

North American Gamma Knife Consortium



STEREOTACTIC RADIOSURGERY RESEARCH, EDUCATION AND PUBLISHING FOR THE PURPOSE OF IMPROVING PUBLIC HEALTH

SUMMER 2014

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NAGKC News Update: Message from the Chairman

The North American Gamma Knife Consortium was formed five years ago to foster scientific multicenter retrospective reports, to understand more about the value and usage of the Leksell Gamma knife for management of less common indications and to design and perform prospective clinical trials. The NAGKC is a 501 C3 tax exempt foundation based in the state of Pennsylvania. Our current membership includes 17 U.S. centers, three Canadian centers and one Taiwanese Center (Taipei). Each site designates one representative to serve on the board of the consortium. The executive committee consists of L.D. Lunsford, MD, of UPMC, Douglas Kondziolka, MD, of NYU Medical Center and Jason Sheehan, MD, of the University of Virginia Medical Center. At the current time, our infrastructure consists of one part-time executive assistant, one part-time clinical trials coordinator (Lisa Baxendell, RN) and legal and tax consultants as needed.

All board members of the NAGKC serve as volunteers and receive no payment. The board is responsible for evaluating proposals from a scientific merit and fiscal standpoint, but has recently authorized the development of a Protocol Review Committee (PRC), as an initial screening process for new proposals from member sites. The initial membership for the protocol review committee will consist of Manmeet Ahluwalia, MD, Veronica Chiang, MD, Jonathan Knisely, MD, and Hideyuki Kano, MD, PhD. The PRC will be responsible for the merit analysis of proposals, and will make suggestions related to statistical methods. We expect the PRC process to stimulate new scientific reports and clinical trials.

An additional proposed subcommittee of the board will hopefully identify and develop new funding sources from industry. The consortium has already published more than seven clinical reports related to retrospective clinical trials, including publications in peer reviewed journals related to nonfunctioning pituitary adenomas, parasellar and sellar meningiomas, and petroclival meningiomas. Three additional publications including a multicenter cooperative venture with Japanese Gamma Knife Society related to hemangioblastomas, a report on posterior fossa meningiomas, and report on esthesioneuroblastomas are currently in press in 2014.

There are almost 10 retrospective clinical trials currently in progress related to long-term outcome related to such clinical issues as chondrosarcoma, craniopharyngiomas, the development and comparison of AVM radiosurgery outcome grading scales, pineal region tumors, facial schwannomas, cavernous sinus hemangiomas, repeat radiosurgery for AVMs, glossopharyngeal neuralgia, hemangiopericytomas, and the risk of edema development after radiosurgery for falx and convexity meningiomas.

Prospective clinical trials include NAGKC 12-01, a randomized controlled study of outcome in patients with five or more brain metastases, with Dr. Igor Barani from UCSF. This trial will evaluate neuro-cognitive outcomes in patients who have SRS alone vs SRS plus WBRT. The 12-01 trial is currently recruiting patients, and additional sites including UPMC and NYU are completing their IRB application process.

NAGKC 12-02 is a multicenter phase II study of glioblastoma border zone radiosurgery coupled with bevacizumab under the direction of Ajay Niranjana, MD. Funding is supplied by a combination of sources from Genentech, Elekta, and the consortium itself. Contracts are currently pending for this at the University of Pittsburgh IRB.

NAGKC 13-01, the Radiosurgery or Open Surgery for Epilepsy (ROSE) is a trial led by Mark Quigg, MD, at the University of Virginia and funded by Elekta. The goal of this trial is to try to complete the data acquisition on a sufficient number of patients originally enrolled in the NIH sponsored ROSE trial, which was closed because of difficulty with recruitment. Contracts have now been issued between the NAGKC and the University of Virginia which will be the PI site for this project.

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Additional projects have been proposed, including 13-02, staged radiosurgery followed by embolization for large volume AVMs with Dr. Kano as proposed PI. 14-01 with Dr. Niranjana as PI, proposes the use of low dose minocycline therapy for the management of adverse radiation effects after brain metastasis SRS. NAGKC 14-02 is a trial under development wherein the value of afatinib plus radiosurgery will be tested in HER-2 positive breast cancer and EGFR-positive lung cancer patients with 1:4 brain metastasis. Dr. Ahluwalia as the proposed PI is currently evaluating funding from potential industry sources.

