Featured Article

Predicting Health Care Workers' Tolerance of Personal Protective Equipment: An Observational Simulation Study

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Abstract
Background: More recently, due to the coronavirus disease 2019 pandemic, health care workers have to deal with clinical situations wearing personal protective equipment (PPE); however, there is a question of whether everybody will tolerate PPE equally. The main objective of this study was to develop a risk model to predict whether health care workers will tolerate wearing PPE, C category, 4B/5B/6B type, during a 30-minute simulation.
Methods: A nonexperimental simulation study was conducted at the Advanced Simulation Center, Faculty of Medicine, Valladolid University (Spain) from April 3rd to 28th, 2017. Health care students and professionals were equipped with PPE and performed a 30-minute simulation. Anthropometric, physiological, and analytical variables and anxiety levels were measured before and after simulation. A scoring model was constructed.
Results: Ninety-six volunteers participated in the study. Half the sample presented metabolic fatigue in the 20 minutes after finishing the simulation. The predictive model included female sex, height, muscle and bone mass, and moderate level of physical activity. The validity of the main model using all the variables presented an area under the curve of 0.86 (95% confidence interval: 0.786—0.935), and the validity of the model had an area under the curve of 0.725 (95% confidence interval: 0.559—0.89).
Conclusions: Decision-making in biohazard incidents is a challenge for emergency team leaders. Knowledge of health care workers' physiological tolerance of PPE could improve their performance.

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Background

Epidemics such as the severe acute respiratory syndrome, the Middle East respiratory syndrome coronavirus, and the Ebola virus, among others, represented a global wake-up call (Coltart, et al., 2017; Rajakaruna, Liu, Ding, & Cao, 2017), substantially changing the way this type of public emergency was handled and highlighting the importance of community and preventive medicine in the management of these complex situations. The coronavirus disease 2019 (COVID-19) epidemic, which emerged in China, has seriously challenged the capacity of national health systems to deal with it, confirming the importance of preventive and protection systems in controlling threats from biological risks (Peeri et al., 2020). In these circumstances, personal protective equipment (PPE) is a fundamental pillar of the health system and allows health care workers to perform their tasks correctly (Glancey, et al., 2017) while protecting themselves against the risk of contamination (Honda & Iwata, 2016). In this moment, when most health care workers are required to wear PPE, it is inevitable that, in many, their performance is affected, compared with normal situations when only trained staff use them. For instance, the Chinese Center for Disease Control and Prevention reported that 3.8% of health care workers (1,716 cases) were infected by COVID-19, of which 14.8% (247 cases) were serious, with 5 deaths, as of February 11th, 2020 (Wu & McGoogan, 2020).

The use of PPE by health professionals guarantees performance with tolerable safety margins but, at the same time, generates physiological and psychological stress because of the constraints imposed by reduced breathability, increased body temperature (T), decreasing visibility, and so forth (Maynard, Kao, & Craig, 2016; Martín Rodríguez et al., 2018). Studies have analyzed the potential contamination faced by professionals during the removal of PPE (Kang et al., 2017; Tomas et al., 2015) and how the body T increases with PPE use (Borg, Costello, Bach, & Stewart, 2017; Buller, Tharion, Duhamel, & Yokota, 2015). A recent cross-sectional study focused on the association between PPE and headaches (Ong et al., 2020).

The main objective of this study was to develop a risk model, based on baseline demographic and physiological parameters, to predict whether individual health care workers will tolerate wearing a PPE—C category, 4B/5B/6B type—against biological risks for 30 minutes.

Key Points

- COVID-19 has meant that health care workers must perform resuscitation with personal protection equipment.
- Fatigue appears early with the use of personal protective equipment.
- Training with this type of protective equipment is essential to prepare to work in these extreme situations.

Materials and Methods

Study Design and Setting

We conducted a nonexperimental simulation study, between April 3rd and 28th, 2017. The study was conducted at the Advanced Simulation Center, Faculty of Medicine, Valladolid University (Spain). Ninety-six randomly chosen volunteers were stratified by sex, level of training, and professional category from an opportunity sample of 164 volunteers.

