RESEARCH ARTICLE

Improving Accuracy and Completeness in the Collaborative Staging System for Stomach Cancer in South Korea

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Abstract

    <u>Background</u>: Cancer staging enables planning for the best treatments, evaluation of prognosis, and predictions for survival. The Collaborative Stage (CS) system makes it possible to significantly reduce the proportion of patients labeled at an "unknown" stage as well as discrepancies among different staging systems. This study aims to analyze the factors that influence the accuracy and validity of CS data. <u>Materials and Methods</u>: Data were randomly selected (233 cases) from stomach cancer cases enrolled for CS survey at the Korea Central Cancer Registry. Two questionnaires were used to assess CS values for each case and to review the cancer registration environment for each hospital. Data were analyzed in terms of the relationships between the time spent for acquisition and registration of CS information, environments relating to cancer registration in the hospitals, and document sources of CS information for each item. <u>Results</u>: The time for extracting and registering data was found to be shorter when the hospitals had prior experience gained from participating in a CS pilot study and when they were equipped with full-time cancer registrars. Evaluation of the CS information according to medical record sources found that the percentage of items missing for Site Specific Factor (SSF) was 30% higher than for other CS variables. Errors in CS coding were found in variables such as "CS Extension," "CS Lymph Nodes," "CS Metastasis at Diagnosis," and "SSF25 Involvement of Cardia and Distance from Esophagogastric Junction (EGJ)." <u>Conclusions</u>: To build CS system data that are reliable for cancer registration and clinical research, the following components are required: 1) training programs for medical records administrators; 2) supporting materials to promote active participation; and 3) format development to improve registration validity.

Keywords: Collaborative stage - completeness - accuracy - stomach - cancer - registration

Introduction

    Cancer is the number one cause of death in South Korea, accounting for 27.6% of the total national death toll in 2012 (Statistics Korea, 2013). As cancer deaths have been steadily increasing, public and individual burdens for cancer treatment are also expected to increase accordingly. The cancer registration project is both fundamental and critical to a national cancer control program that will plan and monitor the priority of cancer management policy (Moore, 2013). Cancer registration statistics lead to predictions regarding medical staff, hospitals, and costs for cancer treatment. Causes of cancer can also be identified by checking the incidence trends and group incidences in the statistics. Furthermore, accurate statistics make it possible to check the effects of prevention, diagnosis, and treatment programs, which can also be used to create materials for cancer information training and promotion. The focus of the cancer registration project is the cancer registration data collected from medical institutions. Factors contributing to a successful cancer registry in South Korea include timeliness of registration reports, completeness and validity of data, and accuracy of reporting data. The cancer registration project, which began in the 1980s (Shin et al., 2005), has made various efforts such as training cancer registrars to ensure quality registration data, distribution of quality management programs, and development of registration guides and training materials.

    Stage information plays an essential role in making treatment decisions for patients by helping to predict a patient's prognosis and to compare treatment results so that increasing survival rates for particular cancers can be identified (AJCC, 2010).

    The Korea Central Cancer Registry has conducted stage classification using the Surveillance Epidemiology and End Results (SEER) Summary Stage (SS) since 2003. The SS was developed to categorize the extent of disease (EOD), which represents how widely the cancer has spread from the primary site (Shambaugh et al, 1977; Young et al, 2012). Although this classification system is applicable to every cancer type and is easy to use, the SS is not readily utilized in clinical research due to the difficulty of associating it with other stage systems, as

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well as a lack of information provided for clinicians. The data items collected for cancer registration in South Korea consist of personal characteristics and cancer information, including primary site, morphology, dates of diagnosis, methods of final diagnosis, initial treatment, etc. However, the data are limited regarding information on incidence rates for cancer patients.

To overcome these limitations, efforts have been made to produce various cancer statistics by expanding additional factors, and the application of the Collaborative Stage (CS) system is also currently being considered. The CS system was developed to merge the principles of three different cancer staging coding systems: the American Joint Committee on Cancer (AJCC) primary tumor, regional lymph nodes, and distant metastasis (TNM) staging; Summary Stage 1977 (SS77); and Summary Stage 2000 (SS2000) (Collaborative Staging Task Force, 2006; Collaborative Staging Task Force, 2012). The CS system is being used to assign stages for cancer cases diagnosed after 2003 in the US, and it has a decisive benefit of properly adjusting and assigning the stage at diagnosis, even when the stage classification system has changed over time. In South Korea, adopting the CS system for the collection of stage information for major cancers (stomach, colorectal, and breast) is being considered.

