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

To the Editor:

Park et al[1] 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 ± 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,[2] and longer biliary stricture was an independent risk factor for worse survival after metal stent insertion,[3] 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.[4]

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.[5]

DISCLOSURE

Both authors disclosed no financial relationships.

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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[1] about our study.[2] 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 ± 1.3 vs 2.4 ± 1.2; $p = .010$).[2] However, the stent lengths for both groups were not meaningfully different (7.0 [6.0-8.0] vs 6.0 [6.0-7.0]; $p = .430$).[2] 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[3-5] 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.[6] 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