



Feasibility and safety of duodenal covered self-expandable metallic stent fixation: an experimental study

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Abstract

Background and aims Migration of duodenal covered self-expandable metallic stents (C-SEMS) is the main cause of stent dysfunction in patients with malignant gastric outlet obstruction. However, the ideal method to prevent migration has not been clarified. We aimed to evaluate the feasibility and safety of duodenal C-SEMS fixation in this experimental study.

Methods We used the over-the-scope clip (OTSC), suture, and clip methods to fix duodenal C-SEMS and evaluated the gripping force of each device and invasion depth based on pathological findings.

Results The OTSC and suturing systems had a significantly higher mean gripping force compared with the clipping system (OTSC vs. clip: 13.2 vs. 1.0 Newtons [N], $P < 0.001$; suture vs. clip: 8.5 vs. 1.0 N, $P < 0.001$). OTSC compression was stronger compared with suturing (OTSC vs. suture: 13.2 vs. 8.5 N, $P = 0.006$). The submucosal layer, but not the muscle layer, was compressed more widely and deeply by OTSC compared with clips based on pathological findings by hematoxylin and eosin staining.

Conclusion Both OTSC and suturing methods used for duodenal C-SEMS fixation were feasible compared with the clipping method. The pathological evaluation of invasion depth indicated that OTSC may be safe even for preventive use. This study suggested that these methods can be applied clinically for duodenal C-SEMS fixation.

Keywords Covered self-expandable metallic stent · Migration · Over-the-scope clip · Stent fixation · Suture

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Gastric outlet obstruction (GOO) often occurs in patients with advanced-stage gastric or pancreatobiliary cancer. It is caused by gastroduodenal stricture or obstruction and is associated with poor oral intake and a decrease in quality of life. Placement of a self-expandable metallic stent (SEMS) has been widely used for palliative treatment of GOO. Recently, uncovered SEMSs (U-SEMSs) and covered SEMSs (C-SEMSs) have become available. Although endoscopic SEMS insertion shows excellent technical success (approximately 92–100% [1–4]), the clinical efficacy of the SEMS is compromised for several reasons [2]. Two major causes of poor clinical outcomes have been reported: poor performance status and stent dysfunction. Because of advanced malignant disease, a poor performance status cannot be avoided. However, there is room for improvement with regard to stent dysfunction. The main cause of stent dysfunction with an U-SEMS is tumor or tissue ingrowth via the stent mesh, which occurs in 4–26% of cases [5–9]. We previously reported that chemotherapy is the only method

to prevent tumor ingrowth [2]. However, patients with GOO generally have advanced-stage cancer [10], and most are not eligible for chemotherapy because of disease progression [11]. In fact, in our previous large cohort, 72.5% (208/287) of patients could not receive chemotherapy after SEMS insertion [12].

The C-SEMS was designed to prevent tumor ingrowth; yet, stent migration occurs in 16–25% of C-SEMS cases and is a major adverse event requiring re-intervention [13, 14]. To prevent C-SEMS migration, improvement in the shape of the stent has been attempted [15, 16]. However, the results were unsatisfactory. Another method is needed.

Some researchers have reported that fixation of SEMSs is beneficial for preventing migration. Methods of SEMS fixation are described as follows. (1) The over-the-scope clip (OTSC) is used to close perforations and fistulae and to control bleeding [17–19]. A few cases have been reported in which OTSC was used to prevent migration of esophageal SEMSs [20–22]; however, to our knowledge no reports have described its use for duodenal SEMSs. Furthermore, because the purpose of the procedure is not therapeutic but preventive, safety should be ensured. (2) An endoscopic suturing method has been developed. Although this method is not generally used in clinical practice, its use has been explored in recent years in experimental models and clinical trials [23–25]. (3) Clips are generally used for closing perforations or controlling bleeding, but they have also been used to prevent C-SEMS migration. However, from our clinical experience, this method might not be ideal for this purpose. These methods, excluding the clip method, have not been well established in daily clinical practice. Before they are used clinically, experimental studies are needed to evaluate their safety [26] for preventive use.

