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## Double bare self-expandable metal stent for distal malignant biliary obstruction



To the Editor:

Park et al<sup>1</sup> reported no significant differences in the 6-month stent patency rates and mortality between partially covered and uncovered double bare self-expandable metal stents (PCDBSs vs UCDBSs) for unresectable distal malignant biliary obstruction. This randomized controlled multicenter trial is of great significance for clinical practice, yet we would like to share our reservations for further research.

First, as shown in the baseline characteristics section, the length of the stricture was longer in PCDBSs than in UCDBSs ( $2.8 \pm 1.3$  vs  $2.4 \pm 1.2$ ,  $P = .010$ ). The length or the degree of stricture might be correlated with disease severity and stent patency,<sup>2</sup> and longer biliary stricture was an independent risk factor for worse survival after metal stent insertion,<sup>3</sup> which is also in accord with the fact that the rate of tumor overgrowth was higher in the PCDBS group than in the UCDBS group (5.5% vs 0.8%). Therefore, we hypothesize that the PCDBS group had selection bias, which would weaken the effect of PCDBSs on stent patency and overall survival, and a propensity-matching analysis may be required.

Second, we would like to know whether there was a significant difference in the total incidence of single adverse events between the 2 groups, regardless of the 2-week time limit, so as to better verify the overall impact of whether or not the novel metal stent is covered on the risk of adverse events.<sup>4</sup>

Third, the authors did not disclose the details of revision for stent dysfunction, which might have had some influence on stent patency and overall survival. For example, radiofrequency ablation can be performed by both endoscopic and percutaneous routes. As a novel adjunctive procedure and a promising therapeutic option in patients with malignant biliary obstruction, radiofrequency ablation can achieve local tumor control, resulting in improved biliary stent patency and a potential survival benefit.<sup>5</sup>

### DISCLOSURE

*Both authors disclosed no financial relationships.*

**Jia-Su Li, MD**  
**Feng Liu, MD**  
*Digestive Endoscopy Center*  
*Shanghai Tenth People's Hospital*

*Tongji University School of Medicine*  
*Shanghai, China*

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### Response:



On behalf of our co-authors, we would like to express our appreciation for the comments made by Li and Liu<sup>1</sup> about our study.<sup>2</sup> Those authors point out that the longer length of the malignant stricture in partial covered double bare metal stent (PCDBS) could lead to a significant difference in the higher incidence of tumor overgrowth in the PCDBS group. As they pointed out, the length of stricture in the PCDBS group was longer than that in the uncovered double bare metal stent (UCDBS) group ( $2.8 \pm 1.3$  vs  $2.4 \pm 1.2$ ;  $p = .010$ ).<sup>2</sup> However, the stent lengths for both groups were not meaningfully different ( $7.0$  [6.0-8.0] vs  $6.0$  [6.0-7.0];  $p = .430$ ).<sup>2</sup> Therefore, the differences in stricture length in both groups could not affect the duration of stent patency. Furthermore, the results of our study are completely in accord with those of previous comparative studies<sup>3-5</sup> between single-layer covered stents and uncovered stents. In general, the rate of ingrowth is less in covered stents because of the membrane-covered mesh of the stent, whereas this benefit may be offset by the increased rate of overgrowth at the edges of the covered stent.<sup>6</sup> Consequently, the difference in stent overgrowth between PCDBS and UCDBS can be attributed to the characteristics of membrane. In addition, selection bias is generally defined as the bias introduced by the selection of individuals, groups, or data for analysis in such a way that proper randomization is not achieved, thereby failing to ensure that the sample obtained is representative of the population intended to be analyzed. Our study is the largest randomized trial to compare covered stents with uncovered stents, and consecutive patients were included by strict criteria. Therefore, there is only a slim chance that selection bias affected of our study. In terms of the total

**TABLE 1. Adverse events (including stent dysfunction) in patients with technical success**

Adverse events	PCDBS, n = 128	UCDBS, n = 127	p value
	No. (%)	No. (%)	
Total	58 (45.3)	63 (49.6)	.575
Early	15 (11.7)	17 (13.4)	.832
Late	51 (40.2)	48 (37.8)	.797

incidence of a single adverse event (AE), which was not addressed in our study, we have data, summarized as [Table 1](#). Total AEs after ERCP were noted in 58 patients (45.3%) in the PCDBS group and 63 patients (49.6%) in the UCDBS group, without significant differences ( $p = .575$ ), and the AEs were minute in clinical situations.

We also agree with the opinion of Li and Liu<sup>1</sup> that an adjunctive procedure such as radiofrequency ablation, photodynamic therapy, or another local antitumor therapy can have some influence on stent patency and overall survival.<sup>7</sup> However, to maintain the consistency of the study, we did not perform additional interventions to prolong stent patency. In detail, our strategy of revision for stent dysfunction included only stent exchange with or without removal of a previously inserted stent by endoscopic or percutaneous approaches, permanent percutaneous catheter placement, or palliative surgical revision. In addition, stent patency in our study was defined as the interval between the time of stent placement and the time of first reintervention caused by to stent dysfunction.<sup>8</sup> Thus, adjunctive local antitumor therapy during a first revisional procedure could not have affected the stent

## DISCLOSURE

*All authors disclosed no financial relationships.*

**Se Woo Park, MD, PhD**  
**Kyong Joo Lee, MD, PhD**  
 Division of Gastroenterology  
 Department of Internal Medicine  
 Hallym University Dongtan Sacred Heart Hospital  
 Hallym University College of Medicine  
 Gyeonggi-do, Korea  
**Moon Jae Chung, MD, PhD**  
**Jung Hyun Jo, MD**  
**Hee Seung Lee, MD**  
**Jeong Youp Park, MD, PhD**  
**Seung Woo Park, MD, PhD**  
**Si Young Song, MD, PhD**  
 Division of Gastroenterology  
 Department of Internal Medicine  
 Severance Hospital  
 Yonsei University College of Medicine  
 Seoul, Korea

**Huapyeong Kang, MD**  
**Eui Joo Kim, MD**  
**Yeon Suk Kim, MD, PhD**  
 Department of Internal Medicine  
 Gachon University College of Medicine  
 Gil Medical Center  
 Incheon, Korea  
**Jae Hee Cho, MD, PhD**  
 Department of Internal Medicine  
 Gangnam Severance Hospital  
 Yonsei University College of Medicine  
 Seoul, Korea  
**Seungmin Bang, MD, PhD**  
 Division of Gastroenterology  
 Department of Internal Medicine  
 Severance Hospital  
 Yonsei University College of Medicine  
 Seoul, Korea

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## The clinical value of narrow-band imaging in biliary strictures



To the Editor:

Shin et al<sup>1</sup> reported the excellent performance of narrow-band imaging (NBI) during peroral cholangioscopy in differentiating biliary strictures, demonstrating 87.5% sensitivity, 91.4% specificity, and 91.3% accuracy, adjusted