Minimize the uncertainty in managing adnexal masses by optimizing your risk stratification process

Optimized Pathway

Adnexal masses planned for surgery

\[ \text{PATIENT} \]

- Minimize Uncertainty
- Benign
- Malignant

Ob/Gyn: Treat

Gyn Onc: Consult or Refer

Optimized Pathway

Benign

Malignant

Minimize Uncertainty in Managing Adnexal Masses by Optimizing Your Risk Stratification Process

Increase Sensitivity for Malignancy in the Care Pathway You Direct

<table>
<thead>
<tr>
<th>Options</th>
<th>Sensitivity</th>
<th>Rate of Cancer Detected</th>
<th>Rate of Cancer Missed</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA-125II*</td>
<td>69%</td>
<td>31%</td>
<td></td>
</tr>
<tr>
<td>Clinical assessment</td>
<td>75%</td>
<td>25%</td>
<td></td>
</tr>
<tr>
<td>Modified ACOG guidelines</td>
<td>80%</td>
<td>20%</td>
<td></td>
</tr>
<tr>
<td>OVA1*</td>
<td>92%</td>
<td>8%</td>
<td></td>
</tr>
<tr>
<td>OVA1 with clinical assessment</td>
<td>96%</td>
<td>4%</td>
<td></td>
</tr>
</tbody>
</table>

Rate of Cancer Detected

Rate of Cancer Missed

Sensitivity by Stage

<table>
<thead>
<tr>
<th></th>
<th>Stage I</th>
<th>Stage II</th>
<th>Early Stage</th>
<th>Pre-menopausal Early Stage</th>
<th>Post-menopausal Early Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA-125II*</td>
<td>64%</td>
<td>71%</td>
<td>66%</td>
<td>46%</td>
<td>75%</td>
</tr>
<tr>
<td>OVA1**</td>
<td>89%</td>
<td>100%</td>
<td>91%</td>
<td>91%</td>
<td>92%</td>
</tr>
</tbody>
</table>

Sensitivity Across Subtypes

<table>
<thead>
<tr>
<th></th>
<th>EOC</th>
<th>Non-EOC</th>
<th>Borderline/LMP</th>
<th>Metastatic to ovary</th>
<th>Non-ovarian malignancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>OVA1†</td>
<td>99%</td>
<td>92%</td>
<td>86%</td>
<td>100%</td>
<td>90%</td>
</tr>
</tbody>
</table>

Confidence in Managing Patients with Negative Results

Negative Predictive Value:

98%

Bristow et al., 2013
n = 494
Confidence Intervals: 95.2–99.2

* High risk cut-off: premenopausal subjects CA125 > 200U/mL; postmenopausal subjects CA125 > 35U/mL. **Intended use is with clinical assessment †With clinical assessment

Patient 1: 41 y/o P3013

Visit type: Pelvic pain
Finding: Right sided pelvic mass; U/S showed 5.5 x 8.4 X 9.1cm mass

“Moderate right ovarian enlargement. Cyst measuring 3.3 x 3.9 cm in size. There is a small amount of tissue along the posteromedial margin of this cyst over an area measuring 5mm in diameter.”

Assessment results:
OVA1 score = 9.4 (elevated risk)

Management:
- Ob/Gyn referred patient to Gyn Onc
- Ovarian cancer identified and optimally staged and debulked

Outcome
Patient was optimally managed by a specialist, reducing risk of reoperation for initial staging and debulking

Patient 2: 34 y/o P0000

Visit type: Annual Exam
Finding: Right sided pelvic mass; U/S showed 11.49cm X 6.47cm mass

“Large complex right adnexal mass likely of ovarian origin. Irregular borders and echogenic wall. There is also questionable mural nodularity.” - Malignancy indeterminate

Assessment results:
OVA1 score = 3.7 (low risk)

Management:
- Ob/Gyn performed laparoscopic surgery
- Benign mucinous cystadenoma identified

Outcome
Patient had minimally invasive surgery and did not have needless anxiety, inconvenience, and cost

OVA1 has been FDA-cleared for use in women meeting the following criteria:

- Are over 18 years of age
- Have surgery planned
- Have an ovarian adnexal mass
- Have not yet been referred to a gynecologic oncologist
- Have not had cancer in the past five years
- Have a rheumatoid factor concentration <250 IU/mL

OVA1 is a qualitative serum test that combines the results of 5 immunoassays into a single numerical result. It is indicated for women who meet the following criteria: over age 18, ovarian adnexal mass present for which surgery is planned, and not yet referred to an oncologist. OVA1 is an aid to further assess the likelihood that malignancy is present when the physician’s independent clinical and radiological evaluation does not indicate malignancy.

PRECAUTION: OVA1 should not be used without an independent clinical/radiological evaluation and is not intended to be a screening test or to determine whether a patient should proceed to surgery. Incorrect use of OVA1 carries the risk of unnecessary surgery, and/or delayed diagnosis.

For more info and kits, contact Customer Service: (844) ASPIRA1 / (844) 277.4721 or support@ASPIRAlab.com