Recommendations for the prevention of recurrence of medical accidents
Number 16

Analysis of Deaths Related to "Airway Obstruction Due to Cervical Surgery"

March 2022

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

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 16)

Fumimaro Takaku
Chair of the Board of Directors
Japan Medical Safety Research Organization

Based on the Medical Accident Investigation System enforced 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 and to prevent recurrence of medical accidents. Along with the advancement and diversification of the current medical surroundings, medical institutions are supposed to have taken preventive measures against medical accidents, accumulating reports of near-miss incident cases so as not to allow serious accidents to occur. In practice, however, serious events do occur in fact, at times resulting in the death of the patient. Such cases have been reported to ISC. I believe that the mission of the Medical Accident Investigation System is to accumulate these reports, to investigate and analyze each case and to provide information for preventing recurrence of serious events.

Six years and five months have elapsed since the enforcement of the Medical Accident Investigation System, and we, ISC, have published our sixteenth report compiled in our Expert Analysis Subcommittee to prevent recurrence of medical accidents. The number of "In-Hospital Investigations" completed and reported to ISC was 1,743 cases in total during the five years and six months from the start of the system to April 2021. As the sixteenth theme of analysis, we decided to take up the cases of deaths related to "airway obstruction due to cervical surgery." The number of target cases that were reported under the Medical Accident Investigation System was 10. The recommendations in this report have been compiled in view of the seriousness of deaths resulting from cervical surgery-related fatal accidents, although they seldom occur.

ISC's measures to prevent recurrences of accidents are based on the analyses of "death" cases and are focusing on "how to avoid accidents that may result in death." "Guidelines" issued by the government and academic societies were examined from broad knowledge. We believe that our measures should be distinguished from such guidelines.

These recommendations do not limit or oblige the discretion of health-care workers, because each medical institution may have different environments and circumstances, such as size and system. With this in mind, we sincerely hope that the recommendations in this report will be widely utilized in each medical institution to avoid deaths related to airway obstruction due to cervical surgery.

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 the recurrence, for their understanding and cooperation.

Recommendations for the Prevention of Recurrence of Medical Accidents (Number 16)

Analysis of Deaths Related to "Airway Obstruction Due to Cervical Surgery"

<Characteristics of the 10 target cases>

- In eight cases, while SpO_2 was monitored after surgery, respiratory rate was not measured.
- All the cases resulted in airway obstruction with hemorrhage.
- In nine cases, it took 5 to 60 minutes to establish the airway after the physician's arrival.
- The surgical procedures used were anterior cervical fusion, thyroidectomy, thyroglossal cyst excision, and cervical lymph node dissection. These surgeries were performed at the following various clinical departments: departments of orthopedics, neurosurgery, surgery, otorhinolaryngology, and Oral and Maxillo-facial surgery.

[Recognizing the risk of airway obstruction]

Recommendation 1

It is essential to recognize that patients undergoing cervical surgery, such as anterior cervical fusion, thyroidectomy, and cervical lymph node dissection, are at risk of developing asphyxia attributable to laryngeal mucosal edema caused by impaired venous return after surgery. Patients experiencing secondary hemorrhage are at particularly high risk of developing asphyxia.

[Observing respiratory status after surgery]

Recommendation 2

Even if airway stenosis progresses due to laryngeal mucosal edema, a decrease in the SpO_2 is not observed until immediately before a sudden change of condition. Therefore, the patient should be monitored for an increase in respiratory rate, and cervical auscultation should be performed to check for the presence or absence of wheezing and stenotic sound.

[Observing symptoms and cervical conditions after surgery]

Recommendation 3

After cervical surgery, the patient should be checked for cervical swelling and for signs of airway stenosis, including the patient complaining of difficulty in breathing, a sensation of sticking sputum, difficulty in swallowing, or increased wound pain, as well as frequent postural changes and restless body motions.

[Establishing postoperative reporting criteria and measures to take]

Recommendation 4

The physician should specify observation items and establish reporting criteria in terms of signs of airway stenosis after cervical surgery. The medical institution should establish a system that enables a medical team responsible for medical care after cervical surgery to promptly take appropriate measures against any signs of airway stenosis.

[Decision to open the wound and measures to take]

Recommendation 5

If swelling of the neck or increase of the neck circumference is observed after cervical surgery and airway stenosis caused by hematoma is suspected, the wound should be re-opened immediately and hematoma evacuation should be performed. At the same time, the physician should prepare to perform surgical airway management in case respiratory status fails to improve.

[Implementing emergency surgical airway management]

Recommendation 6

Tracheal intubation may be difficult for most of the cases of airway stenosis that have progressed after cervical surgery. For cases in which tracheal intubation is difficult, surgical airway management should be performed without hesitation.

[Establishing a system for conducting emergency surgical airway management]

Recommendation 7

Every medical institution that engages in cervical surgery should establish a system that enables emergency surgical airway management to be performed.

The full text of Recommendations No. 16, "The Analysis of Deaths Related to Airway Obstructions Due to cervical Surgery" is available on the website of the Medical Accident Investigation and Support Center.
Please click on the QR code on the right to view the material.

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1. Introduction

1) About cervical surgery

Cervical surgery includes various types of surgery such as thyroidectomy performed for thyroid diseases, anterior cervical fusion for cervical spine diseases, and cervical lymph node dissection for head and neck cancer. These surgeries are performed in various clinical departments; for example, anterior cervical fusion is performed in departments of orthopedics and departments of neurosurgery; thyroidectomy is performed in departments of otorhinolaryngology head and neck surgery and departments of thyroid/endocrine surgery; and cervical lymph node dissection is performed in departments of otorhinolaryngology head and neck surgery and departments of Oral and Maxillo-facial surgery. Anatomically, unlike the thorax and abdomen, which respectively have the thoracic cavity and abdominal cavity, the neck has no cavity. The neck contains various tissues that are located close to one another without space between them. In the middle of the neck run the larynx, which is in the upper airway, and the trachea. If postoperative hemorrhage leads to the formation of hematoma in a narrow space, even large vessels such as the internal jugular veins can be easily obstructed, which may impair venous return. This may result in laryngeal edema, asphyxia, and, in the worst case, fatal outcome. Meanwhile, in patients undergoing anterior cervical fusion, the larynx or the trachea may be reversed or compressed for a prolonged period of time during the surgery. This may cause laryngeal edema even in the absence of postoperative hemorrhage, and may also result in asphyxia and fatal outcome. Among patients undergoing thyroid or head and neck surgery, the incidence of postoperative hemorrhage is reported to be between 1% and 2%.[1)2)] In other words, a university hospital or a large hospital, where head and neck surgery is performed on one or two patients per week, experiences one or two cases of postoperative hemorrhage per year. It seems, however, that most of such cases are discovered at an early stage, treated adequately, and resolved before becoming serious. On this occasion, we analyzed 10 fatal cases reported to the ISC during the five years and six months from the enforcement of the system until April 2021. Other than these cases, we suspect that there may have been cases that did not result in death but in serious complications such as hypoxia due to a delay in taking adequate actions.

The Expert Analysis Subcommittee has set a goal of preventing the recurrence of such accidents. In this report of recommendations, we analyze the 10 cases of death in detail, identify common problems, and present measures for avoiding fatal accidents. We hope this report will be read by all the orthopedists, neurosurgeons, otorhinolaryngology head and neck surgeons, thyroid/endocrine surgeons, and oral surgeons who are involved in cervical surgery, as well as ward nurses. We would be delighted if these recommendations can be of any help in avoiding accidental asphyxia after cervical surgery.

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 P35) at the Medical Accident Investigation and Support Center (hereinafter referred to as ISC) selects the subject (theme) of analysis from the cases of accidents reported to the Center. Then, the Committee establishes an Expert Analysis Subcommittee for each theme (see P34) that consists of medical specialists in the theme and prepares recommendations.

Cervical surgery is performed in various clinical departments such as departments of orthopedics, neurosurgery, otorhinolaryngology head and neck surgery, thyroid-endocrine surgery, and Oral and Maxillo-facial surgery. Accordingly, surgeries for the target cases were also performed in various different clinical departments. All these cases developed airway stenosis with hemorrhage after surgery, which rapidly led to respiratory arrest resulting in death. Considering that it would be essential to analyze the cases, and find and implement measures for prevention of recurrence of similar accidents, we selected such accidents as a theme and established an Expert Analysis Subcommittee under this theme.

3) Patient safety approaches that have been taken in relation to the recommendations

The following patient safety information has been published as patient safety approaches taken in relation to airway obstruction occurring after cervical surgery.

○Japan Medical Safety Research Organization

Cautionary cases: Medical Safety Information No. 5 “Management of the Risk of Airway Obstruction after Thyroid Surgery” (April 2014) (in Japanese)

2. Methods of analysis

1) Extraction of target cases

Of 1,743 in-hospital investigation reports on medical accidents submitted to the Center during the period from October 2015 to April 2021, 16 were cases of cervical surgery-related deaths.

Of the 16 cases, 10 cases of death, which were considered to have been attributable to cervical surgery-induced airway stenosis leading to asphyxia, were selected by the Expert Analysis Subcommittee as the target cases for analysis. The remaining six cases of death, which were attributable to procedure-related complications or other causes that were not asphyxia after cervical surgery, were excluded from the target cases.

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 submitted to the Center. 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 7 “Materials”).

3) Meetings of the Expert Analysis Subcommittee

○ First meeting: December 22, 2020
○ Second meeting: April 20, 2021
○ Third meeting: June 9, 2021
○ Fourth meeting: September 14, 2021

• 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.

Case 1

- The patient was in his/her 50s with cervical radiculopathy and a history of asthma
- Anterior cervical fusion (C3-6) was performed. The duration of the surgery was about 4.5 hours, and the amount of blood loss during surgery was unknown. Tracheal extubation was done after completion of the surgery.
- Induration in the neck was observed when the patient returned to the ward. The patient complained of difficulty exhaling about one hour after returning to the room. The percutaneous arterial oxygen saturation (SpO_2) was 99%. While there was no change in neck circumference, the area of induration increased, and the patient was transported into the intensive care unit (ICU). Tracheal intubation was attempted in vain, and cardiac arrest occurred during re-opening of the wound and tracheostomy. The patient died about one week after the surgery.
- The cause of the death was hypoxic encephalopathy attributable to airway obstruction. Ai (Autopsy imaging): absent. Autopsy: present.

