

Applicability assessment of GOD'S HAND on Hemostasis posterior to Angiography & Interventional Radiology

PARK NAM-YONG, PARK MYEONG-SOO, and LEE JIN-WOOK

Dept. of Diagnostic Radiology Team, St. Mary's Hospital, Catholic University of Korea

Abstract

The purpose of this dissertation lies on the exploration of clinical effect and applicability of GOD'S HAND, the hemostatic tool, which is widely used at the final stage of hematal surgeries. From October, 2010 through March, 2011, a tracking research through a phone survey was made on 148 patients, who received paracentesis on the common femoral artery for the sake of different diagnosis or treatment e.g. hepatic artery chemoembolization, cerebral aneurysm angiography, balloon angioplasty and/or bronchial artery embolization. For those in intensive care unit the data was collected on the basis of their medical records. It is known that some complications may develop posterior to using any hemostatic tool, and are roughly divided into major and minor ones. The major complications comprise the vascular occlusion such as arterial dissection and/or occlusion, any need for further surgery, interventional radiology or internal treatment, and the ineludible extension of hospitalization period. The minor complications comprise any diagnosis which requires mild treatment for inguinal hematoma, continuous pain and/or delayed hemorrhage. The indicator of obesity degree, body mass index (BMI), which divides the weight by the height in linear meter raised to the second power, was deployed to tell the difference in the pressure measured by the patients' physique. Any patient with higher body mass index demonstrated relatively longer stanch time than the ones with lower index after applying differential pressure levels of 100cc, 120cc and 150cc to the subjects, who were classified into three categories e.g. low weight, normal weight and overweight, on the basis of computed body mass indices by each physique, which suggests that obese patients require more time for the control of hemorrhage. A further analysis on the correlations between stanch time and complications of the patients with or without PC(plealet concentrate) and/or FFP(fresh frozen plasma) transfusion indicates that the rate of the patients transfused with plealet concentrate and/or fresh frozen plasma, whose hemostatis ceased within 6 minutes, increased from 78% to 96%, the figure of which is far higher than that of the non-transfused. Out of the whole control group under any surgical measure, seven cases(5%) account for different complications, four(2.7%) for delayed hemorrhage, two(1.4%) for inguinal hematoma, and one(0.9%) for fail. While patients who received any artery surgery with the assistance of Safeguard but without the transfusion of PC and/or FFP needed four hours until the point of hemostasis, only three hours were necessary when GOD'S HAND was exploited for the procedure. In conclusion, GOD'S HAND, the hemostatic tool followed by vascular radiology, is thought to be a safe and useful equipment as it yields the patient at least

an hour earlier walking capability, and alleviates the practitioner's burden shortening five to ten minutes of usual hemostatic time to two to six, and lowers the minor complication rate to 5% from 10% as indicated in existing dissertations on hemostatic tool.

Introduction

Vascular interventional surgery(VIS) has now become prevalent on account of recent increase in diversified and intricate vascular diseases, and the subsequent hemostatic methods used at the last stage of the said operations are incessantly changing and developing each day. Manual pressure and hemostatic equipment are said to be two cardinal means for those hemostatic measures. Manual pressure, which accompanies numberless feasible complications, bears the burden that the practitioner should stanch the puncture site for more than 15 minutes and the patient should rest in bed at least for 8 hours. A multitude of hemostatic tools are recently devised as a measure to lower the possibility of these complications and to lessen the period of bed rest, and AngioSeal vascular closure device with collagen, Perclose suturing device, Safeguard and GOD'S HAND with balloon, and various hemostatic pads are excellent examples of this class. The employment of these equipments renders the patient, who can't rest in bed for hours after the application of any hemostatic device, or who takes anticoagulant therapy due to low thrombocyte index, the earlier walking capability as well as the shorter period of hospitalization while lessening his or her discomfort and reducing the stanch time of the puncture site at the same time. Our staffs applied 50cc of pressure with Safeguard, the balloon-type pressure assisted compression, to the group of subjects, but the exercise afflicted the practitioners with at least from 5 to 20 minutes of procedure and the patients with 4 to 6 hours of bed rest posterior to the foresaid application. The prolonged bed rest could slow down the walking capability and increase the discomfort of the patient, and might have led to another complications such as haematoma, pseudoaneurysm, bleeding and the like. Therefore, the study classifies the degree of pressure to be applied by the physique of the subjects, using GOD'S HAND, the pressure assisted compression, and categorizes the clinical results of hemostatic time and complications by the application and non-application of PC and/or FFP transfusions.

