

Research Article

Comparing the Diagnostic Precision of the RMI and ADNEX Models in Identifying the Ovarian Tumor

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ABSTRACT

Objectives: To assess the diagnostic precision of the ADNEX and RMI models in distinguishing between benign and malignant ovarian tumors while taking histopathology as the gold standard.

Study type: Validation study.

Study duration: 5th April 2022 to 4th October 2022

Settings: Department of Obstetrics & Gynecology, Benazir Bhutto hospital Rawalpindi.

Materials & Methods: 165 patients between the ages of 14 and 65 who had at least one ovarian, para-ovarian, or tubal adnexal mass with a smallest diameter > 3 cm on ultrasound examination were included. Patients who had undergone bilateral adnexectomy or who had an adnexal mass under follow-up prior to the study's commencement were not included. The RMI/ADNEX score was computed. The patient was categorized as either low risk or high risk. To determine the predictive value of both models, the values were correlated with the histology report following surgery. Histopathological analysis of removed tissue serves as the foundation for the reference standard.

Results: The RMI model's diagnostic accuracy, sensitivity, specificity, PPV, and NPV in telling the difference between benign and malignant ovarian masses were 90.11%, 85.14%, 88.17%, 87.50%, and 87.88%, respectively. ADNEX showed sensitivity of 85.56%, a specificity of 81.33%, a PPV of 84.62%, an NPV of 82.43%, and a diagnostic accuracy of 83.64%.

Conclusion: This study concluded that diagnostic accuracy of RMI model in differentiation of benign and malignant ovarian masses is better than ADNEX model.

Keywords: Ovarian Tumours, Risk Malignancy Index, Sensitivity.

INTRODUCTION

Ovarian cancer ranks as the 18th most prevalent cancer overall and the seventh most common disease in women globally.¹ Its non-specific symptoms and lack of screening methods cause a delay in diagnosis, which is often found at an advanced stage. Because of this, it remains one of the most difficult gynecological malignancies to treat clinically. Overall, 44% of people survive after 5 years (92% for Stage I and 27% for Stage IV).²

One of the most frequent difficulties a practicing gynecologist deals with is adnexal

masses. Differentiating between benign and malignant pelvic masses is essential for early pre-operative differentiation, prompt referral, and the best possible care. This has a direct impact on the prognosis and, consequently, the morbidity and mortality of the patient.^{3,4}

Numerous combined techniques have been put out to assess the risk of ovarian cancer. Compared to the previously described individual indicators, the scoring techniques based on menopausal status, ultrasonographic examination, and blood CA-125 produce significantly better results.⁵ The best

noninvasive diagnostic test for women with an adnexal mass is the diagnostic yield of CA-125, a tumor marker commonly employed for ovarian cancer.⁶ The purpose of imaging is to identify unexpected features that may indicate atypical pathology and to identify and describe adnexal masses as likely. Because sonography is widely available, reasonably priced, and has a good sensitivity for mass identification, it is the first imaging study of choice when evaluating women who may have adnexal masses. However, up to 20% of adnexal masses are classed as ambiguous, which limits sonography's ability to diagnose benign masses.⁶

An essential tool for identifying adnexal anomalies is ultrasound. Its sensitivity for cancer is about 90%, while its specificity ranges from 51 to 97%.⁵ Prior to surgery, ultrasound examination—more especially, the subjective evaluation by a qualified examiner—is thought to be the most effective method of distinguishing benign from malignant adnexal tumors. The initial imaging test utilized to characterize an ovarian tumor is typically pelvic ultrasonography. Adnexal masses can be discovered during a pelvic examination or as an unintentional finding on pelvic imaging. They can also manifest as pelvic pain or pressure.

