Breast feeding

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Abstract

Breastfeeding confers multiple benefits to both infants and mothers, with evidence linking breastfeeding to a lower risk of many adverse outcomes including gastroenteritis, respiratory disease, necrotising enterocolitis and otitis media in infants, and a lower risk of breast cancer in mothers. Breastfeeding has also been linked to other health, social and cognitive outcomes including childhood obesity and cognitive development. It is the responsibility of all health professionals to support women during the breastfeeding period, and as part of the NHS Long Term Plan the recommendation that Unicef UK Baby Friendly accreditation occurs across all maternity services and includes a focus on improved support for families with infants in neonatal care. Many mothers are required to use drugs during breastfeeding. Almost all drugs transfer into breast milk and this may carry a risk to a breastfed infant. Factors such as the dose received via breast milk, and the pharmacokinetics and effect of the drug in the infant need to be taken into consideration. Problems should not be overstated however, as many drugs are considered 'safe' during breastfeeding.

Keywords breastfeeding; medication prescribing; pharmacokinetics

Introduction

Benefits of breastfeeding

Breastfeeding is well known to be beneficial to both mother and baby and is promoted throughout the postnatal period. The World Health Organisation (WHO) recommends that infants are exclusively breastfed for the first 6 months of life, and that supplemented breastfeeding is continued until they are two years old. Breastmilk is fundamentally different to formula and affords additional health benefits besides nutrition. The presence of antibodies affords passive immunity to the baby which helps prevent serious infections in the perinatal period. This benefit can be far reaching, with reduction in the risk of gastrointestinal infections, lower respiratory tract infections, necrotising enterocolitis and acute otitis media. The UK millennium cohort study showed that six months of exclusive breastfeeding provided a reduction in hospital admissions due to diarrhoea and respiratory tract infections. There was also some benefit with partial breastfeeding (mixed feeding).

There are also possible longer-term benefits persisting into childhood, including a reduction in risk of childhood leukaemia, atopic dermatitis, childhood asthma, and sudden infant death syndrome. There has also been considerable investigation into the possible benefits breastfeeding can afford the mother, with a possible reduction in the risk of breast cancer, ovarian cancer, type 2 diabetes, and postnatal depression.

It is considered especially important for the preterm infant to have continuous breastfeeding, due to the higher concentrations of anti-inflammatory compounds, IgA antibodies, and immune modulators. In particular, breast-feeding confers protection against necrotising enterocolitis, sepsis and retinopathy of prematurity. It has also been shown to improve gut motility as well as neurodevelopmental outcomes.

The additional health benefits of breastfeeding are especially important in developing countries, due to malnutrition, reduced immunity, contaminated drinking water, and low immunisation rates. Exclusive breastfeeding for up to 6 months, with partial use until 12 months in developing countries, has been estimated to prevent up to 13% of deaths each year in children under 5.

Physiology of breastfeeding

Throughout pregnancy there is hypertrophy of the alveolar-lobular structures in the breast, driven by progesterone, oestrogen, prolactin, and adrenal steroids. New alveoli are formed by budding from the milk ducts. Lactogenic hormones, such as prolactin and placental lactogen, are inhibited throughout pregnancy with oestrogen and progesterone. On delivery of the placenta, there is a rapid fall in progesterone, which triggers milk production. Milk production relies on high levels of both prolactin and cortisol. Prolactin levels fall throughout the puerperium, and only return back to normal on weaning from breastfeeding. Levels of prolactin and production of milk rely on regular nipple stimulation and emptying of secreting glands. This stimulates prolactin production in the anterior pituitary gland.

There should be an externally validated, structured programme implemented by all maternity care providers to encourage breastfeeding using the Baby Friendly Initiative. Mothers and babies should not be separated within the first hour of life if possible and early skin-to-skin contact should be encouraged and continued into the puerperium. Breastfeeding should be encouraged in the first hour of life and support, including positioning and attachment, should be offered.

