

# Closure Device Complications

## **"Complications of a Percutaneous Suture-mediated Closure Device versus Manual Compression for Arteriotomy Closure: A Case-controlled Study"**

- Wagner, et al

**Journal of Vascular Interventional Radiology 2003; 14:735-741**

In this retrospective case-controlled study of 100 consecutive patients, the authors report a 7% overall complication rate with the Perclose Closer device, a rate higher than the 1% complication rate for external compression. The Perclose-related major complication rate of 3% was also higher than the 1.3% rate associated with external compression. An unexpectedly high frequency of major complications was found in a sub-population of young, otherwise healthy women undergoing uterine artery embolization (UAE), where 4 of 65 patients were affected, including one who required prolonged hospitalization with surgical intervention and permanent sequelae. All complications involved "cases of persistent bleeding". Notably, no complications were reported for UAE patients on whom external compression was used. The authors conclude that "significantly more complications were associated with use of a percutaneous suture-mediated closure device than with manual compression".

## **"Commentary - Current Status of Suture-mediated Closure: What is the Cost of Comfort?"**

- Brown, DB

**Journal of Vascular Interventional Radiology 2003; 14:677-681**

This commentary assesses the risks and costs of the use of suture-mediated closure devices against their claimed benefits. The author cites a variety of complications related to the use of the Perclose vascular closure devices and raises questions about routine use of these devices for post-catheterization femoral hemostasis without specific clinical need, given the lengthy learning curves and device failure rates of 4%-11%. Suture-mediated closure complications are also frequently more severe than complications associated with manual compression: "when complications occur, they are potentially more devastating and appear to be more morbid than those after manual compression". The author concludes that although some patients may derive benefit from use of such closure devices, their "routine use after diagnostic angiography can not be endorsed at this time".

## **"Safety of Femoral Closure Devices after Percutaneous Coronary Interventions in the era of Glycoprotein IIb/IIIa Platelet Blockade"**

- Cura, et al

**American Journal of Cardiology, , October 1, 2000; vol. 86, pp.780-782**

The article by Cura, et al, entitled "Safety of Femoral Closure Devices after Percutaneous Coronary Interventions in the era of Glycoprotein IIb/IIIa Platelet Blockade", appeared in the October 1, 2000 issue of the American Journal of Cardiology (vol. 86, pp.780-782). The study, from The Cleveland Clinic, notes that all operators were trained in the use of the closure devices in advance of the study period. A total of 2,918 patients were included in the study, of whom 2,099 were manually compressed, 411 received Angio-Seal, and 408 received Perclose.

Overall complication rates were "similar among the 3 treatment groups" (manual compression, Angio-Seal, Perclose), regardless of whether IIb/IIIa blockade was used. Rates were: 3.1% for manual compression, 2.9% for Angio-Seal, and 3.2% for Perclose.

However, the rate of severe complications was higher in the closure device groups:

- \* Retroperitoneal hemorrhage rate was 10X higher in the Angio-Seal group than in the manual compression group; the rate was 8X higher in the Perclose group.
- \* Rate of access-site-related blood transfusion was 50% higher in the Angio-Seal group, compared to the manual compression group; the rate was 2.1X higher in the Perclose group.
- \* Access site infections occurred only with Perclose, where the rate was 0.5%.
- \* Rate of vascular surgery was 0.4% for manual compression, 0.2% for Angio-Seal, and 1.0% for Perclose, an increase of 2.5x over manual compression.



# Closure Device Complications (continued)

**"Safety of Suture-Mediated Closure Devices";**

**-Kahn, Kumar, Hollander, Frankel**

**Catheterization and Cardiovascular Interventions, 2002 (55:8-13)**

The study "Safety of Suture-Mediated Closure Devices" by Kahn, Kumar, Hollander and Frankel was published in Catheterization and Cardiovascular Interventions in January, 2002. The authors compared major and minor complication rates in patients on whom either Perclose or manual compression was used. This retrospective study, conducted at Maimonides Medical Center between 1997 and 1999, included 8,906 diagnostic and 1,095 interventional catheterization patients. Sheath sizes ranged from 5 Fr to 8 Fr. Patients receiving manual compression were ambulated between 4-6 hours following sheath removal; patients receiving Perclose were ambulated at 4 hours following sheath removal. Perclose patients experienced dramatically higher complication rates than manual compression patients for diagnostic angiography: 2.6% and 4.6% rates for Perclose major and minor complications, respectively, compared to 0.2% and 1.8% for manual compression major and minor complications, respectively. Complication rates for interventional patients were similar between the Perclose and manual compression groups. Perclose deployment success rates were 94% for diagnostic and 90% for interventional catheterizations; re-sterilization preceded Perclose deployment. The study abstract states: "A significantly higher complication rate was noted for both major and minor complications in the diagnostic catheterization patients treated with the Prostar-Plus device compared to diagnostic patients treated with manual compression."



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