Establishing a model to measure and predict the quality of gastrointestinal endoscopy

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Abstract

BACKGROUND
Tens of millions of gastrointestinal endoscopic procedures are performed every year in China, but the quality varies significantly and related factors are complex. Individual endoscopist- and endoscopy division-related factors may be useful to establish a model to measure and predict the quality of endoscopy.

AIM
To establish a model to measure and predict the quality of gastrointestinal endoscopic procedures in mainland China.

METHODS
Selected data on endoscopy experience, equipment, facility, qualification of endoscopists, and other relevant variables were collected from the National Database of Digestive Endoscopy of China. The multivariable logistic regression analysis was used to identify the potential predictive variables for occurrence of medical malpractice and patient disturbance. Linear and nonlinear regressions were used to establish models to predict incidence of endoscopic complications.

RESULTS
In 2012, gastroscopy/colonoscopy-related complications in mainland China included bleeding in 4,359 cases (0.02%) and perforation in 914 (0.003%).
Endoscopic-retrograde-cholangiopancreatography-related complications included severe acute pancreatitis in 593 cases (0.3%), bleeding in 2,151 (1.10%), perforation in 257 (0.13%) and biliary infection in 4,125 (2.11%). Moreover, 1,313 (5.0%) endoscopists encountered with medical malpractice, and 5,243 (20.0%) encountered with the disturbance from patients. The length of endoscopy experience, weekly working hours, weekly night shifts, annual vacation days and job satisfaction were predictors for the occurrence of medical malpractice and patient disturbance. However, the length of endoscopy experience and the ratio of endoscopists to nurses were not adequate to establish an effective predictive model for endoscopy complications.

**CONCLUSION**

The workload and job satisfaction of endoscopists are valuable predictors for medical malpractice or patient disturbance. More comprehensive data are needed to establish quality-predictive models for endoscopic complications.

**Key words:** Endoscopy; Gastroscopy; Colonoscopy; Endoscopic retrograde cholangiopancreatography; Quality control; Predictive model; Performance predictor

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**Core tip:** Tens of millions of gastrointestinal endoscopic procedures are performed each year in China, but there is significant variation in the quality of endoscopy, and the method of measuring quality remains unknown. We collected data from the National Database of Digestive Endoscopy of China to establish a model to measure and predict the quality of gastrointestinal endoscopy in mainland China. The length of endoscopy experience, weekly working hours, weekly night shifts, annual vacation days and job satisfaction were predictors of medical malpractice and patient disturbance. The length of experience and endoscopist/nurse ratio were not adequate to establish a model for the prediction of endoscopic complications.

**INTRODUCTION**

Tens of millions of endoscopic procedures are performed every year in China, but there is significant variation in the quality of endoscopy[1-8]. Factors affecting the quality of endoscopy are complex and include personnel who perform the procedure, as well as procedures and equipment, which all may result in outcome variation. Various organizations have developed structured procedures for the management of underperforming endoscopists. There have been studies about performance measures generated by evidence-based consensus that can be used for upper gastrointestinal endoscopy[9-11]. Performance measures can be used to measure the quality of organizational structure, healthcare procedures or clinical outcomes, providing feedbacks to endoscopists with suboptimal performance to improve their quality of procedures. Hence, it might be beneficial to predict the overall quality of endoscopy in a system consisting of human resources, procedures and equipment. This particularly matters for large developing countries, which urgently need to improve the overall quality of endoscopy.

**MATERIALS AND METHODS**

**Conduct of the survey**

As part of its endoscopy quality initiative, the Society of Digestive Endoscopy of the Chinese Medical Association, with support from the National Health and Family
Planning Commission, conducted a nationwide survey in hospitals in all 31 provinces, autonomous regions and municipalities of mainland China in 2013, to investigate the digestive endoscopy infrastructure and overall performance of endoscopic procedures.

Two sets of questionnaires were used in the survey: one was completed by the endoscopic division of each hospital, collecting data that included hospital characteristics, composition and number of endoscopic staff, type and volume of endoscopic procedures, and endoscopic facilities and equipment. The other was completed by individual endoscopists, collecting clinical practice data that included staff work status, weekly working hours, night shifts, vacation days, revenue, work volume, work satisfaction, medical malpractice and patient disturbance. The endoscopic divisions of 6,127 hospitals and 26,203 endoscopists completed and returned the respective questionnaires. All data were imported into the National Database of Digestive Endoscopy.

**Data synthesis**

The endoscopic divisions of each hospitals were required to follow the Digestive Endoscopy Diagnosis and Treatment Technological Management Regulations by the National Health and Family Planning Commission of China. The survey showed that all of the hospitals had equivalent equipment that had been acquired in accordance with government standards. In the analysis for this study, it was therefore assumed that procedures and equipment were equivalent and there was no difference among the hospitals that participated in the nationwide survey. This assumption meant that the analysis focused on the characteristics of human resources as potential predictive variables at the level of an endoscopic division or endoscopist.