The Research Ethics Committee of the Rio Hortega University Hospital approved the study protocol (PI-41/16). All participants signed informed consent. The study is reported in line with the EQUATOR guidelines (STROBE statement) and was in accordance with Good Clinical Practice and the Declaration of Helsinki.

Participants

Participants were volunteers aged >18 and <65 years who were final year undergraduate medical and nursing students, and physicians and nurses from the emergency department and emergency medical services.

Exclusion criteria were age outside the range of the inclusion criteria, volunteers who had participated in similar studies, and the lack of signed informed consent.

All eligible volunteers underwent a health examination. Those with the following conditions were excluded: arrhythmia; heart rate (HR) > 150 or < 40 bpm; systolic blood pressure (SBP) > 160 or < 80 mmHg; body mass index > 40 Kg/m^2; functional disability or visual or hearing impairments that would prevent completion of the maneuvers performed in the simulated case; oxygen saturation (OS) $\leq$ 92%; capillary glycemia (CG) < 65 mg/dL; fever;

major surgery in the previous 30 days; acute skin disease; systemic immune disease; and anticonvulsant or anticoagulant treatment.

Study Protocol

The height, weight, body fat, muscle mass, bone mass, total body water, and body mass index were measured. The HR, SBP, diastolic blood pressure (DBP), respiratory rate, T, capillary hemoglobin, perfusion index, OS (CG), and capillary lactate (CL) were measured.

The Beck Anxiety Inventory, a self-reported scale composed of 21 items (each item in the range 1–3), with high internal consistency (Cronbach's a = 0.92) (de Oliveira, et al., 2015; Vázquez Morejón, Vázquez-Morejón Jiménez, & Bellido Zanin, 2014), was administered. The sum of the items stratified participants into three levels: low anxiety (0–21 points), moderate anxiety (22–35 points), and potentially concerning levels of anxiety (≥36 points).

To complete the initial assessment, each volunteer completed the International Physical Activity Questionnaire (IPAQ), a self-reported scale composed of seven items that evaluates the level of physical activity (Cronbach's a = 0.73). The IPAQ determines three levels of activity, low, moderate, or high (Macek et al., 2019; Reed et al., 2018).

Each volunteer, guided by an expert in biological risks, and following the protocol of the European Center for Disease Prevention and Control, was equipped with PPE C category (PPE consists of a chemical and biological protection suit, respiratory protection with mask or half mask, gloves, and eye protection), 4B/5B/6B type (waterproof and aerosol proof, with hermetic connections against solid particles suspended in the air) (ECDC, 2014). The standard CoverStar® Plus (ASATEX AG, Bergheim, Germany) equipment was composed of biological protection coverall, hood, overboots, apron, fine dust mask FFP3, disposable gloves, nonpowdered nitrile, and panoramic glasses.

Once equipped with PPEs, volunteers entered a 24 m^2 simulation laboratory with controlled T (30.9°C; interquartile range [IQR]: 30.3%–31.5°C), humidity (51%; IQR: 50%–52%), noise (71 dB; IQR: 56–79 dB), and lighting (641 lumens; IQR: 601–671 lumens).

All groups performed the same simulated clinical case using the SimMan ALS patient simulator (Laerdal, Stavanger, Norway). The simulated procedure was as follows: the medical emergency team (four volunteers) must assist a patient with a suspected biological disease while several events occur during the simulation. At the beginning of the clinical simulation, the patient presented a low level of consciousness, with tachycardia and tachypnea, had oxygen saturation of 89%, was normotensive, had a T of 38.1°C, and had a blood glucose of 76 mg/dL. At minute eight of the simulation, the patient begins to convulse, and incised-

contused injury occurs with heavy bleeding in the left forearm. At minute 20, the patient suffers a nondefibrillable cardiac arrest, with an asystole rhythm. During the clinical simulation, participants are expected to perform an objective structured clinical examination, develop precise advanced airway management techniques (the use of a laryngeal mask or orotracheal intubation), canalize a venous line or intraosseous access, administrate drugs according to the protocol, perform incision-contusion wound dressing or bleeding control through more aggressive maneuvers such as tourniquet and, when the patient undergoes cardiac arrest, administer advanced life support maneuvers according to the protocol.

