Safety of Medicines During Breastfeeding

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King Thutmose III breastfed by a holly tree, about 1500 B.C.
Ch. Beaubrun – Louis XIV with a nurse, around 1640
Breastfeeding Benefits for the Infant

- Optimal nutrition
- Immunoprotection
- More than 1 000 components being of some importance
- Protection against acute diseases (diarrhoea, respiratory infections, otitis media…)
- Possible protection against chronic diseases (hypertension, hypercholesterolemia, obesity, inflam. bowel diseases…)

SÚKL
Breastfeeding Benefits for the Mother

- Better regeneration after delivery
- Better bone remineralisation (lower incidence of hip fractures in postmenopause)
- Lower incidence of ovarian cancer
- Slightly lower incidence of breast cancer in premenopause
- Lower incidence of hypertension
Other Benefits of Breastfeeding

- Psychological
- Social
- Ecological
- Economic

Premature discontinuation of breastfeeding is a handicap for both mother and child.
Breastfeeding Rate

- US 2011 – at birth 79%, at 3 mths 64% (any), 41% (exclusive), at 6 mths 49% (any), 19% (exclusive)
- UK 2012/13 – at birth 74%, for 6-8 weeks 47% (any)
- In EU, highest rate in NO, SE, IC
- CZ – at birth 89%
Pharmacotherapy during Breastfeeding

- 90% of women in NO maternity hospitals
- 90-99% of women in 1st week after delivery (T. Hale)
- 65.9% breastfeeding women in NL (2003)
Breastfeeding termination due to pharmacotherapy

- Absolute contraindication rare
- CI usually relative
- Risk reduction: interruption of breastfeeding (5 T½), choice of less risky drug, timing of breastfeeding
- ADRs in an infant develop gradually
- Close observation of the infant, monitoring
How to make a decision?

- Weigh benefits of breastfeeding to possible risks for the infant
Categories of Risk for the Infant

- Infant’s dose of a medicine taken in breast milk
- Pharmacokinetics in the infant
- Safety profile of the medicine
- Infant’s age/health state

- Risk is different from that in pregnancy
Infant’s dose

- Plasma levels in the mother
- Amount of transfer into breast milk

Nearly all drugs enter into breast milk, risk is related to quantity

- Amount of milk ingested
- Relative infant dose (up to 10% usually supposed to be safe)
- Cumulative dose
Pharmakokinetics in the Infant

- Absorption in GIT (if not absorbed, no systemic ADRs, only gastrointestinal disturbancies)
- Metabolic capacity of the liver
- Renal elimination (preferably medicines with short elimination half-life)
Safety Profile of the Medicine

- Adverse reactions (ADRs) detected in breastfed infants
- Experience with treatment without ADRs in breastfed infants
- Possible ADRs – known safety profile according to SmPC of the medicinal product
- Assessment of possible impact on the infant
Infant’s State

- Premature
- Newborn
- Age
- General state of health
- Specific health problems
Best Choice of Medicine

- Low breast milk levels (low relative infant’s dose - less than 10%)
- Short elimination half-life
- Evidence of use during breastfeeding without ADRs
- Good safety profile
- Indication in newborns and infants
- Monotherapy
- If possible, suitable timing of breastfeeding and drug administration
Close Observation of the Infant

- Close liaison between mother and physician
- Mother should be informed about potential ADRs
- Contact with the physician in case of problems
- If necessary, specific controls (weight, psychomotoric screening, BP, HR, blood count, liver function tests, blood drug levels in the infant...
Most Frequent ADRs

- Drowsiness, lethargy
- Poor suckling, fail to thrive
- Irritability, agitation, crying
- Vomiting, colics
- Diarrhoe, obstipation
- Cutaneous reactions
Classification of Medicines according to the Risk for the Infant

- Influence on milk production (important decrease bromocriptine, cabergoline, estrogens...)
- Contraindication (immunosuppressants, cytostatics, radioactive isotopes, codein...)
- Possibly hazardous (psychopharmaceuticals, antiepileptics, hormone therapy, antiarrhythmics, antihypertensives...)
- Quite safe (heparine, insuline, analgesics, antiasthmatics, PNC antibiotics, topic therapy...)

Where to Find Information

SmPC of medicinal products
for CZ www.sukl.cz
for EU www.ema.europa.eu

Database Toxnet – LactMed
toxnet.nlm.nih.gov