Application of the healthcare failure mode and effects analysis system to reduce the incidence of posture syndrome of thyroid surgery

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Abstract
This study aimed to investigate the application of the healthcare failure mode and effect analysis (HFMEA) to reduce the incidence of posture syndrome of thyroid surgery (PSTS).

Subjects before (n = 78, July 2017–December 2017) and after (n = 114, January 2018–June 2018) HFMEA implementation (The Second Hospital of Nanjing, Nanjing University of Chinese Medicine) were selected. The training for PSTS was optimized using HFMEA.

The occurrence of PSTS was reduced from 59% to 18% after HFMEA (P < .001). Symptoms of pain and nausea and vomiting were also decreased after HFMEA (all P < .001). The critical thinking ability of 34 medical personnel to evaluate the reduction of thyroid postoperative posture syndrome increased from 246 ± 19 to 301 ± 14 (P < .001) after HFMEA.

HFMEA was used to create preoperative posture training procedures for PSTS, bedside cards for training, innovative preoperative posture training equipment, and a diversified preoperative posture training health education model.

Abbreviations: HFMEA = healthcare failure mode and effect analysis, PSTS = posture syndrome of thyroid surgery.

Keywords: HFMEA = healthcare failure mode and effects analysis, postural syndrome, risk control, thyroid postoperative posture, thyroid surgery

1. Introduction
Surgery can be used for the management of patients with various thyroid problems.\(^1\) Due to the rich blood supply and narrow operation scope of thyroid surgery, it is necessary to adopt the “supine position with head and neck extension” to maintain neck hyperextension. This position often leads to postoperative nausea, vomiting, dizziness, headache, and other discomfort symptoms, sometimes accompanied by neck and occipital radiating pain and other symptoms. This syndrome may be called “posture syndrome of thyroid surgery” (PSTS) and can severely affect the quality of life of the patients.\(^2-4\)

Chu and Xiong\(^5\) adopted preventive nursing intervention to reduce the incidence of postural syndrome within 6 hours after general anesthesia, but they neglected the adverse reactions such as nausea and vomiting caused by the anesthetics. Wang et al\(^6\) effectively reduced the incidence of PSTS through the effect of personalized neck hyperextension posture on vertebral artery hemodynamics, but it needed the cooperation of the whole operating room, and the nurses in the ward could not directly operate and monitor the patients. Different approaches have been suggested to manage neck syndromes after surgery, but the results are variables, and their effectiveness is unclear.\(^2,3,7,8\) Therefore, there is a need to refine those approaches.

Healthcare failure mode and effect analysis (HFMEA) is a method of prospective evaluation of a systematic process. Through root cause analysis and process improvement, its purpose is to eliminate or reduce defects in a process.\(^9\) Therefore, the aim of the present article is to present our experience with the application of the HFMEA method to improve the management of PSTS. The results could lead to better management of patients undergoing thyroid surgery.

2. Materials and methods

2.1. Patients
From July 1, 2017 to June 31, 2018, our department applied the HFMEA method to evaluate and improve the procedure of preoperative thyroid posture training, innovate with equipment for preoperative thyroid posture training, improve preoperative thyroid posture health education, and strengthen the training and
assessment of surgical nurses to achieve homogeneous management of patients’ posture training of thyroid surgery. Moreover, adverse reactions such as nausea and vomiting were evaluated 24 hours after surgery, postoperative discomfort caused by anesthetics was excluded, and the incidence of postoperative PSTS was reduced.

Subjects: (78 patients who underwent thyroid surgery) between July 1, 2017 and December 31, 2017) and after (114 patients who underwent thyroid surgery between January 1, 2018 and June 31, 2018) HFMEA management implementation in the Department of Thyroid and Breast Surgery of The Second Hospital of Nanjing, Nanjing University of Chinese Medicine were selected. The Department of Thyroid Surgery of The Second Hospital of Nanjing was established in 2011 by experienced surgeons who are skilled in ultrasound-guided thyroid fine-needle aspiration biopsy (US-FNAB), thyroid benign nodule surgery, thyroid cancer radical surgery, thyroid cancer extended radical surgery, laparoscopy-assisted thyroid cancer radical surgery (improved Miccoli surgery), and thyroid thermal ablation therapy, among others. So far, >1500 thyroid surgeries have been completed by the surgical team. This study has been approved by the Ethics Committee of the hospital (#2018-LY-ky066).

