Establishing an Institutional Gonadal Tissue Cryopreservation Protocol for Patients with Differences of Sex Development

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Disclosures

• All authors have nothing to disclose.
Background

• Advances in fertility preservation (FP) for oncology patients have paved the way for patients with other fertility-threatening diagnoses

• Patients with certain differences of sex development (DSD) diagnoses may have biological fertility
  - E.g, androgen insensitivity, 45X, 46XY

**Background**

- Patients with DSD desire experimental GTC
- Oncology protocols
  - Ovarian tissue: 5 patients
  - Testicular tissue: 2 patients

**Experimental GTC: Oncology vs. DSD**

<table>
<thead>
<tr>
<th></th>
<th>Oncology</th>
<th>DSD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Current Cancer?</strong></td>
<td>Yes</td>
<td>Future risk of malignancy</td>
</tr>
<tr>
<td><strong>Gonads</strong></td>
<td>Normal</td>
<td>Abnormal</td>
</tr>
<tr>
<td><strong>Time from Diagnosis to Treatment</strong></td>
<td>Days</td>
<td>Months to Years</td>
</tr>
<tr>
<td><strong>Outcome</strong></td>
<td>Reported live births</td>
<td>No reported live births</td>
</tr>
</tbody>
</table>
Describe development of IRB-approved GTC protocol for patients with DSD

→disseminate the workflow beyond our institution
IRB Approval Process

- Extensive collaboration
- Education
- Addressing main IRB concern
  - Inclusion criteria: planned gonadectomies performed for malignancy risk
- Half of gonad sent to pathology, half temporarily cryopreserved
Preoperative Counseling

- Multi-disciplinary DSD clinical team meeting: 1 Hour
- Multi-disciplinary clinic appointment: 2-3 Hours
- DSD clinical team regroup to discuss patient care plan: 10-15 Minutes
- DSD clinical team fertility discussion: 1-2 Hours

Consults:
- Psychology consult
- Fertility Preservation consult
- Medical Ethics consult

Timeframes:
- Weeks to months
Postoperative Pathology Pathway

Tumor identified

Remaining tissue recalled for further evaluation

No tumor identified

Findings documented: presence of germ cells? malignancy?
Postoperative Pathology Discussion

- Postoperative counseling
- Family completes and returns tissue disposition form
  - Tissue transferred for long-term cryopreservation
  - Tissue discarded
  - Tissue donated to research lab
  - Tissue disposition documented by FP Provider
### Patients Enrolled 2018-2019

<table>
<thead>
<tr>
<th>Patient</th>
<th>Diagnosis</th>
<th>Germ Cells</th>
<th>Neoplasia</th>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mixed Gonadal Dysgenesis</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>2</td>
<td>Ovotesticular DSD</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>3</td>
<td>Mixed Gonadal Dysgenesis</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>4</td>
<td>Turner Mosaicism</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>5</td>
<td>Swyer Syndrome</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>6</td>
<td>Complete Androgen Insensitivity</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>7</td>
<td>Partial Gonadal Dysgenesis</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>
Conclusions: GTC for DSD Protocol

• **GTC at gonadectomy is technically feasible**
  – No additional surgical morbidity
  – Adequate tissue for anatomic pathological analysis to rule out malignancy

• **Protocol — a template for other institutions**
  – Multidisciplinary team approach
  – Bisected gonad for pathological analysis
  – Documentation of tissue disposition before long-term storage

• **Future research topics**
  – Determination of patient candidacy
  – Quality of germ cells
  – Optimal timing of GTC
Thank you:

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