The simulation lasted 30 minutes, and participants took off the equipment immediately. Twenty minutes after the end of the simulation, the CL and HR were evaluated.

Outcomes and Data Collection

The primary outcome of interest was participant fatigue, which was operationally defined as CL > 4 mmol/L or HR difference between 20 minutes after the end of the simulation and baseline values greater than the 3rd quartile (equivalent to > 31 bpm) after 30 minutes of simulated work with PPE—category C, 4B/5B/6B type—against biological risks. This outcome will be named "fatigue" from now on.

All members of the research staff were aware of the objectives of the study, the standardized way of obtaining the set of vital signs, the anthropometric examination, and the use of electromedical equipment. A procedure for determining the CL and CG was developed with specific training on the operation, cleaning, maintenance, and calibration of the equipment. The traceability of all test strips used was monitored, with control of expiry dates, serial numbers, and batch numbers.

Each volunteer was examined by a member of the research staff (a physician or a registered nurse) who collected the following: demographic variables such as age, sex, and the corresponding group (student or professional); years of work experience and previous experience in biohazard incidents; vital signs; clinical observations; IPAQ; and Beck Anxiety Inventory. Analytical tests were made subsequently.

The anthropometric study was performed using the MC-780U scale (Tanita Corporation, Arlington Heights, IL). To determine the HR, SBP, and DBP, the BP-200 plus monitor (Schiller AG, Baar, Switzerland) was used. The respiratory rate was calculated by counting the complete respiratory cycles for one minute. The T was obtained using Thermo-Scan® PRO 6000 thermometers (Welch Allyn, Inc, Skaneateles Falls). The Pronto 7 device (Masimo, Irvine, CA) was used to determine the hemoglobin level, perfusion index, and OS. The FreeStyle Optium Neo device (Abbott Laboratories, IL) was used to measure the GC, and CL values were

obtained using an Accutrend Plus measuring device (Roche Diagnostics, Mannheim, Germany).

Missing Data

All data were recorded electronically in a specifically created database using XLSTAT® BioMED software for Microsoft Excel®, version 14.4.0. (Microsoft Inc., Redmond, WA).

The database was purified using rank and consistency logical tests, resulting in a total of 28 variables. A complete analysis was carried out, variable by variable, of missing data, leaving only complete data sets. The study variables did not present missing data. The case registration form was tested to eliminate ambiguous elements, guaranteeing the robustness of the data collection instrument.

Data Analysis

Categorical variables were represented as absolute values and percentages, and continuous variables as medians and IQRs because they did not follow a normal distribution. A univariate model was constructed to obtain the odd ratios for each variable, considering fatigue as the outcome variable.

Figure 1 Flow chart of the study population. *Note.* SBP = systolic blood pressure; BMI = body mass index; CG = capillary glycemia.

Logistic regression with all variables as precursors and fatigue as the outcome was carried out. A stepwise procedure with backward and forward searches based on the Akaike information criteria was used to construct the model. Significant variables were selected to build the main model.

Continuous variables were categorized based on the relationship they had with the outcome by determining the range (base range) of values of each continuous variable that corresponded to a higher incidence of less fatigue. Then, the categorical variable was constructed with as many categories as there were ranges of the length of the base range.

Once the final variables to be introduced in the scoring system were selected and the continuous ones categorized, the sample was randomly split into training (2/3) and test (1/3) cohorts, keeping, in each case, the same proportion of the outcome variable with the rest as it was in the whole cohort sample.

