

## CORRESPONDENCE

in patient care at Johns Hopkins. Were Drs. Brimacombe and Berry similarly uninvolved in their institutions, and is it possible that such differing physician involvement and supervision may play some role in the different results?

We look forward to the authors' response.

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**In Reply:**—We, as a research team, are concerned about the issues raised by Drs. Goto and Uezono and appreciate the opportunity to consider them openly. Clearly, we can only comment on the larger, FDA-monitored multicenter study published in *ANESTHESIOLOGY*.<sup>1</sup>

Simply put, our study was a comparison between the COPA and LMA and not between sites. The valid comparison designed in the study is therefore between *devices* at each site and summarized in table 7 of the article. For instance, we compare the LMA *versus* COPA regarding the occurrence of any adverse event (81% *vs.* 61% at The Johns Hopkins Medical Institutions, 48% *vs.* 30% at Cairns Base Hospital, and 42% *vs.* 39% at Nambour General Hospital). Looking at these comparisons, one must recognize that the COPA did at least as well as the LMA. However, one might consider why events were more frequently reported at The Johns Hopkins Medical Institutions for both devices (either because of more overall problems or perhaps superior recognition and recording). In fact, based on this analysis, the Australian sites did not have more difficulty with the COPA compared with the LMA; in only two instances were the percentage of adverse events higher with the COPA.

We have made every effort to perform and report our research in the most unbiased way possible. Because we did not participate in the study reported in *Anesthesia & Analgesia*, we are unable to comment

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**In Reply:**—Drs. Goto and Uezono are incorrect in stating that the study by Brimacombe *et al.*<sup>1</sup> was conducted at the same two Australian institutions as the study by Greenberg *et al.*<sup>2</sup> It was conducted only at Cairns Base Hospital, and Dr. Berry did not directly participate in the clinical aspects of the trial.

We disagree that the results of these trials are "contradictory." In terms of ease of placement, time taken to achieve an adequate airway, first time placement success rates, airway sealing pressure, the number of airway interventions required, and postoperative jaw and neck pain, both trials showed that the laryngeal mask airway (LMA) was the better device. The main contradictory result was that the multicenter trial showed that the

## References

1. Greenberg RS, Brimacombe J, Berry A, Gouze V, Piantadosi S, Dake EM: A randomized controlled trial comparing the cuffed oropharyngeal airway and the laryngeal mask airway in spontaneously breathing anesthetized adults. *ANESTHESIOLOGY* 1998; 88:970-7
2. Brimacombe JR, Brimacombe JC, Berry AM, Morris R, Mecklem D, Clarke G, Barry J, Kirk T: A comparison of the laryngeal mask airway and cuffed oropharyngeal airway in anesthetized adult patients. *Anesth Analg* 1998; 87:147-52

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on the actual design or conduct of their study or effort to control for personal bias, etc. We are therefore unable to comment on the differences in conclusions between the two papers.

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1. Greenberg RS, Brimacombe J, Berry A, Gouze V, Piantadosi S, Dake EM: A randomized controlled trial comparing the cuffed oropharyngeal airway and the laryngeal mask airway in spontaneously breathing anesthetized adults. *ANESTHESIOLOGY* 1998; 88:970-7

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cuffed oropharyngeal airway (COPA) was associated with a lower incidence of oropharyngeal trauma and that the single-center trial had a higher incidence. We consider the postoperative data from the single-center trial more reliable because data collection was double-blinded. Although superficially similar, the two trials were not methodologically identical, and comparisons should be made cautiously. Notable differences were that the multicenter trial involved 62 variably experienced investigators conducting variable case numbers, more than 20 data collectors, unequal-sized groups, total intravenous anesthesia with propofol, and emergence either in the operating room or the post-anesthesia care unit. The single-center trial involved four experienced investigators con-



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**Table 1. Incidence of Problems for the Laryngeal Mask Airway (LMA) and Cuffed Oropharyngeal Airway (COPA) between the Australian and U.S. Study Sites**

	LMA			COPA		
	Australia (n = 108)	U.S. (n = 43)	P Value	Australia (n = 217)	U.S. (n = 85)	P Value
Device failure	0 (0)	4 (9)	0.001	5 (2)	10 (12)	0.0007
Protocol deviations	0 (0)	1 (2)	NS	0 (0)	17 (20)	<0.00001
Complications						
Major	8 (7)	10 (23)	0.007	20 (9)	23 (27)	<0.00001
Minor	29 (27)	17 (40)	NS	46 (21)	27 (32)	0.05
Immediate postoperative	17 (16)	19 (44)	0.0008	8 (4)	17 (20)	<0.00001
Next day postoperative	18 (17)	18 (42)	0.001	21 (10)	25 (29)	<0.00001
Any problem	50 (46)	35 (81)	0.003	71 (33)	52 (61)	<0.00001

Values are number (%) of patients (except P values).

NS = not significant.

ducting 30 patients each, equal-sized groups, one highly experienced data collector (more than 100 observed cases from the first trial) backed up by video recordings that were analyzed independently, isoflurane for maintenance, and emergence only in the operating room. Airway stability in different head and neck positions and the best position for emergence were only investigated in the single-center trial. Definitions for study end-points were frequently different. For example, in the multicenter study an "effective airway" was not defined, but in the single-center study it was defined as an airway sealing pressure  $\geq 10$  cm H<sub>2</sub>O and maintenance of SpO<sub>2</sub> as  $\geq 90\%$  with FiO<sub>2</sub> 0.3–0.4. In the single-center study, airway interventions were classified into major and minor and cataloged for every 5-min epoch, but no such time base was used in the multicenter study.

Drs. Goto and Uezono suggest that some of the difficulties that occurred with the COPA in the multicenter study were related to poor performance at the Australian study sites. In fact, the performance was significantly better at the Australian study sites in all aspects of airway management for the COPA, and most aspects of airway management for the LMA (table 1). As discussed in the original paper, the higher incidence of problems at John Hopkins may reflect the use of more investigators, a lower level of clinical experience, differences in anesthesia practice, or difficulties in following the study protocol. It should be noted that although the overall performance varied between study sites, the relative performance between the devices was generally similar at each study site.

Finally, Dr. Greenberg invented the COPA, and therefore his clinical involvement in the multicenter study for FDA approval was not rec-

ommended. Drs. Brimacombe and Berry did not invent either device and were allowed to participate in the multicenter trial. Their performance was comparable with other Australian investigators as was Dr. Brimacombe's performance in the single-center study.

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1. Brimacombe JR, Brimacombe JC, Berry A, Morris R, Mecklem D, Clarke G, Barry J, Kirk T: A comparison of the laryngeal mask airway and cuffed oropharyngeal airway in adult patients. *Anesth Analg* 1998; 87:147–52
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