

Original Article

Risk factors for agitation after abdominal surgery under general anesthesia and effectiveness of care risk management

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Abstract: Objective: To investigate the risk factors for postoperative agitation in patients who underwent laparotomy under general anesthesia and to observe the effect of targeted care risk management on prevention of agitation, reduction in care-related adverse events and shortening of hospital stay. Methods: This study was subdivided into two phases. In Phase I, we explored the risk factors for postoperative agitation in patients who underwent laparotomy under general anesthesia. The enrolled subjects were 392 patients undergoing laparotomy in our hospital from January 2013 to November 2014. They were assigned to the case group and the control group in terms of the presence/absence of postoperative agitation. The risk factors for postoperative agitation were evaluated with the use of a chi-square test and the multivariate logistic regression analysis. In Phase II, we examined the effectiveness of care risk management interventions targeting at the above-mentioned risk factors on the rates of postoperative agitation, care-related adverse events as well as length of hospital stay. A total of 199 patients with laparotomy between January 2015 and December 2015 were included in Phase II. Results: In Phase I of the study, among 392 patients, postoperative agitation occurred in 82 patients. In univariate analysis and multivariate logistic regression analysis, an age of 70 years or older (adjusted OR (odds ratio) 2.07, 95% CI: 1.26-3.14), the American Society of Anesthesiologists (ASA) Class 3 or higher (OR 1.74, 95% CI: 1.07-2.51), intravenous-inhalation anesthesia (OR 1.52, 95% CI: 1.02-1.78), postoperative urinary intubation (OR 1.35, 95% CI: 1.02-1.78) and postoperative VAS pain score ≥ 6 (1.43, 95% CI: 1.08-2.01) were independent risk factors for postoperative agitation in patients who underwent laparotomy. In Phase II, after care risk interventions targeted at the above-mentioned risk factors were conducted, the rate of agitation was reduced to 10.6% ($P=0.002$), and the rate of associated adverse events dropped from 25.8% to 14.6% ($P=0.002$). Furthermore, the length of ICU stay and of hospital stay after care risk management were also significantly shorter than those in the conventional care period ($P=0.008$ and 0.047 , respectively). Conclusion: The parameters including an age ≥ 70 , preoperative ASA Class ≥ 3 , intravenous-inhalation anesthesia, postoperative urinary intubation and postoperative VAS pain score ≥ 6 can significantly increase the risk for postoperative agitation after laparotomy. Besides, the implementation of care risk management is associated with reductions in the rates of postoperative agitation and care risks, and shorter hospital stay as well.

Keywords: Laparotomy, postoperative agitation, risk factor, care risk intervention

Introduction

Postoperative agitation is a common complication at the stage of anaesthesia after surgery under general anesthesia, which usually occurs within 72 hours after surgery and can be recovered in several hours or days [1]. The mechanisms for the development of postoperative agitation are still unclear. Some researchers hold that due to anesthetic residues, the functions of the cerebral cortex and the ascending reticular activation system have not been fully

recovered. In this case, postoperative agitation may occur when the patient is subjected to external stimuli. Some have also reported that the presence of postoperative agitation may be associated with the damaged neuronal mitochondria attributed to the elevated lactic acid concentration in the brain during anesthesia [2, 3]. Multiple studies have demonstrated that the preoperative variables including age, gender, genetic susceptibility, intraoperative variables including surgical types and sites, and anesthesia factors, together with postoperative

Postoperative agitation and care risk management

variables including pain and intubation stimuli are associated with higher risks for postoperative agitation [2, 4-7].

Postoperative agitation can induce diverse care-related adverse events (e.g. extubation, catheter accidental removal and falls), affecting the patients' postoperative recovery, prolonging hospital stay and increasing medical costs [8-10]. It has been reported that taking measures including identification and screening of risk factors for postoperative agitation, health education, behavioral interventions, and care risk management in the care process can reduce the rate of postoperative agitation and other adverse events [11, 12]. Laparotomy is a common surgical procedure, but a high rate of agitation occurs in the patients in the stage of anaesthesia after surgery under general anaesthesia because the surgery can cause more severe trauma to the human body [13]. Few studies, however, have been involved in causative risk factors for postoperative agitation after laparotomy. In addition, the high rate of agitation after laparotomy has also elicited higher requirements for the patients' care management. Given this situation, we firstly recruited 392 patients undergoing abdomen surgery under general anaesthesia in our hospital from January 2013 to November 2014 to analyze risk factors for their postoperative agitation. Since January 2015, we initiated the care risk management for 199 patients with laparotomy and made an assessment on the effectiveness of the care risk management on the subjects from January to December 2015.

