

# Can A New Study Solve J&J's Talc Problem?



By Chuck Dinerstein, MD, MBA — January 7, 2020

*When last I looked, J&J had \$325 million in judgments against them in lawsuits over talc baby powder and its presumed role as a cause of ovarian cancer in several women. Even the International Agency for Research on Cancer, the people that believe hot beverages are probably carcinogenic, "... has since concluded there is only 'possible' evidence that perineal use of talc-based body powder may be carcinogenic." A new study in JAMA looks at four cohort studies with long-term information on talc use and subsequent self-reported ovarian cancer. It seems that possible may be too strong; they found no linkage.*



Image courtesy of Alf van Beem [1]

Ovarian cancer is, thankfully, given its poor prognosis, a rare disease in the US – estimated lifetime risk of 1.5%. But that low incidence makes it challenging to gather enough of a population to make reliable estimates of associations between the disease and other risk factors, in this instance, the use of powder/talc products in the genital area. That is why researchers combined the data from four studies. [1]

All four are longitudinal studies and were not looking specifically at powder use, but each contained sufficient information to consider acceptable measures of talc dosage and health outcomes. Additionally, the cohorts varied in age, median follow-up, and identified ovarian

cancers. The participant's use of powder was reported differently in each study so, the researchers reduced usage into four categories, never, ever, frequent – at least once a week for 10-13 years and long-term – for more than 13 years.

- Sample size 257,044 women
- Median follow-up 11.2 years
- Median age 57 years
- Ovarian cancer cases self-reported 2213, subsequently medically confirmed 1923
- Ever use 39%, frequent use 22%, long-term use 10%

The study included the usual covariants of interest, age, race, education, BMI, parity, smoking status, use of oral contraceptives or hormonal therapy, and menopausal status.

### **A Bioplausable Explanation of Ovarian cancer**

The cause of ovarian cancer remains unknown, but case reports of the presence of talc in ovarian specimens suggest that talc enters the tissue through a patent route from the vagina, then cervix, uterus, and fallopian tubes into the peritoneal cavity. [2] It's presence presumably results in a chronic local inflammation, which "triggers a carcinogenic process. The relation of talc to ovarian cancer is further complicated by structural similarities to asbestos, a known carcinogen, and the fact that talc was frequently, in the past, contaminated by asbestos. Part of the ongoing J&J litigation is about whether asbestos contamination continued in their products after 1976 and that they knew and hid those findings.

### **Results**

- Ovarian cancer among ever users 61/100,000; for never users 55/100,000
- The cumulative adjusted risk of ovarian cancer by age 70 for never users, 1.16%, for ever users 1.25%
- For medically confirmed cases, the hazard ratio [3] was 1.05, or 5%, for ever and frequent users, but 1.03, 3% for long-term users
- For ever users without a patent reproductive tract, e.g., having undergone a hysterectomy, or tubal ligation or removal, the hazard ratio was 0.99, with a patent tract that value rose to 1.13
- There was no difference in the results when the older cohort, were talc possibly contaminated with asbestos, was compared to the younger cohort. Cohort in this case referring to the specific years of usage, e.g., before 1976

***"In this pooled analysis of 4 large US cohorts, there was no statistically significant association between self-reported use of powder in the genital area and risk of ovarian cancer. There were no clear dose-response trends for duration and frequency of powder use in the genital area in relation to ovarian cancer risk. Although the study was underpowered to detect small changes in risk, this is, to our knowledge, the largest study of this topic to date, and it is believed that no other large prospective cohorts have collected data on powder exposure in the genital area."***

## Limitations

While the study's strength lies in its size and follow-up period, it does come with several significant limitations. It looks primarily at Caucasians, and half the women have BMIs of 25 or less. In addition to the racial disproportion, obesity is considered a risk factor for ovarian cancer, although its contribution is small at best. More importantly, the information on talc/powder usage was obtained only at baseline so we really do not have accurate exposure information. That exposure problem is further compounded by a lack of data on how the talc was applied, which can cause dosage to vary. Finally, even with the large sample size, it may not have been sufficiently "powered" to identify a small, but real risk.

## Where does this leave us?

The higher hazard ratio for women using talc and having a patent reproductive tracts certainly bears further scrutiny. But as the accompanying editorial writes,

*"...women with intact reproductive tracts who used powder in the perineal area developed ovarian cancer more frequently than nonusers is below the effect size that epidemiologists generally consider important and should not be selectively highlighted by the statistically unsophisticated reader as evidence of a relationship."*

That is, one of J&J's problems, the courts, and juries, are statistically unsophisticated. Understanding scientific evidence is frequently a victim in court, so the impact of this study may be negligible.

Ovarian cancer is a life-shattering diagnosis and the question "why me" is a wail of grief as much as a reflective questioning. Our hearts go out to these women. In the court of public opinion, ovarian cancer is such a harsh penalty for the use of "baby powder." I am not sure that science has the power to stop the tears. Will the media report the story and enter it into the court of public opinion?

The possibility that J&J turned a blind eye to a health concern, even one that seems not to be backed by scientific evidence, may be a greater liability for them.

[1] Nurses' Health Study, Nurses' Health Study II, Women's Health Initiative Observational Study, and the Sister Study

[2] The citations considering this bioplausible route looked at a total of 31 samples over three studies. Perhaps most important was the review looking at ovarian tissue in 24 women, 12 frequent uses of talc, 12 who had never used talc. In this study, all the ovarian specimens, treatment, and control demonstrated the presence of talc.

[3] In this case it means the heightened risk of ovarian cancer

Source: [Association of Powder Use in the Genital Area With Risk of Ovarian Cancer](#) [2] JAMA DOI: 10.1001/jama.2019.20079 and the accompanying editorial, Use of Powder in the Genital Area and

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**Links**

[1] [https://upload.wikimedia.org/wikipedia/commons/a/a5/Johnsons\\_Baby\\_Powder\\_1,5\\_OZS\\_talc,\\_pic4.JPG](https://upload.wikimedia.org/wikipedia/commons/a/a5/Johnsons_Baby_Powder_1,5_OZS_talc,_pic4.JPG)

[2] [https://jamanetwork.com/journals/jama/fullarticle/10.1001/jama.2019.20079?guestAccessKey=e8a84e15-2f81-4957-be2b-e14e08d5f9b3&utm\\_source=For\\_The\\_Media&utm\\_medium=referral&utm\\_campaign=ftm\\_links&utm\\_medium=referral](https://jamanetwork.com/journals/jama/fullarticle/10.1001/jama.2019.20079?guestAccessKey=e8a84e15-2f81-4957-be2b-e14e08d5f9b3&utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_medium=referral)