Executive Summary

Current status and Outcomes analysis of Radiosurgery for Spinal tumors

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☐ Introduction

: With the development of health technology, the survival rate and survival period is extended for the cancer patients and the number of patients for metastatic cancer is also increasing gradually. According to the trend, the patients for metastatic spinal cancer are also increasing. Treatments for the metastatic spinal tumor are surgical operation, radiation therapy, radiosurgery and so on, recently radiosurgery is evaluated as the valid treatment for spinal tumor and its utilization is increasing. However, there are not basic data and sufficient studies about the current domestic condition of radiosurgery treatment and the other treatment for metastatic spinal tumor.

Therefore, in this study, the current medical use such as therapeutic frequency, cost and duration of hospitalization by the treatment and the therapeutic performance of the radiosurgery and radiation therapy for the metastatic spinal tumor will be analyzed to provide the evidences on decision-making for the therapeutic method in clinic and the basic data on developing the policy related to the radiosurgery for metastatic spinal tumor.

☐ Study Method

Ⅰ. The national current medical use and therapeutic condition of each treatment for the spinal tumor using the national health insurance claim data

By using the national health insurance claim data occurred from January 1st,2008 to December 31st, 2012, the prevalence and incidence of the spinal tumor (primary positive, primary malignant, metastatic) patients and their medical use were identified.

To identify the therapeutic trend and frequency of the new spinal tumor patients after the benefit introduction (April, 2011) of stereotactic radiosurgery (SRS) on the body, among the new patients diagnosed the spinal tumor from July 1st, 2011 to December 31st, 2011, the national therapeutic condition of radiation therapy, radiosurgery, surgical operation, chemotherapy within 1year after diagnosis were identified.

||. Analysis of therapeutic performance for the metastatic spinal tumor patient using retrospective patient cohort

Among the patients diagnosed with metastatic spinal tumor from 2005~2012 in four hospitals, adults performed with stereotactic radiosurgery (SRS) as the first treatment for the metastatic spinal tumor were subjected as the patient group. Among the patients who received CRT as the first treatment for the metastatic spinal tumor, control group was selected by considering the primary cancer site, the number of metastasized spine, and age.

The clinical data were collected by reviewing each patient' s electronic medical record.

Patient' s general characteristics, the characteristic of the primary cancer, condition of the metastatic spinal tumor, patient' s condition before treatment and prognostic index, patient' s condition after treatment and follow-up(1 month, 3 months, 6 months, 12 months, etc.) was executed. At each follow-up point, we focused if the treated spine site was controlled, if the pain level was changed. The average follow-up duration, local control and pain level change within 6 months, which were defined short-term outcomes as the lastly conditions within 6 months after the first treatment, were analyzed by descriptive statistics, t-test and chi-squared test stratified by primary cancer site.

□ Study Result

ㅣ. The national current medical use and therapeutic condition of each treatment for the spinal tumor patients using the national health insurance claim data

The number of spinal tumor patients were increasing every year, and primary positive spinal tumor was mostly occurred in the age of 40~50' s, malignant spinal tumor was

mostly occurred in the age of 50~60' s and metastatic spinal tumor was mostly occurred in the age of 60' s.

To identify the therapeutic trend of the new spinal tumor patients after the benefit introduction (April, 2011) of stereotactic radiosurgery (SRS) on the body, among the new patients from July 1st, 2011 to December 31st, 2011, use of radiation therapy, radiosurgery, surgical operation, chemotherapy within 1 year after diagnosis were identified. For new patients of primary positive spinal tumor, those who received at least one of radiation therapy, radiosurgery, surgical operation, or chemotherapy once were 57.1%, and they all received surgical operation. Among the new patients of primary malignant spinal tumor, 61.0% received more than one of the four treatments, and among them, patients receiving surgical operation was the most with 72.0%, followed by chemotherapy (26.0%). 76.5% of new patients of metastatic spinal tumor received more than one of the four treatments, and among them, patients receiving chemotherapy (81.5%) was the most, followed by radiation therapy (46.6%). 10.7% received radiosurgery.

To identify the local treatment (radiation therapy, radiosurgery, surgical operation) use condition by the new patients diagnosed with spinal tumor after the SRS benefit, among the patients who received one or more of at least one of the three treatments from July, 201 to December, 2011, treatment use condition was analyzed. For the first treatment selected by the new patient, the most was radiation therapy (69.2%), followed by surgical operation (17.9%) and radiosurgery (12.5%). 80-84% did not perform additional treatment after the first treatment, and the second treatment selected were all radiation therapy such as radiation therapy, radiosurgery, and surgical operation.

II. Analysis of therapeutic performance for the metastatic spinal tumor patient using retrospective patient cohort

1) Analysis of the patient group receiving radiosurgery as the first treatment for metastatic spinal tumor.

