Original Article

ELISA reader does not interfere by mobile phone radiofrequency radiation

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Abstract

Background: The increasing number of mobile phones can physically cause electromagnetic interference (EMI) in medical environments; can also cause errors in immunoassays in laboratories. The ELISA readers are widely used as a useful diagnostic tool for Enzymun colorimetric assay in medicine. The aim of this study was to investigate whether the ELISA reader could be interfered by the exposure to the 900 MHz cell phones in the laboratory.

Materials and Methods: Human serum samples were collected from 14 healthy donors (9 women and 5 men) and each sample was divided into four aliquots and was placed into four batches for the *in-vitro* quantitative determination of human chorionic gonadotropin (hCG). During colorimetric reading of the first, second, and third batches, the ELISA reader (Stat Fax 2100, Awareness Technology, Inc., USA) was exposed to 0.5, 1.0, and 2.0 W exposure of 900 MHz radiation, respectively. For the forth batch (control group), no radiation was applied. All experiments were performed comparing ELISA read out results of the I, II, and III batches with the control batch, using the Wilcoxon test with criterion level of $P = 0.050$.

Results: The final scores in the exposed batches I, II, and III were not statistically significant relative to the control batch ($P > 0.05$). The results showed that 900 MHz radiation exposure did not alter the ELISA measured levels of hCG hormone in I ($P = 0.219$), II ($P = 0.909$), and III ($P = 0.056$) batches compared to the control batch.

Conclusion: This study showed that ELISA reader does not interfere by mobile phone RF radiation at a closed contact (less than 5 cm distance). However, we recommend that medical institutions discuss these issues in the context of their specific use of technologies and frame a policy that is clear and straightforward to guide staff, patients, and visitors.

Key Words: Electromagnetic interference, ELISA reader, mobile phone, radiofrequency radiation

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INTRODUCTION

Electromagnetic interference (EMI) due to

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radiofrequency (RF) radiation from external sources such as cellular telephone, radio communication, computer, radar, and antennas in medical environments is being widely studied by several authors.[1-6] Beside the beneficial characteristics of these devices, the user also have to pay attention to the different sources of EMI in medical environments and particularly the use of a mobile phone inside medical facilities as the most typical situation.

The Medicines and Healthcare Products Regulatory Agency (MHRA) in the U.K. carried out an EMI test on medical equipment using different mobile communication devices and showed that anesthesia machines, respirators, external pacemakers, ECG monitors, defibrillators, infusion pumps, and ventilators are sensitive to EMI.[7-9] Moreover, there are several reports published about EMI problems attributed to the use of a mobile phone near a medical device. Hann *et al.,* reported the prompted malfunction of an epinephrine infusion pump due to a cellular phone received call.[10] Trigano *et al.,* showed electrocardiogram recorded artifacts during 1800 MHz mobile phone ringing that appears 3 second before the first ringing tone and that persisted until end of ringing.[7] Tang *et al.,* found that medical equipment such as ventilators, infusion pumps, defibrillators with an ECG monitor, and fetal monitors are quite susceptible to EMI.[3] They suggested that care should be taken when operating a mobile phone within 1 m of these devices.

As consequence of these facts, many medical environments have prohibited the use of cellular phones in some areas. The factors affecting EMI can be broadly classified into properties of the emitting device (i.e., frequency, which is inversely proportional to wavelength and power of emissions); the physical relationship between the devices (i.e., distance); and susceptibility of the affected device (i.e., electromagnetic shielding).[11]

The ELISA readers are widely used as a diagnostic tool for Enzymun colorimetric assay in medicine, as well as a quality-control check in various industries. Photodetectors (PD), photo-multipliers tubes, or photodiodes are the main parts of detection system of the ELISA readers. Colorimetric assays result a colored light reaction and an ELISA absorbs light in the visible range using a PD. A PD converts light into an electrical signal, and then amplifies that signal to a useful level.[12,13]

Magnetic fields, from sources of RF fields, to which a PD is exposed have an adverse effect on its sensitivity and efficiency.[14,15] However, since fields as weak as the earth's can affect its sensitivity, a PD must be surrounded by a mu-metal and also supplementary shield, usually of soft iron.[13] Nevertheless, the problem is still remains in the optical input system, at flux densities of about few milliteslas (mT).[12,13]

