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***Maternal Audit on ThRombosis Outcome and DecisioN***

Background

The Confidential Enquiry into Maternal Deaths has highlighted that thrombosis and thromboembolism were the most common causes of direct maternal death in UK and Ireland during the years 2013–2015, a trend that has not changed in subsequent reports up to 2023(1).

Prevalence of pulmonary embolism (PE) in pregnant women is reported between 2 and 7%(2), with high-risk PE carrying an elevated mortality up to 37%(3).

Systemic thrombolysis is efficacious and superior to heparin in the context of pulmonary embolism (PE) with haemodynamic instability(4-8) with relatively low rates of maternal and foetal complications(9-11); however, it remains an underused and often last resort option in clinical practice(12) due to concerns regarding haemorrhagic complications, especially uterine bleeding.

The evidence available to support decision-making in the context of high risk/intermediate high-risk PE in pregnancy is affected by heterogeneous clinical reports and absence of randomised clinical trials(13).

In 2019, the ISTH launched an international registry to collect information on high-risk PE and its treatment in pregnancy and the post-partum period, which is currently ongoing (14). Value of medical registries is exceptional in the context of rare and emerging diseases. But global registries can face several challenges which have been highlighted recently.

One of the key issues faced by global registries has been the difference in legal ethical frameworks and data sharing between countries resulting in significant time delays.

In the Women’s Health Strategy, the Department of Health and Social Care has clearly set out to address the lack of research into women’s health conditions, with pregnancy-related health issues being one of the top priorities highlighted in their [call for evidence public survey.](https://www.gov.uk/government/consultations/womens-health-strategy-call-for-evidence/outcome/results-of-the-womens-health-strategy-call-for-evidence-written-responses-from-organisations-and-experts)

In the context of this national and international strive for better evidence and improved maternal outcomes, we wish to perform a comprehensive pan-UK assessment of current management of high-risk and intermediate high-risk PE in pregnancy and puerperium.

Aims

1. To assess current management of high-risk/intermediate high-risk PE during pregnancy and puerperium in the UK and whether this adheres to RCOG guidelines.
2. To assess obstetric and foetal outcomes post high-risk/intermediate high-risk PE.

Methods

This a multi-centre audit. It is a collaboration between the HaemSTAR and UKARCOG, the trainee research networks for haematology and obstetrics and gynaecology, respectively.

Local audit approval will be sought in each trust enrolled in the data collection.

Regional coordinators from each network will identify suitable trainees to input data from different NHS trusts across their area. The capillary distribution of the HaemSTAR network will allow rapid data gathering in a “flash-mob” fashion, already proven successful in other HaemSTAR projects (e.g., ITP-IVIg, TTP, RAPIDO)(15).

Patients will be identified via selecting positive computed tomography pulmonary angiograms (CTPA) or ventilation-perfusion scans (VQ) in female patients of childbearing age (16-49 years of age). This age group was selected to cover the vast majority of cases, while minimising time consumed to screen <16 and >49 years of age, where cases are likely to be very few. Pregnant patients and those up to 6 weeks post-delivery will then be selected to be included in the database. The high-risk and intermediate high-risk PE are defined as per the European Cardiology Society (ESC) criteria(16):

* High-risk PE: acute pulmonary embolism with presence of at least one of
  + Cardiac arrest
  + Haemodynamic shock: (Systolic BP <90 mmHg (or vasopressors requirement) and end-organ hypoperfusion (altered mental status; cold, clammy skin; oliguria/anuria; increased serum lactate)).
  + Persistent hypotension: (Systolic BP < 90 mmHg or systolic BP drop >\_40 mmHg, lasting longer than 15 min and not caused by new-onset arrhythmia, hypovolaemia, or sepsis).
* Intermediate high-risk PE: acute pulmonary embolism with evidence of myocardial necrosis (troponin rise) or right ventricle dysfunction, without haemodynamic instability.

Information collected will include demographics, maternal/obstetric characteristics, PE features, treatment received, maternal and foetal outcomes. Data collection will be gathered in a central database using REDCap data entry platform to ensure uniformity and facilitate multi-source data input on a national level.

Timeline

Retrospective data collection from cases of PE in pregnancy/puerperium diagnosed between 01/12/2014 and 01/12/24.

Target number of cases

200.

Audit standards

Thromboembolic Disease in Pregnancy and the Puerperium: Acute Management - Green-top Guideline No. 37b April 2015.

Data Governance

Data will be recorded retrospectively and collated on a dedicated, encrypted, web-based platform. This will be password protected, and no personal data that can identify the individual patient will be recorded. Registered local investigators will have individual password-protected access to all their centre’s data entered during the audit. Centres will use an identification number assigned by the secure platform to identify each individual patient and allow re-accessing of an individual’s records to allow it to be amended and updated, whilst also preventing duplication of patient entry to the audit. No linkable patient identifier will be held on the database. As such it will not be possible for the central investigating team to identify the patients. Local investigators will only have access to their own site’s data.

We will utilise the Research Electronic Data Capture (REDCap) system to design, host and support the online tool (www.project-redcap.org). This system has been previously used extensively to electronically capture and store sensitive health data in a secure and encrypted format for similar projects within the NHS in the UK. Data will be stored securely and on encrypted and certified servers for a minimum of five years. The data may be used for future research although it should be noted that the anonymised nature of the database means individual patients will not be reverse-identifiable in the future.

Dissemination and Publication of Results

The results of the audit will be disseminated through:

* Local presentations. (Teams at all centers will need to provide the contact details of the local consultant supervisor and the local audit officer).
* Publication in a major haematological journal.
* Presentation at regional and national meetings.

Publications and national presentations will not identify individual Trust performance.

Project team members

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About HaemSTAR

HaemSTAR is a UK-wide network of clinical haematology registrars that is supported by the National Institute of Health Research (NIHR) non-malignant clinical research network (CRN). It has a national steering group who decide on strategy and prioritise the network activity. It has lead members in each NIHR Local CRN who coordinate the local research activity and involvement of other Haematology registrars as is needed. The overarching aim of HaemSTAR is to promote clinical research in non-malignant haematology. It does this in four ways: by increasing the number of participants to non-malignant haematology trials nationally; by enabling effective transition of worthy local audits to the national scale; by developing and rolling out its own national studies which align with NIHR research priorities; and by exposing clinical Haematology registrars to NHS Trust Research and Development (R&D) departments and the NIHR in order to develop Principle Investigator (PI) skills which are not currently part of the Haematology registrar training curriculum. For more information visit www.HaemSTAR.org. For this “Flash-Mob Audit” HaemSTAR will provide support for gaining audit department approval, provide the eCRF and coordinate the activity of Haematology registrars engaged in data collection such that all hospitals with Haematology registrar presence are eligible and encouraged to take part in this audit.

About UKARCOG

Established in 2014, UKARCOG is a network of trainee / junior doctors that work jointly on large audit and research projects in the field of obstetrics and gynaecology (O&G) throughout the UK.

Their overall objectives are:

* Engage the network of UK trainees to undertake audit and research projects.
* Improve healthcare service locally and nationally.
* Perform joint nationwide audit and research projects.
* Support the aspirations, in concert with the RCOG (Royal College of Obstetricians and Gynaecologists), of doctors training in O&G in order to benefit our patients.
* Work collaboratively with other societies outside of obstetrics and gynaecology to further our work.

Through the completion and publication of audit and research projects, UKARCOG aims to improve medical practice and thus the quality of women’s health care. They have a good track record in the completion of National projects. The UKARCOG chair sits in the academic board at the Royal College of Obstetricians and Gynaecologists and therefore well connected with senior academics across the country.

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