At the level of an endoscopic division, the nationwide survey collected data about gastroscopy, colonoscopy, duodenoscopy, endoscopic ultrasonography, endoscopic retrograde cholangiopancreatography (ERCP), and other endoscopic procedures. We selected the three most common procedures to be analyzed, which included gastroscopy, colonoscopy and ERCP. In the analysis, we only considered the overall complications and did not analyze individual complications. Major complications in the records included gastroscopy/colonoscopy/ERCP-related bleeding and perforation, severe acute pancreatitis and biliary infection.

**Statistical analysis**

Multivariable logistic regression analyses were used to examine and identify the potential predictive variables for the occurrence of medical malpractice and patient disturbance. Covariates with \( P < 0.20 \) were selected to be included in the full multi-variable model for prediction. Linear and nonlinear (root, square, log) regressions were used to establish models for predicting the incidence of endoscopic complications. The outcome variables (dependent) and predictor variables (independent) are listed in Table 1.

### RESULTS

**Overview of gastrointestinal endoscopy in mainland China in 2012**

In 2012, gastrointestinal endoscopic procedures were performed in 6,128 hospitals in mainland China, involving 26,203 endoscopists and 14,532 endoscopic nurses. The total number of gastrointestinal endoscopy procedures was 28.77 million. The numbers of gastroscopy, colonoscopy and ERCP procedures were 22.25 million, 5.83 million and 200,000, respectively.

Gastroscopy- and colonoscopy-related complications included bleeding in 4,359 cases (0.02\%) and perforation in 914 cases (0.003\%). ERCP-related complications included severe acute pancreatitis in 593 cases (0.3\%), bleeding in 2,151 cases (1.10\%), perforation in 257 cases (0.13\%) and biliary infection in 4,125 cases (2.11\%).

According to reports from endoscopists, 1,313 (5.0\%) of them encountered with medical malpractice and 5243 (20.0\%) encountered with the disturbance from patients or their relatives.

**Establishment of a model to measure and predict quality of gastrointestinal endoscopy**

Five workload-related factors (length of endoscopy experience, weekly working hours, weekly night shifts, annual vacation days and job satisfaction) were included in the final multivariable model as impact factors for the occurrence of medical malpractice and patient disturbance (Table 2).

Linear and nonlinear (root, square, log) regression models were used to test the
correlation between the incidence of endoscopic complications and two selected impact factors, which included the length of endoscopy experience and the ratio of endoscopists to nurses. However, these two factors alone were not adequate to establish an effective predictive model for gastroscopy/colonoscopy- or ERCP-related complications (Tables 3 and 4).

DISCUSSION

Quality control is an important issue in the practice of gastrointestinal endoscopy[12-21]. The primary objective of this study was to explore the feasibility of establishing a model to measure and predict the overall quality of endoscopic procedures in a system consisting of human resources, procedures and equipment, rather than to measure the performance of specific endoscopic procedures[22-28].

With the exception of endoscopist status (part- or full-time), the other five impact factors were included in the final multivariable logistic model for predicting the occurrence of medical malpractice and patient disturbance. Even the secondary data were not optimal. They did help examine the relationship between clinical outcomes (e.g., complications) and predictors based on a large sample size, which decreased the effect of selection bias. The clinical outcomes, including the incidence of endoscopic complications, occurrence of medical malpractice and disturbance from patients and their families, were regarded as valuable performance measures or quality indicators in other studies[12,13,29]. The predictive variables were deemed to be risk factors that might affect the performance of endoscopic procedures in clinical practice, although there was a lack of strong evidence.

Medical professionals, procedures and equipment were included in the system. One assumption of the study was that the processes and equipment were equivalent among all of the hospitals in the survey. The assumption was made on the basis that all of the hospitals were required by government to follow the same regulations and all of the equipment was accredited by a government agency. It was assumed that these hospitals did not violate the rules and breach the standards, however we did not know the true status of each participant. To overcome this limitation in the future, information about process compliance and equipment accreditation status should be collected and updated regularly in the database.

We used linear and nonlinear (root, square, log) regression models to test the correlation between the incidence of endoscopic complications with the two corresponding impact factors. However, the results were not optimal and the two selected impact factors were inadequate for an effective predictive model. In the current analysis of human resource-related factors, there were only endoscopist data. However, it was clear in clinical practice that patient data are important. For example, the severity of the primary disease could affect the outcome of any endoscopic procedure. The suboptimal results indicated that there could be more impact factors and that their interactions are complex. Nevertheless, this study helped create a framework to establish a model that can help predict the quality of endoscopic procedures to some extent.

The major limitation of this study was that the analysis was based on suboptimal data. The data relevant to the quality of endoscopy from the Chinese National Database of Digestive Endoscopy could not cover all aspects of personnel, procedures and equipment. However, considering the large numbers of included hospitals and endoscopists, these data are still deemed valuable.

