Recommendations for the prevention of recurrence of medical accidents
Number 18

Analysis of Deaths Related to Bleeding Due to Hip Surgery

September 2023

Medical Accident Investigation and Support Center
(Japan Medical Safety Research Organization)

Materials related to the recommendations
- Video explaining the recommendations
- Anatomy that should be understood for total hip arthroplasty (video)
- Checklist for verification of bleeding risk and making preoperative preparations (sample)

The Purpose of “Recommendations for the Prevention of Recurrence”

These recommendations are provided as information based on the medical accident investigation reports from the concerned medical institutions. Among those reports, the Medical Accident Investigation and Support Center accumulates similar cases, investigates and analyzes their common or similar points, and provides them as recommendations.

These recommendations should be regarded as recurrence prevention measures focusing on the importance of avoiding accidents that may result in death, and should be distinguished from the “Guidelines” issued by the government and academic societies. So, this leads to the fact that the recommendations do not set any limit to the discretion of healthcare professionals, nor impose any new obligations or responsibilities.

Based on these considerations, we hope these recommendations will be widely used, taking into account comprehensively various situations such as the user’s medical decision-making, each patient’s condition and age, the wishes of the patient and family, as well as the medical institution’s practice systems and size.

In addition, these recommendations are to provide information to avoid similar deaths, to prevent recurrence, and to ensure patient safety. It is based on the provisions of Medical Care Act, and is not intended to be used as a means for resolving disputes.

In Publishing the Recommendations for the Prevention of Recurrence of Medical Accidents (Number 18)

Morito Monden
Chair of the Board of Directors
Japan Medical Safety Research Organization

Based on the Medical Accident Investigation System launched in October 2015, the Medical Accident Investigation and Support Center (ISC) of the Japan Medical Safety Research Organization (Medsafe Japan) has been working with every effort to promote patient safety, to prevent recurrence of medical accidents, and to improve medical quality.

Along with the increasing advancement and diversification of the medical environment in recent years, medical institutions strive every day to prevent serious medical accidents from occurring. However, serious events do in fact occur in medical settings, at times resulting in the unexpected death of patients. Such cases have been reported to the ISC. Since the system's launch seven years and 11 months ago, more than 2,300 in-hospital investigation reports have been sent to the ISC. Based on these reports, to date we have published 17 recommendations as "Recommendations for the Prevention of Recurrence of Medical Accidents."

We, ISC, have published our eighteenth report compiled to prevent recurrence of medical accidents. As the theme of analysis, we decided to take up the cases of deaths related to bleeding due to hip surgery. Hip surgery has been performed at medical institutions of various scales in Japan. While it rarely results in death, hip surgery is often carried out in older adults with reduced reserve capacity and has the risk of damaging blood vessels that cannot be confirmed by eye in the surgical field. The recommendations in this report have therefore been compiled in view of the seriousness of deaths resulting from hip surgery-related fatal accidents. The number of target cases that were reported under the Medical Accident Investigation System was 20.

The purpose of the Medical Accident Investigation System is to promote safety in medical settings, and providing safe medical care requires widespread initiatives and efforts. "Recommendations for the Prevention of Recurrence of Medical Accidents" have been compiled after examining the cases of death reported to the ISC based on the expertise of that time and in terms of patient safety. The purpose is to "avoid unexpected deaths." These recommendations should be distinguished from guidelines published by academic societies and other organizations, which are examined based on broad knowledge, and do not limit the discretion of health-care professionals or impose any obligations on them. While each medical institution differs in environment and circumstances including its size and structure, we hope that these recommendations will be widely utilized in medical institutions to avoid accidents associated with bleeding due to hip surgery. Additionally, we will continue to review our recommendations to ensure that they aid clinical practice, and will remain committed to providing information that reflects actual medical settings, based on reported cases.

Finally, we would like to express our sincere gratitude to the medical institutions and bereaved families who cooperated in providing in-hospital investigation reports and offering additional information, as well as to the experts of the analysis subcommittee who analyzed the cases in detail and explored the measures to prevent recurrence, for their understanding and cooperation.

Recommendations for the Prevention of Recurrence of Medical Accidents (Number 18)

Analysis of Deaths Related to Bleeding Due to Hip Surgery

<Characteristics of the 20 target cases>

- Low body weight was noted in 14 cases (30-39 kg in five cases and 40-49 kg in nine cases).
- In nine cases, vascular injuries associated with surgical procedures such as drilling and screwing occurred (including suspected cases).
- In all cases, a shock index was calculated to be above "1" through the clinical course.
- Fifteen cases resulted in death within 24 hours post-surgery.

[Ascertaining bleeding risk and making preoperative preparations]

Recommendation 1

In hip surgery, the amount of blood loss is likely to increase depending on the site of fracture, surgical procedures such as revision surgery, and due to decreased blood clotting ability. Individuals with advanced age, a low body weight, anemia, and a low albumin level have reduced reserve capacity and are likely to develop shock. Therefore, these risks should be ascertained before surgery, and preoperative preparation for bleeding should be made to prevent bleeding from progressing to shock.

[Setting approximate time points of starting blood transfusion to be shared before surgery]

Recommendation 2

Approximate time points of starting the preparation for blood transfusion and initiating administration for individual patients (e.g., the amount of blood loss and hemoglobin level) should be specified in consideration of the amount of blood loss anticipated from surgical procedures, circulating blood volume calculated based on the patient's weight, and the system to supply blood products for transfusion in the hospital. The selected approximate time points and blood transfusion volume to be prepared should be shared during the time-out before surgery.

[Evaluating risk for damaging blood vessels that are difficult to identify visually]

Recommendation 3

There is a risk of damaging blood vessels when inserting a spinning device such as a drill and screw. Vascular injuries caused by spinning devices often occur on the opposite side of the screw insertion site in the femur for femoral osteosynthesis and in the acetabulum inside the pelvis for total hip arthroplasty. Therefore, it should be noted that bleeding is difficult to identify visually in the surgical field.

[Assessment of the circulating blood volume during surgery]

Recommendation 4

When hypotension, tachycardia, or other relevant conditions persist even after the infusion, transfusion, or administration of vasopressors during surgery, there may be bleeding that cannot be identified visually. The shock index should be checked, and if it is above "1," hemorrhagic shock should be suspected. All team members should take a time-out during surgery to assess the circulating blood volume and take action accordingly.

[Imaging review before leaving the operating room]

Recommendation 5

When hypotension or tachycardia during surgery persists even after completing the surgery, there may be a pelvic vascular or a deep femoral artery injury even if the amount of blood loss during surgery is small. If hypotension or other relevant conditions persist, the implementation of computed tomography (CT) or ultrasonography should be considered to check for bleeding before the patient is removed from the operation room.

[Prompt actions for postoperative hemorrhagic shock]

Recommendation 6

After surgery, the signs of shock such as hypotension, tachycardia, oliguria, and tachypnea should be monitored. If there is an increase in the shock index or the amount of blood loss, femoral swelling, low back pain, or abdominal pain, the patient should be closely checked for hemorrhagic shock. The circulating blood volume should be checked, and an investigation into the cause and treatment should be started.

The full text of Recommendations No. 18, "Analysis of Deaths Related to Bleeding Due to Hip Surgery" as well as related materials, including the explanatory video, are available on the website of the Medical Accident Investigation and Support Center.
All materials can be downloaded. Please use them for workshops.

Expert Analysis Subcommittee, Committee for Prevention of Recurrence/Medical Accident Investigation and Support Center
September 2023

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[Definition of terms used in this document]

Hip surgery	Hip surgery refers to osteosynthesis (including intramedullary nailing) or total hip arthroplasty/prosthesis replacement (insertion) for proximal femoral (femoral neck, trochanteric, or subtrochanteric) fractures, hip-joint diseases or trauma such as hip osteoarthritis.
Shock index	An index used for the initial assessment of hemorrhagic shock that is a value calculated from the “heart rate divided by systolic blood pressure.” The criteria for normal ranges are 0.5 to 0.7. For details, see Recommendation 4 on page 29.

1. Introduction

1) About hip surgery

Osteoarthritis associated with aging or a fall injury often involves hip fracture, and it is treated with surgery in many cases. The surgical procedures performed are invasive osteosynthesis or prosthetic replacement arthroplasty (including prosthesis insertion) for proximal femoral fracture and prosthetic replacement arthroplasty for osteoarthritis.

According to the "Annual Report 2021 of the Japanese Orthopaedic Association National Registry (JOANR)," invasive osteosynthesis for proximal femoral (femoral neck, trochanteric, or subtrochanteric) fractures was carried out in approximately 100,000 patients per year. In age distribution, the most common age group was patients in their 80s, followed by those in their 90s. Hip replacement arthroplasty (including prosthesis insertion) was conducted in 127,650 patients. The most common age group for osteoarthritis was patients in their 70s and for proximal femoral fracture, it was those in their 80s.[1)] This shows that both surgical procedures are mainly performed in older adults. In addition, hip-joint diseases and injuries including proximal femoral fractures are common, so their surgery has been performed at medical institutions of various scales in Japan. Difficulty in walking due to hip-joint diseases greatly decreases the quality of life of older adults, which adversely affects their life prognosis. With the current rapid aging of the population, the number of patients undergoing hip surgery is anticipated to grow further in Japan.

Hip surgery is relatively highly invasive, except for some of its procedures, so it is a significant physical burden for older adults, who have reduced reserve capacity and various comorbidities. Risks include acetabular or femoral reaming (an operation to drill a hole in the bone to insert an artificial joint) for hip arthroplasty and an increase in bleeding during or after surgery due to exposure of the fracture site for osteosynthesis. In addition, there is a risk of a vascular injury in the pelvis or the femur due to drilling or the use of screws for the installation or fixation of implants and placing a retractor to secure a deep surgical field. An increase in intra- or post-operative bleeding based on body weight makes circulatory dynamics unstable. Occasionally, there is a risk of hemorrhagic shock resulting in death, particularly in older adults.

The Expert Analysis Subcommittee analyzed 20 cases of which the causes of death were determined to be multiple organ failure due to hemorrhagic shock or massive bleeding among deaths associated with hip surgery that have been reported to the Medical Accident Investigation and Support Center (hereinafter referred to as ISC). After the analysis, we publish pre-, intra- and post-operative measures to avoid deaths related to bleeding due to hip surgery as recommendations.

2) Background of the establishment of the Expert Analysis Subcommittee and its significance

To prevent recurrence of similar medical accidents, the Committee for Prevention of Recurrence (see page 42) at the ISC selects the subject (theme) of analysis from the cases of accidents reported to the ISC. Then, the Committee establishes an Expert Analysis Subcommittee for each theme (see page 42) that consists of medical specialists in the theme and prepares recommendations.

Generally, the probability of a vascular injury occurring during hip surgery is considered to be low,[2)3)] but there were several cases of vascular injuries that were identified post hoc among the target cases. Hip surgery has an anatomical characteristic in which vascular injuries are difficult to find visually. Furthermore, it is performed at many medical institutions of various sizes. Thus, all medical institutions carrying out hip surgeries are required to handle perioperative bleeding. In order to take measures to prevent the recurrence of deaths due to bleeding based on these target cases, we have established the Expert Analysis Subcommittee.

2. Methods of analysis

1) Extraction of target cases

Of 2,083 in-hospital investigation reports on medical accidents submitted to the ISC during the period from October 2015 to the end of June 2022, 25 were cases of deaths for which the relation between bleeding due to hip surgery and death could not be denied.

Of the 25 cases, five cases of death, of which the causes were assumed to be associated with complications such as embolism and infection other than bleeding, were excluded from the target cases, and the remaining 20 cases, of which the causes of death were determined to be multiple organ failure attributable to hemorrhagic shock or massive bleeding, were selected by the Expert Analysis Subcommittee as the target cases for analysis.

2) Collecting and sorting of information on target cases

The Expert Analysis Subcommittee analyzed the target cases based on the information presented in the in-hospital investigation reports notified to the ISC. Regarding some ambiguous parts of the reports, additional information was collected to the extent possible with cooperation of the reporting institutions. Information collected was organized according to the investigation items checklist (see Section 8 “Materials”).

3) Meetings of the Expert Analysis Subcommittee

○ First meeting: August 5, 2021
○ Second meeting: November 1, 2021
○ Third meeting: February 3, 2022
○ Fourth meeting: June 2, 2022
○ Fifth meeting: September 28, 2022
○ Sixth meeting: May 9, 2023

• In addition, opinions were exchanged through electronic media and other means.

3. Overview of the target cases

The case overview was prepared by the Expert Analysis Subcommittee based on the in-hospital investigation reports and additional information.

((1) Patient background characteristics, (2) diagnosis/surgical procedure, (3) intraoperative course, the amount of blood loss during surgery, (4) process after returning to the ward, (5) cause of death and diagnostic imaging at the time of death (Autopsy imaging; hereinafter referred to as "Ai"); the status and result of autopsy are presented.)

Case 1 Femoral osteosynthesis

(1) The patient was in his/her 80s, weighing 40-49 kg, with a platelet count in the 80,000s/μL.

(2) Osteosynthesis was performed for femoral neck fracture on the following day of the injury.

(3) There was a small amount of arterial bleeding during drilling in side stop screws. The doctor attempted to stop the bleeding using packing by screw insertion. The blood pressure dropped to 70-79 mmHg, so a vasopressor was administered a few times. The amount of blood loss during surgery was approximately 110 mL. The blood pressure when the patient left the room was 160-169 mmHg. The heart rate was 70-79 beats/min.

(4) The blood pressure decreased to 60-69 mmHg one hour after returning to the ward so the patient was transferred to the coronary care unit (CCU). The hemoglobin (Hb) level was 11-11.9 g/dL, and the blood pressure was 100-109 mmHg, so the patient was determined to have vagal reflex. Thereafter, the blood pressure temporarily decreased. At approximately 11 hours after returning to the ward, the blood pressure was 50-59 mmHg, the breathing was weak, and the Hb level was 9-9.9 g/dL. Thus, bleeding was suspected, and abdominal ultrasonography was carried out, but the bleeding site was unknown. Internal hemorrhage and swelling on the opposite side of the wound (inner thigh) were noted. The blood pressure was not measurable. The patient died about 12 hours after returning to the ward.

(5) The cause of death was hemorrhagic shock due to vascular injury. Ai: present(hematoma in the femoral area). Autopsy: absent.

Case 2 Femoral osteosynthesis (revision surgery/bilateral)

(1) The patient was in his/her late 70s, weighing 40-49 kg, with chronic renal failure, on dialysis therapy, who had undergone bilateral prosthesis replacement.

(2) Bilateral osteosynthesis was performed for bilateral periprosthetic fractures about one week after the injury. The patient had anemia so red blood cells were administered before surgery.

(3) Continuous administration of a vasopressor was initiated from the start of surgery. The blood pressure was 70-79 mmHg. The vasopressor was additionally administered a few times. The amount of blood loss during surgery was approximately 540 mL. The Hb level was 9-9.9 g/dL when the patient left the room. The blood pressure was 110-119 mmHg, and the heart rate was 80-89 beats/min.