Therefore, we experimentally investigated the feasibility and safety of SEMS fixation using the above-mentioned devices. The two major aims of this study were to measure the gripping force of each device and to verify the safety of the devices, especially OTSC, which has not been established for preventive use, in evaluating the depth of invasion based on pathological findings.

Materials and methods

Animal trial

The feasibility and safety of SEMS fixation using each device (OTSC, suture, and clip) were evaluated in porcine stomach. The primary endpoint was successful fixation of SEMS under an endoscopic procedure. The animal experiments were conducted in compliance with the Declaration of Helsinki and Japanese animal protection laws and were approved by the appropriate government authority. The

secondary endpoint was the actual invasion depth, evaluated pathologically, of each device.

All procedures were conducted under general anesthesia with the animal in the supine position. First, we placed a duodenal C-SEMS (Niti-S stent; Taewoong Medical, Seoul, Korea) over the duodenum. The SEMS was deployed in such a way that the oral portion was in the stomach. Subsequently, we loaded each device to the endoscope and placed it on the oral side of the SEMS. In this experiment, we used a typical type of clip (HX-610-090; Olympus, Tokyo, Japan), and a 12/6t OTSC type, which has an OTSC cap diameter of 17.5 mm and clip width of 10 mm. For placing the OTSC system, we first loaded the system onto the endoscope and suctioned the upper rim of the SEMS into the transparent cap and subsequently released the OTSC system. After placing each device, we dissected the digestive tract and evaluated the invasion depth of the device.

Measuring gripping force

Figure 1 shows a schema of the experimental models used to measure gripping force. Each device was attached to the porcine stomach. For suturing, we used 3–0 absorbent thread and sutured the submucosal layer. To measure gripping force, the device was held by a force gauge (ZP-50N; Imada, Tokyo, Japan), and the force required for it to come off was recorded. Each measurement was taken 10 times using each device.

Statistical analysis

Data are expressed as means (2 standard errors of the mean [SE]). Differences in quantitative data between groups were compared using the Students t test. All statistical tests were two sided, and statistical significance was defined as a *P* value < 0.05. All statistical analyses were performed using

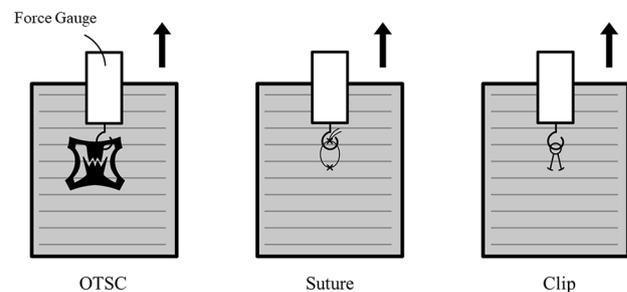


Fig. 1 Schema of the experimental model used for measuring gripping force. Each device was attached to the porcine stomach. To measure gripping force, the device was held by a force gauge (ZP-50N; Imada, Tokyo, Japan), and the force required for it to come off was recorded

SPSS software (version 23; IBM Corporation, Armonk, NY, USA).

Results

Measurement of gripping force

Figure 2 summarizes the gripping force (mean [2 SE]) measurements. The OTSC and suturing system had significantly higher gripping force compared with the clipping system (OTSC vs. clip: 13.2 (2.4) vs. 1.0 (0.2) Newtons [N], $P < 0.001$; suture vs. clip: 8.5 [1.9] vs. 1.0 [0.2] N, $P < 0.001$). Stronger compression was obtained with OTSC than with suturing (OTSC vs. suture: 13.2 [2.4] vs. 8.5 [1.9] N, $P = 0.006$) (Table 1).

Invasion depth of each device

Figure 3A shows the actual endoscopic placement of OTSC and the clips. Compression was stronger and deeper with OTSC than with clips (Fig. 3B). According to hematoxylin and eosin (HE) staining, the submucosal layer was compressed

more widely and deeply with OTSC than with clips. As shown in Fig. 4A, the clips compressed mainly the mucosal layer and only reached a small area of the submucosal layer. The muscle layer was not compressed with OTSC according to HE staining (Fig. 4B).