Case 2

- The patient was in his/her 50s with traumatic cervical disc herniation and transverse process (C6) fracture
- Anterior cervical fusion (C5/6) was performed. The duration of the surgery was about 3.5 hours, and the amount of blood loss during surgery was about 60 mL. Tracheal extubation was done after completion of the surgery.
- At about 1.5 hours after returning to the ward, the patient had the sensation of sticking sputum, and hoarseness. The SpO_2 was 99%. The body position was changed to the lateral position at the patient's request. Immediately after suctioning a small amount of saliva, the patient's SpO_2 became unmeasurable. The patient's face became pale and the eyes rolled back, shortly after which the patient developed respiratory arrest. A nasopharyngeal airway tube was inserted, and tracheal intubation was attempted with difficulty. When gauze was removed to re-open the wound, swelling of the entire neck was observed. Despite the re-opening of the wound and intubation after removal of hematoma, the patient died about one year after the surgery.
- The cause of the death was hypoxic encephalopathy attributable to airway obstruction. Ai: present. Autopsy: present.

Case 3

- The patient was in his/her 60s with cervical spondylotic myelopathy
- Anterior cervical fusion (details unknown) and iliac transplantation were performed. The duration of the surgery was about 1.5 hours, and the amount of blood loss during surgery was small. Tracheal extubation was done after completion of the surgery.
- The patient complained of pharyngeal pain 30 minutes after returning to the ward and then developed wound pain. About two hours later, the amount of bloody fluid from the drain increased. The SpO_2 was 99% with mild swelling of the neck and marked sweating. Sputum retention was observed. Despite several attempts to remove sputum via suctioning, only a small amount of sputum was extracted. The patient complained of difficulty in breathing. Following the suctioning of sputum, the patient's level of consciousness decreased after violent body movements. Tracheal intubation and cricothyroid ligament puncture were attempted but were difficult to perform. After the wound was re-opened, hematoma was removed and tracheal intubation was performed. The patient was transported by ambulance to another hospital, where hematoma evacuation was performed again. The patient died about two weeks after the surgery.
- The cause of the death was hypoxic encephalopathy attributable to airway obstruction. Ai: absent. Autopsy: absent.

Case 4

- The patient was in his/her 50s with ossification of the posterior longitudinal ligament of the cervical spine and mild hemophilia
- Anterior cervical fusion (C5/6) was performed. The surgery duration was about 1.5 hours, and the amount of blood loss during surgery was about 20 mL. Tracheal extubation was done after completion of the surgery.
- A marked increase in sputum started to be observed three hours after the patient returned to the ward. Suctioning was performed for increased sputum about 10.5 hours later. The patient complained of difficulty in breathing and continued to have the sensation of sticking sputum, which was improved by suctioning of the sputum. When the drain was removed about 20 hours later, subcutaneous bleeding was detected. During a bed bath, the patient was found to have notable sweating and malaise and became unable to bring up sputum. Following suctioning of sputum, the patient developed respiratory arrest. Tracheal intubation and cricothyroid membrane puncture were attempted but were difficult to perform. During tracheostomy, a large number of clots were observed. After removal of the clots, the trachea was identified and airway management was performed. However, the patient died the following day.
- The cause of the death was airway obstruction. Ai: absent. Autopsy: absent.

Case 5

- The patient was in his/her 60s with ossification of the posterior longitudinal ligament of cervical spine
- Anterior cervical fusion (C2-7) was performed. Due to a difficulty with tracheal intubation, a fiberscope was used. During the surgery, bleeding was detected from the superior thyroid artery and arrested. The duration of the surgery was about three hours, and the amount of blood loss during surgery was small. The patient returned to the ward while intubated, with tracheal extubation done about 15 hours after completion of the surgery.
- Increased sputum volume and productive cough were observed after extubation. At nine hours after extubation, the patient, in the supine position, exhibited increased wound pain and tachypnea with an SpO_2 of 93% to 96%. At 17 hours after extubation, marked sweating and agitation were observed with an SpO_2 of 93%. After administration of a sedative, excessive bleeding from the drain suddenly occurred with a decreased respiratory rate and heart rate. Tracheal intubation was attempted but was difficult to perform, but intubation using a fiberscope was successfully attempted. However, the patient died two days after the surgery.
- The cause of the death was airway obstruction. Ai: absent. Autopsy: absent.

Case 6

- The patient was in his/her 50s with thyroid cancer
- Total thyroidectomy and cervical lymph node dissection were performed. The duration of the surgery was about five hours, and the amount of blood loss during surgery was about 140 mL. Tracheal extubation was done after completion of the surgery.
- Hoarseness and mild stenotic sound were observed when the patient returned to the ward. At 30 minutes after returning to the room, the patient had discomfort in the wound and a sensation of sticking sputum, for which suctioning of sputum was performed. About one hour later, the patient exhibited violent body movements and complained of difficulty in breathing. The SpO_2 decreased to 90% and the stenotic sound worsened. Swelling of the neck was noted, and the patient was considered to have postoperative hemorrhage, so the wound was immediately re-opened, the hematoma evacuated, and the trachea intubated. After the hematoma evacuation was performed in the operating room, the patient returned to the ward while intubated. On the day after hematoma evacuation, the inserted tube became deviated, so the tube was removed and an oxygen mask was used instead. The patient's respiratory condition subsequently deteriorated. Marked swelling of the neck made it difficult to re-intubate or puncture the trachea, and also to re-open the wound or perform tracheostomy. Before long, cardio-respiratory arrest occurred. The patient died two days after the thyroidectomy.
- The cause of the death was airway obstruction. Ai: absent. Autopsy: absent.

Case 7

- The patient was in his/her 50s with thyroid cancer
- Hemithyroidectomy and cervical lymph node dissection were performed. The duration of the surgery was about two hours. and the amount of blood loss during surgery was 30 mL. Tracheal extubation was done after completion of the surgery.
- Hoarseness and difficulty with phonation were observed when the patient returned to the ward. About four hours later, the patient noticed difficulty with phonation and facial burning sensation. Swelling of the neck was mild in severity and the SpO_2 was 99%. About eight hours later, the patient reported the induration and swelling of the neck. The patient requested to be placed in the lateral position. About 10 hours later, the patient started to press the nurse-call button frequently and complained of difficulties in breathing and in bringing up sputum. The SpO_2 decreased from 95% to 70%, and the patient complained of difficulty in breathing. Shortly after suctioning of sputum, respiratory arrest occurred. Due to a difficulty with intubation, the wound was re-opened, and about 10 mL of clots were found. Cricothyroid membrane puncture was attempted in vain, so tracheostomy was performed instead. The patient died about two weeks after the surgery.
- The cause of death was hypoxic encephalopathy attributable to airway obstruction. Ai: absent. Autopsy: present.

Case 8

- The patient was in his/her 40s with Grave's (Basedow's) disease
- Sub-total thyroidectomy was performed. The duration of the surgery was about 1.5 hours, and the amount of blood loss during surgery was about 240 mL. A laryngeal mask airway was removed after completion of the surgery.
- At about 1.5 hours after returning to the ward, the patient exhibited mild difficulty in breathing, which was alleviated by changing the body position. About four hours later, there was about 300 mL of bloody fluid collected from the drain. A hemostatic agent was administered and compression was performed using gauze. At about nine hours later, while the SpO_2 remained at 98% or higher, the patient exhibited difficulty in breathing, tachypnea, and a sensation of sticking sputum, which were alleviated by changing the patient's body position and elevating the head. At about 13 hours later, the SpO_2 was 98%, and the patient complained of dyspnea due to hitting the bed rail. The patient exhibited an ill complexion and a rapid decrease in SpO_2, which led to cardio-respiratory arrest. When gauze was removed, wound dehiscence occurred, and bloody clots that spilled out of the wound were manually removed. The neck was hardened and unable to be stretched. It was difficult to insert a tracheal tube even though that was attempted. Tracheostomy was performed instead, but the patient died about two weeks after the surgery.
- The cause of death was hypoxic encephalopathy attributable to airway obstruction. Ai: absent. Autopsy: present.

