Analysis of the effect of a root cause analysis in elderly patients with acute pancreatitis: a randomized trial

1. Source of study population

patients with acute pancreatitis (AP) been admitted to our hospital

2. Criteria for selection of clinical cases

2.1 Inclusion criteria:

(I) meet the diagnostic criteria for AP, as set out in the 2014 edition of the Guidelines for Diagnosis and Treatment of Acute Pancreatitis;

(II) be aged ≥60;

(III) have an incidence time of ≤72 h;

(IV) have received no other treatment before admission;

(V) have signed an informed consent form or had a family member sign this form on their behalf.

2.2 Exclusion criteria:

(I) had other heart, liver, kidney, lung, brain or other important organ diseases;

(II) had a mental disorder or a history of mental illness;

(III) had serious acute and chronic infections;

(IV) had malignant tumors;

(V) refused to cooperate with this research.

3. Grouping situation

Divided into experimental group and control group according to the random number table method.

4. Inform the subjects of the grouping situation

Before signing the informed consent form, please explain the grouping of this study to the subjects.

5.Interventions

The control group underwent a routine nursing intervention whereby intervention staff educated patients on AP-related knowledge, informed patients and their families that they needed to actively cooperate with doctors' treatment and the nursing work of the nursing staff, and provided patients with psychological counseling to eliminate their negative psychological emotions. In addition to being provided with the same routine nursing as that provided to the control group, the observation group also underwent a RCA intervention whereby: (I) they were treated by an established intervention group; (II) the root cause was identified; (III) improvement measures were formulated.

The team members of the established intervention group comprised senior and experienced medical staff, including specialists, a head nurse, and specialist nurses. A head nurse was the team leader, and all members of the team underwent knowledge training on RCA. All the intervention personnel had to pass an assessment before implementing the RCA intervention. The intervention group summarized and analyzed previous adverse nursing events in AP, and identified the root causes of adverse events using a brainstorming method. The following three points were identified: (I) the patients had insufficient knowledge of catheterization; (II) the medical staff did not implement adequate preventive measures against complications; and (III) the number of nurses on duty at night was low.

In relation to the formulation of improvement measures, a system was first developed to prevent catheters from falling off. The intervention team selected high-risk patients based on the "Catheter Evaluation and Monitoring Mechanism" and the actual clinical conditions of the hospital. Scores were calculated based on the following two aspects: (I) level of awareness: 1 point was awarded to those with clear awareness, 2 points to those who were unwilling to cooperate with treatment or had a history of sedative drug use before, 3 points to those with vague consciousness, and 4 points to those with irritability; (II) catheter type: 1 point was awarded to those who had indwelling Class III catheters, such as an infusion tube, stomach tube or oxygen inhalation tube, 2 points to those who had indwelling Class II catheters, such as peripheral vein indwelling needle, negative pressure balloon, and deep vein catheter, 3 points to those who had indwelling Class I catheters, such as tracheal cannula, arteriovenous cannula, thoracic tube and ventricular drainage tube. Patients with a score of ≤ 2 were classified as low-risk patients, patients with a score of 3 to 5 were classified as intermediate-risk patients, and patients with a score of ≥ 5 were classified as high-risk patients. Low-risk patients received a catheter assessment once a week, intermediate-risk patients once every 3

days, and high-risk patients once a day.

Second, a publicity and education system was developed for patient infusion risk management. Interveners explained the infusion process to patients and their families in detail, informed patients of the correct method of fist clenching, encouraged patients to express their inner worries and concerns, and provided answers systematically. After successful puncture, the intervention staff thanked the patients for their cooperation, encouraged them to actively receive treatment, quickly established an effective venous channel to maintain the effective circulating blood volume and water-electrolyte acid-base balance, and closely monitored the dehydration status and cardiopulmonary function of the patients, continuously adjusting the infusion speed.

Third, a scientific scheduling system was developed. When the head nurse scheduled the nurses on duty, mid-shift nurses' working hours were appropriately extended, night shift nurses were scheduled to commence work half an hour earlier to increase the number of night shift nurses, and the number of nurses on duty were increased to monitor changes in patients' body temperature, blood pressure, blood gas and respiration.

6. Evaluation indexes

6.1 Clinical efficacy

Clinical efficacy was graded as either markedly effective, effective, or ineffective. It was graded as markedly effective, if after 2 weeks of intervention, the clinical symptoms of patients were significantly reduced, and all indicators had essentially returned to normal. It was graded as effective, if after 2 weeks of intervention, the clinical symptoms of patients were relieved and the indexes were recovered. It was graded as ineffective, if after 2 weeks of intervention, the patients' clinical symptoms and indicators did not improve or even worsened. The total effective rate was calculated using the following formula: (effective number + effective number)/total number × 100% .

6.2 Negative emotions

The Hamilton Anxiety Scale (HAMA) and Hamilton Depression Scale (HAMD) were used to evaluate the anxiety and depression of patients in the two groups before and

after the 2-week intervention. HAMA scale has 14 items, each item 0-4 points, > 7 points indicates that there may be anxiety, the higher the score, the more serious the anxiety. HAMD scale has 17 items, each item 0-4 points, > 7 points indicates that there may be depression, the higher the score, the more serious the depression.

6.3 The incidence of complications

The number of cases of shock, heart damage, infection, renal failure, acute respiratory distress syndrome, and digestive system complications in the two groups in the 2-week intervention period were counted, and the total incidence of complications was calculated.

6.4 Nursing satisfaction

A nursing satisfaction questionnaire was developed and used to evaluate the satisfaction of patients in the two groups after the 2-week intervention. The questionnaire comprised 10 items, each of which was scored from 0–10 points. A total score could range from 0–100 points. A score of 85–100 points indicated that a patient was very satisfied, a score of 70–84 points that the patient was generally satisfied, and a score of <70 points that the patient was not satisfied. Satisfaction was calculated using the following formula: (very satisfied number + generally satisfied number)/total number ×100%.

7. **Statistical analyses**

The statistical analysis in this study was performed using SPSS 20.0 (SPSS Inc., Chicago, IL, USA). The HAMA and HAMD scores of the two groups before and after the intervention were expressed as mean ± standard deviation ($\bar{x} \pm s$), and compared using 2-tailed t-tests. The two groups' clinical efficacy, incidence of complications, and levels of satisfaction with nursing were expressed by rates and percentages, and compared using the chi-squared ($\chi 2$) test or rank-sum test. A P value of <0.05 was considered statistically significant.

Article information: http://dx.doi.org/10.21037/apm-21-579