Executive Summary

Safe and efficient use of radiotherapy equipment from health technology perspective

1. Backgrounds and Objectives

Cancer patients are continuously increasing in Korea and chemotherapy using radiotherapy equipment is increasing. 50% of cancer patients in advanced countries are receiving radiotherapy and about 30% of cancer patients in Korea are receiving radiotherapy currently.

In Korea, radiotherapy equipment is a medical device that is regulated by medical device legislative system and at the same time as a radiation emitting device it is regulated by nuclear safety law. Radiotherapy using radiotherapy equipment is regulated by nuclear safety law but patient safety-centered management system for radiotherapy equipment is needed.

The purpose of this study is to investigate domestic current status on radiotherapy equipment control and to examine relevant management system and recommendations of foreign countries in perspective of healthcare technology, which could supply evidence for preparation of patient-centered safety management system to improve quality assurance of radiotherapy and radiotherapy equipments.

2. Methods

1) Status of radiotherapy equipments and radiotherapy professionals in Korea

Radiation equipments are largely classified into x-ray emitting devices, gamma-ray emitting devices, protontherapy and heavy-ion therapy equipments. The subjects of this study are x-ray emitting devices including LINAC with or without IMRT, Tomotherapy and CyberKnife and gamma-ray emitting devices including GammaKnife and external beam radiotherapy equipment of protontherapy. The status of radiotherapy equipments in Korea was investigated by manufacturers, regions and medical institutions based on June 2012 domestic supply data received from the vendors.

Radiotherapy professionals included radiation oncologists, medical physicists, radiology technologists who work in radiotherapy field. In this study, medical institution inventory data of Health Insurance Review and Assessment Service and specialty society data were collected from July 2012 to August 2012 and investigated.

2) Investigation of domestic and foreign management systems and recommendation associated with radiotherapy equipments

Radiotherapy equipment management systems and recommendation in Korea, Japan, United States, United Kingdom (Europe) were divided by before and after market release and homepages and published literatures of health department, medical device approval authorities, relevant specialty societies, IAEA, WHO of each country were searched and investigated.

3) Radiotherapy professional questionnaire survey

Web-based online survey was conducted by sending emails to approximately 300 clinical doctors of the Korean Society of Radiation Oncology, 700 members of Korean Society Radiotherapeutic Technology and 250 members of Korean Society of Medical Physics through each society.

3. Results

1) Current status of radiotherapy equipments and radiotherapy professionals in Korea

According to the investigation as of June 2012, the number of external beam radiotherapy equipments in Korea is 193 and 78.7% are linear accelerators and 65.2% of total radiotherapy equipments are linear accelerators with intensity-modulated radiation therapy (IMRT) function. 80% of radiotherapy equipments are scattered in Seoul and metropolitan area. The number of radiotherapy equipments per 100,000 population is the highest in Seoul as it is 1.5 and the lowest in Jeju as it is 0.2 and nationwide average is 0.7. 70% of radiotherapy equipments are scattered in upper-scale general hospitals and 28% in general hospitals.

As for radiotherapy professionals, there are 84 medical institutions with radiation oncology in Korea as of June 2012, 189 radiation oncologists, 99 medical physicists and 520 radiology technologists who work in radiation oncology. The number of new patients per 1 professional was the highest in medical physicists as it was 502 per 1, 263 per 1 radiation oncologist and 96 per 1 radiology technologist. As for regions, the number of professionals per 100,000 population was the highest in Seoul as there were 3 radiology technologists, 1.2 radiation oncologists, 0.4 medical physicist and it was the lowest in Jeju as there were 0.8, 0.3 and 0.1 respectively.

2) Investigation of foreign and domestic radiotherapy equipment-related management policies and recommendation

All radiotherapy equipments are approved or reported from approval authorities as medical devices before being released in the market in Korea, Japan, U.S. and U.K. (Europe). They receive

facility, professional and safety management by regulatory authorities after being released in the market.

As for safety management of radiotherapy equipments, the radiation diagnostic equipments and radiotherapy equipments are managed together under the medical service law by Ministry of Health, Labour and Welfare and facility and professional management are done by Ministry of Education, Culture, Sports, Science and Technology in Japan. In United States, radiation diagnostic equipments and radiotherapy equipments are managed together under the state laws by state governments and certain states issue license for facilities that use radiotherapy equipments and conduct audits. Equipment quality control is done voluntarily through institutions such as RPC (Radiological Physics Center). In United Kingdom, radiation diagnostic equipments and radiotherapy equipments are managed together under IR(ME)R2000 law by CQC (Care Quality Commissions) for medical exposure including patient safety and under IRR1999 law by HSE (Health & Safety Executive) for safety control such as professional exposure. The countries that mandated the quality control of radiotherapy equipments as a law are France, Germany and Norway. In Korea, radiotherapy equipment safety control is managed under nuclear safety law by the Nuclear Safety and Security Commission but patient safety laws are not yet prepared.

As for adverse event management and incident report system after market release, medical equipment mechanical adverse events are managed under Pharmaceutical Affairs Act in Japan and in United States, it is managed under Medical Device Reporting Law by the FDA and at the same time, certain state governments collect adverse event data and manage adverse events of radiotherapy equipments under the state law. United Kingdom is one of the countries that collect radiotherapy-related adverse event data systematically. Adverse events due to medical

exposure rather than equipment failure or defects are managed by IR(ME)R2000 Law and adverse events due to equipment failure are managed by IRR199 and equipment performance or safety issues are managed by MDR2002. In Korea, safety data are collected by KFDA when adverse events are due to mechanical failure but it is not managed by the government when adverse events are due to medical exposure.

Radiotherapy QA-related guidelines are published by radiotherapy-related academic societies, IAEA and WHO and defining the role of professionals, qualification requisites and maintenance and repair education is needed for radiotherapy quality control.

3) Radiotherapy professional questionnaire survey

A web-based online survey was carried out on radiotherapy expert 1,226 and 257 expert replied. Finally 244 participants except for missing and error data were included in the analysis (20.0%).

Participants answered that lack of relevant professionals was a main hampering factor affecting the quality and safety management of radiotherapy and equipment. The factors affecting patient safety and treatment results in radiotherapy were professionalism and working experience of radiotherapy work force (128, 52.5%), establishment and implementation of quality assurance process for radiotherapy (51, 20.9%), and continuous quality control for radiotherapy equipment (43, 17.6%). The highest priority for safe and efficient management of radiotherapy and equipment was establishment of regulations for qualification and continuous education and training of radiotherapy professionals. However, it showed the difference of highest priority according to expert functions - establishment of national health insurance system linked with radiotherapy quality management for

radiation oncologists, development of radiotherapy quality assurance guidelines based on domestic circumstances for radiation therapists, and establishment of regulations for qualifications and continuous education and training for medical physicists.

4. Discussion and conclusion

The risk of accidents occurrence during application of radiotherapy equipment on patient is low. However, if an error or incident occurs, it can be very dangerous to the patient. Therefore, management that considers patient safety is necessary. Currently, follow-up management has focused on safety control of radiation facilities and relevant workers, not on safety management for patients. Therefore, quality control plan using medical device used in medical practice that considers patient safety is needed.

Co-operation of relevant stakeholders including government bodies and expert groups is needed to prepare a plan of specific safety management and quality control for safe and efficient radiotherapy using radiotherapy equipment.