Reminder of important clinical lesson

Ortho-phthalaldehyde-induced skin mucous membrane damage from inadequate washing

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Because body fluids and blood have a tendency to adhere to transesophageal echo devices, a high level of sterilisation is required when cleaning them. Ortho-phthalaldehyde (OPA) has been widely used in Japan since being approved as a high-level sterilant. The authors report a patient with widespread, severe skin and mucous membrane damage of the lip, tongue, pharynx and oesophagus areas that was attributed to inadequate washing after the sterilisation of a transesophageal echo device with OPA. This patient experienced sequelae, which did not improve after more than 1 year of continuous treatment. When using medical devices sterilised with OPA, the use of a probe cover, when applicable, is recommended and complete washing prior to use is required.

BACKGROUND

A high level of disinfection is required to sterilise medical devices that touch mucous membranes or blood in the human body, such as endoscopes and bronchoscopes.¹ Ortho-phthalaldehyde (OPA) is a high-level disinfectant developed by Johnson & Johnson (USA); however, skin damage that seems to have been caused by its improper use have been observed in scattered instances. In this study, we report our experience with a case in which widespread and severe damage to the skin mucosa, extending from the lips towards the tongue, throat and oesophagus, was most likely caused by the use of a transesophageal echo device that had been inadequately washed following sterilisation with OPA.

CASE PRESENTATION

The case is a 5-month-old girl. Patch occlusivity was performed at the Department of Cardiovascular Surgery in our clinic, due to intraventricular septal defect. A transesophageal echo device was used by the anaesthesiologist during the operation. The operation required 5 h and 30 min, and the anaesthetic time was 6 h and 45 min. The transesophageal echo device had remained soaked in OPA for approximately 1 week until the day of the operation and was rinsed only under running water for several minutes prior to use on the morning of the operation. A probe cover was not used. There was no abnormality in the transesophageal echo device.

After the paediatric patient returned to her room, discoloration in the corner of her mouth was discovered, and she was referred to the Department of Plastic Surgery. At the time of examination, black discoloration was found on the left half of the lips, the mucous membrane within the mouth and the tongue surface of the paediatric patient (figure 1A). Damage to the skin mucosa due to OPA was suspected, and the use of a steroid ointment was initiated following washing with saline. Oesophagography and

oesophageal endoscopy were performed 18 days after onset. Oesophageal stenosis was not observed on oesophagography, although fur was observed to have adhered all around the oesophagus at 10 cm from the incisor line on oesophageal endoscopy and to have also adhered to the posterior membrane of the oesophageal wall at 13 cm from the incisor line (figure 1B, C).

OUTCOME AND FOLLOW-UP

The damaged area of the skin on the lips had almost healed by 74 days after onset, without obstruction upon oesophageal transit, and oral ingestion was also possible. However, 5-mm-diameter flare and induration appeared outside of the lips approximately 100 days after onset (figure 1D). At the same time, difficulty in swallowing milk also emerged. During this period, she had neither the examination nor the surgery. Although application of steroid ointment to the induration of the lips was resumed, it did not result in improvement, and the paediatric patient is currently under follow-up. Oesophagram was performed again because of difficulty in swallowing, and significant oesophageal stenosis was recognised (figure 1E). There were no such lesions noted in the gastric mucosa. Since the stenosis is continuing until 1 year after onset, we repeat dilation of stenosis with a bougie on twice a month (figure 1F).

DISCUSSION

Traditionally, glutaraldehyde (GA) was the only high-level disinfectant that could be used in Japan. However, reports started surfacing of adverse events such as mucous membrane-irritating effects, bronchial asthma and contact dermatitis that were attributed to volatile GA.^{2–4} OPA is advantageous in that it is less volatile and irritating than GA.⁵ Walsh *et al*⁶ have also reported that OPA is a high-level disinfectant that can sterilise endoscopes in a short time and that bacteria that are resistant to GA had appeared. OPA has been approved for use in Japan since 2001.

Figure 1 Findings of the affected area. (A) The first examination. Colouration was found. (B) Findings of oesophageal endoscope 18 days after exposure. Fur stuck circumferentially to the oesophageal membrane 10 cm from the incisor line. (C) Findings of oesophageal endoscope 18 days after exposure. Fur stuck to the posterior membrane of the oesophageal wall 13 cm from the incisor line. (D) Findings 137 days after exposure. Induration evident. (E) Findings of oesophagram 172 days after exposure. Severe stenosis was observed. (F) Findings of oesophageal endoscope 438 days after exposure. Eleventh procedure to release stenosis with a bougie was done. Mucosal defect was found.

Learning points

- ▶ The problem in this case was attributed to insufficient washing of the transesophageal echo probe, in addition to soaking in OPA for a prolonged period of time, following use.
- ▶ Severe complications resulting in oesophageal stenosis have not been reported in the past. It should be noted that a small amount of residual OPA can possibly cause damage to skin and mucous membranes.
- ▶ Thorough washing should be carried out following use and, if possible, a probe cover should also be used.

As the clinical use of OPA becomes more widespread, reports of chemical burns,^{7 8} pigmentation,⁹ anaphylactic shock^{10 11} and bullous keratopathy¹² attributed to OPA have been increasing. Although there have been such sporadic reports of cases diagnosed as chemical burns, they all showed improvements in short periods of 7–20 days. To our knowledge, this is the first report of a case of sequelae that continued for a long period of more than 1 year. Even a small amount of residual OPA can damage skin mucosa, and the kind of washing that had been performed with GA is insufficient.¹³ When sterilising medical devices with OPA, it is recommended that any residual biological material adhered to the devices be completely removed, and that the devices be washed in water and then soaked in drugs for no more than approximately 5–10 min, and then thoroughly rinsed with a large amount of water after sterilisation has been completed.¹⁴

Competing interests None.

Patient consent obtained.

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Horikiri M, Park S, Matsui T, Suzuki K, Matsuoka T. Ortho-phthalaldehyde-induced skin mucous membrane damage from inadequate washing. *BMJ Case Reports* 2011;10.1136/bcr.02.2010.2709, date of publication

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