Appendix Table C8. Outcomes and interventions of studies that address Key Question 2

| Study | Study Outcomes | Interventions |
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| Chen-2012, #4554 | **Study Objective:** To evaluate outcomes of SBRT in potentially operable patients with primary stage I NSCLC**Primary outcome:** NR**Definition:** NA**Secondary outcome(s):** NR**Definitions:** NA**List of outcomes:**OS, LCT**Cause of death:** Total: 12 (30%)Unrelated to lung cancer: 10 (83%)Related to lung cancer: 2 (17%)**Length of FU:**Median 44 (12-72) mos | **Intervention name:**SBRT**Vendor name:**Cyberknife (Acurray Inc., Sunnyvale, CA)**Dose/frequency/details:**Prescribed dose: 50 Gy (42-60 Gy) to the PTV 80% isodose line3 frsMean 7 days (5-11 days) **Technical details:** Beam energy NR**Treatment Intention:**Curative**Follow-up and Evaluation Criteria:**PET/CT scans at 3 mos intervals after SBRTBiopsy required to confirm progression |
| Iwata-2010, # 1747  | **Study Objective:** To analyzed the safety and efficacy of high-dose proton therapy and carbon-ion therapy applied to stage I NSCLC**Primary outcome:** NR**Definition:** NA**Secondary outcome(s):** NR**Definitions:** NA**List of Outcome(s):** OS, DSS, Local control, Toxicity**Cause of death:** NR**Length of FU:** All patients observed for a minimum of 1.5 years or until death. Median duration of follow-up was 35.5 (18-66) months for living pts & 30.5 (4-66) months for all pts. | **Intervention name:**PBRT**Vendor name:**Synchrotron (Mitsubishi Electric Corporation, Kobe, Japan3-D Rx planning system ((FOCUS-M, CMS, St. Louis, Mo and Mitsubishi Electric Corporation)**Dose/frequency/details:**PBRT 80Gy: 20 fractions, BED 10(Gy): 112PBRT 60 Gy: 10 fractionsBED 10(Gy): 96**Technical details:** Ptswere treated with 150-MeV proton beams **Treatment Intention:** NR**Follow-up and Evaluation Criteria:*** After Rx, pts FU at 1.5, 3, 4.5, 6, 9, and 12 months during the 1st yr, at intervals of 3 months in the 2nd yr, and at 6-month intervals in the 3rd yr.
* CT, tumor marker, Brain MRI and FDG-PET were used to monitor tumor progression.
* Local responses was assessed according to the modified WHO response evaluation criteria.
* Toxicities were evaluated with the CTCAE version 3.0.
* Medically inoperability defined as pts with poor pulmonary function (vital capacity <75% or ratio of FEV 1 to forced vital capacity <60%), a history of major CVD, severe DM, advanced age (80 years old), or other debilitating conditions that preclude surgery.
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| Lagerwaard- 2011, #2122 | **Study Objective:** To evaluate outcomes of SBRT in potentially operable patients with primary stage I NSCLC**Primary outcome:** NR**Definition:** NA**Secondary outcome(s):** NR**Definitions:** NA**List of outcomes:**OS, LCT, toxicity**Cause of death:** Total: 34 (19%)Unrelated to lung cancer: 12 (35%)Related to lung cancer: 14 (41%)Unknown: 5 (15%)**Length of FU:**Median 32 mos  | **Intervention name:**SBRT**Vendor name:**NR**Dose/frequency/details:**Prescribed dose: 60 Gy to the PTV 80% isodose lineBED: > 100 Gy for all fractionations3, 5, or 8 frs2 weeks **Technical details:** Beam energy NR**Treatment Intention:**Curative**Follow-up and Evaluation Criteria:**CT scans at 3, 6, 12 mos after SBRTFDG PET only if relapse suspectedToxicity assessed (criteria NR) |
| Onishi-2011, #2802(longer FU to Onishi-2007, #2803) | **Study Objective:**To evaluate high-dose SBRT for stage I NSCLC in patients who were medically operable but refused surgery **Primary outcome:** OS, CSS, LCT, toxicity**Definition:** NR**Secondary outcome(s):** NR**Definitions:** NA**List of outcomes:**OS, CSS, LCT, toxicity**Cause of death:**NR**Length of FU:**Median 55 mos  | **Intervention name:**SBRT**Vendor name:**NR**Dose/frequency/details:**Prescribed dose: 45-72 Gy at the PTV isocenterBED: Median 116 (100-141) Gy3-10 frsConsecutive days or every other day**Technical details:** 4- and 6-MeV beam energy**Treatment Intention:**Curative**Follow-up and Evaluation Criteria:**First FU at 4 weeks, then every 1-3 mos thereafterChest CT scans every 3 mos for first year then every 4-6 mos thereafterToxicity assessed according to CTCAE v.2.0 |
| Shibamoto -2012,#4629 | **Study Objective:** To report a multi-institutional study of SBRT in inoperable and operable patients with histologically confirmed stage I NSCLC**Primary outcome:** LC at 3-years follow-up**Definition:** Calculated from the start of SBRT**Secondary outcome(s):** OS, CSS**Definitions:** Calculated from the start of SBRT**List of Outcome(s):**OS, CSS, LCT, Toxicity**Cause of death:** Dead: 65 (36%)NR by operability**Length of FU:**36 monthsNR by operability | **Intervention name:**SBRT**Vendor name:**Novalis image-guided system (Varian Medical Systems, Palo Alto, CA)CLINAC 23EX or 21 EXS (Varian)Eclipse v.7.5.14.3 (Varian)BRAINSCAN v.5.31 (BrainLAB, Feldkirchen, Germany)Pinnacle3 (Philips, Madison, WI)**Dose/frequency/details:** Hypofractionated SBRT Total dose: 44-52 Gy to 90% of the isodose line of PTV in 4 frs for 9-21 days **Technical details:** 6-MV photons**Treatment Intention:** Curative**Follow-up and Evaluation Criteria:** * All time intervals were calculated from the start of SBRT
* CT scans of chest and upper abdomen at 2-months intervals up to 6 months, every 2-4 months thereafter
* Toxicity: CTCAE v3.0 criteria during and up to 3 months after RT
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| Takeda-2009, #3700 | **Study Objective:** To analyze clinical outcomes of SBRT for patients with stages IA and IB NSCLC**Primary outcome:** NR**Definition:** NA**Secondary outcome(s):** NR**Definitions:** NA**List of outcomes:**OS, CSS, LCT, toxicity**Cause of death:** NR**Length of FU:**31 (10-72) mos | **Intervention name:**SBRT**Vendor name:**XiO treatment planning system, V.4.2 or v.4.3, CMS, St. Louis, MOLinear accelerator NR**Dose/frequency/details:**Prescribed dose: 50 Gy to the 80% isodose line10 Gy per fraction5 fractions**Technical details:** Beam energy NR**Treatment Intention:**Curative**Follow-up and Evaluation Criteria:*** Monthly for first 6 mos, with chest X-ray
* CT scans at 1 and 3 mos after SBRT, then at 3-mos intervals during first 2 years
* FU interviews and CT scans at 4-6 mos intervals after 2 years
* Toxicity assessed according to CTCAE v.3.0
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