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RESEARCH ARTICLE

MEDICAL PHYSICS

Systematic numerical assessment of occupational exposure to electromagnetic fields of transcranial magnetic stimulation

Simona D'Agostino[1,2] | **Micol Colella**[1] | **Micaela Liberti**[1] | **Rosaria Falsaperla**[2] | **Francesca Apollonio**[1]

[1]Department of Information Engineering, Electronics and Telecommunications, Sapienza University of Rome, Rome, Italy

[2]INAIL, Italian Workers' Compensation Authority, Rome, Italy

Correspondence
Francesca Apollonio, Department of Information Engineering, Electronics and Telecommunications, Sapienza University of Rome, Via Eudossiana 18, 00184 Rome, Italy.
Email: francesca.apollonio@uniroma1.it

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Abstract

Purpose: This study aims to perform a classification and rigorous numerical evaluation of the risks of occupational exposure in the health environment related to the administration of transcranial magnetic stimulation (TMS) treatment. The study investigates the numerically estimated induced electric field that occurs in the human tissues of an operator caused by exposure to the variable magnetic field produced by TMS during treatments. This could be a useful starting point for future risk assessment studies and safety indications in this context.

Methods: We performed a review of the actual positions assumed by clinicians during TMS treatments. Three different TMS coils (two circular and one figure-of-eight) were modeled and characterized numerically. Different orientations and positions of each coil with respect to the body of the operator were investigated to evaluate the induced electric (-E) field in the body tissues. The collected data were processed to allow comparison with the safety standards for occupational exposure, as suggested by the International Commission on Non-Ionizing Radiation Protection (ICNIRP) 2010 guidelines.

Results: Under the investigated conditions, exposure to TMS shows some criticalities for the operator performing the treatment. Depending on the model of the TMS coil and its relative position with respect to the operator's body, the numerically estimated E-field could exceed the limits suggested by the ICNIRP 2010 guidelines. We established that the worst-case scenario for the three coils occurs when they are placed in correspondence of the abdomen, with the handle oriented parallel to the body (II orientation). Working at a maximum TMS stimulator output (MSO), the induced E-field is up to 7.32 V/m (circular coil) and up to 1.34 V/m (figure-of-eight coil). The induced E-field can be modulated by the TMS percentage of MSO (%MSO) and by the distance between the source and the operator. At %MSO equal to or below 80%, the figure-of-eight coil was compliant with the ICNIRP limit (1.13 V/m). Conversely, the circular coil causes an induced E-field above the limits, even when powered at a %MSO of 30%. Thus, in the investigated worst-case conditions, an operator working with a circular coil should keep a distance from its edge to be compliant with the guidelines limit, which depends on the selected %MSO: 38 cm at 100%, 32 cm at

80%, 26.8 cm at 50%, and 19.8 cm at 30%. Furthermore, attention should be paid to the induced E-field reached in the operator's hand as the operator typically holds the coil by hand. In fact in the hand, we estimated an induced E-field up to 10 times higher than the limits.

Conclusions: Our numerical results indicate that coil positions, orientations, and distances with respect to the operator's body can determine the levels of induced E-field that exceed the ICNIRP limits. The induced E-field is also modulated by the choice of %MSO, which is related to the TMS application. Even under the best exposure conditions, attention should be paid to the exposure of the hand. These findings highlight the need for future risk assessment studies to provide more safety information for the correct and safe use of TMS devices.

KEYWORDS

numerical dosimetry, occupational exposure to electromagnetic fields (EMF), risk assessment, transcranial magnetic stimulation

1 | INTRODUCTION

Transcranial magnetic stimulation (TMS) is a neurostimulation and neuromodulation technique developed in the early 1980s,[1] and it is used as a neuro-investigation and diagnostic tool,[2] as well as in clinical practice for therapeutic purposes.[3] When applied over the cerebral cortex, TMS can interfere with neuronal connections, providing important insights in the field of brain connectivity, particularly relevant for brain mapping applications[4,5] or for diagnosing neurodegenerative diseases.[6] Furthermore, because it is noninvasive and minimally painful, it is currently being investigated as a potential treatment for several psychological disorders, including major depression[7] and obsessive-compulsive disorders,[8] for both of which it received Food and Drug Administratioin (FDA) approval, neurological impairments due to stroke,[9] Parkinson's,[10] tinnitus,[11] epilepsy,[12] or chronic pain.[13] TMS is based on the principle of electromagnetic (EM) induction, where a time-varying current flowing inside a conductive wire produces a time-varying magnetic field that is responsible for secondary currents induced in conductive media close by.[14] During TMS applications, the stimulating coil placed over the patient's head generates a high-intensity pulsed magnetic field, up to 2 T, that crosses the scalp. Additionally, owing to the conductive properties of the head tissue, it induces an intense electric field (i.e., E of the order of 100 V/m) that alters the brain neuronal activity,[2,15] achieving the desired clinical or experimental response. However, because the TMS magnetic field spreads in the space around the stimulating coil,[16] the clinician also undergoes an undesired exposure several times a day during treatments. In clinical practice, different relative positions between the patient and the clinician can be assumed, causing the exposure of different body parts, depending on the specific treatment. Furthermore, the operator may hold a part of the coil with the hand while the device is active to increase the coil's stability, which produces an induced E-field in a part of the body rich in peripheral nerve innervation. Therefore, the operator is exposed to an E-field, which should be evaluated and compared to the existing guidelines for occupational exposure to quantify the level of risk. Guidelines for occupational exposure levels to EM fields have been proposed by the International Commission on Non-Ionizing Radiation Protection (ICNIRP 2010[17] and the recent update[18]) and by a Directive from the European Parliament (Directive 2013/35/UE[19]). Despite these guidelines, the risk assessment for occupational exposure to TMS has not been adequately addressed in the scientific literature, where safe distances between the coil and the clinician, derived from considerations that lack of an in-depth analysis on this topic,[20–23] are suggested. A study focussed on the exposure of TMS workers was conducted in 2006 by Karlström et al.,[20] and they experimentally estimated a distance of 70 cm to avoid overexposure to magnetic pulses, as recommended by the ICNIRP guidelines in 2003.[24] For several years, this work remained the only one addressing the problem of occupational exposure during TMS treatments; therefore, it was considered as a reference in the safety guidelines for the use of TMS proposed in 2009[25] by a group of TMS experts. Since the publication of these results, the ICNIRP 2003 guidelines and Directive 2004/40/EC have been updated[17–19]; however, to date, there are no standardized requirements for the conformity assessment of TMS.[26] Consequently, lacking such harmonization in conformity assessment, there is great variability in the adopted methodologies. Thus, the need for a particular international standard concerning TMS devices that could improve safety in work environments has increased in recent years. Few studies have been performed over the last decade to address this topic. Particularly, two studies conducted in 2010[21] and 2016[22] numerically investigated the exposure of workers to TMS systems, finding safety distances of 110 cm and 40 cm, respectively. Despite having the same

objective, these two studies considered different human body models (Brooks Air Force Laboratory[21,27] and Virtual Population[28]) and different exposure conditions (feeding current equal to 7.7 kA at 3.6 kHz in Lu and Ueno[21] and 6 kA at 3 kHz in Bottauscio et al.[22]). Furthermore, Lu and Ueno[21] investigated two coil geometries (i.e., circular and figure-of-eight) for different orientations, but the clinician body was limited to one vertical position, whereas Bottauscio et al.[22] studied only the circular coil for different orientations and vertical positions. This indicates the need for a systematic study that could open the way to a specific technical standard concerning TMS devices, which can improve safety in the work environment. Therefore, an indepth investigation should account for the specificity of TMS devices, in terms of coil geometry and feeding system, and examine the exposure as a function of the device's stimulator output. This is an important aspect because the stimulation intensity in clinical practice is always related to the resting motor threshold of the patient, and it is usually below the maximum output available from the machine.[29,30] Furthermore, many different coil positions and orientations should be considered because clinicians may hold the coil at different heights with respect to their trunk, depending on the patient-holder support, and they may rotate the coil to optimize the treatment. Such analysis would allow the investigation of the exposure of specific body parts and addressing a worst-case scenario. Previous studies have considered these aspects partially by analyzing one or the other.[21,22] Another important aspect is the position of the operator's arm and hand while holding the coil, as this area is inevitably exposed to higher intensities.[31,32] Thus, our study aims to perform a comprehensive analysis that investigates TMS operator exposure in real scenarios to identify the possible critical positions and suggest safer general working instructions for clinicians. We started with an extensive review to identify typical positions, and we modeled the clinician using a realistic anatomical human body model,[33] including changes in body posture. Conversely, a simplified model was used for the patient's head. Exposure to both circular and figure-of-eight coils was investigated under the same conditions, considering different percentages of the maximum stimulator output (%MSO) and different vertical positions of the coil with respect to the clinician's trunk. Additionally, hand exposure has received attention. We evaluated the EM quantities induced inside the operator's body (i.e., the electric [E]-field and the current density [J]) and compared them with the limits reported in the guidelines, referring to both the 2013/35 European Directive[19] and the ICNIRP 2010 guidelines. In particular, the ICNIRP 2010 guidelines specify that exposure limits based on quantities directly related to health effects are referred to as basic restrictions (BRs). The physical quantity used to specify the BRs during exposure to EM fields is the strength of the induced electric field, as it affects the nerves and other electrically sensitive cells. Table 1 summarizes the BRs limits for occupational exposure, where the values are expressed as *rms* quantities, and *f* is the frequency in Hz.

