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Fentanyl

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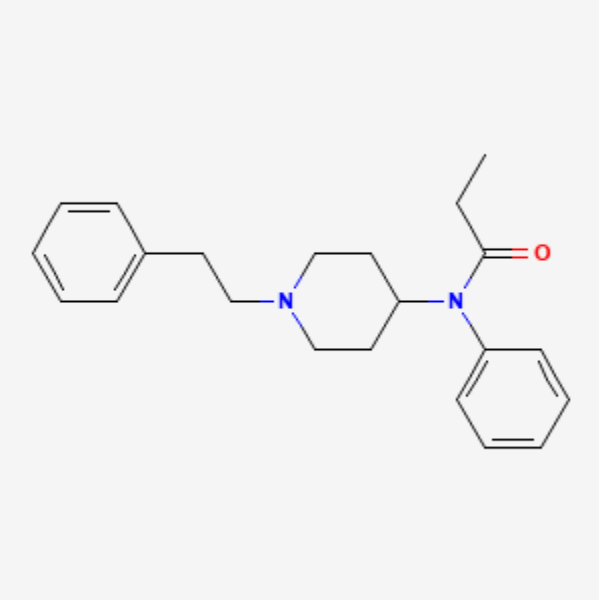

Drug Levels and Effects

Summary of Use during Lactation

When used epidurally or intravenously during labor or for a short time immediately postpartum, amounts of fentanyl ingested by the neonate are usually small and are not expected to cause any adverse effects in breastfed infants. The results of studies on the effect of epidural fentanyl on breastfeeding initiation and duration are mixed, because of the many different combinations of drugs, dosages and patient populations studied as well as the variety of techniques used and deficient designs of many of the studies.

It has been suggested that a cumulative dose of 80 to 150 mcg of fentanyl during labor and delivery reduces breastfeeding success,[1-3] but another study found no marked decrease in breastfeeding success with doses above 150 mcg in motivated women with previous breastfeeding success.[4]

In infants placed skin-to-skin after a normal vaginal delivery, epidural fentanyl given during labor may delay the infant's first suckling in a dose-dependent manner,[5] perhaps because it can persist in the infant's serum for over 24 hours after discontinuation.[6] However, it appears that with good breastfeeding support, epidural fentanyl plus bupivacaine has little overall effect on breastfeeding success.[7-11]

No waiting period or discarding of milk is required before resuming breastfeeding after fentanyl is used for short procedures (e.g., for endoscopy).[12,13] After general anesthesia, breastfeeding can be resumed as soon as the mother has recovered sufficiently from anesthesia to nurse. When a combination of anesthetic agents is used for a procedure, follow the recommendations for the most problematic medication used during the procedure. Limited information indicates that transdermal fentanyl in a dosage of 100 mcg/hour results in undetectable fentanyl concentrations in breastmilk.

Maternal use of oral opioids during breastfeeding can cause infant drowsiness, which may progress to rare but severe central nervous system depression. Newborn infants seem to be particularly sensitive to the effects of even small dosages of narcotic analgesics. Preterm infants are the most susceptible to fentanyl's effects because their clearance is substantially reduced.[14] If fentanyl is required by the mother of a newborn, it is not a reason to discontinue breastfeeding; however, once the mother's milk comes in, it is best to provide pain control with a nonnarcotic analgesic and limit maternal intake of fentanyl to a few days at a low dosage with close infant monitoring. If the baby shows signs of increased sleepiness (more than usual), difficulty breastfeeding, breathing difficulties, or limpness, a physician should be contacted immediately.

Drug Levels

Plasma fentanyl levels of 0.2 to 1.2 mcg/L are required for analgesia via the nonepidural route and plasma levels over 1 to 2 mcg/L may cause respiratory depression. Plasma levels are markedly lower when the epidural route is used. The oral bioavailability of fentanyl is 33% in adults. The usual intravenous of fentanyl for an infant is 1 to 2 mcg/kg. Fentanyl is metabolized to norfentanyl and inactive metabolites.

Maternal Levels. Eight women who had undergone cesarean section received fentanyl 100 mcg epidurally immediately after delivery. Fentanyl was undetectable (<0.1 mcg/L) in colostrum at about 1 hour after the dose.[15]

Thirteen women were given a single fentanyl 2 mcg/kg intravenous dose during either cesarean section or postpartum tubal ligation. Colostrum was collected at 0.75, 2, 4, 6, 8, and 10 hours after the dose. The average peak fentanyl level was 0.40 mcg/L and occurred 45 minutes after the dose. Average levels declined to 0.22 mcg/L at 2 hours and to 0.15 mcg/L at 4 hours then to the lower limit of the assay (0.05 mcg/L) at 6, 8, and 10 hours after the dose.[16] Based on the peak milk fentanyl level reported in this study, an exclusively breastfed infant would receive a fentanyl dose of 0.06 mcg/kg daily.

