

Multi-Institutional Registry for
Prostate Cancer Radiosurgery (RPCR):
Supportive of Local CED

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APRIL 21, 2010 MEDCAC: RADIATION THERAPY FOR LOCALIZED PROSTATE CANCER

- ARHQ reviewed and MEDCAC discussed clinical evidence for radiation therapies including:
 - Stereotactic body radiation therapy (SBRT)
 - External beam radiation therapy (EBRT): 3-dimensional conformal radiation therapy (3-D CRT), intensity modulated radiation therapy (IMRT), proton therapy
 - Brachytherapy (BT): low-dose rate (LDR) and high-dose rate (HDR)
- AHRQ technology assessment¹ noted:
 - “Data on comparative effectiveness between different forms of radiation treatments (BT, EBRT, SBRT) are also inconclusive whether one form of radiation therapy is superior to another form in terms of overall or disease-specific survival”
- Statement by Dr. Marcel Salive, CMS Director, Division of Medical and Surgical Services, Coverage and Analysis Group, at the end of the MEDCAC meeting:
 - “...it does appear there’s a lot of evidence gaps here, there’s a real difficulty drawing conclusions from the evidence reviewed today reflected by the vote. I think that would create a difficulty with doing a national coverage decision in this area...”²
- MEDCAC outcome: No NCD
 - Coverage left to the local contractors, where a vast majority of coverage is determined

1. AHRQ. Comparative evaluation of radiation treatments for clinically localized prostate cancer: an update. 2010.

2. April 21, 2010 MEDCAC transcript. <http://www.cms.gov/medicare-coverage-database/details/medcac-meeting-details.aspx?MEDCACId=54> Accessed March 27, 2012.

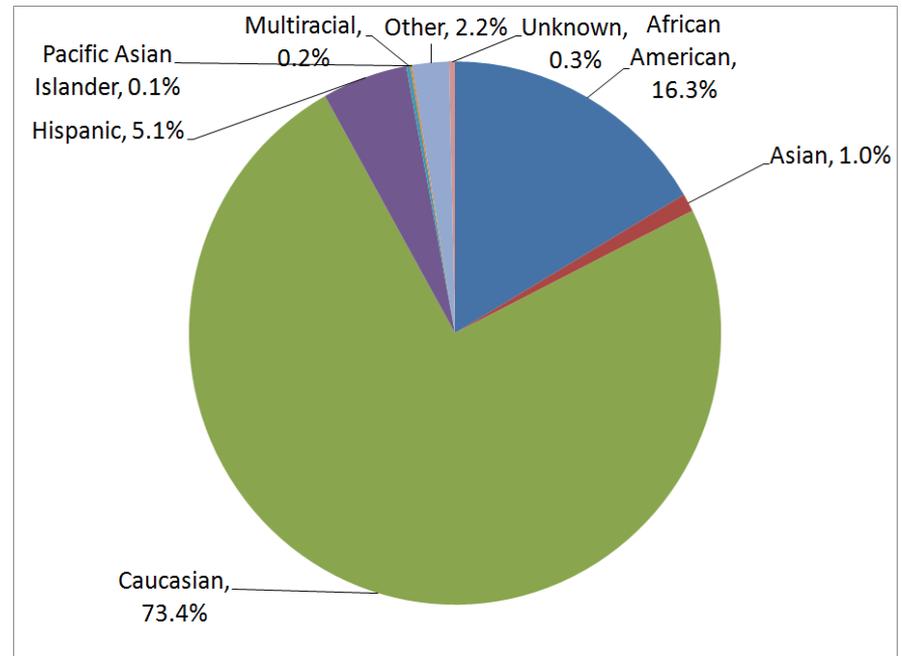
RCPR: UTILIZING REGISTRY AS A WAY TO FILL THE EVIDENCE GAP

- May 2009: Physicians in Florida treating patients with SBRT for localized prostate cancer started developing the registry in response to Florida local Medicare contractor
- April 2010: At MEDCAC, we announced the development of the registry to track and collect clinical outcomes of patients treated with radiosurgery for localized prostate cancer
- July 2010: Multi-Institutional Registry for Prostate Cancer (RPCR) (formerly FRRRA registry) received IRB approval and launched. Currently listed on ClinicalTrials.gov (<http://www.clinicaltrials.gov/ct2/show/NCT01226004>)