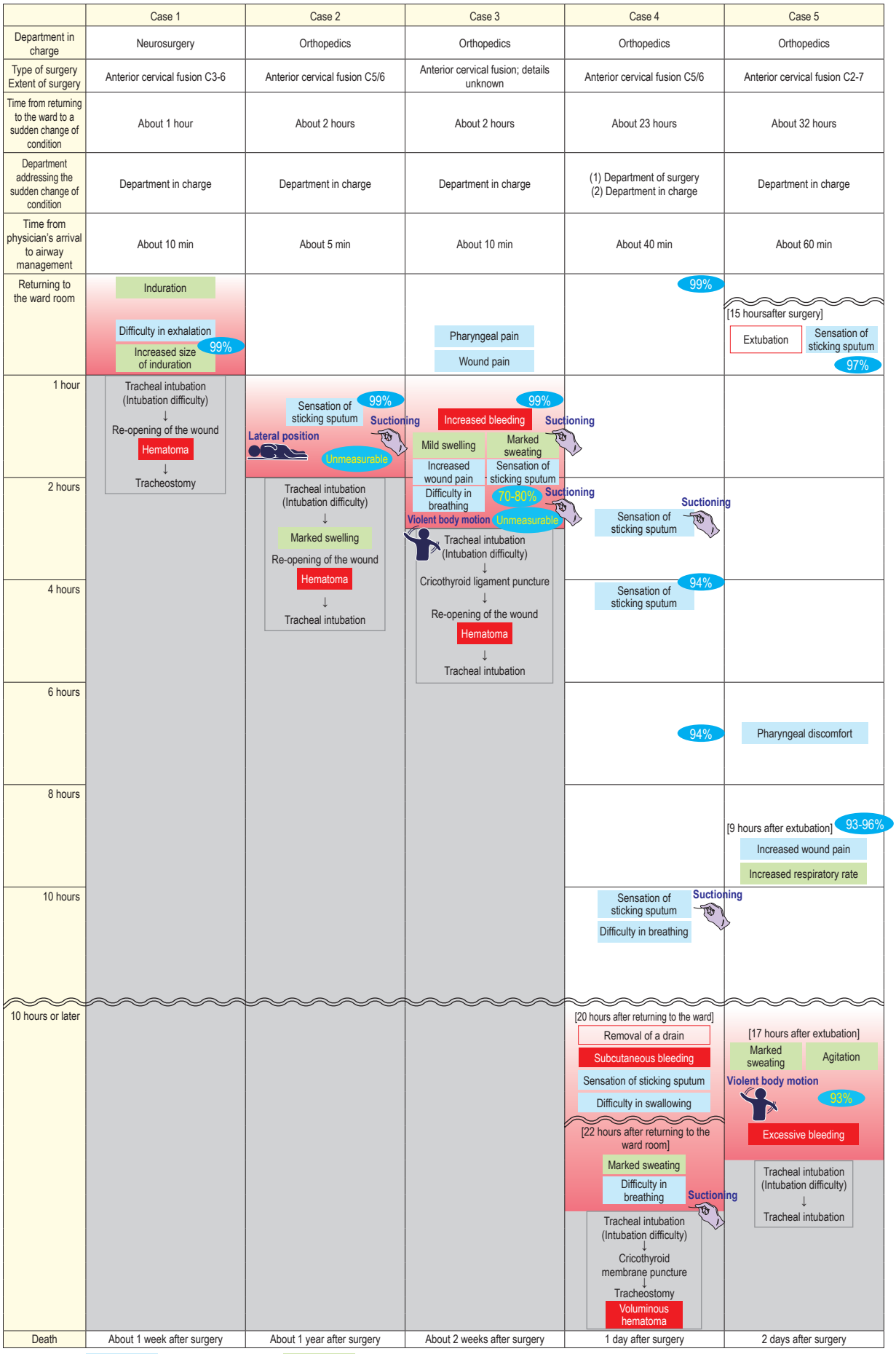
Case 9

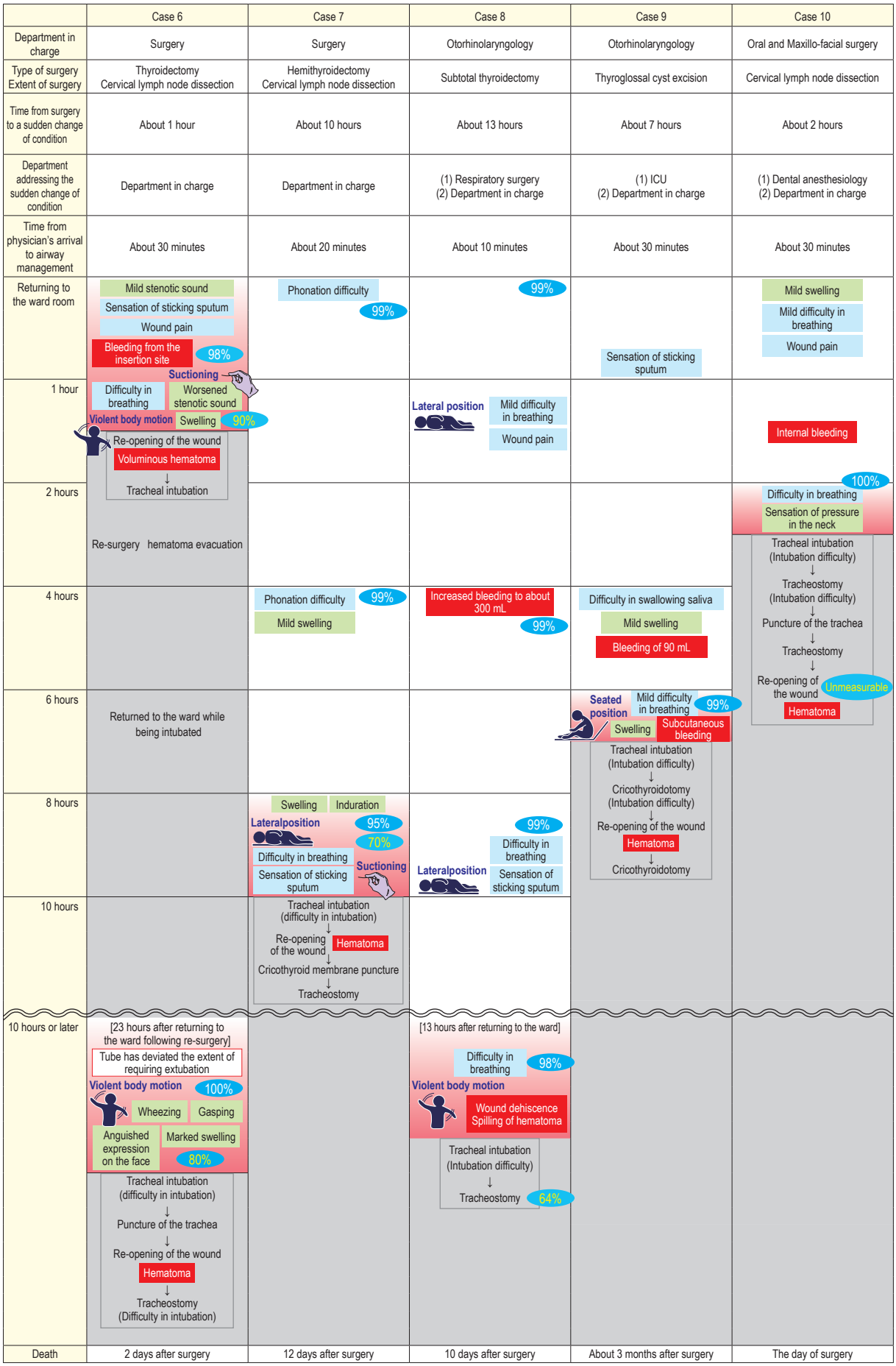
- The patient was in his/her 50s with thyroglossal cyst
- Thyroglossal cyst excision was performed. The duration of the surgery was about 2.5 hours, and the amount of blood loss during surgery was small. Tracheal extubation was done after completion of the surgery.
- At about four hours after returning to the ward, the patient exhibited difficulty in swallowing saliva and mild swelling of the neck. About seven hours later, the patient had mild difficulty in breathing and was in the seated position. Oxygenation was initiated, and the SpO_2 was 99%. Several minutes later, the patient pressed the nurse-call button and was found to be in the seated position with hands clutching the throat. The gauze fell from the wound, around which prominent subcutaneous bleeding and swelling were noted. The patient lost consciousness with eyes rolling back. Although attempted, it was difficult to insert a tracheal tube, so cricothyrotomy was performed. However, due to severe swelling, incision was performed again at a lower area to maintain the patient's airway. Hematoma evacuation was performed, but the patient died about three months after the surgery.
- The cause of death was hypoxic encephalopathy attributable to airway obstruction. Ai: absent. Autopsy: absent.

Case 10

- The patient was in his/her 70s with postoperative metastasis of tongue cancer to the cervical lymph nodes, who was on antithrombotic therapy
- Cervical lymph node dissection was performed. The duration of the surgery was about 6.5 hours. After skin suturing, the wound was partially re-opened to check the hemostatic status due to a large amount of bloody fluid emerging from the drain. No obvious bleeding from deep blood vessels was noted. Hemorrhage was arrested within the checkable range, and the amount of blood loss during surgery was about 800 mL. Tracheal extubation was done after completion of the surgery.
- A small amount of bleeding from the wound, mild difficulty in breathing and swelling of the neck, and nasal congestion were observed when the patient returned to the ward. About 1.5 hours later, internal bleeding was found in the region of the wound. Subsequently, the patient complained of swelling of the neck, difficulty in breathing, and sensation of pressure in the neck. Although attempted, it was difficult to insert a tracheal tube and perform tracheostomy. After cardio-respiratory arrest occurred, an 18G needle was inserted in the trachea and the patient's airway was secured by tracheostomy, which was attempted again. The wound was then re-opened. The patient was transported to another hospital, but died on the same day.
- The cause of death was airway obstruction. Ai: absent. Autopsy: present.

Figure 1　Overview of the target cases




Case 6
Case 7
Case 8
Case 9
Case 10
Department in charge
Surgery
Surgery
Otorhinolaryngology
Otorhinolaryngology
Oral and Maxillo-facial surgery
Type of surgery
Extent of surgery
Thyroidectomy
Cervical lymph node dissection
Hemithyroidectomy
Cervical lymph node dissection
Subtotal thyroidectomy
Thyroglossal cyst excision
Cervical lymph node dissection
Time from surgery to a sudden change of condition
About 1 hour
About 10 hours
About 13 hours
About 7 hours
About 2 hours
Department addressing the sudden change of condition
Department in charge
Department in charge
(1) Respiratory surgery
(2) Department in charge
(1) ICU
(2) Department in charge
(1) Dental anesthesiology
(2) Department in charge
Time from physician's arrival to airway management
About 30 minutes
About 20 minutes
About 10 minutes
About 30 minutes
About 30 minutes
Returning to the ward room
Mild stenotic sound
Sensation of sticking sputum
Wound pain
Bleeding from the insertion site
98%
Suctioning
Phonation difficulty
99%
99%
Sensation of sticking sputum
Mild swelling
Mild difficulty in breathing
Wound pain
1 hour
Difficulty in breathing
Worsened stenotic sound
Violent body motion
Swelling
90%
Re-opening of the wound
Voluminous hematoma
Tracheal intubation
Lateral position
Mild difficulty in breathing
Wound pain
Internal bleeding
2 hours
Re-surgery hematoma evacuation
100%
Difficulty in breathing
Sensation of pressure in the neck
Tracheal intubation (Intubation difficulty)
Tracheostomy (Intubation difficulty)
Puncture of the trachea
Tracheostomy
Re-opening of the wound
Unmeasurable
Hematoma
4 hours
Phonation difficulty
99%
Mild swelling
Increased bleeding to about 300 mL
99%
Difficulty in swallowing saliva
Mild swelling
Bleeding of 90 mL
6 hours
Returned to the ward while being intubated
Seated position
Mild difficulty in breathing
99%
Swelling
Subcutaneous bleeding
Tracheal intubation (Intubation difficulty)
Cricothyroidotomy (Intubation difficulty)
Re-opening of the wound
Hematoma
Cricothyroidotomy
8 hours
Swelling
Induration
Lateralposition
95%
70%
Difficulty in breathing
Sensation of sticking sputum
Suctioning
99%
Lateralposition
Difficulty in breathing
Sensation of sticking sputum
10 hours
Tracheal intubation (difficulty in intubation)
Re-opening of the wound
Hematoma
Cricothyroid membrane puncture
Tracheostomy
10 hours or later
[23 hours after returning to the ward following re-surgery]
Tube has deviated the extent of requiring extubation
Violent body motion
100%
Wheezing
Gasping
Anguished expression on the face
Marked swelling
80%
Tracheal intubation (difficulty in intubation)
Puncture of the trachea
Re-opening of the wound
Hematoma
Tracheostomy (Difficulty in intubation)
[13 hours after returning to the ward]
Difficulty in breathing
98%
Violent body motion
Wound dehiscence
Spilling of hematoma
Tracheal intubation (Intubation difficulty)
Tracheostomy
64%
Death
2 days after surgery
12 days after surgery
10 days after surgery
About 3 months after surgery
The day of surgery

4. Recommendations and explanations to prevent recurrence

[Recognizing the risk of airway obstruction]

Recommendation 1

It is essential to recognize that patients undergoing cervical surgery, such as anterior cervical fusion, thyroidectomy, and cervical lymph node dissection, are at risk of developing asphyxia attributable to laryngeal mucosal edema caused by impaired venous return after surgery. Patients experiencing secondary hemorrhage are at particularly high risk of developing asphyxia.