Ten women were given 50 to 100 mcg of intravenous fentanyl every hour during labor. Their breastmilk was sampled 4 and 24 hours after delivery. The cumulative maternal fentanyl dosages ranged from 50 to 400 mcg and the longest time from last dose to delivery was 3.1 hours (range 0 to 3.1 hours). Fentanyl was undetectable (<0.05 mcg/L) in the milk of 8 of the women 4 hours after delivery and in 2 of the women 24 hours after delivery. Detectable milk levels of fentanyl ranged from 0.12 to 0.15 mcg/L at 4 hours after delivery and from 0.12 to 0.14 mcg/L at 24 hours after delivery.[17] Based on the highest milk level reported in this study, an exclusively breastfed infant would receive a fentanyl dosage of 0.02 mcg/kg daily.

Five women who were 6 to 15 weeks postpartum were given a single dose of 100 mcg of fentanyl intravenously before undergoing general anesthesia. Several milk samples were collected between 5 and 24 hours after the injection from each woman. The authors estimated that the infants would receive an average of 0.005 mcg/kg in the 24 hours after a single dose of fentanyl. This corresponds to about 0.38% of the maternal weight-adjusted dosage. The authors concluded that this amount of fentanyl in milk is unlikely to affect a healthy, term infant.

[18] The infants of mothers not undergoing a surgical procedure might receive a greater dose of fentanyl in breastmilk, but it would be unlikely to be a large dose.

A randomized, prospective study measured colostrum fentanyl concentrations following epidural or intravenous fentanyl during delivery in 100 multiparous mothers undergoing cesarean section and delivering full-term, healthy infants. Epidural fentanyl was given to 50 women in a dose of 100 to 150 mcg in divided doses followed by a continuous epidural infusion of 20 mcg/hour. Intravenous fentanyl was given to 50 women as a single dose of 50 mcg after delivery. Both groups received epidural or spinal bupivacaine in addition. Colostrum samples were obtained 45 minutes and 24 hours after the initial fentanyl dose. At 45 minutes, colostrum fentanyl concentrations were 0.4 mcg/L in the epidural group and 0.19 mcg/L in the intravenous group. At 24 hours, colostrum fentanyl concentrations were 80 ng/L in the epidural group and 0.05 mcg/L in the intravenous group. The authors estimated that in the worst-case scenario, a fully breastfed infant would absorb a fentanyl dose of 0.016 mcg/kg.[19]

A woman was using a transdermal fentanyl patch for chronic back pain during pregnancy and postpartum. The mother required additional analgesia during labor and the infant required treatment for neonatal abstinence syndrome. By 2 weeks postpartum, the mother was using a fentanyl patch in a dosage of 100 mcg/hour which was changed every other day. A sample of pumped breastmilk from one breast contained fentanyl 6.4 mcg/L and norfentanyl 6.2 mcg/L.[20]

Infant Levels. An infant whose mother was using a fentanyl patch in a dosage of 100 mcg/hour which was changed every other day was fed her mother's milk either by bottle or by the breast every 3 hours beginning about 2 weeks postpartum. On day 27 of life, the infant was fed 380 mL of maternal milk following several feedings during the prior 24 hours. The infant's serum fentanyl and norfentanyl concentrations were not detectable (<0.1 mcg/L).[20]

Effects in Breastfed Infants

Fentanyl was possibly the cause of statistically significant, but clinically unimportant, lower neurobehavioral scores in a group of 32 newborns who were less than 24 hours old and whose mothers had received epidural fentanyl during labor.[21]

An epidural fentanyl dosage greater than 150 mcg during labor was associated with slightly lower neurobehavioral scores in the newborns of 177 breastfeeding mothers on postpartum day 1 compared to a lower total dosage or to no fentanyl;[1] however, this might have been a chance association[22] and was probably due to placental transfer of fentanyl prior to delivery and not from breastmilk after delivery. All women also received epidural bupivacaine.