The inclusion criteria were: complied with the diagnostic guidelines for thyroid nodules and differentiated thyroid cancer in China in 2012; 18 to 65 years of age; underwent total or near-total thyroidectomy or thyroidectomy and isthmus resection, under general anesthesia; the surgeon was a member of the research team of this project (n = 2 thyroid doctors in our hospital and participating in the study); without cognitive impairment or difficulties in reading and communication; and signed the informed consent form. The same 2 surgeons operated all the included patients (ie, before and after HFMEA).

The exclusion criteria were: serious comorbidities or diseases; cervical spondylosis; mental disorders, hearing impairment, or intellectual impairment; or intraoperative application of vasoactive drugs.

The withdrawal criteria were: unable to tolerate posture training; could not meet the training requirements; or requested to withdraw from the study.

The diagnostic criteria for postoperative PSTS included nausea, vomiting, dizziness, headache, and other uncomfortable symptoms occurring after thyroid surgery, sometimes accompanied by neck and occipital radiating pain and other symptoms.

2.2. HFMEA team

In June 2017, an HFMEA group was set up to reduce the incidence of postoperative PSTS. It consisted of a head nurse, 2 leaders of nursing responsibility team, 3 backbone nurses, and 2 thyroid doctors. Among them, there were 1 associate chief physician and 1 associate chief nurse, 3 supervisor nurses, 1 attending physician, and 2 nurses. Working seniority was >20 years in 1 person, 10 to 20 years in 2 persons, 5 to 10 years in 3 persons, and 3 to 5 years in 2 persons. The project team members received a 1-month HFMEA system training. Then, they adopted the steps of HFMEA to evaluate the risk of postoperative PSTS in 78 patients between July 1 and December 31, 2017.

2.3. Analysis of the failure cause of postoperative PSTS in patients

The HFMEA team members analyzed the failure causes of postoperative PSTS. The main reasons were: lack of preoperative posture training procedure; lack of preoperative posture training equipment; simple health education form of preoperative posture training; no evaluation on the efficiency of patients’ posture training; lack of professional knowledge training and assessment among nurses; and lack of compliance of preoperative posture training in patients.

2.4. Calculation of RPN

The team members were convened to list all possible failure modes for each step of the procedure. Then, for each failure mode, all possible causes and consequences of failure were identified. After that, the risk priority number (RPN) for the incidence of postoperative postural syndrome of thyroid surgery was jointly determined by the team members using the formula: 

\[ RPN = S \times O \times D \]

where, S is severity, O is frequency of occurrence, and D is likelihood of detection. HFMEA bedside shift report and preoperative posture training; no evaluation on the efficiency of patients’ posture training; lack of professional knowledge training and assessment among nurses; and lack of compliance of preoperative posture training in patients.

### Table 1
HFMEA results of postoperative posture syndrome of thyroid surgery.

| Failure mode                                                                 | Potential failure cause                                | Potential failure consequence                                   | Hazard score |
|------------------------------------------------------------------------------|--------------------------------------------------------|----------------------------------------------------------------|--------------|
| Lack of preoperative posture training procedure of thyroid surgery           | Lack of attention in management                         | Lack of homogeneous management in preoperative posture training of thyroid surgery | 9.8 ± 0.8    |
| Lack of preoperative posture training equipment of thyroid surgery          | Lack of innovation                                      | Failure to reach an effective posture                           | 8.1 ± 0.7    |
| Lack of quality control of preoperative posture training of thyroid surgery | No attention in management                              | Failure to find problems about posture training in time          | 7.6 ± 2.4    |
| Existing forms of health education cannot meet the needs of patients        | Simple health education form of preoperative posture training of thyroid surgery | Lack of posture training                                      | 7.7 ± 1.8    |
| Nurses do not understand the relevant elements of preoperative training     | Lack of professional knowledge training and assessment in nursing staff | Lack of nurses’ guidance on preoperative posture training of thyroid surgery | 7.0 ± 2.6    |
| Patients do not grasp the elements of preoperative posture training          | Nurses do not evaluate the correct rate of posture training in patients in time | Failure to achieve effective training                          | 6.6 ± 1.5    |
| Lack of compliance in preoperative posture training                          | Patients do not pay enough attention                     | Failure to complete posture training                           | 6.0 ± 1.5    |

