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BREAST IMAGING

ORIGINAL ARTICLE

The role of the Kaiser score system in uncertain malignant potential (B3) breast lesions: a pilot study

Fatma Çelik Yabul
Hafize Otçu Temur
Bahar Atasoy
Serdar Balsak
Alpay Alkan
Şeyma Yıldız

Bezmialem Vakıf University Faculty of Medicine, Department of Radiology, İstanbul, Türkiye

PURPOSE

This study aims to evaluate the effectiveness of the Kaiser score (KS) system in assessing breast lesions with uncertain malignant potential (B3).

METHODS

Breast magnetic resonance imaging (MRI) scans from a total of 76 patients with histologically proven B3 lesions were included in this study. The KS was recorded for each MRI scan. The patients were classified based on biopsy results, and upgraded lesions were identified. Statistical analysis was conducted to evaluate the association between high KS values and upgraded lesions.

RESULTS

The mean age of the 76 patients was calculated as 49.6 ± 10.1. A significant association was observed between the KS system and the prediction of malignancy upgrade ($P < 0.001$). Furthermore, among the descriptors, spiculation, margin, and upgrading prediction demonstrated a statistically significant difference ($P < 0.001$). Additionally, the specificity improved when the accepted KS cut-off value was set at seven instead of five. A significant association was also observed between the KS system and the papilloma upgrade rate within the B3 lesion subgroups ($P < 0.001$).

CONCLUSION

Breast radiology plays a crucial role in the diagnosis of B3 lesions. Our findings suggest that the KS system holds promise as a tool for predicting the upgrade potential of B3 lesions.

CLINICAL SIGNIFICANCE

This study demonstrated that the KS system may assist in predicting the upgrade potential of B3 breast lesions. It also demonstrated that spiculation and margin descriptors within the KS system possess a high positive predictive value for upgrade prediction. Additionally, we believe that the KS system can help prevent unnecessary surgeries in patients with B3 lesions.

KEYWORDS

B3 breast lesion, Kaiser score system, breast magnetic resonance imaging, breast, magnetic resonance imaging

Corresponding author: Fatma Çelik Yabul

E-mail: fatmayabul@gmail.com

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Uncertain malignant potential lesions (B3) of the breast can be classified as atypical ductal hyperplasia (ADH), radial scar, papillary lesions, lobular neoplasia (LN), and flat epithelial hyperplasia (FEH). These lesions are commonly characterized by an increased lifetime risk of breast cancer in women.[1-3] Due to the heterogeneity of high-risk lesion groups, upgrade rates for high-risk breast lesions have varied in the literature, ranging from 6% to 32%.[4-6]

The management of B3 lesions is determined by pathological findings, patient age, risk factors, and the type of biopsy performed. Radiological-pathological discordance remains one of the key criteria for excision.[7-9]

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The Kaiser score (KS) system is a decision-making tool in parallel with the Breast Imaging-Reporting and Data System (BI-RADS) classification, considering the morphological and dynamic features in breast magnetic resonance imaging (MRI).[10,11] Dietzel and Baltzer[10] developed a clinical decision tool originally referred to as the Tree flowchart and later renamed the KS after Werner A. Kaiser's contributions to its development. Additionally, they published an essay that included a practical guide for the interpretation of breast MRI examinations using the KS.[10] Their contribution has been further extended with a recently published article in which they emphasized that the KS served as an evidence-based decision-making tool to objectively differentiate between benign and malignant breast lesions.[12]

This study aims to evaluate the upgrade potential of high-risk breast lesions and to determine the role of the KS in avoiding potentially unnecessary surgical excisions.

Methods

This retrospective study was approved according to the principles of the Declaration of Helsinki by the Ethics Committee of the Bezmialem Vakıf University (approval no: E-54022451-050.01.04-3208, date: 20.10.2021), and all participants signed a written informed consent form.

Patient selection

Patients' core biopsy-proven B3 lesions, collected between 2016 and 2021, were retrieved from the archives. Initially, 130 patients were reviewed. Among these, only 81 had MRI scans available in the system. Of the 81 patients, 5 were excluded due to the absence of pathological contrast enhancement on MRI. Patients with excision results or a follow-up period of at least 2 years (24–72 months) were included in this study. Based on these criteria, a total of 76 patients were considered eligible for this study. The age, risk status, and complaints of the patients were recorded.

Main points

- The Kaiser score (KS) system may help predict uncertain malignant potential (B3) breast lesions upgrade.
- Spiculation and margin identifiers in the KS system have a high positive predictive value in upgrade prediction.
- Unnecessary surgeries can be avoided in cases diagnosed with B3 lesions by using the KS system.

