

## Case Study

- 43 year-old female with chronic baclofen use for spasticity secondary to a spinal cord injury.
  - Gave birth to a healthy full-term infant male via spontaneous vaginal delivery.
  - During-and-after the pregnancy the mother had received oral baclofen daily.
  - Began supplying breast milk for her infant shortly after giving birth.
  - Infant began a baclofen taper after birth to prevent Neonatal Abstinence Syndrome.

## Background

- Baclofen
  - Gamma-aminobutyric acid (GABA) agonist used as a muscle relaxant in the treatment of spasticity.
  - Occasionally necessary for pregnant and lactating patients to take baclofen for neurological conditions.
  - Other than one case report within the literature, there is little data regarding distribution of baclofen into breast milk.

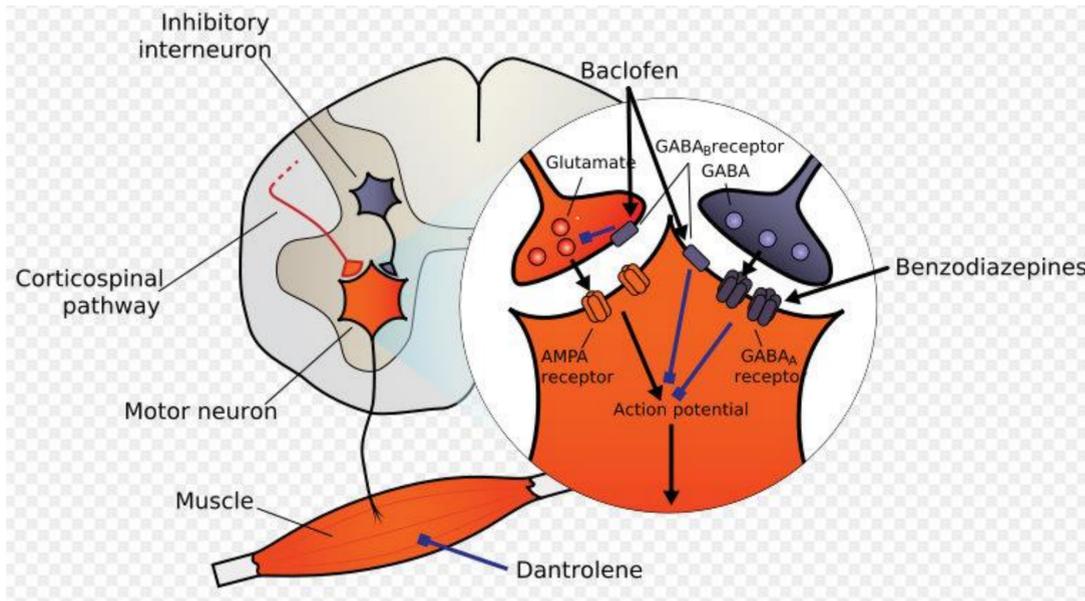


Figure 1: Mechanism of Action of Baclofen

## Hypothesis

- Nursing infants may be exposed to clinically significant amounts of baclofen when the mother is taking oral baclofen.

## Methods

- Single patient chart review was conducted.
- During-and-after pregnancy the mother received oral baclofen, 20 mg four times a day at evenly spaced intervals, between 0600 and 2200 daily.
- For three consecutive days, breast milk samples were collected at estimated trough (0530) and peak (2400) times.
- Using high performance liquid chromatography and tandem mass spectrometry, baclofen concentrations were determined from each sample of breast milk.

## Results

- Baclofen trough levels varied from 0.28 mcg/mL to 0.32 mcg/mL with a mean trough level of  $0.297 \pm 0.021$  mcg/mL.
- Baclofen peak levels varied from 0.32 mcg/mL to 0.38 mcg/mL with a mean peak level of  $0.343 \pm 0.033$  mcg/mL.

	Day 1	Day 2	Day 3	Mean $\pm$ SD
<b>Trough Level (mcg/mL)</b>	0.32	0.29	0.28	$0.297 \pm 0.021$
<b>Peak Level (mcg/mL)</b>	0.38	0.32	0.33	$0.343 \pm 0.033$

Figure 2: Concentrations of Baclofen in Breast Milk

## Discussion

- This case study demonstrates a mother taking oral baclofen, 20 mg four times a day, having breast milk concentrations ranging from 0.28 mcg/mL to 0.38 mcg/mL.
- A 3 kg infant consuming 750 mL of breast milk per day would be ingesting approximately 0.075 mg/kg/day, approximately 1/4<sup>th</sup> the weight-based dose of baclofen (0.29 mg/kg/day) in an average 70 kg adult consuming 20 mg baclofen daily.
- Infants may have longer elimination half-lives and accumulate baclofen at greater concentrations.
- Infants may be more sensitive to the effects of baclofen and chronic exposure could cause significant toxicity or have developmental effects.
- In the infant-mother pair within this case study, the breast milk was initially limited to 1/3 amount of the total daily diet (2/3 formula); only after observing for clinical effects and obtaining levels in milk was the ratio increased to 1/2.
- Infant serum baclofen level on the 2<sup>nd</sup> day of life was 0.54 mcg/mL (therapeutic range 0.08 – 0.40 mcg/mL). Likely sources of baclofen included the baclofen taper, in utero exposure, and breast milk.
- Samples of placenta cord blood were obtained in an attempt to assess the amount of baclofen that crosses the placenta in utero. Unfortunately the samples clotted thus making it unable to obtain baclofen concentration levels.

## Conclusion

- This case study adds to the data on baclofen distribution in breast milk.
- Nursing infants may be exposed to clinically significant amounts of baclofen when the mother is taking oral baclofen.
- Nursing mothers taking oral baclofen may have to limit amount of breast milk intake in infants as distribution may be significant.

