

North American Gamma Knife Consortium

To perform research, provide education, and publish information related to stereotactic radiosurgery for the purpose of improving public health.



Minutes from the NAGKC Board Meeting April 27, 2013

Members of the board or their representatives present included: Dr. Lunsford, Dr. Barnett, Dr. Nirnanjan, Ms. DeCesare, Ms. Gilmore, Ms. Nathanaelson, Dr. Barani, Dr. Kondziolka, Dr. Rosseau, Dr. Hajipanayis, Dr. Smith, and Dr. Sheehan.

The NAGKC board met from 3:30 to 5:15 pm on April 27, 2013 in the Studio 2 room of the New Orleans Marriott in New Orleans, Louisiana. The meeting was called to order by Dr. Lunsford.

The meeting minutes from the prior meeting were approved.

The Gamma Knife meeting in Pittsburgh last fall was successful from both educational and financial standpoints. Profits from the meeting were deposited to the NAGKC account.

Retrospective Trials:

Published or in press retrospective trials include ones on chordomas, cluster headaches, and glomus tumors.

Dr. Sheehan gave an update on the nonfunctioning adenoma project. The manuscript is in press. The parasellar and sellar meningioma manuscript was revised and is being re-reviewed in the Journal of Neurosurgery. Dr. Sheehan requested that any additional data for the posterior fossa meningioma project be sent to Ms. DeCesare within the next few weeks.

Dr. Nirnanjan discussed the craniopharyngioma project. An abstract from this project has been submitted to the ISRS meeting. Data analysis continues, and a manuscript will be forthcoming.

Drs. Lunsford discussed ongoing data collection regarding hemangioblastoma, chondrosarcoma, and trigeminal neuralgia x 3 projects. Dr. Barnett and Dr. Konziolka indicated that the trigeminal neuralgia project's greatest value will be to show if this approach is safe to offer patients. Cleveland Clinic, St. Joseph's, UVA, UPMC, and Emory have all expressed an interest in the trigeminal neuralgia project.

Dr. Sheehan proposed an AVM radiosurgery grading scale project. Dr. Barnett indicated that treatment approaches including dose selection may vary appreciably from

center to center. He and Dr. Lunsford recommended excluded patients who had prior embolization. Dr. Lunsford recommended accruing patients for the study that had a minimum follow up of 5 years after Gamma Knife radiosurgery. Dr. Barani indicated that cloud sharing strategies developed for the 5+ brain metastasis trial could also be employed in the AVM trial to share dose plans and evaluate the plans for quality and significant differences. A decision was made to proceed with the project. Dr. Sheehan will send a datasheet to Ms. DeCesare.

Prospective Trials:

Several prospective trials were discussed.

These projects discussed include the following:

- Stereotactic Radiosurgery for Five or more brain metastases

Dr. Barani discussed the current status of prospective trial NAGKC 12-01. Sites are going through the contract approval and IRB processes. The data collection platform is being designed and vetted so it meets study and regulatory requirements.

Six centers will participate in this 2 year trial. Study accrual is 120 patients. Dr. Lunsford congratulated Dr. Barani and moving forward with this first prospective trial for the NAGKC.

- GK SRS +/- Avastin – Multicenter phase II study of border zone SR with Avastin chemotherapy in patients with recurrent or progressive glioblastoma multiforme

Drs. Niranjana, Kano, and Lunsford have finalized a protocol for this study. UPMC is the coordinating center for this trial. The primary endpoint is overall survival at 6 months post-radiosurgery. A discussion about timing of SRS in relationship to prior radiotherapy and changing the primary endpoint occurred. However, given the extensive prior negotiations with corporate sponsors, the decision was made not to revise the protocol.

Funding has been received from Genentech and Elekta. The trial will encompass 40 patients. Of these 40 patients, 25 would be accrued through UPMC, and 5 each would be accrued at NYU, BNI, and UVA. This proposal has been submitted to Genentech for consideration of funding.

Dr. Kondziolka and others congratulated Dr. Niranjana for receiving funding from Genentech for this study.

- Phase I/II Study to optimize outcomes of large AVM's using radiosurgery followed by embolization

Dr. Lunsford outlined Dr. Kano's AVM protocol, and he asked that members review the protocol and provide feedback. The study is a longitudinal one. Potential sources of funding include Elekta and companies such as Covidien which manufactures Onyx.

- Phase I trial of Afatinib for Stereotactic Radiosurgery (SRS) for Brain Mets for Patients with HER2 positive breast cancer and EGFR positive lung cancer with 1 to 4 Brain Metastases (NAGKC 13-01)

Dr. Ahulwalia described the rationale and the design for this study. Molecular targeted approaches such as this will likely expand as receptor status of tumors are being frequently characterized. FDA approval for the study is pending. Dr. Ahulwalia will keep the group apprised. The NAGKC could be well poised to participate in a phase I trial and, later, a phase II trial.

- Radiosurgery or Open Surgery for Epilepsy (ROSE) Trial

Dr. Barbaro indicated that the ROSE trial was closed through the NIH secondary to difficulties with patient accrual. Elekta has agreed to fund the continuation of this study so as to accrue another 40 patients. Data from these 40 patients could eventually be aggregated with those of the NIH trial.

Centers in the U.K. and India have been very reliable for accruing patients thus far. NAGKC members may also be able to participate. Elekta will send a contract to the NAGKC for review.

IRB Issues:

With the addition of new member centers, your IRB application for data sharing with the NAGKC should be appropriately amended. Also, kindly keep the IRB approval up to date. Send a copy of the approval sheet to Ms. DeCesare.

One violation was noted in the past year. UPMC and UVA IRB's were notified. The violation was deemed minor, and no further action was required.

New Business:

1. Website update

The website has been move from the University of Pittsburgh server to an offsite one. This was necessitated by restrictions for hosting the NAGKC website imposed by the University of Pittsburgh.

2. Newsletter

An updated newsletter will soon be distributed.

3. Authorship

Authorship issues were again discussed. So far, there have been no contentious issues regarding authorship. Written permission for inclusion in an acknowledgements section should likely be obtained for future publications.

4. D&O Insurance

Insurance was recommended for the NAGKC and obtained at a cost of approximately \$1700 for one year.

Financial Update:

The financial report was included as an appendix in the meeting binder and summarized by Dr. Sheehan. The current financial status of the group is secure.

Member dues notices will be sent out by in the next month.

Membership Update:

Applications have been sent to Emory, University Hospitals Seidman Cancer Center, Robert Wood Johnson University Hospital, and St. Joseph's Hospital.

University of Toronto joined the NAGKC last year. University of Kentucky resigned from the group.

Gamma Knife registry:

Dr. Kondziolka discussed the Gamma Knife registry developed by Elekta. Some of the data entry is automated from Gamma Plan. Manual entry of additional data is straightforward and takes little time to accomplish.

The current version of the registry contains analytical tools, but these tools will need further refinement. Some drop down tools should be added. Dr. Kondziolka asked Ms. Gilmore to provide an update on the registry for the group perhaps as early as during the ISRS meeting in June of 2013.

A motion was made to adjourn the meeting. It was seconded and then approved. Dr. Lunsford called the meeting to a close.

Respectfully submitted by

Jason Sheehan