A woman was using a transdermal fentanyl patch for chronic back pain during pregnancy and postpartum. The mother required additional analgesia during labor and the infant required treatment for neonatal abstinence syndrome. By 2 weeks postpartum, the mother was using a fentanyl patch in a dosage of 100 mcg/hour which was changed every other day and the infant was being fed the mother's milk every 3 hours. The infant had no additional medical problems and fed well until discharge after day 27 of life, gaining 500 grams.[20]

A search was performed of the shared database of all U.S. poison control centers for the time period of 2001 to 2017 for calls regarding medications and breastfeeding. Of 2319 calls in which an infant was exposed to a substance via breastmilk, 7 were classified as resulting in a major adverse effect, and one of these involved fentanyl. A one-month-old infant was exposed to fentanyl, morphine, oxycodone, and unspecified benzodiazepines. The infant was admitted to the intensive care unit and described as being agitated and irritable and having tachycardia, confusion, drowsiness, lethargy, miosis, respiratory depression, acidosis, and hyperglycemia. The dosages, routes of administration, and extent of breastfeeding were not reported and the infant survived.[23]

Effects on Lactation and Breastmilk

Fentanyl can increase serum prolactin.[24,25] However, the prolactin level in a mother with established lactation may not affect her ability to breastfeed.

Five women who were 6 to 15 weeks postpartum were given single doses of 100 mcg of fentanyl, 2 mg of midazolam and 2.5 mg/kg of propofol intravenously before undergoing general anesthesia. The women's milk output following the surgical procedure was less than half of the normal milk output of nursing mothers. The authors speculated that milk volume might be reduced postoperatively because of perioperative fluid restriction and volume losses, as well as stress-induced inhibition of milk production.[18]

In 58 breastfeeding mothers who received an epidural fentanyl dosage greater than 150 mcg during labor, 21% reported more difficulty in establishing breastfeeding at 24 hours after delivery compared to 10% of mothers who received to a lower dosage or to no fentanyl. There was no difference in breastfeeding difficulty noted between the groups 24 hours after delivery as determined by a lactation consultant. Women in the high-dose group who could be contacted were more likely to discontinue breastfeeding by 6 weeks after delivery and there was a higher rate of breastfeeding discontinuation at 6 weeks among mothers who reported breastfeeding difficulty 24 hours after delivery.[1] A relatively high dropout rate from the study at 6 weeks clouds the results.[22]

A retrospective study of a random sample of 425 mothers delivering in a maternity unit found a dose-related increased risk of bottle feeding at hospital discharge associated with fentanyl administered during labor.[26]

A prospective cohort study compared women who received continuous epidural analgesia with fentanyl and either bupivacaine or ropivacaine during labor and delivery (n = 52) to women who received no analgesia (n = 63). The average total fentanyl dosage was 124 mcg and the average total infusion time from start to delivery was 219 minutes. The study found no differences between the groups in breastfeeding effectiveness or infant neurobehavioral status at 8 to 12 hours postpartum or the number exclusively or partially breastfeeding at 4 weeks postpartum.[27]

A randomized, prospective study measured infant breastfeeding behavior following epidural or intravenous fentanyl during delivery in 100 multiparous mothers undergoing cesarean section and delivering full term, healthy infants. Epidural fentanyl was given to 50 women in a dose of 100 to 150 mcg in divided doses followed by a continuous epidural infusion of 20 mcg/hour. Intravenous fentanyl was given to 50 women as a single dose of 50 mcg after delivery. Both groups received epidural or spinal bupivacaine in addition. A slight difference was seen in breastfeeding behavior between the groups, with the infants in the intravenous fentanyl group performing slightly worse than those in the epidural group. However, all mothers were able to breastfeed their infants at 24 hours. None had severe breastfeeding problems; 10 women in the epidural group reported mild or moderate problems and 7 women in the intravenous group reported breastfeeding problems. Twenty mothers in the epidural group and 14 in the intravenous group used supplemental bottle feeding, with the difference not statistically significant.[19]

A randomized, multicenter trial compared the initiation rate and duration of breastfeeding in women who received high-dose epidural bupivacaine alone, or one of two low-dose combinations of bupivacaine plus fentanyl. The average fentanyl dosages in the two groups were 97 and 151 mcg in the first stage of labor and 10 and 12 mcg of fentanyl during the second stage of labor, respectively, with great variability. A nonepidural matched control group was also compared. No differences in breastfeeding initiation rates or duration were found among the epidural and nonmedicated groups, but women in the nonepidural group who received systemic meperidine had a lower breastfeeding initiation rate than in the other groups.[28]

A nonrandomized study in low-risk mother-infant pairs found that there was no difference overall in the amount of sucking by newborns, whether their mothers received bupivacaine plus fentanyl, or fentanyl alone by

epidural infusion in various dosages, or received no analgesia for childbirth. In a subanalysis by sex and number of sucks, female infants were affected by high-dose bupivacaine and high-dose fentanyl, but male infant were not.[29] However, the imbalances of many factors between the study groups makes this study difficult to interpret.

