Pathol. Oncol. Res. (2008) 14:123–129
DOI 10.1007/s12253-008-9025-0

ORIGINAL PAPER

Radial Scar-Significant Diagnostic Challenge

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Received: 13 March 2007 / Accepted: 14 December 2007 / Published online: 12 April 2008
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Abstract The prevalence of radial scar (RS) is 0.04% in asymptomatic women participating in population screening for breast cancer. It is important to differentiate RS from concomitant malignancies, which occur in 20–30% of patients, or from small stellate carcinomas which give similar radiomorphology. The aim of our study was to evaluate the effectivity of current breast diagnostic methods in distinguishing between real RS, concomitant malignancy and carcinomas imitating RS. Diagnosis of RS was set up in 61 cases by mammography. Forty-four patients underwent surgical excision: histology showed benign or malignant lesions in 28 and 16 cases, respectively. A series of negative results at follow-up proved the benign nature of the lesion in further 11 cases. Six patients were not available for follow-up. Results of mammography, physical examination, ultrasonography and cytology were evaluated and were compared in 39 benign and 16 malignant cases. Results of examinations were reported on the BI-RADS scale ranging from 1 to 5. The mean categorical scores of all diagnostic processes were around the level of borderline lesions: mammography: 3.49, ultrasonography: 3.06, cytology: 2.47 and physical examination: 1.67. The average age of the patients in the benign and malignant groups were the same: 58years. The two groups did not differ significantly over either distribution of coded mammographical results (p = 0.2092), or the distribution of mammographical parenchyma density patterns (p = 0.4875). However, the malignant and benign groups differed significantly from each other over the distribution of coded ultrasonographic (p = 0.0176) and cytological (p < 0.0001) results. In conclusion, in the preoperative diagnosis of asymptomatic "black-stars", mammography detects the non-palpable lesions, and ultrasonography together with cytology proved better in the analysis, provided FNAB is US guided. Due to the complex diagnostic approach the nature of the "black stars" is known in the majority of cases prior to the surgical biopsy.

Keywords Breast cancer · Mammography · Diagnostic error · Radial scar · "Black star–white star" · Triple test assessment

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Introduction

Since breast cancer constitutes the most common malignancy in women in the industrialised world, finding early breast cancer is in the spotlight of breast screening. During the process of screening, numerous, oncologically irrelevant benign lesions, such as radial scar (RS)/complex sclerosing lesion (CSL) are discovered. The reported prevalence of RS is very low: 0.04% [1], 0.034% [2], RS is regarded by some as premalignant alteration, which is accompanied by malignancy in 10–30% of cases [2], therefore accurate diagnosis is essential. Its appearance on mammograms is similar to the presentation of the most frequent cancers: the star-shaped invasive breast cancer, so differentiation is necessary during the preoperative diag-

nostic processes. The aim of our study was to evaluate whether it is possible to make difference between real RS, RS accompanied by malignancy and malignant lesion that mimics RS by means of usual diagnostic approaches.

Materials and Methods

Study Population

Retrospective analysis of diagnostic processes was performed in 61 cases diagnosed as RS by mammography in the diagnostic laboratory of the MaMMa Clinic from 1 January 1997 to 31 December 2004. We distinguished the group considered malignant based upon histology of the surgically removed lesions from the group of benign growths proven by histology or long-term follow-up. Surgery was performed in 44 cases: histology revealed benign alterations in 28 cases and malignancies in 16 cases, out of which 4 were ductal carcinoma in situ, and 12 were diagnosed as invasive carcinoma—6 invasive ductal, 5 tubular, 1 lobular carcinomas. Although surgery was not carried out because of patients refusal in 11 cases, a series of negative results at follow-up proved the benign nature of the lesion in question. Six patients out of 61 were not available for follow-up, resulting that all together the comparison of 39 benign and 16 malignant cases was performed.

Imaging

In each case the complex examination of the screen detected breast lesion included mammography, physical examination, ultrasonography and cytology.

