Use of an Endoscopic Surgical Spacer during Laparoscopic Pancreatic Tumor Enucleation

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Abstract

A number of recent reports have highlighted the usefulness of laparoscopic surgery for pancreatic surgery; however, the procedure is not yet standard because of its technical challenges. Using an endoscopic surgical spacer (SECUREATM) that we developed, we performed laparoscopic enucleation of a pancreatic tumor in a patient with pancreatic mucinous cystadenoma. The SECUREA is a polyurethane sponge with a radiopaque marker. It is elliptic-cylindrical and measures 6.5 cm on the major axis, 3.5 cm on the minor axis, and 2 cm in height. Herein, we report the intraoperative findings and examine the usefulness of SECUREA for laparoscopic enucleation. The spacer was introduced into the abdominal cavity through a 12-mm trocar, and was grasped with forceps to isolate or extend organs and tissues, thereby ensuring a safe and relatively uncontaminated surgical field. In addition, the high absorptiveness and water-holding capacity of the sponge facilitated removal of exudate, which created a clearer operative field and reduced the technical challenges of drainage manipulation. Indeed, replacement of the sponge was unnecessary because it returned to its original state after the liquid it contained had been aspirated. Our findings suggest that the SECUREA increases safety and reduces the technical difficulties of laparoscopic enucleation. (J Nippon Med Sch 2010; 77: 106-110)

Key words: surgical spacer, sponge, laparoscopic pancreatic tumor enucleation, laparoscopic surgery, endoscopic surgery

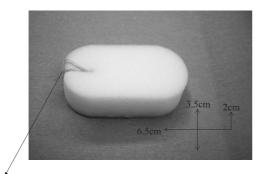
Introduction

When performing endoscopic surgery, it is essential (1) to reduce unnecessary pressure on organs and tissues by safely isolating them while securing the surgical field, (2) to be able to easily remove exudate (blood, lymph, and bile) and effusion, in order to protect the visual field and prevent the spread of exudate, and (3) to prevent secondary injuries caused by the transmission of heat and vibrational energy from autosuture devices. The endoscopic surgical spacer SECUREA[™], which we co-developed with Hogy Medical Co., Ltd., is a medical device that can be effectively employed for all these purposes. In this report, we examine the usefulness of SECUREA for laparoscopic enucleation (Lap-EN) of a pancreatic tumor.

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radiopaque marker

Fig. 1 Image of the sponge spacer The sponge is made of polyurethane and is equipped with a radiopaque marker. It is elliptic-cylindrical and measures 6.5 cm on the major axis, 3.5 cm on the minor axis, and 2 cm in height.

Methods and Materials

Description of the Device

SECUREA is a polyurethane sponge with a radiopaque marker. It is elliptic-cylindrical, and measures 6.5 cm on the major axis, 3.5 cm on the minor axis, and 2 cm in height (**Fig. 1**).

Compliance with Pharmaceutical Affairs Law

SECUREA was used in compliance with the requirements stipulated by the Pharmaceutical Affairs Law (PAL). Before using the device, we verified that its safety had been established at the time of approval.

Hogy Medical Co., Ltd. confirmed adherence to the PAL, and has indicated that, as specified in Article 2, Paragraph 7 of the PAL, SECUREA is a Class I device according to the Japanese Medical Device Nomenclature (JMDN), which is the Japanese version of the Global Medical Device Nomenclature (GMDN). Its nonproprietary description is a "sponge containing an x-ray contrast agent", as detailed in Notification No. 298 of the Japanese Ministry of Health, Labour and Welfare. A number of tests and evaluations of the device were performed. After the safety of SECUREA was confirmed, Hogy Medical Co., Ltd. submitted a medical device marketing notification (Article 14-9 of the PAL; Number 13B1X 00061I40038).

Method of Use

SECUREA was introduced into the abdominal

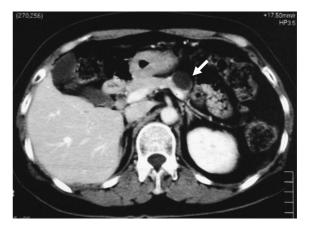


Fig. 2 Computed tomography image shows the pancreatic cystic tumor protruding from the pancreas (**arrow**).

cavity through a 12-mm trocar and manipulated by forceps.

