

# Presentaciones más destacadas en tumores germinales y otros tumores genitourinarios

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# Conflicts of interest

Me or my institution has received honoraria for speaking, advisory role, research funding, travel, accommodations and expenses from

Astrazeneca

Bayer

Astellas

BMS

Bicycle  
therapeutic

Genmab

Gilead

Johnson &  
Johnson

Ipsen

MSD

Merck

Pfizer

Recordati Rare  
Diseases

Roche



- **Cáncer de pene**
  - 1 oral: Estudio randomizado comparando 2 esquemas de QT adyuvante
  - 2 Posters
- **Tumores germinales**
  - 0 orales
  - 7 posters

# Trial schema

## High-risk features:

- $\geq 2$  inguinal LN+
- Bulky lymph node ( $\geq 4$  cm)
- Pelvic LN +
- Peri-nodal extension +

$\geq 1$  high risk feature

1:1  
Randomization

If CrCL < 50ml/min  
Carboplatin AUC 6mg/ml/min Day 1

Follow up

## PF ARM

Cisplatin 75 mg/m<sup>2</sup> Day 1  
5-FU 1000 mg/m<sup>2</sup> Days 1-4  
every 3 weekly x 4 cycles

## PP ARM

Cisplatin 75 mg/m<sup>2</sup> Day 1  
Paclitaxel 175 mg/m<sup>2</sup> Day 1  
every 3 weekly x 4 cycles

Primary endpoint:

- PFS

Secondary endpoints:

- OS
- Loco-regional control
- Adverse events
- QoL

Study duration: March 2017 - October 2024

Patients were assessed between day 7-10 of each cycle to check BC, RFT, serum electrolytes and to evaluate toxicity.

All toxicities were recorded as per the CTCAE (v 4.0)

QoL was assessed at baseline, days 7-10 and 6 weeks after starting adjuvant chemotherapy, completion of treatment and at every follow-up visit.

Follow-up: Patients were followed every 3 monthly for the first 2 years, then every 6 monthly for 5 years



# Sample size estimation

- We assumed median PFS of Platinum plus Paclitaxel arm - **8 months**  
Pagliaro et al. J Clin Oncol. 2010.
- We assumed a non-inferiority margin of **1 month** in median PFS for Paclitaxel arm as compared to 5-FU arm
- Power: **90%** and Confidence interval: **95% (one-sided)**
- Attrition: **10% per year**
- Estimated sample size: **150 patients**
- Due to slow accrual, the study was prematurely closed.

# Results

Baseline characteristics	PF arm (N = 25)	PP arm (N = 24)	p-value
<b>Age (years)</b>			
Median (Range)	49 (29-70)	51 (26-70)	0.480
<b>Co-morbidities</b>			
Hypertension	5 (20%)	5 (20.8%)	0.942
Diabetes Mellitus	5 (20%)	4 (16.7%)	0.763
Coronary Artery Disease	3 (12%)	1 (4.2%)	0.317
Prior phimosis	3 (12%)	1 (4.2%)	0.317
<b>Smoker or smokeless tobacco</b>	9 (36%)	10 (41.7%)	0.773
<b>ECOG PS</b>			0.715
0	2 (8%)	1 (4.2%)	
1	21 (84%)	22 (91.6%)	
2	2 (8%)	1 (4.2%)	
<b>Clinical T stage</b>			0.189
T1	12 (48%)	5 (20.8%)	
T2	8 (32%)	10 (41.7%)	
T3	5 (20%)	8 (33.3%)	
T4	0	1 (4.2%)	
<b>Clinical N stage</b>			0.073
N0	1 (4%)	6 (25%)	
N1	8 (32%)	5 (20.8%)	
N2	11 (44%)	12 (50%)	
N3	5 (20%)	1 (4.2%)	

# Results

Surgical details	PF arm (N = 25)	PP arm (N = 24)	p-value
<b>Surgery</b>			0.995
<b>Glansectomy</b>	4 (16%)	4 (16.7%)	
<b>Partial penectomy</b>	17 (68%)	16 (66.6%)	
<b>Total penectomy</b>	4 (16%)	4 (16.7%)	
<b>Degree of differentiation</b>			0.566
<b>Grade 1</b>	2 (8%)	2 (8.3%)	
<b>Grade 2</b>	12 (48%)	8 (33.3%)	
<b>Grade 3</b>	11 (44%)	14 (58.3%)	
<b>Pathological T stage</b>			0.525
<b>T1</b>	10 (40%)	6 (25%)	
<b>T2</b>	8 (32%)	9 (37.5%)	
<b>T3</b>	7 (28%)	9 (37.5%)	
<b>Pathological N stage</b>			0.950
<b>N2</b>	4 (16%)	4 (16.7%)	
<b>N3</b>	21 (84%)	20 (83.3%)	
<b>LVI or PNI</b>	11 (44%)	9 (37.5%)	0.644

