Adjuvant CDK 4/6 Inhibition for High Risk DDLPS

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Transatlantic Australasian Retroperitoneal Sarcoma Working Group

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Disclosures

- None

Background

- RP Liposarcoma is a recurrent disease
- CDK 4/6 inhibitors have activity in liposarcoma
  - Few studies examining adjuvant CDK 4/6i following surgery

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ORIGINAL ARTICLE – SARCOMA

Adjuvant Palbociclib May be Associated with Delayed Recurrence in Completely Resected Retroperitoneal Liposarcoma: Results of a Single-Institution Retrospective Cohort Study

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- Retrospective single institution case series of patients with RP liposarcoma who received observation or adjuvant CDK 4/6 inhibitor (Palbociclib)
  - Primary surgery or 1st recurrence
- Primary outcome: time to treatment change following surgery
  - Time from surgery to subsequent intervention for recurrent disease
  - Surgery, radiation, or systemic therapy (other than adjuvant Palbociclib)

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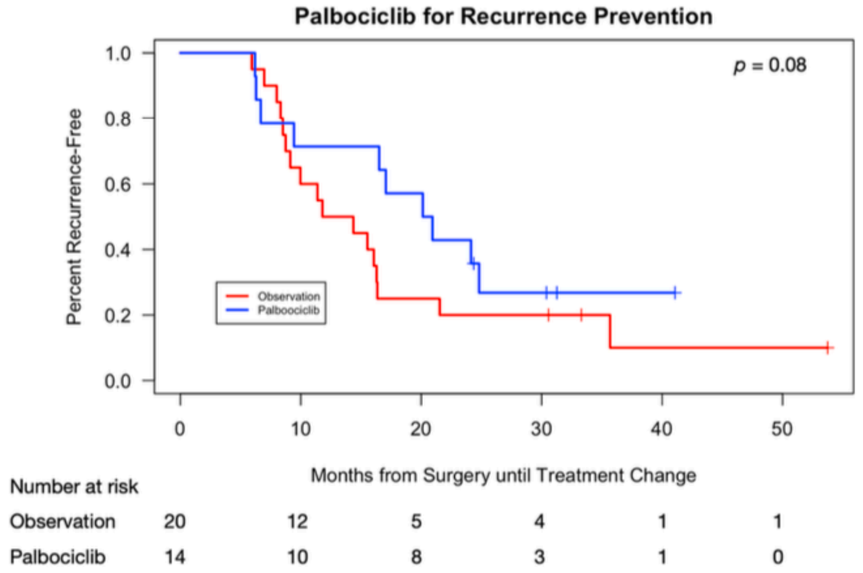


FIG. 1 Time-to-treatment change for patients treated with adjuvant palbociclib for recurrence prevention or postoperative observation following retroperitoneal liposarcoma resection