Magnetic resonance imaging acquisition and image interpretation

All breast MRI scans were conducted using a 1.5 T scanner (Siemens Magnetom Avanto Fit, Siemens Healthineers; Erlangen, Germany) with a bilateral 16-channel breast coil in the prone position. Apparent diffusion coefficient (ADC) maps, subtraction, and maximum intensity projection images were acquired. Axial T2-weighted fat-suppressed imaging [repetition time (TR)/echo time (TE): 4560/59 ms; slice thickness: 4 mm, matrix: 340 × 512], axial T1-weighted imaging (TR/TE: 571/11 ms; slice thickness: 4 mm, matrix: 340 × 512), one precontrast and five postcontrast 3D T1 turbo spin-echo imaging (TR/TE: 5.16/2.38 ms; flip angle: 100, slice thickness: 1 mm), and diffusion-weighted imaging (b-values: 0–800 s/mm^2) series were obtained. The gadolinium-based contrast agent was administered at 0.1 mmol/kg using a mechanical power injector, followed by a 15–20 cm^3 saline flush.

Two breast radiologists evaluated all the images using the Siemens Syngo Via (Erlangen, Germany) workstation. They were blinded to clinical data and histopathology results. The KS was assigned via the online version to the patients after reaching consensus. Descriptors evaluated in the KS were spiculation, dynamic enhancement curves, margins, internal enhancement, and edema around the lesion. Using the KS, the patients were scored from 1 to 11. A score of 5–7 was categorized as BI-RADS 4, and a score of 8–11 was categorized as BI-RADS 5 and considered positive. Optional moderators were noted, such as evidence of microcalcification overlapping the area of contrast and ADC values. The cut-off value was >1.4 ×10^{-3} mm^2/s as recommended in the KS.

Histopathological evaluation

The patients' diagnoses were obtained using one of the following methods: tru-cut biopsy under ultrasonographic guidance (n = 59), vacuum-assisted biopsy (VAB) under mammographic guidance (n = 10), or biopsy under MRI guidance (n = 7). On average, 3–4 samples were obtained for tru-cut biopsies using a 14-gauge needle. The results of core biopsy, surgical excision, or follow-up evaluations were analyzed. Cases with an upgrade to ductal carcinoma *in situ* (DCIS) following excision, including those with progression detected during follow-up, were considered positive.

Statistical analysis

Statistical analysis was performed using SPSS software (IBM Corp. Released 2021. IBM SPSS Statistics for Windows, Version 28.0. Armonk, NY, USA). In addition to descriptive statistics [mean ± standard deviation for continuous variables, frequencies with percentages for categorical variables, and area under the receiver operating characteristic (ROC) curve (AUC) with standard error], the Shapiro–Wilk test was used to assess the distribution of the data. Comparisons of KS descriptors and upgrade rates were performed using Fisher's exact test and the Fisher–Freeman–Halton test. ROC analysis was performed using MedCalc version 12 to assess the overall diagnostic performance of KS in predicting progression, and the optimal cut-off value was determined using Youden's J index. Differences in KS and upgrade rates among high-risk lesion subgroups (ADH, radial scar, atypical papillomas, LCIS, LN, and FEH) were evaluated. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated. A type 1 error rate of $\alpha = 0.05$ was considered statistically significant.

Results

A total of 76 patients were evaluated. Thirty patients were classified as high-risk due to a personal history of breast cancer (n = 8) or a family history of breast cancer in immediate relatives (n = 22). Clinical findings such as pain (n = 12), palpable mass (n = 7), and bloody nipple discharge (n = 6) were present in 33% of the patients. The mean age of the patients was calculated as 49.6 ± 10.1.

The histopathological distribution of lesions is presented in Table 1. Among the 76

Table 1. Histopathological distribution of the B3 lesions

Histopathologic results	n (%)
Papilloma	36 (47.4%)
Flat epithelial hyperplasia	18 (23.7%)
Radial scar	12 (15.8%)
Lobular neoplasia	5 (6.6%)
Atypic ductal hyperplasia	5 (6.6%)
Total	76

B3 lesions, papilloma was the most common diagnosis (47.4%), followed by FEH (23.7%), radial scar (15.8%), LN (6.6%), and ADH (6.6%).

