Intraoperative Pulmonary Barotrauma During Ophthalmologic Surgery. Case Report

(Rev Bras Anestesiol, 2008;58:63-68)

Mrs. Editor,

The Right to Rebut (Law Number 2/99 of January 13, 1999) regarding the case report: Intraoperative Pulmonary Barotrauma During Ophthalmologic Surgery.

Public Information: the case reported by the Revista Brasileira de Anestesiologia happened at the Hospital Municipal Souza Aguiar – Rio de Janeiro, RJ, Brazil, on 02/21/2005 and was reported to the Quality Control and Technical Support of HB Hospitalar Ind. e Com. Ltda. (manufacturer of the equipment) on 02/25/2005, who initiated an analysis of the causes according to internal procedures and requirements regarding:

- ANVISA Registration Number 10261120011
- IEC, MC, and ELM-3678 Certification of 11/28/2001 (Electrical Safety and Compatibility)
- ISO 9000 Certificate Number CE,SIQ-803
- Good Practice of Manufacture Certificate (ANVISA) Number 179127/07-3

In which the results of Tests and Assays performed through Risk Analysis determined that the Anesthesia Machine Conquest 3000, Series 2369, and its accessories DID NOT present any non-conformities in the processes evaluated:

- Project;
- Safety;
- Performance;
- Assembly;
- Ergonomics;
- Fulfillment of statutory requirements; and
- Quality Control

The positive results were presented to the person in charge of investigating the case at the above mentioned Hospital, Dr. Lília Portela, Chief of Anesthesiology, on March 17, 2005 through corroborating documents (Technical Reports) and procedure forms, according to each case.

According to the cause analysis, the situation occurred due to:

1. The equipment mentioned was furnished, as requested by the client, with a smooth silicone tube, approximately 1.20-cm long and connectible intermediates only in the inspiratory branch of the ventilator to allow the assembly of a completely opened system using for this purpose a one-way valve, besides the tube.;
2. As can be seen in the report, the tube is excessively long, and it is not the original tube provided for this application (to connect the ventilator to the circular filter);
3. At the time, the client could not explain why the tubes were changed.

Preventive Actions:

Since this was probably an involuntary mistake made by the client, the engineering department of the HB Hospitalar was communicated immediately to take preventive actions to avoid similar occurrences in the future. It was determined:

1. To use tracheal-type tubing, plain inside with reinforced rings outside to prevent kinking of the tube and interruption of the flow, regardless of the degree of curvature of the tubing (a series item in the manufacture);
2. Specific orientation regarding the procedure of the circular filter operation (assembly and simulations), including a revision of the Manual of the Equipment with emphasis on this item; and
3. The immediate substitution of the tubing of the client's equipment (who was satisfied with the actions taken and sent us a communication reporting the improvements).

Conclusion:

We should mention that HB Hospitalar Ind. e Com. Ltda has been in the market for 55 years, manufacturing and commercializing anesthesia equipment. It is a company with national and international certifications, according to the pertinent legislation, and has sold 220 units of the Conquest 3000 model without any non-conformities secondary to project flaws, performance, or safety. All those statements can be confirmed on consumer protection agencies in the ANVISA web site (www.anvisa.gov.br) or with its clients in Brazil and abroad.

The report mentioned above should have analyzed all facts, especially the conclusions of the manufacturer and the client, in view of the severity of the case, making public, besides the study of the case, the corrective actions taken that demonstrate concern with the most important parties, i.e., the patient and the client.

Thank you very much,

Harry Baukelmann
Director
HB Hospitalar Ind. e Com Ltda.

Réplica

Sra. Editora,

Em resposta a réplica pela HB Hospitalar Indústria e Comércio Ltda., através de sua Gerência Administrativa, ao artigo "Barotrauma Pulmonar no Intra-Operatório de Procedimento Cirúrgico Oftalmológico. Relato de Caso", publicado na *Rev Bras Anestesiol*, 2008;58(1):63-68, vimos esclarecer:

O aparelho em questão, em período de garantia, fez parte de um lote de quatro unidades, adquirido em caráter emergencial pela Secretaria Municipal de Saúde do Rio de Janeiro. De acordo com a chefia do Serviço à época, os mesmos teriam sido montados, como de praxe, pelo fabricante. Todos obedecendo à mesma configuração, não tendo partido da mesma qualquer solicitação para alterações nas condições originais dos referidos equipamentos. Em nosso entender, ainda que o usuário houvesse solicitado alterações que viessem a oferecer riscos operacionais, estas deveriam ser

previamente ponderadas pelo fabricante com o solicitante, dissuadindo-o das mesmas.
Decorrido tempo suficiente para a análise do problema, em nenhum momento nos foi comunicado que providências teriam sido tomadas para que o fato não se repetisse com outros usuários. Ao contrário, segundo o fabricante, o ocorrido aconteceu em decorrência de mau uso do equipamento, que teria sido exposto a improvisações, o que, efetivamente, não houve. Entretanto, o mesmo efetuou a troca do tubo liso, passível de acotovelamento, por outro adequado para a função. Ainda, segundo a replicante, medidas foram tomadas junto ao departamento de engenharia para que se evitasse a repetição do problema, o que revela um reconhecimento oportuno da condição de risco.
Não foi nossa intenção denegrir a imagem da empresa. O objetivo da publicação foi tão-somente alertar aos colegas sobre potenciais complicações com o detalhe técnico apontado, chamando atenção, em caráter didático, para a importância da observação de pormenores pelo anestesiologista.
Atenciosamente,

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Reply

Mrs. Editor,
In response to the reply of HB Hospitalar Ind. e Com. Ltda. through its Administrative Management to the article “Intraoperative Pulmonary Barotrauma During Ophthalmologic Surgery. Case Report”, published in Rev Bras Anestesiol, 2008;58(1):63-68, we would like to explain that:

The equipment used, still during its period of guarantee, was part of a set of 4 units bought on an emergency basis by the Rio de Janeiro County Health Department. According to the chief of the Service at the time, they were all assembled, as usually, by the manufacturer. They all followed the same configuration and the Service in question did not request any changes in the original configuration of the equipment. As we reckon, even if the buyer had requested changes that might trigger hazard, they should have been explained by the manufacturer, preventing the buyer of those changes.
After enough time to analyze the problem, we were not communicated, at any time, that measures were taken to prevent this from ever happening again. On the contrary, according to the manufacturer, what happened was due to the improper use of the equipment that underwent improvisations, which really did not happen. However, the manufacturer exchanged the smooth tubing, amenable to kinking, by another more adequate for this function. And, according to the manufacturer, measures were taken by the engineering department to prevent this from ever happening again, demonstrating a recognition of the risk. It was not our intention to disparage the company. The objective of the report was to alert our colleagues about the potential complications related with the technical problem indicated, calling the attention, didactically, for the importance of the observation of the minimal details by the anesthesiologist.

Sincerely,

Affonso H. Zugliani, TSA
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