Materials and methods

Study design and subjects

This study was approved by the Hospital Ethics Committee and each subject provided their written informed consents.

The study was subdivided into two phases. In Phase I, a case-control study was made to analyze the causative risk factors for postoperative agitation in patients who underwent laparotomy under general anaesthesia. The subjects were 392 patients who were treated with laparotomy in our hospital from January 2013 to November 2014. The patients were included in the study if they were aged 18-90 years, underwent laparotomy under general anaesthesia,

received regular follow-ups for postoperative agitation and kept complete records with regard to the follow-ups. The patients who had preoperative serious cognitive or mental dysfunctions, or took preventive agents for agitation before surgery were excluded from the study.

The data below were collected from the subjects: demographics (gender and age), body mass index (BMI), smoking, preoperative American Association of Anesthesiologists (ASA) physical status classification and the Charlson Comorbidity Index (CCI) score, preoperative hematological tests (hemoglobin, albumin, and creatinine), surgical sites, surgical techniques, anaesthesia condition, postoperative urinary intubation and postoperative pain. Postoperative pain was assessed using the visual analogue scale (VAS) [14].

In Phase II of the study, the effectiveness of care risk management was assessed. A total of 199 subjects were enrolled in Phase II study from January to December 2015. The inclusion and exclusion criteria were the same as described in Phase I. Care risk management was implemented in the key surgical wards. In addition, the causative risk factors for postoperative agitation found in Phase I were also involved in risk identification and management. Apart from risk identification which covered the risk factors found in Phase I of this study and relevant literature, Phase II also included the assessment of patients' risks, determination of the risks and potential consequences of postoperative agitation, establishment of teams for ward care risk management, specification of responsibilities of care risk management, development of care management plans, as well as implementation of sustainable safety monitoring and care interventions. The effectiveness of care risk management was assessed by comparing the variables including the rates of postoperative agitation, the rate of care adverse events and length of hospital stay before and after care risk management.

Criteria for postoperative agitation assessment

The assessment of postoperative agitation was performed using Ricker Sedation-Agitation Scale (SAS) score, which evaluates the patient's awareness and agitation based on seven different categories of behavior. On a

Postoperative agitation and care risk management

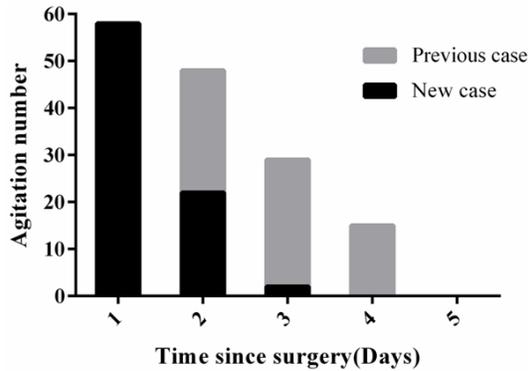


Figure 1. Time of postoperative agitation in patients undergoing laparotomy.

scale of SAS 7 points, SAS 1-7 points indicate unarousable, very sedated, sedated, calm and cooperative, agitated, very agitated and dangerous agitation, respectively [15]. SAS 1-4 points indicate the absence of agitation, and 5-7 indicates the presence of agitation and requiring clinical treatment. In the revised Practice Guideline for the Management of Sedation and Analgesia in Adult Patients in the Intensive Care Unit, the Society of Critical Care Medicine (SCCM) specified the SAS as one of the most reliable and effective tools for assessment of adult postoperative agitation [16]. During the intensive care units (ICU) stay, the ICU nurses examined the patient's severity of postoperative agitation every 4 hours or made assessment on a case-by-case basis.

