the Radiosurgery Society®

Bridging the Gap

RSSearch™ Patient Registry Quarterly Newsletter

Volume II *December 2013*

In this issue:

First Analysis of Patient Demographics, Treatment Practices and Outcomes from RSSearch™ Reported in *Radiation Oncology*

Initial results from the RSSearch™ Patient Registry highlighting patient and lesion characteristics, treatment management practices and outcomes was published in the journal ***Radiation Oncology*** 2013, **8**:275 (25 November 2013; accessed at http://www.ro-journal.com/content/8/1/275/abstract).

The publication titled "The RSSearch™ Registry: patterns of care and outcomes research on patients treated with stereotactic radiosurgery and stereotactic body radiotherapy" describes the design, patient demographics, lesion characteristics and SRS/SBRT treatment patterns of the first 11,457 patients enrolled in RSSearch™. The report also includes subset analyses of patient-related outcomes of two common treatment sites – brain metastases and liver metastases.

"This report is the largest dataset of SRS/SBRT-treated patients in a published registry. RSSearch™ is an ongoing project and we expect the database to continue growing as more centers and patients are treated with SRS/SBRT," said corresponding author of the study, Anand Mahadevan, M.D., Assistant Professor, Radiation Oncology, Beth Israel Deaconess Medical Center, Boston.

The report included 11,820 lesions from 65 treatment locations; 54% extracranial and 46% intracranial. The most common treatment locations were brain/cranial nerve/spinal cord, lung, prostate and liver. SRS/SBRT treatment practices for five common treatment locations including lesions treated in the brain, lung, prostate, liver and pancreas were further explored. Results indicated that for these five treatment sites, the majority of centers were adhering to standardized treatment guidelines, published reports and protocols for SRS and SBRT.

"This report is the largest dataset of SRS/SBRT-treated patients in a published registry," stated Dr. Anand Mahadevan, M.D., Radiation Oncology, Beth Israel Deaconess Medical Center, Boston.

"RSSearch™ represents SRS/SBRT treatment practices in the real-world setting, providing a useful resource for expanding knowledge of SRS/SBRT treatment practices and outcomes," said co-author of the study Clinton Medbery III, M.D., Radiation Oncologist, Department of Radiation Oncology, St. Anthony Hospital, Oklahoma City.

The study included a subset analysis of 799 patients with 952 brain metastases. The median SRS dose was 22 Gy delivered in 1 fraction. The median overall survival rate was 8 months. When stratified by Karnofsky Performance Score, (KPS) patients with good performance status (KPS> 70) had better overall survival rates compared to patients with KPS ≤ 70 (11 months vs. 4 months, respectively).

Continued on page 4

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Geographical Location of RSSearch™ Participating Centers

Support the RSSearch™ Patient Registry Initiative

If you are a Registry participant it is important that you:

- Update your IRB with RSSearch™ protocol and consent forms
- Continue to enter SRS/SBRT screened patients
- Complete screening, treatment and outcome data
- Update patient follow-up information

Become a Registry participant:

- Contact Nalani Brown at nbrown@therss.org

Thank you to our sponsor:

Coordinator's Corner: Meet RSSearch™ Participants

Jonathan A. Gapilango, RN, MSN, OCN, CCRP, NEBC, is Director of Oncology Research at the J. Phillip Citta Regional Cancer Center at Community Medical Center in Toms River, N.J. In the two years since starting RSSearch™, his team has registered 345 patients in the registry. An important aspect to Jonathan's role is to ensure data accuracy and acknowledges the value of each staff member's role in the process – starting with Dr. D'Ambrosio, M.D., Medical Director of the CyberKnife Program and fellow radiation oncologist Rajesh Iyer, M.D. who introduce patients to the project. Dr. D'Ambrosio, explains that "RSSearch™ will show how treatments work in the real-world and enable us to evaluate what we're doing in real time. For instance, if a patient experiences side effects, doctors can compare their treatment plan to others in RSSearch™ and look for differences that could be causing the problem." He also adds that "This is a relatively new field and it will provide more evidence for what works and lead to more people being treated this way."