In a prospective cohort study, 87 multiparous women who received epidural bupivacaine and fentanyl for pain control during labor and vaginal delivery. A loading dose of 0.125% bupivacaine with fentanyl 50-100 mcg. Epidural analgesia is maintained using 0.0625% bupivacaine and fentanyl 0.2 mcg/mL. The median dose of fentanyl received by the women was 151 mcg (range 30 to 570 mcg). The women completed questionnaires at 1 and 6 weeks postpartum regarding breastfeeding. Most women had prior experience with breastfeeding, support at home and ample time off from work. All women were breastfeeding at 1 week postpartum and 95.4% of women were breastfeeding at 6 weeks postpartum.[30]

A nonrandomized study at one Italian hospital compared primiparous mothers undergoing vaginal delivery who received epidural analgesia (n = 64) to those who did not (n = 64). Mothers who requested the epidural analgesia received an initial dose of 100 mcg of fentanyl diluted to 10 mL with saline. After the initial fentanyl, doses of 15 to 20 mL of 0.1% ropivacaine were administered if needed. The only difference between the groups of mothers was a longer duration of labor among the treated mothers. The quality of infant nursing was equal between the 2 groups of infants on several measures; however, more infants in the treated group breastfed for less than 30 minutes at the first feeding.[31]

A national survey of women and their infants from late pregnancy through 12 months postpartum compared the time of lactogenesis II in mothers who did and did not receive pain medication during labor. Categories of medication were spinal or epidural only, spinal or epidural plus another medication, and other pain medication only. Women who received medications from any of the categories had about twice the risk of having delayed lactogenesis II (>72 hours) compared to women who received no labor pain medication.[32]

A randomized study compared the effects of cesarean section using general anesthesia, spinal anesthesia, or epidural anesthesia, to normal vaginal delivery on serum prolactin and oxytocin as well as time to initiation of lactation. General anesthesia was performed using propofol 2 mg/kg and rocuronium 0.6 mg/kg for induction, followed by sevoflurane and rocuronium 0.15 mg/kg as needed. After delivery, patients in all groups received an infusion of oxytocin 30 international units in 1 L of saline, and 0.2 mg of methylergonovine if they were not hypertensive. Fentanyl 1 to 1.5 mcg/kg was administered after delivery to the general anesthesia group. Patients in the general anesthesia group (n = 21) had higher post-procedure prolactin levels and a longer mean time to lactation initiation (25 hours) than in the other groups (10.8 to 11.8 hours). Postpartum oxytocin levels in the nonmedicated vaginal delivery group were higher than in the general and spinal anesthesia groups.[33]

A randomized, nonblinded study compared the use of intramuscular meperidine 100 mg to intranasal (mean dose 486 mcg) or subcutaneous (mean dose 300 mcg) fentanyl for labor analgesia. More women in the meperidine group had difficulty establishing lactation (79%) than in the intranasal (39%) or subcutaneous (44%) fentanyl groups. Mothers who received meperidine reported more sedation, had longer labors, and their infants were more likely to be admitted to the nursery.[34,35]

A retrospective study in a Spanish public hospital compared the infants of mothers who received an epidural during labor that contained fentanyl and either bupivacaine or ropivacaine. Infants of mothers who received an epidural had a lower frequency of early breastfeeding.[36]

A small prospective study in California compared women who received an epidural infusion of fentanyl and ropivacaine to mothers who did not receive an epidermal during labor. All mothers had normal vaginal deliveries and their infants had 1 uninterrupted hour of skin-to-skin contact immediately postpartum. The study found inverse relationships between the amount of fentanyl and the amount of oxytocin received during labor

and the time of the first suckling. Because women who received more fentanyl also tended to receive more oxytocin, the study could not clearly separate the effects of the two drugs.[5]

A randomized, double-blind study compared three epidural maintenance solutions for labor analgesia in women receiving epidural analgesia during labor: bupivacaine 1 mg/mL, bupivacaine 0.8 mg/mL with fentanyl 1 mcg/mL, or bupivacaine 0.625 mg/mL with fentanyl 2 mcg/mL. At 6 weeks postpartum, the breastfeeding rate was 94% or greater in all groups, with no difference among them. All mothers delivered full-term infants and were highly motivated to breastfeed and almost all had vaginal deliveries.[4]

