ELSEVIER

Evaluation of Simethicone for the Treatment of Postoperative Abdominal Discomfort in Infants

Terri D. Voepel-Lewis, BSN, MS,*
Shobha Malviya, MD,† Constance Burke, BSN,‡
Rebecca D'Agostino, RN,§ Sue M. Hadden, BSN,‡
Monica Siewert, BA,‖ Alan R. Tait, PhD#

Department of Anesthesiology, University of Michigan Health Care Center, Ann Arbor, MI

Study Objective: *To determine whether abdominal discomfort is a cause for distress symptoms in infants following administration of inhalational anesthesia, and to evaluate the effectiveness of simethicone in treating this discomfort.*
Design: *Randomized, double-blinded study.*
Setting: *Large tertiary care, university-based medical center.*
Patients: *175 ASA physical status I and II infants under 28 months of age who underwent an inhalational anesthetic for a variety of procedures that were expected to cause relatively little pain.*
Interventions: *Children were assessed for the presence of postoperative abdominal discomfort, and, if evident, were randomly given either simethicone or placebo in a double-blinded fashion.*
Measurements and main results: *Abdominal discomfort was measured using the Faces Legs Activity Cry and Consolability (FLACC) Behavioral Pain Scale. Scores were recorded pre-drug; at 10, 20, and 30 minutes following drug administration; and at discharge. If discomfort had not resolved within 15 minutes after the drug was given, routine analgesics or other medications were administered. Abdominal girth was measured preoperatively, on admission into the postanesthesia care unit (PACU), and at discharge. 21% of infants exhibited symptoms of abdominal discomfort postoperatively. Younger infants were at greater risk for this condition. 36 infants were given either placebo or simethicone, and of these, infants who received simethicone were comfortable earlier and required fewer rescue medications compared with placebo. There were no differences in ability to tolerate oral fluids prior to discharge or in the length of stay in the PACU.*
Conclusions: *Simethicone is a safe and inexpensive medication that may provide anesthesiologists with an effective treatment choice for suspected postoperative abdominal discomfort in infants.*

Keywords: Abdominal discomfort, postoperative; infants; outcomes, postoperative; pediatrics; simethicone.

* Clinical Nurse Specialist, Department of Anesthesiology

† Assistant Professor of Anesthesiology

‡ Clinical Nurse II, Department of Operating Rooms

§ Clinical Nurse III, Department of Operating Rooms

‖ Research Assistant, Department of Anesthesiology

Associate Professor of Anesthesiology

Address correspondence to Ms. Voepel-Lewis at the Department of Anesthesiology, University of Michigan Health Care Center, 1500 E. Medical Center Drive, F3900/Box 0211, Ann Arbor, MI 48109-0211, USA.

Funded in part by a grant from Sigma Theta Tau International Nursing Society, Rho Chapter, Ann Arbor, MI.

Received for publication June 26, 1997; revised manuscript accepted for publication October 9, 1997.

655 Avenue of the Americas, New York, NY 10010

0952-8180/98/$19.00
PII S0952-8180(97)00249-3

Introduction

Infants and young children frequently exhibit symptoms suggestive of abdominal discomfort or colic following general inhalational anesthesia for nonpainful procedures. Although differentiating pain symptoms in preverbal children is difficult, those symptoms associated with abdominal discomfort typically include inconsolability, refusal of oral feedings, abdominal tension, and rigid or arched extremities. Symptoms may resolve spontaneously in some cases; however, the prolonged discomfort and difficulty in evaluation is frustrating for parents and caregivers, and may prolong discharge from the postanesthesia care unit (PACU).

Simethicone is an antifoaming agent that acts by altering the surface tension of mucus-entrapped gas bubbles in the digestive tract, allowing them to coalesce and disperse. This process results in easier expulsion through eructation, passing of flatus, or absorption into the bloodstream.[1,2] Previous investigators have found simethicone to be effective in treating the symptoms of infantile colic and reducing abdominal distention and gas pains in adult females after surgery.[1,3–5] The incidence of abdominal discomfort in infants following anesthesia and surgery, as well as the effectiveness of simethicone in this setting, remains unknown. This randomized, double-blinded study was therefore undertaken to determine whether abdominal discomfort is a cause for distress behaviors in infants following inhalational anesthesia for relatively nonpainful procedures, and to evaluate the efficacy of simethicone in reducing this discomfort. This study was designed to test the hypotheses that simethicone administered postoperatively to treat suspected abdominal discomfort in infants, compared with placebo, reduces discomfort, decreases abdominal girth, and permits earlier resumption of oral intake.

