Ⅵ. 研究業績

研究業績 2018 年

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Ⅰ．国際学会

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○西野直人、栗原唯生
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Ⅲ．地方会・支部会

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Ⅳ．埼玉県

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Ⅴ．川口市医師会、さいたま市医師会

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Ⅵ．全日本民医連・地協、医療福祉連

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Ⅰ．外部機関

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Original

Potential asbestos exposure among patients with primary lung cancer in Japan

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Abstract: Objective: To investigate the extent of asbestos exposure among patients with primary lung cancer in Japan. **Methods:** A retrospective estimation of potential asbestos-exposed individuals, as determined by the presence of pleural plaques identified on chest computed tomography (CT), was conducted on 885 pathologically confirmed primary lung cancer patients (mean age 71.3 years, 641 males). All patients were diagnosed at 29 hospitals across Japan between 2006 and 2007. Since these hospitals belong to the Japan Federation of Democratic Medical Institutions (MINIREN), an organization of medical institutions for workers, the study subjects may contain a higher proportion of workers than the general population. **Results:** Pleural plaques were identified in 12.8% of subjects (15.8% in males and 4.9% in females), consisting exclusively of cases older than 50 years. They were found most frequently on the chest wall pleura (96.5%), followed by the diaphragm (23.9%) and mediastinum (9.7%). Calcifications were seen in 47 cases (41.6%). The highest prevalence of pleural plaques was seen among workers from construction-related fields (37.7%). No distinct lung cancer histology was observed in patients with pleural plaques. Coexistence of pleural plaques and small irregular opacities was observed in 2.5% of subjects. **Conclusion:** In a Japanese population representing more workers than general Japanese, 12.8% of patients with primary lung cancer may have experienced asbestos exposure at some time in the past. Special medical attention should be paid to individuals with a history of employment in construction-related occupations, as workers in this sector showed the highest prevalence of pleural plaques.

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Introduction

Japan was one of the largest asbestos-consuming countries. The importation and use of asbestos in Japan increased after the Second World War, and peaked in the 1970s and 1980s. Total importation between 1930-2005 was estimated at roughly 9.9 million tons[1]. It is well established that either occupational or environmental exposure to asbestos is associated with both malignant and non-malignant respiratory disease. The major malignant diseases of concern are lung cancer and pleural mesothelioma. More than 70% of mesothelioma cases in Japan are believed to be associated with past asbestos exposure[2]. It is difficult to estimate the etiological fraction of lung cancers in a population that is attributable to asbestos exposure. While research linking asbestos exposure and malignancies has customarily followed an asbestos-exposed population[3,4], no published study has yet investigated the proportion of lung cancer cases that are attributable to asbestos exposure in Japan. Additionally, to our knowledge no English-language paper has yet discussed radiologically identified asbestos-related pleural abnormalities in a cohort of primary lung cancer patients. Accordingly, we identified potential asbestos-exposed individuals in a population of patients with primary lung cancer from a group of hospitals in the Japan Federation of Democratic Medical Institutions (MIN-IREN). Asbestos exposure was determined by the presence of pleural plaques, which are the most common and relatively early radiographic manifestation of benign asbestos-related pleural disease, and are considered indicators of past exposure to asbestos[5-7].

Subjects and Methods

Subjects

This hospital-based multicenter study was designed to retrospectively investigate potentially asbestos-exposed individuals among patients with primary lung cancer in Japan. In 2008, we invited a group of hospitals belonging to MIN-IREN to participate in the present study. MIN-IREN was established primarily as an organization of medical institutions for workers. Accordingly, in addition to the healthcare delivered by most hospitals, hospitals of this group also operate clinics specializing in occupational medicine and actively provide care for work-related diseases. Consequently, patients seeking consultation in these hospitals may represent a higher percentage of workers than occurs in the general Japanese population. We asked the participating hospitals to provide medical information, including medical records, chest radiographs (CXR), and chest computed tomography scans (CT) of all patients who were newly diagnosed with primary lung cancer. Initially, information was obtained for 947 cases, diagnosed between Jan 1, 2006 and Dec 31, 2007 in 29 hospitals from 19 prefectures across Japan. All cases were consecutive patients whose diagnosis was confirmed histologically or cytologically. After exclusion of 62 cases with uninterpretable chest images due to metastasis or an advanced stage of the disease, we included information from 885 cases (641 males and 244 females, ages 26 - 94 years) in our final analysis. Written informed consent from the patients was waived, because this was a retrospective study and used anonymized data and images. The study protocol was approved by the ethical committee of Chiba Kensei Hospital.

Collection of clinical and occupational history

Clinical history, history of smoking, and occupational information was retrieved by reviewing medical charts. Information on smoking was available for 692 cases (78.2%). Occupational information was recorded in 615 cases (69.5%); each of these cases was assigned a particular occupational category according to the "Classification of occupations for employment service (ESCO)"[8], defined by the then Ministry of Labor of Japan. If a subject had engaged in multiple occupations, work with the highest potential for asbestos exposure was selected[9].

Evaluation of chest radiographs and CT scans

Of all the radiological images, those closest to the date of diagnosis of primary lung cancer were reviewed. The images were assessed for the presence of benign asbestos-related parenchymal and pleural abnormalities by a panel of experts, consisting of occupational physicians, chest physicians and radiologists, including one B-reader (NS), who received certification from the National Institute for Occupational Safety and Health (NIOSH) of the United States. The panel members were from the participating hospitals, all of whom have many years of experience in interpreting abnormalities in the chest of dust-exposed workers. In discordant cases, a final decision was reached by consensus with the B-reader (NS).

In brief, we evaluated dust-induced parenchymal and pleural changes identified in the CXR and CT as described in the ILO 2000 International Classification of Radiographs of Pneumoconioses (ILO/ICRP)[10], and the International Classification of HRCT for Occupational and Environmental Respiratory Diseases (ICOERD)[11], respectively. Parenchymal changes include both small opacities and large opacities with a radiographic appearance consistent with dust and fiber inhalation. Small opacities, i.e. of up to 1 cm in width on CXR, were accordingly interpreted as small rounded opacities or small irregular opacities. On CT, all measureable, well-defined rounded opacities of up to 1 cm in breadth were recorded as small rounded opacities; while intralobular dot-like lesions or subpleural curvilinear opacities were recorded as irregular and/or linear opacities. A large opacity was defined as an opacity with the longest dimension exceeding

1 cm on CXR or chest CT, as described in the ILO/ICRP and ICOERD, respectively. Pleural plaques represent localized pleural thickening, generally of the parietal pleura. On CXR, pleural plaques may be seen on the chest wall (in-profile plaque or face-on plaque), on the diaphragm, and at other sites. A minimum width of about 3 mm is required for an in-profile plaque to be recorded as present. The ILO/ICRP records pleural plaques on a CXR as absent or present, with the right and left sides assessed separately[10]. On the other hand, the ICOERD differentiates pleural abnormalities on CT as "parietal type", which includes the typical tableland shape as well as the flat (less elevated) thickening of the pleura without subpleural fibrosis; and "visceral type" (also described as diffuse pleural thickening), which is always associated with the presence of subpleural fibrosis or parenchymal bands and rounded atelectasis[12].

In the present study, we considered only CT-confirmed pleural plaques as a surrogate for past asbestos exposure. Since the CT shows a cross-section of the thorax and gives a clear view of the anterior and posterior walls of the thorax, CT is more sensitive and specific than CXR in characterizing dust and fiber-induced pleural changes[13,14]. To increase specificity, we classified pleural lesions on CT into one of four categories: "definite," "probable," "possible," and "none". In practice, we applied "definite" to typical tableland shape lesions as well as less elevated lesions with prominent thickness and extent; "probable" to lesions whose thickness or extent was less well-defined; "possible" if there was a non-specific pleural thickening, or a lesion unlikely to be a pleural plaque; and "none" for CTs that were clear of pleural lesions. The presence of a pleural abnormality was defined by the categories "definite" and "probable." Additionally, only "parietal type" lesions were classified as pleural plaques, while diffuse pleural thickening mainly involving the visceral pleura was omitted.

Statistical analysis

Analyses mainly focused on estimating the portion of potential asbestos-exposed individuals among patients with primary lung cancer; thus, we enumerated the frequency of asbestos-related findings as determined by the presence of CT-identified pleural plaques. In the analyses, we simply defined pleural plaques and parenchymal lung abnormalities as present or absent. We divided age into five categories: younger than 50 years, 50 - 59 years, 60 - 69 years, 70 - 79 years, and 80 years and older. We grouped smoking status into "ever-smokers," which combined current and ex-smokers, and "non-smokers." Occupation was categorized based on the classification of occupations for employment service (ESCO). Comparisons between groups were conducted using the Chi-squared test or Fisher's exact test as appropriate. Continuous variables were compared using the Student t-test. Differences were considered statistically significant at $p < 0.05$. Analyses were performed using Stata 13.1 Special Edition (StataCorp LP, College Station, Texas, USA).

Results

Characteristics of patients with primary lung cancer

Table 1 describes the characteristics of the 885 patients with primary lung cancer. Males made up the majority with 72.4%. Mean age at diagnosis was 71.3±9.9 years (mean±standard deviation), with no observed difference in age between sexes ($p = 0.347$). There was a significant sex difference in the distribution of cases across age categories ($p < 0.005$). Frequency of smoking was 74.4%, with a significant difference in distribution between sexes ($p < 0.001$). With the available information, 43.7% of males were engaged in manufacturing or as laborers, while 29.3% of females were housewives.

Parenchymal lung and pleural abnormalities

Radiographic findings of the 885 patients are presented in Table 2. Of 125 cases (14.1%) found to have pleural abnormalities on CT, we excluded 12 cases with changes mainly in the visceral pleura and recognized 113 cases (12.8%) as having pleural plaques. Chest radiographs identified pleural plaques in 48 cases, or 5.4% (44 males, 6.9%; and 4 females, 1.6%); both methods agreed on 38 cases (4.3%). Examples of pleural plaques detected on chest CT and CXR are presented in Fig. 1. The number of cases with small irregular opacities detected by CT and CXR was 107 cases (12.1%) and 71 cases (8.0%), respectively. The number of concordant findings was 56 cases (6.3%). The two methods showed small rounded opacities in 15 cases (1.7%), with concordance in 13 cases (1.5%). Chest CT identified large opacities in 8 cases (0.9%) while CXR indicated these in 6 cases (0.7%); and the two agreed on 5 cases (0.6%).

Characteristics of 113 patients with pleural plaques on their CT are found in Table 3. A higher prevalence of pleural plaques was seen in males, older age groups, and among smokers. Anatomically, involvement of the chest wall pleura was frequent (109 cases, 96.5%) and the left side predominated (81 cases, 71.7%). Calcification of plaques was detected in 47 cases (41.6%), and the coexistence of irregular opacities in 22 cases (19.5%).

Histologically, the most frequent cell type was adenocarcinoma, which was found in 408 cases (46.1%), followed by squamous cell (264 patients, 29.8%), and small cell (106 patients, 12%) (Table 4). The distribution of cell types differed significantly by sex ($p < 0.001$) and smoking habit ($p < 0.001$); however, no distinct histology of primary lung cancer was observed between patients with or without pleural plaques.

As shown in Table 5, among the major occupational categories, the prevalence of pleural plaques was highest

Table 1. Characteristics of the 885 patients with primary lung cancer according to sex

	Number (%)			*p*
	All	Male	Female	
Number of patients	885	641 (72.4)	244 (27.6)	
Age, years, M ± SD	71.3 ± 9.9	71.1 ± 9.4	71.8 ± 11.3	.347
Age groups, years				<.005
≤49	19 (2.2)	10 (1.6)	9 (3.7)	
50 – 59	94 (10.6)	66 (10.3)	28 (11.5)	
60 – 69	225 (25.4)	173 (27.0)	52 (21.3)	
70 – 79	358 (40.5)	272 (42.4)	86 (35.3)	
≥80	189 (21.4)	120 (18.7)	69 (28.3)	
Smoking[a]				<.001
Ever-smoker	515 (74.4)	455 (87.7)	60 (34.7)	
Non-smoker	177 (25.6)	64 (12.3)	113 (65.3)	
Occupation[b]				
Professional & engineering	44 (7.2)	34 (7.4)	10 (6.4)	
Administrative & managerial	10 (1.6)	4 (0.9)	6 (3.8)	
Clerical	55 (8.9)	43 (9.4)	12 (7.6)	
Sales	43 (7.0)	26 (5.7)	17 (10.8)	
Service	27 (4.4)	11 (2.4)	16 (10.2)	
Security	9 (1.5)	9 (2.0)	–	
Agriculture, forestry & fishery	26 (4.2)	21 (4.6)	5 (3.2)	
Transport & communication	36 (5.9)	34 (7.4)	2 (1.3)	
Manufacturing and general labor	215 (35.0)	200 (43.7)	15 (9.6)	
Housewife	46 (7.5)	–	46 (29.3)	
Jobless	54 (8.8)	34 (7.4)	20 (12.7)	
Others	50 (8.1)	42 (9.2)	8 (5.1)	

[a] Information on smoking was available for 692 cases (78.2%).
[b] Information on occupation was available for 615 cases (69.5%).
p = *p*-value of Student t-test or Chi-squared test; M ± SD = mean ± standard deviation.

among security workers (4 cases, 44.4%), manufacturing and general laborers (52 cases, 24.2%), and transport and communication workers (5 cases, 13.9%); whereas the prevalence of irregular opacities was highest among security workers (3 cases, 33.3%), manufacturing and general laborers (45 cases, 20.9%), and among the jobless (10 cases, 18.5%). A further analysis indicated that, among subcategories of manufacturing and general laborers with more than 10 patients with primary lung cancer, the prevalence of pleural plaques was highest among construction-related workers (37.7%), followed by metal processing (26.7%), civil construction laborers (26.7%), foundry workers (23.5%), miners (22.2%), and electricians (21.4%).

Discussion

Many investigators have evaluated the relationship between CT-identified pleural plaques and respiratory impairment or associated long-term health risks among asbestos-exposed populations[15-18]; however, no published study has yet documented CT-identified pleural plaques among primary lung cancer patients. To our knowledge, this is the first report concerning CT-identified asbestos-related pleural findings among a large number of subjects with primary lung cancer. The main finding of this study is that 12.8% of the study population has pleural plaques on chest CT. Since pleural plaques are the most common radiological manifestation of benign asbestos-related pleural disease and considered an indicator of past asbestos exposure[5-7], we suggest that at least 12.8% of our patients have been potentially exposed to asbestos, either occupationally or environmentally.

Since the prevalence of pleural plaques varies widely between studies, our findings must be considered alongside evidence from other epidemiological studies. In one such study, the reported prevalence of pleural abnormalities, pleural plaques and diffuse pleural thickening was 1.5% among 2633 chest CTs taken between 2009 and 2011 in the United States[19]. That study considered a general population of white, middle-class Americans, compared to our study of Japanese lung cancer patients, and

Table 2. Radiological findings of the 885 patients with primary lung cancer

	Number (%)					
	CT		CXR		CT & CXR	
Pleural plaques[a]	113	(12.8)	48	(5.4)	38	(4.3)
Pleural abnormalities						
Definite	80	(9)				
Probable	33	(3.7)				
Possible	52	(5.9)				
None	720	(81.4)				
Parenchymal abnormalities						
Irregular opacities	107	(12.1)	71	(8.0)	56	(6.3)
Small rounded opacities	15	(1.7)	15	(1.7)	13	(1.5)
Large opacities	8	(0.9)	6	(0.7)	5	(0.6)

[a] The presence of pleural plaques on CT was defined by the categories "definite" and "probable".
CT = computed tomography, CXR = chest radiography, CT & CXR = identified using both methods

included a younger age group (59.2±12.1 years compared to 71.3±9.9 years) and a higher proportion of females (50.3% compared to 27.6%). Another study documented pleural plaques on 5.1% of 1482 chest CTs from a radiological database of a university hospital in Italy[20]. Although this hospital-based Italian study reviewed chest CTs which were taken for various clinical indications including suspected pulmonary embolism or neoplasms, the investigators did not provide information such as age, gender, asbestos exposure, or the period in which the CT scans were obtained for the entire cohort. A large CT screening, conducted between 2003 and 2005 in France, detected pleural plaques in 15.9% of 5545 chest CTs of asbestos-exposed workers[21]. In the French study, the population consisted exclusively of retired male asbestos-exposed workers; the average age (63.5±5.7 years) was younger than ours (71.1±9.4 years). These discrepancies among these studies might be attributable to any of several factors related to the subjects enrolled (such as age, sex, exposure to risk factors), the technology employed in CT imaging, and the definition applied for pleural plaques in each study.

Our findings were derived from the information of relatively large cohort (n = 885), pathological confirmation of primary lung cancer, and accurate determination of pleural plaques based on CT interpretation by a panel of experts. The cases in our study were from a group of hospitals that also operate clinics specializing in occupational medicine; accordingly, patients attending these hospitals may represent a higher proportion of workers than the general Japanese population. Our study may have included a greater percentage of asbestos-exposed individuals than occurs in the general population. Nevertheless, the gender distribution in our cases was close to that seen in the lung cancer registry of the general Japanese population[22]. In contrast, males dominate in asbestos-related[23] or occupationally acquired lung cancer cases[24].

In the cases we analyzed, the frequency of lung cancer cell types was lower for adenocarcinoma and higher for squamous cell and small cell cancers than that seen in a nationwide Japanese primary lung cancer population[22]. The average age and gender distribution of the cases were comparable between the two studies. In our study, no distinct cell type was observed between patients with and without pleural plaques. All major histological types of lung cancer can be related to asbestos[5]; accordingly, the difference in histology distribution from the nationwide report may not affect the prevalence of pleural plaques in our patients. Although smoking information was not reported in the nationwide study, this difference in cell type was thought to be attributable to the smoking habits found in our population.

We found that 12.8% of our study population has pleural plaques; frequency was higher among smokers, 15.3%, compared to 9% among non-smokers. Some investigators consider smoking to be associated with the higher prevalence of pleural plaques[25]; however, there was no support for a causal relationship between smoking habits and pleural plaques[26]. We believe that the higher prevalence of smoking among our cases will not significantly affect the result of this study.

Pleural plaques solely involve the parietal pleura and are considered highly specific for asbestos exposure. Diffuse pleural thickening, on the other hand, involves visceral pleura and is less specific, and may have various etiologies[5-7]. In some cases, it is difficult to distinguish the two conditions based on CXR. However, in this study, we determined pleural plaques based on CT interpretation by

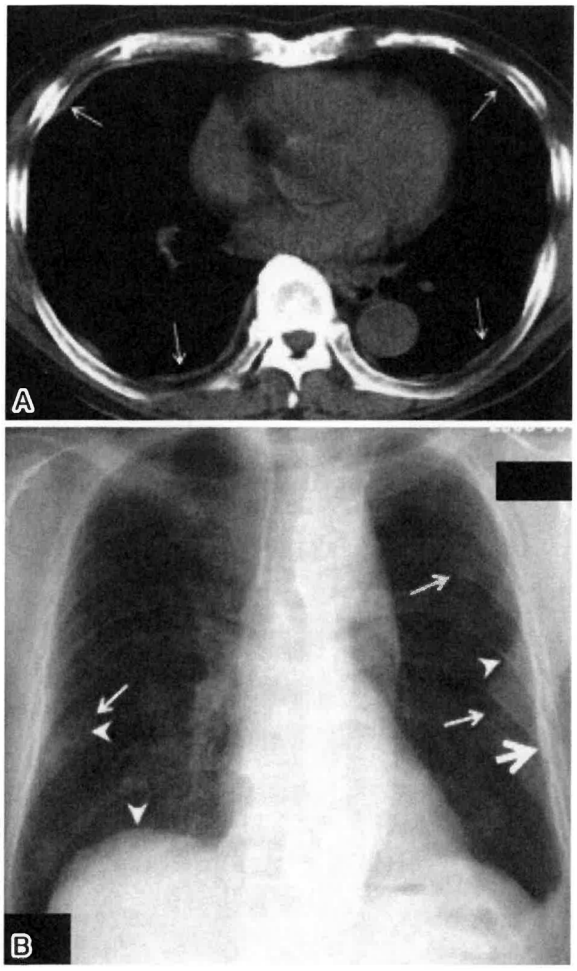

Fig. 1. Examples of pleural plaques on (A) a chest CT (arrows indicate pleural plaques) and (B) a chest radiograph (arrows indicate face-on plaques, thick arrow indicates in-profile plaque, and arrowheads indicate calcified plaques)

a panel of experts, employed a strict CT definition in diagnosis, and considered only those lesions that originated from the parietal pleura and omitted lesions involving the visceral pleura. Thus, it is possible that our study underestimated the actual proportion of pleural plaques and hence asbestos exposure. Since CT has higher sensitivity and specificity than CXR in evaluating pleural abnormalities[13,14], misclassification of pleural plaques in favor of sensitivity is unlikely. On the other hand, CT could have missed some cases of pleural plaques. As Yusa et al.[27] reported in 30 cases with surgically confirmed pleural plaques, 12 cases were undetected in a retrospective CT-examination study. Moreover, the absence of pleural plaques does not necessarily preclude previous asbestos exposure.

Given that 80 - 90% of radiologically identified plaques are attributable to occupational asbestos exposure in non-endemic regions[5], we considered that occupation has an impact on the occurrence of pleural plaques in our patients. Due to the retrospective nature of the present study, occupational information of the cases was limited. However, we could assign 69% of the patients into a particular occupation, allowing us to examine the frequency of pleural plaques on the basis of occupational categories. We found that more than half of our cases with pleural plaques (65%, 52 of the 80 cases of whom occupation could be allocated) consisted of manufacturing and general laborers. Subgroup-analysis of these manufacturing and general laborers revealed that the prevalence of pleural plaques was highest among construction-related workers (37.7%), followed by metal processing (26.7%) and civil construction laborers (26.7%). Since the majority of asbestos-containing products were used in construction materials, automobiles, and industrial machines[1]; special medical attention should be paid to individuals with a history of employment in these occupations as they also are listed under occupations with high risk of asbestos exposure, published by Ministry of Health, Labor and Welfare[9]. Additionally, we have noted that the prevalence of pleural plaques was considerably higher among security workers (4 cases, 44.4%), and transport and communication workers (5 cases, 13.9%). However, the small number of cases in these categories make it difficult to draw any meaningful conclusions.

Regarding our imaging methods, CT can identify pleural plaques in locations that are hidden in CXR, such as the anterior chest wall and paravertebral regions. In addition, CT can distinguish rib fractures, extrapleural fat, or thoracic muscle which may mimic pleural plaques and give false positives in CXR[13]. In this study, among the 885 patients with primary lung cancer, CXR identified pleural plaques in 48 cases (5.4 %), while CT detected plaques in 113 cases (12.8%). Of the 48 cases positive for pleural plaques with CXR, 10 were found to be for other causes, such as pleurisy, diffuse pleural thickening, extrapleural fat, or muscle on CT evaluation. This showed that CT is more sensitive and specific than CXR in characterizing pleural abnormalities. The use of CT for better characterization of pleural abnormalities has important medico-legal implications. Pleural plaques are considered to be an early manifestation of asbestos-related diseases[6,7], and could be an independent risk factor in asbestos-related lung cancer[16]. Early recognition in individuals with likely asbestos exposure is vital to health care. Moreover, identification of pleural plaques in individuals without an established history of occupational exposure could be a trigger for authorities to initiate epidemiological surveillance. Additionally, the compensation system for asbestos-related lung cancer in Japan requires, in addition to occupational history of asbestos exposure, the presence of either radiologically confirmed asbestosis or pleural plaques[28].

Table 3. Characteristics of 113 patients with pleural plaques on chest CT

		Number	(%)
Gender	Male	101	(15.8)
	Female	12	(4.9)
Age, year	≤49	–	–
	50 – 59	8	(8.5)
	60 – 69	32	(14.2)
	70 – 79	51	(14.3)
	≥80	22	(11.6)
Smoking[a]	Ever-smoker	79	(15.3)
	Non-smoker	16	(9.0)
Location	Chest wall	109	(96.5)
	Diaphragm	27	(23.9)
	Mediastinum	11	(9.7)
Chest involvement[b]	Bilateral	43	(38.1)
	Left	81	(71.7)
	Right	67	(59.3)
Calcification		47	(41.6)
Irregular opacities		22	(19.5)
Histology of lung cancer	Adenocarcinoma	46	(40.7)
	Squamous Cell	37	(32.7)
	Large Cell	3	(2.7)
	Small Cell	15	(13.3)
	Others/Unidentified	12	(10.6)

[a] Information on smoking was available for 692 cases (78.2%).
[b] Only plaques on the chest wall pleura were considered.

Table 4. Histological cell types of 885 patients with primary lung cancer according to sex, smoking status, and the presence of pleural plaques

	Number (%)						
	All	Gender		Smoking[a]		Pleural plaque	
		Male	Female	Ever	Non	Present	Absent
	885	641	244	515	177	113	772
Type		(72.4)	(27.6)	(74.4)	(25.6)	(12.8)	(87.2)
Adenocarcinoma	408	242	166	194	120	46	362
	(46.1)	(37.8)	(68.0)	(37.7)	(67.8)	(40.7)	(46.9)
Squamous cell	264	234	30	186	30	37	227
	(29.8)	(36.5)	(12.3)	(36.1)	(17.0)	(32.7)	(29.4)
Large cell	22	14	8	15	3	3	19
	(2.5)	(2.2)	(3.3)	(2.9)	(1.7)	(2.7)	(2.5)
Small cell	106	90	16	74	10	15	91
	(12.0)	(14)	(6.6)	(14.4)	(5.7)	(13.3)	(11.8)
Others/unidentified	85	61	24	46	14	12	73
	(9.6)	(9.5)	(9.8)	(8.9)	(7.9)	(10.6)	(9.5)
p		<.001		<.001		.768	

[a] Information on smoking was available for 692 cases (78.2%); Ever = Ever-smoker, Non = Non-smoker.
p = *p*-value for Chi-squared test or Fisher's exact test as appropriate.

Table 5. Prevalence of CT identified pleural plaques or irregular opacities by occupation

	All	Pleural plaques	Irregular opacities
Number of cases[a]	615[†]	80[¶]	86[§]
Occupation		Number (%)	
Professional & engineering	44	2 (4.6)	6 (13.6)
Administrative & managerial	10	–	1 (10.0)
Clerical	55	4 (7.3)	5 (9.1)
Sales	43	2 (4.7)	3 (7.0)
Service	27	2 (7.4)	–
Security	9	4 (44.4)	3 (33.3)
Agriculture, forestry & fishery	26	–	3 (11.5)
Transport & communication	36	5 (13.9)	3 (8.3)
Manufacturing and general labor	215	52 (24.2)	45 (20.9)
Housewife	46	3 (6.5)	3 (6.5)
Jobless	54	2 (3.7)	10 (18.5)
Other	50	4 (8.0)	4 (8.0)

[a] Number of cases which can be allocated into a particular occupation.
[†] Among the 885 patients with primary lung cancer.
[¶] Among the 113 cases with pleural plaques on chest CT.
[§] Among the 107 cases with irregular opacities on chest CT.

From the present study, we cannot postulate a causal relationship between asbestos exposure and the development of lung cancer in our cases with pleural plaques. The proportion of smokers was fairly high among our cases (74.4%) compared to the general population[29], and tobacco smoking is a well-known risk factor for lung cancer. In addition, asbestos-exposed workers have frequently been exposed to other occupational carcinogens, such as welding fumes and polycyclic aromatic hydrocarbons. In female cases, exposure to environmental radon and air pollutants is more likely to occur than to asbestos. It is difficult to allocate the relative contributions of exposure to asbestos or other carcinogens and smoking in the pathogenesis of lung cancer. Despite the reported independent risk of pleural plaques in lung cancer[16], the issue remains controversial[30], and more importantly, pleural plaques may develop in situations with relatively low asbestos exposure. In addition, there is no distinct cell type to distinguish asbestos-related lung cancer from other lung cancers[6,23]. However, this study showed that more than one-tenth of patients with primary lung cancer may have experienced a possible occupational asbestos exposure.

Since the import and use of asbestos in Japan peaked in the 1970s and 1980s, and given a latency of more than 40 years[23], a considerable number of asbestos-related lung cancers is expected at present, and increasingly in the coming decades. In Japan, lung cancer incidence has steadily increased in both sexes[31], and accounted for 15.3% of all new cancers in males and 10.0% in females in 2012[29]. In the year 2012, there were 113,047 incident lung cancer cases. The number of these cases that can be attributed to asbestos exposure is unknown.