CS registration was planned for 47 training hospitals as a part of the "cancer registry statistics project" in 2012. However, CS collection items and customized training for the medical records administrators who would conduct the collection were not yet ready, and resources for efficient work performance have not yet been made available. Accordingly, it is necessary to show evidence for the accuracy and validity of CS data in order to achieve the goal of improving the quality of cancer registration data by expanding the items included in cancer registration. To do this, the factors which influence the accuracy and validity of CS data must be determined.

The purpose of this study is to examine the basic information needed to make specific plans for designing CS classification training and to improve the quality of CS registry data by analyzing the major factors influencing its accuracy and validity.

Materials and Methods

The study identified CS items and their medical record sources in registered cases of stomach cancer, which has one of the highest incidence and mortality rates in Korea (Leung et al., 2008; Seo et al., 2012; Cho et al., 2013; Jung et al., 2014).

Case Selection and Data Collection

The list of participating hospitals for the CS 2012 survey was provided by the Korea Central Cancer Registry (KCCR). From the available cases, the participating hospitals randomly selected 10% of their subject cases by themselves. Two questionnaires were developed: one assessing hospital characteristics and the other assessing the source of the information in the medical records for stomach cancer. Questionnaires were developed in consultation with registered cancer registrars through

preliminary tests. In the preliminary tests, cancer registrars in ten hospitals were asked to collect 2 or 3 stomach cancer cases using the questionnaire that had been developed, and the questionnaire items were then verified. The main survey was conducted in 39 hospitals, and participants were instructed to answer the verified questionnaires.

Questionnaire for institutions

To identify factors influencing the registration of CS data and to understand the hospitals' circumstances, the following six variables were assessed: location of hospital, regional cancer registry operation, participation in the CS pilot study from the KCCR project in 2011, all cancer cases diagnosed in 2009, number of stomach cancer cases diagnosed in 2009, and existence of full-time medical record administrators for cancer registration.

Questionnaire for registering CS

Codes were assigned to CS questionnaire items according to stomach cancer schema (Table 1). Each item's values and original record sources were collected from the medical record documents. In order to measure the time required for abstracting and registering CS information, the length of time was reported for each case.

Statistical analysis

A chi-square test was conducted to check whether the average time spent in abstracting and registering CS in each institution was related to the six variables measured in the institution questionnaire. Frequency analysis was used for diagnostic path, subsite, morphology type, and differentiation for 233 stomach cancer cases. We created a cross tabulation table for the distribution of information collected for CS by medical record sources in the hospitals. Finally, to identify the factors potentially influencing the accuracy, validity, and efficiency of CS registration, factors contributing to errors were analyzed by checking the missing and erroneous items in each case. All p values are two-tailed, with $p < 0.05$ considered to be statistically significant. All statistical analyses were conducted using SPSS Statistics 21 (SPSS, Chicago, IL, USA).

Results

A total of 233 cases were collected for the study from 39 enrolled hospitals. Of those, 202 cases (86.7%) were from 31 tertiary hospitals (79.5%), and 31 cases (13.3%) were from 8 general hospitals (20.0%) (Figure 1).

Among the 39 hospitals, a mean of 23.6 minutes (SD=12.9 minutes) was found for the time it took to register CS data for one case of stomach cancer. The relationship between the hospital locations and the average time for CS data extraction and registration was not statistically significant (p=0.63). In addition, no statistically significant difference in the average time for abstracting and registering CS data was found for the following variables: regional cancer registry operation, number of cancer cases (all types/sites of cancer) diagnosed in 2009, and number of stomach cancer cases diagnosed in 2009 (p=0.27). In contrast, participation in the pilot study and the existence of full-

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time cancer registrars had borderline significant effects on the average time spent in CS information extraction and registration, with p values of 0.06 and 0.08, respectively. The percentage of hospitals exceeding 20 minutes for abstracting and registering CS was lower by 70% in those that had participated in the CS pilot study compared to those that did not participate. The percentage of hospitals exceeding 20 minutes was also lower by approximately 30% in those with full-time cancer registrars compared to those without such registrars (Table 2).