Mammography Mammography was performed with dedicated equipment (Contour Plus Mammograph (Trex Medical USA).The FUJI AD-Mammo-Fine film-screen cassette system was used with FUJI AD- M films. Films were processed in a Mammoray-Compact E.O.S. daylight machine using extended cycle processing. Each breast was examined in two standard views, (cranio-caudal, mediolateral oblique), and additional views (spot magnifications) were taken when it was necessary for better visualization. Benign "black star" has small radiolucent central core with fine radiolucent lines parallel to dense long spicules. Mammographic findings were categorized on the basis of a five-point rating scale describing the degree of suspicion for malignancy according to the Tabár system [4] and ACR/BI-RADS (Breast Imaging Reporting and Data System of the American College of Radiology) assessment scoring system [5].

Ultrasonography The US examinations were performed using a Diasus-2000 ultrasound system with 7.5–10MHz and 10–22MHz high resolution linear array and Hitachi 4 real-time ultrasound machine equipped with a 7.5MHz linear transducer. Gray-scale US evaluation of breasts and axilla regions were performed. Lesions identified by US were scored on a level of suspicion scale from 1to5. Shape, orientation, echotexture, halo, acoustic attenuation, and architectural distortion were evaluated. US was performed with the knowledge of the clinical and mammographic findings.

Cytology Fine needle aspirations were performed with US-guidance in all cases. Smears, on-site fixed wet and stained with hematoxylin and eosin, were examined by an experienced cytopathologist.

Image Interpretation and Diagnostic Workup

The results of all examinations were coded in the same manner from 1 to 5. 1 means normal tissue or non-diagnostic smear, 2 indicates benign alteration, 3 stands for borderline undefined alteration, 4 is suspicious for malignancy and 5 is definite malignant lesions. This coding provided the possibility of the comparative evaluation of different diagnostic methods and their statistical analysis.

Statistical Analysis

Mann–Whitney *U* test, Pearson Chi-square test, and M-L Chi-square test were used.

Results

Concerning 61 cases diagnosed as RS by mammography, the mean categorical scores of mammography and US were around the level of a borderline alteration: 3.49, 3.06, respectively. Results of cytology and clinical examination showed lower values than the mean categorical score value: 2.47 and 1.67, respectively. Searching for the examination which produces significant differences between the benign and the malignant group, we compared the benign and malignant groups in terms of age, complaints, mammographical characteristics, physical examination, US and cytological findings.

The average age of patients in the two groups was equally 58years. Only 4 cases of 61 reported complaints (6.5%): 3 had palpable mass, 1 had posttraumatic pain. Three out of four proved benign alteration (7.6% of the benign group) and 1 possessed malignant lesion (6.2% of the malignant group). Statistical analysis could not be

