

Commentary

Cancer and CPAP polyurethane foam risk? A challenge in the interpretation of Brauer PR et al 2022 * paper in *The Laryngoscope*.

As always with new findings, and more importantly when they can generate high level of anxiety for our patients, we have to be professional. The Brauer PR et al 2022 * observational and descriptive data are not yet reproduced and not totally solid.

The story: The paper from Brauer PR et al recently accepted in *The Laryngoscope* is reporting an association of cancer in 2021 with CPAP degradation. According to the analysis of a database managed by the FDA, the *Manufacturer and User Facility Device Experience* (MAUDE), a sudden rise of CPAP polyurethane foam material degradation was ‘associated’ to cancer. The rise was sudden from 9 cases from 2014 to 2020 to over 200 for the first 9 months of 2021. From the 2571 CPAP related ‘injuries’, cancer was the second one (4.6%) associated to CPAP problems; headache was first and fire in high oxygen environment the third. More specifically, over the 1902 reports of CPAP material degradation, 174 (9.15%) have been associated to cancer diagnosis.

The problem: The degradation of the polyurethane of CPAP device sound abatement foam was officially announced by the FDA recall notice in July 2021. FDA launch that notice due to the risk of carcinogen exposure. A notice is not a ban; the risk is there and confirmation needs to be proven. This may take years and in the mean time we, physician and dentist in sleep medicine, have to reassure our patients and guide them to the best and safest alternatives.

The cautions: 1) Since the report is mandatory for manufacturers and voluntary for physicians, a bias or lack of information may be a critical issue. MAUDE data is based on reports that may be incomplete regarding the diagnosis, duration of the cancer and its severity, association to comorbidities and site of cancer. Oropharyngeal cancer may have different burden related to CPAP use and comfort; the last is also named *patient-device incompatibility*. Moreover, did family or sleep physician base their ‘voluntary’ report of cancer diagnosis on pathology findings or patient self reports? 2) Brauer’s data presented are descriptive, not yet based on solid statistic to support the probability of risk and bias control. 3) Another methodological concern is raised. Is it possible the sudden rise in the incidence of cancer reports in CPAP users jumped to such level after the July 22, 2021 U.S. FDA safety recall notice? Large public diffusion of the information may have exaggerated the magnitude of the rise. Any type of risk report can be subject to exponential rise with the diffusion of information by media; think at automobile or plane industry and large public reaction.

Many more issues need to be further analyzed before confirmation of such risk due to its important impact for our patient health and quality of life. The last 2 years of COVID publications in scientific and public media warn us to be extremely cautious before jumping to rapid conclusion. A cancer diagnosis is among the most stressful event for a patient and family. Cancer occurrence can result from a combination of environmental and genetic factors. Do we need to reiterate that association is not causality, that CPAP foam and cancer risk is first an health issue not a commercial one? No device is without discomfort, problem and risk. Managing sleep apnea, a putative life-threatening condition, whatever with a CPAP or an oral device, is part of health prevention and maintenance. We have to be professional, guide our patients based on solid evidences and not on marketing.

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* Brauer PR, Bryson PC, Wu SS, Gau VL, Lamarre ED, Kominsky AH. Cancer Risk Associated with Continuous Positive Airway Pressure: A National Study. *Laryngoscope*. 2022 Mar 30. doi: 10.1002/lary.30117. Online ahead of print. PMID: 35352830