Inaugural Southern California Genitourinary Cancer Research Forum

Key Updates in Testicular Cancer

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Disclosures

- Consultant for Veracyte.

This presentation and/or comments will be free of any bias toward or promotion of the above referenced companies or their product(s) and/or other business interests.

This presentation and/or comments will provide a balanced, non-promotional, and evidence-based approach to all diagnostic, therapeutic and/or research related content.

This presentation has been peer-reviewed and no conflicts were noted.

Cultural Linguistic Competency (CLC) & Implicit Bias (IB)

STATE LAW:

The California legislature has passed Assembly Bill (AB) 1195, which states that as of July 1, 2006, all Category 1 CME activities that relate to patient care must include a cultural diversity/linguistics component. It has also passed AB 241, which states that as of January 1, 2022, all continuing education courses for a physician and surgeon **must** contain curriculum that includes specified instruction in the understanding of implicit bias in medical treatment.

The cultural and linguistic competency (CLC) and implicit bias (IB) definitions reiterate how patients' diverse backgrounds may impact their access to care.

EXEMPTION:

Business and Professions Code 2190.1 exempts activities which are dedicated solely to research or other issues that do not contain a direct patient care component.

This presentation is dedicated solely to research or other issues that do not contain a direct patient care component.

Testicular Germ Cell Tumors

Paramount to minimize toxicity while maintaining excellent oncologic outcomes

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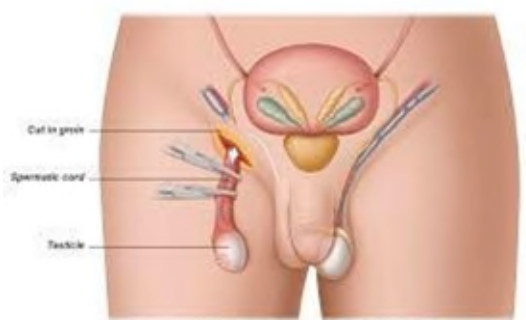
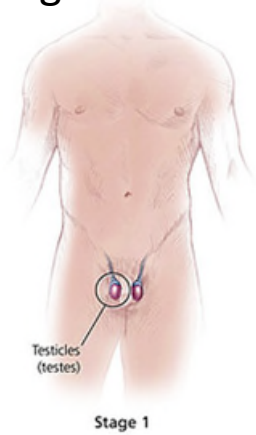
Outline

- **Guideline updates: Improving Survivorship:**
  - **Clinical Scenarios (Stage I and Stage II disease)**
- **Introduction to microRNAs for GCT diagnostics**
  - **Clinical application across the GCT spectrum**

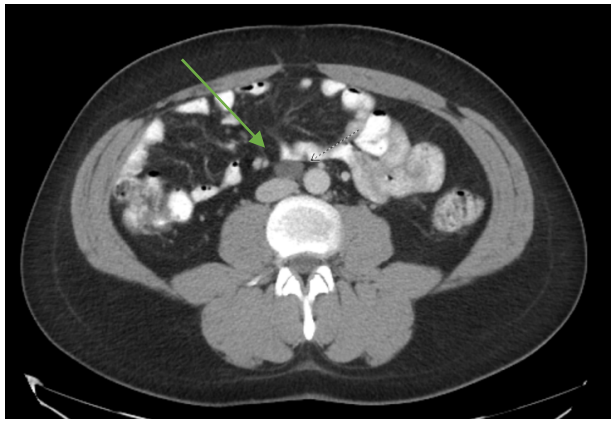
Pre-orchiectomy



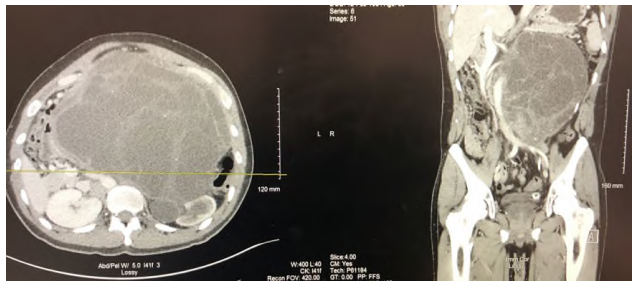
Stage I disease



Stage II disease



Post-chemotherapy



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5 year survival of patients with testis cancer

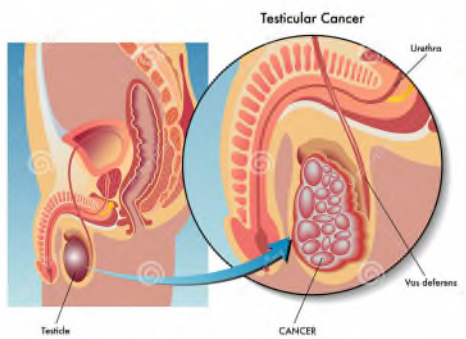
	Seminoma	Proportion of cases	NSGCT	Proportion of cases
Stage I	99%	86%	95-99%	70%
Stage II	95%	7%	90%	20%
Stage III	80-85%	5%	70-80%	10%

Stephenson, Campbell's urology, 10th edition

THE BULK OF GCT PATIENTS HAVE EARLY STAGE DISEASE WITH EXCELLENT SURVIVAL

Stage I Seminoma

- Healthy 23 yo male presents with painless enlarging left testis mass
- No Hx trauma, infection
- No prior Hx UDT
- Exam: large palpable firm mass involving left testis
- US: 6.5 cm hypoechoic lesion with ↑ flow on Doppler replacing most of left testis
- AFP 2; HCG 129
- Orchiectomy: 4.5 cm seminoma, + Rete testis invasion
- Markers normalize, imaging negative



Stage I Seminoma Treatment Principles

- **Survival approaches 100% independent of timing/type of treatment**

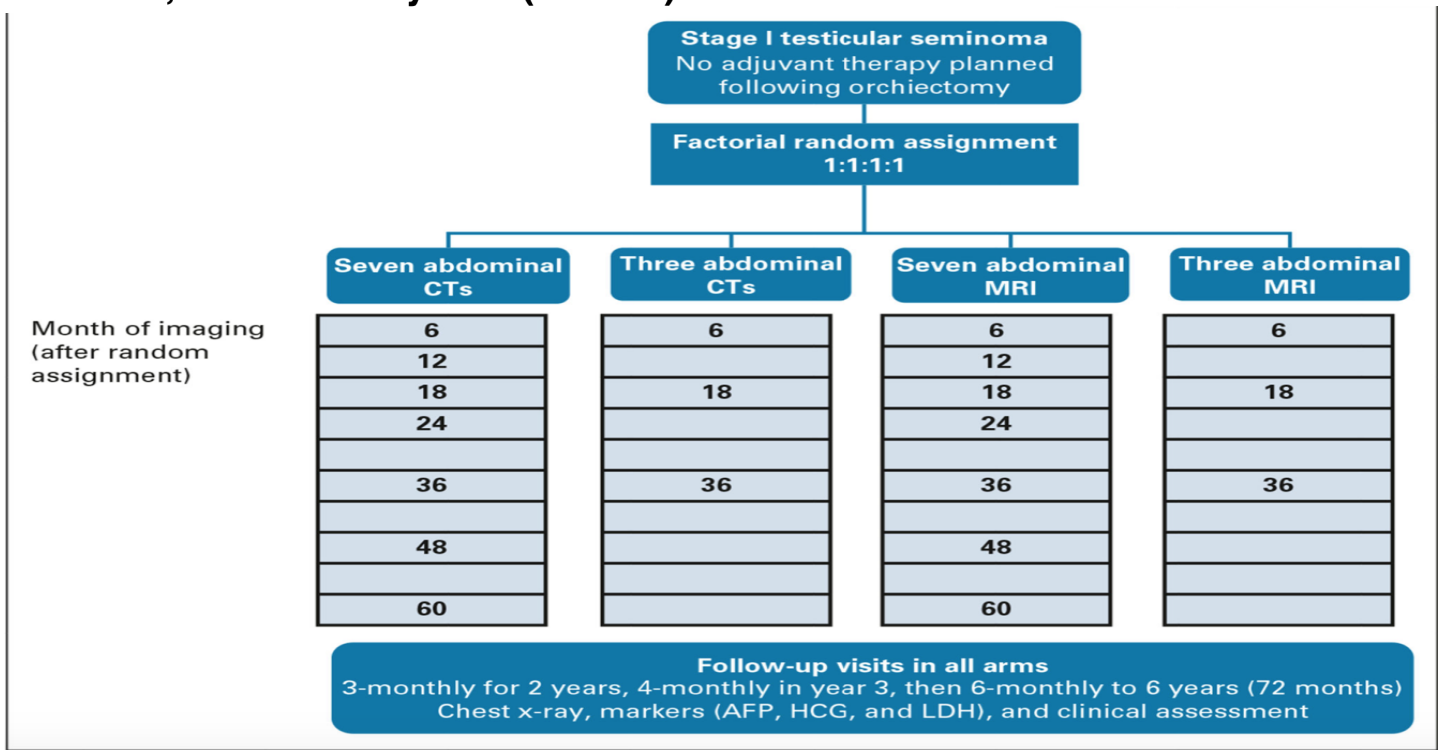
- **Treatment options**
  - **Surveillance**
  - **Single Cycle Carboplatin**
  - **Adjuvant Radiotherapy**

- **Adjuvant therapy “for all” over-treats vast majority of patients**
  - **& associated with acute and chronic toxicities**

- **Risk stratification?**
  - **Size**
  - **Rete testis invasion**

IMAGING ADVANCES: MRI

Imaging Modality and Frequency in Surveillance of Stage I Seminoma Testicular Cancer: Results From a Randomized, Phase III, Noninferiority Trial (TRISST)



Joffe et al, 2022

TRISST trial

- Design and endpoint: Noninferiority RCT of stage I seminoma surveillance
- Primary endpoint: 6 year incidence of stage ≥ IIC relapse

	3CT (n=166)	7 CT (n=169)	3 MRI (n=167)	7 MRI (n=167)
Relapse >IIC	8 (5.1%)	0 (0%)	1 (0.6%)	1 (0.6%)
Relapse >3cm LN	10 (6.4%)	3 (1.8%)	5 (3.1%)	6 (3.6%)

Conclusions:

MRI not inferior to CT

3 scans not inferior to 7

However: MORE recurrences w LN>3cm and stage ≥ IIC with 3 CT.

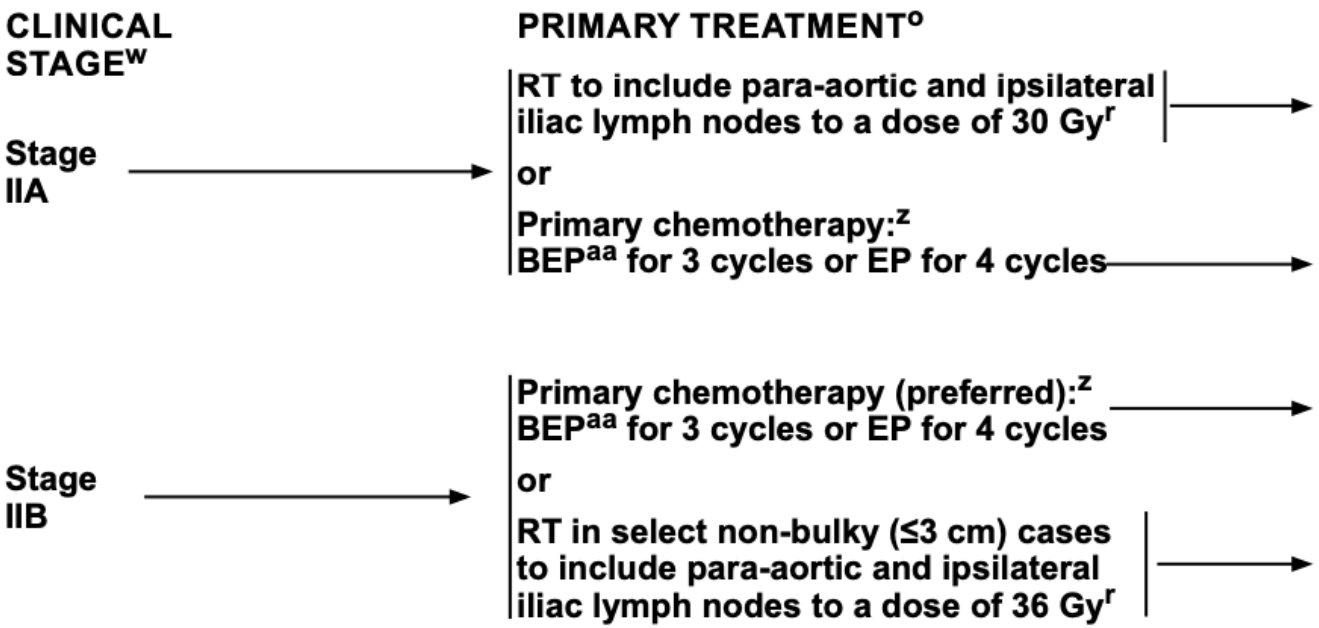
AUA guidelines 2023: Surveillance for stage I seminoma

NCCN (2023)	Year (at month intervals)				
	1	2	3	4	5
H&P	Every 3-6m	Every 6m	Every 6-12m	Annually	Annually
CT ap or MRI	At 4-6, and 12m	Every 6m	Every 6-12m	Every 12-24m	
CXR	As clinically indicated, consider chest CT in symptomatic pts				

Stage I seminoma: updated surveillance schedule (AUA 2023)			
	Years 1-2	Years 3-5	> Year 5
H&P, CT A±P	Every 6m	Every 6-12m	If clinically indicated

Stage II seminoma: Less (toxicity) is more

National Comprehensive Cancer Network®



RPLND for isolated <3cm retroperitoneal disease

1. European trials
2. US trial

WHY RPLND?

