management (e.g. ventilation). It is not uncommon to find such a patient being managed by a series of single-organ specialists (e.g. gastroenterologist, nephrologist, neurologist, cardiologist, etc). As with all other consultations, the consultant intensivist’s recommendations may not be accepted by the primary consultant. The junior staff in the ICU (housemen, registrars) report on that patient to the referring consultant and not to the consultant intensivist.

A Semiclosed or Transitional unit is one which lies in between. There is a mandatory consult and daily rounds by the consultant intensivist, for all patients admitted in the ICU. The primary consultant as well as the consultant intensivist play a significant role in patient care. Orders are written by consultant intensivist or by primary team, in consultation with consultant intensivist. A large proportion of care is provided by the consultant intensivist and his team, in consultation with the primary consultant. There is now an increasing body of literature supporting the closed ICU systems, over open ICUs.\[13-18\]


This study from Turkey looked at the effect of changing over to a closed system in a medical ICU of a university hospital. Data were prospectively collected over 5 months before the policy change (open policy) and over an initial 6 months (early closed policy) and subsequent 12 months (late closed policy) after the policy change. Instituting a closed policy and simultaneously appointing a critical care specialist was associated with the admission of sicker patients and more frequent use of invasive procedures. Compared with open policy, patients were approximately 4.5 times more likely to survive their hospital stay during early closed policy (P <0.001) and approximately five times more likely during late closed policy (P<0.0001). Among patients receiving mechanical ventilation, hospital mortality was lower during the early (57%) and late closed periods (59%), than during open period (91%; P <0.01). The authors concluded that the dual strategy of closed policy and simultaneously appointing an intensivist fostered admission of sicker patients and improved the survival of patients requiring admission to an ICU of a developing country.


This was a prospective cohort study which compared two consecutive time periods of ICU care. In the first period, there was an open ICU organizational structure, wherein critical care specialists consulted on all ICU patients and made recommendations, but the admitting attending physician retained primary responsibility for patient care. The second period had a closed format. The critical care attending physician assumed primary responsibility for all patient care and the admitting physician was a consultant. Despite significantly higher
severity of illness scores during the closed ICU organization, the risk-adjusted mortality score was 0.78, compared with 0.90 in the open ICU organization. Resource utilization did not increase during the closed unit structure, despite higher severity of illness.


A retrospective analysis of two time periods in one hospital was compared, as the ICU administrative structure changed from an open organizational structure to a closed one. In addition, another cohort of patients was prospectively analyzed, wherein one group from one hospital managed in an open ICU organizational structure, was compared with another group from another hospital managed in a closed ICU organizational structure (prospective analysis). Illness severity and primary diagnostic categories between groups, were comparable. ICU and hospital length of stay was less in closed units. An open ICU format was associated with greater mortality prediction.


This is a retrospective review comparing two time periods (open unit vs. closed unit) in a surgical ICU. Mortality and overall complications were significantly higher in the open-unit group, compared with the closed-unit group.


This was a prospective, observational study examining the outcome of acute renal failure requiring replacement therapy (severe acute renal failure), within closed ICU systems in Australia. The study was conducted over a 3-month period in all nephrology units and ICUs in the state of Victoria, Australia. By using the SAPS II score or a recently validated renal-failure specific score, the predicted mortality for these patients was shown to be 59%. Actual mortality was 49.2%. The authors concluded that patients with renal failure managed in closed ICU systems in Australia, had favorable outcomes compared with predicted mortality.


This study is the post hoc analysis of the original Acute Physiology and Chronic Health Evaluation (APACHE) II database. This study was a large, nonrandomized observational study. There were 13 hospitals and 5,030 patients used to develop the APACHE II severity of illness system. The authors ranked ICUs by the actual or observed mortality and the predicted hospital deaths (standardized mortality ratio, SMR). When stratified by SMR, it was demonstrated that the best ICU was well organized, with protocols and policies including the canceling of elective operating room cases, if no beds were available. There were also a high proportion of bedside nurses who had master's degree. In addition, there were no interns (postgraduate year-1) in this unit. The lowest-ranked hospital did not have an organized medical program and had a substantial shortage of nursing. There was an atmosphere of distrust and there was no coordination of care. It is concluded that organized ICUs as defined in this review, had lower mortality.

There is increasing evidence that closed\textsuperscript{(13-18)} or transitional models\textsuperscript{(6-12)} have better outcomes and resource utilisation, than open ICUs. The ISCCM discourages the adoption or continuance of open ICUs. Our preference is for the closed model to be adopted in general medical-surgical, as well as specialty ICUs; however the transitional model is acceptable till closed units are established.

**Executive Summary of Recommendations**

**Defining the functions, role and responsibilities of the consultant intensivist**

**Clinical management**

**Admissions to and discharges from the ICU**

The consultant intensivist must be informed of all admissions to the ICU. Preferably, no ICU admission should take place without the prior knowledge of the consultant intensivist and the decision to transfer the
patient to the ICU should be taken after consultation with the consultant intensivist, or a designated member of the critical care team.

Discharge of a patient from the ICU should be with the knowledge of the consultant intensivist. The consultant intensivist should have the authority to discharge patients from the ICU, in order to accommodate new admissions.

Overall co-ordination about admissions to and discharges from the ICU, should be done by the intensive care medical team.

It is essential to prioritise admissions. The consultant intensivist is ideally placed to triage patients, prioritise admissions and maintain a waiting list. He / she is also best placed to select the patients most suitable for early discharge, to make a bed available for admitting a new critically ill patient. This will ensure that intensive care will be available to patients who most deserve and are most likely to benefit from intensive care.

Responsibility of the consultant intensivist
The consultant intensivist must communicate with the referring consultants and explain the priority for admission, in a logical and scientific manner. The presence of written protocols outlining how patient admissions will be prioritised, is helpful. When discharging a patient from the ICU, the consultant intensivist should be satisfied that the patient is suitable for transfer out of the ICU and should communicate with the referring consultant, the reasons for an early discharge, as well as any special instructions to be followed on the wards.

All patients admitted to the ICU must be seen by a consultant intensivist.
- It is mandatory to have a critical care consult, once the patient is in the ICU.
- Except in a closed ICU where the consultant intensivist and his team takes over care of the patient, the responsibility for patient management is shared between the consultant intensivist and the primary consultant. It is mandatory that the relation between ICU and external consultants is one of an equal partnership.
- The consultant intensivist must do daily rounds on all ICU patients. It is desirable to get radiology, microbiology, pharmacy and input from other disciplines, during these rounds. It is helpful if members from the primary consultant’s team are present during the ICU rounds. During these rounds, the consultant intensivist needs to do the following.
  - Be familiar with all relevant clinical aspects of the history and presentation.
  - Do a focused and relevant clinical examination.
  - Review all the radiology, laboratory and microbiology data. At this point, he/she needs to ensure that all recent test reports have been collected, seen and appropriate action has been taken.
  - Review the input by all the specialists involved in the care of the patient. If needed, further opinions may be sought.
  - Make a clear plan for the next 12-24 hours. This should include all aspects of management including, but not limited to major organ support, fluid therapy, nutrition and antibiotics. It should also specify the appropriate preventive measures including, but not limited to prevention of pressure sores and appropriate DVT and stress ulcer prophylaxis.
  - Check that all prior jobs generated by previous rounds and by other consultants have been completed.
  - Ensure clear documentation of Consultant and junior medical staff notes.
  - It is desirable that all orders are written by the intensive care medical team.
  - The consultant intensivist should periodically review the patient’s progress and may make necessary changes in patient management.
  - A member of the ICU team should accompany the primary consultant on his rounds, to facilitate co-ordination between the consultant intensivist and the primary consultant.
  - Any change in patient management desired by the primary consultant, should take place after discussion and consultation with the consultant intensivist. All new orders should then be written by the intensive care medical team.
  - Progress notes should be written by the intensive care medical team, as well as the primary consultant’s and other consultants’ teams.
  - Common ICU procedures should be performed by the consultant intensivist, or by personnel designated by the consultant intensivist under his / her supervision.
  - The consultant intensivist must be informed of any change in the patients’ condition. This information
should also be communicated to the primary consultant. Any emergency intervention should be performed by the intensive care team.

- The consultant intensivist or referring consultant may seek specialist consultations for the ICU patient, when required. The consultant intensivist must co-ordinate the advice of various consultants and devise a plan of management for the patient as a whole.
- The decision to transport a patient within the hospital or outside the hospital must be taken by the consultant intensivist, in consultation with the primary consultant. The risks and benefits of transport must be considered.
- It is the responsibility of the intensive care team to organise safe transport of the patient from the ICU and back to the ICU. The ISCCM guidelines on transport of the critically ill patient (under preparation) may be followed.

Responsibility of the consultant intensivist

A major responsibility of the consultant intensivist is to ensure that any conflict is avoided, without compromising safety standards and by ensuring that standard practice guidelines and protocols are instituted in the care of the patient. This necessitates adequate communication between ICU and external consultants. The consultant needs to ensure that all ICU procedures are done safely and competently. Teaching and training of junior medical staff is the responsibility of the consultant intensivist.

Communication with patients and their families

- The consultant intensivist must communicate with the patients and / or their family members, the nature and seriousness of the illness, the plan of management and the progress of the patient.

The consultant intensivist should discuss the patient’s progress with the primary consultant and ensure that the patient and family are given accurate and uniform information by all medical and nursing staff.

End of life decisions

- The consultant intensivist should recognise that intensive care may be futile in certain situations and initiate end-of-life discussion with the family, in coordination with the primary consultant. The consultant intensivist must ensure that the primary consultant and other medical and nursing staff are in broad agreement, that an end-of-life discussion should be initiated.
- The consultant intensivist should identify brain-dead patients and liaise with the transplant co-ordinators where appropriate.

Responsibility of the consultant intensivist

It is vital that conflicting information regarding the patient’s illness is not given by different medical teams. This creates an atmosphere of distrust and suspicion and is the basis of dissatisfaction and legal action. In the Indian multicultural context, the intensivist should be sensitive to social and cultural issues. The consultant intensivist is advised to read the end-of-life position statement published by the ISCCM.19

Time Commitment to the ICU

- The consultant intensivist must either be present in the ICU during daytime working hours or in the hospital and rapidly available to the ICU when required.
- In a department with more than one consultant, cross cover between consultants should be ensured. A consultant roster may be made for ICU rounds and cover, procedure supervision, CPR and Medical Emergency Team (MET) and out of hours telephonic consultation and cover.
- It is not mandatory for the consultant intensivist to be present in the ICU at night. However junior medical staff that can effectively interact with the consultant and carry out orders, must be present in the ICU. The consultant intensivist must be continuously available for consultation on phone and come into the ICU if needed.
- Hospital managements should ensure that adequate number of consultant intensivists are appointed to provide coverage at all times, while making provision for leave, conferences, illness and vacations.

Responsibility of the consultant intensivist

There is a need for the presence of trained intensive care medical staff round the clock. It is the duty of the consultant intensivist to appoint, train and teach junior medical staff and roster them so that the ICU is staffed by competent personnel, especially outside routine hours. Written protocols should be available for patient management, including but not limited to patient assessment, procedures, management of common
emergencies and transport.

Privileges Outside the ICU
The consultant intensivist may undertake commitments outside the ICU (e.g. clinics, admission privileges in the ICU and wards), but must ensure that he / she is readily available to the ICU at all times.

Services outside the ICU
- The consultant intensivist may also provide services such as but not limited to
  • Management of patients in the high-dependency unit
  • Medical Emergency Team:
  • Emergency department, including the Trauma team
  • CPR team
  • Artificial airway management
  • Invasive procedures outside the ICU (e.g, Central Line, PICC lines, Lumbar puncture, Insertion of feeding tubes etc)

A consultant intensivist may act as a consultant for the ICU Outreach Services. The outreach services of critical care medicine plays a pivotal role in improving patient care, in wards by providing all logistic support for early recognition of acute life threatening events and treatment interventions to stabilize sick patients who are at the risk of developing life threatening events. The concept of the medical emergency team (MET) is gaining wide acceptance.

Follow-up of patients outside the ICU
- Once a patient has been discharged from the ICU, the consultant intensivist must transfer care to the primary consultant.
- The consultant intensivist may continue to provide care to the patient on the wards, if requested to do so by the primary consultant
- If the consultant intensivist is the primary consultant of the patient, then the above do not apply.

Maintaining standards of intensive care practice
- One of the major roles of the consultant intensivist is to ensure that adequate medical and safety standards are maintained throughout the patients stay. This is best done by the creation and implementation of appropriate protocols and practice guidelines. These include, but are not limited to, protocols for
  • Performance of standard ICU procedures
  • Mechanical ventilation, renal replacement therapy and other major life support
  • Care of the airway
  • Sedation and analgesia
  • Infection control
  • Transport of the ICU patient
- It is the duty of the consultant intensivist to ensure that the nursing, technical and junior medical staff are aware of the protocols and comply with their implementation.
- Maintenance of a clear chain of command is essential for optimal patient care. It is the duty of the consultant intensivist to ensure that major decisions are not made independently by junior medical staff. Its is equally the duty of the consultant intensivist to ensure that major decisions are not unduly delayed, due to inability to contact a consultant. Protocolized care and availability of second on call consultant intensivists should ensure that safety standards are not compromised.

Administration
- When more than one consultant intensivist is appointed in the ICU, it is highly desirable that that they function as a department, rather than autonomous individuals.
- In such a department, one of the consultant intensivists should function as the ICU Director.
- The consultant intensivist should co-ordinate with other departments in the hospital, to ensure that their services are delivered to the ICU in an efficient and timely manner, whenever required.
- The consultant intensivist must play a key role in the design, maintenance and upgradation of the ICU, including the physical structure and equipment in the ICU.
- The consultant intensivist should have a clear role in the choice of equipment, drugs and other consumables like catheters, filters etc. He / she must firmly veto the purchase and use of substandard products, in an attempt at cost saving or profit maximizing.
- The consultant intensivist should interact with the hospital administration to ensure that the ICU is staffed with adequate number of appropriately qualified staff, including junior medical staff, nurses and other paramedical staff.
- The consultant intensivist should maintain unit
statistics and run regular audits and quality assurance and quality improvement programmes for the ICU.

- The consultant intensivist must be member of the hospital infection control committee, purchase committee and play a role in the formulation of antibiotic policies, transport policies, admission and discharge policies, etc.

Payments

- In the interest of transparency and justice, all payments should be documented and be of a rationalized structure
- These should be in accordance with hospital policy and in accordance with the underlying principle of an at par relationship with other consultants. The consultant intensivist may receive a fixed salary, or a fee for service.
- If fee is for service, the fees include consultation charges, which may be more than one in a day and procedure charges.
- Charges for procedures performed by the ICU team in the ICU should be billed to the consultant intensivist. All charges should be at par with similar services provided by other speciality consultants, or departments.

Teaching

- Teaching forms a vital component of the consultant intensivist’s workload. Even in units that do not have formal training programmes, it is essential that junior medical staff is taught the basics of intensive care. This is because medical graduates have had little or no exposure to intensive care during their undergraduate or postgraduate training. Junior medical staff should be taught and encouraged to attend courses including, but not limited to Basic and Advanced Cardiac Life Support, Acute Trauma Life Support and Fundamentals of Critical Care Support. They should be made familiar with management guidelines for common problems, including but not limited to management of acute myocardial infarction and the Surviving sepsis guidelines. Procedures should be taught and supervised and emphasis must be laid on infection control measures, including handwashing, aseptic techniques and rational prescription of antibiotics.
- Training programmes and protocols for nurses should be developed.
- It is also useful to conduct symposia and case discussions in the hospital to increase awareness and confidence in the capabilities of the intensive care unit.

Role of the Consultant Intensivist in a Teaching Hospitals

- Although true for almost all clinical specialties, a teaching ICU more than any other, requires an environment where a teacher assumes the responsibility of role modelling. This is especially important not only in how their ICU trainees are moulded, but also how other residents training in other specialities look at consultant intensivists and ICUs.
- Teaching hospitals should follow as much of a closed model as possible.
- Courses covering concepts of intensive care medicine may be offered to postgraduate students of various faculties. The courses can teach
  - Cardiopulmonary resuscitation
  - Airway obstruction: Early recognition and intervention
  - Circulatory instability: Early recognition and intervention
  - General Principals of Mechanical Lung Ventilation o General Principals of Intensive Care
  - Prevention of Acute Life Threatening Events in patients admitted in wards

Research

- Consultant intensivists are encouraged to conduct research, especially in topics relevant to India
- Consultant intensivists should also participate in acquisition of Indian data relating to global issues in critical care.
- Research may take the form of audits, observational studies and randomised clinical trials
- Audits are valuable for both quality improvement, as well as research projects.
- Consultant intensivists should follow standard ethical and regulatory guidelines in the conduct of research.
- There is paucity of data with the ISCCM on the current models of delivery of intensive care and the current role and status of intensivists across the country. The committee recommends that the ISCCM should maintain a database of ICU’s and survey delivery models and intensive care practice every year. This will not only provide invaluable epidemiological data, but will help track the changing patterns of intensive care.
care delivery in India.

- The ISCCM should consider evolving a mechanism by which patient data (including progress notes and ICU flow-charts) are recorded in a standardised uniform format. All ICUs should also be encouraged to maintain data on admissions and have some scoring system in place. This will facilitate capturing of data on admissions diagnoses, disease patterns, case-mix and epidemiology of intensive care medicine in India. In the long-term, this will help in planning future multi-centre trials in Indian ICUs.

**General Responsibilities of the Consultant Intensivist**

- In the hospital, the consultant intensivist must demonstrate ethical values, expertise and professionalism, in day-to-day work. The consultant intensivist must put the patient at the centre of all decisions and actions.
- The consultant intensivist should promote the culture of competent, compassionate and cost-effective care of the critically ill patient.
- The consultant intensivist should develop and maintain excellent rapport, co-ordination and communication with various colleagues, administrators and other hospital personnel to facilitate high quality patient care.
- The consultant intensivist should evolve a work culture that promotes relationships and avoids conflict.
- The consultant intensivist should continuously upgrade his / her knowledge, competence and skills. This will not only benefit patient care, but also improve confidence in the consultant intensivist and the ICU.
- The consultant intensivist should work towards creating awareness of the speciality of intensive care medicine amongst the medical profession, as well as the general public.

**References**


Guidelines for end-of-life and palliative care in Indian intensive care to units: ISCCM consensus Ethical Position Statement


Executive summary

Purpose
To develop an ethical framework and practical procedure for limiting inappropriate therapeutic interventions to improve the quality of care of the dying in the intensive care unit through a professional consensus process.

Evidence
Since the publication of the last guideline in 2005,[1] there has been an exponential increase in empirical information and discussion on the subject. The literature reviewed address key surveys, observational studies, randomized controlled and interventional studies as well as guidelines and recommendations for education and quality improvement from all over the world and India. Established and evolving bioethical and medico-legal opinions in the world and in India are also included in this review.

The search terms were: End-of-life care; DNR directives; withdrawal and withholding; intensive care; terminal care; medical futility; ethical issues; palliative care; end-of-life care in India; cultural variations.

Materials and Methods
Proposals from the Chair were debated and recommendations were formulated through a consensus process. The members of the Committee took into account the established ethical principles and procedural practices elsewhere in the world, incorporating the socio-cultural and legal perspectives unique to this country.

Guidelines summary

- The physician has a moral and legal obligation to disclose to the capable patient/family, with honesty and clarity, the dismal prognostic status of the patient with justifications when further aggressive support appears non-beneficial. The physician is obliged to initiate open discussions around the imminence of death or intolerable disability, the benefits and burdens of treatment options and the appropriateness of allowing natural death.
- When the fully informed capable patient/family desires to consider the overall treatment goal of “comfort care only” option, the physician should explicitly communicate the standard modalities of limiting life-prolonging interventions.
- The physician must elicit and respect the choices of the patient expressed directly or through his family (surrogates) during family conferencing sessions.
and work towards shared decision-making. He would thus ensure respect to the patient’s autonomy in making an informed choice, while fulfilling his obligation of providing beneficent care.