The value of each variable in the model was derived from the regression coefficients of the regression model's significant variables in the following way: the rounded-integer coefficients of the logistic regression corresponding to significant levels of the categorical variables (value of $p < .05$) were selected to build the scoring system. The final value of the scale was obtained from the sum of each patient's score for each variable (Zhang, Zhang, & Khanal, 2017).

The discrimination validity of the score and the main value were assessed using the area under the curve (AUC) of the receiver operating characteristic (ROC) along with the 95% confidence intervals (95% CIs). For both cases, the p value of the comparison against the null hypothesis (AUC = 0.5) was less than 0.05.

All statistical analyses were performed using our own codes and base functions in R, version 3.5.1 (http://www.R-project.org).

Results

One hundred sixty-four volunteers expressed a willingness to participate. Fifteen subjects did not meet exclusion criteria (Figure 1). Thus, 149 volunteers were eligible, and a random draw was used to obtain the final cohort of 104 volunteers, eight of whom were excluded (either for not signing the informed consent at the time of inclusion or for not completing the study), resulting in a final cohort of 96 participants (Figure 1).

The median age was 26 years (25th–75th percentile: 22–41 years) and 56 (58.3%) were female, 49 (51.0%) were medical and nursing students, and 47 (49.0%) were health care workers. Global demographic characteristics and statistical differences are described in Table 1. Odd ratios are shown in Table 1: female (OR: 0.34, 95% CI: 0.15, 0.80), height (OR: 1.05, 95% CI: 1.00, 1.10), muscle mass (OR: 1.04, 95% CI: 1.00, 1.08), bone mass (OR: 2.18, 95% CI: 1.00, 4.74), and a moderate IPAQ (OR: 9.62, 95% CI: 2.41, 38.35) were the variables that showed a significant p value ($p < .05$) for fatigue.
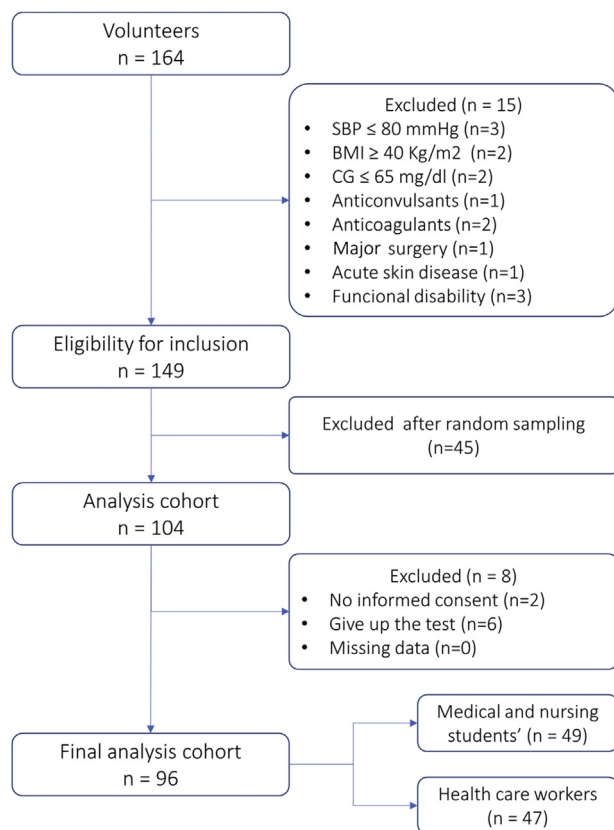
Table 1   Characteristics of the Study Population