# Results

Adjuvant treatment delivery	PF arm (N = 25)	PP arm (N = 24)	p-value
Adjuvant platinum regimen			0.576
Cisplatin	23 (92%)	23 (95.8%)	
Carboplatin	2 (8%)	1 (4.2%)	
Number of cycles of adjuvant chemotherapy			0.085
Zero (0)	3 (12%)	0	
One (1)	5 (20%)	1 (4.2%)	
Two (2)	2 (8%)	1 (4.2%)	
Three (3)	3 (12%)	2 (8.3%)	
Four (4)	12 (48%)	20 (83.3%)	0.009
Completed adjuvant CTRT	12 (48%)	14 (58.3%)	0.469
Safety Set	N = 22	N = 23	
Dose reductions	7 (31.8%)	1 (4.3%)	0.016
Drug discontinuation	10 (45.5%)	4 (17.4%)	0.092
Dose delays	7 (31.8%)	7 (30.4%)	0.920

Reasons for adjuvant carboplatin: Renal dysfunction (2); Cardiac dysfunction (1)



# Adverse events

- Grade 3/4 toxicities:**

54.5% (PF) vs 39.1% (PP) (p=0.300)

- Grade 3/4 gastro-intestinal toxicities:**

31.8% (PF) vs 4.3% (PP) (p=0.016)

- Grade 3/4 hematological toxicities:**

31.8% (PF) vs 13% (PP) (p=0.130)

Toxicities	5-FU + Platinum (N = 22)		Paclitaxel + Platinum (N = 23)		p-value
	Any grade	Grade 3/4	Any grade	Grade 3/4	
Dysphagia	4 (18.1%)	1 (4.5%)	0	0	0.101
Odynophagia	3 (13.5%)	1 (4.5%)	1 (4.3%)	0	0.532
Anorexia	9 (40.9%)	0	9 (39%)	1 (4.3%)	0.671
Diarrhea	10 (45.5%)	2 (9.1%)	7 (30.4%)	1 (4.3%)	0.733
Nausea	10 (45.5%)	0	6 (26%)	0	0.393
Vomiting	6 (27.3%)	0	2 (8.6%)	1 (4.3%)	0.073
Dysgeusia	5 (22.7%)	0	2 (8.6%)	0	0.131
Fatigue	14 (63.6%)	0	13 (56.4%)	2 (8.6%)	0.628
Constipation	9 (40.9%)	0	5 (21.7%)	0	0.290
Fever	3 (13.6%)	0	9 (39.1%)	0	0.094
Infection	5 (22.7%)	1 (4.5%)	5 (21.7%)	3 (13%)	0.390
Hearing loss	4 (18.2%)	0	0	0	<b>0.032</b>
Pain	11 (50%)	0	9 (39.1%)	0	0.037
Mucositis	13 (59.1%)	6 (27.3%)	2 (8.7%)	0	<b>0.002</b>
Myalgia	1 (4.5%)	0	4 (17.4%)	0	0.170

