Evaluation of techniques for detecting breast implant rupture

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Evaluation of techniques for detecting breast implant rupture

Report prepared for AETMIS
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FOREWORD

EVALUATION OF TECHNIQUES FOR DETECTING BREAST IMPLANT RUPTURE

Over the past few years, the safety of silicone gel-filled breast implants has raised a great deal of concern among women, for study reports have suggested a link between such implants and the occurrence of local and systemic complications. Because of this potential health risk, the sale of these implants was halted, even if the toxicity of silicone has not been demonstrated by scientific data. The most frequent local complication is implant shell rupture, which results in exposure of the body to silicone and in a loss of esthetics.

Several imaging techniques are capable of detecting breast implant rupture, but their efficacy, cost and accessibility vary considerably. This being the case, the Québec Minister of Health and Social Services asked the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) to evaluate the efficacy of mammography in detecting breast implant rupture and to assess the potential risks associated with this technique in order to determine if they warrant the use of an alternative method, such as magnetic resonance imaging (MRI).

AETMIS closely examined several recent reports on the detection of breast implant rupture and analyzed published studies postdating these reports. Like other assessment organizations, AETMIS notes that, based on the current state of knowledge, instituting a breast implant rupture screening program cannot be justified. Furthermore, the scientific data do not show that the breast compression required during mammography causes implant rupture, although it can, at the very most, exacerbate an acquired or existing defect.

To issue recommendations concerning the detection of breast implant rupture, one must, on the one hand, examine the efficacy, accessibility and cost of the imaging techniques that are normally used, i.e., mammography, ultrasonography and MRI, and, on the other hand, establish that silicone has no toxic effects. In light of these criteria, AETMIS recommends a mammographic examination followed by a breast ultrasound as the first-line strategy in all cases where implant rupture is suspected on clinical examination. MRI should be reserved for those cases where the results of these two techniques are equivocal or suspicious or when the results of the clinical and radiological examinations are discordant.

In disseminating this report, AETMIS wishes to provide the best possible information to the policymakers concerned by this issue in Québec's health-care system.

Renaldo N. Battista
President and Chief Executive Officer

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SUMMARY

Introduction

Breast implants are used for breast reconstruction after mastectomy or an accident, for correcting congenital malformations, such as breast aplasia, hypoplasia or asymmetry, and for breast augmentation for cosmetic purposes. Up until 1991, most breast implants consisted of a strong silicone shell containing silicone gel. Although the scientific data do not show silicone to be toxic, the potential health risks associated with silicone breast implants led to the voluntary withdrawal of these products from the market and to a moratorium being imposed on their use in Canada and the United States. This moratorium, which was adopted in January 1992, is still in effect.

Silicone implants have been associated with local and systemic complications. The most frequent local complication is implant shell rupture, which results in exposure of the body to silicone and in a loss of esthetics. Breast implant rupture can be detected by mammography, ultrasonography and magnetic resonance imaging (MRI). The purpose of this report, which stems from a request by the Minister of Health and Social Services, is to examine the efficacy of mammography in detecting implant rupture and the potential risks associated with this technique, in order to determine if these risks justify the use of an alternative imaging modality, such as MRI.

Methodology

This report examines published scientific data and bases itself mainly on the conclusions of reports published by the following three organizations: the Agence Nationale d'Accréditation et d'Évaluation en Santé, formerly the Agence Nationale pour le Développement de l'Évaluation Médicale (ANDEM), the Independent Review Group (IRG) in the United Kingdom and the Institute of Medicine (IOM) in the United States. The recentness of these reports, the extent and quality of the resources used to prepare them, the exhaustiveness of the studies examined and the rigour of the analyses performed guarantee the validity of these organizations' conclusions. This detailed examination of the reports was supplemented by an analysis of studies published between January 1999 and August 2001. Lastly, we documented the current practice in Québec by consulting health professionals.

Breast implant integrity

Implant rupture consists of a tear in the shell, which results in the extravasation of the silicone gel into the fibrous capsule (intracapsular rupture) or into the surrounding tissues (extracapsular rupture). Intracapsular rupture, which is the more frequent type, is usually asymptomatic, is undetectable on clinical examination and mammography, and does not cause any breast deformity. There is no consensus as to the indication for implant removal in such cases. Extracapsular rupture, which is a much rarer occurrence, results in the silicone spreading into the breast tissues or distantly into the thoracic cavity, upper limbs or pelvic region, causing breast deformity and a loss of esthetics. This type of rupture constitutes an indication for removal.

The prevalence of rupture depends on the type and model of implant, the implant's physical characteristics, the quality of the shell, and other factors, such as trauma, the compression used during capsulotomy, and wear and aging of the implant. Breast compression during mammography has been suggested as a possible cause of rupture, but the link between mammography and breast implant rupture is not supported by scientific data. However, mammography could exacerbate a

preexisting defect or cause an intracapsular rupture to become extracapsular.

