

Be Cautious in the Interpretation of the Findings of The Laryngoscope 2022 Paper Associating Cancer to CPAP Polyurethane Foam: It is One piece of Evidence, Not the End of the Story!

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As always with new findings, and more importantly when these findings can create a high level of anxiety in our patients, professionals in dental sleep medicine must be cautious in their interpretations.

The Story

Most of you know that a safety issue was officially announced by the Food and Drug Administration (FDA) related to the degradation of the continuous positive airway pressure (CPAP) device polyurethane sound abatement foam. The July 2021 recall notice followed a CPAP company's declaration that the foam carried a potential carcinogenicity risk.¹ An FDA notice is not a ban; rather, it is part of a surveillance process. The mitigation for this issue is still ongoing and the risks remain to be proven.

In the meantime, this recall has generated major concerns and some anxiety in CPAP users and prescribers. We must recognize that a declaration of possible risk is not ultimate proof of a risk. Assessing the causes and effects of a risk is a long process toward a final demonstration of evidence over any reasonable doubt. Until this is confirmed or rejected, physicians and dentists working in sleep medicine must reassure their patients and guide them to the best alternatives for therapy.

The Paper Associating CPAP Foam with Cancer Risk

A 2022 paper from Brauer PR et al., published in *The Laryngoscope*, reported an association of cancer to CPAP foam degradation.² According to the analysis of the databank managed by the FDA, the *Manufacturer and User Facility Device Experience* (MAUDE) database,³ a sudden rise of CPAP polyurethane foam material degradation was associated with cancer during 2021!

The rise was very sudden; from 9 cases between 2014-

2020 to more than 200 cases for the first 9 months of 2021. Among the 2571 CPAP reported 'injuries' (the word used in the MAUDE database), cancer was ranked second (4.6%). More specifically, of the 1902 events reported in relation to CPAP material degradation, 174 (9.15%) have been associated with a cancer 'verdict.' In the order of reported CPAP injuries, reports of headache were first in frequency and, surprisingly, fire with CPAP use in high oxygen environments, the third.

The Cautions in Interpreting the Paper

The Food and Drug Administration (FDA) recommend the following regarding use of *medical device report* (MDR) data file information:³

- “MDR data alone cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between devices. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices.”
- “Confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report. Establishing a cause-and-effect relationship is especially difficult if circumstances surrounding the event have not been verified or if the device in question has not been directly evaluated.”
- “MAUDE data does not represent all known safety information for a reported medical device and should be interpreted in the context of other available information when making device-related or treatment decisions.”³

Other Considerations:

1. Since it is mandatory for manufacturers to report device ‘injuries’ or other complaints and since these data are based on patient self reports, it may be possible they may be imprecise regarding the cancer status: suspected or confirmed by a medical diagnosis.
2. The MAUDE database does not have information on the type of cancer, its duration, severity (staging) and association with other health comorbidities. This is essential in assessing risk specificity.
3. Since the physician declarations are voluntary, accuracy of reported complaints frequency may be questionable. The physician may have judged the complaints or worries related to CPAP device as less critical than other life-threatening patient’s health issues. In a busy practice, some of these complaints may not have been reported on the MAUDE WEB site at all.³ Moreover, patient concerns about foam and cancer risk may not have reached the physician at all, since follow-ups to verify comfort with CPAP are frequently done by independent health care providers.
4. The data presented in the Brauer et al. paper are descriptive.² As listed below, it is obvious that future studies will need to address the power of statistical analysis, assess the probability of risk and strength of the association, identify bias, etc.
5. Finally, can it be possible that the sudden rise in the incidence of cancer reported in CPAP users jumped to such a high level because of global awareness brought on by the FDA safety recall notice?¹ Large public diffusion of that type of health information may have influenced the magnitude of the rise.

Other Studies

A recent retrospective analysis, over a period of 7.5 years, was conducted in a cohort of CPAP-treated patients in four Ontario (Canada) hospital. The study revealed no difference in hazard ratio in incidence of lung cancer when comparing different CPAP devices.⁴ This analysis, with a large sample size, has many merits but it is based on a post-hoc analysis from a governmental registry, merging cancer and CPAP database.

Another governmental registry database comparison, this time from Sweden, analyzed data over an 8-year period. A first statistical comparison revealed significantly higher incidence of all-cause cancer and, more specifically, lung cancer. However, the observed difference disappeared when smoking was included in the model.⁵

More publications will emerge and no single study will provide a clear and final conclusion. There is a need for well-controlled analyses, considering contributing cancer risk and other confounding factors such as age, smoking, gender, time of CPAP use, other comorbidities, etc. For obvious reasons, prospective and randomized controlled studies will not be ethically acceptable; we need to accept such limitations.

Conclusion

The potential risks of cancer due to CPAP foam is an important health concern. We have to remind ourselves that a cancer diagnosis is among the most stressful events a patient can face. Other issues should be further analyzed to confirm such risk and its impact on patient health. These analyses will likely be done in the long-term as cancer may take time to be expressed. Furthermore, cancer occurrence can result from a combination of environmental and genetic factors. Other health conditions may also be associated with such foam particles and volatile product release. Do we need to reiterate that association does not equal causality?

No health device is without discomfort, problem or risk. Managing sleep apnea, a putative life-threatening condition, whether with a CPAP or an oral device, is part of health prevention and maintenance. To better guide our patients, we must stay informed with solid scientific evidences.

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