Breastfeeding and Medication

Breastfeeding and Sleeping Tablets

Being asked about the safety of sleeping tablets by a breastfeeding mum is probably one of the hardest questions there is. My first problem is that I was taught as a pharmacist that sleeping tablets should only be used very short term and as a last resort. They are highly addictive. They do not solve problems long term. My second problem is that in order to induce sleep they have to cross the blood brain barrier and can therefore cause drowsiness in the baby from the amount passing through milk. The third problem is who will be looking after the baby during the night – will it be fed by someone else? Does the mum co sleep in which case how can we keep the baby safe? If mum is going to get up to feed the baby is there a risk that she will fall asleep on the sofa which is an even greater risk of SIDS.

Most mothers who ask about the use of sleeping tablets are suffering from anxiety or depression. It is a chicken and egg situation – does the lack of sleep cause anxiety/depression or is the inability to sleep a symptom of the anxiety/depression?

Many people find that they can be helped to sleep by using the self-hypnosis sites similar to those used for labour and hypno-birthing. Others by meditation or mindfulness and I cannot praise the Headspace app enough. These practices may take several days to work and are not an instant cure for lack of ability to sleep but they do not affect breastfeeding.

Some people find that herbs such as Valerian help. There is limited research on safety but anecdotally they do not appear to cause drowsiness in the baby. LactMed states that " Valerian has no specific uses in nursing mothers, but is most commonly used to treat anxiety and sleep disturbances, and occasionally for self-treatment of postpartum blues or depression. No data exist on the safety and efficacy of valerian in nursing mothers or infants. In general, valerian is well tolerated, with side effects such as dizziness, hangover or headache reported occasionally. Valerian is "generally recognized as safe" (GRAS) for use in food by the U.S. Food and Drug Administration. Valerian is often not recommended during lactation because of the theoretical concerns over its valepotriates and baldrinals which have been shown to be cytotoxic and mutagenic in vitro. Because there is no published experience with valerian during breastfeeding, an alternate therapy may be preferred, especially while nursing a newborn or preterm infant."

January 2019 *The information on this sheet is based upon my professional experience as a pharmacist with a specialised interest in the safety of drugs in breastmilk, supported by evidence from expert sources. However, I cannot take responsibility for the prescription of medication which remains with the healthcare professionals involved. I am happy to discuss the evidence by email wendy@breastfeeding-and-medication.co.uk*

Symptoms of anxiety is better managed by the use of SSRI antidepressants and/or betablockers such as propranolol both of which pass into milk in very low levels. The gold standard is CBT therapy (https://breastfeedingnetwork.org.uk/wp-content/dibm/anxiety%20and%20breastfeeding.pdf).

Depression can be managed by the use of SSRI antidepressants and CBT (https://breastfeedingnetwork.org.uk/wp-content/dibm/antidepressants%20and%20breastfeeding.pdf)

Prescribed sleeping tablets

Insomnia is defined as the inability to achieve or maintain sleep. It may occur short term or become chronic. Insomnia may be a manifestation of an underlying condition such as depression or anxiety. The use of hypnotics is generally only recommended at the lowest effective dose for as short a period as possible with an emphasis on sleep hygiene and non-pharmacological measures. Tolerance develops within a very short space of time (3–14 days). Benzodiazepines are generally regarded as the drugs of first choice. Dependence can become a problem with regular or frequent use and withdrawal leads to rebound insomnia. Use during lactation should be discouraged, as the mother may be unresponsive to the needs of the baby. Co-sleeping after taking sedatives produces an increased risk of SIDS (see Caring for your baby at night, Baby Friendly UK 2017, www.unicef.org.uk/BabyFriendly/Resources-for-parents/Caring-for-your-baby-at-night).

Committee on Safety of Medicines advice

1 Benzodiazepines are indicated for the short-term relief (two to four weeks only) of anxiety that is severe, disabling or subjects the individual to unacceptable distress, occurring alone or in association with insomnia or short-term psychosomatic, organic or psychotic illness.

2 The use of benzodiazepines to treat short-term 'mild' anxiety is inappropriate and unsuitable.

3 Benzodiazepines should be used to treat insomnia only when it is severe, disabling, or the individual is caused extreme distress.