In the follow-up cases (n = 40), no progression was observed. During follow-up, the lesions remained stable in 33 patients (82.5%) and regressed in size in 7 patients (17.5%). Surgical excision was performed in 36 patients (47.3%), and DCIS was detected in 12 of 76 patients following excision. No upgrade to invasive cancer was identified. The overall upgrade rate in patients with B3 lesions was 16%.

Based on MRI results, non-mass enhancement was observed in 34 cases (44.7%), whereas mass enhancement was observed in 42 cases (55.2%). There was no statistically significant difference between upgraded lesions and MRI enhancement patterns ($P > 0.050$).

In the evaluation of optional moderators (suspicious microcalcifications and high ADC values), seven patients had microcalcifications overlapping with the contrast-enhanced area on MRI. Based on the KS, two points were added to these patients. An upgrade was detected in four of them.

No high ADC values were identified in the evaluation of lesions that would warrant a four-point reduction in the KS. All lesion ADC values were below 1.4×10^{-3} mm^2/s. The KS and MRI findings for the upgraded lesions are presented in Table 2.

A positive KS was a significant predictor of lesion upgrade status ($P < 0.001$). In patients with a KS exceeding 5, the sensitivity and specificity for predicting an upgrade were 81.25% and 83.33%, respectively. The NPV, PPV, and overall accuracy were 94.34%, 56.52%, and 82.89%, respectively (Table 3).

When the KS cut-off value was set at 7, the sensitivity, specificity, and accuracy for predicting an upgrade were 68.75%, 98.3%, and 80.2%, respectively, with an AUC of 0.86 and a standard error of 0.07 (95% confidence interval: 0.76–0.93, $P < 0.001$). Additionally, a cut-off value of >6 was identified (Figure 1).

Evaluation of MRI findings showed that spiculation was a significant predictor of lesion upgrade ($P < 0.001$). Furthermore, the subgroups of B3 lesions were analyzed. Among these subgroups, the KS was a significant predictor of the upgrade rate for papilloma ($P < 0.001$).

Discussion

B3 of the breast are commonly encountered in needle biopsies. Due to the potential for malignancy, the management of these lesions following needle biopsy remains controversial, with no universally accepted standard recommendation. Although surgical biopsy is widely recommended for ADH, the management of other B3 lesions should be determined on a patient basis through a multidisciplinary approach. Criteria for surgical excision may include sampling adequacy (e.g., needle gauge, number of samples, and accurate targeting), lesion size, and radiology–pathology concordance.[7-9]

The literature has studied the role of MRI in managing high-risk lesions. Londero et al.[13] reported that the absence of enhancement on breast MRI effectively eliminated the risk of invasive cancer and served as a reliable indicator for excluding surgery in B3 lesions. Similarly, in our study, no progress was seen during follow-up in cases that were di-

Table 2. MRI findings of the upgraded lesions

No	Kaiser score	Spiculation	Margin	Contrast	Edema	Internal enhancement	Pathology
1	3	Negative	Irregular	Type 1	Negative	Homogeneous	FEH
2	3	Negative	Circumscribed	Type 1	Negative	Homogeneous	ADH
3	7	Positive	Irregular	Type 2	Negative	Homogeneous	ADH
4	7	Positive	Irregular	Type 2	Negative	Homogeneous	LN
5	7	Positive	Irregular	Type 2	Negative	Homogeneous	LN
6	2	Negative	Circumscribed	Type 2	Negative	Homogeneous	LN
7	11	Positive	Irregular	Type 3	Positive	Homogeneous	Papilloma
8	5	Negative	Circumscribed	Type 2	Negative	Homogeneous	Papilloma
9	8	Negative	Irregular	Type 3	Negative	Inhomogeneous	Papilloma
10	8	Negative	Irregular	Type 3	Negative	Inhomogeneous	Radial scar
11	8	Negative	Irregular	Type 3	Negative	Inhomogeneous	Radial scar
12	7	Positive	Irregular	Type 2	Negative	Homogeneous	Papilloma
13	11	Positive	Irregular	Type 3	Positive	Inhomogeneous	Papilloma
14	9	Positive	Irregular	Type 3	Negative	Inhomogeneous	Papilloma
15	5	Negative	Circumscribed	Type 2	Negative	Homogeneous	FEH
16	11	Positive	Irregular	Type 3	Positive	Inhomogeneous	Papilloma

MRI, magnetic resonans imaging; FEH, flat epithelial hyperplasia; ADH, atypical ductal hyperplasia; LN, lobular neoplasia.

