Online October 24, 2023
Journal of Neuroendovascular Therapy 2023; 17: 281–285 DOI: 10.5797/jnet.oa.2023-0053

Original Article

Usefulness of Stanch Belt Plus in Postoperative Management after Endovascular Neurosurgery

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Objective: We verified the usefulness of patient management using a balloon-pressurized belt (Stanch Belt Plus) to prevent puncture site hematomas, which can occur at a specific rate even with hemostatic devices after endovascular neurosurgery.

Methods: A total of 113 patients who underwent endovascular surgery with a femoral puncture from April 2019 to September 2020 were divided into two groups: 31 cases using a traditional compression belt and 82 cases using a newly introduced balloon-pressurized belt during this period. The clinical data were analyzed retrospectively. The chi-square test and Mann–Whitney U test were used to test for significant differences.

Results: There were no significant differences in treatment procedures or frequency of hemostatic device use, but the balloon-pressurized belt group had a significantly lower incidence of hematomas (2.4% vs 12.9%, $p < 0.05$) and a significantly lower incidence of moderate or higher lumbago (22.0% vs 41.9%, $p < 0.05$). The incidence of epidermal detachment tended to be low; however, no significant difference was observed (3.7% vs. 12.9%, n.s.).

Conclusion: Patient management with the newly introduced balloon-pressurized belt may decrease the occurrence of groin hematoma and lumbago among complications after endovascular neurosurgery.

Keywords ▶ endovascular treatment, hemostatic device, groin hematoma, lumbago

Introduction

Although endovascular surgery is minimally invasive and has the advantage of enabling early discharge from the hospital, complications at the puncture site often prolong hospitalization. In recent years, notwithstanding the utilization of hemostatic devices to expeditiously achieve hemostasis following endovascular surgery, puncture site hematomas have been observed to occur at a specific rate.[1,2] A puncture site hematoma can lead to hemorrhagic shock in severe cases, and it is crucial to limit bed rest after treatment. However, since there is no consensus on the length of time required for patients to be released, bed rest restrictions to prevent puncture site hematoma vary from institution to institution. Prolonged bed rest is physically painful, and although many patients tend to complain of back pain, there are currently no effective measures to alleviate it.[1)]

Previously, our hospital had used an original compression belt (Matsumoto Gishi. Co., Ltd., Aichi, Japan). This is an elastic 8 cm wide belt wrapped around the groin to compress the puncture site and is secured with Velcro. Initially, patients were restricted from changing positions for a minimum of 20 hours due to the possibility of pressure shifting at the puncture site during body movements. Over the past several years, we have gradually accelerated the weaning process, but patients still complain of back pain. Therefore, in July 2019, we introduced a balloon-pressurized belt (Stanch Belt Plus; Livedo Corporation, Osaka, Japan; https://www.livedo.jp/medical/product/point/index03.html) that does not shift the pressure of the puncture site even during body movements. The attached balloon is positioned just above the puncture site, inflated,

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Received: July 18, 2023; Accepted: October 4, 2023
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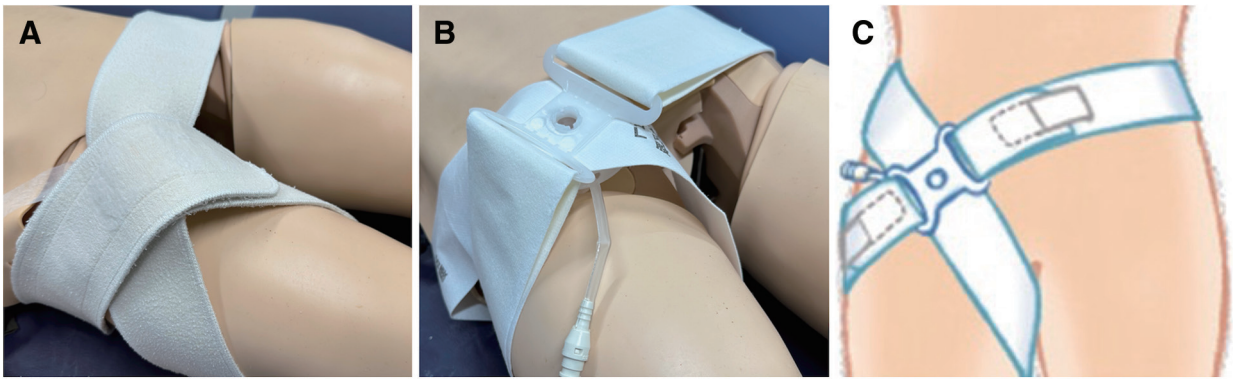

Fig. 1 Appearance and the schema of the compression belts used in this study are shown in (**A**). (**A**) is the traditional compression belt used previously, (**B**) is the balloon-pressurized belt introduced in this study, and its schema is shown in (**C**).