Japan imposed a total ban on asbestos use since 2012; however, there is a growing concern about environmentally acquired asbestos-related diseases. Given that the majority (roughly 70 - 90%) of imported asbestos was used in the production of asbestos-containing cement products for building materials and in construction[1], the main potential source of public exposure of concern today is from the demolition of old asbestos-containing buildings. It is anticipated that the number of demolished buildings containing asbestos will continue to increase until 2030[1]. There is a high risk of significant asbestos dispersal in work areas, and also of environmental pollution. It is crucial to implement safe practices for the management and removal of asbestos to safeguard against the dispersal of asbestos into environment.

Conclusion

The prevalence of pleural plaques in our study differs to some extent from other population studies. Results must be cautiously interpreted due to the fact that this hospital-based study was comprised solely of patients with primary lung cancer, as well as a population representing a higher percentage of workers than the general Japanese population. Our results show that 12.8% of patients with primary lung cancer have pleural plaques on chest CT. Notably, frequency was highest among indi-

viduals with an employment history related to construction, suggesting that these patients have experienced a possible occupational asbestos exposure. Given that pleural plaques are early manifestations of asbestos exposure, and that asbestos exposure is associated with an increased risk of malignancies, early recognition of pleural plaques in at-risk populations is important to initiate proper health surveillance and early detection of malignancies.

Conflict of interest: None declared.

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Implementation Science

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A WHO-HPH operational program versus usual routines for implementing clinical health promotion: an RCT in health promoting hospitals (HPH)

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Abstract

Background: Implementation of clinical health promotion (CHP) aiming at better health gain is slow despite its effect. CHP focuses on potentially modifiable lifestyle risks such as smoking, alcohol, diet, and physical inactivity. An operational program was created to improve implementation. It included patients, staff, and the organization, and it combined existing standards, indicators, documentation models, a performance recognition process, and a fast-track implementation model.
The aim of this study was to evaluate if the operational program improved implementation of CHP in clinical hospital departments, as measured by health status of patients and staff, frequency of CHP service delivery, and standards compliance.

Methods: Forty-eight hospital departments were recruited via open call and stratified by country. Departments were assigned to the operational program (intervention) or usual routine (control group). Data for analyses included 36 of these departments and their 5285 patients (median 147 per department; range 29–201), 2529 staff members (70; 10–393), 1750 medical records (50; 50–50), and standards compliance assessments.
Follow-up was measured after 1 year. The outcomes were health status, service delivery, and standards compliance.

Results: No health differences between groups were found, but the intervention group had higher identification of lifestyle risk (81% versus 60%, $p < 0.01$), related information/short intervention and intensive intervention (54% versus 39%, $p < 0.01$ and 43% versus 25%, $p < 0.01$, respectively), and standards compliance (95% versus 80%, $p = 0.02$).

Conclusions: The operational program improved implementation by way of lifestyle risk identification, CHP service delivery, and standards compliance. The unknown health effects, the bias, and the limitations should be considered in implementation efforts and further studies.

Trial registration: ClinicalTrials.gov: NCT01563575. Registered 27 March 2012. https://clinicaltrials.gov/ct2/show/NCT01563575

Keywords: Strategic implementation , Fast-track implementation , Quality improvement , Clinical health promotion , Health promoting hospitals , Lifestyle risk , Patients , Hospital staff

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Background

Turning evidence into practice in healthcare often takes decades [1–3]. Slow implementation also occurs with patient-centered activities to modify lifestyle risk factors [4], such as clinical health promotion (CHP) aiming at better health gain for patients, staff, and communities.

A sub-type of health promotion [5–7], CHP covers patient-enablement, disease prevention, health promotion, and rehabilitation, which takes place within patient pathways [8, 9]. CHP relies on counseling [10–13] where clinical staff support patients to control and improve both health and modifiable determinants thereof [14, 15], such as daily smoking, risky alcohol drinking, poor nutrition, physical inactivity, and other lifestyle risks [8]. On short term within pathways, CHP has been shown to improve treatment results and prognoses in surgery [16–19], obstetrics [20–22], internal medicine [23–27], and psychiatry [28]. It is also cost-effective [29] and well-received by patients [30–32]. On long term, it can contribute to better public health [16, 33]. Even so, however, CHP is rarely implemented [33].

Furthering implementation of CHP, and of the World Health Organization (WHO) concepts, values, strategies, and standards of health promotion in general, into the organizational structure and culture of hospitals and health services is the aim of the WHO-initiated International Network of Health Promoting Hospitals and Health Services (HPH) [34, 35].

To support the attainment of this goal, a package of validated tools and a recognition of performance (RP) were recently developed by WHO and HPH. The package of tools included five WHO standards with related indicators [34, 36, 37] that were developed according to the International Society for Quality in Health Care (ISQUA) criteria [38], and two HPH documentation models [39, 40]. The RP used HPH certifications recognizing fulfillment of the five WHO standards [41].

To speed up implementation, a 1-year, fast-track implementation model for CHP (Fast-IM) was also added [41]. The Fast-IM was data-driven and used resources related to strategic implementation of evidence [3, 42–49] as well as general quality improvement tools such as the Plan-Do-Check-Act (PDCA) cycle [50]. The Fast-IM aims to set 1-year implementation goals for the individual organization based on own local data identifying important implementation gaps. The Fast-IM incorporates adjustable quality plans with clear, measurable 3-month milestones and is driven by the data [41].

Combined, the package of tools, the RP, and the Fast-IM were evaluated as a WHO-HPH operational program versus usual routines for implementation of CHP. Specifically, the evaluation focused on the operational program's ability to potentially improve dosage, quality, and fidelity of implementation by way of risk identification, CHP service delivery, and standards compliance, and by this route, possibly, improve the health of patients and staff [41].

Aim

The aim of this study was to evaluate if the operational program improved implementation of CHP in clinical hospital departments. This was measured by health status of patients and staff and by implementation process in terms of frequency of CHP service delivery and standards compliance.

Methods

Participants

For our randomized controlled trial with the clinical hospital department as the unit of randomization and analysis (i.e. no cluster), we hypothesized that allocation to the operational program (intervention group) would improve health of patients and staff, increase delivery of CHP services to at risk-patients, and improve WHO standards compliance at the department level, compared to the control group departments continuing usual implementation routines. The service delivery and standards compliance outcomes serve as measures of procedural and structural changes in implementation, and the health outcomes serve as a measure of the potential effect of such changes.

Inclusion criteria were clinical hospital departments responsible for treatment. Exclusion criteria were > 1 department from each hospital and palliative departments, nursing homes, pediatric departments, non-hospital clinics, and primary care facilities since the CHP-specific process components were not validated in these settings.

Based on a secondary outcome (standards compliance), we calculated a sample size of 2×40 clinical departments, because no studies existed on the primary outcome of health status. The power calculation was based on a previous study [40], which had shown that baseline CHP service deliveries could be expected to reach no more than 40% of the at-risk patients. The minimum relevant difference in service deliveries was 30%, the expected outcome was 70%, power was 80%, and two-sided significance was 5% [41].

Full inclusion of the 2×40 departments, along with the 2-year follow-up, was not obtained before an update and revision of WHO standards in 2016, at which point only 48 departments had been included and randomized (Fig. 1). The 48 included departments that participated were recruited via an open call among HPH member hospitals (Fig. 1). Owing to the commitment of HPH members to use WHO standards, and since the revised WHO standards were markedly different, new centers and already participating centers in the RCT

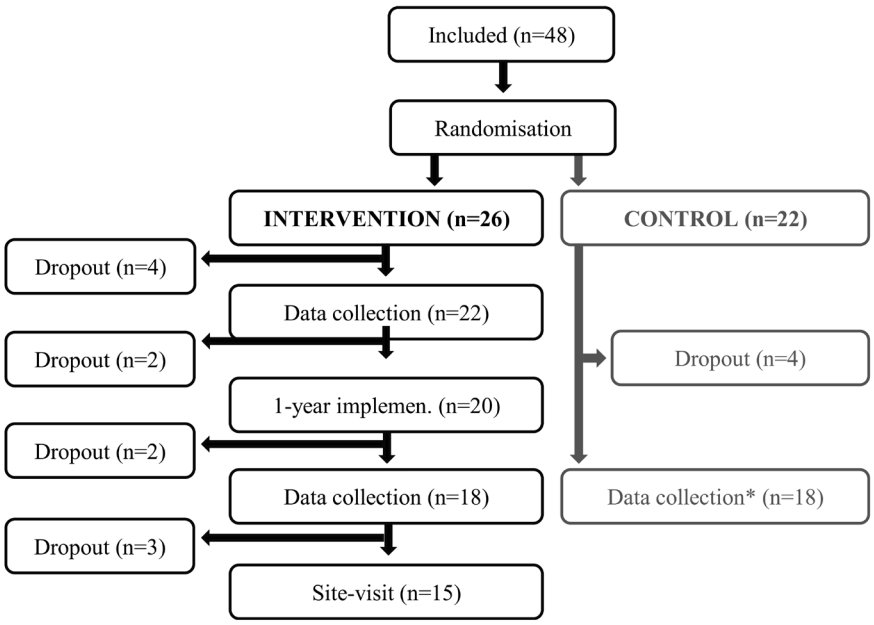

Fig. 1 Trial profile

could not be expected to begin to or continue to use the old version.

Of the 48 included departments, 8 (4 in each group) dropped out after allocation. The remaining 40 departments were from 8 countries/regions in Asia and Europe: Taiwan ($n = 21$), Czech Republic (8), Slovenia (3), Croatia (2), Estonia (2), Japan (2), Denmark (1), and Malaysia (1). Of these, 36 (75% of the originally included 48) completed the study. The characteristics at department-level, staff-level, and patient-level are presented in Table 1. The study was registered at ClinicalTrials.gov (NCT01563575).

Randomization and masking

We randomly allocated departments to undertaking the operational program (intervention group) or to continuing usual implementation routines (control group). An external researcher performed the computerized randomization, using blocks of unknown sizes and stratification by country. Sealed, opaque envelopes concealed allocation numbers from the international research team that enrolled departments. All allocation was video recorded. In view of the nature of the intervention, the participating departments and project staff were aware of their allocation.

Procedures

All data were collected between October 2012 and October 2016. Each department's data collection took 1–3 months. The international research team developed and provided project instruction manuals, forms, and templates [41] (see Additional file 1). All translation and provision of information to staff was handled locally. An introduction seminar covering data collection, surveying, and auditing training was held for staff at all participating departments (online or on location) before randomization and project start.

Participating departments assigned data collection tasks to one or more of their own staff according to local needs and resource availability.

Intervention group

The intervention group began the operational program [41] immediately after allocation. After 1 year, they repeated the data collection and underwent an external audit including interviews with staff and managers [41, 51].

Control group

To reduce the risk of contamination, the control group departments did not measure pre-implementation status but instead waited 1 year. During this wait, they continued their own usual implementation routines (understood as usual management activity—parallel to the clinical term, treatment as usual). These usual implementation procedures presumably varied among participating hospitals, and since all were HPH member hospitals, many worked with the WHO standards already. No data was collected on usual implementation routines in each hospital in advance of the project. After the 1-year wait, the control group departments collected their data (Fig. 1). For convenience, and only

Table 1 Characteristics of the 40 hospital departments that participated and characteristics of the 5285 patients and 2529 staff from the 36/40 clinical departments that submitted data for analyses, presented at the department level as median and range

Hospital departments		Intervention ($n = 22$)	Control ($n = 18$)
Hospital type	Community/general/specialized/university	18/50/9/23%	6/61/11/22%
Ownership	Public/private non-profit/private for-profit	64/27/9%	33/61/6%
Department	Medicine/surgery and obs-gyn/psychiatry	73/18/9%	66/28/6%
Catchment area	Urban/rural/mixed	32/9/59%	61/11/28%
Number of beds	< 200/200–599/> 599	23/36/41%	0/50/50%
HPH member		100%	100%
Patients and staff		Intervention ($n = 18$)	Control ($n = 18$)
Patients ($n = 5285$)		152 (75–201)	142 (29–200)
Age (years) 18–29		8% (0–48%)	5% (0–26%)
30–49		19% (0–56%)	23% (6–66%)
50–69		40% (10–61%)	44% (15–59%)
> 70		33% (0–91%)	28% (0–71%)
Women		52% (28–79%)	55% (32–100%)
BMI		26 (17–44)	25 (16–38)
Daily smoking		10% (0–23%)	10% (2–16%)
Hazardous alcohol drinking		3% (0–13%)	2% (0–8%)
Physical inactivity		60% (15–83%)	66% (32–88%)
Risk of malnutrition		44% (16–72%)	36% (15–60%)
Overweight/obesity		60% (25–92%)	51 (25–86%)
Staff ($n = 2529$)		70 (10–393)	71 (18–223)
Age (years) 18–29		28% (0–66%)	25% (4–52%)
30–49		53% (29–80%)	59% (40–73%)
> 50		19% (0–60%)	16% (0–43%)
Women		80% (49–95%)	85% (64–97%)
BMI		23 (17–34)	23 (17–34)
Daily smoking		5% (0–20%)	8% (0–37%)
Hazardous alcohol drinking		1% (0–9%)	1% (0–12%)
Physical inactivity		73% (24–100%)	79% (27–99%)
Risk of malnutrition		26% (4–60%)	27% (7–47%)
Overweight/obesity		33% (10–75%)	28% (12–52%)

Missing data 0–9%

after the trial had ended, the control group was also offered the operational program. This offer was accepted by 17/18 control group departments.

Data collection (both groups)

The collected data covered patient, staff, and department levels. Validated Short-Form 36 version 2 (SF36v2) health surveys [52, 53] were used to assess patient and staff health. As described in the RCT protocol, each department surveyed 200 consecutive patients or 1 month's population of patients, depending on which of these two stopping-points were reached first, and all staff currently employed by the department [41]. The eight dimensions of SF36v2 were summarized in physical (PCS) and mental (MCS) component scores for analyses, where a score of 100 represented maximum functionality. For identification of patient lifestyle risks and related CHP service delivery, validated medical record audit tools were used [39, 40] according to the operational program [41]. Here, each department audited 50 consecutive medical records concerning documentation of patient lifestyle risks, using the HPH DATA Model [39], and concerning associated delivery of relevant CHP services, using the HPH DocAct Model [40], as described in the protocol [41]. If data was available in the medical record, e.g., "does the patient smoke daily?", the auditing staff member would answer "yes" or "no" as relevant, and that would count as documented risk (either positive or

negative). If data was unavailable, the staff member would answer "unknown" and that would count as undocumented risk [39].

The same approach was used for auditing of CHP service documentation in the records [40]. CHP services can be categorized as either short interventions (SI) or intensive interventions (II) [54, 55]. SI do not exceed three counseling sessions and/or a total contact time of 1 h [55]. II consist of four or more in-person sessions of 10 min or more each [54, 55]. II are often theory-based, offered by trained staff, include patient education and pharmacological support. While the SI/II categorization [54, 55] was used in the study, the design and contents of each CHP intervention were determined locally.

Compliance with the validated WHO standards [34, 36, 37] was also assessed (Table 2). The WHO standards contain 40 measurable elements within five standard domains [34] (see Table 2). Department performance was recognized with a certificate based on standard compliance (91–100% was gold level).

Outcomes

The primary outcome was health status of patients and staff as measured by SF36v2. The secondary outcomes were CHP service delivery to identified at-risk patients as well as WHO standards compliance.

Statistical analysis

The characteristics and results were reported as medians and ranges for each department. The two groups were compared by an external researcher, blinded to group allocation, using non-parametric statistics. Health status and standard compliance were analyzed using the Wilcoxon unpaired test, and service delivery frequencies were analyzed using Fisher's exact test. *P* values below 0.05 were considered significant. All analyses were performed using SAS 9.4.

Results

The response rate of departments was 40/48 (83%), but only 36/48 (75%) submitted complete data sets for the analyses. The data from the 36 departments covered 5285 patients (median per department = 147; range = 29–201) and 2529 staff members (70; 10–393). Overall missing data were 0–9% per factor (Table 1). All results were analyzed at department level.

Health status of patients and staff

No differences in the health of patients or staff were found. At baseline, the intervention group's ($n = 22$) SF36v2 patient PCS and MCS per department were 57 (11–95) and 61 (13–97). Their baseline staff PCS and MCS were 75 (36–97) and 71 (31–96).

At follow-up, the intervention group patient PCS was 58 (7–96) versus 64 (12–98) in the control group ($p = 0.19$), and the patient MCS was 64 (9–98) versus 69 (17–99) ($p = 0.25$). The staff PCS was 74 (34–97) in the intervention group at follow-up versus 73 (36–97) ($p = 0.58$) in the control group, and the staff MCS was 70 (29–95) versus 68 (30–95) ($p = 0.26$). Figure 2 presents the PCS and MCS of patients and staff.

Identification of lifestyle risks and related CHP service delivery

The frequency of at-risk patients was similar: 252 (28%, 24–447) patients per risk factor on average in the intervention group versus 225 (26%, 75–419) in the control group. However, the completeness of patient risk documentation in the medical records was significantly better in the intervention group (81% versus 60%, $p < 0.01$). Delivery of information and/or short intervention (54% versus 39%, $p < 0.01$) and intensive intervention services (43% versus 25%, $p < 0.01$) to at-risk patients were also significantly more frequent in the intervention group. Figure 3 presents the completeness of the departments' documentation of risk per factor and the degree to which systematic CHP interventions were then provided to documented at-risk patients.

Looking at the intervention group at baseline ($n = 22$), the completeness of risk documentation was 65%, delivery of information and/or short intervention services to at-risk patients was 40%, and delivery of intensive intervention services to at-risk patients was 35%.

Standard compliance

The overall compliance with WHO standards was significantly higher in the intervention group (95% versus 80%, $p = 0.02$) (Table 2). Gold-level certificates for fulfilling ≥ 91% of standards were issued to 14 intervention group departments and 9 control group departments. Figure 4 shows the compliance improvements of the intervention group as well as the compliance of the control group. The in-group median standards compliance improvement within the intervention group was 12% (ranging 0–50%).

Sensitivity analysis of the reported data

The reported WHO standards compliance and CHP service delivery were randomly evaluated during the site visits in the intervention group using external medical record audits and interviews. No significant differences were found (Table 3).

CHP service delivery to no-risk patients

Interestingly, CHP services were also delivered to patients with no or undocumented risks. Both groups provided CHP services to 13% of the documented no-risk

Table 2 The 5 WHO standards for health promotion in hospitals: Compliance to the 40 measurable elements (ME) of the intervention and control group, presented as median and range

Standard	No. of ME	Description	Objective	Intervention group ($n = 18$)	Control group ($n = 18$)	*p*
1 Management policy	9	The organization has a policy for HP. The policy is implemented as part of the overall QM system.	To describe the framework for t he organization's HP activities as an integral part of the QM system.	8 (6–9)	7 (3–9)	
		Measurable elements: 1. Stated aims and mission include HP 2. Minutes of governing body reaffirms agreement within the past year to participate in the WHO HPH Network 3. The current quality and business plans include HP for patients, staff and the community 4. Personnel and functions for the coordination of HP are identified 5. There is an identifiable budget for HP services and materials 6. Operational procedures such as practice guidelines or pathways incorporating HP are available in clinical departments 7. Specific structures and facilities required for HP (including resources, space, equipment) can be identified 8. Data are routinely captured on HP interventions and available to staff for evaluation 9. A programme for quality assessment of HP activities is established				
2 Patient assessment	7	In partnership with patients, staff systematically assess the needs for HP activities.	To support patient treatment, improve prognosis and promote the health and wellbeing of patients.	7 (5–7)	6 (1–7)	
		Measurable elements: 1. Guidelines on how to identify smoking, alcohol consumption, nutritional and psycho-social-economic status are present 2. Guidelines/procedures have been revised within the last year 3. Guidelines are present on how to identify needs for HP for groups of patients (e.g. asthma patients, diabetes patients etc.) 4. The assessment is documented in the patient's medical record at admission 5. There are guidelines/procedures for reassessing needs at discharge or end of a given intervention 6. Information from referring physician or other relevant sources is available in the patient's record 7. The patient's record documents social and cultural background as appropriate				
3 Patient information and intervention	6	Patients receive info on significant factors concerning disease/condition, and HP interventions are established in all pathways.	To ensure patients are informed about activities, empowered in an active partnership and to facilitate integration of HP activities in all pathways.	6 (4–6)	4 (1–6)	
		Measurable elements: 1. Information given to the patient is recorded in the patient's records 2. Health promotion activities and expected results are documented and evaluated in the records 3. Patient satisfaction assessment of the information given is performed and the results are integrated into the QM system 4. General health information is available 5. Detailed information about high-risk diseases is available 6. Information is available on patient organizations				
4 Promoting a healthy workplace	10	The management establishes conditions for the development of a healthy workplace.	To support the development of a healthy and safe workplace and to support health promotion activities of staff.	10 (7–10)	8 (2–10)	
		Measurable elements: 1. Working conditions comply with national/regional directives and indicators 2. Staff comply with health and safety requirements and all workplace risks are identified 3. New staff receive an introductory training that addresses the hospital's HP policy 4. Staff in all departments are aware of the content of the organization's health promotion policy 5. The performance appraisal system and continuing professional development include HP 6. Working practices (procedures and guidelines) are developed by multidisciplinary teams 7. Staff are involved in hospital policy-making, audit and review 8. Policies for awareness on health issues are available for staff 9. Smoking cessation programmes are offered 10. Annual staff surveys are carried out including an assessment of individual behaviour, knowledge on supportive services/policies, and use of supportive seminars				
5 Continuity and cooperation	8	The organization has a planned approach to collaboration with other providers and other institutions and sectors.	To ensure collaboration with relevant providers and initiate partnerships to optimize integration of HP activities in pathways.	8 (7–8)	7 (3–8)	

Table 2 The 5 WHO standards for health promotion in hospitals: Compliance to the 40 measurable elements (ME) of the intervention and control group, presented as median and range *(Continued)*

Standard	No. of ME	Description	Objective	Intervention group ($n = 18$)	Control group ($n = 18$)	*p*
		Measurable elements: 1. The management board is taking the regional health policy plan into account 2. The management board can provide a list of health and social care providers working in partnership with the hospital 3. The intra- and intersectoral collaboration with others is based on execution of the regional health policy plan 4. There is a written plan for collaboration with partners to improve the patients' continuity of care 5. Patients/families are given understandable follow-up instructions at out-patient consultation, referral or discharge 6. There is an agreed upon procedure for exchange practices between organizations for all relevant patient information 7. The receiving organization gets a written summary of condition, health needs and interventions already provided 8. If appropriate, a plan for rehabilitation describing roles of the organization/collaborators is documented in the record				
Overall compliance	40			38 (31–40)	32 (12–40)	*0.02*

HP (clinical) health promotion, *QM* quality management, overall 3% missing data

patients and to 9–12% of patients with undocumented risks. In total, across all risks and regardless of risk documentation, 65% of patients in the intervention group and 47% in the control group received CHP services.

Discussion

While we found no differences in the health status of patients and staff between groups, we did find that the intervention group identified patient lifestyle risks better and more frequently delivered related CHP services to at-risk patients compared to the control group that continued usual implementation routines. We also found that the intervention group had an overall higher compliance with the WHO standards.

Service delivery to at-risk patients

Risk documentation and service delivery (Fig. 3) is relevant to healthcare quality, since these issues have been reported to be a general challenge [56, 57] not least for smoking [33, 58, 59]. Reported barriers include lacking treatment resources, awareness of the negative influence of lifestyle risks on treatment results, reimbursement of CHP services, management

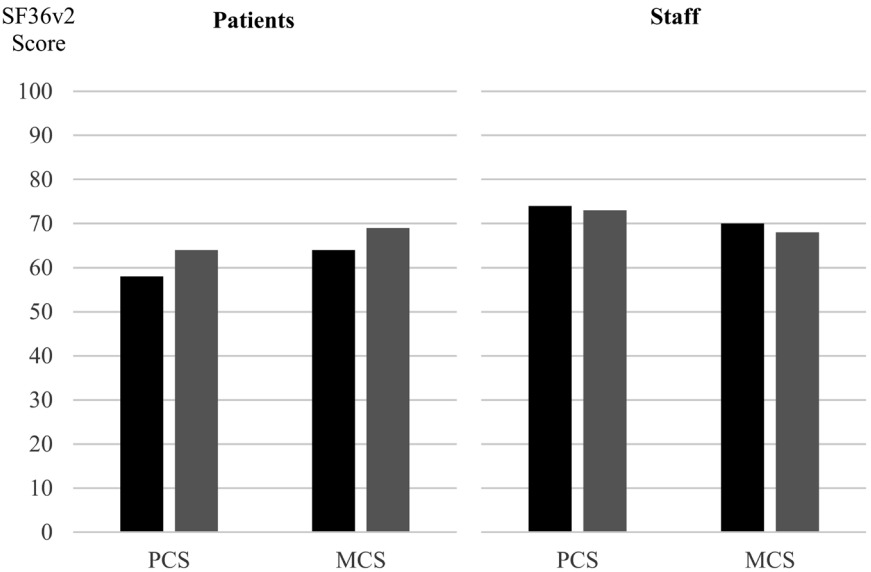

Fig. 2 Comparison of the ($n = 36$) intervention (black) and control (red) departments' patients ($n = 5285$. Median 147; range 29–201) and staff ($n = 2529$. 70; 10–393) health status by Short Form 36 version 2 (SF36v2) presented as median physical component score (PCS) and mental component score (MCS)

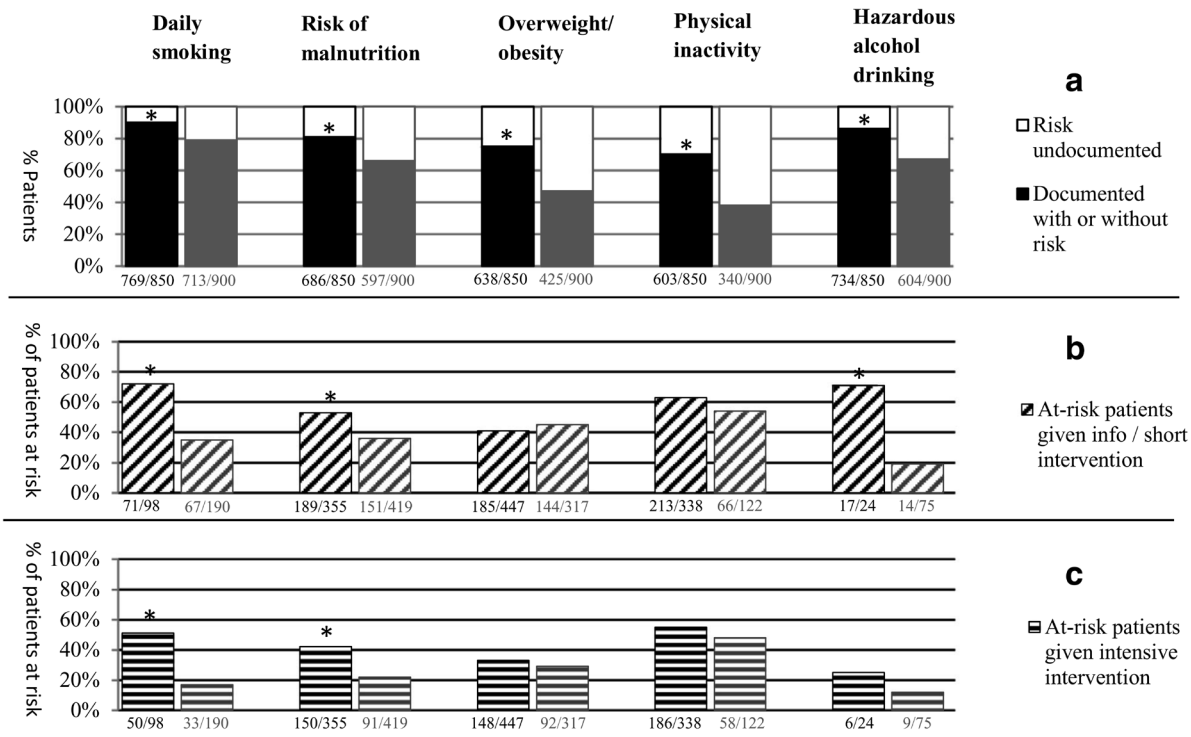

Fig. 3 Comparison of the intervention (black) and control (red) departments' documentation of their 1750 patients' risks in the medical records (2a) and related delivery of information/shorter intervention (2b) and intensive intervention (2c) to at-risk patients (3% missing data. *$P < 0.05$)

support, organizational focus on CHP, competencies of staff, and knowledge of the implementation process [33, 60, 61]. Suggested strategies to overcome these barriers include securing awareness of the evidence of CHP effectiveness, strengthening leadership engagement, and incentivizing CHP treatments [33].

