Leveraging UDI for Advanced Medical Device Safety Study

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Background

The Unique Device Identifier (UDI) is a system used to mark and identify medical devices within the healthcare supply chain. This system is designed to enhance the traceability of medical devices and improve patient safety. Internationally, regulatory bodies such as the FDA (United States), the European Commission (Europe), and other global health authorities have adopted UDI regulations, emphasizing its importance in the medical device industry[1].

Utilizing UDI allows for the identification of medical devices at the model level. This granularity can enhance the tracking and monitoring of device usage, improving the ability to manage recalls, adverse events, and overall device performance management. The Observational Medical Outcomes Partnership Common Data Model (OMOP-CDM) includes a Device_exposure table that can be populated with UDI information. Efforts were made to enhance the functionality of the data model by integrating OMOP-CDM with UDI to provide detailed insights into device usage and associated outcomes[2].

The primary goals of this study are twofold. First, to link UDI with clinical data from hospitals and load this information into the OMOP-CDM. Second, to test feasibility of using UDI for medical device safety study. By achieving these objectives, the study aims to demonstrate the value of incorporating UDI into clinical data models to enhance device surveillance and patient safety.

Methods

Clinical data from Severance Hospital was reviewed to identify information on medical devices prescribed to patients from January 2006 to December 2023. Medical devices with identifiable UDI information were identified. UDI-DI and UDI-PI information was loaded into the Device_exposure table of the OMOP Common Data Model (OMOP-CDM). The Unique_device_id column was populated with UDI-DI codes, and the Production_id column was populated with UDI-PI codes. The UDI-PI code was created by combining the medical device's lot number, product serial number, and expiration date information. The Device_concept_id column was populated with OMOP Concept_id mapped based on SNOMED-CT.

Using the ATLAS tool, a cohort of patients who used Vascular Closure Devices was constructed. The number of patients who experienced vascular complications within 60 days was identified, with diagnoses including Hematoma, Arteriovenous fistula, and Pseudoaneurysm. Comparison groups were established, including those that could be compared without the use of UDI (eg. brand name) and those that required UDI for comparison (eg. Specification such as size).

The incidence rate (IR) and 95% confidence interval (CI) were calculated for each group. The relative risk between groups was determined, and Fisher's exact test was performed to calculate the p-value. This allowed for the evaluation of the statistical significance between the groups.

Table 1. Degree of Medical Device Information Coverage by Code

Device	Brand	EDI	Model	UDI-DI	French Size
Vascular Closure Device	ANGIO-SEAL™ VIP	J4770066	610132	00389701011806	6F
			610133	00389701011790	8F
	MYNX CONTROL	J4770213	MX5060E	10862028000441	5F
			MX6760E	10862028000458	6F/7F

Results

Among all device domain EDI codes managed by the Health Insurance Review and Assessment Service (HIRA) in Korea, 80.02% were mapped to the OMOP standard vocabulary. Among the hospital's medical device management codes, 19,503 (27.9%) were linked with UDI.

We identified 1,336 patients using the Angio-Seal™(St. Jude Medical, Austin, TX) product and 1,479 patients using the Mynx™(AccessClosure, Mountain View, CA) product among the vascular closure devices. Among the Angio-Seal products, 1,232 patients used the 6F size, and 113 patients used the 8F size. Among the Mynx products, 935 patients used the 5F size, and 588 patients used the 6-7F size.

The incidence rates of vascular complications were as follows: Angio (IR: 0.0067, 95% CI: 0.0023-0.0111), Mynx (IR: 0.0088, 95% CI: 0.0040-0.0020), Angio_6F (IR: 0.0065, 95% CI: 0.0020-0.0110), Angio_8F (IR: 0.0088, 95% CI: 0.0026-0.0145), Mynx_5F (IR: 0.0086, 95% CI: 0.0026-0.0145), and Mynx_6/7F (IR: 0.0085, 95% CI: 0.0010-0.0160).