Table 1 Post operative protocol after femoral approach for endovascular treatment

	T group		S group	
Postoperative bed rest restrictions				
Immediately after surgery	Resting on bed and unable to reposition		Resting on bed and unable to reposition	
Four hours after surgery	Same as above		Resting on bed and able to change positions	
The next morning	Rest restrictions are lifted and walking		Rest restrictions are lifted and walking	
Postoperative antithrombotic drugs	Intracranial stent	Carotid stent	Simple coiling	Dural AVF
Oral antiplatelet agents	DAPT	DAPT	SAPT	No agent
Anticoagulant agent (until 24 h)	Continuous IV heparin and argatroban	Continuous IV argatroban	No agent	No agent

AVF: arteriovenous fistula; DAPT: dual antiplatelet therapy; IV: intravenous; SAPT: single antiplatelet therapy

and compressed. **Figure 1** shows a comparison of existing belts and stanch belts and the schema. We believe that this balloon-pressurized belt will enable safe early repositioning, thereby allowing patients to change positions after 4 h. In addition, for patients with fragile skin, such as the elderly and diabetics, the risk of epidermal abrasion due to adhesive tape exists when using the conventional method. However, this balloon-pressurized belt does not use strong adhesive tape; therefore, the risk of epidermal abrasion is thought to be reduced. In this study, we compared the incidence of adverse events before and after the introduction of the balloon-pressurized belt and examined the usefulness of postoperative management using this belt.

Materials and Methods

This research was conducted as a retrospective observational study with the approval of the ethics institutional review board of Nagoya University. Between April 2019 and September 2020, we performed endovascular neurosurgery by femoral artery puncture without intraoperative puncture site hematoma in 215 patients at our institute. Of these, we included 113 cases for which we could obtain all the following items. The patients were divided into two groups: (1) 31 patients who underwent compression using our original traditional compression belt, until June 2019 (Traditional group; T group), and (2) 82 patients who underwent compression with the balloon-pressurized hemostatic belt, after July 2019 (Stanch group; S group). The protocols for postoperative rest restrictions and antithrombic agents are shown in **Table 1**. The patients' clinical backgrounds were compared in terms of age, sex, renal function, body weight, procedure, anticoagulant drug use, and sheath size. In contrast, the posttreatment hematoma incidence at the puncture site, incidence of total and moderate lumbago, analgesic use, and epidermal detachment incidence were compared as safety indices. Puncture site hematoma was defined as hematoma formation associated with arterial bleeding, and venous bleeding without hematoma formation was excluded. The degree of lumbago was rated on an 11-point scale using the Numerical Rating Scale (NRS), and lumbago with a maximum score of 4 or higher on the NRS was defined as moderate or high pain. We prescribed analgesics when requested by the patients, and the nurses suggested oral analgesics when the pain was more remarkable than an NRS of 4 points. Statistical

Table 2 Comparison of clinical background and adverse events between the two groups