Our results indicate that the operational program improved central parts of implementation within 1 year. The possible explanations for this improvement were explored in a nested qualitative study, and here, staff and managers echoed the already reported barriers and stated that the operational program increased awareness of and engagement in CHP within the departments [51]. In this light, it is plausible that the very presence of the study might have contributed to improved implementation by raising awareness of the implementation process. It is also possible that the prominent place CHP services have in the WHO standards may have contributed to improved implementation, and thus that the standards compliance increase found may in fact correlate with the improvements found for risk identification and service delivery. If this explanation holds, it is highly interesting that the Joint Commission has by now adopted tobacco and alcohol screening and treatment measures in their standards [62–64] and that the American College of Surgeons have added smoking as a risk factor in their National Surgical Quality Improvement Program [65]. The effects of adopting such risk documentation and CHP services will prove interesting in future.

WHO standards compliance

Worldwide, healthcare systems use standards and indicators, and these are commonly viewed as an integral and justifiable part of quality management [66].

However, the evidence of the effect of quality improvement using standards and indicators is sparse [66–72]. Randomized studies have found effects on healthcare process and structure outcomes as a result of quality improvement programs [73–76], but either without investigating potential health effects [73, 76] or without finding effect on health [74, 75]. Non-randomized studies have shown mixed results; some have found health effects [77], while others have not [78]. On this basis, improving standards compliance alone (Table 2 and Fig. 4) is not sufficiently robust evidence to merit and inform action, and our study thus also included clinical outcomes related to actual risk identification, service delivery, and health status.

Patient and staff health

For patients, the evidence of the positive effects of integrating CHP services in clinical treatments is growing

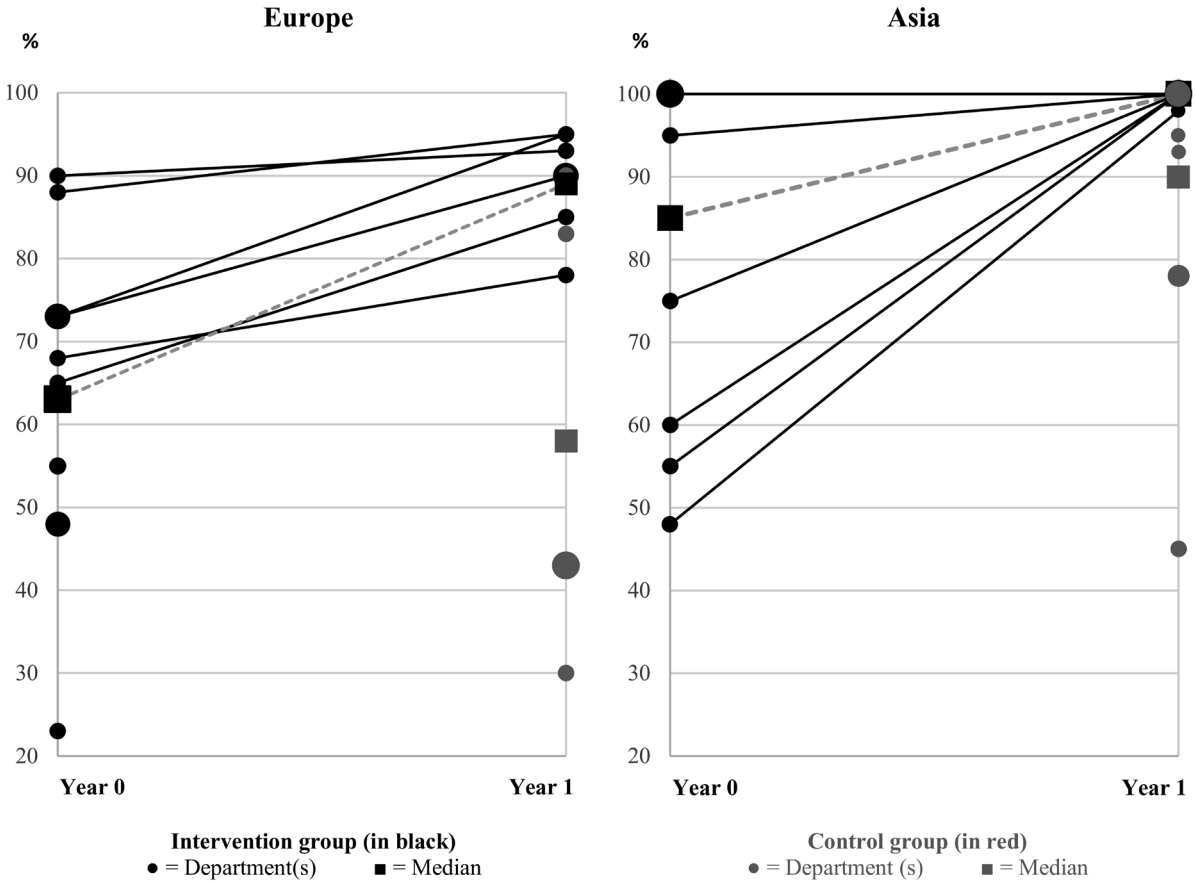

Fig. 4 Compliance with WHO standards for health promotion in hospitals (in %) in the clinical departments of the intervention group (baseline $n = 22$, 1-year follow-up $n = 18$) and of the control group ($n = 18$)

[16, 17, 20, 21, 23, 24, 28, 33]. The reason we did not find evidence of health improvements among patients could relate to our following up on departments and not individuals. Thus, our study does not disprove health effects at the level of individual patients, which are expectable considering the effect of CHP interventions known from the literature on for instance smoking cessation [79]. In our study design, it is possible that fast flow of patients in the departments might have diluted health effects.

Table 3 Sensitivity analysis comparing the internal (IA) and external audit (at site visit) (EA) of medical records in the intervention group for documentation of four risk factors and related service delivery (IA = 850 medical records; in total 4 × 850 = 3.400. EA = 64 medical records; in total 4 × 64 = 256)

	Risk documentation			Service delivery to documented at-risk patients				
	IA	EA	*p*	IA		EA		*p*
	Documented/ total (%)	Documented/ total (%)		At-risk/ documented (%)	Serviced risk/at-risk (%)	At-risk/ documented (%)	Serviced risk/at-risk (%)	
Daily smoking	769/850 (90%)	61/64 (95%)		98/769 (13%)	57/98 (58%)	8/61 (13%)	4/8 (50%)	
Hazardous alcohol drinking	734/850 (86%)	55/64 (86%)		24/734 (3%)	13/24 (54%)	1/55 (2%)	0/1 (0%)	
Physical inactivity	603/850 (71%)	45/64 (70%)		338/603 (56%)	232/338 (69%)	35/45 (78%)	23/35 (66%)	
Nutritional problems	767/850 (90%)	62/64 (97%)		634/767 (83%)	283/634 (45%)	40/62 (65%)	23/40 (57%)	
Total (all four risk factors)	2873/3400 (85%)	223/256 (87%)	0.3	1094/2873 (38%)	585/1094 (53%)	84/223 (38%)	50/84 (60%)	*0.3*

The WHO standards also include staff, and hospitals are notoriously hazardous workplaces [80]. Additionally, staff members are the ones delivering CHP to patients and both health and competencies of staff and managers have been shown to be associated with implementation of CHP. Smoking staff and managers, for instance, are less positive towards smoking cessation [81, 82]. Smoking staff less frequently deliver interventions [83] and follow-up services [84], and smoking managers less frequently adopt no smoking policies [82]. Lacking CHP competencies of staff are also a main barrier to actually delivering services [83, 84]. It seems probable then that improving both competencies and lifestyle risks among staff and managers might reduce barriers to CHP implementation.

The nested qualitative study, which was carried out alongside this RCT, reported that staff and managers were generally positive towards the operational program introduced and considered it to be worthwhile [51].

Just as for patients, the fact that we did not find an effect on staff health might be explainable by our following up on departments rather than individual staff members.

Even so, it can be noted that the staff in our study had a relatively high health-related quality of life, compared to the literature. The staff in our study had a PCS of 73–74 and an MCS of 68–70, as measured by SF36v2, whereas a 2013 sample of 2964 Norwegian nurses had lower PCS and MCS averages of 50 and 48, respectively, using the same 0–100 scale, but measured by SF12 [85].

Interestingly, staff and patients in our study had similar MCS. This could be due to a generally positive culture in HPH hospitals and because only three psychiatric departments took part. Compared to staff, patients had markedly lower PCS, which is readily explainable by their physical illness.

Bias and limitations

Our study has several biases and limitations. One major bias is that the study included only 48 of the targeted 80 departments. Of these, 40 (83%) departments participated, and 36 (75%) departments completed. This small number introduces a high risk of overlooking potentially significant results (e.g., health gain), which a fully powered study might have found (type-2 error).

Along with the open-call inclusion strategy, this might have resulted in a sample of departments with only highly motivated managements, potentially making our results optimistic. Likewise, the small sample size might also have meant that the randomization could not adequately minimize confounding differences between groups.

Another major limitation is the design that did not follow individual patients and staff, which was chosen due to our ambition to show a 1-year health effect at department level and thus avoid clustering. This alone might have rendered the study unable to identify health gains among patients and staff—provided such differences exist.

As this study is one of the first in its area, it might also suffer from risk of type-1 error regarding the significant results on risk identification, service delivery, and compliance. Further, sizeable studies would be needed to reduce this risk.

The lack of blinding resulting from the nature of the intervention adds further risk of bias. However, the analyses were blinded, and all reporting of results was performed in accordance with the level of randomization (i.e., department level), which avoided bias related to the use of clusters.

Both organizational and survey data were collected via self-assessment and self-reporting, which may introduce bias. However, these issues would presumably be relatively similar in both groups, since this is a ubiquitous type of bias in self-reported data, meaning that there is no apparent reason to speculate that it would be more present in one group than the other. Additionally, it was a strength that core tools used in the study had been validated in advance [37, 39, 40, 52, 53] and that the nested qualitative study indicated that staff generally found the project and its data collection doable [51].

Another risk of bias arose from the fact that most countries/regions participated with only a few hospitals each. This produced a skewed geographical distribution in both groups. However, the country stratification modified this risk, which was a strength.

The real-life conditions of the study were also a strength, but only HPH member hospitals were included, which potentially limits the generalization of our findings to non-HPH hospital settings. However, the international participation did broaden the representativeness of the results, which is a strength in terms of generalization.

It was a limitation that usual implementation routines naturally varied between participating departments, but it was a strength that site visits were performed and externally validated data from medical records.

Finally, it was a strength that the control group also showed improved service delivery and compliance after their 1-year implementation, when they were offered the intervention after the study had ended. In total, 17/18 control groups received the afterwards offered intervention, and their in-group results resembled those of the intervention group; standards compliance went up from 80 to 98%, documentation of risk from 60 to 85%, information/shorter intervention from 39 to 79%, and intensive intervention from 25 to 46%. As in the data for the study, no difference could be seen concerning health status.

Perspectives

Faster implementation of evidence has major implications in healthcare. In terms of the evidence for CHP,

clinical departments and the healthcare system could potentially benefit from the operational program because it accelerates CHP implementation. In research, further investigation of the operational program in non-HPH settings should be undertaken. Also, use of the Fast-IM itself might turn out to accelerate evidence-based practices in other areas than CHP—e.g., new clinical procedures, new organizational improvements, or new technological initiatives or solutions.

A possible reason for the scarcity of RCTs in implementation as opposed to in intervention may be cultural and a result of research traditions, but it could also be that it is difficult to conduct them and recruit for them. Even so, interest does appear to be growing and the need for solid, experimental research and adequate reporting thereof is high [86]. We hope that such future, sizable trials will be able to draw from the learnings related to our operational program.

Conclusion

Compared to usual implementation routines, the operational program improved implementation of CHP by better identification of lifestyle risks, more frequent delivery of CHP services, and higher compliance with standards. No differences in health status of patients or staff were found at the level of clinical departments, and the study was limited by low inclusion of departments and by having the department as the unit of analysis as opposed to individual patients and staff. These issues should be considered carefully in strategic implementation efforts and in designing new randomized studies.

Additional file

Additional file 1: Project Materials. (PDF 426 kb)

Abbreviations

CHP: Clinical health promotion; Fast-IM: The fast-track implementation model for clinical health promotion; HPH: International Network of Health Promoting Hospitals and Health Services; MCS: Mental component score (of SF36v2); PCS: Physical component score (of SF36v2); PDCA-cycle: Plan-Do-Check-Act Cycle for Quality Improvement; SF36v2: Short-Form 36 health questionnaire (version 2); WHO: World Health Organization; WHO-CC Denmark: WHO Collaborating Centre for Evidence-based Health Promotion in Hospitals and Health Services; WHO-CC Sweden: WHO Collaborating Centre for Implementation of Evidence-based Clinical Health Promotion

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Availability of data and materials

The data analyzed are not publicly available due to legal agreements with the participating departments but are available from the corresponding author on reasonable request.

Authors' contributions

JKS, project leader and PhD student, drafted the manuscript. HT, principal investigator and supervisor for PhD study, devised the initial hypothesis and protocol. OG was the project advisor. STC was the co-supervisor for the PhD study. STC, MK, MZB, IF, TH, JF, YA, and MØA were responsible for the data collection. All authors revised and approved the final manuscript.

Ethics approval and consent to participate

All data were anonymized at the source, and no person-identifiable information was recorded or transferred. The study included no biological material. The anonymized data were stored and secured by Capital Region Denmark CIMT. Paper records were maintained under double lock. Only the international research team had access to all data. The study was approved by the Internal Review Board of Bispebjerg-Frederiksberg Hospital, University of Copenhagen, Denmark, and by the Danish Data Protection Agency (j.nr. 2012-41-0152 / 2017-41-5029). All participating departments had local approval from their internal review body, department head, and hospital management. Participation in the study was not associated with any risks. The time required to complete forms and surveys was considered a minor inconvenience.

Consent for publication

All participating clinical departments that delivered data obtained local approval from their internal review body, approval from the head of the department, and from the hospital management. Consent from individual patients or staff was not required as no person-identifiable data was captured at any point.

Competing interests

All authors completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare that they have no competing interest for the submitted work.

Publisher's Note

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【 CASE REPORT 】

Extended-spectrum Beta-lactamase-producing *Escherichia coli* Meningitis That Developed from Otitis Media with Cholesteatoma

Motofumi Tosa, Masako Aihara and Junko Murakami

Abstract:
A 78-year-old man had a fever and exhibited disordered consciousness, which led to his transportation to our hospital. On arrival, he exhibited discharge from the ear. Because extended-spectrum beta-lactamase (ESBL)-producing *Escherichia coli* was detected in the ear discharge and cerebrospinal fluid specimens, it was inferred to be the causal bacteria. Pulsed-field gel electrophoresis indicated the same ESBL-producing *E. coli* pattern in the patient's ear discharge, external auditory canal granulation, cerebrospinal fluid, and stool, indicating their common molecular epidemiological origin. Although ESBL-producing *E. coli* is an extremely rare cause of bacterial meningitis, it should be considered as a potential causal bacteria for community-acquired meningitis.

Key words: bacterial meningitis, ESBL-producing *E. coli*, otitis media with cholesteatoma

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Introduction

Bacterial meningitis is a bacterial infection of the brain as well as the arachnoid and pia mater surrounding the spinal cord. Its main characteristics are a sudden onset, headache, and fever; it is indicated by the proliferation of cells in the cerebrospinal fluid with polymorphonuclear cell predominance. Because early treatment has a major impact on the patient's outcome, it is considered a neurological emergency.

Extended-spectrum beta-lactamase (ESBL) is an enzyme that breaks down most beta-lactamase antibiotics, including penicillin, cephem, and monobactam. Infection-causing ESBL-producing bacteria are associated with a poor patient outcome (1). Although ESBL-producing bacteria were previously considered responsible for mainly nosocomial infections, in recent years, community-acquired infections have also been reported, and this has led to concern that the frequency of such cases may increase in the future.

In this study, we report a case of an elderly man with community-acquired bacterial meningitis induced by the direct infiltration of otitis media with cholesteatoma caused by ESBL-producing *Escherichia coli*.

Case Report

The patient was a 78-year-old man with chief complaints of a fever and disordered consciousness. He had a medical history of atrial fibrillation and otitis media and no significant family history. He had been smoking 5-6 cigarettes/day for over 50 years, occasionally consumed alcoholic beverages, and was able to live independently.

One month prior to hospital admission, the patient noticed subjective symptoms of unsteadiness when standing and moving. After noticing difficulty in hearing from the right ear, the patient was diagnosed with right otitis media with cholesteatoma (7 days before admission) at the Department of Otorhinology of our hospital and scheduled for surgery at the Department of Otorhinology at another hospital. Antibiotic ear drops were prescribed, but not antibiotic internal medications. At approximately 1 AM on the day of hospitalization, he developed a fever of 39℃ and suffered urinary incontinence. Consequently, he was transported to the emergency department of our hospital because of a reduced re-

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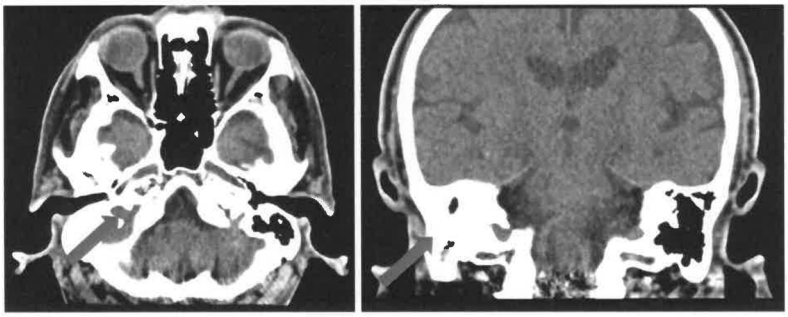

Figure 1. Head CT performed on admission shows poor pneumatization of the right mastoid cells and a shadow in the soft tissue from the right epitympanum to the middle ear.

sponsiveness to questions. He had not complained of any symptoms of headache or earache.

The general characteristics of the patient noted at the time of admission were as follows: height, 165 cm; weight, 56 kg; blood pressure, 145/65 mmHg; heart rate, 111 bpm and irregular; and temperature, 37.5℃. Although the general findings included no thoracoabdominal abnormalities, discharge from the right ear was observed as well as a mass with scabbing on the upper posterior of the right external auditory canal. The neurological findings were a Glasgow Coma Scale (GCS) of E2V3M3, dull responses, and urinary incontinence. No neurological abnormalities were observed in the reflexes or sensory system. However, the cranial nervous system was difficult to evaluate in detail due to the patient's disturbance of consciousness. The meningeal irritation sign of stiff neck and Kernig's sign were also observed.

Blood tests indicated a white blood cell count of 11,930/μL, C-reactive protein level of 5.00 mg/dL, and creatinine level of 1.13 mg/dL as well as a slightly elevated inflammatory response and renal dysfunction. A cerebrospinal fluid examination indicated an opening pressure of 250 mmH_2O, cell count of 656/μL (polymorphonuclear leukocytes, 64%), protein at 302 mg/dL, and cerebrospinal fluid glucose at 45 mg/dL (blood glucose, 145 mg/dL).

Electrocardiography indicated atrial fibrillation. Chest radiography findings were normal. Plain computed tomography (CT) of the chest, abdomen, and pelvis indicated no abnormal findings indicating the source of the fever.

Although CT of the head showed no notable abnormalities, the right mastoid cells had poor pneumatization, and there was a shadow in the soft tissue from the right epitympanum to the middle ear (Fig. 1). Magnetic resonance imaging of the head indicated slight cerebral atrophy, but there were no clear intracranial structural disorders.

Owing to the presence of stiff neck and the cerebrospinal fluid findings, such as protein of 302 mg/dL, cerebrospinal fluid glucose of 45 mg/dL (blood glucose, 145 mg/dL), cell count of 656/μL (neutrophils, 64%), and proliferation of cells with polymorphonuclear cell dominance, we concluded that there was a high probability of bacterial meningitis. This patient was above the age of 50 and was not a compromised host, with no recent history of brain surgery.

In accordance with the 2014 Japanese Guidelines for the Clinical Management of Bacterial Meningitis, we started the patient on initial treatment with a regimen of ceftriaxone sodium hydrate (CTRX) at 4 g/day while monitoring the renal function, ampicillin hydrate (ABPC) at 8 g/day, vancomycin hydrochloride (VCM) at 1.5 g/day, and dexamethasone sodium phosphate at 39.6 mg/day. In addition, irrigation of the ear was also simultaneously performed over several days by the Department of Otorhinology.

His fever subsided on day 2 of hospitalization and his consciousness also improved. However, on the same day, the results of ear discharge culture performed seven days prior to hospitalization indicated *Pseudomonas aeruginosa*; the patient's medication was therefore switched from CTRX to ceftazidime hydrate (CAZ) at 6 g/day. Dexamethasone sodium phosphate was discontinued after four days. On day 4 of hospitalization, ESBL-producing *E. coli* was identified in the ear discharge culture performed seven days prior to hospitalization as well as in all of the cultures performed at hospitalization for cerebrospinal fluid, ear discharge, external ear canal granulation, and stool, so the antibiotics were again switched to meropenem hydrate (MEPM) at 6 g/day and amikacin sulfate (AMK) at 800 mg/day. *P. aeruginosa* was not identified from the cerebrospinal fluid but was identified in the ear discharge culture performed at hospitalization and seven days prior to it.

Given that the blood culture performed prior to the antibiotic administration had been negative, we suspected that ESBL-producing *E. coli* had entered the ear from the stool, and the subsequent otitis media caused meningitis via direct infiltration. As the signs of ear infection began to subside on day 10 of hospitalization, ear irrigation was switched to once a week. The AMK dose was adjusted based on the renal function and blood drug concentration and was administered with MEPM until day 34 of hospitalization. Over the course of hospitalization, the patient's fever, disordered consciousness, and clinical symptoms improved. The final cerebrospinal fluid cell count was 6/μL, and as there were no

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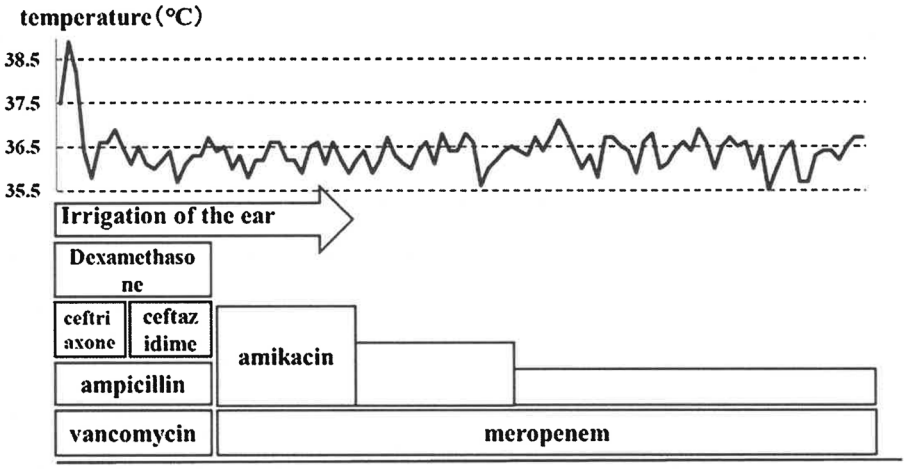

Laboratory findings						
days	1	2	7	14	21	29
WBC(/μL)	11,930	18,220	11,410	10,510	5,990	5,050
CRP（mg/dL）	5	10.61	0.51	0.54	0.24	0.22
cell count（/μL）	656	415	30	16	9	6
CSF/serum sugar	0.31	0.49	0.62	0.56	0.6	0.64

Figure 2. **The patient's clinical course.**

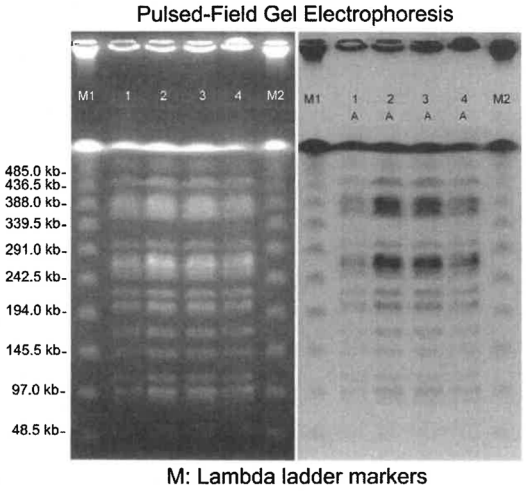

Figure 3. **Pulsed-field gel electrophoresis (PFGE). 1: Cerebrospinal fluid, 2: Ear discharge, 3: External ear canal granulation, 4: Stool. All four specimens had the same type A PFGE pattern.**

notable sequelae, the patient was discharged on day 35 of hospitalization. After discharge, he was admitted to the Department of Otorhinology at another hospital for the previously scheduled surgery (Fig. 2).

To identify the infection route, the patient's cerebrospinal fluid, ear discharge, external ear canal granulation, and stool samples were assessed using pulsed-field gel electrophoresis. The results indicated that all four samples had a type A pulsed-field gel electrophoresis pattern, indicating that all four samples were from the same molecular epidemiological source (Fig. 3).

Discussion

In 1983, Knothe et al. reported that the Friedländer bacillus and other bacteria were resistant to cefotaxime (CTX) and other third-generation cephem antibiotics (2). This was the first report on ESBL-producing bacteria. ESBL is a generic name for a group of beta-lactamases with wide substrate specificity that arises from a spontaneous mutation in the class A beta-lactamase-producing gene; these beta-lactamases have the ability to hydrolyze CTX, ceftazidime, aztreonam, and other cephem antibiotics as well as monobactam antibiotics (3). Beta-lactamase genotypes include TEM, SHV, CMY, GES, OXA, and CTM-M, which are further categorized into a large number of subtypes. Because ESBL genes are located on plasmids, they may be horizontally transmitted to other Gram-negative bacilli strains aside from *E. coli*. In addition, because they are liable to become resistant to multiple drugs, they represent a major risk factor for infection (4). ESBL-producing bacteria seem to be the cause of multiple drug-resistant infections that can prolong hospitalization and increase the cost of treatment (1). In Europe, ESBL-producing bacteria are frequently detected, often in patients in the intensive-care unit (ICU), indicating that they are serious causal agents of nosocomial infections.

The risk factors for ESBL-producing bacteria include intubation and artificial respiration, a period of admission in

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Table. Previous Reports of Meningitis Caused by Extended-spectrum Beta-lactamase (ESBL)-producing *Escherichia Coli*.

Case (Ref.no.)	Year	Country	Age	Infectious pattern	Background	ESBL-type	Antibiotic treatment	Outcome
(11)	2006	Algeria	Child	Nosocomial	No information	CTX-M-15	No information	Cured
(11)	2006	Algeria	Child	Community	No information	CTX-M-15	No information	Cured
(12)	2008	France	Child	Nosocomial	Very low birth weight infant	CTX-M-15	Ceftazidime, vancomycin, netilmicin	Died
(13)	2008	Japan	Adult	Nosocomial	Immunocompromised	Not determined	Meropenem	Cured
(14)	2010	France	Child	Nosocomial	Very low birth weight infant	TEM-52	Imipenem, gentamicin, ciprofloxacin	Cured
(15)	2010	Brazil	Child	Undescribed	No information	CTX-M-2	No information	Died
(16)	2011	Thailand	Child	Nosocomial	Infected cephal hematoma	Not determined	Meropenem	Cured
(7)	2011	Japan	Adult	Community	Diabetes mellitus	Not determined	Meropenem, cefotaxime, gentamicin, levofloxacin	Cured
(8)	2012	France	Adult	Community	Alcoholism, aortic mycotic aneurisms	Not determined	Meropenem, ciprofloxacin	Meningitis cured, died during surgery
(9)	2012	Turkey	Adult	Community	Chronic otitis media, cranialsurgery, cerebrospinal fluid fistula	CTX-M-15	Meropenem, amikacin	Cured
(17)	2012	Thailand	Child	Community	Multiple anomalies of ophthalmic dermoid tumor, cleft lip, cleftpalate, polydactyly, bifid vertebra, and right ear pinna anomalies	Not determined	Meropenem	Cured
(18)	2012	Japan	Child	Nosocomial	Low birth weight infant	Not determined	Meropenem	Cured
(19)	2013	Japan	Child	Nosocomial	Normal	CTX-M-1, TEM	Meropenem	Cured
(20)	2014	Japan	Child	Nosocomial	Low birth weight infant	Not determined	Carbapenem series	Cured
(21)	2015	Canada	Adult	Nosocomial	Ventriculitis after aneurysm clipping	Not determined	Meropenem, gentamicin	Cured
(22)	2016	Japan	Adult	Nosocomial	Immunocompromised	Not determined	No information	Cured
(10)	2016	Japan	Adult	Community	After myocardial infarction	CTX-M-9, TEM	Meropenem	Cured
Present case	2016	Japan	Adult	Community	Serous otitis media	Not determined	Meropenem, amikacin	Cured

the ICU, all types of catheter usage, frequent antibiotic usage, and a severe illness. However, in recent years, some studies have reported that ESBL-producing bacteria have also been identified among community-acquired infection-causing bacteria (3, 5-10).

