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ProSeal™ laryngeal mask airway for surfactant administration in the treatment of respiratory distress syndrome in a premature infant

Máscara laríngea ProSeal™ como via de administração de surfactante no tratamento da síndrome do desconforto respiratório em recém-nascido pré-termo

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ABSTRACT

The administration of surfactant via tracheal cannula with mechanical ventilation is the conventional treatment for infant respiratory distress syndrome. Hemodynamic and respiratory changes due to tracheal intubation and the need for premedication justify the search for less invasive alternatives of surfactant administration. The objective of this study was to describe the use of the *ProSeal*™ laryngeal mask airway as an option for the treatment of respiratory distress syndrome in a premature infant born at 31 weeks of gestation, at 1335 g, with respiratory difficulty after the first hour of life and exhibiting the clinical and radiologic features of respiratory distress syndrome. The surfactant was administered with the use of the *ProSeal*™ laryngeal mask airway at 3.5 hours of life. It was well tolerated, with no need for tracheal intubation. Normal gasometry and radiologic improvement were observed after three and six hours of administration. Oxygen administration was suspended after eight days, with no comorbidities at discharge. The laryngeal mask airway seems to be a painless and less invasive alternative to treat respiratory distress syndrome and may reduce the need for tracheal intubation and mechanical ventilation. The efficacy and advantages of this route of treatment should be confirmed in a study of an adequate sample.

Keywords: Laryngeal masks/utilization; Infant, premature; Respiratory distress syndrome, newborn/drug therapy; Surface-active agents/administration & dosage

INTRODUCTION

The early administration of exogenous pulmonary surfactant via tracheal cannula, after intubation and followed by mechanical ventilation, has become a standard of treatment or prevention for respiratory distress syndrome (RDS) in premature infants due to the widely demonstrated decreases in mortality, incidence of pneumothorax and permanent sequelae.[1] Laryngoscopy and tracheal intubation are, however, procedures associated with a high nociceptive potential and which incur hemodynamic, respiratory and neurological risks. Premedication given to attenuate these effects has inconveniences related to the pharmacodynamic side effects of the drugs, e.g., marked arterial hypotension and apnea, in addition to the intrinsic toxic potential of the drugs.[2]

Furthermore, what the best respiratory support mode for RDS is remains a matter of discussion, considering the association between mechanical ventilation, pulmonary lesions and bronchopulmonary dysplasia.[3]

Two randomized clinical trials have highlighted that initial stabilization with nasal continuous positive airway pressure (CPAP) and, if necessary, treatment with surfactant results in a similar development as that obtained with conventional

This study was conducted at the School of Medicine, Universidade Federal de Minas Gerais – UFMG - Belo Horizonte (MG), Brazil.

Conflicts of interest: None.

