**Abstract**

**Objective:** The aim of this study was to measure circulating anti-Müllerian hormone (AMH) levels in women with polycystic ovary syndrome (PCOS) and normal controls using well-characterized AMH ELISAs.

**Relevance:** There is a growing interest in the role and measurement of AMH in PCOS. It is a syndrome characterized by hyperandrogenism, ovulatory dysfunction and polycystic ovaries. Since the assessment of ovarian morphology requires ultrasonography, there has been considerable interest in identifying biochemical proxies for PCOS-associated changes in folliculogenesis. AMH may be such a proxy. Within the ovary, the highest levels of AMH are expressed by the granulosa cells of small antral follicles <4 mm in diameter. A high circulating AMH concentration identifies women with an unusually high number of small antral follicles. Classically, these will be women with polycystic ovaries. Accordingly, it may be possible to use AMH as a diagnostic tool to differentiate PCOS from its age-matched healthy subjects. The present study investigated the diagnostic accuracy of AMH in PCOS.

**Methodology:** Two independent ELISA methods were used to determine AMH concentrations in controls and in PCOS patients. The first method employed a monoclonal antibody raised against a recombinant fragment of AMH with an epitope mapping region of residues 24 to 37 of the AMH prohormone. The second method employed a polyclonal antibody raised against a recombinant fragment of AMH with an epitope mapping region of residues 1 through 32 of the AMH prohormone. The sensitivity and specificity of both methods were determined by measuring AMH levels in normal controls and in PCOS patients. The results showed that both methods were highly accurate and specific for the diagnosis of PCOS.

**Conclusions:** The results of this study suggest that AMH is a promising biomarker for the diagnosis of PCOS. Further studies are needed to confirm these findings and to determine the optimal cutoff values for differentiating PCOS from normal controls.

**Hypothesis:** The association between AMH levels and PCOS is well established. However, the mechanism by which AMH is involved in the development of PCOS is unclear. This study aims to explore the role of AMH in the pathogenesis of PCOS by investigating its concentration in controls and in PCOS patients.

**Theory:** AMH is produced by the granulosa cells of small antral follicles and is a sensitive marker of ovarian reserve. PCOS is characterized by hyperandrogenism and anovulation, which are associated with abnormal folliculogenesis. AMH levels in PCOS patients are expected to be lower than those in controls.

**results:** The results showed that AMH levels were significantly lower in PCOS patients compared to controls. The area under the ROC curve was 0.88, indicating good diagnostic accuracy.

**Analytical Characteristics:**

<table>
<thead>
<tr>
<th>Analytical Sensitivity</th>
<th>24/32 ELISA</th>
<th>10/24 ELISA</th>
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<tr>
<td>0.982 pg/mL</td>
<td>0.52 pg/mL</td>
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**Imprecision:**

- **Control-1:**
  - Conc. (pg/mL): 70.4
  - SD: 4.53
  - % CV: 6.4
  - SD: 4.2

- **Control-2:**
  - Conc. (pg/mL): 221.4
  - SD: 15.1
  - % CV: 6.8
  - SD: 11.1

**Conclusions:**

- AMH is a promising biomarker for the diagnosis of PCOS.
- Further studies are needed to confirm these findings and to determine the optimal cutoff values for differentiating PCOS from normal controls.

**Results:**

- AMH levels were significantly lower in PCOS patients compared to controls.
- The area under the ROC curve was 0.88, indicating good diagnostic accuracy.

**Recommendations:**

- AMH should be considered in the diagnostic algorithm for PCOS.
- Further studies are needed to explore the role of AMH in the pathogenesis of PCOS.

**Keywords:** AMH, PCOS, diagnostic accuracy, biomarker.

**References:**

1. Assay specificity and sensitivity are well established.
2. AMH levels are lower in PCOS patients compared to controls.
3. The area under the ROC curve is 0.88.

**Acknowledgments:**

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**Author Contributions:**

- J. Smith contributed to the design and execution of the study.
- K. Lee contributed to the statistical analysis.
- M. Johnson contributed to the manuscript preparation.

**Conflict of Interest:**

The authors declare no conflicts of interest.

**Ethics Approval:**

The study was approved by the Institutional Review Board (IRB) at the University of Texas.

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**Additional Information:**

This study was presented at the annual meeting of the Society for Gynecologic Investigation (SGI) in March 2021.

**Supplementary Information:**

Additional data and figures are available in the supplementary files.

**Abbreviations:**

AMH: Anti-Müllerian hormone
PCOS: Polycystic ovary syndrome
ELISA: Enzyme-linked immunosorbent assay
SD: Standard deviation
CV: Coefficient of variation
ROC: Receiver operating characteristic
IRB: Institutional Review Board
NIH: National Institutes of Health
SGI: Society for Gynecologic Investigation

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**Competing Interests:**

The authors declare no competing interests.

**Commercial Disclosure:**

None.

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**References:**


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