# Adverse events

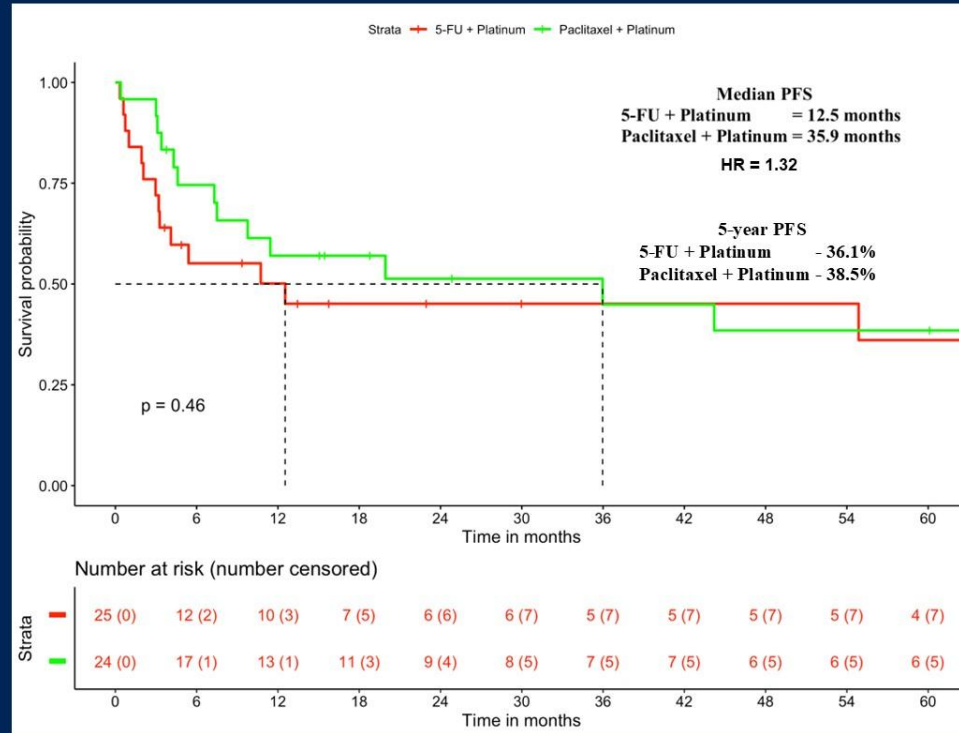
- Hospitalizations:**

40.9% (PF) vs 17.4% (PP) (p=0.082)

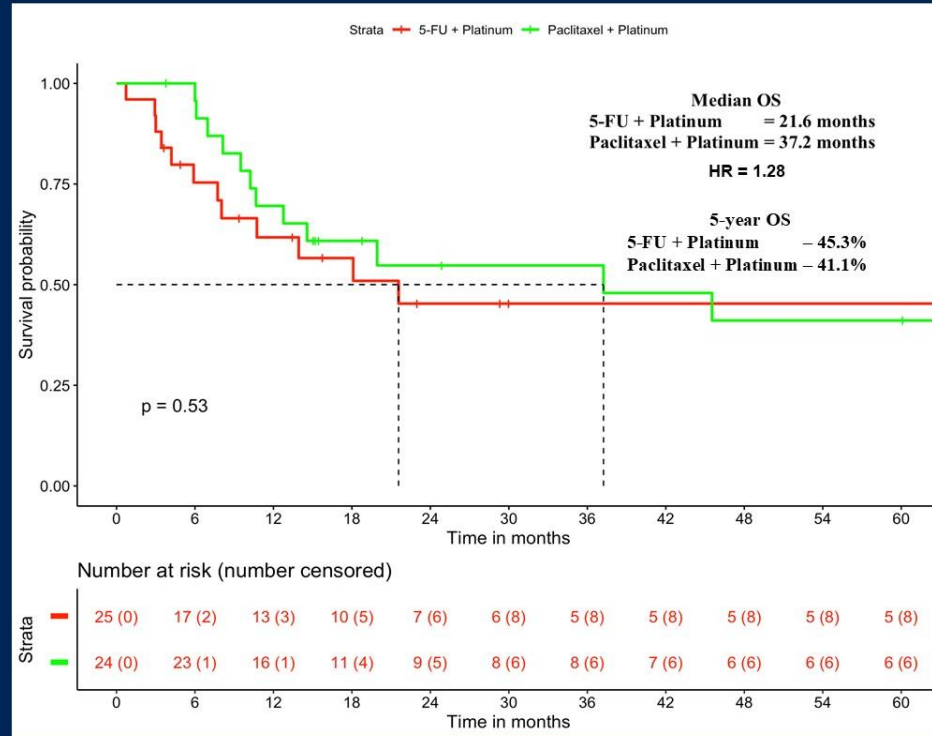
- Sensory neuropathy and Elevated liver enzymes more in Paclitaxel arm**