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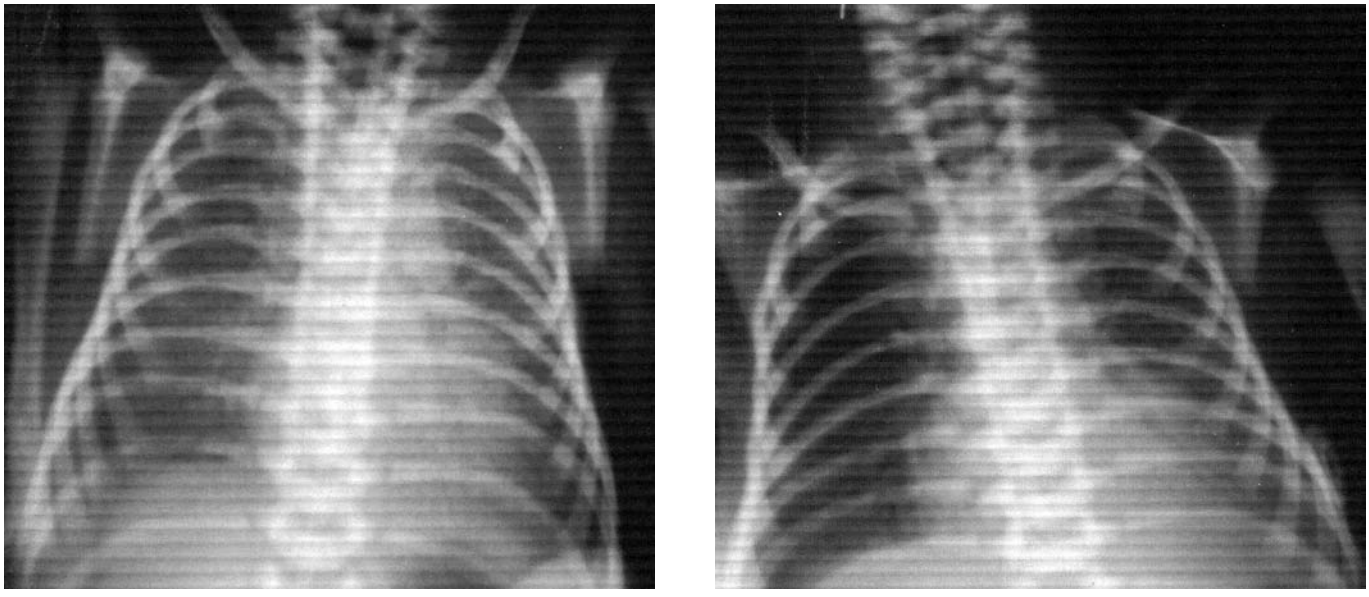
treatment.[3,4] Prophylactic administration of surfactant at 30 minutes of life, followed by brief ventilation and extubation, when compared to treatment with nasal CPAP alone did not reduce the need for mechanical ventilation during the first five days of life or the incidence of morbitities related to prematurity. It is important to note that the INSURE (INtubation, SURfactant and Extubation) therapeutic method implies sedation and analgesia for tracheal intubation in addition to mechanical ventilation until extubation is possible after sedation withdrawal. In this context, the benefits of prophylactic surfactant could be compromised by the short ventilation period required for INSURE.

Recently, alternative, less invasive methods have been proposed for the administration of surfactant that do not depend on the use of positive pressure, even for a short period of time[1]. The use of nebulized surfactant still faces technical difficulties that prevent a final demonstration of its efficacy *in vivo*. In recent years, studies have been published describing the nasopharyngeal instillation of surfactant in the delivery room,[5] administration via a thin endotracheal catheter[6,7] or via a laryngeal mask airway (LMA).[2] The initial results in a small number of patients suggested LMA as a possible alternative route for surfactant treatment. Its well-tolerated introduction and the possibility of surfactant administration without mechanical ventilation and pulmonary damage seem to be potential advantages that need to be confirmed with an adequate sample of patients.[2] In developing countries, alternatives to RDS treatment should allow for the possibility of shorter mechanical ventilation and hospitalization times, which could result in savings of economic and human resources.

This study reports the successful use of the *ProSeal™* LMA for surfactant administration in the treatment of RDS in a premature infant for the first time in Brazil.

CASE DESCRIPTION

A female infant was born at 31 weeks and three days of gestational age with a birth weight of 1335 g, adequate for her gestational age, at the "Hospital Dia e Maternidade Unimed-BH", in Belo Horizonte, Brazil. The mother did not have any abnormalities in the prenatal complimentary tests, and a caesarean section was requested due to gestational hypertension, after administration of a corticosteroid course. The rupture of membranes revealed clear amniotic fluid. Positive pressure ventilation in the delivery room was not necessary, and the Apgar scores at one and five minutes were eight and nine, respectively. Upon admission to the neonatal intensive care unit, the infant was eupneic in room air, but subsequently presented respiratory difficulty. An umbilical vein catheter was placed, and nasal CPAP was indicated (6 cmH_2O with a fraction of inspired oxygen (FiO_2) of 30%). The calculated predictive index of morbidity and mortality, Clinical Risk Index for Babies (CRIB II), was four. The infant developed a progressive worsening of the respiratory effort and an increase in oxygen demand from the first hour of life. The chest X-ray revealed a diffuse reticulogranular pattern (Figure 1), and surfactant administration using the *ProSeal™* LMA number one (Figure 2) for newborns



Before surfactant administration — Six hours after surfactant administration

Figure 1 - Chest X-rays before and six hours after surfactant administration using the *ProSeal™* laryngeal mask airway.

