

Possible differences in exposure from TMS treatment between male and female operators

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Abstract

This paper aims to evaluate the electromagnetic field exposure of a clinical operator performing a treatment protocol of Transcranial Magnetic Stimulation (TMS) on a patient, by means of numerical dosimetry. In particular, the possibility that some differences could occur depending on the gender of the operator is raised, thus pointing out that a risk assessment gender-dependent may be relevant.

1 Introduction

TMS is a neurostimulation and neuromodulation technique [1] investigated in research and used in clinics, for therapeutic and diagnostic purposes. During the TMS treatments, the stimulating coil, placed over the patient's head, generates a high intensity pulsed magnetic field, up to 2 T, owing to an intense current that flows inside the windings of the coil. Since the TMS magnetic field spreads in the space around the source, the clinician also undergoes an undesired exposure. Nevertheless, the topic of the clinician's safety in the workplace, is still poorly addressed in literature [2], which leads to the necessity of conducting the systematic numerical assessment presented in [3]. In this previous study, we showed that several factors can have an impact in the clinician's exposure, among which are the type of coil, its position and orientation with respect to the body and to the hand holding it. Based on the results obtained, we considered the possibility that the clinician's gender could also cause a different extent of exposure and thus influence the risk assessment. Indeed, the anatomical characteristics and the morphological details, as well as the specificity of the tissues and organs may have a significant role in the overall exposure. For example, it should be necessary to consider the shape of the body, the height (typically smaller in females than in males), the presence of adipose tissues in different positions of the human body, as well as the presence of the breast, that could be directly exposed to the source in the case of an operator that holds the coil at the height of the chest. The possibility of a gender effect on the electromagnetic (EM) exposure is confirmed also by recent literature[4]. For instance, in Gallucci et al. 2022 [5], it was shown that the specific absorption rate (SAR) values for a wearable antenna emitting radiofrequency electromagnetic fields (RF-EMF) at 2.45 GHz varied between a male and female model due

to the differences in the amount of muscle tissue and the presence of the breast between the two models. Differences due to the gender have been found also when studying exposure at lower frequencies [6]. Authors examined the electric field (EF) and the current density (J) induced by a 50 Hz magnetic field, under three different orientations, inside the Japanese human male (Taro) and female (Hanako) models [7], and they found increased electric field values inside the male model, with the respect to the female. Such increase was attributed to the larger diameter of the male model. From what was found in the literature, it was deemed worthwhile to analyze the possible differences between male (Duke) and female (Ella) models of the Virtual Population (ViP) [8] in terms of induced quantities in clinicians during TMS treatments. It was therefore decided to carry out a risk assessment of exposure to a TMS coil, using one of the models used in the clinical practice, i.e. the circular coil.

2 Models and Methods

2.1 Source model. This study considered the circular commercial coil Magstim MAG-978400, supplied by a short-duration sinusoidal current of 5.6 kA, with an equivalent frequency of 3 kHz [9]. The highest field strength of magnetic flux density (B) occurs near the inner turn and is equal to 2 T when the coil is fed with the maximum stimulator output (MSO). The coil design and stimulator parameters were based on specifications provided by the manufacturer manual and guide [10].

2.2 Human exposure scenario. To investigate the human exposure caused by the TMS coil during the treatments, a Sim4Life v.6.2 (ZMT, Zurich MedTech AG) project was created, with the Magneto quasi-static module. To model the clinician, the virtual population members Duke and Ella models were considered. Additionally, the dosimetric analysis included the patient's head, modeled by the simplified two-tissue head phantom "Sam" (obtained by IEEE Standards Coordinating Committee 34, Sub Committee 2, Working Group 1 - SCC34/SC2/WG1), available in the software. The two layers of Sam are one representing the shell and one the liquid part, which have been assigned a conductivity of 0.01 S/m and 0.33 S/m respectively [2]. Further, the same exposure conditions analyzed in D'Agostino et al. 2021 [3] for the Duke model,

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are here considered for the female one (Ella). These consist of two orientations (I, II) of the coil with respect to the clinician and four heights (A-B-C-D) of the coil from the ground.



Figure 1. Exposure conditions. Two coil orientations (I and II) and four vertical positions: case A (#shown for Ella), exposure of the chin/neck, case B (#shown for Duke) of the chest, case C of the abdomen and case D of the lower abdomen. For orientation I, the distance between the center of the coil and the surface of the clinician's body is 21 cm, whereas, for orientation II, the distance between the coil side and the surface of the clinician's body is 12 cm.