To our knowledge, there have been only 17 reported cases of meningitis caused by ESBL-producing bacteria, particularly ESBL-producing *E. coli* (Table) (7-22). Although 10 cases were reported in children (11, 12, 14-20), only 7 have been reported in adults (7-10, 13, 21, 22), among which 4 were community-acquired cases, as in the present case (7-10). Genetic testing of ESBL was also conducted in eight cases (9-12, 14, 15, 19).

The detection rate of ESBL-producing bacteria varies by region and institution. A multinational survey reported that 34.5% of Gram-negative bacilli were ESBL-producing bacteria (23). The major risk factors for community-acquired *E. coli* meningitis are alcoholism, cirrhosis of the liver, malignant tumor, diabetes, and the use of immunosuppressants. Nosocomial *E. coli* meningitis often occurs in patients following brain surgery and is resistant to multiple drugs in many cases (8). Rodríguez-Baño et al. reported that the risk factors for community-acquired infection due to ESBL-producing bacteria are diabetes, advanced age (≥60 years), female gender, repeated urinary tract infection, a history of invasive procedures performed in the urinary tract, outpatient care, and the use of antibiotics, such as aminopenicillin, cephalosporin, and fluoroquinolone (24). Yumuk et al. re-

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ported that independent risk factors for community-acquired ESBL-producing *E. coli* (particularly CTM-M type) were fluoroquinolone use, advanced age, and a severe underlying illness (25). However, the only risk factors applicable to the present case were advanced age and outpatient care. Although the present case suffered from atrial fibrillation, he was a healthy elderly individual otherwise. Several case studies of ESBL-producing *E. coli* meningitis have been reported in children, particularly low-birth-weight children (12, 14, 18, 20). However, adults require the presence of certain background circumstances, such as being a compromised patient undergoing immunosuppressant therapy (13, 22), alcoholism (8), diabetes (8), a history of brain surgery (21), or a history of middle ear surgery (9). Therefore, patients, such as the present case, who have few underlying illnesses and who contract community-acquired ESBL-producing *E. coli* meningitis are extremely rare.

Many recent studies have reported an increase in community-based carriers of ESBL-producing bacteria (26). Although the cause of this upsurge is unknown, it has been suggested that healthy individuals' intestines carry bacteria transmitted via food (27). These community-based carriers may bring ESBL-producing bacteria into medical facilities, which then cause hospital transmission and an increase in ESBL-producing bacteria. ESBL-producing *E. coli* carriers account for approximately 10% of all carriers (26-29). In particular, ESBL-producing *E. coli* is often detected in the stool of individuals ≥60 years of age (27). Therefore, in cases such as the present one wherein a patient with community-acquired meningitis had few underlying illnesses and was elderly, the possible involvement of ESBL-producing bacteria should be considered during examinations.

Bacteria usually reach the intraspinal region through one of the following routes: one in which the invasion of bacteremia takes place by the choroid plexus, or one in which the invasion occurs when bacteria cross the blood-brain barrier in other sites. It is important to consider the influence of neighboring organs when attempting to identify the origin of meningitis. Reportedly, 25% of patients with meningitis have a middle ear infection or paranasal sinusitis at the onset of meningitis (30). In the present case, although the bacteria was not identified using the blood culture, both cerebrospinal fluid and ear discharge cultures indicated ESBL-producing *E. coli*, and the pulsed-field gel electrophoresis patterns also indicated that all specimens had the same molecular epidemiological origin. We therefore inferred that the infection route of ESBL-producing *E. coli* was from the stool to the ear and then from a middle ear infection to meningitis via direct infiltration.

Based on experience, in cases of suspected bacterial meningitis, it is necessary to begin antibiotic administration at the point at which the disease is suspected without waiting for the results of bacteria culture procedures. In such cases, the initial antibiotic selection is made on the basis of the results of Gram staining and the patient's history of surgery and immunocompetence. van de Beek et al. (30) reported that the recommended initial antibiotics to be used in cases of community-acquired bacterial meningitis were the combined administration of vancomycin and third-generation cephem antibiotics in patients 16-50 years of age, with the additional use of ampicillin in patients >50 years of age. The treatment guidelines for bacterial meningitis released by the Infectious Diseases Society of America recommend the use of third-generation cephem antibiotics in cases suspected of infection with *E. coli* (31). The antibiotic selection criteria for community-acquired bacterial meningitis listed by this guideline indicate that antibiotics are ineffective in cases such as the present case in which ESBL-producing *E. coli* is present. However, based on the accumulation of reports on bacterial meningitis caused by ESBL-producing *E. coli* in Japan, the 2014 guideline states that carbapenem series are recommended when ESBL-producing bacteria are assumed to be involved.

In conclusion, meningitis caused by Gram-negative bacteria is often associated with poor patient outcomes, so the selection of antibiotics to be used in the initial treatment is an important factor that determines the patient's prognosis (3, 24, 32-34). In cases of community-acquired meningitis in adults and in patients with underlying factors, such as diabetes and exposure to resistant bacteria, the potential infection of ESBL-producing bacteria should be considered, particularly in cases of elderly patients with few underlying factors. In such cases, we believe that it is necessary to consider the use of carbapenem antibiotics as an initial therapy.

The authors state that they have no Conflict of Interest (COI).

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Liver and Pancreatic Sciences

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Research Article

Usefulness and safety of Endoscopic Pancreatic Duct Balloon Dilation (EPDBD) for treatment of pancreatic diseases- pancreatic stone, divisum and pseudocyst

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Abstract

In the 20 years after introducing our original technique-EPDBD (Endoscopic Pancreatic Duct Balloon Dilation) in 1996, we treated 599 cases of pancreas stone, pseudocyst and divisum cases at our hospital by this method. With this procedure, pancreatic stone recurrence rate dropped remarkably, and the success rate of endoscopic pseudocyst and divisum treatments rose dramatically. Complications were moderate pain and light bleeding from the orifice at the time of treatment and slight pancreatitis for several days. This method is very useful and safe, and shows big possibilities for endoscopic treatment of pancreatic diseases.

Introduction

Balloon dilation of choledochus is a popular procedure for bile duct stone treatment. In 1996, we got a hint from this technique, and started our clinical application of pancreatic duct balloon dilation to treat pancreatic diseases [1,2]. The balloon was inserted into the pancreatic duct and dilation of orifice and narrow portion of the duct was done. The objective of this was to

1. ease the discharge of pancreatic stones by expanding the narrow pancreatic duct
2. facilitate the placement of a stent after stone removal
3. suppress stone recurrence by expanding the narrow duct (Table 1).

We then expanded the indication to non-calcified divisum and non-calcified pseudocyst complicated with narrow duct.

In this article, we would like to point out the indications and precise method of this treatment as well as its limitations (Although some cases may overlap, we will examine EPDBD cases in order of pancreatic stone, pseudocyst, and divisum cases).

EPDBD for pancreatic stones

Of the 630 cases of pancreatic stone disease that we experienced over the last 27 years, 588 cases received medical treatment (Table 2). The breakdown of the treatment was as follows: 50 cases of ESWL alone, 90 cases of endoscopy alone, and 448 cases of ESWL + endoscopy. EPDBD was conducted in a total of 538 cases. (via major papilla 445 cases, via minor papilla 93 cases) The purpose of EPDBD in pancreatic disease is shown in table 1. EPDBD is normally performed after EPST of major papilla, but when the Wirsung duct is markedly bent or constricted due to inflammation, or in cases of stone impaction in Wirsung duct, in cases of divisum (complete, incomplete), treatment was performed via the minor papilla.

The balloon dilation catheter that we used (Rapid Exchange Dilatation Balloon catheter 6 mm diameter-Boston Scientific) is extremely useful in that it has a breakthrough strength equivalent to that of the Soehendra type dilation catheter. Gradually the pressure was increased to 6 atmospheres in the papillary part and stenotic pancreatic duct and dilation was performed for one minute multiple times. In our hospital by medical treatment, the percentage of stone disappearance was 75.3% and the rate of pain disappearance was 97.1%, like results reported by other authors. The stone recurrence rate, however, was 5.6%, lower than other reports, thought to be the effect of EPDBD [3,4] (Table 3).

As for complications, there was only some pain and light bleeding at the time of treatment, with the former able to be treated with pain relievers such as pentazocine. Several days after treatment, symptoms of pancreatitis improved with conservative treatment.

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Key words: *Endoscopic Pancreatic Duct Balloon Dilation-EPDBD, pancreatic stone, chronic pancreatitis, pseudocyst, divisum*

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Table 1. EPDBD for Pancreatic disease

Objectives	1. To ease the discharge of stones by expanding the narrow duct 2. Facilitate the placement of a stent after stone removal 3. Supress stone recurrence by expanding the narrow duct 4. To rise the success rate of pseudocyst drainage 5. To rise the success rate of treatment via minor papilla
Indications	1. Pancreatic stone which has duct stricture 2. Pseudocyst which has connecting branch with pancreatic duct 3. Divisum and Wirsung duct obstructed case
Methods	Balloon dilation of orifice and duct stricture in 6 atm., 1 minute, multiple times, then EPS placement

Table 2. 630 cases of pancreatolithiasis in 25 years

Subject		**Total (5-94 Y/O, mean 55)**	**Male (n=514)**	**Female (n=116)**
Disease	Alcoholic	493	452	41
	Idiopathic	77	32	45
	Hereditary	12	6	6
	Hyperparathyroid	16	8	8
	Maljunc. Of p-b	6	1	5
	Autoimmune	7	5	2
	Divisum	12	8	4
	Juvenile	4	1	3
	Post ope of PD, EMR	3	1	2
Treatment	No therapy without symptoms	39	-	-
	Primary operation	3	-	-
	Endoscopy alone	90	-	-
	ESWL alone	50	-	-
	ESWL + Endoscopy	448	-	-

Table 3. Effect of Medical treatment (ESWL and/or Endoscopy)

Stone free	75.3%	443/588
Pain free	97.1%	528/544
Stone relapse	5.6%	25/443
Ope. After medical treatment	2.7%	16/588
Stone relapse (25 cases)		
Alcoholic	19	-
Idiopathic	4	-
Hereditary	2	-
Asymptomatic no therapy	4	-
Re-treatment medically	19	-
Operation	2	-

Pancreas stone treatment-case presentations

Case 1

A 22-year-old male with idiopathic chronic pancreatitis and pancreatic stones (the first implementation of EPDBD at our hospital) with epigastric pain prompting was hospitalized. We performed ESWL several times on large stones in the duct, but small stones remained. Not able to remove the stones and with severe pain continuing, EPDBD was performed under good informed consent (Figure 1). When the papilla and head duct of the pancreas were dilated several times at 6atm for 1 minute, a mechanical crushing tool (ML) could easily be inserted into the pancreatic duct from the open papilla orifice and the stones were crushed and removed easily. Pain improved promptly after treatment and no complications were observed. The patient has been pain-free without restenosis or stone recurrence for 20 years till now.

Case 2

A 72-year-old male with chronic alcoholic pancreatitis and pancreatic stones. Hospitalized with abdominal pains, the patient was found to have a 5-mm stone impacted in the head duct. After EPST of the papilla, EPDBD was performed and the stone easily extracted (Figure 2).

Case 3

A 70-year-old male with alcoholic chronic pancreatitis and pancreatic stones. After ESWL with the Wirsung-duct occluded due to stone impaction, EPST and EPDBD of minor papilla were performed and stone fragments were removed easily via minor papilla (Figure 3).

EPDBD for pseudocyst and abscess

Endoscopic procedure via duodenal papilla (ENPD, EPS) is the treatment of first choice at our hospital with percutaneous or trans gastric-wall drainage as necessary. When good ERP showed traffic between the cysts and the pancreatic duct, a guide wire was inserted into cysts beyond the constricted section and after EPDBD of the stricture, ENPD or long EPS was placed (Figure 4). Of the 152 cases in which this method was attempted, the above treatment was possible in 111 cases with a high rate of placement and effective cyst drainage. The possibility of endoscopic treatment of pseudocysts has been greatly expanded by this method [5,6].

Pancreas pseudocyst treatment-case presentations

Case 4

A 29-year-old female with chronic alcoholic pancreatitis and pancreatic stones was hospitalized with fever, abdominal pain and dyspnea due to pancreatic pleural effusion. ERP showed stones impacted in the Wirsung duct, so EPDBD was performed via minor papilla. ENPD was placed beyond the ruptured point and exchanged for EPS one week later (Figure 5).

Case 5

A 56-year-old male with chronic alcoholic chronic pancreatitis and pseudocysts. The patient was hospitalized with abdominal pain. ERP showed stricture and pseudocysts. After EPDBD, EPS was placed into the cyst (Figure 6).

Case 6

A 68-year-old male with chronic alcoholic pancreatitis and pseudocysts. Stenotic pancreatic duct in the body was dilated and ENPD-EPS was placed into the cyst (Figure 7).

EPDBD for complete and incomplete divisum

There were 17 cases of divisum (8 complete, 9 incomplete-12 with stones, and 5 stone-free) treated at our hospital. EPDBD was done in 2 cases via the major papilla and 14 cases via the minor papilla respectively, then EPS was placed successfully. One case without symptoms was followed up without therapy.

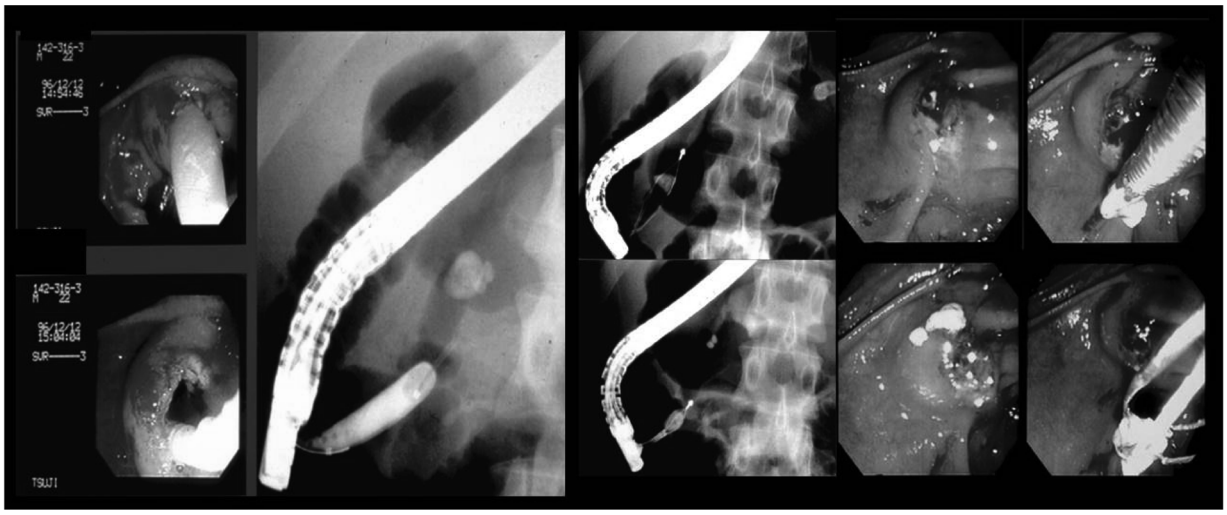

Figure 1. 22 y/o m idiopathic chronic pancreatitis (the first implementation of EPDBD) After EPST, ESWL was done, but fragments could not be removed and severe pain continued. So EPDBD was done (6 atm, 1 minutes, several times). Then stones were removed through opened orifice easily by ML.

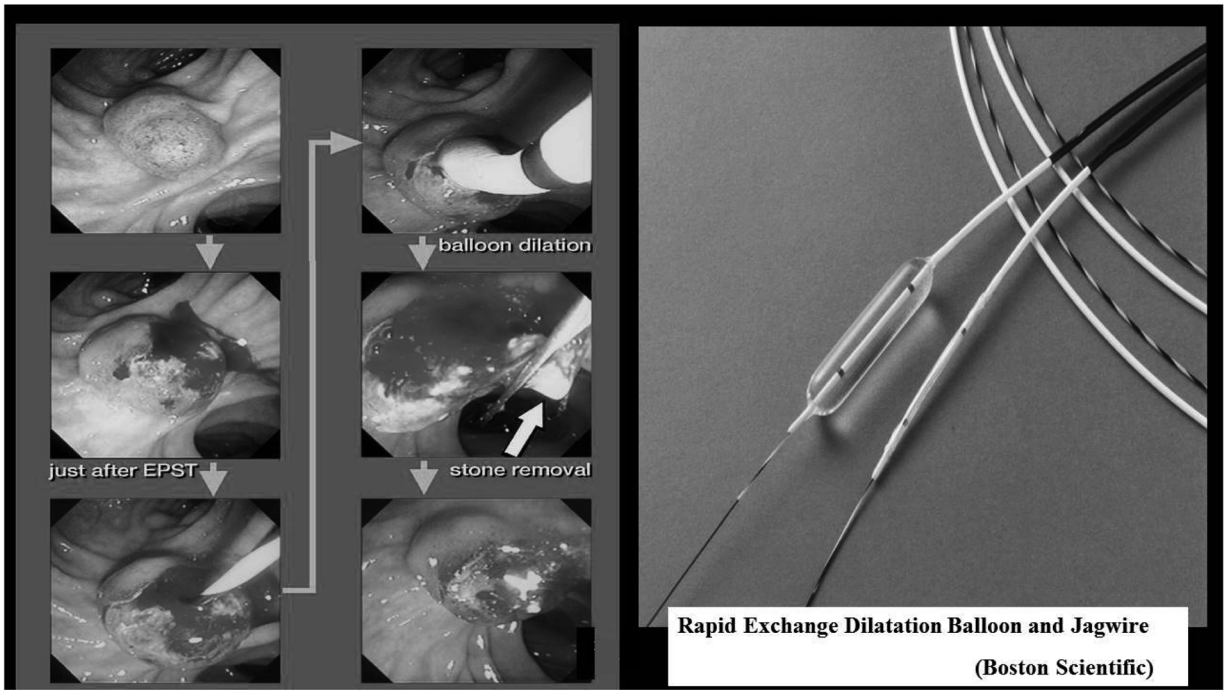

Figure 2. 72 y/o m alcoholic. Small stone (5mm) was impacted in the head duct. After EPST+EPDBD, stone was removed.

Pancreas divisum treatment-case presentations

Case 7

A 72-year-old male with chronic alcoholic pancreatitis, pancreatic stones, and type 2 incomplete divisum [7,8] was hospitalized. A large stone impacted in the Wirsung duct was fragmented by ESWL. Then ERP showed type 2 incomplete divisum. EPST and EPDBD of minor papilla was performed, and stones were expelled (Figure 8-1 and 8-2).

Case 8

A 38-year-old male with pancreatic stones and type 2 incomplete divisum was admitted into the hospital. A guide wire passed through the thin connecting duct between Wirsung and Santorini duct, EPDBD was performed, then stones were expelled and EPS was placed deeply via major papilla (Figure 9).

In endoscopic treating via minor papilla, it is necessary to incise the minor papilla safely [9,10].

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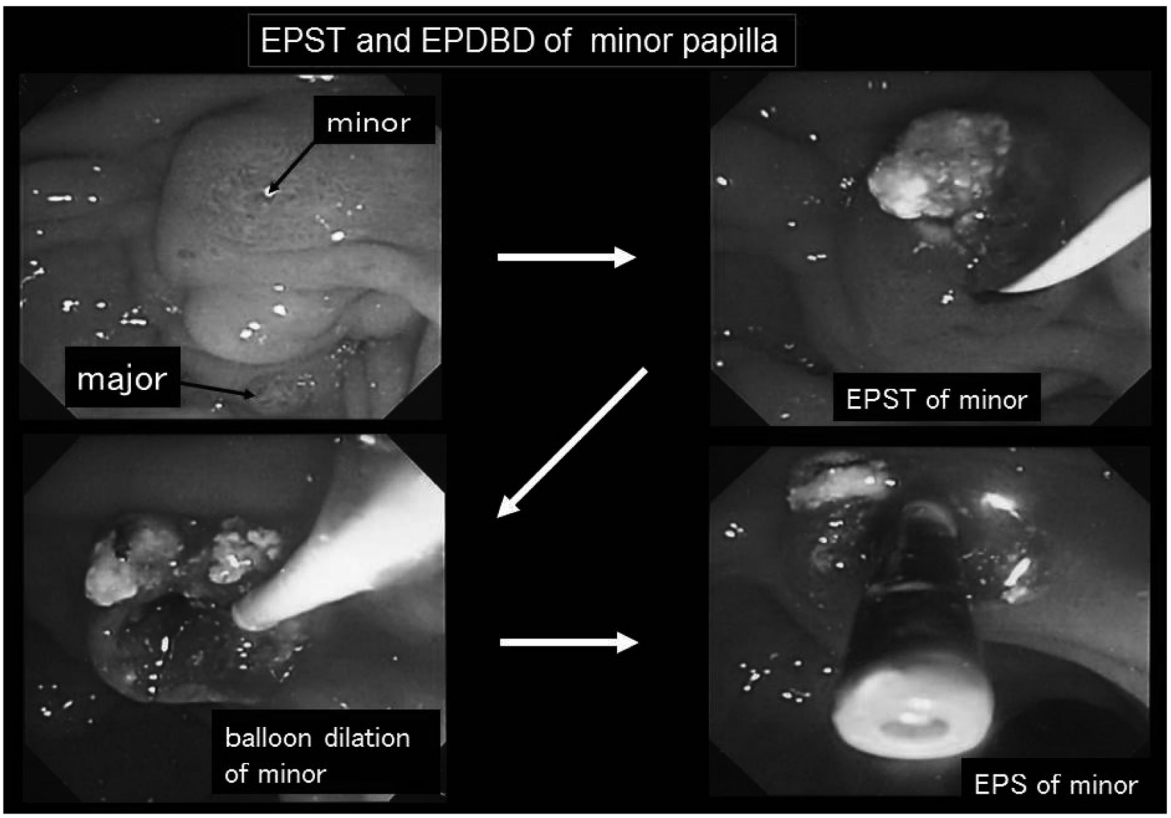

Figure 3. 70 y/o m alcoholic. W-duct was obstructed due to stone impaction, so after EPST and EPDBD stone was removed.

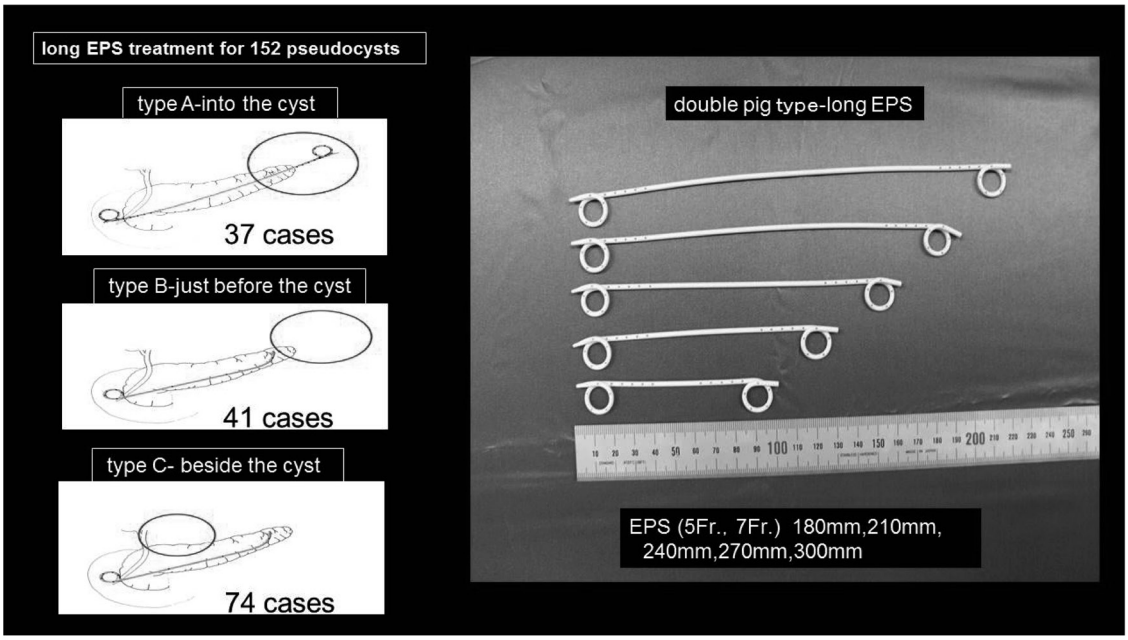

Figure 4. Treatment of pseudocyst. (A) into the cyst. (B) just before the cyst (C) beside the cyst

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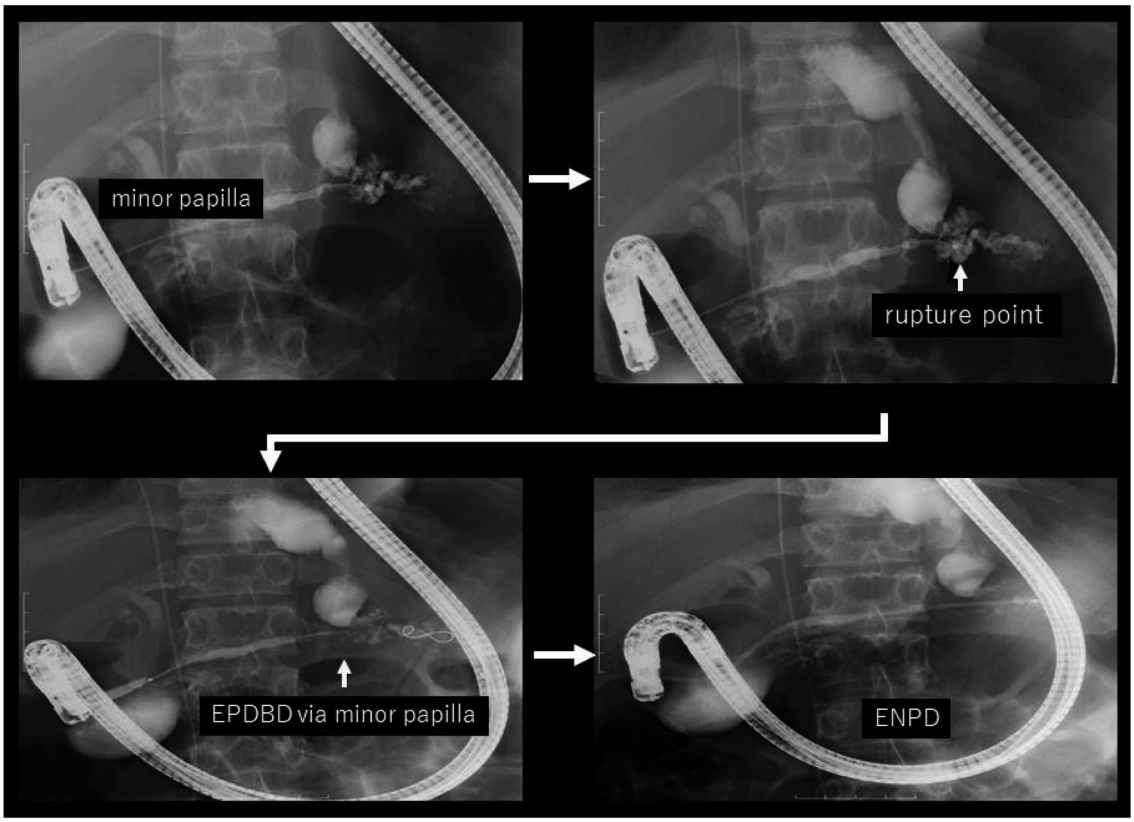

Figure 5. 29 y/o f alcoholic. W-duct was obstructed due to stone impaction, so ENPD and long EPS were placed beyond the rupture point via minor papilla.

