

Executive Summary

Irritable bowel syndrome(IBS) is a chronic condition that is considered to have no structural or biochemical abnormalities that account for the symptoms. IBS is not life threatening condition, however, they could significantly impair the quality of life. IBS is important to public health because they are remarkably common, can be hindering daily activities and they induce a major social and economic burden. Thus, the impact of IBS on public health is probably huge. Despite its potential health relevance, the impact of IBS has received relatively little attention compared to other life threatening diseases in Korea.

The structure of this study is as follows. Firstly, the present study was performed for the national level estimation of the epidemiological characteristics of IBS and socioeconomic cost of the syndrome. Secondly, a questionnaire investigational study was conducted against the patients having IBS to figure out the size of socioeconomic burden of IBS and the factors that have effects on the disease burden. Thirdly, systematic review for Korean and international studies by including the studies of Asian countries was performed to investigate the effects of IBS on the quality of life. Fourthly, a qualitative study was performed against the Korean IBS. Finally, the Korean version of the diagnosis criteria(Rome III) for the diagnosis of functional gastrointestinal disorders, including IBS was developed.

Study results:

1. Disease statistics for major gastrointestinal diseases including IBS

During a single year of 2007, the prevalence of the major digestive diseases were estimated by using the health insurance claims data,

which showed 9.9% for most commonly occurring Gastritis(ICD K29) followed by 4% for gastroenteritis, 3.6% for gastroesophageal reflux disease, 3.3% for peptic ulcer, 3.0% for IBS and 2.6% for constipation along with 2.6% of other functional gastrointestinal disorders. The direct cost including nonpayment developed by the gastrointestinal diseases in the year of 2007 amounted to be 3,649 billion won by taking up 0.4% of national GDP. Among the cost, the expenditure developed by gastrointestinal malignancies took up the largest portion of 36.7% followed by 18.4% of upper gastrointestinal diseases, and by lower gastrointestinal diseases excluding constipation and appendix diseases. The number of examined patients by the most commonly occurring gastroesophageal reflux disease, gastritis, IBS and other functional gastrointestinal disorders that could be classified as the functional gastrointestinal diseases took up 53.6% of total patients numbers examined by gastrointestinal diseases, and the total medical cost for these diseases without considering prescription fee was found to take up 14.4% of the total costs.

IBS is common, and the condition is often chronic, with a relapsing and remitting nature. We defined the IBS patients by any consulting a physician with symptoms. This approach might underestimate the real prevalence of IBS in general population. The Health Insurance Review & Assessment claims database is a nation-wide, large population-based health insurance electronic database, containing all medical and prescription drug claim records covering the entire population of Korea. South Korea operates a mandatory universal National Health Insurance(NHI) system, with a centralized health care claims database that provides a nationwide source of information on health care resources utilization. The patients with IBS were identified as those who had at least a medical and/or disability claim with a primary code or secondary diagnostic codes(1st-4th diagnostic codes) by physician's diagnosis and discharge diagnostic codes. All claims records of outpatients or hospital admissions of patients containing a

diagnosis of the International Statistical Classification of Diseases and Related Health Problems 10th Revisions(ICD-10) codes.

The prevalence of IBS was 5.1% in males and 6.9% in females, yielding a female/male ratio of 1.44. The prevalence of IBS was shown the increased tendency with aging, from 4.6% for 20-29 year old to 8.7% for 60-69 year old, however, the IBS prevalence in 80 decades was lower than that in 70 decades. The 1/5 of IBS patients among the whole IBS patients was in the age group 40-49 years. According to the subtype of IBS, IBS-D was most common subtype in 35.7% of IBS. The proportion of IBS-D subtype was decreasing as becoming old with 48.1% under 20 years and 31.7% above 60 years. IBS-D was more prevalent in men than that in women(38.3% vs. 33.8%).

Diseases that most frequently accompanied IBS were upper gastrointestinal diseases(36.1%) including gastritis and gastro-esophageal reflux diseases, followed by diseases of the respiratory system(12.3%), muscular system diseases(8.0%), somatiform disorders(4.3%) and anxiety disorders(3.1%).

The total reimbursement payments for IBS incurred during the year of 2008 was estimated to be 162 billion won, which corresponds to approximately 0.46% of the total reimbursement payments for the entire population of Korea the same year, which was 35 trillion won. The annual average reimbursement payment for IBS per person was 67,080 won(standard deviation 248,374 won, median 20,030 won).