Table 3. Kaiser score positivity and upgrade ratio

	Upgrade (+)	Upgrade (–)	Total
Kaiser (+)	13	10	23
Kaiser (–)	3	50	53
Total	16	60	76

agnosed as B3 lesions but were not included in the study because MRI did not show any contrast enhancement.

The KS system is a decision-making tool that integrates five morphology and kinetic criteria, along with two optional modifiers (microcalcifications and ADC values), to differentiate benign from malignant breast tumors. The KS system offers a standardized approach to breast MRI evaluation, enhancing its utility in clinical practice. In recent years, there has been a rapid increase in studies employing this flowchart.[14-20] Studies have demonstrated that inter-reader agreement is high and that the KS enhances the diagnostic performance of MRI.[14-18] Wang et al.[19] has also showed that the KS is a useful diagnostic tool that helps radiologists with different levels of breast MRI experiences make more accurate diagnoses. According to Zhang et al.[20], KS is a better way to diagnose breast lesions than BI-RADS, whether the lesions show non-mass enhancement or are evaluated on their own. Furthermore, Wengert et al.[21] gave useful supporting data and pushed for the use of KS to eliminate BI-RADS 4 mammography calcifications. However, no studies to date have specifically evaluated the application of KS in B3 lesions.

In our study, the upgrade rates were comparable with those reported in the literature. However, the excision rates were higher than those documented in previous studies.[4-6] This can be attributed to the large proportion of high-risk patients and the limited availability of VAB in our country.

There were three false-negative cases in our study. Two cases (LN and FEH) were upgraded to low-grade DCIS following excision (Figure 2). It is well-established that MRI has low specificity for detecting low-grade DCIS,[22] which may explain these false-negative results. In one of these cases (ADH), microcalcifications led to an increased score, highlighting the importance of incorporating optional moderators in the KS system.

We observed false-positive results in 10 cases. Four patients had papillomas, and three had radial scars. In the false-positive papilloma cases, the type 2 contrast enhancement pattern contributed to the increased scores (Figure 3). The literature indicates that papillomas are a heterogeneous group that may exhibit varying enhancement patterns,[23] which we believe contributes to the higher false-positive rate. Additionally, contour irregularity and spiculation positivity increased the scores in cases of radial scars. Radial scars were present in

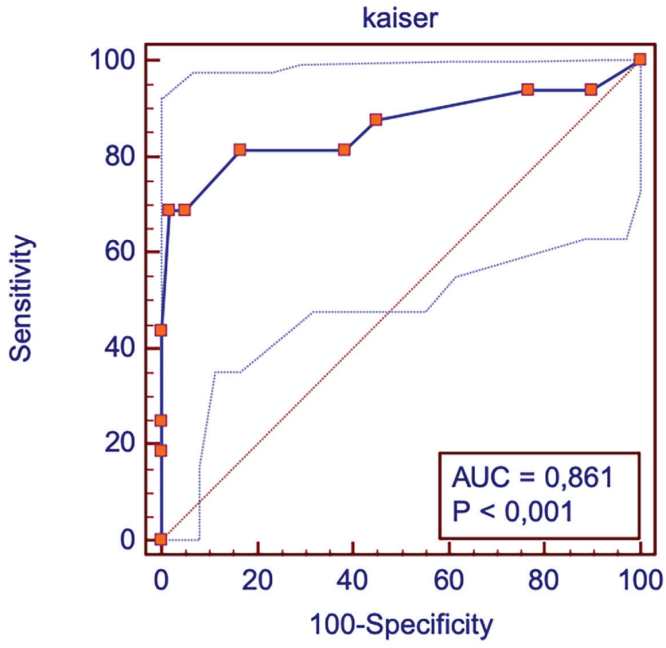

Figure 1. Sensitivity and specificity ratio of KS 7. KS, Kaiser score; AUC, area under the receiver operating characteristic curve.

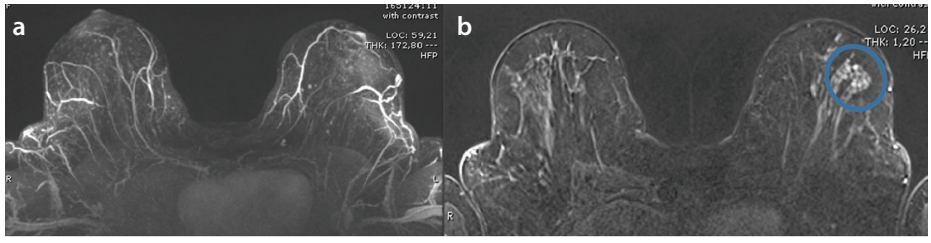

Figure 2. False-negative case, MIP series **(a)** early postcontrast series **(b),** non-mass enhancement, root sign absent, type 2, circumscribed lesion, Kaiser score 2, and BI-RADS 2/3. MIP, maximum intensity projection; BI-RADS, Breast Imaging-Reporting and Data System.