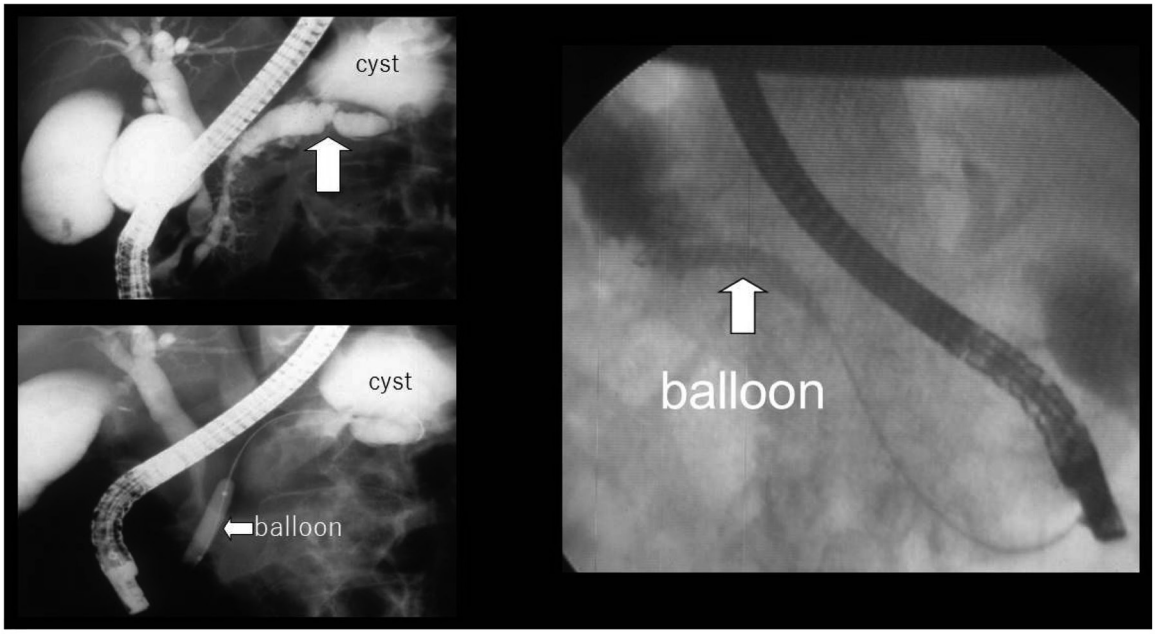

Figure 6. EPDBD of the narrowed duct in body.

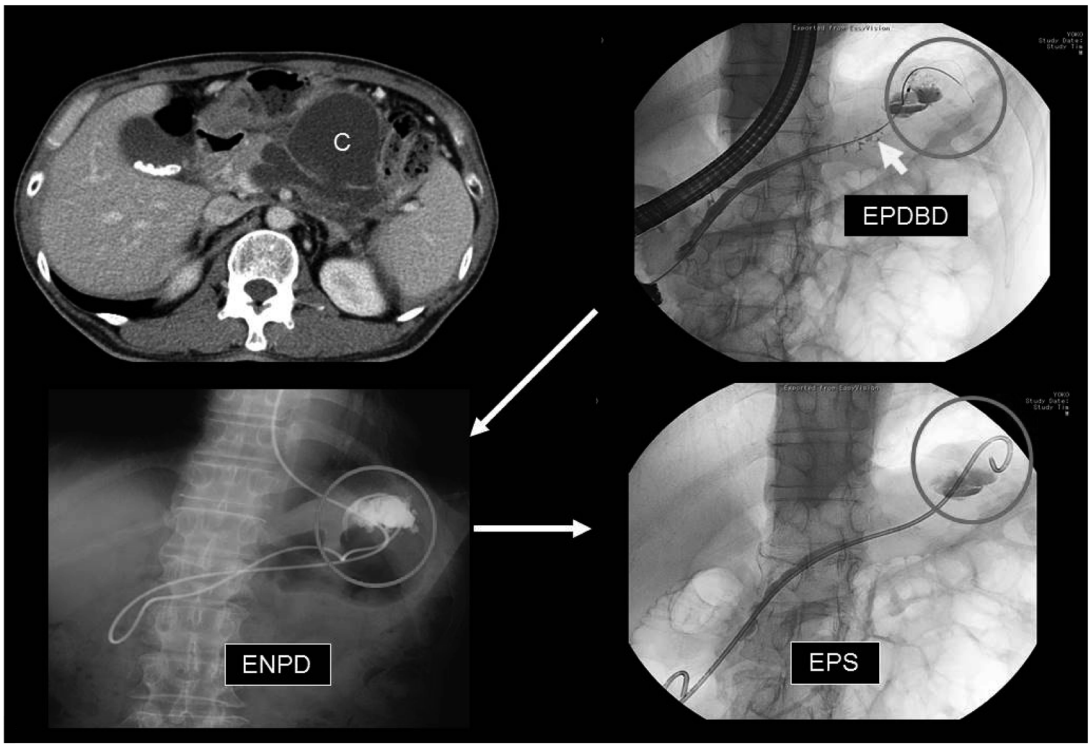

Figure 7. Treatment of pseudocyst by EPDBD+ long EPS. After dilation of the stricture, long EPS was placed into the cyst.

Discussions and conclusions

We introduced EPDBD (Endoscopic Pancreatic Duct Balloon Dilation) therapy in 1996. Dilation of the main pancreatic duct in the major papilla and head was performed, initially with the aim of improving the effectiveness of pancreatic stone removal. It became clear that in repeated cases, the therapy contributed to improvement in pain reduction and decreased recurrence rate. Since then we have gradually expanded its indications and use it to treat non-calcified divisum via minor papilla as well as perform drainage of pseudocyst. A total of 599 cases (538 cases of pancreatic stone, 56 cases of non-calcified pseudocyst, and 5 cases of non-calcified divisum) have been treated with this method. As for complications, some pain and slight bleeding as well as symptoms of pancreatitis were observed after therapy, but all improved with conservative treatment promptly.

According to reports from other authors, the balloons used in EPDBD had diameters of 4mm, 6mm, and 8mm with the purpose of dilation being stent pretreatment, aiding in stone removal, prevention of stone recurrence, improving the flow of pancreatic juice, easy insertion of treatment tools, increasing the stone-free rate, and reducing the rate of recurrence. Regarding dilation time and pressure, procedures at 3-6 atmospheres, or 1-2 minutes, continuously for 30 seconds after the notch disappears, 6-10 atmospheres for 1 minute several times until the notch disappears, usually dilating until the notch disappears have also been reported. There are also reports of the notch occasionally not disappearing due to unremoved stones, and in those cases, pressurization above the prescribed pressure should be avoided to prevent pancreatic duct injury. If EPDBD was done when small stones remain in the duct, it sometimes becomes difficult to expel the stone because small stones enter the small branch cavity. The balloon at the time of dilation also sometimes breaks due to sharp residual stones and it becomes necessary to replace the balloon catheter. It is also recommended that EPS should be placed just after EPDBD to prevent re-stenosis [11,12].

In some authors' reports, stone excretion rate with ESWL and endoscopy was 72.6%, disappearance of symptoms was 91.1%, recurrence rate was 22% at 25.1 months later. Excretion rate and symptom disappearance rate results at our hospital were similar but recurrence rate was significantly lower at 5.6%, considered to be an effect of combined EPDBD therapy [13-21]. However, some limitation is that the effect is not permanent; negative effects on the pancreatic duct and parenchyma is unknown; not knowing how much air pressure and time is best; and not having specialized tools available [22-29].

We believe that even in the deep pancreatic duct, if pressure is lowered and care is taken, large tissue damage will not occur. It is not known however, whether the pancreatic duct and pancreatic parenchyma are histopathologically affected, so cautious treatment is required in the future.

Our hospital's objectives, responses, and methods are explained previously. We believe that this method has a huge effect on lowering the recurrence rate of pancreatic stones, rising the success rate of pseudocyst drainage and the treatment via minor papilla. As treatment tools are improved and the above unknown points become clearer in the future, it is expected that this method will further contribute to the endoscopic treatment of pancreatic stones, pseudocysts, and other pancreatic disorders.

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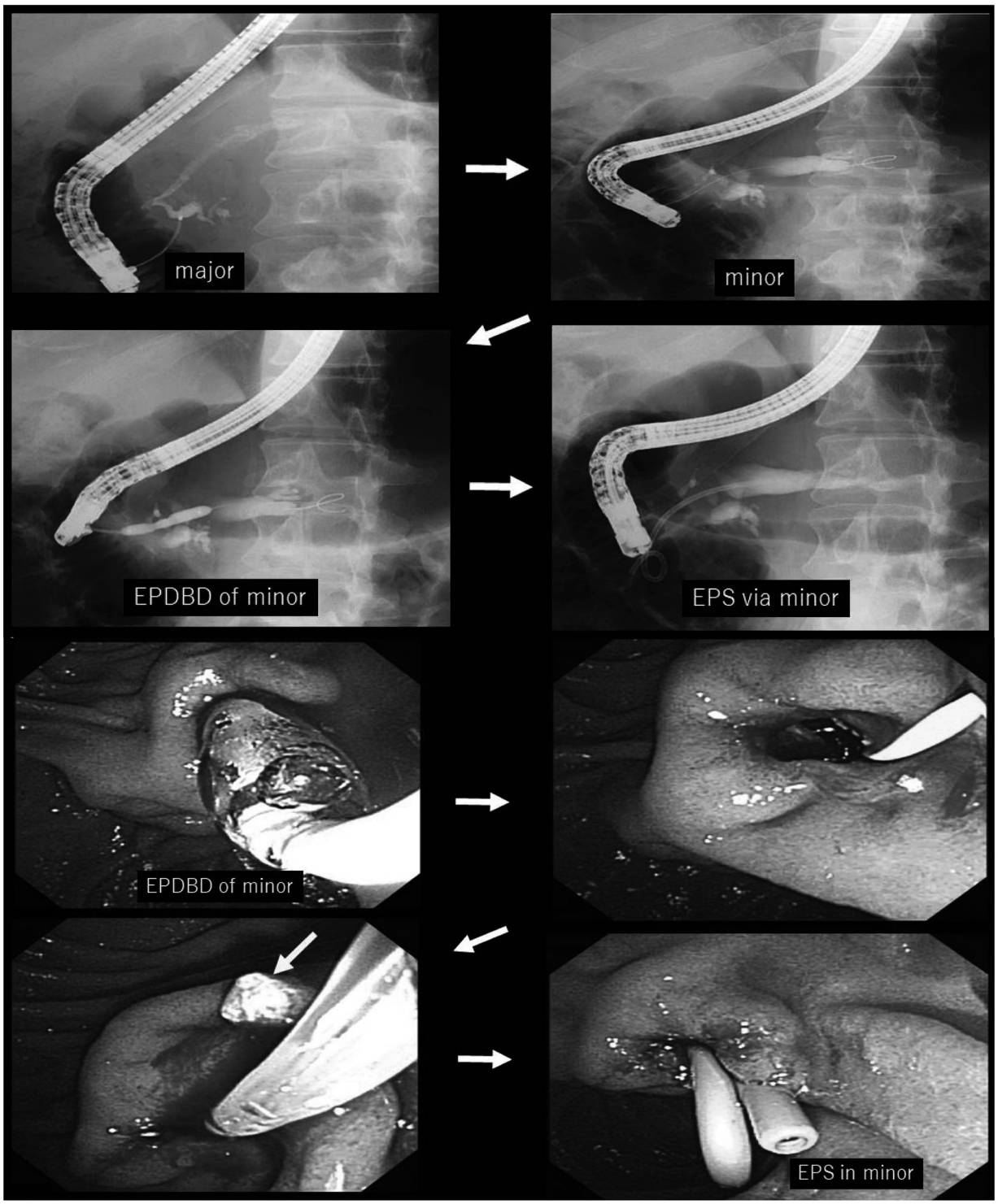

Figure 8. 72 y/o m alcoholic, stone type 2 incomplete divisum. After EPST+EPDBD of minor papilla stones were removed and EPS was placed.

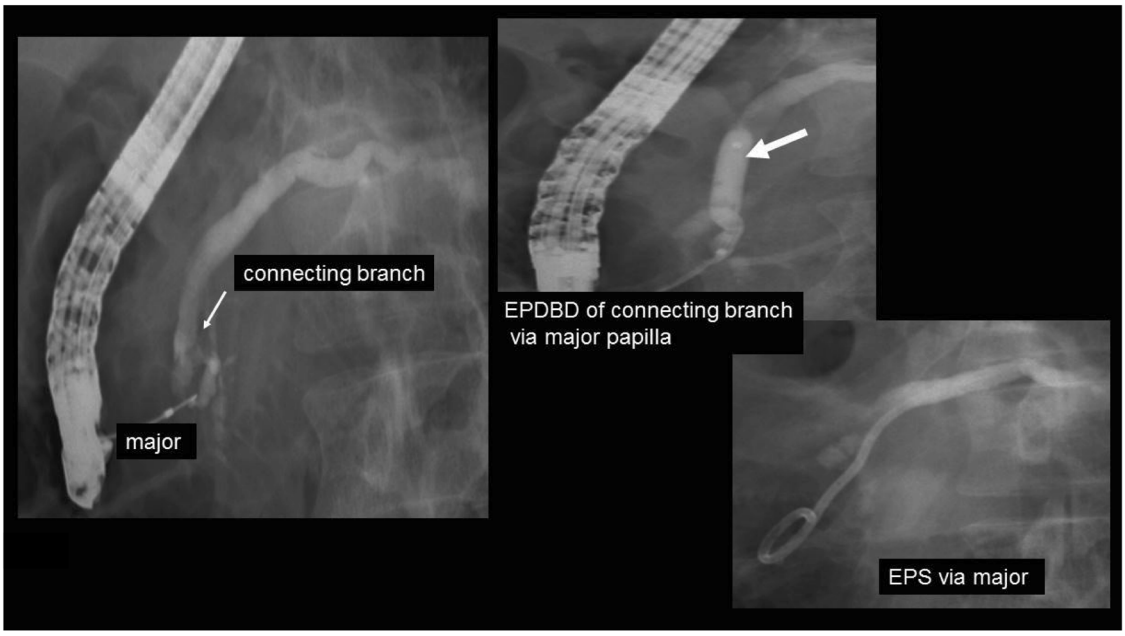

Figure 9. 38 y/o m pancreatic stone, type 2 incomplete divisum. After dilation of connecting branch, EPS was placed via major papilla.

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当院で経験した発症3カ月以内に抗菌薬投与のない *Clostridium difficile* 感染症の2例

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忍　　哲也

【要旨】 *Clostridium difficile* 感染症（以下CDI）は抗菌薬関連腸炎として知られている．当院では2012年1月から2017年10月の間に糞便CD検査法陽性例を209人経験したが，そのうち院内感染例を除くと発症前3カ月以内の抗菌薬使用がないものは2例であった．この2例の共通点は65歳以上の高齢であること，胃酸分泌抑制薬の内服をしていること，それぞれ末期腎不全・アルコール性非代償性肝硬変と糖尿病という重篤な基礎疾患があること　であった．胃酸分泌抑制薬がCDIの発症リスクになるという報告が多数ある．米国からは市中感染例の増加が報告されている．従来考えられているCDIの典型的な背景がなくとも，消化管感染症の鑑別疾患にCDIを挙げるべきと思われた．

【キーワード】 *Clostridium difficile* 感染症，胃酸分泌抑制薬，市中感染

はじめに

Clostridium difficile 感染症（以下CDI）は入院患者における抗菌薬関連腸炎として知られている．しかし抗菌薬使用のみならず高齢，重度の基礎疾患，胃酸分泌抑制薬なども発症の危険因子であると報告されている[1]．CDI発症リスクになり得るのは3カ月以内の抗菌薬使用と言われている[2]が，その期間の抗菌薬投与がない，院外発症のCDIを2例経験したので報告する．

症　例　1

症例：68歳女性．

現病歴：他院で維持透析中であった．2日前の透析後に腹痛が出現し嘔吐を1回認めた．下腹部が張るような痛みが続くため当院を受診した．便秘が疑われ帰宅したが，腹痛が持続し黒っぽい下痢も認めるため3日後に再受診し，急性腸炎の診断で入院した．

既往歴：12年前　高血圧．
11年前　他院腎センター通院開始．
10年前　胆石症　胆嚢摘除術．
8年前　人工透析開始．
2年前　早期胃癌　内視鏡治療　内シャント狭窄　血管形成術．

身体所見：意識清明，血圧123/61mmHg，脈拍92/分・整，体温36.9℃，呼吸数25回/分，身長161.0cm，体重46.0kg．
腹部は平坦・軟であるが全体に圧痛あり，腸蠕動音正常．

生活歴：ADL自立　会社員の夫と同居．
職業　主婦．
喫煙なし　飲酒なし．

内服薬：オルメサルタン，ニフェジピン，ドキサゾシン，アセブトロール塩酸塩，プラバスタチン，ファモチジン，レバミピド，スクロオキシ水酸化鉄，ビキサロマー，沈降炭酸カルシウム，ポリスチレンスルホン酸ナトリウム，ビーマス配合錠®．

入院時血液・便検査結果：白血球22,200/μL，CRP 21.8mg/dLと高度の炎症所見を認めた（**図1**）．

入院後の経過：絶食・セフェム系抗菌薬投与で経過

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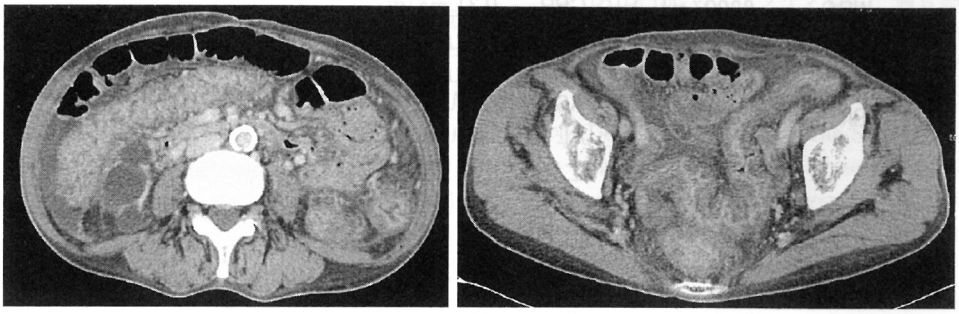
WBC	22200/μl	CRP	21.80 mg/dl	BS	78 mg/dl
RBC	371×10⁴/μl	TP	4.9 g/dl	HbA1c	5.0 %
Hb	11.9 g/dl	Alb	2.6 g/dl		
Plt	13.1×10⁴/μl	AST	10 U/l		
		ALT	11 U/l		
PT	86.8 %	LD	170 U/l		
		ALP	262 IU/l		
		BUN	43.3 mg/dl		
		Cr	7.37 mg/dl		
		Na	136 mEq/l		
		K	4.6 mEq/l	便培養	:異常なし
		Cl	96 mEq/l	血液培養	:異常なし
		CK	67 IU/l		

図1　症例1　血液・便検査所見



結腸壁は全体に肥厚し，少量の腹水を認めた．

図2　症例1　入院5日目のCT検査

をみたが腹痛・水様便が持続し，連日アセトアミノフェンの点滴投与を行った．入院5日目にCTを撮影したところ，結腸全体の著明な壁肥厚・腹水を認めた（**図2**）．

便培養・血液培養では有意な菌の検出はなく，糞便CDトキシンは陰性であったが入院6日目にS状結腸内視鏡検査を行い，偽膜性大腸炎と診断した（**図3**）．バンコマイシンを内服し，症状は軽快した．入院5日目の便嫌気培養では*Clostridium difficile*が検出された．抗菌薬内服歴を確認したが，直近1〜2年間の使用はないとのことであった．

症　例　2

症例：70歳男性．

現病歴：アルコール性肝硬変，糖尿病，前立腺肥大症で通院中であった．3週間前から水様性下痢が出現した．最近では1時間に1回ほどの下痢があり夜も眠れないほどであった．水分摂取はできたが食欲は低下し，生卵などを食べていた．定期診察で下痢を訴え，慢性腎臓病の悪化も認めた．仕事のためその日は帰宅し，2日後に入院した．

既往歴：8年前　健康診断で血糖異常．

5年前　胆嚢摘出術，糖尿病・高血圧治療開始　インスリン導入．糖尿病性網膜症．

4年前　原発性肝細胞癌　ラジオ波焼灼治療．

身体所見：意識清明，血圧120/67mmHg，脈拍63/分，腹部は平坦軟・圧痛なし．

身長163cm，体重65.9kg．

生活歴：ADL自立　妻・息子と暮らす．

職業　鉄工関係．

食事　普段から不規則で1〜2食/日．

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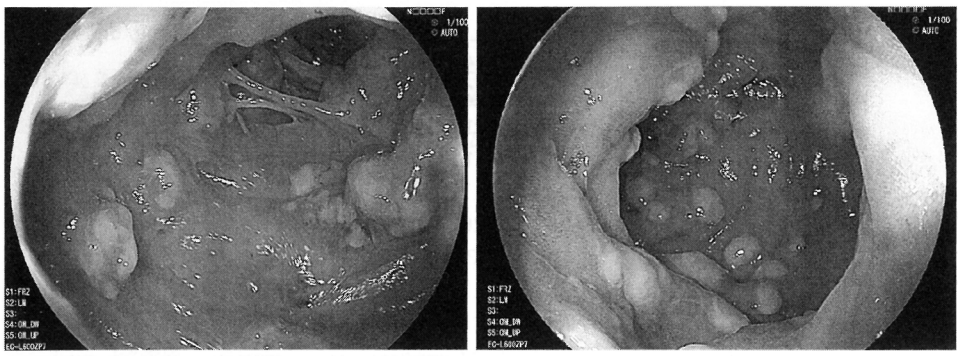

偽膜を認めた.

図3　症例1　S状結腸 内視鏡検査

WBC	6800/μl	CRP	0.31 mg/dl	T-cho	102 mg/dl
RBC	392×10⁴/μl	TP	5.8 g/dl	TG	74 mg/dl
Hb	12.7g/dl	Alb	2.5 g/dl	HDL-cho	60 mg/dl
Plt	16.1×10⁴/μl	AST	29 U/l	LDL-cho	28 mg/dl
		ALT	23 U/l		
PT	86.8 %	γGT	456 U/l	BS	104 mg/dl
		LD	225 IU/l	HbA1c	10.1 %
		BUN	58.0 mg/dl		
		Cr	2.34 mg/dl	NH3	24 μg/dl
		Na	130 mEq/l		
		K	5.2 mEq/l		
		Cl	99 mEq/l		
		UA	8.2 mg/dl		

図4　症例2　血液検査所見

喫煙　3～4年前まで30本/日×45年.

飲酒　1～2合/日.

内服薬：ランソプラゾール，フェブキソスタット，フロセミド，スピロノラクトン，アミノバクト配合顆粒®，シロドシン，タダラフィル，インスリン，グラルギン8単位.

入院時血液検査結果：血液検査では炎症反応は軽度であったが，血清クレアチニン値2.34mg/dLと普段よりも腎機能の低下がみられ，また血糖コントロールも不良であった（**図4**）.

入院後の経過：プロトンポンプ阻害薬によるCollagenous colitisを疑い，同薬剤を中止したところ下痢はやや改善傾向を示したが，糞便CDトキシン陽性でありCDIと診断した．バンコマイシンを内服し，下痢は消失した．抗菌薬使用は4カ月前のレボフロキサシン内服が最後であった.

考　察

当院では2012年1月から2017年10月の間に糞便CD検査法陽性例を209人経験した．発症前3カ月以内の抗菌薬の使用がないものは3例あったが，1例は院内感染と思われることから，それを除く2例を報告した．この2例の共通点は65歳以上の高齢であること，胃酸分泌抑制薬の内服をしていること，それぞれ末期腎不全・アルコール性非代償性肝硬変と糖尿病という重篤な基礎疾患があること　であった.

