ORIGINAL ARTICLE

Face mask and protective eyewear-associated headache among healthcare workers during the COVID-19 pandemic

Cefalea por uso de mascarilla y protección ocular en trabajadores de la salud durante la pandemia de COVID-19

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Abstract

Objective: *The objective of this study was to investigate the prevalence, clinical features, and factors related to personal protective-associated headaches.* **Methods:** *We conducted a cross-sectional study among healthcare workers using an online questionnaire.* **Results:** *We surveyed 305 participants. The N95 face-mask was the most used device by 93%. Of 305 respondents, 206 experienced headaches while wearing protective equipment; 36.06% suffered from a headache disorder before the pandemic. The prevalence of de novo headache was 39.01%. Gender, age, or exposure to coronavirus disease were not determining factors to develop headache. Headache intensity was higher in front-line healthcare workers and was correlated (r = 0.728) with the time wearing protective equipment. The more days per month the participants wore personal protective equipment the shorter the time to headache onset after donning equipment.* **Conclusion:** *Our study confirms the relationship between frequent and prolonged use of protection devices with headaches and reaffirms the implication of external pressure as a primary mechanism.*

Keywords: *Headache. Personal protective equipment. Coronavirus disease 2019. External compression headache. Healthcare workers.*

Resumen

Objetivo: *Investigar la prevalencia, las características clínicas y los factores relacionados con las cefaleas asociadas al equipo de protección personal.* **Métodos:** *Realizamos un estudio transversal entre trabajadores de la salud por medio de un cuestionario en línea.* **Resultados:** *Encuestamos a 305 participantes. La mascarilla N95 fue el dispositivo más utilizado opor 93%. Del total de encuestados, 206 experimentaron cefalea mientras usaban el equipo de protección; el 36.06% padecía algun trastorno cefalálgico antes del inicio de la pandemia. La prevalencia de cefalea de novo fue del 39.01%. El género, la edad o la exposición a la enfermedad por coronavirus no fueron factores determinantes para desarrollar cefalea. La cefalea fue de mayor intensidad en los trabajadores de primera línea y se correlacionó (r = 0.728) con el tiempo que se uso el equipo de protección personal. Mientras más días por mes los participantes usaron el equipo de protección personal menor fue el tiempo de inicio de la cefalea tras la colocación del equipo cada vez.* **Conclusiones:** *Nuestro estudio confirma la asociación del uso frecuente y prolongado de dispositivos de protección con el desarrollo de cefalea y reafirma la implicación de la compresión externa como mecanismo primario.*

Palabras clave: *Cefalea. Equipo de protección persona. Enfermedad por Coronavirus 2019. Cefalea por compresión externa. Trabajadores de la salud.*

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Introduction

In December 2019, several cases of atypical pneumonia emerged in China. A novel coronavirus was identified and named Severe Acute Respiratory Syndrome Coronavirus-2[1,2]. As a consequence of this pandemic healthcare workers (HCWs) were forced to use personal protective equipment (PPE). The prolonged use of PPE has been associated with skin lesions[3], head and facial discomfort due to heat and humidity, pressure, pain, itching[4,5], difficulty breathing, fatigue, exertion,[6] and *de novo* headaches[7-11]. These may negatively impact HCWs' performance and tolerance to long-term use of PPE[12,13].

De novo PPE-associated headaches may have a multifactorial origin. The main proposed mechanism is external compression headache (ECH).[7] ECH is a primary headache coded in the 3rd edition of the International Classification of Headache Disorders[14,15]. The diagnostic criteria are (A) at least two episodes that meet criteria B-D, (B) it is caused by and occurs within, 1 h of constant external compression of the forehead or scalp, (C) the intensity is maximum at the point where external compression occurs, (D) subsides within 1 h after the release of external compression, and (E) not attributable to any other diagnosis[15].

As far as we know, this phenomenon has not yet been studied in our population. Hence, we set out to investigate the prevalence of PPE-associated headache in Mexican HCWs and the conditional probability of developing it based on specific factors.

Methods

We conducted a cross-sectional study at ABC Medical Center from July 8 to August 11, 2020, during phase III of our country's coronavirus disease 2019 (COVID-19) pandemic. Our institution made mandatory for HCWs to wear at least a surgical mask in any hospital area. However, we observed a generalized use of the N95 face mask plus any eye protection device (EPD) among healthcare workers of non-COVID wards (HCWs-NCW).

Based on the hospital census, we invited all the physicians and nurses registered on both campuses to participate in the study. We enrolled front-line healthcare workers (FL-HCWs) and HCWs-NCW of any hospital area (emergency rooms, hospitalization, intensive care unit, and outpatient areas) who agreed to participate and gave written consent. The Institutional Research and Ethics Committee approved the study.

