ASTRO 2026

Data to Dialogue: Communicating Radiotherapy's Value to Advance Care

SEPTEMBER 26-30, 2026 | THOMAS M. MENINO CONVENTION & EXHIBITION CENTER | BOSTON

Outcomes from Phase 2 Trial of Preoperative Image Guided Intensity Modulated Photon Radiation Therapy (IMRT) with Simultaneously Integrated Boost (SIB) to the High-Risk Margin for Retroperitoneal Sarcomas (RPS)

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Disclosure

- Employer: Brigham and Women's Hospital
- No conflicts of interest
- Work supported by NCI grants # U19CA021239 and Federal Share of program income earned by Mass General Hospital on C06 CA059267, Proton Therapy Research and Treatment Center.

Background

- Local recurrence continues to be a significant contributor to treatment failure in RPS despite aggressive surgeries.
- The role of pre-operative radiotherapy (RT) remains controversial, and there is limited prospective data investigating whether different radiation techniques improve local control.
- Thus, we conducted a multi-institutional, prospective Phase II study to assess efficacy and tolerability of preoperative IMRT with selective dose escalation to 63 Gy to the posterior RPS margin (clinical target volume [CTV] 2) at high risk for positive margins to reduce the risk of LR.

Methods

- Patients (pts) >18 years at diagnosis and pathologic confirmation of RPS were enrolled from November 2018 to September 2023.
- Using IMRT, pts received 50.4 Gy in 28 fractions to CTV1 (tumor plus adjacent tissue at risk of subclinical disease) with simultaneous integrated boost (SIB) to CTV2 (high risk posterior margin) to 63.0 Gy in 28 fx.
- Pts with high-grade tumors could receive chemotherapy (CT) prior to RT.
- Pts had restaging and surgery 4-8 weeks after completion of RT.

Methods

- Primary objective was cumulative incidence of local progression (CILP). Secondary endpoints included surgical margin status, disease-free survival (DFS) and overall survival (OS).
- Toxicity was graded using CTCAE v4 and late toxicities were defined as those occurring >3 months after surgery.

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Methods: Target Volumes

GTV

CTV1

CTV2
High
risk



High risk CTV2 is defined jointly by Rad Onc and Surgeon!

Meticulous delineation of bowel (often distorted by tumor) to avoid inclusion in CTV2