CDI発症の危険因子として①腸内細菌叢の撹乱②毒素産生性クロストリジウムの獲得③宿主免疫異常が考えられる[3]（**図5**）．腸内細菌叢を乱すものとしては

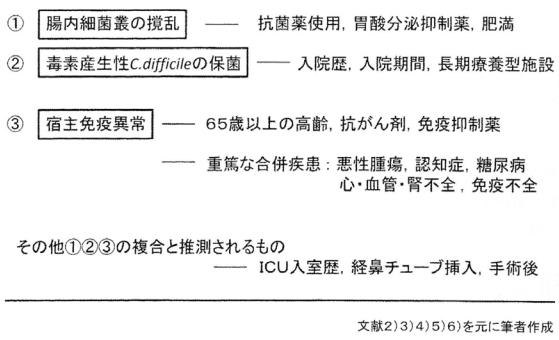

図5　CDI発症の危険因子

最大の危険因子である抗菌薬の使用の他，胃酸分泌抑制薬の使用が挙げられる．また悪性腫瘍・腎不全などの重篤な基礎疾患は宿主の免疫力を低下させると考えられる[4]．JAID/JSCガイドライン2015ではICU入室歴，経鼻チューブ挿入，手術後，肥満なども危険因子に挙げられている[2]．肥満者では腸内細菌叢の多様性が減っていると言われており[5]，腸内細菌叢のうち*Firmicutes*門の比率が増加し*Bacteroidetes*門の比率が低下するとも報告されている[6]．肥満とCDIが関連するメカニズムは明確ではないが，そのような腸内細菌叢の構成異常（dysbiosis）が発症と関連するのかもしれない．

胃酸分泌抑制薬がCDIの発症あるいは再発リスクになるという報告は多数ある[1)7)8)]．規模の大きな研究としては，2012年Kwokらが39研究のメタ解析からPPI使用によりCDIがオッズ比1.74倍増えると述べ，さらにPPIは抗菌薬非使用下であっても独立した危険因子であると述べた報告がある[1]．欧州微生物・感染症学会の指針にも，CDI治療法の一つとしてPPIの必要性を再検討するよう記載されている[4]．一方で，その関連は確定的ではないとする報告も存在する[9]．

CDIは入院中の患者で抗菌薬使用により発症する疾患として知られているが，近年抗菌薬非使用下で12週間以内に入院歴がない市中感染の症例が増加しており注目されている[10]．日本とは医療事情が異なるが，米国では市中感染例が35％との報告がある[11]．

結　語

CDIは入院中かつ抗菌薬投与により発症する場合が典型的であるが，それを逸脱する症例を経験した．胃酸分泌抑制薬とCDIの関連を示す報告も多い．米国からはCDI市中感染例の増加が報告されている．典型的な背景の有無にとらわれず，消化管感染症の場合は常にCDIを鑑別疾患に挙げるべきと思われる．

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特集 高リスク患者の内視鏡

[総論]

妊婦に対する消化器内視鏡診療

増田　剛　　小野未来代

要旨

妊娠中は，X線被曝や内視鏡操作，薬物投与などによる胎児への影響を考慮する必要がある。しかしその一方で，検査を躊躇することで診断が遅れる危険性もあるため，症状をよく観察し，重篤な疾患が疑われるときは積極的に内視鏡などを施行するべきである。妊婦に内視鏡を施行する場合は，妊婦と胎児の安全性が担保されなければならない。適応を検討する際には，①使用薬剤の胎児への影響，②妊娠の安定性の確保，③子宮の物理学的影響，の視点が考慮される必要がある。待機的内視鏡については第2三半期（second trimester：14～27週）に行うことが推奨されている。妊娠中期以降に内視鏡を行う場合は，子宮の増大により消化管の解剖学的位置が変化するために，特に下部消化管内視鏡検査のリスクが高くなることに留意する必要がある。内視鏡の際の薬剤投与については米国食品医薬品局（FDA）の薬剤胎児危険度分類を参考にするとよい。

key words：妊婦，消化器内視鏡，放射線被曝

はじめに

妊娠により消化管の解剖学的変化などが生じ，さまざまな消化器症状を呈する。また，妊娠中はX線被曝や内視鏡操作，薬物投与などによる胎児への影響を考慮し，積極的な検査を躊躇することで診断が遅れる危険性も存在する。妊娠中の消化器内視鏡については，かつては低酸素による胎児への障害，早産，外傷，催奇形性など危険性が指摘されていたが，近年ではその安全性を支持する意見が報告されている[1]。

本稿では，妊娠中に認められる消化器疾患の特徴と，内視鏡を施行する際の留意点について述べる。加えて，自験例の提示を通して，妊娠中の消化器疾患の診断における内視鏡検査とX線使用検査の必要性について考える。

Ⅰ．妊娠中のおもな消化器疾患

1．食道炎

胃酸の逆流により胸やけや食後の胸痛などを認める。原因として，妊娠中は子宮の増大により腹腔内圧が上昇すること，胃内容物の移動速度が遅延すること，食道括約筋の筋力が低下することなどがあげられる。

2．消化性潰瘍

Helicobacter pylori（*H. pylori*）感染や非ステロイド性抗炎症薬（NSAIDs）の内服などが一因で，症状は心窩部痛・食欲不振・胃もたれ・胸やけなどである。多くは制酸剤・ヒスタミンH_2受容体拮抗薬やプロトンポンプ阻害薬（PPI）などの投薬により自覚症状が消失する。プロスタグランジン製剤は子宮収縮作用があり，妊娠中は禁忌である。

3．胃　癌

悪心・嘔吐・上腹部痛などが出現することもあるが特異的なものではない。本邦の妊娠中の胃癌合併頻度は10万人に7人以上と欧米に比べて高率[2]で，ほとんどが*H. pylori*感染によるといわれている。

4．潰瘍性大腸炎

おもな臨床症状は，発熱と持続性または反復性の血便もしくは粘血便である。大腸粘膜および粘膜下層のびまん性非特異的炎症像を呈する。下剤や浣腸により病勢の悪化があるので，原則として前処置は行わず，送気をできるだけ少なくして下部大腸を短時間で観察する。

5．Crohn病

下痢・腹痛が多く，発熱・体重減少・貧血・肛門

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病変による症状を認める。口から肛門までの全消化管に発生する，慢性炎症性疾患である。全層性の炎症で，縦走潰瘍や敷石像など典型的な病変が多いが，アフタ様病変のみの特殊型もある。

6. 虚血性腸炎

もともとの便秘に加え妊娠子宮による腸管の圧迫（腸管内圧の上昇）や，下剤の服用（腸管蠕動の亢進）が要因[3]とされている。また妊娠中は血中エストロゲン値が高くなり，その血栓形成作用により腸管局所の血流が低下し発症する可能性がある[4]。

7. 虫垂炎

妊娠中の急性虫垂炎の頻度は，1,000～2,000人に1人程度と比較的高い[5~7]。重症化しやすく腹膜炎をきたすと流早産や死産の可能性が高くなることが知られている[8, 9]。

8. S状結腸軸捻転

ほとんどが妊娠後期に発症する[10]。機序として過長のS状結腸が増大した子宮により引き上げられ，骨盤に固定された部位で捻転が生じると考えられる[11]。本症は妊娠に合併すると母体死亡率14％[12]，胎児死亡率29％といずれも高く[12]，危険な合併症であると報告されている。

9. 大腸癌

妊娠に合併した大腸癌の発生頻度は10万人の妊婦に対して1～2例[13, 14]で，きわめて稀とされている。実際に大腸癌が診断される時期は妊娠後期が多く，妊娠20週未満で診断される症例は10％に満たない[15]との報告もある。

Ⅱ．妊娠中の内視鏡検査の特徴

近年では経鼻内視鏡や細径内視鏡の普及により，妊婦・施行医ともに検査の認容性は高まっている。鎮痙薬や鎮静薬の使用頻度が低下し，より安全性が向上しているものの，内視鏡が侵襲的な医療行為であることに変わりはない。妊娠中に行う内視鏡で最も重視する点は，当然ながら妊婦と胎児の安全が担保されることである。適応を検討する際には内視鏡を行う確かな理由が存在することが大前提であり，そのうえで，①使用薬剤の胎児への影響，②妊娠の安定性の確保，③子宮の物理学的影響，の視点から適応を考慮する必要がある。

一般的に胎児の体の原器が作られる「器官形成期」である妊娠4～8週は，できれば侵襲的な検査は避けるべきであるが，この時期は本人が妊娠に気づいていないことも多い。待機的に施行可能な状況では，第2三半期（second trimester：14～27週）に行うことが推奨されている[1, 16]が，消化管出血や高度の狭窄，腸管捻転，難治性の下痢や炎症性腸疾患（inflammatory bowel disease：IBD）の悪化，悪性疾患の可能性など，緊急性の高い場合は，インフォームド・コンセントのうえ，慎重かつ積極的に内視鏡を施行すべきである。内視鏡に伴う薬剤については，妊娠中は使用しないことが望ましいが，やむをえず使用する場合は，米国食品医薬品局（FDA）の薬剤胎児危険度分類を参考にカテゴリA，B薬（低用量）については使用できると考える[12, 13]。

妊娠中期以降に内視鏡を行う場合は，子宮の増大により消化管の解剖学的位置が変化するために，特に下部消化管内視鏡のリスクが高くなることに留意する必要がある。

Ⅲ．当院での経験例

2008～2017年の当院における分娩数は5,682症例で，同期間に施行した妊婦に対する上部消化管内視鏡検査は7例，下部消化管内視鏡検査は2例であった。いずれも鎮痙薬や鎮静薬は使用せず，下部内視鏡検査は高圧浣腸のみの前処置で，短時間で愛護的に観察した（**表1**，**表2**）。

上部消化管内視鏡施行例は，いずれも経過観察や内服薬投与で軽快した。症例8では妊娠32週に血便を認め下部消化管内視鏡検査を施行したが，子宮の圧排により病変部まで到達できなかった（**図1**）。産後2日目に頻回の血便と腸閉塞を発症したため緊急内視鏡検査を施行，径40 mmの1型腫瘍を認め，増大した直腸の腫瘤により腸重積を呈していた（**図2**）。産後9日目に腹腔鏡補助下S結腸切除術を施行，高分化腺癌，ly1 v0 壁深達度はpSS，Stage Ⅱであった。術後4年経過した現在，再発を認めていない。

表 1　当院における妊婦の上部内視鏡施行例（2008～2017 年）

症例	妊娠週数	年　代	検査事由	診　断
1	12 週	20 代後半	腹痛・アルコール性慢性膵炎	異常なし
2	14 週	20 代後半	突然の心窩部痛・嘔吐	異常なし
3	16 週	30 代後半	嘔気精査	胃底腺ポリープ
4	18 週	30 代後半	心窩部痛持続・十二指腸潰瘍既往	異常なし
5	23 週	30 代前半	胃痛	裂孔ヘルニア，萎縮性胃炎
6	24 週	20 代前半	嘔吐・吐血	裂孔ヘルニア
7	28 週	40 代前半	持続する胃痛・嘔吐	裂孔ヘルニア，萎縮性胃炎

表 2　当院における妊婦の下部消化器内視鏡施行例（2008～2017 年）

症例	妊娠週数	年　代	検査事由	結果・診断
8	32 週	30 代後半	血便	浣腸のみで S/C まで，子宮の圧排のみ
9	33 週	20 代後半	潰瘍性大腸炎悪化	30 cm まで，軽度～中等度活動性

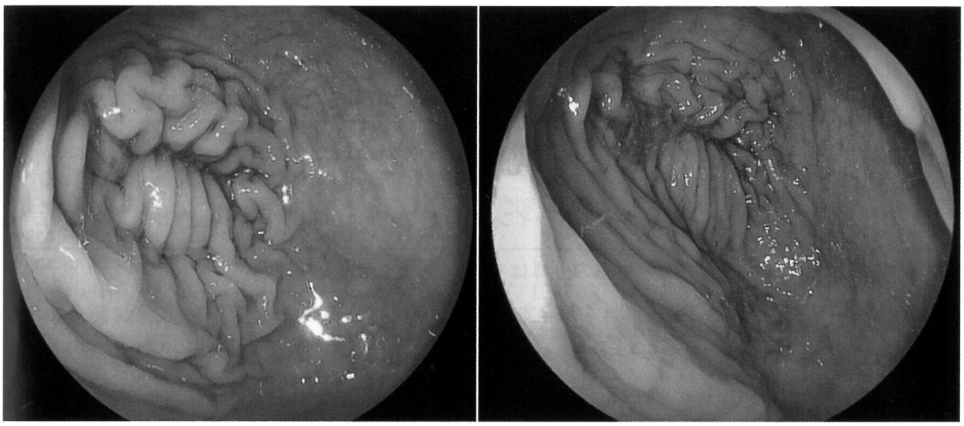

図 1　内視鏡画像（症例 8，妊娠 32 週）
血便を認め大腸内視鏡を施行したが，子宮の圧排で深部に挿入困難

Ⅳ．妊娠中の放射線被曝について

消化器疾患の診断に欠かせない X 線検査の影響についても触れておく。2008～2017 年に当院で 4 例の妊娠合併虫垂炎を経験した（**表 3**）。いずれも診察所見と血液検査，腹部超音波検査などで診断されたが，症例 4 では前回双胎妊娠のため帝王切開の既往があること，腹部症状が強かったことより CT 検査を施行した。症例 2 では腹腔鏡補助下虫垂切除術を，他の 3 症例では開腹下虫垂切除術を施行した。

妊娠中における放射線被曝は最小限にすべきであるが，急性腹症を速やかに診断するためには必ずしも禁忌ではない。実際の日常診療における放射線被曝線量は，胸部単純 X 線で平均 0.01 mGy 以下，腹部単純 X 線で平均 1.4 mGy，腹部 CT 検査では平均 8 mGy と報告されており，単独の検査としては胎児に影響を及ぼすほどの線量ではないといえる（**表 4**）[17]。

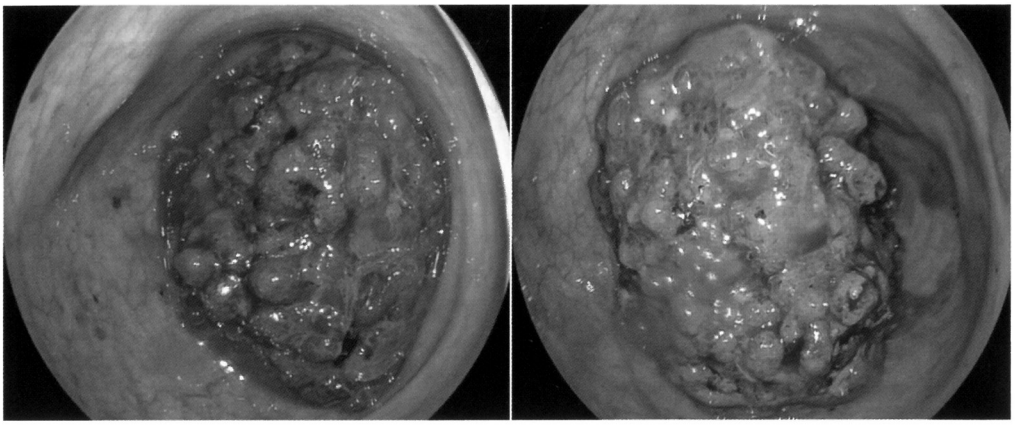

図 2　内視鏡画像（症例 8，産後 2 日目）
血便・腸閉塞あり。緊急大腸内視鏡にて径 40mm の腫瘍を認めた。

表 3　当院における虫垂炎合併妊婦例（2008～2017 年）

症例	妊娠週数	年　代	検査事由	診　断
1	13 週	30 代前半	嘔気・右下腹部痛	蜂巣炎性虫垂炎
2	14 週	20 代後半	心窩部痛・右下腹部痛	カタル性虫垂炎
3	15 週	30 代前半	心窩部痛・右下腹部痛	蜂巣炎性虫垂炎
4	18 週	20 代後半	心窩部痛・右下腹部痛	蜂巣炎性虫垂炎

表 4　「産婦人科診療ガイドライン 産科編 2017」からの抜粋・要約 [17]

・受精後 10 日までの被曝では奇形発生率の上昇はない
・受精後 11 日～妊娠 10 週では催奇形性を誘発する可能性があるが 50 mGy 未満では関連は認められない
・妊娠 9～26 週では中枢神経障害を起こす可能性があるが，100 mGy 未満では影響しない
・10 mGy 程度の被曝で小児癌の発生頻度がわずかに上昇するが，個人レベルでの発癌リスクは低い

おわりに

過去の報告例を検索すると，進行胃癌・進行大腸癌症例の報告が散見される。対象者が比較的若年であり病識に乏しいこと，妊娠中に増加するエストロゲンの腫瘍促進作用や，妊娠の進行に伴う母体の細胞性免疫能の低下，骨盤内血流量増加により癌の発育や遠隔転移が促進されることなどが要因と指摘されている[18]。

1990 年代までは，特に進行胃癌症例の報告が多かったが，検索範囲で近年の新たな報告は少ない。1973 年からの分娩数の漸減と，胃癌ハイリスク群である *H. pylori* 感染者の減少が寄与していると考える。統計上も妊婦の 9 割以上を占める 20～39 歳の年齢層の胃癌罹患者数は著明に減少している。しかし，一方で平均出産年齢の高齢化とともに大腸癌患者数は増加傾向にある（**図 3**）。今後は妊娠に合併した大腸癌症例の存在も念頭において，診療にあたる必要がある。

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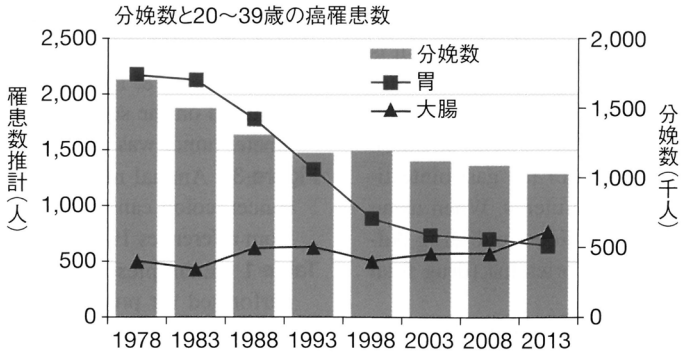

図3　本邦の分娩数と胃癌・大腸癌罹患数の推移

（文献19，20をもとに作成）

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Gastrointestinal Endoscopy for Pregnant Women

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During pregnancy, because of the influence on the fetus of radiation exposure, medication, and endoscopic procedures, etc., there is a risk that diagnosis may be delayed. So even considering the effects of these procedures, there should be no hesitation to perform a timely examination if the presence of severe disease is suspected after good observation of symptoms. When endoscopy is performed during pregnancy, the safety of both mother and fetus should be the highest priority. There are three points to consider before performing endoscopy on a pregnant woman: first, the risks of the drugs for the fetus; second, maintaining a

stable pregnancy, and third, the physical impact on the uterus. If standby endoscopy is required during pregnancy, it is recommended that it be performed in the second trimester of pregnancy (14 to 27 weeks). If endoscopy is required in the third trimester, it is necessary to pay special attention to changes in the anatomical position of the gastrointestinal tract following enlargement of the uterus. When using drugs for endoscopic procedure, the Food and Drug Administration (FDA) Pregnancy Categories list (drug fetal classification) is available for reference.

key words：pregnant woman, gastrointestinal endoscopy, radiation exposure

Legends to Figures and Tables

Figure 1 Case 8: Colonoscopy image at 32 weeks gestation with bloody stool.
It is impossible to insert into the deep part of the colon because of pressure caused by enlargement of the uterus.

Figure 2 Case 8: Bloody stools and intestinal obstruction occurred on the second day after birth, and a 40 mm diameter tumor was confirmed by emergency colonoscopy.

Figure 3 Annual numbers of deliveries and of stomach cancer/colon cancer cases in Japan. (based on the data from references 19, 20)

Table 1 Examples of upper gastrointestinal endoscopy performed for pregnant women in our hospital (2008–2017).

Table 2 Examples of lower gastrointestinal endoscopy performed for pregnant women in our hospital (2008–2017).

Table 3 Examples of pregnant women with appendicitis in our hospital (2008–2017).

Table 4 Quoted from “Obstetrics guidelines 2017”.

乳がん

金子しおり（埼玉協同病院 乳腺外科）

01 ノルバデックス® タモキシフェン

ホルモン受容体陽性乳がんに使用される内分泌（ホルモン）療法薬の一種。閉経状態にかかわらず使用できる薬剤で、SERM（選択的エストロゲン受容体モジュレーター）に分類される。術後補助療法および転移・再発乳がんに使用される。

専門医から「日常的なフォローアップをお願いします」となりやすい疾患群の薬

知っておきたいエビデンス

❶ホルモン受容体陽性乳がんに対する「術後5年間」のタモキシフェン投与は、年齢や閉経状態、リンパ節転移・化学療法併用の有無にかかわらず、再発および死亡のリスクが減少する。

[EBCTCG, et al : Lancet, 2011][1)]

❷タモキシフェンの「5年投与」と「10年投与」を比較したATLAS試験において、10年投与群で10年後以降の再発および死亡のリスクを有意に減少する。

[Davies C, et al : Lancet, 2013][2)]

代表的な病態に応じた使い方

エストロゲンと競合してホルモン受容体（エストロゲンレセプター）に結合し、抗腫瘍効果を発揮する。「閉経前乳がん」や「男性乳がん」では第一選択薬となり、「閉経後乳がん」では**アロマターゼ阻害薬**（p.905）の有害事象が懸念される場合などに選択される。術後補助療法として「5年投与」が標準であるが、症例によっては「10年投与」が検討される。「ホルモン受容体陽性転移・再発乳がん」では、生命に危険を及ぼす転移がない場合は内分泌療法が考慮され、タモキシフェンが使用されることがある。

- 1日1回20 mg内服。添付文書上は、分割投与や40 mg/日までの増量が可。

代謝排泄経路

主として、肝代謝酵素CYP（シトクロムP450）3A4およびCYP2D6により代謝される。

注意しておきたい副作用

ほてり・発汗などの「ホットフラッシュ」が多く聞かれ、患者自身は不快に感じることが多い。有効な薬剤はないが、アドヒアランス向上のためにも、タモキシフェンの効果や必要性、時間経過で症状が軽減することを説明している。「子宮内膜がん」のリスクがわずかに上昇するため、不正出血時には速やかな婦人科受診を勧めるが、定期的な婦人科検診を勧める科学的根拠は示されていない。

使用できない場合の代替薬

変更が必要な時は、担当専門医に相談する。

標準的処方における薬価

- 20 mg錠（1日1錠）：260.5円/日（後発56.8円/日ほか）
- 10 mg錠：133.3円/錠（後発32.2円/錠ほか）

剤形などのデータ抜粋

- 錠剤：10 mg、20 mg

特に注意したい併用薬、併用禁忌薬

パロキセチンや**硫酸キニジン**などの強CYP2D6**阻害薬**（p.893）、**リファンピシン**の併用で、タモキシフェンの作用が減弱する。タモキシフェンの作用が増強するため、抗ウイルス薬の**リトナビル**との併用も注意が必要である。

また、**ワルファリン**との併用でPT-INRが延長する。タモキシフェンに「血栓症」のリスクがあるため、治療前後で血栓症を併発した場合は、血栓症および乳がん担当専門医に相談するのが望ましい。

「骨粗鬆症」の治療薬**ラロキシフェン**は、タモキシフェン同様SERM（selective estrogen receptor modulator）に分類される。併用により効果の低下や副作用増強の可能性もあるため、整形外科および乳がん担当専門医に相談するのが望ましい。

2188-8051/18/紙：¥800/電子：¥1200/論文/JCOPY

乳がん

金子しおり（埼玉協同病院 乳腺外科）

02 アリミデックス® アナストロゾール

ホルモン受容体陽性乳がんに使用される内分泌（ホルモン）療法薬の一種。アロマターゼ阻害薬であり、閉経後患者の術後補助療法・転移もしくは再発時に使用される。LH-RH（黄体形成ホルモン放出ホルモン）アゴニストと併用して、閉経前転移・再発患者に使用することもある。

知っておきたいエビデンス

❶ ATAC試験：閉経後早期乳がん患者への補助療法としてアナストロゾール単独投与は、タモキシフェン（p.904）単独投与と比較して全生存率に有意差はないが、無病生存率を改善した。

[Cuzick J, et al：Lancet Oncol, 2010][1)]

代表的な病態に応じた使い方

閉経後は、卵巣機能が低下しエストロゲンが生成されなくなる代わりに、副腎皮質から分泌されるアンドロゲンを脂肪組織にあるアロマターゼでエストロゲンに変えている。アロマターゼの作用を阻害し、エストロゲン生成を阻害するのが**アロマターゼ阻害薬**である。術後補助療法として、「閉経後患者」の第一選択薬となる。「5年投与」が標準であるが、10年投与の有効性・安全性について臨床試験が進行中である。なお、アロマターゼ阻害薬には、**レトロゾール（フェマーラ®）**、**エキセメスタン（アロマシン®）**もあるが、効果や副作用は変わらない。「ホルモン受容体陽性転移・再発乳がん」において、生命に危険を及ぼす転移がない場合は内分泌療法が考慮され、アロマターゼ阻害薬が使用されることがある。

- 1日1回1 mg内服

代謝排泄経路

主に肝代謝を受ける。

注意しておきたい副作用

- 「関節痛」や「関節のこわばり」が、起床時に手関節に認められることがある。いずれも、鎮静薬と保温・物理療法を組み合わせて経過をみていく。
- アロマターゼ阻害薬を使用した場合、年齢変化と併せて骨密度を年2.6%低下させるが、骨折頻度の増加は証明されていない。しかし、「骨粗鬆症」は骨折の高リスクであるため、骨塩量のモニタリングは必須である。運動や禁煙、カルシウムとビタミンDの摂取についての指導を併用できるとさらによい。
- 「血栓症」のリスクも低いがあるため、治療途中で血栓症を併発した場合は、担当専門医へ相談するのが望ましい。
- 閉経期患者に投与すると、アロマターゼ阻害薬の排卵促進作用により、「月経」が再開する症例がある。投与中に性器出血があった場合は、月経再開か不正出血かを鑑別する必要があり、婦人科への相談が必要である。また、月経が再開した場合には、薬剤の変更が必要なので、担当専門医へ相談する必要がある。

使用できない場合の代替薬

変更が必要な時は、担当専門医に相談する。

標準的処方における薬価

- 1 mg錠（1日1回1錠）：403.6円/日（圀154.0円/日ほか）

剤形などのデータ抜粋

- 錠剤：1 mg

特に注意したい併用薬、併用禁忌薬

アロマターゼ阻害薬は、**タモキシフェン**との併用で効果が低下する。「骨粗鬆症」の治療薬**ラロキシフェン**は、タモキシフェン同様にSERM（selective estrogen receptor modulator：選択的エストロゲン受容体モジュレーター）に分類されるため、アロマターゼ阻害薬とラロキシフェンとの併用も避けたほうがよいと考える。それぞれを処方した整形外科および乳がんの担当医に相談するのが望ましい。

専門医から「日常的なフォローアップをお願いします」となりやすい疾患群の薬

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〔平成29年度後期学術集会一般演題〕
症例報告

分娩後雷鳴様頭痛を発症し，可逆性脳血管攣縮症候群（reversible cerebral vasoconstriction syndrome）と診断された1例

医療生協さいたま生活協同組合埼玉協同病院
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Key words
Reversible cerebral vasoconstriction syndrome
Methylergometrine
Non-Steroidal Anti-Inflammatory Drug
Thunderclap headache
Vasospasm

概要：可逆性脳血管攣縮症候群（RCVS）は，雷鳴様頭痛と呼ばれる突発する激しい頭痛を主徴とし，脳血管検査では可逆性の分節状攣縮を認める疾患である．産褥期に発症する症例もあり，脳出血や脳梗塞を併発する場合，周産期の生命予後を悪化させる可能がある．原因は今までの研究では明確にわからないが，メチルエルゴメトリンの使用は誘因になると言われている．また，RCVSの治療にはカルシウム拮抗薬の血管拡張作用により頭痛が改善できる報告もある．

今回我々は，分娩後メチルエルゴメトリンを使用した症例が雷鳴様頭痛を発症し，RCVSと診断された後ニフェジピンの内服により症状が改善した症例を経験した．症例は26歳1妊0産．妊娠経過には異常は認められず，血圧も正常範囲であった．41週1日陣痛発来し，経腟分娩した．メチルエルゴメトリンを内服し，産褥3日目雷鳴様頭痛を発症，同時に血圧上昇がみられた．発症直後のCT・MRIは明らかな所見を認めず，4日後3回目のMRAでは右後大脳動脈の攣縮を認めた．雷鳴様頭痛を繰り返したが鎮痛剤は効果なく，ニフェジピン内服後症状が改善し，神経学的後遺症はなかった．産褥15日目のMRA検査では後大脳動脈の狭窄は改善し，血圧コントロールも良好となりRCVSと診断した．産褥期のメチルエルゴメトリンの使用は慎重に行う必要があり，産後頭痛の鑑別診断にはRCVSも念頭におくべきであると考えられた．

緒　言

周産期に頭痛を発症する症例は多く報告されており，原因は周産期特有の母体環境変化による脳血管障害がその一つと推測されている[1]．周産期の脳血管障害は脳実質出血，脳静脈血栓症（cerebral venous thrombosis：CVT），くも膜下出血，脳梗塞，可逆性脳血管攣縮症候群（reversible cerebral vasoconstriction syndrome：RCVS），子癇などが上げられる．その中で比較的にまれなのは可逆性脳血管攣縮症候群（RCVS）である．RCVSは繰

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り返す雷鳴様頭痛を特徴とし，脳血管所見として分節状の多発脳血管攣縮を認める症候群である，軽症の場合予後が良好な症例が多いが，血管収縮が強い場合や，脳出血やくも膜下出血を合併する場合，不可逆性的な中枢神経障害を呈する症例もある[2)3)]．近年RCVSの認知度は高まっているものの，画像上では必ずしも明瞭な所見を呈さないため，未だ過少診断されうる疾患である．今回我々は分娩後雷鳴様頭痛を発症し，画像上血管攣縮の判断が明確となるまで症状が遷延した症例を経験したため，文献的考察を加えて報告する．

症　例

症例は26歳，身長166cm，体重48.3kgの1妊0産女性である．既往歴には特記すべき事項がない，アレルギー歴はクリンダマイシン，ミノサイクリンで薬疹になる．家族歴について実母が片頭痛以外に特記すべき事項がない．

現病歴は当院にて初期より妊娠管理されており，妊娠26週より切迫早産の診断にてリトドリン塩酸塩を内服していた．他妊娠経過には異常は認められず，血圧も100/60mmHg前後で上昇はなかった．41週1日陣痛が発来したため入院となった．分娩所要時間13時間54分で，3,105gの女児をアプガースコア値1分後8点5分後9点で娩出した．分娩後2時間よりセファレキシン250mg 6錠/日×3日，メチルエルゴメトリン0.125mg 3T/日×3日の内服を開始した．分娩直後より恥骨周囲に強い痛みが有り，産褥1日目に整形外科受診し，恥骨結合離開と診断された．鎮痛のためジクロフェナクナトリウム坐薬・内服薬を使用し，歩行困難のため産褥3日まで膀胱留置カテーテルを挿入していたが，産褥3日目に歩行器を使用して歩行可能となった．