TABLE 1 ICNIRP-2010 BRs for occupational exposure to time-varying electric and magnetic fields (for preventing health effects)

Exposure characteristic	Frequency range (Hz)	Internal electric field (V m^{-1})
Occupational exposure CNS tissue of the head	1–10 Hz	0.5/f
	10 Hz–25 Hz	0.05
	25 Hz–400 Hz	2×10^{-3} f
	400 Hz–3 kHz	0.8
	3 kHz–10 MHz	2.7×10^{-4}f
All tissues of head and body	1 Hz–3 kHz	0.8
	3 kHz–10 MHz	2.7×10^{-4}f

Note: f, frequency in Hz.
Abbreviations: BRs, basic restrictions; CNS, central nervous system; ICNIRP, International Commission on Non-Ionizing Radiation Protection.

These limits were selected because at frequencies above 400 Hz, limits on peripheral nerve stimulation apply to all body parts. Moreover, the exposure in controlled environments, where workers are informed about the possible transient effects of such exposure, should be limited to fields that induce electric fields in the head and body below 800 mV/m to avoid stimulation of the peripheral and central nervous systems (CNS). Furthermore, guidelines propose different BRs for the CNS and for all other tissues, as summarized in Table 1. At ~3 kHz (typical TMS frequency), the BRs assume the same value. The cited guidelines also suggest considering the local induced electric field as a value averaged in a tissue volume of $2 \times 2 \times 2$ mm^3. For a specific tissue, the 99th percentile of the induced E-field distribution is the relevant value to be compared with the BR. Therefore, in this study, we compared the ICNIRP limits by computing the 99th percentile of the induced E-field inside the body of a healthcare professional performing TMS treatment, which was discretized in $2 \times 2 \times 2$ mm^3 voxels. Therefore, it was possible to estimate the safety distance for compliance with the limits for each coil and for each exposure scenario. This study lays the groundwork for more systematic risk assessment studies and suggests general safety indications to consider when performing TMS.

2 | MATERIALS AND METHODS

2.1 | Classification of clinician/worker exposure scenarios

For the study, we collected information on typical positions assumed by clinicians during TMS treatments by searching different documental sources, such as

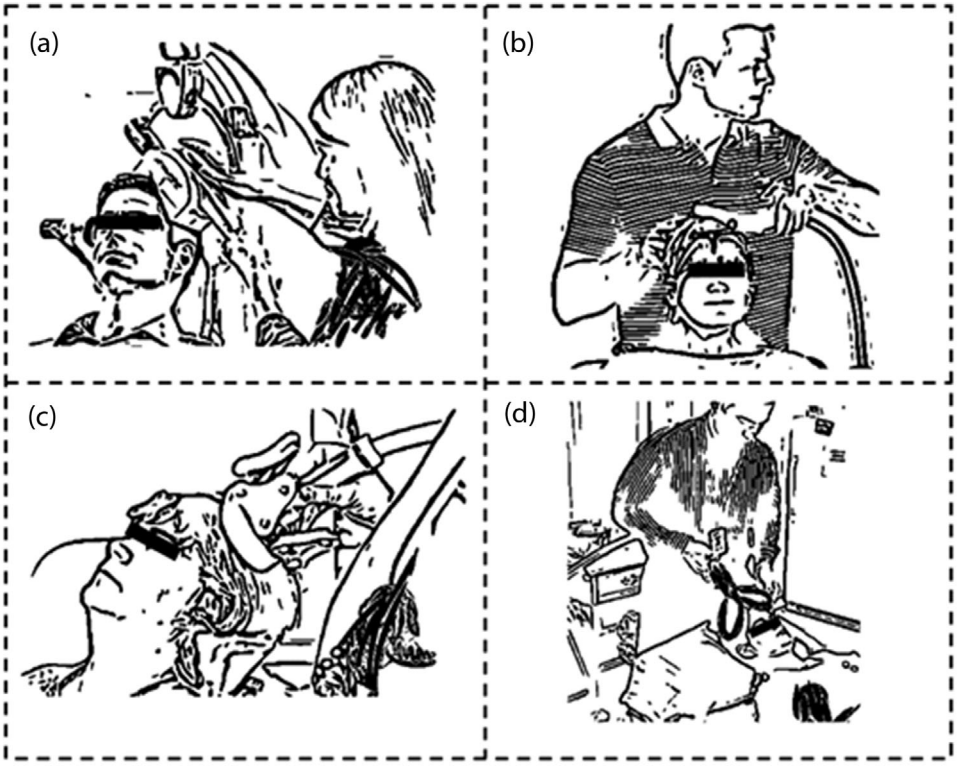

FIGURE 1 Typical relative vertical positions between the transcranial magnetic stimulation (TMS) coil and the clinician: examples of real scenarios and identification of the exposed anatomical areas: (a) exposure of the chin/neck, (b) exposure of the chest, (c) exposure of the abdomen, and (d) exposure of the lower abdomen

company user manuals, websites,[34] papers,[35] and pictures obtained during the measurement campaigns made by the Italian Workers' Compensation Authority (INAIL).[36] Thus, we stored approximately 60 pictures representing clinical scenarios, through which the positions taken by the worker during TMS treatment were identified. The position of the stimulating coil with respect to the clinician depends on various factors, such as the available equipment (e.g., type of coil, presence of a supporting system, and geometry of the supporting system) and the patient's holder (i.e., bed or chair), because they both determine the position of the patient's head with respect to the frontal axis of the clinician (Figure 1).

Another influencing factor is the height of the clinician and the patient, for instance, pediatric patients would likely force the clinician to bend over, bringing the stimulator closer to the chin/neck area. Conversely, when performing a treatment with the patient lying down on a bed, the coil would expose the clinician's lower abdomen (Figure 1d). Therefore, analyzing the working environment suggests that exposure involves mainly four anatomical areas of the clinician:

1. Chin/neck, Figure 1a
2. Chest, Figure 1b
3. Abdomen, Figure 1c
4. Lower abdomen, Figure 1d

2.2 | Dosimetric model for clinician exposure assessment

In this study, we considered three different commercial coil models: the Magstim MAG-9925-00 standard double (simply called the figure-of-eight), Magstim MAG-9784-00 circular coil, and MagVenture MC-125 circular coil. TMS pulses were assimilated to pure sinusoids at equivalent frequencies obtained from the pulse period, as studies have shown that this assumption leads to a negligible error[22,37] when compared with real signals. The features of the TMS devices considered are listed in Table 2.

The coils were reproduced in the simulation environment as dimensionless wires placed at the center of the real wires.[16,38] This implied a 2D coil approximation that may slightly underestimate the induced E-Field, but the overall error was typically below 2%.[16,39]

To model the presence of the operator, we considered an anatomical human body model, Duke, a standard young adult male (34-year-old, 1.77 m, 70.2 kg), member of the Virtual Population (ViP, v.3.0).[33] Duke is a surface-based model obtained from the Magnetic

TABLE 2 Characteristics of the coils used

	Std. Double Magstim MAG-9925-00	Circular Magstim MAG-9784-00	Circular MagVenture MC-125
TMS appliance	Magstim Rapid2	Magstim 200	MagPro R30
Frequency	3 kHz	3 kHz	3.45 kHz
Current (max output)	4.08 kA	5.6 kA	5.6 kA
Inner diameter	5.2 cm	7 cm	2.8 cm
Outer diameter	8.8 cm	12.2 cm	11.4 cm
Turns	9	14	13

Abbreviation: TMS, transcranial magnetic stimulation.