- Pending consensus decisions or in the event of conflict with the family/patient, the physician must continue all existing life-supporting interventions. The physician however, is not morally or legally obliged to institute new therapies against his better clinical judgment in keeping with accepted standards of care.

- The case notes should clearly reflect, through faithful recording of the whole or gist of the proceedings of one or more of the family conferences, the decision-making process and the final decision based on medical appropriateness and patient’s preferences, in order to ensure transparency and accuracy.

- The overall responsibility for an end-of-life decision rests with the intensivist/attending physician of the patient, who must also ensure that a general agreement of other members of the caregiver team exists for the decision.

- If the capable patient/family consistently desires that life support be withdrawn, or that he/she be discharged home to die in situations in which the physician considers aggressive treatment non-beneficial, the treating team is ethically bound to consider withdrawal of the life support modality in question although clear legal guidelines are lacking at present.

- A withdrawal or withholding decision should be implemented after completing a life support limitation form duly signed by the patient’s family and the treating team. The physician is obliged to provide compassionate and effective palliative care to the patient and to attend to the emotional needs of the family.

**Background**

“Dying can be a peaceful event or a great agony when it is inappropriately sustained by life support” Roger Bone.

In the context of critical care, the physician’s approach to the patient has three dimensions: medical, ethical and legal. This is because care of the critically ill involves not only the application of complex and expensive life-supporting interventions, but also, when appropriate, their withholding or withdrawal.

Death is common place in the critical care unit. The dying patient frequently dies in critical care units: it is estimated that one in five Americans and 50% of hospitalized patients die using intensive care.[3] Elsewhere and in India, depending on the case mix 10–36% of patients admitted to ICU die.[4] Thus, for many when a therapeutic trial of intensive care has failed, life-supporting interventions only serve to render the dying process more prolonged and burdensome. End-of-life care (EOLC) is about the quality of dying. Without due care, instead of a “good death” (i.e., a peaceful end occurring in the presence of loved ones), the patient may needlessly experience an artificial and lonely end surrounded by the dehumanizing paraphernalia of critical care.[5] The manner in which death is managed may affect the survivors for the rest of their lives. Also, especially in the Indian context, prolonged and futile life support has undoubtedly imposed enormous economic and human cost on patients and their families that is avoidable. Scarce resources in terms of material and manpower can be optimally utilized for salvageable patients when released from futile applications.

When death seems inevitable or the possibility of restoring meaningful life appears remote, what is the responsibility of the physician? In today’s world, the culture of technological imperative has given way to a pragmatic and humane approach as physicians realize that the mission of intensive care includes the avoidance of inappropriate use of aggressive interventions.[6] The first do-not-resuscitate (DNR) orders were written in 1976.[7] Death is increasingly anticipated and managed with an appropriate end-of-life decision (EOLD).[8] In the US, the proportion of patients dying with a decision to limit life support increased from 51% to 90% over the 5-year period from 1988[9] to 1992.[10] Presently, in the US and in Europe withholding or withdrawal precede death in up to 90% of dying patients in critical care units[11-13] and 10% of admissions.[13] Rates of foregoing of life-support therapy (FSLT) among dying patients in other parts of the world are as follows: Brazil (11–36%);[14] Lebanon (46%);[15] Hong Kong (59%);[16] China (54% withholding, 34% withdrawal);[17] South Africa (87%);[18] Israel (91%).[19]

In the US, high rates of burdensome transfers to hospitals towards the end-of-life among dependent elderly nursing home residents was identified as markers of poor quality EOLC.[20] In Pediatric ICUs, retrospective studies in the last decade suggest that 40–60% of all deaths follow an end-of-life decision and EOLC practices have been standardized.[21,22] Such decisions are also common in neonatal care even to the point of intentional
shortening of the dying process. Professional bodies have recommended early disclosure of prognosis, frank discussions and advanced planning in cancer patients when they are relatively healthy. The competencies-based intensive care training for Europe (CoBATrICE) defined through a multinational consensus includes several skills for end-of-life and comfort care as essential to intensive care training. 

The Surviving Sepsis Guidelines 2008 recommend that limitation of life support and realistic goals of management (1D recommendation) be discussed with the family in appropriate circumstances.

Major conferences such as the European Society of Intensive Care Medicine, the International Symposium of Intensive Care and Emergency Medicine, the American Thoracic Society, and the Society of Critical Care Medicine routinely hold symposia devoted to end-of-life care. A consensus statement on EOLC among several societies was prepared in 2003, which included the American Thoracic Society, European Respiratory Society, European Society of Intensive Care Medicine, Society of Critical Care Medicine and Société de Réanimation de Langue Française. This consensus conference symbolizes a transnational mission to improving the care of dying patients in the ICU.

End-of-life issues and palliative care have come to be regarded as part of mainstream research deserving of grants, funds and collaborative research. Attempts have been made to measure the quality of dying (quality of death and dying (QODD) score) and validated in the community setting. This tool highlights the correlations between symptom control and the quality of death. If validated for critically ill patients, the QODD score could be a standard instrument to use for clinical, educational, research and quality control purposes in the ICU. Thus, end-of-life care is emerging as a comprehensive area of expertise in the ICU and demands the same high level of knowledge and competence as all other areas of ICU practice.

**Barriers to quality EOLC**

European physicians were reported to have had no difficulty in making end-of-life decisions in 81–93% of cases. In contrast, these decisions have been perceived to be difficult in India due to a number of barriers: Unawareness of ethical issues, culture of heroic “fighting till the end,” lack of palliative care orientation and legal and administrative prejudices. Recently, the Economist Intelligence Unit (EIU) ranked India’s end-of-life care last out of 40 countries. India was reported to have scored poorly in all of the indices: basic end-of-life care environment, availability, cost and quality of EOLC. The EIU gave India a score of 2/5 in public awareness of EOLC, which the report attributes in part to Indians’ reluctance to openly discuss death and dying. EIU also reported “lamentably poor” palliative care system in all parts of India except in Kerala, where there exists a community-driven hospice service. The palliative and hospice care movement that has grown exponentially in the US is yet rudimentary in India. The hospice movement in the US has gained wide approval from the public and professionals; 30% of dying patients receiving hospice care. It endorses forgoing of all curative treatments when life expectancy is low. Such considerations are not confused with euthanasia.

The need for social and legal reform, however, is of vital importance to India for several reasons. There is an unbearable financial burden to the average patient as healthcare expenses are borne mostly by the individual. Lack of appropriate policies for limiting life support make fair distribution of scarce facilities impossible in this populous country. Finally, a technologically lingering death takes away the serenity and dignity accorded to it by the prevailing cultural traditions and beliefs.

EOLD in the Indian context with its unique social, cultural, economic and legal complexities have not been adequately studied. There is a paucity of empirical data on the frequency and the manner of foregoing life support in Indian ICUs. The Indian physician’s attitude, which would appear to favor limitation of therapies, is severely hampered in practice by the lack of safeguards in the form of legal guidance. The Indian Society of Critical Care Medicine (ISCCM) in 2005 ushered in significant steps towards improving EOLD by providing a clearly stated professional position.

Reports of the rates of EOLD in India are scarce. The first report appeared as a single table in a review article. It reported an unintentional foregoing of life support in 22% of deaths in a tertiary care hospital. Out of the 48 deaths preceded by some form of treatment limitation, 38 (79%) were discharged terminally as “left against medical advice (LAMA).” Planned discharges for terminally ill patients for ensuring “good death” have been reported from The Netherlands and Tunisia. However, LAMA in India often refers to a unilateral withdrawal decision by the family mainly because of unbearable financial and other burdens, especially since the private sector dominates health-care delivery. Physicians may tacitly endorse this practice as the only
way to prevent perceived social and legal complications of an FLST decision. The social and ethical implications of this practice have been discussed previously.\[35,36,45-47\]

Another report from India prospectively collected as a part of the international SAPS3 study data, recorded an average EOLD rate of 34% in four Mumbai hospitals.\[48\] EOLD preceded 41-50% of ICU deaths in two private hospitals and a cancer referral center that admits both paying and free patients. Most deaths in the cancer hospital and 44 and 27% in the private hospitals occurred outside ICUs. In the public hospital that caters to free patients, 23% deaths occurred in the ICU with an EOLD rate of only 19%. These data reveal physician reluctance for EOLD but not for the rationing of ICU beds. Later, two abstracts have reported EOLD rates of 19 and 91% in predominantly neurological patients\[49\] and elderly patients,\[50\] respectively.

In another recent single center study from a “closed” ICU,\[47\] EOLDs preceded half of 88 patients who died, the majority being withholding or DNR decisions with withdrawals comprising only 7.5%. This study also documented implementation of EOLD through the pathway recommended by the 2005 ISCCM position statement.\[1\] Half the EOLDs took place in the first week after admission to ICU. Advanced chronic disease, premorbid fully dependent state and unresponsiveness to treatment were most frequently cited reasons for these decisions. EOLD was not independently associated with age, APACHE 4 at 24 h of admission and comorbidities. EOLD significantly reduced the therapeutic and cost burdens towards the last 3 days of life. Notably, the use of carbapenems, which could amount to 50% of the expenditure on drugs,\[38\] was curtailed. The presence or absence of third party payment did not affect EOLDs. A recent report from Tata Memorial Hospital, Mumbai showed an EOLD rate of 38% among cancer patients with a withdrawal rate as high as 29%,\[51\]

Cultural influences\[52\] and professional factors impact on EOLC practices.\[53\] In a review that included 102 publications,\[33\] white American and Northern European patients were found to receive less technologically intensive EOLC. Also, physicians with more experience and routinely working in ICU are less likely to recommend technologically intensive care.

There are several impediments to change in critical care practices in India: The approach to the patient is generally “paternalistic” as the concept of autonomy is weak in the prevailing cultural ethos. The physician’s orientation by his training is only to a curative rather than palliative approach to disease no matter the phase of the illness. The physician is generally fearful of being accused of providing sub-optimal care or of possible criminal liability of limiting therapies. Adding to his dilemma there is a virtual absence of legal guidelines (although professional ethical position has been available since 2005) relating to deaths in intensive care units in India. It would appear, based on small surveys that legal anxieties have been the most important factor\[35\] to obstruct appropriate EOLDs and “good patient death”.

The legal position in India

Self-determination of patients relating to medical decisions is not well articulated in our Constitution.\[41,54\] Indeed the position of the law with respect to death in dignity is unclear, as Indian courts have only addressed appeals for Euthanasia.\[34,55\] In the US and in Europe the relevant laws have evolved over the last three decades to accommodate the changing paradigm,\[36-38\] while in India legal opinion is yet to fully explore the issue of terminal care.

The 196th Draft Bill of the Law Commission of India

In a landmark development, the Indian Law Commission published a draft bill on “Medical treatment of terminally ill patients (for the protection of patients and medical practitioners)” in 2006.\[56\] It reviewed the case laws and legal guidelines from several countries and made some notable observations:

- Euthanasia and physician-assisted suicide remain criminal offences, but are clearly distinct from withholding and withdrawal of life support.
- Adult patients’ right to self determination and right to refuse treatment is binding on doctors if based on informed choice.
- The State’s interest in protecting life is not absolute.
- The obligation of the physician is to act in the “best interests” of the patient.
- Refusal to accept medical treatment does not amount to “attempt to commit suicide” and endorsement of FLST by the physician does not constitute “abetment of suicide”.
- Withholding & withdrawal is viewed as an “omission to struggle” on the part of the physician that will not be unlawful unless there is a breach of duty towards the patient.
- Applying invasive therapies contrary to patient’s will amounts to battery or in some cases to culpable homicide.

Proposed reforms by The Law Commission of India

- Clear definitions of competence, informed decision and best interests.
Recognizes patient’s Right to refuse treatment
If a competent patient makes an informed decision, it is binding on the doctor
In case the decision is not an informed one, or in cases of minors or incompetent patients doctors can take decisions in the “best interests” (include medical, emotional, ethical, social and welfare considerations)
Statutory body to constitute a panel of experts to authorize withdrawal and withholding of life support (FLST) decisions
Three experts to be consulted for FLST decisions for incompetent persons
The physician will consult the family but their views are not binding on him/her
Advance directives, and legal powers of attorney shall be deemed invalid for decision-making as it may “create complications”
Provides for Court declarations: Family/physician/hospital can move court on the question of lawfulness of withdrawal of life support. This is viewed as an “enabling”, as opposed to mandatory, provision
Recommends “expeditious” decisions by a division bench of the High Court. Declarations binding on civil and criminal courts in subsequent proceedings
Recognizes patients’ right to receive palliative care
Directs Medical Council of India (MCI) to formulate guidelines on EOLC

The Aruna Shanbaug case
In March 2011, Aruna Shanbaug case received considerable public attention and could impact on physician practice in relation to EOLD. The Supreme Court of India delivered the judgment on a plea for allowing “euthanasia” for a patient in vegetative state for 37 years. The appeal was in the form of a “Public Interest Litigation” filed by a social activist. The Court ruled that “involuntary passive euthanasia was allowed in principle” but must follow a strict procedure involving clearance by a High Court.

Implications of the Shanbaug judgment
In the Shanbaug case, the Court has only addressed implications of euthanasia (whether or not the patient has the right to live or die) and not the larger issue of terminal care of incurable patients (whether or not the patient has the right to self determination and to refuse treatment).
Evidently there is confusion relating to terminology. “Involuntary Passive Euthanasia” used for FLST is a term long discarded and is no longer in contemporary medical usage. In fact this term only refers to practices during the Holocaust in Nazi Germany. In fact, in countries where Euthanasia is legal, it is applicable only to competent, non critically ill patients. Also involuntary application of Euthanasia has no precedence in medical practice.
End-of-life decisions are rooted in the principles of patient autonomy and humane care and not euthanasia. Implicit in the right of consent is the right to refuse all therapies including those that sustain life.

While the judgment itself was restricted to the specific area of whether euthanasia for an incompetent adult is constitutionally sustainable, several comments germane to patient’s Rights were made by the Amicus Curiae (legal expert) appointed by the court:

a) “…in general in common law it is the Right of every individual to have the control of his own person free from all restraints or interferences of others. Every human being of adult years and sound mind has a right to determine what shall be done with his own body (p. 37, Art. 22)”. This implies that a patient cannot be put on life support against his/surgee’s consent even if it is life saving.

b) “…It follows as a corollary that the patient possesses the right not to consent i.e. to refuse treatment (In the United States this right is reinforced by a Constitutional right of privacy). This is known as the principle of self-determination or informed consent (p. 38, Art. 23)”. The usual end-of-life decisions in the ICU are based on refusal of consent and thus do not violate Suicide Laws.

c) “…courts in the West are in favor of passive euthanasia provided the decision to discontinue life support was taken by responsible medical practitioners. If the doctor acts on such consent there is no question of the patient committing suicide or of the doctor having aided or abetted him in doing so. It is simply that the patient, as he is entitled to do, declines to consent to treatment which might or would have the effect of prolonging his life and the doctor has in accordance with his duties complied with the patient’s wishes (p. 38, Art. 24)”. By current medical definitions, refusal of consent does not constitute euthanasia (vide infra for definitions).

d) “…the decision to withdraw the life support is taken in the best interests of the patient by a body of medical persons. It is not the function of the Court to evaluate the situation and form an opinion on its own. In England, for historical reasons, the parens patriae jurisdiction over adult mentally incompetent persons was abolished by statute and such a declaration would be necessary only in case of dispute. Court has no power now to give its consent. In this situation, the Court only gives a declaration that the proposed omission by doctors is not unlawful (p. 40, Art. 31.” This forms the crux of the contemporary legal opinion on the subject. The judgment is thus silent on the wider issue of EOLC.

The judgment reviews the legal guidelines from elsewhere in the world. It quotes from the Dutch Law
Among the four cardinal ethical standards are to be applied.

**Beneficence**

Beneficence implies acting in what is (or judged to be) in the patient’s interest. In critical care, increasingly the physician is expected to care for patients with a high risk of death. As the physician is expected to act in the best interests of the patient and his family, his responsibility should extend beyond medical treatment to ensuring compassionate care during the dying process. In this context, the physician’s expanded goals include facilitating (neither hastening nor delaying) the dying process, avoiding or reducing the sufferings of the patient and his family, providing emotional support and protecting the family from financial ruin. This is not to be confused with Euthanasia, which is a direct intervention by the physician to hasten the dying process by administering a lethal injection. When the physician, acting unilaterally, makes decisions for the patient, he is said to be “paternalistic” 

36,57 Respect for patient’s autonomy requires that Beneficence also consist of educating the patient to enable him to make an informed choice.

**Non-malfeasance**

Means to do no harm, to impose no unnecessary or unacceptable burden upon the patient. This is subject to varied interpretation, as the same act may be construed as harmful or beneficial depending on the circumstances. 

In practical terms, it requires the physician not to act contrary to the patient’s values and perspectives. The doctrine of double effect makes a distinction between intention and merely foreseen consequence. Although Euthanasia is illegal in most countries, aggressive symptom control is allowed even if it might appear to hasten (shorten) death.

**Distributive justice**

Means that patients in similar circumstances should receive similar care. Physicians need to have a socially responsible behavior, which makes it their duty to make optimal use of the material, financial and human resources under their control. The physician may thus provide treatment and resources to one with a potentially curable condition over another for whom treatment will be futile.

**When to initiate end-of-life (EOL) discussions**

A workable instrument of mortality prediction is necessary to identify situations where EOL discussions can begin. Whether a patient is going through the dying process or not is not always clear. Often the clinician’s judgment is colored by his own biases and attitudes towards death. 

As with any diagnostic process, identifying these situations needs expertise and experience. Each of the following criteria is not to be used in isolation, but in

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**Brain death**

In article 10, page 82, the Aruna Shanbaug judgment recognizes brain death as equivalent to death, removing the legal ambiguity that brain death was hitherto recognized only in the context of Human Organ Transplantation Act 1994.

**Ethical foundations for EOLDs**

Bioethical principles fundamental to critical care practice have been well debated and firmly established. Among the four cardinal ethical principles upon which the practice of critical care is grounded in the West, particularly in the US, respect for patient’s autonomy has come to take precedence over the other three, namely, beneficence, non-malfeasance and distributive justice.

**Autonomy**

Means the Right to self determination, where the informed patient has a Right to choose the manner of his treatment. To be able to exercise his autonomy directly the patient should be competent to make decisions and choices. According to US law, in the event that the patient has lost his decision-making capacity, his autonomy is maintained by his wishes expressed in advance in the form of a Will, or by his wishes as expressed by surrogates acting on his behalf ("substituted" judgment i.e., “what would the patient want given the present circumstances”). Substituted judgment does not imply personal preferences of the surrogates/proxy. Advance care planning, healthcare proxy, Advance Directives/Living Will in the US are tools to protect patient autonomy. In the Quinlan case the US Supreme Court clearly affirmed that the surrogates have the right to refuse any unwanted treatment even if life sustaining. Therefore withdrawal of therapy is legally not killing but “allowing the patient to die” of the underlying illness. If the patient’s values and preferences are not known then the “best interest” standards are to be applied.

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(p. 44, Art 53): “……with the exception of several situations that are not subject to the restrictions of the law at all, because they are considered normal medical practice. These are: 1) stopping or not starting a medically useless (futile) treatment; 2) stopping or not starting a treatment at the patient’s request; 3) speeding up death as a side-effect of treatment necessary for alleviating serious suffering.” The ISCCM guidelines are about this aspect of patient care and do not touch upon issues pertaining to euthanasia.
the context of the entire clinical history and status of the patient. When faced with prognostic uncertainty, the physician should not take precipitous decisions but wait for the disease process to unfold. The following list is not to be regarded as definition of medical futility, but should help the physician to recognize when to start discussions on EOL issues.

