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# Initial Experience: New Closure Device for Patients Receiving Heparin

Localized protamine in tissue tract reduces dwell times, allowing for earlier post-intervention discharge of patients from the recovery area.

BY CARLOS D. MEGO, MD, FACC

**S**aving time, improving efficiency, and increasing patient safety and comfort are always welcome developments in our practice. Recently, I have found that I can safely shorten a patient's bed-bound time when I use the Cardiva Catalyst™ III (Cardiva Medical, Mountain View, CA) closure device in my heparinized interventional patients.

## CHALLENGES WITH PATIENT POPULATION AND CLOSURE

My practice is located in McAllen, Texas, in the Rio Grand Valley, about 5 miles north of the United States/Mexico border. Our patient population is primarily Mexican-American and is heavily influenced by cultural habits that may promote obesity. This high rate of obesity has led to significant rates of both cardiovascular and peripheral vascular disease in my patients. My current practice contains a 50/50 mix of coronary and peripheral intervention. I am a true believer in manual compression or manual compression with assist devices for closure of the arteriotomy site. In my opinion, definitive closure devices have too high a risk for potential serious complications, so I do not use them in patients on heparin. One of the biggest challenges with our patient population is having them maintain a recumbent position after intervention. The prevalence of chronic back pain that accompanies obesity in our patients prevents them from lying flat for the traditional 3 to 5 hours after catheterization. Although we have used the Cardiva Catalyst II for closure in our diagnostic cases, we wanted something designed specifically for our patients who receive heparin.

"The Cardiva Catalyst III allows me to keep my patients systemically on heparin, providing important intravascular protection, while it neutralizes heparin locally at the puncture site, thereby accelerating time to hemostasis."

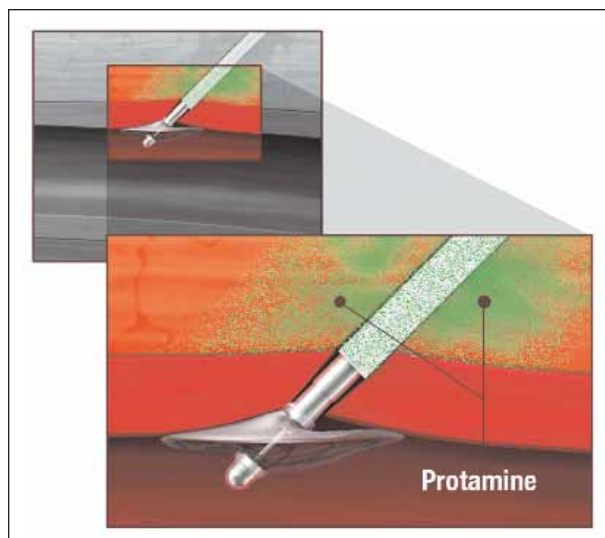


Figure 1. Cardiva Catalyst III: Protamine coating is designed to neutralize heparin in the tissue tract.

### CARDIVA CATALYST III: GETTING PATIENTS MOBILE FASTER

The Cardiva Catalyst III is coated with protamine sulfate that acts to locally neutralize heparin in the tissue tract during interventions (Figure 1). We have found that it allows us to reduce dwell time after intervention to < 1 hour, so our patients are free to be mobile much sooner. This greater than two-thirds reduction in time has also been extremely helpful in managing our patient flow. When I do my rounds in the afternoon between 4 and 5 PM, all of the patients have had their sheaths removed and have received 5 minutes of manual compression, which is our protocol. This allows me to examine each patient's groin to be sure that he or she has started the recovery and healing process without complication before I leave the hospital; it gives me a greater sense of control over each patient's condition.

### ANTICOAGULANT CHOICE

I work in three hospitals, and there is increasing concern about the cost of certain anticoagulants, specifically bivalirudin. There is clear evidence that in certain high-risk coronary populations that bivalirudin is the drug of choice for anticoagulation. Such evidence is not yet available in the treatment of peripheral vascular disease, and I use heparin in all of these patients. I was trained using heparin; it has been around for decades, and I feel very comfortable with it. I also use heparin in approximately 50% of my

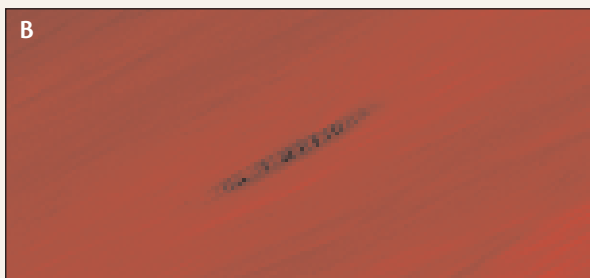
coronary patients. The availability of the Cardiva Catalyst III provides me with the confidence to utilize assisted manual compression in patients being treated with heparin. It brings greater efficiency to the lab, the recovery area, and my practice, and I feel more secure about my patients moving after their procedure. Patients with peripheral vascular disease are at an increased risk of vascular access complications as compared to other groups; the vessels are less elastic, and we are typically inserting larger-diameter and longer

### HOW THE CARDIVA CATALYST WORKS



#### Natural Elastic Recoil

The smooth muscle of the artery relaxes to a pre-dilated state the size of an 18-gauge needle stick (A).