As can be seen from Figure 1, the main differences occur in the positioning of the coil in terms of heights with respect to the ground; this is because Duke is taller than Ella and thus, the heights at which the coil needs to be positioned have been properly scaled. Conversely, the orientations and the distances of the operator with respect to the source, are the same. In reference to the source, as is well known, it is typically used in the real clinical condition at percentage of MSO substantially lower than 100%, i.e. from 30% up to 80% MSO [11]. Therefore, to evaluate compliance with the regulations, the 99th percentile of the induced EF inside the tissues, owing to different %MSO, are evaluated using a post-processing elaboration of the data. These detected values are compared with the limits suggested by ICNIRP guidelines 2010 [12] and the last update 2020 [13], which, at the frequency of work of the TMS here analyzed, is equal to 1.13 V/m (peak value).

3 Results

As a first evaluation of the possible gender differences, the TMS induced EF was compared between the two operators' models inside specific body tissues, to correlate the differences in the EF distribution with internal anatomical characteristics. Particularly, the heart, the central nervous system (CNS), the fat and the breast tissues were investigated, as shown in Figure 2 that reported the corresponding EF distribution induced with the coil placed in case A and Orientation II (identified in our previous study [3]as the worst exposure Orientation).



Figure 2. Orientation II, case A, 100% MSO: EF distribution in body tissues (a) Duke, (b) Ella.

Further analysis is reported in Orientation II for abdomen exposure (case C), which is the worst case condition among the four coil positions and between the two orientations for Duke model, as also shown in [3]. Body slices are considered in this case, where the main male-female differences may be present. The comparison of the induced EF distribution for the two models is shown in Figure 3, supported by the body tissue section in right panel.



Figure 3. Orientation II, case C, 100% MSO. Panel 1 refers to Duke, panel 2 to Ella. Distribution of the induced EF (a)-(b) on the transversal plane at the height of the coil; (c)-(d) in a slice of the hip, 5 cm below from the coil; (e)(f) slices of the body tissues corresponding to the hip slice.

The figure reveals an important behavior of the two models in the body district of the abdomen. In this case we can observe that, although in the slice at the height of the coil, the profile of the distribution of the EF is quite similar (but much more penetrating in Duke than in Ella), moving away from this slice, in the hip region, the EF remained higher in Duke than in Ella. In particular, in slices (a) and (b), there is a very compact area where values equal and above 6 V/m can be found. This area represents the anatomical district directly exposed to the coil: here we can say that the distribution profile is similar, but as anticipated, in Duke it seems to be more penetrating and widens more towards the hips. Moving below at the height of the hip, slices (c) and (d), in Ella we have areas of maximum EF only in the flanks zone, while in Duke, we still find a high EF in the frontal area (absent in Ella) and, as in the female subject,

an extension of the maximum areas towards the lateral flanks. This behavior is only attributed to the anatomical differences between the model, as can be seen from slices (e) and (f) since the two models undergo an identical exposure. This may be due, for e.g., to the greater amount of muscle in the male model. Finally, in order to verify the compliance with the limit and also taking into account the different MSO used in the clinical practice, the percentiles of induced EF are evaluated. Tables 1 and 2 summarize the induced EF for Orientation I and II respectively, for the four coil heights, denoted with capital letters, as shown in Figure 1. In particular, the 99th percentiles of EF for the cases of 30% MSO and 100% (max) are reported and the highest values are highlighted in light grey. The tables also compare the two human models.

Table 1. Orientation $I - 99^{th}$ percentiles of induced EF (V/m) inside Duke (blue) and Ella (red), as a function of MSO.

(A)		(B)		(C)		(D)	
30%	max	30%	max	30%	max	30%	max
1.13	3.77	1.21	4.01	1.30	4.34	1.51	5.02
1.54	5.13	1.28	4.28	1.37	4.59	1.33	4.46

Table 2. Orientation II -99^{th} percentiles of induced EF (V/m) inside Duke (blue) and Ella (red), as a function of MSO.

(A)		(B)		(C)		(D)	
30%	max	30%	max	30%	max	30%	max
1.80	6.00	1.80	6.01	2.19	7.32	2.01	6.71
2.45	8.18	1.84	6.14	2.02	6.72	1.76	5.86

As can be seen the induced EF exceeds the suggested limit (1.13 V/m) in all cases of exposure, even considering the 30% MSO and the worst cases fell in Orientation II. However, there are cases at 30% MSO where the induced EF is slightly above the limit, as cases A for Duke and B for Ella, both in Orientation I. Following, for a better understanding of what occurs inside the clinician's body, maps of induced EF are shown, comparing the two human models.