We applied a digital survey, which was developed by the two neurologists conducting the study on Google Forms and was shared through WhatsApp to HCWs registered in the hospital census. The questionnaire included five sections: (1) information about the study's objective, a consent part approved by all participants before answering the survey, and instructions for completing it, (2) asked about demographic data, (3) inquired about PPE-usage patterns in the last month before inclusion, (4) asked if the participant had suffered a primary headache disorder (PHD) before the pandemic, the type of headache, the use of preventive or acute treatment, and each participant's perception of the behavior of their PHD during the COVID-19 pandemic, and (5) asked about PPE-associated headache phenotypic characteristics. We defined PPE-associated headaches as those in close temporal relationship to the use of PPE, and we categorized them as *de novo* headaches (never experienced before) and PHD present before the pandemic that worsened in frequency or intensity due to PPE wearing.

Statistical analysis

Data analysis was performed using SPSS V.25.0 statistical package program for Windows. We calculated descriptive analyses, percentage distributions of the different categories of the analyzed variables and, in the case of quantitative variables average, standard deviation, variance, asymmetry index, and kurtosis. The Chi-square test was used for 2 × 2 contingency tables and for proportional contrast to stipulate the association or dependency relationship between qualitative variables. We used t-test for independent samples to compare means between groups.

We performed multivariate histograms with the qualitative and quantitative variables to examine the possible probabilistic intersections ($A \cap B \cap C \cap \ldots$) and, based on that, describe the statistical dependence between the analyzed variables and their probability of occurrence. To establish whether there was a correlation between the variables, the Pearson Correlation Coefficient test was employed. The statistical significance was set at the level of $p < 0.05$.

Results

We surveyed 305 HCWs, 153 females (50.16%) and 152 males (49.83%), with an average age of 37.86 ±

9.57 years (mean, SD), range of 47 years (interval 21-68 years), 273 (89.50%) physicians, and 32 (10.49%) nurses. Of respondents, 141 (45.90%) were FL-HCWs and 165 (54.09%) HCWs-NCW. The N95 face-mask was the most used device by 286 (93.77%) participants, 143 (46.88%) used face shield, 125 (40.98%) safety glasses, 121 (39.67%) goggles/visor, and 76 (24.91%) surgical masks. For calculating these frequencies, we used replacement sampling due to the possible use of multiple protective devices. The average use of the different devices was 18.73 ± 9.07 days/month for the N95 face mask, 15.05 ± 9.22 days/month for EPD (googles/visor, face shield) and 12.93 ± 9.28 days/month for the combined used of the N95 face mask + EPD. The average daily use of the N95 face mask was 8.50 ± 5.43 h/day, 5.96 ± 4.35 h/day for safety glasses/goggles/face shield and 5.27 ± 4.49 h/day for the combined use of the N95 face mask + any EPD. Of the total studied population, 36.06% suffered a PHD before the pandemic onset. Tension-type headache was the most frequent disorder reported by $\frac{69}{110} = 0.6272$ or 62.72%, followed by migraine with aura in $\frac{27}{110} = 0.2454$ or 24.54% and migraine without aura $\frac{25}{110} = 0.2272$ or 22.72%. At least $\frac{76}{110} = 0.6909$ or 69.09% of the participants with PHD occasionally used abortive treatment; only $\frac{6}{110} = 0.0545$ or 5.45% took preventive treatment and topiramate was the most used. At least $\frac{69}{110} = 0.6272$ (62.72%) considered that their PHD worsened with the regular use of PPE (Table 1).

Of the 305 persons surveyed, 206 (67.54%) reported PPE-associated headaches, 119 (39.01%) had *de novo* headaches while 87 (28.52%) had a worsening of a PHD. The majority, $\frac{157}{206} = 0.7621$ or 76.21% reported headache of tightening quality, $\frac{42}{206} = 0.2038$ or 20.38% reported pulsatile pain and $\frac{35}{206} = 0.1699$ or 16.99% stabbing pain. We calculated these frequencies with replacement sampling (Table 2).

The time interval between donning PPE to the onset of headache was > 60 min in $\frac{132}{206} = 0.6407$ or 64.07% of HCWs, while it was < 60 min in $\frac{74}{206} = 0.3592$ or 35.92%. After removal of PPE, headache resolved within 60 min in $\frac{146}{206} = 0.7087$ or 70.87% of the cases (Table 3).