Resonance Imaging (MRI) scans of a healthy volunteer, and it has 319 different body structures. Additionally, we considered a posable Duke (ViP., v.3.1[33]), which allows for changes in body posture. The dielectric properties of the tissues were assigned from LF IT'IS database v.4 embedded in Sim4Life (software chosen for the simulations, see below).

Furthermore, the dosimetric analysis included the patient's head, modeled by the simplified two-tissue head phantom Sam (IEEE Standards Coordinating Committee 34, Sub Committee 2, Working Group 1 - SCC34/SC2/WG1), available in Sim4life. This phantom consisted of two compartments, shell, and liquid, with conductivities of 0.01 S/m and 0.33 S/m[32] respectively. The phantom was placed approximately 1 cm below the surface of the coil and positioned at the center of the simulation domain. By considering the patient's head, we ensured the representation of a realistic scenario, with the TMS coil properly loaded. However, it is beyond the aim of this study to analyze the EM quantities induced inside the patient's head.

To consider the exposure of the operator's anatomical districts previously identified (Figure 1), four vertical positions of the TMS coils were chosen, with different distances *h* from the ground, and they are denoted as cases A, B, C, and D (Figure 2).

Additionally, two different orientations of the ensemble coil/Sam were considered for each vertical position, as shown in Figure 2. For orientation I, the model of the clinician is placed behind the coil handle (coil angular positions 0°), and a distance of 21 cm is kept constant between the center of the coil and the surface of the clinician's body model. This distance considers the 20.5 cm length of the coil's handle, plus and 0.5 cm as the closest possible distance between the handle edge and the surface of the human model. For orientation II, the clinician's body model is placed on the side of the coil (coil angular position 90°) at a distance of 12 cm from the extremity of the outermost coil winding to consider the length of the forearm. Both distances are considered with respect to the surface of the Duke's body. A summary of the analyzed conditions is presented in Table 3.

All the exposure conditions were numerically simulated for the two coil models of Magstim for 16 positions, while only three conditions (cases A, B, and C in the II orientation) were considered for the MC-125 circular coil (MagVenture). Additionally, it was crucial to simulate case C because it is the worst-case scenario for the circular coil, and we considered superfluous to simulate case D because it slightly differs from case C.

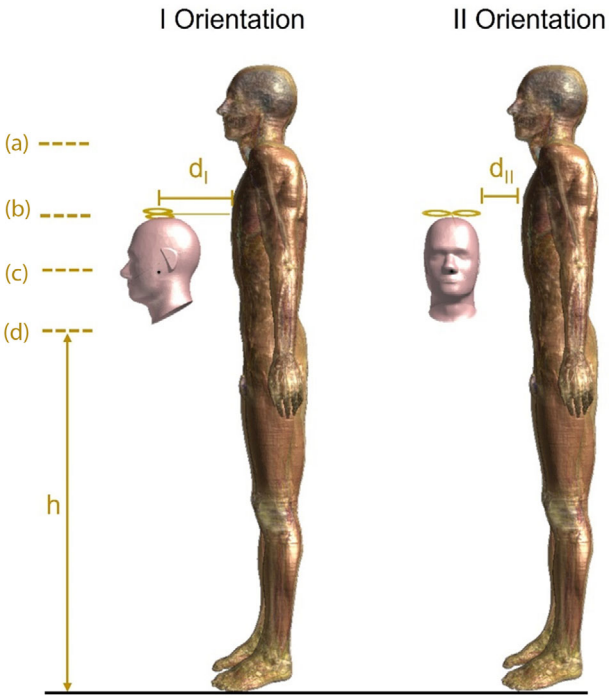

FIGURE 2 The dosimetric model. Two coil orientations (I and II) and four vertical positions: case A-exposure of the chin/neck (h1 = 153.5 cm), case B-exposure of the chest (h2 = 136 cm), case C-exposure of the abdomen (h3 = 112 cm), case D- exposure of the lower abdomen (h4 = 95.3 cm). For orientation I, the distance between the center of the coil and the surface of the clinician's body model (d_I) is 21 cm, whereas for orientation II, the distance between the edge of the coil and the surface of the clinician's body d_{II} is 12 cm

Additionally, we reproduced the clinician while holding the TMS coil, which was implemented by arranging the arm and hand of the Duke model using the Poser tool embedded in Sim4life. Here, dosimetric analysis mainly focused on the hand of the human model, as it is the anatomical district closer than the others to the source. We evaluated both closed (Figure 8b) and open hand

TABLE 3 Exposure conditions

	I orientation	II orientation
Coil angular positions	0°	90°
Distance of surface of Duke (d)	21 cm *From center of coil*	12 cm *From coil windings edge*
Vertical position (h)	A, B, C, D	A, B, C, D

TABLE 4 Data pool

	I orientation	II Orientation	Posable open hand (two distances)	Posable closed hand (one distance)
Magstim Std. Double 9925-00	A - B - C- D	A - B - C – D	✓	✓
Magstim Circular 9784-00	A - B - C - D	A - B - C – D	✓	X
MagVenture circular MC-125	X	A - B – C	X	X

(Figure 8c) conditions, considering distance *d* between the outermost coil winding and the thumb (Figure 8a) as follows:

1. Closed hand, with distance from coil d = 5 cm;
2. Open hand, with distance from coil d = 5 cm;
3. Open hand, with distance from coil d = 2.5 cm;

Hence, a total of 22 exposure scenarios were investigated, and they are summarized in Table 4.

2.3 | Simulations set-up and quantities observed

Dosimetric analysis was performed using the Magneto-Quasi Static solver included in the simulation software Sim4Life (v.4.4, ZMT, Zurich MedTech AG), which finds the EM solution by decoupling the B-field and E-field calculations. The solution to the B-field was obtained according to Equation 1 (Biot–Savart law) and Equation 2, where **A** is the magnetic vector potential; J_0 is the current source; μ_0 is the magnetic permeability (constant over the entire domain Ω); r and r' are the position vector inside the domain and the position vector of the source, respectively.

$$A\ (r) = \frac{\mu_0}{4\pi}\int_{\Omega}\frac{J_0\left(r'\right)}{|r-r'|}d^3r' \tag{1}$$

$$B = \nabla \times A \tag{2}$$

Subsequently, the finite element method (FEM) was applied to solve the Laplace equation and compute the E-field distribution according to Equation 3, in the hypothesis of ohmic current domination, where σ is the conductivity of each tissue, ω is the angular frequency, and ϕ is the electric scalar potential.

$$\nabla \cdot \sigma\nabla\phi = -j\omega\nabla \cdot (\sigma A) \tag{3}$$

The Duke model was discretized with a uniform step of 2 mm along the three Cartesian directions, which corresponded to approximately 73 MegaCells. To estimate the induced E-field, we could not automatically exclude the use at 100% of MSO, because the stimulator output of the coils can be different between treatments. Therefore, it was necessary to consider other values for the identification of the motor stimulation threshold[30] for single patients, which requires different output power from the generator. The coils are typically used at MSO[29] in a range of 30%–80%, values that we considered to conduct the dosimetric analysis, together with the 100% (maximum output), starting from the features listed in Table 2. . To assess compliance with the ICNIRP 2010 guidelines, for each coil configuration, we compared the 99th percentile of the E-field induced inside the Duke model with the limits specified in Table 1. These limits are frequency dependent; thus, the ICNIRP BRs for workers is ∼1.13 V/m (peak value) at 3 kHz. Furthermore, for both orientations, we identified the worst case and evaluated the distance at which the induced E-field decreased below the limits. To obtain these data, we performed further simulations that were added to the 22 mentioned above.

Herein, we refer to the ICNIRP 2010 guidelines and not to the 2020 update, as the changes referred to the EM fields frequency range between 100 kHz and 10 MHz are not considered.

