ORIGINAL ARTICLE

DIAGNOSTIC EFFICACY OF HIGH-RESOLUTION ULTRASOUND IN THE ASSESSMENT OF BREAST IMPLANTS.

Samina Kausar Satti, Adeela Mohyuddin, Qazi Saad Bin Khalid

Department of Radiology, Dallah Hospital Al-Nakheel, Riyadh, Kingdom of Saudi Arabia (KSA).

PJR January - March 2020; 30(1): 12-17

ABSTRACT

OBJECTIVES: To assess retrospectively that ultrasound is an effective diagnostic tool in the imaging of both intact and ruptured breast implants. Magnetic resonance imaging (MRI) was used as the reference method. **STUDY DURATION AND SETTINGS:** Retrospective study was conducted at the Department of Diagnostic Radiology, Dallah hospital, Riyadh, Saudi Arabia. Study duration was 1.6 year (January 2018- June 2019). **MATERIAL AND METHODS:** A sample size of 60 breast implants (total 30 women with bilateral implants) was calculated using the WHO calculator. Ethical approval was taken from the hospital administration. All participants underwent breast US and subsequently MRI examination. Sensitivity, specificity, negative predictive value(NPV) and positive predictive value(PPV) for breast US having MRI as the reference method. Data was analyzed using SPSS version 24. Chi-square and ROC curve analysis was done. p value of ≤0.05 was considered significant. **RESULTS:** Total 60 breast implants were included in the study (30 women with bilateral breast implants). The average age of women was 33.7 years – 5.9SD. Ultrasound findings reported that rupture was intracapsular in 04(6.7%) implants, 1(1.7%) implant had intracapsular & extracapsular rupture with silicone granuloma in the axilla, however, MRI findings revealed that rupture was intracapsular in 8(13.3%) and extracapsular in 1(1.7%) implants. Diagnostic parameters in both groups were sensitivity (94% vs 98%), specificity (55% vs91%), TPV (90% vs 98%), TNV (67% vs 91%) +LR (2.08vs10.8) LR (0.109 vs0.02) in ultrasound and MRI respectively **CONCLUSION:** Ultrasound can be used as the first examination step in breast implant assessment.

Keywords: MRI, Ultrasound, intracapsular, implant rupture, breast augmentation.

Introduction

Breast augmentation is the most common aesthetic surgical procedure performed, worldwide.[1] Breast augmentation has a positive impact on body shaping and imaging. In 1895, Czerny underwent 1st augmentation (transferred a lipoma to breast).[2] Breast implants of silicone gel were introduced by Cronin and Gerow by 1962.[3] Breast implants trend is increasing worldwide the main indication being reconstruction after mastectomy, breast cosmetic augmentation and correction of congenital malformation. A wide variety of breast implants have evolved with saline and silicone gel implants being the most commonly used implants.[4]

Implants rupture is a major reason for implant removal following breast augmentation. Implant rupture is often asymptomatic, without obvious trauma and clinical examination fails to detect it.[1] The exact incidence of breast implant rupture is unknown, although the risk of rupture is directly related to the age of the implant (median lifespan of silicone implant = 10.8 years and is inversely related to the thickness of the elastomer shell.

Correspondence : Dr. Samina Kausar Satti
Department of Radiology,
Dallah Hospital Al-Nakheel,
Riyadh, Kingdom of Saudi Arabia (KSA).
Email: saminasatti@gmail.com

Submitted 24 February 2020, Accepted 13 March 2020

Unlike rupture of a saline implant, which most often occurs in a dramatic fashion and is clinically obvious, silicone implant rupture is frequently asymptomatic and incidentally identified at imaging.[1] Clinical findings, when present, may include changes in breast size or shape, tenderness, a palpable abnormality in the breast or axilla or skin tightening.[8] For these reasons, the diagnosis of implant rupture is based on imaging techniques such as mammography, ultrasound(US) and magnetic resonance imaging (MRI).

