

# Some Vaginal Lubricants May Decrease Motility of Sperm

BY CHRISTINE KILGORE  
Contributing Writer

MONTREAL — Three out of four commonly used vaginal lubricants caused significant decreases in sperm motility in a prospective, controlled study—and it appears that these and other lubricants can impact chromatin integrity as well, Ashok Agarwal, Ph.D., reported.

“Despite warnings by researchers, there is still great confusion among physicians and subfertile couples who are trying to conceive. These lubricants may impact the fertilization process and cause a failure of fertilization,” he said at the joint annual meeting of the American Society for Reproductive Medicine and the Canadian Fertility and Andrology Society.

Of the approximately 11 million couples in the United States who are trying to conceive—6 million of whom have been trying for more than 1 year—an estimated 75% experience an increased incidence of vaginal dryness, Dr. Agarwal told this newspaper, referring in part to data from the National Center for Health Statistics and the Centers for Disease Control and Prevention.

The researchers collected sperm either incubated at 37°C in human tubal fluid (HTF) media (the controls) or in

10% lubricant treatments made with the lubricant samples from normal donors and diluted these samples to  $20-40 \times 10^6$ /mL using HTF with 10% human serum albumin.

In one part of the study, sperm samples from 13 donors were either incubated at 37°C in HTF (the controls) or in 10% lubricant treatments of culture, the mean percentage of progressively motile sperm differed significantly between the controls and three of the four lubricant groups.

Sperm exposed to FemGlide, for instance, were 22% less motile than sperm incubated in HTF.

There were even greater decreases in motility—an 89% decrease and a 60% decrease—in sperm exposed to Replens and Astroglide, respectively, compared with sperm in the control group, reported Dr. Agarwal, director of the Clinical Andrology Laboratory and Reproductive Research Center at the Cleveland Clinic.

In the second part of the study, sperm from 12 donors were processed in the same way and placed in either HTF or 10% KY Jelly, FemGlide, or Pre-Seed. The sperm were cultured for 4 hours to evaluate sperm chromatin integrity after longer exposure to lubricants. After culture, the spermatozoa were flash frozen and analyzed for the percent damaged chromatin using the percent DNA fragmentation index (DFI).

There was no significant difference in the percent damaged chromatin between the HTF control group and the Pre-Seed group. There was a 15% and a 10% increase in DFI after exposure to FemGlide and KY, respectively, compared with control.

“Sperm motility changes occur in a rather quick fashion, and DNA damage takes a little more time,” Dr. Agarwal told this newspaper. “We thought 4 hours [to evaluate DNA damage] is reflective of the real physiologic process.”

Because the lubricant Pre-Seed caused little difference in either sperm motility or chromatin integrity, compared with controls, “we can say that, from our study, this particular compound does appear to fare much better,” he said. “But there should be more studies done in other centers that involve larger numbers of patients.”

At this time, “physicians should just be aware that not every jelly and lubricant is equal. The idea that almost all lubricants not containing spermicides will not damage the sperm is a common misperception,” Dr. Agarwal said.

In fact, the loss of motility observed with three of the four lubricants studied “is similar [in magnitude] to the loss of motility found with contraceptive gels,” he said.

The study was conducted with all lubricants provided at no cost by INGfertility Inc., the manufacturer of Pre-Seed, Dr. Agarwal said. He reported no conflicts of interest. ■

Kate Johnson of the Montreal Bureau contributed to this report.



**In some lubricants the loss of motility was similar in magnitude to that of contraceptive gels.**

DR. AGARWAL

# Small Study: Clomiphene Linked to NTDs

BY DIANA MAHONEY  
New England Bureau

LOS ANGELES — Maternal exposure to clomiphene was independently associated with spinal neural tube defects in a case-control study nested within a live-birth cohort, Yvonne Wu, M.D., reported.

Although several studies have examined the possibility of a link between the ovulation-stimulating drug and neural tube defects, the results to date have been mixed, Dr. Wu said in a presentation at the annual meeting of the Child Neurology Society.