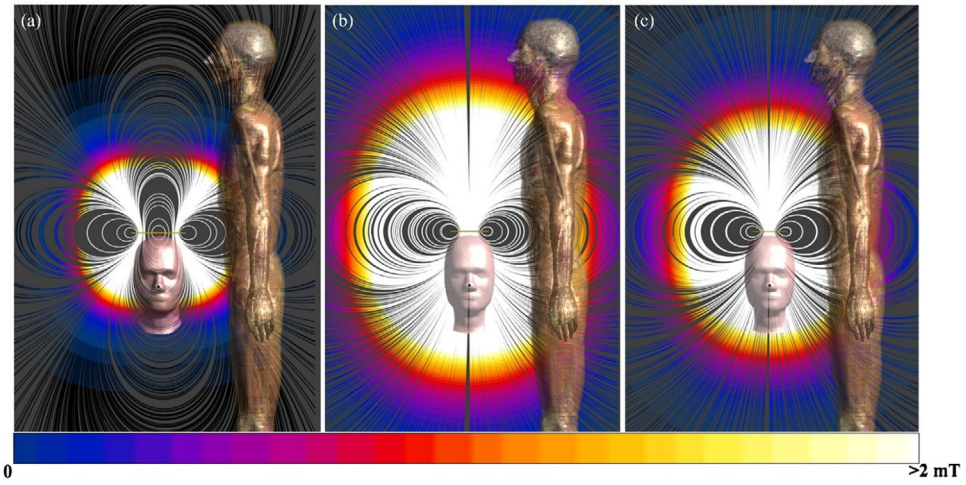

FIGURE 3 Streamline distribution map at a simulaion output of 100%. Worst case exposure of: (a) Std. Double Coil 9925-00, Magstim, (b) circular coil 9784-00, Magstim, (c) circular coil MC-125, MagVenture

3 | RESULTS

3.1 | Whole body exposure

First, we evaluated the streamline of the magnetic flux density (B-field) produced by the three TMS coils. The flux expanded in the free space and through the clinician's body, as shown in Figure 3 for the three coils placed at the level of the abdomen (case C) and oriented according to the II orientation. Notably, all three simulation domains had the same dimensions and the same spatial resolution for a better comparison of the extent of the exposure.

As expected, the B-field distribution generated by the circular coils (Figure 3b,c) differs from that generated by the figure-of-eight because the latter remains confined in a smaller region (Figure 3a). This is because the figure-of-eight coil has a better focality inside the patient's head, compared to the circular one, whose generated B-field is characterized by a greater dispersion. Because the behavior of the two circular coils is similar, with the only difference being that the Magstim coil generates higher B-field intensities, a comparison will be conducted between the two Magstim coils, and results from the MC-125 MagVenture circular coil are reported in the Supporting Information. As shown in Figures 4 and 5, the induced E-field distributions inside the operator's body are reported for the two Magstim coils placed at each exposure scenario described in Figure 2. In particular, the results from orientation I are presented in Figure 4, and those from orientation II are presented in Figure 5. In both cases, the feeding condition at MSO of 50% was considered. The two figures show the induced E-field on the Duke's sagittal plane, passing through the center of the coil, and the maximum full-scale value was set as the limit suggested by the ICNIRP 2010 guidelines at 3 kHz (i.e., 1.3 V/m).

In all conditions shown in Figures 4 and 5, the circular coil caused higher values of induced E-field in the human body, compared to the figure-of-eight. The mapping of the induced electric field shows that in most conditions, a large area of the body is affected by non-negligible electric fields. For instance, during the exposure of the abdomen to the figure-of-eight at orientation II (Figure 5, panel 1-C), the volume of the tissue in which the induced E-field exceeded the limit of 1.13 V/m is 0.12% of the total body, whereas it is 15% during the exposure to the circular coil. For all the scenarios, the exposure to intensities above the ICNIRP limit mainly involved the front of the operator, and some for which this condition reached the back of the model (e.g., Figure 4, panel 2 cases A-B-C-D and Figure 5, panel 1 cases C-D and panel 2 cases A-B-C-D). Considering the exposure to the figure-of-eight placed in position C and oriented according to orientation II (Figure 5, panel 1-C), the E-field induced on the back, at the hip joint reaches a maximum value of 1 V/m, even if in a small area. A more widespread exposure of the back to E-field intensities above 1.13 V/m occurs with the circular coil. Nevertheless, when placed as in case B and orientation II, the E-field induced behind the neck is up to 0.9 V/m. Tables 5 and 6 summarize the levels of exposure for orientations I and II, respectively. For each of these, we reported the induced E-field owing to exposure to a variable magnetic field produced by the TMS when it is set to 30% of stimulator output and the maximum output (100%). The comparison is also between the two models of coils: circular MAG-9784-00 and Std. Double MAG-9925-00.

The results indicated that the exposure to circular coil caused a 99th percentile of induced E-field that

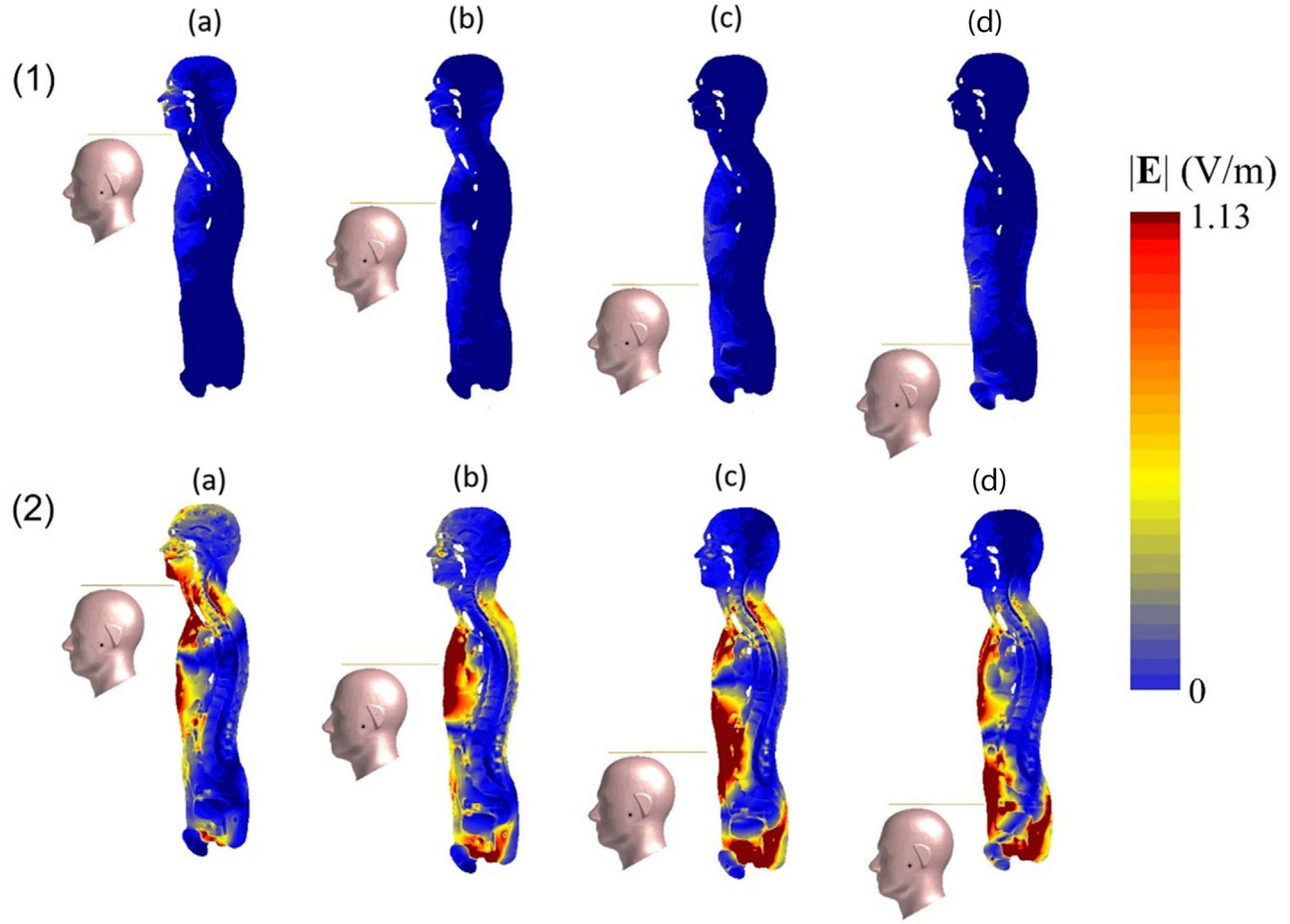

FIGURE 4 E-field map at 50% of the maximum output for orientation I: (1) Exposure to the Double Coil 9925-00 in the four cases, A-B-C-D; (2) Exposure to the Circular coil 9784-00 in the four cases, A-B-C-D