(4) Red blood cells were administered about one hour after returning to the intensive care unit (ICU). Tachypnea was present. About three hours after returning to the ICU, gauze was added because there was bleeding from the wound spreading to the towel under the body. The percutaneous arterial oxygen saturation (SpO_2) was not measurable. Peripheral coldness occurred, and continuous administration of a vasopressor was started. About five hours after returning to the ICU, the blood pressure could be inadequately measured. The Hb level was 11-11.9 g/dL. Contrast-enhanced CT showed no arterial bleeding. The wound bleeding persisted. Fluid replacement and red blood cells were administered by bolus injection. The total amount of absorbed blood in the gauze was approximately 1,000 g. The Hb level was 5-5.9 g/L. The patient died about 20 hours after returning to the ICU.

(5) The cause of death was hemorrhagic shock. Ai: absent. Autopsy: present (femoral bleeding).

Case 3 Femoral osteosynthesis (revision surgery)

(1) The patient was in his/her 90s, weighing 40-49 kg, with cerebral infarction. The patient had undergone osteosynthesis for femoral trochanteric fracture and was on an antithrombotic drug (without interruption).

(2) Osteosynthesis (lag screw exchange) was performed for femoral head perforation after osteosynthesis.

(3) The scarring was remarkable, so the removal of internal fixation materials took time. The blood pressure decreased to 70-79 mmHg so a vasopressor was continuously administered. The Hb level was 6-6.9 g/dL. The amount of blood loss during surgery was approximately 1,140 mL. Red blood cells were ordered immediately after the surgery, but they had to be obtained from another region. When the patient left the room, the blood pressure was 140-159 mmHg and the heart rate was unknown.

(4) After returning to the ward, toe cyanosis and peripheral coldness were noted so the continuous administration of a vasopressor was started. Approximately one hour after returning to the ward, the Hb level was 3-3.9 g/dL, blood pressure was 50-69 mmHg, there were thigh swelling and internal hemorrhage, and cyanosis was spreading. Approximately two hours after returning to the ward, the blood pressure could not be measured, and jaw breathing was noted, so tracheal intubation was carried out. Approximately four hours after returning to the ward, red blood cells were administered. There was approximately 200 mL of bleeding from the wound. Approximately seven hours after returning to the ward, the patient died.

(5) The cause of death was hemorrhagic shock. Ai: absent. Autopsy: absent.

Case 4 Femoral osteosynthesis (revision surgery)

(1) The patient was in his/her 80s, weighing 40-49 kg, and had undergone prosthesis replacement for femoral neck fracture.

(2) Osteosynthesis was performed for periprosthetic fracture approximately three weeks after the injury.

(3) The amount of blood loss was 630 mL, and the blood pressure was 70-79 mmHg soon after the start of surgery. Red blood cells were administered by bolus injection, and the blood pressure was 110-119 mmHg. Thereafter, a vasopressor was administered a few times, but the blood pressure was 50-59 mmHg, and the heart rate was 110-119 beats/min. The amount of blood loss during surgery was 1,550 mL. At the end of surgery, the Hb level was 13-13.9 g/dL. When the patient left the room, the blood pressure was 90-99 mmHg and the heart rate was 100-109 beats/min.

(4) Approximately one hour after returning to the ward, the Hb level was 8-8.9 g/dL and the blood pressure decreased to 60-69 mmHg, so continuous administration of the vasopressor was started. There was wound bleeding and sweating in the whole body was noted. Approximately four hours after returning to the ward, red blood cells were administered. The blood pressure at the time was 110-119 mmHg and the heart rate was 100-109 beats/min. Bleeding persisted. Approximately 12 hours after returning to the ward, breathing arrested, and tracheal intubation was carried out. Disseminated intravascular coagulation (DIC) occurred, and the patient died Day 2 after surgery.

(5) The cause of death was hemorrhagic shock. Ai: absent. Autopsy: absent.

Case 5 Femoral osteosynthesis

(1) The patient was in his/her 90s, weighing 40-49 kg, with arteriosclerosis obliterans. The patient was on an antithrombotic drug (with interruption).

(2) Osteosynthesis (using intramedullary nailing) was performed for femoral trochanteric fracture three days after the injury.

(3) There was no blood loss during surgery. At the end of the surgery, when the traction position was changed to supine, the blood pressure was 50-59 mmHg, and the patient's consciousness level decreased. Fluid loading and a vasopressor were given. The blood pressure at the time was 90-99 mmHg and the heart rate was 110-119 beats/min. The Hb level was 14-14.9 g/dL. Thigh swelling was noted so it was compressed with an elastic bandage. When the patient left the room, the blood pressure was 110-119 mmHg and the heart rate was 100-109 beats/min.

(4) After returning to the emergency unit, the hypotension was determined to be attributable to dehydration; thus, fluid loading was given. Vital signs were unstable so a vasopressor was continuously administered. The Hb level was 7-7.9 g/dL, so red blood cells were administered. The swelling of the affected thigh increased. Approximately one hour after returning to the emergency unit, contrast-enhanced CT showed a deep femoral artery injury. Cardiopulmonary arrest temporarily occurred during embolization. Red blood cells, etc., were administered, but bleeding from the puncture site persisted. The patient died approximately 13 hours after returning to the room.

(5) The cause of death was hemorrhagic shock due to vascular injury. Ai: absent. Autopsy: absent.

Case 6 Femoral osteosynthesis

(1) The patient was in his/her 80s, weighing 40-49 kg, with atrial fibrillation. The patient was on an oral antithrombotic drug (without interruption). The platelet count was in the 90,000s/μL.

(2) Osteosynthesis (using intramedullary nailing) was performed for femoral trochanteric fracture on the following day of the injury. The Hb level was 9-9.9 g/dL, and red blood cells were administered immediately before surgery.

(3) After the patient was placed in a traction position, the blood pressure decreased. A vasopressor was administered, and it was determined that the patient was operable. During the surgery, hypotension was noted, and the heart rate was 100-109 beats/min. The amount of blood loss during surgery was 40 mL. Echocardiography after wound closure showed right ventricular enlargement. When the patient left the room, the Hb level was 8-8.9 g/dL, the blood pressure was 90-99 mmHg, and the heart rate was 130-139 beats/min. Contrast-enhanced CT showed no pulmonary embolism or hematoma around the femur.

(4) Approximately 30 minutes after returning to the high care unit (HCU), the Hb level was 5-5.9 g/dL. The blood pressure was 60-69 mmHg, and the continuous administration of a vasopressor was started. Approximately one hour after returning to the HCU, wound bleeding was noted, so it was compressed and fixed. Approximately two hours after returning to the HCU, red blood cells were administered. The SpO_2 could not be measured, and the pupils dilated. Approximately three hours after returning to the HCU, the patient died.

(5) The cause of death was hemorrhagic shock. Ai: absent. Autopsy: absent.

Case 7 Femoral osteosynthesis

(1) The patient was in his/her 80s, weighing 30-39 kg, with rheumatoid arthritis. The patient was on low-molecular-weight heparin (interruption unknown) for chronic DIC. The platelet count was in the 40,000s/μL.

(2) Conservative treatment was given for femoral trochanteric fracture, and platelet concentrate was administered. The platelet count increased to the 130,000s/μL, and osteosynthesis (using intramedullary nailing) was performed approximately three weeks after the injury.

(3) The blood pressure decreased to 80-89 mmHg so a vasopressor was administered a few times. The amount of blood loss during surgery was 150 g. When the patient left the room, the blood pressure was 170-179 mmHg and the heart rate was 140-149 beats/min.

(4) Approximately 30 minutes after returning to the ward, bleeding from the wound persisted. Blood pressure was 80-89 mmHg and the Hb level was 6-6.9 g/dL. Red blood cells were administered, and the blood pressure was 100-109 mmHg. Approximately five hours after returning to the ward, the patient was transferred to the ICU due to the persistent bleeding and decrease in blood pressure. The patient died approximately 10 hours after returning to the ward.

(5) The cause of death was hemorrhagic shock. Ai: absent. Autopsy: absent.

Case 8 Femoral osteosynthesis

(1) The patient was in his/her 80s, weighing 30-39 kg, with hepatic cirrhosis.

(2) Osteosynthesis (using intramedullary nailing) was performed for femoral trochanteric fracture on the day of injury. The Hb level was 7-7.9 g/dL. The administration of red blood cells was started immediately before surgery.

(3) When a drill was removed from the femoral foramen, arterial bleeding was noted. The skin incision was extended, and the bleeding site in the inner thigh was compressed for hemostasis. The blood pressure decreased to 60-69 mmHg so red blood cells were administered by bolus injection. The bleeding site was filled with a hemostatic agent. After confirming that there was no active bleeding, fluid loading and a vasopressor were given, and the surgery was continued. The blood pressure was maintained at 100-109 mmHg. The amount of blood loss during surgery was approximately 500 g. After wound closure, the affected thigh was compressed with an elastic bandage. When the patient left the room, the Hb level was 4-4.9 g/dL, the blood pressure was 120-129 mmHg, and the heart rate was 80-89 beats/min.

(4) Wound bleeding was noted immediately after returning to the ICU. The Hb level was 4-4.9 g/dL, and the administration of red blood cells and the continuous administration of a vasopressor was started. Approximately four hours after returning to the ICU, the blood pressure decreased to 60-69 mmHg, and the dose of the vasopressor was increased. Approximately five hours after returning to the ICU, the bleeding increased so the gauze was exchanged. The amount of drained blood was small. The blood pressure stayed at 60-79 mmHg; thus, a vasopressor was added. Fresh frozen plasma was administered, but the light reflex disappeared approximately nine hours after returning to the ICU. The patient died approximately 13 hours after returning to the ICU.

(5) The cause of death was hemorrhagic shock due to vascular injury (suspected). Ai: present (hematomas around the femur and in the buttocks). Autopsy: absent.

Case 9 Femoral osteosynthesis

(1) The patient was in his/her early 70s, weighing 30-39 kg. The platelet count was in the 50,000s/μL and the Hb level was 5-5.9 g/dL.

(2) Conservative treatment was given for femoral trochanteric fracture, and red blood cells were administered. The Hb level increased to 9-9.9 g/L, and osteosynthesis (using intramedullary nailing) was performed approximately two weeks after the injury.

(3) It was difficult to reposition the femur and insert lag screws into an appropriate position so the reduction procedure was carried out a few times, and nail positions were adjusted. Approximately 30 minutes after the start of surgery, the amount of blood loss was 200 mL, the blood pressure was 50-59 mmHg, and the heart rate was 110-119 beats/min. A vasopressor was administered a few times, and the blood pressure was 70-89 mmHg. The amount of blood loss during surgery was 630 mL. When the patient left the room, the blood pressure was 80-89 mmHg, and the heart rate was 140-149 beats/min.

(4) When the patient returned to the ward, the Hb level was 6-6.9 g/dL, and thigh swelling was noted. Approximately 30 minutes after returning to the ward, the patient's level of consciousness decreased, and the heart rate was 150-179 beats/min. Fluid loading and the continuous administration of a vasopressor were started. Abdominal ultrasonography showed inferior vena cava collapse. Red blood cells, fresh frozen plasma, and platelet concentrate were administered. The blood pressure at the time was 110-119 mmHg. Cardiac arrest occurred during CT, and the patient died approximately three hours after returning to the ward. CT results suggested bleeding from a deep femoral artery branch.

(5) The cause of death was hemorrhagic shock due to vascular injury (suspected). Ai: absent. Autopsy: absent.

Case 10 Femoral osteosynthesis

(1) The patient was in his/her 80s, weighing 60-69 kg, who had cerebral infarction and was on an oral antithrombotic drug (without interruption).

(2) Osteosynthesis (using intramedullary nailing) was performed for femoral subtrochanteric fracture on the following day of the injury.

(3) There was the anterior and upward displacement of the proximal bone fragment and the distal tip of the proximal bone fragment was prominently displaced convexly forward. The skin incision was extended, and invasive reduction was performed. Approximately one hour after the start of surgery, the amount of blood loss was 1,000 mL, and the blood pressure was 80-89 mmHg. Fluid loading was given, and a vasopressor was administered a few times. The Hb level was 8-8.9 g/dL. Red blood cells were ordered. Irregular antibody screening was carried out, and then they were administered immediately after the end of surgery. The amount of blood loss during surgery was 1,960 mL. When the patient left the room, the Hb level was 4-4.9 g/dL, the blood pressure was 80-89 mmHg, and the heart rate was 80-89 beats/min.

(4) When the patient returned to the HCU, the entire wound gauze was soaked in blood, and the patient's face was pale. Red blood cells were administered. Approximately two hours after returning to the HCU, the blood pressure was 70-79 mmHg, and the heart rate was 110-119 beats/min. The patient did not fully awaken. The wound bleeding persisted, and a vasopressor was administered. Approximately three hours after returning to the HCU, the SpO_2 was 70-79% and the heart rate was 50-59 beats/min. The patient did not respond when their name was called, and cardiac arrest occurred. The patient died approximately four hours after returning to the HCU.

(5) The cause of death was hemorrhagic shock. Ai: present (thigh swelling). Autopsy: absent.

Case 11 Prosthesis replacement

(1) The patient was in his/her 80s, weighing 30-39 kg, and on an oral antithrombotic drug (with interruption).

(2) Prosthesis replacement was performed for femoral neck fracture approximately two weeks after the injury.

(3) The blood pressure was 70-79 mmHg and the heart rate was 100-109 beats/min, so fluid loading was given. The amount of blood loss during surgery was 120 g. When the patient left the room, the blood pressure was 100-109 mmHg and the heart rate was 90-99 beats/min.

(4) Approximately 30 minutes after returning to the ward, the blood pressure was 50-59 mmHg, the continuous administration of a vasopressor was started, and the dose was increased in step by step. The hospital had no system to carry out a blood test during non-working hours, so it was scheduled on the following day. Approximately seven hours after returning to the ward, the amount of drained blood was 280 mL and the blood pressure was 60-69 mmHg. The dose of the vasopressor was increased. Approximately 12 hours after returning to the ward, the blood pressure was 90-99 mmHg and the total amount of drained blood was 320 mL. Approximately 16 hours after returning to the ward, cardiac arrest occurred and the Hb level was 6-6.9 g/dL. Approximately 17 hours after returning to the ward, the patient died.

(5) The cause of death was myocardial infarction (suspected) associated with hemorrhagic shock. Ai: present (no abnormal evidence of bleeding around the hip joint). Autopsy: absent.

Case 12 Prosthesis replacement

(1) The patient was in his/her late 70s, weighing 40-49 kg, with hepatic cirrhosis. The platelet count was in the 50,000s/μL.

(2) Prosthesis replacement was performed for femoral neck fracture approximately one week after the injury.

(3) Hemostasis was attempted using cement in the medullary cavity. The amount of blood loss during surgery was 190 g. When the patient left the room, the blood pressure was 100-109 mmHg and the heart rate was 100-109 beats/min.

