Physical results of Phase II Clinical Trial of 24 Gy Single Fraction SBRT of inoperable stage 1-2 breast cancer

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Purpose

To assess the feasibility of administering 28 stereotactic **single-dose radiation treatments** for breast tumors at our institution. For elderly patients with localized breast cancer who either decline surgery or are not suitable candidates, SBRT (Stereotactic Body Radiation Therapy) could offer a more effective approach to controlling local disease.

Methods and material

Between May 2017 and July 2021, **28 early-stage breast cancer patients** with contraindications for MRI underwent SABR treatment. We used a breast stereotactic prototype with rib dampening (BSRD), developed and patented at our hospital (Figure 1).

In the BSRD setup, patients were seated perpendicular to the CT couch on a rotating platform that stabilized the symphysis and trochanters. The legs were elevated, and the platform rotated until it locked in alignment with the couch's movement direction. Patients leaned against a truncated, V-shaped anti-rotation surface that left the spinous processes exposed and unsupported, shifting their weight to the paraspinal musculature (Figure 2). A Moldcare BR-3 (ALCARE CO., Ltd.) cushion secured the arms, armpits, neck, and head. Next, a thermoplastic mask with a compression belt was applied from the submammary crease to the lower edge of the costal arch, preventing rib movement during unexpected deep breaths or coughing (Figure 3). Finally, five BB markers were placed on the breast to mark the intersections of five sagittal laser references of the stereotactic arch, with the axial laser positioned over the tumor. These markers were covered with transparent, waterproof adhesive dressings, allowing us to control the position of both the patient and the breast independently (Figure 4).

Target definition was achieved using slow CT and high-resolution CT (HRCT), enabling automatic contouring based on the Hounsfield number histogram (Figure 5). Additionally, we obtained a dynamic 4DCT, similar to the acquisitions used in cardiology, without couch displacement, utilizing 16 detector rows for tumor motion analysis. Treatment planning was conducted using the Pinnacle system, applying **a negative margin technique for 4π treatment** with 15 beams (Figure 6). This approach provided high conformity to the target while keeping the dose to organs at risk below the established thresholds (Figure 7).

Malignant breast tumors that measured < 40 mm in greatest dimension were treated by **single fraction SABR of 24Gy**.

The Pinnacle scorecard OAR constraints were:

- Lung MLD<3.6Gy,
- Heart V2.8Gy<10%,
- Chest wall D20cc<16.3Gy,
- Skin (5mm) D1cc<16Gy
- Breast MBD<9Gy.

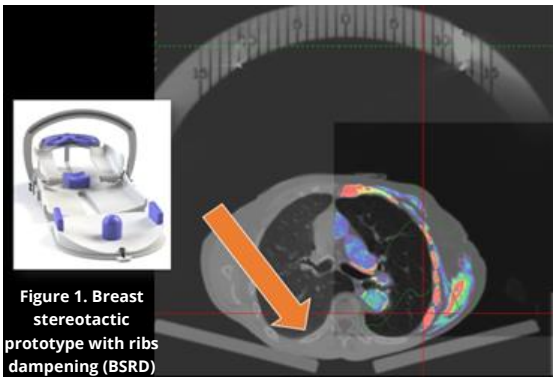

Figure 1. Breast stereotactic prototype with ribs dampening (BSRD)

Figure 2. Patients are positioned on an antirotation truncated V-shaped surface

The patient's positioning was assessed using cone-beam CT (CBCT) aligned with the planning CT. A total of 30 CBCT scans were analyzed. Absolute averages, statistical means, standard deviations, and root mean square (RMS) values of the observed setup errors were calculated. The **total irradiation time was maintained under 12 minutes to maximize biological effectiveness**.

Figure 3. Compression belt is placed from the submammary crease.

Figure 4. Sagittal references of the stereotactic arch.

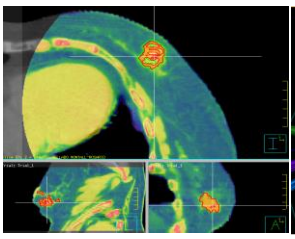

Figure 5. HRCT allows automatic contouring based on CT histogram.

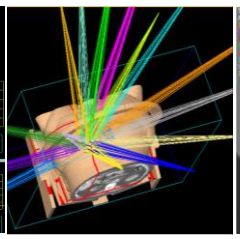

Figure 6. 4π treatment with 15 beams.

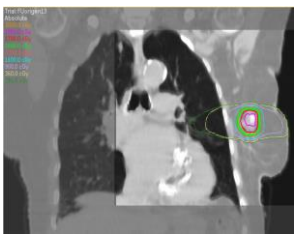

Figure 7. Typical dose distribution.

Results

The **target position deviations were below 1.3 mm**, and the mean doses to the GTV and PTV were 25.14 Gy and 24.45 Gy, respectively, with effective lesion control and no observed toxicity (Table 1).

Conclusion

We have implemented a procedure with high geometric and dosimetric precision, which may enable reduced PTV margins and excellent plan quality, ensuring safe and effective breast SBRT. The results have been promising and may improve the adoption rate of breast SBRT. A larger prospective trial is currently underway.