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Safety of CPAP masks with magnets in patients with cardiac implanted devices

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Abstract

Purpose CPAP mask manufacturers warn of a potential risk of interference between the magnets used to secure the masks and Cardiac Implanted Devices (CIDs). This raises questions about the current safety of these masks in clinical practice.

Methods A single-centre study was conducted at the CHU-UCL-Namur (Godinne) to assess the risk of interference associated with the use of CPAP masks with magnets in patients with pacemakers and defibrillators. The pulmonology and cardiology databases were cross-referenced to identify the patients currently concerned in our hospital. An analysis of the memory of CIDs since the introduction of the magnetic mask and a real-life test involving direct contact between the mask magnet and the CID were carried out under cardiological supervision.

Results Eleven patients (10 males, 71.9±6.9 years; BMI: 30.9±5.2 kg/m^2) were included: 5 with pacemakers, 6 with defibrillators. They had a mask in the context of CPAP (10) or BiPAP (1) therapy (mean device use 7h10±1h12 /day). During follow-up of normal use (median 22.54 months [IQR: 18.3–65.2]), no interference was observed in the device memory. However, direct and prolonged contact between the mask magnet and the device housing case induced asynchronous pacing in 4 out of 5 pacemakers and transient therapies deactivation in 2 out of 6 defibrillators.

Conclusion The use of masks without magnets is preferable in patients with CIDs. Nevertheless, considering the low risk observed in real-world conditions and the ergonomic advantages of these masks, these findings call into question their contraindication provided by manufacturers and support consideration of their use in selected cases.

Keywords Pacemaker · Defibrillator · Cardiac implanted device · CPAP · Magnet · Mask

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Introduction

As part of new regulatory standards for medical device safety, companies supplying continuous positive airway pressure (CPAP) masks have issued a warning letter regarding the use of masks with magnets in patients with implantable metallic devices, such as pacemakers and defibrillators. At the end of 2022 and the end of 2023, Philips Respironics→ and Resmed® issued updates respectively to their safety notifications concerning the use of their masks with magnets [1, 2].

These masks are designed to provide patients with an interface for the application of CPAP therapy, particularly in the treatment of Obstructive Sleep Apnoea Syndrome (OSAS). The magnets are located on the mask at the end of the headgear straps and work together to stabilize the mask when it is worn.

These magnets, with a magnetic field strength of up to 400 mT (4,000 Gauss) according to manufacturers, may interfere with certain implants and medical devices. A safe distance of 15 cm (6 inches) between the mask and the medical implant is recommended, but there is a risk that the magnets may come into closer contact during their handling or in case they become detached inadvertently. Magnetic masks are therefore not recommended by manufacturers if patients, or anyone in close physical contact with them when using the mask, have active medical implants that interact with external magnetic fields, such as CIDs.

The risk for a patient with a pacemaker when exposed to magnetic interference is that the implanted device switches to asynchronous pacing mode. For patients with a defibrillator, exposure to a magnetic field could disable therapies [3]. In all circumstances, the disturbances cease when the magnet is removed, and these events are recorded in the memory of the implanted device.

Magnetic masks are often easier to use for patients, particularly the elderly or those with dexterity problems. The magnetic field generated by the magnets is relatively weak. Therefore, the question arises as to whether the risk is real and justifies the recommendation not to use them.

A few rare cases of interference without serious consequences between magnetic CPAP masks and CIDs have been reported in the literature [4], and a recent prospective study confirmed that the risk remains limited to situations of direct contact [5].

This study aimed to evaluate whether CIDs may be influenced by magnetic interference from magnetic CPAP masks. To address this question, we performed a single-center investigation in a tertiary hospital, focusing on the potential arrhythmogenic risks associated with the combined use of these devices.

Methods

Study population and design

We cross-referenced the pulmonology database of patients wearing CPAP masks with magnets and the cardiology database of patients with pacemakers and defibrillators at the CHU UCL Namur. Of the more than 2,000 patients currently treated with CPAP, 11 were identified as having both a mask with magnets and a CID followed up in our hospital. No further exclusion criteria were applied. These patients had a stable condition and normally functioning CIDs, as demonstrated by appropriate sensing and pacing thresholds, along with normal lead impedances. Patients with an implantable cardioverter defibrillator were also monitored by telemonitoring.

