the Radiosurgery Society®

Bridging the Gap

RSSearch® Patient Registry Quarterly Newsletter

Volume VI *Dec 2014*

In this issue:

Upcoming Events:

Webinar:

Pancreatic Stereotactic Body Radiation Therapy: A Brief Tutorial

January 22, 9:00 am PDT

SBRT for Cholangiocarcinoma

February 4, 8:00 am PDT

Register at www.therss.org

RSSearch® Patient Registry 2014 End-of-Year Summary

This past year was a truly exciting and productive year for the RSSearch® Patient Registry. In 2014, RSSearch expanded internationally to include centers from the US, Germany and Australia. In the past 12 months, 20 centers enrolled over 1,600 new patients treated with stereotactic radiosurgery (SRS) or stereotactic body radiotherapy (SBRT) to bring the total of enrolled patients in RSSearch to over 15,000 patients. In 2014, an average of 85 new patients were enrolled at each center. The number one enrolling center in 2014 was Barnabas Health, Toms River, NJ and the top 10 enrolling centers are listed below. Congratulations to the team at Barnabas Health and all the participating centers and patients that have made this past year a success.

Top 10 Enrolling Centers in 2014

1. Barnabas Health, Toms River, NJ
2. St. John's Radiosurgery Center, Springfield, MO
3. Penrose Cancer Center, Colorado Springs, CO
4. St. Francis Hospital, Memphis, TN
5. Sir Charles Gairdner Hospital, Perth, Australia
6. St. Joseph/Candler, Savannah, GA
7. Mission Hospitals, Asheville, NC
8. Franklin Square Hospital Center, Baltimore, MD
9. Memorial Hospital West, Hollywood, FL
10. Pennsylvania Hospital, Philadelphia, PA

An end of the year review of the aggregate data in RSSearch was conducted and the summary report is included in this issue of *Bridging the Gap* newsletter. The top five treatment locations in 2014 were brain, lung, prostate, bones/joints and liver (Figure 1). The number of men (52%) and women (48%) were evenly distributed and the percent of patients distributed by ethnicity is shown in Figure 2. The majority of patients were Caucasian (83.38%), while African-American patients represented 9.2% and Asian patients represented 0.7%,

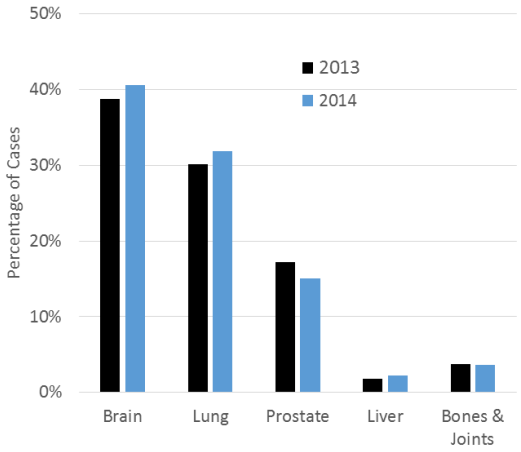

Figure I. Top 5 treatment locations in RSSearch for 2013 and 2014.

of the cohort. The most common primary referral source came from medical oncology (36.6%), neurosurgery (15.3%), urology (11.8%) and pulmonology (9.8%). The distribution of referral sources from all specialties is shown in Figure 3. The most common type of lesions were metastatic (40.7%) and malignant primary (39.2%) lesions (Figure 4). Other types of lesions included benign lesions (7.8%), recurrent lesions (5.3%) and trigeminal neuralgia (3.9%). The median SRS/SBRT dose delivered to all lesions was 30 Gy (range, 5—79 Gy) and the median number of fractions was 3 (range, 1—6).