Dr. Wu stressed that her study is too limited in size and scope to make definitive statements about the association. “The data linking infertility treatment and neural tube defects have been inconsistent, and our results do not really shift the balance yet,” she said. “Our study was an offshoot of an existing [investigation] of cerebral palsy and was not even designed to look at this question.”

Given the study’s limitations, the findings should not impact clinical decision-making. Instead, they should be the impetus for larger, better-defined studies, she said.

In the current study, Dr. Wu and colleagues from the University of California, San Francisco, electronically reviewed the medical charts of 110,624 mothers and their full-term singleton infants born at Kaiser Permanente Northern California between 1994 and 1997 to identify history of infertility exposure and cases of neural tube defects of the spine. For the purposes of the study, infertility exposure was defined as evaluation at an infertility clinic within Kaiser Permanente, physician diagnosis of infertility, or infertility medication prescribed within 60 days of conception. Information on infertility medication and diagnosis was obtained from electronic databases.

Of the full cohort, 18 infants were diagnosed with neural tube defects, including 12 with spina bifida cystica, 4 with tethered cord syndrome associated with sacral lipoma, and 2 with dermal sinus tracts.

Using multivariate logistic regression analysis, the investigators compared the 18 case mothers with 1,610 randomly selected controls from the same cohort. The mothers of babies born with neural tube defects were more likely to be Hispanic, have had a history of infertility, and have been prescribed clomiphene within 60 days of conception. After adjusting for maternal age, ethnicity, gestational age, and birth weight, exposure to clomiphene was the only independent association with neural tube defects of the spine, according to Dr. Wu.

To authoritatively confirm or dismiss the association between clomiphene and neural tube defects, “we need studies that include comprehensive infertility data on all cases of neural tube defects in a population, including those that resulted in pregnancy termination,” she said.

A better understanding of the underlying pathogenesis of neural tube defects and the mechanism of action of clomiphene, both of which are poorly understood, could provide important insight into the possible association between the two as well, Dr. Wu concluded. ■

# High BMI May Cause Oligospermia in Some

BY DOUG BRUNK  
San Diego Bureau

MONTREAL — Men who are overweight or obese have reduced serum testosterone levels, “which may help explain idiopathic oligospermia,” according to William E. Roudebush, Ph.D.

In his study of 90 men, “there was a substantial and significant reduction in testosterone of roughly 25%, regardless [of whether] they were overweight or obese,” said Dr. Roudebush, who presented his findings at the joint annual meeting of the American Society for Reproductive Medicine and the Canadian Fertility and Andrology Society.

“Rather than infertility therapy, maybe something as simple as weight reduction could work,” he said in an interview. “Medical literature states that as BMI increases, there’s an increased conversion of testosterone to estradiol. Excess estradiol can cause a negative impact on testicular function. We know that [men are] going to have dysfunctional spermatogenesis based on that.”

In his observational study of 90 men with a mean age of 34, Dr. Roudebush and his associates at the Atlanta-based Reproductive Biology Associates compared patient BMI scores with their serum levels of testosterone, FSH, LH, and prolactin, as measured by chemiluminescence. Men were grouped by weight according to published BMI values: normal was defined as 20-24 kg/m<sup>2</sup>, overweight as 25-30, and obese as greater than 30.

The mean values were 28.50 for BMI; 459 ng/dL for testosterone; 5.21 mU/mL for FSH; 3.69 U/L for LH, and 8.96 ng/mL for prolactin.

The analysis revealed an inverse relationship between BMI and serum testosterone levels. The mean serum testosterone level in the normal BMI group was 565 ng/dL, compared with almost 429 ng/dL in the overweight group and

## As BMI Increases, Testosterone Decreases

Body Mass Index	Serum Testosterone (ng/dL)
Normal	565
Overweight	429
Obese	416

Source: Dr. Roudebush

almost 416 ng/dL in the obese group.

No other reproductive serum markers had a significant relationship with BMI, but LH level approached significance. “We ran testosterone tests on everybody, but we did not have the approval to run the LH tests across the board, so we did not get enough values back to show statistical significance,” he said.

Beckman Coulter Inc. provided the testosterone test kits. Dr. Roudebush disclosed that he is a paid consultant for Beckman Coulter. ■

Kate Johnson of the Montreal Bureau contributed to this report.