Headache intensity was considered mild by $\frac{96}{206} = 0.4660$ or 46.60% HCWs, moderate by $\frac{106}{206} = 0.5145$ or 51.45%, and severe by $\frac{10}{206} = 0.0485$ or 4.85%. Associated symptoms were neck pain in $\frac{88}{206} = 0.4271$ or 42.71% HCWs, dizziness in $\frac{58}{206} = 0.2815$ or 28.15%, and nausea in $\frac{31}{206} = 0.1504$, or 15.04%. Of the 206 respondents with PPE-associated headaches, 110 (53.39%) reported maximum pain at contact sites of the devices with the craniofacial structures. Only $\frac{35}{206} = 0.1699$ or

Table 1. Demographic Characteristics of 305 Healthcare Workers Who used PPE During COVID-19 pandemic

Characteristics	Healthcare Workers n = 305 (%)
Age (years)	37.86 ± 9.57
Gender	
Female	153 (50.16)
Male	152 (49.83)
Occupation	
Doctor	273 (89.50)
Nurse	32 (10.49)
N95 face mask	286 (93.77)
Days per month worn (days) (mean ± SD)	18.73 ± 9.07
Hours per day worn (h) (mean ± SD)	8.50 ± 5.43
Eye protection devices (EPD)	
Face shield	143 (46.88)
Safety glasses	125 (40.98)
Goggles/visor	121 (39.67)
Days per month worn EPD (days) (mean ± SD)	15.05 ± 9.22
Hours per day worn EPD (h) (mean ± SD)	5.96 ± 4.35
Combination N95 face mask and EPD	
Days per month worn (days) (mean ± SD)	12.93 ± 9.28
Hours per day worn (h) (mean ± SD)	5.27 ± 4.49
Pre-existing primary headache disorder (PHD)	110 (36.06)
Tension type headache	69 (62.72)
Migraine with aura	27 (24.54)
Migraine without aura	25 (22.72)
Preventive treatment for PHD	6 (5.45)
Worsening of PHD with frequent PPE use	69 (62.72)

EPD: eye protection devices; PHD: pre-existing primary headache disorder; PPE: personal protective equipment; SD: standard deviation.

Table 2. Characteristics of PPE-associated headaches in healthcare workers

Characteristics	Healthcare Workers n = 206 (%)
PPE- associated headache	206 (67.5)
De novo headache	119 (39.01)
Aggravated pre-existing PHD	87 (28.52)
Headache attacks per month	5.75 ± 6.52
Headache Type	
Oppressive	157 (76.21)
Pulsatile	42 (20.38)
Stabbing	35 (16.99)
Headache intensity	
Mild	96 (46.60)
Moderate	106 (51.45)
Maximum intensity at contact sites of PPE	110 (53.39)
Associated symptoms	
Neck pain	88 (42.71)
Dizziness	58 (28.15)
Nausea	31 (15.04)
Need for acute analgesic requirement	157 (76.21)
Paracetamol	95 (46.11)
NSAIDs	78 (37.86)
Number of days participants took analgesic medication (days) (mean ± SD)	2.53 ± 3.76

NSAIDs: non-steroidal anti-inflammatory drugs; PHD: Pre-existing primary headache disorder; PPE: personal protective equipment.

Table 3. Time interval between wearing or removal of PPE and the onset or resolution of PPE- Associated headaches (n = 206).

Variable	Value
Time interval between wearing PPE to onset of headache (min), n (%)	
< 15	6 (2.91)
15-30	19 (9.2)
31-45	23 (11.17)
46-60	26 (12.62)
>60	132 (64.1)
Time interval from removal of PPE to resolution of headache (min), n (%)	
< 15	39 (18.93)
15-30	46 (22.33)
31-45	38 (18.44)
46-60	23 (11.17)
>60	60 (29.13)

PPE: personal protective equipment.

16.99% of the cases met the diagnostic criteria for ECH. HCWs with PPE-associated headaches reported an average of 5.75 ± 6.52 attacks per month. During an attack $\frac{157}{206} = 0.7621$ or 76.21% required analgesic treatment. The mean number of days participants took analgesic medication to relieve that the pain was 2.53 ± 3.76 days/month. Paracetamol was the most used analgesic by $\frac{95}{206} = 0.4611$ or 46.11%, followed by non-steroidal anti-inflammatory drugs in $\frac{78}{206} = 0.3786$ or 37.86% (Table 2).

We made a multivariate histogram to analyze the conditional probability of the study variables from the probabilistic intersections between PPE-associated headaches, type of HCW, gender, and age. Thus $\frac{72}{305} = 0.2360$ or 23. 60% had PPE-associated headache, which were female HCWs-NCW between 30 and 40 years old; $\frac{40}{305} = 0.1311$ or 13.11% had PPE-associated headache, which were male HCWs-NCW between 40 and 45 years old, while $\frac{40}{305} = 0.1573$ or 15.73% had PPE-associated headache, which were female FL-HCWs between 25 and 30 years old. Lastly, $\frac{52}{305} = 0.1704$ or 17.04% who experienced PPE-associated headaches were male FL-HCWs between 35 to 42 years old. Therefore, we can infer that caring for COVID-19 patients, gender and age are not independent factors for PPE-associated headaches (Fig. 1).