Cardiac device interrogation and outcome

Patients underwent comprehensive device interrogation, including lead testing and review of the arrhythmic event registry. When events were recorded, all available electrograms (EGMs) were systematically analysed, and recordings compatible with magnetic field interference were documented in the patient's medical record. All cardiology visits following initiation of magnetic mask use were reviewed. Furthermore, all patients were invited for real-time assessment of CID behaviour during close and prolonged contact between the mask magnets and the device generator, under direct cardiological supervision. This study was approved by the local ethics committee (internal CE Mont-Godinne No.: 198/2024; NUB: B0392024000066). The consent of all patients was obtained.

Statistical analysis

Continuous data are expressed as mean +/- standard deviation or median and interquartile range [IQR], depending on distribution normality. Categorical data are expressed as number and percentage. No inferential analyses were performed due to the small sample size.

Results

Eleven patients were studied. 10 were males, mean age was 71.9 +/- 6.9 years, and mean BMI was 30.9 +/- 5.2 kg/m^2. One patient had bilevel positive airway pressure (BiPAP) in the context of chronic respiratory failure related to a right pneumectomy and left diaphragmatic weakness. Others had CPAP for OSAS. Patients used their PAP devices with good adherence (average use of 7h10 +/- 1h12 over the

past year). Five patients used Philips Respironics Amara View®magnetic masks and six used Resmed®, Airfit nasal® and Airfit facial®, masks (Fig. 1). Of the 11 patients, 6 were already using a magnetic mask at the time of their cardiac device implantation. Five had pacemakers (two Medtronic®, one Abbott®, one Biotronik®, one Boston Scientific®), only one of whom was pacemaker-dependent, and six had implantable cardioverter defibrillators (two Medtronic®, two Abbott®, one Biotronik®, one Boston Scientific®).

During a median follow-up period of 22.54 months [IQR: 18.3–65.2] with normal use of the magnetic mask, no alerts were noted in the memory of the CIDs. No alerts were reported in the data obtained with telemonitoring. However, when the mask magnet came into close contact with the CID housing case, 4 out of 5 pacemakers (80%) (2 Medtronic®, 1 Biotronik®, 1 Boston Scientific®) switched to asynchronous pacing mode and 2 out of 6 implantable cardioverter defibrillators (33.3%) had their therapies disabled (2 Medtronic®). These disturbances ceased immediately after removal from the magnetic field and were recorded in the memory of the implanted devices.

The results are detailed in Table 1.

Discussion

In this study of 11 patients with CID using a mask with magnets, no interference was observed during normal use of the mask over a median period of 22.54 months. However, during direct and prolonged contact between the mask magnet and the CID housing case, transient interference was observed in more than half of the cases: switching to asynchronous pacing mode for 4 out of 5 pacemakers (80%) and temporary disabling of therapies for 2 out of 6 defibrillators (33.3%). Our data suggest that the potential for interference exists but may be confined to scenarios of direct contact, as such interference was not observed under real-world conditions.

These observations are consistent with those reported by Schwartz et al. [4]., who described two cases of inappropriate activation of magnetic mode in patients with St Jude Medical®dual-chamber pacemakers using masks with magnetic attachments (Resmed AirTouch F20® and Philips Respironics Wisp®). The authors observed several nocturnal episodes of magnetic response recorded in the memory of the implanted device, which were reproduced experimentally by placing the mask magnet directly on the device. The magnetic field strength measured in the vicinity of a mask magnet was 136 Gauss.

More recently, Ruoff et al. [5] conducted a prospective study on 13 patients with CID using a magnetic CPAP mask. There was no interaction during normal use. A single interaction (1/13, or 8%) was observed when the mask (Resmed Airfit F30®) came into direct contact with the CID housing case. The authors also measured the magnetic field strength of six magnetic masks. This ranged from 0.2 to 0.4 mT (4,000 Gauss) at a distance of 5.1 cm (2 inches) and from 200 to 291 mT (2,910 Gauss) in case of direct contact. These values confirm that the risk only becomes significant when the mask is placed in contact with the housing case. In the absence of magnetic field measurements between these two distances, Ruoff et al. were unable to determine the minimum distance required to prevent interaction.