Women cannot always breastfeed after birth or may chose not to do so. HIV-positive mothers, particularly those not on antiretroviral drugs during pregnancy, are advised to avoid breastfeeding to reduce the risk of infection in the infant. Women on a variety of medications for chronic health conditions may have to weigh up the risk/benefit ratio of breast-feeding. In the absence of suckling, lactation eventually stops of its own accord. In the meantime, women can experience breast engorgement, leakage of milk, discomfort and pain. Clinicians may provide treatment to suppress lactation and reduce these symptoms. Cabergoline is a dopamine agonist used to suppress lactation. It exerts its effect through the inhibition of prolactin release from the anterior pituitary gland. Compared to bromocriptine, the older dopamine agonist, cabergoline is better tolerated with significantly less rebound breast activity and a simple administration schedule.

Mastitis

Mastitis means inflammation of the breast with systemic symptoms. It can range in severity from a blocked duct to breast

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abscesses requiring surgical incision and drainage. On examination, mastitis is typically seen in wedge-shaped sections of the breast tissue. The affected area becomes red, firm, and tender generally associated with systemic symptoms such as fever, rigors, lethargy, muscle aching or nausea. Mastitis can be infectious or non-infectious. Mastitis occurring in the absence of nipple damage and secondary to poor drainage of the breast is likely to be non-infectious. Advise published by the WHO on mastitis recommends that in systemically well women with localised symptoms, first line treatments should be commenced for 24 hours before antibiotics are started. First line management involves improved drainage of the breast; encourage increasing frequency of feeds, and improving the attachment and positioning of infants to the breast. Heat can be used before the feed (shower, warm face cloth) to improve the mother's relaxation and milk flow. If infants are not feeding effectively, expressing milk by hand or pump, focusing on the affected area, can help. There is little evidence for the effectiveness of antibiotics. However, antibiotics are recommended immediately for women who are acutely ill, or in the early postpartum period when nipple damage is present. A clean catch specimen of milk should be sent for culture if the mastitis does not resolve within 48 hours or appears to be severe. If the affected area of the breast remains firm after feeds, a diagnostic ultrasound may be necessary to exclude a deep abscess.

Principles of prescribing in breastfeeding mothers

Women with chronic conditions are often advised to reduce or stop their medications whilst breastfeeding due to concerns regarding possible adverse effects in their infants. This advice is often not based on evidence-based information, and there may be limited data for the excretion of these medications into breastmilk. Often, the level of drug in breastmilk is negligible.

When considering the risk posed to the infant, it must be weighed up with the benefit for the mother, how it actually affects breastmilk and production, the amount excreted into breastmilk, and the extent of oral absorption from the infant. The pharmacological properties of each drug should be carefully considered. Generally, a drug is more likely to be excreted into breastmilk if it is of small molecular weight, highly lipid soluble, has low maternal serum binding, and lack of ionisation. If a drug has a long half-life it is more likely to accumulate in breastmilk, and a drug with high oral bioavailability is more likely to be absorbed by the infant. The dose response must also be considered and may need to be titrated against the effective dose versus harmful dose present in breastmilk.

The physiology of the infant is also an important consideration, with preterm infants at higher risk of adverse effects from different drugs. This is due to immaturity of metabolic pathways and reduced clearance of the drug. This is especially true of infants with chronic conditions themselves, as they have less reserve to effectively clear toxic metabolites.

The concentration of a drug in breast milk correlates with the concentration of a drug in maternal blood. The concentration peaks when the drug level in the mother peaks and then diffuses out of the breast milk. Women are often counselled to express and discard their breastmilk (or 'pump and dump') to protect the baby from exposure to drugs secreted in breast milk, however adjusting the timing of breastfeeds to avoid exposing infants to peak concentrations of drugs may also be effective.

Lactmed

An essential resource for healthcare professionals is the LactMed® database. This provides comprehensive and up to date information on drug levels in breastmilk, and the possible adverse effects these can cause to the infant. This resource was set up as a response to the rapidly changing data and advice available via the internet that was outpacing official statements from the American Academy of Pediatrics (AAP). The information provided by the database is derived from peer reviewed scientific literature and therefore is evidence based.