Survival

Primary Chemotherapy Primary Radiation	
Cardiac disease	Secondary Malignancies
HTN	Diabetes
Metabolic syndrome	Cognitive impairment
Secondary Malignancies	Anxiety/Depression
Ototoxcity	Hypogonadism/Fertility
Neurotoxicity	Pulmonary complications

Survivorship

Courtesy Clint Cary

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JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

Multi-Institutional Assessment of Adverse Health Outcomes Among North American Testicular Cancer Survivors After Modern Cisplatin-Based Chemotherapy

Chunkit Fung, Howard D. Sesso, Annalynn M. Williams, Sarah L. Kerns, Patrick Monahan, Mohammad Abu Zaid, Darren R. Feldman, Robert J. Hamilton, David J. Vaughn, Clair J. Beard, Christian K. Kollmannsberger, Ryan Cook, Sandra Althouse, Shirin Ardeshir-Rouhani-Fard, Steve E. Lipshultz, Lawrence H. Einhorn, Sophie D. Fossa, and Lois B. Travis, for the Platinum Study Group

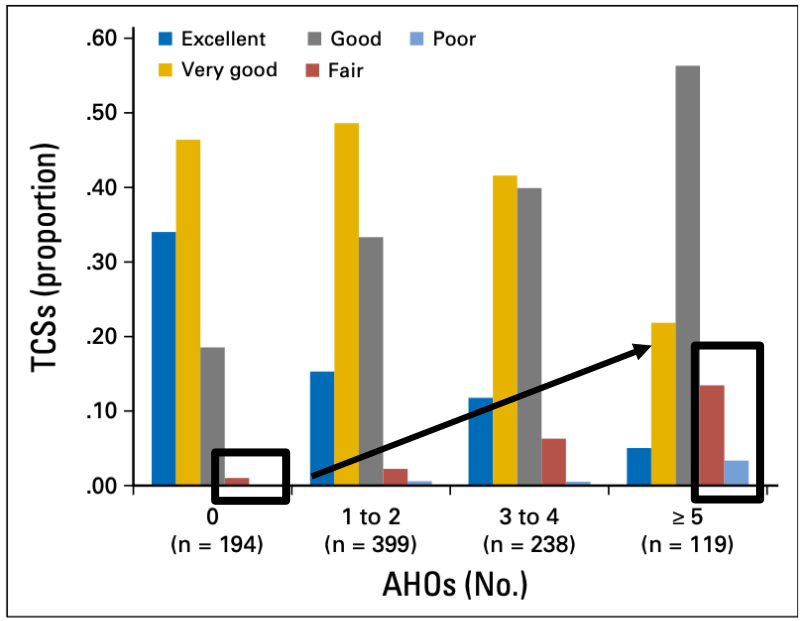


Fig 1. Proportion of testicular cancer survivors (TCSs) with excellent, very good, good, fair, and poor self-reported health by number of adverse health outcomes (AHOs). *P* value for association of number of AHOs with self-reported health was < .01 (Mantel 1df χ^2 test of trend). Self-reported health was not indicated by one participant with one to two AHOs and one participant with three to four AHOs.

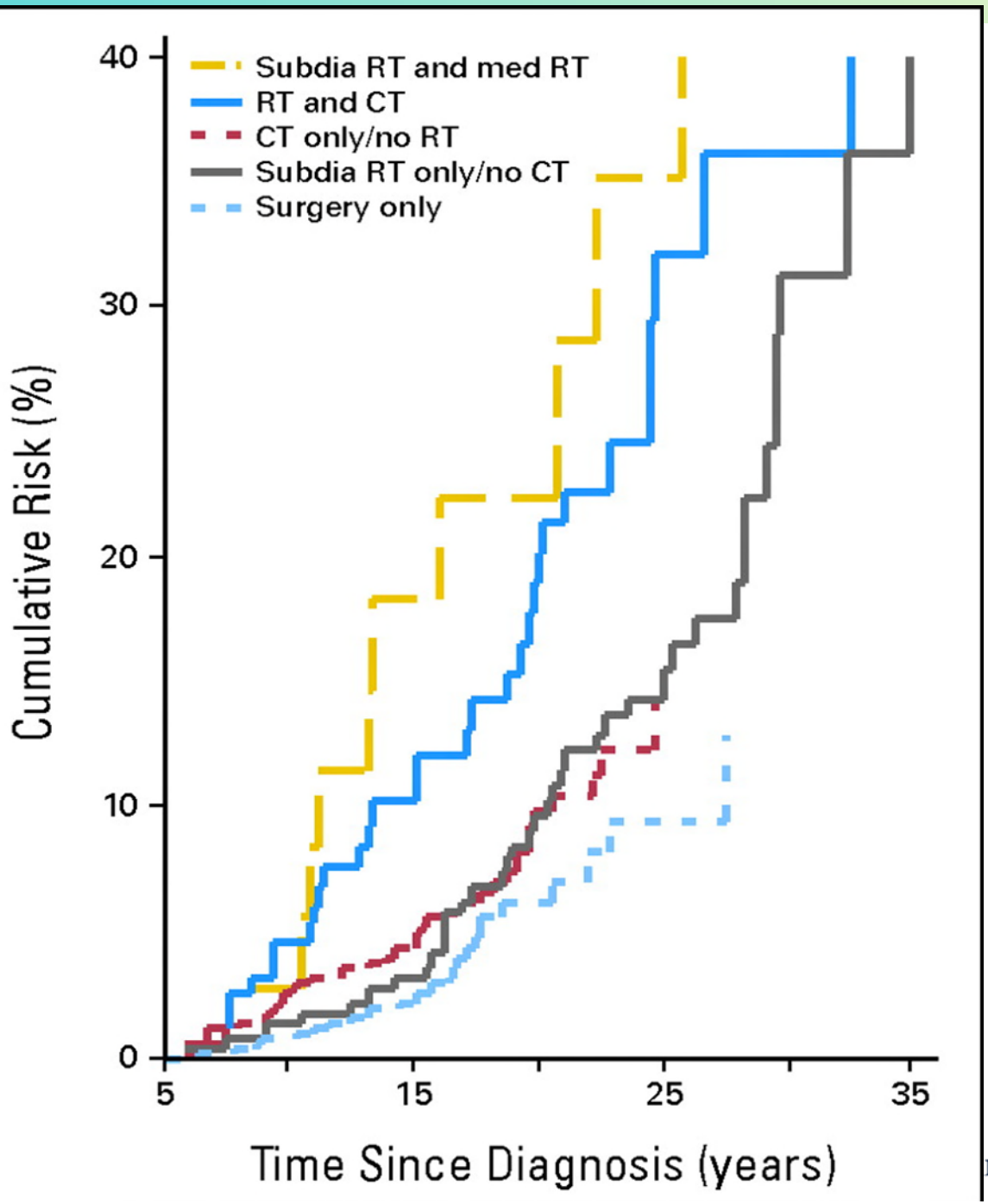
- 952 Testis cancer survivors treated with either BEPx3, BEPx4, or EPx4
- Median time since chemotherapy, 4.3 years
- 79.6% reported at least 1 Adverse health outcome
- Self-reported health Fair/Poor
  - 1% with No AHO vs. 16.8% with > 5 AHO's

Fung et al. *J Clin Oncol* 2017;35:1211-22

Stage II seminoma

Significant risk of long-term toxicity→

novel strategies to limit toxicity

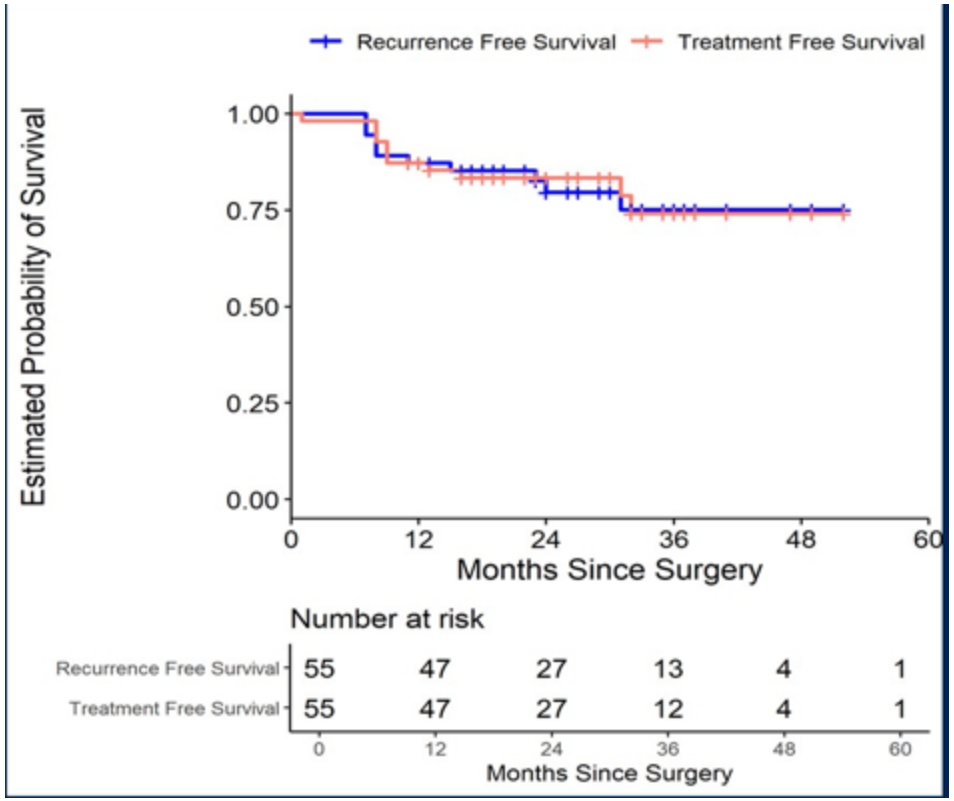


- JCO 2007: van den Belt-Dusebouit

Surgery for Early Stage Metastatic Seminoma

- **Phase II trial of RPLND as First-Line Treatment for Testicular Seminoma With Isolated Retroperitoneal Disease (1-3cm)**
- **Pure testicular seminoma**
- **Stage I with 1-3cm relapse**
- **Stage IIA/IIB**
  - **No more than 2 LN (1-3cm) in any dimension**
- **LN must be in RPLND template**
- **Imaging within 6 weeks of surgery**
- **Normal serum markers (1.5X ULN)**

Surgery for Early Stage Metastatic Seminoma



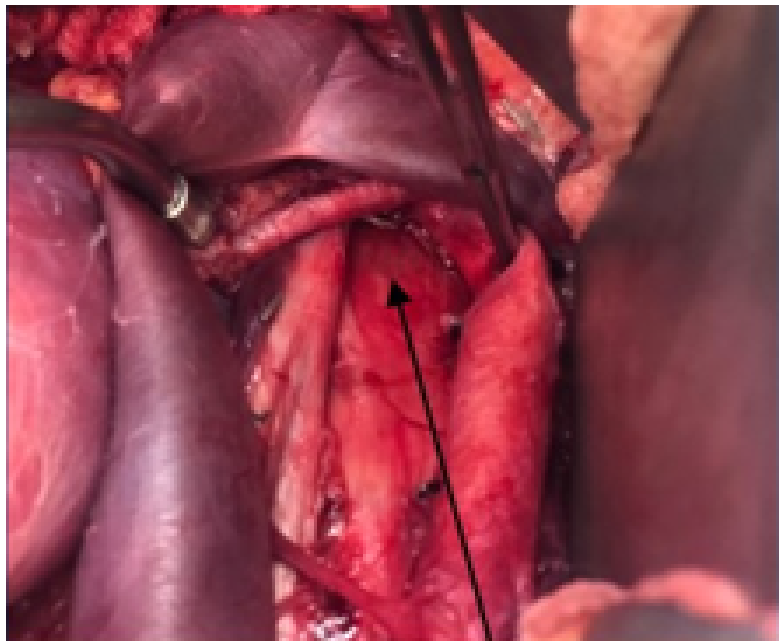
- **33 month follow up**
- **Recurrence in 12 patients (22%)**
  - **Chemotherapy: 10 pts**
  - **Repeat Resection: 2 patients**
- **Time to recurrence: 10.2 months**
- **100% overall survival**

Trial		N	F/U	Relapse	DOD
SEMS[1]	US	55	24	22%	0%
PRIMETEST	Ger	30	21	31%	0%
COTRIMS[1]	Ger	21	21	9.8%	0%
				15.4%[2]	

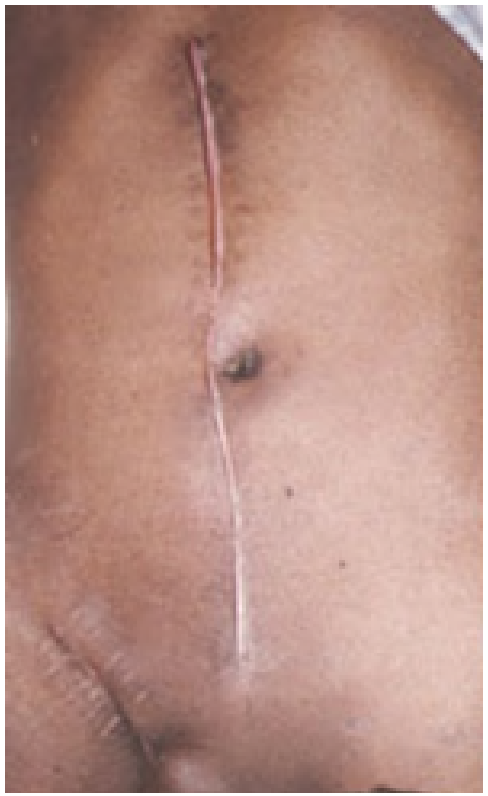
Surgery for Early Stage Metastatic Seminoma

