Prospective study evaluating the treatment outcomes for localised recurrent, resectable retroperitoneal liposarcoma (ReLaPSe)

Angela Hong
Radiation Oncologist, The University of Sydney
Sydney, Australia

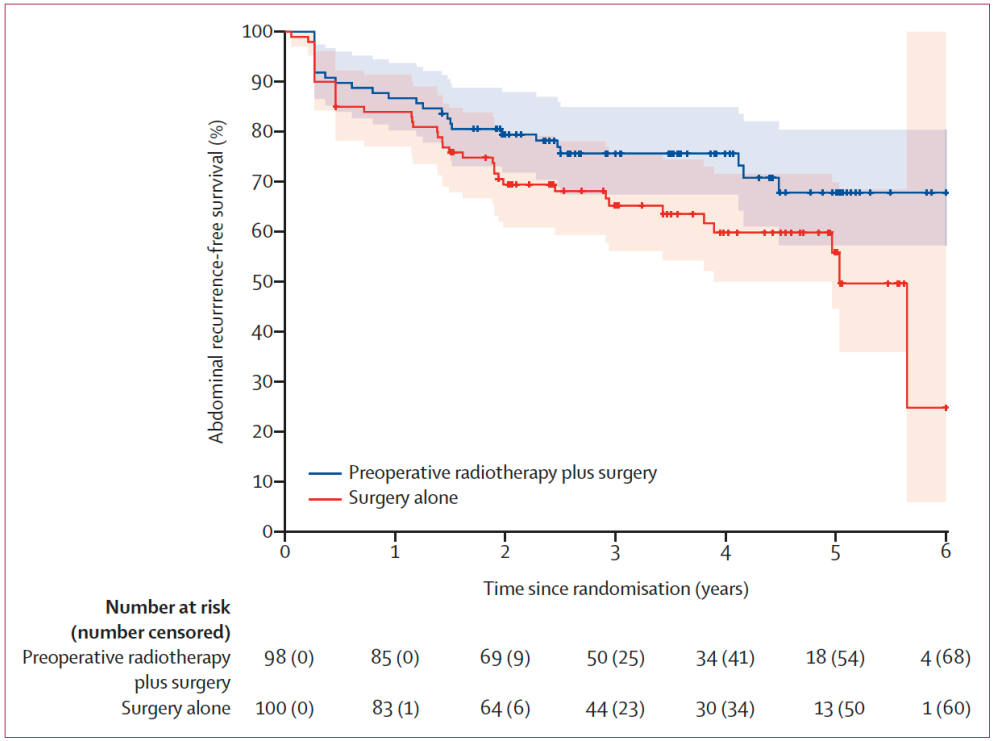
THE UNIVERSITY OF SYDNEY

ANZSA
Australia and New Zealand Sarcoma Association

angela.hong@sydney.edu.au @angelahong

Background

- Local recurrence remains a management issue
- MacNeill et al: 21.5% local recurrence only
- Role of preoperative RT is unclear
  - More challenging to deliver



Number at risk (number censored)							
Preoperative radiotherapy plus surgery	98 (0)	85 (0)	69 (9)	50 (25)	34 (41)	18 (54)	4 (68)
Surgery alone	100 (0)	83 (1)	64 (6)	44 (23)	30 (34)	13 (50	1 (60)

Figure 3: **Second sensitivity analysis of abdominal recurrence-free survival in the liposarcoma subgroup**
Shaded areas around the lines represent the 95% CI. HR=hazard ratio.

STRASS post hoc analysis for liposarcoma:

3 yr ARFS: Sx 65·2% vs preop RT+Sx 75·7% (HR 0·62, 95% CI 0·38–1·02)

ReLaPSe

Aim

- Prospective study evaluating the outcomes of curative treatment for localized, recurrent, resectable retroperitoneal liposarcoma

Study design

- Treatment as per local MDT recommendation
- Non-randomised, two parallel groups:

Group 1

- Surgery with preoperative RT (any chemo)

Group 2

- Surgery without preoperative RT (surgery alone, surgery with postoperative RT, any chemo)

- 100 patients (minimum of 40 patients per group) over 3 yrs

Primary objective

- Abdominopelvic recurrence-free survival (ARFS) from the date of treatment to the date of radiological abdominopelvic relapse or death
    - Liver metastasis as distant metastatic event

Secondary Objectives

1. Overall survival
2. Cumulative incidence of 2nd local recurrence from surgery
3. Cumulative incidence of distant metastases
4. Local disease progression during preoperative RT rendering disease no longer operable
5. Distant disease progression during preoperative RT
6. Toxicity of preoperative RT
7. Pathological response to preop RT (EORTC-STBSG criteria)
8. Radiology response to preop RT (RECIST 1.1 and Choi criteria)
9. Unplanned R2 resection
10. Patient reported QoL assessment
11. Stratified analysis of use of chemotherapy
12. Validation of the recurrent RPS nomogram and the dynamic primary RPS nomogram

Eligibility

- First localized, recurrent liposarcoma of retroperitoneal space or pelvis after previous macroscopically complete resection (R0/R1 resection)
- No previous RT (previous chemo is allowed)
- well-differentiated or dedifferentiated liposarcoma (exclude myxoid LPS)
- likely R0/R1 resection and all disease must be deemed to be treatable by RO as per MDT
- No distant mets

Exclusion criteria

- Unresectable disease or likely R2 resection as per local MDT
- Extent of recurrence where preoperative RT to all visible disease is not deemed to be feasible
- Contradiction for RT such as history of bowel obstruction or mesenteric ischemia or severe chronic inflammatory bowel disease
- Myxoid liposarcoma histology

Treatment

- As per local MDT recommendation
- Preop RT: 45-50.4Gy, covering all disease
  - at the treating sarcoma centre strongly recommended (no centralized QA)
- Surgery: 4-8 weeks after RT
- Chemotherapy as per local MDT

Patient reported quality of life assessment

- EORTC QLQ-C30 v3.0 and QLQ-STO22 (validated gastric cancer-specific questionnaire)
  - baseline
  - during the last week of RT
  - within 2 weeks prior to surgery
  - 3 months after surgery

Translational research

- Multiple timepoints: original, recurrence, post RT
- fresh, FFPE, PBMC/serum
- Potential questions:
  - intratumoral heterogeneity within a WD and/or DD component of LPS
  - Radiation induced changes in tumour and blood
  - Evolution from original LPS to recurrent disease

Follow up

- Every 3-6 months for 5 years for disease status and survival status

- Target recruitment period: 3 years

Logistics

- Feedback on final protocol
- Database build and statistical analysis with Milan Group
- Australia & New Zealand Sarcoma Association: central coordinator
- Expression of interest

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ReLaPSe

Surgeon Survey (baseline, after RT, postop)

What is the operability of this tumor?

- Very easy
- Easy
- difficult
- very difficult

What aspect of the operation do you envisage to be most difficult?

- vascular dissection
- retroperitoneal dissection
- deep margin (muscle/bone)
- visceral involvement (specify)