Statistical analysis

The comparison of the differences in categorical variables before and after care risk management between the case group and the control group were examined with the use of a two-sided chi-squared test or the Fisher's exact test whereas the comparison of the mean continuous variables was made using a two-sample independent t-test. The multivariate logistic regression was used to analyze the risk factors for postoperative agitation. The variables with significance level less than 0.1 on the univariate analysis were included for the multivariate logistic regression analysis. On the multivariate analysis, the likelihood ratio test was performed based on the maximum local likelihood. The independent variables were further selected using the stepwise regression method. The SPSS statistical software (version 19.0) was utilized for data analyses. A two-sided

P value less than 0.05 was considered to be statistically significant.

Results

Risk factors for postoperative agitation

Univariate analysis: Of the 392 eligible patients, postoperative agitation occurred in 82 patients (20.9%). The agitation occurred in 58, 22, and 2 patients on day 1, day 2 and day 3 after surgery and all recovered on day 5 after surgery (**Figure 1**).

The rates of males in the case group and the control group were 41.5% and 45.5%, respectively, so the difference was insignificant. Besides, the two groups differed insignificantly in such variables as smoking, BMI, and preoperative blood tests (hemoglobin, albumin and creatinine). The patients in the case group aged 70 years or above, and the rates of ASA Class ≥ 3 were 81.7% and 52.4% respectively, which were significantly higher than those of the control group (63.5% and 31.6%; $P=0.002$ and 0.001 , respectively). The CCI score for the patients in the case group was 1.10 ± 0.70 , significantly higher than that of the patients in the control group (0.92 ± 0.70 ; $P=0.039$).

Table 2 shows comparison of intraoperative and postoperative factors between the two groups. Of the 392 patients, 166 underwent gastrointestinal surgery, 149 hepatobiliary surgery, 28 had operations in the urinary system, 26 pancreatic surgery and 23 had operations in other parts of the body. No significant differences were found in operation time and sites, and blood loss between the two groups. The rate of patients undergoing laparotomy in the case group was 89.0%, markedly higher than that of the control group (78.4%; $P=0.030$). In addition, the proportions of patients with intravenous-inhalation anesthesia, postoperative urinary intubation and postoperative VAS pain score ≥ 6 in the case group were strikingly higher than those of patients in the control group ($P<0.05$).

Risk factors for postoperative agitation in patients undergoing laparotomy

According to the findings shown in **Tables 1** and **2**, the variables including age, preoperative ASA Class, CCI score, surgical methods, anesthesia techniques, postoperative urinary intu-

Postoperative agitation and care risk management

Table 1. Demographic and preoperative characteristics of the patients in both groups

Characteristic	Control group (n=310)	Case group (n=82)	x ² /t	P
Gender			0.424	0.515
Female	169 (54.5)	48 (58.5)		
Male	141 (45.5)	34 (41.5)		
Age (Mean ± SD)			9.724	0.002
<70	113 (36.5)	15 (18.3)		
≥70	197 (63.5)	67 (81.7)		
Smoking			0.243	0.622
Yes	172 (55.5)	43 (52.4)		
No	138 (44.5)	39 (47.6)		
BMI	25.4±4.7	24.7±3.6	1.254	0.210
ASA Class			12.212	0.001
<3	212 (68.4)	39 (47.6)		
≥3	98 (31.6)	43 (52.4)		
CCI score	0.92±0.70	1.10±0.70	2.071	0.039
Preoperative blood test				
Hemoglobin (g/dl)	12.4±1.68	12.1±1.72	1.411	0.159
Albumin (g/dl)	3.62±0.59	3.51±0.47	1.562	0.119
Creatinine (mg/dl)	0.96±0.29	1.03±0.43	1.739	0.083

Table 2. Comparison of intraoperative and postoperative factors between the two groups

Characteristic	Control group (n=310)	Case group (n=82)	x ² /t	P
Operation time (min)	189.1±67.2	201.5±72.7	1.460	0.145
Operation site			7.307	0.121
Gastrointestinal	127 (41.0)	39 (47.6)		
Hepatobiliary	124 (40.0)	25 (30.5)		
Urinary system	18 (5.8)	10 (12.2)		
Pancreas/Spleen	23 (7.4)	3 (3.7)		
Other	18 (5.8)	5 (6.1)		
Surgical technique			4.695	0.030
Laparoscopy	67 (21.6)	9 (11.0)		
Laparotomy	243 (78.4)	73 (89.0)		
Blood loss (ml)	432.5±234.2	477.8±258.9	1.523	0.129
Anesthesia			7.521	0.006
Total intravenous	199 (64.2)	43 (47.6)		
Intravenous-inhalation	111 (35.8)	39 (52.4)		
Postoperative urinary intubation			7.022	0.008
No	183 (59.0)	35 (42.7)		
Yes	127 (41.0)	47 (57.3)		
Postoperative VAS pain score			5.932	0.015
<6	179 (57.7)	35 (42.7)		
≥6	131 (42.3)	47 (57.3)		