TABLE 5 Orientation I - percentiles of detected induced E-field (V/m) as a function of percentages of the maximum stimulator output (%MSO)

		Chin/neck		Chest		Abdomen		Lower abdomen	
	%MSO	30%	100%	30%	100%	30%	100%	30%	100%
Std. Double Coil (MAG-9925-00)	99th	0.08	0.27	0.07	0.25	0.08	0.26	0.09	0.31
	99.9th	0.15	0.50	0.12	0.38	0.13	0.43	0.16	0.53
Circular coil MAG-9784-00	99th	1.13	3.77	1.21	4.01	1.30	4.34	1.51	5.02
	99.9th	2.13	7.09	2.18	7.28	2.34	7.81	2.78	9.27

TABLE 6 Orientation II - percentiles of detected induced E-field (V/m) as a function of %MSO

		Chin/neck		Chest		Abdomen		Lower abdomen	
	%MSO	30%	100%	30%	100%	30%	100%	30%	100%
Std. Double Coil MAG-9925-00	99th	0.33	1.11	0.31	1.04	0.40	1.34	0.38	1.26
	99.9th	0.62	2.07	0.55	1.85	0.72	2.41	0.76	2.54
Circular coil MAG-9784-00	99th	1.80	6.00	1.80	6.01	2.19	7.32	2.01	6.71
	99.9th	3.44	11.48	3.01	12.87	4.00	13.33	3.91	11.73

Abbreviation: %MSO, percentages of the maximum stimulator output.

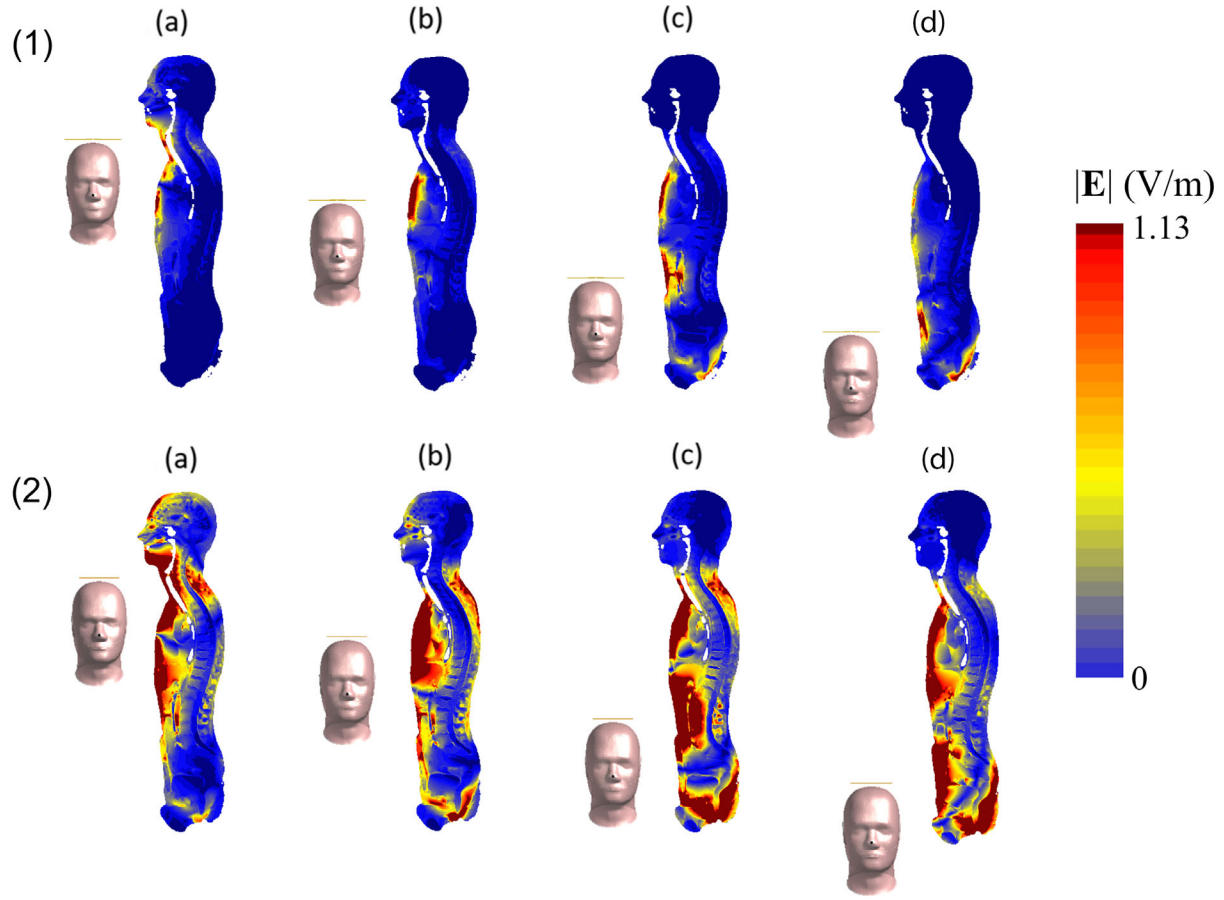

FIGURE 5 E-field map at 50% of the maximum output for orientation II: (1) Exposure to the Double Coil 9925-00 in the four cases, A-B-C-D; (2) Exposure to the Circular coil 9784-00 in the four cases, A-B-C-D

exceeded the ICNIRP limits of 1.13 V/m in all the conditions, whereas only two cases show values exceeding the guidelines for the figure-of-eight coil, that is, C (abdomen) and D (lower abdomen), in orientation II.

Therefore, by addressing the critical conditions that could expose the clinician to an induced electric field above the ICNIRP limits, the safety distances between the operator and the coil that would guarantee exposure below the limit at our working frequency were evaluated. Figures 6 and 7 show the data for the circular MAG-9784-00 placed in the two worst case scenarios: case- D (lower abdomen) in orientation I and case- C (abdomen) in orientation II. For these cases, we evaluated the 99th percentile as a function of the distance for each considered percentage of the stimulator output.[41] The results are presented in Figures 6 and 7 for orientations I and II, respectively.

Generally, the induced E-field decreased as the distance increased, and the stimulator's percentage of output decreased. Therefore, the possibility of exceeding the E-field limit could be considerably reduced when the operator stays at specific distances from the coil, which gradually increases as a function of the stimulator output. Considering exposure to the figure-of-eight coil, the induced E-field exceeds 1.13 V/m only in cases C and D of orientation II at an MSO of 100% (Table 6). In the worst-case scenario (i.e., case C), we established that the induced E-field decreases to 0.91 V/m at a distance of 15 cm, indicating that the exposure limits are respected if the coil is moved 3 cm away from the reference position (i.e., 12 cm from the edge of the coil). Conversely, a compliant scenario for the circular coil fed at an MSO of 100% is obtained at 38 cm from the edge of the coil in orientation II (Figure 7, red line), or at approximately 44 cm from the center of the coil in orientation I (Figure 6, red line). These distances can be reduced by feeding the coil with a lower %MSO, reaching values down to 19.8 cm and 24 cm at an MSO of 30% for orientation II (Figure 7, blue curve) and orientation I (Figure 6, blue curve), respectively. From these data, it is confirmed that the circular coil herein considered remains the most "critical" device, and the distance that the clinician must keep to avoid exceeding the limits during a TMS treatment is more than twice the distance that should be maintained with the figure-of-eight coil.