(4) When the patient returned to the ward, the Hb level was 9-9.9 g/dL. Approximately two hours after returning to the ward, the blood pressure was 110-119 mmHg and the heart rate was 130-139 beats/min. Drugs were administered for nausea and pain. Wound bleeding was noted. Approximately five hours after returning to the ward, there was blood on the top layer of the wound gauze. The blood pressure was 110-119 mmHg and the heart rate was 120-129 beats/min. Approximately 15 hours after returning to the ward, ventricular tachycardia was seen, and the Hb level was 4-4.9 g/dL. CT showed bleeding equivalent to approximately 620 mL around the gluteus maximus muscle. The patient died approximately 16 hours after returning to the ward.

(5) The cause of death was ventricular tachycardia associated with bleeding. Ai: present. Autopsy: absent.

Case 13 Prosthesis replacement (revision surgery)

(1) The patient was in his/her 80s, weighing 30-39 kg, who had undergone osteosynthesis (using intramedullary nailing) for femoral trochanteric fracture and was on an oral antithrombotic drug (with interruption).

(2) Prosthesis replacement was performed for trochanteric pseudarthrosis.

(3) The blood pressure decreased to 80-89 mmHg. A vasopressor was administered a few times, and fluid loading was given. The amount of blood loss during surgery was approximately 560 mL. When the patient left the room, the blood pressure was 130-139 mmHg and the heart rate was 70-79 beats/min.

(4) Approximately one hour after returning to the ward, the patient's hospital gown was soaked in blood from the wound. The amount of drained blood was 300 mL. Approximately two hours after returning to the ward, the blood pressure was 60-69 mmHg, and a vasopressor and fluid loading were given. Approximately eight hours after returning to the ward, the total amount of drained blood was 650 mL. Approximately nine hours after returning to the ward, the patient's level of consciousness decreased, and the blood pressure could not be measured. A vasopressor and fluid replacement were administered by bolus injection. The blood pressure was 130-139 mmHg. Approximately 11 hours after returning to the ward, the Hb level was 4-4.9 g/dL, and red blood cells were administered. The patient died Day 2 after surgery.

(5) The cause of death was hemorrhagic shock. Ai: absent. Autopsy: absent.

Case 14 Prosthesis replacement (revision surgery)

(1) The patient was in his/her 90s, weighing 60-69 kg, who had undergone osteosynthesis (using intramedullary nailing) for femoral neck fracture.

(2) Prosthesis replacement was performed for lag screw perforation of the femoral head and femoral head necrosis.

(3) Red blood cells and a vasopressor were continuously administered from the start of surgery. During the surgery, the procedure was difficult due to severe hip joint contractures. There was a large amount of bleeding from the medullary cavity, and hemostasis was attempted with stem insertion. The blood pressure was 70-79 mmHg so fluid loading was given, and red blood cells and a vasopressor were administered a few times. At the end of surgery, the Hb level was 10-19 g/dL and the amount of blood loss during surgery was 1,340 mL. At the time of extubation, generalized cyanosis was noted. When the patient left the room, the blood pressure was 90-99 mmHg and the heart rate was 70-79 beats/min.

(4) After returning to the ward, an additional dose of red blood cells was administered. Approximately one hour after returning to the ward, the blood pressure was 70-79 mmHg; thus, the dose of the vasopressor was increased. Approximately nine hours after returning to the ward, the amount of drained blood was 90 mL. Approximately 12 hours after returning to the ward, the Hb level was 10-10.9 g/dL. The serum potassium level elevated so glucose insulin therapy was administered, but the patient died Day 2 after surgery.

(5) The cause of death was multiple organ failure (suspected severe hepatic blood flow disturbance). Ai: absent. Autopsy: absent.

Case 15 Total hip arthroplasty (revision surgery)

(1) The patient was in his/her 80s, weighing 40-49 kg, who had undergone osteosynthesis (using intramedullary nailing) for femoral trochanteric fracture.

(2) Total hip arthroplasty was performed for post-traumatic hip osteoarthritis.

(3) The amount of blood loss increased while working on the acetabulum, resulting in a blood pressure of 80-89 mmHg and a heart rate of 100-109 beats/min, so a vasopressor was administered a few times. Thereafter, hypotension was noted; thus, the continuous administration of a vasopressor was started. The amount of blood loss during surgery was 660 mL, and red blood cells were ordered. When the patient left the room, the Hb level was 8-8.9 g/dL, the blood pressure was 60-69 mmHg, and the heart rate was 110-119 beats/min.

(4) Immediately after returning to the ward, the blood pressure was 50-59 mmHg, the heart rate was 110-119 beats/min, SpO_2 was not measurable, and there was peripheral coldness. The dose of the vasopressor was increased. Red blood cells were administered. Approximately two hours after returning to the ward, the blood pressure was 50-79 mmHg and the heart rate was 120-129 beats/min. Approximately three hours after returning to the ward, the total amount of drained blood was 350 mL. Jaw breathing occurred, and tracheal intubation was carried out. The patient died approximately four hours after returning to the ward.

(5) The cause of death was hemorrhagic shock due to vascular injury (suspected). Ai: absent. Autopsy: absent.

Case 16 Total hip arthroplasty (bilateral)

(1) The patient was in his/her 60s with unknown body weight.

(2) Bilateral total hip arthroplasty was performed for bilateral hip osteoarthritis.

(3) The blood pressure was 90-99 mmHg. Autologous blood was administered, and a vasopressor was administered a few times. Furthermore, salvaging autotransfusion was implemented. The amount of blood loss during surgery was 1,200 mL. The patient complained of shortness of breath and low back pain. When the patient left the room, the blood pressure was 80-89 mmHg and the heart rate was 100-109 beats/min.

(4) Immediately after returning to the ward, peripheral coldness was noted. The SpO_2 could not be measured. The patient complained of shortness of breath and low back pain/abdominal pain. The body position was adjusted, but there was no improvement. The Hb level was 11-11.9 g/dL. Approximately one hour after returning to the ward, the patient lost consciousness. The Hb level was 9-9.9 g/dL. Jaw breathing occurred, and tracheal intubation was carried out. Approximately two hours after returning to the ward, contrast-enhanced CT suggested hematoma in the pelvis so the patient was transferred to the ICU. Approximately four hours after returning to the ward, angiography revealed no arterial injury. Approximately seven hours after returning to the ward, the amount of drained blood was approximately 600 mL. Red blood cells, fresh frozen plasma, and platelet concentrate were administered. The patient died Day 2 after surgery.

(5) The cause of death was hemorrhagic shock due to vascular injury. Ai: present (pelvic hematoma). Autopsy: present (external iliac vein injury).

Case 17 Total hip arthroplasty

(1) The patient was in his/her 60s, weighing 60-69 kg, who was on steroid therapy for hepatic cirrhosis and organizing pneumonia. The platelet count was in the 70,000s/μL.

(2) Total hip arthroplasty was performed for hip osteoarthritis.

(3) The amount of blood loss was large from immediately after the start of surgery, and it was difficult to see when cutting the acetabulum due to bleeding. During surgical procedure, the fractures of the acetabulum and femur were identified, and they were fixed with Kirschner wire. The blood pressure was 40-49 mmHg. Red blood cells were ordered and administered immediately before wound closure. The amount of blood loss during surgery was 1,300 mL. At the end of surgery, the Hb level was 5-5.9 g/dL. When the patient left the room, the vital signs were unknown.

(4) Approximately one hour after returning to the ward, the blood pressure was 50-69 mmHg, and the continuous administration of a vasopressor was started. Approximately three hours after returning to the ward, the patient had wound pain and buttock pain. The Hb level was 5-5.9 g/dL. The amount of blood loss was 220 mL. Approximately seven hours after returning to the ward, the blood pressure was 50-59 mmHg, the heart rate was 120-129 beats/min, and the amount of drained blood was in the tube only. Approximately 10 hours after returning to the ward, the Japan Coma Scale (JCS) was III-300, jaw breathing occurred, and tracheal intubation was carried out. The dose of the vasopressor was increased. The blood pressure was 60-69 mmHg and the heart rate was 40-49 beats/min. CT was performed (details unknown). The patient died Day 2 after surgery.

(5) The cause of death was multiple organ failure associated with hemorrhagic shock. Ai: present (hematomas around the surgical site/retroperitoneum). Autopsy: absent.

Case 18 Total hip arthroplasty

(1) The patient was in his/her late 70s, weighing 40-49 kg, who had undergone aortic valve replacement and was on an oral antithrombotic drug (with interruption).

(2) Total hip arthroplasty was performed for hip osteoarthritis.

(3) Bleeding occurred in association with surgical approach to the acetabulum. The blood pressure was 40-49 mmHg. Autologous blood and a vasopressor were administered a few times. A hemostatic agent was applied to the surgical field, and the wound was closed. The blood pressure was unstable, and additionally, salvaging autotransfusion was performed. The amount of blood loss during surgery was 1,700 mL. When the patient left the room, the blood pressure was 60-69 mmHg and the heart rate was 90-99 beats/min.

(4) Immediately after extubation, the blood pressure was 50-89 mmHg. Swelling of the affected thigh increased and the amount of drained blood was 300 mL. Considering the possibility of vascular injury, angiography was scheduled to be implemented at another medical institution. During transfer, cardiopulmonary arrest occurred, and the patient died approximately one hour later.

(5) The cause of death was hemorrhagic shock due to vascular injury (suspected). Ai: absent. Autopsy: present.

Case 19 Total hip arthroplasty

(1) The patient was in his/her early 70s, weighing 50-59 kg.

(2) Total hip arthroplasty was performed for hip osteoarthritis.

(3) The posterior acetabulum was lost when cutting the acetabulum, leading to an increase in myeloid bleeding. A cup was secured but it was unstable, so drilling and screw insertion were performed a few times. The blood pressure decreased to 50-59 mmHg; thus, the continuous administration of red blood cells and a vasopressor was started. However, the heart rate was 100-109 beats/min and the Hb level was 6-6.9 g/dL. The amount of blood loss during surgery was 2,600 mL. When the patient left the room, the blood pressure was 80-89 mmHg and the heart rate was 90-99 beats/min.

(4) When the patient returned to the ward, the blood pressure was 60-69 mmHg. Pale complexion was noted. Wound bleeding persisted. The Hb level was 8-8.9 g/dL, and the patient had low back pain. The blood pressure decreased to 40 mmHg, and red blood cells were administered. Approximately one hour after returning to the ward, the blood pressure was not measurable and the heart rate was 100-119 beats/min. Jaw breathing occurred so tracheal intubation was carried out. Fresh frozen plasma and a vasopressor were administered. The patient died approximately five hours after returning to the ward.

(5) The cause of death was hemorrhagic shock due to vascular injury (including myeloid bleeding). Ai: present (retroperitoneal bleeding). Autopsy: present (small vessel injury in the retroperitoneal space).

Case 20 Total hip arthroplasty

(1) The patient was in his/her early 70s, weighing 50-59 kg, with rheumatoid arthritis.

(2) Total hip arthroplasty was performed for rheumatic hip disease.

(3) The acetabulum was filled with necrotic tissue, which was difficult to separate. There was bleeding from a drill hole in the acetabulum. Hemostasis was attempted with packing by screw insertion. The blood pressure decreased to 50-59 mmHg. Red blood cells were administered. When changing the body position after wound closure, abdominal distension was noted. When laparotomy was performed, there was 1,000 to 2,000 g of bleeding in the retroperitoneal space and 3 to 4 cm of an external iliac vein injury. Fresh frozen plasma and platelet concentrate were administered, but the bleeding could not be controlled. Abdominal packing was performed, and the wound was closed. The amount of blood loss during surgery was 4,800 mL. When the patient left the room, the blood pressure was 70-79 mmHg and the heart rate was 130-139 beats/min.

(4) Treatment was continued in the ICU. The patient died approximately 13 hours after returning to the ward.

(5) The cause of death was hemorrhagic shock due to vascular injury. Ai: absent. Autopsy: present.

Table 1 Overview of the target cases <List>

* This chart has been created based on the in-hospital investigation reports and additional information.

RBC 2 units
FFP 2 units
Plt concentrate 10 units

Autologous blood or Salvaging autotransfusion

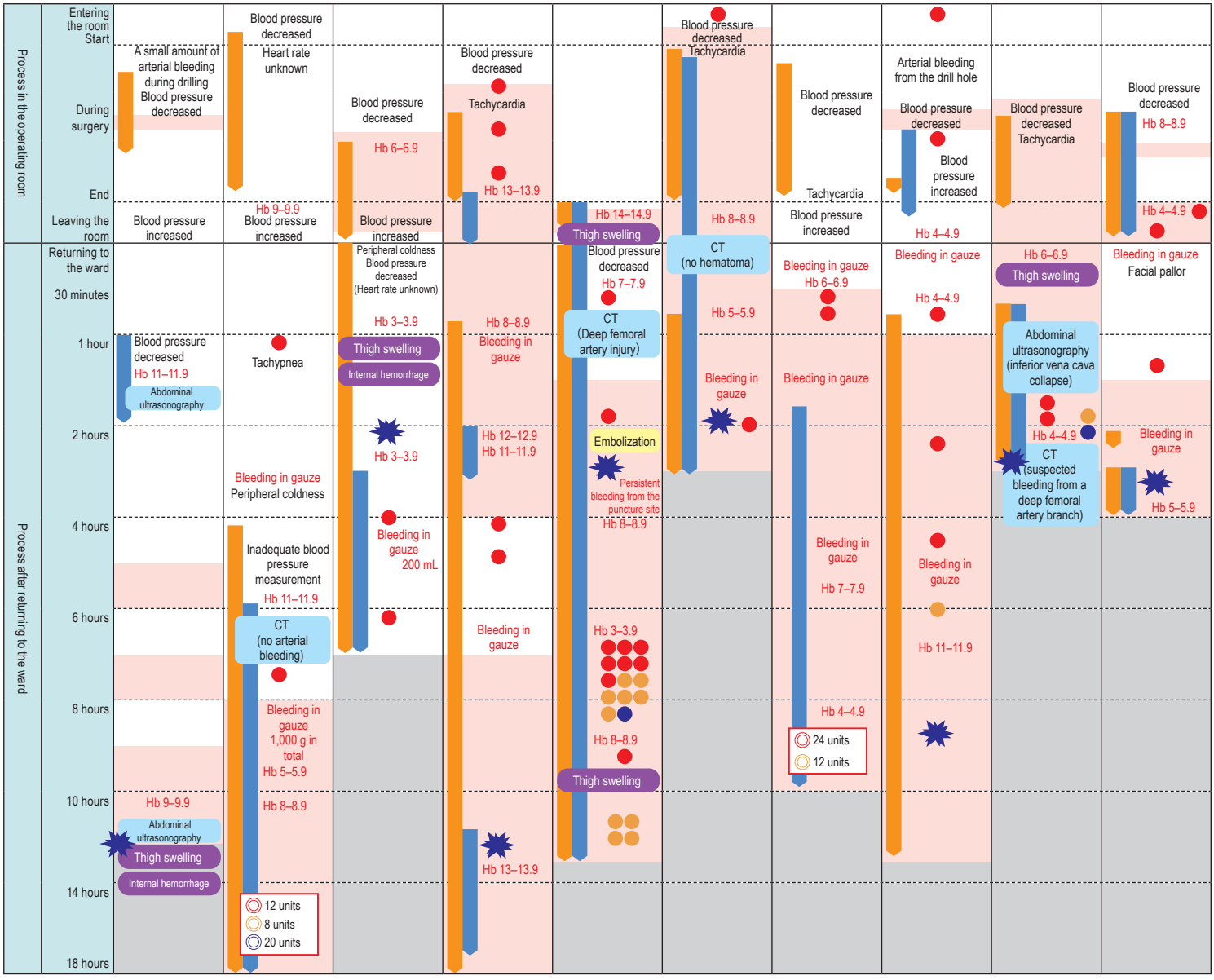
Those with unknown dosing time
Total amount of RBC
Total amount of FFP
Total amount of plt concentrate

