A New Hemostasis Valve for Neuroendovascular Procedures

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Key words: angiographic device, hemostatic valve, angiography

Summary

A hemostasis valve is routinely used in neuroendovascular procedures to decrease the risk of thromboembolism^{1,2}. Recently, a new hemostasis valve that is designed to minimize blood loss has been introduced. We report our initial experience in using this new hemostasis valve.

In neuroendovascular procedures, a hemostasis valve is commonly used for continuous irrigation of guide and microcatheters to decrease the risk of thromboembolism^{1,2,3}. A conventional hemostasis valve has a rotating seal at the end, which is turned open or closed each time a wire or microcatheter/guidewire is introduced or extracted. Often this results in significant back bleeding. When a rotating seal is adjusted suboptimally during a wire or microcatheter manipulation, leakage of pressurized saline from the end of a hemostasis valve results in stagnation of blood within a guiding catheter, which becomes a potential source of emboli during a procedure.

The Guardian Haemostasis Valve (Zerusa Limited, Galway, Ireland) is a new hemostasis valve that is designed to minimize blood loss during interventional procedures by minimizing the opening time of the valve during wire or microcatheter insertion.

A continuous sealing mechanism during wire or microcatheter positioning minimizes blood

loss and stagnation of blood within the guide catheter. We report our initial experience with the Guardian hemostasis valve.

Technique

The Guardian has two sealing mechanisms. One is an on/off switch mechanism to open and close the primary seal for inserting a wire or microcatheter (figure 1A,B). This seal opens with a single hand, usually with the thumb, by pushing in and out the distal "plunger" end via a "clicking" motion (figure 1A,B). By pushing in, the distal end seal opens and by releasing, the seal closes.

When pushing in the plunger completely, the mechanism "clicks" and the valve remains open. Depressing the plunger again results in another "click" and releases the plunger closing the valve. The mechanism is analogous to a "clicking" mechanism of a pen. In practice, this "clicking" mechanism is rarely used. It is more common to partially open the valve by halfway depressing the plunger and maintaining pressure with the thumb while introducing the wire or microcatheter (figure 2A), and then quickly releasing thumb pressure to let the plunger recoil back to the original position, allowing almost instantaneous opening/ closing of the valve (figure 2B).

The opening time of the seal during device insertion is minimal. The second mechanism is

Figure 1 Guardian Haemostasis Valve. A) 1: Indicates primary seal controlled by pushing and releasing the plunger. When the plunger is pushed all the way in, the plunger clicks in to an opening position. Pushing the plunger again results in another clicking then releases the plunger closing the primary valve. The primary seal provides minimal device insertion time and continuous sealing during device extraction. 2: Indicates rotating device lock that provides stability to wires and shafts. 3: Inner lumen of the hemostasis valve is 8Fr, allowing multiple device delivery. B) Guardian Haemostasis Valve with the plunger clicked in for primary seal opening (upper), and clicked out for seal closure (lower).

a rotating device-lock that provides a soft-grip to lock devices such as wires and shafts in place (figure 1A). The Guardian has an 8 French inner lumen, which allows delivery of multiple devices such as carotid stents and double catheters such as in balloon remodelling techniques for aneurysm treatment.

Discussion

We report our initial experience with the Guardian hemostasis valve. The device-user interface is well designed and easy to understand. It requires less experience than the conventional hemostasis valve to become proficient.

Minimizing blood loss during endovascular procedures is important. With multiple insertions, extractions, and exchanges of catheters and wires, small blood loss in each step can be significant.

The Guardian system is designed to minimize blood loss by reducing valve opening/closing time while providing a continuous flush system. The quick access system also reduces the possibility of blood stagnation within the guide catheter, reducing the risk of thromboembolism. We found the Guardian hemostasis valve useful in pediatric cases, particularly in neonatal cases, where minimizing blood loss is particularly important.

Blood loss can be significant during over-the-wire exchange procedures, especially with large-bore devices such as carotid stents. Optimal sealing with a conventional hemostasis valve has been difficult because of tapering change in the caliber of a catheter. It is not easy to optimally adjust the valve to the changing caliber of the catheter and manipulate the catheter at the same time. With the Guardian hemostasis valve, once a catheter or a wire is inserted, the elastic end of the primary seal maintains an optimal closure of the valve, which eliminates the need for frequent valve adjustment to prevent blood leakage. We have been able to significantly reduce blood loss during over-the-wire exchange procedures. The Guardian enabled us to concentrate on the procedure by eliminating frequent attention that was previously paid to the valve. The Guardian also minimizes possible blood contact for physicians and co-workers, reducing biohazardous risks. In many cases, no observable blood loss was seen on the drapes covering the patient.

Figure 2 Opening and closure of the primary seal. Partial opening and closure of the primary seal during introduction of devices such as a guidewire. By using this technique, the opening time of the valve is minimal. One can minimize blood loss and blood stagnation within a guiding catheter. A) Halfway depression of the plunger by maintaining pressure to the plunger with the thumb. B) Release of the valve results in recoil of the plunger providing instant closure of the primary valve.

We point out several drawbacks of the Guardian system. First, the angle of the “Y” is obtuse so that a guidewire or a microcatheter will migrate back into the pressurized saline side arm if they are inserted without attention. On some occasions, the microwire was damaged. Second, the primary seal leaks with power injections, when performing aortograms. Therefore, the second rotating valve must be closed tightly before such injections. Third, the Guardian hemostasis valve contains small amount of air in the silicone hub that connects the Guardian to the guide catheter. We tap out the air meticulously in the descending aortic

arch before catheterizing selectively. Fourth, we must also actively look for back bleeding during wire removal by opening the primary seal whenever there is a suspicion of an occlusive catheter tip to a vessel, i.e. “the suction effect”. This is because the primary seal is tightly closed that we do not see air reflux when creating negative pressure by wire removal as observed with a conventional hemostasis valve.

Although improvements are forthcoming, we have found the Guardian hemostasis valve an improvement over conventional hemostasis valves and recommend its routine use with the caveats described.

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