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CARTAS AL DIRECTOR

LMA Supreme™: New design or a pig in a poke?

LMA Supreme™: ¿nuevo diseño o gato por liebre?

To the Director,

We are presenting an apparently simple case of a laryngeal mask malposition that have raised our concerns about the quality of airway equipment and marketing policies.

A 35-year-old male without any relevant medical condition presented for a routine ambulatory surgery procedure under general anesthesia. Evaluation of the airway prior to the induction only revealed a potential difficulty of ventilation due to the presence of beard and overweight (27 BMI). After the induction of anesthesia, a size 5 LMA Supreme ''new cuff'' (The Laryngeal Mask Company, Le Rocher, Victoria, Mahe, Seychelles) was inserted at first attempt by an experienced anesthesiologist (more than 1000 uses). During the insertion, the mask needed to be rotated 45° to overcome a slight resistance, but the insertion could be easily accomplished until the airway tube was in a normal position. However, once the respiratory circuit was connected, a huge leak was noticed through the mouth without any sign of effective ventilation. During the repositioning maneuvers, the cause of the leak was identified clearly: the tip of the mask was protruding out of the mouth beneath the airway tube (Fig. 1A). The mask was successfully reinserted and the case proceeded uneventfully. No desaturation or mucosal trauma was observed.

This case was one of the several incidents reported through the national registry of incidents in anesthesia (www.sensar.org) by different institutions, confirming our impression that the new design of LMA Supreme does not perform the same as the original version. We then compared a sample of a ''new'' and ''old'' size 3 LMA Supreme (Fig. 1B) in terms of resistance to bend of the tip, the cuff and the

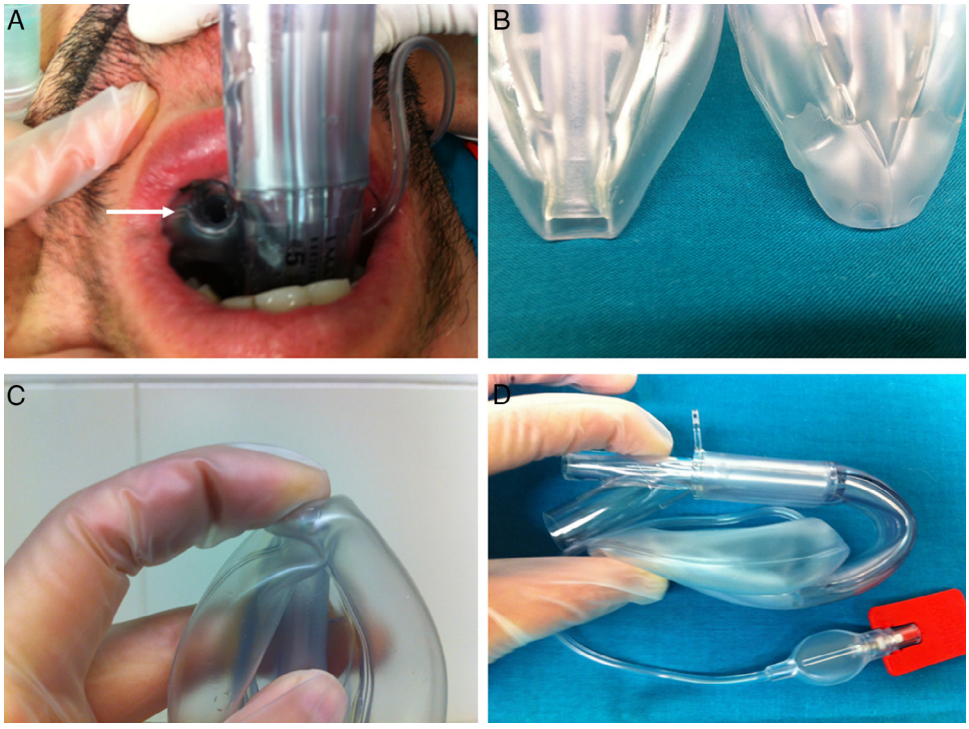

Figure 1 (A) The tip of the cuff protruding out of the mouth of the patient between the LMA airway tube and the tongue. (B) Posterior view of the tip of the original cuff (right) and the new cuff (left). (C) Anterior view of the tip of the new cuff under slight finger compression. (D) Lateral view of the airway tube completely collapsed.

tube (Fig. 1C and D). It was obvious that the non-reinforced tip was easily deformed by a slight pressure and that the tube could be completely folded obstructing the air passage. Furthermore, the distal 4 cm piece of the gastric tube was dislodged during manipulation of the device. These cannot be considered just ''cosmetic changes'', as claimed by the new manufacturer (Teleflex, Limerick, Pennsylvania, USA).

