Journal of Clinical and Nursing Research, 2025, Volume 9, Issue 11
http://ojs.bbwpublisher.com/index.php/JCNR
Online ISSN: 2208-3693
Print ISSN: 2208-3685

A Case of Medical Damage Identification of Balloon Rupture and Retention Complicated with Acute Ischemic Stroke

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Abstract: Percutaneous transluminal angioplasty and endovascular stenting have become very important methods for the treatment of carotid artery stenosis and vertebrobasilar artery stenosis. In this case, the patient suffered from balloon rupture during the operation, with the tip of the balloon catheter retained and fixed on the stent in the subclavian artery segment, and subsequent acute ischemic stroke complicated by balloon rupture and retention. This is a rare type of device and operation-related complication. Through this case, a detailed analysis of the faults and deficiencies in the diagnosis and treatment of balloon rupture during interventional surgery is conducted, in order to provide a reference for solving similar problems.

Keywords: Balloon rupture; Stroke; Stent implantation; Medical damage

Online publication: Dec 5, 2025

1. Clinical case

1.1. Brief case introduction

Wu, male, 76 years old, was admitted to a local Grade A tertiary hospital on February 1 due to “dizziness for 3 weeks, aggravated for 1 day”. On February 8, he underwent cerebral angiography + percutaneous vertebral artery stenting + percutaneous vertebral artery balloon angioplasty. During the operation, the balloon ruptured, and the tip of the balloon catheter was retained and fixed on the stent in the subclavian artery segment. At 5 a.m. on February 9, the patient developed right limb weakness and decreased muscle strength. MRI showed multiple recent subcortical small infarcts in the brain tissue. The patient was discharged on February 27, with right limb weakness confirmed by the discharge examination. For the needs of medical dispute mediation, both the doctor and the patient entrusted a forensic identification institution to conduct a medical damage identification.

1.2. Summary of medical history

Wu was admitted to the hospital on February 1 due to "dizziness for 3 weeks, aggravated for 1 day".

(1) Past medical history

He underwent coronary artery bypass grafting in a hospital 11 years ago due to coronary heart disease, had diabetes for many years, and received cervical artery stenting in a hospital 8 years ago due to multiple cerebrovascular stenosis.

(2) Specialist examination

Conscious, with appropriate answers. Muscle strength of all limbs was Grade 4, without fasciculation or involuntary movement. Pathological reflexes were not elicited. Urination and defecation were normal.

Admission diagnosis including

(1) Post bilateral vertebral artery stenting

(2) Coronary atherosclerotic heart disease, post bypass grafting

(3) Type 2 diabetes mellitus

(4) Post bilateral subclavian artery stenting

(5) Dizziness to be investigated

Cerebral infarction? Posterior circulation ischemia?

(6) Cerebral atrophy

On February 4, Wu underwent "aortic arch angiography + cerebral angiography". Intraoperative findings included extensive cerebral arteriosclerosis, severe stenosis in the right vertebral artery stent, occlusion of the V4 segment of the right vertebral artery, severe stenosis of the C4 segment at the origin of the right internal carotid artery, moderate to severe stenosis of the right external carotid artery, and severe stenosis at the origin of the inferior trunk of the right middle cerebral artery. On February 8, the patient underwent "cerebral angiography + percutaneous vertebral artery stenting + percutaneous vertebral artery balloon angioplasty". During the operation, a balloon inflation device was used to slowly inflate the balloon to dilate the blood vessel and release the stent. However, the balloon dilation was still unsatisfactory. Angiography showed that there was still severe stenosis at the opening of the right vertebral artery, with a slight improvement compared with before. Cerebral angiography was performed, which showed that severe stenosis still existed at the origin of the right vertebral artery, the distal vascular opacification and blood flow velocity were slightly improved compared with before the operation, and the tip of the balloon catheter was retained and fixed on the stent in the subclavian artery segment.