The database gives information on the drug structure, levels in the breastmilk, effects on breastfed infants and on lactation. It will also suggest alternative drugs to consider, where appropriate.

Case study 1

A 25-year-old booked late in her first pregnancy at 20 weeks' gestation. She was diagnosed with Graves' disease 7 years' prior and was commenced on Carbimazole 40 mg once daily. One year later she was given a 'block and replace' regimen and 100 mcg Levothyroxine was added to the Carbimazole. She had several relapses of her hyperthyroidism due to non-compliance. She presented at 20 weeks' gestation with a goitre, palpitations and tremors, and biochemical evidence of hyperthyroidism. She was commenced on propylthiouracil 300 mg twice daily and propranolol 20 mg daily. At 37 weeks' gestation she was euthyroid. She went into spontaneous labour and had an emergency caesarean section for suspected fetal distress at 39 + 6 weeks. She breastfed for 3 months. She is planning to have radioactive iodine treatment.

Discussion

Hyperthyroidism in pregnancy can have serious effects on the developing fetus and therefore is important to control thyroid levels. In particular, neural development can be affected, as well as cardiac failure and hydrops in severe disease.

During pregnancy the aim is to maintain a mildly hyperthyroid state, as aggressive management of T3 and T4 concentrations may result in fetal hypothyroidism. Women with symptomatic or overt hyperthyroidism need treatment, with the aim of trimester specific T4 and T3 concentrations exceeding the upper limit of non-pregnant patients. Mild or non-symptomatic disease does not need to be treated. There are three main ways that hyperthyroidism is treated: thionamides; symptomatic relief of hyperthyroidism with beta blockers; and surgical management with thyroidectomy.

For treatment with breastfeeding, methimazole is recommended due to the risk of hepatotoxicity associated with PTU. PTU has however been shown to not be concentrated in breastmilk, with insignificant serum levels to affect the infant so is still a viable treatment option. There are also no cases of neonatal liver injury associated with PTU therapy when breastfeeding. There is less data associated with carbamazepine, and studies have

examined doses up to 30 mg daily with no neonatal effects. To reduce the risk of possible adverse reactions, it is recommended that methimazole is given in divided doses. Studies have looked up to 20 mg daily doses, and if doses exceed this then infants should have thyroid function checked at one and three months.

Methimazole is free in serum, compared to PTU which is mostly protein bound. Therefore, more methimazole is present in breastmilk. Despite this, there is no difference with either drug in serum thyroid hormone concentrations or in thyroid function tests. Infants have been shown to have normal thyroid function, growth and development with treatment of both methimazole and PTU.

Case study 2

A 39-year-old booked at 10 weeks in her second pregnancy. Her first child was born without complications 21 years previously. She was known to have idiopathic generalised epilepsy and was taking levetiracetam 1000 mg twice daily, lamotrigine 200 mg twice daily, and 5 mg folic acid which was commenced by her general practitioner. Her last seizure was one year prior to the pregnancy, which was triggered by tiredness. Levels of levetiracetam and lamotrigine were monitored in pregnancy, and her lamotrigine was increased accordingly. She had a vaginal delivery at 40 + 1 weeks. Her medications were decreased to pre-pregnancy doses. She commenced fully breastfeeding. She had a tonic-clonic seizure which the patient attributed to tiredness at 4 weeks postpartum. She is now mixed feeding with the support of her family. She has been seen for postnatal contraception and had a Mirena IUS fitted.

Discussion

The immediate postpartum period is a high-risk period for exacerbation of seizure frequency due to increased stress, sleep deprivation, missed medication and anxiety. Mothers should be well supported in the postnatal period to ensure that triggers of seizure deterioration is minimised. Seizures can result in accidental injuries to the mother and the baby, such as drowning, falls, burns and electrocution.

