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## ORIGINAL ARTICLE

# Efficacy and safety of chloral hydrate sedation in infants for pulmonary function tests

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### KEYWORDS

Chloral hydrate;  
Hypnotics and  
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### Abstract

**Objective:** To describe the efficacy and safety of chloral hydrate sedation in infants for pulmonary function tests.

**Methods:** All sedation attempts for pulmonary function tests in infants carried out between June 2007 and August 2014 were evaluated. Obstructive sleep apnea and heart disease were contraindications to the exams. Anthropometric data, exam indication, used dose, outcomes of sedation and clinical events were recorded and described.

**Results:** The sedation attempts in 277 infants (165 boys) with a median age of 51.5 weeks of life (14–182 weeks) were evaluated. The main indication for the tests was recurrent wheezing (56%) and the chloral hydrate dose ranged from 50 to 80mg/kg (orally). Eighteen (6.5%) infants had some type of clinical complication, with the most frequent being cough and/or airway secretion (1.8%); respiratory distress (1.4%) and vomiting (1.1%). A preterm infant had bradycardia for approximately 15min, which was responsive to tactile stimulation. All observed adverse effects were transient and there was no need for resuscitation or use of injectable medications.

**Conclusions:** The data demonstrated that chloral hydrate at the employed doses is a safe and effective medicament for sedation during short procedures in infants, such as pulmonary function tests. Because of the possibility of severe adverse events, recommendations on doses and contraindications should be strictly followed and infants should be monitored by trained staff.

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## PALAVRAS-CHAVE

Hidrato de cloral;  
Hipnóticos e  
sedativos;  
Lactente

## Eficácia e segurança do hidrato de cloral na sedação de lactentes para testes de função pulmonar

### Resumo

**Objetivo:** Descrever a eficácia e a segurança do hidrato de cloral na sedação de lactentes para testes de função pulmonar.

**Métodos:** Foram avaliadas retrospectivamente todas as tentativas de sedação para exames de função pulmonar em lactentes feitas entre junho 2007 e agosto 2014. Apneia obstrutiva do sono e cardiopatia foram contraindicações para os exames. Dados antropométricos, indicação do exame, dose empregada, desfechos da sedação e intercorrências clínicas foram registrados e descritos.

**Resultados:** Avaliaram-se as tentativas de sedação de 277 lactentes (165 meninos) com mediana de 51,5 semanas de vida (14-182). A principal indicação para os testes foi sibilância recorrente (56%) e a dose de hidrato de cloral usada variou entre 50-80mg/kg (via oral). Dezoito (6,5%) lactentes apresentaram algum tipo de intercorrência clínica e foram as mais frequentes: tosse e/ou secreção na via aérea (1,8%); desconforto respiratório alto (1,4%) e vômitos (1,1%). Um lactente prematuro apresentou bradicardia por cerca de 15 minutos, responsiva a estimulação tátil. Todos os efeitos adversos observados foram transitórios e não houve necessidade de manobras de reanimação e uso de medicações injetáveis.

**Conclusões:** Os dados demonstraram que o hidrato de cloral, nas doses empregadas, é um medicamento seguro e eficaz para a sedação de lactentes em procedimentos de curta duração, como os testes de função pulmonar. Devido à possibilidade de eventos adversos graves, as recomendações referentes à dosagem e contraindicações devem ser seguidas de forma rígida e os lactentes devem ser monitorados por equipe treinada.

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## Introduction

Chloral hydrate (CH) is a hypnotic sedative drug widely used in recent decades to sedate children. Although its exact mechanism of action remains uncertain, the CH is metabolized to trichloroethanol, the active metabolite responsible for the hypnotic effects. The half-life of this metabolite is 8–12h in preschoolers, but can be up to four times longer in newborns and preterm infants.<sup>1,2</sup>

CH is the sedative of choice for pulmonary function tests in infants and has been used in several laboratories for more than 25 years.<sup>1,3</sup> It is the drug of choice due to several factors. It is administered orally, does not require venipuncture and induces adequate sedation degree and duration for pulmonary function assessment procedures to be carried out.<sup>1</sup> Additionally, the available reference equations for pulmonary function parameters were obtained after sedation with CH and use of other sedatives could hinder comparisons and induce biases.<sup>3</sup> In a recent survey carried out at 148 pulmonary function laboratories in infants worldwide, 79% of them used CH as a sedative for exams.<sup>4</sup>

The use of CH for sedation in young children, however, is not a consensus and severe adverse events, including deaths, have been reported.<sup>2,5</sup> Recently, the Brazilian National Health Surveillance Agency (ANVISA) has banned the sale of CH in the country for lack of evidence of its efficacy and safety. The aim of this article is to describe the experience of the pulmonary function laboratory in infants treated at the Discipline of Allergy, Clinical Immunology and Rheumatology of the Department of Pediatrics of Escola

Paulista de Medicina (Unifesp) regarding the use of CH in necessary sedation for pulmonary function tests.

## Method

This is a retrospective case series, which evaluated all sedation attempts for pulmonary function tests in infants between June 2007 and August 2014. The pulmonary function tests were carried out in infants weighing  $\geq 4$ kg and no history of respiratory infection in the previous two weeks. On the day of the pulmonary function test, the infants that came to the service had fasted for at least 3h and received an oral dose of chloral hydrate after clinical evaluation. All tests were performed with the infant in the supine position with slight neck extension and tests were carried out with continuous heart rate and oxygen saturation monitoring. A physician and a physical therapist trained in emergency care were present in all examinations and resuscitation equipment was available during all tests.

Lung volumes and forced expiratory flow were measured using specific equipment (Infant Pulmonary Lab, Collins-Spire, USA), according to existing recommendations.<sup>6,7</sup> In brief, lung volume was measured during the infants' spontaneous breathing movements; then, the airway was occluded for a few seconds, at some moments during breathing. Forced expiratory flows were obtained using the rapid thoracoabdominal compression technique with high lung volumes. Flow-volume curves were obtained by compression of an inflatable jacket placed around the infant's chest and abdomen after inspiration with positive pressure

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