Administration of a vasopressor (continuous administration or single dose)
Fluid loading (bolus injection or increase in the fluid replacement dose)

Hypotension: Systolic blood pressure ≤90
Tachycardia: Heart rate ≥100
Tachypnea: Respiration rate >22

Cardiopulmonary arrest
Dilation of the pupil
Blood pressure immeasurable

Case No.	Case 1	Case 2	Case 3	Case 4	Case 5	Case 6	Case 7	Case 8	Case 9	Case 10
Age	In his/her 80s	In his/her late 70s	In his/her 90s	In his/her 80s	In his/her 90s	In his/her 80s	In his/her 80s	In his/her 80s	In his/her early 70s	In his/her 80s
Diagnosis	Neck fracture	Periprosthetic fracture	Screw perforation of the femoral head after trochanteric fracture	Periprosthetic fracture	Trochanteric fracture	Trochanteric fracture	Trochanteric fracture	Trochanteric fracture	Trochanteric fracture	Subtrochanteric fracture
Emergency operation	○	–	–	–	○	○	–	○	–	○
Type of surgery	Osteosynthesis	Osteosynthesis (revision surgery, bilateral)	Osteosynthesis (revision surgery)	Osteosynthesis (revision surgery)	Osteosynthesis Intramedullary nailing	Osteosynthesis Intramedullary nailing	Osteosynthesis Intramedullary nailing	Osteosynthesis Intramedullary nailing	Osteosynthesis Intramedullary nailing	Osteosynthesis Intramedullary nailing
Surgical vascular injury	Yes	–	–	–	Yes	–	–	Yes (suspected)	Yes (suspected)	–
Amount of blood loss during surgery (approx.) (Approximate ratio to the circulating blood volume)	110 mL (4%)	540 mL (18%)	1,140 mL (36%)	1,550 mL (55%)	0 mL	40 mL (1%)	150 g (6%)	500 g (20%)	630 mL (24%)	1,960 mL (47%)
Weight (kg, range)	40	40	40	40	40	40	30	30	30	60
Decreased blood clotting ability	Decreased platelet count	On dialysis	Antithrombotic drug	–	Antithrombotic drug	Antithrombotic drug Decreased platelet count	Antithrombotic drug Decreased platelet count	–	Decreased platelet count	Antithrombotic drug
Anemia (Hb <13.0 for male, <12.0 g/dL for female)	–	–	○	○	○	○	○	○	○	○
Low albumin (<4.1 g/dL)	○	–	–	○	○	○	○	○	○	○



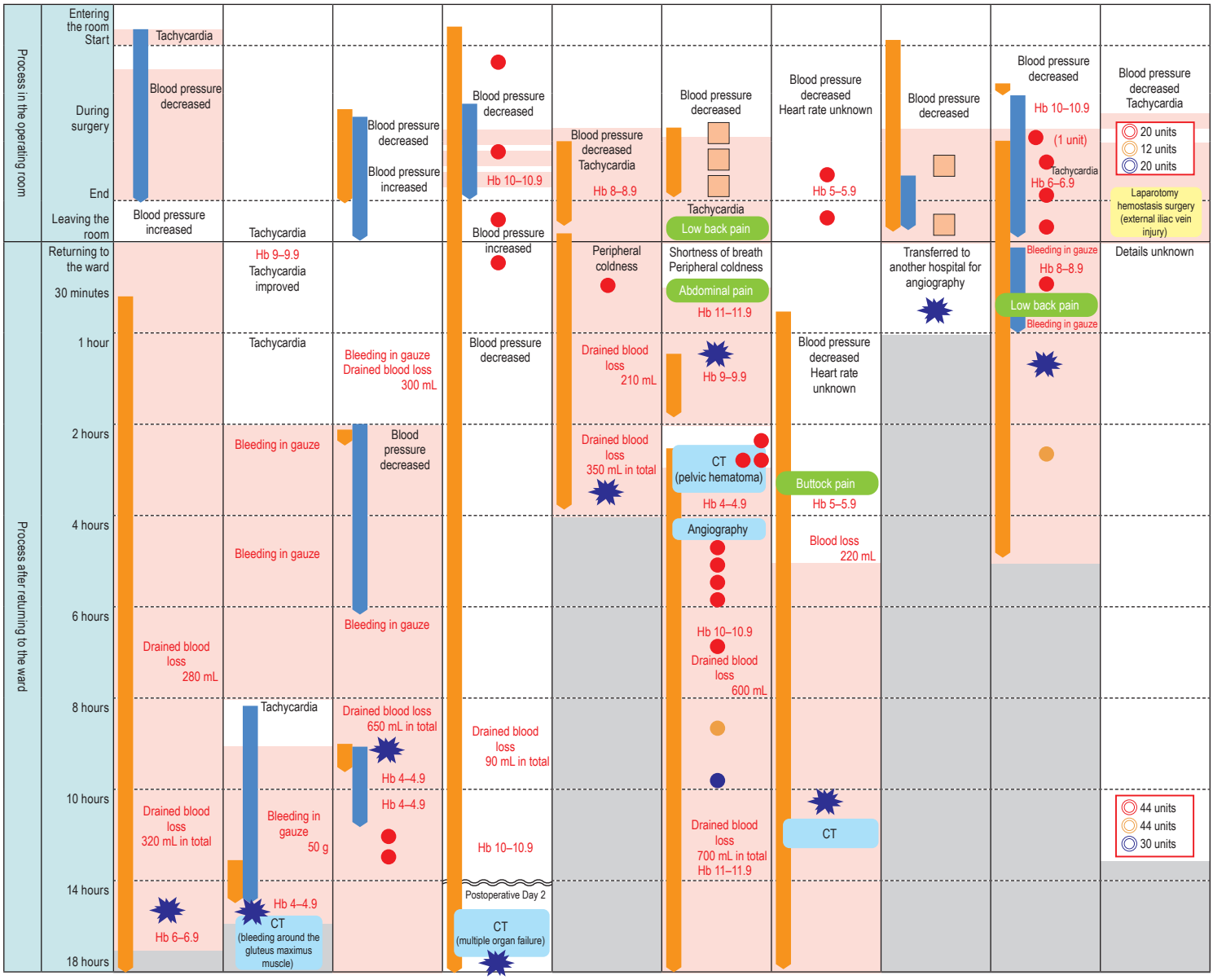
From return to ward until death	About 12 hours	About 20 hours	About 7 hours	About 2 days	About 13 hours	About 3 hours	About 10 hours	About 13 hours	About 3 hours	About 4 hours
Ai or autopsy finding	Hematoma in the femoral area	Femoral bleeding	–	–	–	–	–	Hematomas around the femur and in the buttocks	–	Thigh swelling
Number of beds	300-399	500-599	100-199	200-299	400-499	400-499	700-799	300-399	300-399	700-799

Shock indices were calculated post hoc during the process of the analysis for the recommendations. The background color shown on the left was used for those with a shock index above 1.
(The white background color was used for those for which no shock index could be calculated due to a lack of information on the heart rate or systolic blood pressure.)

Finding shows bleeding (thigh)

Finding shows bleeding (pelvis)

Case No.	Case 11	Case 12	Case 13	Case 14	Case 15	Case 16	Case 17	Case 18	Case 19	Case 20
Age	In his/her 80s	In his/her late 70s	In his/her 80s	In his/her 90s	In his/her 80s	In his/her 60s	In his/her 60s	In his/her late 70s	In his/her early 70s	In his/her early 70s
Diagnosis	Neck fracture	Neck fracture	Trochanteric pseudarthrosis	Femoral head necrosis	Post-traumatic hip osteoarthritis	Hip osteoarthritis	Hip osteoarthritis	Hip osteoarthritis	Hip osteoarthritis	Rheumatic hip disease
Emergency operation	–	–	–	–	–	–	–	–	–	–
Type of surgery	Prosthesis replacement	Prosthesis replacement	Prosthesis replacement (revision surgery)	Prosthesis replacement (revision surgery)	Total hip arthroplasty (revision surgery)	Total hip arthroplasty (bilateral)	Total hip arthroplasty	Total hip arthroplasty	Total hip arthroplasty	Total hip arthroplasty
Surgical vascular injury	–	–	–	–	Yes (suspected)	Yes	–	Yes (suspected)	Yes	Yes
Amount of blood loss during surgery (approx.) (Approximate ratio to the circulating blood volume)	120 g (6%)	190 g (6%)	560 mL (20%)	1,340 mL (29%)	660 mL (19%)	1,200 mL	1,300 mL (29%)	1,700 mL (54%)	2,600 mL (65%)	4,800 mL (120%)
Weight (kg, range)	30	40	30	60	40	–	60	40	50	50
Decreased blood clotting ability	Antithrombotic drug	Decreased platelet count	Antithrombotic drug	–	–	–	Decreased platelet count	Antithrombotic drug	–	–
Anemia (Hb <13.0 for male, <12.0 g/dL for female)	○	○	○	○	○	–	–	–	–	–
Low albumin (<4.1 g/dL)	○	○	○	○	○	–	○	○	–	–



From return to ward until death	About 17 hours	About 16 hours	About 2 days	About 2 days	About 4 hours	About 2 days	About 2 days	About 1 hour	About 5 hours	About 13 hours
Ai or autopsy finding	No abnormal evidence of bleeding around the hip joint	–	–	–	–	Pelvic hematoma, external iliac vein injury	Hematomas around the surgical site/ retroperitoneum	–	Small vessel injury in the retroperitoneal space	–
Number of beds	200-299	300-399	300-399	100-199	<100	500-599	200-299	<100	200-299	500-599

4. Recommendations and explanations to prevent recurrence

[Ascertaining bleeding risk and making preoperative preparations]

Recommendation 1

In hip surgery, the amount of blood loss is likely to increase depending on the site of fracture, surgical procedures such as revision surgery, and due to decreased blood clotting ability. Individuals with advanced age, a low body weight, anemia, and a low albumin level have reduced reserve capacity and are likely to develop shock. Therefore, these risks should be ascertained before surgery, and preoperative preparation for bleeding should be made to prevent bleeding from progressing to shock.

● The amount of blood loss is likely to increase depending on the site of fracture, surgical procedures such as revision surgery, and due to decreased blood clotting ability.

Bleeding is more likely to increase during hip surgery for femoral trochanteric or subtrochanteric fractures compared with that for femoral neck fracture because there is a greater blood flow. The risk of bleeding also increases for fractures with significant dislocation, contracture, deformity, revision surgery, and bilateral surgery because these surgeries are more difficult and the duration of surgery is longer.

Of the 20 target cases, there were trochanteric or subtrochanteric fractures in seven cases, revision surgery in six cases, and bilateral surgery in two cases; their procedures were likely to increase the amount of blood loss. In addition, in 13 of the 20 target cases, the blood clotting ability was decreased due to thrombocytopenia associated with blood or hepatic disease, oral administration of antithrombotic drugs, or dialysis therapy. Of eight cases where the patients had been on antithrombotic drugs, the drugs were interrupted before surgery in four cases. With regard to antithrombotic drugs before surgery, the "JCS/JHRS 2020 Guideline on Pharmacotherapy of Cardiac Arrhythmias" classifies orthopedic surgery into a procedure that, in principle, requires the interruption of anticoagulants because it has a high risk of bleeding.[4] In contrast, the American College of Cardiology/American Heart Association Guidelines state that the continuation or interruption of antiplatelet therapy when surgical treatment is performed in patients who underwent coronary artery stent placement should be comprehensively determined according to cardiovascular risks.[5] When patients are on antithrombotic drugs, the decision to interrupt or continue them should be made individually based on the level of the risk of background vascular lesion, the invasiveness of surgery, and the need of emergency surgery, but it is important to understand that antithrombotic drugs carry the risk of increasing the amount of blood loss (see Column 1).

● Individuals with advanced age, a low body weight, anemia, and a low albumin level have reduced reserve capacity and are likely to develop shock.

Older adults often have various comorbidities and reduced physical reserve capacity. In 15 of the 20 target cases, the patients were older adults aged 75 years or older, and nine of them were in their 80s and three were in their 90s.

When considering the amount of blood loss during surgery, since the circulating blood volume is relative to body weight, it is essential to first focus on body weight (see Recommendation 2). When the body weight is low, even if the amount of blood loss is the same, the ratio of the amount of blood loss is higher, which may occasionally be fatal, especially in older adults. Of the 20 target cases, the body weight was 40-49 kg in nine cases and 30-39 kg in five cases.

If patients have anemia, bleeding is likely to lead to circulatory failure. The World Health Organization (WHO) defines anemia as a hemoglobin level of <13.0 g/dL for adult men and <12.0 g/dL for adult women.[6] Based on this criterion, anemia had been present before surgery in 13 of the 20 target cases. In addition, low albumin levels may

be associated with postoperative complications and the prognosis. The "Clinical Laboratory Guidelines JSLM2021" states that the lower limit of the common reference range of albumin levels is 4.1 g/dL.[7] Albumin levels were low in 15 cases. Hemoglobin and albumin levels decrease with aging, especially in older adults, so they are often lower than the reference levels for general adults, and there is a greater risk of bleeding leading to shock.

In 17 of the 20 target cases, the patients had at least one of the background characteristics, namely advanced age, a low body weight, anemia, or a low albumin level. Some of the patients lost a large amount of blood during surgery while others had a small amount of blood loss during surgery; thus, the amount of blood loss and the process varied. Nonetheless, if patients have these background characteristics, they have a reduced reserve capacity for bleeding and are likely to develop shock.

In summary, before performing a surgery, it is essential to understand the risks that may increase the amount of blood loss (such as surgical procedures) and the risk of having a reduced reserve capacity for bleeding that could easily trigger shock. Please use the "Checklist for verification of bleeding risk during hip surgery and making preoperative preparations (sample)" (see Table 2) as a reference.

Column 1: The effect of administration of antiplatelet agents/anticoagulants on hip surgery

Hip surgery is frequently performed in older adults who are often taking oral antithrombotic drugs for various comorbidities. When performing an emergency surgery, a decision to interrupt antithrombotic drugs before and after the surgery needs to be made after examining the bleeding risk and the risk of thrombus formation for each patient. Patients who are on antithrombotic drugs commonly have concomitant conditions such as cerebral infarction, coronary artery disorder, and atrial fibrillation. Considering postoperative thrombotic complications and postoperative activity of daily living (ADL), it may be beneficial to perform early surgery while continuing the treatment.