Discussion

This study demonstrated the gripping force of each device (OTSC, suture, and clip) and the invasion depth, which is probably related to the safety of the device, using pathological specimens. Many attempts have been made to prevent migration of duodenal C-SEMSs; however, the results have not been satisfactory. To fix duodenal C-SEMSs to prevent migration, clips have generally been used because they are readily available and familiar to surgeons. We experimentally evaluated the feasibility and safety of OTSC and suture methods for fixing duodenal C-SEMSs compared with the traditionally used clip method.

Many efforts have been made to optimize SEMSS [27, 28]. Currently, duodenal C- and U-SEMSs are available for malignant GOO. Recent randomized controlled trials of C- and U-SEMSs demonstrated a significantly lower incidence of tumor ingrowth with C-SEMSs (1–3%); however, this advantage over U-SEMSs was offset by a high rate of stent migration (13–32%) [13, 29, 30]. Some researchers have reported the utility of the partial C-SEMS, which prevents tumor ingrowth by the covered part and migration by the uncovered part [15]. However, a subsequent trial, which was similar in structure, showed that migration was not prevented [16]. It is controversial whether the partial C-SEMS can prevent migration. We previously reported that longer C-SEMSs are preferable to prevent tumor in- and overgrowth [2, 31]. Since the covered membrane of the SEMS prevents tumor ingrowth at excellent rates (1–3%), we speculate that a longer covered part could prevent tumor ingrowth and provide favorable SEMS patency in cases without migration. According to our argument, we think that a method to prevent migration different from changing the SEMS structure should be established. Fixation of esophageal SEMSS, which migrate at a high rate (up to 50%) [32, 33], has been attempted. Although several studies have shown the usefulness of fixation of esophageal SEMSS, to the best of our knowledge, few studies have applied this approach to duodenal SEMS. Furthermore, esophageal and duodenal strictures show important differences according to the primary cancer, structure of the digestive organ, and treatment

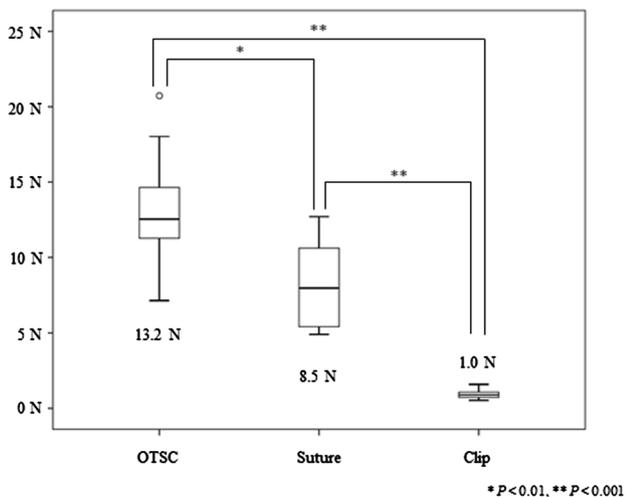


Fig. 2 Comparison of gripping force (mean) among the devices. The OTSC and suturing systems had significantly higher gripping force compared with the clipping system (OTSC vs. clip: 13.2 vs. 1.0 N, $P < 0.001$; suture vs. clip: 8.5 vs. 1.0 N, $P < 0.001$). OTSC compression was stronger compared with suturing (OTSC vs. suture: 13.2 vs. 8.5 N, $P = 0.006$). OTSC, over-the-scope-clip

Table 1 Comparison of gripping force among each device

	OTSC	Suture	<i>P</i> value	OTSC	Clip	<i>P</i> value	Suture	Clip	<i>P</i> value
Gripping force, N	13.2 (2.4)	8.5 (1.9)	0.006*	13.2 (2.4)	1.0 (0.2)	<0.001**	8.5 (1.9)	1.0 (0.2)	<0.001**

