Obstetric Cholestasis – Full Clinical Guideline

Reference No.: Obst/07:23/C6

Contents

1. Introduction

Obstetric Cholestasis (OC) is a multifactorial condition of pregnancy characterised by **pruritis**, (usually involving the palms and soles of the feet) in the **absence of a skin rash** with abnormal liver function tests (LFTs/BAs), which resolves postpartum.
The condition affects 0.7% of pregnancies.
Clinically the importance lies in the potential fetal risks which include spontaneous preterm birth, iatrogenic preterm birth and fetal death.

2. Purpose and Outcomes

- To ensure that staff are aware of the management of women with obstetric Cholestasis and to provide guidance for the management of this condition
- This guideline pertains to women with **pruritis in pregnancy without a rash**

3. Abbreviations

ALT	-	Alanine Transaminase
ANC	-	Antenatal Clinic
AST	-	Aspartamine Transaminase
BA	-	Bile Acids
Bd	-	Twice daily
CTG	-	Cardiotocography
LFT	-	Liver Function Tests
OC	-	Obstetric Cholestasis

Od	-	Once daily
PO	-	Orally
PT	-	Prothrombin Time
Qds	-	Four times daily
UDCA	-	Ursodeoxycholic Acid
USS	-	Ultrasound Scan
γGT	-	Gamma Glutamyl Transferase

4. Key Responsibilities/Duties

All maternity staff when caring for women must ensure that at each contact they must include possibilities of OC as part of the assessment.

5. Diagnosis of Obstetric Cholestasis (OC)

Intense itching - pruritis associated with OC typically involves intense itching of the palms of the hands and soles of the feet. **There is usually no rash**. It is generally worse at night. Examine the skin for a rash or signs of other causes of itching, including eczema, dermatitis.

Clinical history - It is more common in a patient with a history of OC in a previous pregnancy (recurrence risk of 50%), those with a family history of OC and multiple pregnancy. Other symptoms should also be elicited including dark urine, pale stools (steatorrhoea).

Biochemistry – Elevated serum Bile acids (>14µmol/L),
Elevated transaminases (AST, ALT) – Usually moderate (3 Fold, ALT > 40)
Raised gamma glutamyl transferrase (γGT) 20% of cases
Mild elevation of Bilirubin (less common)

Consider other causes of abnormal LFTs (especially with normal BA results) .This may include Acute Fatty Liver, Pre eclampsia, Hepatitis A, B and C, Cytomegalovirus, Primary Biliary Cirrhosis and Chronic Active Hepatitis.
A consultant opinion should be sought if not a classic presentation of OC before a diagnosis is confirmed.

Initial Assessment

- History
- Examination
- Biochemistry post prandial: Serum BA , LFTs, PT
- Inform Pregnancy Assessment Unit / Maternity Assessment Unit(MAU)
- Review of Results by Pregnancy Assessment Unit (PAU)/ Maternity Assessment Unit(MAU)
- Medical review (Consultant /Registrar)
- Further management guide see Appendix B

6. Risks associated with Obstetric Cholestasis

- Premature delivery (iatrogenic and spontaneous)
- Meconium aspiration

(The evidence for other risks remains inconclusive / theoretical - Post partum haemorrhage, fetal haemorrhage, stillbirth (rate is similar to general population), Caesarean section rates are high but may be related to interventions).

7. Management following the Diagnosis of Obstetric Cholestasis

7.1 Treatment - for symptom management only.

- **Topical emollients**
- **Chlorphenamine – 4mg PO 4 -6 hourly as required**
- **Ursodeoxycholic acid** (UDCA) - **250 mg PO bd** (titrate against symptoms - can be increased up to 500mg PO qds - the assessment & titration can be undertaken by a suitably experienced midwife.

- **There is no evidence that UDCA treatment improves fetal or neonatal outcome.**
- **There is also no significant improvement in symptoms from the use of URSO**

Optional additional treatment on indication only in the presence of prolonged prothrombin time or steatorrhoea:

- **Vitamin K (water soluble) – Menadiol 10mg PO od.**
  Ensure the prescription is written out using the full pharmacological name/details

In times of Menadiol shortage there is no suitable alternative and so no Vitamin K supplement should be prescribed.

