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"LATEST-CAUSE ANALYSIS"

as an approach for making Preventive Measures

from the experiences of 2,000 cases, reported to "Medical Accident Investigation System / Japan"

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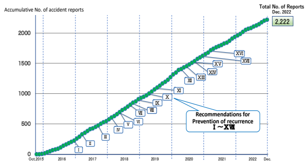
Introduction

"Medical Accident Investigation / Japan" has experienced more than 2,000 cases of unexpected death, in 8 years. From "In-hospital Invest. Report", we made preventives.

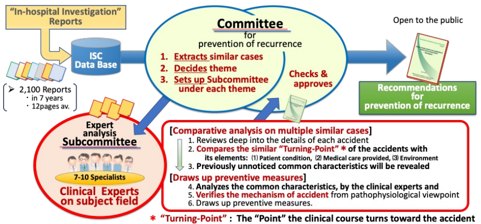
Accumulation curve of "In-hospital investigation"



	Preventive Measures made from Invest. Reports	No. of Target Cases	Total No. of Reports at that time
Ⅰ	Analysis of deaths related to Central Venous Catheterization	10	226 [Dec.2016]
Ⅱ	Acute Pulmonary Thromboembolism	8	330 [Mar.2017]
Ⅲ	Anaphylaxis caused by Injections	12	476 [Sep.2017]
Ⅳ	Early Post-Tracheostomy Troubles	5	607 [Feb.2018]
Ⅴ	Laparoscopic Cholecystectomy	7	697 [May 2018]
Ⅵ	Naso-Gastric Feeding Tube Insertion	6	697 [May 2018]
Ⅶ	Noninvasive Positive Pressure Ventilation / Tracheostomy PPV in General Ward	8	817 [Sep.2018]
Ⅷ	Xray/CT Diagnosis in Emergency Medicine	12	851 [Oct.2018]
Ⅸ	In-hospital Tumble & Fall	11	908 [Dec.2018]
Ⅹ	Preliminary Bowel Preparation for Colonoscopy	12	1,004 [Apr.2019]
Ⅺ	Liver Biopsy	10	1,102 [Jul.2019]
Ⅻ	Thoracocentesis	9	1,408 [Apr.2020]
XⅢ	Gastrostomy and Gastrostoma Management	13	1,456 [Jun.2020]
XⅣ	Catheter Ablation	18	1,539 [Sep.2020]
XⅤ	Erroneous Administration of Medicine	36	1,539 [Sep.2020]
XⅥ	Airway Obstruction due to Cervical Surgery	10	1,743 [Apr.2021]
XⅦ	Central Venous Catheterization – Ⅱ	44	1,627 [Dec.2020]

Method

The process for "Preventive measures"


"In-hospital Investigation" Reports
ISC Data Base
2,100 Reports
・in 7 years
・12pages av.
Committee
for
prevention of recurrence
Checks & approves
Open to the public
Recommendations for prevention of recurrence
Expert analysis Subcommittee
7-10 Specialists
Clinical Experts on subject field

1. Extracts similar cases
2. Decides theme
3. Sets up Subcommittee under each theme

[Comparative analysis on multiple similar cases]

1. Reviews deep into the details of each accident
2. Compares the similar "Turning-Point" * of the accidents with its elements: (1) Patient condition, (2) Medical care provided, (3) Environment
3. Previously unnoticed common characteristics will be revealed

[Draws up preventive measures]

4. Analyzes the common characteristics, by the clinical experts and
5. Verifies the mechanism of accident from pathophysiological viewpoint
6. Draws up preventive measures.

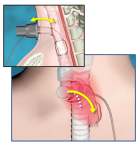
* "Turning-Point" : The "Point" the clinical course turns toward the accident
"Similar case" : Cases the turning-point are similar

Prevent. Measures: EXAMPLE Ⅰ

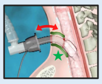
Recommendations for the prevention of recurrence Number 4

Analysis of deaths related to "Dislocation or Misplacement of a tracheostomy tube in the early post-tracheostomy period"

The target 5 cases was extracted from 607 reports of "In-hospital investigation" in 2 years and 5 months (Oct. 2015 ~ Feb. 2018), under the Medical Accident Investigation System,



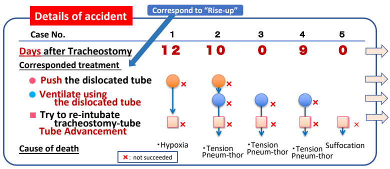
"Tube rise-up" in daily medical care



- Pt. care: ・Postural change ・Tube management
- Pt. self: ・Pt's own movement
- Pt. on respirator: ・Tension to the tube toward respirator

Usually, the tracheostomy fistula is firmly organized, [★] the tube returns to the proper position easily.