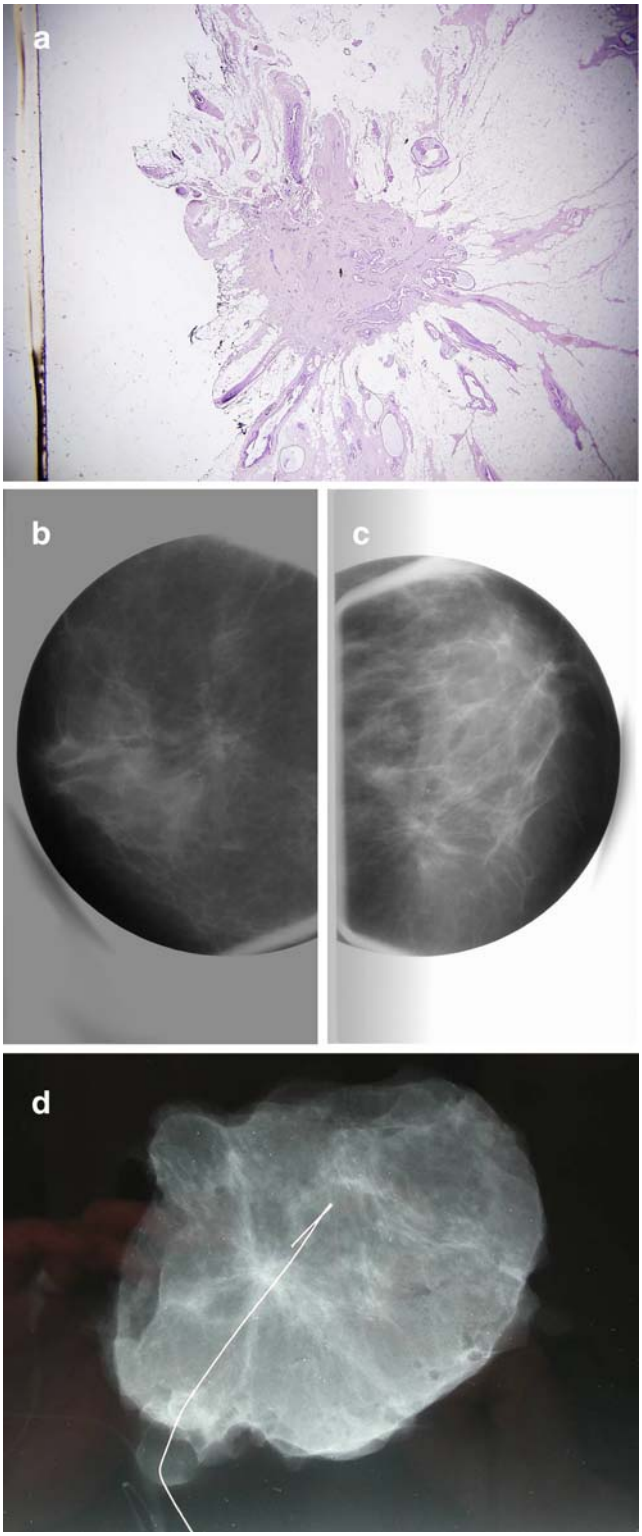

Fig. 1 Double view (**a**. and **b**. picture), hook-wire localised specimen mammogram (**c** picture) and histological image (**d**) of radial scar. Double view image of radial scar demonstrates that its characteristic features including radiolucent core with *long and slender radial spicules* (ábrák a CD-n) mammogram 1=a, mammogram 2=b, specimen=c, M106-01=d

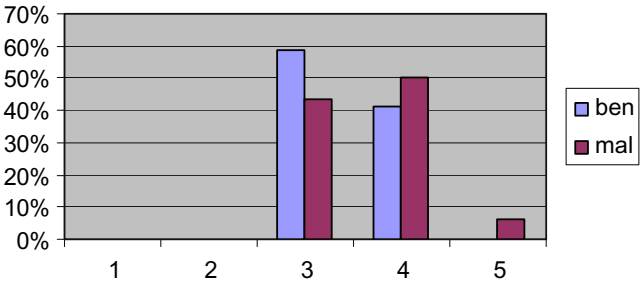

Fig. 2 Distribution of mammographic codes of benign and malignant groups does not show significant differences (p=0.2092 Person Chi-square test, p=0.2042 M-L-Chi-square test)

carried out due to the small number of patients having complaints.

We chose the members of the study population according to the mammogram indicating RS (Fig. 1). The distribution of mammographical codes did not differ significantly in the benign and malignant groups (Fig. 2). Frequencies of the five breast parenchyma types based on parenchyma density and anatomic parenchyma pattern, classified by Tabar, were the same in both groups compared to healthy individuals (Fig. 3). Although the selections of "little black stars" were based upon radiomorphological images, the distribution of ultrasound scores was significantly different in the benign and the malignant groups (Fig. 4).

Cytology proved the most effective process in differentiation between real benign RS and lesions accompanied by histologically malignant alterations. Cytological samples taken by ultrasound-guided fine needle aspiration differ from each other with remarkably significance (Fig. 5).