The mobile phone technology uses frequency range from 880 to 1800 Mega Hertz (MHz).[16,17] The magnetic field strength transmitted from the antenna of the majority of all cellular phones at about 7.5-10 cm distance from the antenna is well over 0.002 mT. However, at distances less than 2.5 cm from the phone antenna, it emits electromagnetic fields (EMFs) of up to 0.01 mT.[18] Of interest, mobile phone RF radiation might directly interfere the ELISA diagnostic system and cause spurious results.[19]

The aim of this study was to investigate whether the ELISA reader could be interfered by the exposure to the 900 MHz cell phones in the laboratory. At present, there is only evidence that the RF radiation does not affect the serum analytical equipment at a far distance (1.4 m),[2] while, according to the best of our knowledge, there is no data for the closed contact with the methodology and analysis described here.

MATERIALS AND METHODS

GSM mobile phone simulator

In this work, due to the uncertainties associated with the use of a mobile phone,[20] a GSM mobile phone simulator (designed and produced at the School of Medicine, Isfahan University of Medical Sciences) was used for microwave irradiation. In this experiment, similar to GSM mobile phone, the frequency of 900 MHz radiation (a wavelength of about 33.4 cm) was used. The simulator power was adjustable from 0 to 2 W but in this study, 0.5, 1.0, and 2.0 W were used for exposure. It should be noted that, according to the International Commission for Non-Ionizing Radiation Protection (ICNIRP) and the Federal Communications Commission (FCC), the reference level for RF exposure is peak power density.[21-23] It is a commonly used term for characterizing an RF electromagnetic field. The signal bandwidth was 200 kHz (similar to GSM mobile phone channels). There were some irradiation sources in the laboratory (i.e. the wireless networks in the laboratory). Since, the study was performed in a distinct place of the laboratory and background radiation were identical, power density of these sources was not monitored during the study.[20]

Immunoassay and exposure

This study was performed based on an immunoassay technique for the *in-vitro* quantitative determination of human chorionic gonadotropin (hCG) level.[6]

Human serum samples were collected from 14 healthy donors (9 women and 5 men) and each sample was divided into four aliquots and was placed into four batches. The mean age ± SD of the donors was 38.6 ± 12.9 years. "For the assay, two different anti-hCG monoclonal antibodies were used, one adsorbed on the wells and the other conjugated to horseradish peroxidase (HRPO). During the first incubation, the hCG in calibrators and samples was bound to both monoclonals at once, by forming aspiration and washing. The residual enzyme activity in the wells, which was directly proportional to the hCG concentrations in calibrators and samples, was measured by adding a chromogen solution (tetramethylbenzidine, TMB) in a substrate-buffer to the wells".[6] ELISA reader (Stat Fax 2100, Awareness Technology, Inc., USA) was used for the colorimetric reading at 450 nm wavelength. During colorimetric reading of the first, second, and third batches (I, II, and III batches), the ELISA reader was exposed to 0.5, 1.0, and 2.0 W exposure, respectively. For the forth batch (control group), no radiation was applied to the reader and the batch completed the reading under identical conditions during the study period. The distance between the simulator antenna and each batch, was kept at 5 cm. Recently, we found that 900 MHz RF radiation exactly during the immunoassay cycle could alter the hCG level in the serum in laboratory.

All specimens (aliquots) were kept at room temperature to avoid the effect of temperature on the assay. Results were determined via a calibration curve which was generated instrument-specifically with a master curve via the reagent barcode. All experiments were performed comparing ELISA read out results of the I, II and III batches with the control batch. To avoid the variability inherent to the assay used, all tests were performed for three independent experiments.

Statistical analysis

Mean values and standard deviations (SD) were calculated and statistical significance of the differences between exposed and control batches were evaluated. A computer program (SPSS version 16.0, Chicago, IL, USA) was used for statistical analysis. Data were analyzed by the Wilcoxon test (nonparametric version of paired samples *t*-test). All hypotheses were tested using a criterion level of $P = 0.05$.