Details of accident


Correspond to "Rise-up"
Corresponded treatment
Push the dislocated tube
Ventilate using the dislocated tube
Try to re-intubate tracheostomy-tube Tube Advancement
×: not succeeded

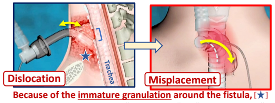
Case No.	1	2	3	4	5
Days after Tracheostomy	12	10	0	9	0
Cause of death	・Hypoxia	・Tension Pneum-thor	・Tension Pneum-thor	・Tension Pneum-thor	Suffocation

Common characteristics

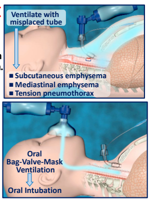
- ≦ Within 2 weeks
- "Tube rise-up"
- Push*
- Ventilate using the tube*
- Push & Advance the tube*

(* : If not mentioned in the report, asks as an additional question.)

Condition of "Early Post-tracheostomy"



Because of the immature granulation around the fistula, [★] tube advancement makes "Dislocation" to "Misplacement".



× Do not ventilate with dislocated or misplaced tube, subcutaneous ventilation may make lethal hypoxia.

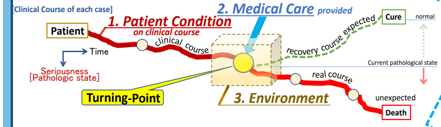
○ Ventilate with "Oral Bag-valve-mask" as an emergency treat.

Preventive measures

1. Risk of "Two weeks" after tracheostomy should be recognized.
2. Do not stick to re-intubate the dislocation suspected tube, which may make "Misplacement".
3. ・Do not ventilate using the dislocation or misplacement suspected tube, which makes lethal hypoxia.
   ・Use "Oral Bag-valve-mask".

Steps for the "Latest-cause analysis"

Ⅰ. "Turing-Point" towards the accident



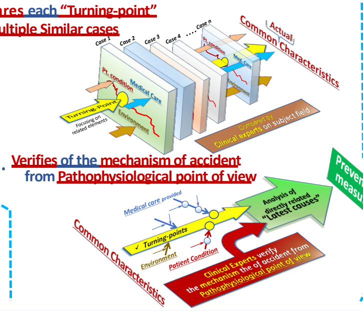
Elements composing "Turning-Point"

1. *Patient condition on clinical course*
   - Pathologic state, Co-morbidity, Homeostasis, etc.
   - Shortness of information
2. *Medical care provided*
   - Treatment itself (Pt. Care, Customs, etc.)
   - Health-care professionals (Experience, etc.)
   - Instruments
3. *Environment*
   - Hospital System, Environment
   - Shortness of information

➢ Individual accident has its own "Turning-Point" which the clinical course turns towards the accident. composed of three elements.

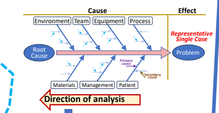
Ⅱ. Compares each "Turning-point" of Multiple Similar cases

Ⅲ. Verifies of the mechanism of accident from Pathophysiological point of view


Case 1
Case 2
Case 3
Case 4
…. Case n
Pt. condition
Medical Care
Environment
Turning-Point
Focusing on related elements
Compared by Clinical experts on subject field
Actual Common Characteristics
Medical care provided
Turning-points
Environment
Patient Condition
Clinical Experts verify the mechanism the of accident from Pathophysiological point of view
Analysis of directly related "Latest causes"
Common Characteristics
Preventive measures

Differences between Root-cause analysis and ours

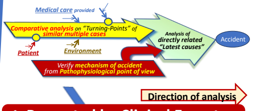
Root cause analysis



1. Promoted by **Expert** on **Analysis**
2. Theoretical consideration

Latently related causes

Our method:
Comparative Latest cause analysis


Medical care provided
Comparative analysis on "Turning-Points" of similar multiple cases
Patient
Environment
Verify mechanism of accident from Pathophysiological point of view
Analysis of directly related "Latest causes"
Accident
Direction of analysis