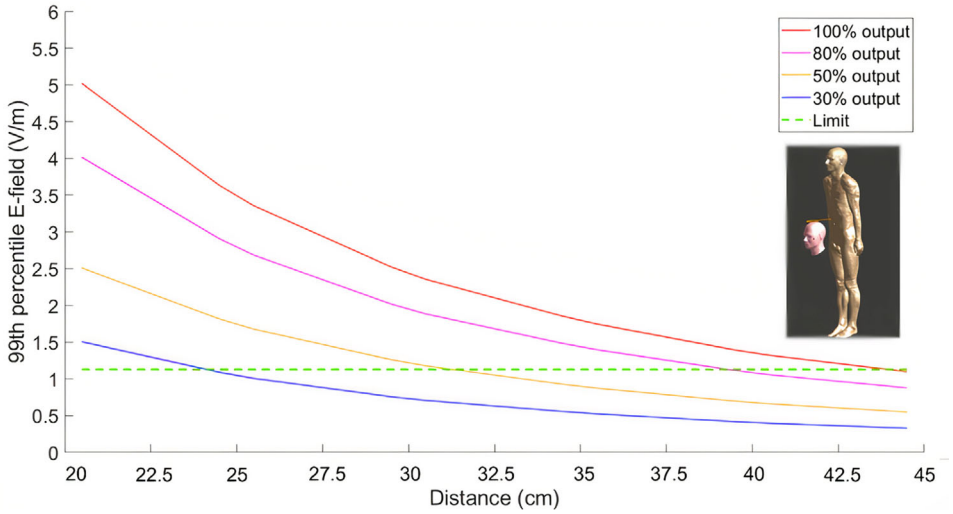

FIGURE 6 99th percentile of induced E-field for case D - lower abdomen (worst case scenario in orientation I owing to exposure to circular coil Magstim 9784-00) as a function of the distance from the center of the coil

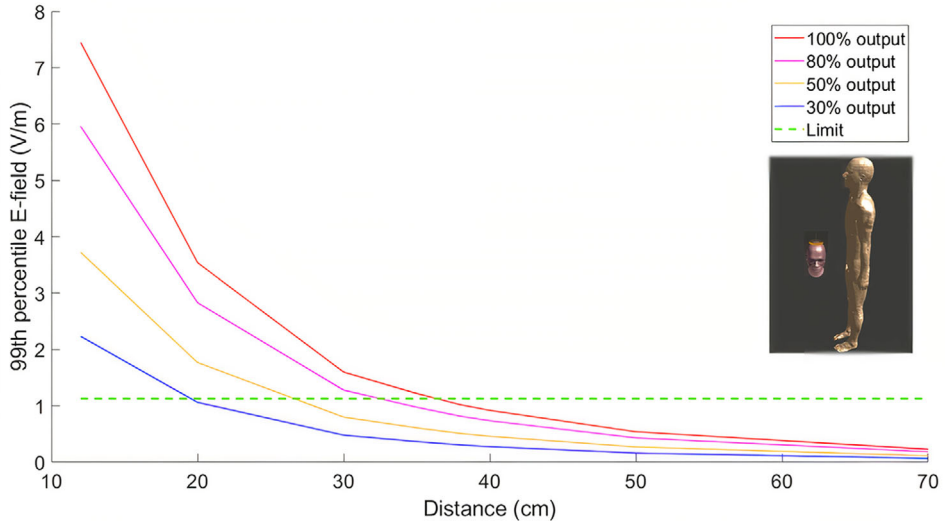

FIGURE 7 99th percentile of induced E-field for case C - abdomen (worst case scenario in orientation II owing to exposure to circular coil Magstim 9784-00) as a function of the distance from the coil windings edge

3.2 | Limb exposure: Focusing on the hand

For an indepth investigation, the intensities induced on the hand by simulating the condition of the operator that holds the TMS coil were considered. We studied the exposure to a variable magnetic field produced by the Std. Double MAG-9925-00 because it resulted in the lowest values and is most frequently used for long-lasting treatments (i.e., repetitive [r] TMS protocol).

As described in the methods section, we evaluated the case of Duke holding the coil with a slightly open hand at two distances between the thumb and the outermost winding (2.5 cm and 5 cm, Figure 8a) and the case of a closed hand at a distance of 5 cm. The distribution of the induced electric field on the surface of this area of the body is shown in Figure 8b,c for the closed hand and open hand at 2.5 cm, respectively.

It is evident that proximity to the source caused a non-negligible induced E-field in the area of the thumb muscles. Furthermore, as shown in Figure 8b, for the closed hand, a peak of the E-field is induced at the contact between the thumb and index finger, suggesting that the type of grip affected the extent of the area exposed to noncompliant intensities. Table 7 summarizes the percentiles of the electric field distribution on the hand area to estimate the maximum values induced in the three conditions investigated in this study.

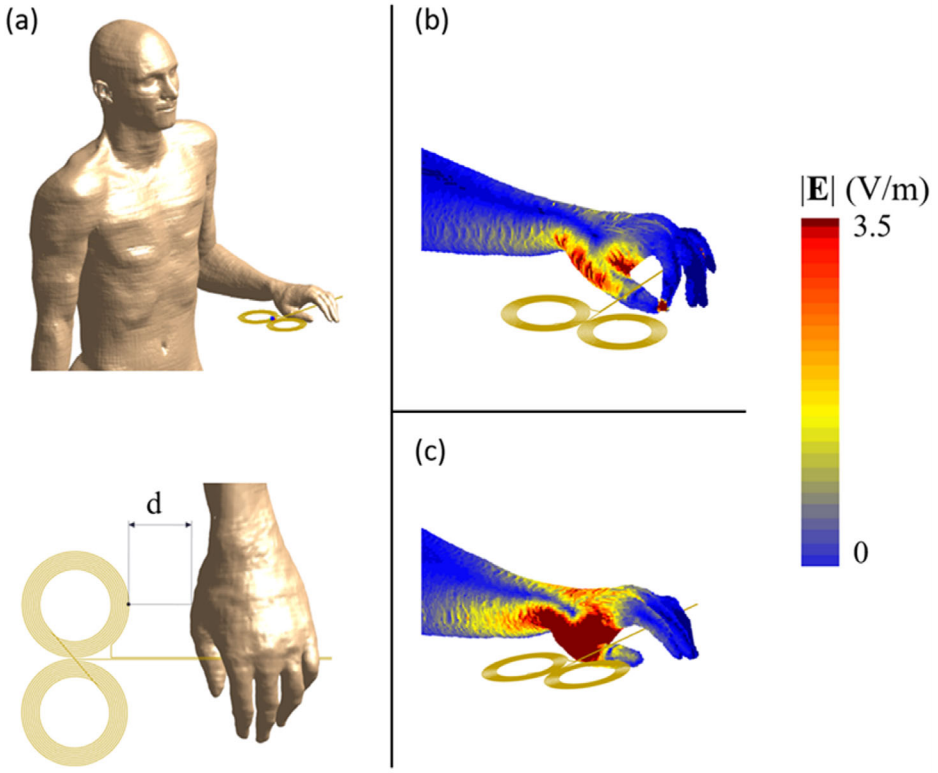

FIGURE 8 Exposure condition: (a) On the top the human model of the Duke posable model, on the bottom the illustration of hand's distance d; (b) $EF_{induced}$ on the surface of the closed hand 5 cm from coil edge; (c) $EF_{induced}$ on the surface of the open hand 2.5 cm from coil edge

TABLE 7 Induced E-field (V/m) in the operator's hand

Percentile as a function of percentage of stimulator output					
		30%	**50%**	**80%**	**100%**
Closed hand *d = 5 cm	99th	0.85	1.43	2.28	2.85
	99.9th	1.03	1.71	2.74	3.42
	99.99th	1.2	2	3.20	4.01
Open hand *d = 5 cm	99th	0.9	1.5	2.4	3
	99.9th	1.11	1.85	2.96	3. 7
	99.99th	1.23	2.06	3.3	4.12
Open hand *d = 2.5 cm	99th	2.22	3.69	5.91	7.02
	99.9th	3.01	5.03	8.04	10.06
	99.99th	3.44	5.74	9.19	11.49

*d: distance between the coil edge and the hand, as shown in Figure 8a.