SSO 2026

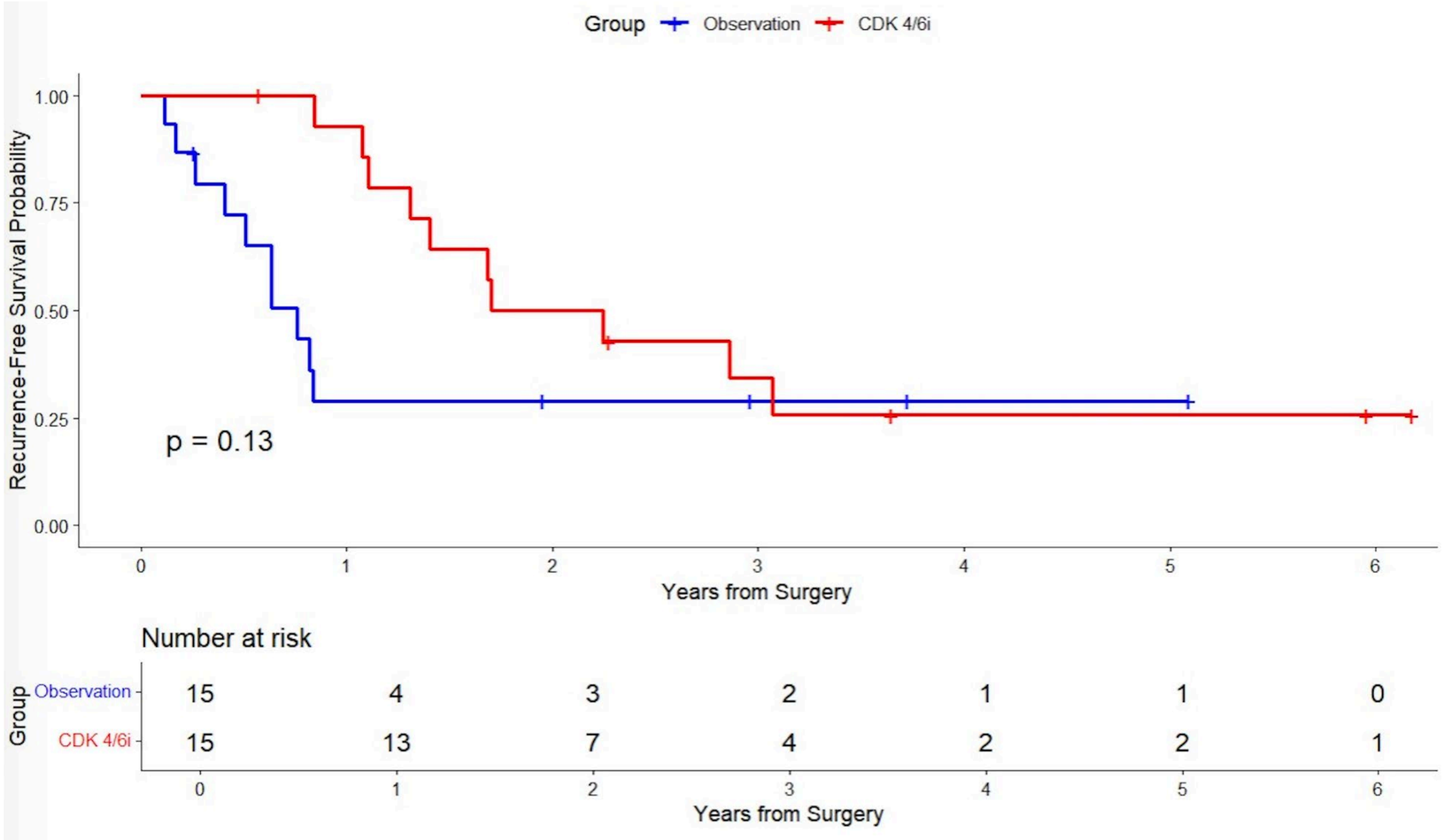
- 53 primary resections
  - 33 grade 2/3 DDLPS, 13 of whom received CDK 4/6 inhibition
  - All patients underwent comprehensive complete gross resection

- Outcomes
  - Time to recurrence
  - Time to treatment change

Demographics – Primary Resections

	Post-Operative Observation (n = 38)	Adjuvant CDK4/6 Inhibition (n = 15)	p-value
Age	63.3 (14.2)	62.3 (10)	0.78
BMI	31.3 (8.2)	30.4 (7.7)	0.71
Tumor Size	23.8 (11.3)	30 (16.6)	0.20
% DDLPS	20 (53%)	13 (87%)	0.02*
FNCLCC Grade 2	9 (24%)	6 (47%)	
FNCLCC Grade 3	9 (24%)	7 (47%)	
Neoadjuvant Radiation	7 (18%)	1 (6.7%)	0.42
Neoadjuvant Systemic	1 (2.6%)	2 (13%)	0.19
Sarculator 5-year Disease Free Survival	58.3 (23.6)	36.5 (24.3)	0.007*