Variable*	Total (N = 96)	No Fatigue (n = 48)	Fatigue (n = 48)	Odds Ratio (95% CI)	p-value
Age (years)	26 (22–41)	28 (23–40)	24 (22–41)	0.99 (0.95–1.03)	0.773
Sex					
Male	40 (41.7)	14 (29.2)	26 (54.2)		
Female	56 (58.3)	34 (70.8)	22 (45.8)	0.34 (0.15–0.80)	**0.014**
Worker/student					
Students	49 (51.0)	23 (47.9)	26 (54.2)		
Workers	47 (49.0)	25 (52.1)	22 (45.8)	0.78 (0.34–1.73)	0.540
Training in biological risk					
None	43 (44.8)	23 (47.9)	20 (41.7)		
Basic	20 (20.8)	8 (16.7)	12 (25.0)	0.92 (0.37–2.29)	0.864
Advanced	33 (34.3)	17 (35.4)	16 (33.3)	1.59 (0.51–4.91)	0.417
Anthropometric study					
Height (cm)	168 (162–173)	165 (161–172)	170 (164–178)	1.05 (1.00–1.10)	**0.037**
Weight (kg)	68 (58–79)	65 (57–74)	69 (61–81)	1.02 (0.99–1.05)	0.059
Fat (%)	21.7 (16.3–27.7)	22.2 (17.9–27.7)	20.7 (15.2–27.8)	0.98 (0.94–1.03)	0.656
Muscle mass (%)	47.0 (42.1–60.8)	44.9 (41.2–59.8)	52.6 (42.9–62.0)	1.04 (1.00–1.08)	**0.039**
Bone mass (%)	2.5 (2.3–3.2)	2.4 (2.2–3.1)	2.7 (2.3–3.2)	2.18 (1.00–4.74)	**0.048**
Total water (%)	57.3 (53.3–61.1)	57.0 (53.4–60.7)	57.3 (53.2–61.6)	0.99 (0.93–1.06)	0.967
BMI (kg/m^2)	23.9 (21.4–26.7)	23.2 (20.9–26.1)	23.9 (21.9–27.0)	1.05 (0.95–1.17)	0.260
IPAQ					
Low	49 (51.0)	16 (33.3)	33 (68.8)		
Moderate	30 (31.3)	18 (37.5)	12 (25.0)	9.62 (2.41–38.35)	**0.001**
High	17 (17.7)	14 (29.2)	3 (6.3)	3.11 (0.73–13.19)	0.124
BAI (points)	4 (2–7)	3 (2–7)	4 (2–8)	1.01 (0.91–1.11)	0.823
Basal vital signs					
Heart rate (bpm)	68 (62–75)	66 (60–71)	70 (64–76)	1.01 (0.97–1.06)	0.460
SBP (mmHg)	130 (120–138)	129 (121–136)	132 (119–139)	1.01 (0.98–1.04)	0.334
DBP (mmHg)	80 (73–87)	79 (73–86)	84 (74–90)	1.04 (0.99–1.08)	0.060
RR (bpm)	17 (15–18)	17 (15–18)	17 (15–18)	1.03 (0.80–1.33)	0.797
Temperature (°C)	36.7 (36.1–37.1)	36.7 (36.2–37.0)	36.7 (36.4–37.1)	1.20 (0.55–2.62)	0.635
HB (mg/dL)	13.7 (12.6–14.8)	13.5 (12.6–14.6)	14.2 (12.6–15.0)	1.15 (0.87–1.51)	0.319
Perfusion index (%)	2.0 (1.1–4.8)	1.9 (1.1–4.9)	2.2 (1.1–4.7)	1.01 (0.88–1.16)	0.849
Saturation (%)	98 (97–99)	98 (97–100)	98 (97–99)	1.09 (0.82–1.44)	0.524
CG (mg/dL)	106 (97–116)	107 (96–114)	106 (97–120)	1.01 (0.98–1.03)	0.361
CL (mmol/L)	2.1 (1.4–2.9)	2.0 (1.5–2.5)	2.2 (1.3–3.3)	1.18 (0.89–1.57)	0.236
Final vital signs					
Heart rate (bpm)	91 (83–101)	88 (81–94)	97 (85–108)	1.06 (1.02–1.11)	**0.001**
CL (mmol/L)	3.2 (2.3–4.5)	2.6 (1.7–3.1)	4.5 (3.4–5.3)	4.19 (2.30–7.64)	**<0.001**

*Values expressed as the total number (fraction) and medians (25 percentile–75 percentile) as appropriate. Statistical significance values are given in bold.
Note. CI = confidence interval; BMI = body mass index; IPAQ = International Physical Activity Questionnaire; BAI = Beck Anxiety Inventory; SBP = systolic blood pressure; DBP = diastolic blood pressure; RR = respiratory rate; HB = hemoglobin; CG = capillary glycemia; CL = capillary lactate.

