Analysis of mechanical and biological effects of ultrasonically activated devices

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1. Introduction

In recent years, a couple of studies have suggested that unexpected postoperative pancreatic fistula (POPF) occurs more frequently in laparoscopic surgery than with conventional open surgery for gastric cancer. POPF could lead to serious postoperative complications such as intraabdominal hemorrhage and/or anastomotic leakage, thus it must be avoided whenever possible.

The direct cause of POPF has been unclear in most patients undergoing laparoscopic gastrectomy with neither splenectomy nor pancreatosplenectomy. Ultrasonically activated devices (USADs) have been suspected to be associated with this complication [1,2], since they are widely used for lymph node dissection during laparoscopic gastric cancer surgery, and cavitation generated from the blade in USADs may have a harmful effect on various biological tissues [3–6]. In this study, we analyzed the mechanical and biological effects of USADs with two different types of blade and addressed the question of whether USADs could be the direct cause of POPF after laparoscopic gastric cancer surgery.

2. Materials and methods

2.1. USADs

A laparoscopic USAD handpiece with a straight blade (SCP39, Covidien Japan, Tokyo) or a curved blade (ACE36J, Ethicon Endo-Surgery Japan, Tokyo) was used with an appropriate generator. The configuration of each blade is shown in Fig. 1. Both devices employ an ultrasonic energy of 55.5 kHz for activation. The blade was activated while its handpiece was fixed on a precision positioning table mounted on a metal framework in all the experiments (Fig. 2).

2.2. Observation of cavitation bubble generation

The general appearance of cavitation bubble generation from the activated blade in degassed water was recorded using a digital high-speed video camera (Exilim HS EX-ZR750, Casio) for 10 s, which is the recommended limit for activation of USADs by manufacturers (Fig. 2). Video images were closely examined afterward.

2.3. Analysis of mechanical effects of USADs

In order to evaluate the destructive capabilities of the activated blades, the tip or the side of each blade was placed in contact with a five-layer stack of aluminum foils (11 μm thickness per layer) and the USAD was activated for either 1, 3, or 5 s, which is the recommended limit in general clinical use (Fig. 3). Each activation trial was performed 10 times and the destructive capability was estimated as the mean numbers of broken foil layers.

2.4. Analysis of biological effects of USADs

Three male, castrated 3-month-old domestic pigs weighing 30–40 kg were used in this experiment. Under general anesthesia, laparotomy was performed and the pancreas was exposed. The tip or the side of the blade was placed in contact with the pancreas, and the USAD was activated for either 1, 3, or 5 s, which are the same durations as those in the mechanical analysis. As a control, an conventional electric scalpel was also activated with the tip of the blade in contact for the same durations. Each site at which the device was activated was excised separately into blocks, serially sectioned, and stained with either hematoxylin and eosin (HE) or AZAN. The experimental protocol was reviewed and approved by the Chiba University Institutional Animal Care and Use Committee.

2.5. Statistical analysis

To determine the independent and combined effects of the activation time, the number of broken foil layers and the site of contact, comparisons between groups were performed by three-way ANOVA followed by multiple comparison testing using the Bonferroni correction. All statistical analyses were performed using SPSS version 20 (IBM Japan, Tokyo).

3. Results

3.1. Observation of cavitation bubbles

Cavitation bubbles were generated from both the tip and the side of the curved blade (Fig. 4) but only the tip of the straight blade (Fig. 5).

3.2. Analysis of mechanical effects of USADs

The mean number of broken aluminum foil layers significantly increased as the activation time increased for both types of blade (Fig. 6). Also, the mean numbers of foil layers...
layers broken by the curved blade significantly exceeded those broken by the straight blade at all activation times tested (Fig. 6 and Table 1). Pairwise comparison of the blade type and contact site revealed a significant difference between straight and curved blades regarding the tip and the side, respectively (Table 1). However, a significant difference could not be found between the tip and the side for the curved blade (Table 1).