Discussion

Epidemiology

The RS/CSL is a non-palpable breast lesion in most of the cases, recognised mainly thanks to the wide-spread popu-

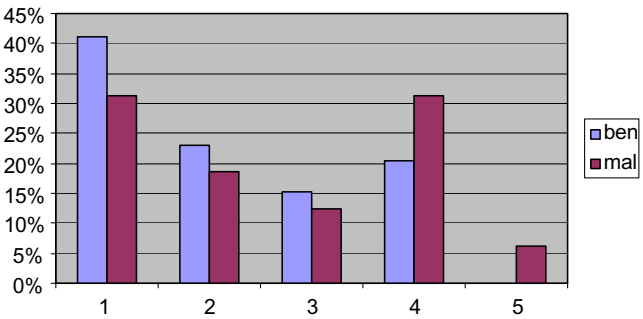

Fig. 3 Distribution of breast types of benign and malignant groups proved no significant difference (p=0.4875 Pearson Chi-square test, p=0.4845 M-L-Chi-square test). Breast types:1=glandular, 2=adiposus, 3=retroareolar fibrotic, 4=adenotic, 5=fibrotic

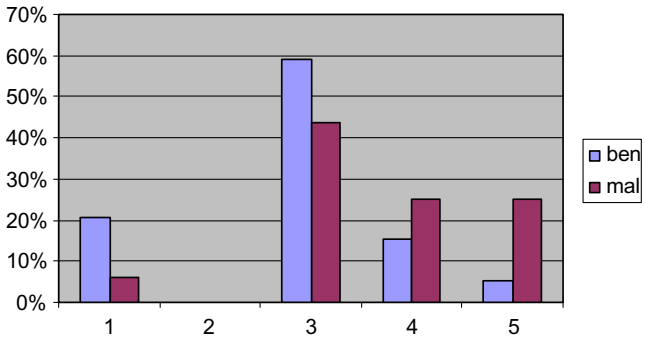

Fig. 4 Distribution of sonographic code in benign and malignant groups: the difference is significant (p=0.0176 Mann Whitney test)

lation screening. Its prevalence confirmed by histology is 0.04% [1], while the prevalence of RS-like entities represented at mammography is 0,072% [7] The almost twofold difference between these two data is explained: 20 to 30% [8], or 40% [9] of lesions suspected as RS by mammography are not real RS-s, but malignancies. The possibility of associated atypical ductal hyperplasia and in situ carcinoma increases parallel to the size of lesion and the age of the patient [10]. RS itself hardly, but its co-existence with atypical hyperplasia considerably increases the risk of subsequent invasive tumor [11]. The prevalence of RS in the pre- and postmenopausal age groups is nearly the same: 52% and 48%, respectively [2].

Pathology

RS is a benign lesion comprising fibroelastotic centre, surrounded by radial bands of proliferating ductal elements. According to post mortem examinations, it is common in the breast and is often accompanied by other benign lesions [12]. The terms of RS and CSL indicate basically the same alteration [13]: the term RS is used in cases of smaller than 10mm and CSL in cases of larger sclerotic lesions, respectively. Mammographical and histological RS-s do not accord well each other. Very small RS-s are only visible microscopically, and remain unrecognisable by mammography. However, according to some authors, RS belonging to any order of magnitude implies a remarkable risk factor for carcinoma [2], and it is presumed to be an independent risk factor of malignant breast diseases [14]. RS may be accompanied by invasive carcinoma, atypical ductal hyperplasia (ADH), atypical lobular hyperplasia (ALH) or in situ carcinoma, although the exact mechanism, the process of development is not entirely classified [15, 16]. A radiological finding of RS may represent malignancy in 30–50% of the cases. The most frequent concomitant malignancy is tubular carcinoma [1, 16, 17, 18], although metaplastic low-grade adenosquamosus carcinoma are sometimes revealed in the background [17]. Pathological comparison of real RS and tubular carcinoma, based on traditional and thick-section examination, showed, that stellate zone consists of epithelial structures in case of RS, while it is composed of fibrovascular bundles in invasive carcinoma Well-differentiated tubular carcinoma has a transitional form between them [19].

Beyond classic pathology, methods of molecular pathology do researches on the difference between benign and malignant alterations, as well as on the link between premalignant and malignant lesions [20]. Proteoglycans, one group of materials having key role in the regulation of proliferation and in the interaction between tumor cell and extracellular matrix, are suitable for revealing tumor dissemination with the view of diagnosis [21, 22].

It is more than interesting, that lack of sialomucin CD34 is characteristic of the stromal fibroblasts in invasive carcinomas, in RS and also reactive fibrosis has similar features [23].

