ONO-1: Organization, Operation and Management of a BNCT Treatment Facility and Regulatory Aspects

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The medical staff at the BNCT facility consists of a variety of professionals. They are radiation oncologists, specialists in nuclear medicine, medical physicists, radiation technologists, pharmacists, nurses, etc. In clinical practice, specialists in departments corresponding to each tumor type are also included. However, the central players among the facility staff is the radiation oncologists and radiation science related professionals, otherwise there is no steady development of BNCT. The number of staff required depends on the number of patients. However, assuming four treatment days per week and three patients per day, 4 radiation oncologists will be required for prior treatment planning and simulation. Five medical physicists, 2 specialists in nuclear medicine, 8 clinical radiation technologists, 5 nurses, and 2 pharmacists are required. The operation of the cyclotron is left to the company. Treatment planning requires accurate and deep knowledge on the neutron distribution, the concentration of B-10 drug in tissues, and the biological effects produced by the reaction. In particular, since recurrent cases are often treated, the time required to consider the tolerable dose, including the dose of preceding X-rays, is incomparable to conventional particle beam treatment. At present stage, close joint work between the medical staff at the BNCT facility and specialists in the department for each kind of cancer is essential. In future, an independent operation of the facility by the specialists of radiation medical science will increase like as curent radiotherapy. The decision of the indication of BNCT to an individual case have to be made through impartial deliberations on the cancer board. This process is indispensable for BNCT to obtain a definitive position in cancer treatments. It is also a place to educate physicians and others who may not have enough knowledge about BNCT. In Japan, the clinical utility of cyclotron neutron source / irradiation systems and boron drugs has been verified in legally-based clinical trials. Based on the results, the Ministry of Health, Labor and Welfare has formally approved BNCT for recurrent /locally advanced inoperable head and neck cancer. Medical expenses are covered by government-controlled health insurance. It is expected that malignant glioma will follow. Radiation exposure to medical personnel engaged in BNCT is a very important issue. In my system, the patient is completely fixed to the irradiation bed in the preparation room next to the irradiation room, and the patient on the bed is automatically moved to the irradiation position, so the exposure dose to the medical staff is negligible level. Given the future of BNCT, it is necessary to obtain an approval of indication to various type of cancers, just like current particle beam therapy. For that, new scientific ideas also are required.