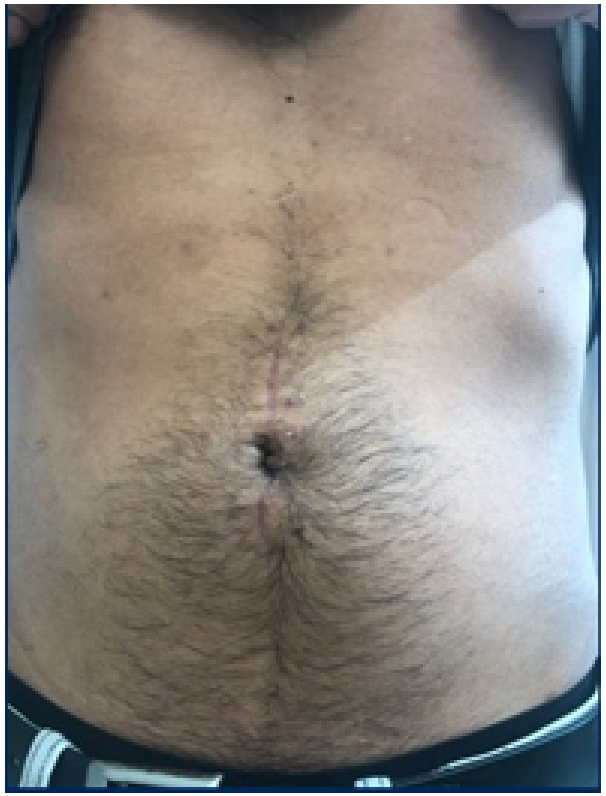
	Short term (Clavien Dindo grade)
1	Incision ulceration (I)
2	Ileus (II)
3*	Ileus (II)
4*	Pulmonary embolism (II)
5	Chylous ascites (III)
	Long term (>30 days)
1	Incision hernia- radiographic
2	Anejaculation- bilateral dissection, non-nerve sparing
3	Anejaculation - bilateral dissection, non-nerve sparing
4	Anejaculation - left modified template, non-nerve sparing

*same patient



Contemporary RPLND





Historical RPLND	Modern RPLND
Week or more hospital stay	1-2 day admission
Long surgical procedure times	2-3 hour surgery
NG tubes	Complication rates low single digits
Higher morbidity	Most all normal ejaculation

Stage II seminoma considerations

- **Surgery may allow for safe avoidance of chemotherapy/radiation therapy**
- **Very low long-term toxicity**
- **Further optimization**
  - **Stage I with relapse vs Stage II at presentation**
  - **Bilateral templates**
  - **Short-interval imaging to optimize patient selection**

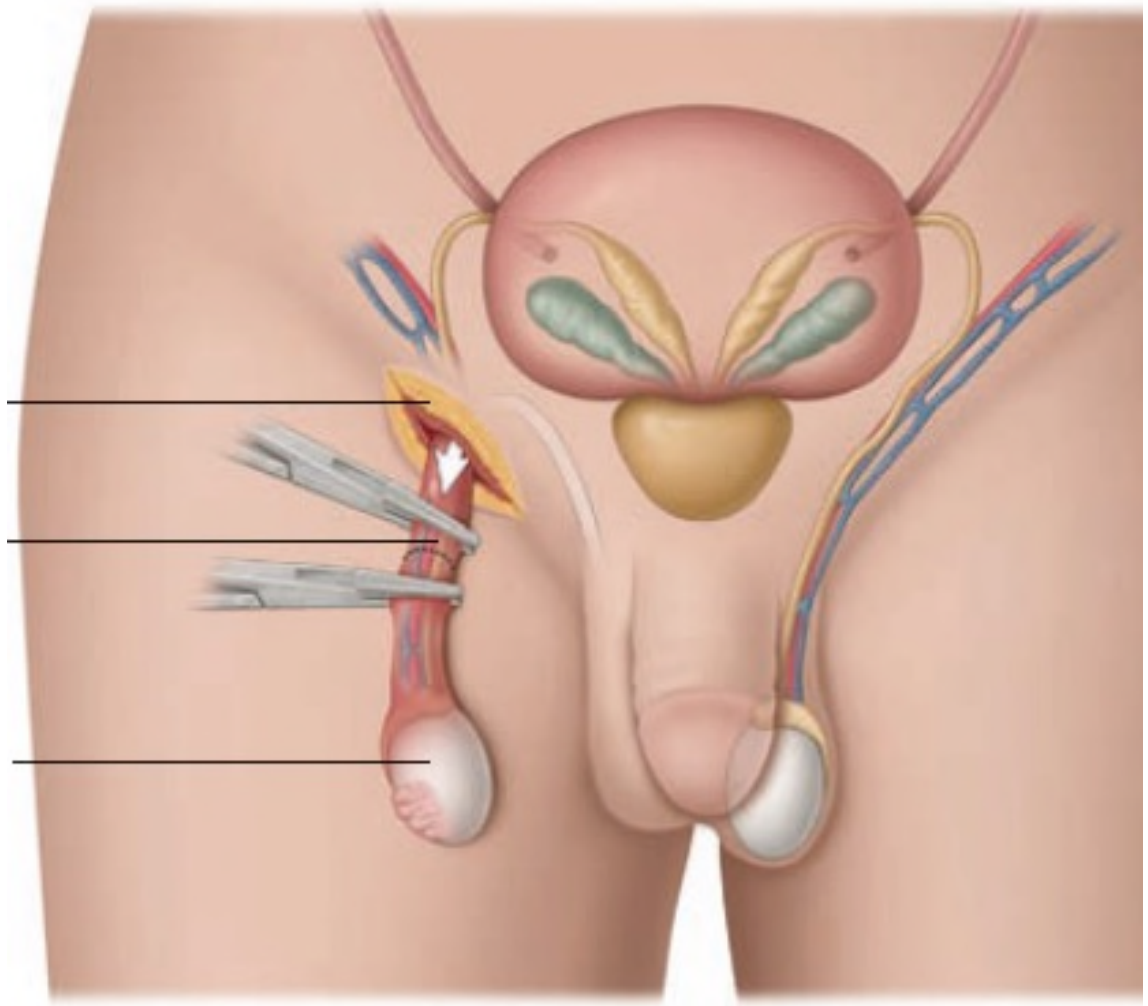
AUA guidelines 2023

- Seminoma stage IIA/IIB with LN ≤ 3cm; recommend RT or cisplatin-based combination chemotherapy based on shared decisionmaking
  - For patients who wish to avoid long term toxicity, RPLND may be offered

- Seminoma stage IIB with LN>3cm, recommend cisplatin-based combination chemotherapy

Stage 1 NSGCT

NSGCT: 30% risk of relapse



Current Predictors

- Current risk stratification is rudimentary at best
  - NSGCT:
    - + LVI and high embryonal carcinoma → 50% occult metastases
- Serum tumor markers only expressed
  - 60% of NSGCT

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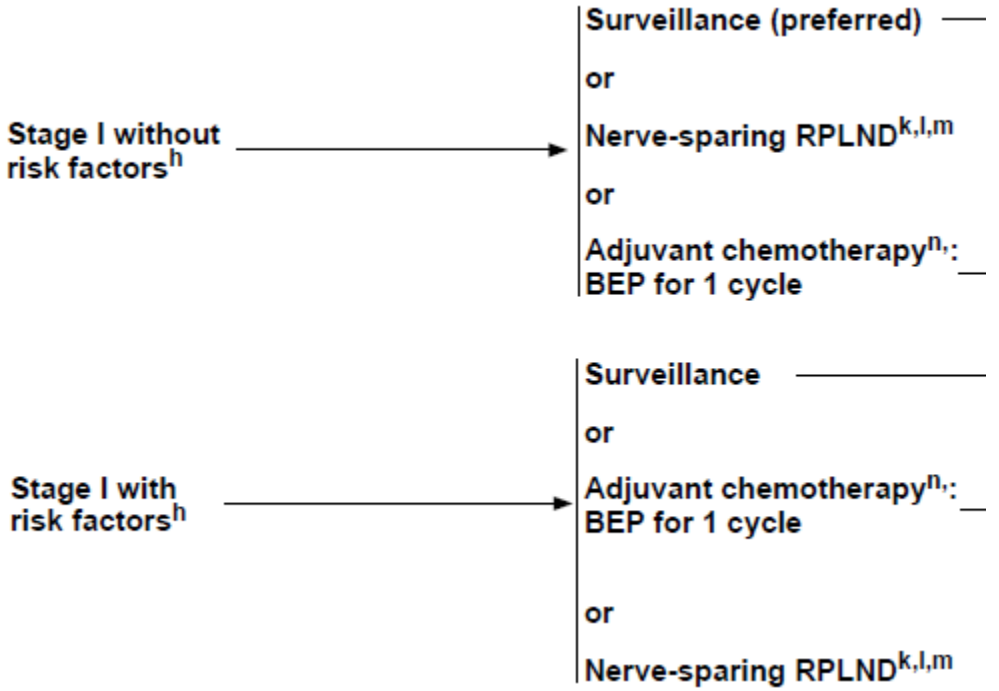

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Surveillance vs Treatment

Surveillance

- Pro: Noninvasive
- Con: 15-45% relapse1

Single Cycle Adjuvant BEP

- Pro: Less toxic, <5% relapse
- Con: High overtreatment

RPLND

- Pro: Diagnostic and therapeutic
- Con: Invasive surgery

American Urological Association

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1. Nayan M. Eur Urol. 2017
2. Tandstad T. J Clin Oncol. 2009

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Surveillance vs Treatment

Stage IA

Observation is the standard

Caveat: If malignant transformation

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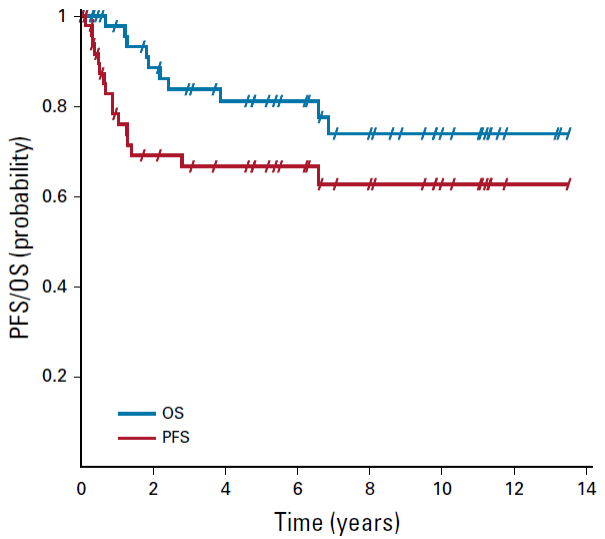
32. Clinicians should recommend RPLND or chemotherapy for patients with stage IIA NSGCT with normal post-orchiectomy serum (S0) AFP and hCG. (Moderate Recommendation; Evidence Level: Grade B)

Stage IB

Balanced discussion of Surveillance, RPLND, BEPx1

Favor surveillance

Outcome of Men With Relapses After Adjuvant Bleomycin, Etoposide, and Cisplatin for Clinical Stage I Nonseminoma



1. Nayan M. Eur Urol. 2017
2. Tandstad T. J Clin Oncol. 2009
3. Fischer S. JCO 2019

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Stage II NSGCT: What do national guidelines say?

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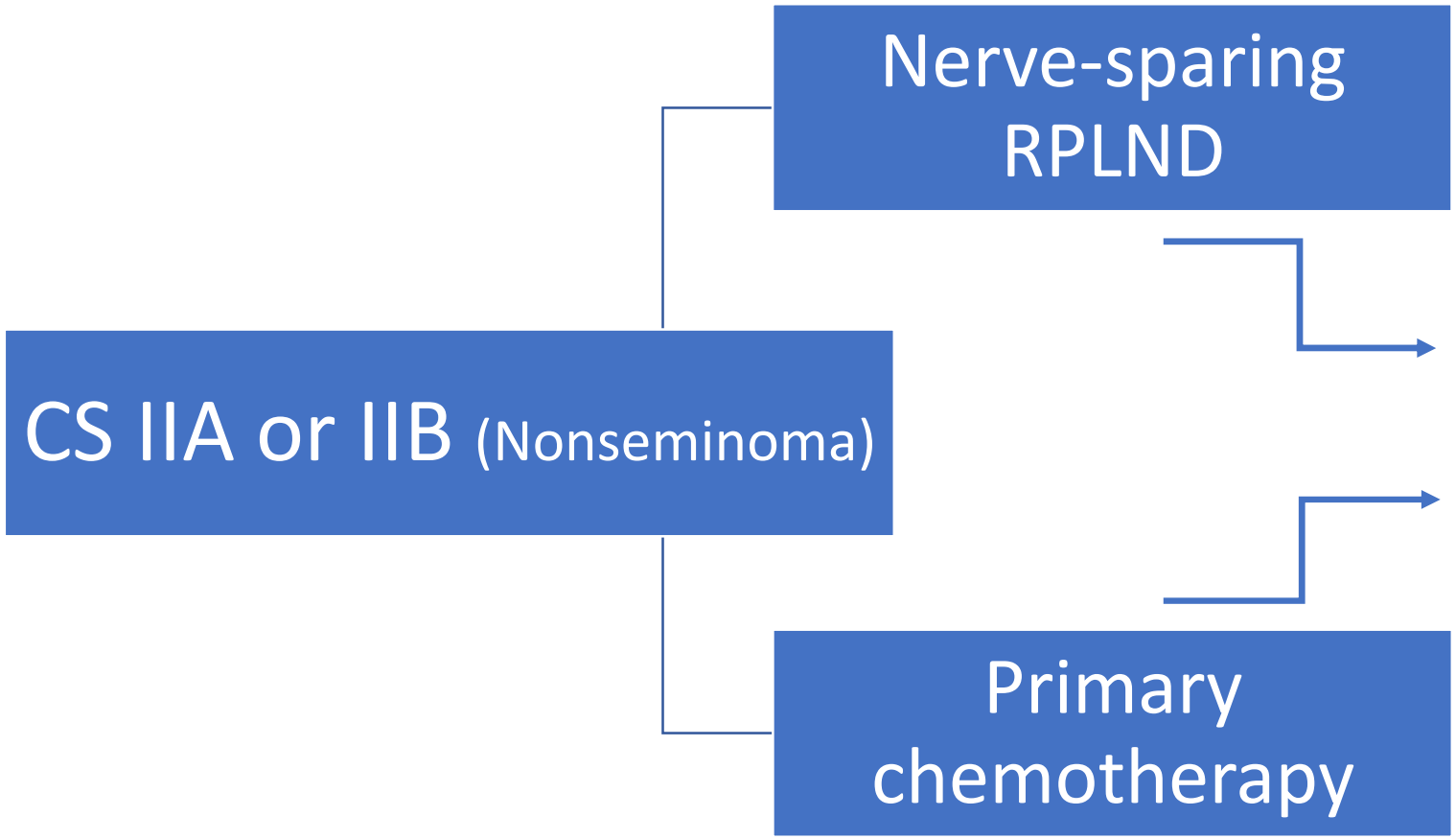