	T group (n = 31)	S group (n = 82)	Total (n = 113)	p value
Patient demographics				
Mean age (range)	63.5 (13–85)	63.8 (26–85)	63.7 (13–85)	n.s.
Age (≥75 years), n (%)	9 (29)	19 (23)	27 (24)	n.s.
Sex (female), n (%)	16 (52)	45 (55)	61 (54)	n.s.
eGFR (median) (mL/min/1.73 m^2)	72.9	66.8	67	n.s.
Mean body weight (kg)	60.3	59.7	59.9	n.s.
Body weight (<50 kg), n (%)	5 (19)	19 (23)	24 (21)	n.s.
Procedure				
Aneurysm embolization, n (%)	24 (77)	63 (77)	87 (77)	n.s.
CAS, n (%)	5 (16)	8 (10)	13(12)	n.s.
Dural AVF embolization, n (%)	2 (6)	11 (13)	13 (12)	n.s.
Sheath size (≥8 F), n (%)	7 (23)	46 (56)	53 (47)	<0.01
Use of hemostatic devices, n (%)	29 (94)	78 (95)	107 (95)	n.s.
Postoperative anticoagulant use, n (%)	19 (61)	42 (51)	61 (54)	n.s.
Adverse event				
Puncture site hematoma, n (%)	4 (13)	2 (2)	6 (5)	<0.05
All lumbago, n (%)	16 (52)	51 (62)	67 (59)	n.s.
Lumbago of moderate degree or more, n (%)	13 (42)	18 (22)	31 (27)	<0.05
Use of analgesics, n (%)	4 (13)	7 (9)	11 (10)	n.s.
Epidermal detachment, n (%)	4 (13)	3 (4)	7 (6)	n.s.

AVF: arteriovenous fistula; CAS: carotid artery stenting; eGFR: estimated glomerular filtration rate

analysis was performed using Statcel (OMS Publishing Co. Ltd., Saitama, Japan). There were no changes in the postoperative protocol for anticoagulant or antithrombotic medications during the study period. Patient background factors of the two groups were compared using simple tabulation. The $\chi 2$ test was used for comparisons between groups, and the t-test was used for comparisons of means. P value <0.05 was considered to be significant.

Results

Of 113 patients included in the analysis, there were 61 women with a mean age of 63.7 years (13–85 years). A summary of patient background factors between the two groups is presented in **Table 2**. There was no difference in the male-to-female patient ratio. Treatment procedures included aneurysm embolization in 87 patients, carotid artery stenting in 13 patients, and dural arteriovenous fistula embolization in 13 patients. A sheath size of 8 Fr or 9 Fr was used in 46.9% of cases. The use of hemostatic devices did not differ significantly between the two groups, with the Exoseal (Cordis, Fort Pierce, FL, USA) being used in 106 (93.8%) cases and the Angioseal (Terumo, Tokyo, Japan) in only one case. Postoperative anticoagulants were administered to 54% of patients. There were no significant differences in background factors, except for the use of sheaths larger than 8 Fr in 56.1% of the patients in the S group.

A graphical representation of the frequency of adverse events is presented in **Fig. 2**. The incidence of puncture site hematoma was 12.9% in the T group and 2.4% in the S group, which was significantly lower in the S group than that in the T group (p <0.05). The incidence of lumbago was similar in the T (51.6%) and S (62.2%) groups. However, the incidence of moderate or high lumbago was 41.9% in the T group, 22.0% in the S group, and significantly lower in the S group than that in the T group (p <0.05). The use of analgesics was 12.9% in the T group and 8.5% in the S group, and the incidence of epidermal detachment was 12.9% in the T group and 3.7% in the S group. Both incidence rates tended to be lower in the S group, but the differences were not statistically significant.

Discussion

Puncture site hematoma is one of the most common complications of endovascular treatment, and its incidence is reported to be 0.6%–9.7%.[1–3] Well-known risk factors include older age, female sex, low body weight, renal failure, large sheath size, use of hemostatic devices, and anticoagulant therapy.[4–6] This complication can lead to anemia in severe cases and requires blood transfusions or surgical procedures to stop bleeding.[7] Although postoperative rest restriction is widely used to prevent these serious complications, there is no unified view on the appropriate timing

