support for the use of epidural analgesia in nulliparous analgesia. In the description, we did not precisely and explicitly state cervical diameter, which resulted in a misunderstanding by these authors that our citations were incorrect. We apologize for this confusion. In addition, these previous publications included primarily a Western population, and it is uncertain whether the results would be similar in an Asian population. Therefore, we did our trial to test the effect of early epidural analgesia at a median cervical dilation less than 2.0 cm on the risk of cesarean delivery in Chinese women.

In addition, Wong *et al.* point out that our definition of the length of labor in the table was inconsistent with the footnote explanation in table 2 of our article. The authors are correct, and we have requested that a correction be published, which will appear in an upcoming issue of this journal. We clarify again that, in our study, the length of labor refers to the period from the onset of regular uterine contraction to the time after delivery of placenta. Using this definition point, there was no statistically significant difference in the length of labor between groups. Moreover, the analgesia time in both groups was longer than the labor time, mainly because epidural analgesia was not stopped until about 1 h later after the placenta was delivered to reduce early postpartum pain resulting from uterine contraction or perineal trauma during delivery.

FuZhou Wang, Ph.D., M.Sc.,* XiaoFeng Shen, M.Sc., M.P.H, XiRong Guo, M.D., YuZhu Peng, M.D., M.P.H., XiaoQi Gu, M.D., ShiQin Xu, M.Sc. *The Affiliated Nanjing Maternity and Child Health Care Hospital, Nanjing Medical University, Nanjing, Jiangsu, China. zfwang50@njmu.edu.cn

References

1. Wang F, Shen X, Guo X, Peng Y, Gu X: Labor Analgesia Examining Group: Epidural analgesia in the latent phase of labor and the risk of cesarean delivery: A five-year randomized controlled trial. ANESTHESIOLOGY 2009; 111:871–80
2. Wong CA, Scavone BM, Peaceman AM, McCarthy RJ, Sullivan JT, Diaz NT, Yaghmour E, Marcus RJ, Sherwani SS, Sproviero MT, Yilmaz M, Patel R, Robles C, Grouper S: The risk of cesarean delivery with neuraxial analgesia given early versus late in labor. N Engl J Med 2005; 352:655–65
3. Wong CA, McCarthy RJ, Sullivan JT, Scavone BM, Gerber SE, Yaghmour EA: Early compared with late neuraxial analgesia in nulliparous labor induction: A randomized controlled trial. Obstet Gynecol 2009; 113:1066–74
4. Ohel G, Gonen R, Vaida S, Barak S, Gaitini L: Early versus late initiation of epidural analgesia in labor: Does it increase the risk of cesarean section? A randomized trial. Am J Obstet Gynecol 2006; 194:600–5

(Accepted for publication January 8, 2010.)

Sensory Nerve Damage after the Use of the *LMA Supreme*™

To the Editor:

The *LMA Supreme*™ (Laryngeal Mask Company Limited, Le Rocher, Victoria, Mahe, Seychelles) is the first and only single-use laryngeal mask airway (LMA) with gastric access that combines the desirable features of the *LMA-Fastrack*™, *LMA-Proseal*™, and *LMA-Unique*™.[1] Until now, no adverse effects have been reported related to its use. We report on a 64-yr-old woman (height, 174 cm; weight, 68 kg) scheduled for breast-conserving surgery for breast cancer. After general anesthesia induction with boluses (2 mg/kg of propofol and 1 μg/kg of remifentanil over 30 s), the patient's lungs were ventilated using a facemask for 2 min. A size 4 *LMA-Supreme*™ was chosen according to the manufacturer's guidelines and inserted at the first attempt using a one-handed rotational technique with the patient's head in the semisniffing position. The *LMA-Supreme*™ cuff was inflated to and maintained at 60 cm H_2O. No air leaks were detected. The *LMA-Supreme*™ was secured to the patient's face with adhesive tape, according to manufacturer's instructions. Anesthesia was maintained with infusion of propofol (6 $mg \cdot kg^{-1} \cdot min^{-1}$) and remifentanil (0.2 $\mu g \cdot kg^{-1} \cdot min^{-1}$). The lungs were ventilated with an oxygen–air mixture (fraction of inspired oxygen 0.3). A tidal volume of 600 ml was administered through volume-controlled ventilation with a peak airway pressure of 14 cm H_2O. Ten minutes after insertion of the *LMA-Supreme*™, peak airway pressure increased from 14 to 18 cm H_2O and a 20% leakage occurred. The anesthesiologist repositioned the *LMA-Supreme*™ by gently moving it further inward into the pharynx until the air leaks ceased and refixed the device in the new position with the fixation tab (FT) in contact with the patient's upper lip. The surgical procedure lasted 80 min. The patient was then awoken and *LMA-Supreme*™ removed. The patient complained of a slightly swollen upper lip with sensory loss to the midline that was confirmed by examination. Neurologic findings corresponded to a pressure damage in the infraorbital nerve, a branch of the maxillary nerve (second branch of the trigeminal nerve), which innervates the upper lip. The complication started to improve after a week and regressed completely after 14 days.

LMA-Supreme™ is a new ventilatory device with innovative constructive features such as the FT that, although generally favorable, requires special attention. For example, the FT is a rectangular structure molded onto the manifold at right angles and it projects over the patient's upper lip. The FT was not present in any previous model of LMA masks and has been designed to facilitate insertion and fixation of the *LMA-Supreme*™.[2] According to the manufacturer's instructions, the distance from FT to the upper lip should be between 0.5 and 2 cm. If the tab is flush against the upper lip, a larger size *LMA-Supreme*™ should be used.[2] The FT to lip distance is easy to keep at the beginning of anesthesia but it may be not so during anesthesia. The tape securing the mask is passed across the FT and may make it hard to visualize the FT-to-lip distance especially where the FT connects with the bite block. Also, cuff pressure may change during anesthesia and alter FT-to-lip distance.

