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ORIGINAL ARTICLE

A randomized controlled trial of the laryngeal mask airway for surfactant administration in neonates☆,☆☆

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KEYWORDS
Laryngeal mask airway;
Preterm infant;
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Abstract
Objective: To compare the short-term efficacy of surfactant administration by laryngeal mask airway versus endotracheal tube.
Methods: Preterm infants (28–35 weeks of gestational age), weighing 1 kg or more, with respiratory distress syndrome, requiring nasal continuous positive airway pressure, with increased respiratory effort and/or fraction of inspired oxygen (FiO_2) $\geq$ 0.40 to maintain oxygen saturation 91–95%, were randomized to receive surfactant by LMA following nCPAP or by ETT following mechanical ventilation (MV). The primary outcome was a clinical response defined as $FiO_2 \leq 0.30$ three hours after surfactant. Secondary outcomes for LMA group were: need of surfactant retreatment during the first 24 h, MV requirement, and presence of surfactant in gastric content.
Results: Forty-eight patients were randomized; 26 in the LMA group and 22 in the ETT group. Six of 26 patients (23%) in the LMA group and five of 22 patients (22.7%) in the ETT group did not meet the primary outcome ($p = 0.977$). Fourteen (53.8%) of the LMA patients were not intubated nor ventilated; 12 (46.1%) were ventilated: for surfactant failure (23%), for nCPAP failure (11.5%), and for late complications (11.5%). Groups were similar regarding prenatal status, birth conditions, and adverse events. No significant gastric content was found in 61.5% of the LMA patients. Oxygen and second dose surfactant requirements, arterial/alveolar ratio, and morbidities were similar among groups.

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☆☆ Study conducted at Universidade Federal de Minas Gerais (UFMG), Faculdade de Medicina, Belo Horizonte, MG, Brazil.
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Conclusions: Surfactant administration by LMA showed short-term efficacy, with similar supplementary oxygen need compared to surfactant by ETT, and lower MV requirement. Further studies with larger sample size are necessary to confirm these results.

PALAVRAS-CHAVE
Máscara laríngea;
Neonato prematuro;
Surfactante pulmonar

Ensaio controlado randomizado de máscara laríngea para administração de surfactantes em neonatos

Resumo

Objetivo: Comparar a eficácia de curto prazo da administração de surfactante por máscara laríngea em comparação ao tubo endotraqueal.

Métodos: Neonatos prematuros (28–35 semanas de idade gestacional), pesando 1 kg ou mais, com Síndrome do Desconforto Respiratório, necessitando pressão positiva nasal contínua nas vias aéreas, com aumento do esforço respiratório e/ou fração de oxigênio inspirado (FiO_2) $\geq$ 0,40 para manter a saturação de oxigênio 91–95%, foram randomizados para receber surfactante por ML seguido por nCPAP ou por TE seguido por ventilação mecânica (VM). O resultado clinico primário foi definido como $FiO_2 \leq$ 0,30 três horas após o surfactante. Os resultados secundários do grupo de ML foram: necessidade de segunda dose de surfactante nas primeiras 24 horas, necessidade de VM e presença de surfactante no conteúdo gástrico.

Resultados: Quarenta e oito pacientes foram randomizados; 26 no grupo de ML e 22 no grupo de TE. Seis dentre os 26 pacientes (23%) do grupo de ML e cinco dentre 22 pacientes (22,7%) do grupo de TE não apresentaram o resultado primário (p = 0,977). Quatorze (53,8%) dos pacientes do grupo de ML não foram intubados nem ventilados; 12 (46,1%) foram submetidos a VM: por falha do surfactante (23%), por falha da nCPAP (11,5%) e por complicações tardias (11,5%). Os grupos foram semelhantes em relação às condições pré-natais e de nascimento e a ocorrência de eventos adversos. Não foi encontrado conteúdo gástrico significativo em 61,5% dos pacientes do grupo de ML. As necessidades de oxigênio e da segunda dose de surfactante, o índice arterial/alveolar e as morbidades foram semelhantes entre os grupos.

Conclusões: A administração de surfactante por ML mostrou eficácia de curto prazo com necessidade complementar de oxigênio semelhante ao surfactante por TE e menor necessidade de VM. Serão necessários estudos adicionais com tamanho da amostra maior para confirmar esses resultados.

Introduction

Surfactant treatment in neonatology practice has substantially reduced mortality and improved the prognosis of respiratory distress syndrome (RDS).[1,2] Traditionally, surfactant has been given by endotracheal tube (ETT), however, superimposed lung injury from facemask-bag or ETT-bag positive pressure ventilation (PPV) followed by mechanical ventilation (MV) may impair surfactant function and trigger an inflammatory response in the lung, leading to bronchopulmonary dysplasia (BPD).[1,3] In the era of noninvasive respiratory support, neonatologists began to search for new techniques that might allow nasal continuous positive airway pressure (nCPAP) and surfactant at the same time, without ETT and MV.[4–6]

The laryngeal mask airway (LMA) is a supraglottic airway device designed to maintain a seal around the laryngeal inlet to deliver PPV in situations of difficult airway management and anesthesia practice.[7–9] For newborns, LMA has shown its potential in a variety of circumstances, mainly in neonatal resuscitation and drug administration.[6–10] A few observational studies and a small randomized controlled trial (RCT) have reported the administration of surfactant through LMA.[3,6,10] Until now, there has been no published prospective RCT comparing surfactant administration by LMA vs. ETT and MV.

The aim of the present study was to assess if surfactant administration through LMA followed by nCPAP has the same short-term clinical efficacy for RDS treatment as the conventional treatment by ETT followed by MV.

Methods

Study design and patients

This prospective single-center RCT (CAAE 00160287000-10 and NCT01173237) was conducted in the neonatal intensive care unit (NICU) of Maternidade UNIMED-BH, in Belo Horizonte, Brazil, between July 2011 and May 2014. The ethics