Antiepileptic medications are well known to have teratogenic effects in the antenatal period. This includes congenital malformations, growth restriction and neurodevelopmental delay. The central nervous system is particularly vulnerable to the effects of these medications due to the lack of the blood brain barrier until after birth. Because of this, mothers with epilepsy often have considerable anxiety regarding their medication when breastfeeding, and often will receive conflicting advice. Generally, there is limited safety data of antiepileptic medications with lactation. Because of this, LactMed remains a valuable resource for clinicians when evaluating if an antiepileptic medication is safe with breastfeeding. Another resource is 'Medications and Mother's Milk' by Hale et al., and with this can classify drugs as safe, moderately safe and possibly hazardous.

Phenytoin, valproate and carbamazepine are thought of as safe antiepileptic medications during breast-feeding. This is due to their high degree of protein binding, and so have relatively low excretion into breastmilk. Phenytoin is thought to be generally compatible with breastfeeding, and if maternal concentrations are in therapeutic range there is low infant serum levels. There are some case reports of adverse effects in infants with mothers using phenytoin, but often this is in combination with other drugs. There are no case reports of adverse reactions in infants with mothers using valproate monotherapy. The only concern is a theoretical risk of hepatotoxicity, therefore sometimes there is recommendation that infants should be monitored for liver dysfunction. Carbamazepine will transfer to breastmilk to some degree, however the serum concentrations and active metabolite are often below the therapeutic range for infants. There are some case reports of liver dysfunction, with poor suckling and growth restriction, with carbamazepine monotherapy.

Moderately safe antiepileptics include lamotrigine, oxcarbazepine, leviteracetam, topiramate, gabapentin, pregabalin and vigabatrin. This is mostly due to their relatively reduced protein binding compared to the previous drugs. Of note, lamotrigine is 55% protein bound and will be excreted into breastmilk in moderate amounts. There is a limited capacity in infants to metabolise lamotrigine, and therefore there may be relatively high serum concentrations. Despite this, it is relatively well tolerated and is compatible with breastfeeding. Infants should however be monitored for rash, poor suckling and drowsiness; and have levels checked if there are any concerns. Leviteracetam is actually highly excreted into breastmilk, due to small molecular weight and low degree of protein binding. Paradoxically serum concentrations in the infant are low and so indicates it is readily eliminated. Therefore, it is thought to be highly compatible with breastfeeding. There are similar findings to this with topiramate, gabapentin, pregabalin and vigabatrin.

Hazardous antiepileptic medications include phenobarbital and its prodrug primidone; benzodiazepines, ethosuximide and zonisamide. Phenobarbitol has a very long half-life with low protein binding, and so has potential to accumulate with breastfeeding. There is a similar problem with benzodiazepines, with a long half-life and slow elimination in neonates. This is particularly true with diazepam, with reports of drowsiness and reduced weight gain when mothers are taking it daily.

The general opinion is that the benefits of breastfeeding to an infant will far outweigh the potential harm posed from moderate drug exposure. To mediate this, there should be close monitoring of the child whist antiepileptics are being used that have the potential to accumulate. If there are any concerns, the serum level for these drugs can be measured to monitor potential side effects. If medication doses were increased in pregnancy due to increased clearance, the dose should be reduced in the postnatal period. If there are any concerns from the woman, it may be useful to recommend breastfeeding at a time when the dose of the drug is likely to be at its lowest point i.e. just prior to the next dose, to reduce the risk that their baby would be affected.

Case study 3

A 32-year old with known rheumatoid arthritis booked at 8 weeks gestation in her first pregnancy. She was using etanercept

(anti-TNF) 50 mg s/c weekly and hydroxychloroquine 200 mg once daily. She was Ro and La antibody negative. She stopped the etanercept at the end of the second trimester. Her arthritis remained well controlled, and she went on to have a spontaneous vaginal delivery at 38 + 4 weeks. She fully breast-fed her baby. She had a flare of her rheumatoid 4 weeks postnatally and was recommenced on etanercept and a course of prednisolone. At that time breastfeeding was a challenge due to pain and stiffness in the hands and wrists. During the flare she mixed fed with the support of her family, and this continued until weaning at 6 months.