The explanation on the timing of surgery and anesthesia for patients who are on antiplatelet agents/anticoagulants in the "Japanese Orthopaedic Association (JOA) Clinical Practice Guideline on the Management of Hip Fractures, 3rd Edition" describes the effects on the general condition while being treated with antiplatelet agents or anticoagulants as follows:[8]

- In patients who were on low-dose acetylsalicylic acid, even when early surgery was performed, there was no difference in the amount of blood loss during surgery, but the rate of postoperative transfusion increased.
- In patients who were on warfarin, there was no increase in the incidence of complications or mortality. However, it is preferable to control the international normalized ratio (INR) to 1.5 or lower. If the INR is 1.5 or higher on the day before surgery, the use of fresh frozen plasma (FFP) or vitamin K is useful.
- In patients who are on clopidogrel, even if early surgery is carried out in 24 to 48 hours without interruption or standby as with those who are not on clopidogrel, the surgery is safe without increasing the incidence of complication or mortality. However, the rate of transfusion may elevate.
- There is an observational study of early surgery in patients who were on antiplatelet agents or anticoagulants in Japan. The study suggested that treatment with these drugs is not associated with the incidence of complications or mortality.

● Preoperative preparation for patients at risk of bleeding

<Consultation on the blood clotting ability>

Of the 20 target cases, the blood clotting ability was reduced due to comorbidities in 13 cases, and the surgery was elective in nine cases. Of these, no consultation with related medical departments was made in four cases. For elective surgery, it is desirable to do a consultation before preparing for the perioperative period.

In contrast, emergency surgery was performed in four cases, three of which was femoral osteosynthesis within 24 hours after the injury. No consultation with related medical departments was implemented. For proximal femoral fracture, while the prognosis of early surgery is considered to be good, if early surgery is prioritized, it is difficult to hold a prolonged consultation and make a preoperative assessment. An intra- and post-operative management plan assuming the occurrence of bleeding should be examined with related medical departments with a view of the merits and demerits of early surgery as well as the administration of reversal agents if patients are using antithrombotic drugs (see Column 2).

<Preparation for transfusion>

Of the 20 target cases, surgery was initiated without preparing a transfusion in 11 cases. In 10 of these cases, the patients had bleeding risks such as advanced age, body weight of 30-49 kg, and a decreased blood clotting ability.

The duration of femoral osteosynthesis is short, and there is almost no blood loss in some cases, so the surgery may be performed without preparing a transfusion. However, even if a transfusion is unlikely to be required, if patients have a reduced reserve capacity for bleeding and there is a risk of developing shock, it is important to prepare in advance so that transfusion can be promptly given when needed. In addition, there was a case where the administration was delayed due to irregular antibody screening. It is desirable to conduct not only a blood typing test, but also an irregular antibody screening beforehand if possible (see Column 3).

Elective surgery is carried out for total hip arthroplasty, so preparation for autologous blood transfusion and salvaging autotransfusion should be considered.

Since the environment for preparing transfusion varies from one medical institution to another, a system to order it should be prepared, and it is necessary to simulate actions in case a transfusion is required.

<Postoperative management plan>

When the bleeding risk is judged to be high, postoperative management at a department where intensive monitoring and treatment can be performed such as the ICU should be considered. Furthermore, medical institutions without a department that can implement vascular surgery to treat vascular injuries, or a radiology department that can carry out interventional radiology (IVR) should consider collaborating with supporting hospitals in ordinary times so that any suspected vascular injuries or hemorrhagic shock can be promptly handled.

In 13 of the 20 target cases, the patients were managed in the general ward after the surgery, and some of the medical institutions had no ICU. Each medical institution determines whether it can conduct hip surgery while taking into account the level of difficulty, the surgeon’s experience, its medical care system, and other relevant matters. During this time, the ability of the hospital to handle bleeding should also be examined, and if it is difficult, they should request another medical institution to perform the surgery as well.

<Explanation and consent regarding the bleeding risk to be implemented before surgery>

For the risks associated with hip surgery, while there is an anatomical characteristic that bleeding is difficult to see (see Recommendation 3), physicians rarely informed this to patients and their family members at present. Providing such information when explaining the surgery is beneficial for patients to understand the risks associated with treatment.

In addition, any risk of increasing the amount of blood loss or shock should be explained to patients and their family members before the surgery. As measures for bleeding risk to be implemented by the surgeon team, it is important to also explain about consultation with related medical departments, preparation for transfusion, actions to be taken in the event of bleeding, and the postoperative management system to them and to obtain their consent. It is preferable to share information with the patients regarding the bleeding risks ascertained by the surgeon team using the "Checklist for verification of bleeding risk during hip surgery and making preoperative preparations (sample)" (see Table 2).

Column 2: Reversal agents for direct oral anticoagulants (DOACs)

In Japan, the following reversal agents are available: Prizbind® Intravenous Solution (idarucizumab), a specific reversal agent for dabigatran, since November 2016; and Ondexxya® for Intravenous Injection (andexanet alfa), a reversal agent for direct factor Xa inhibitors, since May 2022. We will introduce them as a possible therapeutic option in the future as emergency interventions for bleeding while patients are on anticoagulants.

● Prizbind® Intravenous Solution (idarucizumab)

Prizbind will be used in patients treated with dabigatran when the reversal of its anticoagulant effect is required for life-threatening or uncontrolled bleeding or emergency surgery or procedures that are anticipated to cause significant blood loss.

● Ondexxya® for Intravenous Injection (andexanet alfa)

Ondexxya will be used in patients treated with apixaban, rivaroxaban, or edoxaban tosilate hydrate when the reversal of their anticoagulant effects is required for life-threatening or uncontrolled bleeding.

Column 3: Blood typing test and irregular antibody screening (Type & Screen: T&S)

T&S is a method for preparing blood when it is anticipated that transfusion is unlikely to be immediately required, including elective surgery patients. Prior to the surgery, a blood typing test is performed first in the patient, and then an irregular antibody screening is carried out. If the results are positive for RhD and negative for irregular antibodies, no prior cross-matching analysis is needed. When transfusion is urgently necessary, it should be implemented after confirming the blood type for transfusion or performing only some of the major tests of the cross-matching analysis.[9)]

<Note>

Usually, the process of preparing for transfusion is to conduct a blood typing test and irregular antibody screening for the patient, check the blood type for transfusion, and carry out the major and minor tests of the cross-matching analysis. (The minor tests may be omitted as long as the ABO blood typing test is properly done for the patient, because irregular antibodies have been confirmed to be negative if the red blood cell product is from Japanese Red Cross Society in Japan.)

Table 2　Checklist for verification of bleeding risk during hip surgery and making preoperative preparations (sample)

*See Recommendations 1 and 2.

Patient name	Male/Female	Patient ID		Blood type	
Date of surgery	DD/MM/YYYY (　　)　Elective surgery/Emergency surgery				
Diagnosis					
Stock of blood products for transfusion in the hospital	RBC　(　　) units FFP　(　　) units				
Time required for ordering a blood product in the hospital	min	Time required for ordering a blood product from outside the hospital			min

Items to check for bleeding risk		Patient information	If there is a risk ☑
Type of surgery			
Anticipated amount of blood loss*			
Risk of increasing the amount of blood loss	Disease condition	☐ Trochanteric/Subtrochanteric fracture　☐ Fracture with significant displacement ☐ Contracture/Deformity/Defect　☐ Bilateral surgery	☐
	History of surgery	☐ Revision surgery	☐
	Blood clotting ability	☐ Plt (　) 0,000/μL　☐ PT-INR (　)　☐ APTT (　) sec　☐ FIB (　) mg/dL ☐ Blood disease　☐ Hepatic disease ☐ Antithrombotic drug (　) ☐ Dialysis therapy	☐
Reserve capacity for bleeding	Age	(　) years	☐
	Body weight and circulating blood volume	(　) kg Body weight × 70 mL = Circulating blood volume (　) mL	☐
	Ratio of the anticipated amount of blood loss to the circulating blood volume	Anticipated amount of blood loss (　) mL / Circulating blood volume (　) mL × 100 ⇒ (　)%	
	Hb	(　) g/dL	☐
	Alb	(　) g/dL	☐

If it is determined that there is bleeding risk or the risk is high, consider the following preoperative preparation.

Items to prepare before surgery	Implementation/Verification Results
Consultation on blood clotting ability (Examine according to the level of urgency)	☐ Necessary [☐ Assessment of blood clotting ability　☐ Interruption of the antithrombotic drug ☐ Preparation for transfusion　☐ Other:] ☐ Not necessary ☐ Omitted due to emergency surgery
Amount of blood product for transfusion to be prepared*	☐ RBC (　) units　☐ FFP (　) units ☐ Plt concentrate (　) units　☐ Autologous blood (　) mL ☐ Salvaging autotransfusion　☐ T&S　☐ None
Postoperative management	☐ ICU, etc.　☐ General ward
Action to be taken in the event of bleeding (vascular injury)	☐ Handled in the hospital [☐ Vascular surgery treatment　☐ IVR treatment]
	☐ Anticipated amount of blood loss [☐ Vascular surgery treatment　☐ IVR treatment]
Contents of explanation on bleeding risk	☐ Anticipated amount of blood loss　☐ Preparation for transfusion　☐ Action to be taken in the event of bleeding
	☐ Consultation with related medical department regarding the blood clotting ability　☐ Postoperative management system

Items to check to start transfusion	Review results
Ratio of the anticipated amount of blood loss to the circulating blood volume	(　) %　[Anticipated amount of blood loss/Patient's circulating blood volume × 100]
Criteria for initiating transfusion*	☐ Amount of blood loss (　) mL　☐ Hb (　) g/dL ☐ BP (　) mmHg　☐ Heart rate (　) beats/min

Items to check for transfusion during the time-out before surgery (example) (Items with *)

☐ Anticipated amount of blood loss
☐ Amount of blood product for transfusion to be prepared
☐ Criteria for initiating transfusion

[Setting approximate time points of starting blood transfusion to be shared before surgery]

Recommendation 2

Approximate time points of starting the preparation for blood transfusion and initiating administration for individual patients (e.g., the amount of blood loss and hemoglobin level) should be specified in consideration of the amount of blood loss anticipated from surgical procedures, circulating blood volume calculated based on the patient's weight, and the system to supply blood products for transfusion in the hospital. The selected approximate time points and blood transfusion volume to be prepared should be shared during the time-out before surgery.

● Specify an approximate time point for starting transfusion

The trigger level for transfusion during the perioperative period is considered to be a hemoglobin level of 7 to 8 g/dL. It is recommended to maintain the hemoglobin level at around 10 g/dL for patients with heart disease such as coronary artery disorder and pulmonary function impairment.[10)]

For hip surgery, the anticipated amount of blood loss varies according to surgical procedures such as femoral osteosynthesis, total hip arthroplasty, as well as their revision surgery and bilateral surgery. Thus, surgical procedures for individual patients and the patient's circulating blood volume should be used as references for determining when to start transfusion. The circulating blood volume is calculated as the body weight multiplied by 70 mL. For example, when the amount of blood loss is 500 mL, it is approximately 11% of the circulating blood volume for a patient weighing 65 kg, but approximately 24% of the circulating blood volume for a patient weighing 30 kg.

For the target cases, the approximate time point for starting transfusion was not specified in six cases and was left up to the anesthesiologist during the surgery, and was established in eight cases. In these eight cases, the amount of blood loss according to general hemoglobin levels and each surgical procedure was used as a criterion, and the amount above 20% of the patient's circulating blood volume was set for some cases. When combining the cases with and without the criterion, transfusion was actually given at the time when the amount of blood loss reached more than 20% of the circulating blood volume in the eight cases.

Once blood products for transfusion are ordered and received from the blood center, usually they cannot be returned, so it is not realistic to prepare them for all surgeries. In addition, the availability of stocks in the hospital, the time required for receiving them from the blood center, and the time required for supplying blood products for transfusion by the clinical laboratory department's system vary from one medical institution to another. Therefore, it is difficult to uniformly define how much blood products for transfusion should be prepared for surgery. In two of the 20 target cases, after transfusion was ordered, it was found that there was no stock in the hospital, and it took more than 60 minutes to obtain it before transfusion was finally carried out.

In summary, the approximate time points for starting the preparation of transfusion and its administration for each patient should be specified while taking into account the ratio of the amount of blood loss anticipated from a surgical procedure to the circulating blood volume calculated based on the patient's body weight and the system for supplying blood products for transfusion in the hospital. Bleeding that is not visible in the surgical field may occur for a hip surgery (see Recommendation 3), so the amount of blood loss alone may be inadequate as a criterion for starting the preparation of transfusion and its administration. For this reason, the approximate time points based on hemoglobin levels should be defined as well. In particular, when changes in vital signs are noted, it is preferable to check the hemoglobin level.

Take a time-out before initiating surgery, and share the approximate time point of starting transfusion among the team members

The "time-out" is defined in the "WHO Guidelines for Safe Surgery 2009" as "a brief pause immediately before skin incision, to confirm the identity of the patient, the procedure to be performed, and the operative site."[11] It is also implemented when information needs to be shared among the team members during surgery, such as immediately before wound closure and when there is a large volume of blood loss.

The Guidelines recommend that before skin incision, the team should discuss the risk for large-volume blood loss and ensure that appropriate intravenous access is established, and confirm the availability of blood products if needed for the operation.[12] Furthermore, the "Surgical Safety Checklist" in the Guidelines includes items to check, for example, if there is a risk of blood loss of at least 500 mL before the induction of anesthesia, and the anticipated amount of blood loss before skin incision.[13]

Among the target cases, information on taking a time-out before the start of surgery was obtained for 15 cases, and a time-out was taken for 13 cases. Their check items included a surgical procedure, the operative site, and the anticipated amount of blood loss. It is critical to share not only the anticipated amount of blood loss but also the approximate time points of starting the preparation of transfusion and its administration, and the amount of blood product for transfusion to be prepared (and if not prepared, the time required for supplying a blood product for transfusion in the hospital) among all operation team members during the time-out before initiating the surgery.

[Evaluating risk for damaging blood vessels that are difficult to identify visually]

Recommendation 3

There is a risk of damaging blood vessels when inserting a spinning device such as a drill and screw. Vascular injuries caused by spinning devices often occur on the opposite side of the screw insertion site in the femur for femoral osteosynthesis and in the acetabulum inside the pelvis for total hip arthroplasty. Therefore, it should be noted that bleeding is difficult to identify visually in the surgical field.

● Spinning devices such as a drill and screw are likely to damage blood vessels.

Of the 20 target cases, surgical operations such as drilling and screwing were assumed to have damaged blood vessels in nine cases. In hip surgery, since a drill and screw are rotating tools to insert components, there is a high risk of vascular injury. Depth gauges and retractors also carry a similar risk.

When planning the operation before surgery using an imaging test to decide the drilling direction and insertion length, the bone deformity and defect, thinness, and other factors should be checked, and the proximity of the sites of drilling and screw insertion close to blood vessels should be confirmed. In five of the nine cases where vascular injuries were assumed to have occurred, severe deformities were noted. If the bone tissue is fragile or deformed due to osteoporosis, implants cannot be adequately fixed, and re-fixation may be required. Unplanned procedures resulting from these may cause vascular injury, so such information should be shared among operators and assistants.