RPCR

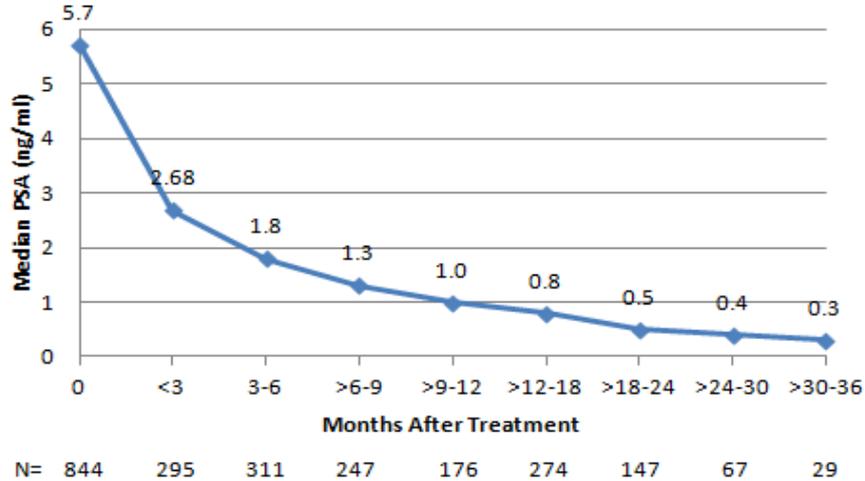
- Co-Directors:
 - Mark Perman, MD
 - Debra Freeman, MD
- Purpose
 - Collect data on the clinical utilization of SBRT to treat prostate cancer
- Data collected
 - Baseline clinical information
 - Treatment outcomes and effectiveness
 - Overall survival
 - Biochemical disease free survival (BDFS)
 - Surrogate outcomes: prostate specific antigen (PSA), international prostate symptom score (IPSS), sexual health in men (SHIM), and visual analogue scale (VAS)
 - Treatment toxicity
 - Urinary and rectal complications
 - Sexual health
- Number of participating centers (as of 4/16/12): 41 – includes every MAC where evidence collection is required

- Patient demographics (as of 4/16/12):
 - 858 patients treated
 - Median age: 68 years old