Figure 4. EF maps for Orientation II: (a) exposure of Ella; (b) exposure of Duke, both for the four cases, A-B-C-D. The maximum of the color bar is set to the limit suggested by ICNIRP guidelines. Coil is fed at 30% MSO.

In Figure 4, it is interesting to observe the differences in the distribution of the EF, between the two models, in particular for cases A and B. In case A, the head of Ella is much more invaded by the induced EF, what occurs in these tissues justifies the higher CNS exposure found in Ella (Figure 2). In case B, a defined and narrower region of intense red is observed in Ella's breast, while in Duke, the intense red covers a larger area of the chest. This suggests that the dielectric properties of Ella's tissue are confining the induced quantities to a smaller region. Cases C and D exhibit unique behaviors as well, as demonstrated in Figure 3 for case C and with more extensive and deeper exposure for Duke in case D. These findings indicate that the EF distributions vary among the human models.

4 Discussion and Conclusions

The analysis conducted in this study aims to highlight possible differences in the exposure of the operator that performs the TMS treatment, due to the gender. Critical issues in the use of this device were already addressed in our previous studies [3][14], in which we evaluated a not negligible exposure of the human male model. Therefore it was considered of importance to deepen the issue taking into account the specificity of the staff exposed to the magnetic field produced by the TMS and thus the exposure gender-dependent. As a first observation, it is considered the comparison of what occurs in specific districts of the bodies of the two operators exposed to the TMS source at 100% MSO (Figure 2). This latter helps us in understanding the extent to which the field distributes in tissues, which would not be otherwise considered by focusing only on percentiles inside the bodies. Starting from the heart, the distribution shows to be different in the two models, since in Duke a larger area characterized by the blue color is present with respect to Ella. This shows how the induced EF distribution in the same organ or tissue can be different between subjects, even when considering the same exposure condition. This is because the heart intrinsically differs from subject to subject, e.g. bigger, more rotated, more inclined, and in particular (for female cases) behind the breast tissue, and so on. A similar situation, for example, occurs in the fat, because of its different amount in the two models. Then, by observing the distribution of the induced EF in the CNS tissue of the two models, it seems that the exposure of the head of Ella is higher than in Duke, indeed, herein it is found a 99th percentile of 5.66 V/m and 4.32 V/m, for Ella and Duke respectively. Of great importance is what occurs in the breast tissues in the case of Ella; it can be seen that the entire tissue is uniformly affected by intensities higher than 6 V/m, with a 99th percentile equal to 8.86 V/m. Clearly, this does not appear in the Duke model where the tissue is absent, showing a critical condition for the female clinicians, that would not occur if one performs the dosimetry on a male model. Moreover, to verify the compliance, the 99th percentiles are evaluated, also considering different percentages of MSO. Tables 1 and 2 show that in all the cases examined, the limit of 1.13 V/m, is exceeded, even at 30% MSO. In particular, the Orientation II has been identified as the worst exposure

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condition, with cases A and B showing a higher induced EF in Ella compared to Duke. In case A, the percentile increase is 26.6%, while in case B, it's 7.32%. For the remaining two cases (C-D), Ella has a lower evaluated value compared to Duke. This latter is in line with the literature, where overall, the induced quantities evaluated in the female model were lower than in male one, except the chest exposure, where also in [5] it was found a higher value in Ella.

Conversely, in Orientation I, Ella has also a slightly higher induced EF compared to Duke for the case C (+5%), although the main difference occurs in the cases A (+26.5%) and B (+6.4%), similarly to Orientation II. With high probability, the different results, between the two orientation, strongly depend by the source orientation and thus by the different coupling with the human model, that have distinct body shapes.

The results of this gender-dependent study, indicate that anatomy plays a crucial role in risk assessment and found that the extent of exposure can vary slightly depending on the operator performing the TMS treatment. Ella's body shape, with a physiological curvature of the back, leads to greater exposure of the head and central nervous system. This is due to her head having different dimensions compared to Duke, which may result in a different coupling with the source. Then, it is found that where there are objective differences between the male and female subjects i.e., in the chest (for the presence of the breast) and in the abdomen (for the different amount and distribution of muscle and fat), wide differences in the behavior of the distribution of the EF are revealed. As a whole, this analysis would be a useful starting point for improved awareness of the importance of variability among human subjects in risk assessment. These results, e.g. could pave the way for the evaluation of an error percentage to be considered in risk assessment results to take into account the body characteristics of the workers, such as those observed between male and female. Therefore, the issue could also extend to other categories and differences (races, weight, etc.), opening a new method of risk assessment.

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