● Pathogenesis of laryngeal mucosal edema leading to airway obstruction after cervical surgery

The surgical procedures performed in the 10 target cases were anterior cervical fusion in five cases, and total thyroidectomy, thyroid lobectomy, subtotal thyroidectomy, thyroglossal cyst excision, and cervical lymph node dissection in one case each. All these cases developed hemorrhagic edema of the laryngeal mucosa, which caused airway obstruction resulting in death.

The larynx is located in the middle of the respiratory tract, which runs from the oral and nasal cavities to the trachea, and anterior to the 4th to 6th cervical vertebrae. It is surrounded by a framework of cartilage and its cavity is lined by mucous membrane. Since cervical surgery can disturb the return of the venous blood around the larynx, laryngeal edema is likely to occur after such surgery. Furthermore, if postoperative bleeding occurs and hematoma is formed, the blood flow of the vein, including the internal jugular vein, is disturbed, and resulting aggravation of edema of the glottis, the narrowest part of the larynx, can lead to airway obstruction (see Figures 2-5).

● Characteristics by type of surgery

After cervical surgery, the laryngeal mucosa is in a state that makes it susceptible to the development of postoperative edema. If bleeding occurs when the laryngeal mucosa is in such a state, it can result in airway obstruction. Even if bleeding does not occur, anterior cervical fusion, which requires prolonged retraction (retraction of the respiratory tract/esophagus using a muscle hook or retractor, etc.), may result in ischemia in the tissue around the respiratory tract or disturb venous return, depending on the status of the resection or coagulation of the vein, which may lead to airway stenosis.

In total thyroidectomy, if bilateral injury of the recurrent laryngeal nerve, which runs between the thyroid gland and the trachea, occurs, both vocal cords may be fixed in the midline, resulting in airway obstruction. Anterior cervical fusion can also cause recurrent laryngeal nerve palsy and result in unilateral or, in rare cases, bilateral vocal cord paralysis.

Figure 2　Flowchart of the mechanism of onset

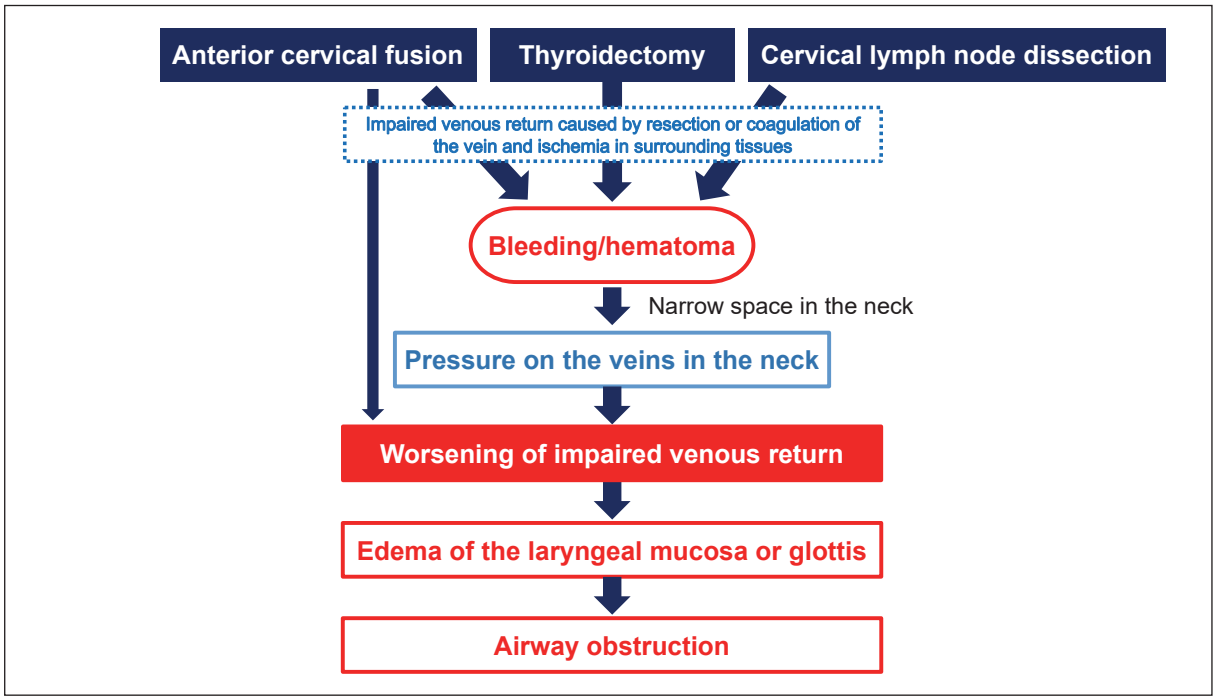


Figure 3　Anatomical/physiological images at the onset of airway obstruction

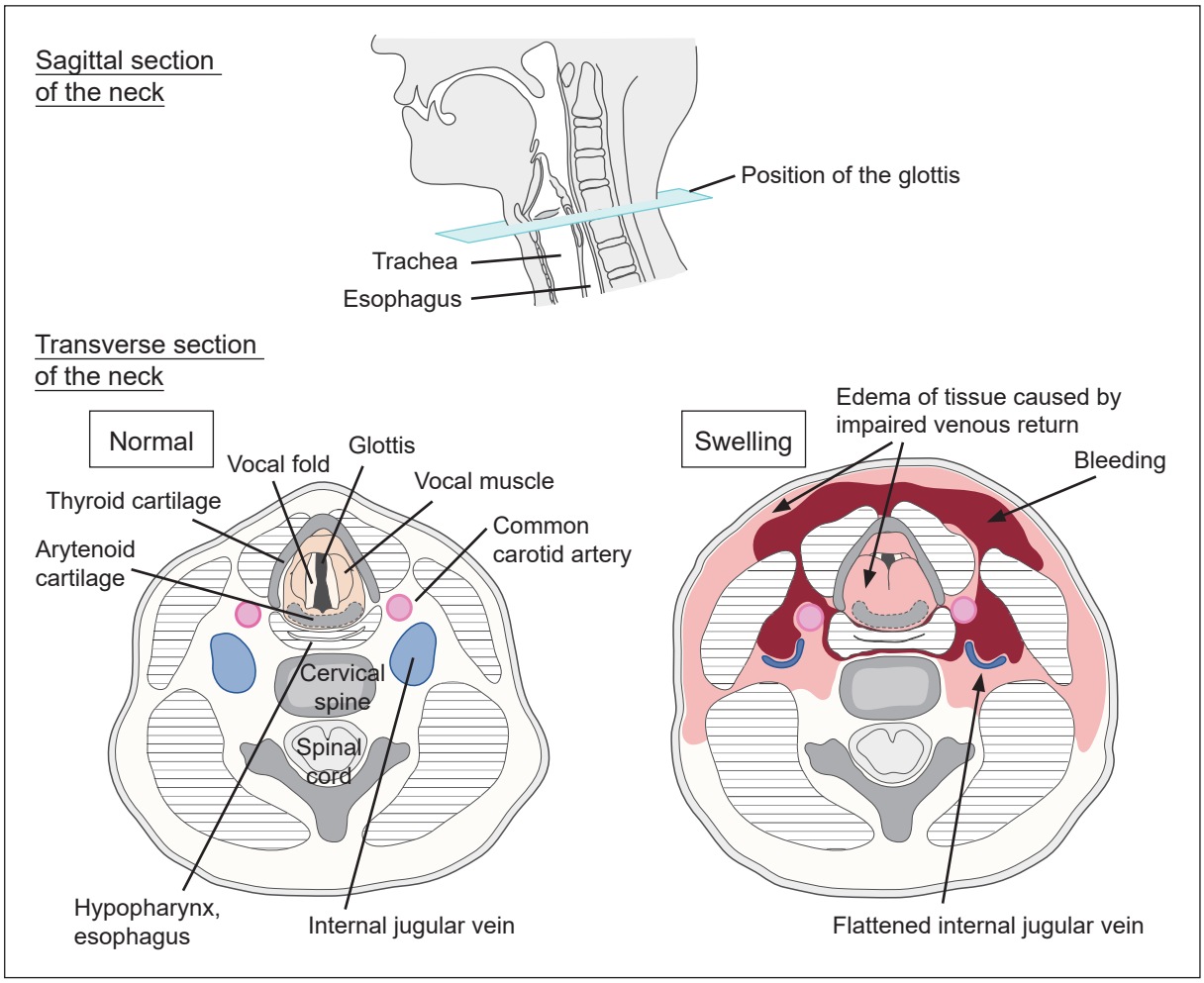


Figure 4　Normal larynx

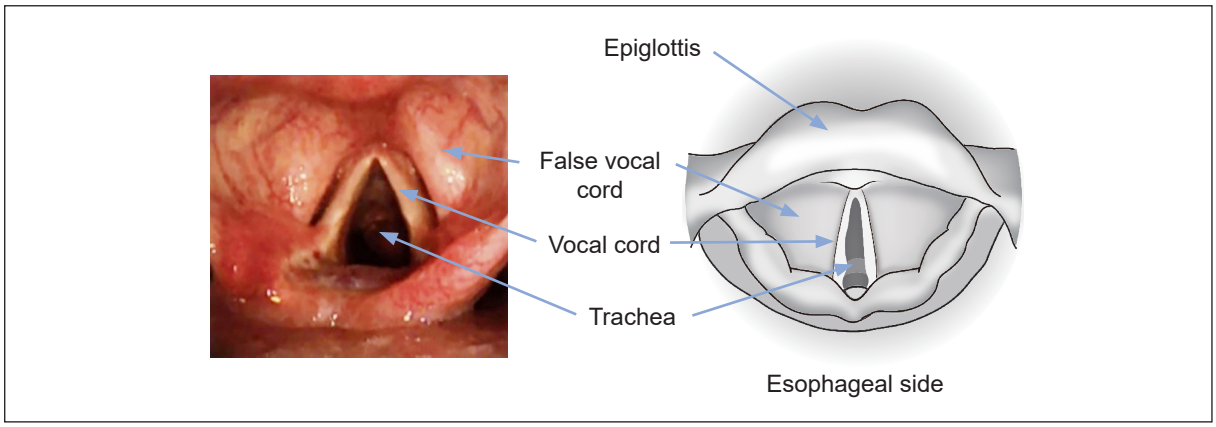
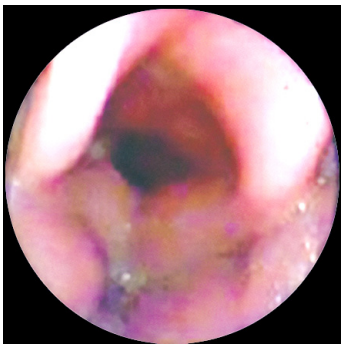
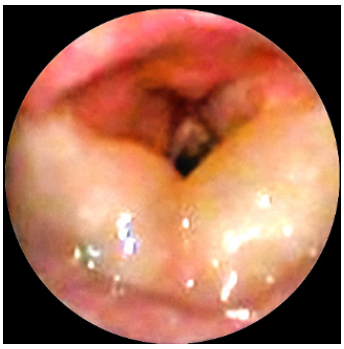
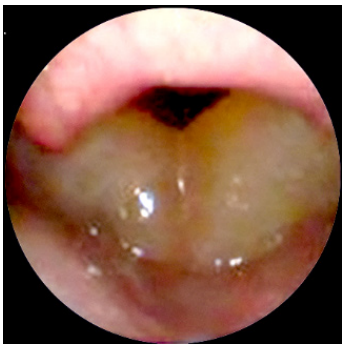