The evolution of the NAGKC includes the development of an advisory board and the development of subcommittees related to publication protocol review, membership and development. Retired members of the NAGKC board will serve on the advisory board as well as selected other neurosurgeons, radiation oncologists, medical oncologists, and medical physicists.

One additional potential role of the NAGKC would be to serve as the oversight group for the continued development of the database registry related to Gamma knife radiosurgery, a project funded by Elekta. The oversight of this product and its potential role in radiosurgery multicenter trials may make it a good fit for the further role of the NAGKC.

Emerging Needs

As a 501 C3 independent foundation, adequate separation from our collaborating academic institutions has continued to be a goal. We need to enhance website management, develop an expanded clinical trials management group, find additional fundings sources and negotiate indirect cost agreements with sponsored trials in order to maintain the fiscal responsibility. A number of road blocks have been identified including the difficulty in finding adequate funding sources. Federal government sources are impossible at the present time and industry sources are extremely competitive. Because of the need for firm contractual relationships, legal delays have been problematic in rapid turnaround of contracts between the funding sources to the NAGKC. In turn developing contractual relationships with member sites that will be the primary investigators for clinical trials is also time consuming. As always, the need to rely on each institutional IRB for approval of research projects continues to be a significant time lag.

The NAGKC continues to grow and enlarge. In addition to the subcommittee development, it is clear that we need to update the bylaws. We have entered a more mature phase of growth. This may include dropping the initial proposed requirement for case contributions for continued participation and the introduction of a 1-year probationary period for new sites. We will need to obtain specific space and to develop expanded infrastructure with the hiring of new dedicated personnel.

Finally, the NAGKC wants to sponsor a new NAGKC scientific conference in 2015. Gene Barnett, MD, has volunteered to stimulate consideration of the scientific conference possibly in Cleveland in 2015.

Overall, the consortium has grown scientifically and in terms of impact. Our advantage is that we all have the same technology and from that common bond we have found that strong science can emerge. We invite other centers to consider membership.

Sincerely, L. Dade Lunsford, MD.

Board Meeting in New York City

The 2014 board meeting was held at the New York City Sheraton Times Square from 4:00 to 5:30 p.m. on May 11, 2014. The meeting was chaired by Dr. Lunsford and attended by all representative members.

Meeting Minutes

The meeting was called to order by L. Dade Lunsford, MD. The minutes from the past meeting were discussed and approved. Members update was noted including the center from Taiwan. This addition makes the NAGKC an international organization. Other centers that have also recently joined include Emory Healthcare/St. Joseph's Hospital (2013), William. Beaumont Hospital (2013), North Shore-LIJ Health System (2013), Taipei Veterans General (2014), University Hospitals: Seidman Cancer Center, Penn State Hershey Medical Center, and Washington Hospital.

A discussion of the recently published or in press trials was held. Also retrospective trials in progress were noted. The process of study design, proposals, data collection, and data sharing was noted. Current retrospective clinical trials include craniopharyngioma, AVM grading, pineal region tumors, cavernous sinus hemangioma, glossopharyngeal neuralgia, hemangiopericytomas, and facial schwannomas.

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Daniel Pieper, MD, from the Beaumont group proposed a retrospective study would evaluate the predictive value of tumor volume in patients with brain metastases. Igor Barani, MD, detailed his prospective trial of brain metastases. Approximately 20 patients have been accrued at UCSF thus far. Yale has recently had its site visit. Dr. Barani has requested a no-cost extension. Ajay Niranjana, MD, updated the group on a study for glioblastoma using GKRS and Avastin. IRB Approval has now been received from UPMC. The target accrual is 40 patients. Dr. Niranjana will draft a multicenter protocol to broaden the patient accrual at other member centers. The ROSE trial contract is working its way through the administrative process at UVA. The study will hopefully accrue a smaller number of patients. Patients could be accrued through other countries including England and India.