To estimate the maximum value, we computed the percentile up to 99.99th because the area of interest was reduced to the hand only. Therefore, considering lower percentiles (as the 99th percentile) may not be representative of the exposure because it would exclude local spikes occurring at the point of contact between the two fingers, which is well detected by the 99.99th percentile, and it is 4 V/m in the case of maximum stimulator output. Considering maximum output, for the closed hand, a 99th percentile of induced E-field in the hollow between the thumb and the forefinger of approximately 3.89 V/m (or 1.6 V/m with 30% of stimulator output) is achieved, whereas 3.5 V/m (or 1.05 V/m, at 30%) is achieved on the surface of the thumb. In the second case (open hand at 5 cm), in the hollow between the thumb and the forefinger, we evaluate the E-field that achieved 4.5 V/m (or 2.25 V/m, at 30%) and 4 V/m (or 1.2 V/m, at 30%). However, the surface of the thumb is characterized by a large area where 3.5 V/m (or 1.05 V/m, at 30%) is obtained. The last case (open hand at 2.5 cm) is characterized by induced E-field peak equal to 12 V/m (or 3.6 V/m, at 30%) on the surface of the thumb, whereas we detected 10.5 V/m (or 3.15 V/m, at 30%) in the mentioned hollow between the fingers. These results indicate noncompliance with the corresponding limits suggested by the guidelines.

3.3 | Analysis of the induced current density

Exposure of the human body to the previously shown time-varying magnetic fields also results in the induction of a current density inside the human body.

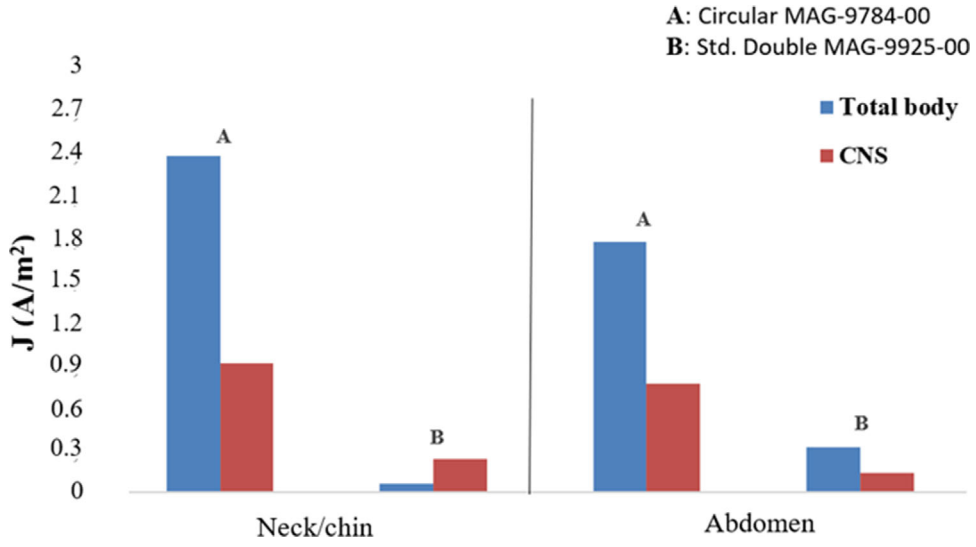

FIGURE 9 Bar graph representing the 99th percentile of the current density induced in the whole body (blue) and in the central nervous system (CNS) only (red) by the circular coil (A) and the figure-of-eight coil (B) for two cases of exposure: neck/chin (case-A orientation I) and the abdomen (case-C orientation II)

Our results indicated that such exposure can cause a non-negligible induced current density, as shown in Figure 9, which illustrates two exposure conditions: case A (exposure of the chin/neck) for orientation I and case C (exposure of the abdomen) for orientation II.

The graph shows that the exposure to the magnetic field produced by Std. Double MAG-9925-00 causes a lower induced current density in the CNS than that caused by the circular MAG-9784-00. Furthermore, in all the evaluated exposure scenarios, J induced inside the CNS was lower than that induced in the whole body, with the exception of the exposure of the chin/neck to the figure-of-eight coil, where a greater J is induced in the CNS with respect to the whole body. Conversely, the circular coil exhibited the same behavior.

4 | DISCUSSIONS

4.1 | Comparison with previous literature

In this study, a systematic numerical assessment of the operators' exposure to the EM field produced by a TMS was performed to rigorously investigate the risks for occupational health associated with TMS application. The need for comprehensive studies on the operators' exposure to TMS arises from the lack of a standardized methodology for the conformity assessment of occupational exposure. Over the past decades, few computational studies have investigated this aspect and provided suggestions regarding the safety distance that the operator should maintain from the TMS coil. In 2010, Lu and Ueno[21] performed a dosimetric evaluation of the clinician exposure to a circular and a figure-of-eight coil, which resulted in a safety distance of 110 cm for both coils, oriented with their surface parallel to the surface of the chest, as would be done during a cerebellar TMS.[42] Furthermore, the exposure to different angular positions of the two coils was investigated. However, a cross analysis between angle and distance was not conducted, and the safety distance was estimated only in the aforementioned position, which is not commonly considered in clinical practice. A similar analysis was conducted in a more recent study by Bottauscio et al.,[22] where they investigated the exposure of the clinician to a circular coil. The coil was placed at three heights from the ground (i.e., at the level of the chest, neck, and eyes), and it was evaluated in the same angular positions for each height, as in Lu and Ueno.[21] Lu and Ueno[21] computed the safety distance for all rotations of the coil. Furthermore, they proposed the use of a passive shield to reduce the safety distance between the operator and the coil from 64 to 38 cm. In both the aforementioned studies, the evaluation of the safety distance was limited to the coil placed at the level of the chest,[21,22] and some exposure scenarios evaluated were far from real ones, such as case #C (coil at the level of the eyes) in Bottauscio et al.[22] Generally, the different anatomical regions that might be exposed during TMS treatment depend on whether the patient is sitting or lying down and on the relative height between the patient and the clinician. Hence, in this study, we conducted a review to common exposure scenarios and identify the positions generally assumed by the clinician while performing TMS treatment. In addition to the exposure of the chest, considered both in Lu and Ueno[21] and Bottauscio et al.[22] and of the chin/neck considered only in

Bottauscio et al.,[22] we evaluated the exposure of abdomen and lower abdomen, thus conducting an indepth analysis.

In all four exposure scenarios, we aimed to compare the behavior of two widely used types of coils (i.e., circular and figure-of-eight) placed along two different angular orientations with respect to the clinician's body. Because the exposure to a variable magnetic field produced by TMS devices shows a strong reliance on the percentage of the stimulator output (%MSO), it was necessary to evaluate ways in which the operator exposure changed with different %MSO. Thus, in addition to the maximum stimulator output (%MSO = 100%), we considered 30%, 50%, and 80%, while the aforementioned studies considered exposure solely to the maximum stimulator output (100%).[21,22] This can lead to conservative conclusions, given that TMS treatments are typically conducted at 50% of the stimulator output, and lower (30%) or higher (80%) stimulation intensities can be considered for research purposes.[29,30] Our results at 100% were consistent with the previous literature, particularly with those from Bottauscio et al.,[22] where the 99th percentile of the induced E-field at the closest distance between the center of the coil and the operator body axis (i.e., 30 cm) was up to 4 V/m when the axis of the operator body and the axis of the coil are parallel. In similar conditions (i.e., circular coil at the level of the chest – case B, orientation I), an induced E-field of 4.01 V/m was found inside the operator's body at a distance of 21 cm between the center of the coil and the surface of the operator's body. From the investigation of the exposure of other body parts with respect to Bottauscio et al.,[22] we estimated that the 99th percentile of the E-field above the limit suggested by the ICNIRP 2010 guidelines (1.13 V/m) occurred in all exposure conditions with the circular coil, and the highest value was induced with the coil placed at the level of the abdomen in orientation II (i.e. 7.32 V/m). For the latter our condition (case-C, orientation II), the safety distance was estimated as 38 cm (distance between the edge of the coil and body surface), which is closer than the distance estimated in Bottauscio et al.[22] This difference can be attributed to the different geometrical characteristics of the simulated coils, as can be observed comparing Table 2 with their Table 1.[22] For the exposure to the figure-of-eight, the 99th percentile of the E-field never exceeds the ICNIRP limits in orientation I, whereas it exceeded in cases C and D of orientation II, which are cases that were not investigated in previous works.[21,22]

To elucidate the different exposure scenarios evaluated, the induced current density was studied, as it was done in the study by Lu and Ueno,[21] which addressed the issue of the internal currents in the body of the clinician, because they referred to the ICNIRP 1998 guidelines.[43] Their results indicated that the commercial figure-of-eight has less leakage magnetic field and a lower current density induced in the operator's body compared with the circular coil, as confirmed in our study. Furthermore, they established that at a distance of 70 cm, the current density induced by exposure to the figure-of-eight coil and the circular coil averaged in a 1 cm^2 of CNS tissue were 13.9 mA/m^2 (or 19.2 mA/m^2 without simulating the cable, i.e. coil only) and 33.9 mA/m^2 (or 25.6 mA/m^2 without cable).[21] Compliance with the ICNIRP 1998 BRs occurred at a distance of 110 cm for both coils. Although the induced current density is no longer a quantity considered for the exposure compliance, it still provides a quantitative indication of what occurs inside the body of the clinician performing the treatments. Moreover, **J** (A/m^2) is not negligible in our study as well, where the peak of the induced current density at the minimum distance of 12 cm between the body and the circular coil was 2.37 A/m^2 and 0.9 A/m^2, considering total body and the CNS exposure only, respectively (Figure 9). To better understand these values, they can be compared with the limits suggested by ICNIRP 1998,[43] set at 3 kHz a maximum acceptable induced current equal to 0.04 A/m^2 (peak) for occupational exposure.

