Metal versus Plastic Biliary Stents in Pancreatic Cancer Patients

: Safety and Effectiveness Comparison Using OMOP CDM

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Post-Marketing Vigilance

Gap between Drug vs Medical Device

	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

Research objective

- **Can we utilize the Device_exposure table in CDM for Medical Device Vigilance analysis?**

- To validate this approach, we conducted a comparative study:

  Case Study: Metal vs Plastic Biliary Stents in Pancreatic Cancer Patients

  - Leveraging OMOP CDM infrastructure
  - Utilize Device_exposure table for real-world medical device safety analysis
  - Addressing clinically relevant questions with device-related outcomes

Metal vs Plasic: Clinical Challenge

- According to ESGE guidelines, endoscopic biliary drainage is the preferred first-line treatment for malignant biliary obstruction

- The optimal choice between plastic stents (PS) and metal stents (MS) remains controversial in clinical practice
    1. **Limited real-world evidence:** Lack of large-scale, multi-institutional data reflecting actual patterns
    2. **Heterogeneous study population:** Previous studies included mixed cancer types (pancreatic cancer, cholangiocarcinoma, etc.), reducing the accuracy of the analysis

Metal vs Plasic: Clinical Challenge

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)

- Changing Practice Patterns
  - Traditional: Metal stents preferred (longer patency, short survival expected)
  - Current: Shift toward plastic stents (easier replacement, improved survival)
  - **Gap: Is this trend safe for pancreatic cancer patients?**

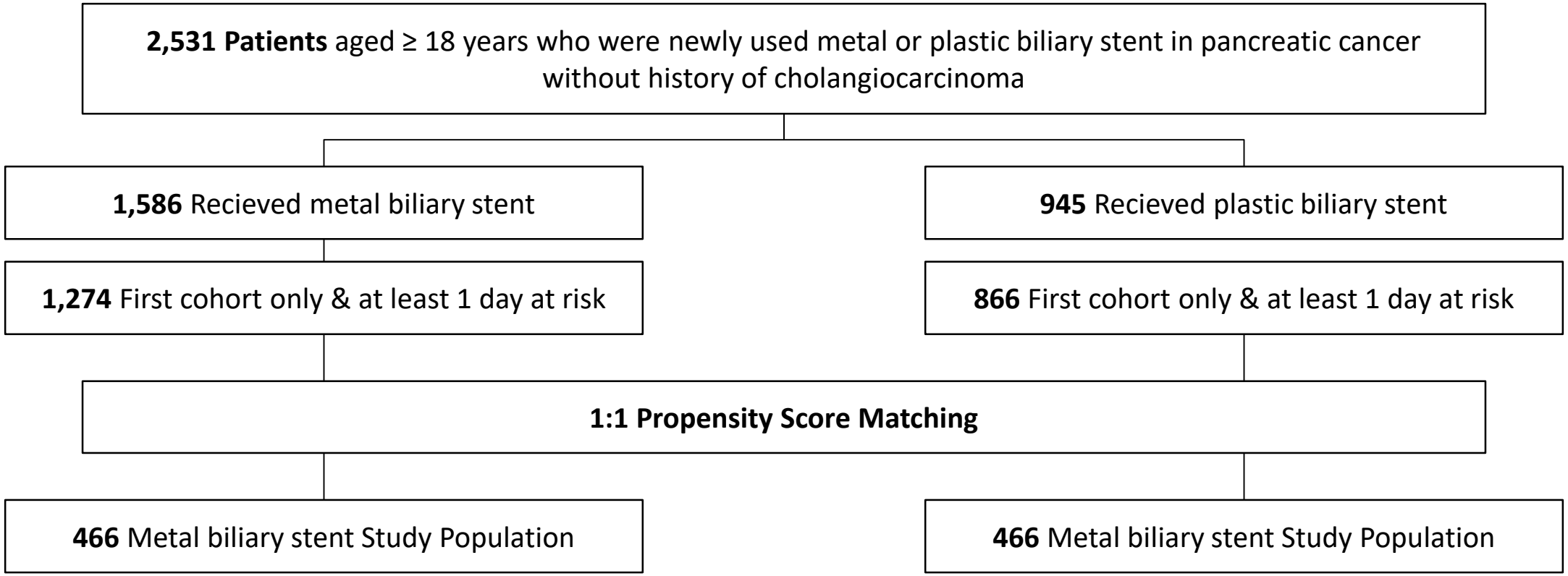
Objectives & Methodology

- **Data Source:** Severance Hospital, South Korea
- **Date:** 2006.01.01 – 2024.12.31
- **CDM Version:** v5.4

