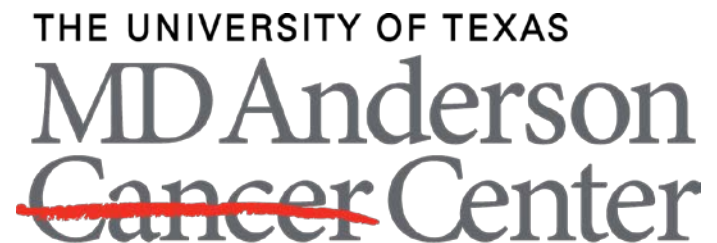


Low Risk Endometrial Cancer Surgical Protocol

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Making Cancer History®

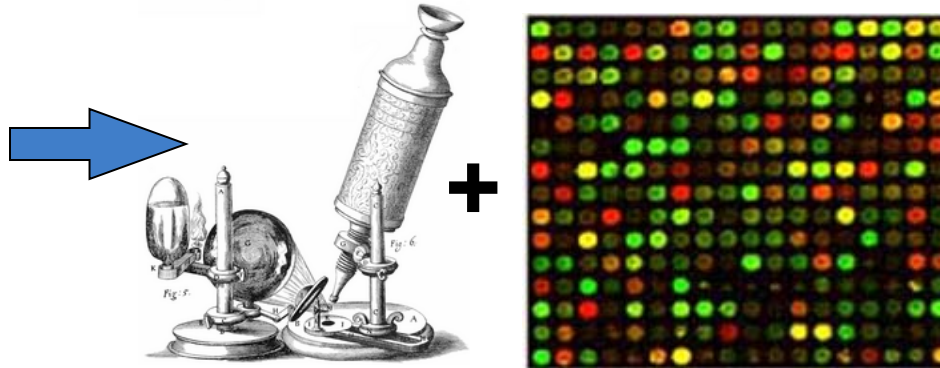
Clinical Decision-Making

- **Pre-operative biopsy**
- **Intra-operative frozen section**
- **Final surgical pathology**

- **+ Molecular diagnostics**

Molecular Diagnostics

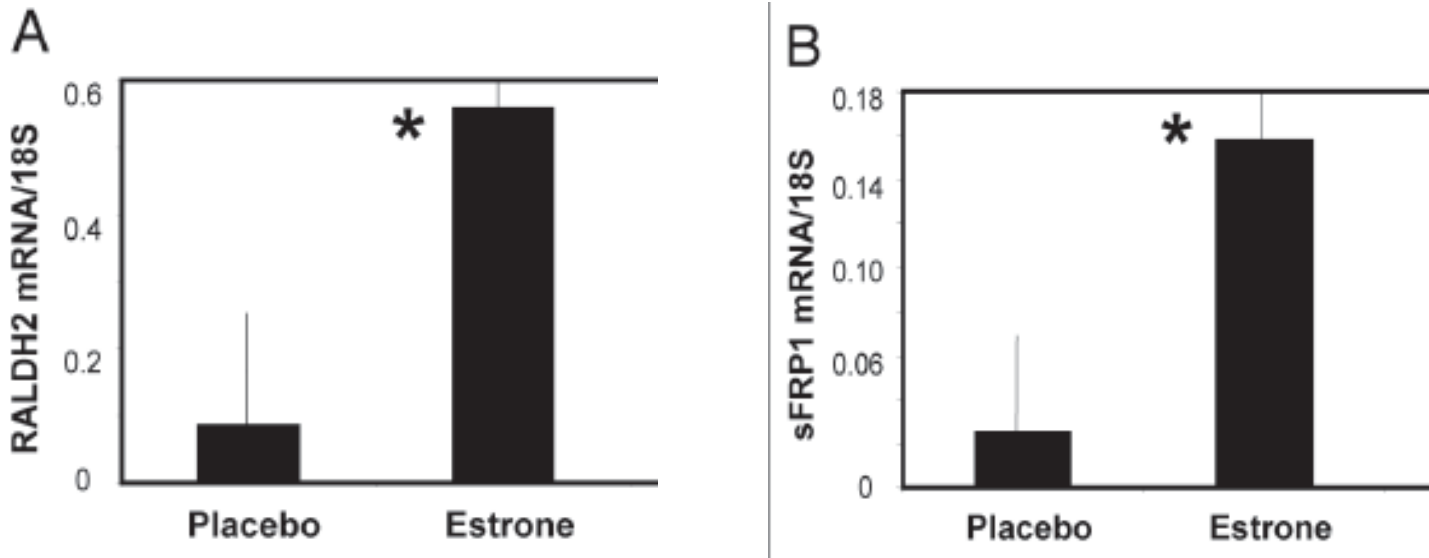
**Endometrial
Biopsy**



Grade 2 endometrioid adenocarcinoma expressing genes X, Y, and Z, which are predictive of deep myometrial invasion and disease outside the uterus.