分娩後3日目深夜に突然首筋から後頭部や頭頂部にかけて激しい頭痛を発症した．頭痛は両側頭部で拍動性があり，1時間以上持続した．痛みが強く，頭を抱え，悲鳴を上げてベッド上で身を捻っている状態であった．血圧174/79mmHg，心拍51回/分，体温37℃，意識清明であった．閃輝性暗点，痙攣，片麻痺，言語障害，視野狭窄などの神経学的所見はなく．血液検査所見WBC 8,800/μl，HB 13.8g/dl，Plt 26.0万/μl，CRP 1.78mg/dl，FDP 7.1μg/ml，Dダイマー2.7μg/ml，フィブリノーゲン417mg/dl，CK 419IU/*l*と異常を認めなかった．緊急で頭部CTを行ったがくも膜下出血を初めとする頭蓋内出血，脳梗塞，脳腫瘍などの画像所見は認めず，副鼻腔及び乳突蜂巣も異常がなかった（図1）．MRIでは急性期梗塞像はなく，FLAIR画像でも脳虚血，脳浮腫なし，MRAでは脳動脈に明らかな狭窄や閉塞，瘤を認めなかった（図1）．血圧が174/79mmHgと上昇したためニカルジピン1mg静注後1mg/hで持続投与した．頭痛が持続するためアセトアミノフェン1,000mgを点滴にて投与した．2時間後血圧138/80mmHg，心拍52回/分，SpO2 98%，頭痛は持続しているが発症時より改善を認めた．カルシウム拮抗薬の副作用として頭痛が誘発される可能性があるため降圧剤はプロプラノロール10mg 3錠×3/日内服を選択した．原因を精査するため，翌日朝（発症6時間後）頭部CTを再検したが，頭蓋内に明らかな出血は認めなかった（図2）．発症後9時間頭部MRI，MRAの再検も拡散強調画像で急性期梗塞を疑うような異常高信号を認めなかった（図2）．また同日脳神経外科を受診し，発症時と発症後再検の画像検査より重症な病態は否定的であった．頭痛が反復し，不眠も続いていたため産後の疼痛感受性亢進あるいは抑制系の減弱と考え，ベッド上の安静，ジクロフェナクナトリウム，アセトアミノフェン，ジアゼパム，トリプタン製剤の内服で対処した．その後も強い頭痛を繰り返すため産褥5日目にペイクリニック外来受診した結果，痛みが後頚部から後頭部へ拡大するため緊張性頭痛の可能性が高いと診断された．出産後エストロゲンの低下，産後長期間のベッド上生活より血流の低下が原因となっている可能性が高いとのことで，アセトアミノフェン500mg 4T×4/日，ジクロフェナクナトリウム25mg 3T×3/日，疼痛時アセトアミノフェン1,000mg/回により鎮痛を図ったが，頭痛の改善は依然乏しかった．そのため産褥8日目再度頭部MRIとMRAを行った．MRIの拡散強調で拡散低下を来たす病変は指摘できず，FLAIR画像

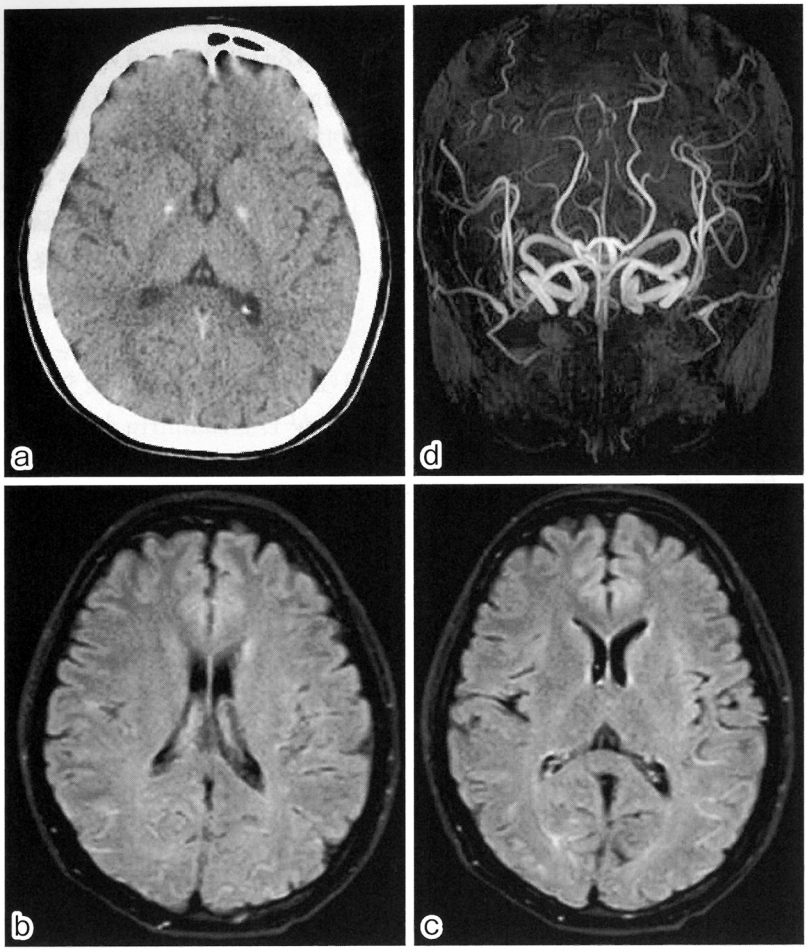

図1　発症時頭部単純CT・頭部MRI
(a) 発症時頭部CT．(b，c) 発症時MRI・FLAIR．(d) 発症時MRA．(a)，(b)，(c)，(d) とも明らかな異常がなかった．

で右後頭葉皮質～皮質下に不整形な高信号病変が幾つか見られた（図3）．MRAで右後大脳動脈遠位部に血管攣縮の所見を認めた．頭蓋内の梗塞や出血は認められなかった（図3）．脳外科による読影でRCVSの可能性が高く，カルシウム拮抗薬で血管拡張する事より改善が期待できるため，プロプラノロール内服を中止し，ニフェジピン20mg 2錠×2/日内服を開始した．ニフェジピンを内服後半日で頭痛の疼痛スケールは4/10に改善し，翌日には1/10まで軽快した．血圧も120/80mmHg未満，コントロール良好となり，産褥11日目に退院となった．産褥15日目でMRI・MRAを再検し，右後大脳動脈遠位部の狭窄は改善しており（図4），頭痛も見られないため，ニフェジピン内服を終了した．

考　察

日本における妊産婦死亡調査では，脳血管障害が間接妊産婦死亡の中では最も多く，直接妊産婦死亡を合わせた全体でも第3位の疾患になっている[4]．臨床現場では激しい頭痛，意識消失，痙攣などの症状に遭遇した場合，くも膜下出血，脳動脈瘤，脳梗塞，モヤモヤ病，脳静脈血栓症，海綿状血管腫などの脳血管障害を考える．本症例は発症後初期に上記疾患を疑い，頭部CTと頭部MRI・MRAを行ったが，くも膜下出血や脳実質病変を

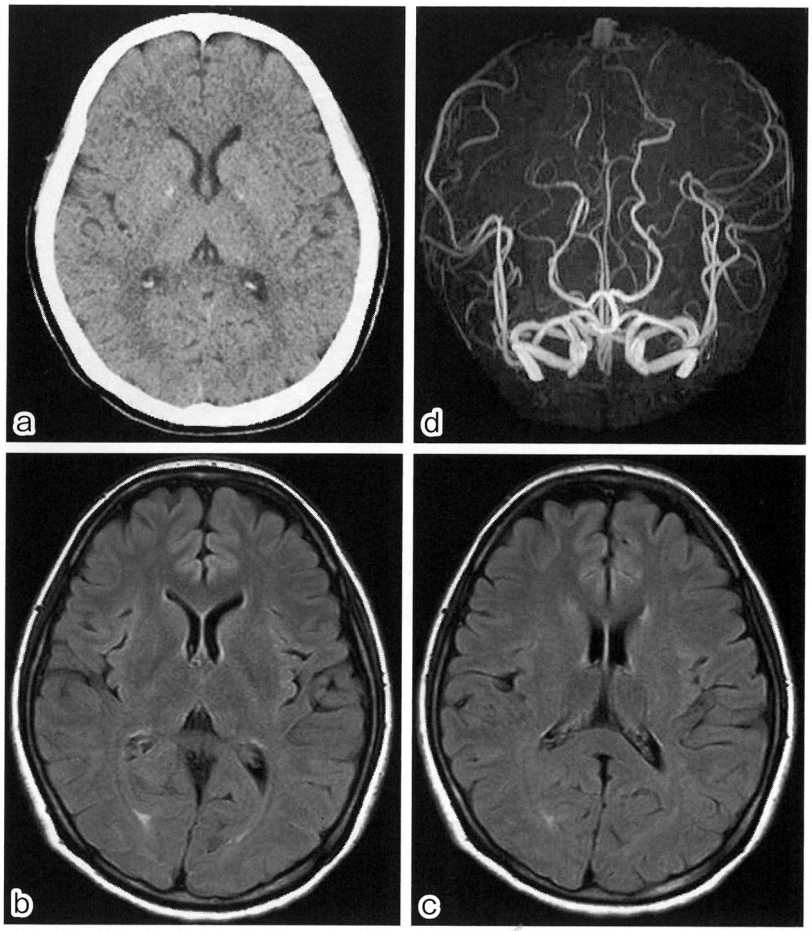

図 2　発症 10 時間後頭部単純 CT・頭部 MRI
（a）発症 10 時間後頭部 CT.（b，c）発症 10 時間後 MRI・FLAIR.（d）発症時 10 時間後 MRA.（a），（b），（c），（d）とも明らかな異常がなかった.

認めなかった．画像上積極的に脳血管障害を疑う所見がなく，神経学的な所見もなかったため，緊張性頭痛や片頭痛など原発性頭痛を考え，ジクロフェナクナトリウム，アセトアミノフェン，トリプタン製剤を投与した結果，症状が遷延した．発症後 4 日の MRA では RCVS を疑う血管攣縮がみられたため，カルシウム拮抗薬を投与し，頭痛は劇的に改善した.

RCVS の疾患概念自体は最近提唱されたもので，突然発症する頭痛とそれに伴う可逆性の脳血管収縮を呈する症候群である．急性発症の雷鳴様頭痛は RCVS において特徴的症状であり，画像上では分節状の多発脳血管攣縮を認める．しばしば脳出血や脳梗塞を併発し，不可逆性的な中枢神経障害を引き起こし，重篤な転帰に至るものも存在する．診断基準としては 2007 年の Calabrese らの 5 項目の基準（表 1）をはじめ，2013 年の国際頭痛分類第 3β 版（ICHD-3β）にも Calabrese らにより広義の新たな診断基準が提唱されている（表 1）[2)5)]．本症例は①脳動脈瘤やくも膜下出血が否定される；②突然発症の強い頭痛である；③ MRA で多巣性，分節状の脳血管収縮が観察される；④脳血管の攣縮は 4 週以内に消失し，画像上の可逆性が確認されると Calabrese らの診断基準 5 項目中 4 項目を満たしている．このため脳脊髄液検査はしていないが RCVS と診断された.

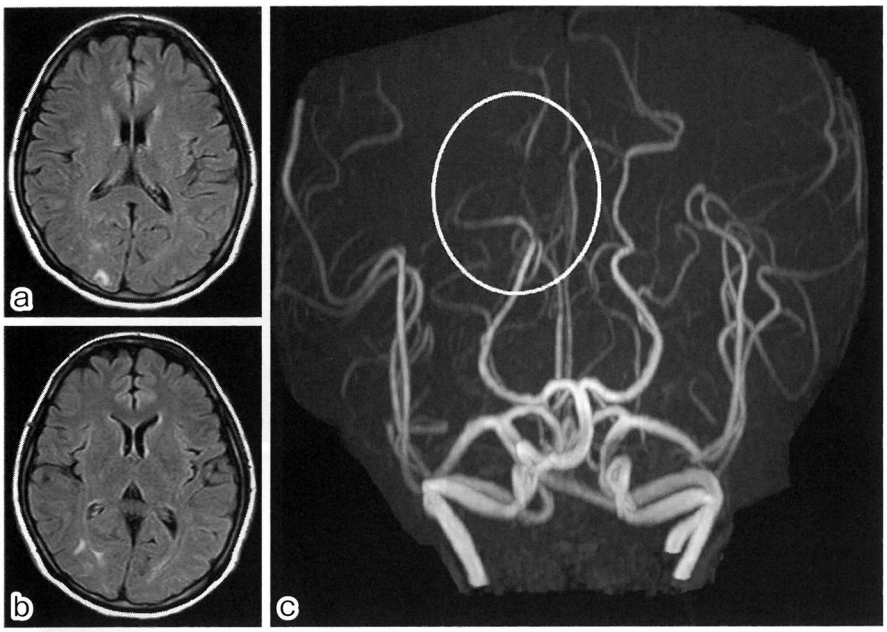

図3　発症後4日頭部MRI
発症後4日（a），（b）MRI/FLAIR，右後頭葉皮質～皮質下に不整形な高信号病変を認める．
（c）MRA 右後大脳動脈遠位部に血管攣縮の所見を認める．

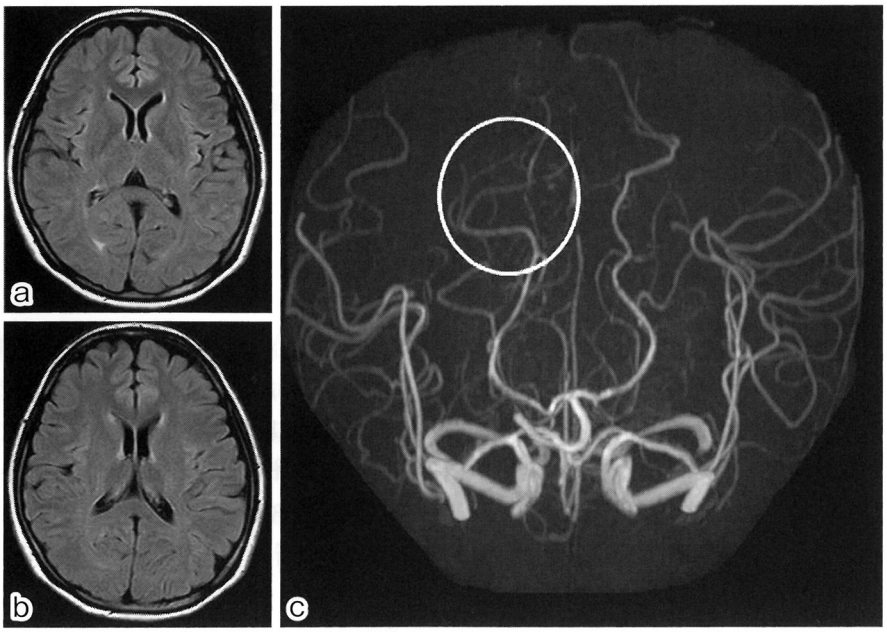

図4　発症後15日頭部MRI
発症後15日（a），（b）MRI/FLAIR，拡散強調画像で拡散低下を来たす病変は指摘できず；脳内に出血，梗塞，腫瘍性病変は指摘できず．（c）MRA，明らかな動脈瘤や異常血管，狭窄性病変，閉塞性病変は指摘できず．

表1　Calabreseらの新たな診断基準

① 急性の強度の頭痛（しばしば雷鳴頭痛）がある．局所神経症状あるいは痙攣はあることもないこともある．
② 脳動脈瘤の部分的攣縮を血管造影（カテーテル法，MRA，CTA）で認める
③ 動脈瘤性くも膜下出血を認めない
④ 正常あるいはほぼ正常の髄液所見（蛋白＜100mg/dl，細胞数＜15白血球/μl）
⑤ 12週以内に完全あるいは実質的な動脈攣縮の正常化を認める

表2　国際頭痛分類第3β版（ICHD）-3β ＜可逆性脳血管攣縮症候群による頭痛＞

A．診断基準Cを満たすあらゆる新規頭痛である．
B．Reversible cerebral vasoconstriction syndrome（RCVS）は下記のように診断される
C．少なくとも下記の1項目を認める証がある
1，神経学的局所症状及び/または痙攣を伴う，もしくは伴わない頭痛に，血管造影で「数珠（strings and beads）」状を呈し，RCVSと診断される
2，頭痛は下記のどちらか，または両者の特徴を有する
a）雷鳴様頭痛で発症し，1ヶ月以内は繰り返し生じる
b）性行為，労作，感情的興奮，バルサルバ手技，入浴やシャワー浴で誘発される
3，発症後1ヶ月以降は新たな激しい頭痛は生じない
D．他のICHD-3β頭痛診断では十分に説明できず，動脈瘤によるくも膜下出血が適切な検査で除外されている．

RCVSの原因はいまだに解明されていないものの，発症誘因は様々な要素が報告されている．2011年Singhalらは139症例のRCVS症例を分析し，そのうち81％は女性であった．誘発原因を解析したところ①妊娠と産褥，子癇，妊娠高血圧腎症；②血管作動薬，交感神経作動薬，ドパミン・セロトニン系に作用する薬剤，血液製剤など；③原発性の片頭痛，労作性頭痛，性行為，感冒；④高カルシウム血症，ポルフィリア，褐色細胞腫，外傷後，脳動脈瘤など様々である．その中で産褥は約9％を示している[6]．産褥期におけるRCVSは分娩後の血中エストロゲン・プロゲステロンの急速な低下が発症の誘因として推定されており，妊娠高血圧合併や血管動作薬の使用も誘因と推測されている[7]．

本症例は妊娠出産症例であるが，症状経過より子宮収縮促進のためメチルエルゴメトリンの投与はその誘因の一つと考えられた．メチルエルゴメトリンは産後子宮収縮促進剤としてよく使われているが，分娩後の血管収縮が高血圧を引き起こし，脳卒中が起こる場合もある事が報告されている[8]．当院では高血圧を呈する患者さんには慎重投与としているが，本症例は出産前血圧正常のため，出産後3日間投与した．RCVSの発症は産褥3日目で，発症時血圧の上昇を認めた．メチルエルゴメトリン内服後4〜7日でRCVS症状が出現する症例も報告されており，投与後1週間は経過観察が必要と提言されている．本症例も産褥3日目の発症であり，改めてメチルエルゴメトリンは慎重投与すべきである事を認識した．

また，RCVSが重大な脳血管障害を併発するのは発症から2週間前後が多く，早期診断の重要性が分かる[9]．本症例は産褥3日目で発症し，血圧の上昇も伴い，周産期2次性の頭痛の原因の一つであるRCVSはすでに念頭に置くべきであったが，画像検査上で明らかな所見がないため診断に至らなかった．文献上では発症初期の頭部MRAにて脳血管攣縮が目立たない産褥期RCVSも報告されており，早期診断には血管攣縮以外の所見も参考にする必要がある[10]．本症例は発症4日目に3回目のMRI・MRA検査で右後大脳動脈の攣縮が観察された他，FLAIR画像で右後頭葉皮質〜皮質下

に不整形な高信号病変が幾つか見られ，攣縮している右後大脳動脈領域の脳浮腫と考えられた．

RCVSの治療に関しては明確なエビデンスがないものの，誘因となる薬剤を中止し，高血圧をコントロールする事が上げられる．また，カルシウム拮抗薬より血管攣縮が解除され頭痛が改善する事が報告されている[11]．本症例は3回目のMRI・MRAでわずかな血管攣縮を発見し，RCVSと考えた後ニフェジピン内服を開始したところ症状が劇的に改善し，産褥15日目のMRI・MRAでは右後大脳動脈の攣縮は明らかに回復したため，この症例においてはカルシウム拮抗薬による治療が有効であったと考えられた．

結　語

本症例より周産期の頭痛，血圧上昇などの症状がある場合積極的に画像検査を行い，安易にメチルエルゴメトリンを使わず，使う時には慎重に経過を観察する必要があると考えられた．また，RCVSは重症の脳血管障害に至る場合がある事を認識し．鎮痛剤が無効な周産期の頭痛の鑑別診断においてはその可能性を念頭におくべきであると考えられた．そして，RCVSが疑われた場合カルシウム拮抗剤の投与を行うことで不可逆性脳血管障害の発症リスクを低減できる可能性があると考えられた．

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原　著

医療記録の質向上を目指した患者による医療記録監査の試み
—患者閲覧用電子カルテを用いて—

A trial of POMR-audit by patients aiming at POMR quality improvement
—using electronic medical record for patients—

○野　田　邦　子[1)2)]　平　嶋　久美子[1)]　大　津　由　季[1)]
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要旨：患者が医療記録を監査し医療者にフィードバックすることで記録の質が改善するかどうかを検討した。患者は問題志向型医療記録の読み方を学んだ後、患者用電子カルテ端末を用いて監査を実施した。患者が重視したのは「主訴の受け止めと専門的判断」であった。2回のフィードバック後、外来経過記録は診療情報管理士による監査の評点で有意な改善がみられた（p＝0.033）。患者による監査は医療記録の質改善に有用と考える。

キーワード：患者の医療活動参加　患者による医療記録の閲覧　問題志向型診療録　品質改善　コミュニケーション

1．背景および目的

医療提供過程において患者と医療者の信頼関係に基づくパートナーシップが形成され、双方が納得できる結果として患者にとって最善と思える質の高い健康を実現することが医療のめざす方向であると考える。

これまで、「患者、家族と医療者のコミュニケーションツール」としての患者の問題志向システム（The problem oriented system，以下POS）の意義に関する議論[1)]や、「情報の発信源」としての患者の役割に着目した患者・市民グループによるワークショップの取り組み[2)]、また医療安全の分野における患者参加のさまざまなとりくみが報告され、医療の安全性および質の確保における患者－医療者間のコミュニケーションの重要性が指摘されている[3)4)]。また情報の非対称性を克服する観点からは用語のわかりにくさの問題が提起され[5)]、心理的問題などの視点からの分析・提案もなされている[6)7)]。

一方で、医療記録の開示請求に際して、患者等が自由に申し立てをできるようにその理由を尋ねることは不適切とされているが、2015年の調査報告[8)]で請求理由を尋ねる病院の複数がその理由として「病院に関する不信感の有無の確認のため」と答えており、開示請求を不信の表れととらえる傾向がある。「患者等が疾病と診療内容を十分理解し、医療従事者と患者等が共同して疾病を克服するなど、医療従事者等と患者等とのより良い信頼関係を構築する」という「診療情報の提供等に関する指針」の理念[9)]からはまだ距離がある。

また、医療記録の質に関して、財団法人日本医療機能評価機構の病院機能評価では、評価事業が開始された1995年当初から現在の新しい評価の枠組み（3rdG:Ver.1.1）まで一貫して、「診療記録を適切に記載している」、「診療記録の質的監査を行っている」ことが評価の要素として挙げられており、医療の質において記録の適切性は重要な要素として位置づけられている。しかしその達成度は、「一般病院2（主として、二次医療圏の比較的広い地域において急性

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期医療を中心に地域医療を支える基幹的病院）」228病院において「2.1.2診療記録が適切に記載されている」の評価が「A（適切である）」の病院が42.1%、「B（中間）」の病院が57.5%で、全89項目中２番目に達成度が低い状況にある[10]。「診療記録の監査」は、多くの病院で工夫され、診療情報管理部門や監査チーム、各職種の上級者等による形式監査及び質的監査が行われているところであるが、POSの核心である患者の問題に迫れているかどうかは、患者自身に確かめない限り判断できない。医療者がアセスメントした患者の問題とその解決の過程は「患者自身が感じている問題と一致しているか」「納得・共有できるかどうか」「その解決方法は患者自身が受け入れられ実現可能であるか」を、患者が監査しフィードバックできれば医療者は医療記録の対象である患者を意識することにつながり、適切に記載しようとする内的動機が高まり医療記録の質向上が期待できると考えるが、これまでにこのような点に着目した取り組みの報告は見当たらない。

そこで我々は、①「POSの考え方を学んだ患者であれば、情報が過不足なく収集され記録されているか、患者本人が感じている健康上の問題または医療要求を医療者が適切にアセスメントしているかという、診療情報管理士等の第三者には監査しえない本質部分を監査することができる」、②「情報収集と問題のアセスメントの質は患者からのフィードバックを受けることで高まる」、という研究仮説をたてた。

本研究の目的は、コミュニケーションの手段としてPOSの教育を受けた患者が自身の医療記録を監査し医療者にフィードバックすることで、科学的合理的プロセスの記録としての医療記録の質に変化をもたらすかどうかを明らかにすることである。

2．対象および方法

本研究の目的を達成するために、患者による医療記録の監査－医療者へのフィードバックを介入とし、その前後での医療記録の変化を診療情報管理士が測定する介入研究として計画した。

1．研究対象

本研究の協力病院は、許可病床数401（急性期一般病床327、回復期リハビリ病床50、緩和ケア病床24）を有し、標榜診療科31、１日入院患者数305人、外来患者数1046人（2015年10月時点）の基幹型臨床研修病院である。2004年４月に電子カルテを導入し2014年９月に更新、現在は日本電気株式会社MegaOakHR8.0を使用している。2011年８月より、患者と医療者のコュニケーション改善を目的とした患者閲覧用電子カルテ端末「マイかるて」を院内３箇所に設置し運用[11]している。

2015年２月時点で「マイかるて」を利用している患者に対して、自身の医療記録を監査しフィードバックする「マイかるてモニター員（以下モニター員）」を募集し、研究協力の同意が得られた患者を研究協力者とした。

2．患者による監査(記録チェック)－フィードバックと医療記録の変化の測定

研究方法の全体図を**図１**に示した。診療情報管理士が行う監査と区別し、モニター員が行う監査を記録チェックとする。モニター員は1.5～２ヶ月の間をおいて２回記録チェックとフィードバックを行い、診療情報管理士は第１回のフィードバック直前と２回のフィードバックを経た約６ヶ月後に監査を行った。以下にその手順を述べる。

1）モニター員養成と記録チェックの方法

(1) ガイダンスと第１回記録チェック(**図１－①**)

モニター員に対し、「マイかるて」の操作方法とPOMRの考え方、記録チェックのしかた、モニター員の役割についてガイダンスを実施した。その後、モニター員は**図２**に示すモニター員用チェックシートを用いて記録チェックを実施した。モニター員用チェックシートの作成にあたっては、文献12－15）を参考にした。記録チェック項目はPOMRの構成要素ごとに、患者が伝えたことの反映、特定された問題の納得性、わかりやすさの観点から設定し、判断基準は「わかった」「感じた」というモニター員の主観とした。また医療者にフィードバックしたい内

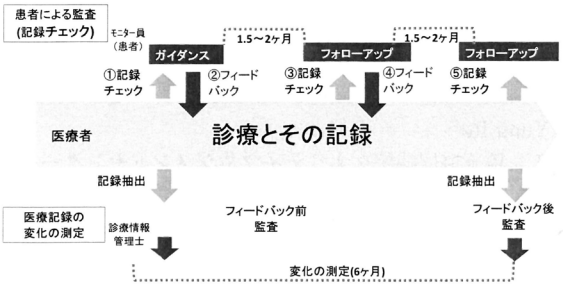


図１　研究方法の全体図

◆モニター員用チェックシート　　第（1・2・3）回　月　日実施　　モニター員番号（　　）

チェック方法：選択肢（□）のあるものは、最も当てはまるもの1つにチェックを入れ、色つきの欄には、なるべく具体的な事柄を書いてください

記録項目・内容	No	チェックポイントおよび記入欄			
1 基礎データ（初診時／入院時）					
現病歴（今回症状の経過）	1-1	あなたが「伝えたこと」が「正しく伝わっていない」と感じる部分はありましたか	□正しく伝わっていないと感じた	□伝わっていた	□伝えた内容が記載されていない
生活像・既往歴・家族歴	1-1-1	「正しく伝わっていない」と感じたのはどんなことですか			
診察所見・検査データ					
2 問題リスト（初診時／入院時）					
重要なものから	2-1	あなたが解決したい問題が書かれていましたか	□解決したい問題とは違った	□解決したい問題が書かれていた	□何が問題が記載されていない
今回の病状に関係する以	2-1-1	「不十分」または「違う」と感じたことは何ですか			
前からある（存在する）問題					
社会生活上の問題	2-2-2	どのように、またはなぜ「違う」と感じましたか			
3 初期計画（初診時／入院時）					
#1- 診断計画・治療計画	3-1	説明された内容と違うと感じた部分はありますか	□違うまたは説明されていない	□説明されたとおりだった	□計画が記載されていない
マネジメントプラン	3-2	あなたの生活や仕事の問題に対する計画が含まれていましたか	□含まれていない	□含まれている	
説明計画	3-3	わかりにくい内容はありましたか	□何をするのかよくわからない	□計画はわかりやすい	□計画が記載されていない
	3-3-1	「違う」と感じたことや「わかりにくかったこと」はどんなことですか			
4 経過記録（再診・2回目以降／入院2日め以降）					
#1- 問題の特定	4-1	問題は特定されていますか	□問題が記載されている	□記載されていないがわかる	□問題は記載されていない
S 患者の主観的症状	4-2	「伝えたこと」が「正しく伝わっていない」と感じる部分はありましたか	□正しく伝わっていないと感じた	□伝わっていた	□伝えた内容が記載されていない
O 客観的観察・データ	4-2-1	「正しく伝わっていない」と感じるのはどんなことですか			
A SとOを見ての判断	4-3	SとOに基づいてAPが書かれていると思いましたか	□SOとは関係がないようだ	□SOに基づいている	□Aが記載されていない
P Aにもとづく計画	4-4	P（計画）でわかりにくい点はありましたか	□何をすることかわからない	□わかりやすい	□Pが記載されていない
	4-5	あなたへの説明と異なる（または説明されていない）と感じることはありましたか	□違ったまたは説明されていない	□説明されたとおりだった	□計画が記載されていない
説明の記録	4-6	説明された内容と違うと感じる部分はありますか	□違ったまたは説明されていない	□内容が簡潔に記載されている	□説明を受けていない
	4-7	あなたが質問した内容は記載されていますか	□質問内容が記載されていない	□質問と答えが記載されている	□質問しなかった
カンファレンス	4-8	各専門職種の意見は反映されていますか	□発言したかどうかわからない	□専門職種が何をするのかわかった	□カンファレンスがされていない
	4-9	話し合われた方針がわかりやすいですか	□何をするのかわからない	□次までの方針が明確である	□方針が記載されていない
5 全体					
難しい用語や略語	5-1	わからない用語はありましたか	□わからない用語があった	□わからない用語はなかった	
	5-1-1	それはどんな用語ですか（いくつでも書いてください）			
不快な言葉	5-2	直してほしいと思う記載はありましたか	□直してほしい記載があった	□特に気づかなかった	
専門職同士の連携	5-3	各専門職が連携して治療を進めていると感じましたか	□互いに連携していると感じた	□それぞれ他職種と関係なく進めていると感じた	
問題解決	5-4	問題解決（健康回復）のために、あなた自身がすることは記載されていましたか	□記載されていない	□あなたがするべきことが書かれている	
その他	5-5	医師、看護師その他のスタッフに伝えたいことがあればお書きください			