Bedside checklist for initiating EOL discussions
1. Advanced age coupled with poor functional state due to one or more chronic debilitating organ dysfunction, e.g., end-stage pulmonary, cardiac, renal or hepatic disease for which the patient has received/declined standard medical/surgical options.
2. Catastrophic illnesses with organ dysfunctions unresponsive to a reasonable period of aggressive treatment.
3. Coma (in the absence of brain death) due to acute catastrophic causes with nonreversible consequences such as traumatic brain injury, intracranial bleeding or extensive infarction.
4. Chronic severe neurological conditions with advanced cognitive and/or functional impairment with little or no prospects for improvement, e.g., advanced dementia, quadriplegia or chronic vegetative state.
5. Progressive metastatic cancer where treatment has failed or patient has refused treatment.
6. Post-cardiorespiratory arrest poor neurological recovery after at least 3 days (7 days in case of therapeutic hypothermia).
7. Comparable clinical situations coupled with a physician prediction of low probability of survival.
8. Patient/family preference to limit life support or refusal to accept life support.

Rationale
Absolute certainty in the anticipation of death is impossible. However, mortality prediction is central to communication and decisions in the critical-care setting. A variety of scoring systems have been developed based on physiological variables, however, none is reliable enough to be adequate for individual patients.69,70 Physician subjective estimates of intensive care survival <10% are associated with a high probability of subsequent intensive care support limitation and intensive care mortality,69,71 but it is difficult to standardize.72 Absolute objectivity in mortality prediction has so far been elusive. The American Thoracic Society definition of futility is therefore suggestive rather than definitive: “a life-sustaining intervention is futile if reasoning and experience indicate that the intervention would be highly unlikely to result in a meaningful survival for that patient”.73

End-of-life decisions are not based on mortality prediction alone. Crucial to these decisions are quality of life estimates integrated with patient/family preferences and therefore a strictly evidence-based decision cannot be expected. Since it is rooted in “patient- and family-centeredness” it needs to be individualized.

Despite these difficulties empirical data has accumulated that can guide the physician’s predictive judgment. Indirect evidence for the validity of the “checklist” is found in the form of epidemiological data on ICU mortality and ICU use by decedents,12 prospective and retrospective observational studies on FLST12,13,69,70 and from predictive tools that have been used in prospective studies on DNR and FLST in both Emergency Room and ICU settings.74,75 These data help to identify the patient characteristics that physicians generally use for limiting aggressive therapy.

In the US, Angus et al.3 reported epidemiological data, which revealed that among infants most deaths occurred in hospitals, especially ICUs while above the age of 75 years both ICU and hospital admissions at the time of death decreased, and beyond 85 years, it was the least at 14%. ICU use was found to be limited for metastatic cancer as compared to acute myocardial infarction. These data clearly suggest that advanced age and certain disease conditions lead the physicians to limit ICU admission and aggressive treatments.

According to a multicenter, prospective, observational study in Europe, decisions for limitation were related to age and diagnosis among others.13 Age, poor prognosis and poor quality of life were among the reasons cited in studies from France12 and Canada.70 In the latter series, the mean age of patients undergoing withdrawal of support was 65 +/- 14.6, most of whom had severe or extreme dysfunction of at least one organ system. They also found that the timing of FLST decisions from ICU admission depends on the type and severity of the disease. In a recent US survey, 19% of the elderly in nursing home setting have a risk ratio of 2.10 for transition to an ICU in the last month of life that has been identified as a marker of poor quality of EOLC.20

It should be noted that “cut off” values for age or duration of observation before considering EOLC are hard to determine as they vary with the overall health status of the patient and the nature of his disease.
found that physician prediction of low probability of survival, physician perception of patient preference to limit life support, medical rather than surgical diagnosis and age are the strongest independent determinants of DNR directives. An earlier study by the same group did not find age or severity of illness as independent predictors for FLST decisions for the latter as compared to setting DNR directives are more complex requiring physician-family consensus. Similarly, Le Conte et al. reported the determinants of DNR directives to be advanced age (mean age 75 +/-13 years), chronic cardiopulmonary disease, metastatic cancer or patients with acute non-treatable illness.

In another Canadian study, it was found that having DNR and FLST checklists improved the conduct of EOLC in the ICU as perceived by nurses. In acute processes, response to therapy may often be surprisingly good and observations over time or serial scoring coupled with physician prediction may improve prognostication. In the ETHICUS study, the greatest frequency of limitations occurred for acute neurological diseases. For quadriplegics, the option of home ventilation should be offered along with information and counseling, but the choice of the patient or family should guide the decision.

In the US as many as 60% of deaths from strokes, heart failure and traumatic brain injury has some form of treatment withdrawal. Among patients of traumatic brain injury, early palliative care discussion resulted in decreased rate of unnecessary elective surgeries and increased rate of withdrawal of mechanical ventilation without tracheotomies. Where there is no reluctance for withdrawal of mechanical ventilation, a time-limited trial of intensive care would be possible in cases with uncertain prognosis.

The bedside neurological examination remains one of the most reliable and widely validated predictors of functional outcome after cardiac arrest. The absence of neurological function immediately after return of systemic circulation (ROSC), however, is not a reliable predictor of poor neurological outcome. The reliability and validity of neurological examination as a predictor of poor outcome depends on the presence of neurological deficits at specific time points after ROSC. Absence of papillary light response, corneal reflex, or motor response to painful stimuli at day 3 provides the most reliable predictor of poor outcome (vegetative state or death). The somatosensory-evoked potentials (SSEP) are probably the best and most reliable prognostic neurophysiologic test because it is influenced less by common drugs and metabolic derangements.

Prognostication strategies established in patients who were not treated with hypothermia might not accurately predict the outcome of those treated with hypothermia. Hypothermia may mask neurological examination or delay the clearance of medication, such as sedative or neuromuscular blocking drugs that may mask neurological function.

For pediatric patients

Worldwide pediatricians are becoming more proactive in managing death and dying. In a survey of 33 French ICUs, 40% of dying children had an end-of-life decision predominantly among neurological emergencies. The EACRCPC guidelines cite the following situations as justification for limitation and withdrawal of interventions: 1. The permanent vegetative state. 2. The “no chance” situation where there is expectation of imminent death despite aggressive treatment. 3. The “no purpose” situation where there is decrease in quality of life despite potentially extended survival. 4. The “unbearable” situation where in the face of progressive illness further treatment is more than that can be borne.

Guidelines for limiting life-support interventions

Guideline 1

The physician has a moral and legal obligation to disclose to the capable patient/family, with honesty and clarity, the dismal prognostic status of the patient with justifications when further aggressive support appears non-beneficial. The physician is obliged to initiate open discussions around the imminence of death or intolerable disability, the benefits and burdens of treatment options and the appropriateness of allowing natural death.

Rationale

Respect for patient’s autonomy and the imperative to act in his best interest are the basis for providing timely, transparent, accurate information along with its balanced and individualized interpretation, as worldwide we move away from the “paternalistic” model of care. The patient/surrogates are thus able to make a genuinely informed choice.

It is important for the physician to identify a suitable family member as a surrogate decision-maker for the patient, as studies have shown that less than 5% of patients are able to communicate with the physician regarding issues relating to life support.
The “family” means spouse, children, parents, siblings and the next of kin who is available or even a trusted friend, though a hierarchy of surrogates does not exist in Indian Law for making medical decisions.

Advance directive stating the patient’s preference is not a practice in India but public awareness in this regard should be encouraged. Prior informal expression of preferences by the patient should receive due consideration. Curative and palliative measures are coexistent but varying in degree at different phases of critical illness. Therefore, the physician must initiate discussions early with a clear expression of the patient’s condition. Waiting, watching, and postponing discussions on prognosis may be more stressful to the family as well as the ICU staff.

Practice points
• It is important that the physician gives as accurate a prognosis as is possible, clarifying that uncertainty is inherent in the treatment of critical illness, in a language and in terms that the family can understand.
• It is the responsibility of the physician to inform the capable patient or his family the diagnosis, prognosis, the range of therapeutic interventions available as well as the option of no therapy, including their risks, benefits, costs and consequences.

Guideline 2
When the fully informed capable patient/family desires to consider the overall treatment goal of “comfort care only” option, the physician should explicitly communicate the standard modalities of limiting life-prolonging interventions.

If the patient or family do not desire the continuation of life-supporting interventions, the available options for limiting the supports should be identified as follows:
1. Do-not-resuscitate status (DNR)
2. Withdrawal of life support
3. Withholding of life support
Definitions: modified from (11)

Full resuscitation (CPR)
Aggressive ICU management up to and including resuscitative attempts, in the event that cardiorespiratory arrest occurs.

Withdrawal of life support
The cessation and removal of an ongoing medical therapy with the explicit intent to not to substitute an equivalent alternative treatment. It is fully anticipated that the patient will die following the change in therapy primarily because of the underlying disease conditions.

Withholding of life support
The considered decision not to institute new treatment or escalate existing life support modalities (intubation, inotropes, vasopressors, mechanical ventilation, dialysis, antibiotics, intravenous fluids, enteral or parenteral nutrition) with the understanding that the patient will probably die from the underlying condition.

Do not intubate/resuscitate (DNI/DNR)
Aggressive ICU management up to, but not including endotracheal intubation (DNI) or attempts at CPR (DNR).

Active shortening of the dying process (SDP)
Deliberate administration of large doses of drugs (barbiturates, morphine) until death ensues.

Physician-assisted suicide (PAS)
A medical doctor provides patients with means to kill themselves.

Euthanasia
The intentional killing of a patient by the direct intervention of a doctor, ostensibly for the good of the patient or others.

Requests for Euthanasia have been turned down (K Venkatesh vs State of Andhra Pradesh, Aruna Shanbaug vs The Union of India). In fact, suicide and abetment to suicide are declared punishable by the Indian Penal Code, though this is not the case in most countries.

As per the Indian Penal Code and the Supreme Court ruling the committee of the Indian Society of Critical Care Medicine forbids the use of Euthanasia and Physician-Assisted Suicide.

Euthanasia is allowed in the Netherlands and Belgium under certain strict regulations and is applicable only to conscious and competent patients who directly appeal for it. PAS is legal only in the State of Oregon in the US.

In India, in Gian Kaur vs State of Punjab, the Supreme Court has ruled that the Right to life enshrined in the article 21 of the constitution cannot be interpreted to include a Right to die. However, the point of reference here was abetment to suicide as the validity of suicide laws was being challenged. Gian Kaur was accused of abetting the suicide of her daughter-in-law not in the
context of terminal illness but in a case of immolation. The plea of the accused was that abetment is not unlawful if suicide itself was not. The Supreme Court disallowed such an interpretation and the judges clarified that only taking of one’s life in health is unlawful, not the pursuing of a natural end towards death in dignity. The right to privacy sanctions choosing a dignified process of death which is indeed the basis of legislations for limiting life support throughout the developed world.

**Brain death**

An irreversible cessation of all functions of the brain including the brainstem. In the US, brain death is death. This category does not include patients who maintain brainstem function, such as patients with persistent vegetative state.

In India, brain death was initially defined only for the purpose of beating heart organ retrieval in the Transplantation of Human Organ Act 1994. Outside of this context, in the Aruna Shanbaug case the judges have ruled that brain death is equivalent to death (p. 52, Art 103). In the opinion of the Committee, there should no longer be any ambiguity in this regard in physicians’ communication to the patient’s family.

**Guideline 3**

The physician must elicit and respect the choices of the patient expressed directly or through his family (surrogates) during family conferencing sessions and work towards shared decision-making. He would thus ensure respect to the patient’s autonomy in making an informed choice, while fulfilling his obligation of providing beneficent care.

**Rationale**

Communication with the family is the key to making appropriate decisions and ensuring quality EOLC in the ICU.\[^{28,32,85-89}\] If the best interests of the patient and family are to be served, they should be involved in an informed decision-making process at the outset. Surrogates need to be well informed and free from incapacitating anxiety and depression to be able to function effectively as substitute decision-makers for the patients.

Early and effective communication facilitates a more smooth transition from curative to palliative care, reduces the frequency of futile care and decreases the frequency of conflicts and potential for litigation between families and healthcare workers.\[^{32,85-95}\] The correlates of effective communication and family satisfaction include the provision of adequate time, frequent and consistent information provided by a single contact physician, preferably an intensivist, adequacy of physician and nurse staffing and help from the family physician.\[^{87-89}\] Ensuring enough time for the family to ask questions and express themselves further enhances family satisfaction.\[^{96}\]

Empirical evidence from other cultures may not be applicable in India, where data on the impact of socio-cultural influences upon family needs are sparse. In a multicenter survey in North India,\[^{97}\] 536 family members of 238 patients were included. The instrument of the survey was an Indian customized version of the modified Molter’s questionnaire.\[^{89}\] Out of the five domains in the instrument (Information, Comfort, Support, Assurance and Proximity), the priority for the Indian family in this study would appear to be Information needs (e.g., details of patient’s condition and discussion on prognosis) as opposed to Assurance needs (e.g., that patient is well cared for, having hope) for the American family.

**Practice points**

We can however integrate the generalizable points into ICU practice in India:

- The discussions should be between the family and an intensivist. The presence of a nurse and a junior doctor will ensure consistency in subsequent discussions. It is desirable for the primary consultant and/or the family physician to be present. The communication should be patient-centered aimed to understand the patient as a person. This has been found to establish a healing relationship with the family.\[^{98}\]
- There should be multiple conferencing of adequate duration. Family must be given adequate time and opportunity to ask questions and to express their views and emotions so that they do not feel “rushed” into a decision. This should also be done in a manner that ensures privacy, in a waiting room or similar area.\[^{98}\]
- The possibility of death should be discussed along with the medical and palliative treatment options. The intensivist should enquire into any previously stated terminal care wishes or preferences directly or indirectly expressed by the patient. The discussions should include the relevant economic, ethical and legal issues.\[^{99}\]
- The family members may express feelings of guilt or remorse that should be resolved with patience. It might be useful to remind the family that death is inevitable and medical science cannot offer cure...
in all situations; that during the dying process the patient needs a humanistic approach rather than a purely technical one. The family should receive assurances that due care will be taken to alleviate patient’s pain and distress. In case the family has difficulties in accepting the possibility of death, counseling by a professional psychologist may be considered.

**Guideline 4**

Pending consensus decisions or in the event of conflict with the family/patient, the physician must continue all existing life-supporting interventions. The physician however, is not morally or legally obliged to institute new therapies against his better clinical judgment in keeping with accepted standards of care.

**Rationale**

The physician should not unduly influence the family in decision-making. Though the emphasis on patient autonomy versus medical paternalism varies in different countries and societies, the worldwide trend is towards a shared decision model. This would minimize the influence of physician preferences, social and religious biases on the issue of forgoing life support.

Several professional recommendations support the view that the physician may not be pressurized to apply treatments he does not find appropriate.

**Practice points**

- The physician should guard against imposing his own values on end-of-life decisions or be in any way manipulative or coercive.
- Decision may be taken in a stepwise manner towards deescalating the treatment through discussions until the clinical picture becomes clearer to the family.
- Conflicts may be resolved through improved communications, deferring decisions, seeking second opinions, or a psychologist’s consultation.
- For conflict resolution one may seek the help of other senior physicians of the hospital or the hospital’s ethics committee, if in existence.
- The physician may not subject a patient to a particular therapy, even if the family may demand it, if it is against his professional judgment.

**Guideline 5**

The case notes should clearly reflect, through faithful recording of the whole or gist of the proceedings of one or more of the family conferences, the decision-making process and the final decision based on medical appropriateness and patient’s preferences, in order to ensure transparency and accuracy.

**Rationale**

Documentation implies transparency, clarity, and evidence of an evolving decision-making process that indicates appropriate care on the part of the physician. This would be helpful to the physician to demonstrate his bona fide intentions in the event of litigation. It would provide security for the patient in case of mala fide intentions on the part of caregivers or his own family.

It would also ensure that the patient is informed of all the therapeutic choices available and that overall management plans are spelt out for him. Clear documentation is strongly recommended by European professional societies and the American Thoracic Society.

**Practice Point**

Details of the communications between the medical team and the family should be documented accurately and completely.

The Committee does not regard the signature of a family representative to be a mandatory requirement. The specific modalities withheld or withdrawn should be documented.

**Guideline 6**

The overall responsibility for an end-of-life decision rests with the intensivist/attending physician of the patient, who must also ensure that a general agreement of other members of the caregiver team exists for the decision.

**Rationale**

The physician in charge of the patient is ultimately responsible for the decision although the process requires full participation by the family/patient. The burden of the decision should not be put upon the family as several studies have found surrogates wanting in decision-making capabilities for the patient. The leadership role assumed by an intensivist with his experience and expertise generates trust and confidence in the family. Physicians/intensivists should minimize inconsistencies between members of the treating team.

**Practice point**

Medical decisions and prescriptions should be made by the primary physician/intensivist. This should take into
consideration and integrate the opinions of the various subspecialists involved in the patient’s care. The primary physician/intensivist should ensure communication and uniformity between the various members of the healthcare team.

**Guideline 7**

If the capable patient/family consistently desires that life support be withdrawn, or that he/she be discharged home to die in situations in which the physician considers aggressive treatment non-beneficial, the treating team is ethically bound to consider withdrawal of the life support modality in question although clear legal guidelines are lacking at present.

**Rationale**

Physician’s obligation to respect patient’s autonomy and to act in the patient’s best interests does not permit him to continue a futile treatment even though the legal position is unclear. In the absence of case law, the physician may be apprehensive of the potential for litigation in the future. Obtaining signed consent for withdrawal of support may be viewed as protective to the physician but as coercive to the family. The process of withdrawal must find a suitable balance between the two concerns. This is because throughout the developed world the patient has the legal Right to refuse all treatment\(^{[105-108]}\), and because there is wide consensus regarding the equivalence of withholding and withdrawal of life support.\(^{[32]}\)

**Practice points**

- Since Indian Law has no clear stand on end-of-life issues except that suicide and abetment to suicide are punishable offences,\(^{[41,54,56]}\) withdrawal even with the expressed consent of the patient or next of kin can be misinterpreted post hoc. If the physician is uncertain about withdrawal he may offer the family gradual de-escalation or non-escalation of curative interventions.
- The physician must ensure clear documentation of the detailed discussions with members of the family who should be specified. The concerned physician, family member or both may then sign the records.
- Terminal care may be offered in the ICU, or in another area of the hospital in keeping with the wishes of the family. If the patient is discharged from the hospital pre-terminally as a shared decision, an appropriate discharge process (“discharged on request” or “Terminal discharge”) in keeping with the hospital policy should be followed.

**Guideline 8**

A withdrawal or withholding decision should be implemented after completing a life support limitation form duly signed by the patient’s family and the treating team. The physician is obliged to provide compassionate and effective palliative care to the patient and to attend to the emotional needs of the family.