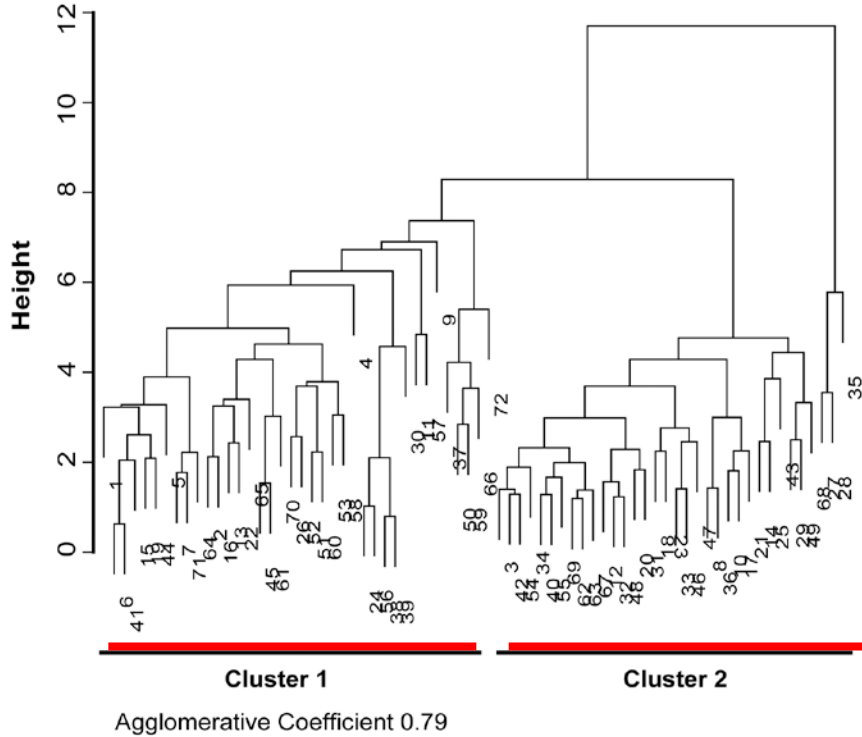
Molecular data - “value added”

Estrogen-Induced Genes



Six endometrial genes highly induced by estrogen were identified in post-menopausal women taking estrogen-based hormone replacement therapy.

Cluster Analysis



Cluster 2
 high expression of
 E2-induced gene

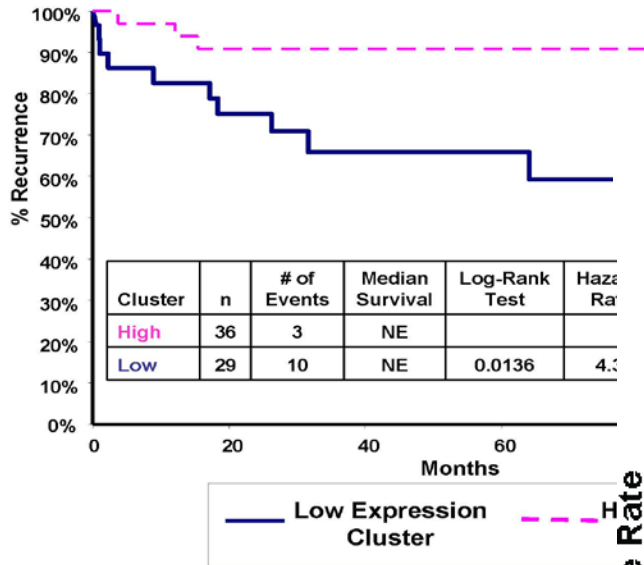
Cluster 1
 low expression of
 E2-induced gene

