EMORY UNIVERSITY SCHOOL OF MEDICINE

Women's Mental Health Program

Department of Psychiatry and Behavioral Sciences

EMORY WMHP BLOG

Hale's Breastfeeding Safety Ratings: Part 1 – Rating System

Thomas Hale's *Medications and Mothers' Milk*, now in its 14th edition, has become the standard reference for rating the breastfeeding safety of medications. In this series, we will provide a summary of Dr. Hale's ratings and recommendations for the major classes of psychiatric medications. In this first entry in the series, we present the key components of Dr. Hale's lactation safety rating system.

One estimate of risk is provided by the level of exposure for a nursing infant. Dr. Hale reports the ***Relative Infant Dose (RID)*** for each medication as an index of the level of exposure. Expressed as a percentage, the RID is calculated by dividing the infant's total daily ingestion of a medication via nursing (expressed as mg per kg infant body weight) by the mother's daily dose of the medication (expressed as mg per kg maternal body weight). Dr. Hale advises that "a Relative Infant Dose of <10% is considered safe", though we would caution that this is a general observation that has never been objectively verified.

Earlier studies had utilized milk:plasma ratio as an index of the level of exposure, but milk:plasma ratios have been abandoned in favor of RID in recent years. We agree with Dr. Hale that "the milk:plasma ratio is virtually worthless" because it does not provide an estimate of the total amount of a drug that is transferred to a nursing baby.

Finally, Dr. Hale rates each medication according to a 5-category system of ***Lactation Risk Categories***. Hale's rating for each medication is determined by the degree to which the medication has been studied (NOTE: Newer and seldom-used medications typically have not been well-studied) and the level of risk that has been identified for the particular medication. Hale's risk categories include:

- **L1 SAFEST** – Drug has been taken by many breastfeeding women without evidence of adverse effects in nursing infants OR controlled studies have failed to show evidence of risk.
- **L2 SAFER** – Drug has been studied in a limited number of breastfeeding women without evidence of adverse effects in nursing infants.
- **L3 MODERATELY SAFE** – Studies in breastfeeding have shown evidence for mild non-threatening adverse effects OR there are no studies in breastfeeding for a drug with possible adverse effects.
- **L4 POSSIBLY HAZARDOUS** – Studies have shown evidence for risk to a nursing infant, but in some circumstances the drug may be used during breastfeeding.
- **L5 CONTRAINDICATED** – Studies have shown significant risk to nursing infants. The drug should NOT be used during breastfeeding.

Additional Thoughts from the Emory WMHP

- **MATERNAL (SIDE) EFFECTS PREDICT INFANT SAFETY CONCERNS** – This is an intuitive observation that is a helpful aid in directing the focus of your concern. If a medication causes sedation in the mother, then her nursing infant should be observed for sedation. If a medication causes appetite or weight loss, then her nursing infant's growth should be carefully monitored.
- **MATERNAL LAB MONITORING SHOULD ALSO BE PERFORMED FOR THE INFANT** – Numerous medications have safety concerns that require regular laboratory monitoring. For example, liver enzyme tests must be monitored for women taking valproate, carbamazepine, and nefazodone. Blood cell counts must be monitored for women taking valproate, carbamazepine, oxcarbazepine, and clozapine. Kidney function must be monitored for women taking lithium. We recommend that if a breastfeeding mother is taking a medication that requires laboratory monitoring, then these same laboratory tests should be monitored in her infant as well.
- **PREGNANCY EXPOSURE IS MUCH HIGHER THAN BREASTFEEDING EXPOSURE** – In our experience, the level of fetal exposure to a psychiatric medication during pregnancy is typically at least 10-fold higher than the level of exposure that occurs via nursing. Consequently, if a child has already been exposed to a medication throughout pregnancy, then nursing simply continues that same exposure at a much lower level.

- **LONG-TERM EFFECTS OF BREASTFEEDING EXPOSURE ARE NOT YET WELL-STUDIED** – Dr. Hale's ratings focus upon risks identified during infancy when the child is still nursing. There may be developmental effects of nursing exposure that will not be evident until much later. For this reason, we recommend that you consider discontinuing nursing if you must begin taking a new medication.
- **"PUMPING & DUMPING" CAN REDUCE EXPOSURE TO OCCASIONAL MEDICATIONS** – Peak breast milk concentrations of a medication generally occur within the first hours following a dose. If you must take an "as needed" dose of a medication (e.g., sleep medication, pain medication), your baby's level of exposure to the medication can be reduced by following these steps: 1) maintain a supply of breast milk that you have pumped and stored; 2) take the medication immediately after a feeding; 3) at your baby's next feeding, bottle feed your baby some of the breast milk that you have previously stored (or formula); 4) at this time, pump breast milk from both breasts and discard (dump) that breast milk; 5) resume regular breastfeeding at the next feeding.

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