Materials and Methods

This study was made on 148 patients of St. Mary's Hospital under treatment for common femoral artery to ultimately apply them an interventional radiology on the employment of GOD'S HAND from October, 2010 through March, 2011. The body mass index of each patient was measured by different balloon pressure conforming with his or her physique, adopting GOD'S HAND, the balloon-type hemostatic device, which works by pressure between 100 and 150cc. Did we also study the correlation between complications and hemostatic time, measuring their thrombocyte indexes and prothrombin indexes. Subsequent research on the hemostatic time and homorrhagic complications was carried out through a phone survey.

To differentiate the pressure by the physique of each subject, body mass index (BMI), which divides the weight by the height in linear meter raised to the second power, was used. The pressure of 100cc was applied to those under 18.4, 120cc to those from 18.5 to 25.0, and 150cc to those over 25.1 for the successful hemostatis. (Refer to Table 1)

Table.1. Classification of Body Mass Index

Body Mass Index(BMI)	Obesity Degree
-18.4	Low Weight
18.5-23.9	Normal
23.0-24.9	Overweight
25.0-29.9	Mild Obesity
+30.0	Moderate Obesity

Following the relevant treatments, we applied manual pressure for 2 minutes after pressurizing the balloon. When the hemorrhage continued, we arrested the bleeding for another 4 minutes. In the event of prolonged hemorrhage with all 6 minutes of general measures, we arrested the bleeding for another 4 minutes, 10 minutes in total.

The patient rested in bed for 3 hours in the event that his or her thrombocyte index and prothrombin index were within normal range, and for 5 hours in the event that he or she was transfused with plealet concentrate and/or fresh frozen plasma. In general, any patient was transfused when his or her thrombocyte index was under 40,000 or prothrombin index under 70%.



Figure 1. How to use GOD'S HAND

The initial styptic step with GOD'S HAND starts with taking out about 4cm of the sheath and removing the tape in the center attached to the balloon. Attach the product approximately 1cm above the puncture site thereupon, and put a small gauze and then affix an adhesive tape on the part of skin which contacts with the balloon.



Figure 2. How to use GOD'S HAND

Affix a supplementary tape around and let the patient easily receive the balloon pressure. Use a 50cc syringe and apply the pressure of 100~150cc in line with the patient's physique. Adjust the center of balloon by hand and remove the sheath while applying the pressure at the same time. Make sure to apply proper degree of pressure so that the puncture site does not bleed further.

Results

148 patients who underwent hemostatic measures through GOD'S HAND range from the 22-year-old to 88-year-old(Average 62.3-year-old), including 107 males(72%) and 41 females(28%) (Refer to Figure 3)

Figure 3. Age Distribution

The types of treatment implemented in the angiographic suite are comprised of 104 cases of hepatic artery embolization, 15 cases of cerebral aneurysm angiography, 7 cases of balloon angioplasty or stent insertion for thrombosis, 8 cases of bronchial artery embolization and 14 other cases. (Refer to Figure 4)

Figure 4. Types of Treatment

The number of patients transfused with plealet concentrate and/or fresh frozen plasma a day before the treatment was 46, which accounts for 36% of the whole. (Refer to Figure 5)