Materials and Methods

Following approval from the University of Michigan Health Care Center Institutional Review Board and written consent from parents, 175 ASA physical status I and II infants aged less than 28 months were enrolled in this study. Infants were included in the study if they were scheduled to undergo general anesthesia via mask or laryngeal mask airway (LMA) for minor noninvasive procedures that included cast changes, examination with anesthesia, or myringotomy and tube placement. Children were excluded if the procedure was more invasive than planned, endotracheal intubation was required, or antiemetics or analgesics other than acetaminophen were administered intraoperatively, or for mental impairment.

General anesthesia was induced with halothane and nitrous oxide (N_2O) and maintained with halothane or isoflurane in all cases, and all infants breathed spontaneously throughout their procedures. Crying on induction of anesthesia was scored using a 3-point scale (1 = quiet/no crying; 2 = moderate crying; 3 = severe crying). Following induction of anesthesia, 20 mg/kg of rectal acetaminophen was administered for analgesia as indicated at the discretion of the anesthesiologist. Postoperatively, infants were observed by the PACU nurse for behavioral signs suggestive of abdominal discomfort, including crying, abdominal or other muscular tension, refusal of bottle or oral fluids, and inconsolability. Discomfort was scored using the Faces Legs Activity Cry and Consolability (FLACC) Pain Behavior Assessment Tool.* Children with symptoms of abdominal discomfort, whose FLACC scores were 5 or greater, received 0.3 ml of simethicone or placebo in a randomized (computer-generated random numbers table), double-blinded fashion. FLACC scores were recorded prior to drug administration; at 10, 20, and 30 minutes thereafter; and discharge to home. If distress symptoms had not resolved within 15 minutes following administration of drug, routine rescue medications or analgesics were given at the discretion of the PACU nurse and anesthesiologist caring for the child. Abdominal girth was measured preoperatively, on arrival in the PACU, at 30 minutes after drug administration, and at discharge. Data regarding oral intake, nonpharmacologic comfort measures, pharmacologic drugs administered, and postoperative length of stay were recorded.

Unpaired t-tests were used to analyze parametric data. Nonparametric data were analyzed using chi-square, Mann-Whitney U, and Wilcoxon rank tests where appropriate. Data are presented as means ± standard deviation where applicable, and statistical significance was accepted at the 5% level ($p \leq 0.05$).

Results

Enrolled in this study were 175 infants (13.6 ± 6 months of age) scheduled to undergo a number of procedures including myringotomy and tube placement (57%), cast change (18%), eye examinations with anesthesia (14%), tear duct probing (8%), and cystogram (3%). In the PACU, 37 (21%) children demonstrated symptoms suggestive of abdominal discomfort, and 36 of these were randomized to receive either placebo or simethicone. These infants were younger than those without symptoms, but they were otherwise similar in group characteristics (*Table 1*). The incidence of abdominal discomfort was not affected by the type of airway management (*i.e.,* LMA *vs.* face mask) or by a history of colic or prior simethicone use. There were no differences in abdominal girth change from baseline between children who exhibited discomfort and those who did not. However, accurate measurements of baseline girth in infants who were unable to cooperate and remain still preoperatively was difficult, thereby rendering the measurements unreliable. There was no difference in the incidence of postoperative abdominal discomfort relative to the level of experience of the anesthesiologist or nurse-anesthetist who managed the child's airway during the procedure.

Of the 37 children who exhibited postoperative distress behaviors, 17 received simethicone, 19 received placebo,

* Merkel S, Voepel-Lewis T, Shayevitz J, Malviya S: FLACC pain assessment tool: reliability and validation with existing tools [Abstract]. *Anesthesiology* 1994;81:A1359.

Table 1. Description of Children With and Without Symptoms of Abdominal Discomfort

	Discomfort (n = 37; 21%)	No Discomfort (n = 138; 79%)
Age (months)	10 ± 4*	14 ± 6
Gender		
male	24 (71%)	73 (56%)
female	10 (29%)	58 (44%)
Cried moderately to severely on induction	24 (67%)	99 (74%)
Method of induction		
LMA	6 (16%)	25 (18%)
Face mask	31 (84%)	112 (82%)

*Significantly younger compared with infants with no discomfort ($p = 0.0003$).