Dr. Lunsford outlined the concept of a prospective clinical AVM study that looks at studying the effects of embolization in patients treated with radiosurgery. A proposal has been sent to Mr. Jonas Garding at Elekta who is reviewing it for funding consideration. Dr. Niranjana has proposed a study of minocycline to reduce the risk of ARE's for brain metastases. The drug would be given after prior failure of steroids being tapered in the setting of patients with documented ARE's. Funding from Elekta is still under consideration. Dr. Ahluwalia described the study of Afatinib for HER2 positive breast CA and EGFR positive lung CA patients. The study is a phase 1 trial for selected metastasis patients, but if safety was demonstrated, hopefully it would lead to a phase 2 trial through the NAGKC.

The NAGKC is a 501-3(C) registered through the state of Pennsylvania. We are functioning as a foundation as opposed to a public charity. The NAGKC maintains D&O insurance. Dr. Lunsford indicated the bylaws require each member center to contribute at least 10 patients per year to ongoing studies. Douglas Kondziolka, MD, noted that this requirement could potentially be lowered. Dr. Lunsford reviewed the composition of the board. Michael McDermott, MD, noted that Dr. Barani can take his place on the board for the representative for UCSF. A motion was made to approve the substitution of Dr. Barani for Dr. McDermott. The remainder of the board was reappointed for another term. The composition of the board was approved unanimously by the members in attendance.

Jason Sheehan, MD, presented the financial update for the NAGKC. The financial state of the NAGKC is a sound one. Dr. Kondziolka suggested that the group should consider adding indirect charges particularly to clinical trials. Drs. Lunsford and Kondziolka also noted that the NAGKC should support another meeting in 2015 and 2016. Dr. Lunsford encouraged interested parties to submit a proposal for hosting the next NAGKC scientific meeting. John Lee, MD, from University of Pennsylvania and Gene Barnett, MD, from Cleveland Clinic will consider hosting an education meeting of the consortium in that time frame.

Recently Published NAGKC Retrospective Trials

Non Functioning Pituitary Adenomas

Sheehan JP, Starke RM, Mathieu D, Young B, Sneed PK, Chiang VL, Lee JY, Kano H, Park KJ, Niranjana A, Kondziolka D, Barnett GH, Rush S, Golfins JG, Lunsford LD: Gamma Knife radiosurgery for the management of nonfunctioning pituitary adenomas: a multicenter study. *Journal of Neurosurgery* 119:446-456, 2013.

Object: Pituitary adenomas are fairly common intracranial neoplasms, and nonfunctioning ones constitute a large subgroup of these adenomas. Complete resection is often difficult and may pose undue risk to neurological and endocrine function. Stereotactic radiosurgery has come to play an important role in the management of patients with nonfunctioning pituitary adenomas. This study examines the outcomes after radiosurgery in a large, multicenter patient population.

Methods: Under the auspices of the North American Gamma Knife Consortium, 9 Gamma Knife surgery (GKS) centers retrospectively combined their outcome data obtained in 512 patients with nonfunctional pituitary adenomas. Prior resection was performed in 479 patients (93.6%) and prior fractionated external-beam radiotherapy was performed in 34 patients (6.6%). The median age at the time of radiosurgery was 53 years. Fifty-eight percent of patients had some degree of hypopituitarism prior to radiosurgery. Patients received a median dose of 16 Gy to the tumor margin. The median follow-up was 36 months (range 1-223 months).

Results: Overall tumor control was achieved in 93.4% of patients at last follow-up; actuarial tumor control was 98%, 95%, 91%, and 85% at 3, 5, 8, and 10 years postradiosurgery, respectively. Smaller adenoma volume (OR 1.08 [95% CI 1.02-1.13], $p = 0.006$) and absence of suprasellar extension (OR 2.10 [95% CI 0.96-

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4.61], $p = 0.064$) were associated with progression-free tumor survival. New or worsened hypopituitarism after radiosurgery was noted in 21% of patients, with thyroid and cortisol deficiencies reported as the most common postradiosurgery endocrinopathies. History of prior radiation therapy and greater tumor margin doses were predictive of new or worsening endocrinopathy after GKS. New or progressive cranial nerve deficits were noted in 9% of patients; 6.6% had worsening or new onset optic nerve dysfunction. In multivariate analysis, decreasing age, increasing volume, history of prior radiation therapy, and history of prior pituitary axis deficiency were predictive of new or worsening cranial nerve dysfunction. No patient died as a result of tumor progression. Favorable outcomes of tumor control and neurological preservation were reflected in a 4-point radiosurgical pituitary score.