It is desirable to use a drill stopper in the length set beforehand to avoid drilling deeper than the insertion length measured prior to surgery. In four of the nine cases where vascular injuries were assumed to have occurred, no drill stopper was used. A long screw enables the stable fixation of implants, but a screw that is too long penetrates the bone, increasing the risk of vascular injury. Therefore, it is difficult to generalize the appropriate length. There was a case where a screw penetrated the acetabulum, resulting in vascular injury; therefore, it is important to select the screw length according to the patient's condition based on preoperative images.

● In hip surgery, it may be difficult to identify a vascular injury visually.

Of the nine cases where vascular injuries were assumed to have been caused by surgical operations such as drilling and screwing, the operators actually identified arterial bleeding in the surgical field in two cases. In the remaining seven cases, vascular injury could not be confirmed during the surgery, but postoperative imaging, autopsy, etc., revealed vascular injuries or hematomas in the femoral area or pelvis.

Among hip surgical procedures, the surgical field of femoral osteosynthesis is a narrow space in the deep femoral area, so if vascular injury occurs on the opposite side of the site of instrument insertion, it is difficult to identify bleeding visually. In total hip arthroplasty, bleeding cannot be easily found visually if vascular injury occurs in the pelvis. This difficulty in identifying bleeding visually during surgery greatly differs from usual surgical operations. When a large artery is damaged by a drill, blood squirts out from the drill hole, and the blood pressure often decreases immediately after that. In contrast, if a thin artery or vein is damaged, bleeding gradually progresses when the bleeding site is compressed by its surrounding muscle or organ. Thus, hypotension, tachycardia, and other relevant conditions associated with bleeding may not immediately appear. It is essential to undertake surgery by recognizing that vascular injury associated with surgical operation, which is not visible, may occur during hip surgery and that symptoms of vascular injury may slowly manifest.

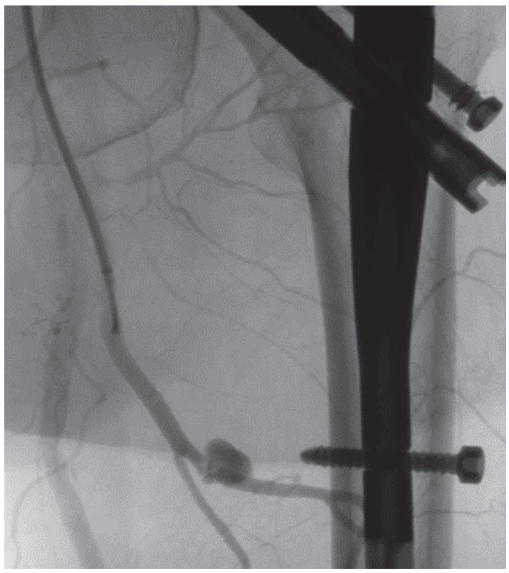
Actually, bleeding due to vascular injury, which is difficult to identify visually, is rarely explained to the patients or their family members before surgery. In addition to the bleeding risk mentioned in Recommendation 1, we hope that explaining the risk of vascular injury caused by surgical operations before surgery will be considered in the future.

● Concept to avoid vascular injury

<Leg position for femoral osteosynthesis>

The femoral reduction procedure is performed with the affected leg placed in adduction, internal rotation, and traction using a traction table. While fluoroscopically checking the reduction, the bone is fixed with screws after drilling using a plate and intramedullary nails. The common femoral artery/vein, deep femoral artery/vein, superficial femoral artery, lateral circumflex femoral artery/vein, or other blood vessels may be damaged when drilling for side stop screws to fix a plate or intramedullary nails or inserting screws (see Figure 1). Of the 10 cases of femoral osteosynthesis, vascular injury occurred in four cases and there were deep femoral artery injuries in two cases.

Figure 1　Image showing a deep femoral artery injury



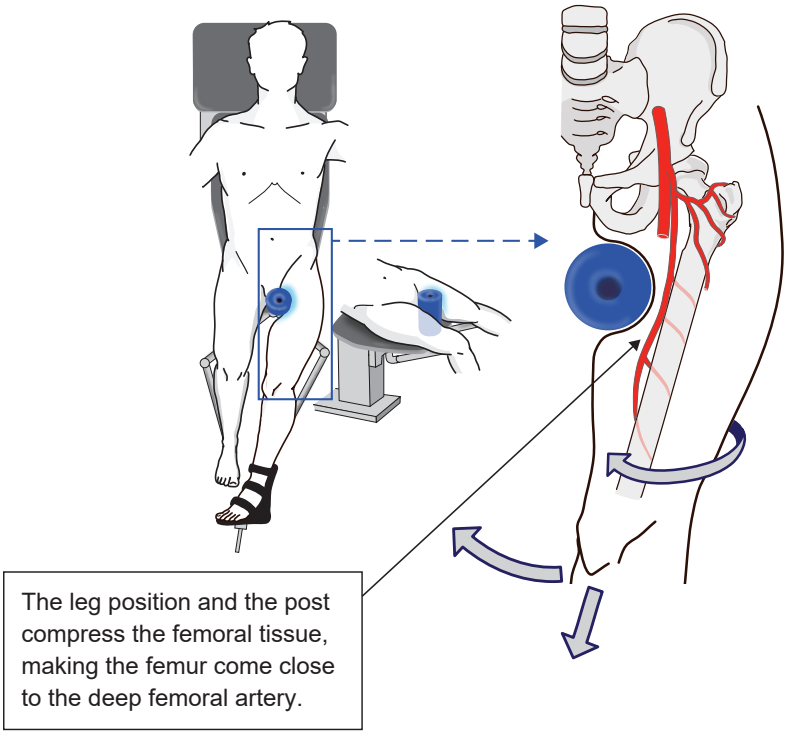
A drill and screws were used for surgery, and a false aneurysm was identified three days later.

Nishikawa T, Otani S, Kato S, et al. Pseudoaneurysm of the Deep Femoral Artery Revealed after Operation of Femoral Trochanteric Fracture: Report of Two Cases. Journal of Kanagawa Orthopaedics and Traumatology Society. 2021; 34 (4): 129-132[14] (in Japanese) (reprinted with permission).

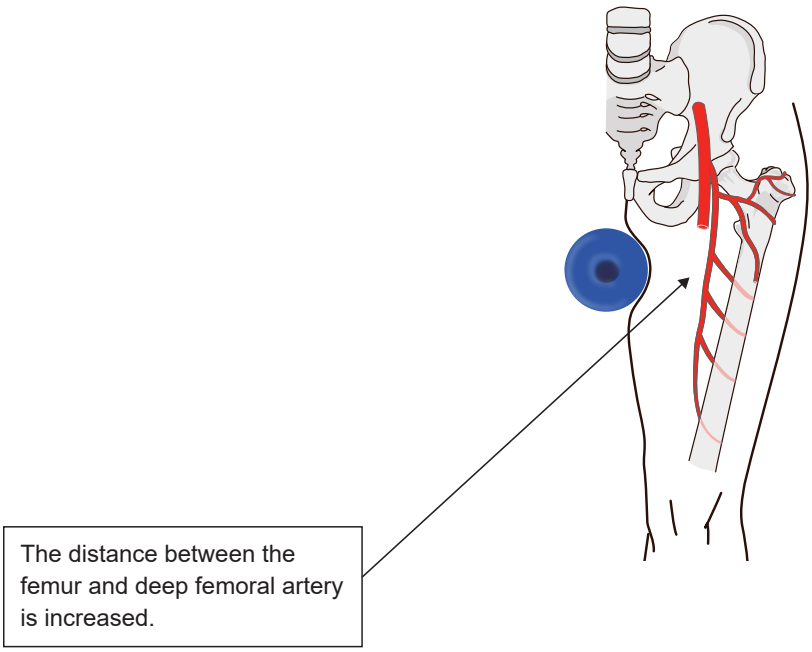
At that time, while it varies among individuals, the leg positions such as adduction, internal rotation, and traction, and the post of the traction table may compress the thigh, and the deep femoral artery may come close to the femur, which is likely to cause vascular injury (see Figure 2-(1)). It has been reported that when loosening adduction, internal rotation, or traction, the compression of the thigh by the post is released, creating the farthest distance between the femur and blood vessel (see Figure 2-(2)).[15] In eight of the 10 cases of femoral osteosynthesis, the leg position was not adjusted, such as loosening traction when drilling a hole for side stop screws. One of the approaches to avoid vascular injury is to release adduction, internal rotation, or traction once until reduction is maintained, adjust the leg position to keep a distance between the femur and blood vessels, and then carry out drilling.

Figure 2 Changes in the positional relationship between the deep femoral artery and femur by the adduction, internal rotation, and traction of the hip joint

(1) The leg in adduction, internal rotation, and traction



(2) Adduction, internal rotation, and traction loosened

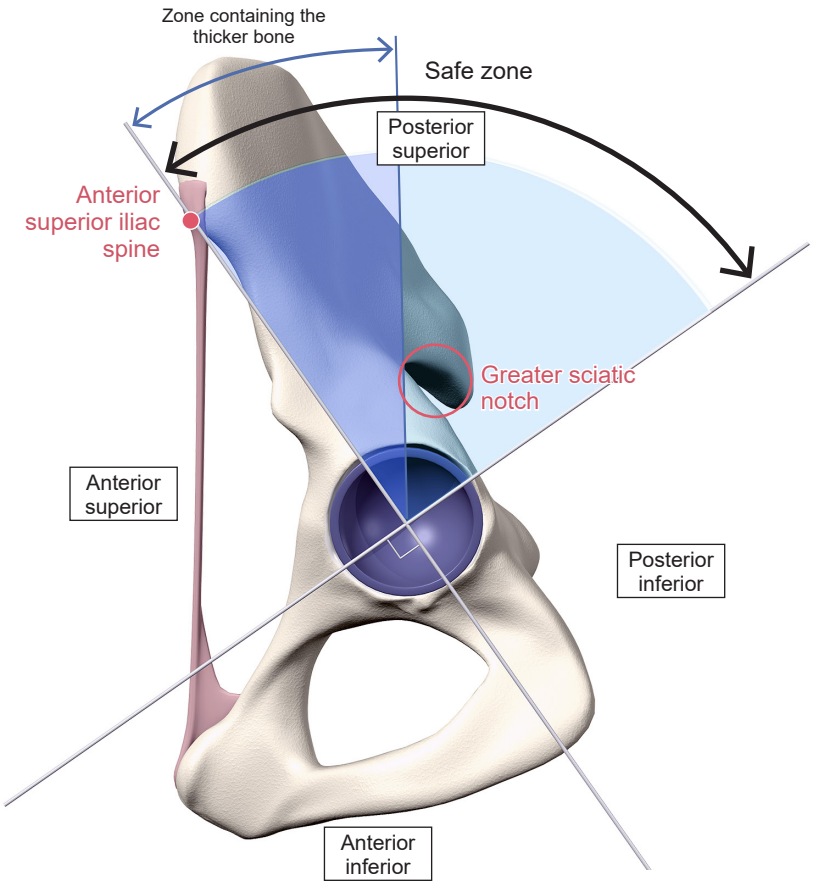


<Safe zones in the acetabulum for total hip arthroplasty>

In total hip arthroplasty, screws are often used to fix a cup on the acetabulum side because acetabular aplasia is present in many Japanese patients. However, drilling and screwing for fixation may damage blood vessels in the pelvis. In five of the six cases of total hip arthroplasty, vascular injury (including those suspected) occurred in the pelvis, two of which were external iliac vein injuries.

A study on areas where vascular injury is likely to occur when inserting screws in the acetabulum has been reported for vascular injuries in total hip arthroplasty. In the report, the acetabulum is separated into quadrants, which are formed by drawing two lines: One line is from the anterior superior iliac spine through the center of the acetabulum, while the other line is drawn perpendicular to the mid-point of the acetabulum. The posterior superior quadrant contains sufficient bone stock and distance from blood vessels, and thus it is considered to be a safe zone.[16] In particular, the zone between the straight line from the anterior superior iliac spine through the center of the acetabulum and the line from the center of the acetabulum passing proximal to the greater sciatic notch contains the thicker bone and is safe (see Figure 3-(1)). Inserting a drill or screw in this safe zone is a way to avoid vascular injury. However, note that the number of screws that can be inserted in the safe zone is limited in patients with acetabular aplasia, and if there is a bone deformity or defect, a drill or screw cannot always be inserted in the safe zone.

Figure 3-(1)　Safe zones for the insertion of drills and screws



Even in the safe posterior superior zone (see Figure 3-(2) a, b, and c), the possibility of damaging arteries, veins, or nerves cannot be ruled out depending on the direction of inserting screws, etc. Points to note for this are as follows:

When inserting a screw posteriorly in direction (a), the superior gluteal artery/vein or nerve may be damaged.

When inserting a screw posteriorly and inferiorly in direction (b), the sciatic nerve may be damaged.

When inserting a screw anteriorly and superiorly in direction (c), the external iliac artery/vein may be damaged.

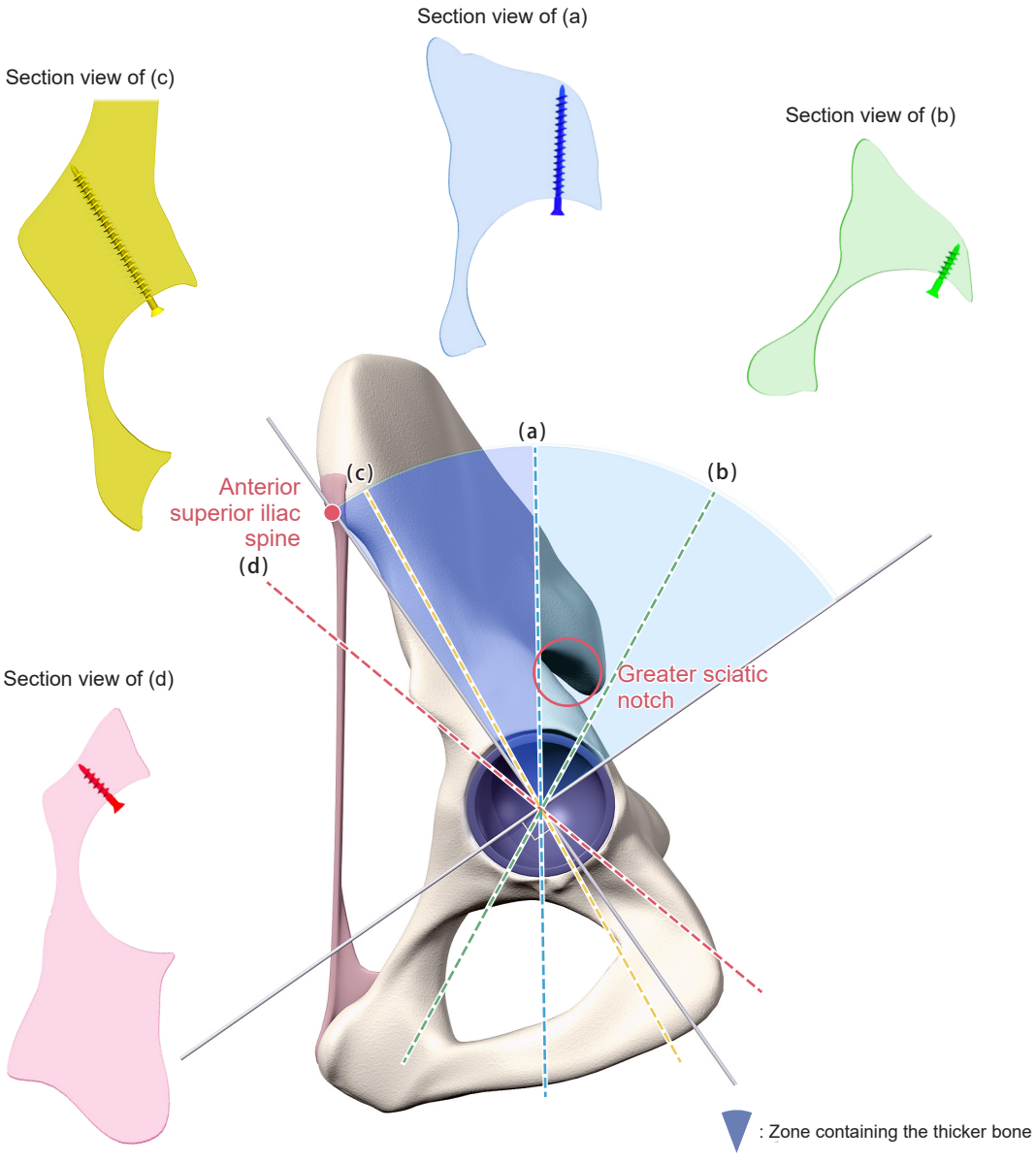
Careful attention should be paid when a screw, etc., has to be inserted out of the safe zone.