**Rationale**

A hospital policy on EOLC and a defined standard operating procedure along with an Ethics committee to oversee such decisions can be very useful to facilitate such decisions.\(^{[109]}\)

The US Supreme Court implicitly endorses the practice of using analgesics and sedatives to ensure that no patient dies in pain or distress,\(^{[52]}\) However, in high doses side effects may take place that may hasten the dying process. Physician-assisted suicide needs to be distinguished from these as hastening of death is unintended, the primary goal of therapy being only alleviation of pain dyspnea, or distress. Quill and associates termed it “the double effect” to distinguish the intended and unforeseen effects.\(^{[63]}\) With the transition of the primary goal of treatment from “cure” to “care”, symptomatic management of pain and distress should be intensive, though calibrated despite the unintended risks of sedation and respiratory depression.\(^{[110]}\)

Since the Court cannot recognize intentions, we should take care to document the use of opiates and the indication for their use.\(^{[56]}\) This reduces the likelihood of misinterpretation or abuse.\(^{[52,56]}\)

**Practice points**

A life-support limitation form should be duly filled and signed by two or more members of the family and treating team. The form should carry the following details: diagnosis(es), reason(s) for end-of-life decision, whether or not the patient has decision-making capacity, the modality of life support limitation, specifies what should be withheld/withdrawn and what should be continued. Signatures of the representatives of an ethics committee, if in existence are desirable for authentication. Education of all members of the caregiver team and resolving doubts and fears is crucial to successful implementation of end-of-life decisions. It is also imperative that the members of the caregiver team be trained on all aspects of palliative care to ensure quality EOLC.\(^{[111]}\) Research has shown that quality of EOLC is poor at present and several interventions show promise.\(^{[112]}\)

When patient undergoes withdrawal/withholding of life-sustaining modalities, the physician is ethically
obliged to continue to provide care that would alleviate the patient’s and family’s distress.

- All ethical issues relating to withdrawal should be discussed thoroughly with the family.
- If the patient is conscious and *compos mentis*, he should be clearly and with sensitivity explained what is expected to happen when a support is withdrawn. He should be reassured that possible pain or distress will be prevented by medication and prompt action should be taken for symptom relief.
- The optimal dose of opiates is determined by increasing the dose until the patient’s comfort is ensured. There is no maximum dose recommended.
- The physician should continue to be available to the family for guidance and counseling.
- For patients discharged home for terminal care suitable arrangements for transport and home care should be made. If endotracheally intubated, the patient should be extubated only upon being reached home (after anticipatory sedation to prevent pain/distress as for withdrawal in-hospital). A tracheotomy may remain and oxygen supplementation is optional.
- The patient’s family should be allowed free access to the patient during the last days of his life. In this situation, it would be permissible to allow children to visit the patient. The family should be encouraged to participate in the general care and nursing of the patient. Music, books, TV etc. that can help alter the environment should be made available. The patient should be allowed every opportunity to experience spiritual meaning and fulfillment. Performance of non-obtrusive bedside religious services or rites should be encouraged.

**Medical futility and unilateral decisions by physicians**

There are situations when the patient’s family may insist on continuing life-support or adding new interventions despite hopeless prognosis. The physician may have to act against his better judgment and thus face loss of self-esteem and professional integrity. Even in cases of documented brain death, there have been occasions when supports have had to be continued due to surrogates’ unreasonable stand that everything possible should be done. We are obliged to define these situations and seek legal instruments to implement unilateral withdrawal of support.

**What constitutes medical futility?**

Here we are referring to clinical situations where in the absence of brain death the physician believes that continuing life support is futile. Clear and unequivocal situations of medical futility are rare.

Futility may be “quantitative” (how low are the odds of success) or “qualitative” (what are the desired ends). There is no consensus among physicians about the exact definition of futility. More often than not, the issue is conflict resolution. There may be misunderstandings regarding prognosis, the family may be pursuing unrealistic and unwanted plans, or the physician may be seeking to impose his ideas on the family. In extraordinary instances, the physician may face the prospect of overriding family demands to take a unilateral decision based on ethical principles. Examples of situations where the physician may consider unilateral action: patient has a prognosis of imminent death; patients with metastatic cancers in whom treatment has failed or has been declined; the very elderly with dementia; chronic vegetative state with organ dysfunction.

The proposed course of action may be:

- A second opinion from another physician not hitherto involved in the care of the patient.
- Multiple counseling sessions with the family explicitly informing the family the hopeless prognosis of the patient and the futility of continuing life support.
- If the family is intransigent, then suggesting transfer to another treating team willing to continue supports.
- To set up a committee of doctors to counsel the family. The committee may also take the help of a social worker, psychologist or priest to help resolve barriers to understanding. Seeking a judicial review of medical cases for EOLs has no precedence in India but has been recommended by the Indian Law Commission and the *Shanbaug* judgment. Therefore, from the legal perspective unilateral action is not available to the Indian physician at present.

**Conclusions**

Setting goals appropriate to clinical situations of poor prognosis are an integral part of critical care. Quality critical care requires that the practice be well grounded in ethical principles and that the ICU staff is trained in the skills of end-of-life care. A consensus regarding the practices relating to end-of-life care in Indian ICUs should eventually lead to the evolution of appropriate legislation in keeping with the changing needs of critical care practice.


55. Aruna Ramachandra Shanbaug vs The Union of India & Ors. Writ PETITION(CRIMINAL). NO. 115 OF 2009(Supreme Court of India Proceedings).

56. Lauk JM, Alpers A. Legal aspects of withholding and withdrawing life support from critically ill patients in the United States and providing palliative care to them. Am J Respir Crit Care Med 2000;162:2929-32.


84. Woolfson BJ, Kissane JM, Cooper LA, Diffey BL, Dorey GC. Meeting the needs of Intensive Care Unit patient families. Am J Respir Crit Care Med 2001;163:135-9.


patients from North India. Crit Care Med 2007;35:12.


101. Luce JM. Physicians do not have a responsibility to provide futile or unreasonable care if a patient or family insists. Crit Care Med 1995;23:760-6.


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Guidelines for noninvasive ventilation in acute respiratory failure


Non-invasive ventilation (NIV) refers to the application of artificial ventilation without any conduit access to the airways i.e., without an endotracheal or tracheostomy tube. NIV has now assumed a prominent role in the management of acute respiratory failure[1-6] Possible indications of NIV has increased both in and out of hospital settings. By avoiding endotracheal intubation, NIV decreases incidence of complications associated with invasive ventilation like airway problems, nosocomial pneumonia (21%) and sinusitis (5-25%).[7-10]

The purpose of this document is...

• To disseminate updated information regarding the appropriate use of NIV by the physicians involved in the care of critically ill patients in India.
• To provide guidelines for appropriate application of NIV in acute respiratory failure.
• To give guidelines for selection of interface, mode of ventilation, choice and use of ventilators and their maintenance.
• To set the minimum standards for care of patients receiving NIV in and outside ICU.
• To provide guidelines for setting up an NIV facility.
• To promote research on this subject in the country.

Methods

The executive committee of Indian Society of Critical Care Medicine selected the chairperson. The chairperson then identified the members of the committee from amongst prominent workers in the field from all over India. Each member was allotted one aspect of the guidelines. All the members prepared the allotted aspect.

All these sections were presented and discussed in a meeting and modifications were suggested. The chairperson then compiled all the sections into one draft document, which was sent to all the members. This was followed by a series of meetings where each recommendation was discussed and graded. The first guidelines were published in 2006.

The executive committee of Indian Society of Critical Care Medicine decided to revise the existing guidelines. Chairperson with the help of members prepared a revised document after an intensive literature search, which included Medline, Cochrane analysis and references in major articles from 1980 to 2012.

The current guidelines were sent to all the participants and they were asked to update the section allotted to them last time. Then document was discussed among the members for their views. The changes suggested by the members were then incorporated by the chairman.

The guidelines were than circulated among members for final comment. This final statement represents the result of this process.

Grading of recommendations

Wherever applicable, recommendations were graded on the basis of modified version of the evidence-based recommendations, which have been used earlier for grading for community-acquired pneumonia.[12] All available and relevant articles till Dec 2012 were considered. Evidence based recommendations were chosen as they are dynamic and they can change as new evidence becomes available.

Evidence based grading system used to rank recommendations

<table>
<thead>
<tr>
<th>Evidence level</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Level I (High)</td>
<td>Evidence comes from well-conducted, randomized controlled trials</td>
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</table>
Evidence comes from well-designed, controlled trials without randomization (including cohort, patient series and case control studies). Level II studies also include any large case series in which systemic analysis of NIV use was conducted.

**Indications**

There are a large numbers of studies describing the use of NIV in various conditions but most of the randomized controlled trials (RCT) have been done predominantly in COPD. Evidence is accumulating on the use of NIV in other conditions.

There are four ways in which noninvasive mechanical ventilation can be used\[6,23]\:

- Noninvasive mechanical ventilation can be used in addition to medical treatment in selected patients of respiratory failure early in the course of illness as a measure to avoid tracheal intubation.
- When invasive ventilation is indicated, a trial of NIV can be given before intubation in selected patients.
- Noninvasive mechanical ventilation can be used in patients who are not candidates for intubation or in patients who refuse intubation.
- Noninvasive ventilation can also be used during weaning from invasive ventilation to avoid reintubation.

**Hypercapnic respiratory failure**

*Chronic obstructive pulmonary disease*

Patients with COPD are prone to exacerbations with progression of their disease. A significant number of COPD exacerbations are complicated by hypercapnic respiratory failure with significantly increased mortality and morbidity. Tracheal intubation and mechanical ventilation has so far been the standard modality for managing these patients; which is associated with significant complications.

In the last decade many studies have been published on the role of NIV in treating severe episodes of acute respiratory failure in COPD patients. This has dramatically modified outcome in these patients.\[13-31\]

These well-conducted, randomized controlled trials have shown that when NIV is used in addition to standard medical therapy, it decreases rate of endotracheal intubation rate and mortality as compared to medical therapy alone.\[13-23\] The majority of these studies included patients with severe exacerbation of COPD who had pH <7.35 and higher intubation rates in their control groups. There are only few studies, which have not shown any benefit of NIV. These studies tended to include patients with mild respiratory failure.\[24,25\] NIV also shortens the length of ICU and hospital stay compared with medical therapy alone.\[14,15\] Several meta-analyses have been published on these controlled trials.\[28-29\] Lightowler *et al.* in a Cochrane review have shown that the application of NIV in patients with hypercapnic respiratory failure is advantageous in terms of decreasing intubation rates, treatment failure and mortality and it should be applied early, before severe hypercapnia and acidosis ensue.\[28\] Keenan *et al.* systematically analyzed the results of 15 studies and came to the same conclusions.\[29\] In addition, they also found that the benefits of NIV were not demonstrated in patients with mild exacerbation.

Most of the above mentioned studies excluded patients who required immediate intubation. However, another RCT reported use of NIV versus conventional mechanical ventilation in patients who had a mean pH of 7.2 and who failed medical treatment and required immediate assisted ventilation\[21\]. In these patients, noninvasive ventilation was no worse than endotracheal intubation.\[21\]

The intubation rate in NIV group was 52%, which is higher than in other randomized controlled trials, which is not surprising because sicker patients who had failed medical treatment were included in the study. This trial illustrated that even at this stage, intubation was avoided by NIV in almost 50% patients but there was no significant difference in ICU or hospital mortality.\[21,32\]

The patients who could be managed by noninvasive ventilation successfully required less hospital admission in the year after hospital discharge.

Squadrone *et al.*\[23\] evaluated the effects of NIV in patients with COPD who were deemed to require intubation and compared the outcome with a matched set of patients who had earlier been ventilated invasively for COPD. Though 40 out of the 64 patients on NIV needed intubation, patients who were successfully managed with NIV had decreased mortality rate and length of ICU and post ICU stay.

In another RCT, it has been shown that hypercapnic coma with GCS <8 can be treated as successfully as awake patients with NIV.\[23\] In this open non-controlled study, between groups of acute respiratory failure patients with GCS scores less than 8 vs. more than 8, the mortality rates were similar. Thus, the beneficial effects of NIV are also seen in the sicker sub group of COPD patients. One must
remember, however, that these studies were conducted in the controlled environment of an ICU where facilities for close monitoring were available.

In the review by Keenan et al.,[33] 14 out of 16 identified RCTs had lower incidence of endotracheal intubation (RR 0.39, 95% confidence interval [CI] 0.28-0.54) and hospital mortality (RR 0.52, 95% CI 0.36-0.76) among patients who received noninvasive positive-pressure ventilation. Most of these trials included patients with severe exacerbations with arterial pH <7.35. 3 RCTs which included patients with milder exacerbations did not showed reduction in risk of endotracheal intubation (RR 0.71, 95% CI 0.16-3.08) or hospital mortality (RR 1.05, 95% CI 0.07-6.36).[33]

Celikel et al.[38] have also shown that early NIV had a success rate of 93% whereas the same was reduced to 67% if initiated late.

RCTs by Antonelli et al.[34] and Li et al.[39] compared noninvasive positive-pressure ventilation with intubation and conventional mechanical ventilation for patients with severe exacerbation of COPD requiring immediate assisted ventilation. Use of noninvasive positive-pressure ventilation resulted in avoidance of intubation in more than half of the patients, but there was no significant difference in the intensive care unit or in hospital mortality. In a randomized controlled crossover trial, Dreher et al.[36] compared the 6 weeks of high intensity NIV (mean inspiratory pressures of 28.6 ± 1.9 mbar) with low intensity NIV (mean inspiratory pressures of 14.6 ± 0.8 mbar) in controlling nocturnal hypoventilation in patients with severe chronic hypercapnic COPD. High intensity NIV was better tolerated and shown to be superior in controlling nocturnal hypoventilation. Jolliet P[37] evaluated the use of helium–oxygen (heliox; 80:20 mixture) in controlling nocturnal hypoventilation in patients with severe exacerbation of COPD. High intensity NIV was better tolerated and shown to be superior in controlling nocturnal hypoventilation. Jolliet P evaluated the use of heliox during NIV to reduce intubation in more than half of the patients, but there was no significant difference in the intensive care unit or in hospital mortality. In a randomized controlled crossover trial, Dreher et al. compared the 6 weeks of high intensity NIV (mean inspiratory pressures of 28.6 ± 1.9 mbar) with low intensity NIV (mean inspiratory pressures of 14.6 ± 0.8 mbar) in controlling nocturnal hypoventilation in patients with severe chronic hypercapnic COPD. High intensity NIV was better tolerated and shown to be superior in controlling nocturnal hypoventilation. Jolliet P evaluated the use of heliox–oxygen (heliox; 80:20 mixture) in controlling nocturnal hypoventilation in patients with severe exacerbation of COPD.

All these studies conclude that when applied in addition to standard medical therapy in COPD patient with acute hypercapnic respiratory failure, NIV results in the following:

- Reduction in the rate of endotracheal intubation
- Reduction in the in-hospital mortality
- Reduction in the complications like nosocomial pneumonia
- Reduction in ICU and hospital length of stay.

**Recommendations**

- NIV should be considered in patients of COPD in addition to standard medical therapy, when they present in acute severe exacerbation (pH <7.35, and hypercarbia). (Level 1)
- Patients with relatively mild exacerbation of COPD (pH >7.35) may not benefit from NIV. (Level II)
- NIV can be administered both in ICU as well as in general medical/emergency wards in COPD patients, though patients with a relatively severe exacerbation (pH <7.30) are better managed in an ICU setting. (Level II)
- No recommendation can be made currently about the use of NIV versus intubation and conventional mechanical ventilation in patients who have severe exacerbation of COPD that requires assisted ventilation, because of insufficient evidence.
- Heliox cannot be recommended routinely in patients with severe exacerbation of COPD who are receiving NIV. (Level II)

**Practice points**

- At the time of presentation, all patients with acute exacerbation of COPD should have arterial blood gas analysis besides clinical evaluation
- NIV should be started in ICU. However, in less severe cases, a trained nurse or respiratory therapist can administer it in medical wards or in the emergency room
- The important point is to initiate it as early as possible. Patients on NIV should be closely monitored during the first 1-2 hours and ABG should be repeated, at the end of 1 and 4 hours
- For the first 24 hours NIV should be given for as much time as possible except during feeding and physiotherapy. Later on, the duration can be decreased depending upon the clinical condition and physiological parameters (SpO₂ and ABG).

**Neuromuscular disease/ chest wall deformity**

NIV is effective in chronic ventilatory failure due to chest wall deformity and neuromuscular diseases. However, there are very few studies, which have examined the use of NIV when these patients become acutely ill. These patients constitute a very small proportion of patients with respiratory failure.[38-41] There are no randomized controlled trials but only a few retrospective case series, which have suggested that NIV alleviates gas exchange abnormalities and avoids intubation in patients with neuromuscular diseases and
kyphoscoliosis who present with respiratory failure.\cite{41}

**Recommendations**

NIV may be tried in patients with neuromuscular disease and chest wall deformity when they present in acute-on-chronic respiratory failure. (Level III)

**Acute asthma**

One may assume that NIV should be as effective in asthma as in COPD, both being disorders of airway resistance. However, this has not been confirmed by any randomized controlled trials. This may be due to the fact that the natural history and pathophysiology of asthma is entirely different.\cite{42-46}

In a retrospective analysis of 33 asthmatics, the outcome of 22 patients managed with NIV was compared with 11 patients who were managed by endotracheal intubation and ventilation. NIV patients were less hypercapnic and gases improved rapidly in this group.\cite{42} In a randomized controlled trial, Soroksky et al.\cite{44} has shown that in selected patients with severe asthma, the addition of NIV to conventional treatment can improve lung functions, alleviate exacerbation faster and reduce the need for hospitalization. However, in another randomized trial no benefit of NIV was demonstrated.\cite{46}

In an 1 small RCT by Soma et al., comparing two pressure levels noninvasive positive pressure ventilation with oxygen therapy alone, a greater reduction in dyspnea and a greater increase in FEV1 were reported for the NIV group.\cite{47} Although the evidence for the use of NIV in asthma is inconclusive\cite{45} a trial on NIV in carefully selected patients is justified, particularly in patients who fail to respond promptly to medical treatment and have no contraindication. It has also been suggested that aerosolized medicines may be delivered more effectively by NIV.\cite{48}

In a retrospective cohort study by Murase et al.,\cite{49} the need for endotracheal intubation in severe attack of asthma was decreased after introduction of NIV. They concluded that NIV is a useful and acceptable method of stabilizing patients with severe attack of asthma. In a meta-analysis by Ram et al. concluded that application of NIV in patients with status asthmaticus still remained controversial.\cite{45} Large prospective randomized controlled trials are needed to determine the role of NIV in these patients.\cite{45}

**Recommendations**

- NIV is not recommended for routine use of asthma exacerbation. (Level II)
- NIV may be tried in ICU in patients of acute severe asthma who fail to respond quickly to medical treatment and have no contraindication. (Level III)

**Acute respiratory failure in obstructive sleep apnea**

Patients with acute or chronic respiratory failure caused by severe obstructive sleep apnea syndrome have been treated successfully with NIV.\cite{50} CPAP has also been used in these patients of severe decompensated obstructive sleep apnea.\cite{51} If respiratory acidosis is present, NIV should be used and they should be transitioned to CPAP once they are stable. So far, there are no randomized controlled trials to prove this application. NIV therapy has also been found to be effective in the treatment of patients with obesity hypoventilation syndrome providing a significant improvement in the clinical status and gas exchange.\cite{52} Carrillo et al. compared the efficacy of NIV in episodes of AHRF caused by OHS and COPD in 716 consecutive patients (173 with OHS and 543 with COPD) with AHRF (arterial pH <7.35 and Pa (CO2) >45 mm Hg) treated with a similar protocol of NIV. They concluded that patients with OHS can be treated with NIV during an episode of AHRF with similar efficacy and better outcomes than patients with COPD.\cite{53}

**Recommendations**

- CPAP/NIV is recommended for obstructive sleep apnea presenting as acute respiratory failure. (Level III)
- NIV is recommended for patients of obesity hypoventilation syndrome (Central alveolar hypoventilation syndrome) with acute respiratory failure. (Level I)

**Cystic fibrosis**

There are few case series on the role of NIV in patients with cystic fibrosis. Hodson et al.\cite{54} used NIV in six patients with Cystic Fibrosis who developed acute retention of CO2 superimposed on chronic retention. Out of the six patients, four survived until heart-lung transplant. In another large study the same team\cite{55} used NIV in 113 patients with cystic fibrosis who were being evaluated for lung transplant and experienced acute respiratory failure. Eight had successful transplant and ten were on waiting list.