Characteristics of the cancers in the 233 study cases are as follows. The most frequent precipitant of the stomach cancer diagnosis was the patient's own perception of symptoms (42.1%), and the next was screening (40.3%). The most common stomach cancer subsites were antrum (42.9%) and body (33.9%). Tubular adenocarcinoma was the most common morphological type of stomach cancer (43.8%), followed by adenocarcinoma, not otherwise specified (27.0%). Regarding differentiation, poorly differentiated type accounted for the highest proportion by 34.8% (Table 3).

Table 4 shows the sources of the medical records used for extracting CS system information, presented according to CS item. Three noteworthy points were identified from

Table 1. List of CS schema for stomach cancer*

CS Tumor Size
CS Extension
CS Tumor Size/Extension Evaluation
CS Lymph Nodes
CS Lymph Nodes Evaluation
Regional Nodes Positive
Regional Nodes Examined
CS Metastasis at Diagnosis
CS Mets Evaluation
CS Site-Specific Factor 1: Clinical Assessment of Regional Lymph Nodes
CS Site-Specific Factor 2: Specific Location of Tumor
CS Site-Specific Factor 13: Carcinoembryonic Antigen (CEA)
CS Site-Specific Factor 14: Carcinoembryonic Antigen (CEA) Lab Value
CS Site-Specific Factor 15: Carbohydrate Antigen 19-9 (CA 19-9) Lab Value
CS Site-Specific Factor 25: Schema Discriminator: Involvement of Cardia and Distance from Esophagogastric Junction (EG Junction)
*Excluding Gastrointestinal Stromal Tumor and Neuroendocrine Tumor
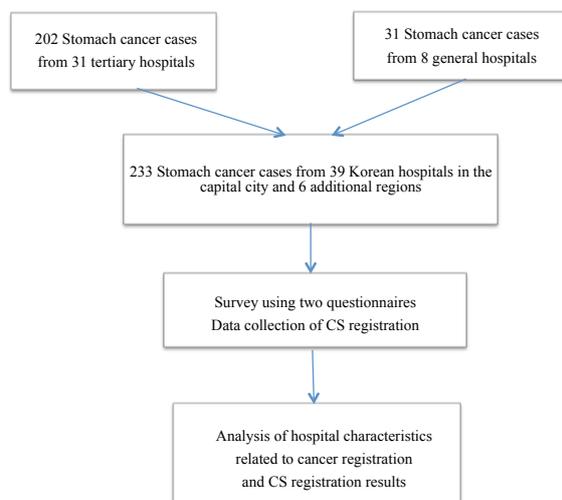
Figure 1. Flow Chart of Data Collection of CS Registration for Stomach Cancer Cases

the analysis. First, major items, excluding Site-Specific Factors (SSF), were usually obtained from pathology reports and discharge summaries, while information on distant metastasis at the time of diagnosis was abstracted from radiology reports. Second, the information for SSF 13, SSF 14, and SSF 15, which are tumor markers, was found to be mostly abstracted from laboratory reports. Finally, the "missing" rate was relatively high, at 30% of SSF items.

Errors were examined by analyzing CS registration results for each hospital (Table 5). The most frequent errors were found in "CS Extension," "CS Lymph Nodes," and "CS Metastasis at Diagnosis (Mets at DX)." The errors

Table 2. Average Time Required for Extracting and Registering CS Data for Stomach Cancer

	≤20 minutes N (%)	20 minutes N (%)	Hospitals (N=39)	P value (x^2 test)
Region				
Capital areas	9 (47.4)	11 (55.0)	20 (51.3)	0.63
Others	10 (52.6)	9 (45.0)	19 (48.7)	
Regional cancer registry operation				
No	13 (68.4)	17 (85.0)	30 (76.9)	0.27
Yes	6 (31.6)	3 (15.0)	9 (23.1)	
Participation in 2011 CS pilot study				
No	11 (57.9)	17 (85.0)	28 (71.8)	0.06
Yes	8 (42.1)	3 (15.0)	11 (28.2)	
All cancer cases diagnosed in 2009				
<3,000	10 (52.1)	14 (70.0)	24 (61.5)	0.27
≥3,000	9 (47.4)	6 (30.0)	15 (38.5)	
Stomach cancer cases diagnosed in 2009				
<400	9 (47.4)	13 (65.0)	22 (56.4)	0.27
≥400	10 (52.6)	7 (35.0)	17 (43.6)	
Full time cancer registrar				
No	7 (36.8)	13 (65.0)	20 (51.3)	0.08
Yes	12 (63.2)	7 (35.0)	19 (48.7)	

