


Report on the breakage of the tip of a radial endobronchial ultrasonic probe sheath during bronchoscopy

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Keywords

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Abstract

A lesion in a 73-year-old woman that was suspected to be right lung cancer was biopsied under ultrasound-guided bronchoscopy with a guide sheath. The procedure was completed without a noticeable problem, but after 3 days, it was found that the tip of the ultrasonic probe sheath was broken and that the broken fragment was missing. Based on the concern that the fragment had been left in the lung, the patient was examined by computed tomography scan 4 days after the biopsy, and bronchoscopy was repeated 38 days after the biopsy, but no fragment was detected. These procedures and an investigation by the Olympus Corporation led to the conclusion that the fragment was not in the lung, and it was not found in a subsequent surgical specimen. Breakage of devices may occur at any time regardless of progression of fatigue (wear) with increased use, and thorough device management before, during, and after use is important.

Introduction

Bronchoscopic biopsy using an ultrasonic probe (UM-S20-17S, Fig. 1) with a guide sheath to confirm that the target lesion is reached is an established and routine procedure, but familiarity with the possible breakage of related devices is important. We experienced breakage of the tip of the ultrasonic probe sheath of a bronchoscope. The Olympus Corporation reported one other incident of breakage of a tip as of November 2015, but the case at our hospital was the first occurrence of breakage of the UM-S20-17S probe.

Case Report

A nodular shadow suspected to be lung cancer was observed in the right lower lobe of a 73-year-old woman on chest X-ray. Bronchoscopic lung biopsy under endobronchial ultrasonography with a guide sheath (EBUS-GS) was performed to obtain a definite diagnosis. No noticeable complication occurred during the procedure, which was successfully completed. The bronchoscope and peripherals used were recovered as usual by nurses at the site. Three days after the examination, breakage of the tip of the ultrasonic probe sheath was found, and a request for an investigation was immediately placed with the manufacturer, Olympus

Corporation. We do not have a procedure to confirm whether a device is damaged after use in an examination. As the echo probe was not used for 3 days afterwards, it was not checked for damage, and the damage was not noticed for 3 days. The company provided the following report. This incident occurred during only the third time of use. The tip of the ultrasonic probe sheath was broken due to fracture of the region joining different materials of the sheath, and approximately 50 mm of the sheath was lost (Fig. 2). Regarding the cause, several deformations were present in the sheath, and the sheath had narrowed at several sites. The entire length of the broken UM-S20-17S was approximately 73 mm longer than a normal probe of the same model, and combined with the 50-mm broken tip and entire length of approximately 73 mm, the sheath was markedly elongated by 123 mm in total (Fig. 3). This suggests that the skid resistance increased excessively during the removal of the echo stopper of the combined device and that this elongated the sheath. The removal of the stopper may have continued under the excessive skid resistance and caused breakage of the transparent region at the sheath tip with the echo stopper. Therefore, it was concluded that the tip did not break off during the examination but rather broke and was lost during cleaning after the examination.

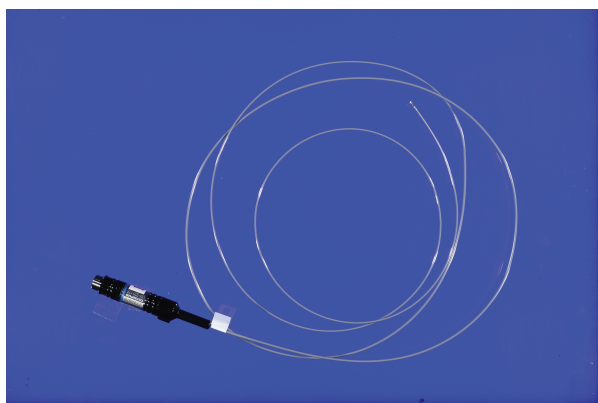


Figure 1. An ultrasonic probe (UM-S20-17S).

Along with this investigation, to confirm that the broken tip was not left in the body, computed tomography (CT) was performed 4 days after the examination, and bronchoscopy was repeated at 38 days. No findings demonstrated the broken tip in the lung, suggesting that the tip had not become detached in the lung. Subsequently, lung cancer was definitely diagnosed in the patient, and