Discussion

Autoimmune diseases are a common problem in pregnancy. They are associated with higher risks of maternal and foetal complications and should be carefully managed. They are wide ranging, including inflammatory bowel diseases (IBD), rheumatoid arthritis and systemic lupus erythematosus (SLE). In some diseases, such as with rheumatoid arthritis, in is more likely that symptoms will improve in pregnancy with the risk of rebound symptoms postnatally. Therefore, it is important to review anti-inflammatory medications to help prevent disease flares.

There are risks of disease flares on discontinuation of medication, or in the case of transitioning to another drug. Active inflammatory bowel disease during pregnancy is known to cause poor pregnancy outcomes. In the case of antiphospholipid syndrome and SLE, there is a higher risk of developing pre-eclampsia and pregnancy complications.

Therefore, when considering stopping anti-inflammatory medications, it must be weighted up against the potential harm that a flare of the disease might have. Often, the medication will have less risks associated with it compared to a disease flare.

Non-steroidal anti-inflammatory drugs are commonly used in the treatment of pain in arthritis. In breastfeeding, the commonly prescribed ibuprofen and naproxen are considered safe, and can be used in combination with other analgesia such as paracetamol which has an excellent safety profile.

Chloroquine and hydroxychloroquine are antimalarial drugs which are widely used in rheumatic diseases. They work by blocking the activation of toll like receptors in the innate immune response. A withdrawal of hydroxychloroquine may lead to acute exacerbation of the disease. Both chloroquine and hydroxychloroquine have been shown to cross the placenta during pregnancy, but neither have been shown to be harmful. A minimal amount has been found in the breastmilk during lactation, and there are no reports of adverse effects in breastfed children with these drugs.

Glucocorticoids are widely used in rheumatology due to their anti-inflammatory properties. They are compatible with each trimester of pregnancy and breastfeeding. These drugs can have considerable side effects including weight gain, osteopenia, immune suppression, hyperglycaemia, hypertension, and bone avascular necrosis. These drugs have limited transfer to the breastmilk, and so are safe to use with breastfeeding. Women who take high doses (50 mg or more) are advised to delay breastfeeding by 4 hours after taking their dose, to reduce the concentration in the milk.

Thiopurines such as azathioprine and its active metabolite 6-mercaptopurine act in rapidly dividing cells, in particular T lymphocytes. They block synthesis of RNA and DNA precursors to interfere with cell division and synthesis. Azathioprine is commonly used as it is an effective immunosuppressant which reduces the need for prolonged steroid use. It can be started at up to 2 mg/kg/day with disease flares, and if the woman is already taking >20 mg prednisolone per day. Animal studies have shown teratogenicity of the thiopurines, through the metabolite thioinosinic acid. However, in humans the developing foetus is unable to metabolise and produce this, and so has no toxic effects. There is minimal transfer of azathioprine into the breastmilk, and so is safe with breastfeeding.

Sulfasalazine is the first line agent for inflammatory bowel disease. It is a compound of 5 aminosalicylic acid (5-ASA) and sulfapyridine. It is a potent inhibitor of the folate carrier, and so folate supplementation is essential pre-conception and in the antenatal period.

It is detected in breastmilk, and there is a case report of a breastfed infant developing bloody diarrhoea whilst their mother was taking it. It therefore compatible with breastfeeding in a healthy full term infant.

Cyclophosphamide has a potent immunosuppressive effect as an alkylating agent. It is used in rheumatic disease, in particular severe lupus nephritis. There are multiple effects on the developing foetus, and the risk is higher when exposed during the first trimester. Complications include miscarriage, microcephaly, limb defects, and growth deficiency. It is known to be excreted in breast milk and to cause neutropenia and thrombocytopenia in the infant, and so is recommended to be avoided.

Methotrexate is widely used in rheumatic diseases. It works by interfering with in purine synthesis, and reducing tetrahydrofolate availability. There is association with major birth defects and 'methotrexate embryopathy'. There are recent studies which suggest there are low levels in breast milk, however due to its significant side effect profile it cannot be recommended with breastfeeding.