Patient

The patient was a 58-year-old woman who was referred to our hospital for treatment of a rapidly growing pancreatic tumor measuring 4 cm in length. The patient had no chief complaint or notable past or family history. Her height was 148 cm, weight 51 kg, and BMI 23.3 kg/m². On admission, she had no concomitant illness. Blood biochemistry on admission. including markers. tumor was unremarkable. Pancreatic mucinous cystadenoma was diagnosed based on findings from abdominal ultrasonography, computed tomography (CT), and magnetic resonance imaging (MRI). Lap-EN was selected because of the absence of intracystic nodules, which suggest malignancy, and because the tumor protruded from the pancreas and was located far from the main pancreatic duct (Fig. 2).

Intraoperative Findings

With the patient in the supine position, we inserted a 12-mm trocar through which SECUREA was introduced into the abdominal cavity (Fig. 3). We made a partial incision in the omental bursa and inserted SECUREA through it (Fig. 4a). This created sufficient space in the omental bursa cavity for us to expand the incision while perceiving depth and distance (Fig. 4b). Most of the tumor protruded from the pancreas, as preoperative imaging had indicated, and we proceeded to perform enucleation as planned. We manipulated SECUREA with forceps

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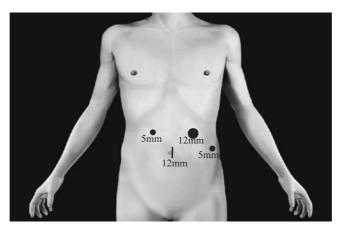


Fig. 3 Four trocars were inserted, as shown.

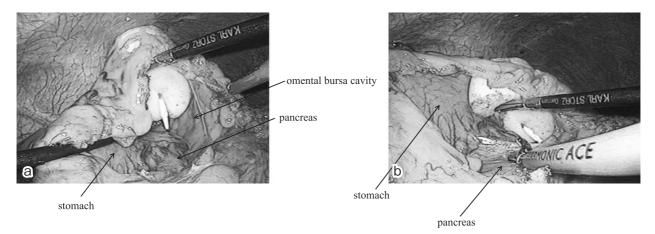


Fig. 4 After the omental bursa was partially incised and the SECUREA was inserted, a suitable space was created in the omental bursa cavity (Fig. 4a), after which the incision could be enlarged while visualizing depth and distance (Fig. 4b). Because there was no need to grasp the stomach wall or the greater omentum, the procedure could be performed without the usual concern for crush injury or damage to adjacent tissues.

to exclude the stomach from the surgical field toward the cephalad end, which allowed us to expose the front of the pancreas (Fig. 4a). Because it was unnecessary to pull the stomach wall or greater omentum away from the surgical field, we were able to perform the procedure without the usual concern for crush injury or secondary damage to tissues. Furthermore, the stomach could be excluded from the surgical field to some extent simply by placing SECUREA in the omental bursa (Fig. 5a). Consequently, we were able to use forceps, which would have been used for isolating the stomach, for other purposes. In particular, the extra pair of forceps proved helpful for the delicate maneuvers used to enucleate the tumor from the pancreas parenchyma, including the accurate expansion of the incision (Fig. 5b). SECUREA was also useful for

excluding and extending the transverse mesocolon at the inferior margin of the pancreas. Indeed, we were able not only to separate the inferior margin of the pancreas from the surgical field, but also to consistently observe and clean the enucleated site after resection (Fig. 6a). In addition, when SECUREA was placed near the pancreas during resection, it rapidly absorbed blood and exudates, which prevented their spread and improved visibility in the surgical field, which had been degraded by accumulating effusion (Fig. 5a). Moreover, an aspiration tube placed over SECUREA was sufficient to aspirate the exudate. This prevented poor visibility caused by the simultaneous aspiration of pneumoperitoneum gas.

During intraperitoneal irrigation after resection, an aspiration tube was placed over SECUREA to

A Sponge Spacer for Endoscopic Surgery

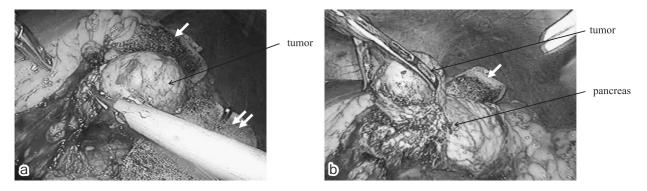


Fig. 5 Because the use of SECUREA in the omental bursa permitted us to isolate and excluded the stomach from the surgical field (**single arrow**) (Fig. 5a), the forceps that would normally be used for this purpose could instead be used for other purposes during the procedure. In particular, the extra pair of forceps was useful for the delicate maneuvers used to enucleate the tumor from the pancreas parenchyma, including the expansion of the area of resection (Fig. 5b). Because blood and exudate were rapidly absorbed by the SECUREA, there was little diffusion, and less degradation of the surgical field due to accumulating effusion (**double arrow**) (Fig.5a).