Favor RPLND

- For marker negative IIA
- For selected marker negative IIB

Stage II Nonseminoma

American Urological Association

Guideline Statement 32

Clinicians should recommend RPLND or chemotherapy for patients with stage IIA NSGCT with normal post-orchiectomy serum (S0) AFP and hCG. (Moderate Recommendation; Evidence Level: Grade B)

Guideline Statement 33

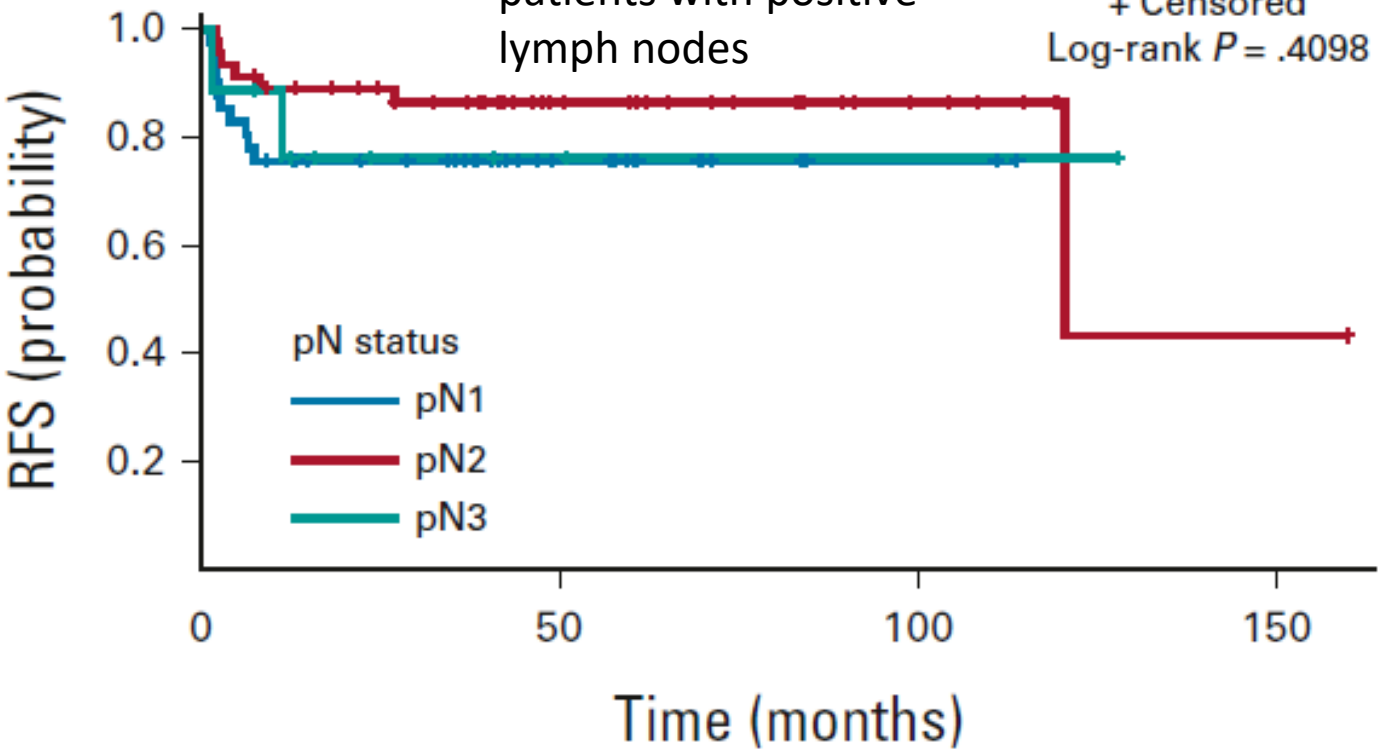
In patients with clinical stage IIB NSGCT and normal post-orchiectomy serum AFP and hCG, clinicians should recommend risk-appropriate, multi-agent chemotherapy. (Moderate Recommendation; Evidence Level: Grade B). Clinicians may offer RPLND as an alternative to chemotherapy to select patients with clinical stage IIB NSGCT with normal post-orchiectomy serum AFP and hCG. (Conditional Recommendation; Evidence Level: Grade C)

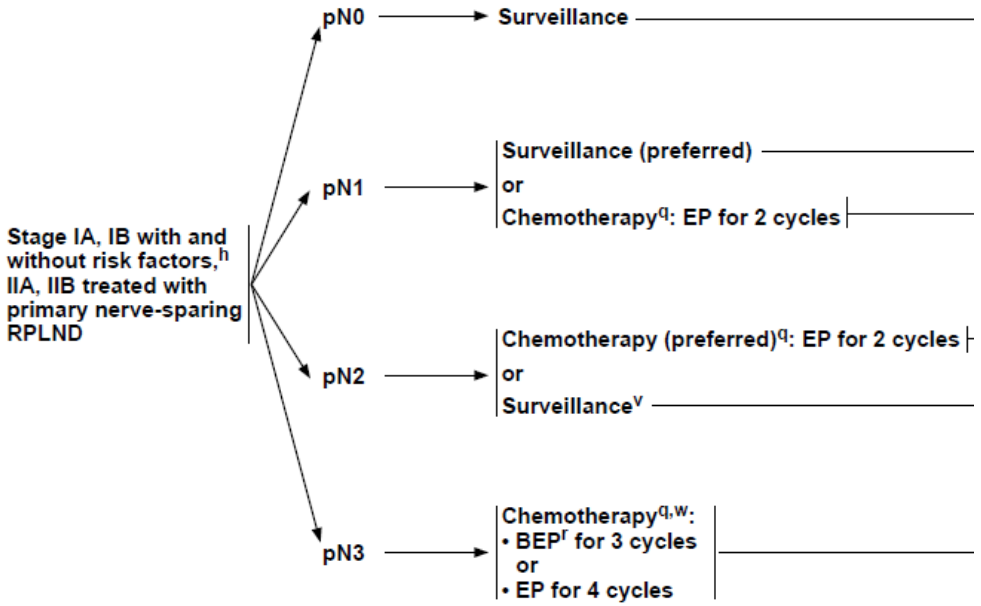
Stage II Nonseminoma

Primary Retroperitoneal Lymph Node Dissection for Patients With Pathologic Stage II Nonseminomatous Germ Cell Tumor—N1, N2, and N3 Disease: Is Adjuvant Chemotherapy Necessary?

Isamu Tachibana, MD[1]; Sean Q. Kern, MD[1]; Antoin Douglawi, MD[1]; Yan Tong, MS[2]; Mohammad Mahmoud, MD[1]; Timothy A. Masterson, MD[1]; Nabil Adra, MD[3]; Richard S. Foster, MD[1]; Lawrence H. Einhorn, MD[3]; and Clint Cary, MD, MPH[1]

~80% RFS probability for patients with positive lymph nodes





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Stage II Nonseminoma

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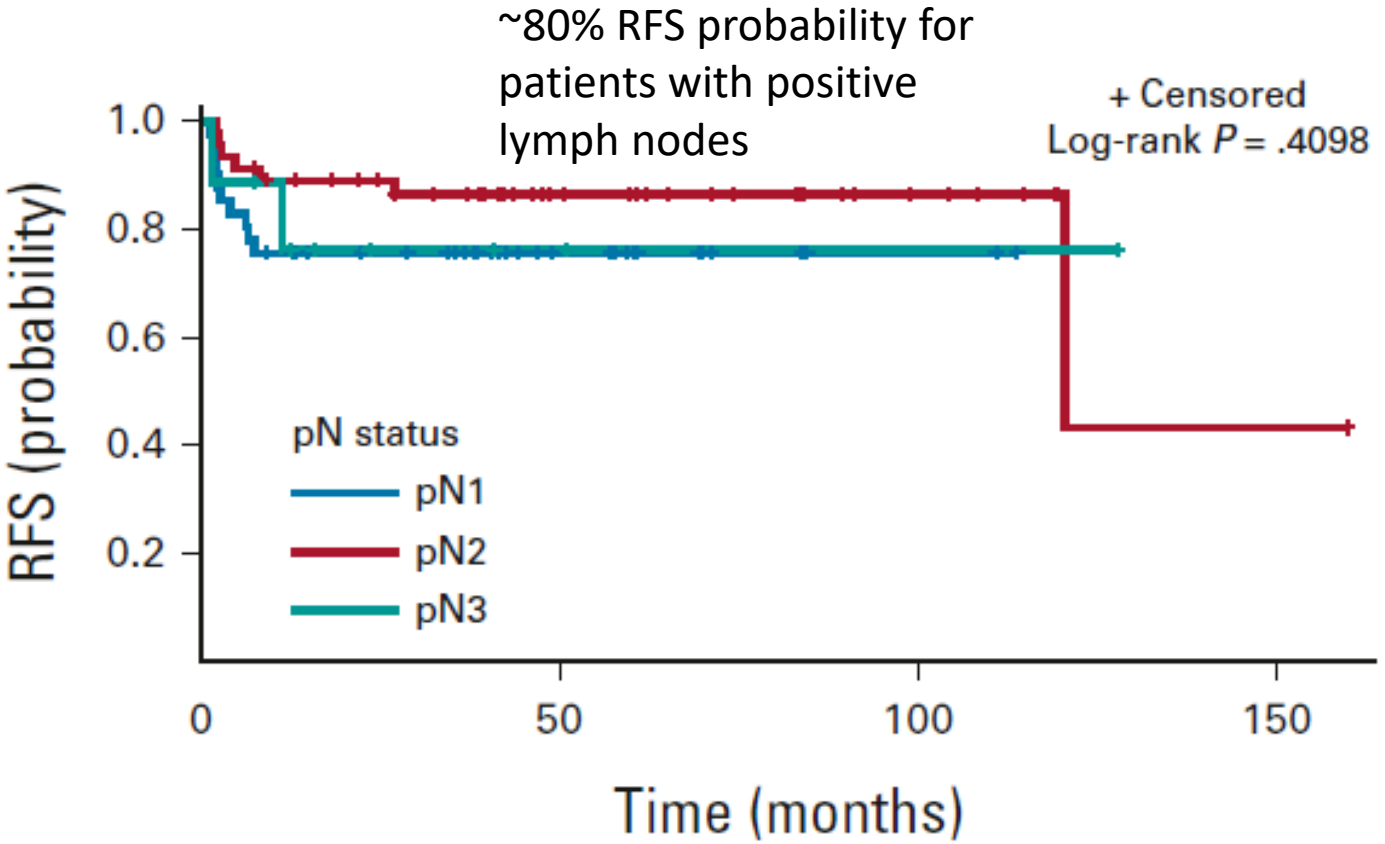
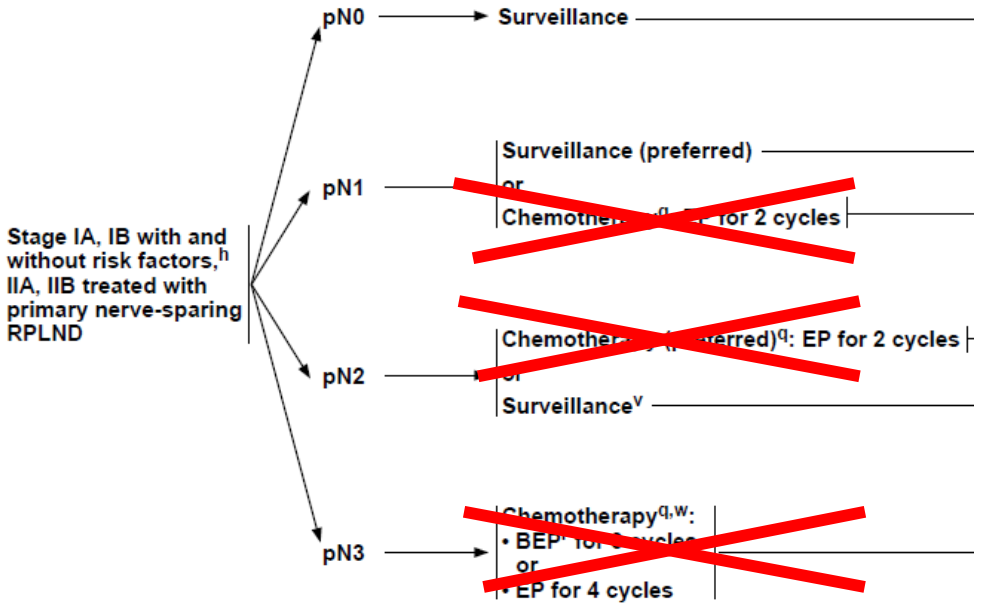
~80% RFS probability for patients with positive lymph nodes





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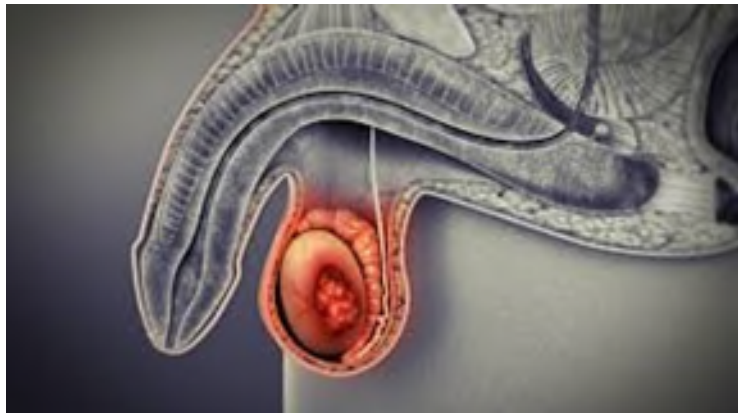
Contemporary series indicate that surgical monotherapy is curative in well-selected pN+ patients

Outstanding issues: Testicular cancer shrouded in uncertainty

- Diagnosis
- Stage I disease: Who will relapse?
- Stage II:
  - pN0?
  - Develop metastases?
- Post-chemo NSGCT/seminoma
  - Fibrosis necrosis only?