Diagnosis

Radiologically detectable RS is generally asymptomatic, therefore it is often screen-detected. There are two reasons for precise diagnosis: lesions which are potentially precancerous or often accompanied by local malignancy, and entities which are similar to the most frequent, stellate type of invasive carcinoma must be firmly distinguished from real benign RS. On mammogram, 9% of stellate entities are benign RS [15]. Evaluation of 142 RS-s showed that 66% of mammographical RS-s proved to be real RS histologically, 29% are intraductal carcinoma (IDC), and 7% are fibrocystic benign breast disease [8].

Age

According to the literature, the average age of women having malignant lesion simulating RS is significantly higher than the age of women with real RS [8]. In our study we cannot support this statement, since all our

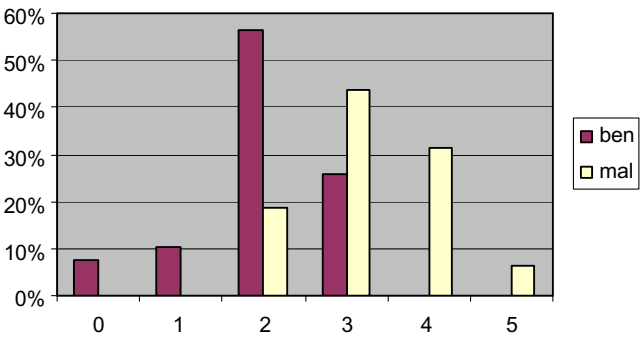

Fig. 5 Distribution of cytological evaluation: The two groups significantly differ over the distribution of "C" codes (p<0.0001 Mann Whitney test)

patients were in the screening age group: every patient was over 50.

Mammography

The dens or radiolucent central core and the length and location of spicules serve as a basis for differentiation of small stellate lesions on mammography. Dens central area larger than 5mm refers to malignancy; pertaining sensitivity and specificity are 84.6% and 73.7%, respectively. The tiny radiolucent central core with long, slender bands of spicules is characteristic of a benign lesion; relating sensitivity is 86.7%, specificity is 61.5% [24]. However, based on other analysis, only 62% of RS presented as "black-star", while 32% of them appeared as small "white-star" with dens central core [25]. The size of spicules extends from 29mm to 50mm, the centres from 5mm to 50mm. The core/spicule proportion spreads in wide interval: between one half and one tenth, but it often cannot be determined due to the dens stroma [25]. In accordance with others we experienced that differential diagnosis based on mammography does not correspond with the histologically confirmed findings due to such a broad spectrum of criteria [26].

The most frequent concomitant malignancy, tubular carcinoma, is a slow-growing, low-grade cancer which is found rarely in its pure form (1.5%) [27]. Its low agressivity is reflected in the fact axillary surgery is needed only in 15% of cases [28]. Induraco DS at al examined tiny tubular carcinomas not larger than 10mm; 80% of those were stellate lesions on mammography, 40% were accompanied by microcalcification [29]. Mitwick analysed the data of 79 tubular carcinoma sized 20mm in average, pertaining sensitivity was 87% [30]. In accordance with the literature data, we didn't find significant difference in our study between the benign and the malignant stellate group at mammography. By the first perception RS got score 3 because its uncertain appearance, in lack of further diagnostic prosec real differentiation was hardly possible. However, it may be appreciated that not one real benign RS got score 5. Neither RS nor malignancy accumulated in any breast type classified by Tabar [6]. Our results suggest that breast types demonstrate the same distributions in patients belonging to either group as compared to healthy individuals.

Size

To achieve an appropriate surgical biopsy, precise measurements of lesion are required to avoid unnecessary normal breast tissue removal. On the other hand, the lesion must be excised in its entirety.

