Expert opinion by Prof. dr. N. de Vries*

October 2022

Philips Sleep and Respiratory Care CPAP devices and home ventilators FSN 2021 05 A & 2021 06 A.

Prof. Dr. N. de Vries,
ENT-specialist, OLVG hospital Amsterdam, Netherlands.

Every day, I see patients in my practice who are suffering from Obstructive Sleep Apnoea (OSA) and are seeking treatment. As an ear, nose and throat (ENT) specialist with a special interest in diagnosis and treatment for OSA, my main domain is finding suitable treatment options for these patients.

OSA[1] affects around 400,000 people in the Netherlands and nearly 1 billion people worldwide.[2] This makes OSA the most common sleep-related breathing disorder in the Netherlands and worldwide. However, 80% of the people suffering from OSA are not even diagnosed yet[3]. If untreated, OSA can lead to grave diseases like high blood pressure, higher risk of stroke and myocardial infarction, depression and burnout.[4] There are also several studies that indicate that apnoea is associated with a slightly elevated risk of developing cancer, depending on the severity of the apnoea (0.046% higher compared to people without OSA).[5,6,7] All these different health risks might be not widely known, but are very important to be aware of. OSA can be severe and should be treated at such. Therefore, treating patients as soon as possible, especially when they suffer from severe apnoea, is important. Finding them the right therapy is crucial to prevent further health complaints and possible risks.

Treatment of OSA

In the Netherlands we have several OSA treatments available that are reimbursed by insurance companies. Think of oral devices, positional therapy, sleep surgery, neurostimulation and lifestyle interventions. Worldwide, the most used treatment for OSA is the usage of a continuous positive airway pressure (CPAP) device, in particular in relation to moderate to severe OSA. The CPAP device keeps the airway of patients open throughout their sleep. CPAP is an important treatment for a large group of patients..

Field Safety Notice Philips Respironics

In June 2021, Philips Respironics issued a field safety notice after discovering a potential health risk related to a component in a certain number of their sleep apnoea devices**. The purpose of the precautionary notice was to warn physicians and patients of possible problems with their devices that may lead to unsafe situations. This is a precautionary measure and does not necessarily mean that there is indeed an unsafe situation. It does mean that it needs to be researched and analysed in more detail. It is understandable that the Philips Respironics field safety notice has caused uncertainty amongst patients and their families. As a doctor, I fully understand the concerns that patients might have as they rely on these devices for their health.

(continued on next page)

Patient studies

As is very common in healthcare, patient studies around the use of CPAP devices had been conducted even long before the field safety notice was issued by Philips Respironics. Recent examples of these studies have been performed by renowned institutes like the European Respiratory Society, the Ontario Ministry of Health, and the Lung Health Foundation. I have studied all available independent research worldwide that has been conducted to assess the actual potential negative impact of Philips Respironics' devices on patients. In total, there were 13 relevant independent epidemiological studies[8] identified that followed patients suffering from OSA who were treated with PAP therapy. I have reviewed all 13 studies and I will highlight three that were most rigorous.

No increased risk of using Philips Respironics' devices

The first study was conducted in Canada and is, among others, supported by the Ontario Ministry of Health and the Lung Health Foundation. This study followed 6,903 patients diagnosed with OSA and who have used a PAP device over a period of 7.5 years. The patients used PAP devices from several different manufacturers. No statistically significant difference in overall cancer risk was found between users of the Philips Respironics device and users of other devices.

The second study was conducted in France and was supported by the Pays de la Loire Sleep Cohort Study Group. This study followed 4,400 patients with OSA that used a PAP device over a period of 7.2 years. Similar to the Canadian study, there is no statistically significant difference in risk of developing cancer between users of Philips Respironics devices and users of other devices.

Thirdly, a large study was conducted in Sweden where 48,391 patients with OSA who used CPAP devices were followed throughout a period of 2.4 years. Of the patients, 18,561 had a device with polyurethane foam (PUF), the component in question. 29,830 patients in this study used a device without PUF. Initially, a slight increase in the risk to develop cancer was found, but this effect disappeared after correcting for smoking behavior. This study confirms the result of the Canadian study.