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Current GCT serum markers are underwhelming

- **Conventional tumor markers lack specificity:**
  - **AFP: HCC, liver disease, familial**
  - **hCG: bladder, renal, gastric, lung, marijuana, cross-reactivity with LH**
  - **LDH: any clinical setting with rapid cell turnover**

Table 1 | **Serum AFP and hCG levels in GCTs**[22]

GCT histological subtype	AFP	hCG
Yolk sac tumour	++	-
Seminoma	-	±
Embryonal carcinoma	±	±
Choriocarcinoma	-	++
Teratoma	±	-

AFP, α-fetoprotein; GCT, germ cell tumour; hCG, human chorionic gonadotrophin. ++, strongly positive levels; ±, levels may be negative or moderately positive; –, negative levels.

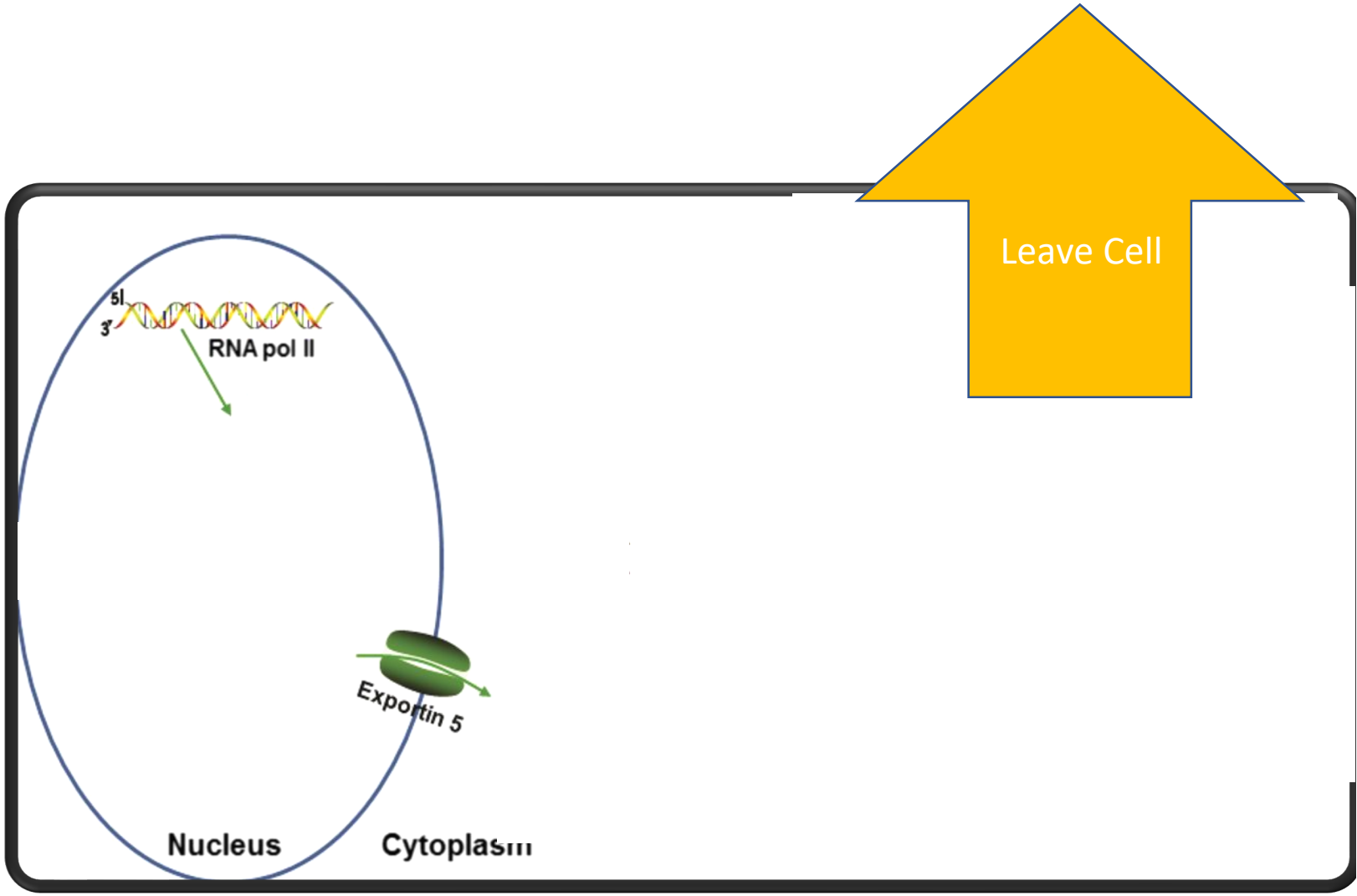
Testicular cancer shrouded in uncertainty

Sensitive and specific biomarkers may allow for precise, individualized treatment recommendations

Circulating miR-371a-3p holds the promise to be such a biomarker

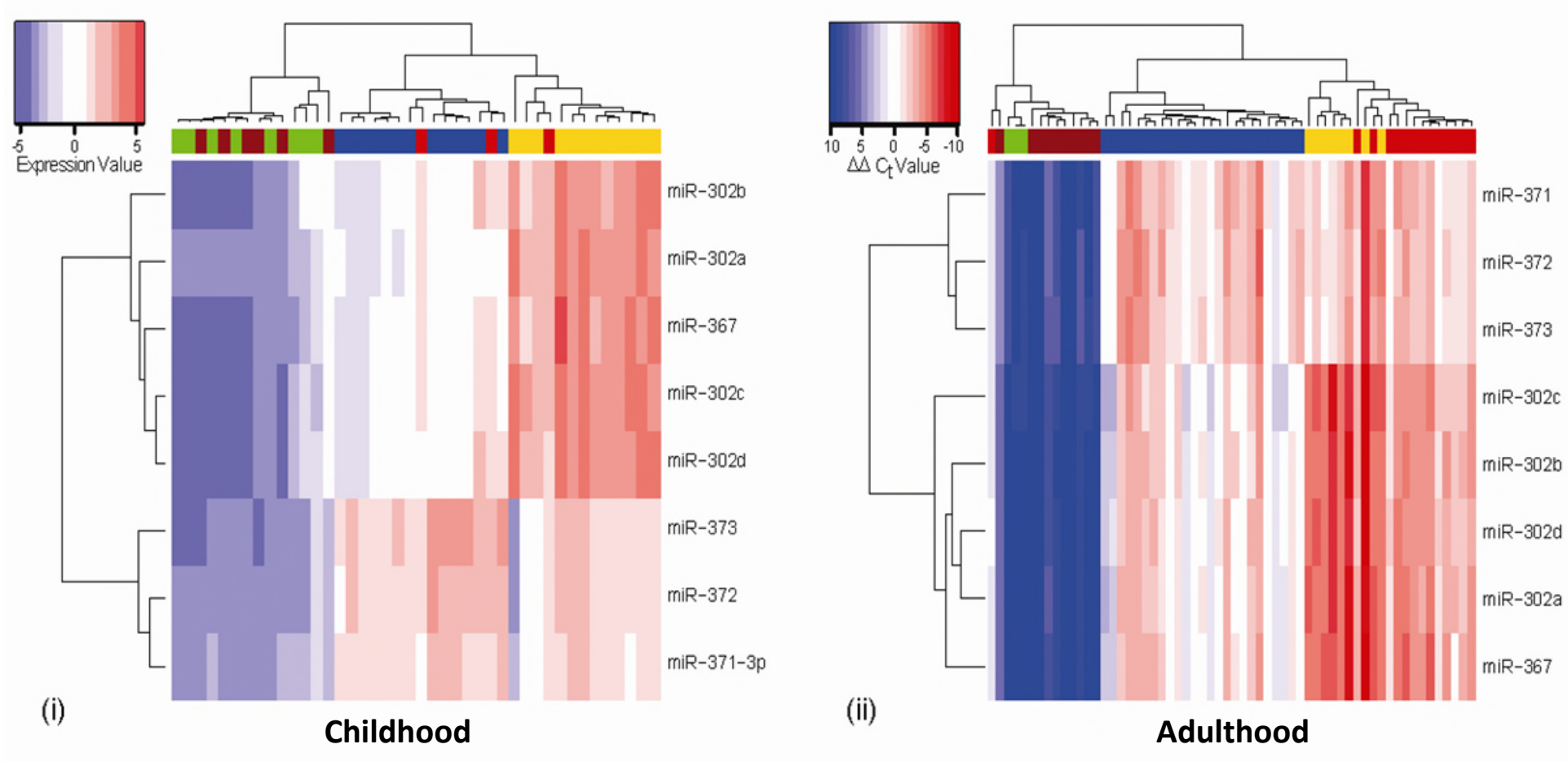
What are miRNA?

- Small non coding RNAs
- Epigenetic gene regulation
- Released from nucleus
- Intercellular communication
- Dysregulated in many malignancies



1. Mitchell PS. Proc Natl Acad Sci U S A. 2008
2. Li Z Nutr Metab (Lond). 2018

A panel of 8 miRNAs segregate malignant GCT



Yolk sac tumour | Germinoma | Embryonal carcinoma | Teratoma | Normal gonad

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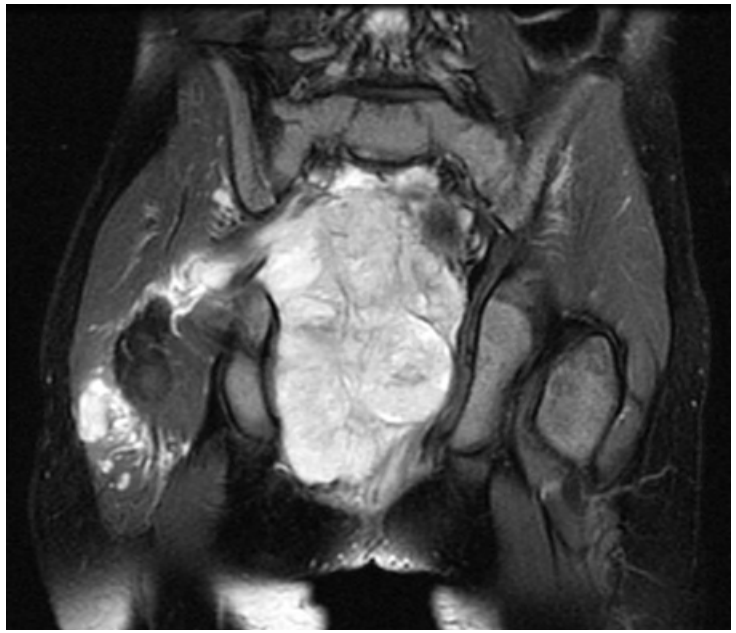
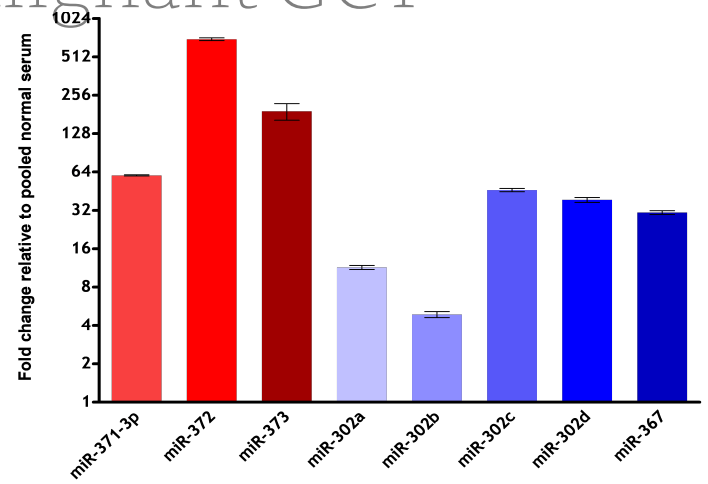
Palmer, et al. *Cancer Res*, 2010.

