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A study on safety and efficacy of hypofractionated radiotherapy in post-operative breast cancer patients

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【Introduction】FNCA (Forum for Nuclear Cooperation in Asia) is a Japan-led cooperation framework for peaceful use of nuclear technology in Asia. The cooperation consists of FNCA meetings and the project activities with the participation of Australia, Bangladesh, China, Indonesia, Kazakhstan, Korea, Malaysia, Mongolia, Philippines, Thailand and Vietnam. Radiation oncology project is one of ten projects, and conducting multicenter cooperative clinical trials on radiotherapy for common cancers in Asia have been carried out since 1994. The object of this joint group is to establish safe and effective, technically feasible and economically reasonable treatment in Asian countries.

【Objective】We have been conducted clinical trial of hypofractionated radiotherapy for post-operative breast cancer since 2013. The aim of this protocol is to prove that hypofractionated whole breast irradiation (HF-WBI) in breast conserving therapy (BCT) and hypofractionated post mastectomy regional radiotherapy (HF-PMRT) are as safe and as effective as conventionally fractionated radiotherapy and superior in terms of convenience. If the hypofractionated radiotherapy is equally useful for Asian patients, more patients will be able to receive radiotherapy in radiotherapy resource-poor countries.

【Methods】The eligibility criteria for HF-WBI are patients who have undergone breast conserving surgery and have been histopathologically confirmed to have breast cancer, tumor size is either Tis, T1 or T2, undergone a lymph node dissection (including sentinel lymph node biopsy) and has been histopathologically confirmed to have 3 positive lymph nodes or less. The eligibility criteria for HF-PMRT are patients who have undergone mastectomy and have been histopathologically confirmed to have breast cancer, without positive margin, undergone a lymph node dissection (including sentinel lymph node biopsy) and has been histopathologically confirmed to have less than 8 positive lymph nodes. Patients with parasternal lymph node metastasis are excluded. Radiotherapy consisted of 2.7 Gy per fraction, 16 times, up to the total dose of 43.2 Gy to conserving breast on HF-WBI, or chest wall and supraclavicular fossa on HF-PMRT. The patients who have high grade factors, which are age less than 50, positive axillary lymph node metastasis, lymph vascular invasion, positive surgical margin are added 3 times boost irradiation to the tumor bed up to the total dose of 51.3 Gy. The accumulation number of cases was set as 200 cases in both arms.

【Results】From February 2013 to October 2016, 184 cases of HF-WBI and 131 cases of HF-PMRT were registered. In HF-WBI arm, the median age was 50 years old (range, 24–79). The clinical stage was 0 in 21 patients (11%), 1A in 100 (54%), 1B in 2 (1%), 2A in 42 (23%), and 2B in 19 (10%), respectively. One hundred five patients with high risk factors received boost radiotherapy to tumor bed. The median treatment duration was 26 days (range, 18–54). Acute dermatitis of grade 2 or more have been observed in 30 patients (17%) and grade 2 acute subcutaneous toxicity in 6 patients (3%). In regards to the late toxicity, grade 2 lung toxicity was observed in 2 patients, grade 2 skin toxicity in 1, grade 2 subcutaneous toxicity in 1, grade 1 heart toxicity in 5, and grade 2 heart toxicity in 2. One loco-regional recurrence, 2 distant metastases and 1 breast cancer death have been observed. In HF-PMRT arm, the median age was 48 years old (range, 24–74). The clinical stage was 2A in 50 patients (38%), 2B in 50 (38%), 3A in 27 (21%), 3B in 3 (2%), and 3C in 1 (1%), respectively. The median treatment duration was 21 days (range, 19–49). Acute dermatitis of grade 2 or more have been observed in 6 patients (5%) and grade 2 acute subcutaneous toxicity has been observed in one patient (1%). Acute grade 1 heart toxicity has been observed in 15 patients (11%) and late grade 1 heart toxicity in 6 patients (5%). Three loco-regional recurrence, 7 distant metastases and 3 breast cancer deaths have been observed.

【Conclusion】In the intermediate analysis, HF-WBI and HF-PMRT have almost the same effectiveness and

safety as conventional fractionation. Additional registration and longer follow up must be needed to obtain final results.

Country

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