Zopiclone : has similar sedative and anxiolytic activity to those of the benzodiazepines. It is claimed to initiate sleep rapidly, without reduction of total rapid-eye-movement (REM) sleep. Matheson et al. (1990) studied 12 women who took a single dose of zopiclone 7.5 mg in the early post-natal period. They found low levels of transfer via breastmilk equivalent to 1.4% of the weight-adjusted maternal dose. The babies were not allowed to breastfeed for up to ten hours but displayed no adverse effects when they resumed breastfeeding. The BNF reports that it is secreted into breastmilk and that it should be avoided.

Reference

- Matheson I, Sande HA, Gaillot J, The excretion of zopiclone into breastmilk, Br J Clin Pharmacol, 1990;30:267–71.

Zolpidem: an imidazopyridine with similar sedative properties to the benzodiazepines but minimal anxiolytic properties. It has a rapid onset and a short duration of action, and is used as a hypnotic in the short-term management of insomnia. It undergoes first-pass metabolism and has an oral bio-availability of 70%. It is 92% bound to plasma proteins. Hale reports a personal communication case report of a baby who became excessively somnolent when its mother took 100 mg sertraline and 10 mg zolpidem, which resolved when the hypnotic was discontinued (Hale 2017 online access). In five women given a 20-mg dose of zolpidem (normal dose 10 mg), after three hours the amount of drug detected in breastmilk ranged between 0.76 and 3.88 µg. This is taken to indicate the peak level to which the baby would be exposed (Pons et al. 1989). No detectable zolpidem was found in subsequent milk samples. The BNF reports that there is only a small amount secreted into breastmilk but that it should be avoided.

References

- Reported in Hale T, Medications and Mothers' Milk (2010) as a personal communication.
- Pons G, Francoual C, Guillet P, Moran C, Hermann P, Bianchetti G, Thiercelin JF, Thenot JP, Olive G, Zolpidem excretion in breastmilk, Eur J Clin Pharmacol, 1989;37:245–8.

Temazepam: is 96% plasma protein bound. It is a short-acting benzodiazepine with a half-life reportedly between 8 and 15 hours. It is used in short-term management of insomnia but should not be used for more than 14–28 days. Lebedevs et al. (1992) studied ten women all with babies less than 15 days old. The mothers were given 10–20 mg for two nights before milk levels were studied. No adverse effects were noted in any of the babies. Temazepam levels were detected in breastmilk in only one of the ten mothers. The authors considered that breastfed neonates would ingest negligible amounts of temazepam. It is not licenced for use in children. The BNF recommends that benzodiazepines are present in milk, and should be avoided if possible during breastfeeding.

Reference

- Lebedevs TH, Wojnar-Horton RE, Yapp P, Roberts MJ, Dusci LJ, Hackett LP, Ilett KF, Excretion of temazepam in breastmilk, Br J Clin Pharmacol, 1992;33:204–6.

Nitrazepam: Matheson et al. (1990) studied nine women who received 5 mg nitrazepam nightly for five nights. No adverse effects were noted in the infants. The average amount of nitrazepam received by the breastfed baby in the morning was calculated to increase from 1 to 1.5 µg per 100 millilitres. The authors concluded that nitrazepam was compatible with breastfeeding in the immediate post-natal period but that further studies were necessary to confirm safety in the longer term. Relative infant dose is quoted as 2.9% (Hale 2017 online access). It is not licenced for use in children. It is 87% plasma protein bound. Half-lives of 24–30 hours have been reported (Martindale 2017). The BNF recommends that benzodiazepines are present in milk and should be avoided if possible during breastfeeding.

Reference

- Matheson I, Lunde PK, Bredesen JE, Midazolam and nitrazepam in the maternity ward: milk concentrations and clinical effects, Br J Clin Pharmacol, 1990;30:787–93.