NIV resulted in improvement in hypoxemia in these patients but not in hypercapnia. Flight et al. studied 47 patients with cystic fibrosis from 1991 to 2010, of whom 36% underwent lung transplantation, 28% died without transplantation and 30% remain alive on NIV. They concluded that NIV may slow or reverse the decline in
lung function in advanced CF. NIV was increasingly used beyond a bridge to transplantation at their centre.\cite{56}

**Recommendations**
- NIV may be helpful as rescue therapy to support acute respiratory failure in cystic fibrosis, providing a bridge to lung transplantation. (Level III)

**Interstitial lung diseases**
The evidence for use in interstitial lung disease (ILD) in terminal stage is limited although it has been mentioned in case series. In end stage of ILD, these patients have severe hypoxemia and low lung compliance. NIV would not be expected to offer much benefit.\cite{57}

**Recommendation**
NIV is not recommended for interstitial lung disease with acute or chronic respiratory failure. (Level III)

**Acute hypoxemic respiratory failure**

Data on successful application of NIV in patients with acute hypoxemic respiratory failure is less and conflicting. This is mainly due to varied etiologies in the sub groups of patients causing hypoxemic respiratory failure (HRF) included in most of the published studies.\cite{58-73}

The first RCT of NIV among non-COPD patients with HRF, conducted by Wysocki et al.,\cite{58} found no benefit in terms of reduction of intubation rate or hospital mortality. Since then, a number of randomized controlled trials\cite{58-62} that included patients of HRF have produced conflicting results.

The meta analysis by Wysocki et al. and Keenan et al.\cite{61,73} of the randomized trials\cite{58-70} suggests that patients with hypoxemic respiratory failure are less likely to require endotracheal intubation when NIV is added to standard therapy. However, the effect on mortality is less clear and the heterogeneity among studies suggests that its effectiveness varies among different patient populations. As such, suggesting that NIV is beneficial for all patients presenting with acute hypoxemia would be misleading.\cite{73} In addition, the diagnostic category of hypoxemic respiratory failure is too broad to apply to individual patients in these studies. Recently, a few studies have focused on some of the individual diagnoses within the large category.\cite{89-95} It has been found to be very effective in cardiogenic pulmonary edema.\cite{66,72,83} NIV may also be efficient when some components or degree of cardiac decompensation participates in the clinical feature, even if it is not the main or only cause of episode of respiratory failure.

**Recommendations**
- NIV may be useful in selected patients of hypoxemic respiratory failure. (Level I)
- NIV can be tried in ICU in hypoxemic respiratory failure. (Level III)

**Role of NIV in cardiogenic pulmonary edema**

A number of randomized controlled trials\cite{66-73}, have studied the use of noninvasive ventilation in acute cardiogenic pulmonary edema. They have compared CPAP with standard medical therapy to standard medical therapy alone, NIV with standard medical therapy versus standard medical therapy alone, CPAP with standard therapy versus NIV with standard therapy alone or combinations of these 3 treatments and found similar results with the two techniques in terms of improvement in arterial blood gases, respiratory frequency and reduction in endotracheal intubation rate.

Recently, NIV has increasingly been used in combination with medical treatment for acute cardiogenic pulmonary edema.\cite{66,72,74,83,84} Nava et al.,\cite{78} in the emergency department, found that NIV improved PaO$_2$/FiO$_2$ ratio, respiratory rate and dyspnea significantly faster than the group receiving medical therapy plus oxygen. However, intubation rate, hospital mortality and duration of hospital stay were similar in the two groups. In the sub group of hypercapnic patients, NIV improved PaCO$_2$ significantly faster and reduced the rate of intubation compared with medical therapy. Adverse events, including myocardial infarction, were evenly distributed in the two groups.

In a prospective randomized controlled trial, Salman et al.\cite{96} concluded that in patients with acute cardiogenic pulmonary edema, NIV results in a more rapid improvement in respiratory distress and metabolic disturbance compared to standard medical therapy but no improvement in short-term mortality. Chadda et al.\cite{99} found NIV superior to CPAP in unloading the respiratory muscles when patient were studied after at least 24h stabilization period. In another study, Mehta et al.,\cite{71} comparing pressure support plus PEEP with CPAP in patients with acute cardiogenic pulmonary edema showed that NIV reduced the sensation of dyspnea and improved the gas exchange more than CPAP alone but they found a higher rate of myocardial infarction in the Pressure Support group. Following this, several studies have compared NIV and CPAP directly over the past year and found both to be equally effective in the treatment of acute cardiogenic pulmonary edema.\cite{80,81,82} In addition, these studies also indicated that NIV does not increase myocardial infarction rates.\cite{80,82}
In a recent large RCT which compared NIV, CPAP and oxygen therapy alone, rapid improvement in respiratory distress and metabolic disturbances was found in NIV group alone but no significant effect on mortality. In a meta-analysis by Weng et al. that included randomized trials comparing continuous positive airway pressure and bilevel ventilation with standard therapy or each other, they found that evidence still supports the use of NIV in acute cardiogenic pulmonary edema. Continuous positive airway pressure reduces mortality more in cardiogenic pulmonary edema due to acute myocardial ischemia. In a recent review on NIV, lower hospital mortality (NIV; RR 0.84, 95% CI 0.63-1.13 and CPAP; RR 0.73, 95% CI 0.51-1.05) was reported in acute cardiogenic pulmonary edema.[2]

Recommendations

- CPAP/NIV is recommended in addition to standard medical treatment in cases of cardiogenic pulmonary edema. (Level I) NIV is preferable in patients associated with hypercapnic respiratory failure (Level II)
- CPAP/NIV is equally effective in cardiogenic pulmonary edema (Level I).

Role of NIV in transplant and Immunosuppressed patients

In immunosuppressed patients with acute respiratory failure invasive mechanical ventilation is associated with high mortality rate.[98] A number of studies have underlined the worst prognosis for neutropenic patients with acute respiratory failure requiring invasive mechanical ventilation.[98] NIV seems to be an alternative in these patients because of the lower risk of complications; as it prevents endotracheal intubation and its associated complications.[98]

In a randomized trial of 40 solid organ transplants patient with HRF, Antonelli et al. compared NIV with facemask to standard treatment and found a significant reduction in rate of endotracheal intubation, fatal complications, length of stay in the ICU and ICU mortality. However, there was no difference in-hospital mortality.

In another prospective RCT, by Hilbert and colleagues, 52 immuno-suppressed patients (30 patients with hematological malignancies and neutropenia, 18 who received immunosuppression to prevent rejection of solid organ transplantation and four with HIV syndrome), were randomized to receive conventional medical treatment or NIV plus conventional treatment. Patients were recruited at an early stage of HRF. NIV significantly reduced the rate of intubation and serious complications. Both ICU and hospital mortality were significantly reduced. In this prospective RCT on immunocompromised patients treated with NIV, authors obtained impressive results in the sub group of patients with hematological malignancies and neutropenia.

In another recent retrospective study involving 158 Italian ICUs, better outcome was observed in patients with successful NIV compared to invasive ventilation or invasive ventilation after NIV failure in patients with hematologic malignancies, particularly in patients with ARDS.[99]

Recommendation

NIV is recommended early in the course of hypoxic respiratory failure in immunocompromised patients, particularly in those with hematological malignancies. (Level I)

Role of NIV in lung resection surgery and abdominal surgery

Thoracic and upper abdominal surgery are associated with marked and prolonged post operative reduction in functional residual capacity, leading to hypoxemic respiratory failure due to widespread atelectasis at basal lung zones.

Auriant et al. conducted a randomized controlled trial in patients who experienced respiratory distress after lung resection. With the use of NIV, a reduction in endotracheal intubation and a clear benefit in terms of hospital survival was observed.

The use of NIV to prevent respiratory failure who underwent high risk surgical procedure that include major vascular procedures, such as elective abdominal vascular surgery, lung resection surgery or thoracoabdominal vascular surgery had been tried in few trials. The result from these two trials showed a reduced rate of endotracheal intubation but no significant difference in hospital mortality.

However before initiating NIV in postoperative patients with ARF, a surgical complication should be eliminated and treated. Use of postoperative NIV in high risk patients by a trained and experienced ICU team, with careful patient selection, can be considered.

Recommendation

NIV may be used in patients who develop respiratory distress or respiratory failure after lung resection or abdominal surgery. (Level II)
There is no recommendation about the use of NIV to prevent respiratory failure after high-risk surgical procedures, because of a lack of RCTs.

**Role of NIV in severe community acquired pneumonia**

Few studies have reported the use of NIV in patients with HRF in community acquired pneumonia (CAP) and published results are conflicting. Among 30 patients with hypoxemic respiratory failure receiving NIV, Benhamou et al. found no difference in response rate in patients with and without pneumonia.

Confalonieri et al. demonstrated major benefit of NIV in patients with severe CAP, by reducing the rate of endotracheal intubation and duration of stay. This benefit, however, was almost entirely explained by the subgroup of patients with COPD. Other studies of severely hypoxemic patients with pneumonia have shown a high rate of failure in this subgroup. NIV cannot therefore be recommended for all patients with severe CAP.

Ferrer et al. showed that, provided a very careful selection of the patient performed (exclusion of hemodynamic instability, several organ failures, lack of cooperation, abundant secretions etc.), NIV can be very successful in community acquired pneumonia.

**Recommendation**

- NIV may be used in the ICU with caution in selected patients with community-acquired pneumonia particularly in those with associated COPD (Level II)
- NIV cannot be recommended with severe community-acquired pneumonia without prior history of COPD, because of insufficient evidence.

**Role of non invasive ventilation in ARDS**

There is limited literature on the use of NIV in ARDS. In an uncontrolled study by Rocker and coworkers, NIV was applied with the help of facemask to ten patients with ARDS. Intubation was avoided in 67% of patients. Two controlled studies comparing NIV with a conventional approach included some patients of ARDS. The rate of intubation was 40% for patients of ARDS randomized to NIV and the mortality rate in these patients was 35%. But in a multicentre RCT involving patients with mild ARDS, NIV significantly decreased intubations but nonsignificantly decreased hospital mortality. They concluded that NIV is safe in selected patients with mild ARDS.

In a prospective cohort study, in European intensive care units, NIV could avoid intubation in up to 54% of treated patients. A Simplified Acute Physiology Score (SAPS) II >34 and the inability to improve Pao/Fio after 1 hr of NPPV were predictors of failure.

Agarwal R et al. analysed the role of non-invasive ventilation in acute lung injury/acute respiratory distress syndrome in 13 studies. They concluded that there is risk of an almost 50% NIV failure rate in patients with ALI/ARDS. So NIV should be cautiously used in patients with ALI/ARDS. There is a need for a uniform NIV protocol for patients with ALI/ARDS.

In a study by Chen et al., NIV resulted in improvement of vital signs, gas-exchange and sense of dyspnea and they recommended that NIV could be used as a substitute tool for endotracheal intubation in selected patients of SARS. Han et al. reported the successful use of NIV in hypercapnic patients of SARS. Endotracheal intubation was however required in 1/3 of the patients who initially had a favorable response to NIV.

The above results should be interpreted cautiously and one should be very careful while applying NIV in ARDS patients. It should ideally be restricted to hemodynamically stable patients who can be closely monitored and where facility for endotracheal intubation is available.

**Severe H1N1 pneumonia with ARDS**

With recent 2009 pandemic H1N1 with severe ARDS, use of NIV was reported by few case reports and two prospective cohort studies. They found that NIV was used in 25% to 30% of patients but had very high failure rates with 70% to 90% of these patients’ required subsequent intubation and invasive ventilation. In a prospective study involving 98 patients with new pulmonary infiltrate (s) sustained by H1N1 virus and a PaO2/FiO2 <300, 38/98 required immediate endotracheal intubation, while the others received NIV as a first line therapy; 13/60 patients failed NIV and remaining 47/60 patients were successfully ventilated with NIV. It was concluded that early application of NIV, with the aim to avoid invasive ventilation, during the H1N1 pandemics was associated with an overall success rate of 47/98 (48%). Patients presenting at admission with high SAPS II score and a low PaO2/FiO2 ratio and/or unable to promptly correct gas exchange are at high risk of intubation and mortality.

**Recommendation**

- NIV may be used with great caution in cases of Mild ARDS and that too only in controlled settings of an ICU. (Level III)
- The application should be reserved for hemodynamically stable patient who can be closely monitored in an ICU where facilities for invasive ventilation are present.
**Trauma**

Patients who sustain trauma can develop respiratory failure. Some of these patients with a flail chest or mild acute lung injury might respond to NIV therapy. In a retrospective analysis of 46 trauma patients who were treated with NIV, Beltrame et al. found rapid improvement in gas exchange and success in 72% of the patients.[98]

CPAP with regional anesthesia when compared to invasive ventilation in patients with chest trauma resulted in fewer ICU and hospital days for CPAP group.[100] In another study, when NIV along with regional anesthesia was used in patients with blunt thoracic trauma with acute respiratory failure, it proved to be a safe and effective method to improve gas exchange in these patients.[100] Another RCT, reported a lower mortality rate (2/22 v. 7/21; P < 0.01) for the group receiving CPAP by mask, but the small number of patients (n = 43) and the single-centre design raise concerns regarding general applicability of these findings. These patients should however be treated in ICU. In a single centre prospective randomized controlled trial involving severe thoracic trauma patients with PaO2/FiO2 ratio <200, NIV significantly reduced intubation compared to oxygen therapy.[106]

**Recommendation**

CPAP or NIV can be considered for hemodynamically stable patients of chest trauma with respiratory distress. (Level II)

**Role of NIV in “do not intubate” patients for palliative care**

There is a group of patients with acute respiratory failure who are poor candidates for endotracheal intubation due to advanced age or co-morbidity. There are also patients who do not want intubation (DNI) but accept NIV. Levy and colleagues[107] instituted NIV to a group of 114 patients with DNI status for ARF and found that 49 (43%) patients could be treated successfully and survived to discharge.

Patients with congestive heart failure had significantly better survival than those suffering from COPD, cancer, pneumonia or other diseases. Meduri et al. had shown that NIV offers an effective, comfortable and dignified method of supporting patients with end stage disease and acute respiratory failure.[111]

**Recommendation**

NIV can be recommended in selected do not intubate patients. (Level II)

**Role of NIV for preoxygenation**

In a prospective randomized study, Baillard et al. compared the preoxygenation by the noninvasive ventilation and nonrebreather bag-valve mask. Preoxygenation was performed for 3 minutes before rapid sequence intubation. At the end of preoxygenation, arterial oxygenation was significantly higher and significantly lesser number of patients had arterial desaturation in the noninvasive ventilation group. They concluded that preoxygenation was better performed with noninvasive ventilation compared to nonrebreather bag-valve mask.[108]

In a prospective multicentre controlled study, Jaber et al. concluded that implementation of intubation management protocol can reduce immediate life threatening complications associated with endotracheal intubation in ICU patients.[109] Preoxygenation with noninvasive ventilation constitutes an important part of this protocol. In another randomized controlled study including morbidly obese patients, noninvasive ventilation improves oxygenation better compared to conventional methods of preoxygenation during induction of anesthesia.[110]

**Recommendation**

NIV can be recommended for better preoxygenation during induction of anesthesia. (Level I)

**Role of NIV during fiberoptic bronchoscopy (FOB)**

Fiberoptic bronchoscopy is a usual procedure to establish the diagnosis in acute respiratory failure. But these patients are at risk of endotracheal intubation during fiberoptic bronchoscopy.[100] NIV might decrease the risk of bronchoscopy related complications in patients with hypoxemic respiratory failure.[111] In a small prospective study,[100] by Agarwal et al., including 6 patients with PaO2/FiO2 ratio <200, FOB was performed NIV support. NIV was started 10 minutes before and continued for 30 minutes after the procedure. All patients maintained SpO2 >92% during FOB. In another prospective study by Clouzeau et al., they concluded that FOB bronchoalveolar lavage can be performed safely in hypoxemic patients on NIV.[112]

In another prospective study involving 40 hypoxemic patients requiring NIV, Baumann et al., concluded that FOB can be performed with an acceptable risk.[113]

**Recommendations**

NIV can be used in selected hypoxemic patients to perform fiberbronchoscopy. (Level III)
Practice Points for hypoxemic respiratory failure

- These patients should preferably be ventilated with a full-face mask during the acute phase and may be shifted to nasal mask once the condition stabilizes.
- Hypoxemic respiratory failure should preferably be treated with an ICU ventilator as a higher FiO₂ can be administered with it.
- Pressure preset modes with PEEP are recommended in these patients. The ventilator used to provide NIV should have a fast rise time and ability to increase the inspiratory flow rates to maintain constant pressure in the face of major air-leaks.
- Non-invasive mechanical ventilation should be discontinued if there is (a) no improvement in gas-exchange and dyspnea, (b) significant mouth leak, (c) severe mask intolerance, or (d) no improvement in mental status within 30 min of the application of NIV in an agitated hypoxemic patient.[75]

NIV in weaning from mechanical ventilation

NIV can be used to reduce muscle fatigue and can thus serve as a bridge between invasive support and spontaneous breathing to reduce the time on invasive mechanical ventilation. It is attractive to speculate that the many complications of endotracheal mechanical ventilation (ETMV) can be prevented by successful early weaning to NIV. This principle can also be extended to include the postextubation period in an attempt to reduce the incidence of reintubation and the additional risks of late nosocomial pneumonia.

NIV has been applied in the following 3 ways for either reducing time on endotracheal mechanical ventilation or for preventing reintubation:
- As a part of an early weaning strategy, when patient fails a trial of spontaneous breathing.
- After conventional weaning and extubation to prevent postextubation failure.
- When signs of respiratory failure develop after extubation.

As a weaning strategy in patient who fails a trial of spontaneous breathing

Case series and studies by Nava et al.[115] and Ferrer et al.[116] support the use of NIV in this condition for selected patients of COPD. However, most of these trials included only patients who had exacerbations of COPD. However, for the non-COPD respiratory and primarily non-respiratory conditions, evidence for its benefit is lacking.

Nava et al.[115] studied the efficacy of NIV for early extubation in patients of COPD on mechanical ventilation. In this 3-centre prospective study, patients were initially mechanically ventilated for 48 hours and then extubated after a successful spontaneous breathing trial (SBT). Those who failed the SBT were randomized to two groups. The intervention group was extubated to NIV support and the conventional group continued to be on MV for gradual weaning through daily reductions of pressure support. There were predetermined criteria for reintubation. When NIV was thus combined with a 48-hr period of invasive ventilation, the total period of ventilation, ICU stay, and incidence of pneumonia and 60-day mortality were reduced.

In a prospective, randomized, single center study by Girault et al.,[116] continued invasive pressure support was compared with systematic extubation to NIV support in patients who failed a 2-hour weaning trial. With matched baseline characteristics, the NIV group had a shorter duration of invasive ventilation but there was no reduction in the total duration of respiratory support or of 3-month mortality.

Ferrer et al.[117] similarly studied the efficacy of NIV in reducing the time of weaning from invasive ventilation. This multicentre Spanish study involved 43 mechanically ventilated patients who had failed weaning trials for 3 consecutive days. NIV was applied virtually continuously in the first 24 hours postextubation. This study also showed decreased mortality, ICU days and incidence of VAP, septic shock and total mechanical ventilator days in the NIV as compared to the control group. Additionally, this study also showed a reduced incidence of tracheostomy in the NIV group.

However, the methodologic limitations and general applicability of these results are still under question because of concerns like safety, feasibility and resource limitations, hence the use of NIV for these patients requires both considerable expertise and the ability to closely monitor the patients, because urgent reintubation may be required.

