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REVIEW ARTICLE

Mechanical Property and Problems of the Self-expandable Metal Stent in Pancreaticobiliary Cancer

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Self-expandable metal stent (SEMS) is effective for biliary drainage, especially in pancreaticobiliary cancer. The mechanical properties, material, and design of SEMS are important in preventing recurrent biliary obstruction and complication. Radial and chronic expansion forces play roles in preventing stent migration and collapse. Complications, such as stent impaction, cholecystitis, and pancreatitis, were related to the axial force. The nickel–titanium alloy shows more flexibility, conformability, and optimal axial force compared to previously used stainless steel. Additionally, the stent structure affected the mechanical properties of SEMS. Therefore, understanding the mechanical properties, material, and design of SEMS will provide the best outcome for biliary drainage, as well as better SEMS development.

Key Words: Self expandable metal stents; Pancreatic neoplasms; Bile duct neoplasms; Mechanical properties; Recurrent biliary obstruction

INTRODUCTION

The main problem of biliary drainage in malignant biliary obstruction is stent clogging. Stent diameter was considered an important factor. The self-expandable metal stent (SEMS) was first introduced for biliary stenting in the 1990s. The SEMS had a lower rate of recurrent biliary obstruction and re-intervention due to its larger diameter (10 mm) compared to conventional endoprostheses at that period [1,2]. However, the larger diameter of the stent, the more difficult to pass the stent through the tight stricture. In that era, the SEMS (Wallstent; Medinvent SA, Lausanne, Switzerland) was made using medical-grade stainless steel. It was braided into a tubular mesh. The stent was constrained on a small-diameter delivery catheter. After deployment, it returned to its original diameter by its expansion force. This development has been adopted from endovascular and urethral stents [3,4]. In the past 30 years, SEMS had been developed for many purposes for biliary drainage.

MAIN SUBJECTS

Mechanical properties of SEMS

Radial force and chronic expansion force

The radial force (RF) is the force to expand the SEMS against the tumor compression. The chronic expansion force is similar to RF, it is the force to maintain the expansion of SEMS after deployment [5]. These parameters are related to stent migration in case of the RF is lower than 4.0 N [6].

Axial force (AF)

The AF is the straightening force when the SEMS is bent. It also can be called an anti-bending force. The AF has a reverse correlation with the length of SEMS [7]. The AF affected the stent conformability and SEMS-related complications (e.g., pancreatitis, cholecystitis, stent impaction) [8].

Materials

Stainless steel

The medical-grade stainless steel was firstly used in the first biliary SEMS [1]. However, the discovery of a new nickel-titanium superelastic shape memorial alloy suited for SEMS. This alloy becomes more popular.

Nitinol

Nitinol was developed by The Naval Ordnance Laboratory to be used for the nose cone of a naval missile. This alloy is a mixture of nickel and titanium. Its name nitinol comes from Nickel Titanium Naval Ordnance Laboratory. Nitinol has a combination of properties that cannot be found in other materials. It has the property of shape memory, superelasticity, high radial force, corrosive resistance, and biocompatibility [9]. Compare to stainless steel in the same stent design, the nitinol SEMS has higher RF and lower AF. Therefore, the nitinol stent seems to have more conformability to the bile duct.

Stent structures

The Nitinol SEMS mainly made by nitinol wire-based and nitinol tube-based stent designs [9,10]. There were main 3 types of stent design; braided, specially braided/knitted stent and laser-cut (Fig. 1). The nitinol wire can be welded or knitted into a tubular shape to form the braided and specially braided/knitted stent. The nitinol tube was laser-cut into a pattern to form the laser-cur stent.

Laser-cut SEMS made from a nitinol tube and the tube was cut into the pattern. This SEMS has a tight junction between the mesh of the stent. This design has more AF than other types. The specially braided/knitted SEMS made from nitinol wire and knitted into a tubular structure. The loose joint made this type of SEMS has less AF compared to the others [5].

SEMS related complication

Tumor overgrowth

In malignant biliary obstruction. The tumor overgrowth can occur around 4–7% [11]. The tumor overgrowth was caused by a tumor that grew into the proximal or distal opening of the stent. This probably occur by the length of the stent across the tumor was too short. A longer stent should be inserted if this condition occurs [5].