We performed a multivariable histogram to analyze the statistical dependence between the variables time interval between wearing PPE to the onset of headache, type of HCW, gender, and age. The development of headache after wearing PPE for more than 60 min was the modal column in the analyzed variables. We can infer from the studied sample that the probability of female HCW-NCW referring headache due to PPE use for more than 60 min regardless of age $\frac{39}{305} = 0.1278$ is 12.78%. The probability that a male HCW-NCW refer headache from PPE use for more than 60 min, regardless of age, which is $\frac{27}{305} = 0.0885$ or 8.85%. A female FT-HCW's probability to refer headache due to PPE use for more than 60 min no matter the age is $\frac{29}{305} = 0.095$ 9.5%. Finally, the probability that a male FT-HCW has a headache due to PPE use for more than 60 min irrespective of age $\frac{30}{305} = 0.0983$ is or 9.83%. (Fig. 2) These results show that none of the variables studied are independent factors for PPE-associated headaches,

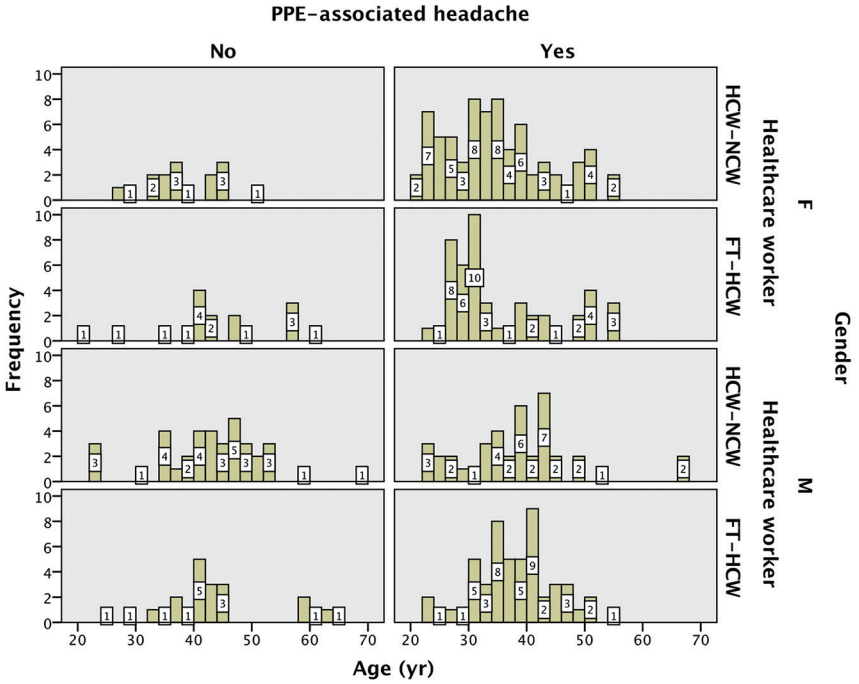

Figure 1. *Tetra-variable histogram, PPE-associated headache, gender, age, and type of healthcare worker. We observed no relationship between age, gender, and type of healthcare worker with PPE-associated headaches.*
F: female; FT-HCW: front-line healthcare worker; HCW-NCW: healthcare worker of a non-COVID ward; M: male; PPE: personal protective equipment; yr: years.