On mammography, the size of RS varies within wide limits, regarding both the size of the core (5–50mm) and the bands (29–50mm) [25]. Often due to the fibrotic, adenotic stroma, i.e. "dens breast" on mammogram, the size of RS cannot be measured accurately, therefore we didn't perform mammographic measurements. On ultrasound, the average size of the lesion in the group of real RS-s and in the malignant group was 8.8mm ± SD 6.9mm and 11.1mm ± SD 5.9mm, respectively The difference is not significant ($p = 0.4074$)

Results of MRI examination are promising regarding size determination. Comparison of MRI and mammography showed that although differentiation between benign and malignant stellate lesions is not perfect on MRI, but measurement of dimensions and borders of lesions is more precise [31]. However, according to other examinations, RS does not accumulate contrast material at MRI; pertaining sensitivity is 83%, specificity is 89% [32]. Nevertheless, contrast enhanced MRI distinguishes benign and malignant stellate lesions better compared to mammography [26].

Ultrasonography

Earlier, RS was not examined by ultrasonography, however, due to the improved imaging qualities of the technique, US differentiated more accurately the normal glandular tissue from cystic and solid lesions. US is substantial in the examination of dens or rather fibrotic breast tissue which can be hardly visualised on mammography, therefore US became a routine method in clinical breast diagnosis. It has an important role in guiding sampling, especially in of RS, when the lesion can be identified only in one projection with X-ray, consequently it cannot be located precisely at mammography [33].

According to literature more than half of the mammographical findings suggestive of RS can be also visualised by US; these borderline lesions often simulate the imaging appearance of malignancy [34]. In our study 14.7% of all lesions examined did not appear on US imaging. 21% of real RS-s—8 cases out of 39—and 6% of small stellate malignancies—1 case out of 16—were not detectable with US. These results correspond with the physical properties of the lesions: US more often is unable to produce image about real RS-s with small fibroelastic core, but shows much better image even in case of tiny malignancy rich in cells. US findings of the benign and the malignant groups differ significantly from each other when coding categories are compared ($p = 0.0176$). This finding is in accordance with others' experience who differentiate between RS and small carcinoma with good result [35].

Cytology

The two widely used preoperative sampling methods—CNB, FNAB—are equally used for examining small stellate lesions. Core needle biopsy is very reliable in case of circumscribed lesions with microcalcification, however,

according to literature data, removal of at least 12 tissue-cylinders is necessary for precise diagnosis of RS accompanied by ADH [40, 41]. Stereotactic core needle biopsy has 85% sensitivity, which allows omission of surgical removal in cases of RS. Consequently, mammographical follow-up itself is enough according to several authors [39]. Although RS does not have any specific cytological feature [36, 25], its sensitivity (67%) and specificity (91%) of cytology makes this method suitable for differentiating between benign and malignant forms [25, 36–38]. Our and others experience proves that this process can be safely used for preoperative diagnosis [3]. The higher sensitivity of the core-biopsy could be explained only by the stereotaxic guidance, which precious, but labor-intensive and time-demanding technique, should be done only in case of US-undetectable lesion. Even so we prefer cytology because of its quickness and simplicity.

Based on comparison of diagnoses on tubular carcinoma and RS, it is established while diagnosis on tubular carcinoma almost always turned out to be right, the correct diagnosis of RS was merely set up in 50% of cases, and overestimation was seen in up to 40% of cases [18]. Using cytophotometric analysis, the nuclear area is larger and there are more aneuploid cells in tubular carcinoma compared to RS [42]. Immunocytochemical demonstration of myoepithelial cells (SMA, p63, CD10, S100) distinguishes the benign and malignant alterations in many cases, although S100 and SMA are not always reliable [36].

Our cytological appraisal revealed that concerning the distribution of cytological codes, real RS-s and the small stellate malignancies imitating RS, differ significantly from each other ($p < 0.0001$). Contrary to published data [3], false negative result did not occur in the malignant group. However, high C3 (undetermined) ratio reflecting the borderline category was experienced in both groups which renders histological examination necessary by all means.

Summary

In conclusion, the asymptomatic real RS-s detected by breast screening, and the group of concomitant malignancy do not differ over mammographical presentation; there are no special parenchyma and density patterns which occurs more frequently in RS-s. However, significantly different appearances of the benign and the malignant groups by ultrasonography and cytology renders differentiation more precise. Because of the excellent cooperation between radiologist, and cytologist in our daily practice we have achieved acceptable level of definite preoperative diagnosis in this borderline, difficult group of screen-detected breast lesions.

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