7.2 Monitoring

- Repeat LFT's and BA 1 -2 weekly.
- Results to be reviewed and patient informed in case of any changes to management plan.
- Follow up appointment in ANC for patients with OC diagnosed.
- Serial Ultrasound scans (USS) and antenatal Cardiotocography (CTG) **should not** be undertaken in the absence of other obstetric indications (see patient management checklist)
- There is no evidence of increased adverse outcome with bile acids <100

8. Labour

- There is no evidence to support delivery prior to 39 weeks **except** in the case of
  BA 40 -99 when delivery from 38 weeks should be discussed.
  BA > 100 when delivery from 35 weeks should be discussed
- Inform women of increased risk of maternal morbidity from early intervention

9. Intrapartum

- Continuous fetal monitoring with CTG
- IV access
- Blood for - FBC, GS, LFT and coagulation (if BA> 40, or significantly elevated LFTs)
- Active management of third stage
- Postnatal Vitamin K should be offered to the neonate

10. Post natal

- Document in GP discharge letter for follow up at 6 weeks post natal to check that LFTs have returned to normal. If not, then the GP should consider further hepatological investigation.
- Do not repeat biochemistry within 10 days postnatal (as likely to still be raised)
- Inform patient that there is a 50% risk of recurrence in future pregnancies and the need for consultant booking
- Avoid oestrogen containing methods of contraception

11. Monitoring Compliance and Effectiveness

Monitoring requirement	• Number of OC cases diagnosed • Perinatal outcome of cases of OC • Gestational age at delivery Percentage of women with prolonged prothombin time receiving Vitamin K antenatally • Number of women with completed post natal Follow up
Monitoring method	Retrospective casenote review
Report prepared by	Designated medical staff
Monitoring report sent to:	Business Unit Audit Forum
Frequency of report	Approx. 3 years

12. References

NICE: Itch in pregnancy. July 2015

RCOG Green- top Guideline No 43. **Obstetric Cholestasis** April 2011
Handbook of obstetric Medicine (4th Edition) 2010: Catherine Nelson- Piercy

Geenes VL, Williamson C. Intrahepatic Cholestasis of Pregnancy. W J Gastroenterology 2009, 15(17): 2049 -66

Patient information leaflet:

Obstetric Cholestasis

This information is for you if you have been diagnosed with Obstetric Cholestasis

What is obstetric Cholestasis?

- Obstetric Cholestasis is a disorder that affects your liver in pregnancy. It causes a build up of bile acids in your body. This causes itching of the skin without a rash. (particularly in the palms of your hands and the soles of your feet)
- The symptoms get better after your baby is born
- It is uncommon in the UK and affects about 7 in every 1000 women.
- Obstetric Cholestasis is more common among women of Asian origin (affecting about 15 in every 1000 women)

What causes Obstetric Cholestasis?

- The cause of Obstetric Cholestasis is not fully understood, but it is thought that various factors including hormones, genetic and environment may be involved.

What does it mean for me?

- Obstetric Cholestasis can be very uncomfortable but it does not have any serious consequences for your health
- Most women will experience itching. This can start at any time in the pregnancy but usually begins after 28 weeks. . Often it starts on the palms of your hands and the soles of your feet and it may spread over your arms and legs. Itching can vary from mild to intense and tends to be worse at night. This may make you tired and exhausted during the day if you have had your sleep disturbed.
- A few women may develop jaundice (yellowing of the skin). Jaundice can cause pale stools and dark urine.

What does it mean for my baby?

- The effects of Obstetric Cholestasis on the baby are still not clear
- Increased chance that your baby may pass Meconium before being born. This makes the fluid around your baby green or brown in colour.
- Increased chance of premature birth.
- Some small studies suggested that stillbirths may be more common in women with Obstetric Cholestasis. Recent research shows that the risk of stillbirth is the same as in women without Obstetric Cholestasis (1 in 200). We do not know whether this is attributable to a general improvement in obstetric care , neonatal care, improvement in women ‘s overall health or early induction of labour

How is obstetric Cholestasis diagnosed?