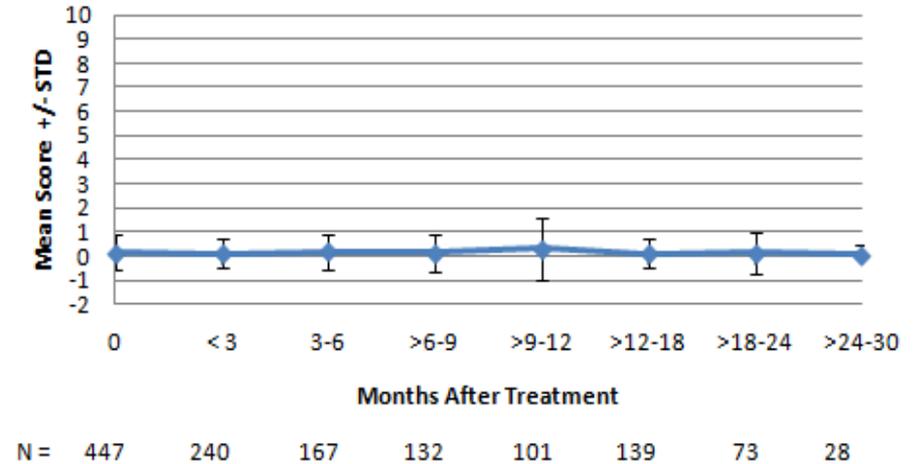


RPCR: CLINICAL OUTCOMES

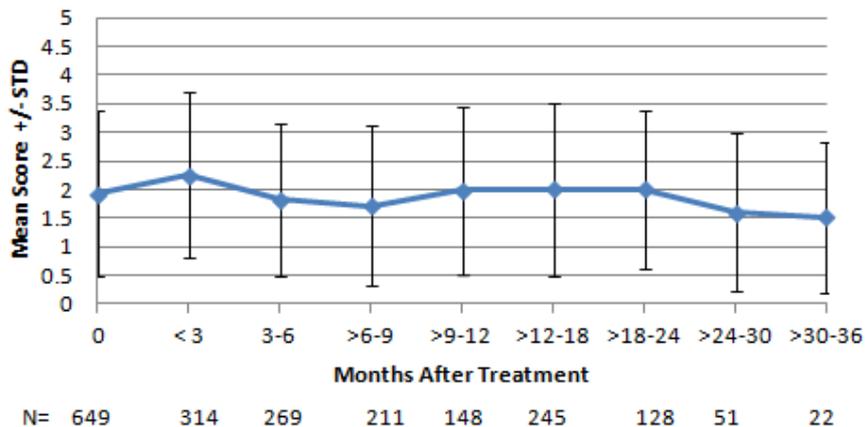
PSA



VAS Pain Score

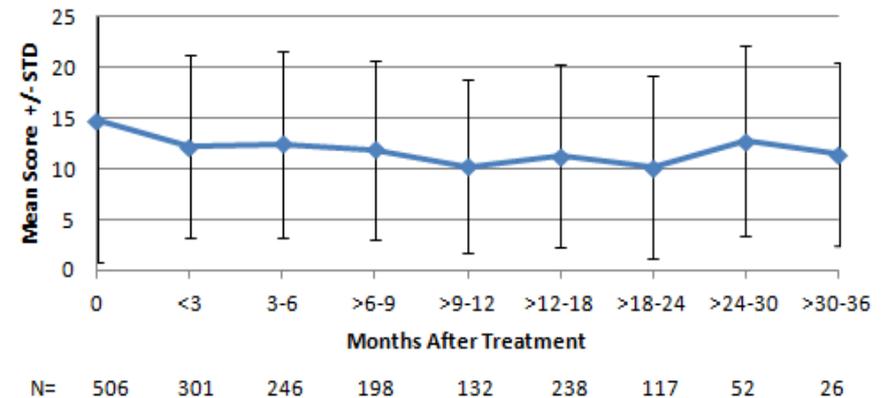


Quality of Life - Urinary Function



Note: Quality of Life score from IPSS questionnaire

Sexual Function



Note: Total score from International Index for Erectile Function-5 questionnaire

RPCR: A COLLABORATIVE PROCESS

- Registries, like the RPCR, are a cost-effective way to provide Medicare beneficiaries access to innovative therapies while gathering additional data to demonstrate that the treatment is as good as or better than other currently covered options
- RPCR is a collaborative approach – involving both care providers and local Medicare contractors – that is being utilized to provide access to SBRT for localized prostate cancer
- **Recommendation:**
 - Successful implementation of registries requires collaboration between multi-stakeholder groups (e.g., Medicare , users of the technology, manufacturers, etc.)
 - Set realistic and standard expectations for evidence development across all therapy options
 - Avoid ever moving goal post
 - Improved transparency across all organizations
 - Specific suggestions to local Medicare contractors for enhanced partnership:
 - Mutually agree on defined timeframes and sign posts for success (or failure)
 - Serious adverse events
 - Determination of equivalence/reasonableness
 - Statistical significance
 - Once agreed upon criteria are met, local contractor would remove registry requirement