Matched Time to Recurrence

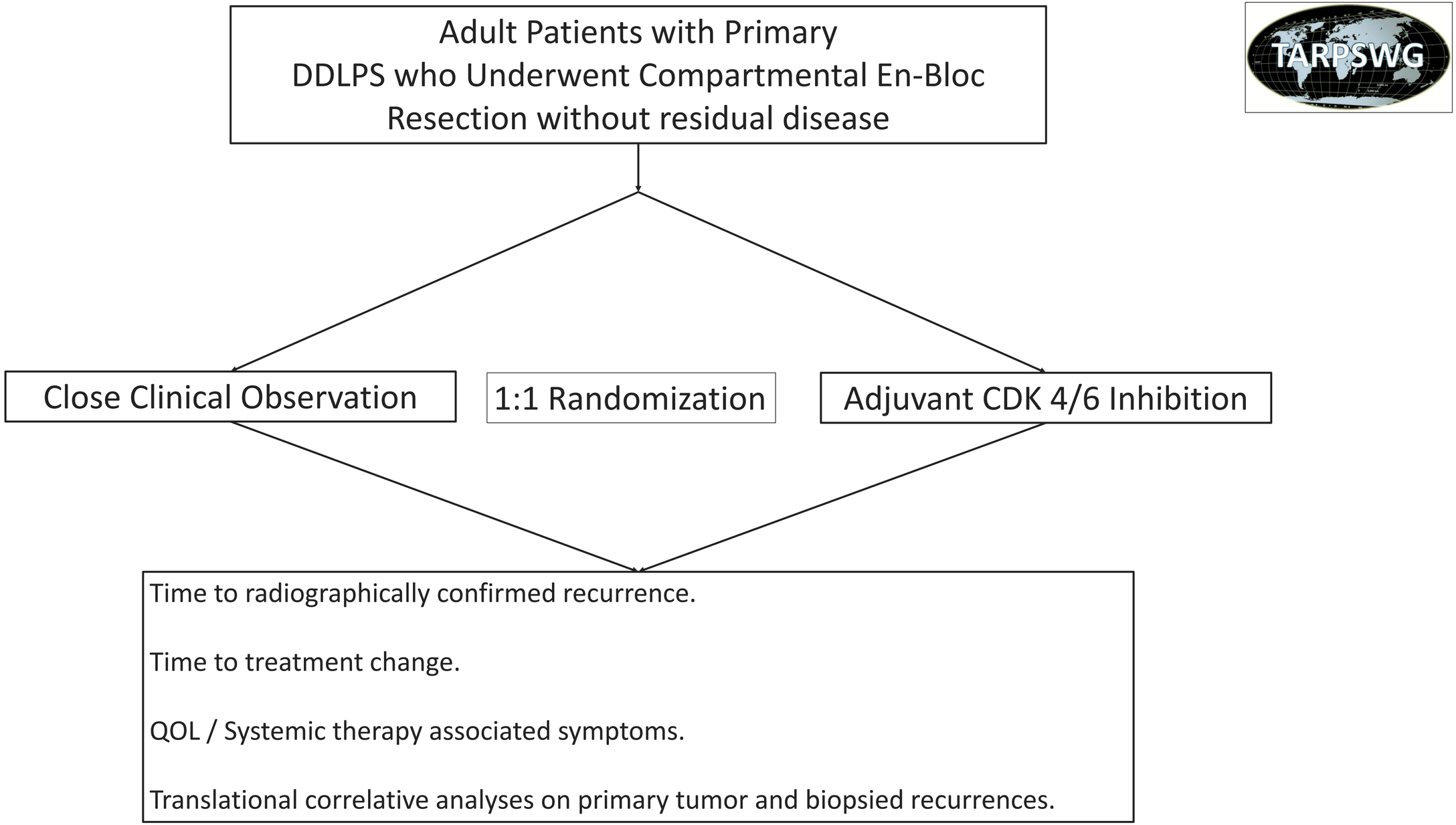


Proposal

- Prospective multi-institutional trial comparing CDK 4/6 inhibition to standard observation following comprehensive resection of “high risk” RP liposarcoma
  - Primary outcome: Time to Recurrence
  - Secondary outcome: Time to treatment change, AEs, QOL, translational analysis of biopsy proven recurrence
- Primary endpoint: 2 years

Inclusion Criteria

- Medically fit patients who underwent comprehensive resection of RP liposarcoma and within 90 days of surgery are medically fit for oral CDK 4/6 inhibition
  - Cross-sectional imaging and labs prior to intervention and Q3 months
  - Stratify based on neoadjuvant radiation and systemic therapy


Adult Patients with Primary
DDLPS who Underwent Compartmental En-Bloc
Resection without residual disease
Close Clinical Observation
1:1 Randomization
Adjuvant CDK 4/6 Inhibition
Time to radiographically confirmed recurrence.
Time to treatment change.
QOL / Systemic therapy associated symptoms.
Translational correlative analyses on primary tumor and biopsied recurrences.

Limitations

- Sample size estimated ~150-200 patients for an RCT
  - ~60 for a single arm study with historical controls
    - Matching from institutional databases and RESAR

- If single arm, what effect size would you need to convince you?