REVIEW

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How to Improve the Quality of Screening Endoscopy in Korea: **National Endoscopy Quality Improvement Program**

Yu Kyung Cho

Department of Internal Medicine, College of Medicine, The Catholic University of Korea, Seoul, Korea

In Korea, gastric cancer screening, either esophagogastroduodenoscopy or upper gastrointestinal series (UGIS), is performed biennially for adults aged 40 years or older. Screening endoscopy has been shown to be associated with localized cancer detection and better than UGIS. However, the diagnostic sensitivity of detecting cancer is not satisfactory. The National Endoscopy Quality Improvement (QI) program was initiated in 2009 to enhance the quality of medical institutions and improve the effectiveness of the National Cancer Screening Program (NCSP). The Korean Society of Gastrointestinal Endoscopy developed quality standards through a broad systematic review of other endoscopic quality guidelines and discussions with experts. The standards comprise five domains: qualifications of endoscopists, endoscopic unit facilities and equipment, endoscopic procedure, endoscopy outcomes, and endoscopic reprocessing. After 5 years of the QI program, feedback surveys showed that the perception of QI and endoscopic practice improved substantially in all domains of quality, but the quality standards need to be revised. How to avoid missing cancer in endoscopic procedures in daily practice was reviewed, which can be applied to the mass screening endoscopy. To improve the quality and effectiveness of NCSP, key performance indicators, acceptable quality standards, regular audit, and appropriate reimbursement are necessary. Clin Endosc 2016;49:312-317

Key Words: Endoscopy; Mass screening; Stomach neoplasms; Quality

INTRODUCTION

Gastric cancers are the leading cause of cancer-related deaths in Korea. In Korea, a population-based screening for gastric cancer was implemented in 2002 as part of the National Cancer Screening Program (NCSP), based on the national guidelines established in 2001.² Either esophagogastroduodenoscopy (EGD) or upper gastrointestinal series (UGIS) is performed biennially for adults aged 40 years or older for gastric cancer screening. To improve the endoscopic quality of NCSP, the Korean Society of Gastrointestinal Endoscopy

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Correspondence: Yu Kyung Cho

Department of Internal Medicine, Seoul St. Mary's Hospital, College of Medicine, The Catholic University of Korea, 222 Banpo-daero, Seocho-gu, Seoul 06591,

Tel: +82-2-2258-6024, Fax: +82-2-2258-2055, E-mail: ykcho@catholic.ac.kr

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(KSGE) developed the National Endoscopy Quality Improvement (QI) Program. This program incorporates qualifications of endoscopists, QI for instruments available at the endoscopy unit and for endoscopic procedures (including sedation and reprocessing of endoscopes), and measurement of endoscopy screening outcomes.³ The main purpose of the national QI program is to enhance gastric cancer detection in the earlier stage and lower cancer-related mortality. To accomplish this, high-quality performance of endoscopic services is required. We reviewed the current status and performance of screening endoscopy, and discussed how to improve the quality of screening endoscopy and endoscopic services to increase gastric cancer detection rate.

THE CURRENT STATUS OF NATIONAL CANCER SCREENING PROGRAM IN **KOREA**

In Korea, the number of screening endoscopy performed

Table 1. Sensitivity to Detect Gastric Cancer by Endoscopy in the National Cancer Screening Program of Korea and Japan

| Country | Time period | Population | <3 Years miss rate, n (%) | Positive predictive value, % (95% CI) | Sensitivity, % (95% CI) | Specificity, % (95% CI) | Study design |
|----------------------|-------------|------------|------------------------------|---------------------------------------|--------------------------------|----------------------------|-----------------|
| Korea ⁶ | 2002-2005 | 765,813 | 1,093/3,498 (40) | 6.2 (6.0-6.4) | 69.0 (66.3–71.8) | 96.0 (95.8–96.2) | Screening |
| Japan ^{7,8} | 1990–1995 | 51,411 | 188/730 (25.8) | | 88.6 (69.8–97.6) ^{a)} | | Retrospective |

CI, confidence interval.

per year is continuously increasing. The total number of people invited to participate in the NCSP was 12,985,842, and the participation rate was 45.4% in 2011; 72.6% of the participants chose endoscopy for the screening.⁴ Endoscopic services are easily accessible in Korea, and after the introduction of the national gastric cancer screening program, a larger number of physicians have begun performing EGDs. Endoscopic specialists and members of the KSGE are increasing,⁴ but their number is relatively small to meet the nationwide volume of screening endoscopy. A large number of screening endoscopy procedures are still performed in primacy clinics.