The nursing record showed that the patient developed right limb weakness at about 5 a.m. on February 9. The right upper limb could still be lifted off the bed surface, and obvious flexion of the right lower limb was observed under pinprick. The muscle strength of the right upper limb was Grade 3-, the right lower limb was Grade 3-, and the left limb was Grade 4, without fasciculation or involuntary movement. The on-duty doctor was reported and instructed to observe. No changes in muscle strength were recorded in the examinations at 6 a.m. and 7 a.m. At 7:40 a.m., the patient's right muscle strength decreased to Grade 2. The on-duty doctor was reported, symptomatic treatment was given, and tirofiban solution was continuously pumped. The temporary medical order showed that "cranial plain scan and magnetic resonance functional imaging" were issued at 9:01 a.m. Head MRI showed that:

(1) Multiple recent subcortical small infarcts (acute phase, subacute phase) in the left frontal lobe, right temporal occipital lobe, right corona radiata, pons, right margin of the medulla oblongata, and right cerebellar hemisphere.

(2) Consider multiple recent cerebral infarcts in the left frontal lobe, right temporal occipital lobe, right corona radiata, pons, right margin of the medulla oblongata, and right cerebellar hemisphere.

On February 9, the patient underwent "cerebral angiography". During the operation, a snare was extended and slowly advanced upward in an attempt to snare the retained balloon from the lower end. However, multiple attempts failed to firmly snare the balloon. After withdrawing the snare, routine anteroposterior and lateral angiography was performed. The blood flow of the patient's right subclavian artery and right vertebral artery had no significant change compared with before this operation, and the broken end of the balloon was anchored on the stent in the right subclavian artery segment without displacement. After treatment, the patient's condition did not improve.

On February 27, the family requested voluntary discharge. Physical examination at discharge: Conscious, tired spirit, reluctant to speak and move, right limb weakness. Muscle strength of the right upper limb was Grade 1, the right lower limb was Grade 1+, and the left limb was Grade 3. Blood pressure was low. NIHSS score: 9 points (right sensation 1 + right limb 4 + 4), mRS: 5 points.

1.3. Focus of dispute

The focuses of dispute in this case are:

(1) Whether the medical institution's disposal measures after the balloon rupture during the operation on February 8 were in line with specifications

(2) Whether the medical institution's disposal was timely after the postoperative occurrence of limb weakness

(3) Whether the medical institution fully fulfilled the informed consent obligation during the diagnosis and treatment activities

1.4. Identification opinions

The medical institution had faults in the diagnosis and treatment activities:

(1) Failed to timely remove the broken balloon

(2) Failed to timely recheck muscle strength and perform head CT or MRI examination

(3) Insufficient preoperative informed consent

(4) Irregular medical record writing. The analysis holds that there is a direct causal relationship between the medical institution's faulty acts and the damage consequences suffered by Wu

2. Discussion

2.1. On the disposal of intraoperative broken balloon

The 76-year-old patient in this case underwent "cerebral angiography + percutaneous vertebral artery stenting + percutaneous vertebral artery balloon angioplasty" due to illness. During the operation, the surgical device (balloon) ruptured and remained in the blood vessel. According to clinical routines, the broken balloon catheter should be removed as soon as possible [1]. In particular, the patient had underlying diseases such as diabetes mellitus and coronary heart disease. Intraoperative findings included severe stenosis in the right vertebral artery stent, occlusion of the V4 segment of the right vertebral artery, multiple stenosis of the right internal and external carotid arteries, and severe stenosis at the origin of the inferior trunk of the right middle cerebral artery. The local blood flow after this operation was not improved, so the possibility of postoperative neurological complications

was extremely high. However, medical record data showed that after the balloon rupture during the operation, the medical institution only fixed it on the stent in the subclavian artery segment and did not take measures to remove the broken balloon. Even in the first postoperative course record on February 8, there was no subsequent treatment plan by the medical institution for the disposal of the retained broken balloon. It was not until the patient suffered an acute ischemic stroke on February 9 that the medical institution considered surgical removal of the retained balloon. It can be seen that during the diagnosis and treatment process, the medical institution failed to timely take measures to remove the retained balloon, which was inconsistent with clinical routines and constituted a fault [1].

