

# Results of Vascular Clip Closure Device at King Hussein Medical Center

*Sizeph Haddad MD\*, Izzeddin Qtaish MD\*, Jan Al-Shishani MD\*\**

## ABSTRACT

**Objective:** To assess the results of vascular clip closure devices used following percutaneous transfemoral endovascular procedures.

**Methods:** This is a retrospective review of 69 patients who were managed with vascular clip closure device following transfemoral peripheral endovascular interventions during the year 2009, at King Hussein Medical Center. The success of the device in achieving hemostasis, as well as the associated complications were evaluated.

**Results:** Technical success defined as successful deployment of the device was achieved in 65 patients. Two minor complications and one major complication occurred following the deployment of the device.

**Conclusion:** Femoral arterial access clip closure devices are both safe and effective, and are advised to be used in patient at high risk of bleeding at the arterial access site.

**Key words:** Vascular closure device, peripheral endovascular intervention, endovascular complications, femoral access.

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## Introduction

In recent years, the number of patients undergoing peripheral endovascular interventions has increased.<sup>(1)</sup> The commonest access site for endovascular interventions is the common femoral artery,<sup>(2,3)</sup> which is used as a port to deliver catheters, balloons, and stents.

Accessing the femoral artery can be associated with complications that can result in significant patient discomfort, and may require more advanced clinical interventions, such as blood transfusion or even vascular surgery.<sup>(2,4)</sup>

Hemostasis at the femoral access site is classically achieved by manual compression.<sup>(1,5)</sup> However, in recent years we have witnessed the emergence of a variety of vascular closure devices, which are used to achieve hemostasis at the femoral access site, decreasing the risk of bleeding and the time to

ambulation, particularly in high risk patients.<sup>(2,6-9)</sup>

This is a retrospective review, of a single center study, conducted at King Hussein Medical Center to assess the results of Starclose Vascular Closure System (Abbott Vascular, Redwood City, CA) used to manage the femoral arterial access site in 69 patients. The technical success of the device, as well as associated complications were evaluated.

## Methods

During the year 2009, a total of 244 patients underwent transfemoral peripheral endovascular intervention at King Hussein Medical Center. Of these patients, 213 patients underwent therapeutic (angioplasty, stenting, and/or intra arterial thrombolysis) transfemoral peripheral endovascular intervention, via a retrograde approach. The right common femoral artery was accessed in 136 patients,

From the Departments of:

\*Radiology, Interventional Radiology Section, King Hussein Medical Center, (KHMC), Amman-Jordan.

\*\*Vascular Surgery (KHMC)

Correspondence to be addressed to Dr. S. Haddad, P.O. Box 855062 Amman 11855 Jordan, E-mail: [sizephed@yahoo.com](mailto:sizephed@yahoo.com)

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**Table I: Clinical indications for Starclose device use.**

Clinical Indication	Patients Number
Administration of High dose of Heparin	41
Administration of Thrombolytic Therapy	12
Uncooperative Patients	7
Unfavorable Body Habitus	7
Coagulopathy	2
Total Number of Patients	69

**Table II: Successes, failures and complications of starclose device**

	Successful VCCD*	Failed VCCD*
Patients Number	65	4
Major Complications	1	1
Minor Complications	2	0
Total complications	3	1

\*VCCD: vascular Clip Closure Device.

and the left common femoral artery was accessed in 77 patients. A single-wall puncture technique was used. The access sheath size was 6 or 7 Fr.

In 175 patients, the common femoral artery access sheath was pulled out after the procedure, and manual compression was used to achieve hemostasis.

In 69 patients who were considered to be at high risk for bleeding from the access site a percutaneous vascular clip closure device was used to close the femoral access in our study group. The indications for use of vascular clip closure device are shown in Table I. The device was deployed according to the technique recommended by the manufacturer, and approved by the Food and Drug Administration.

