

Exploration into Application of Neotype Hemostatic Material Arista™ in Neurosurgical Operation

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[Abstract] Objective: This is to observe the effects of the neotype hemostatic material Arista™ in controlling the active bleeding and local oozing of blood in neurosurgical operation, and to explore its indications in neurosurgical operation. **Method:** 48 patients were selected who received operative treatment at the department of neurosurgery of Air Force General Hospital from April 2008 to May 2009, and were divided into the trial group with 24 patients and the control group with 24 patients in accordance with the random digits table method. Arista™ was used in the trial group for arresting bleeding, while gelatin sponge was used in the control group for arresting bleeding by compression. The hemostasis time and effects were observed between the two groups. **Result:** Hemostasis was successful at the bleeding sites of all 48 patients. The hemostasis time for the trial group was 1.88 ± 0.74 minutes, that for the control group was 3.38 ± 0.92 minutes, and the comparative difference between the two groups was statistically significant ($Z = 4.711, P = 0.001$). **Conclusion:** The neotype hemostatic material Arista™ can potently and quickly control the active bleeding and local oozing of blood that occur in neurosurgical operation, is better than the use of gelatin sponge for hemostasis by compression and the routine surgical operation technique, and has better value to be promoted in clinical application.

[Key words] Arista™, Neurosurgical Operation

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[Abstract] Objective To evaluate the efficacy of a novel hemostatic material Arista™ in the management of active and local bleeding in neurosurgery, and discuss the indications for its application. **Methods** Forty-eight patients undergoing elective craniotomy in our department between April, 2008 and May, 2009 were randomized into the test group ($n=24$) and control group ($n=24$) with intraoperative hemostatic management using Arista™ and gelatin sponge, respectively. The hemostasis time and efficacy of the two materials were compared. **Results** Hemostasis was effective in all the 48 patients. The mean hemostasis time in the test group and control group was 1.88 ± 0.74 min and 3.38 ± 0.92 min, respectively, showing a significant difference between them ($Z=4.711, P=0.001$). **Conclusion** Arista™ allows more efficient management of active and local bleeding than gelatin sponge during neurosurgeries and has great potential for clinical application.

[Key words] Arista™; Neurosurgery

The problem of bleeding in neurosurgical operation has been perplexing those who perform the operation all the time, and it may cause the operation visual field to be unclear, and make it highly possible to result in tissue injury while electric coagulation is performed on brain stem, important nerves and area close to blood vessels, so that severe complications occur after operation. Currently, gelatin sponge is widely applied clinically for arresting bleeding, but will cause space occupying effect after its dilation, and therefore, a quick, safe and potent hemostatic material is urgently needed as the auxiliary approach for the neurosurgeon to arrest bleeding. Arista™ is a neotype hemostatic material developed by Medafor Company in the United States, and it can quickly and effectively control the oozing of blood in neurosurgical operation, guarantee operation visual field, and has no space occupying effect. This study is to explore the indications and hemostatic effects of Arista™ in neurosurgery through clinical observation on the use of the neotype hemostatic material Arista™ in craniocerebral operations performed at Air Force General Hospital from April 2008 to May 2009.

Data and Method

I. Clinical Data

Forty-eight (48) patients who received craniotomy surgery were selected, and were divided into the trial group and the control group according to the random digit table method, and each group had 24 patients. The age of the trial group was between 17 ~ 60 years old, the average age was 36.2 ± 7.9 years old, 13 patients were male, and 11 patients were female; the age of the control group was between 18 ~ 69 years old, the average age was 37.8 ± 6.2 years old, 12 patients were male, and 12 patients were female. Tumor resection through craniotomy: there were 8 patients in the trial group (4 patients with neurogliocytoma, 2 patients with meningioma, 2 patients with metastatic tumor), and there were 8 patients in the control group (5 patients with neurogliocytoma, 1 patient with meningioma, 2 patients with metastatic tumor); transnasal sphenoid pituitary tumor resection: there were 8 patients in the trial group and 8 patients in the control group; intracerebral hematoma clearance: there were 8 patients in the trial group and 8 patients in the control group

II. Test Material

Gelatin sponge (commodity name: Gelfoam); neotype hemostatic material Arista™ (commodity name Arista™).

III. Method of Operation

The sites for hemostasis were those with active bleeding and local oozing of blood in surgical operation. Arista™ was used in the trial group for hemostasis, and the method was to use a suction apparatus to clear the accumulated blood on the wound surface first, quickly spray Arista™ styptic powder, and then use dry cerebral cotton sheet for applying continuous pressure; gelatin sponge was used in the control group, and the method was to clear the accumulated blood on the wound surface, quickly cover it with gelatin sponge, and then use wet cerebral cotton sheet to cover the gelatin sponge for applying continuous pressure.

IV. Evaluation Index

Time was recorded for the two groups at the same time, time began to be recorded when hemostatic material was used, and cerebral cotton sheet was opened every 1 minute to observe the hemostatic effects until stop of bleeding was observed, which was the hemostasis time. If bleeding was not controlled in more than 5 minutes, it was considered a hemostasis failure, and other methods would be used instead to control bleeding. After bleeding was kept under control, observation was performed to see whether or not obvious phenomenon of potential oozing of blood existed.

V. Statistical Treatment

SPSS13.0 statistical software was used for treatment, the successful hemostatic condition at the bleeding sites was expressed with the mean value and standard deviation for hemostasis time, t-test and rank sum test were used for comparison, and the difference was shown to have statistical significance with $P \leq 0.05$.