LMA = laryngeal mask airway.

and 1 child was treated with an antiemetic. There were no differences between groups with regard to age, weight, or procedure. Additionally, children in both groups received the same amounts of preemptive acetaminophen. *Figure 1* presents the FLACC discomfort scores for each group. Baseline FLACC scores were similar prior to drug administration. Although both groups showed significant improvement with time, the simethicone group had significantly less discomfort than the placebo group by 20 minutes. By discharge, however, the FLACC scores of both groups were similar.

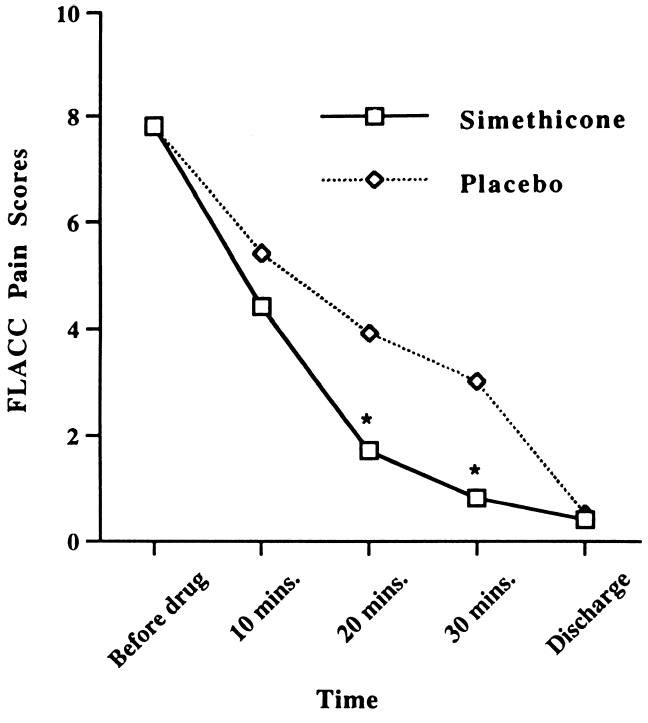

Figure 1. Change in Faces Legs Activity Cry and Consolability (FLACC) Scores from baseline through discharge. *Less than placebo ($p < 0.05$).

Table 2. Postoperative Outcomes of Study Groups

	Simethicone (n = 17)	Placebo (n = 19)
Vomiting	5 (29%)	2 (11%)
Retain Oral Fluid	15 (88%)	19 (100%)
Required rescue medications	2 (12%)	9 (47%)*
PACU Stay (min)	67 ± 20	68 ± 23

*Significantly greater than simethicone group ($p = 0.02$).

PACU = postanesthesia care unit.

There were no differences between groups in the incidence of vomiting or in the ability to retain oral fluids prior to discharge (*Table 2*). Children who received placebo were significantly more likely to require additional rescue medications during their PACU stay ($p = 0.02$; *Table 2*). Rescue medications included codeine, morphine sulfate, metoclopramide, and simethicone. The length of PACU stay between groups was also similar (*Table 2*).

Discussion

The present study found that 21% of infants who underwent minor, relatively painless procedures demonstrated signs of abdominal discomfort postoperatively. Furthermore, those who received simethicone became comfortable sooner than did those who received placebo, and only two children (12%) in the simethicone group required a rescue medication compared with nine (47%) in the placebo group. These findings suggest that abdominal discomfort may have caused the distress behaviors in these infants postoperatively, and that simethicone effectively reduced this discomfort.

While the precise etiology of postoperative abdominal discomfort is not well documented, it is thought to result from crying and swallowing of air on induction, or from anesthetic gases or air entering the stomach during and throughout the procedure. Although infants who exhibited postoperative distress in this study tended to be younger, they did not exhibit greater degrees of crying on anesthetic induction than did children without distress symptoms. Younger infants may have greater difficulty handling air or gas in their digestive tracts, and therefore exhibit greater distress until this gas is expelled. The use of a face mask or LMA did not affect the incidence of abdominal discomfort in infants. Interestingly, a previous study demonstrated a higher incidence of postoperative nausea and vomiting in women who received mask ventilation prior to tracheal intubation by less experienced anesthesia personnel[6] however, we found no relationship between the level of experience of the person managing the child's airway and the incidence of postoperative abdominal discomfort. However, infants in this study were spontaneously breathing throughout their procedures, whereas subjects in the aforementioned study were manually ventilated.