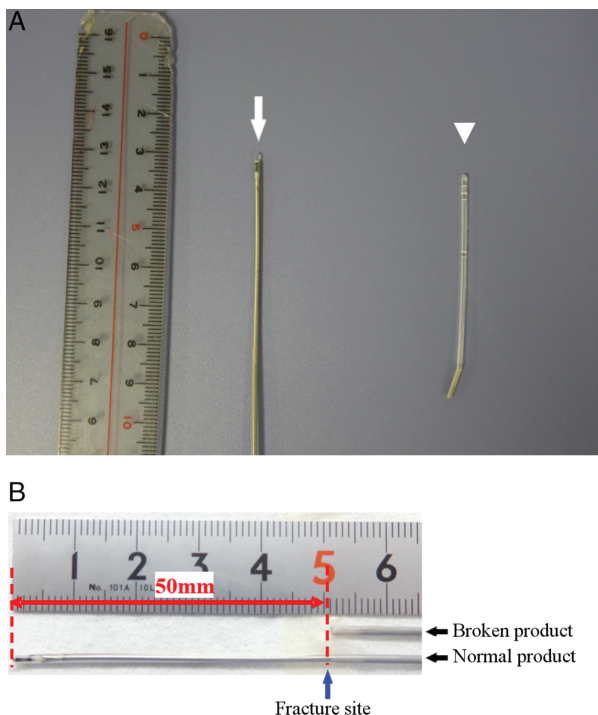


Figure 2. (A) The fracture region of the tip of the echo probe sheath that was assumed to have broken off (arrow head) was reproduced according to the report from the Olympus Corporation. A normal echo probe is indicated with an arrow. (B) The region joining different materials of the sheath (blue arrow) was fractured, and an approximately 50-mm transparent region of the sheath was lost.

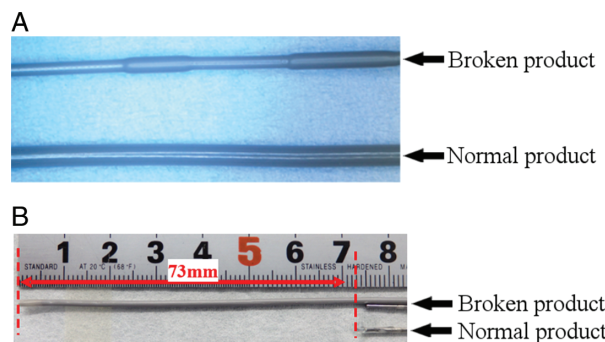


Figure 3. (A) Several deformations were present in the sheath, which became narrow at several sites. (B) The entire length of the broken UM-S20-17S was approximately 73 mm longer than a normal probe of the same model; therefore, combined with the 50-mm broken tip, the sheath was elongated by 123 mm in total.

resection of the right lung was performed by a surgeon at our hospital. A careful search for the residual broken fragment in the resected lung specimen was performed by the pathology department, but no tip was found. No complication due to a residual fragment of the tip has occurred in the patient.

Discussion

Since EBUS-GS-guided transbronchial biopsy of the peripheral lung was first reported by Kurimoto et al. [1], the frequency of its use has steadily increased, and the rate of breakage of peripherals, such as the incident reported here, may increase in the future. In a study of 965 examinees [2], radial probe breakage occurred in four cases (0.4%) with no guide sheath breakage. According to the Olympus Corporation, two incidents of echo probe breakage have been confirmed as of November 2015. The first incident was breakage of an older-model probe during adjustment before examination in 2013, and the second was the present case, which was the first incident with the UM-S20-17S model. The type was different, but an incident of breakage of an echo probe during upper gastrointestinal endoscopy has also been reported to the Olympus Corporation. Breakage of peripherals has also been occasionally reported [3,4], and a review of safety management at each institution was required [5]. In our institution, the absence of defects in a device, including damage, is confirmed before each use of the device for a radial EBUS examination, including its initial use. The absence of defects in the echo probe was confirmed on the day of the examination, and the probe was used because no problems or damage were present. In our hospital, the bronchoscope and related devices are prepared by the physician, but devices and materials are recovered after bronchoscopy by nurses at the site. After this incident, physicians have increased efforts to

inspect the device and materials after examination to improve safety management. In addition, when inserting into or removing from the ultrasound stopper is difficult, the physician is urged to handle the device while protecting it with gauze containing ethanol to reduce resistance as much as possible, as recommended by the Olympus Corporation.

We received the result of an investigation from the Olympus Corporation showing that breakage of the sheath likely occurred because friction resistance was loaded on the outer surface of the echo probe upon removal of the stopper attached to the echo probe and because the sheath coating the surface was separated from the echo probe. Our case demonstrates that it is necessary to reconfirm procedures for handling ultrasonic probes used for bronchoscopy, and careful inspection of breakage of related devices should be routinely performed before and after an examination. Breakage of devices is not frequently reported, and an accumulation of incident reports may facilitate safety management at all institutions.

Disclosure Statement

Appropriate written informed consent was obtained for publication of this case report and accompanying images.

Acknowledgments

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