Table 3. Detailed Items Distribution of Registered Stomach Cancers (233 Cases)

Detailed items	N	%
Diagnostic path		
Screening	94	40.3
Incidental finding	15	6.4
Symptom detected	98	42.1
Unknown	11	4.7
Others	15	6.4
Subsites		
Gastric cardia, Esophagogastric junction (C16.0)	13	5.1
Fundus (C16.1)	1	0.4
Body, corpus (C16.2)	79	33.9
Antrum, pyloric antrum (C16.3)	100	42.9
Prepylorus, pylorus (C16.4)	6	2.6
Lesser curvature, NOSa (C16.5)	9	3.9
Greater curvature, NOSa (C16.6)	1	0.4
Overlapping of lesion of stomach (C16.8)	10	4.3
Stomach, NOSa (C16.9)	14	6
Morphology		
Tubular adenocarcinoma (M8211/3)	102	43.8
Adenocarcinoma, NOSa (M8140/3)	63	27
Adenocarcinoma, intestinal type (M8144/3)	11	4.7
Signet ring cell carcinoma (M8490/3)	35	15
Others (M8000/3~M8560/3)*	22	9.4
Differentiation		
Well differentiated, NOSa	47	20.2
Moderately differentiated, Moderately well differentiated, Intermediate differentiation	64	27.5
Poorly differentiated	81	34.8
Undifferentiated, Anaplastic	0	0
Grade of differentiation not determined	41	17.6

aNOS=Not Otherwise Specified *Except for M codes above

Table 4. Distribution of Information for CS Registration By Medical Record Sources

Items	Discharge summary N (%)	Progress note N (%)	Operation record N (%)	Pathology report N (%)	Radiology report N (%)	Laboratory report N (%)	Referral N (%)	Others N (%)	Missing N (%)
Tumor Size	1 (0.4)	0 (0.0)	3 (1.3)	144 (61.8)	14 (6.0)	0 (0.0)	0 (0.0)	5 (2.1)	66 (28.3)
Extension	6 (2.6)	0 (0.0)	1 (0.4)	149 (63.9)	23 (9.9)	0 (0.0)	0 (0.0)	4 (1.7)	50 (21.5)
Lymph Nodes	6 (2.6)	1 (0.4)	0 (0.0)	138 (59.2)	60 (25.8)	0 (0.0)	0 (0.0)	1 (0.4)	27 (11.6)
Regional Nodes Positive	5 (2.1)	0 (0.0)	0 (0.0)	132 (56.7)	11 (4.7)	0 (0.0)	0 (0.0)	1 (0.4)	84 (36.1)
Regional Nodes Examined	5 (2.1)	0 (0.0)	0 (0.0)	129 (55.4)	11 (4.7)	0 (0.0)	0 (0.0)	1 (0.4)	87 (37.3)
Metastasis at diagnosis	20 (8.6)	0 (0.0)	17 (7.3)	13 (5.6)	148 (63.5)	0 (0.0)	2 (0.9)	3 (1.3)	30 (12.9)
SSF1 Clinical Assessment of Regional Lymph Nodes	4 (1.7)	0 (0.0)	1 (0.4)	13 (5.6)	182 (78.1)	0 (0.0)	0 (0.0)	2 (0.9)	31 (13.3)
SSF2 Specific Location of Tumor	5 (2.1)	0 (0.0)	5 (2.1)	174 (74.7)	10 (4.3)	0 (0.0)	1 (0.4)	7 (3)	31 (13.3)
SSF13 Carcinoembryonic Antigen (CEA)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	7 (3)	141 (60.5)	0 (0.0)	9 (3.9)	75 (32.2)
SSF14 Carcinoembryonic Antigen (CEA) Lab Value	1 (0.4)	0 (0.0)	0 (0.0)	8 (3.4)	7 (3)	140 (60.1)	0 (0.0)	1 (0.4)	76 (32.6)
SSF15 CA 19-9 Lab Value	1 (0.4)	0 (0.0)	0 (0.0)	8 (3.4)	6 (2.6)	121 (51.9)	0 (0.0)	6 (2.6)	91 (39.1)
SSF25 Involvement of Cardia and Distance from Esophagogastric Junction (EGJ)	3 (1.3)	0 (0.0)	3 (1.3)	45 (19.3)	11 (4.7)	0 (0.0)	2 (0.9)	14 (6)	155 (66.5)