Toxicities	5-FU + Platinum (N = 22)		Paclitaxel + Platinum (N = 23)		p-value
	Any grade	Grade 3/4	Any grade	Grade 3/4	
Cardiac events	4 (18.1%)	1 (4.5%)	0	0	0.101
Skin rashes	2 (9%)	0	2 (8.6%)	1 (4.3%)	0.572
Febrile neutropenia	1 (4.5%)	1 (4.5%)	0	0	0.301
Sepsis	1 (4.5%)	1 (4.5%)	0	0	0.301
Vascular events	4 (18.1%)	1 (4.5%)	1 (4.3%)	0	0.146
Neutropenia	11 (50%)	5 (22.7%)	6 (26.1%)	2 (8.7%)	0.063
Anemia	14 (63.6%)	1 (4.5%)	11 (47.7%)	1 (4.3%)	0.600
Thrombocytopenia	10 (45.4%)	2 (9.1%)	3 (13%)	0	0.058
Hyponatremia	9 (40.9%)	1 (4.5%)	8 (34.8%)	0	0.571
Hypokalemia	4 (18.2%)	1 (4.5%)	2 (8.7%)	0	0.315
Hypomagnesemia	5 (22.7%)	0	5 (21.7%)	0	0.285
Elevated liver enzymes	2(9.1%)	0	9(39.1%)	0	<b>0.019</b>
Sensory neuropathy	1 (4.5%)	0	9 (39.1%)	0	<b>0.019</b>
Elevated serum creatinine	0	0	1 (4.3%)	0	0.323
Elevated serum bilirubin	0	0	2 (8.7%)	0	0.225

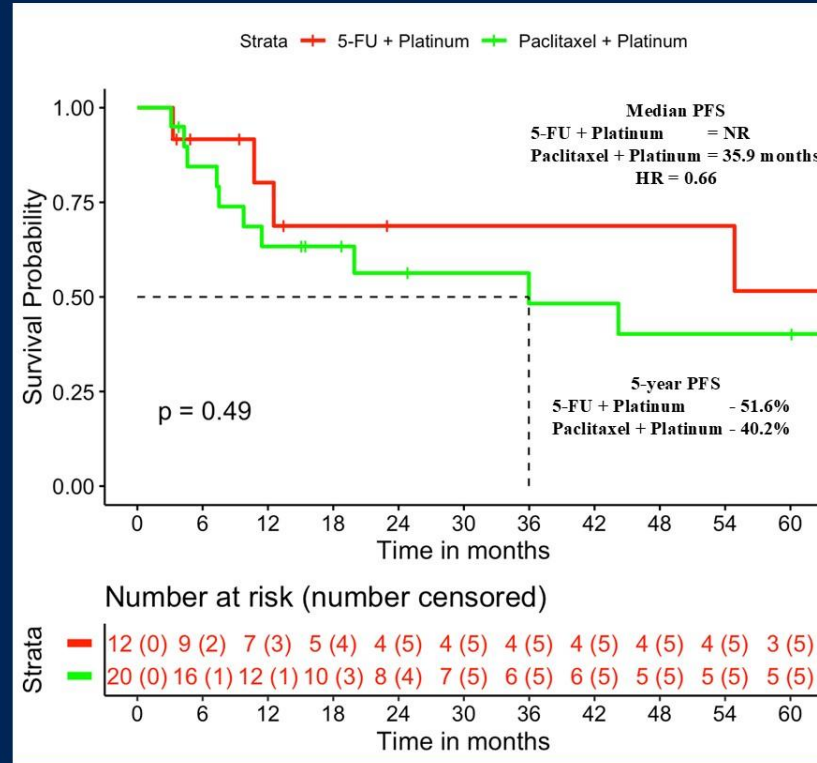
# Efficacy - ITT (Median follow-up: 60.1 months)