Conclusions: Gamma Knife surgery is an effective and well-tolerated management strategy for the vast majority of patients with recurrent or residual nonfunctional pituitary adenomas. Delayed hypopituitarism is the most common complication after radiosurgery. Neurological and cranial nerve function were preserved in more than 90% of patients after radiosurgery. The radiosurgical pituitary score may predict outcomes for future patients who undergo GKS for a nonfunctioning adenoma.

Parasellar & sellar meningiomas

Sheehan JP, Starke RM, Kano H, Kaufmann AM, Mathieu D, Zeiler FA, West M, Chao ST, Varma G, Chiang VL, Yu JB, McBride HL, Nakaji P, Youssef E, Honea N, Rush S, Kondziolka D, Lee JY, Bailey RL, Kunwar S, Petti P, Lunsford LD: Gamma Knife radiosurgery for sellar and parasellar meningiomas: a multicenter study. *Journal of Neurosurgery* 120:1268-1277, 2014.

Object: Parasellar and sellar meningiomas are challenging tumors owing in part to their proximity to important neurovascular and endocrine structures. Complete resection can be associated with significant morbidity, and incomplete resections are common. In this study, the authors evaluated the outcomes of parasellar and sellar meningiomas managed with Gamma Knife radiosurgery (GKRS) both as an adjunct to microsurgical removal or conventional radiation therapy and as a primary treatment modality.

Methods: A multicenter study of patients with benign sellar and parasellar meningiomas was conducted through the North American Gamma Knife Consortium. For the period spanning 1988 to 2011 at 10 centers, the authors identified all patients with sellar and/or parasellar meningiomas treated with GKRS. Patients were also required to have a minimum of 6 months of imaging and clinical follow-up after GKRS. Factors predictive of new neurological deficits following GKRS were assessed via univariate and multivariate analyses. Kaplan-Meier analysis and Cox multivariate regression analysis were used to assess factors predictive of tumor progression.

Results: The authors identified 763 patients with sellar and/or parasellar meningiomas treated with GKRS. Patients were assessed clinically and with neuroimaging at routine intervals following GKRS. There were 567 females (74.3%) and 196 males (25.7%) with a median age of 56 years (range 8-90 years). Three hundred fifty-five patients (50.7%) had undergone at least one resection before GKRS, and 3.8% had undergone prior radiation therapy. The median follow-up after GKRS was 66.7 months (range 6-216 months). At the last follow-up, tumor volumes remained stable or decreased in 90.2% of patients. Actuarial progression-free survival rates at 3, 5, 8, and 10 years were 98%, 95%, 88%, and 82%, respectively. More than one prior surgery, prior radiation therapy, or a tumor margin dose < 13 Gy significantly increased the likelihood of tumor progression after GKRS. At the last clinical follow-up, 86.2% of patients demonstrated no change or improvement in their neurological condition, whereas 13.8% of patients experienced symptom progression. New or worsening cranial nerve deficits were seen in 9.6% of patients, with cranial nerve (CN) V being the most adversely affected nerve. Functional improvements in CNs, especially in CNs V and VI, were observed in 34% of patients with preexisting deficits. New or worsened endocrinopathies were demonstrated in 1.6% of patients; hypothyroidism was the most frequent deficiency. Unfavorable outcome with tumor growth and accompanying neurological decline was statistically more likely in patients with larger tumor volumes ($p = 0.022$) and more than 1 prior surgery ($p = 0.021$).

Conclusions: Gamma Knife radiosurgery provides a high rate of tumor control for patients with parasellar or sellar meningiomas, and tumor control is accompanied by neurological preservation or improvement in most patients.

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Petroclival meningiomas

Starke R, Kano H, Ding D, Nakaji P, Barnett GH, Mathieu D, Chiang V, Yu JB, Hess J, McBride HL, Honea N, Lee JY, Rahmathulla G, Evanoff WA, Alonso-Basanta M, Lunsford LD, Sheehan JP: Stereotactic radiosurgery of petroclival meningiomas: a multicenter study. *Journal of Neuro-Oncology* 2014.

