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1 **Intensive care medical procedures are more complicated, more**
2 **stressful, and less comfortable with Ebola personal protective**
3 **equipment: A simulation study**

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21 **Running Title** Impact of Ebola personal protective equipment

22 **Keywords**

23 Ebola virus disease; Intensive care; Protective equipment; Stress; Workload; Task
24 performance

To the editor

26 Ebola virus disease (EVD) is a life-threatening condition. Appropriate management of
27 organ failure, hemodynamic instability, and metabolic disorders significantly improves
28 survival. This implies that life-saving procedures are undertaken in case of need, including
29 endotracheal intubation, nasogastric tube placement and central venous catheter (CVC)
30 insertion. The challenge is to provide high quality of care to patients with life-threatening
31 EVD, under optimal safety conditions for health care workers, *i.e.* with reinforced personal
32 protective equipment (PPE), ensuring that no exposure to patient blood or any other body
33 fluid occur [1-3]. We assessed the impact of Ebola PPE use on the performance of senior ICU
34 physicians during common intensive care unit (ICU) procedures, and on the workload, in a
35 simulation environment.

36 The study was performed in our simulation department. Thirteen volunteer senior ICU
37 physicians performed orotracheal intubation and nasogastric tube placement on a simulation
38 mannequin (*Megacode Kelly Sim*, Laerdal™, Stavanger, Norway), and CVC insertion on a
39 dedicated echogeneous task trainer (CAE Healthcare™, St Laurent, QC, Canada). The use of
40 ultrasound for CVC insertion was left to the discretion of the physician. Each participant had
41 to complete all procedures twice, one with standard protection, and one with Ebola PPE, in an
42 order determined by the randomization. The Ebola PPE consisted in a N95 Particulate
43 Filtering Face Respirator, with large protective glasses, surgical hood, fluid resistant
44 coveralls, boot covers, and two pairs of gloves, as recommended [4]. All sequences were
45 recorded using an HD video camera. Participants were equipped with a thoracic belt for the
46 monitoring of heart rates and chest wall movements to record upper body tilt (Zephyr
47 BioHarness 3™, Annapolis, USA). Procedural time was independently assessed by two
48 reviewers, using a video tagging software (StudioCode™, Marseille, France). Equipment
49 ergonomics were assessed for each participant after the complete course, using a Likert scale

50 asking three questions for each procedure: i) stress during the task (from 1, major stress to 5,
51 no stress); ii) equipment's ease of use (from 1, very difficult to 5, very easy), and iii) comfort
52 (from 1, very uncomfortable to 5, very comfortable). The task workload was assessed using
53 the National Aeronautics and Space Administration Task Load Index (NASA-TLX), a
54 multifaceted tool for perceptual (subjective) workload evaluation [5], based on a weighted
55 average of ratings on six subscales: mental demand, physical demand, temporal demand,
56 performance, effort, and frustration. These steps provide a global score from 0 to 100, higher
57 values indicating heavier workload. All tests were performed using Statview 5.0.1 (SAS
58 Institute, Cary, NC, USA). Mann-Whitney and Kruskal Wallis non-parametric tests were
59 used for procedural time analysis and Likert scale comparisons. Physiological parameters
60 comparison used a Laird and Ware regression test with R [6], and the lme4 library [7].
61 NASA-TLX data were compared using a non-parametric Wilcoxon test. Data are provided as
62 median [interquartile ratio], unless specified otherwise.

63 Global success rate for the complete procedure course was 100% with standard
64 protection, and 85% with Ebola PPE ($p=0.48$). Higher degrees of body tilt were measured
65 with Ebola PPE, as compared to standard protection ($p<0.05$). In most cases, procedures were
66 rated as easier, and more comfortable with standard protection, than with Ebola PPE (Table
67 1). Median global task load index was higher with Ebola PPE, as compared to standard
68 protection, for orotracheal intubation (44.3 vs. 20.3, $p=0.007$), and nasogastric placement
69 (38.9 vs. 25.6, $p=0.008$, Figure 1). For CVC insertion, global task load index was not
70 significantly different for the whole group (58.6 vs. 37.6, $p=0.182$). However, differences
71 were significant for the 7 physicians who performed ultrasound-guided procedures (54.9
72 [34.7-67.1] vs. 29.5 [14.1-50.1], $p=0.028$), but not for the 6 physicians who didn't use
73 ultrasound (76 [52.9-84.9] vs. 46.3 [36-58.9], $p=0.686$). Physical demand was higher with
74 Ebola PPE as compared to standard protection for nasogastric tube placement (2.5 [0.9-5.2]

75 vs. 0.6 [0.4-0.9], $p=0.022$), and CVC insertion (3.6 [1.8-13.4] vs. 1.2 [0.4-2.5], $p=0.009$), but
76 nor for orotracheal intubation.