- You may be diagnosed with Obstetric Cholestasis if you have unexplained itching in pregnancy with abnormal blood tests (liver function and bile acid tests). These get better after your baby is born. This diagnosis is made once other possible causes for the itching and abnormal liver function tests have been ruled out.
- Although itching is a common symptom, only a small proportion of women will have Obstetric Cholestasis
- You skin will be examined carefully to ensure that other skin conditions are not the cause of your itching. It is possible that you may have more than one condition
- You may be offered one or more blood tests to help diagnose Obstetric Cholestasis.
- If the itching persists and no cause is found , these blood tests may need to be repeated

What extra care will I need?

- Once diagnosed with Obstetric Cholestasis, you should be under the care of a consultant and have your baby in a consultant led maternity unit with a neonatal unit
- You are likely to have liver function tests once a week until you have had your baby. You will be given blood request forms to have your bloods repeated on a weekly basis. You will be contacted via telephone when the results are reviewed if there is any change in the management plan. You can have these bloods done weekly either at the RDH blood room, London Road Community Hospital or your GP surgery phlebotomy service.
- You should monitor babies movements as instructed and contact the Pregnancy Assessment unit if there is any change
- When you are in labour, you will be offered continuous monitoring of your baby's heart rate.

Can obstetric Cholestasis be treated?

- There is no cure of Obstetric Cholestasis. However it gets better after the baby is born.
- Treatment may help ease the symptoms for most women
- Non of the treatments offered affects the outcome for your baby
- Treatments may include Ursodeoxycholic acid ((UDCA) often known as URSO). This reduces the level of bile acids in your blood and helps to improve the liver function tests. It may reduce the itching. There is not enough evidence to say whether it reduces the small chance of stillbirth or whether it is completely safe for your baby, but it is a commonly prescribed medication for obstetric Cholestasis.
- Obstetric Cholestasis may cause a problem with the clotting mechanism of your blood, making you more prone to bleed for longer than usual. If your blood clotting time is prolonged, you will be recommended to take a daily dose of Vitamin K until you have had the baby to reduce complications if you start to bleed.
- Your baby should be offered vitamin K shortly after birth, as are all babies.

When is the best time for my baby to be born?

- It may be that an option of having labour induced after 37 weeks of pregnancy, particularly if your blood tests indicate significant abnormality
- Early induction may carry an increased risk of a caesarean section
- Early induction may carry an increased chance of your baby needing admission to the special care baby unit
- The doctors looking after you will discuss what is best for you and baby in your individual situation.

What Follow–up should I have?

- Obstetric Cholestasis gets better after birth.
- It is important that you have a follow up appointment with a health care professional so that we can check your blood results have normalised and that your itching has gone away
- If your symptoms or your blood results have not settled by 6- 8 weeks following delivery, then it may suggest a different problem and you should be referred to a specialist
- There is a high chance of Obstetric Cholestasis happening again in a subsequent pregnancy (40 – 90 in 100 women)
- You should avoid oestrogen containing contraceptive pills and may wish to discuss alternative contraception

If you have any further questions please ask the doctors or the midwives that are looking after you.

PROPOSED FURTHER MANAGEMENT PLAN

Itching
No Rash

OC serology testing

- ☐ **BA**
- ☐ **LFTs**
- ☐ **PT**

Normal BA or <19
Normal LFTs

Repeat 2 weekly if still symptomatic

BA ≥ 19

Normal BA
Abnormal AST/ALT (> 40)

Inform PAU/ MAU

PAU/MAU Medical Review:
If there are any concerns with the diagnosis or significantly elevated Liver enzymes, the following can be considered:
- ☐ Rule out other causes such as: PET, HELLP, viral hepatitis, fatty liver, chronic active hepatitis
- ☐ Clotting screen
- ☐ Liver USS

Treatment:
- ☐ Topical emollients / chlorphenamine
- ☐ UDCA 250mg PO bd

If prolonged PT or steatorrhoea add:
- ☐ Vit K: Menadiol 10mg PO od

BA ≥40 +/- ALT > 40 - repeat bloods weekly
BA < 40 - repeats bloods 2 weekly

Postnatal
- GP to repeat LFTs at 6/52
- Referral to Hepatology if not normalised

Intrapartum:
- Continuous Electronic monitoring
- IV access/ FBC/ GS/ LFTs +/- coag
- Vit K neonate