Tumor ingrowth

Tumor ingrowth is caused by tumors that grow across the mesh of SEMS. The incidence of tumor ingrowth was 29% in uncovered SEMS. This increases the re-intervention rate in patient with uncovered SEMS [9]. From this information, cover material has been developed in the 2000s with various types of material such as polytetrafluoroethylene (PTFE)

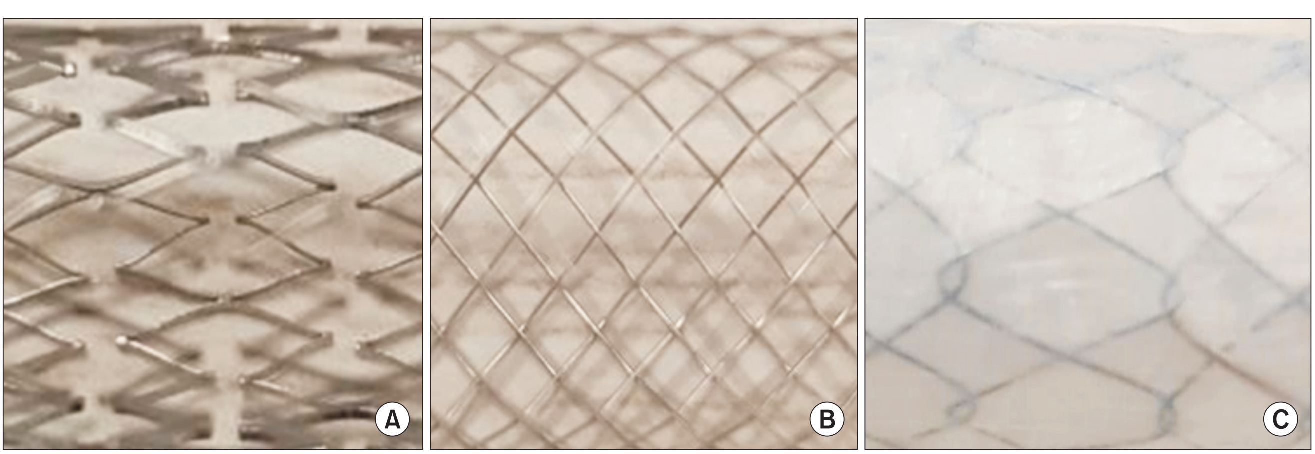

Fig. 1. Stent structure: (A) Laser-cut, (B) Braided, (C) Specially braided.

(Fig. 2) [12], silicone [13], and polyurethane [14]. The tumor in growth rate lowered in covered SEMS. In comparison between covered and uncovered SEMS, the covered can reduce the re-intervention rate and total cost of biliary drainage [11]. However, the covered biliary stent's weakest point was the migration because the covered material did not allow ingrowth or epithelial hyperplasia that played a role to prevent migration

Stent migration

The stent migration rate was 3–15% in covered SEMS [6,15,16]. This is the weakest point of covered SEMS because of lack of tumors in growth/epithelial hyperplasia. SEMS with low RF (< 4 N) was also associated with stent migration. The anti-migratory system was developed to improve stent patency rate.

Outer uncovered SEMS

This new type of stent was designed to have external uncovered wire by inserting PTFE membrane between two uncovered SEMS (ComVi; Taewoong Medical Inc., Seoul, Korea). This stent had lower migration rate compared to conventional covered SEMS (migration rate 2.1% vs. 17%) [17].

Flare end

Flare end of SEMS play important role in stent migration prevention in the ex-vivo study [18]. In vivo, SEMS with flare end (Fig. 3) seems to have lower stent migration compared to conventional SEMS [19,20]. However, the SEMS with flare end in previous study also had another type of anti-migratory system.

Flap

The flap was the structure that acted as the anchor of the SEMS. It showed 0–3% migration [21,22]. And the anchoring flap SEMS (MI Tech, Seoul, Korea) showed lower migration rate compared to flare-end SEMS in benign biliary stricture [21].

Bank/irregular cell width

Bank was the irregular stent diameter along caliber of stent. The SEMS with bank (modified Zeo stent; Zeon Medical Inc., Tokyo, Japan) had 0% migration rate compared to 70% of The SEMS without bank [19].

Irregular cell width (Fig. 4) SEMS (Bumpy; Taewoong Medical Inc., Seoul, Korea) provided different magnitudes of segmental RF depending on the cell sizes. There was no stent migration in benign pancreatic duct stricture during 3 months.

Bank and irregular cell width were similarly formed into irregular caliber to prevent migration.

Bile duct kinking/stent impaction

This complication is related to poor stent conformability

Fig. 2. Polytetrafluoroethylene covered self-expandable metal stent.

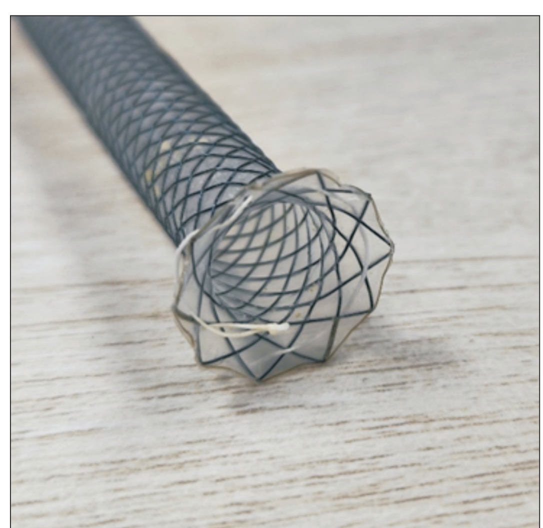

Fig. 3. Self-expandable metal stent with flare-end.