Figure 5　Classification of laryngeal edema[3] with modification

		
50% stenosis Moderate symptom	75% stenosis Severe symptom	90% stenosis Life-threatening hazard

Recognition and sharing of the risk of airway obstruction after cervical surgery

In four of the 10 target cases, the attending physician was aware of the risk of developing airway stenosis resulting in asphyxia after cervical surgery and explained this risk to the patients and their families. It seems some physicians considered that postoperative airway stenosis would rarely result in asphyxia. In two cases, the attending physicians recognized this risk but did not explain it to the patients and their families. In the remaining four cases, the attending physicians did not recognize the risk of airway stenosis resulting in asphyxia. Written explanation of this risk was not provided to relevant patients and their families in any of the 10 cases.

Physicians must recognize the risk of developing laryngeal edema that may result in airway obstruction after cervical surgery and should explain the risk of serious outcomes, even if rare, to patients and their families using an informed consent form for surgery that presents information about the risk of airway obstruction. Physicians should also advise patients in advance to tell healthcare professionals as soon as they notice any subjective symptoms.

It was in only two cases that physicians shared the risk of postoperative bleeding and airway obstruction with ward nurses who were in charge of postoperative management of patients. However, physicians must, without fail, share information of the risk of airway obstruction with nurses who engage in postoperative management of patients and make sure before surgery that relevant information will be promptly shared among them if any sign of postoperative airway stenosis, as shown in the Recommendation 3, is found.

Consideration of the timing of tracheal extubation and patient management

In nine of the 10 target cases (excluding one case of anterior cervical fusion), tracheal extubation was performed at the completion of surgery, after which patients were returned to the ward.

In cervical surgery that includes anterior cervical fusion and thyroidectomy, extubation is generally performed on the day of surgery. However, the timing of extubation should be carefully considered for patients who are at high risk of developing postoperative laryngeal edema, such as those undergoing total thyroidectomy, bilateral cervical lymph node dissection, extensive vertebrectomy, and prolonged surgery. In such cases, the recommendation is to manage patients in the ICU after surgery if possible. If patient management in the ICU is difficult, patients should be strictly managed with monitoring and reporting as presented in Recommendations 2, 3, and 4.

During night shifts, the daytime staffing standard transfers to the night-time one in general wards and only duty physicians are in charge of clinical departments. This means that the number of healthcare professionals who can observe patients after surgery and take measures in an emergency decreases. Healthcare professionals need to keep this in mind and manage patients by determining the feasible timing of extubation based on the size of the medical institution and patient risk factors.

[Observing respiratory status after surgery]

Recommendation 2

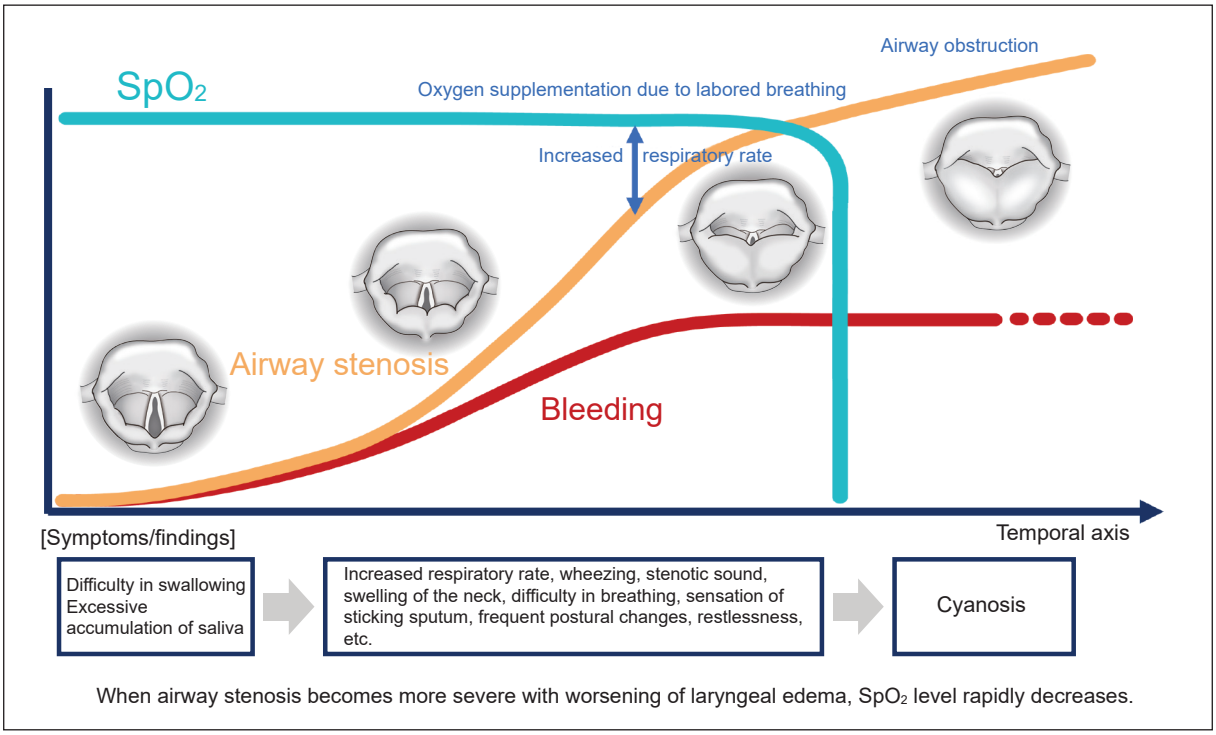
Even if airway stenosis progresses due to laryngeal mucosal edema, a decrease in the SpO_2 is not observed until immediately before a sudden change of condition. Therefore, the patient should be monitored for an increase in respiratory rate, and cervical auscultation should be performed to check for the presence or absence of wheezing and stenotic sound.

Normal percutaneous arterial oxygen saturation (SpO_2) is maintained until immediately before airway obstruction

In eight of the 10 target cases, an SpO_2 of ≥ 96% was maintained until immediately before a sudden change of condition.

The SpO_2 level decreases when the body's ability to ingest oxygen into the body falls, such as in patients with lung or heart diseases. However, when airway stenosis occurs after cervical surgery and tidal volume decreases, the respiratory rate increases to compensate for the reduced tidal volume. For this reason, even if airway stenosis occurs, a certain level of SpO_2 is retained and the amount of oxygen in the blood is maintained as long as the higher respiratory rate compensates for the lower tidal volume. As a result, a decrease in SpO_2 is not observed until airway stenosis progresses to a substantial level.

Figure 6 Changes in the level of airway stenosis caused by laryngeal edema and SpO_2



When airway stenosis becomes more severe with worsening of laryngeal edema, SpO_2 level rapidly decreases.

SpO_2 as well as respiratory rate and respiratory status should be monitored

SpO_2 was continuously monitored in all the 10 target cases. Meanwhile, continuous monitoring of the respiratory rate was performed only in two cases.

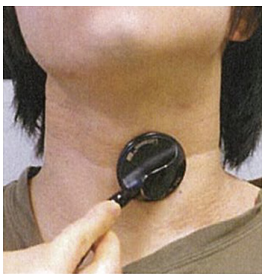
Compared to measuring SpO_2, which is easy to do, measuring the respiratory rate takes more time. In recent years, measuring the respiratory rate has often been omitted in general wards.[4)]

Even if airway stenosis occurs due to laryngeal edema after cervical surgery, a certain level of SpO_2 is maintained as long as the increased respiratory rate and labored breathing compensate for decreased tidal volume. A sudden decrease in SpO_2 occurs with the progression of airway stenosis resulting from further aggravation of laryngeal edema (see Figure 6). In order to detect airway stenosis after cervical surgery at an early stage, therefore, healthcare professionals should not only measure SpO_2 but also measure the respiratory rate and auscultate over the thyroid cartilage to listen to respiratory sound at the larynx (see Column 1). If wheezing is detected, even faintly, the patient may have developed laryngeal edema. It is also important to assess the patient's respiratory status, including any abnormality in the respiratory pattern such as prolonged expiration and retractive breathing.

Column 1: Cervical auscultation

The sound to find through cervical auscultation is basically the same as the sound of asthma detected through chest auscultation. When air passes through a narrow space, it produces sound.

In the presence of laryngeal edema in particular, saliva and sputum produce moist rales that sound like a rumbling in the neck. In severe cases, stenotic sound can be heard even without a stethoscope. Neck retraction* during inspiration is also a clinical finding that suggests severe stenosis. For auscultation, a stethoscope should be placed around the thyroid cartilage, either on the right or left of it (choose the side that may affect the wound less).



(From the Guidelines for management of postoperative care following cervical surgery, Nagoya University Hospital)[5)]

* Neck retraction: With obstruction of the upper respiratory tract, the patient breathes using accessory respiratory muscles other than the diaphragm and intercostal muscles, which puts pressure on the lower respiratory tract. As a result, some areas, such as the area above the sternum or above the clavicle, are depressed during inhalation.

[Observing symptoms and cervical conditions after surgery]

Recommendation 3

After cervical surgery, the patient should be checked for cervical swelling and for signs of airway stenosis, including the patient complaining of difficulty in breathing, a sensation of sticking sputum, difficulty in swallowing, or increased wound pain, as well as frequent postural changes and restless body motions.

Patient's complaints include signs of airway stenosis

When the larynx is swollen and begins to cause airway stenosis, changes in the inner cavity of the respiratory tract may be found as subjective symptoms of the patient.