Petroclival meningiomas are difficult to treat due to their intimate location with critical structures, and complete microsurgical resection is often associated with significant morbidity. In this study, we evaluate the outcomes of petroclival meningiomas treated with Gamma Knife radiosurgery (GKRS) as an adjunct to microsurgery or a primary treatment modality. A multicenter study of 254 patients with a benign petroclival meningioma was conducted through the North American Gamma Knife Consortium. One hundred and forty patients were treated with upfront radiosurgery, and 114 following surgery. Multivariate analysis was used to determine predictors of favorable defined as no tumor progression following radiosurgery and the absence of any new or worsening neurological function. At mean follow up of 71 months (range 6-252), tumor volumes increased in 9 % of tumors, remained stable in 52 %, and decreased in 39 %. Kaplan-Meier actuarial progression free survival rates at 3, 5, 8, 10, and 12 years were 97, 93, 87, 84, and 80 % respectively. At last clinical follow-up, 93.6 % of patients demonstrated no change or improvement in their neurological condition whereas 6.4 % of patients experienced progression of symptoms. Favorable outcome was achieved in 87 % of patients and multivariate predictors of favorable outcome included smaller tumor volume (OR = 0.92; 95 % CI 0.87-0.97, $p = 0.003$), female gender (OR 0.37; 95 % CI 0.15-0.89, $p = 0.027$), no prior radiotherapy (OR 0.03; 95 % CI 0.01-0.36, $p = 0.006$), and decreasing maximal dose (OR 0.92; 95 % CI 0.96-0.98, $p = 0.010$). GKRS of petroclival meningiomas achieves neurological preservation in most patients and with a high rate of tumor control.

NAGKC Retrospective Trials - In Press

- Hemangioblastoma (JNS, in press)
- Posterior fossa meningioma (JNS, in press)
- Esthesioneuroblastoma

NAGKC Retrospective Trials - In Progress

- Chondrosarcoma
- Craniopharyngioma
- AVM radiosurgery grading scale
- Pineal region tumors
- Facial schwannoma
- CS hemangioma
- Repeat SRS for AVMs
- Glossopharyngeal neuralgia
- Hemangiopericytoma
- Falx/convexity meningioma edema

Potential NAGKC Prospective Clinical Trials

- 13-02: Staged stereotactic radiosurgery followed by embolization for large volume AVMs (PI: Dr. Kano)
- 14-01: Minocycline for ARE in brain metastasis (PI: Dr. Niranjana)
- 14-02: A Phase I trial of Afatinib for SRS brain metastases for patients with HER2 positive breast cancer and EGFR positive lung cancer with 1-4 brain metastases (Dr. Ahluwalia)

NAGKC Presentations at 17th Leksell Gamma Knife® Society, New York

- NAGKC - Gliomas: Ajay Niranjana, Pittsburgh, PA
- NAGKC - Epilepsy (ROSE): Nicholas Barbaro, Indianapolis, IN
- NAGKC - Metastases & Cognition: Igor Barani, San Francisco, CA
- Report Of The North American Gamma Knife Consortium: Ajay Niranjana, Jason Sheehan, Douglas Kondziolka, and L. Dade Lunsford.

Ongoing NAGKC Prospective Clinical Trials: Update

- 12-01: Randomized controlled study of outcomes in patients with five or more brain metastases (PI: Dr. Barani): Approximately 20 patients have been accrued at UCSF thus far. Yale has recently had its site visit. Other site visits are imminent.



Neurocognitive Outcomes In Patients Treated With Radiotherapy For Five Or More Brain Metastases (NAGKC 12-01)

Purpose: This is randomized study of neurocognitive outcomes in patients with five or more brain metastases treated with stereotactic radiosurgery (SRS), specifically the Gamma Knife (GK) system, or whole-brain radiation therapy (WBRT). The primary aim of this study is to compare the change in neurocognitive function outcome between baseline and 6 months in WBRT versus SRS treatment groups.

