YONSEI University college of medicine
Department of biomedical systems informatics

Metal versus Plastic Biliary Stents in Pancreatic Cancer Patients

: Safety and Effectiveness Comparison Using OMOP CDM

Yiju Park[1,2], Changhoon Han[1,2], Seng Chan You[1,2]

[1]Department of Biomedical Systems Informatics, Yonsei University, Seoul, Korea [2]Yonsei Institute for Digital Health, Yonsei University, Seoul, Korea

I. BACKGROUNDS

Post-marketing medical device vigilance remains a significant challenge in clinical practice, as it presents unique challenges compared to drugs due to the greater diversity and complexity[1]. Research utilizing real-world data for device vigilance is still limited, as existing infrastructure may not be well equipped to monitor safety issues that may otherwise go unreported. This study aimed to validate whether the DEVICE_EXPOSURE table in OMOP CDM can be effectively used for medical device vigilance analysis through a comparative study.

According to ESGE guidelines[2], ESGE recommends the endoscopic placement of a 10-mm diameter metal stent for preoperative biliary drainage of malignant biliary obstruction (strong recommendation). However, recent advances in neoadjuvant therapy have improved survival outcomes in pancreatic cancer patients, creating frequent needs for stent replacement during treatment[3]. While metal stents provide longer patency, their replacement is technically difficult once occluded. Plastic stents offer easier replacement and removal, leading to emerging preference even in patients with expected long-term survival, despite being traditionally recommended only for those with short life expectancy.

Given this shift in clinical practice patterns, we sought to validate whether this trend toward plastic stents is safe for pancreatic cancer patients. This study utilized real-world data to compare survival outcomes between metal and plastic biliary stents, validating whether current clinical trends have a positive or neutral impact on patient prognosis.

	Pharmacovigilance	Medical Device Vigilance
Target	Pharmaceuticals (drugs, vaccines, etc.)	Medical devices (diagnostics, therapeutics, implants, etc.)
Cause of Adverse Event	Single cause (chemical/biological action of the drug itself)	Multifactorial causes (device malfunction, user errors, environmental factors, etc.)
Korean Case	MOA-CDM (Medical record Observation and Assessment for drug safety) established and in use	MDV-CDM (Medical Device Vigilance) under development

Metal Biliary Stent (MS)	Plastic Biliary Stent (PS)
	
• Higher cost • Difficult to replace • Long patency (5-6 months)	• Lower cost • Easy to replace • Short patency (2-3 months)

II. METHODS

This retrospective cohort study utilized clinical data from Yonsei University Severance Hospital, transformed into OMOP CDM version 5.4 format. The study period spanned from January 1, 2006 to December 31, 2024.

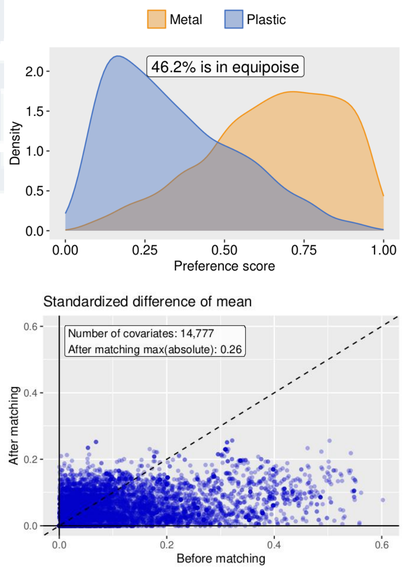
We employed a new-user cohort design targeting adult patients with pancreatic cancer who underwent their first biliary stent insertion. The index date was defined as the date of first biliary stent placement, either metal or plastic. Patients with prior biliary stent placement or incomplete follow-up data were excluded from the analysis. Additionally, pancreatic cancer patients with a previous history of cholangiocarcinoma were excluded due to the high heterogeneity in patient characteristics between cholangiocarcinoma and pancreatic cancer cohorts. Specifically, hilar cholangiocarcinoma often requires multiple stent insertions at the bifurcation of the left and right hepatic ducts, making these cases unsuitable for comparative analysis. The primary outcomes were all-cause mortality at 365 days after stent implantation.

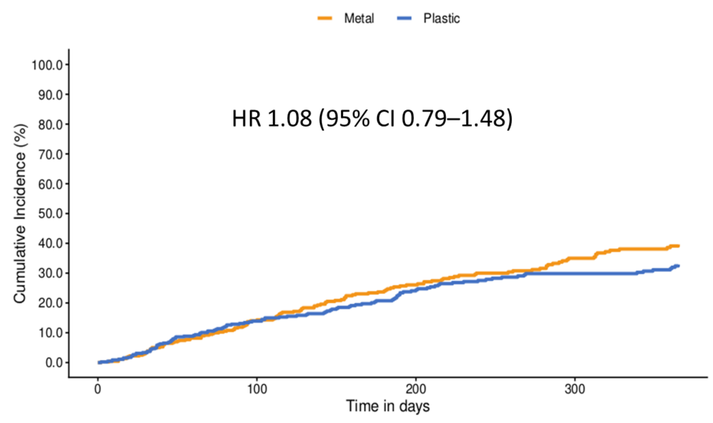
Statistical analysis was performed using Cox proportional hazards models to estimate hazard ratios after 1:1 propensity score matching. Clinical equipoise was assessed by calculating the proportion of overlap in the preference-score distributions between the metal stent and plastic stent groups. Outcome was evaluated at 365 days following stent implantation.

III. RESULTS

After propensity score matching, 466 patients were included in the final analysis. Clinical equipoise was achieved with 46.2% overlap between the treatment groups, indicating reasonable balance in treatment preferences.

The analysis of all-cause mortality revealed no significant difference between metal and plastic stent groups at either time point. At 365 days post-implantation, the hazard ratio was 1.08 (95% CI 0.79–1.48, p=0.63). This finding suggests that survival outcomes are comparable between the two stent types in pancreatic cancer patients.





IV. CONCLUSION

Our study demonstrated no significant difference in all-cause mortality between metal and plastic biliary stents in pancreatic cancer patients at 365-day follow-up periods. This finding supports the current clinical trend toward plastic stents in selected patients. The easier replacement of plastic stents does not compromise patient survival, indicating they may be a practical choice in modern pancreatic cancer care.

Beyond clinical implications, this study successfully demonstrated the feasibility of comparative medical device research using the OMOP CDM DEVICE_EXPOSURE table for vigilance analysis. As a single-center study, limitations include potential unmeasured confounders and selection bias. To address these limitations, we have established MDV-CDM infrastructure across ten tertiary hospitals in South Korea, with multi-center validation currently underway. We plan to pursue international collaborations to further validate our findings across diverse populations and healthcare systems, contributing to a robust framework for post-marketing medical device surveillance using standardized real-world data.

[1] Choi, Sooin, et al. "Preliminary feasibility assessment of CDM-based active surveillance using current status of medical device data in medical records and OMOP-CDM." Scientific Reports 11.1 (2021): 24070. [2] Dumonceau, Jean-Marc, et al. "Endoscopic biliary stenting: indications, choice of stents, and results: European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline–Updated October 2017." Endoscopy 50.09 (2018): 910-930. [3] Springfeld, Christoph, et al. "Neoadjuvant therapy for pancreatic cancer." Nature Reviews Clinical Oncology 20.5 (2023): 318-337.