As a result of the hard work and efforts of the participating centers, several abstracts from RSSearch were presented at the Radiosurgery Society (RSS) Annual Meeting held May 7-10, 2014 in Minneapolis, MN, including "SBRT for Early-Stage Lung Cancer: Outcomes from the RSSearch Patient Registry" presented by Clinton

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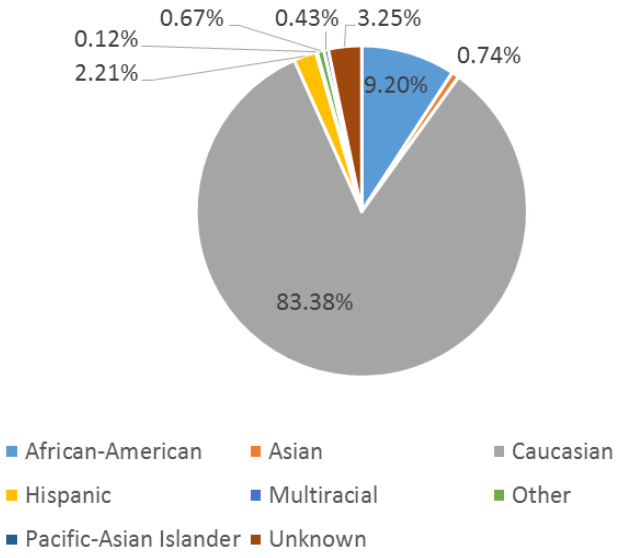

Figure 2. Distribution of patients based on ethnicity.

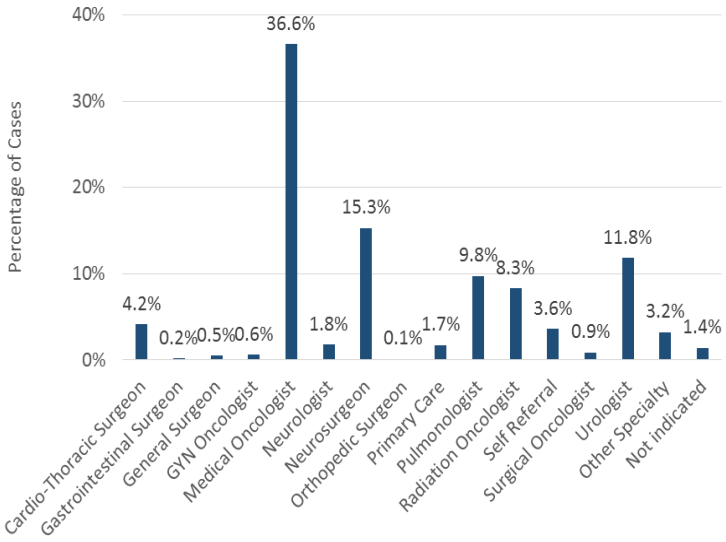

Figure 3. Referral sources for patients enrolled in RSSearch in 2014.

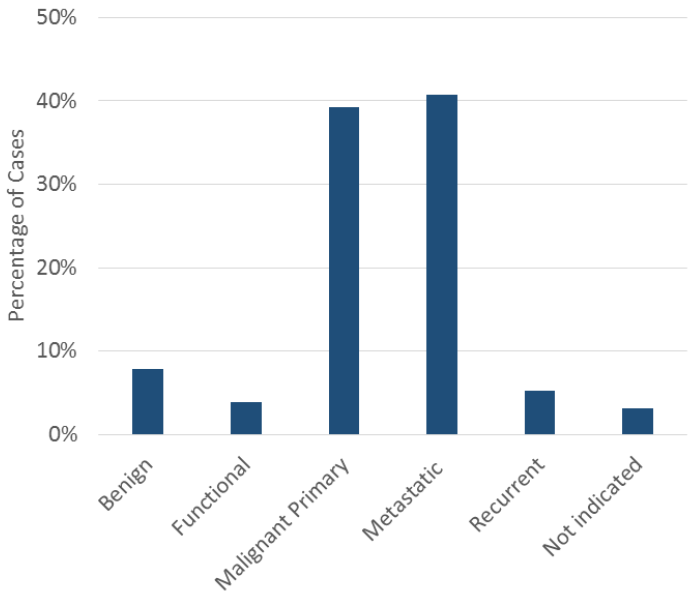

Figure 4. Distribution of lesion type.

Continued from page 1.