From the national cancer screening data of 2002 to 2005, the positivity rate for endoscopy screening was 42.1 per 1,000 screenings. Gastric cancer detection rate was 2.61 per 1,000 screenings. A total of 1,083 interval cancers occurred within 1 year of a negative endoscopy screening result (rate 1.17/1,000).5 The sensitivity of endoscopy screening and UGIS to detect gastric cancer was 69.7% (95% confidence interval [CI], 66.4 to 72.4) and 36.7%, with specificity of 96.0% and 96.1%, respectively.6 In Japan, stomach cancer has been screened by nationwide screening programs using UGIS and endoscopy similar to those in Korea.⁷⁻⁹ As a population-based screening approach in Japan, endoscopic screening has been performed in 18.3% of the municipalities.8 If the diagnostic sensitivity of screening endoscopy is compared between Korea and Japan, the gastric cancer detection rate in Korea appears lower; however, the varying definitions of interval cancer, different study populations, and methods used in the analysis should also be considered in the comparison (Table 1).

Data about the influence of endoscopy screening programs on gastric cancer mortality are limited in Korea. However, in relation to the effect on detecting gastric cancer in its earlier stage, the odds ratios for localized gastric cancer diagnosis in endoscopy- and UGIS-screened patients, compared with that in never-screened patients, were 2.10 (95% CI, 1.90 to 2.33) and 1.24 (95% CI, 1.13 to 1.36), respectively. This shows that endoscopy is better in detecting the early stage of cancer than UGIS in Korea. 10 Recently, the 15-year follow-up population-based cohort study performed in Japan showed that endoscopic screening reduces gastric cancer mortality by 67% compared with radiographic screening. 11 This study shows the

difference in the cumulative hazard of gastric cancer mortality widened after 3 years from the first screening. Another Japanese study reported that endoscopic surgical dissection has been performed for almost half of the early cancers detected by endoscopic screening. ¹² The results also suggest that endoscopy is better in detecting cancer in the earlier stage and in reducing gastric cancer-related mortality compared to UGIS.

THE CURRENT STATUS OF THE NATIONAL ENDOSCOPY QUALITY IMPROVEMENT PROGRAM

The National Endoscopy QI program was initiated in 2009 for the quality control of endoscopic screening protocols and aimed to enhance the quality of medical institutions and improve the effectiveness of the NCSP. The National Cancer Center and the National Health Insurance Service (NHIS) organized the endoscopy QI program in cooperation with the KSGE.³ Endoscopic quality standards were initially designed through a broad systematic review of other endoscopic quality guidelines and discussions with experts. The standards comprise five domains: qualifications of endoscopists, endoscopic unit facilities and equipment, endoscopic procedure, endoscopy outcomes, and endoscopic reprocessing (Table 2).3 Quality standards have improved in the past 5 years, supported by the KSGE and the NHIS. All institutions at which endoscopic screening is performed should undergo an annual QI audit implemented by the NHIS.

Recently, many quality indicators for gastrointestinal (GI) endoscopy were published. Quality measurement is subdivided into structure, procedure, and outcome. Structural measures reflect aspects of healthcare infrastructure. Process measures show whether certain actions are being actually done during endoscopic procedures. Outcome measures analyze the actual results of care, such as adverse events or clinical outcomes. Outcomes are generally the most important measures. For example, in colonoscopy, the outcomes are adenoma detection rate and perforation rate. In screening endoscopy, the detection of premalignant lesion or cancer would be the direct outcome, but it is very insensitive and hardly measurable.

^{a)}It was calculated be incidence method in prevalence screening.



Table 2. Quality Criteria of EGD in the National Quality Improvement Program of Screening Endoscopy³

Criteria for 'qualification of endoscopist'

- 1. Qualification of endoscopists performing EGD
 - 1) Is the endoscopist a specialist who is able to perform EGD?
 - 2) Did the endoscopist receive endoscopy training for more than 1 year after becoming a medical specialist?
- 2. Continuous medical education for EGD (one point per 1 hour education)

Criteria for 'process'

- 1. Are fasting state, general health status, and past medical and medication history of the patients checked before the EGD?
- 2. Has the patient received explanations for the necessity, notabilia, and any complications of EGD?

Or have they been asked to sign informed consent?