Median Gene Expression

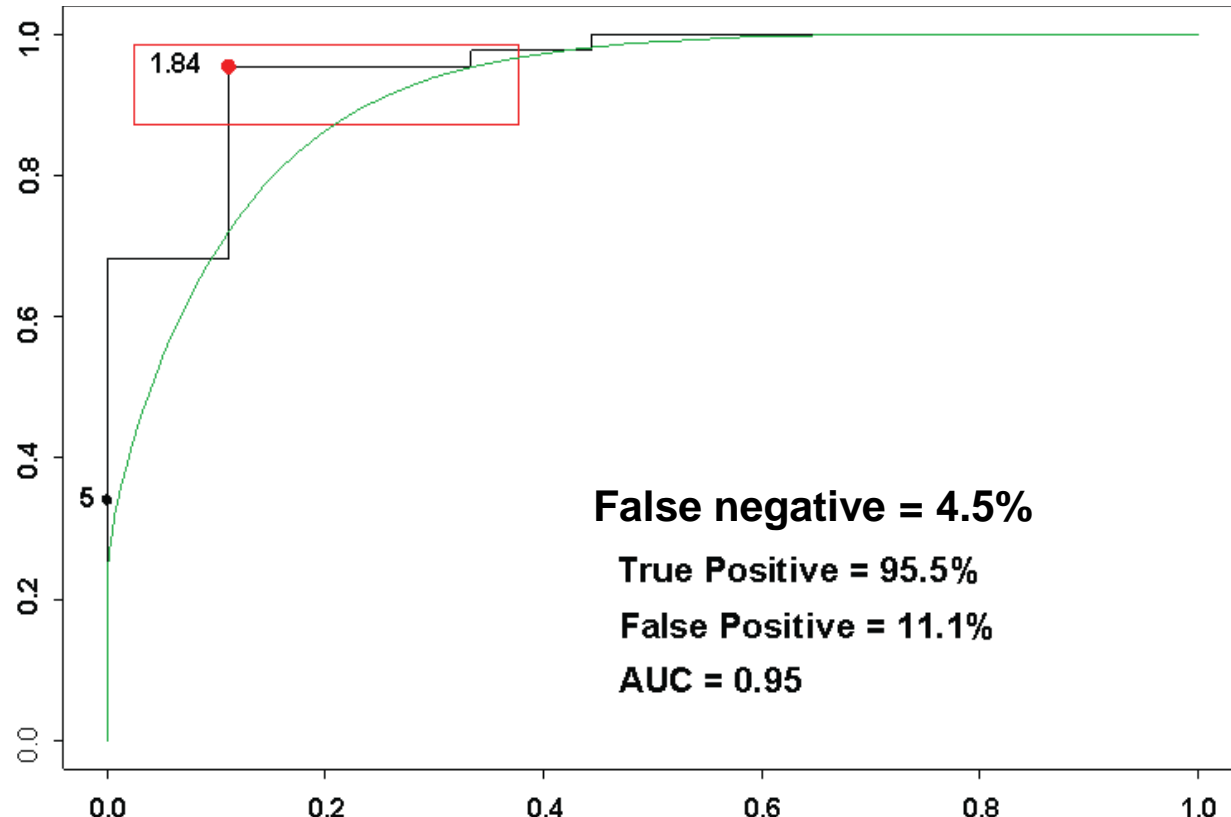
Gene	Cluster 1	Cluster 2
IGF -1	14.64	85.62
RALDH2	4.28	49.31
sFRP1	8.18	47.86
sFRP4	13.73	406.82
IGF -1R	37.32	71.00
EIG121	9.49	232.72

Potential Clinical Utility

Time to Recurrence



Low vs. High Risk



False negative = 4.5%

True Positive = 95.5%

False Positive = 11.1%

AUC = 0.95

Median follow-up = 33 months
Recurrences: 35% (10/29)
- including 2
8% (3/36) of

PA12-0550

Prediction of recurrence among low risk endometrial cancer population

Primary Objective:

Validate use of molecular panel to predict recurrence

Secondary Objectives:

- PPV/NPV/Spec/Sens of sentinel mapping
- CA125, HE4
- Evaluate molecular markers
 - Predict lymph node involvement
 - Compare to GOG 99 criteria, Mayo criteria

Study Criteria (n=~500)

- **Inclusion**

- Grade 1-2 endometrioid
- Candidate for surgery
- Prior hormonal therapy allowed

- **Exclusion**

- Deep myometrial invasion, cervical disease
- Peritoneal disease
- Contraindications to surgery, mapping

Treatment Plan

- **Preoperative labs**
- **Intra-operative mapping-Cervical injection (blue dye, radiocolloid or fluorescence)**
- **Full lymphadenectomy only if indicated based on frozen section**
- **Molecular testing on all tumors**

Current Accrual

Potential	262
Pre-enrolled	2
Ineligible	45
Declined	20
Contra	17
Pending	0
Enrolled	178
SNB Attempted	154
SNB Successful	110
SLN +	8
Extranodal +	9
False Negative	3
Pending Path	5

Interested?

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