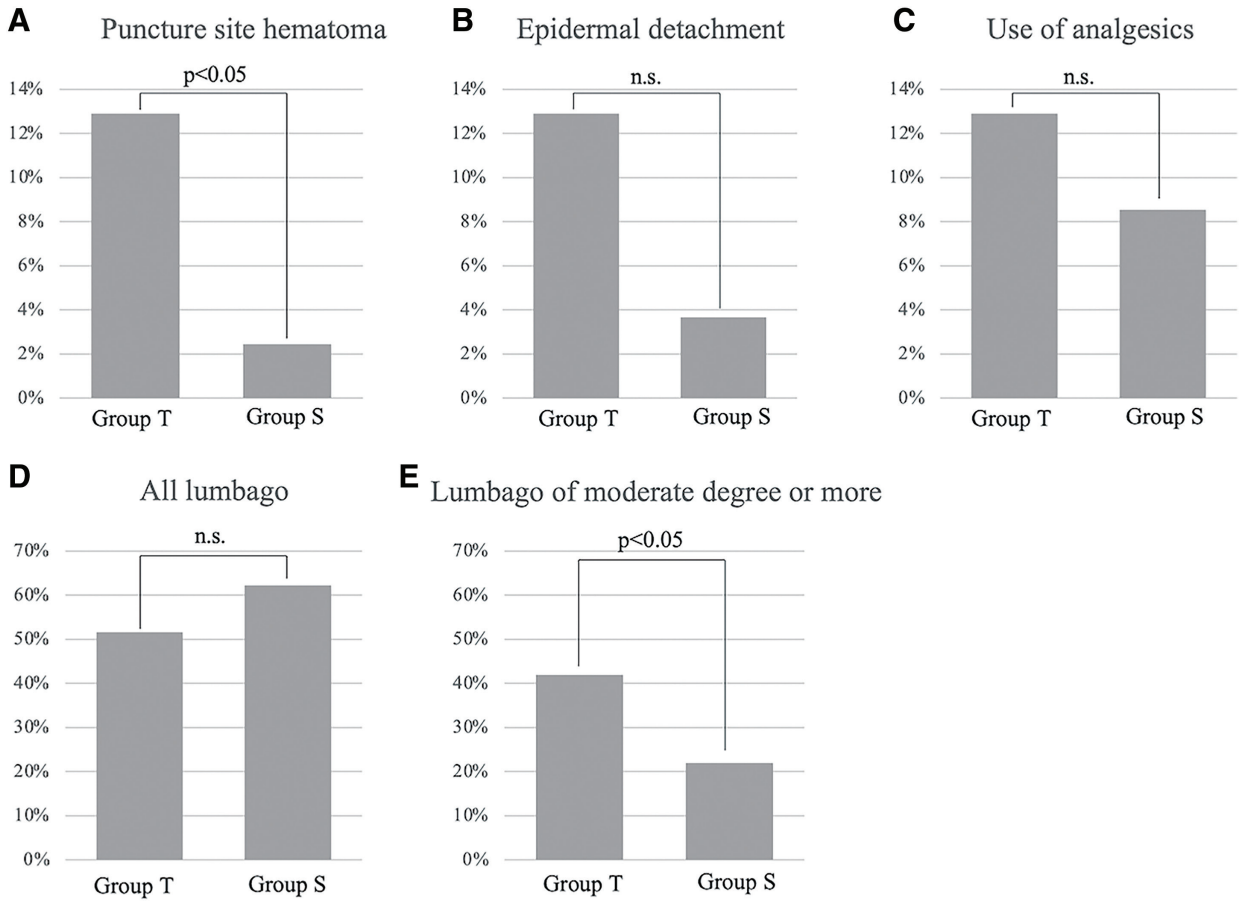

Fig. 2 A comparative analysis of the incidence rate of every adverse event between the two groups is depicted in bar graphs (**A**) through (**E**). Through statistical examination, significant differences were discovered in the frequency of moderate to severe levels of puncture site hematoma and lumbago. n.s.: not significant

of withdrawal from bed rest. The timing is usually set according to the ideas and traditions of the physicians at each institution. There are no reports on the correlation between bed rest restriction after endovascular treatment and the occurrence of puncture-site hematoma. Hemostatic devices were originally intended to enable early weaning, and the average time to start walking was 2.5 h, as suggested in the United States (US) Pivotal study by Exoseal[8]; this approach is mainly followed in our hospital. In Japan, some facilities provide a relatively long rest period for safety reasons. At our hospital, patients can walk at 12 hours or later in the morning after the treatment day. In addition, unlike the Pivotal study from the US, which used a 6-Fr sheath, 46.9% of our patients used an 8–9-Fr sheath, and the postoperative anticoagulant use rate was high at 54%. The reason for a prolonged bed rest restriction is that many patients have an increased risk of bleeding. However, prolonged rest restriction tends to cause lumbago and disuse syndrome in the elderly. Even if the treatment is less invasive, it dramatically impairs patient comfort; therefore, it is desirable to shorten the rest restriction as long as it does not compromise safety. Our traditional compression belt compresses the puncture site using a lateral pulling force. However, it has the disadvantage that the compression site tends to shift owing to the patient's body movements.

