

CLINICAL INSIGHTS

PATENTED TECHNOLOGY TO SEAL ACCESS SITES

Powder Technology Reduces Hold Times, Time to Ambulation and Increases Patient Comfort for Diagnostic Cardiac Procedures

BACKGROUND

Atlantic CardioNet is a freestanding outpatient cardiac cath lab located in Melbourne, FL. Atlantic CardioNet opened in December 1997. The four physicians that currently utilize the facility - Gopal Gadodia, MD, Shashin Desai, MD, Tim Ahmed, MD and Peter Dovgan, MD – focus on cardiac and other diagnostic procedures. The lab consists of one procedure suite and 6 recovery rooms. CardioNet employs a 7-member staff and averages approximately 50 cases per month or 600 per year.



The CardioNet Staff

INTRODUCTION

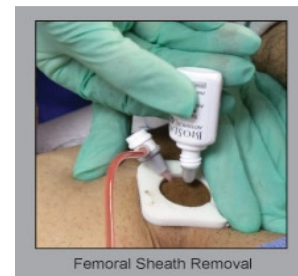
In an effort to reduce hold times and time to ambulation, CardioNet evaluated StatSeal ADVANCED Powder for hemostasis following sheath removal from diagnostic procedures. Prior to the trial, the staff employed manual compression to achieve hemostasis. In rare cases V+ Pad, FemoStop or a C-clamp compression device was used for compromised patients. The average hold time was approximately 20 minutes and ambulation protocol was 3.5 hours following the procedure.

Cath Lab Manager Jim Freymiller learned from staff at a nearby hospital that StatSeal ADVANCED is clinically proven to reduce hold times. “Patient comfort is of utmost importance to us,” says Jim. “Some patients experience significant discomfort when lying flat for extended periods of time. So if a product can help increase patient comfort, I wanted to evaluate it for our lab.”

StatSeal ADVANCED is a topical hemostatic powder that controls external bleeding from sheath removal following vascular access procedures. The powder is a mixture of a hydrophilic polymer and potassium ferrate. The powder forms an occlusive physical seal through simultaneous iron-mediated agglomeration of blood solids/proteins and rapid dehydration of the blood. Seal formation is independent of the clotting cascade. This seal stops the flow of blood.

THE EVALUATION

During a five-month period, November 2010 to April 2011, StatSeal ADVANCED Powder was applied to 114 patients following diagnostic procedures as an adjunct to manual pressure. Sheath sizes ranged from 4 to 8 Fr and 41% had dual access sites.



Following product application, CardioNet staff recorded time to hemostasis (TTH) and time to ambulation (TTA) for each patient. Demographic information including age, known medical conditions, medications (including anticoagulants), blood pressure, INR and platelet level was also recorded. Staff was asked to rate the efficacy of StatSeal and its ease of use as compared to the control of manual pressure, or the occasional pad or clamp adjunct.

As previously noted, the objective of the trial was to evaluate the efficacy of StatSeal ADVANCED to achieve hemostasis, reduce hold times and decrease time to ambulation for patients undergoing cardiac diagnostic procedures. Secondary objectives were to report the incidence of complications such as hematomas or rebleeds that occurred during the evaluation.

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RESULTS

Average hold time was 10.5 minutes.

Average TTA was 1.67 hours or 1 hour, 40 minutes. Based on published data, CardioNet staff was comfortable ambulating at 2.5 hours at the beginning of the evaluation using StatSeal. As the study progressed ambulation times went from 2.5 hours to 1.5 hours consistently. There were instances where the patient was ambulated in one hour.

63% of patients were on anticoagulants (ranging from aspirin therapy to Coumadin and Pradaxa). Hold times for these patients averaged 10 minutes and TTA averaged 1.61 hours. Likewise, patients with high INRs (4%) or low platelets (9%) had similar average hold times and TTA, thus there appears to be no difference in efficacy based on drug therapies or blood chemistry.

Shortened hold times and TTA also do not appear to be affected for hypertensive patients. 63% of patients were chronically hypertensive and had an average hold time of 10.8 min. with TTA averaging 1.7 hours. 39% of patients were acutely hypertensive with similar average hold times and TTA.

8 procedures (7%) had minor complications consisting of rebleeding or small hematomas. 3 hematomas were noted (<3%). For incidents of rebleeding after initial hemostasis, an additional 5 to 8 minutes hold time achieved complete hemostasis in all cases.

There was overwhelming user preference for StatSeal as compared to the control. The overall rating of StatSeal ADVANCED was 4.98 on a scale of 1 to 5 (1=StatSeal is much worse, 5=StatSeal is much better).

Staff Ratings of StatSeal

98%	Considered StatSeal ADVANCED to be effective in controlling bleeding from diagnostic procedures.
99%	Considered StatSeal ADVANCED to be efficient and time saving as compared to the control manual pressure.
99%	Considered StatSeal ADVANCED convenient and easy to use.

IMPLICATIONS FOR PRACTICE

Through an evaluation of StatSeal ADVANCED Powder, **CardioNet realized a 48% decrease in average hold time (from 20 minutes to 10.5 minutes). Time to ambulation decreased by 57% (from 3.5 hours protocol to 1.5 hours average)** from pre-StatSeal use. In several cases during the evaluation, patients were ambulated earlier (<1.5 hours), however, with current staffing levels they could not keep up with the increased lab throughput.

Many patients undergoing cardiac procedures have health issues such as arterial disease, diabetes, obesity and back pain so decreased hold times and earlier ambulation increase patient comfort. Staff evaluation forms noted that there were fewer complaints of back pain.

In addition to patient satisfaction, StatSeal increases staff comfort. Due to the repetitive motion put on wrists while performing manual compression, many clinicians suffer from wrist pain and often carpal tunnel. One CardioNet nurse stated that without StatSeal she may not be able work. She commented, "The decrease in hold time with StatSeal has helped save my wrists!"

Due to the increase in patient and staff satisfaction plus the time savings, CardioNet now uses StatSeal ADVANCED as an adjunct to manual pressure for hemostasis following all sheath pulls.