The validity of the main model, using all the variables, had an AUC of 0.86 (95% CI: 0.786–0.935) (Figure 2). Based on the stepwise selection procedure from the main model, the scoring model included the following: worker/student, sex, muscle mass, bone mass, SBP, DBP, saturation, and IPAQ. The final variables from the logistic regression with their odd ratios are shown in Table 2; the value of both selected variables (sex and IPAQ) were obtained from the round value of the estimate, which was divided by two, maintaining their sign (negative and positive, respectively), because the sign indicates whether they are positive or negative, respectively. Figure 3 shows the relationship between the score value and the percentage of patients with fatigue for the training cohort; patients with negative values for the score had a lower probability of fatigue than those with positive values. The validity of the model had an AUC of 0.725 (95% CI: 0.559–0.89) (Figure 4). Further details of the model are shown in Table 3.

Discussion

In this nonexperimental simulation study, we obtained a model with the capacity to predict whether health care
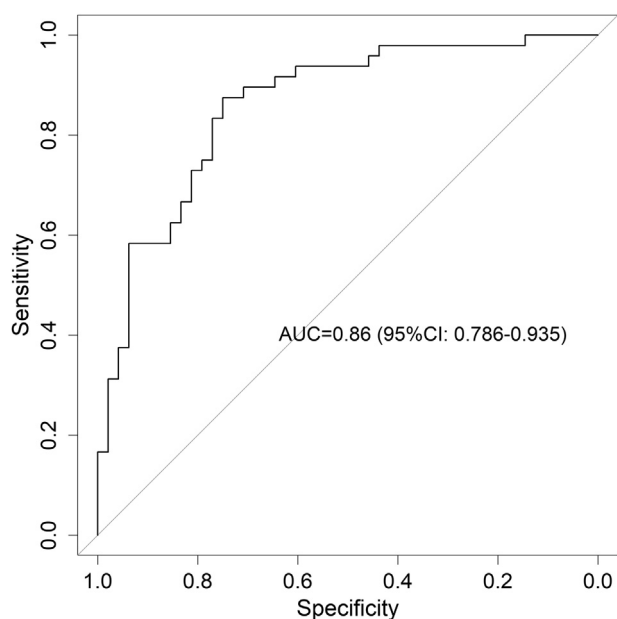
Figure 2   Receiver operating characteristic (ROC) by fatigue for the main model. The bold line shows the value of the ROC curve. The values in the graph represent the area under the curve (AUC) and its 95% confidence interval.

Figure 3   Receiver operating characteristic (ROC) by fatigue for the scoring model. The bold line shows the value of the ROC curve. The values in the graph represent the area under the curve (AUC) and its 95% confidence interval.

workers will develop metabolic fatigue while wearing PPE against biological risks after 30 minutes of intervention. The model consists of five easy-to-obtain noninvasive parameters such as sex, height, muscle mass, bone mass, and IPAQ stratification.

Studies have analyzed the use of PPE and how they affect fine motor skills (Merchan & Clemente-Suárez, 2019; Schumacher, Arlidge, Garnham, & Ahmad, 2017) or how the use of PPE influences the quality of resuscitation (Chen, Lu, Yi, & Chen, 2016). In line with our study, other studies addressed the issues of thermal perception and perceived effort when working under these conditions (Borg, et al., 2017) (Borg, Stewart, & Costello, 2015), the increase in HR more than recommended maximum levels (Martín Rodríguez et al., 2018), and the relationship between PPE and headaches (Ong et al., 2020).

