협회 창립20주년 기념 한 · 중 · 일 학술대회 발표논문

Production and Quality control of PET-Radiopharmaceuticals in Japan

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At May 2005, the numbers of 83 PET-facilities have been operated in Japan. It was 63 at September 2004. These PET facilities promote the medical diagnosis of various diseases(cancer, brain disorders and heart function) for patient under covering medical insurance system and the medical check of cancer seeking by 18F-FDG for healthy people.

Every PET facility in Japan has the accelerator,hot cell, chemistry devices and PET instruments. Commonly used PET radio-nuclides (11C, 13N, 15O and 18F) have been produced by the nuclear reaction of 14N(p, n)11C, 16O(p, ´)13N, 15N(p, n)15O or 14N(d, n)15O and 18O(p, n)18F. Other positron emitting nuclides such as 34mCl, 38K, 45Ti, 48V, 52Fe, 62Cu(62Zn), 68Ga(68Ge), 76Br, 82Rb(82Sr) and 124I were produced for the research.

The labeled compounds are routinely synthesized on line systems for gasses compounds and by automated synthesis system for 11C and 18F labeled radiopharmaceuticals.

The committee of Japan radioisotope association approved 13 PET radiopharmaceuticals (11CO, 11C-acetic acid, 11C-methionin, 11C-cholin, 11C-N-methylspiperone, 13N2, 13NH3, 15O2, C15O, C15O2, H215O, 18FDG and 18FDOPA) with the quality regulation for clinical use. The clinical PET using 15O2, C15O, C15O2 and 18F-FDG is supported by governmental medical insurance system from 2002. The committee of Japanese society of nuclear medicine recommends the guideline of production and quality controlof these PET radiopharmaceuticals and the guideline of clinical application.

The quality regulation of PET radio-

pharmaceuticals is same as ordinal radiopharmaceuticals but only the timing of the sterilization check is deferent from the case of long half life radiopharmaceuticals. The results of sterilization check come out after the clinical use because of short half life of PET radiopharmaceuticals. But the data can be used as process validation.

The development history of 18F-FDG, production process and quality controlwill be reported as an example and the requirements to clinical trial of new developed PET radiopharmaceuticals will be also suggested.

Recently, commercial deliver of FDG have been started in Japan. This means that another hundred of new PET facility without acceleratorwill be operated in near future. KRIA