The risk of malignancy index (RMI), created in 1990 by Jacob et al., is a widely used model. It has a sensitivity of 82.1% and a specificity of 82.6%.⁶ Assessment of various adnexal neoplasia is part of more modern models (ADNEX).⁷ Its sensitivity is 83.8%, while its specificity is 92%.⁶

There hasn't been a thorough formal evaluation of these two approaches' comparative performance. In order to recommend a model with greater diagnostic accuracy, the purpose of this study is to compare the performance of the ADNEX and RMI models when applied to adnexal masses in therapeutically relevant groups.

METHODOLOGY

A validation research was conducted in the Department of Gynecology at BBH in Rawalpindi between April and October of 2022. A non-probability, consecutive sampling technique was used to get the data. Comprehensive physical examinations, in-depth evaluations of medical histories, and necessary laboratory testing were all part of the data collection procedure. Since the study was approved by the IRB. Each patient gave

their informed consent to participate in the study after being fully informed of its goals, assured of the confidentiality of the information they contributed, and informed that there would be no risks to them. use a calculator for sensitivity and specificity; Ninety-five percent confidence level, 82.1% sensitivity RMI, 82.6% specificity, 35.3% prevalence, 10% absolute precision, and 165 sample size.⁶

Patients between the ages of 14 and 65 who had at least one ovarian, para-ovarian, or tubal adnexal mass (with a smallest diameter greater than 3 cm) on ultrasound examination and were hospitalized for definitive surgery met the inclusion criteria.

Exclusion criteria include: a history of bilateral adnexectomy; a lesion was deemed physiological if its smallest diameter was less than 3 cm; a conservative management of the adnexal mass; pregnancy at presentation; and a patient with an adnexal mass that was being monitored prior to the study's commencement.

Age, marital status, parity, presenting problems, and family history of CA were all noted in their comprehensive medical history. The following characteristics were observed on ultrasonography: Tumor size, septa presence, locularity, solid components and their diameter, papillary projections, ascites, and unilateral or bilateral

The RMI/ADNEX score was determined using the aforementioned features. The patient was categorized as either low risk or high risk. The RMI model uses the formula $U \times M \times CA125$ to determine the risk of malignancy, with 200 serving as the cut-off for malignancy. To determine the predictive value of both models, the values were correlated with the histology report following surgery. Histopathological analysis of removed tissue serves as the foundation for the reference standard.

SPSS-24 was used to enter all of the data. For both qualitative and quantitative variables, descriptive statistics were computed. Data was displayed using frequency and percentages for qualitative characteristics, such as marital status, education, socioeconomic position, occupation, presenting complaints, menstrual history, and ultrasound results suggestive of benign and malignant ovarian tumors. The mean and SD were used to display data for quantitative variables such as age and tumor marker

levels. To ascertain sensitivity, specificity, and PPV, NPV, a 2/2 table was created.

| Ovarian carcinoma on RMI/ADNEX | | Ovarian carcinoma on Histopathology | |
|--------------------------------|-----|-------------------------------------|----|
| | | Yes | No |
| | Yes | TP | FP |
| | No | FN | TN |

RESULTS

The study's age range was 14–65 years old, with a mean age of 49.56 ± 9.74 years. According to Table I, the majority of the patients, 129 (78.18%), were between the ages of 41 and 65. The illness lasted 6.58 ± 1.44 months on average. Table I displays the patient distribution based on confounding variables. CA-125 was 224.43 ± 24.54 IU/ml on average. The average level of LDH was 476.61 ± 19.83 IU/L. AFP levels were 2.89 ± 1.75 IU/ml on average. The average BHCG was 1.36 ± 0.76 IU/L.

There were 82 True Positives and 11 False Positives among the patients who had positive RMI tests. Table II shows that of the 72 RMI-negative patients, 63 were True Negative and 9 were False Negative

($p=0.0001$). The RMI model's overall sensitivity, specificity, PPV, NPV, and diagnostic accuracy in differentiating between benign and malignant ovarian masses were 90.11%, 85.14%, 88.17%, 87.50%, and 87.88%, respectively, when histopathology was used as the gold standard.