The two main categories of breast implant rupture are intracapsular implant rupture and extracapsular implant rupture depending on the location of ruptured silicone with respect to the fibrous capsule.[5] The Intracapsular rupture is the most common type (77-89%).[6] The integrity of the implant is breached in intracapsular rupture, but the fibrous capsule is intact; so the leaked silicone is confined within the fibrous capsule.[8-12] On USG, the intracapsular rupture demonstrates horizontally stacked echogenic lines traversing through the implant interior levels, termed the stepladder sign .Isoechoic silicone may be found between the fibrous capsule and the implant surface, indicative of minimal prosthetic collapse; however, these findings should be confirmed with MRI.[8-12] Ultrasound has a reported sensitivity and specificity, respectively of 50-70 and 55-84% in detecting implant rupture.[1-4] Ultrasonography is used widely for implant rupture detection. Ultrasonography is operator dependent and does not use ionizing radiation.[11]

MRI represents the gold standard for the assessment of implant status and the latest step before the surgery in cases of rupture.[15-17,22] It has a reported sensitivity and specificity of 72 - 94 and 85 - 100 %, respectively The most reliable MR sign of intra-capsular rupture is represented by the linguine sign which consists of curvilinear hypo-intense lines within the hyperintense silicone-filled implant due to the collapse of the implant shell in silicone gel. Other signs of intracapsular rupture are the teardrop sign, keyhole sign, and sub-capsular line sign. In the case of extracapsular implant rupture, MR sequences detect the presence of silicone particles in periprosthetic tissues and in lymph nodes.[15-17,22]

Magnetic resonance imaging (MRI), ultrasonography (US) and mammography are important diagnostic techniques for diagnosing breast implants ruptures. Each technique has its own weaknesses and strengths depending upon the choice of implant patients. Choice of technique depends upon several factors like availability of technique, contraindications, cost of examination and expertise of radiologists.[10]

Limited data is available on diagnostic accuracy of ultrasound in breast implant rupture. Present study aims to assess the diagnostic accuracy of ultrasound in recognizing signs of signs of intra- or extracapsular rupture of silicone breast implants by using the MRI findings as the reference standard.

Material and Methods

This retrospective, single-centre study was conducted at department of Radiology, Dallah Hospital, Riyadh. Study duration was 1 year and 6 months (January 2018- June 2019). Sample size of 30 patients was calculated with confidence interval of 95%, prevalence of rupture 9%,[12] absolute precision of 7% (sample size of 64 implants was rounded off to 60) using WHO calculator (all patients underwent bilateral breast implants). Patients of breast implants were selected through non-probability consecutive sampling. Ethical approval was taken from the ethical review board. Inclusion criterion was based upon women age >18 years, underwent breast implants with bilateral or unilateral augmentation and patients with no comorbidities (Diabetes mellitus, hypertension and cardiovascular disorder). Exclusion criteria were based upon patients contraindicated for MRI and ultrasound, patients with psychological diseases (depression, anxiety), pregnant and breastfeeding women. Patients were undergone through MRI and ultrasound testing. Ultrasound assessment was done with a probe of 13 MHz (Philips Ultrasound System) using radial and antiradical technique. MRI was done with 1.5T MR imaging device (GE MRI), equipped with four channel phased array coil. MRI was performed without contrast medium injection and regardless of menstrual cycle phase. Breast implants were assessed for normal appearance and rupture (intracapsular or extracapsular). Ultrasound was assessed for intracapsular and extracapsular rupture by using the findings of stepladder sign, inhomogeneous echo-texture of implant lumen, snowstorm sign and discontinuity of implant capsule . MRI evaluation of intra and extra capsular findings were based upon

keyhole sign, linguine sign, presence of siliconomas or free silicone particles and teardrop sign.

Data was analyzed using SPSS version 24. Mean and standard deviation were calculated for descriptive data while frequencies/ percentages were calculated for qualitative data. Chi-square test and ROC curve analysis was applied on data. P-value ≤0.05 was considered significant.