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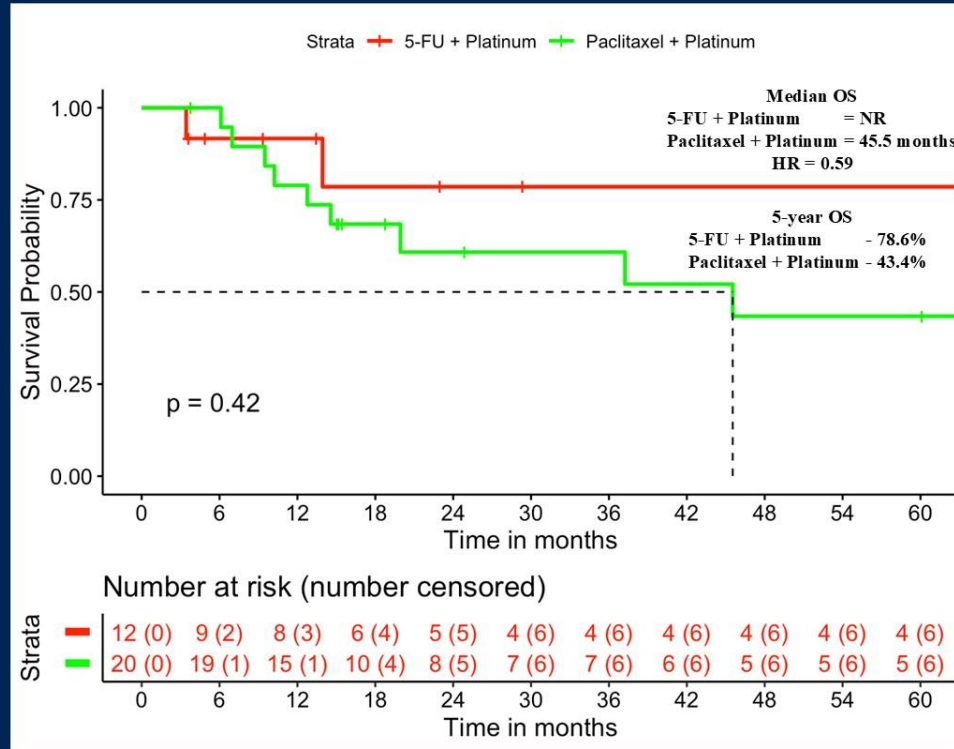


# PFS among those who completed 4 cycles (n=32)





# OS among those who completed 4 cycles (n=32)



# Conclusiones

Primer ensayo aleatorizado en adyuvancia

Estudio negativo. Platino-Paclitaxel no diferencias estadísticamente significativas con PF; menor toxicidad

¿Debería ser el nuevo estándar en adyuvancia?

Pero, no deberían los pacientes N2/N3 tratarse con QT neoadyuvante?

¿Papel de tripletes o de QT+IO periooperatoria?

# Surgical staging of patients with cN0 PSCC

- Delayed occult LN metastasis in PSCC = ↓ CSS rate
- Only 20-25% of cN0 pts Will have occult metastasis

High risk	Intermediate risk	Low risk
≥pT1b OR	pT1a AND	pTa, pTis and pT1 AND
G≥3	G2	G1 AND
OR lymphovascular perineural invasion	No LV/PN invasion	No lymphovascular/ perineural invasion

Surgical staging?



# #506844: Long-term outcomes of dynamic sentinel lymph node biopsy in clinically node-negative penile cancer

Authors: Vivaan Dutt, Anand Raja; Cancer Institute (WIA), Adyar, Chennai, India



CANCER INSTITUTE  
(WIA) Trust | Hope | Cure

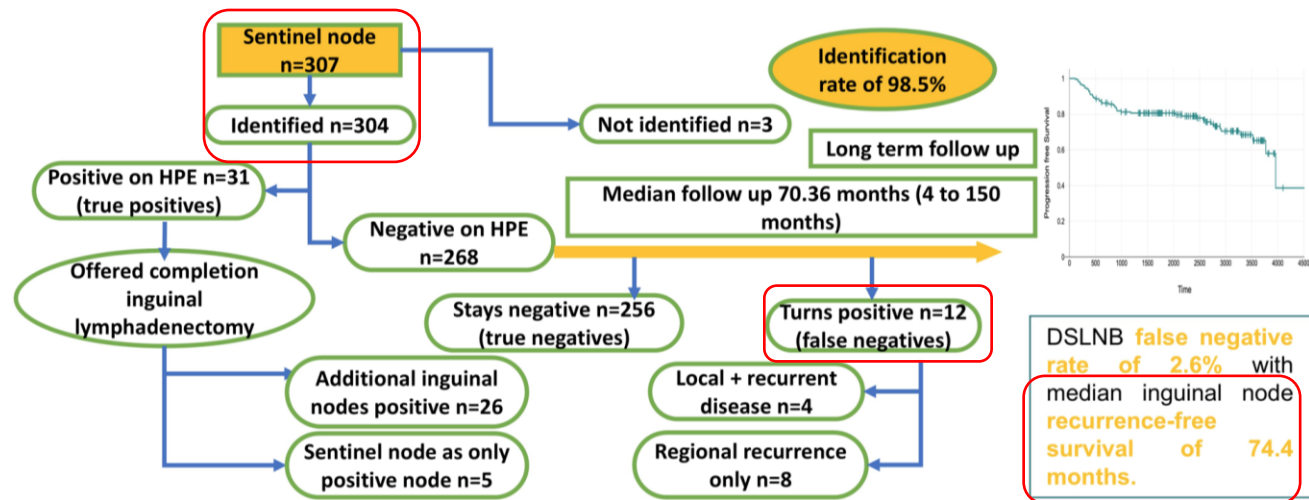
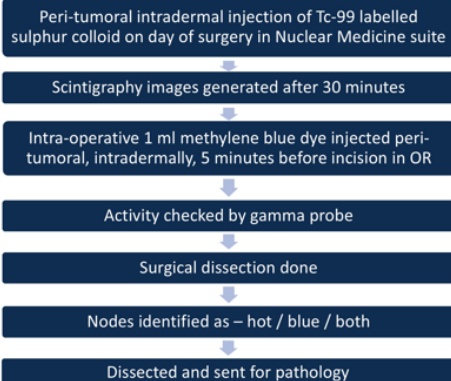
## Background