Although we had hypothesized that simethicone would improve the ability to tolerate oral fluids, this was not the case in our study. Additionally, there was no difference in the length of PACU stay between groups. These findings indicate that for some infants in this study, postoperative abdominal discomfort resolved spontaneously. However, for other infants, rescue medications may have facilitated oral intake as well as early discharge to home.

An early study[7] that evaluated abdominal distention in adult patients who underwent nonabdominal procedures demonstrated a significant increase in abdominal girth during anesthesia with high concentrations of N_2O. In our study, however, preoperative abdominal girth measurement was very difficult, in that infants were sometimes crying and restless during the measurement. Postoperatively, all infants were asleep and quiet during the first measurement recorded in PACU. These variable conditions made girth measurement unreliable. Furthermore, infantile colic is not necessarily associated with any degree of abdominal distention. Some infants may be more sensitive to air or gas in their digestive tract in the absence of any physical evidence of distention. Because more infants who received simethicone quieted sooner, this study suggests that abdominal discomfort was indeed present in the absence of any obvious distention. Findings from this study, therefore, do not support abdominal girth as a measure of abdominal discomfort in infants postoperatively.

Although abdominal discomfort from air swallowing and postoperative gaseous distention is typically self-limiting, it can add significant stress to patients and their families. It also presents a challenge for assessment and evaluation by anesthesiologists and nurses in the PACU. The FLACC assessment tool provides an objective method of quantifying distress behaviors in infants; however, similar to other behavioral tools, it may be nonspecific in defining the etiology of the distress. Interpretation of pain behaviors, therefore, requires careful consideration of the context of these behaviors. Infants in our study had undergone procedures that were expected to be associated with little postoperative pain. Additionally, simethicone was more effective than placebo in reducing FLACC scores in these patients, which suggests that the discomfort captured by the measurement tool was indeed related to abdominal discomfort. However, difficulties in pain assessment and interpretation of pain behaviors in this preverbal population remains a limitation of this study.

Postoperative pain management is one of the goals of anesthesiologists providing care in the PACU, and patient comfort is typically a standard outcome criteria for discharge.[8] Although analgesics such as acetaminophen, nonsteroidal anti-inflammatory drugs, and opioids and nonpharmacologic strategies are commonly used in this setting, these techniques may be inappropriate or unsuccessful in the treatment of abdominal discomfort related to entrapment of gas or air. This study demonstrated that 21% of infants who underwent general inhalational anesthesia for relatively nonpainful procedures exhibited symptoms of abdominal discomfort postoperatively. Younger infants were at greater risk for this condition, and simethicone was more effective in eliminating the discomfort than was placebo. Furthermore, infants who received simethicone required fewer opioids and other medications. Simethicone is less expensive than these other medications and has no reported severe side effects. Thus, it may provide anesthesiologists with an effective treatment choice for suspected abdominal discomfort in infants.

Addendum

The cost of simethicone as incurred by our institution was $8.64 per 30 ml bottle. Because each patient received a total dose of 0.3 ml, the cost of simethicone per study dose was less than ten cents.

Acknowledgments

The authors would like to thank each of the PACU nurses at C.S. Mott Children's Hospital who participated in and supported this study.

References

1. Becker N, Lombardi P, Sidoti E, Katkin KS: Mylicon drops in the treatment of infant colic. *Clin Ther* 1988;10:401–5.
2. Danielsson B, Hwang CP: Treatment of infantile colic with surface active substance (simethicone). *Acta Paediatr Scand* 1985;74:446–50.
3. Stahlberg MR: Infantile colic: occurrence and risk factors. *Eur J Pediatr* 1984;143:108–11.
4. Sethi KS, Sethi JK: Simethicone in the management of infant colic. *Practitioner* 1988;232:508.
5. Gibstein A, Cooper JJ, Wisot AL, Rosenthal AH: Prevention of postoperative abdominal distention and discomfort with simethicone. *Obstet Gynecol* 1971;38:386–90.
6. Hovorka J, Korttila K, Erkola O: The experience of the person ventilating the lungs does influence postoperative nausea and vomiting. *Acta Anaesthesiol Scand* 1990;34:203–5.
7. Lewis GB: Intestinal distension during nitrous oxide anaesthesia. *Can Anaesth Soc J* 1975;22:200–1.
8. *ASPAN Standards of Perianesthesia Nursing Practice, 1995 ed.* Thorofare, NJ: American Society of Peri-Operative Nursing (ASPAN) Publications. 1995:42–3.