- 3. Is the patient's status monitored and recorded during the EGD?
- 4. Is endoscopic biopsy performed in order to verify any suspicious lesions?
- 5. Are retroflexed or close observations of the EGD made in order to have more precise observation for the suspicious lesion?
- 6. Is the EGD inserted thoroughly into the duodenum and photo documentation of the second part of the duodenum obtained at all times?
- 7. Are the instruments for emergency resuscitation or therapeutic endoscopy available in case of any complications?
- 8. Does the EGD report include information about the location, shape, and size of sighted polyps/cancerous lesions?
- 9. Are the results of the EGD preserved as digital files or photo documents?
- 10. Is informed consent for conscious sedative endoscopy obtained?
- 11. Are SaO2 and heart rate monitored during conscious sedative endoscopy?
- 12. Is the patient managed based on discharge criteria when leaving the endoscopy unit after conscious sedative endoscopy?

Criteria for 'facility and equipment'

- 13. Are the cardia and fundus observed clearly with the retroflexed vision of the EGD from the gastric angle?
- 14. Are there endoscopy examination rooms for EGDs separate from those at the outpatient clinic?
- 15. Do you maintain a specimen reception registry for EGD?
- 16. Do you maintain a medication administration registry for EGD?

Criteria for 'outcome'

- 17. Is the date of examination precisely recorded in the EGD report?
- 18. Is the registration number precisely recorded in the EGD report?
- 19. Is the name of the endoscopist precisely recorded in the EGD report?
- 20. Is the presence of medication usage (e.g., anesthetics, analgesics, and sedatives) precisely recorded in the EGD report?
- 21. Is the presence of biopsy tests precisely recorded in the EGD report?
- 22. Are the EGD findings precisely recorded in the EGD report?
- 23. Is the endoscopic diagnosis precisely recorded in the EGD report?
- 24. Is the Helicobacter pylori infection test performed in cases of gastric or duodenal ulcer?
- 25. Do endoscopists attend endoscopy quality education or does your hospital have such a program?

Criteria for 'reprocessing'

Is the reprocessing process followed by the 'endoscopy cleansing and disinfection guidelines of Korean Society of Gastrointestinal Endoscopy'?

- 26. Is the precleaning and cleaning process completely performed?
- 27. Is the endoscopy channel brushed repeatedly during the reprocessing process?
- 28. Are all detachable parts including valves and rubber cap separated from the endoscope and exchanged for every examination?
- 29. Are the disinfectant solutions changed optimally according to recommended cycles of the disinfectant solution manufacturer?
- 30. Is the soaking time obeyed according to the guidelines of the disinfectant solution manufacturer?
- 31. Are the reusable components and accessories disinfected?
- 32. Do the clinicians, nurses, and cleansing staff attend the endoscopy cleansing and disinfection education of the 'Korean Society of

Gastrointestinal endoscopy'?

- 33. Is the reprocessing room and equipment available?
- 34. Optimal keeping of the endoscope after the reprocessing process
 - 1) Is the endoscope hung vertically after the reprocessing process?
 - 2) Is the endoscope reprocessed just before the first examination of the next day?

EGD, esophagogastroduodenoscopy.

Table 3. Improvement in the Current Endoscopic Quality Standards

Performance target is focusing to meet minimum standard requirement, rather than high quality endoscopic service

The priority outcomes measurement is not defined

e.g., Whether prophylactic antibiotics are administered for appropriate indication^{a)}

Evidence based studies are required to support the use of indicators

The indicators measuring patient's satisfaction are necessary

The after-procedure outcome measurement is necessary

e.g., Documentation of adverse events^{a)}

Communication with referring physicians^{a)}

Documentation of follow-up

Table 4. Limiting Factors and Suggestions to Minimize Missing Cancer in Screening Endoscopy in Daily Practice

| Limiting factor | Suggestion | | | | |
|---|---|--|--|--|--|
| Technical limitations in endoscopy technique and lesion recognition | | | | | |
| To reduce endoscopists' errors | Specially trained endoscopists. Continuous medical education Adequate supervision of trainees | | | | |
| To reduce sampling errors | Multiple biopsies Proper sampling | | | | |
| More meticulous endoscopy | Increase patient tolerance (e.g., adequate sedation) | | | | |
| To increase lesion recognition | Mucolytics to improve mucosal visibility Longer procedure time Extensive photographic documentation | | | | |
| After-procedure errors | Appropriate follow-up schedule Notification to patients | | | | |
| Pathologists' errors | | | | | |