Results

Total 60 breast implants among 30 women (bilateral implants) were included in the study. Mean age of women was 33.7 years – 5.9SD. There were 17 (56.7%) patients in the age group 19-40 years and 13 (43.3%) in the age group >40 years. Out of all implants, 48 (80%) were normal, 4(6.7%) right implant rupture, 4 (6.7%) left implant rupture and 4 (6.7%) were ruptured (2 patients with bilateral implant rupture) in ultrasound. In MRI results, 51 (85%) implants were normal, 3 (5%) were right rupture, 2 (3.3%) were left rupture and 4(6.7%) were ruptured (2 patients with bilateral rupture). MRI results also showed that out of all ruptured implants 8(13.3%) were intracapsular, 1 (1.7%) extracapsular, 1 (1.6%) were both intracapsular and extracapsular rupture with silicone granuloma in axilla. However, ultrasound results showed that out of all ruptured implants 4 (6.7%) were intracapsular, 1 (1.7%) with both intra and extracapsular having silicon granuloma in axilla and 2 (6.7%) with bilateral rupture. Clinical signs were present in 7 (23.3%) patients while absent in 23 (76.7%) patients. Among all those patients who had normal breast implant 49 (81.7%), 46 (76.7%) were ultrasound positive and 3(5%) were ultrasound negative. Similarly among all those who had rupture breast implant 11 (18.3%), 51 (8.3%) were ultrasound positive and 6 (10%) were ultrasound negative. Among all those who had normal breast implants 49(81.7%), 48 (80%) were MRI positive while 1 (1.7%) were MRI negative. Out of all patients with ruptured implant 11 (18.3%), 1 (1.7%) were MRI positive and 10 (16.7%) were MRI negative as shown in (Tab. 1).

Diagnostic parameters in both groups were sensitivity (94% vs 98%), specificity (55% vs91%), TPV (90% vs 98%), TNV (67% vs91%) +LR (2.08vs10.8) LR (0.109 vs0.02) in ultrasound and MRI respectively as shown in (Tab. 2).

Ultrasound	Breast Implant		Total	P value
	Normal	Rupture		
Positive	46(76.7%)	5(8.3%)	51(85%)	0.001
Negative	3(5%)	6(10%)	9(15%)	
MRI				
Positive	48(80%)	1(1.7%)	49(81.7%)	0.000
Negative	1(1.7%)	10(16.7%)	11(18.3%)	
Total	49(81.7%)	11(18.3%)	60(100%)	

Table 1: Association between breast implant rupture, ultrasound and MRI

Diagnostic parameters	Ultrasound	MRI
Sensitivity	94%	98%
Specificity	55%	91%
True positive value (TPV)	90%	98%
True negative value (TNV)	67%	91%
Positive likelihood ratio (+LR)	2.08	10.8
Negative Likelihood Ratio (_LR)	0.109	0.02