After conventional weaning and extubation to prevent postextubation failure

NIV application to all immediately postextubated patients had no impact on duration of ICU stay or reintubation rates.[118] However, Ferrer et al.[119] demonstrated in a RCT that when NIV was applied immediately after extubation to those patients, who had high risk of respiratory failure (age ≥ 65 yrs, APACHE II ≥ 12 at the time of extubation, cardiac failure at the time of intubation), it resulted in decreased reintubation and
ICU mortality in this group as compared to the controls. In a recent trial by the same author, they found that early NIV post-extubation diminished risk of respiratory failure and lowered 90-day mortality in patients with chronic respiratory disorders who developed hypercapnia during a spontaneous breathing trial.\textsuperscript{[120]}

In another study, in high risk patients (patients who had hypercapnia, congestive heart failure, ineffective cough and excessive tracheobronchial secretions, more than one failure of a weaning trial, more than one comorbid condition, and upper airway obstruction) early application of NIV, immediately after extubation, is effective in reintubation and ICU mortality.\textsuperscript{[121]} In a prospective observational study in pediatric patients, Mayordomo-Colunga \textit{et al.}\textsuperscript{[122]} concluded that postextubation NIV seems to be useful in avoiding reintubation in high risk children when applied immediately after extubation. NIV was more likely to fail when applied after development of respiratory failure and in neurologic patients.

\textit{When signs of respiratory failure develop after extubation}

Hilbert applied NIV intermittently in 30 patients of COPD in whom postextubation failure occurred within 72 hrs. He found significant reduction in reintubation rates, duration of MV, ICU stay and mortality in patients, who also received NIV support as compared to those who received only medical therapy.\textsuperscript{[123]}

Keenan \textit{et al.},\textsuperscript{[124]} in a single center, prospective randomized study applied NIV to half the patients of a heterogeneous group who had postextubation failure within 48 hours. Although the duration of mechanical ventilation decreased in the NIV group, there was no significant reduction in mortality, reintubation rates or duration of ICU stay.

However a prospective, randomized, multicentre studies involving 37 centers from 8 countries, showed different results. 221 patients who developed post extubation failure within 48 hours were randomized for NIV vs. standard treatment. There was no difference in reintubation rates, which was 25% in each. Significantly, there was a trend towards a higher mortality in the NIV group (26 vs. 14\%, $P = 0.48$). The median time from extubation to reintubation was also significantly more in the NIV group (12 hours vs. 2.5 hours $P = 0.02$). The higher mortality in the NIV group was attributable to the delay in reintubation, as 38\% of those who were reintubated died in this group as compared to 22\% in the standard treatment group ($P = 0.06$). There was a trend towards benefit of NIV in the subset of COPD patients but the patient number was too small for analysis.\textsuperscript{[125]}

\textbf{Recommendations}

- NIV may be used to expedite weaning from invasive ventilation in uncomplicated cases of COPD who fail a trial of spontaneous breathing, but only in centres that have expertise in this therapy and an expertise always available for reintubation. (Level II)
- NIV can be recommended in patients after extubation who have a high risk of developing respiratory failure and reintubation and only in centres with expertise in this therapy. (Level I)
- We suggest that NIV should not be used after planned extubation in patients who are considered to be at low risk of respiratory failure (Level II)
- The use of NIV to reduce chances of reintubation in the event of post extubation respiratory failure in non-COPD cases is not recommended. It may, however, be used in COPD patients, but the evidence is still insufficient. (Level III)

\textbf{Practice points}

If NIV is applied for weaning from invasive mechanical ventilation or for postextubation failure in COPD, the following procedure could be adopted:

- A spontaneous breathing trial (SBT) should be given after at least 48 hours of stabilization on mechanical ventilation. If SBT is successful, extubate the patient
- If the patient fails SBT, then stabilize patient with full support on mechanical ventilation for 1 hour
- After stabilization, extubate the patient to NIV support
- Initially apply NIV continuously (22-24 hrs) with discontinuation only for feeding, drinking or expectoration
- Gradually, reduce time on NIV according to patient’s requirement or by a validated protocol
- In cases of COPD who develop post extubation respiratory failure, NIV support should be applied only if there are no contraindications and the patient is compliant
- The above protocol is recommended only in ICU settings and in centers that have expertise in this protocol based therapy and a continuous specialist is always available for reintubation if required.

\textbf{Contraindications}

There are no absolute contraindications for the use of NIV. Some contraindications have, however, been suggested. Most contraindications have been determined by the fact that they were the exclusion criteria in many studies.\textsuperscript{[126,127]}
• Inability to protect the airways - comatose patients, patients with CVA or bulbar involvement, confused and agitated patients
• Hemodynamic instability - uncontrolled arrhythmia, patient on very high doses of inotropes
• Inability to fix the interface - facial abnormalities, facial burns, facial trauma, facial anomaly
• Severe GI symptoms - vomiting, obstructed bowel, recent GI surgery
• Life threatening hypoxemia
• Copious secretions
• Conditions where NIV has not been found to be effective
• Non-availability of trained medical personnel
• Predictors of Success with Noninvasive Ventilation.

It is evident that not all patients with respiratory failure may be suitable for the successful application of NIV. NIV has not been universally successful, with reported failure rates of 7-50% mainly due to the heterogeneity of the study populations. It would appear, that those with a very mild form or very severe form of the disease do not benefit from NIV. Justifiably, there are concerns about incorrect selection of patients leading to delay in instituting invasive ventilatory support. NIV is not a substitute for endotracheal mechanical ventilation, but only a way to prevent it by providing support early enough, before severe derangements take place. Understanding the determinants of success will help in accurate patient selection for NIV and a timely switchover to invasive mechanical ventilation.

The following factors have been considered to influence immediate failure with NIV application:
• The baseline respiratory abnormalities at admission like respiratory rate, heart rate, pH and PaCO₂
• The severity of illness as assessed by APACHE or SAPS score
• Degree of encephalopathy as assessed by GCS score or the encephalopathy score
• Pre admission functional status as reflected by forced vital capacity (FVC) and the degree of restriction of the activities of daily living
• Inability to clear secretions
• Associated diseases such as pneumonia
• Response to NIV after its initiation
• Technical factors related to interface, mode and device used for ventilation, patient-ventilator synchrony, humidification and rebreathing and flow resistance.
• Education and training of physicians and nurses involved in the use of NIV support.

Soo Hoo et al. retrospectively studied a small number of patients? Who received nasal NIV? No differences in age, baseline pulmonary function or respiratory rate were found between those who succeeded and those who failed NIV. They also found that patients with hypercapnia at baseline did better as compared to those with hypoxemia alone.

In 17 consecutive patients with respiratory failure due to a variety of causes, Wysocki et al. found that those who were successfully ventilated with NIV had a higher pCO₂ and lower pH (7.33 vs 7.45) and a lower A-a O₂ difference at baseline. However, Ambrosino et al., on the other hand, in a retrospective review of a larger study of 59 episodes in 47 patients of COPD found that lower baseline PCO₂ values (79 vs. 98) and higher pH values (7.28 vs 7.22) correlated with success of NIV support. Keenan et al. in a recent systematic review of 15 randomized controlled trials observed that the benefit of NIV in COPD is demonstrable only in those with severe exacerbations and not in those with milder ones.

The level of consciousness at admission has been used to predict success or failure. Most studies have excluded patients with altered sensorium due to theoretical concerns about the risk of aspiration. Guidelines have also cautioned against its use in the presence of altered consciousness. Anton et al. studied 44 episodes of exacerbations in 36 patients of COPD and confirmed the findings of Ambrosino et al. that baseline level of consciousness and pH values correlate with success. Several studies have however demonstrated success with NIV in the presence of altered sensorium and even coma. Benhomou achieved a success rate of 65% even in those with severe respiratory acidosis and encephalopathy. Diaz et al. showed that patients in hypercapnic coma with GCS <8 can be treated as successfully with NIV. Similar observations were reported by Mani who found that intubation could be avoided even with encephalopathy at baseline and initial rise of PCO₂ on NIV. This was achievable if there was no deterioration of consciousness, in the initial hours of application of NIV support.

Plant et al. in a large, multicentric, prospective study concluded that lower PCO₂ and higher pH levels after 2 hrs NIV support correlated with success and that it is possible to calculate the risk for intubation based on these and other values.

In a prospective, randomized controlled trial Confalonieri found that in the subgroup with COPD, the 2 month survival rate was better in those who received NIV than in those who received conventional treatment alone. Baseline APACHE
scores were found to have no significant impact on the outcome with NIV, although its efficacy differs in various disease conditions. Plant et al., however, in a prospective multicentre study found correlation of APACHE >29 with failure of NIV.[129] Response to NIV may also indicate the chances of success. Studies appear to indicate that this can be gauged early within the first 2 hours. Ambrosino et al. went on to suggest that those who did not improve within 1-2 hrs in terms of PCO₂ and pH values should be intubated.(133) Carratu et al.[145] have shown that patients who improve have increased pH and decreased PaCO₂ at 2 hours post NIV whereas those who fail have no change in these two parameters. Other predictors of early failure were a low pH, low GCS and higher APACHE II scores. In a failure risk model for NIV in COPD, Confalonieri et al.[146] have recently shown that a GCS <11, APACHE >29, respiratory rate more than 30 and pH <7.25 predicted a 50% failure risk and a pH of less than 7.25 at two hours post NIV predicted a 90% failure risk.

Several other studies have adopted short-term (1-4 hours) trials to predict failure and indeed most guidelines advice this.[5,57,135,139,141,142] Benhomou noted that the only factor that determined outcome was the tolerance to the mask.[137] Similarly, Ambrosino found compliance to be an important factor. Air leak is another factor recognized to be important.[133]

A late failure, i.e., respiratory failure occurring after 48 hrs of support with NIV has been recognized. Moretti et al.[143] found that 23% of patients deteriorated late. When those who refused intubation were then given more aggressive NIV, they did worse in the in-hospital period than those who had accepted invasive ventilation (mortality of 93% compared to 52%). Patients with late failures had significantly lower activities of daily living (ADL) scores, lower pH and associated complications at admission.

In a prospective study of 27 hypercapnic patients, Campo et al. concluded that late NIV failure in elderly patients was associated with early sleep disturbances including abnormal EEG pattern, disruption of the circadian sleep cycle and decreased REM sleep.[144] Recommendations

- NIV is likely to succeed in patients with exacerbations of COPD of more than mild severity and in selected cases of hypoxemic failure. (Level I)
- NIV may be applied when established contraindications are absent, in all patients where it is indicated, irrespective of age, baseline APACHE score, degree of chronic respiratory disability and pre-intervention pH or PaCO₂. (Level II)
- After NIV initiation, deterioration of clinical and arterial blood gases in the initial (1-4) hours predicts failure and calls for an early switch to invasive ventilation. (Level II)
- Presence of encephalopathy in COPD may not predict failure of NIV. However, failure to improve with NIV in few hours suggests failure. (Level II)
- Presence of pneumonia in patients of COPD does not preclude a trial of NIV. (Level II)
- Patient’s intolerance of mask, poor compliance or the presence of excessive air leak predicts failure of NIV. (Level III)
- (Level II. In the event of late failure I).

Practice points

- NIV should be discontinued if the patient is unable to tolerate the mask despite best efforts or does not accept this form of support. Such patients should receive invasive support early
- In edentulous patients who are awake and able to protect their airway, dentures should be placed in the mouth to ensure a good mask fit and to minimize air leak
- Monitor RR, HR and BP, level of consciousness, pH, pCO₂ and pO₂/SpO₂ closely in the initial hours after NIV initiation in order to detect early signs of failure
- In case of deterioration of the above parameters in the initial few hours, discontinue NIV and initiate invasive ventilation without undue delay
- Risk of failure is high in hypoxemic respiratory failure
- ARDS is an independent risk of failure.

Application of noninvasive ventilation

Modes of noninvasive ventilation

All modes of ventilation that are used invasively can theoretically also be used for applying noninvasive ventilation. However, NIV is usually delivered in the form of assisted ventilation where every breath is supported. Rarely however, controlled mechanical ventilation used.[145]

There are four principal modes in which noninvasive ventilation can be used:

Controlled mechanical ventilation

Patient’s breathing effort is not required and the ventilator provides full ventilatory support. On the NIV
machines, this mode is referred to as ‘timed’ mode (T).

**Assist control ventilation**

Assist control ventilation not only assures full ventilatory support to the patient but also allows spontaneous breathing efforts by the patient. This mode provides back-up safety rate, should the patient not trigger the ventilator. This mode is referred to ‘spontaneous/timed’ mode on NIV machines (S/T).

**Assist mode**

Ventilator augments the inspiratory effort made by the patient. Assist mode doesn’t provide back-up safety rate, should the patient not trigger the ventilator. Therefore assist mode will work only if the patient is able to trigger the ventilator with his own effort. This mode is referred to ‘Spontaneous’ mode on NIV machines (S).

**Continuous positive airway pressure**

A constant pressure is applied to the airway throughout the respiratory cycle. This mode doesn’t provide inspiratory support, so the patient should have the capacity to breathe spontaneously. This isn’t a mode of mechanical ventilation in true sense and used mainly in hypoxemic respiratory failure due to cardiogenic pulmonary edema.

**Proportional assist ventilation**

The ventilator assists the patient by generating volume and pressure in proportion to patient’s effort, creating a ventilatory pattern that matches metabolic demands on a breath-by-breath basis. Till date, there is no data to show any advantage of PAV.

**Equipment to be used for NIV and its Maintenance**

**Ventilators**

Conventional ICU ventilators with full monitoring and alarm systems, portable volume preset ventilators and portable pressure preset ventilators have all been used for providing NIV.

The advantages of typical ICU ventilators are the presence of full alarm systems, ability to deliver a precise/high FiO₂ and the ability to prevent rebreathing. Newer NIV ventilators incorporate many of these features for their use in the acute care setting, albeit at significantly increased cost. Portable non-invasive ventilators and conventional critical care/ICU ventilators are equally effective when used for NIV, in particular ventilators with oxygen blenders are preferred for patients with hypoxemic respiratory failure.[145-147]

NIV ventilators can be basically classified into pressure or volume preset, though some models incorporate both the modalities in a single machine. In volume-preset ventilation, the set parameter is the tidal volume delivered and airway pressure is variable depending on lung characteristics. In pressure-preset ventilation, the set parameter is the applied airway pressure and tidal volume delivered is variable.

Pressure preset ventilation could be either pressure controlled or pressure support. In pressure controlled ventilation the delivered pressure and the time for which it is applied is preset. In pressure support ventilation, the applied pressure is preset but the duration for which it is applied is dependent on the patient effort. Pressure support breath is terminated when the flow rate decreases to a predetermined percentage of the initial flow rate. Although the concept of NIV was started with the use of volume-preset ventilators, pressure preset ventilation is now the predominant mode used in NIV.

NIV ventilators providing bilevel positive airway pressure ventilation are the most popular. These machines deliver two treatment pressures. A higher pressure is applied when the patient inhales and is called IPAP (inspiratory positive airway pressure) and a lower pressure is applied when the patient exhales called the EPAP (expiratory positive airway pressure). The difference between these two pressures is the effective pressure support. EPAP is equivalent to applying PEEP in a spontaneously breathing subject.

The advantage of volume-preset ventilators is that they provide a relatively constant tidal volume in the face of changing lung characteristics (increasing airways resistance/worsening lung compliance) whereas with pressure-preset machines the tidal volume will vary with changing lung characteristics.

The advantage of pressure-preset machines is that they compensate for leaks, which are common in patients on NIV, either from the mask or the mouth. Most pressure-preset machines also offer facility for EPAP, which has advantages in certain patients. The peak airway pressure can also be limited unlike volume-preset machines, which do not limit peak pressure. This can create problems of gastric distension and barotrauma in certain susceptible patients (bullous lung disease). Another great disadvantage of volume-preset machines is that the flow is fixed and if the flow demand of the subject is greater, then it will lead to ‘flow starvation’ and consequently patient ventilator asynchrony. In pressure-preset machines, flow will vary according to patient’s demands making it easier
for a subject to synchronize with the ventilator. Volume preset machines also tend to be more bulky and costlier when compared to their pressure counterparts, which are lighter and more portable.

There have been a number of studies comparing volume and pressure preset machines in various groups of patients. Pressure preset ventilation has been shown to be as effective as volume preset ventilation in terms of improving breathing pattern and gas exchange parameters.\textsuperscript{146-152} Pressure preset machines are also simpler to use, lighter and cheaper. Lab studies using lung models have also shown the better leak compensation ability of pressure-preset ventilation.\textsuperscript{153}

The choice of a machine providing assist or assist control mode depends on the patient’s disease severity.\textsuperscript{154,155} In sick patients, who are being ventilated for acute respiratory failure, a machine with assist/control facility is desirable whereas a machine with only assist mode could ventilate a stable patient with chronic respiratory failure on domiciliary ventilation. There is a substantial cost difference between these two types of machines. Staff familiarity and training with the ventilator is an important determinant of success and it is desirable to use a single model of ventilator in a particular area.

**Use of EPAP/bi level machines**

- The ability to provide an EPAP on pressure-preset ventilators is advantageous. Unlike ICU ventilators, which separate inspiratory and expiratory gas mixtures, portable ventilators used for NIV have single tubing with a potential for rebreathing expired gas.\textsuperscript{156}
- The application of EPAP flushes dead space CO\textsubscript{2} and prevents rebreathing.
- EPAP also helps in alveolar recruitment, prevents atelectasis and stabilizes the upper airway during sleep.
- EPAP has been found to be more useful in improving gas exchange parameters in patients with chest wall/neuromuscular disease as compared to patients with COPD.\textsuperscript{157}
- In patients with COPD who have significant intrinsic PEEP, EPAP can offset this iPEEP, decrease the work of breathing and improve trigger sensitivity.\textsuperscript{158}

**Triggering**

- Triggering or changeover from expiration to inspiration is crucial for the success of NIV. A ventilator that triggers to the inspiratory phase in a very sensitive manner, thereby responding to patient’s efforts, prevents ventilator-patient dysynchrony. At the same time, it should not be so sensitive that it auto-triggers.\textsuperscript{159}
- An effective trigger is crucial for the success of NIV, particularly in acute respiratory failure.\textsuperscript{160} Both pressure and flow triggering have been used and no clear superiority of one mode over the other has been established. In patients with COPD, flow triggering, by ensuring a constant flow through the circuit, does reduce the amount of auto-PEEP thereby ensuring some advantage for flow triggering.\textsuperscript{161} In general, flow triggered devices appear to be more sensitive than pressure triggered devices and are associated with a lesser work of breathing.\textsuperscript{162}

**Pressurization**

- The ventilator should have the ability to meet the flow demand of the patient. Flow demand depends mainly on the resistance and compliance or the underlying pathology. Gas flow can be increased either by increasing inspiratory pressure support or by reducing pressure rise time.\textsuperscript{160}

**Cycling**

- Cycling or changeover from inspiration to expiration, in harmony with the patient’s breath, is another important function that a good ventilator must be able to perform.
- Cycling is also called expiratory triggering. The criteria used for expiratory triggering can have an impact on the efficiency of NIV and patient-ventilator synchrony. The usual criterion used in pressure support ventilators is a decrease in inspiratory flow from a peak to a threshold value (for example 25\% of peak flow). This varies amongst various NIV machines. Since most patients with COPD or air leaks have high end inspiratory flows, a high flow threshold (25 to 40\%) should be chosen for these patients as a lower threshold may lead to prolonged inspiratory times.
- Ventilators with a facility for adjustable maximal inspiratory times also permit better patient-ventilator synchrony. Settings the maximal inspiratory time (Ti) at one second is a reasonable approach. When patients with COPD have air leaks, the ventilator does not decrease the inspiratory flow, thereby not allowing the decrease in inspiratory flow, which cycles the machine to expiration. This leads to prolonged inspiration and patient-ventilator dysynchrony. By setting the inspiratory duration to no more than half the respiratory cycle duration, this effect can be minimized.\textsuperscript{168,169} Therefore, machines with adjustable expiratory triggers offer advantages.