77 Although these findings are not unexpected given the constraints and discomfort of
78 Ebola PPE reported by health care workers, the application of simulation procedures in this
79 study provided evidence-based, and quantitative data, on the impact of currently
80 recommended Ebola PPE on these life-saving procedures. This innovative model may be used
81 to compare different combinations of Ebola PPE, and select those with lower impact on
82 quality of care and workload, while still ensuring effective protection. Person-to-person
83 transmission of Ebola virus primarily occurs through contact with infected patients' fluids [1-
84 3]. During ICU procedures, often performed in emergency, physicians are at risk for
85 contamination [7-9], and the use of a dedicated Ebola PPE is mandatory. All health care
86 providers potentially involved must receive adequate training for correct use of Ebola PPE,
87 including safety (i.e. no breaches in protection), and efficacy (i.e. being able to provide
88 appropriate care with maximum ease, dexterity, comfort, and minimal stress) [3,4]. Because
89 the management of patients with EVD is a complex process, simulation plays a major role in
90 the preparation of health care worker to anticipate the difficulties that may arise while taking
91 care of patients suspected of, or confirmed with, EVD [10].

92 Our study has limitations. First, sample size was limited. However, this study was
93 performed in a homogeneous group of senior, experienced ICU physicians. Second, the use of
94 manikins, in a simulated environment, is merely a proxy for the actual clinical scenario.
95 However, only simulated conditions enables to perform a standardized, randomized study,
96 with prospective collection of an extensive set of data, and extensive post-hoc debriefing. We
97 found that common ICU procedures are more complicated, more stressful, and less
98 comfortable, with Ebola PPE. These necessary protections increase workload, and may be
99 associated with increased risk of severe adverse events, either for the patient (procedure

100 failure, complications), or the physician (Ebola virus transmission). Ebola PPE should be
101 evaluated by simulation and ergonomics studies as the one reported herein, to optimize the
102 selection of Ebola PPE that would ensure both the safety of health care workers, and the
103 quality of care for patients suspected of EVD.

104

105 **Transparency declaration**

106 All authors: no potential conflict of interest.

107

108 **Acknowledgment**

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110 of Western France, and the dedicated technicians from the simulation department of Brest
111 University of Medicine, who made this study possible.

112

113 **Highlights**

- 114 • This simulation study analyzed the impact of Ebola personal protective equipment (PPE)
115 on ICU procedures
- 116 • Nasogastric tube, central venous catheter, and orotracheal intubation are adversely
117 affected by Ebola PPE
- 118 • This model may be used for the selection of Ebola PPE with limited impact on ICU
119 procedures

