Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2018/027 Issued: 26 July 2018 at 11:00

Breast implants, all types, makes and models – Continue to report suspected cases of Breast Implant Associated - Anaplastic Large Cell Lymphoma (BIA - ALCL)

Summary

UK update on BIA-ALCL

Action

- Report all suspected cases of BIA-ALCL in patients who have had breast implants or who have had them removed, to MHRA (for cases occurring in England and Wales) to NIAIC (if in Northern Ireland) or to IRIC (if in Scotland). Where known, please provide as much information as possible in the report, including, details of the breast implant at diagnosis and any previous implants, diagnostic criteria (including CD30 and ALK status), treatment and outcome. You should also report directly to manufacturers if your national system does not.
- Continue to strongly encourage patients to self-examine their breasts and axillae (underarms) for any changes such as lumps, swellings or distortions and to consult their implanting surgeon or GP if they have any concerns.
- Clinicians should discuss the potential risk of BIA-ALCL when consenting new patients, and with any patient returning for review of their breast implants. There is no indication for any routine action in the form of explantation or regular imaging.
- If you are contacted by asymptomatic patients concerned about this issue, they can be reassured BIA-ALCL remains a rare form of cancer which can be successfully treated when detected at an early stage.
- If you are a patient reading this and have concerns about BIA-ALCL please speak to your healthcare professional.

Action by

- Directors of surgical units involved in breast reconstruction and augmentation.
- Medical directors.
- Plastic surgeons and all surgeons involved in breast reconstruction and augmentation.
- Nurse executive directors.
- Specialist nurses involved in breast cancer care.
- Radiation & medical oncology departments
- General practitioners (for information only).

Deadlines for actions

Actions underway: 09 August 2018
Actions complete: 06 September 2018

Department of Health An Roinn Sláinte Männystrie O Poustie www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Background

Anaplastic Large Cell Lymphoma (ALCL) is a rare type of non-Hodgkin's lymphoma of which there are several subtypes. In 2016 the World Health Organisation (WHO) defined a specific provisional type of ALCL called Breast Implant-Associated ALCL (BIA-ALCL). The provisional entity has been widely clinically accepted as a definitive definition.

MHRA is issuing this updated alert to further encourage healthcare professionals to continue reporting suspected cases of BIA-ALCL.

Since publishing MDAs in 2011 and 2014, encouraging healthcare professionals to report cases of anaplastic large cell lymphoma (ALCL) in patients with breast implants, MHRA has received 48 reports of BIA-ALCL in the UK, 40 of which meet the WHO diagnostic criteria. There have also been more cases reported worldwide since publication of the WHO definition. In the UK, the estimated risk of BIA-ALCL, based on the reported confirmed cases is 1 per 28,000 implants sold. This estimate is based on data for all types of breast implants known to be sold in the UK and reported cases of BIA-ALCL confirmed to meet the WHO criteria until December 2017. This is an estimate as some cases may not have been reported to the manufacturer or to MHRA during this period, additionally all devices known to be sold in the UK may not have been implanted.

MHRA continues to review adverse event reports and current literature to build a more accurate picture of the occurrence of this rare disease in association with breast implants.

In 2017 the European Scientific Committee on Health Environmental and Emerging Risks (SCHEER) published a report which concluded there is currently insufficient scientific information available to perform a methodologically robust risk assessment on a possible association of breast implants with the development of ALCL. However, worldwide research is continuing and there are a number of competing theories as to the aetiology. The current evidence indicates those with breast implants have a very low, but increased risk of developing BIA-ALCL.

MHRA's independent expert advisory group, the Plastic, Reconstructive and Aesthetic Surgery Expert Advisory Group (PRASEAG), is reviewing risks associated with BIA-ALCL. The group advises that clinicians should discuss the potential risk of BIA-ALCL when consenting new patients. If diagnosed early, BIA-ALCL can be successfully treated, usually with surgery alone, and there is no indication for any routine action in the form of explantation or regular imaging.

MHRA has published a webpage with background information and case numbers which is updated regularly. A joint statement on BIA-ALCL has also been issued by the British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS), the Association of Breast Surgeons (ABS) and the British Association of Aesthetic Plastic Surgeons (BAAPS) and MHRA, this is available on a dedicated webpage. Future updates on case numbers will be also be added to the dedicated BIA-ALCL webpage; if further regulatory action is needed an MDA will be issued.

All breast implant procedures should continue to be submitted to the Breast and Cosmetic Implant Registry (BCIR).

Note: The recommendations in this Medical Device Alert (MDA) replace the advice previously given in MDA/2011/017 and MDA/2014/027.

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

CAS and NICAS liaison officers for onward distribution to all relevant staff including:

- Clinical pathologists
- Clinical pathology directors
- Directors of surgical units involved in breast reconstruction or augmentation
- Directors of surgical units involved in breast reconstruction or augmentation
- Haematologists
- Medical directors
- Medical oncologists
- Medical oncology, directors of
- Nursing executive directors
- Plastic surgeons and all surgeons involved in breast reconstruction or augmentation
- Radiation & medical oncology departments
- Radiation oncologists
- Radiation oncology, directors of
- Radiology departments
- Specialist nurses involved in breast cancer care

NHS England area teams

CAS liaison officers for onward distribution to all relevant staff including:

- General practitioners

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2018/027** or **2018/007/009/264/001**.

Technical aspects

Customer services, MHRA

Tel: 020 3080 6000

Email: info@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

Reporting adverse incidents in England
Through Yellow Card https://yellowcard.mhra.gov.uk/

Northern Ireland
Alerts in Northern Ireland are distributed via the NICAS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre, CMO Group,
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk
https://www.health-ni.gov.uk/niaic

Reporting adverse incidents in Northern Ireland
Please report directly to NIAIC using the forms on our website.

Scotland
Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre, Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

Reporting adverse incidents in Scotland

NHS Boards and Local Authorities in Scotland – report to Health Facilities Scotland.

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to Health Facilities Scotland.

Private facilities providing care to private clients report to the Care Inspectorate and MHRA.

Wales
Enquiries in Wales should be addressed to:
Healthcare Quality Division, Welsh Government

Tel: 02920 823 624 / 02920 825 510

Email: Haz-Aic@wales.gsi.gov.uk

Reporting adverse incidents in Wales
Report to MHRA through Yellow Card https://yellowcard.mhra.gov.uk/ and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).