Table 2: Diagnostic accuracy of ultrasound and MRI

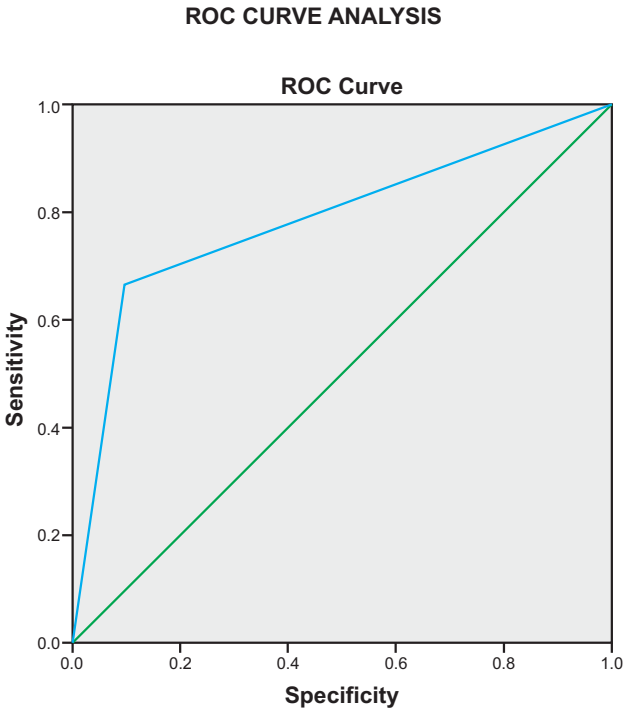

Figure 1(A): Ultrasound ROC curve

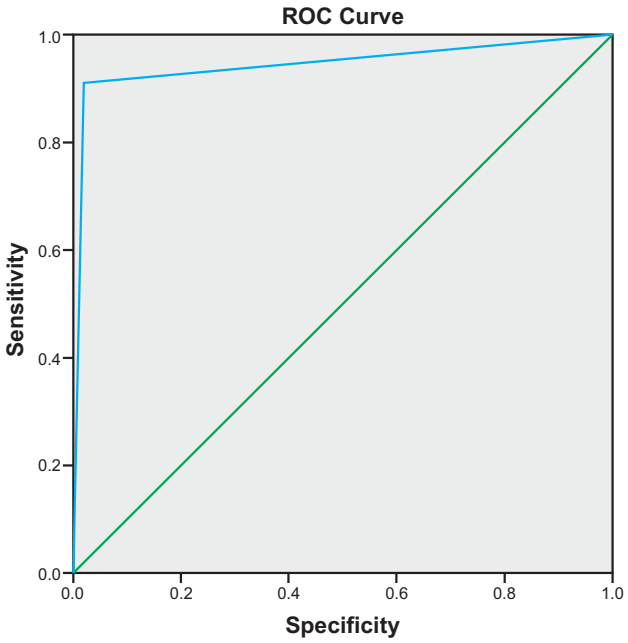

Figure 1(B): MRI ROC curve

Figure 2: Ultrasound breast demonstrating snow storm appearance of axillary lymph node representing silicone infiltration due to extracapsular rupture. Multiple intraluminal membranes represent intracapsular rupture.
MRI confirms both extracapsular and intracapsular rupture of silicone implants. Ultrasound Images demonstrate how the snow storm appearance makes ultrasound highly sensitive for the diagnosis of extracapsular rupture.

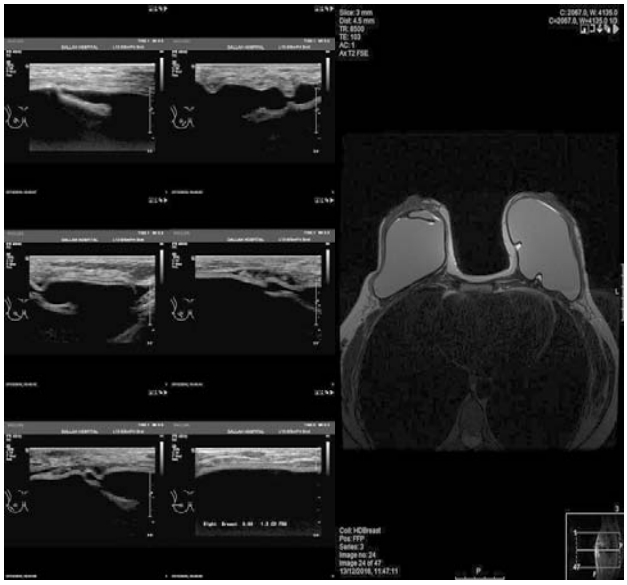

Figure 3: Ultrasound breast showing subcapsular fluid and intraluminal membrane due to intracapsular rupture.
MRI confirms the findings of ultrasound.