Of the individuals with ADNEX, 77 had True Positive results and 14 had False Positive results. Table III shows that of the 74 individuals who tested negative for ADNEX, 13 were False Negative and 61 were True Negative ($p=0.0001$). The overall sensitivity, specificity, PPV, NPV, and diagnostic accuracy of ADNEX were 85.56%, 81.33%, 84.62%, 82.43%, and 83.64% respectively.

Table I: Descriptive Statistics (N=165)

| | | Frequency | %age |
|----------------------|----------------|-----------|-------|
| Age (years) | 14-40 | 36 | 21.82 |
| | 41-65 | 129 | 78.18 |
| Education | Uneducated | 53 | 32.12 |
| | Educated | 112 | 67.88 |
| Marital status | Unmarried | 39 | 23.64 |
| | Married | 126 | 76.36 |
| Menopausal status | Pre-menopause | 78 | 47.27 |
| | Post-menopause | 87 | 52.73 |
| Occupation | Housewife | 89 | 53.94 |
| | Working | 76 | 46.06 |
| Socioeconomic status | Poor | 53 | 32.12 |
| | Middle | 68 | 41.21 |
| | Upper | 44 | 26.67 |
| Dysmenorrhea | Yes | 78 | 47.27 |
| | No | 87 | 52.73 |
| Dyspareunia | Yes | 36 | 21.82 |
| | No | 129 | 78.18 |

Table-II: Diagnostic Accuracy of RMI Model.

| | +ive on Histopathology | -ive on Histopathology | P-value |
|-------------|------------------------|------------------------|---------|
| +ive on RMI | 82 | 11 | 0.0001 |
| -ive on RMI | 09 | 63 | |

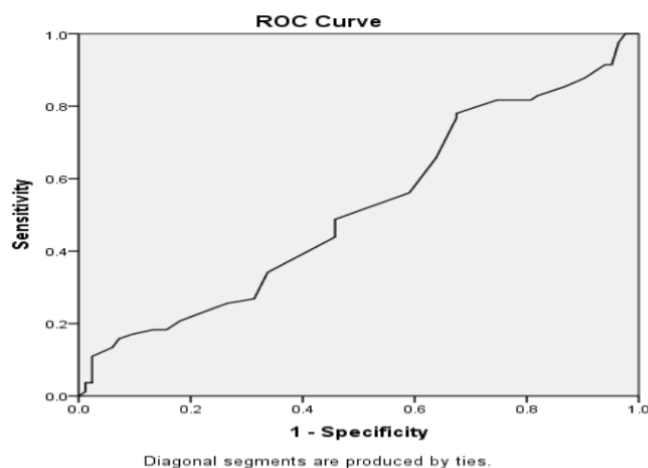
Sensitivity: 90.11%

Specificity: 85.14%

PPV: 88.17%

NPV: 87.50%

Diagnostic Accuracy: 87.88%



Area under curve = 0.517

Table-III: Diagnostic accuracy of ADNEX model.

| | +ive on Histopathology | -ive on Histopathology | P-value |
|---------------|---------------------------|---------------------------|---------------|
| +ive on ADNEX | 77 | 14 | 0.0001 |
| -ive on ADNEX | 13 | 61 | |