We propose CL and HR as fatigue parameters. Lactate is a highly sensitive biomarker that provides accurate information about anaerobic metabolism (Brooks, 2018; Hall, 2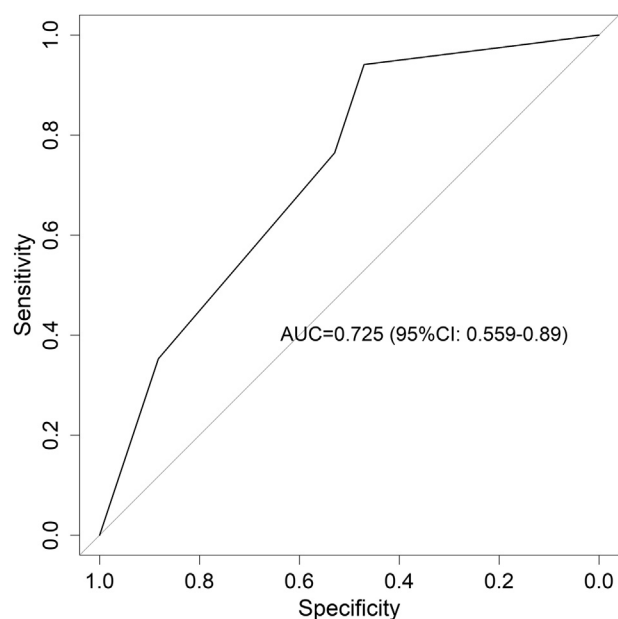016) that is easy to obtain and highly validated in sports physiology (Faghy, Lomax, & Brown, 2019), and in other clinical contexts (Hermann, et al., 2019). A CL level >4 mmol/L—lacticaemia—after 20 minutes of rest implies continued high metabolic demand (Proia, Di Liegro, Schiera, Fricano, & Di Liegro, 2016). The other parameter considered critical to determine fatigue was an HR difference (between baseline values and 20 minutes after the end of the simulation) greater than the 3rd quartile (>31 bpm). During the simulation, the HR was expected to rise but return to normal values after the activity. This is not true for subjects presenting fatigue, in whom a longer HR recovery time was observed (Le Meur, Buchheit, Aubry, Coutts, & Hausswirth, 2017; Micklewright, St Clair Gibson, Gladwell, & Al Salman, 2017).

We found that female was a positive factor against metabolic fatigue. In fact, males presented 8.4% more cases of fatigue than females. This difference may be explained by the higher percentage of muscle mass in males (Castellani & Young, 2016). The lower muscle mass in females limits their thermogenic response capacity although

Table 2   Variables in the Scoring Model

Variable	Estimate	Scale Value	Std. Error	Z Value	Odds Ratio (95% CI)	*p*-value
Sex						
Female	−2.02	−2	0.92	−2.18	0.13 (0.01−0.71)	0.029
IPAQ						
High	3.2	3	1.12	2.85	24.5 (3.43−309.5)	0.004

Note. Std = standard; CI = confidence interval; IPAQ = International Physical Activity Questionnaire.
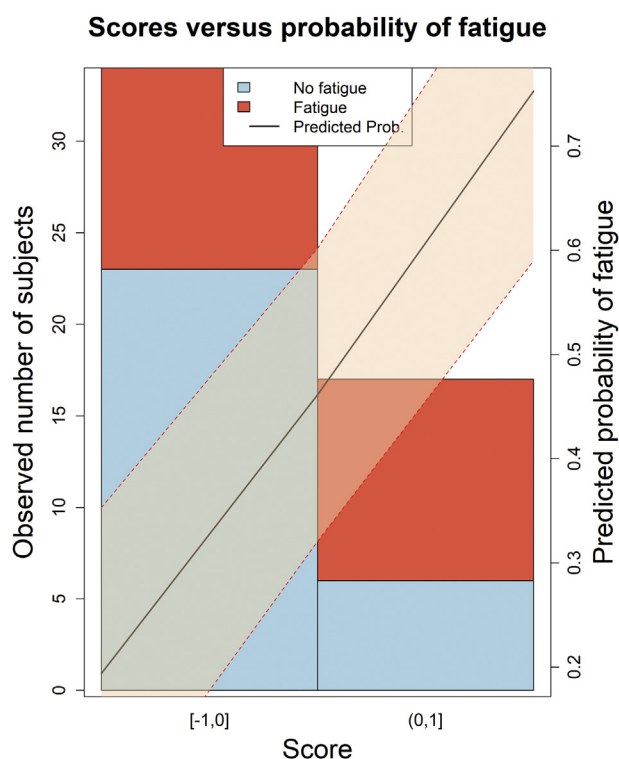
Scores versus probability of fatigue