Table 5. List of Errors and Corrections in CS Registration for Stomach Cancer

Schema description Item / Detailed information	Code (Error)	Error Description	Code (Correction)	Correction Description
Tumor size				
3 x 2.5 x 1.6 cm	51	Exact size to nearest millimeter is 51mm	30	Exact size to nearest millimeter is 30mm (3cm)
Extension				
With invasion to muscle propria	400	Invasion through muscularis propria, NOSa	200	Invades into but not through muscularis propria
Invasion to submucosa	50	(Adeno)carcinoma, noninvasive, in a polyp	160	Invades submucosa (superficial invasion)
Invasion into subserosa	505	Invasion of/through serosa	400	Subserosal tissue/(sub)serosal fat invaded
Adenocarcinoma	50	(Adeno)carcinoma, noninvasive, in a polyp	999	Unknown; extension not stated
T3/4N0MX	810	Stated as T4 [NOS] with no other information on extension	480	Stated as T3 with no other information on extension
Lymph Nodes				
Metastasis to 5 out of 38 regional lymph nodes	100, 110	Coded only when stated as specific regional lymph node(s)	500	Regional lymph node(s), NOS
Multiple regional lymph node enlargement. AGC T3N2M1	500	Regional lymph node(s), NOS	660	Stated as pathologic N2 with no other information on regional lymph nodes
CT: staging N3, Enlarged multiple conglomerated perigastric lymph nodes	100	Coded only when stated as specific regional lymph node(s)	710	Stated as pathologic N3 with no other information on regional lymph nodes
Metastasis at diagnosis				
Bone metastasis, peritoneal seeding		Double-coded both CS Extension (Code 800; Further contiguous extension) and CS Mets at DX (Code 50)		Coded to CS Mets at DX only
Malignancy metastatic adenocarcinoma	50	Distant metastasis plus distant lymph node(s)	40	Distant metastasis except distant lymph node(s)
Body fluid, cytology, and cell block: Malignancy metastatic adenocarcinoma Bone metastases, Metastatic lymphadenopathies	50	Distant metastasis plus distant lymph node(s)	40	1. Distant metastasis except distant lymph node(s); 2. Malignant (positive) peritoneal cytology
SSF1				
CT: extensive severe adenopathy, perigastric	100	Metastases in 1-2 regional lymph nodes, determined clinically	999	Regional lymph nodes involved pathologically, clinical assessment not stated`
SSF14, SSF15				
Not documented in patient	998	Test not done	999	Unknown or no information
SSF25				
Primary site code: C16.0	000, 010	Applied to Stomach Schema	982	Should be applied to Esophagus GE Junction (EGJ) Schema

*NOS: Not Otherwise Specified

from these three items were similar in that they were derived from misinterpretation of the clinical descriptions in the medical record. Two types of errors were found in the SSF data. One was a case of inappropriately applying the given schema: the stomach schema was applied when the subsite of a tumor location was the esophagogastric junction (EGJ), meaning that the EGJ schema should have been used. The other SSF error involved confusion among three SSF codes: 988 "not applicable," 998 "test not done," 999 "unknown or no information." Specific examples of the errors and corrections are provided in Table 5.

Discussion

Collecting cancer registration data with the CS staging system allows for the conversion of existing SEER Summary Staging data into AJCC TNM Staging format, as well as the collection of more detailed data in addition to stage codes from clinical data. These data sets based on the CS system better serve researchers, such as preventive

100.0

6.3

75.0

56.3

50.0

31.3

25.0

0

Newly diagnosed without treatment

medical scientists, who use them for study, and clinical doctors, who use them for treatment and prognosis.

