Current and Future COG Testiclar Germ Cell Tumor Protocols

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Informed Consent and enrolling patients in COG protocols

Open COG Testicuar GCT Studies

- AGCT1531
 - ◆ Low and standard risk patients

- AGCT1532
 - Intermediate and poor risk patients

- A031102
 - Relapsed and refractory patients

 Large study encompassing low and standard risk malignant GCT's at multiple sites

Surveillance for low risk

◆ PEb/BEP versus Ceb/BEC for standard risk

Surveillance for low risk patients

- All COG Stage 1 malignant GCT's
 - Any age
 - ◆ Recurrences can be enrolled in Standard Risk Arm
 - Study miRNA's as markers for relapse

 Compare cisplatin versus carboplatin (with etoposide and bleomycin) for standard risk patients

◆Pre-pubertal (< 11 years) Stage II-IV</p>

◆Post-pubertal (11-24 years) Stage II or Stage III-IV with IGCCC good risk

IGCCC Good Risk

No non-pulmonary visceral metastases

- S0 or S1 tumor markers
 - ◆AFP < 1000 ng/ml
 - ♦ HCG < 5000 IU/ml</p>
 - ◆LDH < 3 x ULN</p>

 Compare cisplatin versus carboplatin (with etoposide and bleomycin) for standard risk patients

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◆Post-pubertal (11-24 years) Stage II or Stage III-IV with IGCCC good risk

COG Surgical Guidelines - Orchiectomy

- Try to get CT pre-operatively
- Inguinal incision with vascular control
- Can extend incision onto scrotum
- <u>Excisional</u> biopsy is recommended if benign histology suspected
- Scrotal orchiectomy is OK(ish)
- Prior trans-scrotal biopsy Stage II

COG Surgical Guidelines – Retroperitoneum before chemo

- Lymph nodes ≥ 2 cm presumed (+)
- Lymph nodes < 1 cm presumed (-)</p>
- Lymph nodes 1-2 cm
 - ◆ Repeat imaging and if still ≥ 1 cm
 - Biopsy OR consider positive

COG Surgical Guidelines – Retroperitoneum after chemo

- Mass > 1 cm with normal markers
 - Surgery

- Mass with elevated but NOT rising markers and complete resection possible
 - ◆Surgery

COG Surgical Guidelines – Retroperitoneum after chemo

What RP surgery?

- < 11 years of age</p>
 - ◆ Resection of mass only

- ≥ 11 years of age
 - ◆ RPLND

RP in Prepubertal Malignant GCT

Positive nodes were always YST

 Residual mass after chemotherapy with normal AFP – necrosis (2 cases)

COG Surgical Guidelines – Retroperitoneum after chemo

What RP surgery?

- < 11 years of age</p>
 - Resection of mass only

- ≥ 11 years of age
 - ◆ RPLND

 Accelerated BEP versus standard BEP as first line for intermediate and poor risk GCT

AGCT1532 Target Population

- 11 45 years of age
- Metastatic testis GCT with any of:
 - ◆AFP > 1000 ng/ml
 - ♦ HCG > 5000 IU/L
 - ◆LDH > 3.0 x ULN
 - Non-pulmonary visceral metastases

A031102 - Primary Objective

 Overall survival for patients with relapsed or refractory GCT

 Conventional dose TIP versus High dose TI-CE regimen with autologous stem cell transplant

A031102 - Inclusion criteria

- Male ≥ 14 years of age
- Germ Cell tumor any site
- Prior first line chemotherapy
- Persistent/recurrent disease
 - Mass with biopsy
 - Mass with persistently elevated markers
 - Rising markers

A031102 - Randomized to:

TIP

- Pacilitaxel
- Ifosfamide
- Cisplatin

TI-CE

- Pacilitaxel
- Ifosfamide
- High dose carboplatin and etoposide
- Autologous stem cell infusion

General Cancer Protocols

Establishing continuous cell lines/xenografts

Pembrolizumab for refractory/relapses

Long-term follow-up and health promotion

Future studies

 Using tumor genetics and miRNA to stratify patients

 Continue to minimize morbidity for prepubertal patients and improve survival for high risk patients

Increase AYA patient enrollment

How to become the GU cancer surgeon

Availability and affability

- Visibility
 - ◆Tumor board
 - ◆COG

Lines