- **Study Cohorts: Metal Biliary Stent (Target) vs. Plastic Biliary Stent (Comparator)**
  - **Inclusion Criteria:**
    - Age ≥ 18 years
    - Pancreatic cancer diagnosis after stent insertion
  - **Exclusion Criteria:**
    - Cholangiocarcinoma diagnosis before stent insertion
- **Outcome:** All-cause mortality within 365 days

Result

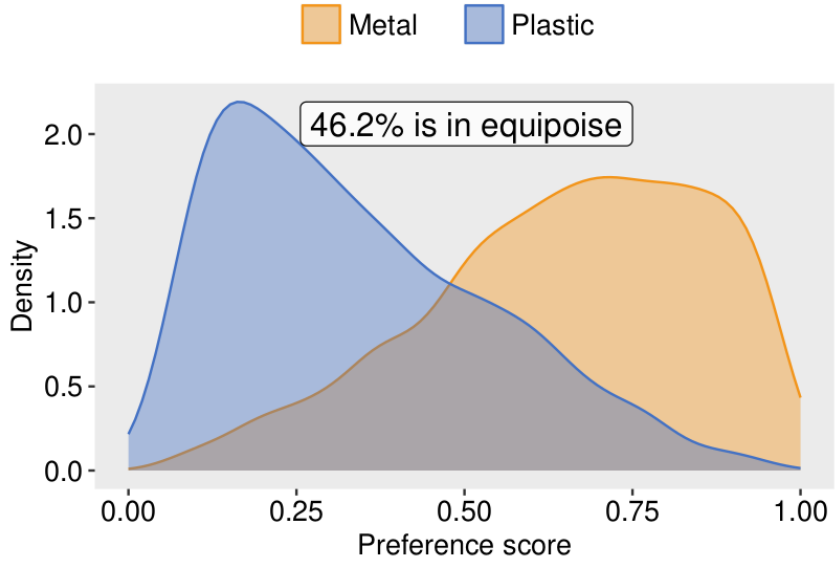
- Single-center case study (PLE) at Severance Hospital
  - 1:1 Propensity Score Matching to control confounding factors
  - After PSM, 466 patients in each group