Accordingly, efforts to adopt the CS staging system have been made since 2011 in South Korea, together with research on the validity of its application, so that the existing system can be transitioned into the CS staging system. Major factors determining the quality of data in CS stage registration include the validity of the medical records, data collection, and coding ability of cancer registrars working within the CS system. Further factors include the readiness of the supporting system for efficient cancer registration, as well as the registrars' openness to adoption of the CS system and responsibility for registration. Thus, it is necessary to analyze the factors impeding the validity and accuracy of CS registration and to establish plans to enhance the validity by examining the current conditions of medical records containing CS registration items. It is also desirable to find ways to more readily extract information during CS registration and to enhance the efficiency of CS registration in the electronic medical record environment. This can be done by analyzing the sources of medical records used for CS registration items and the methods of entering CS registration items into medical records. All of these strategies can be utilized to develop CS system training and guides, so that CS registration can be successfully established in the near future.

In this study, the error list from the CS registration data revealed that the most frequent code errors were found in "CS Extension," "CS Lymph Nodes," "CS Mets at DX," and "SSF25 Involvement of Cardia and Distance from EGJ." Major errors were primarily coding errors, which were thought to result from registrars' applying coding guides incorrectly; input errors were also found. There were some cases when the proper schema could not be selected from the available choices of schema for stomach and EGJ. Different schema should be used for stomach cancer according to the subsite, and the corresponding SSF items should differ accordingly. However, the available selection of schema was frequently incorrect. In general, there was considerable missing information in the medical records, which are the bases for coding, and, in many cases, the contents were not detailed enough to be used for coding. More detailed and specific guides for selecting items should be created since item selection for medical records is not easy using the information in the current CS registration guide.

We propose corrections based on the results of analyzing in detail the common errors found in 39 hospitals. In SSF1, there were a number of cases when lymph adenopathy or lymph node enlargement was coded as being involved in cancer. Lymph adenopathy or lymph node enlargement should be coded as 999 (Regional lymph nodes involved pathologically, clinical assessment not stated; Unknown if regional lymph nodes clinically evident; Not documented in patient record). In case of coding of lymphovascular invasion was frequently confused with that of regional lymph node invasion; lymphovascular invasion should not be coded under regional lymph node invasion. The code 988 was incorrectly used; code 988 is usually used as "not applicable (information not collected for

this case)" when the item is not relevant to the cancer type. It should not be confused with "no information" or "unknown information" for the given items. A metastatic or extension site was often double-coded as both extension and metastasis. The areas for metastasis should be anatomically understood for each cancer type, and either extension or metastasis should be selected for coding. Reports of non-specific regional lymph node involvement or lymph node in pathology report were often coded as specific lymph node involvement using unsuitable codes for each unspecified item. It should be confirmed whether specific regional node involvement was reported or specific lymph nodes were indicated in the pathological report, and appropriate codes should be assigned. Codes for TNM information were omitted. When no information is found other than T3 or N2, it should be recognized that relevant codes are in the schema, and proper codes should be assigned.

Based on the findings in this study, we propose the following suggestions for successful adoption of the CS registration system. First, training objectives should be determined for the future expansion of CS registration institutions or cancer types. The following are proposed as factors for successful CS registration expansion: one-on-one customized training, genetic tests for SSF registration, pathology-related training, and customized group clinical and integrative training. Second, data collection needs to be complete to ensure the validity of the CS registration data. Insufficient data, due to missing tests for registration items, have a negative influence on the validity of the data. To solve this problem, flexible expansion of items is needed and can be achieved by limiting CS registration items to only the essential or by putting priority on only those items needed for domestic registration. For other cancer types, registration items need to be selected only after checking the current conditions of the medical institutions and their ability to collect data for the given items.

We can draw the following implications from the present study. First, the use of CS registration in hospitals can be expanded by developing supporting materials to promote the active participation of hospitals. Second, education programs for medical record administrators in participating hospitals can be developed. Third, CS registration information can be utilized as the basis for developing an electronic data-processing environment used to extract information. Finally, the study results can be used as base material for the development of a CS registration format, which can help improve the validity of CS item registration.

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