RESULTS

Figure 1 illustrates a comparison of serum hCG hormone with S.D. for each donor (a, b, and c) among control, and the exposed batches I, II and III at 450 nm reading. The hCG concentrations were varied from 0.219 ± 0.0034 to 2.8840 ± 0.01469 mIU/mL. Table 1 gives the average hCG level for each batch at 450 nm reading. Figure 2 shows the averaged scores of hCG with different levels in I, II, III and control batches at 450 nm reading. The final scores in the exposed batches I, II, and III were not statistically significantly relative to the control batch ($P > 0.05$) [Figure 2]. The results showed that 900 MHz radiation exposure did

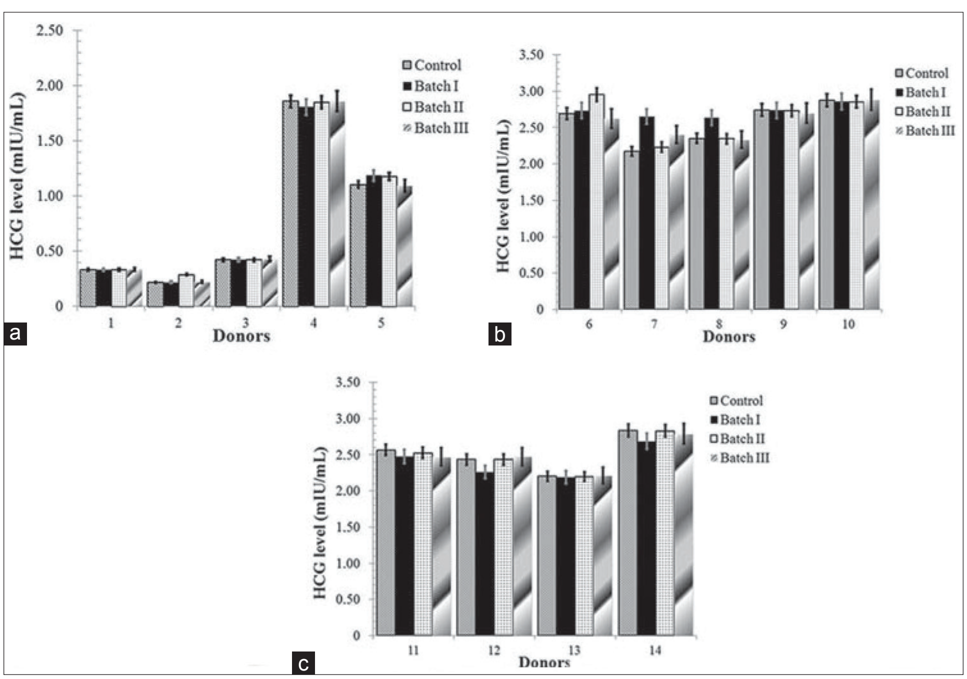

Figure 1: A comparison of serum hCG hormone with S.D. for each donor (a, b, and c) among control, and the exposed batches I, II, and III at 450 nm reading

Table 1: HCG averaged scores in the 450 nm reading among control, and the exposed batches I, II, and III in the test

Batch	HCG Concentrations (mIU/mL) Mean±SD
Control	1.914±0.975
I*	1.941±0.981
II	1.940±0.975
III	1.916±0.968

HCG: Human chorionic gonadotropin, **Refers to 0.5 W exposed batch

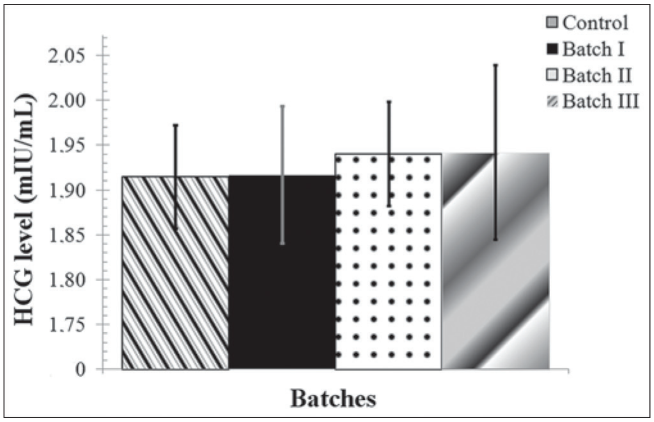

Figure 2: A comparison of average serum hCG hormone with S.D. among control, and the exposed batches I, II and III at 450 nm reading

not alter the ELISA measured levels of hCG hormone in I (P = 0.219), II (P = 0.909) and III (P = 0.056) batches compared to the control batch. In other words, the ELISA reader did not interfered by the exposure to the 900 MHz cell phones in the laboratory.