Sponsor: University of California, San Francisco

Collaborators: NAGKC

ClinicalTrials.gov Identifier: NCT01731704


Study Type: Interventional

Study Design: Allocation: Randomized
 Endpoint Classification: Efficacy Study
 Intervention Model: Parallel Assignment
 Masking: Open Label
 Primary Purpose: Treatment

Official Title: A Randomized Controlled Study Of Neurocognitive Outcomes In Patients With Five Or More Brain Metastases Treated With Radiosurgery Or Whole-Brain Radiotherapy

Condition	Intervention
Brain Metastases	Radiation: Stereotactic radiosurgery (SRS) Radiation: Whole brain radiation therapy (WBRT)

- 12-02: Multicenter Phase II Study of border zone SR with Bevacizumab chemotherapy in patients with recurrent or progressive glioblastoma multiforme (PI: Dr. Niranjana): The study has now been approved by University of Pittsburgh IRB. The target accrual is 40 patients. Dr. Niranjana will draft a multicenter protocol to broaden the patient accrual at other member centers.



Border Zone Stereotactic Radiosurgery With Bevacizumab in Patients With Glioblastoma Multiforme (NAGKC 12-02)

Purpose : This is a phase II study on the usage of stereotactic Gamma Knife radiosurgery as a boost to the tumor bed border zone in conjunction with the usage of bevacizumab

Sponsor: University of Pittsburgh

Collaborators: Genentech & NAGKC

ClinicalTrials.gov Identifier: NCT02120287

Study Type: Interventional

Study Design: Endpoint Classification: Efficacy Study
 Intervention Model: Single Group Assignment
 Masking: Open Label

Primary Purpose: Treatment

Official Title: Multicenter Phase II Study of Border Zone Stereotactic Radiosurgery With Bevacizumab in Patients With Recurrent or Progressive Glioblastoma Multiforme

Condition	Intervention	Phase
Glioblastoma Multiforme	Drug: Bevacizumab	Phase 2
Glioblastoma - Category	Procedure: Border Zone Stereotactic Radiosurgery (BZ-SRS)	

- 13-01: Radiosurgery or open surgery for epilepsy (ROSE) (PI: Drs. Barbaro/Quigg): The ROSE trial contract is working its way through the administrative process at UVA. The study will hopefully accrue a smaller number of patients. Patients could be accrued through other countries including England and India.



New NAGKC Members

- Emory Healthcare/St. Joseph's Hospital (2013)
- William Beaumont Hospital (2013)
- North Shore-LIJ Health System (2013)
- Taipei Veterans General (2014)
- University Hospitals: Seidman Cancer Center
- Penn State Hershey Medical Center
- Washington Hospital

Save The Date: North American Gamma Knife Scientific Session

The 2nd Scientific Conference of the North American Gamma Knife Consortium will be held in Cleveland, Ohio, on June 27-28, 2015. Sponsored by the Cleveland Clinic, the conference hotel will be the Cleveland Hyatt Regency at 420 Superior Avenue East and the meeting will be held across the street at the Louis Stokes Auditorium of the Cleveland Public Library.



Spotlight: NYU Langone Medical Center

NYU has provided Gamma Knife radiosurgery services since 1997 under the leadership of John Golfinos, MD, and Stephen Rush, MD.

In late October 2012, Hurricane Sandy flooded lower Manhattan and destroyed the Gamma Knife facility and adjacent imaging complex. Douglas Kondziolka, MD, Erik Parker, MD, and Joshua Silverman, MD, PhD, performed Gamma Knife radiosurgery on NYU patients at South Nassau Communities Hospital two days per week, and at Hackensack University Medical Center, Columbia Presbyterian Hospital, and Northern Westchester Gamma Knife center on one day per week each. We are indebted to those hospitals and their staff for their incredible support during that time. Strong regional connections were made.

Over the next 18 months, site clean-up, removal of the old unit, and redesign and construction of a brand new facility was performed. The new Center for Advanced Radiosurgery was designed with four private patient preparation rooms, nursing station, multiple work stations for dose planning, a new Perfexion unit, waiting room and conference facility. It reopened in late April. Patients have radiosurgery on 4-5 days per week with current annual practice of 400-500 patients per year. All our patients are entered into the Gamma Knife registry for prospective data collection and outcomes. Current medical staff includes Drs. Kondziolka, Golfinos and David Harter, MD, (neurosurgery), and Drs. Silverman, Rush and Kevin L. Du, MD, (radiation oncology). Medical physics support is provided by Kerry Han, PhD, and Stewart Becker, PhD.