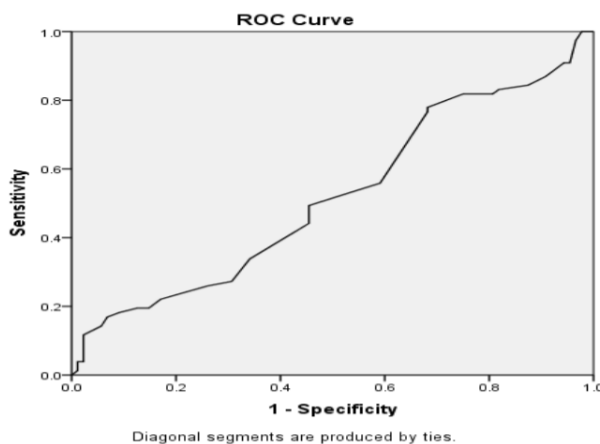
Sensitivity: 85.56%

Specificity: 81.33%

PPV: 84.62%

NPV: 82.43%

Diagnostic Accuracy: 83.64%



Area under curve = 0.519

DISCUSSION

In order to determine how well the ADNEX and RMI models differentiate between benign and malignant ovarian tumors, I conducted this study using histology as the gold standard. The RMI model's overall sen, spec, PPV, NPV, and DA in differentiating between benign and malignant ovarian masses were 90.11%, 85.14%, 88.17%, 87.50%, and 87.88%,

respectively, when histopathology was used as the gold standard. With the RMI cut-off value set at 200, and >200 being classified as malignant, the computed sensitivity was 70.5%, the specificity was 87.8%, and the PPV and NPV were 70.5% and 87.8%, respectively.⁸ According to another study conducted in Pakistan, RMI has a 91.3% sensitivity, 76.9% specificity, 87.5% PPV, and 83.3% NPV when it

comes to identifying malignancy.⁹ In 1999, Morgante et al.¹⁰ discovered that RMI 2 was superior to RMI 1 in terms of accuracy in differentiating ovarian illness. In a research by Van Trappen et al.¹¹, 123 patients were treated in a sequential manner using RMI cutoff values of ≥ 25 and $< 1,000$. The sensitivity and specificity were 94% and 90%, respectively.

Van Den Akker et al. studied 548 individuals in 2010; the mean age of those with benign lesions was 52, whereas that of those with malignant tumors was 62. 53 borderline malignancies (10%), 80 malignant masses (24%), and 415 benign masses (76%), were included in this investigation. Mucinous cystadenoma and serous cystadenocarcinoma were the most prevalent benign and malignant tumors, respectively. ADNEX with CA125 had sensitivity and specificity of 0.93 and 0.77, while RMI had 0.61 and 0.92 respectively. For ADNEX with CA125 and RMI at the chosen levels, the test's likelihood of being helpful at a hypothetical new facility for surgical patients was 96% and 15%, respectively.¹²

Manjunath et al. conducted a study on 152 patients who had pelvic masses. Of these masses, 61.2% (n=93) turned out to be malignant (serious cystadenocarcinoma being the most prevalent) and 38.8% (n=62) were found to be benign (cystadenoma being the most common). The optimal cutoff threshold for all three RMIs was 200, and there were no appreciable differences in the derived parameters.¹³ One hundred individuals with pelvic masses participated in a study conducted by Obeidat et al. RMI > 200 showed sensitivity of 90% and specificity of 89%.¹⁴

Another study comprised 172 individuals, of whom 131 had benign tumors (76.2%), 15 had borderline tumors (8.7%), and 26 had malignant tumors (15.1%). In patients with malignant ovarian masses, RMI-3 had a sensitivity of 80.7%, a specificity of 93.1%, and a diagnostic accuracy of 91%. These percentages were, respectively, 76.9%, 93.8%, 71.4%, 95.3%, and 91% for RMI-4. RMI-3 gave patients with borderline ovarian masses a sensitivity of 60%, a specificity of 93.1%, a PPV of 50%, a NPV of 95.3%, and a diagnostic accuracy of 83.7%. These percentages were 52.9%, 93.1%, 50%,

93.8%, and 88.5%, respectively, for RMI-4. Malignant adnexal masses are more accurately predicted by RMI-3 and RMI-4 than by borderline adnexal masses.¹⁵

According to a study of 302 women with adnexal masses, an RMI with a cutoff point of 250 had 88.2% sensitivity and 74.3% specificity for finding invasive lesions.¹⁶ An RMI > 250 had an 88.5% sensitivity for identifying invasive lesions in 182 women with pelvic masses, according to another study.¹⁷ 116 diagnostic studies for adnexal cancer were examined in a systematic review.¹⁸ Similar to our findings, the published result indicated that RMI has a sensitivity of 78% and specificity of 87% for malignant mass diagnosis at the cutoff point of 200. The study's cutoff value of 126.75 for the risk malignancy index yielded specificity of 90.2%, and sensitivity of 88.6%.