The sites of primary cancer for the patients received radiosurgery as the first treatment for metastatic spinal tumor were in the order of lung, liver, kidney, breast, and colorectal, which was 65% of the total patients subjected. The patient' s average age before radiosurgery by the primary cancer site was the lowest with 54.6 years of age for patients with breast cancer, and the highest with 65.8 years of

age for patients with lung cancer.

At the baseline, which was shortly before the first treatment for metastatic spinal tumor, 80 patients (44.4%) among total 180 patients were in progress of disease condition for the primary cancer, and among them, 31 lung cancer patients (63.3%) were in progress as their primary cancer, which was the higher rate than other primary cancers.

In the frequent primary cancer, the main five primary cancers (lung, liver, kidney, breast, colorectal cancer) were limited to identify the patient' s general condition and the clinical symptoms at the baseline. When the overall patient' s condition was divided through ECOG (Eastern Cooperative Oncology Group) Scale, only three patients (1.7%) among total 180 patients were in Scale 0 (All activities possible identical to before the disease without any limit), and 122 patients (67.8%) were Scale 1 (Limited in difficult physical work, but possible to move or do simple work). There was no difference in ECOG Scale distribution according to the each primary cancer.

In the pain level survey, the most with 65 patients (36.1%) relieved of pain from analgesic treatment and for colorectal cancer patients, the frequency of still having slight pain after the analgesic treatment but over 50% was improved was the highest with 7 patients (53.8%). For ambulatory ability, 108 patients (60%) of total patients were able to walk without any aid such as cane, walker or wheelchair, 35 patients (19.4%) had symptoms related to the spinal nerve appealing disorder in the lower and the upper limb sense or in the motor system.

Among the patient' s conditions based on the each follow-up point, lastly investigated condition within 6 months after the first treatment was defined as the 'short-term condition' and the follow-up duration, local control on the radiosurgery site, and the pain level change were analyzed for outcomes. In the radiosurgery group, the short-term follow-up duration was average of 3.4 months, and there was no difference depending on the primary cancer. 86 patients (47.8%) among total 180 patients couldn' t identify the local control of the radiosurgery site, and 71 patients (39.4%) showed to be controlled. For change in pain level, 76 patients (42.2%) among total patients showed to increase in pain level after the radiosurgery than before, but this was able to be not limited on the pain condition of the radiosurgery site, and it is seen to have reflected the overall pain condition of the metastatic

spinal tumor patient.

2) Comparison of the patient group with radiosurgery and the control group with radiation therapy using the matched pair

Metastatic spinal tumor patients who received radiosurgery as the first therapy on the metastatic spine site were selected as the patient group, and considering the primary cancer, the number of metastasized spine and age of the metastatic spinal tumor patients who received radiation therapy as the first treatment on the spine site were selected as the control group. When selecting the pair for the each group, it was limited to frequent primary cancers such as lung, liver, kidney, and breast and selected by matching 1:1 in random extraction method.

As a result of the t-test for short-term follow-up duration by the four major primary cancers, there was no statistical difference. The cumulative logistic model and generalized linear model for the local control condition and pain level change on the treated site were applied, but the model suitability was not appropriate for lung cancer, kidney cancer, and breast cancer and statistic comparison was not possible, and for liver cancer, as a result of the exact test and chi-square test for the short-term patient condition change, it was not statistically significant.

□ Conclusions and policy proposals

In this study, national health insurance claim data and retrospective patient cohort data were utilized to provide the prevalence and incidence of Korean spinal tumor patients, medical use and therapeutic condition of the treatments for spine tumor patients.

As for Korea, the number of spinal tumor patients and the medical use are increasing every year. Considering that the survival rate and the survival period of the cancer patients are extended from the recent development of health technology, it is expected that metastatic spinal tumor patients will increase more. Therefore, it is considered that development of medical health policy related to reasonable spinal tumor therapy in which all relevant therapeutic fields such as the neurosurgery and the radiation oncology are all considered will be required.

In this study, the therapeutic performance of the radiosurgery and radiation therapy in metastatic spinal tumor patients through retrospective patient cohort data was not

identified clearly. There is a report that for radiation therapy, there are many number of fractionated therapy, but patient' s physical pressure is low on therapy and the therapeutic performance can be high for patients with high metastasis, and for radiosurgery, the number of fractionated therapy is short, but the patient' s physical pressure is high on therapy, and for 1~2 metastasis, the therapeutic performance can be good. For metastatic spinal tumor patients, considering that the median survival period is 6-12 months, selecting the reasonable radiation therapy by taking into account the strong and weak point between the therapies will be necessary.

Currently, clinical department mostly participating in the radiosurgery and the radiation therapy are neurosurgery and the radiation oncology. It is considered that selecting and applying the treatment through collaboration between the two clinical departments which can be the best for the patient is required, and performance of mutual collaborative clinical trial for creating the best clinical basis is necessary. Especially, performance of multi-center prospective random controlled clinical trial to provide the therapeutic performance and indications will be necessary.

Key Words Metastastic Spinal tumor, Spinal tumor, stereotactic radiosurgery, Outcome Analysis