The symptoms reported by patients after cervical surgery at an early stage in the target cases were "a sensation of sticking sputum or increased sputum," "difficulty in swallowing saliva," and "pharyngeal pain." Edema in the laryngeal mucosa enhances secretion discharge, which is noticed by the patient as "a sensation of sticking sputum or increased sputum." If the patient frequently clears sputum and uses a larger amount of tissue paper after returning to the ward, this can be regarded as a symptom of airway stenosis. It is also notable that patients in seven cases felt difficulty in being in the supine position and requested "a change of body position," such as changing to the lateral position, elevation of the head, and changing to the seated position. Some patients even became "restless." In addition, patients complained of "difficulty in breathing" in seven cases and "aggravation of wound pain" in two cases. With the progression of airway stenosis, some patients may require a change of body position so that they will be able to breathe more easily, and some other patients may exhibit violent body movements as if they are struggling to manage to breathe.

When the patient complains of "a sensation of sticking sputum," "postural change," "difficulty in breathing," and/or "wound pain" after cervical surgery, healthcare professionals should keep in mind that they may be signs of airway stenosis, so closely monitor the patient for the clinical courses and changes of these symptoms (see Figure 7 and Table 1).

Observation of the neck

Besides paying attention to the patient's complaints, observing the wound is also important. When observing the wound after cervical surgery, check for the presence or absence of "swelling or induration of the neck" and "subcutaneous bleeding," and the "amount of fluid emerging from the drain" and "drainage characteristics" and the like.

"Swelling or induration of the neck" and "subcutaneous bleeding" were observed in seven of the 10 target cases.

As a subjective indicator, measurement of neck circumference is one of the methods for observing swelling of the neck. A report says that, taking other findings into account, a more than 2-cm increase in neck circumference should be regarded as an obvious indicator of swelling of the neck and that the wound should be re-opened.[6] Recently, use of the "string method" was reported as an easy way to measure changes in neck circumference[7] (see Column 2). However, care should be taken because no change in neck circumference is observed in patients undergoing anterior cervical fusion. To protect the wound, it is advisable to use protective materials that enable healthcare professionals to observe changes in the wound, such as a transparent film, so that they can inspect the wound visually or by feeling it with the hand at any time.

Figure 7　Symptoms caused by laryngeal edema

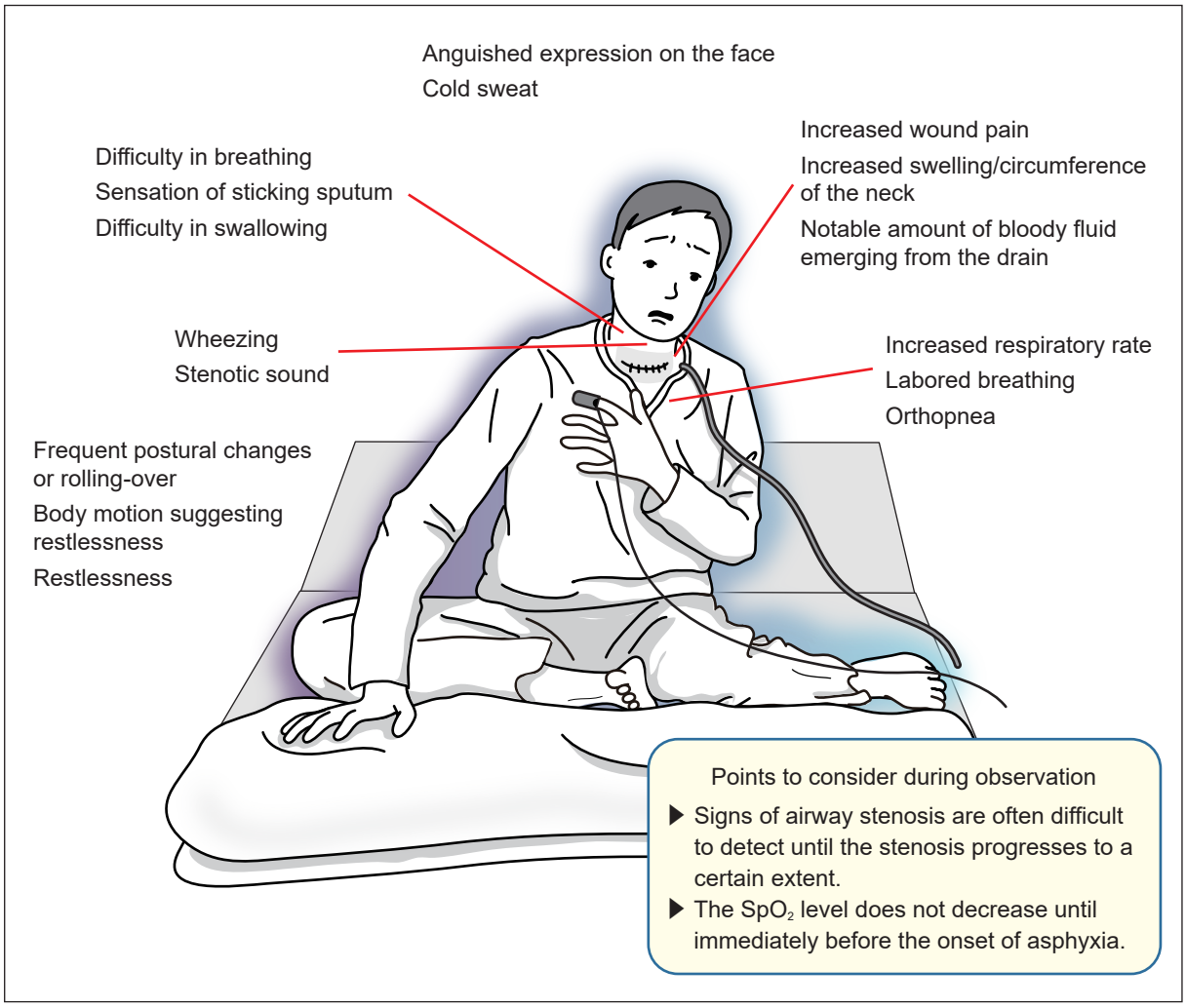


Table 1　Main signs of airway stenosis (observation items checklist)

Subjective symptoms	☐ Unpleasant feeling in the pharynx ☐ A sensation of sticking sputum or increased sputum ☐ Excessive accumulation of saliva and difficulty in swallowing saliva ☐ Difficulty in breathing ☐ Aggravation of wound pain (pain in the neck)
Objective symptoms	☐ Swelling/induration of the neck ☐ Subcutaneous bleeding ☐ Increased neck circumference ☐ Notable amount of bloody fluid emerging from the neck drain ☐ Wheezing and stenotic sound detected by auscultation of the neck ☐ Labored breezing (shoulder breathing, retractive breathing, etc.) ☐ Orthopnea ☐ Increased respiratory rate ☐ Frequent postural changes or rolling-over ☐ Restlessness ☐ Anguished expression on the face ☐ Cold sweat

● *Invisible* airway stenosis should be suspected based on observational findings and patient's complaints

Observational findings after cervical surgery are classified into *visible* changes, such as "increased amount of bloody fluid emerging from the drain" and "swelling of the neck," and *invisible* changes; that is, changes in cervical soft tissues including those in the larynx. These two types of changes do not necessarily occur simultaneously. In particular, when changes like "swelling or induration of the neck" are observed, this should be interpreted as suggesting that airway stenosis has occurred. When the patient frequently clears sputum and complains of wound pain and the need for postural change, the patient can be suspected to have airway stenosis. Be sure to comprehensively assess whether the patient has developed airway stenosis and requires urgent medical treatment based on the results of observing objective symptoms including "swelling of the neck," "amount of bleeding from the drain or the wound," "respiratory rate," and "breathing sounds" in addition to the clinical courses or changes of symptoms reported by the patient.

● Risk of aggravation of airway stenosis by stimulation with sputum suctioning

When the patient complains of a sensation of sticking sputum and difficulty in excreting sputum, suctioning of sputum is generally performed in consideration of potential airway obstruction with sputum.

In four of the 10 target cases, suctioning of sputum performed once or twice induced a loss of consciousness or a rapid decrease in SpO_2. In these cases, the patients complained of "a strange sensation in the pharynx," "a sensation of sticking sputum," "difficulty in breathing," "wound pain," "increased bleeding," "subcutaneous bleeding," "swelling of the throat," and "postural change" before suctioning of sputum, and the amount of sputum collected was small.

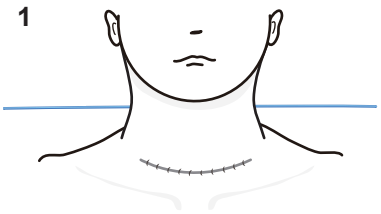
In cases where signs of airway stenosis are observed and laryngeal edema is suspected, keep the following possibility in mind: stimulation with sputum suctioning can induce laryngospasm, which may lead to sudden aggravation of laryngeal edema, resulting in airway obstruction.

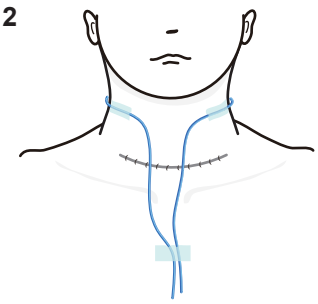
Column 2: Example of an observation method for swelling of the neck – the string method[7] –

The string method is a way to observe changes in neck circumference after cervical surgery. Once the surgery is complete, a piece of string (silk thread) about 75 cm long is placed around the neck, taped at each side of the neck, and then crossed over itself to make an "x," at which both the string and the skin are marked with a pen. Thereafter, changes in the distance between the marked points on the string and the marked point on the neck are periodically measured. If the neck is swollen due to a reason such as postoperative bleeding, a gap emerges between the mark on the string and that on the neck. Measurement of this gap can contribute to early detection of swelling of the neck. With periodic measurement and by pre-specifying reporting criteria, such as "inform the physician when the gap between 'both marks on the string (#7A)' or 'the mark on the string and the mark on the skin (#7B)' becomes 2 cm or longer," swelling of the neck can be assessed based on an objective index.