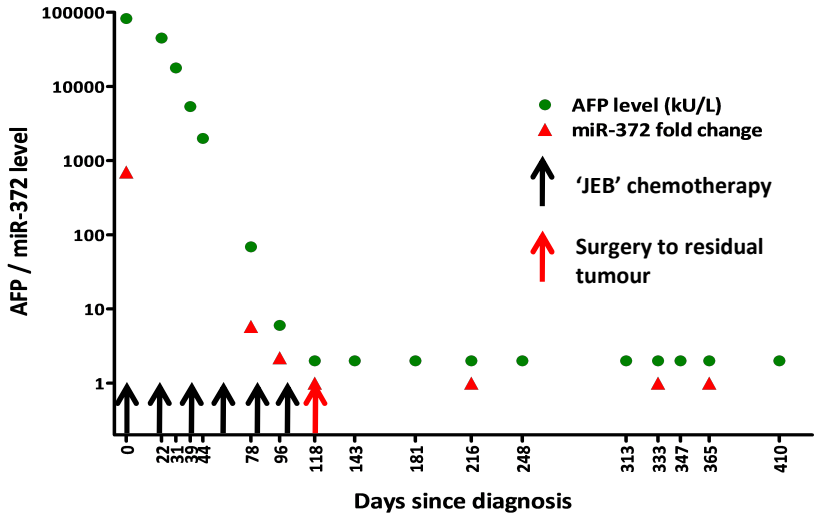
Serum miRNAs are sensitive to malignant GCT

4 year old male

History - abnormal gait & constipation
Serum AFP - 82,340 kU/L
Histology - malignant GCT (YST)







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Murray et al. *Am J Clini Pathol*, 2011

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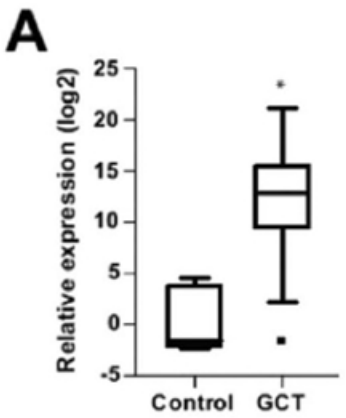
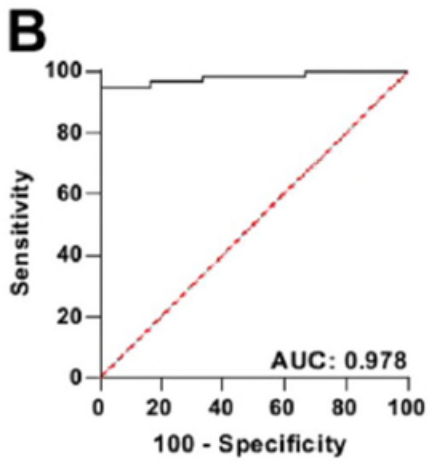
Clinical Scenario: Pre-orchiectomy

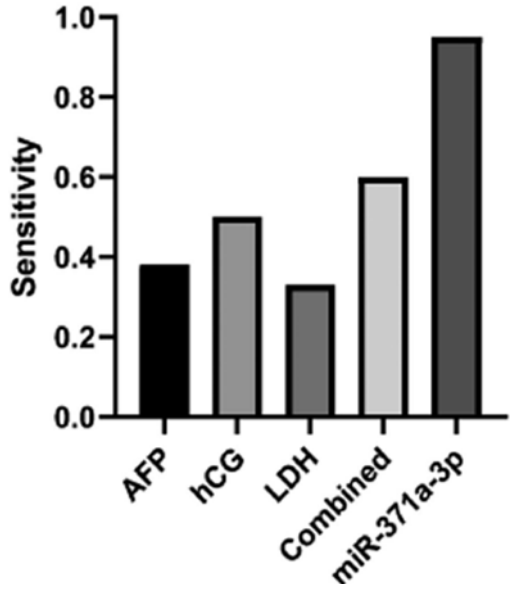
Real-World Application of Pre-Orchiectomy miR-371a-3p Test in Testicular Germ Cell Tumor Management

Table 1. *Patient characteristics at presentation*

	Viable GCT		Control		p Value
No.	58		11		
Median age (IQR)	30	(26–40)	54	(43–56)	<0.0001
% Race (No.):					
White	48	(28)	36	(4)	
Hispanic	48	(28)	36	(4)	
Black	2	(1)	-		
Asian	2	(1)	28	(3)	
% Histology (No.):					
Seminoma	50	(29)	-		
NSGCT	50	(29)	-		
Pure teratoma	-		9	(1)	
Benign	-		55	(6)	
Leydig cell tumor	-		18	(2)	
Secondary metastasis	-		18	(2)	
% Composite stage (No.):					
I	78	(45)	9	(1)	
II	10	(6)	9	(1)	
III	12	(7)	27	(3)	
N/A	-		55	(6)	







	AUC	Threshold	Sensitivity	Specificity	NPV	PPV	Accuracy
miR-371a-3p	0.978	23.5	0.931	1	0.733	1	0.942
Conventional serum tumor markers	0.79	NL*	0.579	1	0.314	1	0.647

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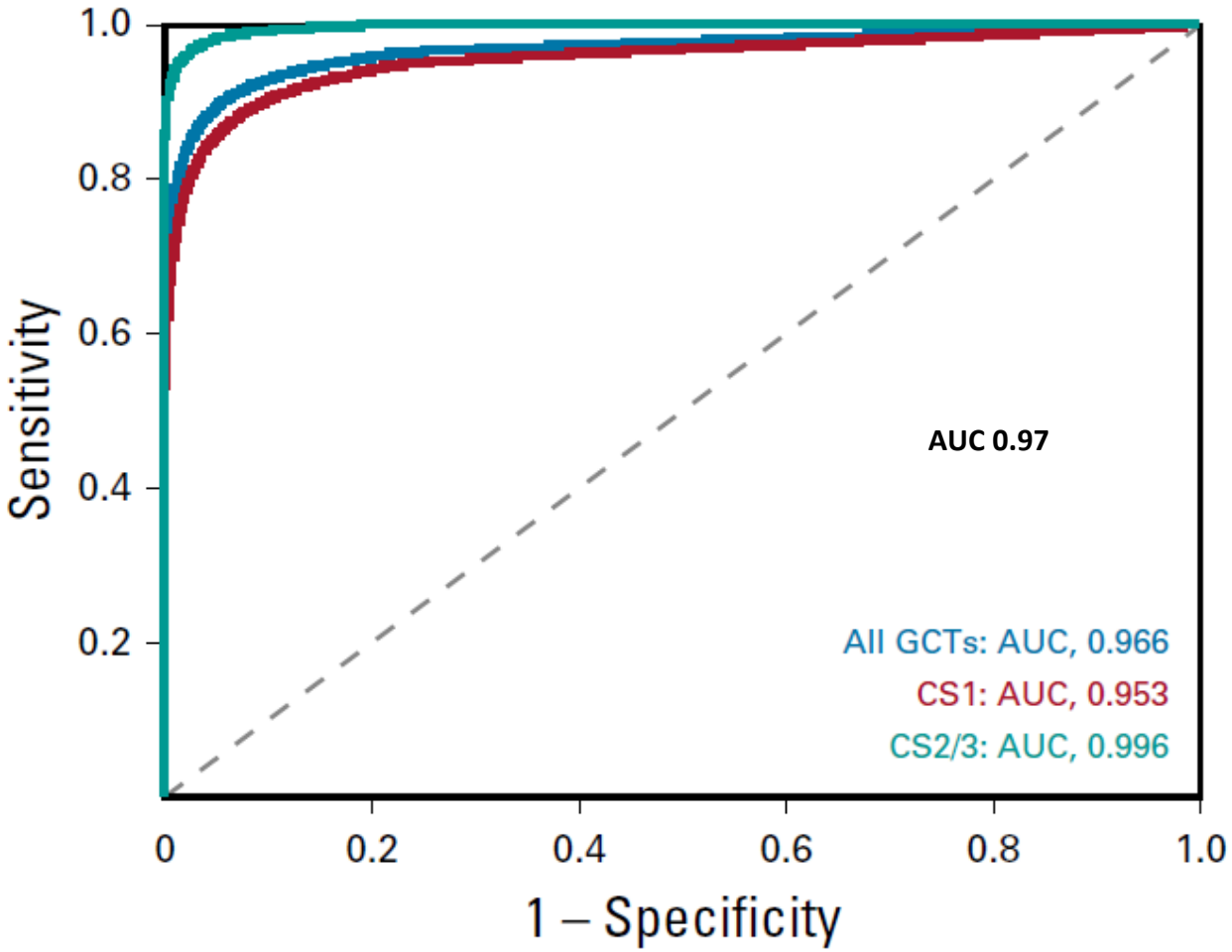
Badia, Lafin, Bagrodia et al 2021

THE JOURNAL of UROLOGY®

Serum miR-371a-3p at diagnosis in malignant GCTs

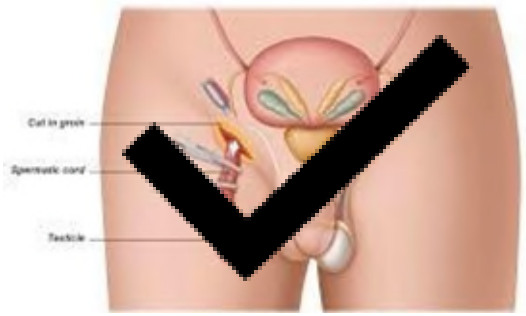


n=874; 616 malignant GCT *vs.* 258 controls

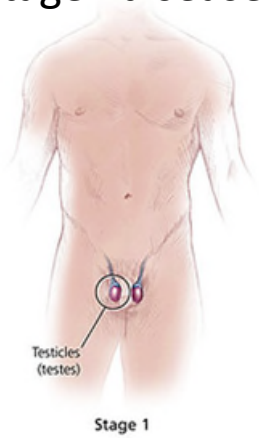
Conclusion

- miRNA 371 has excellent diagnostic accuracy in the pre-orchiectomy setting
- miRNA 371 performs better than conventional STMs to predict pathology

Pre-orchiectomy

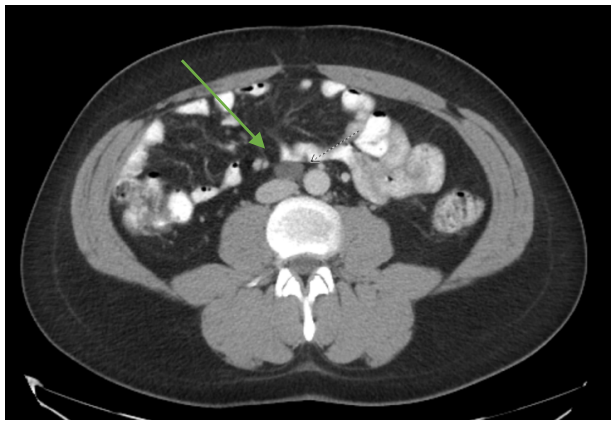


Stage I disease

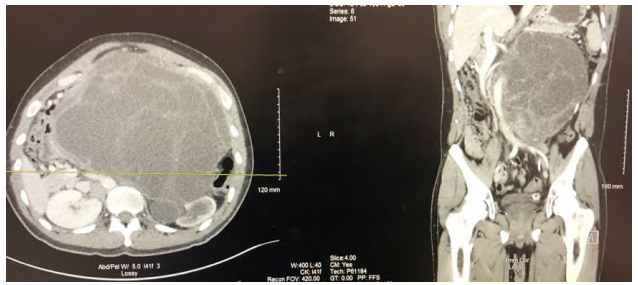


Stage 1

Stage II disease



Post-chemotherapy



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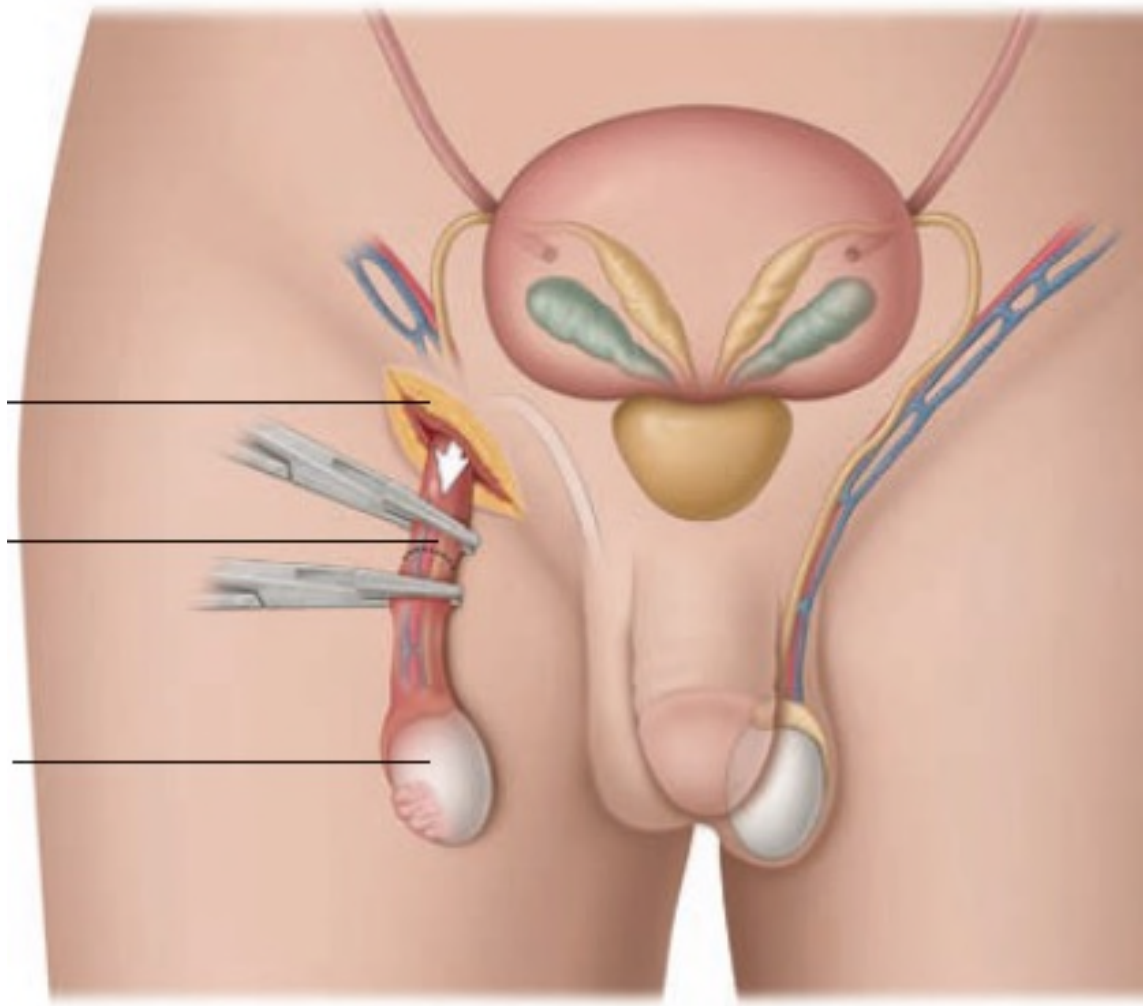
Stage 1 NSGCT