4.2 | Compliance with ICNIRP 2010 BRs for operator exposure to TMS: Dosimetric assessment

As previously stated, all the discussed studies evaluated TMS exposure with the operator working at 100% of the stimulator output. Nevertheless, as shown in TMS clinical and research studies,[29,30] this technique is usually adopted at lower stimulator outputs. Our results indicated that not only the choice of the TMS coil but also the selected stimulator output significantly affected the extent of the exposure. Notably, the percentage of machine output is chosen based on the TMS treatment; hence, the distance between the clinician's body and the coil is the principal quantity that should be varied to guarantee compliance with the guideline limits. Based on this, we evaluated the 99th percentile of the induced E-field with increasing distances between the source (i.e., TMS coil) and the body of the human model under %MSO other than 100% (i.e., 30%, 50%, and 80%). This analysis was conducted for the worst-case scenario of each coil orientation, that is, circular coil in case D (i.e., the lower abdomen) for orientation I and case C (i.e., the abdomen) for orientation II (Figure 2). For the latter case, the induced E-field can be made compliant to the limits by moving the operator approximately 38 cm away from the edge of the source, if working at the maximum output or approximately 19.8 cm when working at 30% of the stimulator output. Conversely, under our investigated conditions, a stimulator output of 80% ensures that the electric field induced by the figure-of-eight coil is compliant with the guidelines in all the cases studied. It should be emphasized that these distances are obtained

from dosimetric quantities and not from environmental measurements, because this study aimed to estimate the EM quantities induced inside the clinician's body, rather than providing indications regarding the zoning of the work environment. This study aims to make the worker aware of any possible risk while performing the treatment, as the quantities found are not negligible. Our study revealed a considerably different behavior between the two coils, and we established that the circular coil induced an electric field greater than the figure-of-eight under the same exposure conditions, which is consistent with previous studies at the 100% stimulator output.[21,22] Finally, to compare the two coils further, the fraction of body volume exposed to E-field over the guidelines limit was calculated. It was observed that in typical TMS working conditions of %MSO = 50%, the E-field above 1.13 V/m was induced in a small fraction of the body (0.12% of total body volume) by the figure-of-eight coil and in a larger fraction (15% of total body volume) by the circular coil. As a reference, it should be noted that the heart volume is equal to almost 0.85% of the total body for this male model of a standard man, Duke. Therefore, according to our results, the type of coil entails different general safe indications, depending on its angular orientation and the part of the body exposed. We estimated that in orientation I, the figure-of-eight coil induces an E-field below the ICNIRP limits for all the stimulator output, even at the closest distance from the coil (Figure 4 and Table 5). Conversely, in some cases studied for orientation II, the induced E-field exceeded the limits suggested by ICNIRP 2010, when considering both the circular and the figure-of-eight coil (see Figure 5 and Table 6). This implies that each treatment deserves specific attention.

Another important issue concerning operator exposure is the proximity of the upper limb to the source. Because the clinician often holds the handle of the TMS device without using any mechanical tools to maintain position, it is important to evaluate the exposure of this area of the body. Furthermore, after analyzing real working scenarios, it emerged that the operator may often hold the applicator during a TMS treatment. Thus, for a more realistic numerical analysis, we focused on reproducing a realistic configuration of the hand. Here, we excluded works that do not consider anthropomorphic virtual body models,[31,32] only one study that considered the operator with bent arm holding the coil was found in literature.[31] However, the influence of the hand aperture on exposure assessment was not investigated. Our results indicated that grip affected the exposure intensity. When the coil is held with the hand closed (i.e., touching the thumb and the index finger), the induced E-field is higher compared to when the coil is held with a slightly open hand, and it focuses at the tips of the two fingers. We considered two distances to take into account the possibility of grabbing the coil with two hands, which would cause the hand to be closer to the coil, as well as the case in which the operator grabs the handle with only one hand but closer to the source. Considering the 99th percentile of the internal E-field, we demonstrated that for a distance of 5 cm (for both configurations of the hand: open and closed), the compliance is achieved at 30% of the maximum output, indicating that the exposure of the hand can also be in compliance with the guidelines without the use of mechanical tools. For the case of the hand closer to the coil (2.5 cm from windings), the safety limits were exceeded at all the evaluated stimulator outputs. As shown for the exposure of the total body, the distance increases when the output power increases. When considering the exposure focused on the hand, the maximum distance allowed is limited by the length of the coil handle, which may be too short and prevent respecting the ICNIRP limits. Therefore, the aspect concerning auxiliary handpieces or insulating protection sleeves should be investigated in future studies. As regards the methods to improve the safety in workplace, being pending the publication of relevant technical standards indicating, if any, which methods in the TMS use can guarantee safety of the operator even if the limits for health effects are exceeded, similarly to the case of MRI equipment, the reduction of exposure levels can be achieved using, if medical practice allows, a plastic rod provided by the manufacturer to keep the applicator in place. This mode could effectively distance the operator from the applicator and result in compliance with the limits of the induced E-field. Finally, it is important to note that the ICNIRP guidelines are not mandatory, but the Directive 2013/35/EU must be respected (with transposition by 2016), and for the latter, the same ICNIRP limits apply, as far as our study is concerned.

5 | CONCLUSIONS

In this study, a simulation-based safety assessment of operator exposure to two models of commercial coils was conducted to investigate the induced E-field and compare it with the limits suggested by the ICNIRP 2010 guidelines. The study demonstrated that during a TMS treatment, various factors can influence the exposure of the clinician, such as the type of coil, its vertical position, and orientation with respect to the clinician the stimulator output intensity, as well as the position and the degree of aperture of the hand of the operator performing the TMS. In particular, our results indicated that the circular coil induces a higher E-field with respect to the figure-of-eight coil owing to its geometric configuration that caused a greater dispersion of the magnetic field and resulted in exceeding the guideline limits in a higher number of configurations. For each exposure scenario, we conducted a whole-body analysis and evaluated the minimum distance allowed to maintain the induced E-field levels below the ICNIRP 2010 limits. Furthermore, we focused on the local exposure of the hand, and the

results indicated that to reduce the induced E-field on the area of the hand, one should avoid holding the coil too close to the turns as well as holding it with a tightly closed hand. In this study, a thorough analysis of different exposure scenarios of clinicians to TMS sources is reported, and a systematic numerical assessment of compliance to the ICNIRP 2010 guidelines was conducted, considering both the whole body and local exposure. However, the results of the dosimetry assessment presented in this article are specific to the exposure scenario examined and therefore cannot be extended to all the practices performed with the TMS. Although a comprehensive risk analysis is beyond the scope of this study, the results obtained provide useful insights for future risk assessment studies.

6 | STUDY LIMITATIONS

The exposure assessment was conducted considering the exposure owing to the coil only, neglecting the feeding cable. The possible exposure owing to the cable proximity to the operator body is interesting and worth exploring deeper, although it is beyond the scope of this study. First, the B-field decreases rapidly when moving away from the cable; therefore, we focused on the coupling between the coil generated field and the operator. For a more accurate modeling, more construction details of the cable can be included. A final consideration of the geometry approximation of the analyzed coils is that we used a 2D model, whereas it is possible that a 3D model would produce slightly higher fields.

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CONFLICT OF INTEREST

The authors have no conflict of interest to report.

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