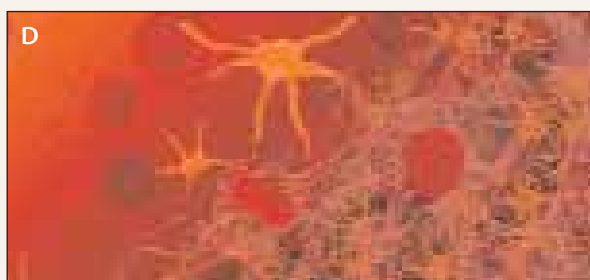
#### Tissue Apposition

Optimized tissue apposition facilitates vessel healing (B).



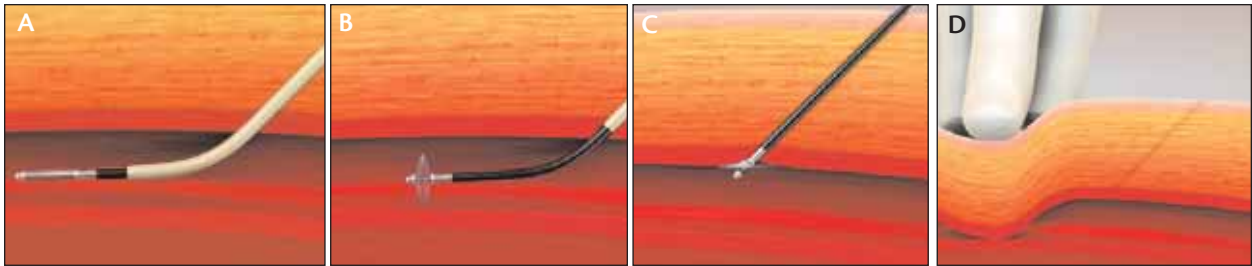
#### Localized Protamine

The application of localized protamine is designed to neutralize the effects of heparin at the puncture site in the tissue tract (C).



#### Coagulation

The proprietary Cardiva Catalyst hemostatic coating stimulates both the intrinsic and extrinsic pathways of the coagulation cascade forming fibrin, the backbone of the clot (D).



**Figure 3. Usage: Four simple steps. Step 1:** The Cardiva Catalyst is inserted through the existing sheath (A). **Step 2:** The Cardiva Catalyst is deployed, and the sheath is removed (B). **Step 3:** The disc temporarily seals the arteriotomy, reducing the size to an 18-gauge needle stick (C). **Step 4:** After the appropriate dwell time, the Cardiva Catalyst is removed, and a small amount of manual compression is conducted until hemostasis is achieved (D).

introducer sheaths. For all of these reasons, management of the access site is even more important in these patients. The Cardiva Catalyst III allows me to keep my patients systemically on heparin, providing important intravascular protection, while it neutralizes heparin locally at the puncture site, thereby accelerating time to hemostasis. Another very critical advantage of the Cardiva Catalyst line of products is their very small intravascular profile. Unlike a dwelling sheath, the Cardiva Catalyst allows excellent distal blood flow to a limb, which is either known to be (ipsilateral peripheral cases) or might be (coronary and contralateral peripheral cases) compromised already.

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#### HOW IT WORKS

The Cardiva Catalyst has a unique design that works with the vessel's natural elastic recoil, as well as the coagulation cascade (Figure 2). I can quickly and reliably deploy the device with minimal trauma to the vasculature (Figure 3). Minimizing such trauma is extremely important for the healing process. By removing the large-diameter introducer sheath and leaving behind the

18-gauge-diameter Cardiva Catalyst wire, I take advantage of the natural tendency for tissue apposition provided by the elastic and muscle fibers within the arterial wall. The protamine sulfate coating provides potent, local heparin reversal, thus facilitating localized progression down the coagulation cascade. Once the Cardiva Catalyst is removed, there is no foreign body left behind to either cause complications or interfere with the physiological healing process.

#### CONCLUSION

The Cardiva Catalyst II, which I use for diagnostic work, and the Cardiva Catalyst III, which I use for interventional work on patients receiving heparin, provide my patients and me with what I believe are the best possible closure alternatives currently available. I have long been impressed with Cardiva Catalyst II for its minimal vascular trauma, reliance on natural arteriotomy recoil, and facilitation of distal arterial flow. With the Cardiva Catalyst III, I now have the confidence to take advantage of those features in my patients on heparin because of the powerful reversing capabilities of protamine exposure in the tissue tract. This confidence has allowed me to begin to mobilize my patients more readily and to transfer them more quickly out of the much more costly recovery area to a regular hospital bed. I can also leave the hospital at the end of my lab day knowing that all of my patients have been discharged from recovery with final hemostasis and are resting comfortably. ■

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