RCOG¹⁹ says that a cutoff value of 250 can give a sensitivity of 70% and a specificity of 90%. Our study may also get a sensitivity of 70.5% and a specificity of 93.5% with the same cutoff value of 250. Using the conventional RCOG limit of 250, another study confirmed that RMI is a good way to predict how well patients with adnexal masses will do. The study exhibited a sensitivity of 70.5% and specificity of 93.5%. RMI was checked with a cutoff point of 126.75, which gave it an overall accuracy of 89.4%, a sensitivity of 88.6% and a specificity of 90.2%.²⁰

In my study, using histopathology as the gold standard, ADNEX was able to tell the difference between benign and malignant ovarian masses with an overall sensitivity of 85.56%, specificity of 81.33%, PPV of 84.62%, NPV of 82.43%, and diagnostic accuracy of 83.64%. The ADNEX model was used in the study by Soo Jeong et al. to determine the best cut-off point for ovarian cancer discrimination at 90% sensitivity. For every participant, 47.3% was the ideal cut-off point as established by the Youden index approach.²¹ Regardless of the patient's menopausal status, Tug et al.'s analysis in another non-tumor location revealed that an ideal cut-off value of 14.05% produced more balanced findings for sensitivity and specificity.²²

Viora et al.²³ and Epstein et al.²⁴, however, discovered the contrary. They

noted that the ADNEX model's diagnostic accuracy matched, if not exceeded, the subjective evaluation of professional sonographers. The ADNEX model is not meant to replace expert evaluation, but rather to assist novice sonographers and gynecologists in categorizing patients for suitable therapy.²⁵ In the meanwhile, we need to be mindful that professional sonographers aren't always accessible. Additionally, this model's sensitivity at the 15% cut-off was somewhat lower (10%: 0.96, 15%: 0.92) than the ADNEX model at the 10% cut-off, but its specificity (10%: 0.69, 15%: 0.82) was noticeably higher.²⁶

Many benign tumors will also be identified at the 10% risk of malignancy cut-off of ADNEX, as advised by an international consensus statement.²⁷ It would appear from this that the need for gynecological oncological knowledge has been resolved (in western countries). The suggestion made by Sundar et al. supports this.²⁸ In a real-world situation, Sundar et al. compared RMI (cut-off 250) with ADNEX head-to-head in postmenopausal women exhibiting symptoms suggestive of ovarian cancer (ROCKETS trial).²⁸ This suggests that great sensitivity is now more important than high specificity. A lower cut-off, like 25 or 50, can be used to boost the sensitivity of RMI. Nevertheless, a meta-analysis of data from 23 Italian centers found that ADNEX's clinical value is better than RMI's at RMI score 25.²⁹

This study had a number of drawbacks. Because this was a single focus arrangement, the results' applicability to various locations may be examined in terms of propensity and breaking point. Furthermore, no one with a variety of instructive experiences conducted ultrasonography examinations during our experiment. Additional research is needed in Pakistan in several suggestive habitats with varying levels of ultrasonography capability

CONCLUSION

This study found that the RMI model's diagnostic accuracy in distinguishing between benign and malignant ovarian masses is superior to that of the ADNEX model. This has not only significantly enhanced our capacity to differentiate ovarian tumors prior to surgery, but it also aids surgeons in making informed

decisions. Therefore, we advise that this straightforward and user-friendly RMI model be regularly used in all suspected ovarian lesions in order to diagnose ovarian cancer prior to surgery and choose the best surgical strategy.

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