Despite the unprecedented development of treatment equipment and technology, various intraoperative and postoperative complications of percutaneous transluminal angioplasty and endovascular stenting still occur from time to time. The "Guidelines for Interventional Diagnosis and Treatment of Carotid Artery Stenosis in China" issued by the National Health Commission points out that the complications of carotid artery stenting include not only puncture site complications, but also neurological complications caused by embolism, thrombosis and cerebral hemorrhage, as well as injuries to blood vessels at the lesion site, operation path blood vessels and distal blood vessels, cardiovascular events and death, and in-stent restenosis. Research results by Wholey et al. show that within 30 days after carotid artery stenting, the incidence of transient ischemic attack is 3.07%, minor stroke is 2.14%, and major stroke is 1.20% [2].

In this case, the intraoperative balloon rupture with the tip of the balloon catheter retained and fixed on the stent in the subclavian artery segment is a rare type of device and operation-related complication, and there are currently few relevant reports in domestic literature. Based on current clinical experience analysis, the causes of catheter and guidewire rupture may be related to problems with the quality of the equipment or rough surgical operation. It may also be related to the patient's own multiple severe arterial stenosis, as well as the performance of bilateral subclavian artery and vertebral artery stenting, especially the severe stenosis in the right vertebral artery stent, which led to high surgical complexity and difficulty. In addition, relevant reports have pointed out that it is relatively difficult to remove the broken catheter and guidewire, which requires targeted improvements to surgical instruments and methods on the basis of conventional operations. This has reference value for the clinical disposal of relevant situations [3,4].

It is worth noting that Article 1223 of the Civil Code stipulates: "If a patient is harmed due to defects in drugs, disinfection products, or medical devices, or the transfusion of unqualified blood, the patient may claim compensation from the drug marketing authorization holder, producer, or blood supply institution, or from the medical institution. If the patient claims compensation from the medical institution, the medical institution has the right to recover compensation from the liable drug marketing authorization holder, producer, or blood supply institution after making compensation." If the balloon catheter rupture in this case is caused by product quality problems, the medical institution has the right to recover compensation from the liable producer after compensating the patient. However, in practice, medical institutions often become the subject of compensation liability due to problems such as the difficulty in accurately identifying medical product defects and the relative difficulty in medical product identification [5].

After the balloon catheter rupture in this case, it could not be removed even after surgery, making medical product identification impossible, and thus the product defect problem could not be determined. At present, there is no standardized handling process for the identification and rights protection related to medical damage caused by medical product quality, which still needs to be studied and improved by experts and scholars in the industry.

2.2. Discussion on postoperative duty of care

According to clinical routines, postoperative neurological function assessment should be conducted in a timely manner and compared with that before treatment to determine the therapeutic effect and promptly detect any new neurological symptoms. When new neurological damage is suspected, cranial CT or MRI scanning should be performed immediately [6].

In this case, the 76-year-old patient underwent cerebrovascular interventional therapy on February 8, during which the balloon ruptured and remained in the blood vessel. As a foreign body in the human body, a broken and retained balloon can activate the coagulation mechanism. In addition, the fixation of the balloon on the stent changes the local hemodynamics of the blood vessel after surgery, reducing local blood flow shear stress and making it easy for exogenous thrombi to attach to the stent. The risk of complications such as thrombosis and embolism is significantly higher than that of ordinary people. Considering the patient's underlying diseases such as diabetes mellitus and coronary heart disease, as well as complex lesions including severe stenosis in the right vertebral artery stent and occlusion of the V4 segment of the right vertebral artery at the surgical site, the medical institution should have closely monitored the patient's condition changes after surgery, conducted thorough neurological function assessments, prepared risk predictions and response measures, and provided corresponding diagnosis and treatment in a timely manner when complications might occur to avoid serious damage consequences.