NSGCT: 30% risk of relapse



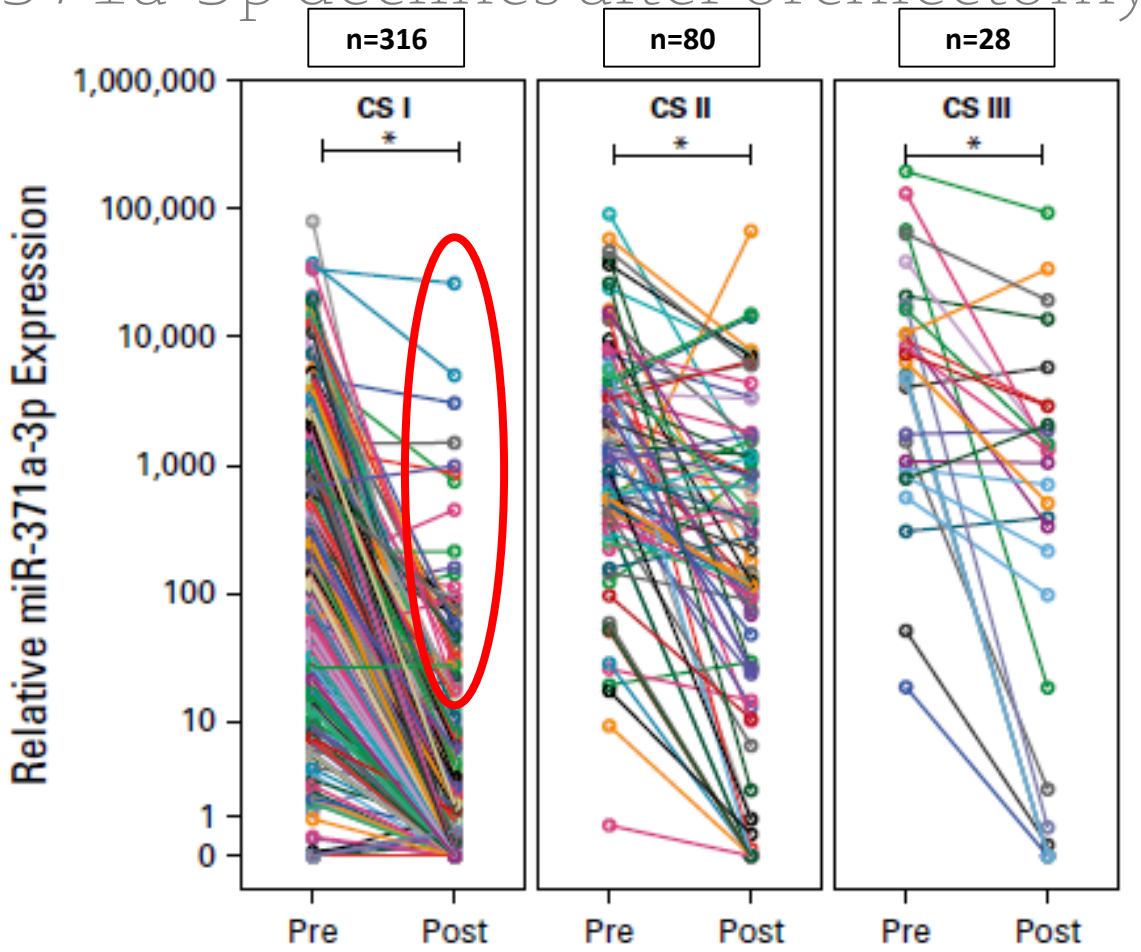
Case

- **HPI: 24 year old with right T2N0M0S0 NSGCT 50% EC, 45% Teratoma, 5% YST**
- **Elects for RPLND: 1/33 nodes positive 0.5 cm focus of EC**

Pre-RPLND miRNA-371a-3p
POSITIVE

Serum miR-371a-3p declines after orchiectomy in stage 1 disease

n=874; 616 malignant GCT *vs.* 258 controls



Dieckmann *et al*, *Journal Clinical Oncology*, 2019

Serum MicroRNA-371a-3p Levels Predict Viable Germ Cell Tumor in Chemotherapy-naïve Patients Undergoing Retroperitoneal Lymph Node Dissection

John T. Lafin[a,1], Nirmish Singla[a,1], Solomon L. Woldu[a], Yair Lotan[a], Cheryl M. Lewis[b], Kuntal Majmudar[b], Anna Savelyeva[a], Payal Kapur[b], Vitaly Margulis[a,c], Douglas W. Strand[a], Matthew J. Murray[d,e], James F. Amatruda[f], Aditya Bagrodia[a,*]

- Serum collection in chemotherapy-naïve patients prior to RPLND
- Bilateral full-template or extended modified template RPLND
- RPLND histology classification:
  - Benign
  - Viable GCT (seminoma or NSGCT)
  - Teratoma only

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Results: Clinicopathologic characteristics

Number of patients	**24**
Median age at RPLND (IQR), years	**27 (21-33)**
Orchiectomy histology # (%):	
-Benign	**2 (8.3)**
-Pure seminoma	**4 (16.7)**
-Pure NSGCT	**2 (8.3)**
-Mixed NSGCT	**16 (66.7)**
pT stage # (%):	
-pT0	**2 (8)**
-pT1	**13 (54)**
-pT2	**9 (38)**
Clinical N stage # (%)	
-cN0	**12 (50.0)**
-cN1	**9 (37.5)**
-cN2	**3 (12.5)**
Composite clinical stage # (%):	
-I	**12 (50.0)**
-II	**12 (50.0)**

Results: Clinicopathologic characteristics

RPLND histology # (%):	
-Benign	**10 (41.7)**
-Viable GCT (seminoma or NSGCT)	**11 (45.8)**
-Teratoma only	**3 (12.5)**
pN stage # (%):	
-pN0	**10 (41.7)**
-pN1	**6 (25.0)**
-pN2	**7 (29.2)**
-pN3	**1 (4.2)**

Performance characteristics of serum miRNAs in detecting viable GCT

miRNA	Sensitivity	Specificity	PPV	NPV	Accuracy
miR-371a	100%	92%	92%	100%	96%
miR-367	73%	85%	80%	79%	79%
miR-372	100%	31%	55%	100%	63%
miR-373	55%	92%	86%	71%	75%
miR-375	0%	95%	0%	75%	69%

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miRNAs in low stage disease

- Dieckmann et al:
  - Decrease in circulating miR-371a-3p following orchiectomy
  - Presence of miR-371a-3p after orchiectomy associated with 83% sensitivity and 96% specificity for identifying relapses
- Nappi et al:
  - 25 patients with stage 1 GCT
  - miR-371a-3p correctly identified all patients that ultimately recurred (1/25) and those that did not (24/25)

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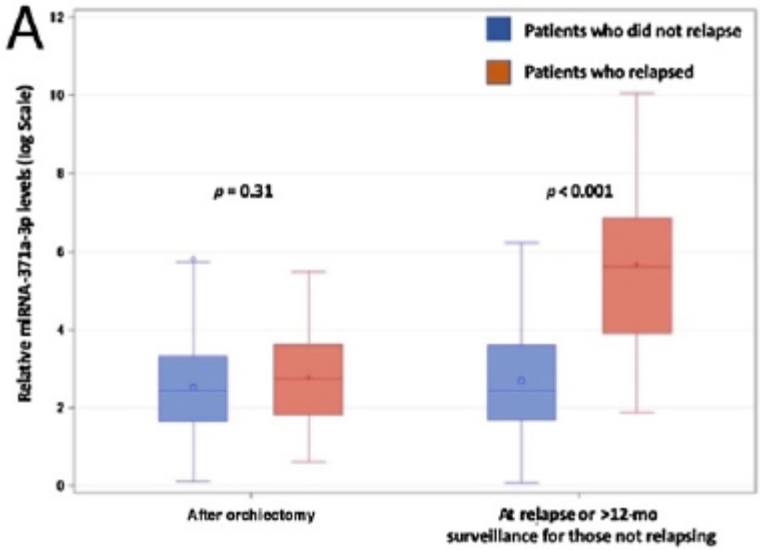
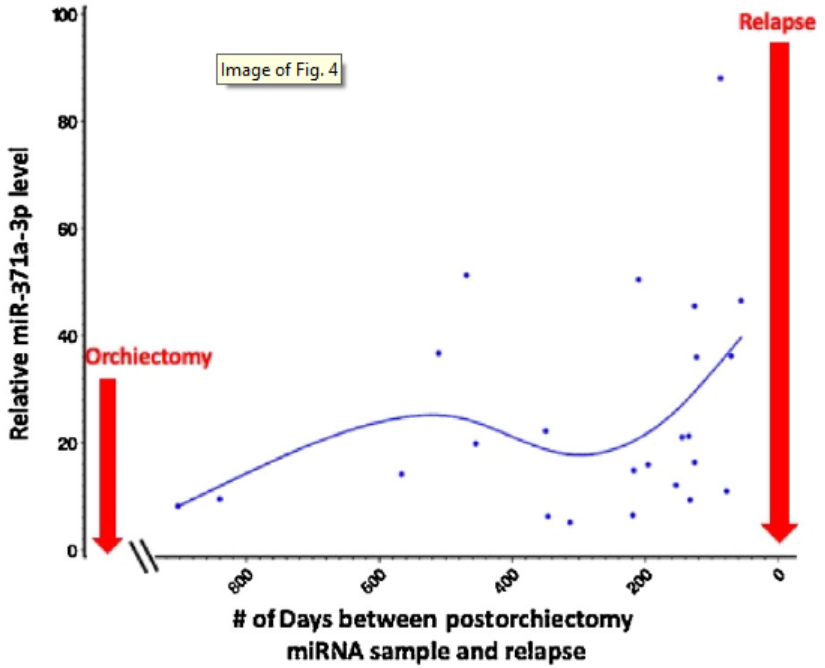
Utility of Serum miR-371a-3p in Predicting Relapse on Surveillance in Patients with Clinical Stage I Testicular Germ Cell Cancer

João Lobo [a,b,c,d], Ricardo Leão [e,f,g,h], Ad J.M. Gillis [a], Annette van den Berg [a], Lynn Anson-Cartwright [g,h], Eshetu G. Atenafu [i], Kopika Kuhathaas [g,h], Peter Chung [j], Aaron Hansen [k], Philippe L. Bedard [k], Michael A.S. Jewett [g,h], Padraig Warde [j], Martin O'Malley [l], Joan Sweet [m], Leendert H.J. Looijenga [a,†,], Robert J. Hamilton [g,h,†,*]*

- 151 stage 1 patients
- 23% relapse rate
- NO ASSOCIATION BETWEEN POST-ORCHIECTOMY MIR-371 AND RELAPSE
- MIR-371 ELEVATED IN 94% OF RELAPSES





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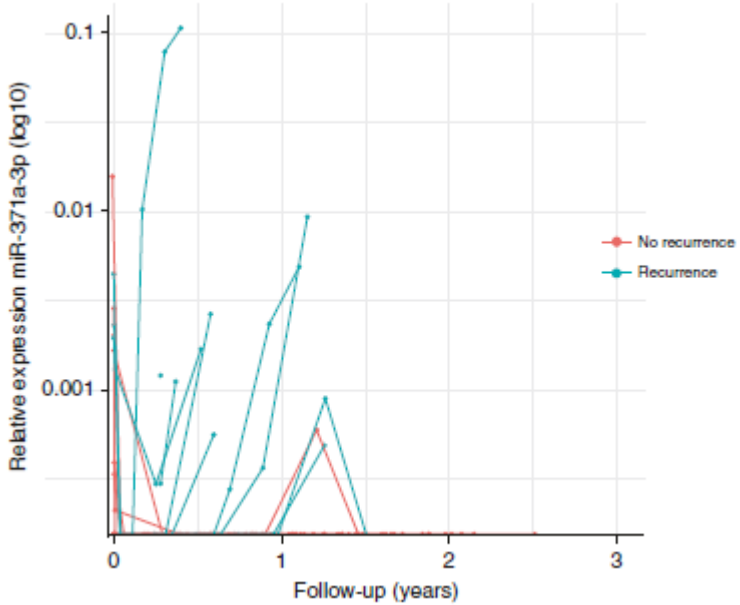
Detection of recurrences using serum miR-371a-3p during active surveillance in men with stage I testicular germ cell tumours

Christian D. Fankhauser[1,13✉], Ailsa J. Christiansen[1,2,13], Christian Rothermundt[3], Richard Cathomas[4], Marian S. Wettstein[1], Nico C. Grossmann[1], Josias B. Grogg[1], Arnoud J. Templeton[5], Anita Hirschi-Blickenstorfer[6], Anja Lorch[7], Silke Gillessen[3,8,9,10], Holger Moch[2], Joerg Beyer[11] and Thomas Hermanns[1]

- **33 stage 1 patients**
- **Serum serially collected during surveillance**
- **10/33 (30%) relapse rate**
- **Early post-orchiectomy miRNA not indicative of relapse**
- **miRNA levels elevated ~2 months before clinical detection**



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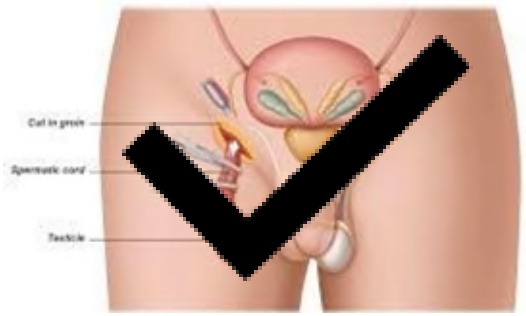
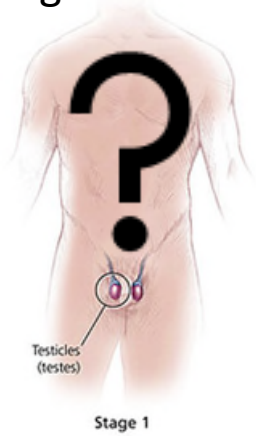
Conclusion