Prescribed sedatives for anxiety

Diazepam: Diazepam has a long half-life (with terminal metabolite being present for two to five days) and accumulation is possible. The plasma elimination is further extended in neonates due to poor hepatic function. It is 98% plasma protein bound. A shorter-acting anxiolytic is preferable for use for more than a few days, particularly in neonates. Brandt (1976) conducted a study of four post-natal women who were given 10 mg diazepam at bedtime for six nights. He concluded that even with a neonate, a maternal dose of 10 mg produced breastmilk levels too small to cause any untoward effects in the baby. Erkkola and Kanto (1972) studied three infants whose mothers were taking 10 mg diazepam three times daily from delivery. The babies were observed for six days during which period no symptoms of sedation were noticed. However, Patrick et al. (1972) reported on a single mother taking the same dose. At 8 days of age (three days after the mother commenced diazepam) symptoms of lethargy, EEG changes and weight loss were apparent in the infant and attributed to the diazepam exposure. Relative infant dose quoted as 7.1% (Hale 2017 online access). It is licenced for use in children only to control convulsions. Diazepam is also a drug that may be abused in large doses. Close observation of the baby should be undertaken and the mother encouraged to reduce the dosage as far as possible under supervision of a detoxification service if necessary. The BNF suggests that benzodiazepines are present in milk and should be avoided if possible during breastfeeding. Diazepam is used to relieve muscular spasm following back injuries and use for a short period of time should not preclude it from use by lactating mothers in these circumstances. However, babies should be observed for sedation. Single doses of diazepam may also be used in situations such as fear of flying, before surgery or other anxiety-provoking situations with continued breastfeeding as normal

References

- Brandt R, Passage of diazepam and desmethyldiazepam into breastmilk, Arzneimittelforschung, 1976;26:454–7.
- Erkkola R, Kanto J, Diazepam and breastfeeding, The Lancet, 1972;299:1235–6, Letter.
- Patrick MJ, Tilstone WJ, Reavey P, Diazepam and breastfeeding, The Lancet, 1972;299:542–3, Letter.

Alprazolam (Xanax): a benzodiazepine but is preferred due to the shorter half-life (12–15 hours). Oo et al. (1995) obtained multiple milk and serum samples from eight lactating subjects up to 36 hours after a single oral dose of 0.5 mg alprazolam. The milk plasma ratio was determined to be 0.36, a level too low to produce clinically significant levels. No outcomes were available as the infants were not breastfed. Reports of withdrawal in infants exposed in utero and breastfed are documented (Anderson and McGuire 1989). Hale quotes a relative infant dose of 8.5% (Hale 2017 online access). The BNF states that all benzodiazepines are present in milk and should be avoided if possible during breastfeeding.

References

- Oo CY, Kuhn RJ, Desai N, Wright CE, McNamara PJ, Pharmacokinetics in lactating women: prediction of alprazolam transfer into milk, Br J Clin Pharmacol, 1995;40(3):231–6.
- Anderson PO, McGuire GG, Neonatal alprazolam withdrawal—possible effects of breast feeding, DICP, 1989;23(7–8):614.

Lorazepam: is 85% bound to plasma proteins and is 90% bio-available. Half-life is reported as 10 to 20 hours. A post-partum study (Summerfield and Nielsen 1985) found clinically insignificant amounts of lorazepam in breastmilk even at a dose of 2.5 mg twice daily for the first five days post-natally. Whitelaw et al. (1981) estimated that an exclusively breastfed infant would be exposed to 7 µg per kilogramme per day with a maternal dose of 2.5 mg twice daily The single infant studied showed no signs of sedation. The dose used in this study is more than the usual maximum of 2 mg daily. Relative infant dose is quoted as 2.5% (Hale 2017 online access). It is licenced for use in children only to control convulsions. The BNF suggests that benzodiazepines are present in milk and should be avoided if possible during breastfeeding. LactMed reports that lorazepam has low levels in breastmilk, a short half-life relative to many other benzodiazepines, and is safely administered directly to infants. Evidence from nursing mothers indicates that lorazepam does not cause any adverse effects in breastfed infants with usual maternal dosages and that no special precautions are required. Using Kelly (2012) data lorazepam may be taken as one of the safest benzodiazepines if use is important.

References

- Kelly LE, Poon S, Madadi P, Koren G, Neonatal benzodiazepines exposure during breastfeeding, J Pediatr, 2012;161:448–51.
- Summerfield RJ, Nielsen MS, Excretion of lorazepam into breastmilk, Br J Anaesth, 1985; 57:1042–3.
- Whitelaw AG, Cummings AJ, McFadyen IR, Effect of maternal lorazepam on the neonate, BMJ (Clin Res Ed), 1981;282(6270):1106–8.

Sleeping tablets

Avoid if possible. Use for as short a time as possible. Observe baby for drowsiness. Avoid falling asleep with the baby in bed, on a chair or sofa