Values are means (2SE). OTSC over-the-scope clip. * $P < 0.01$, ** $P < 0.001$

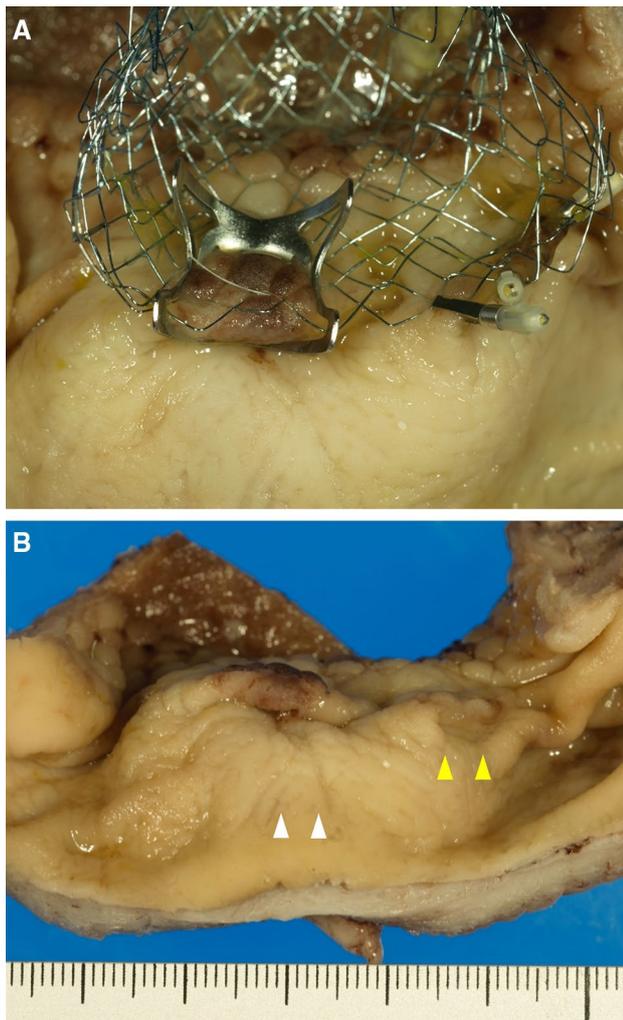


Fig. 3 Actual endoscopic placement of the OTSC and clips (A). OTSC (white triangle) showed stronger and deeper compression compared with clips (yellow triangle) (B). OTSC, over-the-scope-clip. (Color figure online)

(chemotherapy and radiation therapy). The only study [34] that has used endoscopic clipping to prevent migration of duodenal C-SEMSs observed no stent migration. However, this report consisted of a small number of cases ($n=25$), and we occasionally experience stent migration even if we use clips to fix duodenal SEMSs. Because migration of esophageal SEMSs with clips occurred in 13% of cases [35], the potential risk of duodenal SEMS migration with clips may be higher than reported previously.

Because the purpose of the devices evaluated here is preventive, their safety should be ensured. In the present experimental study, we compared the OTSC, suture, and clip methods for SEMS fixation.

Based on the concept and design, we speculated that OTSC is superior to clips in terms of gripping force. As we expected, the OTSC had significantly higher gripping