In 87.6% cases, drugs were prescribed related to IBS, while the remaining cases had either no prescriptions or drugs were prescribed for conditions other than IBS. The mean duration of prescription per case of outpatient visit was 9.1 days(± 11.6 days). The mean number of drugs per prescription was 5.5. Anti-spasmodics were the most frequently prescribed drugs for IBS constituting 75.2% of prescriptions, followed by probiotics(64.5%) and prokinetic drugs (43.5%). Most prescriptions included three types of drugs(34.1%),

followed by four types of drugs(28.2%) and two types of drugs(20.3%).

Anti-spasmodics were the most frequently prescribed(38.4%), followed by medicines for probiotics(38.2%) and prokinetics(9.7%) for single drug prescription. When two drugs were given, the combination of anti-spasmodics and probiotics(35.8%) was the most frequent therapy, followed by the combination of antispasmodics and prokinetics(7.1%) and medicines for probiotics and antibiotics(6.1%).

2. Questionnaire investigational study for patients with IBS

A questionnaire was devised to seek a method to reduce the disease burden by figuring out the factors that have effects on the disease burden of IBS. The contents of the questionnaire included with the symptoms of IBS, quality of life, accompanying diseases, loss of productivity, satisfying level for medical institute, education and information level, direct and indirect medical cost, family problems, along with general characteristics. Total numbers of IBS patients who were participated the questionnaire investigational study through medical institutes ranged to be 273 patients by including 118 male patients(43.2%) and 155 female patients(56.8%). More than 54% of the respondents had moderate to severe disease severity more than 'serious' level.

When their quality of life was checked out, the characteristic estimation of the life quality by having IBS resulted to show lower score in 'food avoidance' or in 'health concern(worry)' domain compared to other domains, and the score in 'sexuality' was higher than other domain. The estimation of patients' quality of life by using the EQ-5D tool resulted with 0.889 that was lower than the score(EQ-5D index) of 0.933 that was scored by the general population in Korea, and the index was found to be lower than that of patients with hemorrhoids(0.925), that of the patients with atopic dermatitis(0.924), and that of the patients with gastric and duodenal

ulcer(0.901).

As the past history, peptic ulcer disease was the most common type of accompanied disease followed by urological diseases and hypertension, and 41.9% of the respondents had a family history of intestinal problems.

A survey for the circumstances of experiencing difficulties in a work by IBS showed that 1/3 of the participants responded to have more or less difficulties(scored higher than 3) in a work and 10.8% of the participants responded to have quite lots of difficulties(scored higher than 6). However, the average disease duration of the questionnaire respondents was 10.34 years.

The patients with IBS revealed to use over-the-counter drug(8.1%), health functional foods(8.4%), health aid tools(4.8%), and folk remedies(8.8%).

IBS is a chronic disease that is difficult for its complete recovery, and the patients visited several medical centers when their symptoms are not improved. Before diagnosed as IBS patients, 1 out of 3 patients found to visit more than 3 different medical institutions, and more than 15% the patients responded to visit another institution even after diagnosed as IBS patients. Other than that, the cases of visiting other medical departments or having repeated medical examinations were high due to its difficulty in treatment and distrust against the diagnosis.

The patients scored the previous IBS related medical examinations as 5.8 point in 10 point scale, and the satisfaction level for medical examination tended to be lowered by the seriousness of subjective symptom severity. The information regard on IBS was mainly gathered by physicians or by internet. The IBS related information was mainly the type on symptoms and management and prevention of IBS. But the satisfaction level of the information scored average of 6.1 point in 10 point scale, and the score was lowered to the average of 5.6 point when they were asked whether the acquired

information was helpful or not in actual life and in their health, and the score was tended to be lowered by the seriousness of subjective symptom severity.