Repositioning or replacing a laryngeal mask with a different sized mask or with an endotracheal tube is required in some patients because of mask malfunctioning. Reposition-

ing the mask is the first and most often successful approach for air leaks. In a recent study, 13 cases of air leaks occurred out of 100 insertion of *LMA-Supreme*™ and all were taken care of with repositioning.[1] Replacing the mask is easy after induction of anesthesia but may involve risk of airway loss and pulmonary aspiration when performed during surgery.[3,4] Although recommended in the manufacturers' instruction, when the FT-to-lip distance was less than 0.5 cm, we did not find any case of mask replacement in the growing literature on *LMA-Supreme*™. Our practical experience has shown us that *LMA-Supreme*™ is an excellent device. In this case, however, the reducing FT-to-lip distance went undernoticed. The case taught us that the performance of *LMA-Supreme*™ has to be closely monitored throughout anesthesia and also for FT-to-lip distance.

Michele Carron, M.D.,* Ulderico Freo, M.D., Carlo Ori, M.D. *Istituto di Anestesia e Terapia Intensiva, Università di Padova, Padova, Italy. micarron@libero.it

References

1. Timmermann A, Cremer S, Eich C, Kazmaier S, Bräuer A, Graf BM, Russo SG: Prospective clinical and fiberoptic evaluation of the Supreme laryngeal mask airway. ANESTHESIOLOGY 2009; 110:262–5
2. Verghese C, Ramaswamy B: LMA-Supreme—a new single-use LMA with gastric access: A report on its clinical efficacy. Br J Anaesth 2008; 101:405–10
3. Stix MS, Borromeo CJ, Sciortino GJ, Teague PD: Learning to exchange an endotracheal tube for a laryngeal mask prior to emergence. Can J Anaesth 2001; 48:795–9
4. Keller C, Brimacombe J, Bittersohl J, Lirk P, von Goedecke A: Aspiration and the laryngeal mask airway: Three cases and a review of the literature. Br J Anaesth 2004; 93:579–82

(Accepted for publication September 25, 2009.)

Erroneously Published Fospropofol Pharmacokinetic–Pharmacodynamic Data and Retraction of the Affected Publications

To the Editor:

As described in a letter to the editor, published in ANESTHESIOLOGY, *Anesthesia and Analgesia*, and the *European Journal of Anaesthesiology*,[1–3] an analytical propofol assay inaccuracy was discovered after all six initial studies on the pharmacokinetic–pharmacodynamic and tolerability of fospropofol had been published.[4–9] This assay inaccuracy makes the measured propofol plasma concentrations in these previously published studies unreliable.

All six affected studies were phase I and II studies sponsored by a pharmaceutical company (Guilford Pharma, Baltimore, MD, and later MGI Pharma, Baltimore, MD) and were performed in two independent academic-based phase I centers in Gent, Belgium, and Erlangen, Germany. Because of the stage of the drug testing, the study drugs were made available by the initial sponsor. As described previously,[1–3] the sponsor developed and validated a specific propofol assay. Both academic centers had no influence on the choice of methodology for sample handling and chemical analysis. For all six studies,[4–9] assays were performed at an external laboratory (MDS Pharma Services, Montreal, Canada) as per the sponsor's decision. Finally, the original publications were coauthored by both academic and sponsor-based investigators.

In a letter to the editor,[1–3] the initial owner of the drug (MGI Pharma, not affiliated with the academic centers from the original studies) declared that additional studies were planned using an appropriate assay to describe the pharmacokinetics and pharmacodynamics of fospropofol in healthy volunteers and patients. They stated their intent to publish these results shortly along with an estimate of the degree of error from the previously published studies reporting results using the old assay. In the response article, the editors-in-chief of ANESTHESIOLOGY, *Anesthesia and Analgesia*, and the *European Journal of Anaesthesiology* requested a publication within the next 12 months validating the new assay, analyzing the likely error and bias in each of the six articles in question, and determining how the error and its correction would influence the conclusions.

The planning of studies was delayed primarily because of the transfer of ownership of the drug to another pharmaceutical company in mid 2009 (Eisai, Woodcliff Lake, NJ). As a result and although requested by the academic investigators immediately after the publication of the letter to the editor,[1–3] the investigators from the original studies were not able to reanalyze the pharmacokinetics–pharmacodynamics of fospropofol in human volunteers within the deadline of 12 months given by the editors-in-chief. As such, we, the undersigned corresponding and senior authors from the six original articles, in the name of all coauthors, request that the articles in question that provide flawed pharmacokinetic–pharmacodynamic data be retracted. We regret that we are unable to successfully resolve the problem within the given timeframe. *(See a list of retracted articles from ANESTHESIOLOGY on page 1058 of this issue.)*

Michel M. R. F. Struys, M.D., Ph.D.,* Jörg Fechner, M.D.,† Jürgen Schüttler, M.D.,† Helmut Schwilden, M.D., Ph.D.† *University of Groningen, Groningen, The Netherlands, and University of Ghent, Gent, Belgium. m.m.r.f.struys@anest.umcg.nl. †University of Erlangen-Nuremberg, Erlangen, Germany.

References

1. Shah A, Mistry B, Gibiansky E, Gibiansky L: Fospropofol assay issues and impact on pharmacokinetic and pharmacodynamic evaluation (letter). ANESTHESIOLOGY 2008; 109:937; reply
2. Shah A, Mistry B, Gibiansky E, Gibiansky L: Fospropofol assay issues and impact on pharmacokinetic and pharmacodynamic evaluation. Anesth Analg 2009; 108:382

Support was provided solely from institutional and/or departmental sources.