（A3版で印刷）

図2　モニター員用チェックシート

容を具体的に記載する欄を設けた。

(2)　第1回フィードバック（図1－②）

記入されたモニター員用チェックシートを回収し記録チェック結果とフィードバックしたい具体的記載の内容をまとめ、医療者およびモニター員に知らせた。フィードバックは、マイかるてモニター員だよりとして院内各部門へ配布するとともにマイかるてコーナー3箇所に掲示した。

(3)　第2回記録チェック（図1－③）

モニター員は第1回フィードバック実施後に2回目の記録チェックを行い、モニター員用チェックシートに記入してモニター員のつどいに参加した。モニター員のつどいでは、医療記録の記載内容を理解するためのフォローアップとして汎用医療用語の解説と検査結果の見方の実習、意見交換を行った。

(4)　第2回フィードバック（図1－④）

記入されたモニター員用チェックシートを回収して記録チェック結果とフィードバックしたい具体的記載の内容をまとめ、医療者およびモニター員に知らせた。第1回と同様の方法に加え、電子カルテ起動時の初期画面に要点を掲載のうえ全文の閲覧を可能とし、電子カルテを利用する全医療者の目に触れるようにした。

(5)　第3回記録チェック（図1－⑤）

モニター員は第2回フィードバック実施後に3回目の記録チェックを行い、モニター員用チェックシートに記入してモニター員のつどいに参加した。3回の記録チェックを通しての気づきや提案などの意見交換を行った。

2）医療記録の変化の測定

モニター員からのフィードバック前と2回のフィードバックの後（約6ヶ月後）に実施された診療情報管理士による監査の結果を用い、前後の評点の変化を項目別に比較した。監査対象は常勤医師50人の入院記録（ない場合は外来記録）各1例とした。

監査項目はPOMRの、退院時サマリーを除く4つの構成要素（基礎データ、問題リスト、初期計画、経過記録）と全般事項の5項目で、それらはさらに全34の小項目から成る。各小項目の評価基準は、内容の重みを考慮して2段階評価または3段階評価に設定している。監査シートを図3に示した。

3人の診療情報管理士が独立して監査を実施し、各小項目についての監査者3人の平均点を評点とし、さらに項目別の合計点を算出した。

◆監査シート　No.　ID(　　)　監査日(　/　)　科外来/　病棟(　/　～　/　)　医師略名(　　)　監査者(　　)

記録項目	No.	評価基準	項目得点	コメント	小計/合計
1 基礎データ(初診時/入院時記録)		医師記録			/10
生活像	1-1	生活像が具体的にイメージできる	2　1　0		
現病歴	1-2	経過が理解できる	2　1　0		
既往歴	1-3	現在の問題に影響のある既往歴	/　1　0		
家族歴	1-4	血族の遺伝性疾患、生活習慣関連	/　1　0		
診察所見	1-5	ターゲットの症状、鑑別のための系統的診察	2　1　0		
検査データ	1-6	キーとなるデータの所見がある	/　1　0		
最新のデータ	1-7	入院時、退院時、外来のみの場合1年以内	/　1　0		
2 問題リスト(初診時/入院時記録)		医師記録			/6
#1- 重要なものから	2-1	順序(重要なものから、過不足なく)	2　1　0		
	2-2	発生時期(追加など)・解決有無が明記されている	/　1　0		
	2-3	既存の問題で影響のある問題	/　1　0		
	2-4	療養継続に影響する生活社会的問題が挙げられている	/　1　0		
	2-5	心理的問題があげられている	/　1　0		
3 初期計画(初診時/入院時記録)		医師記録			/4
診断計画	3-1	内容・時期	/　1　0		
治療計画	3-2	内容・期間	/　1　0		
マネジメントプラン	3-3	誰が・何を	/　1　0		
説明・教育計画	3-4	誰に・いつ	/　1　0		
4 経過記録		医師/看護/薬剤師/PT・OT・ST/栄養士/他			/20
#1- 問題の特定	4-1	どの問題についてかが明記されている	2　1　0		
S　患者の主観的症状	4-2	問題にそった訴えである	2　1　0		
O　患者の客観的データ	4-3	客観的である(主観的評価でない)	2　1　0		
	4-4	具体的である(データ、状態、性状など)	2　1　0		
A　SとOを見ての判断	4-5	アセスメントがされている	2　1　0		
	4-6	メディカルスタッフの記録を反映している	2　1　0		
P　Aにもとづく計画	4-7	Aに基づいてPが立てられている	2　1　0		
	4-8	チーム共通の方針となっている	2　1　0		
free 説明の記録	4-9	説明した要点が記載されている	/　1　0		
	4-10	患者の受け止めとその対応	/　1　0		
free カンファレンス	4-11	参加者が記載されている	/　1　0		
	4-12	問題と到達、方針が記載されている	/　1　0		
5 全般事項		医師/看護/薬剤師/PT・OT・ST/栄養士/他	2点　1点　0点		/10
難解な用語	5-1	難解な用語が使用されていない	□なし　□<5個　□>=5個		
略語の使用	5-2	標準的でない略語が使用されていない	□なし　□<5個　□>=5個		
わかりやすさ	5-3	わかりやすい(論理的、時系列)	□良　□可　□わかりにくい		
不快な言葉	5-4	人格を傷つける言葉、物扱いの表現がない	/　□ない　□ある		
スタッフ間の連携	5-5	つながりがあることがわかる	/　□可　□わからない		
問題解決	5-6	解決または未解決の場合課題が明確である	□明確　□一部　□不明確		
6 合計評価得点					/50

※ 評価基準　2:基準通り　1:一部を満たす　0:基準どおりでないまたは記載なし

図3　監査シート

3．監査結果の分析方法

統計解析はIBM SPSS Statistics 19.0を用いた。評点は等間隔と仮定して評点を計算し、ノンパラメトリック手法を用いて分析を行った。対応のない2群比較にはMann-WhitneyのU検定を、対応のある2群比較はWilcoxon符号付き順位和検定を用いた。すべて有意水準を0.05として検定を行った。

1）医療記録の質変化

病院全体としての医療記録の変化を見るため、フィードバック前後の項目別および合計評点を比較した。

2）医師別医療記録の変化

医療記録の変化は主に医師の行動変容の結果と考えられることから、フィードバック前後の監査結果を、医師ごとの対応データとして比較した。フィードバック前後のデータのある48医師について、監査した全ての医療記録の項目別評点の変化と、入院記録と外来記録に分けた時の項目別評点を比較した。外来記録については経過記録と全般事項のみを比較した。

4．倫理的配慮

モニター員にはフィードバックの内容により診療上の不利益を生じないこと、診療担当医には個人が特定されない方法でフィードバックすること等を説明し研究協力を求めた。本研究は国際医療福祉大学倫理審査委員会の承認（14-Ig-112）および研究協力病院倫理委員会の承認（14-5-1）を得た。

3．結　果

1．フィードバック内容

表1にフィードバックした項目別の主な具体的内容を示した。記録チェックを実施したモニター員は第1回14人（性別：男9人女5人、年代：30代1人、40代4人、50代、60代、70代各3人）、3人が通院終了したため第2回11人（性別：男8人女3人、年代：30代1人、40代3人、50代1人、60代、70代各3人）であった。ただし第2回の11人のうち2人の記録チェックの提出は第3回記録チェック時となり

表1　モニター員のフィードバック

項目	第1回	第2回
①基礎データ	・伝えたことが違う意味に受けとられているように感じた（主訴）	特になし
②問題リスト	特になし	特になし
③初期計画	・自分の病気がよくわかっていなかったため記載内容が理解できなかった ・説明はていねいだが記録がない	特になし
④経過記録	・検査結果の総合的判断がほしい(A) ・助言指導内容がわかりにくい(P) ・プランが説明されていない(P)	・主訴の受け止めが不十分、受け止めたうえでの説明がほしい(S,P) ・「様子をみましょう」では不安、専門的判断の説明がほしい(A,P)
⑤全般事項	・専門用語がわからない ・問題解決のため自身がすることは書かれていたが説明は丁寧でなかった	・不快に感じる記録あり ・配慮がほしい
医療者に伝えたいこと	・多くの専門職種が関わっていることを知った	・医療情報の共有によって病気の理解が進み、療養に向き合うことができることを実感した

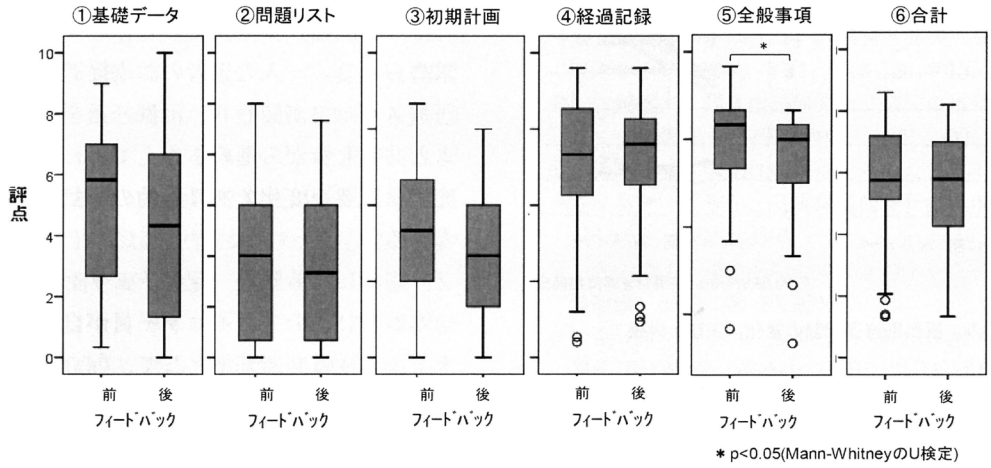


図4　医療記録の評点の変化

表2　医療記録の評点の変化

項目（配点）	フィードバック前		フィードバック後		p-value	
	中央値	四分位偏差	中央値	四分位偏差		
①基礎データ（10点）	5.83	2.13	4.33	2.67	0.106	
②問題リスト（6点）	2.00	1.29	1.67	1.29	0.670	
③初期計画（4点）	1.67	0.67	1.33	0.63	0.191	
④経過記録（20点）	13.33	2.83	14.00	2.13	0.463	
⑤全般事項（10点）	8.33	0.67	8.00	0.63	0.010	*
⑥合計（50点）	28.83	5.08	29.00	6.67	0.524	

＊p<0.05(Mann-WhitneyのU検定)

フィードバックには間に合わなかった。

2．医療記録の変化

1）病院全体の医療記録の変化

監査対象となった医療記録の記載医師50人の診療科内訳は内科24人、外科10人、産婦人科4人、小児科3人、整形外科3人、泌尿器科2人、皮膚科2人、精神科1人、緩和ケア内科1人であった。フィードバック前後の医療記録の評点を**表2**、**図4**に示した。⑤全般事項で中央値が配点10点中8.33から8.00とわずかに低下した（p＝0.010）ほかは有意な変化は見られず、また、④経過記録の四分位偏差は2.83から2.13となった。

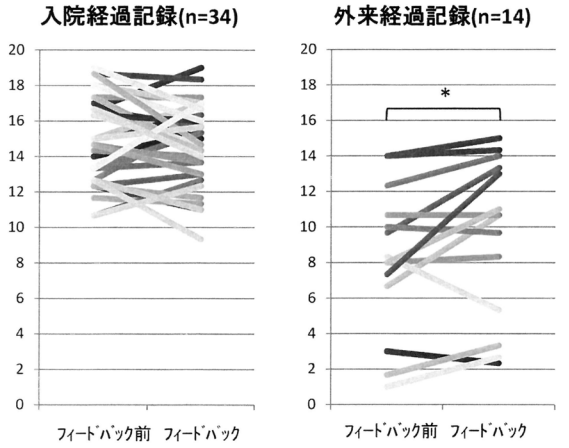
2）医師別医療記録の変化

フィードバック前後とも評価対象となった医師48人の医療記録の評点の変化を入院・外来別に示した（**表3**）。入院記録では⑤全般事項での有意な低下があった（p＜0.001）が他の項目に有意な変化はなかった。一方、外来記録は①基礎データ、②問題リスト、③初期計画のフィードバック後の中央値が0点であり、①と③が有意に低下した結果となったが、④経過記録においては有意な改善を認めた（p＝0.033）。図5に医師別経過記録の変化を全体および入院、外来別に示した。フィードバック前の外来経過記録の中央値は8.17と、20点の配点に対して半分以下であったが、14人中8人で増点した。

表３　医師別医療記録の変化（中央値）入院・外来別

	入院(n=34)			外来(n=14)		
	フィードバック前	フィードバック後	p-value	フィードバック前	フィードバック後	p-value
①基礎データ	6.00	5.50	0.139	3.00	0	0.016 *
②問題リスト	2.67	2.33	0.404	0.50	0	0.799
③初期計画	2.00	1.67	0.252	8.33	0	0.016 *
④経過記録	14.83	14.83	0.480	8.17	10.67	0.033 *
⑤全般事項	8.50	8.00	<0.001 *	7.50	7.33	0.421
⑥合計	34.17	31.50	0.032 *	21.50	17.83	0.363

*p<0.05（Wilcoxon符号付き順位和検定）



*p<0.05 Wilcoxon符号付き順位和検定

図５　医師別経過記録の変化、入院と外来

４．考　察

１．外来経過記録改善の意義

結果２項で述べたように、医療記録全体としての有意な改善は得られなかった（表２、図４）が、外来経過記録では有意な改善が得られた（表３、図５）。経過記録以外の項目での改善が得られなかった要因として、外来記録においては、５つの評価項目のうち①基礎データ、②問題リスト、③初期計画が初診時にほぼ限られることから、今回の監査対象期間において初診記録が含まれていないものが多数あったことによると考えられる。今回フィードバック後の14の外来記録中９記録の評点が０点であったが、監査対象期間に初診時記録が含まれていなかったのか、初診時記録はあったが記録が不十分だったのかが監査結果から区別できなかった。入院記録においては大きな変化はみられていない。今回の結果で低下したという証拠にはならないと考える。一方、経過記録は毎回必ず記載されるものであり特に外来通院患者においては中心的要素である。外来経過記録のうち、特に第１回の評点が低かった記録の多くが大きく改善したことが、全体の経過記録の四分位偏差が2.83から2.13となった（表２）主因と考えられ、底上げ効果につながったものと考える。

外来記録は短時間で効率的な診療を求められる状況にあって、患者の訴えを十分に聞き、的確な判断のもとに問題点と療養上の目標を共有できる内容が求められる。一人の患者の診療経過に多くの医師・医療スタッフが関わり、治療経過を患者・医療チームと共有しながら進めるうえで、外来の経過記録の充実は重要な変化であり目的の一部を達成できたと考える。

２．患者による監査（記録チェック）の有用性

本試行において、モニター員が自身の医療記録をチェックする判断基準として、「わかった」「～である（ない）と感じた」という主観による判断を用いた。その結果不十分であると判断された項目は、診療情報管理士による監査結果と概ね一致していた。表１に示したとおり、モニター員が「不十分」と指摘しその具体的内容として記載した「主訴の受け止め」は患者の解決したい問題であり、POSの中心的部分といえる。POSの思考過程を理解したうえで自分（患者）の問題は何かを意識しながら判断したものであり、第三者では判断できない内容である。POS医療記録における患者自身による監査の意義がこの点にあるものと考える。日野原が著書POSの序論の中で、Weedが患者による監査の可能性を示唆していることに触れている[16]が、その試行的とりくみとして意義あるものと考えられた。一方で、当事者であるがために、省略されていても理解できてしまう場合もあると考えられることから、診療情報管理士など第三者による監査は依然として必要である。今後は、形式監査の大部分が情報システムによって可能となるであろうことを考えると、初診時記録、診療計画書、カンファレンス記録、説明と同意の記録、サマリー、診療情報提供書といった、い

くつかのキーとなる記録についての質的監査やチームでのケースレビューのようなものがより重要になるものと考える。

3．ガイダンスとフォローアップの重要性

今回モニター員に対して、医療を良くするとりくみであることの動機づけと、POSの考え方と監査の具体的な方法についてガイダンスを行った。またその後実施した2回の「モニター員のつどい」では、わからない用語や疑問などのフォローアップとモニター員相互の意見交換も行った。慣れたところで汎用専門用語の解説や、疑問に答える場を設けたことは、モニター員用チェックシートには記入されていないどのような用語や記載方法が理解を妨げているのかを知り、フィードバックに含めるうえでは有用だった。一方で、モニター員という特別な役割であっても「こんなこと聞いたら怒られないか？」「○○と思われたらイヤだ」などといった発言が、3回の記録チェックを終えた段階でも表出される等、質問することに対する緊張や恐れといった心理状態がほぐれるのに時間を要した。

これらのことより、ガイダンスによって医療記録の内容を理解し医療提供のプロセスを理解することが可能であることがわかった。POMRの構造を学び、患者である自分の問題が特定されその問題を解決するための記録であるという読み取り方を学び、自分が理解できたか、どう思ったかを判断基準とすること、フィードバックする特別な役割を設定したことは、医療記録という極めて専門的な内容について感想や意見を述べることに関しての心理的ハードルを下げる効果があったものと考える。

今回6ヶ月間にガイダンス1回とフォローアップ2回、計3回の「モニター員のつどい」を行ったが、効果と効率性の観点からは、方法や期間についてさらに工夫が必要である。

5．結　語

患者が自身の医療記録を監査し医療者にフィードバックすることを試みた。病院全体としての医療記録の改善は有意でなかったが、外来経過記録は有意に改善し、本試みが有用であることが示唆された。

COI：本研究に関して著者および共著者らに開示すべき利益相反はない。

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労働者の健康問題について⑨

じん肺・アスベスト外来のとりくみ

埼玉協同病院　健康増進センター長　小池　昭夫

はじめに

埼玉県川口市は、古くから鋳物産業が盛んで、じん肺患者が多いという地域的特性があります。埼玉民医連のセンター病院である埼玉協同病院は、川口市の指定医療機関としてじん肺・アスベスト外来にとりくんでいます。

2017年　じん肺申請者件数（検診のみをのぞく）

申請支援件数　18件	管理区分申請	労災	5件
		未確認	5件
		申請できず	2件
		申請中	2件
		状態悪化時再申請	3件
	管理区分申請	救済法	1件

指定医療機関になるまでの経過

埼玉協同病院でじん肺・アスベスト外来が開設されたのは、正式には2006年２月になります。当時、川口診療所の所長をしていましたが、週１回、埼玉協同病院でも外来診療を行い、2005年12月からじん肺・アスベストの患者を診察していました。じん肺・アスベスト外来では、まずは職歴などの問診を行い、身体所見を記録した後、じん肺管理区分についての説明をします。患者が希望すればＳＷにつないで管理区分申請の援助を行います。その際、胸部レントゲン撮影、採血検査、肺機能検査、ツベルクリン反応はセットで実施しています。

2005年６月に明らかになった兵庫県尼崎市のクボタ工場の従業員と周辺住民のアスベスト被害、いわゆるクボタショックによって、アスベスト被害が社会問題となりました。埼玉協同病院のじん肺・アスベスト外来の開設当初は、鋳物工場で働いていた労働者や、大工の受診が多くあり、徐々に患者が増加し、３年目でピークとなりましたが、その後は徐々に減少していきました。原因は、埼玉協同病院がじん肺の指定医療機関ではなかったため、じん肺管理区分の申請はできても、その後の管理は別の医療機関につながざるを得なかったためです。

働くもののための医療機関として、じん肺・アスベスト疾患に専門的に対応できるようになることをめざし、埼玉民医連では呼吸器専門医を確保する活動を続けてきました。それがようやく実を結び、埼玉協同病院に呼吸器専門医を迎え、2017年５月からじん肺、９月からアスベストの指定医療機関になることができました。現在、じん肺・アスベスト外来の新規受診者は月４人ほどですが、じん肺検診の受診者は年間50人受け持っています。

じん肺・アスベスト外来にとりくんで

じん肺の指定医療機関は地域性を考慮して指定されるため、新たに指定を受けるにはハードルが高くなります。しかし、川口市で長年じん肺の指定医療機関であった近隣病院の呼吸器専門医が退職したため、埼玉協同病院がその後継に手を上げることとなりました。

現在、埼玉協同病院のじん肺・アスベスト外来を受診する患者には、埼玉土建組合の健康診断の結果から受診を勧められたケースが多くなっています。健康診断でプラークの発見から受診につながれば、早期発見、早期治療が可能となり、社会資源を活用しながらフォローをしていくことができ、患者の負担も軽減されます。しかし、健診後受診になかなかつながらない人が多く、埼玉土建

組合との連携が必要となります。埼玉土建国保組合のとりくみとして、保健師による禁煙指導や、肺がん発見に特化した肺ドックなどを検討しています。

また、建設労働者以外にも、さまざまな職業の人からアスベスト疾患が見つかっています。珍しいものでは、銭湯のお湯を沸かすために使用していた建材にアスベストが含まれていたためにアスベスト粉じんを吸ってしまったというケース、飲食店でお店の改装を自分で行っていて、その建材にアスベストが含まれていたというケース、耕運機メーカーの駆動ベルトにアスベストが織り込まれていたというケースなどがありました。また公団住宅の建材にアスベストが含まれていることが判明してからは、公団住宅に住んでいる人からも相談があり、プラークが見つかったというケースもありました。

東日本大震災では、建材として使用されていたアスベストが飛散したという問題もあります。被災地支援で現地に行った際、防じんマスクについての講義を行いました。今後、再び災害が起きれば、そうした対応が必要になると考えます。

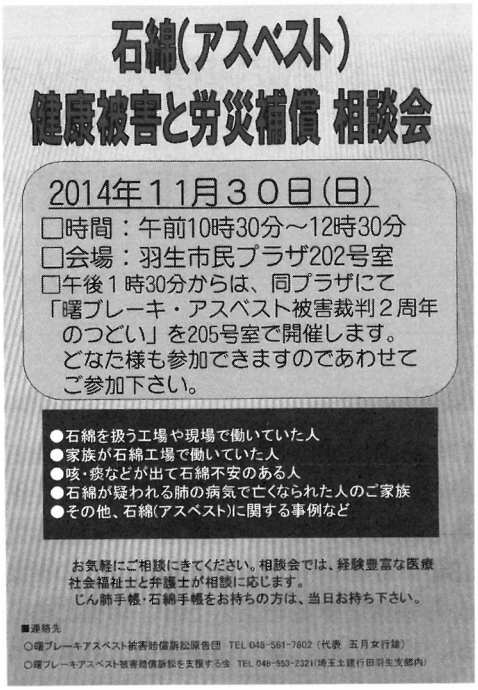
おわりに

アスベストは生産から廃棄まで管理が必要であり、その被害は「複合ストック型の公害」です。きちんと廃棄されるまで管理が行き届かなければ、新たな健康被害を引き起こしてしまう恐れがあります。

例えば、廃棄された布を利用してウエスを作成する会社で、アスベスト肺の患者が見つかったというケースがあります。

アスベストによる健康被害は多くの人に知られるようになってきてはいますが、さまざまなところでアスベストが使用されているため、思いもよらぬところでその被害に遭うということが起こる恐れがあります。

アスベスト被害についての情報を広く知らせていくだけでなく、健康診断などでプラークなどが見つかったときに相談することができ、社会資源の活用につながるところまでの支援を受けることができるじん肺・アスベスト外来の存在は、ますます重要になっていくと考えられます。



相談会の案内チラシ


研修医に呼吸保護具の講義（2011年5月、石巻赤十字病院）

埼玉協同病院年報　掲載基準・論文投稿規定

1．資格：筆頭著者および責任著者は埼玉協同病院職員に限る。

2．論文内容：当院の学術活動、診療技術の水準を反映するものとする。

◎論文区分；論文の区分は、研究論文・技術論文・総説、症例、資料、報告、その他とする。

3．既に、医中誌や Pub Med 等のデータベースに収載された雑誌に掲載されたあるいは accept された論文は、その旨を明記し別冊 1 部を年報編集委員会に提出する。それ以外の論文は「4．執筆要項」に従う。

4．執筆要項

◎概要：和文または英文とし，希望の論文の区分を必ず明記する。（論文の区分は学術教育委員会の意向によって変更を指示する場合もある）

原稿はワープロを用いてＡ４・縦、横書きに印字する。

英文（文献を含む）の場合も同様にＡ４・縦、横書きに印字する。

なお、共著者がある場合、筆頭著者および責任著者は全員が本論文の投稿を承諾したことを確認する。

◎論文の構成：表題、著者名、所属、所在地、和文要旨、キーワード、および本文とし、図表をつける。共著の場合、著者全員の所属を記す。

◎論文の長さ：要旨および文献を除いた本文の長さは総説が 12,000 字以内、研究・技術論文・資料・技術講座 8,000 字以内、症例報告 6,000 字以内、その他 5,000 字以内とする。図表・写真は、１点につき 400 字換算し上記に含める。

◎表題：表題は内容を簡潔、的確に明示するものとし略語はなるべく用いない。

◎要旨：和文　400 字以内（できれば英文も 200word 以内）Key Word：５word 以内

◎図（写真原稿を含む）、表等はＡ４版で１枚ずつ別の用紙に作成し、上記原稿の余白に挿入位置を指示する。

◎図表の番号や、標題名、解説等は、白黒プリントにして原図を１／４程度に縮小しても読み取れるように確認する。

◎文献：本文に用いられた文献は引用順に整理して文末に一括記載し、「著者名：題名・雑誌名（または書名）・巻数・ページ：発行年」の順とする。

◎その他　　原稿の頭に「分類」、末尾に「発表先または掲載雑誌名」を記載する。

上記に基づいて原稿が出来上がり次第、年報編集委員会が指定するフォルダに保存もしくは提出する。

※発表に用いたパワーポイントに、発表原稿を文字化した文章を付したものは上記の「論文」には該当しない。必ず「4．執筆要項」に従って記載する。

2013 年制定

2015 年改訂

編集後記

職員の協力により無事 31 巻目の「年報 2018」を発行することができました。

ここ数年医療を取り巻く状況は更に厳しいものとなっています。医療そのものが発展することは喜ばしいことですが、ある程度大きな病院になると細分化が進み、職員一人ひとりの顔が見えなくなってきていると感じます。

2018 年度は埼玉協同病院の大規模なリニューアルに向けた論議が開始されました。7 年先を見越したリニューアルとなり、ますます職員の力の結集が重要となります。まだ議論は始まったばかりですが、この年報に掲載された各職場や委員会の取り組みをさらに継続、発展させたいと考えています。

今回の発刊にあたり、私たちの医療を見直すとともに、今後もより一層地域への医療貢献に役立てればと思っております。

「年報」の背表紙は虹色がモチーフとなっており、今年は青色となっております。皆様のお手元に届き書棚が虹色に飾られることを楽しみにしております。

2019 年 7 月 25 日　　埼玉協同病院年報作成委員会メンバー一同

埼玉協同病院年報作成委員会　メンバー

市川　大輔　　山梨　　忍　　松本　　茂

根岸　千尋　　戸邉美穂子

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