D = likelihood of detection, HFMEA = healthcare failure mode and effect analysis, O = frequency of occurrence, S = severity.
2.5. Development of preoperative posture training procedure and quality standard for thyroid surgery
According to the failure mode analysis, the HFMEA team drew up a flowchart of preoperative posture training for thyroid surgery. The patients were given the first posture training immediately on the day of admission, and the primary nurses helped patients adjust pillow height to ensure effective posture. Posture training was conducted 2 hours after the 3 meals. The training time was gradually increased from 5 to 10 minutes per training session to 40 to 60 minutes per training session. At the end of each training session, the patients and primary nurses signed the bed-end card of training and indicated whether there was any discomfort.

2.6. Innovation of preoperative posture training equipment for thyroid surgery
The HFMEA management team designed an innovative air cushion pillow for neck posture training before thyroid surgery.

![Flow chart of preoperative posture training of thyroid surgery.](Zhang et al. Medicine (2019) 98:51 www.md-journal.com)
The occurrence of posture syndrome within 24 hours after thyroid surgery before and after HFMEA management implementation was determined, based on the occurrence of headache, dizziness, nausea, vomiting, and/or neck and shoulder stiffness. The numeric rating scale (NRS) was used to evaluate the degree of pain (including headache, shoulder, and neck pain), nausea, and vomiting before and after the implementation of HFMEA management in patients who undergo thyroid surgery: 0, painless; 1 to 3 points, mild pain; 4 to 6 points, moderate pain; 7 to 9 points, severe pain; 10 points, sharp pain. According to the WHO classification standard, nausea and vomiting were classified into grades: grade 0, no nausea and vomiting; grade I, nausea and vomiting only; grade II, transient vomiting accompanied by nausea; grade III, vomiting needs treatment; and grade IV, uncontrollable vomiting.

The critical thinking ability of 34 medical staff before and after HFMEA management implementation for reducing postoperative PSTS was evaluated. The Critical Thinking Disposition Inventory-Chinese Version (CTDI-CV) includes 7 dimensions: truth-seeking, open mind, analytical ability, systematization ability, self-confidence, thirst for knowledge, and cognitive maturity. Each dimension includes 10 items. The 6-point Likert scoring method is used for each item: 6 points, strongly agree; 5 points, agree; 4 points, slightly agree; 3 points, slightly disagree; 2 points, disagree; 1 point, strongly disagree. A score ≥40 indicates that a certain trait has a strong performance. A total score of ≥280 points indicates a positive critical thinking ability. The content validity of CTDI-CV is 0.89, and the Cronbach’s α is 0.90. The CTDI-CV was applied before and after HFMEA management implementation. The questionnaire was completed anonymously within 20 minutes. In this study, the effective recovery rate was 100%. There were no missing items in all questionnaires.

2.10. Statistical analysis

SPSS 24.0 (IBM, Armonk, NY) was used for statistical analysis. Continuous data were expressed as means ± standard deviation and analyzed using the Student t test. Categorical data were expressed as frequencies and rates and analyzed using Fisher exact test. P < .05 was considered statistically significant.

3. Results

3.1. Characteristics of the patients

There were no significant differences in demographics, clinical characteristics, surgical methods, and type of anesthesia before and after HFMEA management implementation (Table 2). Nursing intervention before HFMEA management was routine thyroid care. The incidence of postoperative posture syndrome was 59%.