The relative risks (RR) were as follows: Angio vs. Mynx (RR= 1.3050, p=0.6694), Angio_6F vs. Angio_8F (RR= 1.3630, p=0.5472), Mynx_5F vs. Mynx_6/7F (RR=0.9940, p=1.0000).

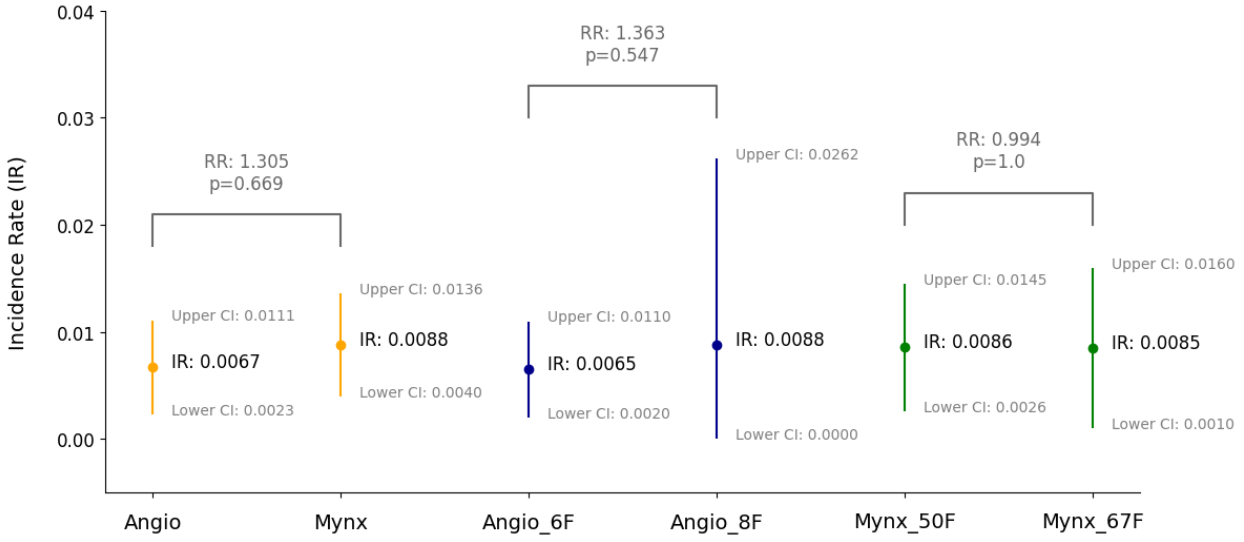

Figure 1. Incidence of vascular complications within 60 days following the use of a VCDs.

Conclusion

Incorporating the Unique Device Identifier (UDI) into the DEVICE_EXPOSURE table of the OMOP Common Data Model (OMOP-CDM) has demonstrated potential in enhancing medical device data analysis. Comparisons between VCD brands can be conducted using claim codes (EDI) without UDI information. However, comparisons based on specific specifications are feasible only when UDI information is mapped.

The Angio-Seal, a vascular closure device initially used, employs a collagen plug for hemostasis and an anchor that covers the incision site from within the vessel, making it an 'active' device. On the other hand, the later-developed Mynx uses a polyethylene glycol (PEG) sealant to cover the incision site from outside the vessel, categorizing it as a 'passive' device[3].

Consistent with findings from a reference study comparing adverse event rates between these two brands, our study also observed no statistically significant difference in the incidence of vascular complications between Angio-Seal and Mynx[4]. The French size of vascular closure devices (VCDs) is determined by the size of the vascular sheath used during coronary angiography, with larger sheath sizes reportedly increasing the risk of complications[5]. However, our study did not find any significant difference in vascular complication incidence rates based on French size.

This study has the limitation of being conducted at a single center. Future plans include conducting multicenter studies and adjusting for patient characteristics between groups to enhance the analytical power. In conclusion, the integration of UDI into clinical data models represents a significant advancement in medical device management. This study underscores the importance of adopting UDI systems to enhance data quality, facilitate detailed device tracking, and support robust clinical and epidemiological research. The findings advocate for the broader implementation of UDI integration, demonstrating its potential to improve healthcare outcomes.

References

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