> ***"RSSearch™ will show how treatments work in the real-world and enable us to evaluate what we're doing in real time," stated Dr. David D'Ambrosio, M.D., Radiation Oncology, Toms River, NJ.***

Jonathan emphasizes that success of the registry requires collaboration between everyone on his team including Debbie Moriarty, RN, MSN, OCN, CyberKnife nurse manager whose role is to obtain patient consents and ensures the data is current. Research nurse, Lennette Gonzales, RN, MSHS, OCN, CCRP, collects patient data and inputs patient information into the registry and Mary Ellen Suggs, clinical research associate, handles regulatory submissions. All contribute important components to successful registry program.

New Jersey CyberKnife at the J. Phillip Citta Regional Cancer Center is a service of Community Medical Center, a Barnabas Health facility. For more information, call (732) 557-3120.

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SRS/SBRT Articles of Interest:

The intent of this section is to highlight and summarize the results of relevant articles on SRS/SBRT originating from RSSearch™ and elsewhere. If you have an article you would like to submit, please email the RSS at admin@therss.org

Re-irradiation with SBRT as a novel treatment option for isolated local recurrence of pancreatic cancer after multimodality therapy: experience from two institutions

Aaron T. Wild, Susan M. Hiniker, Daniel T. Chang, Phuoc T. Tran, Mouen A. Khashab, et al. J Gastrointest Oncol. 2013 December; 4(4): 343–351 doi: 10.3978/j.issn.2078-6891.2013.044

Summary: In this study, Wild A.T. et al. conducted a retrospective analysis of patients with pancreatic ductal adenocarcinoma that received re-irradiation with SBRT for isolated recurrence or local progression. Eighteen patients were included in the study and treated at either Johns Hopkins University, Baltimore, MD or Stanford University Cancer Center, Palo Alto, CA. Fifteen patients had previously undergone resection with conventionally fractionated radiation therapy (CRT) and 3 patients had received definitive CRT. The median CRT dose was 50.4Gy in 28 fractions and all patients had received gemcitibine. Isolated local recurrence or local progression developed without evidence of distant metastases at a median of 13.1 months. 16 of 18 patients received 5 Gy x 5 fractions; 1 patient received 4 Gy x 5 fractions; 1 patient received 5.5 Gy x 5 fractions. Median follow-up was 34.3 months and the median interval time from recurrence/progression to SBRT was 2.4 months.

The authors reported a benefit for survival and progression-free survival (PFS) in patients who recurred/progressed > 9 months after surgery or definitive CRT vs. patients who recurred/progressed within 9 months after surgery. Median survival was 11.3 months vs. 3.4 months ($p = 0.019$) for patients with recurrence/progression > 9 months compared to those who recurred/progressed within 9 months, respectively. Median PFS was 10.6 months vs. 3.2 months ($p = 0.03$) for patients with recurrence/progression > 9 months vs. recurrence/progression within 9 months, respectively. In addition, the authors observed effective palliation in 57% of patients who reported symptoms prior to SBRT. Acute grade 2 toxicity was reported in 25% of patients and there were no acute grade ≥ 3 toxicity. One patient had a late grade 3 small bowel obstruction and there were no other late toxicities. The authors concluded that re-irradiation of an isolated recurrence/progression of pancreatic cancer using 5 fraction SBRT is safe and may be no more toxic than SBRT to radiation-naïve patients. Patients who recur/progress after 9 months after surgery or definitive CRT may benefit most from SBRT re-irradiation in terms of survival and PFS.

"As chemotherapy improves for pancreatic cancer, more patients will likely present with local recurrence or progression following conventional radiation therapy. Our study suggests that SBRT may be a good option for well selected patients," stated corresponding author Joseph Herman, M.D., Radiation Oncology, Johns Hopkins University School of Medicine, Baltimore, MD.