Breast implants and breast imaging

Evaluating implant integrity

The diagnostic techniques assessed in this report are mammography, ultrasonography and MRI. A literature search only revealed case series in which the reference test was surgery and which met preestablished criteria. The series were small and included women whose implants were removed for various reasons, such as the presence of symptoms of rupture or other symptoms that could be due to implants, or for personal reasons. It is difficult to compare and interpret the results of these studies, since they do not always make a distinction between rupture, silicone bleed and silicone extravasation.

Mammography

Mammography is a relatively inexpensive and easily accessible radiological examination technique. A good number of women of various ages, some with and some without breast implants, are undergoing mammography in the Québec Breast Cancer Screening Program or, outside this program, for diagnostic purposes. Mammography is very sensitive in detecting extracapsular ruptures, which account for 10 to 20% of all ruptures, but it is not very sensitive in detecting intracapsular ruptures, which are more frequent and clinically silent. With a specificity of 97%, mammography yields few false-positive results and thus poses a smaller risk of unnecessary implant removal. It does pose a small risk of ionizing radiation exposure, especially in young women, but this risk is very small, thanks to the new techniques being used. The possibility of an implant rupturing due to breast compression has not been demonstrated, although this could happen with implants with preexisting defects.

Ultrasonography

Ultrasonography is a relatively inexpensive and easily accessible examination technique. It has an average sensitivity of 55% (range: 25 to 100%, depending on the study) and an average specificity of 77% (range: 50 to 92%, depending on the report). Ultrasonography can detect both intracapsular and extracapsular ruptures. Rupture detectability depends on the operator's experience and the instrument's technical quality. Ultrasound does not involve any type of radiation. Hence, there is no associated risk for women.

Magnetic resonance imaging

MRI is a sensitive (average of 77%) and specific (average of 94%) examination technique. It has the ability to detect both intracapsular and extracapsular ruptures. However, it is expensive and time-consuming. The fact that the scanners are less accessible and the resulting long waiting lists are major obstacles to the broader use of MRI. MRI requires the use of breast coils, which are dedicated surface coils. The use of this exploratory technique is contraindicated in women with a pacemaker, an aneurysm clip or other metallic foreign object and in women with claustrophobia.

Choice of technique

Based on the results presented and on the recommendations by several organizations and authors, systematic breast implant rupture screening cannot be recommended. In certain cases, a clinical examination performed by an experienced physician may suffice to determine if a defective implant

should be removed. The use of detection techniques should be limited to cases where an implant is presumed to have ruptured. The technique of choice should be that with the best sensitivity (so that true cases of rupture are not missed) and the best specificity (to avoid false positives and unnecessary removal). However, other factors need to be considered, such as the cost of the examination, the availability of the technology in the community, the experience of the professionals who will be performing and interpreting the examination, and the technique's complications and limitations. It is also important to note the lack of consensus regarding the indication for removal in cases of intracapsular rupture and the adverse esthetic consequences of removing an implant.

Given the foregoing and the current state of knowledge regarding the efficacy of techniques for evaluating breast implant integrity, mammography and ultrasonography should be performed first when there are clinical signs or a presumption of breast implant rupture. MRI should be used to confirm the diagnosis when the mammography and ultrasonography results are equivocal or suspicious or when they do not agree with the findings of the clinical examination.

Conclusions and recommendation

In light of the scientific data examined in this report, AETMIS draws the following conclusions:

Conclusions

- The current state of knowledge reveals a lack of scientific data demonstrating the toxicity of silicone breast implants or the adverse health effects of silicone in women. This said, breast implant rupture is a local complication that has mainly esthetic consequences. However, if silicone turns out to be toxic to women, research should focus on the very use of breast implants rather than on implant rupture, for it is recognized that silicone migrates by sweating, even from intact implants, and that an implant shell is a source of silicone exposure.
- For now, published study reports do not provide explicit justification for setting up a program for implant rupture screening in asymptomatic women, since most of these studies involved women in whom the likelihood of rupture was high.
- Few studies have examined the role of mammography in iatrogenic implant rupture. The compression required during mammography could exacerbate a preexisting defect or cause an intracapsular rupture to become extracapsular, without constituting the primary cause of the rupture.
- The utility of MRI seems to reside in better detection of intracapsular rupture. However, such ruptures are generally asymptomatic, and there is no consensus regarding the indication for removal.
- Since MRI is slightly less specific than mammography in detecting extracapsular rupture, its use could result in the removal of intact implants. Yet, the risks and adverse esthetic consequences of this procedure could be worse than those associated with keeping the implant in place, despite an intracapsular rupture.
- MRI is an expensive technique, and in Québec, time on the waiting list for MRI is at least one year. On the other hand,

mammography and ultrasonography are accessible screening tools and are already being used by the vast majority of the women in the Québec Breast Cancer Screening Program or, outside this program, for diagnostic purposes.