Figure 5. Application of Transfusion

Out of 148 patients in total, the hemorrhage was arrested within 2 minutes in 62 cases(42%), 6 minutes in 72 cases(49%), 10 minutes in 10 cases(6%), and 20 minutes in 3 cases(3%) along with 1 failed case. When the pressure of 100cc was applied, the hemorrhage was arrested within 2 minutes in 19 cases(58%), 6 minutes in 11 cases(33%), and 10 minutes in 3 cases(9%). When the pressure of 120cc was applied, the hemorrhage was arrested within 2 minutes in 40 cases(41%), 6 minutes in 49 cases(51%), 10 minutes in 6 cases(6%), and 20 minutes in 2 cases(2%). When the pressure of 150cc was applied, the hemorrhage was arrested within 2 minutes in 3 cases(17%), 6 minutes in 12 cases(67%), 10 minutes in 1 case(5%), and 20 minutes in 1 case(5%) along with 1 failed case. (Refer to Figure 6)

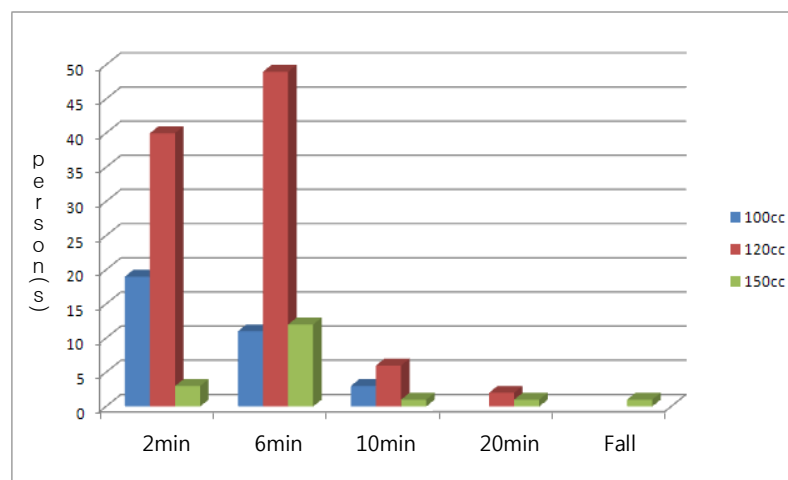


Figure 6. Correlation between pressure used and hemostatic time

The above indicates that the patient with higher body mass index tends to need more hemostatic time. Three of the subjects whose bleedings stopped at 20 minutes of styptic measure were one with less than 40,000 of thrombocyte index, another who regularly took Urokinase 130, and the other with unusual medical history whose hemorrhage refused to cease for more an hour after coronary angiography posterior to one-off brachial angiography. The only failed case, the prothrombin index of which was 32%, required over an hour of manual pressure for the incessant bleeding after the relevant balloon involved treatment. For those transfused with plealet concentrate and/or fresh frozen plasma demonstrated their hemostatic time as follows. (Refer to Figure 7)