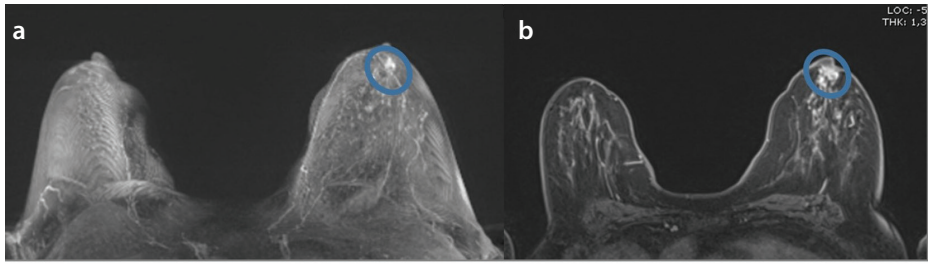

Figure 3. True-positive case, MIP series **(a)**, early postcontrast series **(b)** mass, inhomogeneous enhancement, root sign absent, type 3, Kaiser score 8, and BI-RADS 5. MIP, maximum intensity projection; BI-RADS, Breast Imaging-Reporting and Data System

six of the patients with false-positive results. Radial scars are inherently characterized by irregular contours.[24] In the KS system, scoring begins at six points due to the spiculation positivity commonly observed in radial scars, leading to false-positive outcomes.

Evaluation of the KS descriptors revealed that 11 patients exhibited positive spiculation and contour irregularity. The KS values of all 11 cases ranged from 6 to 11, and 8 of them were upgraded (Figure 4). These findings show that spiculation positivity and contour irregularity are significantly associated with lesion upgrade.

Our study identified three cases with edema, all of which underwent an upgrade. Recent studies have shown that peritumoral edema is associated with poor prognosis.[25] Consequently, the presence of edema may have a high positive value for predicting B3 lesions upgrade.

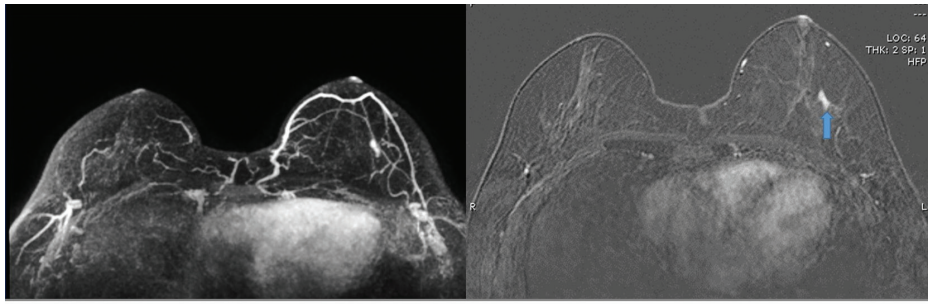

Figure 4. Root sign present, mass lesion, type 2 enhancement, edema absent, Kaiser score 7, and BI-RADS4. BI-RADS, Breast Imaging-Reporting and Data System.

Additionally, the internal enhancement pattern may significantly influence the prediction of lesion upgrade. The inhomogeneous enhancing pattern increased the lesion score from 4 to 8. Significantly, three of these lesions are confirmed true positives.

The acceptance of a 5 KS value for differentiating malignant from benign tumors resulted in an accuracy of 82.89%. Nevertheless, when the cut-off value was set at 7, the specificity (98.3%) improved without significantly reducing accuracy.

The limitations of our study include the heterogeneity of B3 lesion pathologies. The study included a small number of ADH lesions because their exclusion would not have made a statistical difference. The high number of papillomas may be due to the broad MRI indication, which aimed to reduce the risk of papillomatosis and detect cancer in the ipsilateral breast.[26] Furthermore, our study is single-centered and retrospective in design. Additionally, two breast radiologists conducted the KS assessment; however, another limitation is the absence of statistical analysis for inter-reader agreement. This study can be conducted prospectively on specific B3 lesion subgroups.

In conclusion, we speculate that increasing the KS threshold value in future studies with larger sample sizes could help avoid unnecessary surgeries. In conclusion, the KS system demonstrates the ability to predict B3 lesion upgrade accurately.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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