Medbery, III, M.D. St. Anthony's Hospital, OK and "Stereotactic Body Radiotherapy for Early-Stage Prostate Cancer" presented by Joanne Davis, Ph.D., The Radiosurgery Society®. Highlights of the RSS 2014 Annual Scientific Meeting can be found in Future Oncology, Volume 10, Number 15 **http://www.futuremedicine.com/toc/fon/10/15.**

The Radiosurgery Society® (RSS) also continued to strive to improve and update RSSearch®, making the database more efficient and comprehensive for it's participants. The database was upgraded to include drop-down boxes in the Screening field to capture multiple treatment platforms and updated the reporting tools to make it easier to access data. The RSS administration also secured the registered the trademark for RSSearch® Patient Registry to further facilitate marketing and branding efforts. The RSS staff and Board of Directors are excited to start the 2015 New Year and continue supporting the RSSearch Patient Registry.

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An Update on the Business Associates Agreement and What It Means for RSSearch® Participants

All centers participating in RSSearch® will need to have a Business Associates Agreement or legal equivalent in place with the Radiosurgery Society®. The HIPAA Privacy Rule requires that a covered entity (health plans, health care clearinghouses, certain health care providers, etc.) obtain satisfactory assurances from its business associate (in this case the Radiosurgery Society) that the business associate will appropriately safeguard the protected health information (PHI) it receives or creates on behalf of the covered entity. The satisfactory assurances must be in writing, whether in the form of a contract or other agreement between the covered entity and the business associate.

A covered entity's contract or other written arrangement with its business associate must describe the permitted and required uses of PHI by the business associate. The business associate will not use or disclose the PHI other than as permitted or required by the contract or as required by law; and that the business associate utilizes appropriate safeguards to prevent use or disclosure of the PHI other than as provided for by the contract. Where a covered entity knows of a material breach or violation by the business associate of the contract or agreement, the covered entity is required to take reasonable steps to cure the breach or end the violation, and if such steps are unsuccessful, to terminate the contract or arrangement.

The RSSearch® Patient Registry meets HIPAA requirements regarding patient privacy and transmission of PHI. All patient data is de-identified prior to use for research/analysis and there is no specifically identified patient-to-patient, physician-to physician or geographic comparisons performed. RSSearch is managed in a secure environment by Advertek®, Inc. an independent developer of web-based registries. Confidentiality of individual patient information is maintained by Advertek. Only limited information such as dates of service (consult, treatment, followup dates, etc) are made available for purposes of research and analysis.
If you have any questions, please contact Nalani Brown at nbrown@therss.org

Frequently Asked Questions & Answers:

Question: Why do I need Institutional Review Board (IRB) or Ethics Committee (EC) approval if it is a Registry?

Answer: IRB/EC oversight assures that appropriate steps are taken to protect the rights and welfare of patients participating as subjects in a study. A key goal of the IRB is to protect human subjects from physical or psychological harm, which they attempt to do by reviewing research protocols and related materials. The protocol review assesses the ethics of the research and its methods, promotes fully informed and voluntary participation by prospective subjects capable of making such choices and seeks to maximize the safety of subjects.

Question: When is the best time to approach the patient about informed consent for the registry?

Answer: This will depend on the situation. Some centers incorporate the RSSearch education and consent process during the initial consultation for SRS/SBRT. In other cases, patients and their families are too overwhelmed with information at the time of initial consultation to understand the Registry & informed consent. In this situation, centers will present RSSearch to the patient at the SRS/SBRT planning or treatment session and find patients and families are very receptive at this time.

Looking for CME Credits?

Online Self-Assessment Modules (SAMs) focused on stereotactic body radiotherapy are now available on the Radiosurgery Society website http://www.therss.org/education/online_sams.aspx . Visit the site today to register for:

Stereotactic Body Radiotherapy for Head & Neck Tumors

Presented by Maged Ghaly, MD and Dwight Heron, MD, FACRO, FACR

Stereotactic Body Radiotherapy for the Treatment of Locally Advanced Pancreatic Cancer and Colorectal Liver Metastases

Presented by Albert Koong, MD, PhD and Joseph Herman, MD, MSc

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Coordinator's Corner: Meet RSSearch™ Participants

Kimila Jones, RN, BSN, is the CyberKnife Coordinator at the Regional Cancer Center at St. Mary's Medical Center in Huntington, West Virginia, where they have been participating in the Registry since 2008. "Our center was searching for a system to track and evaluate patient outcomes when we were introduced to ReCKord (now known as the RSSearch® Patient Registry)" Jones said. "We liked that RSSearch is an international, multi-site/multiplatform SRS/SBRT database. Now, our goal is to not only improve patient outcomes in our community, but in the SRS/SBRT community worldwide. Our center has added over 750 patients to RSSearch and has contributed information to two peer-reviewed studies."