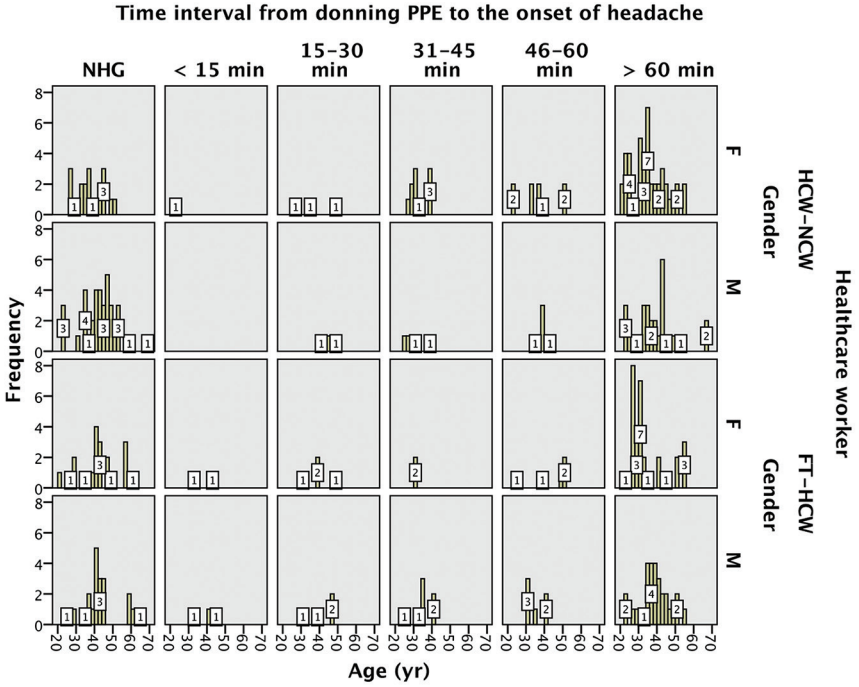

Figure 2. *Tetra-variable histogram, time interval from donning PPE to the onset of headache, gender, age, and type of healthcare worker. The modal column was the onset of headache more than 60 min after wearing PPE. None of the variables studied are independent factors for PPE-associated headaches, but headache frequency increased as the longer HCWs wore the PPE.*
F: female; FT-HCW: front-line healthcare worker; HCW-NCW: healthcare worker of a non-COVID ward; M: male; min: minutes; NHG: non-headache group; PPE: personal protective equipment; yr: years.

but headache frequency increased as the longer HCWs wore the PPE (Table 3).

We analyzed the statistical dependence between the variables, headache intensity, gender, age, and type of healthcare worker using multivariable histogram. The highest frequency reported was a moderate headache in female FL-HCWs regardless of age $\frac{30}{305} = 0.0983$, or 9.83% and in $\frac{26}{305} = 0.0852$ 8.52% male FL-HCWs. We observed the opposite in the modal column for HCWs-NCW, who presented with a mild headache $\frac{32}{305} = 0.1049$ or 10.49% in women and $\frac{20}{305} = 0.0655$ or 6.55% in men; thus, we can infer that providing COVID-19 care is determinant for headache intensity (Fig. 3).

To determine the statistical dependence between the variables, PPE-associated headache, history of PHD, and gender, we elaborated a trivariate histogram and a contingency table to determine the probabilistic intersections between these variables. Thus, the probability that a HCW without a history of PHD does not manifest PPE-associated headache is $\frac{76}{305} = 0.2491$ or 24.91%, of which $\frac{26}{305} = 0..3421$ or 34.21% were women and $\frac{50}{76} = 0.6578$ or 65.78% were men. The probability that a participant without a history of PHD manifests PPE-associated headache is $\frac{119}{305} = 0.3901$ or 39.01%, of which $\frac{59}{119} = 0.4957$ or 49.57% were women and $\frac{60}{119} = 0.5942$ or 50.42% were men. The probability that a participant with a history of PHD does not manifest PPE-associated headache is $\frac{17}{305} = 0.0557$ or 5.57%, $\frac{7}{17} = 0.4117$ or 41.17% were women and $\frac{10}{17} = 0.5882$ or 58.82% were men. Finally, the combined probability of having a history of PHD and manifesting PPE-associated headache is $\frac{93}{305} = 0.3049$ or 30.49%, of which $\frac{61}{93} = 0.6559$ or 65.59% were women and $\frac{32}{93} = 0.344$ or 34.40% were men. In the sample studied, $\frac{119}{305} = 0.3901$ or 39.01% denied a history of PHD and experienced PPE-associated headache; this combination has the highest probability of occurrence (p = 0.3901), followed by the combined probability of having a history of PHD and experiencing PPE-associated headache in $\frac{93}{305} = 0.3049$ or 30.49% (p = 0.3049). In the latter intersection, $\frac{61}{93} = 0.6559$ or 65.59% were women, while in men, the highest combined probability is not having experienced PPE-associated headaches nor a history of PHD in $\frac{50}{76} = 0.6578$ or 65.78% (Fig. 4).

We made error bars to compare the mean and confidence intervals for the mean at 95% confidence limit of the days per month the N95 face mask and the EPD were used alone and combined, and we found a significant difference in both $p \leq 0.001$, demonstrating a greater use of the N95 face mask (Fig. 5).When we compared means difference between the average hours per day, the N95 face mask and the EPD were used alone and combined, we also found a significant difference $p \leq 0.001$, meaning the daily average use of the N95 face mask is higher.

We made an error bar to compare time intervals from donning the PPE to headache onset according to the number of days per month that the PPE was used. We observed that the more days per month HCWs worn PPE, the shorter was the time interval between donning PPE and headache onset (Fig. 6).

Finally, we calculated the correlation coefficient between the time interval from donning PPE to headache onset and headache intensity (r = 0.728), showing a high correlation between these variables. Inversely, we found a correlation between the time interval between doffing PPE to headache resolution and headache intensity (r = 0.662).

Discussion

We surveyed 305 Mexican HCWs to investigate the association between PPE use and *de novo* headaches. The prevalence of *de novo* PPE-associated headaches in our study was 39.01%, quite similar to the reported prevalence in another studies[7-11].