Leflunomide acts as a pyrimidine synthesis inhibitor and is used in rheumatoid arthritis to improve joint pain and prevent long term damage. Along with this, it inhibits T cell proliferation and protein tyrosine kinases. It is strongly associated with teratogenic effects. There are no data available on the levels in breast milk and so it is advised to avoid. Mycophenolate mofetil (MMF) is mainly used in SLE nephritis, and with renal transplant to avoid graft rejection. It inhibits purine synthesis and prevents B and T cell lymphocytes. There are well documented teratogenic effects associated with it. There is no documentation with its concentration in breastmilk and therefore it is contraindicated.

Cyclosporine and tacrolimus are calcineurin inhibitors and inhibits activation of T and B lymphocytes. They are used in the prevention of organ transplant, and also in treatment of rheumatoid arthritis and psoriasis. There is limited data on their effect during pregnancy, and data is mostly based on women with solid organ transplants. Both drugs are detected in minimal

concentrations in breast milk, and no adverse effects have been reported with their use in breast feeding; therefore, it is considered compatible with breastfeeding.

Biologic anti rheumatic drugs: Biologic disease modifying anti-rheumatic drugs (bDMARD) are used for treatment of rheumatoid arthritis, ankylosing spondylitis, psoriasis, psoriatic arthritis, and inflammatory bowel diseases (IBD). The use of anti-TNF agents is considered safe throughout pregnancy. The monoclonal antibodies (infliximab, adalimumab, and golimumab) will cross the placenta in the third trimester. Studies have shown no difference in rate of miscarriage and birth defects compared to controls. Due to concerns regarding immunosuppression in the infant, if used in the last 30 weeks of gestation live attenuated vaccines are advised to be postponed until 6 months. This includes BCG and rotavirus vaccines.

The anti-TNF drug certolizumab pegol is a newer agent, and has been advised from the British Society of Rheumatology that it is the only agent that can be safely to use throughout pregnancy and with breastfeeding. It also is the only agent that allows the neonate to have a full vaccination programme, including live attenuating vaccines.

Generally breastfeeding is encouraged with the monoclonal anti-TNF agents and the only concern comes from antenatal administration. Low levels of these drugs are found in breastmilk but are thought to be generally compatible with breastfeeding. It is thought that protein digestion in the infant's stomach would denature much of the compound.

The use of the monoclonal anti-TNF drugs is especially important in the management of IBD in pregnancy. A large review from *The Toronto Consensus Statements for the Management of Inflammatory Bowel Disease in Pregnancy* has recommended that women on 5-ASA, thiopurine and monoclonal anti-TNF agents should continue throughout pregnancy to prevent disease flares. They also recommended that they should be considered in disease flares which are resistant to corticosteroid therapy.

Rituximab is a CD20 inhibitor which acts on activated B cells. It has not been shown to have an increased rate of malformations, and so can be used in early gestation. Due to potential B cell depletion in the infant, it is advised to be discontinued in later stages of pregnancy. There is limited evidence regarding its penetration into breastmilk, but due to its properties as a large protein molecule it is unlikely to be absorbed due to low bioavailability. There is limited data in the following biologic agents (Abatacept, CTLA4 signalling inhibitor; Tocilizumab, a humanized IgG1 which blocks IL-6 action; Ustekinumab, a IL-2 and IL-23 inhibitor; Belimumab; Tofacitinib, a JAK3 inhibitor). Because of this, it is advised for all of them to be avoided throughout pregnancy and with lactation. ◆

FURTHER READING

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Practice points

- It is the responsibility of all health professionals to support women who wish to breastfeed.
- Health professionals can help women overcome most breastfeeding challenges without the need to stop breast feeding.
- Most medicines are compatible with breast feeding; safety can be checked on dedicated websites.
- Select drugs with a short half-life, high protein binding, low oral bioavailability, high molecular weight.
- Use caution when advising on drugs and breastfeeding if the infant is born preterm or at low birthweight.