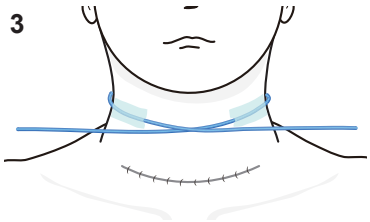
<Procedure for the string method>

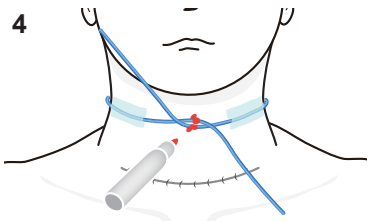
Before returning to the ward (when still in the operating room)

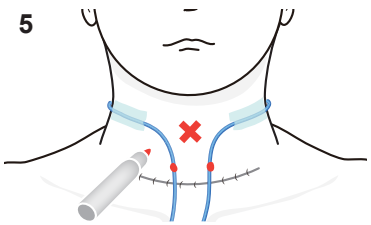


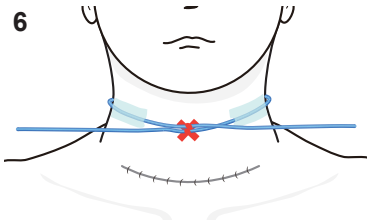


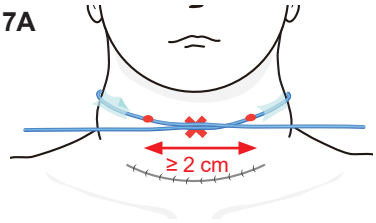
After returning to the ward (when lying on the bed in the ward)

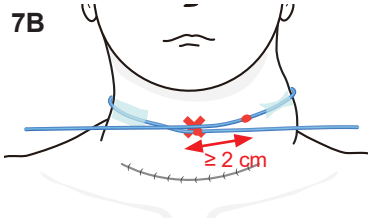












1. Pass a piece of string (silk thread No. 0, 75 cm long) behind the neck of the patient on the operating table.
2. Put the string around the neck and tape it at each side of the neck. Both ends of the string are taped to the anterior chest.
3. After transferring the patient to the bed in the ward, remove the tape from the anterior chest and cross the string horizontally over itself at the center of the anterior neck.
4. Mark the string with a pen at the crossing point and the skin immediately beneath that point.
5. Mark an "X" clearly on the marked point on the skin.
6. Confirm that the marks on both sides of the string and the mark on the skin fit one another perfectly. (Keep the string as shown in #2 after completing measurement.)
7. Periodically cross the string over itself on the X-mark on the skin and measure the gap between the mark on the string and the X-mark (#7A and #7B in the above figure).

[Establishing postoperative reporting criteria and measures to take]

Recommendation 4

The physician should specify observation items and establish reporting criteria in terms of signs of airway stenosis after cervical surgery. The medical institution should establish a system that enables a medical team responsible for medical care after cervical surgery to promptly take appropriate measures against any signs of airway stenosis.

Provision of specific and clear postoperative instructions that make it easy to take timely actions

In terms of signs of airway stenosis, specific observation items or criteria for reporting to the physician, such as "measurement of neck circumference," "enlargement of the area of induration," and "occurrence of difficulty in breathing," were prespecified only in one of the 10 target cases. In the other cases, instructions provided were "monitor the patient for bleeding," "start oxygen administration when SpO_2 decreases," and "administer relevant drugs when the patient becomes restless," etc., none of which were specific observation items or reporting criteria for potential airway stenosis.

Given that progression of laryngeal edema after cervical surgery could be fatal, it is essential to specifically prespecify what to observe (observation items), how to observe (e.g., frequency of observation), and for what cases actions (e.g., calling the physician and activating the emergency medical system) should be taken (criteria for taking actions), instead of giving vague postoperative instructions. This is to ensure that prompt and sufficient measures can be taken for any sign of airway stenosis. Therefore, effective instructions should be provided and shared for individual cases in order to enable healthcare providers in charge of postoperative management, such as nurses, to take appropriate action upon observing any symptom related to laryngeal edema (see Table 1) in the patient.

System for taking prompt action for any sign of airway stenosis

Nursing teams in six of the 10 target cases had some *concerns*, none of which they usually had about postoperative clinical courses of patients. Their *concerns* were about the patients' "difficulty in swallowing saliva," "difficulty in breathing," "increased amount of bleeding," and "aggravation of swelling of the neck." These *concerns* were reported to the physician in three of the six cases, and the physician examined the patient promptly only in one of these three cases. Meanwhile, in the remaining three cases in which their *concerns* were not reported to the physician, nursing teams took countermeasures for their *concerns* such as fluid replacement, oxygen administration, and frequent visits to the patient room, in accordance with postoperative instructions. In all six cases, these *concerns* occurred during the night shift for duty physicians.

As presented in Recommendation 2, even if airway stenosis progresses after cervical surgery, a certain level of SpO_2 is often maintained until immediately before airway obstruction. Therefore, it is difficult to determine whether the patient is exhibiting signs of airway obstruction based only on symptoms observed in the patient. However, if laryngeal edema results in airway stenosis, the patient's respiratory status can rapidly deteriorate, giving the physician no time to lose in treatment. Nurses, therefore, need to monitor the patient according to the pre-specified observation items and reporting criteria, and to report to the physician and ask the physician to treat the patient as soon as they notice any symptom or change that suggests potential airway stenosis so that prompt and sufficient action can be taken for the patient. To achieve this, it is essential to establish a system that enables both the nurses in charge of monitoring the patient and the attending/duty physician to share information about any change in the patient's condition after cervical surgery without delay, and then take appropriate action. Reporting to the physician and asking the physician to examine the patient can ensure the patient's safety even if this would end up being over-triage. From the viewpoint of safety management, establishing a patient safety culture that encourages anyone taking care of the patient, when concerned about any change in the patient's condition, to ask other healthcare providers for their opinions is paramount.

The physician who is asked to see the patient should examine the patient, keeping in mind the potential need to re-open the wound and perform surgical airway management, as shown in Recommendations 5 and 6, and, if possible, perform an endoscopic examination of the laryngeal condition.

[Decision to open the wound and measures to take]

Recommendation 5

If swelling of the neck or increase of the neck circumference is observed after cervical surgery and airway stenosis caused by hematoma is suspected, the wound should be re-opened immediately and hematoma evacuation should be performed. At the same time, the physician should prepare to perform surgical airway management in case respiratory status fails to improve.

● Decision to open the wound and measures to take when bleeding is suspected

In four of the 10 target cases, nurses reported to the physician about the amount of bleeding and swelling of the neck before a sudden change of condition. In these cases, the physician gave instructions for fluid replacement and administration of hemostatic agents, and to change gauze against bleeding. In nine of the 10 target cases, the physician came to the patient's room after receiving the report of an urgent situation after a sudden change of condition and attempted tracheal intubation first and then re-opening of the wound.

When airway stenosis caused by bleeding is suspected after cervical surgery, the physician should re-open the wound first and then attempt hematoma evacuation. At the same time, it is important for the physician to prepare for surgical airway management (e.g., tracheostomy, cricothyroidotomy), because there would be no time to lose if no improvement is observed in respiratory status despite hematoma evacuation or if no hematoma is observed.

<Patients undergoing thyroidectomy, etc.>

As shown in Recommendation 1, if hematoma has formed in a narrow space in the neck, veins are compressed under the weight of the hematoma, disturbing the return of the venous blood and aggravating edema. Laryngeal edema can result in airway stenosis. Therefore, if hematoma is suspected, it is important to re-open the wound promptly by removing sutures and removing hematoma. After thyroidectomy, in particular, blood tends to accumulate in the original space for the thyroid, and hematoma often pools immediately beneath the skin incision site. Re-opening the wound relieves pressure in the neck and improves impaired venous return. This may alleviate laryngeal edema, and improvement in respiratory status can be expected. Re-opening the wound can also help smooth the steps for the physician to conduct surgical airway management.

<Patients undergoing anterior cervical fusion>

If airway stenosis caused by postoperative bleeding is suspected, the wound may be re-opened and hematoma may be evacuated. However, prolonged tracheal/esophageal retraction during the surgery is often jointly responsible for airway stenosis occurring after cervical spine surgery, and in some cases a large amount of hematoma is not observed. In a case of airway stenosis that is not primarily caused by hematoma, sufficient airway management cannot be achieved only by re-opening the wound and removing hematoma; surgical airway management must be performed simultaneously with re-opening of the wound. Before re-opening the wound, it is extremely difficult to determine whether the cause of airway stenosis is hematoma or respiratory tract edema attributable to prolonged tracheal retraction. Therefore, the physician should prepare to confirm the presence of hematoma and remove it after re-opening the wound, as well as to perform surgical airway management without delay.

[Implementing emergency surgical airway management]

Recommendation 6

Tracheal intubation may be difficult for most of the cases of airway stenosis that have progressed after cervical surgery. For cases in which tracheal intubation is difficult, surgical airway management should be performed without hesitation.

Risk of attempting tracheal intubation when airway stenosis has progressed

In all target cases, when emergent airway management was initiated, intubation was difficult to perform because of difficulty in opening the mouth of the patient due to respiratory tract edema.

It is often difficult to perform tracheal intubation if airway stenosis has progressed after cervical surgery. Furthermore, tracheal intubation attempts can induce laryngospasm due to laryngeal expansion or laryngeal irritation by a laryngoscope or tube insertion, increasing the risk of developing airway obstruction that may hinder manual ventilation. Therefore, before attempting tracheal intubation, the physician should recognize this risk and prepare to perform surgical airway management immediately in case intubation is difficult.

Surgical airway management should be performed as soon as possible

In four of the 10 target cases, tracheal intubation was successful after a sudden change of condition. The time to complete intubation from the physician's arrival was about 5, 10, 30, and 60 minutes in one case each. Meanwhile, in the other six cases, emergent surgical airway management was performed after attempting tracheal intubation. The time to the start of surgical airway management after the physician's arrival was about 10 minutes in two cases, about 20 minutes in one case, about 30 minutes in two cases, and about 40 minutes in one case.

Tracheal intubation is often difficult for cases of airway stenosis that have progressed due to laryngeal edema with impaired venous return. Cases of respiratory arrest require immediate action because mortality increases every several minutes, reducing the chance of saving the patient's life. If the patient is assessed as developing airway obstruction, it is critical to perform surgical airway management as soon as possible. For patients who have developed asphyxia after cervical surgery and who are in a life-threatening condition, *the wound should be re-opened immediately* on site and hematoma evacuation should be performed to a maximum extent. If the patient's respiratory status cannot be improved by doing the above, it is advisable to perform surgical airway management without delay rather than sticking to tracheal intubation.

[Establishing a system for conducting emergency surgical airway management]

Recommendation 7

Every medical institution that engages in cervical surgery should establish a system that enables emergency surgical airway management to be performed.

Establishment of a system that allows surgical airway management in cases of emergency

In nine of the 10 target cases, no criteria had been pre-specified in terms of emergency surgical airway management after cervical surgery. In four cases, duty physicians from another clinical department addressed a sudden change of condition.