3.2. Occurrence of the PSTS

The comparison of the occurrence of the posture syndrome at 24 hours after thyroid surgery before and after HFMEA management implementation is shown in Table 3. The incidence of the postoperative PSTS was significantly lower after HFMEA management (17.5% vs 59.0%, P < .001). The pain score was also decreased after implementation (1.8 ± 1.8 vs 2.9 ± 2.1, P < .001), as well as nausea and vomiting grade (P < .001) and other symptoms (P < .001) (Table 3).

3.3. Staff critical thinking

Table 4 shows that all dimensions of critical thinking ability of the 34 medical staff before and after HFMEA management implementation were improved after implementation (Table 4).
The total score changed from $246 \pm 19$ to $301 \pm 14$ ($P < .001$).

4. Discussion

The incidence of PSTS is about 60%. Through root cause analysis and process improvement, the purpose of HFMEA is to eliminate or reduce defects in a process. The present study aimed to investigate the application of HFMEA to reduce the incidence of PSTS. The results showed that HFMEA could be used to evaluate and create preoperative posture training procedures for PSTS, bedside cards for preoperative posture training, innovative preoperative posture training equipment, and the implementation of a diversified preoperative posture training health

| Table 2 | Characteristics of the patients who underwent thyroid surgery before and after HFMEA management. |
|---------|---------------------------------------------------------------------------------------------|
|         | Before HFMEA management (n = 78) | After HFMEA management (n = 114) | $P$  |
| **Sex** |                                |                                |      |
| Male    | 25 | 32.1% | 25 | 21.9% | .117 |
| Female  | 53 | 67.9% | 89 | 78.1% | .851 |
| **Age, y** | 42.1 ± 12.3 | 41.1 ± 11.7 |      |
| **Marital status** |                                |                                |      |
| Married | 60 | 76.9% | 89 | 78.1% | .851 |
| Unmarried | 18 | 23.1% | 25 | 21.9% | .787 |
| **Degree of education** |                                |                                |      |
| Junior high school or below | 18 | 23.1% | 20 | 17.5% | .787 |
| High school | 10 | 12.8% | 14 | 12.3% | .997 |
| University or above | 20 | 25.6% | 30 | 26.3% | .803 |
| **Occupation** |                                |                                |      |
| Managers | 22 | 28.2% | 33 | 28.9% | .803 |
| Salesman | 12 | 15.4% | 17 | 14.9% | .787 |
| Technician | 8 | 10.3% | 12 | 10.5% | .997 |
| Service worker | 13 | 16.7% | 21 | 18.4% | .787 |
| Self-employed person | 13 | 16.7% | 15 | 13.2% | .997 |
| Worker | 6 | 7.6% | 10 | 8.8% | .997 |
| Others | 4 | 5.1% | 6 | 5.3% | .997 |
| **Body mass index, kg/m²** | 21.8 ± 3.5 | 22.0 ± 4.2 | .708 |
| Underweight (<18.5) | 7 | 52.6% | 10 | 65.8% | .066 |
| Normal (18.5–24.9) | 64 | 47.4% | 85 | 34.2% | .665 |
| Overweight or obese (≥25) | 7 | 1.3% | 16 | 3.5% | .665 |
| **Course of disease, mo** | 5.2 ± 6.4 | 4.9 ± 7.1 | .803 |
| **Payment method** |                                |                                |      |
| Medical insurance | 41 | 52.6% | 75 | 65.8% | .066 |
| At one’s own expense | 37 | 47.4% | 39 | 34.2% | .665 |
| **Surgical method** |                                |                                |      |
| Total or near-total thyroidectomy | 70 | 89.7% | 100 | 87.7% | .665 |
| Thyroidectomy and isthmus resection | 8 | 10.3% | 14 | 12.3% | .665 |
| **Pathological types** |                                |                                |      |
| Papillary carcinoma | 77 | 98.7% | 110 | 96.5% | .341 |
| Follicular carcinoma | 1 | 1.3% | 4 | 3.5% | .341 |
| Operative time, min | 63.9 ± 15.9 | 60.9 ± 11.9 | .117 |
| Anesthesia time, min | 124.5 ± 24.4 | 123.4 ± 19.9 | .708 |
| Length of stay, days | 5.7 ± 2.1 | 6.1 ± 2.3 | .324 |
| Hospitalization expenses (×10,000 Yuan) | 1.47 ± 0.31 | 1.46 ± 0.29 | .279 |
| **Staging of thyroid cancer** |                                |                                |      |
| Age <45 y |                                |                                |      |
| Stage I | 14 | 18.0% | 26 | 22.8% | .936 |
| Stage II | 30 | 38.5% | 40 | 35.1% | .936 |
| Age >45 y |                                |                                |      |
| Stage I | 4 | 5.1% | 8 | 7.0% | .936 |
| Stage II | 6 | 7.7% | 10 | 8.8% | .936 |
| Stage III | 10 | 12.8% | 12 | 10.5% | .936 |
| Stage IVa | 10 | 12.8% | 10 | 8.8% | .936 |
| Stage IVb | 3 | 3.8% | 5 | 4.4% | .936 |
| Stage IVc | 1 | 1.3% | 3 | 2.6% | .936 |
| Diabetes | 7 (9.0%) | 11 (9.7%) | .875 |
| Fasting blood-glucose | 5.4 ± 1.8 | 5.4 ± 1.7 | .937 |
| Hypertension | 11 (14.1%) | 18 (15.8%) | .749 |
| Systolic pressure | 115.1 ± 20.0 | 116.4 ± 21.6 | .681 |
| Diastolic pressure | 73.0 ± 12.1 | 73.3 ± 13.9 | .901 |