DISCUSSION

EMI has been responsible for many life-support and critical care medical device malfunctions, which raises concerns about the safety of patients who depend on these devices.[17] Recently, several reports have been published about EMI problems attributed to the use of a mobile phone near a medical device. Moreover, regarding the serum analytical equipment, there was only evidence that the RF radiation does not affect these devices at a far distance (1.4 m).[2] In medical laboratory for serum analysis, ELISA readers are widely used as a useful diagnostic tool for Enzymun colorimetric reading. In this experiment, we aimed to investigate whether ELISA reader could be interfered by the closed contact (less than 5 cm distance) exposure to the 900 MHz cell phones in the laboratory.

Results of this study showed that during serum colorimetric reading, ELISA reader does not interfere by mobile phones exposure at a close contact [Table 1 and Figure 1]. The reason could mainly be due to electromagnetic shielding of the PD of ELISA reader.[11] Generally, a PD is surrounded by a metal shield, usually of soft iron and this shielding decreases the degree of malfunction due to mobile phone exposure.

There are some factors affecting the EMI in the medical laboratory such as properties of the emitting device, the distance between the devices, and electromagnetic shielding of the affected device.[11] The frequency of electromagnetic radiation plays an important role in relation to the length of various electric components in the susceptible device. Long wavelengths (low frequencies) transfer minimal energy to small electronic components, and very short wavelengths (extremely high frequencies) are easily shielded. Frequencies between 10 kHz and 1 GHz are generally the most problematic.[11] In this work, similar to GSM mobile phone, the frequency of 900 MHz radiation, which is within the above-mentioned problematic range, was used. Clinically relevant EMI is very uncommon at distances greater than 1 m since for electromagnetic fields, the energy level falls rapidly as the distance from the source increases (proportional to the square of the distance, namely inverse square law).[24,25] Although many factors affecting EMI are difficult to predict, the reduction in field strength with distance is generally predictable. Recently, Helhel *et al.,* found that mobile phone usage, 1.4 m farther than the serum analytical equipments does not cause EMI.[2] However, some equipment such as electrocardiograms (ECGs) are susceptible to mobile phones EMI at a closer distance (less than 0.4 m). However, the critical distance is not a concern itself, but also the location and orientation of both sources and medical equipments are important as mentioned in ANSI C63.18.[26] The electromagnetic shielding of the affected device affects the degree of malfunction that may occur. Newer devices are designed according to more stringent standards, with attention to shielding and electromagnetic immunity, and are less susceptible to EMI.[2]

In this study, due to the uncertainty and confusion with respect to possible effects of mobile phone usage such as unknown amount of energy, a GSM mobile phone simulator was used for microwave irradiation. The 0.5, 1.0, and 2.0 W powers, as peak power densities were used for exposure, similar to GSM mobile phone. For comparison purposes, a commercially available cell phone (Nokia, Model 1202, India) produces 1.09 Watt per kilogram (W/kg) of the tissue locally in the head specific absorption rate, at 900 MHz RF radiation.[20]

Some institutions have followed, the evidence presented earlier, that all significant interference problems occur at distances of 1 m or less.[9] However, we found that there is no need for such distances from an ELISA reader during colorimetric reading. The 1 m rule can be established, in which the use of mobile technologies is permitted even in highly instrumented areas, such as the ICU, provided that they are deactivated within 1 m of any functioning device.[7-9]

More accurate follow-up studies are needed for the evaluation of the EMI due to RF radiation from external sources such as mobile phones in medical environments. The results here should be confirmed in larger series, employing repeated exposure-power-related effect, especially for greater powers (more than 2 W powers).

CONCLUSION

The increasing number of mobile phones, their base transceiver stations, and other wireless systems as well as electromagnetic irradiation emitted from computers and other laboratory devices that can physically interfere with each others, can also cause errors in immunoassays in laboratories. In this study, it was found that ELISA reader does not interfere by mobile phone radiofrequency radiation. However, we recommend that medical institutions discuss these issues in the context of their specific use of technologies and frame a policy that is clear and straightforward to guide staff, patients, and visitors.

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