**Alarms**

- Alarms on non-invasive ventilators are basic and
detect disconnection (low pressure alarm), high pressure, worsening leaks (flow alarm) and power failure. More sophisticated alarms add to the complexity and cost of machines. As NIV is used on more stable patients than conventional ventilation, a whole lot of alarms are not needed.

**Oxygen administration**

- Supplemental oxygen can be administered by connecting oxygen directly to a port on the mask or to a T-connector in the ventilator circuit. Unlike classical ICU ventilators, non-invasive ventilators lack the ability to deliver precisely controlled oxygen-air mixtures to patients. The FiO₂ will vary according to the patient's respiratory pattern. High levels of FiO₂ cannot be achieved because of dilution by base flow (EPAP). One can only achieve a high Fio₂ with ICU ventilators. The best way to monitor oxygen administration is by pulse oxymetry.

**Humidification**

- As physiological humidification mechanisms are unaltered in NIV and much of the air being breathed is ambient and consequently better humidified, humidification is not routinely needed. It may be useful in patients with thick or tenacious secretions and patients who develop nasal stuffiness, dryness and congestion. It can be provided with simple or heated pass-over humidifiers, a pass-through humidifier or a heat and moisture exchanger. Whereas the first two require an extrinsic water source, heat and moisture exchangers reuse the moisture in the expired air for humidification. It is important to remember that these devices can alter the triggering characteristics of the ventilator and caution needs to be exercised. This problem occurs least with pass over humidifiers.
- It is important to remember that air leaks will produce increase in the base flow with consequent more nasal symptoms and rectification of the air leak by appropriate methods alone can circumvent the need for additional humidification.[165]

**Sedation during NIV**

- Patient agitation is a relative contraindication for NIV. Sedation helps in reducing anxiety and respiratory rate but it must be administered with caution in a monitored setting. Benzodiazepines and opioids are the most commonly used agents but dexmedetomidine is useful in agitated patients as it decreases agitation without inducing respiratory depression.[166]

A basic ventilator-designed specifically for NIV should therefore comprise the following features:

**Pressure preset-pressure support**

- Capable of providing pressures at least up to 25 cm H₂O
- Capable of generating high flows for meeting patient inspiratory flow demand (60-100 LPM)
- Should ideally have spontaneous timed option
- Sensitive trigger, preferably flow based
- Lightweight/portable
- Basic alarms
- Capable of supporting a breath rate of at least 40 breathes per minute
- Additional desirable attributes include adjustable pressure rise time (ramp), adjustable inspiratory and expiratory triggers, battery backup, simple control knobs and ability to prevent inadvertent change of parameters (cover or lock out facility).

**Recommendations**

- Both ICU ventilators and portable NIV ventilators can provide NIV. Portable pressure preset bilevel ventilators are advantageous in terms of patient comfort. They are also less expensive, lightweight and easier to maintain. (Level III)
- Staff familiarity with the ventilator is important in outcome and it is desirable that one area be equipped with one particular model for ease of training. (Level III).

**Patient ventilator interface**

Interfaces are devices that connect the ventilator tubing to the patient and facilitate the entry of pressurized gas into the upper airways during NIV. Choice of interface is a major determinant for NIV success or failure. The various interfaces available include-Nasal mask, Oronasal mask, Full face mask, Mouth piece, Nasal pillows and Helmet.

- Oronasal mask is the most commonly used interface for respiratory failure, followed by nasal mask, helmet or mouth piece. They are available in multiple sizes to suit pediatric and adult patients. It is very important to choose appropriate sized interface, (small, medium, large, wide or narrow) as it strongly affects patient’s comfort and influence the development of NIV problems.[168]

The advantages of nasal mask include less dead space, less claustrophobia and minimum complications especially if vomiting occurs. However, full-face masks are used in acute respiratory failure since very dyspneic patients are mouth breathers. It is especially important to remember that full-face masks can add substantial dead
space with consequent risk of rebreathing expired gas mixtures, they also tend to be more claustrophobic. There are not enough published studies to make firm recommendations and there are not many patients’ tolerance direct comparison studies of efficacy. Anton et al. compared the efficacy and patient tolerance of nasal and full facemasks during acute exacerbations of COPD. They concluded that NIV improves ABG and respiratory indices regardless of type of mask used. Navalesi et al. compared the efficacy of NIV using nasal and full facemasks in patients with chronic respiratory failure. They found that the nasal mask was better tolerated, though the minute ventilation was significantly higher and PaCO$_2$ was significantly lower with a full facemask. Studies in patients with acute hypercapnic respiratory failure have shown an overall bias in favor of a facemask in producing quicker improvement in blood gases. A recent randomized controlled trial comparing nasal and oronasal masks found both to be equally efficacious in the reduction of PaCO$_2$ or respiratory rate in patients with acute respiratory distress, though the full facemask was better tolerated.

Recently, a novel interface, a helmet, has been described, which is a clear plastic cylinder that fits over the head and seals with straps under the shoulders. It does not seal the nose and mouth, thereby improves comfort. Two studies have compared CPAP via helmet in patients of hypoxemic respiratory failure with historically matched controls who used standard full-face masks. Both studies found that the helmet permitted more prolonged delivery of CPAP and was better tolerated. However, in patients with hypercapnic respiratory failure due to COPD, the helmet appeared to be less efficient.

In a recent study by Fodil et al., it was found that between different interfaces the effective dead spaces differed only modestly (110 to 370 ml) while their internal volumes were markedly different (110 to 10000 ml). A variety of mask accessories are available that optimize mask fit, comfort and prevent troublesome side effects like nasal bridge pressure sores and leaks. Mask templates are available for sizing masks for individual patients. Choice of headgear or the strap that hold the mask is especially important and an element of elasticity must be present in the headgear material to prevent undue tension on the subject’s skin, especially the nose. Mask cushions help in increasing comfort and preventing leaks and excessive pressure on the skin. Foam spacers aid in prevention of nasal bridge pressure sores by transferring pressure onto them. Elastic chinstraps are particularly useful in preventing air leaks through the mouth. Masks with anti-asphyxia valves permit breathing, if the ventilator stops functioning. The range of accessories is large and their optimal use is best learnt by continuous practice of NIV.

**Mask selection**

**Exhalation devices**

- A variety of exhalation devices are available which vent the expired air to the exterior and also introduce an intentional leak in the system to flush the mask and circuit, thereby preventing rebreathing. These could either be simple exhalation ports built into the mask or could take the form of a separate attachment in the circuit (simple swivel valves, disposable exhalation ports or non-rebreathing valves)
- It is important to remember that CO$_2$ rebreathing can occur with NIV using standard exhalation valves. Moreover, masks add significant dead space. If a patient while on NIV has unexplained rise of CO$_2$ or non-improvement of CO$_2$, this possibility should be considered
- This problem can be tackled by either using a non-rebreathing valve or by increasing the level of EPAP, which flushes the mask and circuit. However, it is important to remember that at commonly used levels of EPAP, especially when the respiratory rate is high, a substantial rebreathing volume may still be present. Because the ventilators trigger algorithm takes leak flow into account, only breathing circuits, exhalation valves and masks that are recommended by manufacturer should be used.

**Recommendations**

- Both nasal and full-face masks can be used for providing NIV successfully. However, in the acute setting full-face masks appear to be advantageous. (Level I)
- A unit should be equipped with a range of masks and accessories since the interface is crucial to the success of NIV. (Level III)
- A proper exhalation device should be used because of a possibility of rebreathing during NIV and worsening hypercapnia. (Level III).

**Maintenance**

All ventilators should be maintained strictly according to the manufacturer’s recommendations. This includes both preventive maintenance and rectification of faults by qualified personnel. Care of the ventilators should be delegated to a specified person and all ventilators when not being used should be parked in a single designated area of the hospital. An inventory of equipment should
be maintained.

Since most ventilators have a base flow (EPAP) even during expiration, there is no airflow from the patient back into the ventilator. Therefore the risk of contamination of the ventilator is extremely low, especially when an outlet bacterial filter is being used.

Superficial cleaning of the ventilator exterior with a slightly dampened cloth and a mild detergent between patient uses is satisfactory. Unplug the unit before cleaning. Ensure that the unit is dry before plugging it in. Do not use bleach, chlorine or alcohol based solutions to clean the exterior of the ventilator.

The air inlet filter on the ventilator should be regularly inspected to see if it is blocked by dirt or contains holes and replaced when it appears dirty. There is no firm limit of time in which the filter has to be changed since the life of the filter will depend on the dust in the ambient atmosphere. Follow the manufacturer’s recommendations regarding the time frame for change. The filter must be changed when the unit is unplugged. Under no condition, should the unit be running without a filter in place. Only the filter recommended by the manufacturer should be used. Failure to replace a dirty filter may cause drop in ventilator flow and pressures and may elevate the operating temperature of the machine with consequent damage to the sensitive ventilator internal circuitry. All filters are disposable and must not be reused after washing.

A ventilator performance verification check should be performed periodically and preferably before use in each new patient to see if the ventilator is adequately pressurizing. The aim is to see whether the ventilator is indeed pressurizing the circuit at the same level as set on its control. This can be done in ventilators with a built in pressure monitor or a simple hand held commercially available manometer. This can be done by occluding the circuit outlet and measuring the pressures at the outlet and ensuring that the pressure matches with that set on the machine. This should be done at different settings of pressure, for example, at 5 cm, 10 cm, 15 cm of IPAP and EPAP. This should be done in all the modes available on the ventilator. The triggering and cycling function of the machine should be checked in all the modes (S, S/T and T). By creating a small leak in a circuit to simulate a trigger, the cycling from IPAP to EPAP can be verified. It is also important to see whether the unit cycles at the set rate on the BPM control in the S/T and Timed modes.

If the ventilator is equipped with alarms, verify the functioning and responsiveness of the alarms and their settings. If an outlet filter is being used, it is important to know its resistance characteristics. The pressure at the mask port should be verified when the ventilator is in use to see if the filter is causing any pressure drop in the circuit.

Ventilator accessories like fuses and batteries should be replaced strictly following the specifications and procedures as described by the manufacturer. No unqualified personnel should be allowed to service or repair the unit. Electrical safety checks should be undertaken at least once a year. It is helpful to have a maintenance schedule so that planned preventive checks can be undertaken. An annual maintenance contract with the manufacture is recommended.

**Accessories**

All accessories stamped, as single use should not be recycled amongst patients. Masks and exhalation valves require high-level disinfection between patients. The manufacturer’s recommendations should be strictly followed as regards to the nature of the disinfecting agent. Both heat (dry-pasteurization, moist-autoclaving) and chemical methods (per acetic acid, gluteraldehyde) are used. While using heat, it is important to know the temperature, duration of exposure and type of heat used. While using chemical disinfection, it is important to know the type of chemical and its concentration and exposure time.

**Cleaning and disinfecting of accessories**

It is not recommended to re-use disposable interfaces. The following recommendation is only for re-usable interfaces. Re-usable masks should first be cleaned, prior to using any disinfection or sterilization method.

**Steps**

- Remove the headgear and spacer
- Soak the parts in a commercially available enzymatic cleaner
- Clean the mask with a soft bristle brush in a solution of cool tap water and a commercially available ammonic detergent. Do not use cleaning products that contain conditioners or moisturizers because they will leave a residue
- Rinse thoroughly under cool running tap water and then air dry
- Disinfection/Sterilization process can be done by following the manufacturers recommendation
- If adhering substances cannot be adequately removed, replace the mask
- Reusable ventilator tubing is difficult to sterilize by
these methods because of its long length and should preferably be autoclaved
• All fabric accessories (headgear, chin straps) should be washed at 65 degree centigrade cycle for 10 minutes and dried before use. This cycle is available on most washing machines. Drying of all masks and accessories should take place in room air and not in sunlight. Automated combined washing/disinfecting/drier systems are available, though they add cost.

Recommendations
• Each unit should have a person designated for maintenance of ventilators. Qualified personnel should do preventive maintenance according to the manufacturer’s recommendations (level III)
• Parts labeled, as single use should not be recycled. Reusable parts should be disassembled into components, washed to remove organic matter and subjected to high-level disinfection strictly following the manufacturer’s recommendation (level III).

Practice points for equipment
• Clinicians must be fully aware of the various characteristics (trigger, cycling, ramp etc) of their NIV machine and should use them optimally for better patient-ventilator synchrony
• It is desirable to lock the set parameters to prevent inadvertent change by staff or attendants
• For patients not showing the expected fall in CO₂ levels, the problem of rebreathing of expired breath should be considered
• A full range of accessories should be available for optimal ventilator-interface synchrony. These add some cost but are helpful in improving efficiency of ventilation. In particular, elasticized headgear should be used to prevent pressure sores on the nose/face
• It is highly desirable to use the circuit tubing, masks and exhalation devices recommended by the ventilator manufacturer as this can affect ventilator performance
• A protocol for ventilator maintenance and sterilization should be in place. The ventilator operator manual and the manufacturer’s website provide rich information.

Practical application

Patient selection
The success of NIV depends on selecting the right patient. This process should take into account the diagnosis, clinical status of the patient, risk of failure and clinical judgment of the caregiver. One must also consider the evidence supporting the effectiveness of NIV in that particular patient.

It has been recommended that the need for ventilation according to clinical criteria must first be established [Table-1].

<table>
<thead>
<tr>
<th>Table 1: Clinical criteria</th>
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<tr>
<td>Moderate to severe respiratory distress</td>
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<tr>
<td>Tachypnea, (respiratory rate &gt;25/min)</td>
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<tr>
<td>Accessory muscle use or abdominal paradox</td>
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<tr>
<td>Blood gas derangement pH &lt;7.35, PaCO₂ &gt;45 mmHg</td>
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<tr>
<td>PaO₂/FiO₂ &lt;300 or SpO₂ &lt;92% with FiO₂ 0.5</td>
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Practice points
Application of NIV using portable pressure ventilator[177]
• Choose the correct interface
• Explain therapy and its benefit to the patient in detail. Also discuss the possibility of intubation
• Set the NIV portable pressure ventilator in spontaneous or spontaneous/timed mode
• Start with very low settings. Start with low inspiratory positive airway pressure (IPAP) of 6-8 cm H₂O with 2 to 4 cm H₂O of EPAP (Expiratory positive airway pressure). The difference between IPAP and EPAP should be at least 4 cm H₂O
• Administer oxygen at 2 liters per minute
• Hold the mask with the hand over his face. Do not fix
• Increase EPAP by 1-2 cm increments till all his inspiratory efforts are able to triggers the ventilator
• If the patient is making inspiratory effort and the ventilator does not respond to that inspiratory effort, it indicates that the patient has not generated enough respiratory effort to counter auto PEEP and trigger the ventilator (in COPD patients). Increase EPAP further till this happens. Most of the patients require EPAP of about 4 to 6 cm H₂O. Patient who are obese or have obstructive sleep apnea require higher EPAP.
• When all the patient’s efforts are triggering the ventilator, leave EPAP at that level
• Now start increasing IPAP in increments of 1-2 cm up to a maximum pressure, which the patient can tolerate without discomfort and there is no major mouth or air leak
• In some NIV machine, inspiratory time (Ti) can be adjusted. Setting the Ti at one second is a reasonable approach
• Now secure interface with head straps. Avoid excessive tightness. If the patient has a nasogastric tube put a seal connector in the dome of the mask to minimize air leakage
• After titrating the pressure, increase oxygen to bring oxygen saturation to around 90%
• As the settings may be different in wakefulness and sleep, readjust them accordingly.

When NIV is being initiated for acute respiratory
failure, close monitoring and the capability to initiate endotracheal intubation and other resuscitation measures should be available in the same setup. Start NIV preferably in the ICU or in the emergency room in acute respiratory failure.

**Application of NIV using a critical care ventilator**

- The first step is to select a ventilator, which is capable of fulfilling the needs of the patient
- Explain the therapy to the patient
- Choose the appropriate mode. Usually pressure support or pressure control modes are preferred. Standard critical care ventilators using flow by system allow the patient to breathe without expending effort to open valves. In selected patients like those suffering from neuromuscular diseases, volume assist or volume control mode may be used
  - Choose an appropriate interface
  - Keep FiO$_2$ 0.5.

**Using pressure approach**

- Start with low settings like inspiratory pressure support at 5-6 cm H$_2$O and PEEP at 2 cm H$_2$O
- Initiate NIV while holding the mask in place and confirm optimum fit. If it is big or small or loose, change it
- Secure interface with headgear or hold mask. It should be tight, but not over-tight. Small leaks are acceptable
- Now increase PEEP till all his inspiratory efforts are able to trigger the ventilator
- If the patient is making inspiratory effort and the ventilator does not respond to that inspiratory effort, it indicates that the patient has not generated enough respiratory effort to counter auto PEEP and trigger the ventilator (in COPD patients). Increase PEEP further till this happens
- Once the patient’s all inspiratory efforts are triggering the ventilator then start increasing pressure support further, keeping certain patient’ comfort in mind. (Reduce respiratory rate, reduced use of accessory muscle etc., Ensure that there are no major leaks
- When there is significant mouth leak, there may be asynchrony. In that case, pressure control will be the preferred mode of NIV and one can set up the inspiratory time to avoid asynchrony
- After adequate ventilation has been achieved, increase fraction of oxygen concentration to maintain Oxygen saturation more than 90%
- A peak inspiratory pressure more than 25 cm is rarely required in COPD, but higher pressures can be used when using NIV for other indications. PEEP is usually titrated between 5-10 cm H$_2$O to improve triggering and oxygenation.

**Monitoring**

Monitoring is important not only for optimizing ventilator setting, but also to warn against impending catastrophe if NIV fails.$^{[127]}$

**Subjective response**

- Once NIV is successfully initiated the smooth adaptation of the patient to the ventilator is very important
- One should try to make the patient comfortable by loosening the head strap or changing the interface. NIV should alleviate his symptoms like dyspnea. Once the patient is more comfortable, he tolerates NIV better.

**Physiological response**

- Simple vital sign should show an improvement. These can be assessed by examination of chest wall movement, heart rate, respiratory rate, mental state and patient coordination with the ventilator. One of the first signs of a good response to non-invasive ventilation is a drop in the respiratory rate within a first few hours. Evaluation of the patient ventilator synchrony is difficult without visualization of flow and pressure waveforms
- This is possible in ICU ventilators with graphic displays and advanced NIV ventilators. Air leak and patient ventilator asynchrony should be monitored and corrected as and when required and one must remember that the tidal volume displayed may be misleading, particularly during use of bi-level ventilators. The readout is usually inaccurate in the presence of air leaks.

**Adequate gas exchange**

- Oxygen Saturation or pulse oxymetry in the acute setting is a most fundamental measurement and should be maintained >90%. ABG is used to judge the effectiveness of noninvasive ventilation. In acute respiratory failure, ABG should be checked at baseline and at 1-4 hours
- A number of studies have shown that improvement in arterial blood gas tensions particularly in pH, after a short period of NIV predicts a successful outcome.$^{[5,57,136,142]}$ It is recommended that ABG be done at least once a day in stable patients. Before discontinuing NIV, the patient’s ABG without NIV for one hour may be a good guide to predict weaning from NIV.
Problems and complications

NIV is both safe and well tolerated in both acute and chronic settings, when applied in appropriately selected patients. However, there can be problems, which can be solved by judicious application of NIV.

Problems related to the interface

- Interface related problems are the most commonly encountered complications of NIV. An improperly fitting mask and excessive strap tension cause discomfort (30-50%), nasal bridge redness (5-10%), feeling of pressure over nose and claustrophobia (5-10%). The discomfort at the point of skin contact is related to the strap tension necessary to control air-leak. Pressure sores occur when excessive pressure is applied for too long.