In contrast, the newly introduced Stanch Plus Belt is designed to compress the puncture site with a balloon and is less prone to displacement. The incidence of postoperative puncture site hematoma was meaningfully as low as 2.4%, suggesting that the belt is safe for patients to change position by themselves. The fact that there are fewer puncture site complications despite the large number of cases with sheaths larger than 8 Fr reinforces the safety of this belt. Even with the use of hemostatic devices such as the Exoseal and Angioseal, puncture site complications occur at a rate of 1%–5%,[1,2,8] and we have similarly reported a 5.9% rate of puncture site hematoma in a population with 91% hemostatic devices in the past.[6] The change in belt type alone significantly reduced puncture site hematoma

formation in this study. This suggests that continuous puncture site compression with the stanchion belt during postoperative rest was successful. The incidence of moderate or higher back pain was significantly decreased in the group using the newly introduced belt, suggesting that the ability to change positions by oneself after 4 h was effective in alleviating lumbago. In other words, the time until the patient is able to change positions in bed is more than 16 hours faster in the S group than that in the T group, resulting in less back pain.

The limitations of this study are as follows: the small number of patients treated, the retrospective nature of the study at one institution, the subjective definition of hematoma formation, and the fact that all patients were not evaluated for deep vein thrombosis. In addition, puncture site complications might not have increased in the conventional belt group, even if bed rest had been discontinued earlier, because of our institution's longer bed rest time compared to existing reports. Although this research suggested the usefulness of managing patients with balloon-pressurized belts, a survey with a uniform protocol at more centers is needed for further validation.

Conclusion

We modified the device to compress the puncture site after endovascular neurosurgery. The introduction of this new device resulted in a significant reduction in puncture site hematoma and moderate-to-severe lumbago, suggesting the usefulness of the Stanch Belt Plus for safety and patient comfort.

Disclosure Statement

Takashi Izumi received lecture fees from Medtronic Inc. and a consigned research fund from Kanaka Medix. The remaining authors have no conflict of interest related to this work.

References

1) Das R, Ahmed K, Athanasiou T, et al. Arterial closure devices versus manual compression for femoral haemostasis in interventional radiological procedures: a systematic review and meta-analysis. *Cardiovasc Intervent Radiol* 2011; 34: 723–738.
2) Koreny M, Riedmüller 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.
3) Sato M, Matsumaru Y, Sakai N, et al. JR-NET Study Group Affiliations. Detailed analysis of puncture site vascular complications in Japanese Registry of Neuroendovascular Therapy (JR-NET) and JR-NET2. *Neurol Med Chir (Tokyo)* 2014; 54(Suppl 2): 17–22.
4) Berkowitz SD, Stinnett S, Cohen M, et al. 2001. Prospective comparison of hemorrhagic complications after treatment with enoxaparin versus unfractionated heparin for unstable angina pectoris or non-ST-segment elevation acute myocardial infarction. *Am J Cardiol* 2001; 88: 1230–1234.
5) Sinnaeve PR, Alexander JH, Bogaerts K, et al. Efficacy of tenecteplase in combination with enoxaparin, abciximab, or unfractionated heparin: one-year follow-up results of the Assessment of the Safety of a New Thrombolytic-3 (ASSENT-3) randomized trial in acute myocardial infarction. *Am Heart J* 2004; 147: 993–998.
6) Tamari Y, Izumi T, Nishihori M, et al. Case-control study of postprocedural arterial puncture site hemorrhage after neuroendovascular treatment. *Nagoya J Med Sci* 2021; 83: 125–133.
7) Stone GW, Witzenbichler B, Weisz G, et al. Platelet reactivity and clinical outcomes after coronary artery implantation of drug-eluting stents (ADAPT-DES): a prospective multicentre registry study. *Lancet* 2013; 382: 614–623.
8) Wong SC, Bachinsky W, Cambier P, et al. A randomized comparison of a novel bioabsorbable vascular closure device versus manual compression in the achievement of hemostasis after percutaneous femoral procedures: the ECLIPSE (Ensure's Vascular Closure Device Speeds Hemostasis Trial). *JACC Cardiovasc Interv* 2009; 2: 785–793.