3.3. Analysis of biological effects of USADs

Histological analysis revealed that coagulation necrosis and protein clotting occurred around the site of activation in all specimens tested using the electric scalpel (Fig. 7). For the sites activated using the USADs with both types of blades coagulation necrosis was found but protein clotting covering
the damaged sites was rarely observed in any of the specimens (Figs. 8 and 9). Furthermore, hyaline generation was observed only with USADs activation. Similar tissue degeneration was observed when using the tip of the blade of both types of USAD; however, degeneration of the pancreatic parenchyma could not be found in the site activated with the side of the straight-type blade (Fig. 9(b)).

4. Discussions

Analysis of the video images of cavitation bubble generation in degassed water showed a marked difference between the curved and straight blades, especially around the side of the blades. Almost no bubble generation was observed around the side of the straight blade, whereas many bubbles appeared to be generated around the same area of the curved-type blade during activation.

Interestingly, differences potentially relevant to bubble generation were observed in the analysis of the mechanical and biological effects of the USADs. Mechanical analysis of the USADs revealed almost no breakage of the foils in contact with the side of the straight-type blade, whereas the breakage of at least two foil layers in contact with the same site of the curved blade. Animal experiment showed a similar difference between the straight and curved blades. Both types of blade caused coagulation necrosis in the activated sites of the tissue; however, the side of the straight blade did not appear to cause any pancreatic parenchyma degeneration.

The data from these three experiments suggest that the side of the curved type blade inflicts more destructive energy on objects in contact with it than the side of the straight blade. However, because our study included only two commercially available products, one with a straight blade and the other with curved blade, the various differences observed in this study might have arisen from inherent specific properties of the products unrelated to the configuration of the blade. Both products employ 55.5 kHz ultrasonic energy, and the findings of three different experiments indicated similar tendencies. USADs utilize harmonic ultrasound waves transmitted through a metal rod; therefore, the configuration of the blade is most likely to affect the generation of cavitation bubbles.

Furthermore, the histological findings of the sites activated with USADs were revealed to be different from those activated with a conventional electric scalpel. Areas of degenerative tissue activated with the electric scalpel were covered with thick protein clots, but much fewer clots were found around the damaged areas activated with the USADs. Although no involvement of pancreatic ductules was revealed in this study, exposed acinar cells that are not covered with protein clots presumably secrete pancreatic juice. These histological findings might be associated with the higher incidence of pancreatic fistula for gastric cancer patients after laparoscopic surgery compared with conventional open surgery, which does not involve the frequent usage of USADs around the pancreas.

Fig. 7 Histological findings of the site activated with the tip of electric scalpel. The specimen was stained with hematoxylin and eosin staining. The white arrow indicates coagulation necrosis and the gray arrow indicates protein clots.

Fig. 8 Histological findings of the sites activated with the tip (a) or side (b) of the curved blade. The specimens were stained with hematoxylin and eosin staining. The white arrows indicate coagulation necrosis and black arrows indicates hyaline degeneration.

Fig. 9 Histological findings of the sites activated with the tip (a) and side (b) of the straight blade. The specimens were stained with hematoxylin and eosin staining. The white arrow indicates coagulation necrosis and the black arrow indicates hyaline degeneration.
Surgeons are generally aware that touching biological tissues with an activated USAD blade may have a harmful effect on the biological tissues; however, they pay little attention to the effect of the side of the activated blade. Since the activated blades of USADs generate much fewer protein clots in biological tissues, they cause only minor macroscopic changes to the surface of the pancreas compared with those of conventional electric scalpels. Therefore, surgeons might have caused pancreatic tissue damage during laparoscopic lymph node dissection around the pancreas without realizing it.

The findings revealed in this study do not directly account for the increased incidence of POPF after laparoscopic gastric cancer surgery. However, these findings suggest the importance of comparing clinical outcomes between patients treated using USADs with straight and curved blades. Further analysis of the relationship between the sound field around each blade of a USAD and the generation of the cavitation bubbles is also necessary to examine the validity of the results of this study.

5. Conclusion

The differences in histological changes induced by activation with a conventional electric scalpel and with USADs were elucidated. The distribution of biologically harmful cavitation generated on the blade of USADs was also revealed to be different between straight and curved blades. Although these findings do not directly link USADs with POPF, the data provide us an important hint for revealing the direct cause of POPF after laparoscopic gastric cancer surgery.

References