3. Calculation of the burden of irritable bowel syndromes

The total expenditure in 2008 for healthcare services and pharmacy services related to IBS, estimated through claims data from the HIRA were approximately 349.9 won. Transportation costs were also estimated, considering the number of times healthcare services were utilized, to be 90.3 billion won. Thus the direct costs for IBS, including both medical costs and transportation costs, were estimated to be 440.2 billion won. Indirect costs, based on loss of productivity, were estimated to be 145.2 won, thus the total burden of irritable bowel syndromes was estimated to be 585.4 billion won(Table). The ratio of medical costs was the highest at 60.0%, followed by transportation costs at 15.4% and productivity loss costs at 24.8%. The proportion of Inpatients was about 2% of the total patients, but they consumed about 16% of the total disease costs. And patients who visited outpatient clinics three or more times was about 20% of the total patients, but over 50% of the total disease costs were spent by them. If other medical costs incurred by patients, such as over-the-counter drug costs and health food costs, are added to the aforementioned costs, using the results of a patient survey separately conducted on IBS patients, the total amount is estimated to be 773.8 won. Based on the results of sensitivity analysis, the total expenditure for medical care related to IBS was estimated to be 556.3 billion won at the minimum and 640.6 billion won at the maximum, depending on whether excessively abnormal values were removed, the adjustment of the number of days of administration and the adjustment of employment rates.

The average amount of costs per patient was 240 thousand won,

while it was around 680 thousand won for patients who visited outpatient clinics three or more times.

4. Systematic review for social burden and quality of life of IBS

To conduct the systematic review for social burden and quality of life of IBS in our nation and in Asian countries, the publications related with IBS were searched in systematic method in Korean and other databases, and the final literatures were selected according to the selection/exclusion criteria for the preparation of a final conclusion. Since the literatures about social burden were not nearly available, the studies on quality of life were discussed. Compared to a normal healthy population, IBS patients in Korea revealed low quality of life with high stress point and visited medical centers more frequently and took more medications. In case of Asian region, their quality of life was also lower than a normal healthy population with high prevalence for psychiatric diseases by showing high anxiety score, and the frequency of receiving abdominal surgery was high and frequently visited medical institutions by showing high prevalence for urinary bladder symptoms.

5. Qualitative study for the disease experience of IBS patients

To investigate the Korean specific circumstance of the IBS studies unlike to those of other studies for IBS patients, a qualitative study was carried out for IBS. Analyses were performed based on the patients' interview data that were acquired on the following 5 topics of including the symptoms of the disease, causes of the disease, psychiatric stress, social life and disease management. Through the detailed statement of patients, the characteristic complexity and variation of the symptoms and the uncertainty of the symptom were considered for the patients to experience more difficulties in handling

the disease. Due to the disease name of 'irritable bowel syndrome', the family or close friends of the IBS patients recognized the 'irritable' as 'nervousness' and tried to understand the 'intestinal disease' by relating its causes with dietary habit. Other than the psychiatric stresses caused by IBS, the patients were found to have isolated or alienated feeling due to unsatisfactory recognition for their roles. These circumstances shrink social activity of the patients. Frequently, patients were not convinced the diagnosis of IBS because of negative results of the medical examination with sustained GI symptoms. Therefore, they tended to seek the additional medical services.

6. Development of Korean version of functional gastrointestinal disorder diagnosis ROME III criteria(ROME III)

Korean version of questionnaire development was carried out for the diagnosis of functional gastrointestinal disorders including irritable bowel syndrome. For the development of Korean version of the internationally accepted ROME III criteria, the approval of the ROME committee was acquired and the Korean version questionnaire was accomplished through the translation/back-translation of the criteria. By using the translated Korean version of ROME III, a questionnaire investigation was performed for general population by including 786 people. The investigational study revealed that 49.7% of the population was diagnosed as the patients with functional gastrointestinal diseases, and the diseases were the most common types of diseases in the primary and tertiary medical centers. The most common types of the functional gastrointestinal diseases were found to be functional dyspepsia and irritable bowel syndrome.

The healthcare utilization burden by IBS appears to be high because of the high morbidity although no mortality. IBS patients

consume health care resources related with gastrointestinal and extra-intestinal comorbidities with work productivity losses.

Despite the low mortality, one third of the patients utilized higher healthcare institutions, which was associated with increased medical costs. The fact that the diagnoses of IBS is an exclusion diagnosis, made after excluding organic diseases, may contribute to distrust of primary treatment or lack of patient understanding. Developing and implementing active education programs to enhance patients' understanding of IBS and instill confidence in the treatment regimens may be an efficient method to reduce the burden of IBS. In addition, guidelines for diagnoses and treatment should be developed to induce the use of appropriate healthcare services, as well as to judge the utility.

This is the first study in Korea to identify the functional gastrointestinal disorders with a high prevalence rate and low mortality rate that carries a high disease burden. Thus, it is expected that the results of this study can be utilized in policy decision making to allocate of health care resources, and preparing guidelines for clinical studies and treatment.