1 -2 weekly reviews of LFT's and BA
Consultant care ANC as appropriate
If BA ≥ 100: offer IOL from 35^{+0} – 36^{+6} weeks.
If BA 40 -99: offer IOL from 38^{+0} - 38^{+6} weeks.
If BA 19 -39 offer IOL from 39^{+0}

CHECK LIST FOR OC

Patient Details Phone contact No:

- ☐ OC diagnosed:
    - BA: …… at gestational age: ……weeks
    - LFTS (N/Abnormal)
    - PT (normal/prolonged)
- ☐ Patient information leaflet given
- ☐ ANC Follow up appointment made
- ☐ Patient sticker, pregnancy details and phone number added to the list in PAU(RDH/ MAU (QHB)
- ☐ Blood request forms for patient (BA and LFTs). Explanation to patient about regular blood test and day for the test to be done
- ☐ URSO prescribed. Advise that dose can be increased depending on symptoms to 500mg URSO qds PO if required.
- ☐ If > 37/40 - book IOL for 40 weeks gestation, sooner if BA > 100 or significantly deranged LFTs
- ☐ If patient DNA blood test for review
    a. 1st - FU phone call. Advise for blood test and give day for test for the next week. Record in electronic notes.
    b. 2nd – FU phone call. Advise for repeat blood test and review in PAU/MAU within 1 week.
- ☐ Electronic letter to GP

MONITORING OF OC BLOOD RESULTS

- Blood testing for LFT and BA will be repeated 1 -2 weekly once OC diagnosed
- Patients will be given blood request forms so that they can be done at the patients convenience (RDH blood room, QHB phlebotomy, LRCH blood room, GP surgery if bloods come to our lab for analysis)
- The patient will be responsible for ensuring the test is performed as agreed so that the results can be reviewed on a set day during the week
- List of all the patients diagnosed with OC and requiring monitoring of serum BA and LFT will be kept in PAU / MAU
- Ideally a set day in the week for review of results, therefore patients should be advised to have the blood test done a day or two beforehand
- Telephone call to the patients after results reviewed to advise of changes in care plan if applicable

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OBSTETRIC CHOLESTASIS LETTER TO GP

GP Name: Dr **GP National Code:** G **National Practice Code:** C **GP Address:**
Patient Name: **Patient HN:** **Patient DOB:** **Patient NHS Number:**
Patients Address:

Date:

Dear Dr

The below named patient has been diagnosed with OC in pregnancy

Patient:

Gestation: [ ] weeks.

EDD: [ ]

Blood results as follows:

Bile Acid: [ ]

AST/ALT: [ ]

Heptatis screen: [ ]

Additional Information:

[ ]

Please would you arrange for a repeat of LFT's and BA 6/52 Postnatal and refer on to Hepatology should those results remain abnormal.

Yours Sincerely,

PATIENT NAME: **HOSPITAL NO:** **NHS NO: DOB:**
DATE & TIME:
****END OF DOCUMENT****

Documentation Control

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Version Amendment	Version	Date	Author	Reason
	1	March 2007	Dr J Ashworth Consultant Obstetrician	New
	2	February 2009	Dr J Ashworth Consultant Obstetrician	Review
	3	November 2012	Miss S Rajendran Consultant Obstetrician	Review
	4	May 2017	Miss S Rajendran Consultant Obstetrician	Review
UHDB	1	May 2020	Miss S Rajendran Consultant Obstetrician	Review & Merge
	2	May 2023	Miss S Rajendran Consultant Obstetrician	Review
Intended Recipients: All staff with responsibility for caring for women in the Antenatal period				
Training and Dissemination: Cascaded through lead midwives/doctors, Published on Intranet, NHS mail circulation list. Article in BU newsletter.				
To be read in conjunction with:				
Consultation with:	Midwifery, Obstetric Staff			
Business Unit sign off:	02/05/2023: Maternity Guidelines Group: Miss S Rajendran – Chair 19/06/2023: Maternity Governance Group - Mr R Deveraj			
Notification Overview sent to TIER 3 Divisional Quality Governance Operations & Performance: 20/06/2023				
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Key Contact:	Joanna Harrison-Engwell			