Screws, etc., are rarely inserted in direction (d), but in the anterior superior direction, the external iliac artery/vein may be damaged.

In addition, in the anterior inferior direction, there are obturator artery/vein and nerve, so caution should be exercised.

When inserting screws, etc., for fixing a cup during total hip arthroplasty, the safe zone should always be taken into consideration, and it is important to perform the operation while being aware that there are blood vessels on the back of the acetabulum.

Figure 3-(2)　Directions of screw insertion and their section views (the cup in each section omitted)



*Video

“Anatomy that should be understood for total hip arthroplasty -Avoiding pelvic vascular injuries-”

Expectation for the development of a drill and diagnostic imaging for preventing vascular injury

Usually, excessive drilling is avoided using a drill stopper or the operator's common sense, and the presence of bone penetration is checked post hoc by fluoroscopic imaging after the operation. In order to prevent vascular injury, it is preferable to develop, for example, a function that automatically stops the spinning when the tip of the drill has penetrated the bone in the course of drilling.

Preoperative contrast-enhanced CT to check the vessel course is becoming common for revision surgery or when the bone is significantly deformed. In some medical institutions, intraoperative navigation is used, or organ models are created using a three-dimensional printer. However, there are cases where blood vessels were damaged even when intraoperative navigation or organ models were utilized, so the current systems have limitations. Going forward, we anticipate the development of a system showing a vessel course that is synchronized with the surgical procedure, a navigation system for checking the direction and depth of drilling and screw insertion in real time, and an operation-supporting robot.

[Assessment of the circulating blood volume during surgery]

Recommendation 4

When hypotension, tachycardia, or other relevant conditions persist even after the infusion, transfusion, or administration of vasopressors during surgery, there may be bleeding that cannot be identified visually. The shock index should be checked, and if it is above "1," hemorrhagic shock should be suspected. All team members should take a time-out during surgery to assess the circulating blood volume and take action accordingly.

● Checking a shock index

The shock index is used for the initial assessment of hemorrhagic shock (hypovolemic shock). It is a value calculated from the ratio of the heart rate to systolic blood pressure. However, the medical history, history of drug treatment, and other relevant matters may affect the heart rate and blood pressure. In such a case, it may not be possible to accurately determine the shock, but it can be easily used during surgery regardless of the size or the status of personnel structure of the institution where the hip surgery is performed. For this reason, the present Recommendations recommend the use of the shock index (see Column 4).

Criteria for the normal ranges of the shock index are 0.5 to 0.7[17] and should be used as an index for assessing shock. A shock index score of 1 is considered to be the clinical state of approximately 20% loss of circulating blood volume and can be a criterion for starting the administration of red blood cells. When the score is above 1, hemorrhagic shock is suspected. If hypotension or tachycardia is observed, it is essential to pay attention to changes in the shock index over time.

For hip surgery, as mentioned in Recommendation 3, bleeding in the inner femoral area or the pelvis is not visible, and blood pooled in a drape or floor cannot be accurately checked only by counting the number of gauzes or the amount of blood aspirated. When hemodynamics is unstable, and hypotension, tachycardia, or oliguria persists even after fluid replacement, blood transfusion, or the administration of vasopressors, there may have been a greater amount of blood loss than the surgeon is aware.

In 18 of the 20 target cases, hypotension or tachycardia occurred during the surgery, and fluid loading, blood transfusion, or vasopressors were given. In eight of these cases, the vascular injuries were assumed to be caused by surgical procedures such as drilling and screw insertion. In two cases, arterial bleeding was visible and stopped during the surgery, whereas the vascular injuries could not be identified visually in six cases during the surgery.

In the process of the analysis for the present Recommendations, when the intraoperative shock index was calculated post hoc, it was above 1 in 14 cases during the process (see Table 1). The shock index was actually checked during surgery in four cases. When hypotension or tachycardia persists even after giving fluid replacement, blood transfusion, or vasopressors for elevating the blood pressure, vascular injury may have occurred at a site that is not visible during surgery. In such a case, the shock index should be checked, and if its score is above 1, hemorrhagic shock should be suspected.

Taking a time-out during surgery and an assessment of the circulating blood volume

When the shock index score is above 1, hemorrhagic shock is suspected so a time-out should be taken during surgery to share the information among team members. Of the 14 cases with a shock index score greater than 1 during the surgery, a time-out was taken in only one case during the surgery. In hip surgery, there may be bleeding that cannot be identified visually. Thus, it is important that all team members stop their operations once whenever possible, assess the circulating blood volume with the surgeon based on the operation in the surgical field, information on blood loss, and general condition such as vital signs, and consider the actions to take.

For the assessment of the circulating blood volume, the changes over time in vital signs, the amount of blood loss, urine output, the changes in the shock index, and hematological values should be used as references. In the 14 cases with a shock index score greater than 1 during the surgery, hemoglobin levels were measured in six cases, and blood gas tests were also carried out in three cases. As for blood tests, in addition to checking the hemoglobin level, which reflects the degree of bleeding, adding a blood gas test, if possible, makes it possible to ascertain the severity of metabolic acidosis based on pH and lactate levels. If the circulating blood volume is determined to be insufficient based on the data, the infusion rate should be increased, and red blood cells need to be administered.

An increase in the amount of blood loss may result in coagulation defect due to coagulation factor deficiency. Fresh frozen plasma or platelet concentrate should be administered according to blood clotting ability and platelet counts. When there is a large amount of blood loss or its risk is high, adequate clotting factor replacement in the early stage is suggested to improve the outcome.[18] In four of the 20 target cases, the amount of blood loss during surgery was equivalent to 50% of the circulating blood volume, but only red blood cells or autologous blood was administered. Changes in blood clotting ability should be checked, and the early administration of fresh frozen plasma or platelet concentrate should be considered as well.

Actions to take until the arrival of a blood product for transfusion

In nine of the 20 target cases, blood products for transfusion were urgently ordered during or immediately after the surgery. In three of them, there was one intravenous line before the blood products for transfusion arrived. If the anticipated amount of blood loss is ≥500 mL for adults, normally, the insertion of two large-diameter intravenous lines or central venous catheters are considered to enable appropriate fluid resuscitation.[19] In order to promptly administer a blood product for transfusion after its arrival, it is preferable to ensure two or more intravenous lines beforehand.

Furthermore, in the case where it takes time to supply blood products for transfusion from the blood center for geographical reason, it has been considered acceptable for medical institutions with blood products to provide them to medical institutions that require them.[20] Establishing a cooperation system with medical institutions that keep a stock of blood products for transfusion in ordinary times leads to prompt actions during an emergency.

Actions to take when a vascular injury is suspected during a surgery

In femoral osteosynthesis, if there are findings such as hypotension and the swelling of the affected leg after drilling, vascular injury may have occurred at a site that is not visible. If a vascular injury is suspected, cooperation should be, as necessary, requested to related medical departments, and the identification of the bleeding site by angiography should be examined.

In two of the 10 cases of femoral osteosynthesis, femoral arterial bleeding was recognized during the surgery. Hemostasis was attempted using packing by inserting a screw in the drill hole and directly applying pressure. Ai revealed hematomas in the femur and buttocks. Astriction alone may be insufficient for femoral arterial injury. When the surgeon becomes aware of bleeding, hemostatic treatment should be considered.

In reality, however, the guidelines do not specify the diagnostic method to take when a vascular injury is suspected during surgery or the actions to be taken when a vascular injury is identified, so we hope that academic societies will consider them in the future.

Column 4: What is the shock index?

The shock index is a concept proposed by Allgöwer, et al. in the 1960s. It is a value calculated from the "heart rate divided by systolic blood pressure."[21] Criteria for normal ranges are 0.5 to 0.7. Its usefulness and appropriateness have been studied, but the definition has not been established in guidelines by academic societies at present. Only the approximate amount of blood loss is included in the "Guide for Management of Critical Bleeding in Obstetrics."[22] The shock index is often used for the early assessment of hemorrhagic shock by obstetricians, the outpatient emergency unit, and for trauma. It cannot replace the measurement of central venous pressure or the circulating blood volume. It is essential to evaluate changes over time in the shock index. If the score is above 1, approximately 20% loss of the circulating blood volume is anticipated. The shock index has been employed in general clinical practice as an instrument that can approximately evaluate hemodynamics.

However, the shock index may be affected by anesthetics, the depth of anesthesia during surgery, the level of pain, medical history, history of drug treatment, and other relevant matters. In older adults, hypertensive patients (particularly those who are on antihypertensive drugs such as β blockers and calcium antagonists), and patients with heart failure, the heart rate does not adequately respond even if the hemodynamics changes. Thus, one should note that the shock index may not accurately reflect the amount of circulating blood loss in some cases. For this reason, it is important not to make a clinical judgement based on the shock index alone, but to assess the patient's condition in combination with other vital signs.[23]

[Imaging review before leaving the operating room]

Recommendation 5

When hypotension or tachycardia during surgery persists even after completing the surgery, there may be a pelvic vascular or a deep femoral artery injury even if the amount of blood loss during surgery is small. If hypotension or other relevant conditions persist, the implementation of computed tomography (CT) or ultrasonography should be considered to check for bleeding before the patient is removed from the operation room.

Implementation of an imaging test when returning to the ward from the operating room

The shock index was calculated post hoc for the 20 target cases and was above 1 in 11 cases during the process from the completion of surgery to returning to the ward. Of these, the amount of blood loss during surgery was small in some cases. Even if the amount of blood loss during surgery was small, a deep femoral artery or blood vessels in the pelvis, which cannot be visually detected, may be damaged during surgery. If hypotension or tachycardia persists even after completing surgery, it is important to check whether or not there is bleeding. Thus, the stabilization of vital signs should be ensured, and the implementation of CT should be considered when removing the patient from the operating room to the ward.

If it is difficult to perform CT, ultrasonography should be conducted if possible because it may easily show hematoma in the femoral or abdominal area.

Even when a hemostatic procedure was carried out during surgery, if hypotension or other relevant conditions persist, there may be bleeding. In such a case, it is essential to implement CT when the patient is returning to the ward to check the status of the hemostatic procedure.

Diagnosis of bleeding and actions

If bleeding is identified, contrast-enhance CT (scanning the arterial phase and venous phase) or angiography should be performed, and if it is arterial bleeding, a measure such as direct surgery and endovascular treatment with coil embolization should be promptly discussed with related medical departments.

When a contrast-enhance CT or angiography does not reveal a pelvic arterial injury, there is the possibility of venous injury. In one case of external iliac vein injury associated with total hip arthroplasty, blood transfusion and a vasopressor were given during surgery, but hypotension persisted. The patient's condition suddenly deteriorated approximately one hour after returning to the ward. The CT showed a pelvic hematoma, but the arteriography could not detect the source of bleeding so conservative treatment was administered. It is often difficult to perform surgical treatment when the site of bleeding cannot be identified even for skilled vascular surgeons, so venography from the femoral vein approach to confirm the site of bleeding should be considered as well. In recent years, it has been reported that hemostasis can be done with an IVR technique using stent grafts.[24)]

Collaboration with vascular surgeons and radiologists

For femoral arterial injury and pelvic vascular injury, the determination of the bleeding site and review of a treatment policy by specialists such as vascular surgeons and radiologists are essential. If these can be handled in institutions, consultation with a vascular surgeon and radiologist should be held, and the site of bleeding should be promptly assessed using angiography.

In two cases of external iliac vein injury, actions for bleeding were taken in collaboration with medical departments in the hospital. These procedures may be urgently taken in the night, so it is preferable to arrange collaborations with related medical departments and other medical institutions beforehand according to the size of medical institutions.

[Prompt actions for postoperative hemorrhagic shock]

Recommendation 6

After surgery, the signs of shock such as hypotension, tachycardia, oliguria, and tachypnea should be monitored. If there is an increase in the shock index or the amount of blood loss, femoral swelling, low back pain, or abdominal pain, the patient should be closely checked for hemorrhagic shock. The circulating blood volume should be checked, and an investigation into the cause and treatment should be started.

● Observation of the signs of shock and review of the shock index

In 18 of the 20 target cases excluding those transferred to another hospital or treated with laparotomy hemostasis, postoperative management was carried out in each case as giving symptomatic treatment such as blood transfusion for hypotension, tachycardia, and other relevant conditions. A review of records revealed that there was a patient who had signs of shock such as hypotension, tachycardia, oliguria, peripheral coldness, tachypnea, and disturbed consciousness soon after returning to the ward. However, although the signs were present, they were assumed to be attributable to other causes, for example, "bleeding associated with lavage fluid," "hypotension due to vagal reflex," "tachycardia due to the effect of dehydration," and "tachypnea due to the effect of pain" in response to the report of hypotension and bleeding through the gauze. When the shock index was calculated post hoc, it was above 1 when the patient returned to the ward in some cases or increased over time in some cases (see Table 1), showing decreases in the circulating blood volume.

After surgery, it is necessary to observe the signs of shock such as hypotension, tachycardia, and oliguria, check for any increase in the shock index, and determine whether or not there is a decrease in the circulating blood volume due to bleeding (see Table 3).