bation and postoperative VAS pain score ≥6 might be risk factors for postoperative agita-

tion in patients with laparotomy. After the logistic regression analysis on the above factors, we found that an age ≥70 years, pre-operative ASA Class ≥3, intravenous-inhalation anesthesia, postoperative urinary intubation and postoperative VAS pain score ≥6 (adjusted OR, 2.07 (95% CI: 1.26-3.14), 1.74 (95% CI: 1.07-2.51), 1.35 (95% CI: 1.02-1.78), 1.52 (95% CI: 1.12-2.05) and 1.43(95%CI:1.08-2.01), respectively) were independent risk factors for postoperative agitation in patients with laparotomy (**Table 3**).

Comparison of postoperative agitation, adverse events and length of hospital stay of patients before and after care risk management

Considering the found risk factors for postoperative agitation after laparotomy, we began to carry out targeted care risk management from January 2015. We compared the three variables including postoperative agitation, adverse events and length of hospital stay between the 199 patients who had received care risk management between January and December of 2015 and the 392 patients who were given routine care interventions from January 2013 to November 2014 (**Table 4**). The rates of postoperative agitation and adverse events before and after care risk management were 20.9% versus 10.6% (P=0.002), and 25.8% versus

14.6% (P=0.002), respectively. In addition, patient's ICU stay and hospital stay after care

Postoperative agitation and care risk management

Table 3. Multivariate logistic analysis on risk factors for postoperative agitation in laparotomy

Characteristic	OR*	95% CI	P
Age		1.26-3.14	0.01
<70	1		
≥70	2.07		
ASA Class		1.07-2.51	0.021
<3	1		
≥3	1.74		
Anesthesia		1.02-1.78	0.038
Total intravenous	1		
Intravenous-inhalation	1.35		
Postoperative urinary intubation		1.12-2.05	0.031
No	1		
Yes	1.52		
Postoperative VAS pain score		1.08-2.01	0.040
<6	1		
≥6	1.43		

Note: *Adjust CCI score and surgical techniques.

risk management were significantly shorter than those of patients during routine care ($P=0.008$ and 0.047 , respectively).

Discussion

Postoperative agitation is an adverse reaction of patient under general anesthesia. Previous literature has revealed that laparotomy is an independent risk factor for postoperative agitation. However, few studies have been focused on the rate of postoperative agitation and risk factors after laparotomy. And the results are not consistent across all the studies [17-19]. In the present study, the rate of agitation after laparotomy was 20.9%, which was similar to the results of other studies but lower than those of other studies [17, 20, 21]. For example, according to Ganai et al., the rate of agitation in patients was as high as 60% after laparotomy [18]. The greater difference in the rate of agitation after laparotomy may be due to the facts that the age distribution and inclusion criteria of the patients varied in all the studies.

The causes of agitation after laparotomy are not quite clear, but it is deemed to be implicated in preoperative, intraoperative and postoperative factors. Multiple studies have demonstrated that older age significantly increases the risks for agitation in adult patients with laparotomy, which was also validated in the

present study [19, 22]. However, other studies have suggested that being male is not a risk factor for the presence of agitation after laparotomy [2]. Thus, more studies are required to explore the association between the above two factors. In the present study, higher ASA class was also a risk factor for the presence of postoperative agitation, which is similar to other findings. This may be related to the poor physical status and greater fluctuation in heart rates and blood pressure of the patients during surgery and anesthesia, and also to inadequate anesthesia depth as the patients need large amount of anesthetics [23, 24]. Previous studies have shown that preoperative factors including gender, smoking, low levels of hemoglobin/albumin, other comorbidities, and low BMI can also significantly increase the risk of agitation after laparotomy [7, 19, 25, 26]. Nevertheless, the above results were not found in the present study. As a result, further studies are still needed to investigate the association between these factors and agitation after laparotomy.