- Patient should be clinically evaluated at each mask change for trigger-sensitivity and pressure settings.

Practice points

- The smallest size mask that just encompasses the nose is usually the best nasal mask.
- Forehead spacers should be used and replaced regularly to redistribute pressure away from nasal bridge.
- Strap tension should be adjusted so that no fewer than two fingers can be accommodated under them.
- Use elasticized head straps.
- A barrier dressing over the nasal bridge may be used from the outset to reduce risk of complications.
- If ulceration occurs over nasal bridge, artificial skin ('Duoderm') may be applied to the area for greater protection.
- When NIV is being initiated just hold the mask (without the strap being tied) on the nose or face for a few minutes so that the patient gets adjusted to the pressure and does not feel claustrophobic. Though this is time consuming, it helps in increasing mask tolerance.
- Some leak is inevitable. If the patient is able to trigger the ventilator, accept a small leak.
- Full face mask may be advantageous in patients who are unable to tolerate a nasal mask due to some nasal pathology.

Problems associated with air pressure and flow

- Air Pressure and Flow can cause minor problems, which can be managed with simple measures.
- Leaks large enough to render NIV ineffective have been reported in only a minority of patients. Air pressure in nose and sinuses may cause pain, burning, coldness or ear pain (10-30%), nasal congestion (20-50%) and dryness (10-20%). Oral dryness can be caused by a air leak through mouth. High nasal airflow related to air leaking through the mouth increases nasal resistance.

- Gastric distension can occur in some patients but is rarely intolerable.
- Air leak on the side of nose may also cause eye irritation. Excessive tightening of mask strap could be responsible for this.

Practice points

- Use correct sized mask and headgear to minimize leak
- In acute respiratory failure, use full-face mask to prevent for excessive mouth leak
- Initiate NIV with relatively low inspiratory pressure (6-8 cm H₂O) and then titrate upward as tolerated.
- For nasal congestion, use topical nasal steroids or anti histamines
- For nasal dryness, use topical saline or emollient spray
- Oral dryness responds to reducing mouth leak. One may use a chinstrap or change to full-face mask
- Intermittent nebulization with saline can help in humidification
- Humidifiers may increase ventilator circuit resistance, interfering with triggering and rendering ventilator pressure settings inaccurate; hence their use should be avoided.
- Simethicon may help in gastric distension
- Adjust the strap, use soothing eye drops or use bubble mask for eye irritations.

Problems associated with intolerance to NIV

- Intolerance to NIV may be due to mask intolerance or patient ventilator asynchrony. Improper size or fitting of mask and excessive strap tension are the important reason for mask intolerance
- Patient - ventilator asynchrony in NIV was observed when PSV mode was used and there was a major air leak. 10-15% of patients are not able to tolerate the sensation of foreign body on the face or the airflow.

Practice point

- Intolerance should be dealt with patience and persistence
- Adjustment in EPAP may help in patients with presumed auto PEEP
- Adjust inspiratory support to assure adequate inspiratory time. Use of ventilators that allow setting of inspiratory trigger sensitivity and a shorter
inspiratory duration (0.5-1.5 sec) may ameliorate asynchrony
• Reassure and encourage the patient. Suggest to the patient to let the machine breathe for him.

Problems associated with failure to ventilate adequately
• Failure to ventilate could be due to air leaks, rebreathing, poor patient compliance or progression of the primary disease.
• Air leak: There is no airtight conduit with NIV hence it is not possible to achieve a leak free assembly.
• CO$_2$ rebreathing: The BiPAP and other bi-level ventilators use bias flow during exhalation to flush exhaled CO$_2$ out through an exhalation valve. Ferguson and Gilmartin$^{[126]}$ have demonstrated that rebreathing may interfere with the capability to lower CO$_2$ when used with certain expiratory valves at a low expiratory pressure. Swivel exhalation valve (BiPAP) has been shown to prevent rebreathing when expiratory pressures are <4 cm H$_2$O
• Position of exhalation port affects dynamic dead space. Port over nasal bridge is the best in this regard followed by that elsewhere within the mask and those in between mask and ventilator circuit.
• In patients with advanced restrictive thoracic and parenchyma lung diseases or progression of primary disease, the set support may be inadequate and may need to be increased.

Major complications
Major complications are infrequent (5%) if the patient is appropriately selected. They include:
• Delay in intubation and worsening of prognosis
• Major desaturation and cardiac arrest in hypoxemic respiratory failure
• Aspiration pneumonia occurs in up to 5% of patients. It is most often seen in patients who are reluctant or decline to undergo endotracheal intubation and may have some impairment of airway protective mechanisms but desire trial of NIV
• Hypotension: Is infrequent among appropriately selected patients. In case the patient has inadequate intravascular volume or underlying cardiac disease, the mild increase in intrathoracic pressure may decrease venous return and cause hypotension. Development of auto PEEP is another reason for causing hypotension in COPD patients.$^{[127]}$
• Pneumothorax may occur in patients with bullous lung disease. The bullae may rupture and produce pneumothorax if high insufflation pressures are used (>25 cm H$_2$O)$^{[128]}$. When CPAP/BiPAP is used in patients with rib fractures there is a risk of developing pneumothorax which is similar to that occurring in invasive ventilation.

Practice point
• Exclude patients with compromised upper airway function or those who have a problem clearing secretions
• Do not permit at risk patients anything by mouth till they are stabilized. Use of nasogastric or orogastric tubes in these patients is undesirable
• Adequate hydration of the patient must be assured. In patients with pulmonary edema begin with CPAP alone or bilevel ventilation using low inflation pressures (11-12 cm H$_2$O - IPAP; 4-5 cm H$_2$O EPAP) while monitoring clinical response.$^{[62]}$
• Use of NIV should be avoided in patients with uncontrolled ischemia or arrhythmias until these problems are stabilized
• Inspiratory pressures should be kept at minimum effective level in patients with bullous lung disease. Patients with chest wall trauma who are being treated with NIV or CPAP should be monitored in ICU.

Location of NIV
It is understandable that various countries have different standards of care and definitions of ICU, high dependency unit (HDU) and general ward. Even in our country, model of hospital care varies from city to city. Different patterns of staffing, facilities, resources, degree of training and monitoring systems may be prevalent in ICUs, HDUs and general wards. For discussion purposes on NIV we will define these areas as mentioned below:
• Intensive care unit: ICU is a unit with high ratio of medical staff to patient. Facilities for invasive ventilation and invasive/noninvasive monitoring are present
• High dependency unit: HDU is a clinically specified area where the facility for continuous monitoring of vital signs is present and the staffing ratio is in between ward and ICUs
• General ward: A General ward is a place where patients with a variety of conditions and varying degrees of severity are managed. There is a variable staffing pattern in various hospitals but it is not as intensive as HDUs and ICUs.

As one does not require sedation and paralysis for NIV, it is possible to apply this modality outside the ICU. It is expected that the application of NIV outside the ICU will ease the pressure on ICU beds. Randomized controlled trials have proved the effectiveness of NIV in both ICU and wards.$^{[18]}$ One must remember that these studies were done in units committed to ventilation
by noninvasive approach and with required expertise. This factor, more than any other, has been important in determining the outcome.

The outcome of NIV is remarkably similar in different settings viz. research institutes and peripheral usual care providers. Studies have shown that regardless of the location, the success of NIV is similar between community teaching hospitals and ICUs across Europe. When a well-trained staff is available, it really does not matter. There are only a few prospective randomized controlled studies of NIV outside the ICU. These studies lacked the number, which precluded conclusive inferences. However, in a large study covering 13 centers (n = 236), NIV was applied in the general wards by the usual ward staff, using a bilevel device in spontaneous mode, following a simple protocol. The study showed that with NIV treatment failures could be reduced from 27 to 15% (P < 0.05) and mortality in these patients reduced from 20 to 10% (P < 0.05). In patients with pH < 7.3, results of initial treatment in the ward was inferior to that of patients treated in the ICUs. It was also demonstrated that early NIV in a general ward resulted in a better outcome than providing no ventilatory support for acidic patients outside the ICUs. However, most of the patients studied were those with acute exacerbation of COPD. The results thus indicated that NIV could be applied with benefit outside the ICU by trained usual ward staff and early introduction of NIV in a general ward results in a better patient outcome.

There are no RCTs of NIV outside ICUs in patients with hypoxemic respiratory failure or for weaning. Currently, some data is available from the study of Antonelli et al. Although, theoretically NIV can be applied in the Emergency Department (ED), in India the distinction between ED and ICU fades away in many hospitals. Most patients with an acute exacerbation of COPD coming to ED do not actually need NIV. Those patients who remain acidotic and tachypnoeic after a while after starting standard medication should be put on NIV in the ED. However, it is imperative that staff trained to initiate and monitor NIV is available in the ED. CPAP has been shown to be of benefit in acute cardiogenic pulmonary edema in the emergency department. The time spent in emergency ward will vary from hospital to hospital. In some hospitals as soon as the patient is stabilized and bed is arranged, he is shifted to the ward. Others have observation facilities for few hours. NIV can be started in the emergency ward and the patient quickly transferred to a place where mask expertise is available.

Success of NIV depends on the initial evaluation and/or the response to a short-term trial. This obviously depends upon the skill of the staff and basic minimal monitoring of parameters to detect early failure. The first few hours are of vital importance and it is mandatory to monitor parameters (SpO2, arterial Blood Gases, vital signs, patient comfort, mask leaks and the patient’s ability to expectorate) by trained personnel, be it a nurse, respiratory therapist or a physician. There is not much information especially in randomized clinical trials in the literature on who should perform NIV. In fact many of the guidelines published have taken for granted the automatic and universal existence of respiratory therapists. In a country like India respiratory therapists are scarce and nurses are not trained in NIV. So for some time to come, it will be the physicians who will take primary responsibility of initiating and monitoring NIV.

It is important that the attending staff be able to detect the non-responding patient by frequent clinical examination and persistently abnormal blood gases. They should also be familiar with the equipment, explanation of the procedure to the patient and potential complications of NIV. Nurses, physiotherapists or respiratory therapists may be the caregivers and this will also depend on local availability and enthusiasm and expertise.

If a patient has pH < 7.3, they are better managed in HDU or ICU.

**Recommendations**
- In acute respiratory failure, NIV can be provided in many locations in the hospital like in ICU, high dependency area, respiratory ward or NIV unit, emergency ward or general ward. However, in India for the time being ICU is the best place. (Level III) Choosing a location for NIV will depend on many factors like clinical state of the patient, severity of respiratory failure, significant co-morbidity and the condition for which NIV is being applied. This will also depend on whether the patient will be intubated if NIV fails, patient’s nursing requirements and skill level of the physician, experienced nurse and therapist. (Level II)
- A trained person who could be a physician, physiotherapist or a house nursing staff can initiate NIV. The outcome will depend on the training of the individual. Minimal mandatory requirements of the staff should include the ability to monitor the NIV trial, vital parameters (such as saO2, paCO2, pH, vital signs, patient comfort, mask leaks, patient’s ability
to handle secretions etc) and more importantly to recognize failure of NIV. (Level III)

• A ward with trained staff will show a better outcome than an ICU with high nurse doctor ratio and high level of monitoring but little experience of NIV. (Level III)

• Patient who require continuous NIV and cannot sustain oxygenation during even a brief discontinuation are better managed in ICU or HDU. (Level III)

• There must be a proper protocol of who will start and who will monitor the patient and at what frequency the ABG will be sent. (Level III)

• Any area, which has the following facilities, can be used for applying NIV: (Level II)
  - Staff with training and expertise in NIV on a 24 hr basis
  - Rapid access to endotracheal intubation and invasive mechanical ventilation
  - Facilities for monitoring
  - Oximetry
  - Frequent monitoring by staff nurse and documentation.

NIV should be applied in the ward on only those patients who are suffering from a disease state where the role of NIV has been established. (Level III)

• Patient who fulfills the following criteria can be ventilated in the wards:
  - COPD patients (pH >7.30), who are not seriously ill
  - Patients who can protect their airways
  - Requirement of intubation appears unlikely.

Trained staff nurse should be available to monitor patient frequently. It is also essential to have good nurse to patient ratio with a minimum of one to four in the ward.

• Patients who fulfill the following criteria can be ventilated in HDU and emergency ward.
  - Patient who can tolerate brief discontinuation of NIV mask.
  - Patient suffering from COPD, cardiogenic pulmonary edema, acute respiratory failure in obstructive sleep apnea and mild cases of hypoxemic respiratory failure.
  - PH <7.3 but more than 7.2.

In addition to trained staff to monitor NIV, intubation equipment should also be available in the same area.

Those patients who have a greater likelihood of failure should always be ventilated in the ICU i.e., pneumonia, ARDS and asthma.

Starting NIV service (158)

NIV services can be started if the following conditions are fulfilled.

• Availability of necessary equipment. A simple pressure targeted machine would be ideal
• There should be supply of range of nasal, facemasks and tubes
• Facility for cleaning and disinfecting mask and tubing should be available
• Trained staff with basic knowledge of NIV, masks and ventilatory circuit should be available. They should know how to adjust setting, how to manage leaks and minor problems including cleaning and disinfecting
• Nurses with previous experience in the ICU/NIV are useful
• One physician trained in NIV should be available on call 24 hours a day.

Management of COPD with limited resources

COPD, the 12th most common disease worldwide, is a major cause of mortality and morbidity. The 2002 WHO world health report lists it as the fifth leading cause of death in the world. It is expected that by 2020, COPD will become the third most common cause of death. The burden of COPD is high in developing countries. The morbidity data greatly underestimates the true prevalence of the disease due to under reporting. The median values of prevalence rates of COPD in India have been estimated to be 5% in males and 2.7% in females. In 1996 the total number of adult patients more than 30 years of age was estimated to be 8.16 million males and 4.21 million females. The comparatively higher prevalence rates of COPD in women in developing countries is due to a high exposure to indoor particulate air pollution caused by cooking with biomass fuels in poorly ventilated dwellings. Thus we face a large, often underestimated, burden of COPD, which is predicted to assume epidemic proportions in the next decade.

Patients with COPD are prone to exacerbations as their disease progresses. Exacerbations in COPD are associated with significant morbidity and mortality. In a large study, Connors and colleagues studied more than 1000 patients admitted to hospital with severe hypercapnic exacerbations of COPD. Half of these patients had to be admitted to the ICU, with 35% of them needing mechanical ventilation. Hospital mortality was 11%. Seneff et al. have also demonstrated a high in-hospital mortality of 24% in COPD patients admitted to the ICU.

In our country, a large number of patients with COPD die due to a lack of management facilities when they present in acute exacerbations with hypercapnic respiratory failure. These patients cannot on most
occasions be shifted to a well equipped centre as facilities for invasive ventilation are few and the numbers of ICU beds are far less than needed. There is, therefore, a pressing need for simple, inexpensive but effective therapeutic interventions for treating critically ill patients even in centers where ICUs are not available.

NIV reduces the need for intubation, risk of treatment failure, length of hospital stay and mortality in these patients. Although earlier studies of NIV in COPD patients have been reported in an ICU setting, there is now enough evidence that NIV can be initiated even in general wards with simple ventilators. In a landmark prospective multicentric study in patients of COPD in 14 centers in UK, Plant et al. demonstrated that the need for intubation was reduced from 27 to 15% by NIV in general wards and hospital mortality was reduced from 20 to 10%. The ward staff with little or no previous experience was able to administer NIV after training. NIV was administered with an unsophisticated ventilator and only the levels of inspiratory and expiratory pressures were adjusted according to a simple protocol. This study of ward based NIV for acute exacerbations of COPD confirmed that it is a highly cost-effective treatment. This data suggests that non-invasive ventilation in wards can avoid admissions to intensive care units and reduce both costs and deaths, especially in developing countries.

In a survey of NIV in patients with acute exacerbations of COPD in UK, about 20% centers used clinical guidelines without ABG to select patients for treatment with NIV. These included exhaustion and failure to improve on standard treatment. In another study, Plant et al. have estimated that 46.7% patients admitted to a district general hospital in UK were hypercapnic and 20% had respiratory acidosis (pH < 7.35). There was however a consensus in the panel that the number of patients deserving treatment in our country is large with a wide demand supply gap.

The skills required for NIV are easily learnt and the equipment required is relatively inexpensive. The complication rate is very low when compared to invasive ventilation. Physicians and nurses can use NIV early outside the ICU to prevent deterioration in the patient’s condition as NIV can be started at an early stage in the evolution of respiratory failure. Reversing respiratory failure is likely to be easier at an early stage when, theoretically, lower pressures used for shorter periods may improve the physiological disturbances.

NIV in general wards thus appears to be a suitable treatment modality for low-income countries because of the limited availability of ICU facilities. The expert panel therefore believes that there is evidence to support the use of NIV in acute exacerbations of COPD even in smaller centers without ICU facilities.

Another significant question raised by some members and the international reviewer was whether or not NIV can be administered in selected COPD patients with acute exacerbations in the absence of facility for ABG. Equipment for NIV and oxymetry is much easier to install and maintain than a blood gas testing facility. The expert panel believes that this simple and inexpensive modality should be tried in selected patients even in the absence of blood gas testing facility or ICU, if well trained staff is available. At present such patients get only medical treatment and many of them die due to unavailability of any ventilatory support. Of course it may lead to overuse of NIV but it will save many lives.

**Recommendations**

- “NIV can be used if the arterial blood gases report of a patient with acute exacerbation of COPD shows a pH < 7.35 with a paCO2 > 45 mm Hg, even if facilities for invasive ventilation are not available” (level III)
- The expert panel recommends that in acute exacerbations of COPD, NIV can be used even if no facilities for ABG testing or ICU are available in the following circumstances: (Level III)
  - Failure of exacerbation to respond to initial medical management with increasing dyspnea
  - Use of accessory muscles with paradoxical chest and abdominal movements or onset of new physical signs-cyanosis, peripheral edema or mild confusion, lethargy or alteration in sensorium
  - Appearance of signs of hypercapnia-peripheral venous dilatation, tachycardia despite optimal oxygen saturation, bounding pulse with wide pulse pressure, asterixis (flaps), throbbing headaches
  - Persistent or worsening hypoxemia despite supplemental oxygen
  - Significant co-morbid disease-cardiac, uncontrolled diabetes etc.
- The expert panel recommends that facilities for NIV with adequately trained staff should be made available for treating patients with COPD at all levels of care-primary health centers, small nursing homes in towns, secondary care (district level hospitals, large multispeciality nursing homes in cities) and tertiary care level (medical colleges, corporate and specialty hospitals). (Level III)
- In circumstances of NIV application in the absence
of ABG facilities or invasive ventilatory support and ICU care physicians must educate themselves on the signs of failure of NIV support and refer patients to a higher level of care if feasible after 4 hours of trial. (Level III)

**Practice points**

In addition to trained staff, the following minimum equipment should be available before NIV service can be initiated:

- Pulse oxymetry
- Portable pressure ventilator
- Adequate supply of oxygen
- ECG monitoring.

**References**

5. BTS guidelines noninvasive ventilation for acute respiratory failure. Thorax 2002;57:192-211.
24. Li J, Zhang D, Huang X, et al. Comparison of healing effect of...
46. Holley MT, Morrissey TK, Seaberg DC, Afessa B, Wears RL. Ethical dilemmas in a randomized trial of asthma treatment: Can Bayesian statistical analysis explain the results? Acad Emerg Med 2001; 8:1128-35.


Hess DR. The evidence of noninvasive positive-pressure ventilation in the care of patients in acute respiratory failure: A systematic review of the literature. Respir Care 2004;49:810-29.


Hill NS. Complications of noninvasive positive pressure ventilation. Resp Care 1997;42:452-42.


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