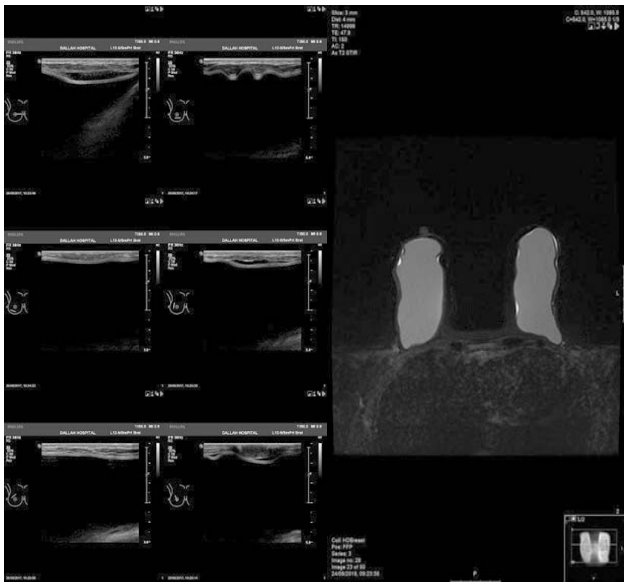

Figure 4: False positive case due to reverberation artifact mimicking an intracapsular intracapsular rupture.
No rupture seen on MRI.

Discussion

Most breast implant rupture patients do not manifest clinically significant signs or symptoms.[7,8] Ultrasound and MRI are widely accepted as the imaging studies of choice to definitively evaluate the implant integrity with a sensitivity and specificity of greater than 90% in evaluating implant rupture.[19,22] Limitations of MRI

include expense, need for scanners with specific breast coil technology, time to complete study and patient limitations due to other medical implants.

Ultrasound represents a valid tool and first-level technique for evaluating implant integrity. It is cheap, easily available, however, it is an operator-dependent diagnostic study.[14,15,22] In a cost analysis comparison between ultrasound and MRI for screening for implant rupture, ultrasound was found to be significantly more cost-effective in both symptomatic and asymptomatic women with breast implants.

In the present study, MRI and ultrasound findings showed intra and extracapsular (6.7% vs 13.3%, 0% vs 1.7% respectively) rupture of the implant. Moschetta et al reported that out of 22 women 19 showed linguine signs and 3 showed keyhole signs on MRI assessment.[16] Majjers et al reported that under ultrasound examination 65% women had intracapsular and 35% had extracapsular rupture.[17]

In present study ultrasound showed 94% sensitivity and 55% specificity, TPV 90%, TNV 67%, + LR 2.08 and - LR 0.109. Bassetti et al reported that overall diagnostic parameters for ultrasound in breast implant rupture women was 79%, 63%, 70%, 65% and 77% sensitivity, specificity, accuracy, PPV and NPV respectively.[18] Another similar study reported that pooled sensitivity and specificity for ultrasound was 60.8% and 76.3%.[19]

In present study, MRI showed sensitivity, specificity, TPV, TNV and accuracy was 98%, 91%, 98%, 91% and 94% respectively. Cher et al reported that MRI showed 85% sensitivity, 90% specificity, 81% positive predictive value and 92% negative predictive values in symptomatic women while 78% sensitivity, 71% specificity, 20% positive predictive values and 97% negative predictive values.[20] Spear et al reported that diagnostic odds ratio, overall diagnostic test performance was 14 times higher with MRI in symptomatic patients as compared asymptomatic patients (sensitivity 87% specificity 89.9%).[21]

Limitations: our study has some limitations mainly due to small sample size, single center study, and inclusion of symptomatic patients.

Conclusion

Ultrasound can be used as the first examination in the follow up of patients with breast implants. The US detection of intracapsular rupture requires further evaluation by means of MRI which represents the most sensitive technique in this field. In the case of extracapsular rupture US diagnosis, surgical implant removal could be proposed without further investigation.

Conflict of Interest: None

References

1. Juanpere S, Perez E, Huc O. Imaging of breast implants-a pictorial review. Insights Imaging. 2011; **2(6):** 653-70.

2. Frank S, Mahdi R, Sherko K. Imaging in patients with breast implants-results of the First International Breast (Implant) Conference 2009. Insights Imaging. 2010; **1(2):** 93-7.