Unlike studies published so far, we included HCWs-NCW in addition to FL-HCWs. The most used device was the N95 face mask, but as expected, FL-HCWs used more frequently the N95 face mask plus any EPD. Both types of HCWs worn the PPE for the same time. There was no difference in PPE-associated headaches prevalence between both groups, but

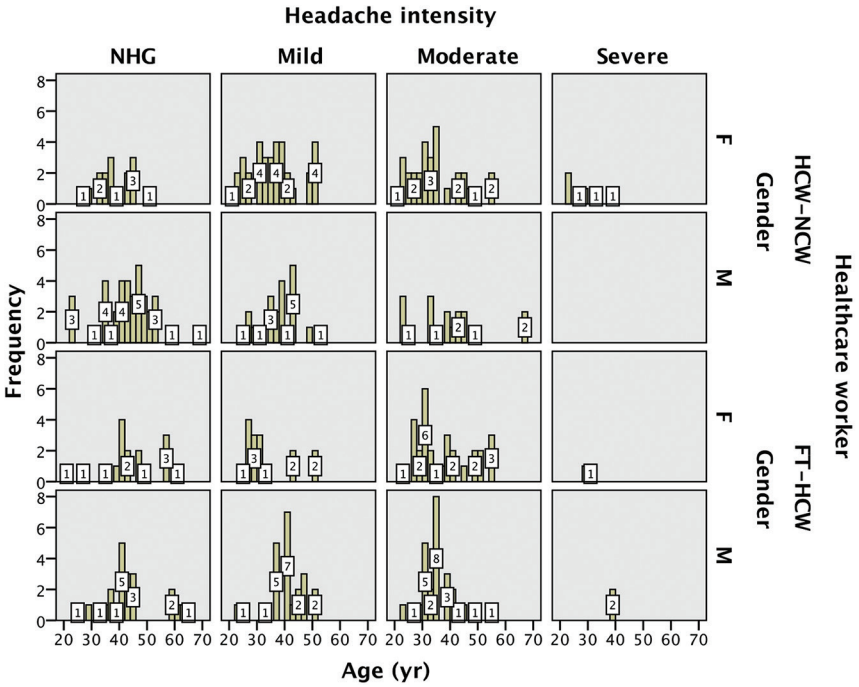

Figure 3. *Tetra-variable histogram, intensity of PPE-associated headache, gender, age, and type of healthcare worker. We observed a higher intensity of PPE-associated headaches among FT-HCW compared to HCW-NCW.*
F: female; FT-HCW: front-line healthcare worker; HCW-NCW: healthcare worker of a non-COVID ward; M: male; NHG: non-headache group; PPE: personal protective equipment; yr: years.

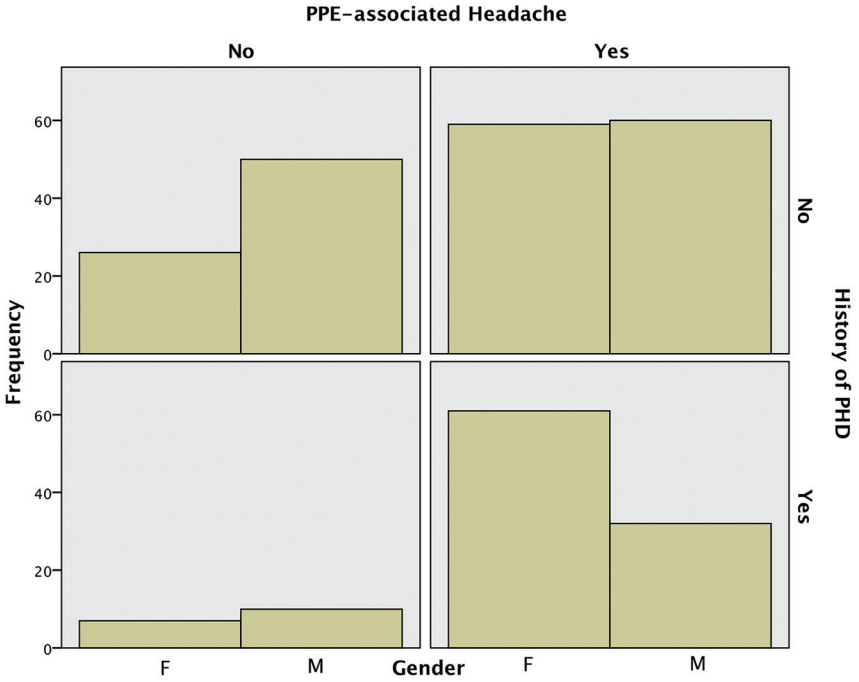

Figure 4. *Tri-variable histogram, PPE-associated headache, history of primary headache disorder and gender. The highest frequency was for the intersection PPE-associated headache and absent history of PHD followed by having a history of PHD and experiencing PPE-associated headache.*
F: female; PHD: primary headache disorder; PPE: personal protective equipment; M: male; yr: years.