Table 3 Observation items for determining bleeding and hemorrhagic shock after hip surgery

- ☐ Hypotension
- ☐ Tachycardia
- ☐ Tachypnea
- ☐ Decreased level of consciousness
- ☐ Oliguria
- ☐ Peripheral coldness/cold sweating/cyanosis
- ☐ Increase in the amount of drained blood/blood in gauze
- ☐ Wound pain
- ☐ Unrest
- ☐ Thigh swelling (in the case of femoral osteosynthesis)
- ☐ Abdominal pain/abdominal distension/low back pain (in the case of total hip arthroplasty)
- ☐ Increase in the shock index

Checking and reporting urine output and the amount of drained blood after surgery

In the 18 cases for which the surgeon team continued postoperative management, the nurses mainly reported hypotension and tachycardia to the physicians, while urine output was not reported for any of the cases. In nine of the 18 cases, urine output was poor after the surgery. Nonetheless, there were cases where urine output was followed up after the patients' conditions suddenly deteriorated and where urine output was instructed to be monitored once every four to six hours or once a day. Furthermore, there were cases where the output was not reported even though a large amount of drained blood was detected. Postoperative observation should focus not only on blood pressure and the heart rate, but also on oliguria and increases in bleeding through gauze and the amount of drained blood, and if these are identified, they should be reported to the physicians as information for assessing hemodynamics after surgery (see Table 3).

Symptoms suggesting bleeding after hip surgery

In four cases of femoral osteosynthesis, thigh swelling occurred after the surgery, and the deep femoral artery was injured in two of them. In two cases of total hip arthroplasty, the patients complained of low back pain or abdominal pain soon after the surgery, and there was bleeding in the pelvis.

Bleeding after hip surgery cannot always be detected only with the amount of drained blood or bleeding through gauze. When bleeding increases in a narrow and closed space in the thigh, it does not necessarily flow out to the external area but eventually causes swelling. Bleeding in the pelvis is difficult to detect based on findings on the external surface, but patients may complain of pain or discomfort in the lower back or abdominal. However, if the patient has reached the stage where swollen abdomen can be seen, bleeding has often already worsened. When thigh swelling, low back pain, or abdominal pain occurred, there is the risk of persistent bleeding due to a vascular injury involving the deep femoral artery, external iliac artery/vein, etc. Therefore, if there are signs of shock, an increase in the shock index, and femoral or abdominal findings after surgery, one should check closely for hemorrhagic shock (see Table 3).

Confirming the circulating blood volume and actions to be taken for the site of bleeding when hemorrhagic shock is suspected

Unstable hemodynamics and circulatory failure in major organs eventually lead to a fatal outcome. There was a case where the signs of shock persisted and the shock index elevated even after fluid/blood transfusion. When hemorrhagic shock is suspected, the current treatment should be revised, and the circulating blood volume should be confirmed as soon as possible. First, get the appropriate staff while giving fluid resuscitation or blood transfusion to the patient. Then, the presence or absence of bleeding and the site of bleeding should be checked using blood tests, ultrasonography, and CT, and treatment should be initiated. It is important to quickly carry these steps out in collaboration with related medical departments.

In 15 of the 20 target cases, the patients died within 24 hours after surgery. There were cases where the nurses had requested physicians to examine the hypotension or tachycardia in the patients, but the physicians did not do so but only verbally give instructions to administer drugs or continue observing. When physicians do not examine patients after receiving a report of their conditions or when the patients' conditions do not improve, nurses should consider consulting senior physicians, or the on-call doctor in other departments, nighttime head administrator, etc., if it is during the night. In addition, the items to check (see Table 3) and reporting criteria/route should be specified in ordinary times for promptly identifying hemorrhagic shock after hip surgery and appropriately handling it. Physicians should not just give instructions by telephone when they receive a report, but establish a system suitable for the conditions of each institution, such as directly examining patients. Furthermore, even if the reporting was overtriage, physicians should accept it, respect the process, and foster an organizational culture that enables mutual collaboration.

Column 5: Sudden deterioration of the condition due to surgical complications and DNAR

In the target cases, no intensive treatment was given at the time of sudden deterioration in patients for whom Do Not Attempt Resuscitation (DNAR) was confirmed with their family members prior to surgery or at the time of sudden deterioration. Currently, a policy for the extent to which intensive treatment and tests should actually be carried out is often decided when the conditions of older adult patients suddenly deteriorate during the perioperative period. However, for hip surgery, which is performed with the aim of treating the patient and the expectation that the surgery will improve daily living, refraining from investigating into the cause of and giving treatment for sudden deterioration due to surgical complications differ from a DNAR.

A DNAR is a policy based on a patient's declaration of intention that is taken into consideration only when there is no chance of saving the patient's life or at the time of cardiopulmonary arrest due to the natural course of underlying diseases; it should be viewed as separate from sudden deterioration due to surgical complications.[25] It is desirable to reconfirm the term, definition, and correct understanding of DNAR again.

5. What we expect of (or what we want to propose to) academic societies, companies, etc.

We expect academic societies and companies to tackle the following issues and thereby make it easier to further improve patient safety.

● What we expect of academic societies

We expect the Japanese Orthopaedic Association and related academic societies to examine and disseminate the following items.

(1) Review of the methods of diagnosis and handling of vascular injuries during hip surgeries

We would like the academic societies to consider presenting the methods of diagnosing and handling vascular injuries, such as the deep femoral artery during femoral osteosynthesis and pelvic vascular injury during total hip arthroplasty, in guidelines and other relevant materials.

(2) Review the explanation that should be given to patients undergoing a hip surgery

We would like the academic societies to examine the concept of preoperative explanation and how specific explanations should be given regarding the bleeding risk, vascular injury, and the characteristics of bleeding during a hip surgery.

(3) Demonstration of cases where contrast-enhance CT is recommended for understanding the vessel course before surgery

We would like the academic societies to specify for which patients a three-dimensional structure should be established based on contrast-enhance CT results, and the positional relationship between the vessel course and the femur or pelvis should be verified to prevent a vascular injury during a hip surgery.

● What we expect of companies

(1) Development and distribution of a drill to avoid a vascular injury

We would like companies to consider the development and distribution of a function to automatically stop drilling after penetrating the bone so that the drill does not pass through the femur or acetabulum, which will cause a vascular injury.

(2) Development of a navigation system and surgery-supporting robot for avoiding vascular injury

Currently, there is no function to check the direction and depth of drilling and screw insertion on a real-time basis or to control the drill for avoiding a vascular injury. We would like companies to examine the development of navigation systems, surgery-supporting robots, or other relevant devices with a function to avoid vascular injuries that can be used when joint deformity or bone destruction is severe.

● What we expect of the government

(1) Revision of medical service fee points

Robot surgery units to support the formation of the acetabulum and reliable implant fixation during total hip arthroplasty are covered by the national health insurance. We would like to see the medical service fee points revised so that such treatment becomes more widely used.

6. Conclusion

The present Recommendations analyzed in detail 20 cases of deaths, which were assumed to be attributable to hemorrhagic shock associated with hip surgery, reported to the Medical Accident Investigation and Support Center and provided 6 recommendations.

As measures to be taken before surgery, the bleeding risk should be assessed first using various indices with related medical departments. If the risk is judged to be high, blood products for transfusion should be secured, and ICU management after surgery should be prepared, and if it is a small-scale medical institution, collaboration with a supporting medical institution should be made. In addition, we have recommended the time point of starting blood transfusion to be shared among the treatment team members, while taking into account the anticipated amount of blood loss and the system of supplying blood products for transfusion in the hospital. We also mentioned the need to recognize the risk of vascular injuries associated with drilling during a surgery and of establishing a system for administering blood transfusion without delay as a team using vital signs, shock index, the amount of blood loss, and hematology data during surgery. Hypotension and unstable vital signs during and after surgery suggest the possibility of a deep vascular injury that was not detected during surgery, so we have stated the necessity of conducting appropriate blood tests and imaging tests. Furthermore, we have emphasized the importance of promptly diagnosing hemorrhagic shock and taking actions after surgery based on a patient's clinical findings, vital signs, and test data because there were cases where postoperative management was found to be inadequate.

Hip surgery is a common surgery in the orthopedic field. The number of surgeries is expected to continue to grow in the future. It should be noted that many of the target patients are older adults with comorbidities and reduced reserve capacity for bleeding. In addition, the risk of damaging the deep femoral artery or pelvic vessels associated with surgical procedures should be fully recognized. The surgery can be performed in medical institutions of any size, but there are small medical institutions without blood products for transfusion readily available and it takes time to order them. Depending on the general condition of a patient before the surgery, the anticipated amount of blood loss, and the level of difficulty of surgical procedures, it is also necessary to establish a system to transfer the patient to an appropriate medical institution.

Finally, we would like to express our sincere gratitude to the medical institutions that worked on investigating the causes of the accidents and the prevention of recurrence, and cooperated in sharing the in-hospital investigation reports. We would also like to express our deepest condolences to the patients who died due to the accidents and to the bereaved families. We hope that the Recommendations will be useful to healthcare professionals as a step toward improving patient safety.

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8. Materials

Bleeding due to hip surgery/Investigation items checklist

Items		Viewpoints		Concrete items
Basic information	Patient information	Age/Sex		Age: years Sex: ☐ Male ☐ Female
		Height/body weight		Height: cm Body weight: kg
		Diagnosis		
		Medical history		
		Type of surgery		(☐ Unilateral ☐ Bilateral)
	Blood tests	Blood count (blood collection date:)		☐ Hb: g/dL ☐ Plt: 0,000/μL ☐ Other:
		Biochemical (blood collection date:)		☐ Alb: g/dL ☐ T-P: g/dL ☐ Other:
		Coagulation (blood collection date:)		☐ PT: sec ☐ APTT: sec ☐ PT-INR: ☐ Other:
		Transfusion-related (blood collection date:)		☐ Blood type ☐ Irregular antibody screening ☐ T&S
Cause of death	Autopsy/Ai	Autopsy results (injured vessel: including those estimated)		
		Ai results (injured vessel: including those estimated)		
	Other	Image findings		
Ascertaining bleeding risk and making preoperative preparations	Bleeding risk	Risk factors for increasing bleeding	Disease condition	☐ Trochanteric fracture ☐ Subtrochanteric fracture ☐ Fracture with significant displacement ☐ Contracture ☐ Deformity ☐ Defect ☐ Bilateral surgery
			History of surgery	☐ Revision surgery
			Decreased blood clotting ability	☐ Decreased plt ☐ Dialysis therapy
			Antithrombotic drug	Drug name: Interruption: ☐ Yes ☐ No
		Reserve capacity for bleeding		☐ Advanced age ☐ Low body weight ☐ Anemia ☐ Low albumin
	Preoperative preparation	Consultation with related departments about blood clotting ability		☐ Yes (☐ Assessment of blood clotting ability ☐ Interruption of antithrombotic drug ☐ Preparation for blood transfusion) ☐ No
		Preparation for blood transfusion		☐ Red blood cells ( ) units ☐ Fresh frozen plasma ( ) units ☐ Platelet concentrate ( ) units ☐ Autologous blood ( ) mL ☐ Salvaging autotransfusion ☐ T&S
		Postoperative management plan		☐ Management in the ICU, etc. ☐ Management in the general ward
		Cooperation in the event of bleeding	In the hospital	☐ IVR (☐ Available ☐ Not available) ☐ Vascular surgery (☐ Available ☐ Not available)
			Out of hospital	☐ Vascular surgery (Available:) ☐ No
		Details of explanation on the bleeding risk		☐ Bleeding risk ☐ Preparation for blood transfusion ☐ Actions to be taken in the event of bleeding ☐ Postoperative management plan
Establishment and sharing of the approximate time point of starting blood transfusion	Setting	Anticipated amount of blood loss		mL
		Ratio of the anticipated amount of blood loss to the patient's circulating blood volume*		% [*circulating blood volume (mL) = Patient's body weight × 70 mL]
		Items for establishing the approximate time point		☐ Amount of blood loss mL ☐ Blood pressure mmHg ☐ Heart rate beats/min ☐ Hb g/dL
		Blood supply system	Stock in the hospital	units
			Time required	Time required for ordering a blood product in the hospital min
				Time required for ordering a blood product from outside the hospital min
	Sharing	Check items during the time-out before starting surgery		☐ Type of surgery ☐ Operative site ☐ Anticipated amount of blood loss ☐ Other: ☐ Approximate time point of instructing and starting blood transfusion ☐ Amount of blood product for transfusion to be prepared

Items		Viewpoints		Concrete items
Intraoperative management	Intraoperative procedure and bleeding	Adjustment of the traction position (in the case of femoral osteosynthesis)		☐ Yes ☐ No
		Findings when a tool such as a drill and screw is inserted		☐ Yes (☐ Bleeding ☐ Hypotension ☐ Requires an unplanned procedure ☐ Other:) ☐ No
		Discovery of vascular injury		☐ Yes ( ) ☐ No
		Hemostatic procedure		☐ Yes ( ) ☐ No
		Amount of blood loss during surgery		mL
		Ratio of the amount of blood loss to the circulating blood volume		%
	Course during the surgery	Course such as vital signs and in-out		
		Changes in the shock index		
		Action taken for hypotension and tachycardia		☐ Fluid transfusion ☐ Vasopressor ☐ Blood transfusion (☐ Red blood cells units ☐ Autologous blood mL)
		Time-out during surgery	Check items	☐ Process of surgery ☐ Amount of blood loss ☐ Changes in vital signs ☐ Changes in the shock index
			Assessment of the circulating blood volume	☐ Hypotension ☐ Tachycardia ☐ Shock index ☐ Amount of blood loss ☐ Oliguria ☐ Manipulation of the surgical field ☐ Other: ☐ Blood test ·Blood count (☐ Hb: g/dL ☐ Plt: 0,000/μL ☐ Other:) ·Coagulation (☐ PT: sec ☐ APTT: sec ☐ PT - INR:) ·Blood gas (☐ pH: ☐ Lactic acid: mmol/L ☐ Other:)
		Circulating blood volume and treatment for blood clotting ability		☐ Blood transfusion (☐ Red blood cells units ☐ Autologous blood mL ☐ Platelet concentrate units ☐ Fresh frozen plasma units) ☐ Intravenous line ensured
Returning to the ward	Imaging test	Test method		☐ CT (☐ Plain ☐ Contrast-enhanced) ☐ Ultrasonography
		Findings of bleeding		☐ Yes ( ) ☐ No
Postoperative management	Postoperative course	Signs of shock		☐ Hypotension ☐ Tachycardia ☐ Tachypnea ☐ Decreased level of consciousness ☐ Oliguria ☐ Peripheral coldness/cold sweating ☐ Unrest ☐ Increase in the shock index
		Findings based on which bleeding was determined		☐ Increase in the amount of drained blood ☐ Increase in blood in gauze ☐ Wound pain
				Femoral osteosynthesis: ☐ Thigh swelling Total hip arthroplasty: (☐ Abdominal pain ☐ Abdominal distension ☐ Low back pain)
		Details reported to the physician		
	Search of the bleeding site	Test method		☐ CT (☐ Plain ☐ Contrast-enhanced) ☐ Ultrasonography
		Findings of bleeding		☐ Yes ( ) ☐ No
	In-hospital system	Consultation/reporting system when the condition does not improve		☐ Yes ☐ No

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Conflicts of interest
The Medical Accident Investigation and Support Center has confirmed the status of conflicts of interest self-declared by the respective members of the Expert Analysis Subcommittee in terms of the contents of this report of recommendations.

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Recommendations for the prevention of recurrence of medical accidents (Number 18)

Analysis of Deaths Related to Bleeding Due to Hip Surgery

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