The two studies mentioned above, as well as our own observations, point to the same conclusion: the risk of interference exists but remains circumstantial, only in cases of direct and prolonged contact between the magnet and the housing case of the CID. These situations are rare during normal use of the mask but are not impossible. Some patients sometimes unknowingly remove their mask during sleep and may leave it on their chest, while others sleep in positions that reduce the distance between the magnet and the housing case.

The medium surrounding the implanted device does not appear to play a significant role: patients whose devices detected the magnet through direct contact with the skin had a BMI ranging from 21.8 to 33.4 kg/m².

Clinically, magnetic masks offer significant ergonomic advantages, particularly for elderly patients or those with dexterity issues. For these patients, removing magnetic masks could compromise compliance with the therapy. It therefore seems essential to adopt an individualised

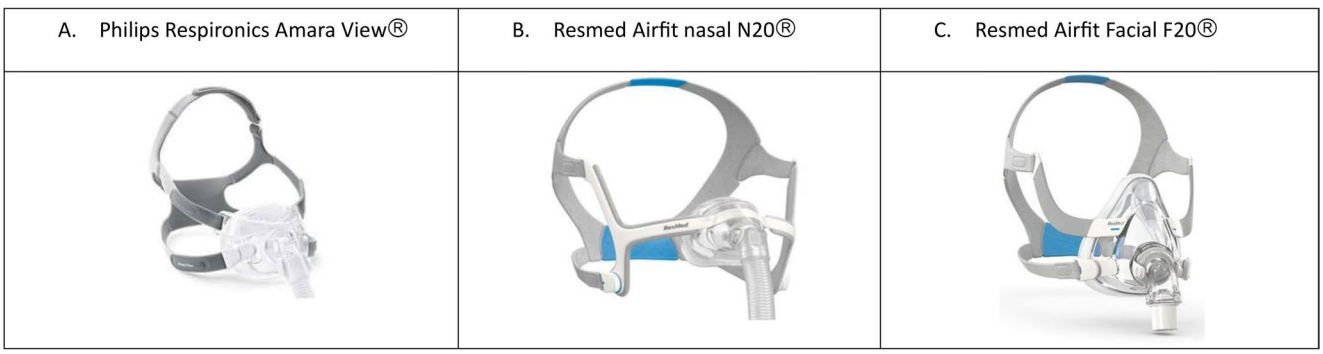

Fig. 1 Masks

Table 1 Results. CID=Cardiac Implanted Device; PPM=Permanent Pacemaker; ICD=Implantable Cardioverter-Defibrillator; CRT-D=Cardiac Resynchronization Therapy with a Defibrillator; DOO=asynchronous dual-chamber pacing mode (Dual – None – None); HFrEF=Heart Failure with reduced Ejection Fraction; CRF=Chronic Respiratory Failure; PAP=positive airway pressure; OSA=obstructive sleep apnoea; OAHI=obstructive apnoea-hypopnoea index; M=male; F=female; BMI=Body Mass Index