In conclusion, endoscopist workload-related factors might be valuable predictors for medical malpractice or patient disturbance. More comprehensive data are needed to establish a quality predictive model for endoscopic complications.
Table 2  Results of multivariable logistic regression analysis for occurrence of medical malpractice and patient disturbance

| Impact factors                      | OR (95%CI)       | P value |
|------------------------------------|------------------|---------|
| Length of experience in endoscopy  | 0.77 (0.75-0.78) | < 0.0001|
| Workload as weekly working hours   | 0.90 (0.86-0.94) | < 0.0001|
| Workload as weekly night shifts    | 0.96 (0.92-0.99) | 0.0132  |
| Workload as annual vacation days   | 1.02 (1.0-1.03)  | 0.0178  |
| Job satisfaction                   | 2.24 (2.12-2.36) | < 0.0001|

Table 3  Results of regression analysis for incidence of endoscopic retrograde cholangiopancreatography-related complications

| Impact factors                      | Linear regression analysis | Nonlinear (root) regression analysis | Nonlinear (square) regression analysis | Nonlinear (log) regression analysis |
|------------------------------------|----------------------------|-------------------------------------|----------------------------------------|------------------------------------|
| Intercept                          | 0.0326                     | 0.0343                              | 0.0312                                 | 0.0222                             |
|                                    | 0.0000                     | 0.0007                              | 0.0000                                 | 0.0022                             |
|                                    | 0.1949                     | 0.1307                              | 0.3407                                 | 0.1389                             |
| Length of experience in endoscopy  | -0.0000                    | -0.0065                             | -0.0001                                | -0.0048                             |
|                                    | 0.0895                     | 0.7124                              | 0.5579                                 | 0.4635                             |
|                                    | -0.0018                    | 0.1307                              | 0.3407                                 | 0.1389                             |

Table 4  Results of regression analysis for incidence of gastroscopy/colonoscopy-related complications

| Impact factor                      | Linear regression analysis | Nonlinear (root) regression analysis | Nonlinear (square) regression analysis | Nonlinear (log) regression analysis |
|------------------------------------|----------------------------|-------------------------------------|----------------------------------------|------------------------------------|
| Intercept                          | 0.0064                     | 0.0075                              | 0.0059                                 | 0.0070                             |
|                                    | 0.0000                     | 0.5274                              | 0.4250                                 | 0.5821                             |
|                                    | -0.0000                    | 0.6422                              | 0.8793                                 | 0.8611                             |
| Length of experience in endoscopy  | -0.0000                    | -0.0003                             | -0.0006                                | -0.0002                             |
|                                    | 0.4461                     | 0.5274                              | 0.4250                                 | 0.5821                             |
|                                    | -0.0000                    | 0.8081                              | 0.8793                                 | 0.8611                             |

ARTICLE HIGHLIGHTS

Research background
There are increasingly more gastrointestinal endoscopic procedures performed every year. However, there is significant variation in quality, and the causative factors are complex. Well-accepted predictive models have not been developed.

Research motivation
No related research has focused on this field in China before. However, the quality control of gastrointestinal endoscopy is an important issue. According to our national survey, we found that a number of adverse effects were related to gastrointestinal endoscopy. Therefore, we collected data from the National Database of Digestive Endoscopy of China, aiming to establish a model to measure and predict the quality of gastrointestinal endoscopy in mainland China.

Research objectives
Quality control is an important issue in gastrointestinal endoscopy. The primary objective of this study was to explore the feasibility of establishing a model to measure and predict the overall quality of endoscopic procedures in a system consisting of human resources as well as processes and equipment, rather than to measure the performance of specific endoscopic procedures.

Research methods
Related data were obtained from the nationwide survey in hospitals in all 31 provinces, autonomous regions and municipalities of mainland China in 2013. Multivariable logistic regression analyses were used to examine and identify the potential predictive variables for the occurrence of medical malpractice and patient disturbance.

Research results
In 2012, gastroscopy and colonoscopy-related complications included bleeding (0.02%) and perforation (0.003%). Endoscopic retrograde cholangiopancreatography (ERCP)-related complications included severe acute pancreatitis (0.3%), bleeding (1.10%), perforation (0.13%) and biliary infection (2.11%). Moreover, 5.0% of endoscopists encountered with medical
malpractice and 20.0% encountered with the disturbance from patients or their relatives. Multivariable logistic regression analyses showed that five workload-related factors, including length of endoscopy experience, weekly working hours, weekly night shifts, annual vacation days and job satisfaction, were predictors for medical malpractice and patient disturbance. However, the length of endoscopy experience and the ratio of endoscopists to nurses were not adequate to establish an effective predictive model for gastroscopy/colonoscopy or ERCP.

Research conclusions
In this study, we found for the first time that the workload and job satisfaction of endoscopists are valuable predictors for medical malpractice or patient disturbance. These findings suggest that in the clinical practice, decreasing the workload and increasing the welfare of endoscopists may improve the quality of gastrointestinal endoscopy.

Research perspectives
This study cannot build an ideal model for predicting the quality of gastrointestinal endoscopy. In the future, more comprehensive data are needed to establish quality-predictive models for endoscopic complications. The optimal method would be a multicenter prospective structured study.

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