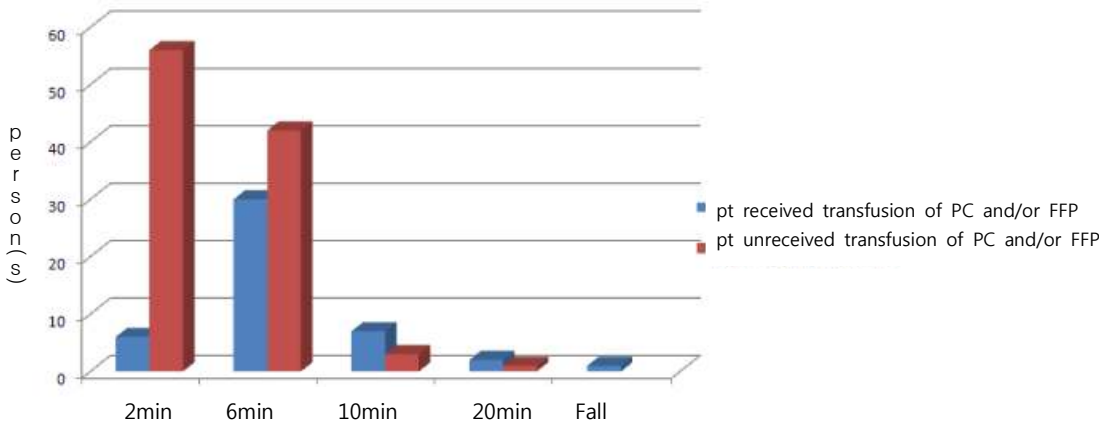


Figure 7. Hemostatic time by the application of transfusion of PC and/or FFP

Figure 7 indicates that the rate of the patients transfused with plealet concentrate and/or fresh frozen plasma, whose hemostatis ceased within 6 minutes, increased from 78% to 96%, and the rate of those, whose hemostasis ceased within 2 minutes, increased drastically from 13% to 55%. Furthermore, 95% of the subjects showed no indication of complications while only 5% of them showed some types of complications. Only 4 of the patients were reported to have had rebleeding in addition to 2 cases of hematom and 1 failed case. Among 7 defective subjects, 5 had thrombocyte index less than 50,000, one was prescribed with Urokinase 130, and the last one was extremely overweight. GOD'S HAND also prominently shortened the hemostatic time to 2~6 minutes from 5~20 minutes which was usual with Safeguard, and the decrease in thrombocyte index relatively increased hemostatic time as well.

Results and Discussions

Any complications occurred in the puncture site procrastinate the period of expected hospitalization and sometimes require either transfusion or extra surgical measures. In such cases, hemostatic equipment is used to reduce the time of bed rest and the possibilities of complications. This study employed different pressure levels of balloon-type hemostatic tools according to the physique of each subject. Higher body mass index indicated the need for a longer hemostatic time, and so did the fatter physique. Any subject transfused with platelet concentrate and/or fresh frozen plasma demonstrated longer hemostatic time as well as higher possibility of complications. In sum, GOD'S HAND, which is often used after interventional radiology, decreased hemostatic time as well as higher possibility of complications after all. However, the patients with lowered thrombocyte index and/or prothrombin index, or with Urokinase or Heparin, or with difficulty in bed rest due in large part to the unconsciousness, acted as big variables. The study exploited a small gauze on the puncture site applied to prevent skin peeling and/or any contact dermatitis, which could minimize the dermatologic side effects. Lastly, those who required more hemostatic time than usual relaxed with the balloon pressure in half after 3 hours of bed rest.

References

1. Interventional Radiology, Korea Society of Interventional Radiology p184-188 ; 2007
2. The Analysis on the Clinical results of using Hemostatic equipment after Angiography and/or Interventional Radiology (Korea Society of Cardio-Vascular Interventional Technology) written by KIM, GYEONG MOOK and four researchers. p229~231; 2007.
3. A Study on the Applicability of Compression Device for Common Femoral Artery, Journal of Korea Society of Cardio-Vascular Interventional Technology Volume 6-2, written by JO, IN HWAN and six researchers. p59-63; 2004. p59-63; 2004
4. A Study on Safety and Clinical Effect of Hemostatic Equipment after Paracentesis on the Common Femoral Artery, written by KIM, SEONG HWAN, p1-20 ; 2007
5. A Study on Feasibility of Reduced Bed Rest after Interventional Radiology through Femoral Artery, written by PARK, JI HONG, p127-132 ; 2009
5. Geoffrey A. Gardiner, Jr, et al. Complication of Transluminal Angioplasty. Interventional Radiology Vol 159, No. 1 p201-207; 1986
6. Koreny M, Riedmuller E, Nikfardjam M, et al. Arterial puncture closing devices compared with standard manual compression after cardiac catheterization: systematic review and meta-analysis. JAMA 2004;291:350-357.