A prospective cohort study in 1204 Israeli women on the effect of labor epidural analgesia during labor, the following protocol was used: bupivacaine 0.1% 15 mL and fentanyl 100 mcg in 5-mL increments, followed by an epidural infusion of bupivacaine 0.1% 10 mL and fentanyl 2 mcg/mL, with a patient-controlled epidural analgesia modality with 5 mL bolus with a lock-out time of 15 minutes. At 6 weeks postpartum, the breastfeeding and exclusive breastfeeding rates were lower (74% and 52%, respectively) in mothers who received the epidural analgesia than in those who did not (83% and 68%, respectively). However, the difference was mostly accounted for by parity, with the intervention having little effect on multiparous women.[37]

A prospective study in an Australian hospital compared mothers who received epidural fentanyl analgesia, subcutaneous morphine or neither during labor and delivery. When controlled for labor induction, instrumental delivery and special care nursery admission, no difference was seen between the 3 groups in breastfeeding rates at discharge or at 6 weeks postpartum.[38]

A randomized, partially blinded study in a hospital in Thailand compared intravenous meperidine and fentanyl for pain during active labor. Mothers received either meperidine 50 mg (n = 46) or fentanyl 50 mcg (n = 46) initially and then every 1 (fentanyl) or 2 (meperidine) hours as requested by the mother. The percentages of infants who breastfed in the first 24 hours were only 61% for meperidine and 54% for fentanyl, although the difference was not statistically significant. Care of the infants (e.g., skin-to-skin in the first hour) was not reported.[39]

A multicenter, prospective cohort study in Hong Kong of 1277 women who gave birth found that women who received epidural analgesia with either fentanyl or morphine had no decreased frequency of breastfeeding in the first hour compared to mothers who did not receive epidural analgesia. All epidural injections were combined with a local anesthetic, but the exact dosages were not given.[40]

A prospective, observational study in Norway found that infant spontaneous suckling was negatively associated with any intrapartum fentanyl use. The odds of non-exclusive breastfeeding were doubled with epidural fentanyl analgesia and were 4 times higher with intravenous plus epidural fentanyl compared to no opioid exposure. Compared to higher doses, intravenous fentanyl doses greater than 200 mcg resulted in a reduction in exclusive breastfeeding and spontaneous suckling, and an increase in breastfeeding problems.[2]

A nonrandomized, nonblinded study in a Serbian hospital of women near term who underwent cesarean section compared general anesthesia (n = 284) to spinal or epidural anesthesia (n = 249). Spinal anesthesia consisted of hyperbaric bupivacaine 12 mg and fentanyl 0.01 mg; epidural anesthesia consisted of isobaric bupivacaine 0.5% (0.5 mg per 10 cm height) and fentanyl 0.05 mg. General anesthesia consisted of propofol 2.3 mg/kg and succinylcholine 1.5 mg/kg for induction and intubation, followed by an anesthetic gas mixture and oxygen. Reportedly, nitric oxide (possibly nitrous oxide) was 50% of the gas before delivery and 67% after delivery. Sevoflurane was also used in some cases. After delivery and cord clamping, mothers received fentanyl 3 mcg/kg and rocuronium 0.5 mg/kg intravenously for placental delivery. After surgery, neuromuscular block reversal was performed with neostigmine and atropine. All patients received 1 mg/kg of diclofenac every 8 h for 24 hours after delivery and 98% of general anesthesia patients also received 100 mg of tramadol and 78.5% received acetaminophen 1 gram. No regional anesthesia patients received tramadol or acetaminophen. Patients receiving one of the regional anesthetic protocols established lactation sooner (56% and 29% after 18 and 24 hours,

respectively), while 86% of women receiving general anesthesia did not establish lactation until 36 to 48 hours after surgery.[41]

In a study of primiparous women with an uncomplicated pregnancy, some women received epidural analgesia with ropivacaine (dose not specified) and fentanyl in a median dose of 121 mcg (IQR 77 to 192 mcg), some received oxytocin alone and other received neither. Breastfeeding outcomes in the three groups were compared at 3 days, 1 month and 4 months postpartum. The study found no relationship between low-dose oxytocin use and breastfeeding success, but that epidermal analgesia lowered milk supply at 3 days and 1 month postpartum, and decreased rates of breastfeeding at 4 months postpartum.[3]

Alternate Drugs to Consider

Acetaminophen, Butorphanol, Hydromorphone, Ibuprofen, Morphine

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Substance Identification

Substance Name

Fentanyl

CAS Registry Number

437-38-7

Drug Class

Breast Feeding

Lactation

Milk, Human

Analgesics, Opioid

Narcotics

Anesthetics, Intravenous

Opiates