At medical institutions that carry out cervical surgery, physicians should perform airway management immediately to save the patient's life when airway stenosis occurs after surgery. However, it is not easy even for physicians of a clinical department in charge of the surgery to immediately assess the status of airway stenosis caused by impaired venous return due to cervical hematoma and then perform surgical airway management. In addition, many medical institutions in Japan adopt the concept of primary care physician, under which it might be psychologically difficult for a physician to re-open the wound of the patient operated on by another physician and to perform surgical airway management.

Therefore, it is recommended that the clinical department in charge should pre-specify necessary procedures and criteria that enable any physician addressing the emergency situation to re-open the wound, determine whether emergency surgical airway management is needed, and perform it if needed in emergency circumstances. Furthermore, the clinical department in charge should provide duty physicians and nurses in charge of postoperative management with details of such procedures and criteria. Medical institutions should establish emergency calling procedures and a system suitable for surgical airway management depending on their size and medical resources. In addition, a medical team involved in taking care of patients after cervical surgery should have workshops on emergency surgical airway management, prepare necessary materials and procedures, conduct team training, and enhance communication between physicians and nurses.

It is difficult for a single clinical department or a single ward to deal with wound re-opening, emergency surgical airway management, and resuscitation. Therefore, information about patients at such risk should be shared in advance with duty physicians, duty nurse manager, and nurses in charge of postoperative management.

Fostering of human resources capable of performing emergency surgical airway management

In nine of the 10 target cases, the first physician who addressed the postoperative event, regardless of clinical department, attempted tracheal intubation first. In patients who had undergone thyroidectomy, for example, which was performed in three of the target cases, the incidence of asphyxia caused by postoperative cervical hematoma is as low as 0.7% to 1.75%,[8)9)] indicating that physicians experience the treatment of this event at a very low frequency. In medical institutions engaging in cervical surgery, it is advisable that duty physicians experience tracheostomy as much as possible in a non-emergency setting to acquire skills needed for emergency surgical airway management.

Wards should be equipped with tools for wound re-opening and performing tracheostomy needed for emergency surgical airway management

In only two of the 10 target cases, the relevant wards were equipped with scalpels, pean forceps, and tracheostomy kits. Medical institutions engaging in cervical surgery should always have the instruments needed for emergency surgical airway management at hand. In case of cervical surgery, airway obstruction tends to occur soon after surgery, which means that the wound can be re-opened by removing sutures. It is recommended that medical institutions should prepare themselves properly and promptly address emergency cases by allocating suture scissors (and/or stapler removers, as needed) to relevant wards.

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

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

We expect the Japanese Society of Otorhinolaryngology Head and Neck Surgery, Japanese Society of Oral and Maxillofacial Surgeons, Japan Association of Endocrine Surgery, The Japanese Orthopaedic Association, and The Japan Neurosurgical Society to continuously acknowledge, enlighten, and educate regarding items (1) through (4) below, and expect the same from the Japan Association of Nursing Academies regarding items (1) through (3).

(1) Acknowledgement/enlightenment about cervical surgery-related patient safety information

We would like each academic society to acknowledge and enlighten the members of the fact that there are some cases resulting in accidents due to lack of knowledge about the risk of airway obstruction caused by bleeding.

(2) Acknowledgement of monitoring methods for respiratory status after cervical surgery

We would like each academic society to acknowledge that respiratory status after cervical surgery should be monitored not only by measurement of SpO_2 but also by measurement of the respiratory rate in response to airway stenosis and by auscultation of the respiratory tract in the neck.

(3) Observation items and reporting criteria after cervical surgery

We would like each academic society to clearly indicate the observation items and reporting criteria after cervical surgery, and to take effective measures to share the lessons learned from medical accidents such as by holding regular workshops.

(4) Acquisition of surgical airway management skills and provision of educational opportunities

We would like each academic society to include surgical airway management in the early training programs and to consider providing educational opportunities such as simulation training for obtaining proficiency in surgical airway management skills (e.g., tracheostomy, cricothyroidotomy).

(5) Development of training simulators for surgical airway management

We would like companies to develop training simulators for obtaining proficiency in surgical airway management skills and to widen their use.

6. Conclusion

Most cervical surgeries are not so highly invasive and enable patients to walk and eat by mouth from the day after surgery. Because of this, the target cases include those in which physicians or nurses seemed to have insufficient understanding of the risk of developing laryngeal edema resulting in asphyxia after cervical surgery. In this report of recommendations, therefore, we first emphasized the need to recognize the risk of asphyxia due to laryngeal edema after cervical surgery. Then, we reviewed the cases of deaths closely and revealed that patients in many of the cases were conscious and maintained normal SpO_2 levels until immediately before asphyxia occurred. Therefore, we recommended that postoperative patients should be monitored not only for SpO_2 but also for respiratory rate. In retrospect, these patients sent out many signals. Symptoms such as a sensation of sticking sputum, difficulty in swallowing, inability to lie in the supine position, and restlessness are signs indicating that airway stenosis is starting to occur. We hope these recommendations will be read by not only physicians but also nurses who are closest to patients in the ward.

In the latter half of this report, we summarized, as recommendations, information that should be shared with physicians engaging in cervical surgery as well as physicians who may serve as duty physicians for surgical care. First of all, it is important to suspect postoperative bleeding when swelling of the neck is noted after cervical surgery, and to re-open the wound immediately to perform hematoma evacuation. This procedure, which can reduce pressure in the neck, is expected to improve the return of venous blood and thereby alleviate laryngeal edema. If the patient has already developed airway stenosis and requires emergency airway management, the physician should know that it is no longer possible to perform oral intubation at this stage. The physician should prioritize surgical airway management rather than sticking to oral intubation and unnecessarily losing time for treatment. When the neck is swollen due to postoperative bleeding, however, surgical airway management is not always easy to do. Tracheostomy should be selected if the event occurs after thyroidectomy, because the trachea can be easily reached by re-opening the wound and removing hematoma. If the event occurs after cervical lymph node dissection or anterior cervical fusion, tracheostomy or cricothyroidotomy should be selected according to the case.

Even if skillful physicians perform surgeries with the utmost care, postoperative bleeding cannot be completely avoided, so keep in mind that the patient's life depends on how postoperative bleeding or laryngeal edema can be discovered at an early stage and how adequately it is treated.

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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7. Materials

Airway obstruction due to cervical surgery/Investigation items checklist

Items		Viewpoints	Concrete items
Basic information	Patient information	Age/Sex	Age: Sex:
		Clinical department	
		Primary disease	
		Medical history	
		Type of surgery	
		Height/body weight	Height: cm Body weight: kg
		Oral drug (antithrombotic drug)	Drug name: Dose interruption: ☐ Yes ☐ No
	Blood tests	Blood count (blood collection date:)	☐ Hb: g/dL ☐ Plt 0,000/μL ☐ Other:
		Coagulation (blood collection date:)	☐ PT: % ☐ PT: sec ☐ APTT: sec ☐ PT-INR: ☐ Abnormal coagulation factor level: ☐ Other:
Cause of death	Autopsy Ai	Autopsy results	
		Ai results	
	Other	Image findings	
Information sharing about risk of airway obstruction caused by surgery	Medical team	Information sharing about risk of airway obstruction	☐ Surgeon (department) team ☐ Anesthetist, etc. ☐ Ward nurses
		Discussion about timing of extubation	☐ Yes ( ) ☐ No
		Discussion about a room for the patient to use after surgery	☐ Yes ( ) ☐ No
	Patient/family	Recipient of explanation	☐ Patient ☐ Family: ☐ Other:
		Explanation method	☐ ICF for surgery ☐ Verbally ☐ Other:
		Explanation of complications	☐ Risk of postoperative bleeding ☐ Risk of airway obstruction ☐ Actions to take in case of complications
		Presentation of complications in the ICF for surgery	☐ Risk of postoperative bleeding ☐ Risk of airway obstruction ☐ Actions to take in case of complications
		Reaction of patient/family	
Information about surgery		Duration of surgery	☐ Duration of intubation (from to) Time needed: hours minutes
			☐ Duration of surgery (from to) Time needed: hours minutes
		Amount of blood loss	☐ Amount of blood loss (mL)
		Area of drain placement	
		Dressing material	☐ Transparent protector ( ) ☐ Gauze
		Special considerations during surgery	☐ Yes ( ) ☐ No
		Time/place of return from the operating room	☐ Time ( ) ☐ Place ( )

Items		Viewpoints		Concrete items
Postoperative management	Postoperative observation items	Signs of airway stenosis (Subjective symptoms)		☐ Strange feeling in the pharynx ☐ Sensation of sticking sputum or increased sputum ☐ Excess accumulation of saliva and difficulty in swallowing it ☐ Difficulty in breathing ☐ Increased wound pain (neck pain)
		Signs of airway stenosis (Objective symptoms)	Neck	☐ Increased respiratory rate ☐ Induration in the neck ☐ Subcutaneous bleeding ☐ Neck circumference when returned to the ward: ( ) cm ☐ Increased neck circumference (≥ 2 cm)
			Drain	☐ Amount of bloody fluid emerging from the drain
			Respiratory status	☐ Increased respiratory rate ☐ Wheezing and stenotic sound detected by auscultation of the neck ☐ Frequency of suctioning ☐ Orthopnea ☐ Labored breezing (e.g., shoulder breathing, retractive breathing)
			Body motion, facial expression, etc.	☐ Frequent postural changes or rolling-over ☐ Restlessness ☐ Anguished expression on the face ☐ Cold sweat
	Information sharing	Criteria for reporting to the physician		☐ Yes ( ) ☐ No
		Instruction from the attending physician to the duty physician		☐ Yes ( ) ☐ No
Decision to re-open the wound, and measures	Re-opening of the wound	Person re-opening the wound		Department: Experience with wound re-opening: ☐ Yes ☐ No
		Kits for re-opening of the wound		☐ Allocated to the ward ☐ Allocated to another section: ( )
Emergency surgical airway management (SAM)	Preparation	Attempt of (oral/nasal) intubation		☐ Yes ( ) times ☐ No
		Allocation of cricothyroidotomy kits		☐ In the ward ( ) ☐ In another section ( )
		Allocation of tracheostomy kits		☐ In the ward ( ) ☐ In another section ( )
	Implementation	Person performing emergency SAM		Department:
				Experience in cricothyroidotomy: ☐ Yes ☐ No
				Experience in tracheostomy: ☐ Yes ☐ No
Establishment of system for emergency SAM	Education/ training	Training for acquisition of skills		☐ Physician in the department in charge ☐ Duty physician ☐ Other
	System	Specification about emergency SAM, system for asking or consulting another department		☐ Yes ( ) ☐ No
		System for medical collaboration with another hospital		☐ 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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Analysis of Deaths Related to "Airway Obstruction Due to Cervical Surgery"

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