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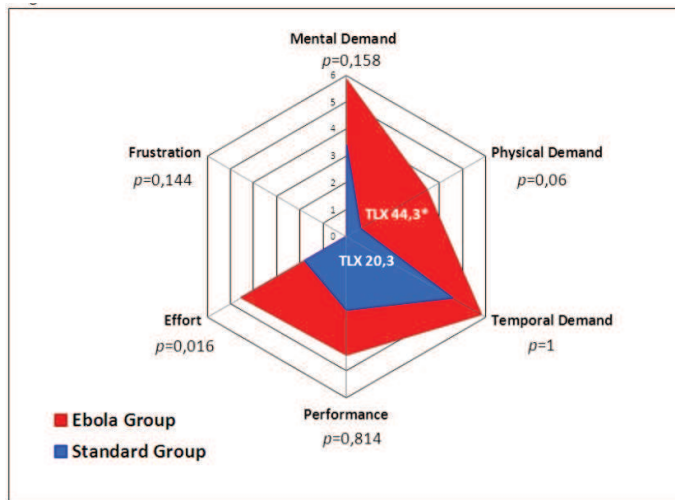
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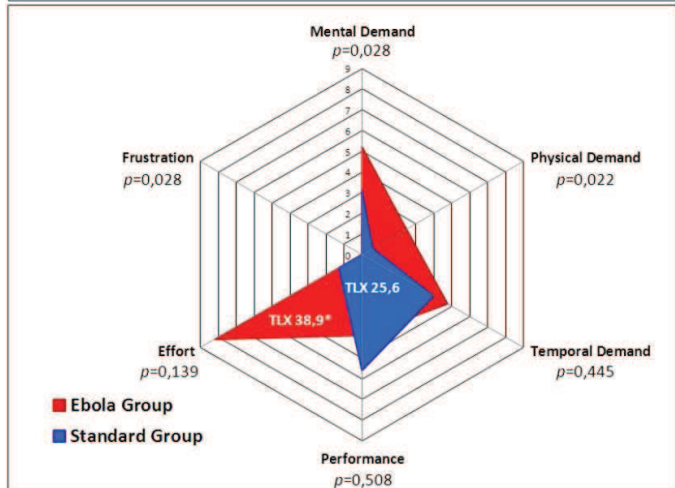
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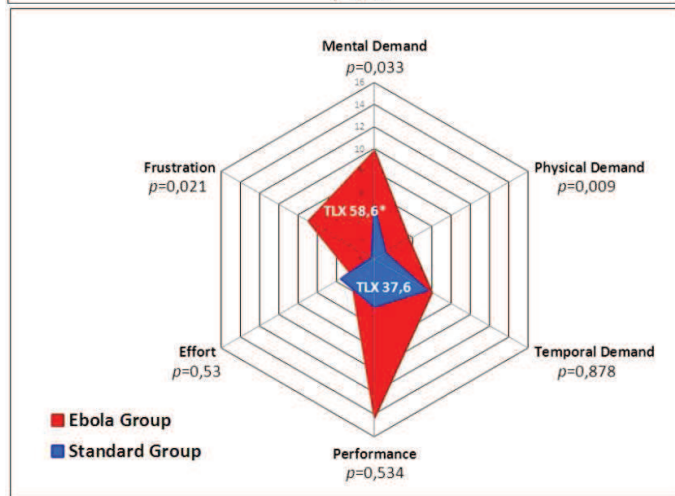
151 **Figure 1.** National Aeronautics and Space Administration Task Load Index (NASA-TLX) for
 152 orotracheal intubation (1A), nasogastric tube placement (1B), and central venous catheter
 153 insertion (1C), with Ebola or standard personal protective equipment



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157

Table 1. Comparison of physiological conditions and ergonomics during common intensive care medical procedures with Ebola personal protective equipment (PPE), and with standard protection

Variables ^a	Ebola PPE (n=13)	Standard protection (n=13)	<i>p</i> value
Overall			
Duration, <i>sec</i>	289 [236-440]	167 [139-407]	0.53
Heart rate, <i>bpm</i>	102 [95-111]	93 (90-104)	0.057
Upper Body tilt, <i>degrees</i>	14 [12-15]	7 [6-9]	0.044
Orotracheal Intubation			
Duration, <i>sec</i> ^b	34 [30-46]	35 [24-38]	0.36
Stress	4 [3-4]	4 [4-5]	0.018
Ease of use	4 [1.8-4]	5 [4-5]	0.01
Comfort	3 [1.8-4]	4 [4-5]	0.01
Nasogastric Tube placement ^b			
Duration, <i>sec</i>	37 [26-61]	30 [22-40]	0.08
Stress	4 [3-4.5]	4 [4-5]	0.11
Ease of use	4 [2.5-4]	4 [4-5]	0.12
Comfort	2.5 [1.5-4]	4 [4-5]	0.008
Central Venous Catheter			
Duration, <i>sec</i> ^c	199 [123-355]	128 [81-368]	0.79
Stress	3 [2-3.25]	4[3-5]	0.013
Ease of use	2 [1.75-3.25]	4 [2-4.25]	0.13
Comfort	1 [1-2]	4 [3-4]	0.003

^a values are median [interquartile range]

^b one participant could not complete orotracheal intubation with Ebola PPE, and was excluded for orotracheal intubation duration measurement and nasogastric tube questionnaire (not completed).

^c two participants could not insert central venous catheter with Ebola PPE and were excluded for central venous catheter duration measurement.

Stress, Ease of use and comfort during the procedures are Likert scales from 1 to 5: For Stress during the task, 1 for major stress and 5 no stress; for ease of use, 1 very difficult and 5 very easy; for comfort, 1 very uncomfortable and 5 very comfortable.