SBRT for lung malignancies: preliminary toxicity results using a flattening filter-free linear accelerator operating at 2400 monitor units per minute

Brendan M Prendergast, Michael C Dobelbower, James A Bonner, Richard A Popple, Craig J Baden, Douglas J Minnich, et al. Radiat Oncol. 2013; 8: 73.doi: 10.1186/1748-717X-8-273

Summary: There has been recent interest in the development of flattening filter-free (FFF) linear accelerators for SBRT applications. FFF linacs have been shown to deliver increased dose rates, resulting in decreased treatment times. Although there is a growing interest in this recent technological advancement, there is limited data reporting on safety and efficacy using FFF linacs for the SBRT treatment of lung cancer. *Continued on page 4*

the Radiosurgery Society®

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Initial Outcomes from RSSearch™

Continued from page 1

For patients with KPS > 70, the 3-month, 6-month and 12-month local control rate was 95%, 85% and 74%, respectively. These results are comparable to studies from single institutions and cooperative groups such as RTOG 95-08.

54% of patients enrolled in RSSearch™ listed Medicare as the primary payer

In a second subset analysis, outcomes were reported for 174 patients with 204 liver metastases. The majority of patients (54%) had liver metastases from colorectal cancer. The median SBRT dose was 45 Gy (range 10—60 Gy) delivered in 1-5 fractions (median 3 fractions). Median overall survival was 22 months. Local progression-free survival at 6, 12 and 18 months was 91%, 69% and 60%, respectively. These results demonstrate that patient outcomes can be performed from RSSearch™. Future analyses are planned to evaluate other treatment sites including prostate, lung, and pancreas.

"Reporting quality measures is becoming a necessary part of patient care. It is important to remind everyone that in 2015, the Centers of Medicare and Medicaid Services (CMS) will require physicians to participate in a qualified clinical data registry or CMS' Physician Quality Reporting System to report quality measures for Medicare Part B participants and those who do not participate will be penalized. This current study lists Medicare as the primary payer for 54% of patients enrolled in RSSearch, suggesting that the new CMS regulations could potentially impact a significant number of physician centers treating patients with SRS/SBRT," stated Kristine Gagliardi, Executive Director of the Radiosurgery Society.

Thank you to all the RSSearch™ participating centers, the patients who participated in the registry, the co-authors of the manuscript, Advertek, and all others who contributed to the manuscript and continue to support RSSearch™.

SRS/SBRT Articles of Interest:

Continued from page 3

In this retrospective analysis, Prendergast et al. present their initial experience treating lung malignancies with SBRT using a FFF linac operating at 2400 monitor units per minute. Toxicity data were reported for 64 patients with lung malignancies. The median SBRT dose was 48 Gy delivered in 4 fractions (range 30-60 Gy in 3-5 fractions). Acute grade 2 pulmonary toxicities were reported in 5 patients and acute grade 3 pneumonitis occurred in one patient. There were no acute grade 4/5 toxicities and there were no non-pulmonary toxicities reported. In a subset of 49 patients with a minimum of 30 days follow-up, the authors reported the most common late toxicity was asymptomatic grade 1 pulmonary toxicity which was observed in 20 of 49 patients. Eight patients had late grade 2 pulmonary toxicity, four patients had late grade 3 toxicity, and one patient had a late grade 4 pneumonitis. One late grade 5 toxicity was reported in a 75 year-old medically inoperable patient with a 4.3 cm peripheral lesion treated with 48 Gy delivered in 4 fractions. Statistical analysis was performed and no significant correlation was found for tumor size, number of fractions, BED or tumor location with acute toxicity. The study reported that the number of SBRT fractions did suggest that 3 vs. 4–5 fractions was associated with lower rates of late pulmonary toxicity ($p = 0.04$). The authors concluded that their initial results using FFF SBRT showed acceptable rates of acute toxicities and did not yield elevated treatment-related toxicity in lung SBRT. They recommended continued assessment to study the toxicity of late effects of FFF SBRT for lung cancer.

"As stereotactic radiosurgery continues to assume a larger role in treating lung cancer, this manuscript represents our ongoing efforts to provide this treatment in the safest possible manner," commented corresponding author Douglas Minnich, M.D., Division of Cardiothoracic Surgery, Department of Surgery, University of Alabama at Birmingham, AL.