However, medical record data show that the patient suddenly developed unilateral limb weakness at 5 a.m. the day after surgery, indicating new neurological damage. The medical institution should have considered the possibility of acute ischemic stroke, conducted timely systematic physical examination and cranial CT or MRI scanning for differential diagnosis, and provided a basis for subsequent treatment plans. But nursing records indicate that the medical institution did not recheck the patient's muscle strength until 7:40 a.m., 2 hours and 40 minutes after the onset of right limb weakness, and did not perform cranial MRI until 9:01 a.m. It is evident that when the patient showed signs of neurological damage such as unilateral muscle strength decline, the medical institution failed to fulfill its duty of care during diagnosis and treatment, did not timely recheck muscle strength or perform cranial CT/MRI to confirm the diagnosis, which constituted a fault.

2.3. Causal relationship analysis

Preoperatively, the medical institution did not mention the possibility of balloon rupture in the preoperative discussion or informed consent, indicating that it failed to predict this complication before surgery. Intraoperatively, given the patient's high-risk factors including a history of coronary artery bypass grafting, diabetes mellitus, and cerebrovascular stenosis interventional surgery, as well as the persistent severe stenosis of the right vertebral artery after balloon angioplasty, the medical institution failed to promptly remove the broken and retained balloon, leading to its prolonged retention in the blood vessel, which could induce severe complications such as acute ischemic stroke.

Additionally, postoperatively, when right limb weakness occurred, the medical institution did not timely recheck muscle strength or perform cranial CT/MRI, delaying the timely detection and diagnosis of the condition, which was not conducive to alleviating the damage consequences. In summary, the medical institution had multiple faults in the perioperative management, and there was a direct causal relationship between these faulty acts and the damage suffered by Wu.

On the other hand, considering the patient's advanced age of 76, underlying diseases such as diabetes mellitus

and coronary heart disease, history of cerebrovascular stenosis interventional surgery, as well as complex lesions at the surgical site (severe stenosis in the right vertebral artery stent and occlusion of the V4 segment of the right vertebral artery), the interventional surgery involved complex vascular lesions with high difficulty and increased risks. Furthermore, although the medical institution attempted to remove the broken balloon the next day, multiple attempts failed, indicating the certain difficulty in removing such broken balloons. Therefore, there was also a direct causal relationship between the patient's own underlying diseases, medical risks, and the resulting damage.

3. Conclusion

There are few reports on device-related complications of vascular interventional surgery in relevant literature at home and abroad, and there is a lack of mature treatment measures. This indicates that such situations have not attracted the attention of the academic community and are likely to be overlooked by clinicians in terms of potential risks during diagnosis and treatment. Although rare, the rupture of guidewires and catheters, stent detachment, and other complications will not only increase the difficulty and risk of surgery but also seriously affect the clinical prognosis of patients. Therefore, through this case report, the authors hope to conduct in-depth research on the causes, mechanisms, and response measures, so as to attract the attention of clinical experts and scholars to relevant content and provide reference for clinical practice. On the other hand, it reminds clinicians not to ignore the occurrence of relevant complications during diagnosis and treatment. They should conduct sufficient risk assessment and formulate emergency response plans during the perioperative period, take timely and effective response measures when similar conditions occur, and fully fulfill relevant legal obligations such as the obligation of informed consent and duty of care to avoid or reduce damage consequences.

Funding

The Open Project of the Key Laboratory of Forensic Genetics of the Ministry of Public Security (Project No.: 2024FGKFKT08); Guangdong Provincial Forensic Science of Evidence Materials (Nantian), Engineering Technology Research Center Open Projects Fund (Project No.: ETRC202302)

Disclosure statement

The authors declare no conflict of interest.

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