High morbidity associated with radical inguinal lymphadenectomy. Dynamic sentinel lymph node biopsy (DSLNB) has emerged as a viable alternative. However, data on efficacy of DSLNB is limited



## Methods

A retrospective analysis of patients who underwent DSLNB with dual technique (blue dye + radiocolloid) for cN0 penile cancer was done. Data was collected between 2010 to 2018 from a prospectively maintained database



SLNB POSITIVITY BY EAU RISK CATEGORY	% of cases	% of SLNB positive
High	77	21.2
Intermediate	15.3	11.4
Low	7.7	6.9

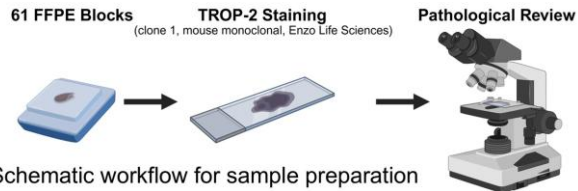


# TROP-2 Expression In Germ Cell Tumors (GCT)

Noah H. Richardson, MD<sup>1</sup>, Tareq Salous, MD<sup>1</sup>, Jennifer King, MD<sup>1</sup>, Nasser H. Hanna, MD<sup>1</sup>, Muhammad Idrees, MD<sup>2</sup>, Thomas M. Ulbright, MD<sup>2</sup>, Lawrence H. Einhorn, MD<sup>1</sup>, Andres Acosta, MD<sup>2</sup>, Nabil Adra, MD<sup>1</sup>

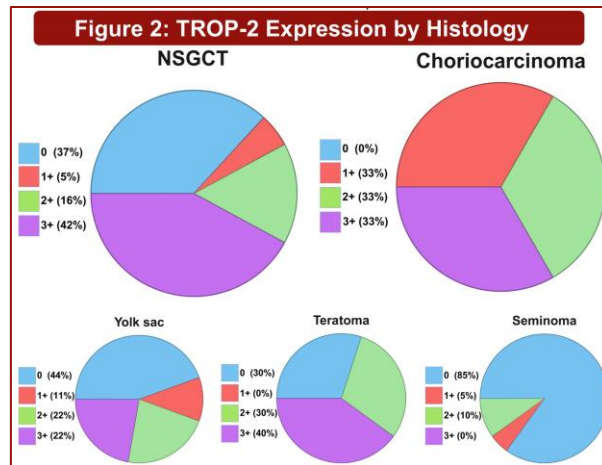
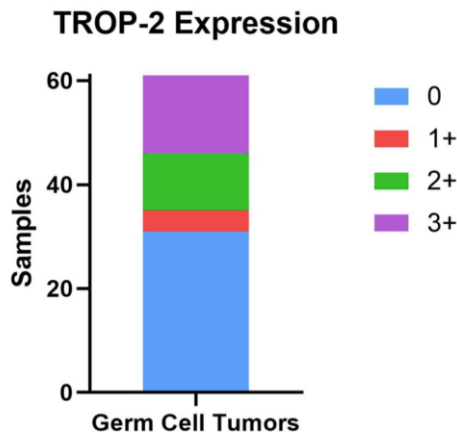
<sup>1</sup>Indiana University Melvin and Bren Simon Comprehensive Cancer Center, Indianapolis, IN

<sup>2</sup>Department of Pathology, Indiana University School of Medicine, Indianapolis, IN



## Baseline Characteristics

Characteristic (N)	N=61 (Range/%)
Median age (years)	37 (18-58)
Male patients	59 (97)
Pathological site	
• Testis	13 (21)
• Metastatic	48 (79)
Histology	
• NSGCT	19 (31)
• Choriocarcinoma	3 (5)
• Yolk sac tumor	9 (15)
• Teratoma	10 (16)
• Seminoma	20 (33)



## Conclusion

- TROP-2 expression varies across histology in GCT.
- Seminoma appears to have lowest expression of TROP-2.
- Higher TROP-2 expression was noted in choriocarcinoma and yolk sac tumor samples indicating potential as a target in these histologic subtypes.

