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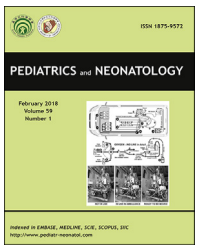

Short Communication

A customized iNO therapy device for use in neonatal emergency transport

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1. Introduction

The use of inhaled Nitric Oxide (iNO) to treat persistent pulmonary hypertension (PPH) in near-term and full-term neonates significantly improves oxygenation,[1,2] and it is useful and safe.[3,4] The "Equipment" section of the most recent edition of the "*Guidelines for Air and Ground Transport of Neonatal and Pediatric Patients*"[5] clearly states the need to include iNO administration equipment among the specific recommendations for Neonatal-Pediatric Transport. The efficacy, safety, and use of iNO during air and ground transport have been evaluated,[6,7] and it was found that iNO can be safely delivered during transport in a variety of ways.[1] Some commercially available delivery devices are now on the market, but they have to be adapted to various modes of transport or local regulations. In this brief communication, we describe a customized iNO therapy device for use in our Neonatal Emergency Transport Service (NETS) in the Liguria region, Italy.

2. A device description

Our trolley for neonatal transport contains two ventilators,[8] three syringe pumps, a suction unit, a multifunction monitor, a transcutaneous monitor, a defibrillator, and four 3-L/200 atm tubes, of which two are for oxygen and two are for air. The weight of the trolley as per this set up, that includes the transport bag, averages approximately 170 kg (375 pounds). When we decided to improve the quality of our NETS, fitting it with an iNo device, we mainly took into consideration what device(s) was/were available and the effects of the increase in the weight on trolley handling. Currently, in Italy, the only available delivery system is the iNOmax transport system (INO Therapeutics LLC d/b/a Ikaria, Inc., NJ, USA, available at: http://inomax.com/wp-content/uploads/2015/01/20010_rev_05_INOmax_DSIR_Operation_Manual_with_Links.pdf). The INOmax system weighs approximately 15 kg (33 pounds), thus increasing the total trolley weight to approximately 185 kg (400 pounds), i.e., increasing both the weight (approximately 9%) and the handling difficulties with the trolley. A further important consideration was to imagine the possible number of transports per year that might potentially require iNO therapy. PPH is estimated to affect around 10,000 full-term and near-term neonates in the USA annually, calculated on a birth rate of around 4 million births (2013) (http://www.cdc.gov/nchs/fastats/births.htm), and the prevalence of PPH has been estimated at around 1.9 per 1000 live births based on 71,558 newborns with a broad variation observed among the centers (0.43–6.82 per 1000 live births).[3,9] In Italy, epidemiological data are currently not available; we have experienced no more than 2–3 cases per year during the last five years of NETS activity. These figures, in our opinion, do not warrant keeping the iNO device permanently assembled in the transport trolley. Thus, we decided to build a semi-permanent device mounted inside the

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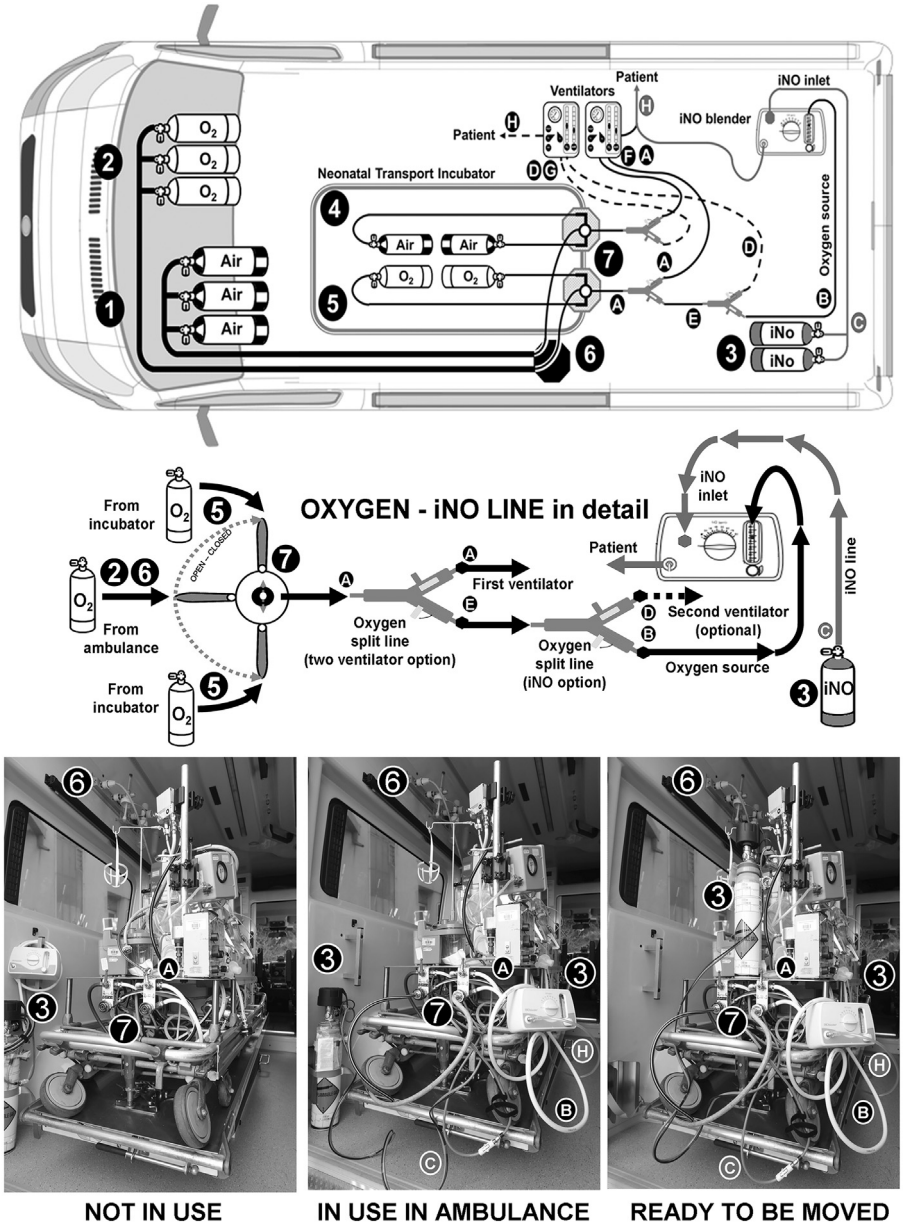