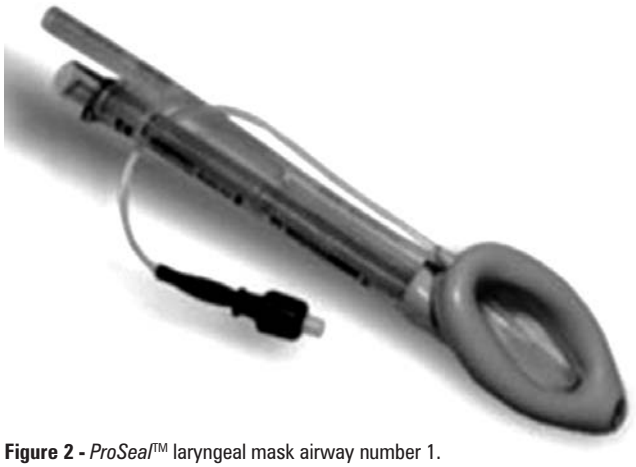


Figure 2 - *ProSeal*™ laryngeal mask airway number 1.

or children up to 5000 g was then indicated. The mother signed the free and informed consent form, allowing for the procedure and this case report.

The LMA was inserted in the oral cavity according to the Brain technique,[8] using lidocaine gel for topical anesthesia. After insertion, the LMA cuff was inflated with 4 mL of air to prevent leakage with a peak pressure tested to 30 cmH_2O. The correct positioning of the LMA was confirmed by checking for the bilateral entry of air and confirming symmetrical and satisfactory chest expansion. The mask insertion occurred in less than 20 seconds without the occurrence of adverse events during the procedure. The degree of difficulty of inserting the LMA was rated as a 3 on a visual analog scale from 0 (no difficulty) to 10 (impossible to insert). After checking the correct positioning of the LMA, a urethral probe number 6, cut at the opening of the LMA, was introduced without resistance through the vent for the administration of 200 mg/kg of surfactant (at 3.5 hours of life) as a bolus via syringe. Positive pressure ventilation was performed again for 120 seconds to enable the distribution of the surfactant, followed by the withdrawal of the MLA and restarting of nasal CPAP. During insertion of the LMA, the following were recorded: a heart rate (HR) of 128 bpm and a minimum oxygen saturation of 77% (for less than ten seconds). Next, the orogastric probe was introduced, and 2 mL of clear fluid secretions were aspired.

The monitoring of the patient was performed by means of hemodynamic and respiratory parameters measured before (time 0) and after the administration of surfactant (at 20, 35, 60 minutes and then every 30 minutes up to six hours), including the respiratory rate (RR), Silverman-Anderson score (SAS), heart rate (HR), mean blood pressure (BP) and extremities perfusion (Table 1). Additionally, pain was evaluated by means of the Neonatal Infant Pain Score (NIPS) during the procedure at the following times: baseline on nasal CPAP (NIPS = 4), shortly after the introduction of the LMA (NIPS = 0) and after the removal of the LMA on CPAP (NIPS = 5). Gasometric and radiological parameters were evaluated, respectively, three and six hours after surfactant administration. Figure 1 shows the improvement in pulmonary inflation compared to the radiological test prior to surfactant administration.

Table 1 – Clinical, gasometric and respiratory support data one to six hours after surfactant administration using the *ProSeal*™ laryngeal mask airway

Clinical gasometric data	BASELINE	Time from surfactant administration					
		1 h	2 h	3 h	4 h	5 h	6 h
HR (bpm)	128	127	144	153	146	150	141
RR (irpm)	66	60	89	64	77	50	43
SAS	3	3	4	4	3	1	1
Mean AP (mmHg)	71		39	39	42	44	41
Extrem perf (+/4+)	3+	4+	4+	4+	4+	4+	4+
$SatO_2$ monitor (%)	93	96	95	93	95	94	95
Nasal CPAP	6	6	6	6	6	6	6
FiO_2 (%)	50	40	35	30	30	30	30
Arterial pH				7.31			
paO_2 (mmHg)				57			
$paCO_2$ (mmHg)				42.4			
BE				-5.0			
$SatO_2$ (%)				85.5			

HR - heart rate; RR - respiratory rate; SAS - Silverman-Anderson score; AP - arterial pressure; extrem perf - extremity perfusion; SaO_2 - arterial saturation of oxygen; CPAP - continuous positive airway pressure; FiO_2 - fraction of inspired oxygen; paO_2 - partial pressure of oxygen in arterial blood; $paCO_2$ - partial pressure of carbon dioxide in arterial blood; BE - base excess.