Result

Hemostasis was successful at the bleeding sites of all 48 patients, the hemostasis time for the trial group was 1.88 ± 0.74 minutes, that for the control group was 3.38 ± 0.92 minutes, and the comparative difference was statistically significant ($Z = 4.711, P = 0.001$). In various types of craniocerebral operations, the hemostasis time for the trial group was all better than that for the control group, and the comparative difference was statistically significant ($P = 0.05$). Refer to Table 1 for specific details.

Table 1 Comparison of Hemostasis Time in Use of Arista™ and Gelatin Sponge in Different Types of Surgical Operations ($\bar{x} \pm s$, min)

Tab.1 Hemostasis time of Arista™ and gelatin sponge in different surgeries (*Mean*±*SD*, min)

Groups (No. of Patients)	Types of Surgical Operation		
	Brain Tumor Surgery	Transnasal Sphenoid Pituitary Tumor Surgery	Intracerebral Hematoma Clearance
Trial Group (24)	2.00±0.76	1.88±0.83	1.75±0.71
Control Group (24)	3.75±1.04	3.38±0.92	3.00±0.76
t value	3.860	3.420	3.410
P value	0.002	0.004	0.004

Discussion

The hemostatic methods of bipolar electrocoagulation and gelatin sponge compression are normally used in neurosurgical operations. For small artery angiorrhaxis, bipolar electrocoagulation is indubitably an effective hemostatic method, but for venous hemorrhage or oozing of blood on brain tissue surface, gelatin sponge and cotton sheet are currently still used for hemostasis by compression. The hemostatic method not only involves longer time for arresting bleeding, but is also unfavorable for the completion of surgery because the gelatin sponge residue will affect operation visual field, and it is extremely easy to result in wrong judgment at postoperative CT re-examination because the gelatin sponge absorbed blood clot in the early stage after surgical operation is shown as high density shadow on CT. In addition, because the dilation that results from absorption of blood by gelatin sponge will cause space occupying effect, there is the danger for compression

on nerves and blood vessels. Therefore, neurosurgeons are currently in urgent need of a hemostatic material that can arrest bleeding quickly, potently and safely.

Arista™ styptic powder is produced by Medafor Company in the United States, which is made through purifying vegetable starch to remove vegetable protein and keep only vegetable polysaccharide and further through the use of 28 d emulsification cross linking technology to finally obtain the polysaccharide globular elastic particles with diameter at 100 micra and with tens of thousands of micropores evenly distributed on the surface, namely MPH particles. The micropores on the surface of particles play the role of molecular sieves, can quickly absorb the water content in the blood, gather the formed elements (including blood platelet and fibrinogen) in the blood on the surface of particles to form the "instant gelatin", which plays the role of mechanically sealing the cut on the blood vessel, and the gathering of formed elements has simultaneously accelerated and reinforced the intrinsic coagulation mechanism. Overseas animal experiments and clinical applications prove that MPH particles have quick effects for hemostasis^[1,2], no adverse reaction has been found^[3] and there is no postoperative delayed hemorrhage^[4]. Animal experiment study shows that the hemostatic particles added into plasma and tissues can be decomposed by diastatic enzyme into maltose and glucose within 72 hours, will leave no residue in the body in the end, and will be entirely absorbed inside the body^[5,6].

Among the 24 patients on whom Arista™ styptic powder was applied in this group, 16 patients received craniotomy surgery, and upon CT re-examination after surgery, not a single patient had intracerebral or extradural hemorrhage. Normally, the major reason for the occurrence of extradural hematoma is the oozing of blood at dura mater and muscles. When Arista™ styptic powder was used to spray on the outside of cerebral dura mater and on the surface of muscles, the bloody fluid in the postoperative drainage tube was significantly reduced, and the cerebrospinal fluid drained in the drainage tube was relatively clear. In this trial, gelatin sponge was used for tumor cavity hemostasis on 1 patient with pituitary gland tumor in the control group, and because the dilation of gelatin sponge caused compression on the optic nerve, the vision of the patient decreased after surgery, and the vision was kept only through a second surgical operation to remove the gelatin sponge, while no such condition occurred when Arista™ styptic powder was used. Through its application in the neurosurgical operation, this study confirms that the hemostatic effects of the neotype hemostatic material Arista™ is obviously better than gelatin sponge hemostasis, and complications such as intracerebral delayed hematoma and infection were not found to have occurred to patients in the trial group in the process of surgical operation, and proves that it has the feature for potent, safe and quick hemostasis. In this trial, it has been found that the hemostatic effects of Arista™ styptic powder are poor for arteriolar bleeding, and it is mainly applicable for intracerebral micrangium oozing of blood and venous hemorrhage, such as the cerebral hematoma clearance wound surface, the tumor bed after tumor resection, and the extradural and muscle surface with oozing of blood in the skull closure process. In application, the suction apparatus is first used to remove the accumulated blood on the wound surface, on which Arista™ is sprayed quickly, pressure is applied with dry cerebral cotton sheet for 1 ~ 3 minutes or no pressure is applied, and hemostasis is quick and complete, and the operation visual field is clear in the surgery. Nevertheless, the appearance of any surgical hemostatic material may only be used as the auxiliary measure for surgical operation, and can

(To be continued on Page 861)

[unrelated text]

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by no means be used to completely replace surgical operation, but this auxiliary function cannot be ignored either. Fact proves that Arista™ can improve surgery efficiency, save surgery time, prevent against oozing of blood on the wound surface after surgery, reduce the difficulty and risk of surgery for surgeons and have relatively good value in clinical application.

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