To our surprise, this new device just appeared several weeks ago in the stocks of the surgical areas without any notification about this unexpected change from the company, the purchasing managers of our hospitals, or the local distributors that have been selling the LMA since its introduction in Spain. The website of LMA products was not up-dated by the time we wrote this letter. The only reference to the modification in the package is a ''new cuff'' label below the size number, the suppression of any mention to Dr. Brain and the color of the box (black instead of blue). Anecdotal comments among colleagues from different hospitals that have communicated several incidents have been the only source of information to date. The explanation offered by the company upon request was that ''the design was modified to allow more efficient manufacturing''.

It is not an uncommon practice to introduce modifications or improvements in marketed airway devices. We have seen, for instance, different versions of the Laryngeal Tube (VBM Medizintechnik GmbH, Sulz, Germany) or the Ambu Aura laryngeal mask (Ambu A/S, Ballerup, Denmark). All these new releases were officially presented and followed by studies comparing the new version to the previous one and to other similar devices available at the moment. To our knowledge, this is the first time that changes in the design and materials of a marketed LMA device have been introduced, and this has been done without a preceding announcement.

Furthermore, the distribution by simply replacing the original LMA Supreme version at the end of the stocks seems not the correct way to proceed and may lead to product withdrawal in some institutions. In public health hospitals, this kind of equipment is purchased after a competitive bid and one of the main arguments in favor of a particular device is the availability of published evidence on their clinical performance. To our knowledge, there is no evidence at all supporting the new cuff and new materials of the LMA Supreme.

Note from the committee

Representatives of the company whose article/material-farmaco is cited in the letter to the Director, declined to respond.

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Congreso de la Sociedad Europea de Anestesiología (European Society of Anaesthesiology). Referencia de la participación de los anestesiólogos españoles y de las conclusiones más importantes del congreso

European Society of Anaesthesiology Congress. The participation of the Spanish anaesthesiologists and the most important conclusions of the congress

Sr. Director:

Con motivo del reciente European Anaesthesiology Congress, Euroanaesthesia 2013, que ha tenido lugar en Barcelona el pasado mes de junio, me gustaría transmitir el balance de la participación de los anestesiólogos españoles en el mismo, así como hacer una breve referencia a algún aspecto de interés que se trató en el congreso y durante la Asamblea General.

Este es el congreso con más número de profesionales inscritos en los últimos 8 años. Del total de 7.925 inscritos, 338 eran españoles. Es con mucho el Euroanaesthesia Meeting con más afluencia, seguido del Euroanaesthesia Meeting 2005, que también tuvo lugar en España, en este caso en Madrid.

Cada año, la presencia de anestesiólogos de nuestro país, tanto en la European Society of Anaesthesiology (ESA, «Sociedad Europea de Anestesiología») como en el European Anaesthesiology Congress, se va incrementando, lo que refleja una creciente preocupación por el desarrollo de nuestra especialidad en España dentro del marco europeo. Actualmente contamos con la presencia de especialistas españoles en 8 comités de la ESA.

Como ponentes en el Euroanaesthesia 2013 participando en talleres, cursos de actualización, sesiones o en la dirección de sesiones de póster contamos con 27 anestesiólogos españoles que participaron en 39 sesiones diferentes, frente a los 14 que estuvieron presentes en el Euroanaesthesia 2010. Respecto al total de pósters presentados (901), el 14% (129) fueron enviados desde hospitales o centros de investigación de España. El Dr. Brogly, del Hospital Universitario La Paz, y la Dra. Benito, del Hospital General Universitario Gregorio Marañón, ambos en Madrid, participaron en la ronda de Best Abstract con la presentación de sus investigaciones *Use of CUSUM learning curves to evaluate how residents of anaesthesia learn ultrasound guided femoral*