- miRNA 371 is promising in post-orchiectomy setting
- Early post-orch miR-371 may not predict relapse
  - Likely a sensitivity issue

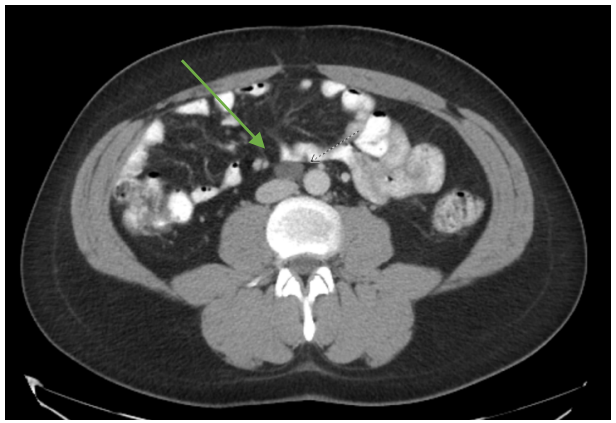
Pre-orchiectomy



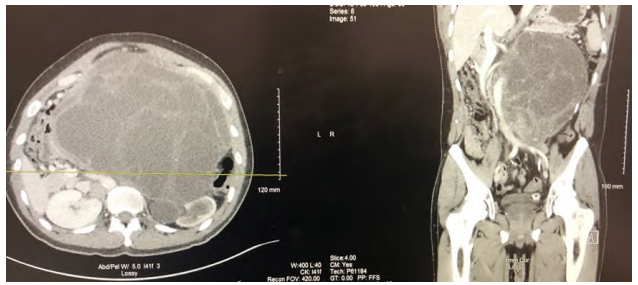
Stage I disease



Stage II disease



Post-chemotherapy



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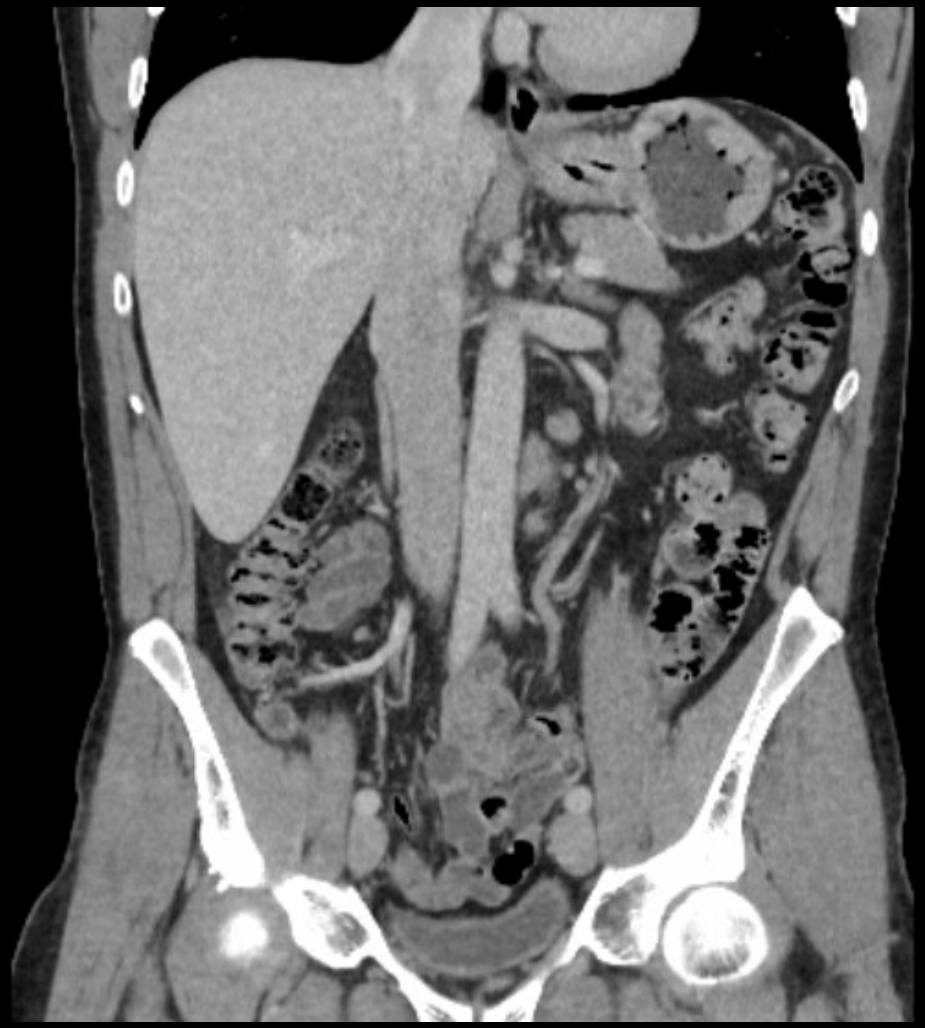
Case

- 44 year old with right testicular mass: 45% sem, 30% YST, 20% EC, 5% teratoma
- Repeat imaging in 8 weeks
  - No change



Case

- **Scheduled for RPLND in 8 weeks with repeat imaging 1 week prior**
- **Bilateral Full template RPLND**
  - **0.5 cm focus of seminoma in 1/18 paraaortic LNs**
  - **3 mm focus of seminoma in 1/14 interaortocaval LNs**

Pre-RPLND miRNA-371a-3p
POSITIVE

miR in Stage II Disease

- Prospective serum collection from 32 consecutive chemotherapy-naïve patients immediately prior to RPLND
- Bilateral full-template or extended modified template RPLND performed
- RPLND histology classification:
  - Benign
  - Viable GCT (seminoma or NSGCT)
  - Teratoma only

Patient characteristics (n=32)

Age	Years	Median (IQR)	28 (23.5-35.0)
pT Stage	pT0	N (%)	2 (6.3)
	pT1		14 (43.8)
	pT2		16 (50.0)
cN Stage	cN0	N (%)	12 (37.5)
	cN1		15 (46.9)
	cN2		4 (12.5)
	cN3		1 (3.1)
Clinical Stage (CS)	CS I	N (%)	12 (37.5)
	CS II		20 (62.5)
RPLND Histopathology	Benign	N (%)	9 (28.1)
	Seminoma		12 (37.5)
	Non-Seminoma		11 (34.4)
pN Stage	pN0	N (%)	9 (28.1)
	pN1		11 (34.4)
	pN2		11 (34.4)
	pN3		1 (3.1)
Pathologic Stage (PS)	PS I	N (%)	9 (28.1)
	PS II		23 (71.9)

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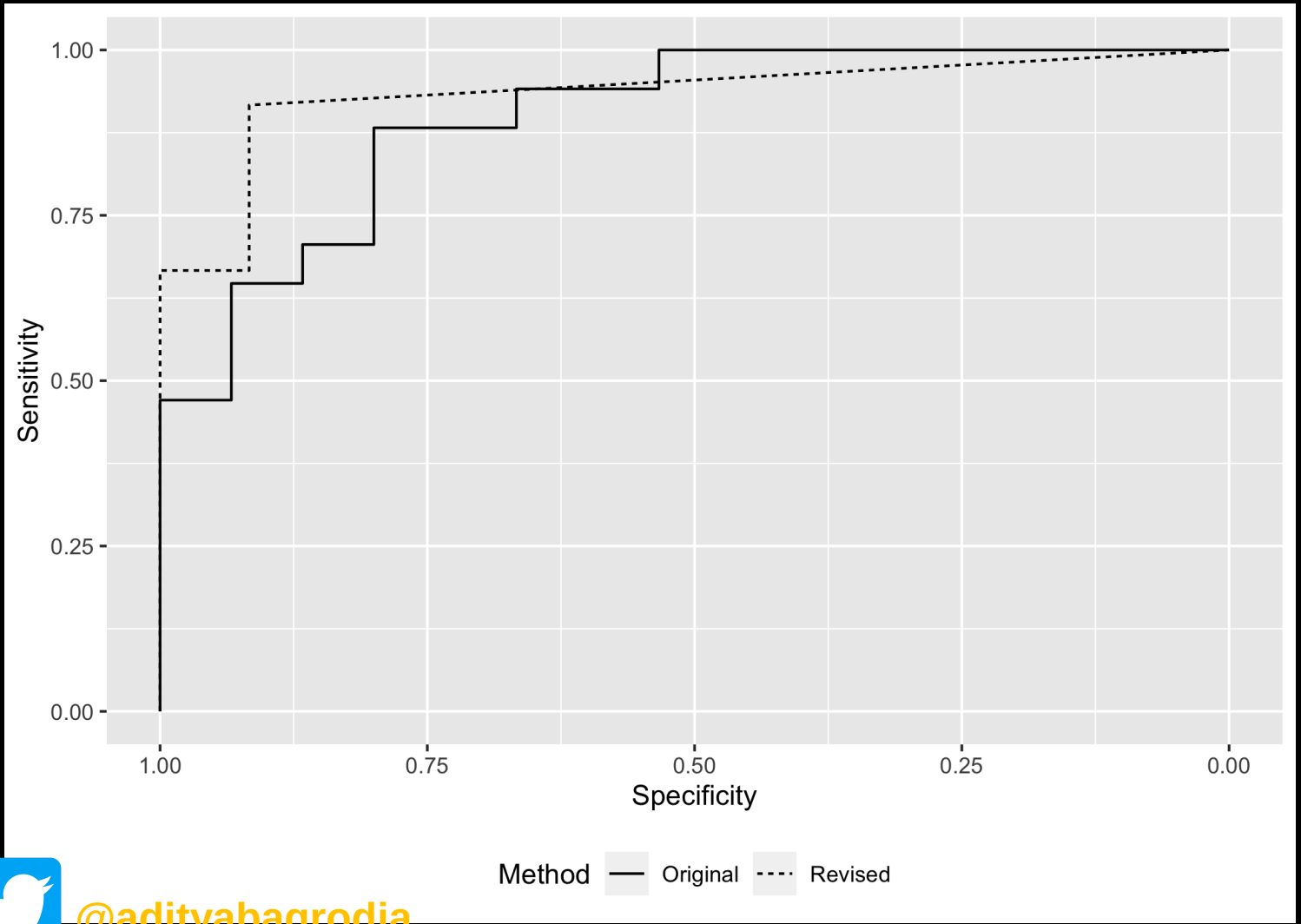
Performance of serum miR-371a-3p test in patients with stage II disease.



	value
Threshold	35
Sensitivity	0.92
Specificity	0.92
AUC	0.934 (0.835-1)
PPV	0.92
NPV	0.92
Accuracy	0.92

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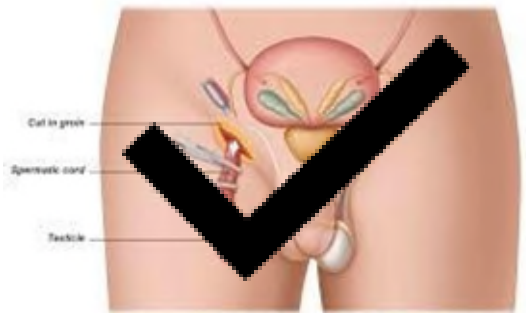
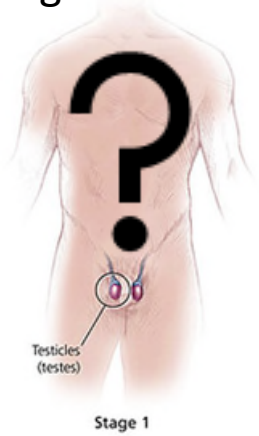
Conclusion

- miRNA 371 is promising for stage II disease

Pre-orchiectomy

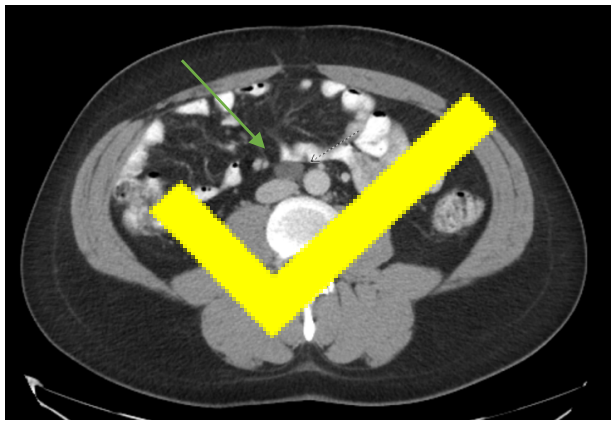


Stage I disease

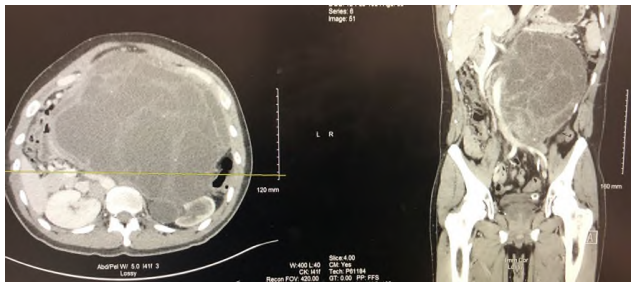


Stage 1

Stage II disease



Post-chemotherapy



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Conclusions

Early-stage testicular cancer management must maintain oncologic outcomes and prevent long term toxicity

Surgery for early-stage disease is curative in most patients at high volume centers

microRNAs poised to change the way we diagnose and manage patients

Thank you!

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