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and AF. If SEMS had high AF, it will straighten the curve bile duct resulting in bile duct kinking at the end of the stent (Fig. 5). The risk factors of bile duct kinking were acute angulation of the bile duct and SEMS with high AF. The bile duct kinking or stent impaction can be reduced by using stent length as long as possible because longer SEMS demonstrated lower AF and higher conformability [10,23].

Cholecystitis

Acute cholecystitis occurred in 6.9% of patients with SEMS with median of 7 days from stent placement. Gallbladder drainages were required in 92% of patients. The risk factors of cholecystitis were tumor involvement of cystic duct opening, SEMS with high AF (≥ 0.4 N) and short stent length (≤ 60 mm) but the covered SEM was not associated with cholecystitis. Cholecystitis occurred 10.8% in high AF SEMS and 1.9% in low AF SEMS [8]. Recent developed flower-type SEMS which had five-petal-shape design with side groove showed less gallbladder blockage compared to conventional covered SEMS in animal model [24]. However, further clinical study was required to prove the concept of this SEMS.

Pancreatitis

Pancreatitis occurred in 6% of patients with SEMS. Most of patients had mild pancreatitis. This was caused by compression of pancreatic orifice from stent expansion and compression by SEMS's axial force. The risk factors of pancreatitis were non-pancreatic cancer, SEMS with high AF (≥ 0.4 N) and pancreatic duct injection. Pancreatitis occurred 8.3% in high AF SEMS and 2.1% in low AF SEMS [25].

Food impaction

Food impaction can occur after SEMS placement across the ampulla because it bypassed sphincter of Oddi. This allowed food to reflux into bile duct. The risk factors of food impaction were irregular inner surface of SEMS, uncovered/partial-covered SEMS and duodenal obstruction [26]. The irregular inner surface or uncovered SEMS may serve as anchor for the food to attach and accumulate in the SEMS [17]. Duodenal obstruction induced food stasis in duodenum caused food reflux and attach to the SEMS. The anti-reflux system was developed to prevent this condition. Many types of anti-reflux valve showed low rate of food impaction in pilot studies such as dome with cross [27] and s-shaped valve [28]. However, some types of anti-reflux valve unable to prevent food reflux [29,30] and cause stent occlusion by valve malfunction. Hu et al. [31] conducted randomized study to compare partially covered SEMS and SEMS with anti-reflux valve. This study showed lower stent dysfunction rate in SEMS with anti-reflux valve group. However, the main

Fig. 4. Self-expandable metal stent with varying cell width.

Fig. 5. Bile duct kinking/stent impaction (arrow) in patient with pancreatic cancer. CBD, common bile duct.

Table 1. Risk factors of recurrent biliary obstruction and complications caused by the self-expandable metal stent

Recurrent biliary obstruction	Stent factor	Patient factor
Tumor overgrowth	Short stent length	Malignant stricture
Tumor ingrowth	Uncovered/partially covered type	Malignant stricture
Stent migration	Covered type	Benign stricture
	Low radial force	Chemotherapy
	High axial force	
	Lack of anti-migratory system	
Stent impaction/bile duct kinking	High axial force	Acute angle of bile duct
	Short stent length (causing to high axial force)	
Food impaction	Placement across papilla	Delayed duodenal motility
	Uncovered/partially covered type	Duodenal obstruction
	Lack of anti-reflux system	
Complications		
Cholecystitis	High axial force	Tumor involvement to cystic duct opening
		Presence of gallstone
Pancreatitis	High axial force	Non-pancreatic tumor

Adapted from the article of Isayama et al. (Curr Gastroenterol Rep 2016;18:64) [5] with original copyright holder's permission.

cause of stent dysfunction was tumor ingrowth. Lee et al. [32] developed the wind sock anti-reflux valve and conduct randomized controlled trial. This study showed SEMS with wind sock anti-reflux valve had less duodenobiliary reflux and higher stent patency rate in comparison with covered SEMS.

CONCLUSION

Understanding the mechanical properties of SEMS will provide a better outcome in patients with malignant biliary obstruction. In summary (Table 1), the SEMS with high RF prevents stent migration. The stent with low AF prevents complications from SEMS such as acute cholecystitis, pancreatitis and stent impaction/bile duct kinking. The covered SEMS was designed to prevent tumor ingrowth but its weakest point is the stent migration. Thus, the anti-migratory system can prevent stent migration in covered SEMS. This is important knowledge in developing and using the SEMS. However, SEMS and patient factors should be considered together to prevent recurrent biliary obstruction and complications.

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CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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