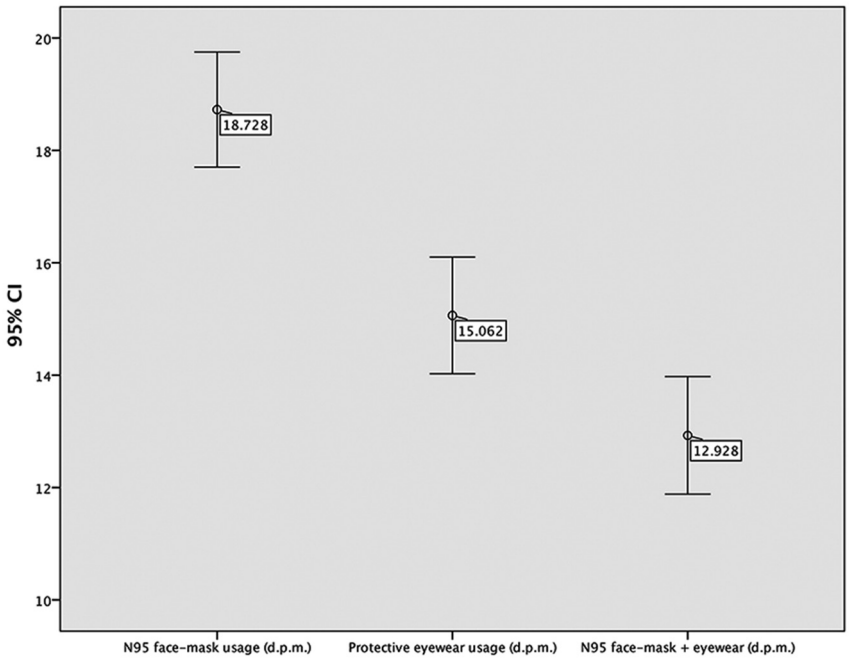

Figure 5. *Comparative error between days per month use of N95 face mask, eye protection devices, and the combination N95 facemask + eye protection devices. The N95 face mask was used significantly more days per month compared to the other devices. d.p.m: days per month.*

headache intensity was higher in FL-HCWs (moderate vs. mild).

The most frequent phenotype of PPE-associated headache in our study was moderate intensity headache, oppressive quality accompanied by neck pain and dizziness, which is consistent to what has been published in other studies. We identified as predisposing factors for this type of headache wearing PPE for more than 60 min, wearing PPE more days per month, and having a pre-existing PHD.

A third of our participants reported having had a PHD before the pandemic. Surprisingly, few HCWs (only 5.45%) used preventive treatment for their PHD. Tension-type headache was the most reported disorder and at least 62.72% of HCWs considered, their PHD worsened during the current pandemic. Most of the participants (84.54%) with a history of a PHD reported having headaches while using PPE. However, cases of *de novo* PPE-associated headache were higher than cases of PHD worsening.

We observed an inversely proportional relationship between the number of days HCWs wore PPE and the time period, in which headache developed. Therefore, we can infer that frequent (several days per month) and prolonged (several hours per day) exposure to PPE could trigger headaches in a shorter period with each exposure. A possible explanation for this phenomenon could be that chronic exposure to a nociceptive stimulus (in this case, the compressive mechanical or traction effect exerted by the different devices and their elastic bands on the pericranial soft tissues) would induce sensitization of the craniofacial nociceptive system and the cervical trigeminal complex favoring a decrease in the threshold for presenting headache each time the exposure to the stimulus occurs. This mechanism is the pathophysiological basis of ECH, which results from the continuous activation of the superficial sensory nerves of the face, head, and neck (branches of the trigeminal or occipital nerve), caused by sustained pressure on the pericranial soft tissues[14,15]. Although only 17% of the participants in our study met the diagnostic criteria for ECH, we observed that in the majority of participants, headache occurred in close temporal relation to PPE wearing.

ECH is not the only probable mechanism involved in PPE-associated headaches. Several authors have found physiological alterations in users while wearing an N95 face mask associated with symptoms such as discomfort, fatigue, dyspnea, dizziness, and headache. In addition, increased serum CO_2 levels (re-inhalation of exhaled air)[16], decreased oxygen saturation

