



## Editorial

## Off-label Use of Devices and Drugs in Interventional Radiology

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Off-label use pertains to using devices or drugs in ways that deviate from the approved applications specified by regulatory agencies.<sup>1</sup> As innovation often outpaces the development of formal protocols and guidelines, using off-label devices and techniques in interventional radiology (IR) is a common practice worldwide.

Developing new devices and using existing devices for unique and valuable indications have played a vital role in saving lives and advancing IR. This practice has led to broader treatment options, improved patient outcomes, and created potential cost-savings. These innovative applications enable IR practitioners to address complex cases that may not have approved treatments available. Due to their success and safety, many of these techniques have seamlessly become integral to everyday IR practice.

While the off-label use of drugs and techniques in IR presents numerous opportunities for better outcomes, it is essential to acknowledge the ethical and safety implications.

In routine IR practice, off-label techniques, devices, and drugs may be used in as high as 84% procedures.<sup>2</sup> Common off-label drugs in IR include intra-arterial heparin, which is approved only for intravenous and subcutaneous routes, to reduce perioperative thrombosis. Nimodipine, approved for intravenous use to relieve vasospasm, is routinely administered intra-arterially in neurointervention. Glycoprotein IIb/IIIa antiplatelet drugs approved for coronary interventions are used for acute ischemic stroke interventions. Histoacryl (B. Braun, Melsungen, Germany), approved for wound closure, is routinely used as an embolic material rather successfully in IR practice.

Often, devices are used outside of what the manufacturer recommends in the IFU (instructions for use). Reusing catheters and balloons labeled for single use after appropriate sterilization to reduce costs is a worldwide interventional

practice.<sup>3,4</sup> Sharp recanalization techniques exemplify another facet of off-label practice; techniques such as the use of the reverse end of a guidewire, TIPS (transjugular intrahepatic portosystemic shunt) needle for crossing stubborn occlusions are off-label but are time-tested and well-adapted techniques.<sup>5</sup> The recanalization of hepatic veins in cases of Budd-Chiari syndrome employs a transjugular liver biopsy (TJLB) cannula—a device intended for an entirely different purpose.<sup>6</sup> This imaginative use, clearly venturing beyond the IFU of the device, reflects the ingenuity of practitioners in crafting solutions to unique problems.

The Swan-Ganz catheters for pulmonary artery pressure monitoring are used for balloon occlusion tests of the internal carotid artery and hepatic venous wedge pressure measurements.<sup>7,8</sup> Frequently, coronary balloons and stents find application in the field of neurointervention.<sup>9</sup> This creative reassignment of devices is propelled by their accessibility and cost-effectiveness.

Resorting to the use of off-label techniques and drugs in IR is often done to tackle problems or circumstances that may not have a solution established in standardized protocols and guidelines. The use of these techniques is driven by a combination of necessity and innovation. Emergencies often demand swift decision-making. The interventionist may opt for off-label methods based on strong medical and technical knowledge, believing these approaches can prevent adverse outcomes. The unavailability and unaffordable costs of an approved drug or device for a particular procedure may also drive off-label use. By repurposing existing drugs or techniques, interventionists can provide optimal care without imposing an undue financial burden on patients or health care systems.

Unlike approved uses, off-label applications lack the rigorous testing and scrutiny that regulatory agencies

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demand for conventional approvals. This could expose patients to unexpected risks and unintended consequences. The manufacturer can't be responsible for malfunctions outside the IFU. Reusing single-use devices after sterilization risks compromising their structural integrity and facilitating the transmission of blood-borne pathogens. Additionally, the lack of standardized guidelines for off-label use might lead to inconsistent practices among interventionists. A technique that may be safe in one hand may not be in another. There is the possibility of underreporting complications associated with using off-label techniques, potentially resulting in erroneous assumptions regarding the safety of their application.

The Food and Drug Administration (FDA) guidance states that when a physician employs an off-label drug or medical device, it is imperative to ground their decision in robust medical evidence.<sup>1</sup> The stance of the Society of Interventional Radiology (SIR) aligns with this principle, endorsing the ethical use of an FDA-approved medical device or drug for an unapproved application. This ethical application should be backed by credible scientific evidence and expert medical opinion.

Off-label use in IR is a balancing act between improved outcomes using innovative techniques and patient safety. For devices eligible for reuse, a meticulous protocol for disinfection and sterilization must be rigorously followed, coupled with a thorough assessment of their structural integrity and function. Practitioners must exercise caution when using techniques or devices in ways that are yet to be fully validated. Patient safety and informed consent should remain paramount, with clinicians thoroughly discussing potential risks and benefits.

Dissemination of information related to off-label use is crucial. This can be achieved by publishing original observations and results in peer-reviewed journals. Sharing experiences, complications, and best practices at conferences helps practitioners learn from each other's successes and mistakes. Encouraging collaboration between centers and creating consensus committees can help standardize off-label use. Individual departments can state their policy to relevant accreditation agencies. Professional societies should take leadership in formulating clear consensus guidelines for

off-label use. This may expedite the time-consuming and arduous process of seeking regulatory approval for additional indications for an already approved device or medication.

By balancing patient safety and innovation, the IR community can harness the power of off-label use to push the boundaries of medical practice, ultimately improving patients' lives worldwide.

#### Conflict of Interest

None declared.

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