The additional ten studies support the outcomes of the Canadian, French, and Swedish studies. If you wish to peruse the studies, you can easily do this by consulting the website **https://pubmed.ncbi.nlm.nih.gov/**.[9]

Conclusion

I fully understand how the field safety notice might have caused concerns among patients. However, when critically reviewing the presently available studies, there is no statistically significant difference in overall cancer risk between users of Philips Respironics CPAP devices and other CPAP devices. Looking at the presently available data, my advice on the use of the Philips Respironics CPAP devices has not changed. Moreover, I believe it is very important to continue treating OSA due to the related complaints and the high likelihood of it leading to other severe health issues.

**** This expert opinion is prepared in collaboration with Prof. dr. N. de Vries. As a health technology company, Philips is affiliated with the Stichting Gedragscode Medische Hulpmiddelen. We are committed to the Gedragscode Medische Hulpmiddelen (GMH), which includes standards for responsible interactions between suppliers and healthcare professionals. Philips is a supporter of the Healthcare Transparency Register (TRZ).***

(continued on next page)

References

1. OSA is a disorder caused by repetitive collapse of the upper airway during sleep and can be classified into three categories: mild sleep apnoea (score of 5-15 events per hour of sleep), moderate sleep apnoea (score of 15-30 events per hour of sleep) and severe sleep apnoea, (score of >30 events per hour of sleep).

2. Benjafield AV, Ayas NT, Eastwood PR, Heinzer R, Ip MSM, Morrell MJ, Nunez CM, Patel SR, Penzel T, Pépin JL, Peppard PE, Sinha S, Tufik S, Valentine K, Malhotra A. Estimation of the global prevalence and burden of obstructive sleep apnoea: a literature-based analysis. Lancet Respir Med. 2019 Aug;7(8):687-698. doi: 10.1016/S2213-2600(19)30198-5. Epub 2019 Jul 9. PMID: 31300334; PMCID: PMC7007763.

3. Faria A, Allen AH, Fox N, Ayas N, Laher I. The public health burden of obstructive sleep apnea. Sleep Sci. 2021 Jul-Sep;14(3):257-265. doi: 10.5935/1984-0063.20200111. PMID: 35186204; PMCID: PMC8848533.

4. Yeghiazarians Y, Jneid H, Tietjens JR, Redline S, Brown DL, El-Sherif N, Mehra R, Bozkurt B, Ndumele CE, Somers VK. Obstructive Sleep Apnea and Cardiovascular Disease: A Scientific Statement From the American Heart Association. Circulation. 2021 Jul 20;144(3):e56-e67. doi: 10.1161/CIR.0000000000000988. Epub 2021 Jun 21. Erratum in: Circulation. 2022 Mar 22;145(12):e775. PMID: 34148375.

5. Cheng H, Li D. Investigation into the association between obstructive sleep apnea and incidence of all-type cancers. A systematic review and meta-analysis. Sleep Med 2021;88:274-28

6. Cheng L et al. Obstructive sleep apnea and incidence of malignant tumors: a meta-analysis. Sleep Med 2021;84: 195-204.

7. Nieto et al. Sleep-disorder breathing and cancer mortality. Am J Resp Crit Care Med 2012;186:190-194

8. **Summary of a systematic literature review of Positive Airway Pressure device use and cancer risk (philips.nl)**

9. The website **https://pubmed.ncbi.nlm.nih.gov** is a medical search engine and free to use for everyone. If you want to consult the full studies, please type "**obstructive sleep apnea & cancer & cpap**" in the search bar

****CPAP and BiLevel PAP Devices***
Continuous Ventilator, Minimum Ventilatory Support, Facility Use: *E30 (Emergency Use Authorization)*
Continuous Ventilator, Non-life Supporting: *DreamStation ASV, DreamStation ST, AVAPS, SystemOne ASV4, C-Series ASV, C-Series S/T and AVAPS, OmniLab Advanced+*
Noncontinuous Ventilator: *SystemOne (Q-Series), DreamStation, DreamStation Go, Dorma 400, Dorma 500, REMstar SE Auto*

Mechanical Ventilators
Continuous Ventilator: *Trilogy 100, Trilogy 200, Garbin Plus, Aeris, LifeVent*
Continuous Ventilator, Minimum Ventilatory Support, Facility Use: *A-Series BiPAP Hybrid A30 (not marketed in US), A-Series BiPAP V30 Auto*
Continuous Ventilator, Non-life Supporting: *A-Series BiPAP A40 (not marketed in the US), A-Series BiPAP A30 (not marketed in the US)*