



PATIENT SAFETY EVENTS RELATED TO THE PLACEMENT OF DRUG-ELUTING STENTS

By Patient Safety Authority

Drug-eluting stents (DES) offer patients less invasive options to reopen and maintain blocked coronary arteries. Advances in the design and manufacture of DES have made them smaller, allowing them to be placed in more severely blocked arteries. This also allows more complex patients to undergo less invasive stenting procedures.

A recent review of high harm event reports submitted to the Pennsylvania Patient Safety Reporting System (PA-PSRS) included a patient safety event involving the failure of a DES during a percutaneous coronary intervention that resulted in a patient's death. In this event, the balloon shaft broke, and the balloon was left in the coronary artery. Attempts to retrieve and remove the balloon failed, and the patient suffered cardiac arrest and passed away.

This event report prompted further investigation into the complications associated with the placement of DES. Balloon tears or ruptures,^{1,2} stent separation from the balloon,³ and guidewire fractures⁴ are serious complications that can arise when placing DES and can result in patient harm. We searched PA-PSRS for other similar event reports and found an increase in the number of these types of events from 2021 to 2022. Representatives from the Patient Safety Authority (PSA) also spoke with clinicians familiar with the placement of DES. From these conversations, it was determined that these types of events were likely due to a failure of the device. Furthermore, these events may be underreported in PA-PSRS, as there is some expectation of complications from a clinician's perspective, especially given the complexity of some of the patients who require this type of procedure.

It is important for clinicians to remember that any occurrence that meets the definition of an incident or serious event⁵ must be reported to PA-PSRS, including events that are not anticipated by the *patient*. Accurate reporting is crucial for keeping track of any new or upgraded devices and understanding any potential complications to ensure patient safety. When these events are

reported to PA-PSRS, the PSA can analyze their impact on patient safety and identify any trends or mitigating factors to improve patient safety. The PSA can then share this information with facilities and practitioners across the state and beyond, ultimately preventing harm by providing awareness and tools to enhance patient safety.

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About the Author

Patient Safety Authority (patientsafety.pa.gov) is an independent state agency that oversees the Pennsylvania Patient Safety Reporting System (PA-PSRS), the largest database of its kind in the United States.

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