Sex (M/F)	Age (years)	BMI (kg/m²)	Mask	PAP initiation	PAP indication	Start of magnetic mask use	Average use over the last year (h/d)	CID type	CID indication	PPM dependant yes/no	Device	CID implantation	Device interrogation date	Magnet response episode in the device memory	Magnet-induced response upon direct contact
M	70	33.4	Philips Respironics Amara View®	13/10/2014	OSA OAHI 65/h	16/11/2016	8h34	PPM	Sick sinus syndrome	No	Medtronic Advisa®	06/01/2015	7/04/2025	NO	YES (DOO 85)
M	85	33	Resmed Air Fit Facial F20®	28/08/2019	OSA OAHI 42/h	28/08/2019	4h35	ICD	CRT-D for HFrEF	No	Boston Scientific Resonate®CRT-D	25/11/2021	15/04/2025	NO	NO
F	78	21.8	Philips Respironics Amara View®	30/09/2020	OSA OAHI 17.3/h	30/09/2020	8h05	PPM	Sick sinus syndrome	No	Medtronic Azure®	30/04/2019	3/06/2025	NO	YES (DOO 85)
M	78	28.1	Resmed Air Fit Facial F20®	24/06/2019	OSA OAHI 45.1/h	28/04/2023	6h45	PPM	Second-degree atrioventricular block type 1+non-sustained ventricular tachycardia	No	Abbott Assurity®	1/08/2019	14/03/2025	NO	NO
M	75	31.6	Philips Respironics Amara View®	14/03/2016	OSA OAHI 26.4/h	11/07/2017	7h56	PPM	Third-degree atrioventricular block	Yes	Boston Scientific Accolade®	12/01/2018	8/05/2025	NO	YES (DOO 100)
M	62	29.1	Resmed Air Fit Facial F20®	02/01/2014	OSA OAHI 56/h	10/03/2023	7h10	PPM	Sick sinus syndrome	No	Biotronik Enitra®	24/08/2023	4/06/2025	NO	YES (DOO 100)
M	73	40.3	Philips Respironics Amara View®	09/09/2015	OSA OAHI 62/h	15/03/2016	7h09	ICD	CRT-D for HFrEF	No	Biotronik Acticor®	28/09/2023	10/01/2025	NO	NO
M	68	35.6	Philips Respironics Amara View®	11/10/2010	OSA OAHI 63/h	11/04/2016	7h06	ICD	Ventricular tachycardia	No	St-Jude Medical Ellipse®	16/01/2019	28/03/2025	NO	NO
M	62	34.5	Resmed Air Fit Nasal N20®	02/02/2022	OSA OAHI 52.9/h	04/03/2022	8h07	ICD	Severe HFrEF	No	Abbott Gallant®	14/11/2023	7/03/2025	NO	NO
M	68	25.8	Resmed Air Fit Facial F20®	13/06/2022	CRF	16/06/2023	5h32	ICD	HFrEF and ventricular tachycardia	No	Medtronic Claria®CRT-D	2/06/2021	13/03/2025	NO	YES (therapies deactivation)
M	72	26.8	Resmed Air Fit Nasal N20®	02/09/2013	OSA OAHI 50.2/h	11/03/2025	7h50	ICD	CRT-D for HFrEF	No	Medtronic Claria®CRT-D	12/05/2021	27/05/2025	NO	YES (therapies deactivation)

approach, based on an assessment of the risk/benefit ratio and collaboration between pulmonologists and cardiologists.

Moreover, in our study, 6 CIDs were placed after the CPAP therapy initiation. A reciprocal interaction between pulmonologists and cardiologists is necessary in that case: cardiologists and technicians should pay attention to patient treated by CPAP device by asking them the presence of magnets on the mask. In that case, CPAP therapy must be continued, with the recommendation to reassess the possibility of using a mask model without magnets.

Similarly, sleep laboratories teams should ask patients if they have a CID before considering the choice of a mask.

The patient should be informed of the low risk and be involved in the decision whether or not to continue using magnets on their mask.

Based on our observations, it seems important to continue to favour masks without magnets in patients with CID. Nevertheless, as the current clinical risk remains very limited, the benefit/risk ratio could be assessed on an individual basis. A test involving contact between the mask magnet and the CID housing case under cardiological supervision could be considered, as well as close monitoring by cardiac telemonitoring following the placement of the magnetic mask. For our patients, continued use of the magnetic mask was discussed on a case-by-case basis after providing detailed information.

Our results should be interpreted considering certain limitations. First, the small sample size: the study was limited to patients followed for both CID and PAP therapy at our hospital. Therefore, a second limitation is its monocentric nature. Patients with CID or undergoing PAP therapy at another hospital were not included in our study. Finally, the mainly descriptive nature of the study, which was underpowered to identify predictors of device interaction. However, our study includes patients fitted with devices from different manufacturers, both in terms of CIDs and mask types.

Conclusion

Our observations show the absence of interaction between CIDs and CPAP masks with magnets during normal use of the masks. A risk of temporary disruption of the CID appears only in case of direct contact between the magnet and the CID housing case. This result highlights the importance of favouring the use of masks without magnets in these patients but, given the low risk and the ergonomic benefits of magnetic masks, their use could be discussed on a case-by-case basis in certain patients.

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Data availability The datasets generated and analysed in this study are available from the corresponding author on reasonable request.

Declarations

Ethical approval Ethics committee CHU UCL Namur Mont-Godinne approved the study (No.: 198/2024; NUB: B0392024000066).

Conflict of interest All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

Informed consent Informed consent was obtained from all individual participants included in the study.

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