Figure 4 Probability of fatigue based on the value of the score. The bar graph shows the number of patients in the training cohort for each scale value (presenting no fatigue in blue and fatigue in red). The trend line shows the estimated probability of fatigue.

this lower adaptation to thermal change is not a limitation but rather makes females more thermally competent when using this type of PPE (Mantooth, Mehta, Rhee, & Cavuoto, 2018). Likewise, taller subjects tolerated the simulation worse. Taller subjects with greater muscle and bone masses are not always better adapted for certain type of physical work (Cornell, Gnacinski, Meyer, & Ebersole, 2017; Giandolini, Bartold, & Horvais, 2019). The last variable included in the model is the IPAQ. Subjects with a moderate or high level of activity had better physiological capacity to work with this type of PPE (Dorner, Wilfinger, Hoffman, & Lackinger, 2019). Physical activity improves aerobic capacity and resistance to metabolic stress (Loyen et al., 2016; Reed et al., 2018).

Our results point to the existence of a phenotype of subjects presenting better tolerance to fatigue while wearing PPE: shorter females with low muscle and bone masses and physically active. Variables possibly expected to be

relevant, such as experience (students or workers), training in biological risk, or the level of anxiety (Li et al., 2018), did not influence the model.

The model could be useful to differentiate, based solely on baseline demographic and physiological parameters, which health care workers will be better suited to work with PPE or, conversely, which subjects will require higher levels of training to work satisfactorily while wearing PPE.

The strength of the simulation is in the diversity encompassed in the sample, which included students and professionals, male and female, and nurses and physicians, representing a robust and illustrative sample of the health care system.

The study had some limitations. First, the potential bias in the selection of volunteers that was based solely on opportunity criteria. All subjects were recruited from the public health system or the Faculty of Health Sciences of the University of Valladolid, in line with similar studies (Alhmidi, et al., 2016; John, Tomas, Hari, Wilson, & Donskey, 2017). Second, although the sample size permits preliminary results and internal validation, it is too small for external validation of the model, which would require a multicenter study to determine the physiological impact on workers wearing PPE under biological risks. Third, lactate was selected as a biomarker because it is easy to obtain, has been previously validated, and is cheap. However, other biomarkers such as cortisol, C-reactive protein, and so forth, cannot be ruled out and will be considered in future studies. With the aforementioned caveats in mind, this model should be interpreted with caution because it is a preliminary study.

In conclusion, given that a high percentage of subjects suffer from fatigue using PPE in a simulated incident against biological risks, any model aimed at improving the correct selection of health personnel to work in critical and complex situations while wearing PPE must be considered. Our proposed model can differentiate between subjects with good or bad tolerance of a 30-minute simulation with PPE, C category, 4B/5B/6B type, shedding light on which baseline variables could potentially anticipate work fatigue.

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Table 3 Measures in the Scoring Model for Each Value Threshold

Threshold	Se	Sp	PPV	NPV	DA
−1	100	0	50	NA	50
0	91.6	45.8	62.8	84.6	68.7
1	31.2	91.6	78.9	57.1	61.4

Note. Se = sensitivity; Sp = specificity; PPV = positive predictive value; NPV = negative predictive value; DA = diagnostic accuracy.

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