BACKGROUND

Testosterone, delivered by pellet implant, has been successfully used to treat depression and fatigue in women. Breast feeding has been listed as a contraindication to testosterone therapy, despite a paucity of data to support this recommendation. Previously, in our practice, testosterone therapy has been withheld from nursing mothers until they discontinued breast feeding.

PURPOSE AND HYPOTHESIS

The purpose of this study was to evaluate maternal absorption of testosterone and its excretion into breast milk by three methods of delivery:

- Sublingual drops, 1 mg twice daily
- Vaginal cream, 0.5 mg applied daily in the morning
- Pellet implant, 100 mg implanted in subcutaneous tissue

Research hypothesis: Based on the pharmacokinetics of drug excretion in breast milk, testosterone is not expected to be significantly excreted in breast milk (molecular size > 200, non basic pH, fat solubility, significant protein binding) or absorbed into infant blood. In addition, testosterone has a low/no intrinsic toxicity.

MATERIALS AND METHODS

A 34 year-old breast feeding mother presented with symptoms of depression, anxiety, irritability, memory loss, aches and pains (MRS validated survey). Testosterone tested low by capillary bloodspot and serum. The patient was treated with testosterone delivered by: sublingual, vaginal cream and lastly, subcutaneous pellet implant. Sublingual hormones are known to peak rapidly in serum and be measurable for up to 4 hours. Vaginal hormones have been shown to be readily absorbed and peak in serum between 4 and 6 hours. Testosterone delivered by pellet implant shows continuous serum levels above endogenous ranges with diurnal variation. Elevated serum testosterone levels, above normal ranges, are expected with exogenous testosterone, delivered by pellet implant. Doses of 100 mg and above have been shown to relieve symptoms without evidence of major side effects or complications.

The mother was monitored for symptomatic improvement (MRS validated survey) and signs of testosterone excess (none). The infant was monitored for clinical signs of testosterone excess (none).

Specimen Collection

Baseline testosterone levels were obtained from maternal capillary blood and breast milk. During sublingual and vaginal testosterone therapy, serial maternal capillary testosterone and testosterone levels in breast milk were measured at 2 hour intervals. With maternal testosterone therapy delivered by pellet implant, testosterone levels were measured in maternal capillary blood and breast milk at once/twice daily intervals. Infant capillary bloodspot (heel-stick) testosterone was monitored day 2, day 7, week 4 and month 5.

Methodology: Breast milk, ZRT laboratory, Beaverton, OR

Breast milk samples (Collected into specimen tubes, labeled and frozen) were liquid extracted with hexane. After removal of the hexane layer, an additional liquid extraction was performed by adding an appropriate hexane solution to remove nonpolar lipids. After removal of the acetone layer, the lipids were reconstituted in an aqueous buffer. The same procedure was followed for assay commercially with purchased whole milk spiked with known amounts of testosterone. Reconstituted samples were assayed on a commercially available serum testosterone enzyme immunoassay (DRG International) following the given SOP following the addition of extracted standards and breast milk samples.

Methodology: Capillary Bloodspot, ZRT laboratory, Beaverton, OR

A minimum of 6 drops of capillary blood from the finger tips (or heel of the infant) were collected onto filter paper and allowed to dry. Dried blood spot samples were punched from dried samples. After steroid extraction, the samples, along with standards, were added to a 96-well enzyme immunoassay for testosterone (DRG). From this point the standard procedure for serum testing was followed and results given in ng/mL.

RESULTS

Testosterone was measurable in maternal blood by all three methods of delivery:

- Sublingual drops (p = .12)
- Vaginal cream (p = .17)
- Pellet implant (p = .17)

Testosterone was absent from infant blood (>10 ng/dL) during testosterone therapy by pellet implant.

CONCLUSIONS

Maternal testosterone therapy is safe for the breast fed infant.

Testosterone delivered by sublingual drops, vaginal cream and pellet implant is absorbed (measurable in maternal blood) but not measurably excreted into breast milk.

Testosterone, delivered by pellet implant is effective in relieving symptoms of testosterone deficiency and was not measurably increased in breast milk or measurable in infant serum.

Testosterone, by pellet implant may be a safer and more physiologic alternative to psychotropic medications.

Further studies should be done and guidelines revised.

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