Recommandation

- Given the data on the efficacy and accessibility of the different techniques, AETMIS believes that, if there is a clinical presumption of rupture, the course of action should be modeled on the one which is detailed in the algorithm proposed by Samuels and colleagues and which is embraced by the IOM. A mammographic examination followed by a breast ultrasound is the recommended strategy of first recourse. If the results of these two examinations are normal, it is advisable to provide a clinical follow-up. If either of these examinations reveals an extracapsular rupture, the implant is removed. If the results of these examinations reveal an intracapsular rupture, some women may choose to keep their implants and to undergo a periodic clinical follow-up. Lastly, if the results are equivocal or suspicious or do not agree with the findings of the clinical examination, MRI is performed.

GLOSSARY

Accuracy:
Sum of the true positives (TP) and true negatives (TN) divided by the total number of implants examined. Formula: (TP + TN)/(TP + FP +TN + FN).

Adjuvant:
A preparation which, when administered at the same time as an antigen, increases the immune response to the antigen.

Axillary adenopathy:
Acute or chronic inflammation of the lymph nodes in the axillary fossa.

Breast coil:
A surface coil used in magnetic resonance imaging of the breast. There are double breast coils for imaging both breasts simultaneously.

Capsular contracture:
Prolonged contraction of the capsule surrounding an implant.

Capsule:
The fibrous membrane consisting of dense connective tissue surrounding an implant. It can be supple or hard and tough. It can present with visible calcifications on mammography or computed tomography [Gorczyca et al., 1997; IOM, 2000].

Capsulotomy:
Loosening of the periprosthetic capsule through external maneuvers (closed capsulotomy) or surgical intervention (open capsulotomy).

Case series:
A descriptive study without a comparison group.

Cohort study:
A study conducted without a comparison group and in which the subjects are selected on the basis of one or more characteristics and followed over time to measure the effects of those characteristics.

Elastomer:
A synthetic polymer with the properties of natural rubber, such as high extensibility and elastic recovery capability.

Excision:
Surgical removal of an organ, tumor or foreign object.

Extracapsular rupture:
A tear in the shell and the fibrous capsule surrounding an implant, with extravasation of the silicone gel into the surrounding tissues [Gorczyca et al., 1997].

Extravasation:
The effusion of a fluid outside of the vessels or organs that normally contain it.

False-negative rate:
The proportion of negative results (FN) yielded by a test in individuals with the disease. Formula: 1- sensitivity.

False-positive rate:
The proportion positive results (FP) yielded by a test in individuals without the disease. Formula: 1- specificity.

Gel bleed:
Microscopic diffusion of fluid silicone (oil or gel) through the intact shell of a silicone gel-filled implant. Gel bleed does not constitute rupture.

Iatrogenic rupture:
Rupture of a prosthesis caused by a physician or by medical treatment.

Intracapsular rupture:
A tear in an implant shell without extravasation of the silicone gel into the surrounding tissues, since the gel remains within the intact fibrous capsule [Gorczyca et al., 1997].

Mammary parenchyma:
The functional tissue of the mammary gland.

Negative predictive value (NPV):
The probability of not having the disease if the result of the test is negative. Formula: TN/(TN + FN).

Periprosthetic:
Situated around a prosthesis.

Positive predictive value (PPV):
The probability of having the disease if the result of the test is positive.
Formula: TP/(TP + FP).

Prosthetic:
Relating to a prosthesis, its use or its application.

Sensitivity:
The proportion of true positives (TP) in individuals with the disease.
Formula: TP/(TP + FN).

Shell:
Semipermeable membrane of variable thickness that contains silicone gel and gives the augmented breast a natural appearance and contour. It is made of silicone polymers, which give it its elasticity [Gorczyca et al., 1997].

Silicone:
A generic name given to silicium compounds containing oxygen atoms and organic groups. These compounds can exist in various forms, such as oils, resines and elastomers.

Specificity:
The proportion of true-negative results (TN) in individuals without the disease.
Formula: TN/(TN + FP).

LIST OF ABBREVIATIONS

A:	Accuracy
ANDEM:	Agence Nationale pour le Développement de l'Évaluation Médicale, a French agency renamed *Agence Nationale d'Accréditation et d'Évaluation en Santé* (ANAES)
CC:	Capsular contracture
CI:	Confidence interval
FDA:	Food and Drug Administration (U.S.)
FSE:	Fast spin echo
IOM:	Institute of Medicine (U.S.)
IRG:	Independent Review Group (United Kingdom)
MDA:	Medical Devices Agency (United Kingdom)
MRI:	Magnetic resonance imaging
NPV:	Negative predictive value
PPV:	Positive predictive value
QBCSP:	Québec Breast Cancer Screening Program
RAMQ:	Régie de l'assurance maladie du Québec (Québec, Canada)
RR:	Relative risk
Sn:	Sensitivity
Sp:	Specificity
TN:	True negative
TP:	True positive