"We like that RSSearch® is an international, multi-center and multi-platform SRS/SBRT database. Now, our goal is to not only improve patient outcomes in our community, but in the SRS/SBRT community worldwide. Our center has added over 750 patients to RSSearch and has contributed information to two peer-reviewed studies" stated Kimila Jones, RN, BSN at the Regional Medical Center in Huntington, WV.

St. Mary's Medical Center is among the largest healthcare facilities in West Virginia, with centers of excellence in cardiac care, cancer treatment, emergency/trauma services, neuroscience, and joint replacement. St. Mary's CyberKnife Center is led by board certified radiation oncologist Sanjeev Sharma, M.D., and radiation oncologist Philip Lepanto, M.D. For more information about St. Mary's CyberKnife, call (304) 399-7460 or email Kimila at Kimila.Jones@st-marys.org.

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

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SRS/SBRT Article 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

The Risk of Malignancy Anywhere in the Body after Linear Accelerator (LINAC) Stereotactic Body Radiosurgery

Maryam Rahman, Dan Neal, William Baruch, Frank J. Bova, Barbara H. Frentzen and William A. Friedman

Stereotact Funct Neurosurg 2014; 92:323-333, DOI: 10.1159/000365225

In this retrospective study, Rahman et al investigated the rates of malignancies in patients treated with stereotactic radiosurgery (SRS) compared to cases that would be expected in an age– and gender-matched group. Using the Florida Cancer Data System (FCDS), a state-mandated patient registry, 2369 patients previously treated with SRS at the University of Florida were included in the analysis. Rates of malignancies were calculated for patients with meningiomas, schwannomas, arterial venous malformations (AVM) and other lesions (e.g. pituitary adenoma, trigeminal neuralgia) and matched to patients from the SEER database.

Before determining the rates of malignancies following SRS, the authors first evaluated the reliability of the using the FCDS registry to determine cancer rates in patients treated with SRS at the University of Florida. A total of 862 metastases patients were treated with SRS between 1988—2011 at the University of Florida. Of this cohort, 847 patients appeared in the FCDS registry, resulting in a match-rate of 98.3%. The authors concluded that the FCDS registry was a reliable method for determining cancer rates in their SRS population.

Cancer rates were then determined for patients with meningioma, schwannoma, AVM and other lesions. A total of 438 patients with WHO grade I meningiomas previously treated with SRS were analyzed. The mean treatment dose was 1,342 cGy and the median follow-up time per patient was 5.3 years. For patients with ≥ 5 years of follow-up (n=202), the observed cancer rate in the meningioma patients was 3.96% compared to the expected rate of 10%. A total of 482 schwannoma patients were identified with a mean treatment dose of 1,285 cGy. For patients with ≥ 5 years follow-up, the observed cancer rate was 4.93% compared to the expected rate of 12.5%. A total of 502 AVM patients were previously treated with a mean dose of 1,684 cGy. Of these, 165 AVM patients had ≥ 5 years follow-up and the observed cancer rate was 3.64% compared to the expected rate of 4.43%. There were 85 patients included in the "other" category and the observed cancer rate in "other" category was 0% compared to the expected rate of 6.36%.

"Our research provides good evidence that malignancy rates after treatment with radiosurgery are not higher than the natural rates of malignancy in the general population," stated Maryam Rahman, M.D. M.S., Department of Neurosurgery, University of Florida.

The authors concluded that in a large population of neurosurgical patients from a cancer registry, there was no increased risk of malignancy in their SRS population compared to the general population in the follow-up period. When asked about the significance of this study, Maryam Rahman, M.D., M.S. Assistant Professor, Department of Neurosurgery, Preston A. Wells Jr Center for Brain Tumor Therapy, University of Florida and co-author of the study commented, "Our research provides good evidence that malignancy rates after treatment with radiosurgery are not higher than the natural rates of malignancy in the general population. The risk of secondary malignancy for each individual patient treated with radiosurgery remains unknown. However, for many neurosurgical disorders, the risks associated with radiosurgery, including secondary malignancy, are much lower than invasive surgical interventions." The authors further concluded that these findings will need to be confirmed using prospective observational trials.