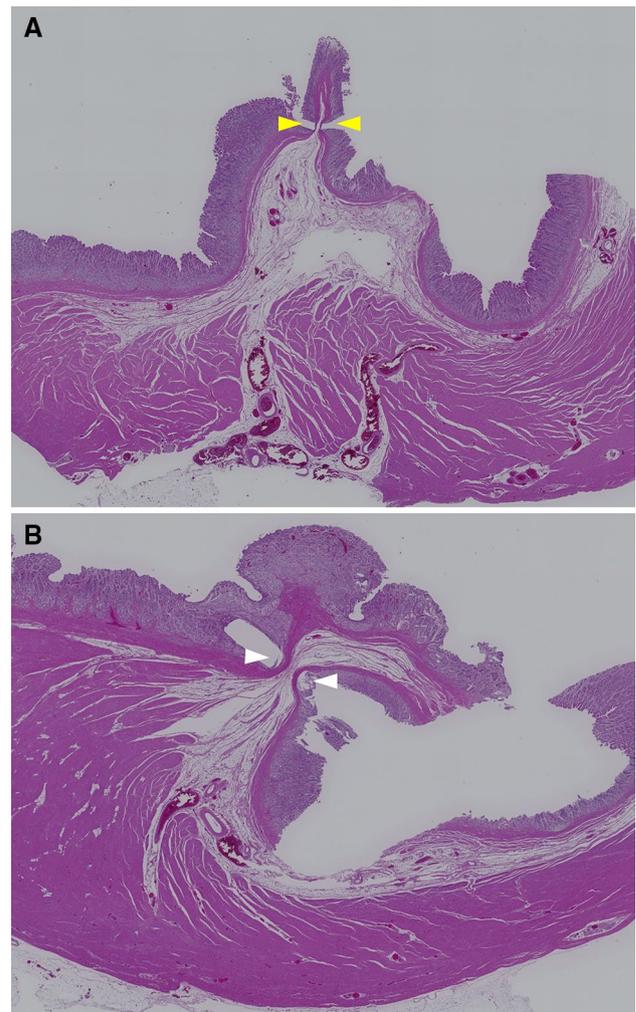


Fig. 4 Evaluation of gripping depth by HE staining. A Clips compressed mainly the mucosal layer and only reached a small area of the submucosal layer (yellow triangle). B OTSC showed wider and deeper compression of the submucosal layer compared with clips, but the muscle layer was not compressed (white triangle). HE hematoxylin and eosin, OTSC over-the-scope-clip. (Color figure online)

force compared with the clipping system (OTSC vs. clip: 13.2 [2.4] vs. 1.0 [0.2] N, $P < 0.001$). Our only concern is the safety of the OTSC: if the OTSC grabs the muscle layer of the stomach, it could cause gastrointestinal perforation in the long term. However, in the present study, only the submucosal layer, and not the muscle layer, was compressed with OTSC. These findings may suggest that the OTSC is superior to clips in terms of gripping the mucosal/submucosal layer and can be used safely.

The suturing system was also superior to clips from the viewpoint of gripping force (suture vs. clip: 8.5 [1.9] vs. 1.0 [0.2] N, $P < 0.001$). In a recent large case series, Bick et al. [23] revealed that suturing systems for esophageal fully C-SEMSs reduced rates of stent migration (sutured fully C-SEMS vs. fully C-SEMS: 9.4% vs. 39.5%, $P < 0.01$). Various suturing

methods have been developed for flexible endoscopy [23–25]. As with OTSC, the suturing system may be useful for gripping. A disadvantage of the endoscopic suturing system is that it requires a specific device and training to become accustomed to its use. Even if the physician has practiced for the procedure, it requires some time to suture under endoscopic guidance. An OTSC is easier to use because it is easily mounted and installed onto an ordinal, single-channel flexible endoscope. If the suture method is further developed and generally available in the future, both the OTSC and suture methods may be useful to prevent migration of duodenal C-SEMSs.

This study is not without limitations. First, the work was performed using a porcine model and laboratory equipment. However, to investigate the feasibility and safety of new fixation methods, experimental studies should be performed before the method is used in everyday clinical practice. Second, we selected three fixation methods for this study; other methods may also be available. Last, in our country, the use of an endoscopic suturing system in vivo has been limited, and the system was not available. Although we only evaluated the efficacy of a suturing system in ex vivo models, suturing may not cause perforation because the technique has been used in surgery for a long time.

In conclusion, both OTSC and suturing methods used for fixation of duodenal C-SEMSs were feasible compared with the clipping method. The pathological evaluation of invasion depth suggests that OTSC is safe, even for preventive use. The OTSC method is relatively simple and versatile compared with the suturing method. We believe our efforts will contribute to establishing an anti-migratory method for duodenal C-SEMSs.

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Compliance with ethical standards

Disclosures Drs. Yasuki Hori, Kazuki Hayashi, Itaru Naitoh, Hiroyuki Kato, Tatsuma Nomura, Katsuyuki Miyabe, Michihiro Yoshida, Naruomi Jinno, Makoto Natsume, Akihisa Kato, Go Asano, Shuji Takiguchi, and Kiyokazu Nakajima have no conflicts or interest of financial ties to disclose.

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