## Limitations and Future Directions

- Treatment history and outcomes was not available for patient samples.
- NSGCT samples did not have specific histologic subtypes characterized.
- Currently we are analyzing additional choriocarcinoma and embryonal carcinoma specimens to further characterize expression in these subtypes commonly found in treatment resistant disease.



# Clinical utility of a tumor-naïve circulating tumor DNA (ctDNA) test to predict outcomes in patients with advanced testicular germ cell tumor (aTGCTs) - ID 5032

Vitor Vasconcellos<sup>1</sup>, Fabiana Bettoni<sup>2</sup>, Mauricio Pereira<sup>1</sup>, Gabriel Watarai<sup>1</sup>, Diogo Araújo<sup>1</sup>, Maria José Alves<sup>1</sup>, Elisangela Coser<sup>2</sup>, Ernande dos Santos<sup>2</sup>, Miyuki Uno<sup>1</sup>, Roger Chammas<sup>1</sup>, Diogo Bastos<sup>2</sup>, Anamaria Camargo<sup>2</sup>

<sup>1</sup> Instituto do Câncer do Estado de São Paulo, São Paulo, Brazil; <sup>2</sup> Hospital Sírio-Libanês, São Paulo, Brazil

- Copy number gains (CNG) of chromosome 12p are highly specific for TGCTs.
- Objective: To evaluate clinical utility and prognostic value of ctDNA test based on **12p CNG** detection
- SOX5 and BCAT1 selected as surrogate markers of chr 12p CNG
- Blood samples collected before 1st line treatment.

## Correlation: ctDNA and STM

### Patients characteristics (N=31)

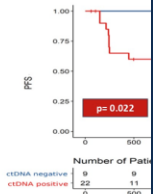
Characteristic	Value
Median age	31 years
Histology	
Seminoma	6 (19%)
NSGCT	25 (81%)
Staging	
II	16 (52%)
III	15 (48%)
Metastasis sites	
Liver	6 (19%)
Bone	1 (3%)
Lung	12 (39%)
Non-regional nodes	7 (23%)

Characteristic	Value
IGCCCG	
Good	17 (55%)
Intermediate	4 (13%)
Poor	10 (32%)
First Line Treatment	
BEP	7 (27%)
EP	9 (35%)
VIP	10 (38%)
Radiotherapy	3 (9.5%)
RPLND	2 (6.5%)

- We developed a **highly sensitive (88%) and specific (100%)** assay for detecting **12p CNG in ctDNA**.

### Survival

PFS: ctDNA



PFS	Events
PFS - 2 years	

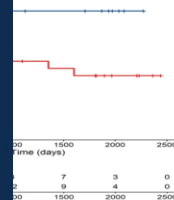
- Pre-treatment ctDNA detection correlated only with LDH, not AFP or bHCG.

- Pre-treatment ctDNA detection demonstrated **superior** clinical and prognostic value for PFS and OS compared to STM

Variable (n)	ctDNA neg (n - PFS)	ctDNA pos (n - PFS)
Normal STM (10)	4 (no event)	6 (1 events, 16%)
Elevated STM (21)	5 (no event)	16 (8 events- 50%)
Normal LDH (22)	9 (no event)	13 (3 events, 23%)
Elevated LDH (9)	No patient	9 (6 events, 66%)

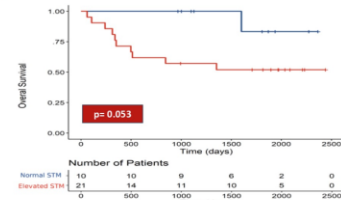
### ctDNA and STM

PFS: ctDNA



PFS	Events
PFS - 2 years	

OS: STM



OS	Events
OS - 2 years	

GRACIAS!!



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LA SOCIEDAD AMERICANA  
DE ONCOLOGÍA CLÍNICA**