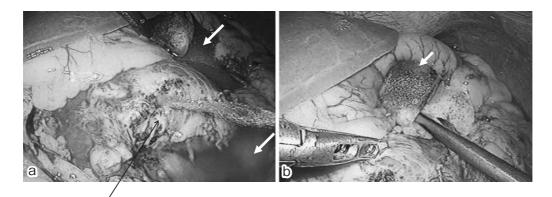




Fig. 6 The SECUREA (**arrow**) was also useful for mobilizing, excluding, and expanding the transverse mesocolon at the inferior pancreas. By these means, it was possible to separate the inferior pancreas from the surgical field, and to ensure optimal observation and rinsing of the enucleated segment after removal (Fig. 6a). Moreover, since the effusion and irrigation liquid could be aspirated through the SECUREA (**arrow**), the effusion could be completely removed without aspirating healthy tissues (Fig. 6b).

drain the effusion and irrigation solution. As a result, we were able to completely remove the effusion without accidental aspiration of tissues (**Fig. 6b**). The duration of surgery was 2 hours and 54 minutes, and the volume of blood loss was small.

Postoperative Course

On day 1 of illness, the patient had flatus, and enteral nutrition was thus started. After the procedure, she developed a grade A pancreatic fistula—according to the criteria of the International Study Group for Pancreatic Fistula (ISGPF)¹—but it abated with conservative management. On day 14 of illness, she was discharged from the hospital. The

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histopathological findings of the resected specimens indicated that the tumor was a mucinous cystadenoma.

Discussion

Endoscopic surgery is performed in a number of fields because of its cosmetic advantages and minimal invasiveness. However, as compared with laparotomy, endoscopic surgery has a number of disadvantages in digestive surgery. The techniques required are often difficult to master, and visibility is a significant concern. The considerable technical requirements of endoscopic surgery place great demands on digestive surgeons. To reduce these demands, we developed SECUREA (1) to permit the use of forceps to safely exclude organs and tissues from the surgical field, (2) to prevent the spread and facilitate the removal of exudate, and (3) to prevent secondary injuries caused by the use of surgical instruments.

Since 1994, when laparoscopic pancreatectomy was first reported by Gagner et al², the usefulness of this procedure has been gradually acknowledged, and the number of reports of laparoscopic pancreatectomy continues to increase in Japan and other countries³⁻⁶. The present authors were quick to adopt laparoscopic distal pancreatectomy and pancreaticoduodenectomy laparoscopic for pancreatic surgery and have previously described the clinical advantages of these procedures⁵⁶. Enucleation of pancreatic tumors is a functionpreserving procedure for benign lesions, such as pancreatic endocrine tumors and cystic pancreatic disease, and for pancreatic tumors with low malignancy potential. There have also been a number of reports of patients who have undergone laparoscopic procedures because of their minimal invasiveness7.

The pancreas is located in the retroperitoneum, and the distal pancreas is deeply embedded in the left subdiaphragmatic space. Therefore, it is difficult to view fully, even if the abdomen is opened. The use of a laparoscope vields detailed visual information on local areas, and allows surgery to be performed with less blood loss. However, securing a satisfactory surgical area with appropriate isolation of the spleen, stomach, liver, and mesocolon is challenging, and secondary injuries associated with grasping of organs or tissues are always a concern. In the present patient, SECUREA allowed us to easily secure the surgical field without grasping organs or tissues. In endoscopic surgery, even a small amount of blood or exudate can degrade visibility. Because the pancreas is dorsal to the abdomen, exudate constantly accumulates in the center of the surgical field. Thus, in addition to an increase in the frequency of drainage, precise aspiration is required. This problem is typically addressed by inserting gauze; however, gauze must be frequently replaced because of its poor water

absorbency. In contrast, SECUREATM has good water-holding capacity and can be restored to its original state in the abdominal cavity by aspirating the exudate it contains. There is therefore no need for replacement. Furthermore, because effusion can be drained through the sponge, the aspiration tube does not come into contact with tissues, and the amount of pneumoperitoneum gas aspirated in the abdominal cavity is decreased.

Conclusions

We reported the intraoperative findings of laparoscopic enucleation using an endoscopic surgical spacer (SECUREA). SECUREA allowed for safe and precise exclusion of organs and tissues from the surgical field and for removal of exudate. These findings indicate that SECUREA facilitates the creation of a surgical field during laparoscopic enucleation.

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