Clinical outcome: there was tolerance of enteral feeding after 48 hours of life, with the suspension of nasal CPAP on the 7th day of life and of oxygen on the 8th day. The following complimentary exams showed no alterations: echocardiogram (7th day of life), transfontanellar ultrasound (5th, 19th and 29th days of life) and otoacoustic emission test (21st day of life). An examination of the fundus (29th day of life) showed no retinopathy of prematurity. The newborn was discharged with the mother at 33 days of life.

DISCUSSION

In 2004, Brimacombe et al. reported, for the first time, their sucessful experience of using surfactant via LMA in two infants born at weeks 30 and 37 of gestation.[7] A year later, in Italy, eight newborns with RDS between 28 and 35 weeks were satisfactorily treated with surfactant using the classic LMA number 1. The procedure was well tolerated, with no need for sedatives or analgesics.[2] In 2008, the same group of Italian researchers used the new LMA model *ProSeal*™ number one, with good results[9] The LMA was then proposed by the Italian authors as

a feasible, minimally invasive and effective alternative for surfactant administration. These results justified the conduct of a larger clinical trial for the confirmation of the initial results.[2]

In 2008 and 2009, German researchers described a previously unpublished method of surfactant administration via a thin endotracheal catheter introduced by laryngospcopy.[6] The first multicenter results of the study conducted in Germany using this method have recently been made available. Despite the sucess in the treatment of RDS, this method is limited by the difficulty of the technique and by not eliminating the pain and intense trauma related to laryngoscopy in active, non-asphyxiated newborns without sedation or analgesia.[1]

A recent systematic review of the Cochrane Library identified a single study in which surfactant was administered via LMA as a treatment for RDS in 26 patients with birth weights ≥1200 g. When the patients were compared to non-treated ones, a short-term reduction of the mean FiO_2 required to maintain an oxygen saturation level between 88 and 92% was observed for 12 hours after the intervention. No differences were found between subsequent mechanical ventilation, endotracheal surfactant, pneumothorax or days on oxygen. The authors concluded that these results are encouraging and justify new clinical trials with sufficient sample power to evaluate RDS prophylaxis and treatment with this method of surfactant administration.[10]

A randomized clinical trial is currently recruiting patients at the Federal University of Minas Gerais (Universidade Federal de Minas Gerais). The objective of this trial is to compare the efficacy, safety and prognosis (incidence of bronchopulmonary dysplasia) of exogenous surfactant replacement for the treatment of RDS in premature infants by two different administration methods and different ventilatory approaches as follow: instillation by LMA followed by nasal CPAP versus instillation by tracheal cannula followed by mechanical ventilation. The authors believe that in addition to being less invasive, the LMA surfactant administration is simpler, accessible and incurs less side-effects (pain and hemodynamic or neurologic alterations) when compared with surfactant administration following tracheal intubation.

RESUMO

A administração de surfactante pela cânula traqueal e ventilação mecânica é o tratamento convencional da síndrome do desconforto respiratório em prematuros. Alterações hemodinâmicas e respiratórias da intubação traqueal e pré-medicação justificam a busca por alternativas menos invasivas de administração de surfactante. O objetivo do presente estudo foi descrever o uso da máscara laríngea *ProSeal™* como opção para o tratamento da síndrome do desconforto respiratório em recém-nascido pré-termo com 31 semanas de gestação, 1.335 g, dificuldade respiratória após a primeira hora de vida, e quadro clínico e radiológico de síndrome do desconforto respiratório. O surfactante foi administrado pela máscara laríngea *ProSeal™* com 3,5 horas de vida, com boa tolerância e sem necessidade de intubação traqueal. Gasometria normal e melhora radiológica, após 3 e 6 horas. O oxigênio foi suspenso após 8 dias; alta sem comorbidades. A máscara laríngea parece ser alternativa indolor e menos invasiva de via de tratamento da síndrome do desconforto respiratório, com possibilidade de redução de intubação traqueal e ventilação mecânica. Por meio de amostra adequada, devem ser confirmadas a eficácia e as vantagens dessa via de tratamento.

Decritores: Máscaras laríngeas/utilização; Prematuro; Síndrome do desconforto respiratório do recém-nascido/quimioterapia; Tensoativos/administração & dosagem

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