Some factors in the process of laparotomy under general anesthesia can also affect the occurrence of postoperative agitation. In some studies, in laparotomy, higher rates of postoperative agitation have been reported during the operations made in the parts of body including the liver, spleen and in the upper gastrointestinal tract, but we did not find the specific surgical sites were associated with the presence of postoperative agitation [20]. Some researchers also argued that the rate of agitation after laparoscopy was higher than that of open surgery. However, in our study, although univariate analysis showed that the surgical pathway was correlated with the risk of postoperative agitation, no significant association between the two was found after adjustment of other factors. This was similar to the results of other studies [27]. In the present study, intravenous-inhalation anesthesia significantly increased the risk of agitation after laparotomy, which was consistent with the results of previous studies [2]. The reasons might be attributed to the use of different anesthetics. Propofol is the major anesthetics used to maintain anesthesia in total intravenous anesthesia whereas sevoflurane is the primary anesthetics in intravenous-inhalation anesthesia. However, sevoflurane and other inhalation anesthetic drugs were reported to

Postoperative agitation and care risk management

Table 4. Comparison of postoperative agitation and adverse care events before and after risk management

Outcome	Routine care (n=392)	Risk management (n=199)	χ^2/t	P
Agitation	82 (20.9)	21 (10.6)	9.855	0.002
Adverse event				
Extubation/Catheter accidental removal	32	11		
Fall down from bed/Fall	30	8		
Cutaneous injury	35	10		
Rupture incision	4	0		
Total (%)	101 (25.8)	29 (14.6)	9.637	0.002
ICU stay (d)	3.7±1.9	3.2±1.8	2.675	0.008
Hospital stay (d)	18.2±5.6	17.1±5.4	1.980	0.047

more significantly increase the risk of postoperative agitation as compared to propofol [28, 29].

In a systematic review, postoperative ureteral intubation is an independent risk factor for postoperative agitation, and our study also validated this result, which was similar to the results of some studies conducted in patients with non-neurosurgery [2, 30]. In addition, we also found that postoperative pain (VAS score ≥ 6) was significantly associated with the presence of agitation after laparotomy. However, in some studies, no significant association has been found between pain and postoperative agitation [7]. Therefore, further studies are required to explore whether postoperative pain increases the risk of postoperative agitation after laparotomy.

Other studies have demonstrated that, similar to the operations made in other parts of the body, the rates of adverse events like agitation after laparotomy increased significantly [8, 23]. In order to effectively prevent the care risk and reduce the rate of care risk, our hospital began to conduct the care risk management of the major surgical wards since January 2015. Some studies have indicated care risk management might be effective in preventing and reducing adverse events in surgical care [31]. Similarly, in the present study, we first conducted a case-control study to determine the causative risk factors for agitation after laparotomy and then immediately examined the risk factors in the practice of care risk management. We found that after the implementation of care risk management following laparotomy, postop-

erative agitation, unplanned extubation, falls, falling down from bed and other adverse care events significantly reduced among the patients. Besides, their ICU stay and hospital stay were also significantly shortened as compared with those with routine care.

In the present study, we analyzed the risk factors for postoperative agitation in pa-

tients with laparotomy from the preoperative, intraoperative and postoperative perspectives, and evaluated the effectiveness of care risk management. However, there were still some limitations in the study. The study was designed as a retrospective study, so it is difficult to avoid some bias. Moreover, the variables analyzed in the study might not cover all the risk factors affecting postoperative agitation. Despite the multivariate analyses were performed, it was hard to completely rule out the effects of other known/unknown confounding factors. In addition, the assessment of care risk management was based on the comparison before and after the implementation of care risk management, rather than random comparison between randomization. Thus, the study might be affected by some confounders, either.

In conclusion, in the present study, we analyzed the causative risk factors for postoperative agitation in patients who received laparotomy and assessed the effectiveness of care risk management on reducing adverse care events. The findings may provide certain reference to the future work and study in identification of postoperative agitation, prevention and reduction of corresponding adverse consequences. In the future, however, more prospective studies with large sample size are needed to investigate the risk factors for agitation after laparotomy, and more randomized controlled trials are also required to further assess the effectiveness of care risk management.

Disclosure of conflict of interest

None.

Postoperative agitation and care risk management

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Postoperative agitation and care risk management

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