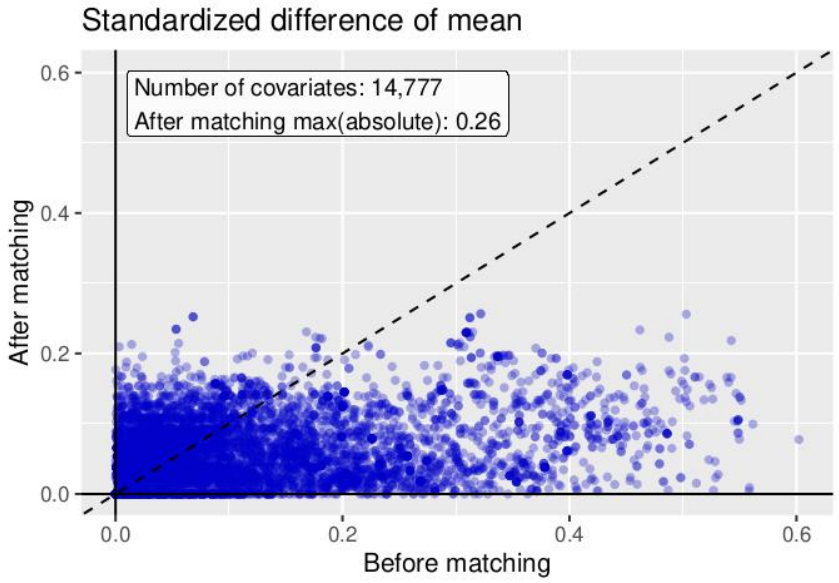


Result

Baseline Characteristics

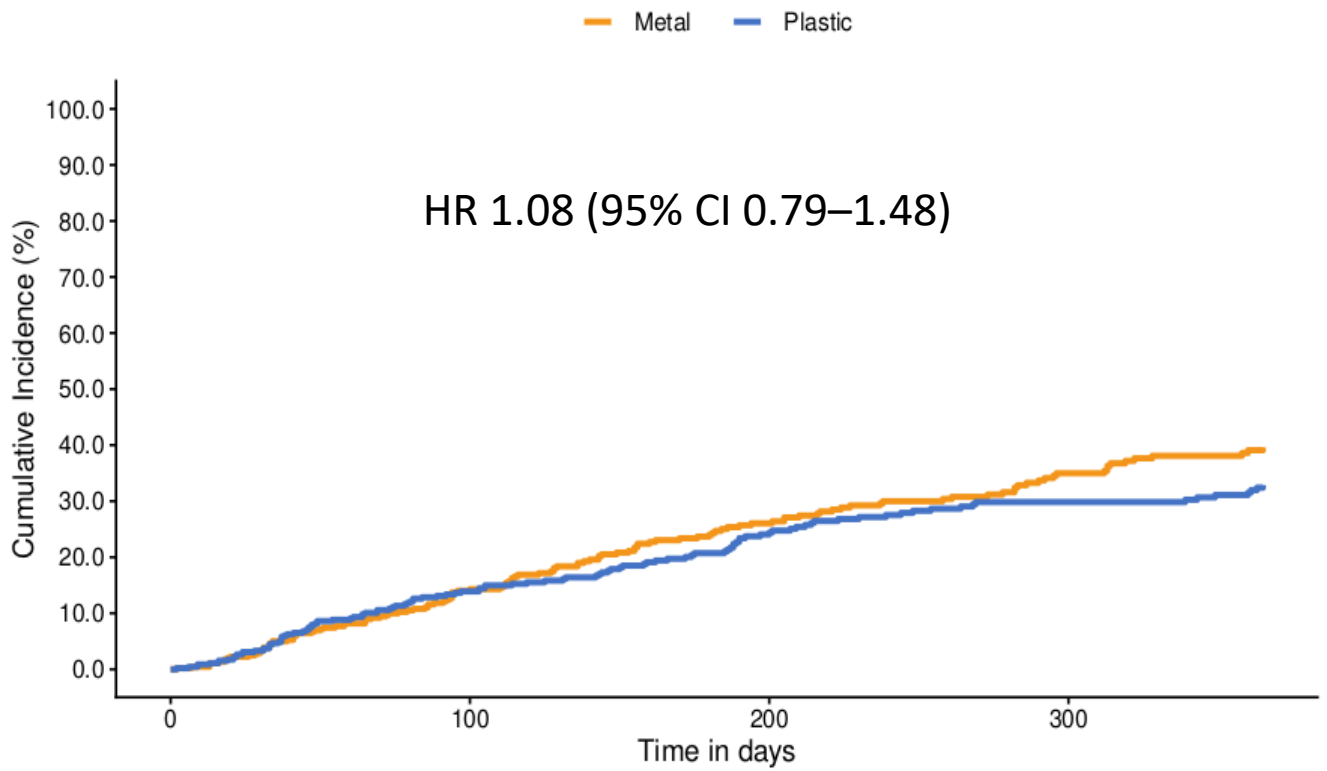
	Before PS			After PS		
	Metal (%)	Plastic (%)	std.diff	Metal (%)	Plastic (%)	std.diff
Age group						
45–49	4.3	5.0	0.05	5.6	3.4	0.10
50–54	8.6	9.0	-0.03	9.0	11.4	-0.08
55–59	10.8	10.0	-0.01	11.2	10.1	0.04
60–64	16.4	17.4	0.03	17.6	18.7	-0.03
65–69	17.5	16.1	-0.03	17.6	16.5	0.03
70–74	16..2	16.1	0.04	15.5	13.1	0.07
75–79	11.9	12.1	0.00	12.0	12.2	-0.01
80–84	7.0	8.7	-0.01	5.6	9.7	-0.15
85–89	3.2	2.2	-0.06	3.2	1.9	0.08
Female	49.0	43.8	0.10	45.7	43.8	0.04
DM	30.6	23.6	0.16	24.2	26.8	-0.06
GERD	19.0	11.1	0.22	13.9	15.5	-0.04
UTI	2.2	0.7	0.13	1.3	1.1	0.02





Result

There was no significant difference in mortality between the two groups



Number at risk				
Metal	466	306	214	151
Plastic	466	322	224	173

Discussion

- No significant difference in all-cause mortality between metal and plastic biliary stents in pancreatic cancer patients
  - Supports current trend toward plastic stents
  - Easier replacement may not compromise survival

→ **Plastic stents might be a practical choice in modern pancreatic cancer care**

- Successfully demonstrated that a comparative study of medical devices is feasible
- Study Limitations
  - Single-center study
  - Unmeasured confounders and selection bias may exist

Current Progress & Network

Establish Korean Network: 10 major tertiary hospitals enrolled in MDV-CDM network

Ajou University Hospital	Gachon University Hospital	Hanyang University Hospital, Guri	Hanyang University Hospital,	Korea University Hospital, Guri
Korea University Hospital, Anam	Seoul National University Hospital	Severance Hospital, Shinchon	Severance Hospital, Gangnam	Severance Hospital, Yongin

Currently conducting multi-center validation using the MDV-CDM network

Next step Expanding to international collaboration