1. Promoted by Clinical Expert
2. Compare active similar cases
3. Verify mechanism of accident

Directly related causes

Prevent. Measures: EXAMPLE Ⅱ

Recommendations for the prevention of recurrence Number 16

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

10 cases of Airway Obstruction from 1,743 reports in 5 years and 7 months (Oct. 2015 ~ Apr. 2021), under the Medical Accident Investigation System,

Cervical Surgery and Applicable clinical department

Disease	Operation	cases
➢ Vertebra disease :	Ant. cervical spinal fusion	5
➢ Thyroid disease :	Thyroidectomy Cyst resection	3 1
➢ Carcinoma of Neck region :	Cervical LN dissection	1
	Total	10

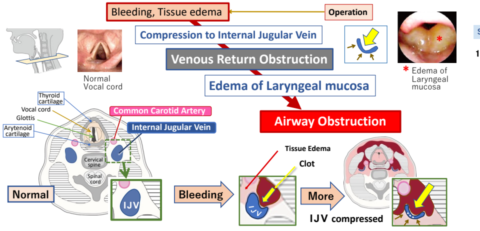
Cause of death (All 10 cases)

"Airway obstruction" caused by "Edema of Laryngeal mucosa"

Risk of airway obstruction

Recommendation 1
Cervical surgery has a risk of "Venous return obstruction" with edema of laryngeal mucosa followed by "Airway obstruction". Especially, in case of postoperative bleeding.

Mechanism of "Airway Obstruction" due to Cervical Surgery

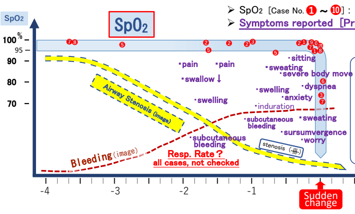


Observation of the respiratory condition and SpO_2

Recommendation 2
"SpO_2" does not correspond to the progression of airway obstruction due to edema of Laryngeal mucosa.
"SpO_2" falls only immediately before the sudden deterioration.
We must check respiratory rate increase and other "Signs & Symptoms".

Airway stenosis due to the edema of laryngeal mucosa and "SpO_2"

➢ SpO_2 [Case No. ❶ ~ ❿] : actual value of each case
➢ Symptoms reported [Prior to "Sudden change"]



After the sudden change

- ➢ Time to secure "Airway"
  29min. average
  Oral Intubation trials ⇒ Failed : average 1.8 times
- ➢ Time to heartbeat restart
  45min. 5cases
  Failed 4cases
  No arrest 1case
- ➢ Cause of death
  Hypoxic encephalopathy

Close observation of Post-operative signs and symptoms of cervical region

Recommendation 3
After cervical operation, a close observation is mandatory on signs and symptoms of airway obstruction, such as "Dyspnea", "Phlegm obstruction", "difficulty in swallowing", "Increasing cervical wound pain", "Respiration Rate increase", and "Frequent disquieting postural change", etc.

Symptoms and signs due to Edema of Laryngeal mucosa

"SpO_2" is not reliable
Alert is too late

[Homeostasis]
Efforts to keep the SpO_2
are those signs & symptoms

Symptoms
- ➢ Dyspnea
- ➢ Phlegm obstruction
- ➢ Difficulty in swallowing
- ➢ Increasing wound pain

Signs

➢ Respiration	Rate increase Stenotic sound or stridor Forced respiration, Orthopnea
➢ Cervical region	Swelling Circumference increase Bloody discharge
➢ Disquieting	Sitting up, Cold sweat Frequent postural change Agonized look

Decision to open the wound. Not Oral-Intubation but "Tracheostomy"

Recommendations 5, 6
- ➢ If you doubt the "airway obstruction" ➡ Immediately open the wound and remove hematoma
- ➢ If the airway obstruction progressed ➡ Do not hesitate "Tracheostomy", No "Oral Intubation"

Conclusion

Two ways in approaches

from accident reports to making preventive measures

Accident

Latently related **Root causes**	Immediately related **Latest causes**
"Root-Cause Analysis"	**"Comparative Latest-Cause Analysis"**
Promoted by Expert on Analysis	Promoted by Clinical Expert on Subject field
Preventive measures **on System**	Preventive measures **on Case Specifics**

Clinically implementable and effective preventive measures

These two approaches combined, will build up a significant preventive measures.