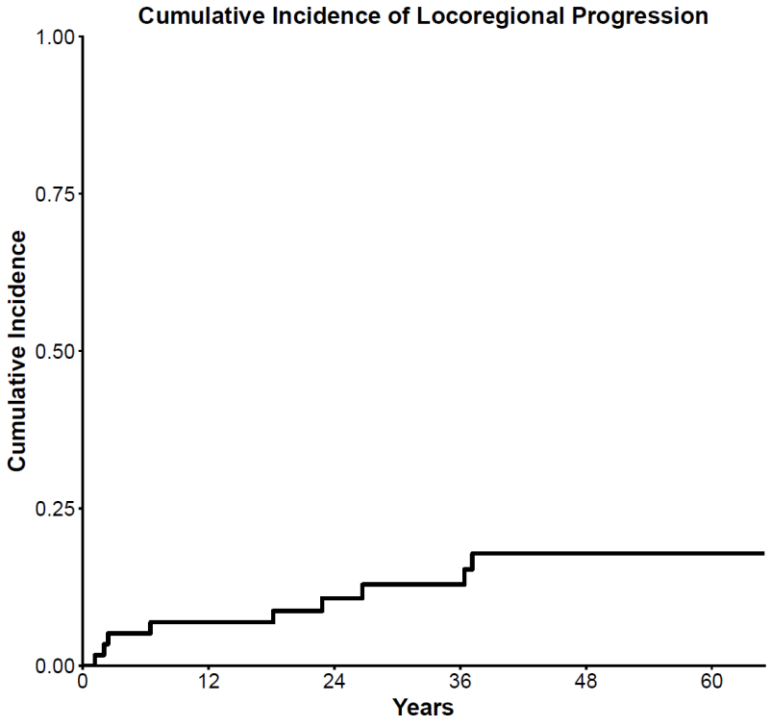
Results

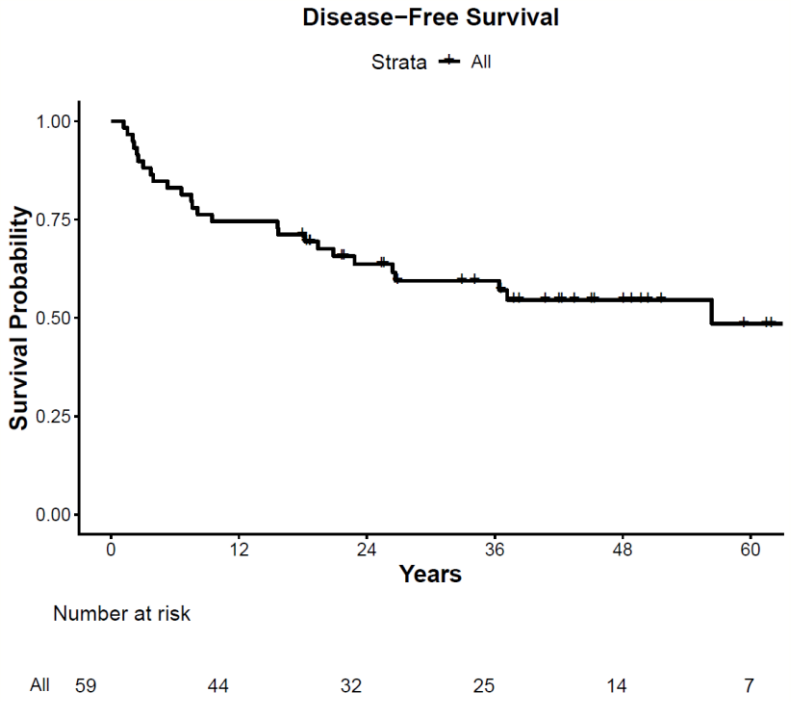
- In the cohort, 45 had liposarcoma (LPS) (29 with de-differentiated LPS,15 with well-differentiated LPS, 1 with myxoid LPS), 6 leiomyosarcoma, and 9 other histologies.
  - 1 patient with DDLPS died due to disease progression before starting RT and was excluded from further analysis
- 5 patients did not undergo surgery (3 due to metastases, 1 due to local progression, and 1 declined)
- Of the 54 patients who underwent surgery, 33 had negative margins (R0), 19 had positive margins (R1), and 2 patients had gross residual disease (R2)

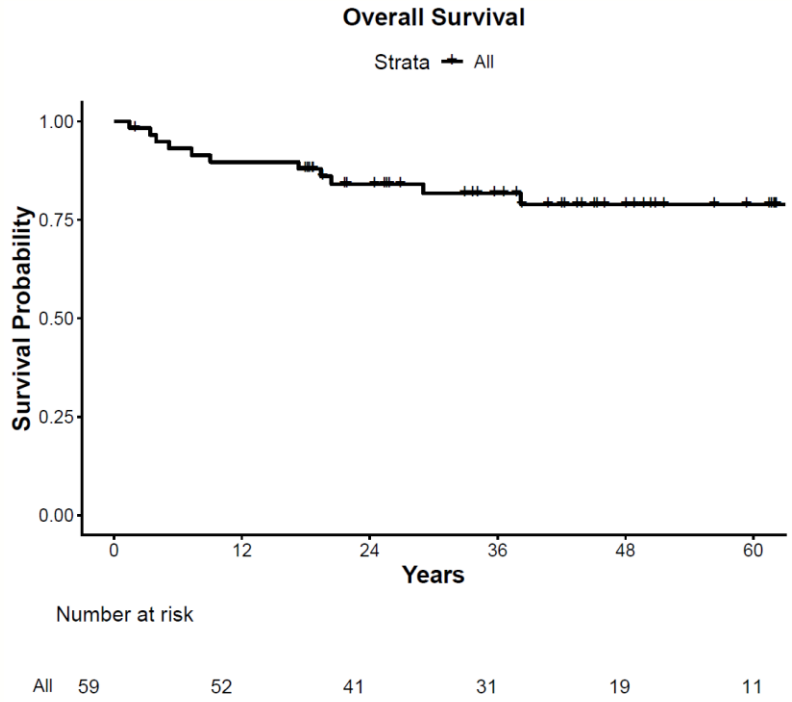
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Results

- With a median follow-up of 37.8 months (range: 1.4-73.4), 3-year CILP, DFS, and OS were 12.9%, 59.5%, and 81.8%, respectively.
- Of the 10 pts with local or marginal progression, 3 had local progression after 36 months (36.4, 37.1, and 66.0 months).







Results

- Clavien-Dindo morbidity: 0(19), 1(21), 2(10), 3a(2), 3b(1), 4a(0), 4b(1), 5(0).
  - 1 patient had sepsis related to fungemia
- Nine pts had late RT-associated grade ≥3 toxicities including:
  - Weight loss (n=2)
  - Abdominopelvic pain (n=1)
  - Bladder perforation (n=1) occurring 4 months after surgery
  - Chronic kidney disease (n=1)
  - Fatigue (n=1)
  - Lymphopenia (n=1)
  - Myelodysplastic syndrome (n=1) after prior chemotherapy
  - Neutropenia (n=1)
  - Small bowel obstruction (n=1) occurring 4 months after surgery

Conclusions

- Dose escalation to 63 Gy using a simultaneous integrated boost with strict dose constraints to normal organs was safe in most patients but can be associated with toxicity
- Local failure rate of 12.9% at 3 years is promising with DFS and OS similar to data in prior published studies
- Limitations are histology heterogeneity, not randomized, completed at a limited number of high-volume centers
- Late toxicities can occur, highlighting importance of long-term follow-up
- Further study is needed to determine whether this approach improves outcomes compared to standard 50/50.4 Gy (as was done in STRASS)

Questions?