Achieving hemostasis after the deployment of the device, with or without applying three minutes or less of manual compression was considered as immediate hemostasis. Technical success of the device was defined as successful deployment of the device followed by immediate hemostasis. Unsuccessful deployment of the device or failure to achieve immediate hemostasis was considered as technical failure of the device.

A 2 hour bed rest was advised after successful deployment of the device. A 6 hours bed rest was advised following device failure, or for patients treated primarily by manual compression.

The success of the device was evaluated, as well as complications related to the use of the device.

The angiographic and interventional procedures were performed in the interventional radiology section. Advanced medical treatments, or surgical interventions were carried out in the Vascular Surgery Department.

## Results

Technical success was encountered in 65 patients (94%). Failure to deploy the device occurred in one patient. In 3 patients there was persistent bleeding from the access site after deploying the device for more than 3 minutes despite manual compression.

Manual compression was used to achieve hemostasis in cases of device failure.

In the group of patient who met the definition of technical device success, two patients presented with non expanding groin hematoma within 48 hours of the procedure, and were treated conservatively. Another patient represented with a retroperitoneal hematoma that necessitated admission to the hospital, and blood transfusion. The patient had no progression in the hematoma, and was discharged after 3 days.

In the group who met the definition of technical device failure, one patient presented with a common femoral artery pseudoaneurysm, which was treated by compression under ultrasound guidance. The technical device success and failure, along with encountered complications are shown in Table II.

Our study shows a high technical success rate of the device with the advantage of early mobilization of the patients, and with acceptable complication rates.

## Discussion

Recent technical advances in the endovascular interventional field, combined with the increase in the number of peripheral vascular patients have resulted in establishing peripheral endovascular interventions as a major part of the clinical practice in most of the world's medical centers.

In the majority of these interventions, the common femoral artery is primary vascular access,<sup>(2,3)</sup> because of its anatomical accessibility, and the ability to achieve hemostasis by compression against the head of femoral bone.

Accessing the femoral artery can result in complications. Minor complications include bleeding not requiring transfusion or surgical intervention, hematoma (<5 cm), and pain at puncture site. Major complications include hematoma (>5 cm), bleeding requiring transfusion or surgical intervention, pseudoaneurysm, arteriovenous

fistula, retroperitoneal hemorrhage, plug embolization, and groin infection.<sup>(10)</sup>

Minor access site related complications occur in about to 10% of patients undergoing transfemoral endovascular interventions, and 1-2% of these complications require vascular surgical intervention or blood transfusion.<sup>(2)</sup>

Many studies have suggested that several factors including concomitant anticoagulation or antiplatelets therapy tends to increase the risk of complications in the vascular access sites when only manual compression is used.<sup>(2,11)</sup>

Bleeding at the access site is a commonest encountered complication, and over the years, several vascular closure devices have been developed to help achieve hemostasis especially in patients who are at a higher risk of bleeding.<sup>(7,12)</sup>

The increase in the number of performed interventional procedures, as well as the more liberal use of new anti-platelet agents, has resulted in increased risk of bleeding with resultant increase in the frequency of closure devices usage.<sup>(13-15)</sup>

The StarClose Vascular Closure System (Abbott Vascular, Redwood City, CA) is a unique vascular closure device, currently used in our institute, which utilizes a nitinol clip to achieve vascular closure.<sup>(16-18)</sup>

In this retrospective review conducted at King Hussein Medical Center, we have included patients who have underwent transfemoral endovascular intervention during the year 2009. In patients who were considered to be at high risk for bleeding, the femoral access was managed by Starclose device at the end of the procedure. The success of the device to achieve hemostasis, as well as the occurrence of complications at the access site was evaluated.

Apart from 4 cases where we encountered failure of the Starclose device, there was a high technical success rate in achieving immediate hemostasis (94%).

## Conclusion

Femoral arterial access clip closure devices are both safe and effective, and are advised to be used in patient at high risk of bleeding at the arterial access site.

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