Data on the majority of EGD indicators in practice are limited. The American Society for Gastrointestinal Endoscopy (ASGE) developed quality indicators for EGD.¹³ Thirteen of the 22 quality indicators had the evidence to be recommended strongly and a clear benefit if they are used. In terms of the National Endoscopy QI program, most of the quality measurement is focusing on the endoscopic procedure and structure. Measurement of outcomes, such as adverse event and patient-satisfaction, is lacking (Table 3). The most important difference is that the performance target is focusing on minimum quality standard, rather than directing a high-quality endoscopic service. Many physicians, including surgeons and family doctors, besides specially trained endoscopists are participating in the screening endoscopy, and some endoscopic units are small-scale. Improving the standards of all the low performers, including endoscopists or endoscopic units, to above the minimum quality standard threshold is important in the nationwide endoscopy QI.

THE EFFECTS OF THE NATIONAL ENDOSCOPIC QUALITY IMPROVEMENT PROGRAM: THE FEEDBACK SURVEYS

Recently, KSGE conducted two feedback surveys in medical institutions that participated in the screening endoscopy and national endoscopic QI audit. The two surveys were conducted in 2014 to 2015, 5 years after the national endoscopic QI program launching. The surveys aimed to evaluate the subjective opinion of medical institutions on the effect, burden, and cost of QI. Sixty-seven medical institutions in which many endoscopists perform a number of screening endoscopy responded to whether the QI program raised awareness for endoscopic quality (93%) or improved endoscopic practice (40%). The percentages of respondents who reported improvements in gastric cancer diagnosis, the qualifications of endoscopists, the quality of facilities and equipment, endoscopic procedure, and endoscopic reprocessing were 69%, 60%, 66%, 82%, and 75%, respectively. Reasonable quality standards (45%) and incentives/reimbursement (38%) were considered important to

^{a)}Examples of American Society of Gastrointestinal Endoscopy quality measurement.



the success of the QI program.¹⁷

In the survey, several respondents felt that QI was associated with some degree of burden (48%), especially financial burden caused by purchasing new equipment, such as endoscopes or endoscopic monitoring system. Some primary clinics and private organizations performing screening endoscopy still use too poor or too old endoscopic equipment. Replacing those poor endoscopic systems is important for proper endoscopic inspection.

The second survey, where over 500 doctors responded, showed that physician awareness, familiarity, and agreement were potential barriers to national endoscopic QI program adherence. A good agreement to the national endoscopic QI program was reported, but only 37.3% of the respondents were familiar with the QI criteria. Therefore, efforts to improve familiarity with the national endoscopic QI program may be necessary.¹⁸

HOW TO MINIMIZE MISSED CANCER IN SCREENING ENDOSCOPY IN DAILY ENDOSCOPIC PRACTICE

The main purpose of the national QI program is to enhance the detection of and diagnostic accuracy for gastric cancer and lower cancer-related mortality. Cancer detection rate is the most important, but most outcome parameters in screening endoscopy of upper GI cancer are insensitive. In the meta-analysis of missed upper GI cancer, missing gastric cancer with EGD is not uncommon, with one out of 10 cancers being potentially missed.¹⁹ Of these missed lesions, almost three-quarters were attributed to endoscopists' error. 20,21 Several studies showed that specialized training in endoscopy is important to increase cancer detection rate.²² There is clear evidence that structured training programs can result in significant improvement in endoscopy quality.²² However, despite the overall improvement, an unacceptable variation in endoscopic quality was still noted.²³ Technical limitations in endoscopy technique and lesion recognition, inappropriate follow-up, and errors in pathologic diagnosis are common causes of missed gastric cancer (Table 4). 24-28 Specialized training in or supervised endoscopy, use of mucolytics, appropriate use of sedation, longer inspection, extensive photo documentation, and multiple biopsies to reduce sampling error can be considered to reduce the miss rate.²³

CONCLUSIONS

The main purpose of the national QI program is to enhance

gastric cancer detection and to lower cancer-related mortality. The national endoscopic screening is successful in participation and down staging of cancer, but it may be suboptimal in the quality and effectiveness aspect. The quality of screening endoscopy performed nationwide is important because of the high volume, high cost, and performance variability affecting outcomes. To improve the quality, performance measurement is essential, and the development of robust, consensus- and evidence-based key performance measures is the first step. In addition, the effort to avoid missing cancer in every endoscopic procedure is needed in daily practice.

| Conflicts of Interest $_$ | | |
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