Fig. 1 Upper panel: A schematic diagram showing the device assembly. Lower panel, from left to right: The device not in use, as stored inside the ambulance; then set up for use in the ambulance; and finally, when the trolley is ready to be moved from the ambulance. 1 and 2: Air and oxygen ambulance spares, respectively (three 10-L cylinders each). 3: NO cylinders (an iNOmax device). 4 and 5: Air and oxygen neonatal transport incubator spares, respectively (two 3-L cylinders each). 6: Fixed gas connections in the ambulance. 7: Gas connections on the neonatal transport incubator. A: An oxygen line to the ventilator. B: An oxygen source to the iNO blender. C: A NO line to the iNO blender. D: An optional second oxygen line to the second ventilator (for twins only). E: A split oxygen line to be used optionally for twins or for iNO therapy. F: An airline to the ventilator. G: An optional second airline to the second ventilator (for twins only). H: A line to the patient from the ventilator. Note: Turn the iNO blender setting dial to the delivered concentration (15—20 ppm); turn the oxygen flow-meter to the flow rate 5—14 L/min; before connecting to the patient, and be sure to purge the NO_2 from the system.

ambulance; this device, which is therefore always available during transport, may be immediately and easily moved from the ambulance and transferred onto the trolley only if and when necessary and without any interruption of the iNO administration. This way, iNO therapy is always available, but at the same time, the trolley is free from the burden and weight of the iNO device. This "custom" system is shown in the Fig. 1 (see the legend for complete details).

3. Discussion

In our regional setting of perinatal care, iNO therapy is not available at all of the referring hospitals. We consider our solution to be safe, cheap, and appropriate in our specific setting on the basis of specific conditions, including the fact that a) the 2 l size "iNOmax" cylinder at 155 bar will deliver

up to 20 ppm nitric oxide for almost 10 h at approximately 10 l per minute; b) in our geographical setting, the longest transport may average approximately 3 h; c) although we can expect no more than 2—3 cases per year on the basis of our prior NETS activity, by applying the device proposed herein, we can be ready at any time to deal with patients who unexpectedly need iNO therapy during transport; d) the proposed method complies with local regulations; e) a specific training and practice program has been completed with this system; and f) by moving the iNOmax device from the ground ambulance to the neonatal transport incubator, it can be used in the helicopter. Previous experience by Kinsella et al.,[6] who evaluated the effects of the possible accidental release of NO into the transport vehicle by simulating the catastrophic release of the entire NO cylinder into the transport vehicle, led to the conclusion that NO and NO_2 concentrations remained within safe ranges during transport even in vehicles (fixed wing and rotor wing aircraft, and ground vehicles) with no air exchange. The portable device described herein is certified and authorized for use in Italy; no specifications have been provided on "how" we must use the device, i.e., if it has to be anchored to the ambulance, or to the trolley, or other possibilities. Thus, our article describes how we have tried to solve the problem; the suggested solution is certainly feasible within the limits of the Italian law. A variety of regulations are surely present in other countries and the readers must be warned that this solution may not be allowed in other/some countries. We believe that iNOmax in transport is not considered "off-label" in Italy or in countries in which iNOmax has been certified. We believe that how each individual transport service decides to carry the device does not influence its correct use.

In conclusion, we believe that the proposed device may be a satisfactory solution in cases of low annual iNO therapy use in neonatal transport, avoiding the risk of overloading the transport trolley while being sure of the possibility to treat severely affected newborns at any time.

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