Introduction

To improve the patency of biliary stents, various efforts have been made, from diversifying stent designs to adding specific functions into the stent. The ideal stent can be defined as a stent with longer patency with less complications. Basically, the stent is a foreign body in a human body; it is eventually obstructed. Developing a lifelong stent is impossible. However, many newly developed biliary stents show much improved patency and safety. In this lecture, I will discuss about the up-to-date efforts for prolonging the biliary SEMS patency.

Design Modifications

The radial and axial forces are important mechanical properties of SEMS that determine a stent function. A stent with moderately strong radial force with low axial force is ideal for biliary SEMS. SEMS with knitted structure tend to show a lower axial force. Debate on the covered and brae SEMS is still continuing. However, according to a recent meta-analysis, covered SEMS group had lower incidence of adverse events. There was no significant difference in dysfunction, but covered SEMS tended to work better, with no differences in stent patency, patient survival, and complications. The advantage of full-covered SEMS is its removability. Because of prolonged survival among the patients with unresectable malignant biliary obstruction, there is a possibility of re-intervention after SEMS insertion. The main drawback of full-covered SEMS is a high rate of stent migration. However, current modifications of stent design markedly reduced this complication. Stent with good confirmability and low axial force can prevent stent migration. Attaching anti-migration flap, pin and barb system also prevent stent migration. Bumpy type stent with alternating radial force segment showed very low stent migration rate.

Sludge formation in the inner lumen of the covered SEMS is an important cause of stent dysfunction. SEMS with a larger diameter (12 mm) is associated with low incidences of sludge formation. Food impaction at the distal end of the exposed metal stent causes early stent dysfunction. To prevent this phenomenon, inner and outer covering membranes are thermal plated bonded by heat and pressure.

When a biliary stent is inserted via the transpapillary route, networks of large dietary fibers are formed due to duodenobiliary reflux; this intraluminal framework plays an important role in the multifactorial process of
stent clogging. Accordingly, many studies have focused on improving stent patency through the use of anti-reflux biliary stent, designed to suppress duodenobiliary reflux. The anti-reflux system has shown conflicting results based on valve shape. Studies have reported varying degrees of efficacy, and its clinical efficacy has not yet been established due to a lack of large-scale prospective studies. Current study showed SEMS with anti-reflux valve of the windsock type is superior in terms of the duration of stent patency compared to conventional SEMS.

**Functioning Stents**

The use of covered SEMS cannot prevent the tumor ingrowth completely. This is because the membrane used in the stent is biodegraded in vivo by hydrolysis, oxidation, and continuous contact with bile flow. Given the limitations associated with the use of covered SEMS in the physical suppression of ingrowth, there have been efforts to coat similar stents with antitumor drugs, which would prevent the tumor invasion into the membrane and exhibit local tumor suppression effect. Antitumor agents used in drug-eluting stents include hydrophilic paclitaxel and hydrophilic gemcitabine. Despite various modifications, there are no available data related to the feasibility and efficacy of the stent that incorporates an antitumor agent; however, efforts to improve and demonstrate the effectiveness of drug-eluting stents are on-going. Although its safety has been indicated by animal and human studies, its efficacy in terms of stent patency, in comparison with conventional stents, has yet to be demonstrated.

Modifications of the stents used in malignant biliary obstruction are designed to increase the stent patency; functioning stents such as drug-eluting stents and stents equipped with anti-reflux valve are examples of such modifications. There are limitations in prolongation of stent patency only by modifying the stents because the stent is basically a foreign body in the human body. Currently introduced stents with different concepts are still at the conceptual or experimental stage. However, DES with the increased stent patency is expected to be available for clinical use soon, through the development of various surfactants and drug enhancers, modification of stent structures, and improvements in stent materials, metal surface treatments, drug coating techniques, and polymer types.

**Conclusions**

The efforts for developing functional stents with improved stent patency, which would lead to an increase in patient survival, should continue. A new therapeutic paradigm of applying a specific stent for a specific purpose will be established in a near future.

**References**

