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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References


(Accepted for publication December 14, 1998.)

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.1

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 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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Reference


(Accepted for publication December 14, 1998.)
Table 1. Incidence of Problems for the Laryngeal Mask Airway (LMA) and Cuffed Oropharyngeal Airway (COPA) between the Australian and U.S. Study Sites

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

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 endpoints 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 scaling pressure ≥ 10 cm H₂O and maintenance of SpO₂ as ≥ 90% with FICO₂ 0.5-0.6. 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 Johns 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 recommended. 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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(Accepted for publication December 14, 1998)