HFMEA = healthcare failure mode and effect analysis.
education model. Strengthening training and assessment of thyroid medical personnel can reduce the incidence of PSTS.

Although the role of exercise for managing neck pain is controversial in the general population of patients,[7,8] some studies showed a benefit of such exercises for patients undergoing thyroid surgery. Indeed, Takamura et al[2] developed an exercise regimen and showed that the patients who used this regimen had lower symptoms scores from 1 week to 1 year after surgery. Ayhan et al[12] showed that neck stretching exercises performed immediately after total thyroidectomy alleviated neck pain and disability. In the present study, 59% of the patients had postural syndrome of thyroid surgery before the implementation of HFMEA. After HFMEA management implementation, the occurrence of postoperative PSTS decreased from 59% to 18%. This decrease was more significant than in the studies by Han et al[13] and Huang et al.[14] As a quality management tool, HFMEA put forward the concept of “doing things well at one time.”[15,16] After HFMEA management implementation, pain, nausea, vomiting, and other discomfort symptoms of patients undergoing thyroid surgery were significantly reduced. For patients, revising preoperative posture training procedure, innovating preoperative posture training equipments, and implementation of diversified health education can prompt patients to grasp the method of posture training correctly, press patients to carry out posture training effectively, and enhance patients’ tolerance to unnatural surgical postures,[15] thus effectively reducing the occurrence of the posture syndrome after surgery.

At present, most hospitals in China use sandbags, pillows, and mats for preoperative training to prevent the occurrence of postural syndrome. These tools are often used in a non-standardized manner, and the patient might feel uncomfortable when using them. In addition, these tools cannot be individually adjusted according to individual differences, and the occurrence of the position syndrome cannot be significantly reduced. The training air cushion pillow developed in the context of the present study includes a back cushion body, a neck cushion body, a head cushion body, and an external control system. From the mechanical point of view, the back, shoulder, and head cushions have strong stability. When used, the cushions conform to the actual patient, which enhances patient’s comfort during posture training. The neck cushion supports the neck muscles in the supine position, and prevents the venous return of the neck from being blocked and causing insufficient blood supply. The external control system allows adjustment for each component. According to the individual height adjustment of different patients, the sternocleidomastoid muscle can be gradually extended, and the critical thinking ability of nurses after HFMEA management considerably improved in all dimensions. The critical thinking ability of nurses refers to their ability to question reasonably and solve problems scientifically, which is mainly embodied in being good at identifying clinical problems and making clinical decisions.[11] The present study showed that the critical thinking ability of nurses after HFMEA management in reducing postoperative PSTS was significantly improved in all domains. The main reason is that the HFMEA prospective evaluation system process was implemented, and all failure modes related to nurses’ ignorance of the training elements of