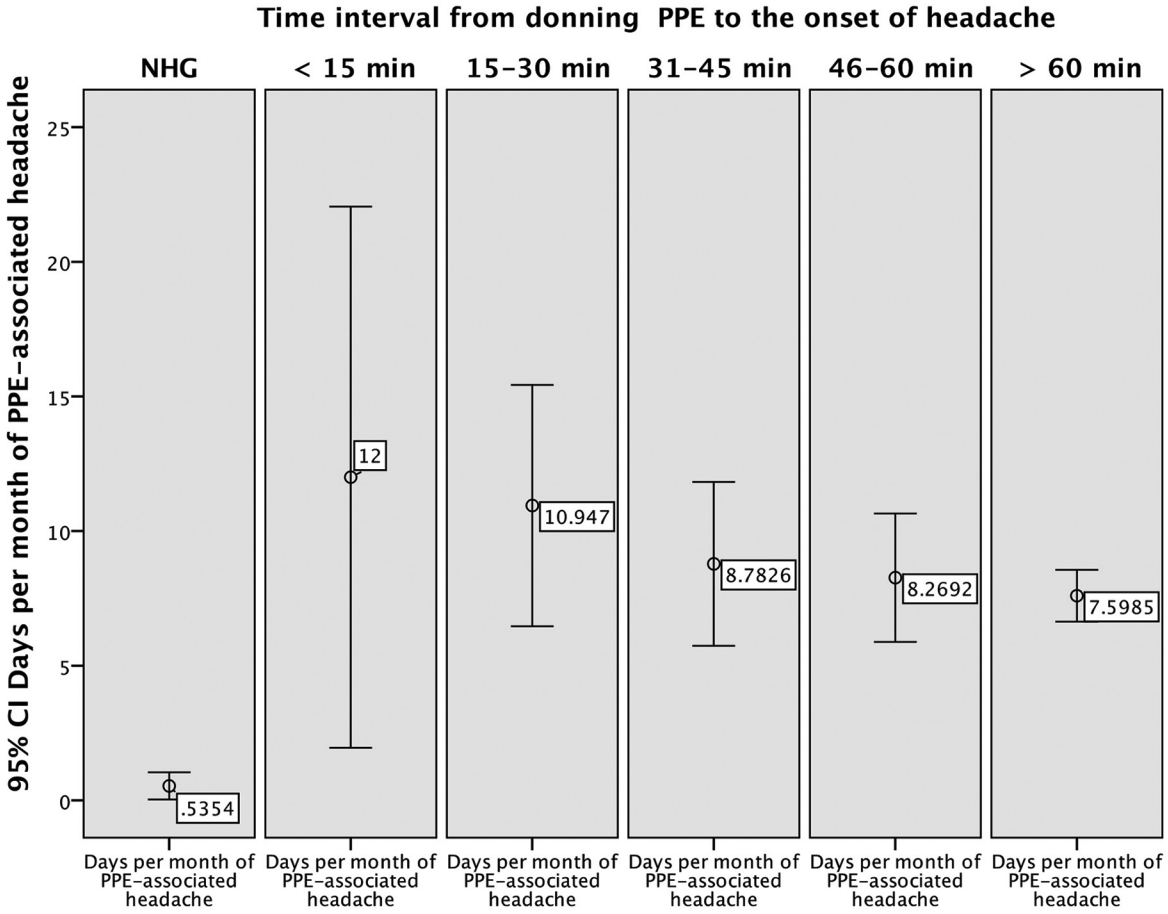

Figure 6. *Error graph of the time interval between donning PPE to Headache Onset. The error graph shows that the more days per month HCWs worn PPE, the shorter was the time interval between donning PPE and headache onset.*
Min: minutes; NHG: non-headache group; PPE, personal protective equipment.

(SpO_2)[17-19], increased heart rate, and blood pressure compared to baseline have been observed after wearing PPE for 4 h[19,20]. An increase in heart rate may be due to several conditions: a high respiratory resistance caused by an N95 face mask moist on the inside (as a consequence of the local rise in temperature and sweating), the level of user's physical activity, baseline physical condition, an increase in CO_2 retention, and anxiety associated with face mask use[19,21].

The adverse effects of prolonged use of PPE lies could limit adherence when using protective devices and put the staff at risk of infection. We believe that further research and the development of new technologies and devices that guarantee proper protection without the related side effects should be carried out.

The strengths of our investigation are that we included FL-HCWs and HCWs-NCW; thus, we obtained a representative sample of the staff in our institution at risk of developing headaches due to PPE use; also, we included a gender-balanced group. The weaknesses of our study are that we conducted a cross-sectional study, we did not objectively measure the pressure exerted by the devices and their elastic bands on the craniofacial structures. Other physiological (hypoxemia, hypercapnia, dehydration, increased local temperature), and psychological (stress, anxiety) factors that may trigger PPE-associated headaches were not considered or analyzed in our study.

Conclusions

Like other symptoms brought on by PPE use, headaches have a multifactorial origin and, although external compression is a relevant factor, it is not the only one. Therefore, future research should consider the different pathophysiological mechanisms that seem to be involved in developing symptoms in individuals wearing PPE. Studies published so far, including ours,

have analyzed the individual factors proposed to be causal. However, as far as we know, no study has covered all the proposed triggering factors for *de novo* PPE-associated headaches in their analyses. Based on current published data of predisposing conditions that lead HCWs to develop PPE-associated headaches, we believe that future research should focus on the development of novel protective devices less harmful than current ones.

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Conflicts of interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained the written informed consent of the patients or subjects mentioned in the article. The corresponding author is in possession of this document.

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