3. Colombo G, Ruvolo V, Stifanese R. Prosthetic breast implant rupture: imaging-pictorial essay. Aesthetic Plast Surg. 2011; **35(5):** 891-900.

4. Yang N, Muradali D. The augmented breast: a pictorial review of the abnormal and unusual. Am J Roentgenol. 2011; **196(4):** W451-60.

5. Brown SL, Middleton MS, Berg WA, Soo MS, Pennello G. Prevalence of rupture of silicone gel breast implants revealed on MR imaging in a population of women in Birmingham, Alabama. AJR 2000; **175:** 1057-64.

6. H Imich LR, H Imich LR, Friis S. Incidence of silicone breast implant rupture. Arch Surg. 2003; **138(7):** 801-6.

7. H Imich LR, Vejborg IM, Conrad C. The diagnosis of breast implant rupture: MRI findings compared with findings at explantation. Eur J Radiol. 2015; **53(2):** 213-25.

8. H Imich LR, Vejborg IM, Conrad C. Untreated silicone breast implant rupture. Plast Reconstr Surg. 2014; **114(3):** 204-14.

9. Herborn CU, Marincek B, Erfmann D. Breast augmentation and reconstructive surgery: MR imaging of implant rupture and malignancy. Eur Radiol. 2012; **12(3):** 2198-206.

10. Tark KC, Jeong HS, Roh TS. Analysis of 30 breast implant rupture cases. Aesthetic Plast Surg. 2015; **29(3):** 460-9.

11. Gorczyca DP, Gorczyca SM, Gorczyca KL. The diagnosis of silicone breast implant rupture. Plast Reconstr Surg. 2017; **120(1):** 49S-61S.

12. Glynn C, Litherland J. Imaging breast augmentation and reconstruction. Br J Radiol. 2008; **81(2):** 587-95.

13. Berg WA, Berg WA, Nguyen TK. MR imaging of extracapsular silicone from breast implants: diagnostic pitfalls. Am J Roentgenol. 2012; **178(4):** 465-72.

14. Handel N. The effect of silicone implants on the diagnosis, prognosis, and treatment of breast cancer. Plast Reconstr Surg. 2017; **120(1):** 81S-93S.

15. Di Benedetto G, Cecchini S, Grassetti L. Comparative study of breast implant rupture using mammography, sonography, and magnetic resonance imaging: correlation with surgical findings. Breast J. 2018; **14(3):** 532-7.

16. Moschetta M, Telegrafo M, Capuano G. Intraprosthetic breast MR virtual navigation: a preliminary study for a new evaluation of silicone breast implants. Magn Reson Imaging. 2013; **31(8):** 1292-7.

17. Maijers MC, Niessen FB. Prevalence of rupture in poly implant prothŁse silicone breast implants, recalled from the European market in 2010. Plast Reconstr Surg. 2012; **129(6):** 1372-8.

18. Bassetti E, Pediconi F, Luciani ML. Breast prosthesis: management of patients after plastic surgery. J Ultrasound. 2011; **14(3):** 113-21.

19. Song JW, Kim HM, Bellfi LT, Chung KC. The effect of study design biases on the diagnostic accuracy of magnetic resonance imaging for detecting silicone breast implant ruptures: a meta-analysis. Plast Reconstr Surg. 2011; **127(3):** 1029-44.

20. Cher DJ, Conwell JA, Mandel JS. MRI for detecting silicone breast implant rupture: meta-analysis and implications. Ann Plast Surg. 2011; **47(4):** 367-80.

21. Spear SL, Murphy DK, Slicton A, Walker PS. Inamed silicone breast implant core study results at 6 years. Plast Reconstr Surg. 2017; **120(7-1):** 8S-16S.

22. Lindenblatt N, El-Rabadi K, Helbich TH, Czembirek H, Deutinger M, Benditte-Klepetko H. Correlation between MRI results and intraoperative findings in patients with silicone breast implants. Int J Womens Health 2014; **6:** 703-9.