| Table 3 |
| Comparison of the incidence of postural syndrome in patients undergoing thyroid surgery before and after HFMEA. |
| --- |
| **Group** | **Before HFMEA management (n = 78)** | **After HFMEA management (n = 114)** | **P value** |
| No posture syndrome occurred | 32 (41.5%) | 94 (82.5%) | <.001 |
| Posture syndrome occurred | 46 (59.0%) | 20 (17.5%) | <.001 |
| Pain score | 2.9 ± 2.1 | 1.8 ± 1.8 | <.001 |
| Nausea and vomiting | | | |
| Grade 0 | 57 (73.1%) | 105 (92.1%) | <.001 |
| Grade I | 9 (11.5%) | 5 (4.4%) | <.001 |
| Grade II | 5 (6.4%) | 2 (1.8%) | <.001 |
| Grade III | 7 (9.0%) | 2 (1.8%) | <.001 |
| Grade IV | 0 (0.0%) | 0 (0.0%) | <.001 |
| Obvious discomfort during surgery | | | |
| Posture cannot be maintained | 8 | 3 | <.001 |
| Asthma | 2 | 1 | <.001 |
| Dyspnea | 4 | 1 | <.001 |

HFMEA = healthcare failure mode and effect analysis.

| Table 4 |
| Comparison of critical thinking ability of 34 medical staff before and after HFMEA management in reducing postoperative posture syndrome of thyroid surgery. |
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| **Dimension** | **Before HFMEA management (n = 34)** | **After HFMEA management (n = 34)** | **P** |
| Truth-seeking | 36.3 ± 3.2 | 48.7 ± 4.6 | <.001 |
| Open mind | 33.7 ± 4.0 | 43.0 ± 3.7 | <.001 |
| Analytical ability | 33.1 ± 5.2 | 42.4 ± 4.1 | <.001 |
| Systematization ability | 38.7 ± 3.9 | 42.4 ± 4.6 | <.001 |
| Self-confidence | 32.3 ± 6.8 | 38.0 ± 5.1 | <.001 |
| Thirst for knowledge | 35.1 ± 5.8 | 40.0 ± 3.4 | <.001 |
| Cognitive maturity | 36.8 ± 4.3 | 46.0 ± 2.9 | <.001 |
| Total score | 246.0 ± 18.5 | 300.5 ± 14.3 | <.001 |

HFMEA = healthcare failure mode and effect analysis.
preoperative posture in the process were analyzed. This allowed diversified training and assessment, which stimulated nurses’ thinking to enable them to observe more scientifically and precisely the effectiveness and scientific aspects of patients’ posture exercise, to promote the implementation of nursing work in a more planned and effective way. Hence, patients’ exercise was more effective, and the occurrence of posture syndrome after surgery was reduced.

Similar outcomes of HFMEA were observed in a variety of conditions. Hover et al[18] showed that HFMEA reduced the occurrence of infections of neurosurgical sites, leading to substantial reductions in-hospital stay and costs. Similarly, the application of HFMEA led to reductions of central line-associated bloodstream infections in neonates, improving outcomes.[19] Therefore, HFMEA can be used to optimize different types of healthcare processes.[20,21]

The present study has limitations. The sample size of this study is small, and larger numbers of patients from multiple centers are required to validate the findings. In addition, the follow-up time was short (7 days), and the long-term neck outcomes should be examined. Third, HFMEA was applied in the context of a Chinese hospital, limiting the generalizability of the results. The same protocol should be examined in the Western context. Finally, the temporality of the study is a limitation (comparison before/after HFMEA), and future studies should examine the influence of HFMEA using a simultaneous comparison.

5. Conclusions

HFMEA was used to evaluate and create preoperative posture training procedures for PSTS, bedside cards for preoperative posture training, innovative preoperative posture training equipment, and the implementation of a diversified preoperative posture training health education model. Strengthening training and assessment of thyroid medical personnel can reduce the incidence of PSTS.

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