The Laryngoscope

Effect of Bluetooth Headset and Mobile Phone Electromagnetic Fields on the Human Auditory Nerve

Marco Mandalà, MD, PhD; Vittorio Colletti, MD; Luca Sacchetto, MD; Paolo Manganotti, MD, PhD; Stefano Ramat, PhD; Alessandro Marcocci, MD; Liliana Colletti, PhD

Objectives/Hypothesis: The possibility that long-term mobile phone use increases the incidence of astrocytoma, glioma and acoustic neuroma has been investigated in several studies. Recently, our group showed that direct exposure (in a surgical setting) to cell phone electromagnetic fields (EMFs) induces deterioration of auditory evoked cochlear nerve compound action potential (CNAP) in humans. To verify whether the use of Bluetooth devices reduces these effects, we conducted the present study with the same experimental protocol.

Study Design: Randomized trial.

Methods: Twelve patients underwent retrosigmoid vestibular neurectomy to treat definite unilateral Ménière's disease while being monitored with acoustically evoked CNAPs to assess direct mobile phone exposure or alternatively the EMF effects of Bluetooth headsets.

Results: We found no short-term effects of Bluetooth EMFs on the auditory nervous structures, whereas direct mobile phone EMF exposure confirmed a significant decrease in CNAPs amplitude and an increase in latency in all subjects.

Conclusions: The outcomes of the present study show that, contrary to the finding that the latency and amplitude of CNAPs are very sensitive to EMFs produced by the tested mobile phone, the EMFs produced by a common Bluetooth device do not induce any significant change in cochlear nerve activity. The conditions of exposure, therefore, differ from those of everyday life, in which various biological tissues may reduce the EMF affecting the cochlear nerve. Nevertheless, these novel findings may have important safety implications.

Key Words: Bluetooth headset, electromagnetic field, cochlear nerve action potentials, intraoperative monitoring, mobile phones.

Level of Evidence: 4.

***Laryngoscope*, 124:255–259, 2014**

INTRODUCTION

The possibility that long-term mobile phone use increases the incidence of astrocytoma, glioma, and acoustic neuroma has been investigated in several studies.[1,2] Despite the fact that most neurophysiological studies have reported inconsistent results regarding the effects of electromagnetic fields (EMFs) of mobile phones on neural structures,[3] alterations of the normal electrophysiological activity of the auditory system have been reported.[4] Recently, our group published evidence that exposure to cell phone EMFs induces deterioration of intraoperative acoustically evoked cochlear nerve compound action potentials (CNAPs) in humans.[5]

Bluetooth is a popular radio technology that is commonly used in everyday life, frequently associated with mobile phones, and hands-free headsets, in particular, are its most common application.

Bluetooth (as well as ZigBee) devices are being increasingly adopted in medical instruments, typically to monitor remotely and inexpensively vital signs such as pulse oximetry, heart rate, electrocardiograms, and noninvasive blood pressure.[6] EMFs emitted by communication devices could also cause interference with medical equipment. In intensive care units, it was previously shown that EMFs emitted by mobile phones may cause minor alarm triggers, whereas Bluetooth devices appear to cause no interference with ventilator function.[7] The current guidelines for the United States and Europe, in terms of brain tissue exposure to radio waves emitted from mobile phones, limit the specific absorption rate (SAR) for general use to 1.6 W/kg averaged over 1 g of tissue and 2 W/kg averaged over 10 g of tissue.[8] Bluetooth operates at a higher frequency (2.4 GHz) than cell phones, and is potentially more hazardous to nervous tissue given an equal transmission power. Yet, class 2 devices such as Bluetooth are restricted to much lower transmission power (2.5 mW) than cell phones (900 MHz global system for mobile communications [GSM] phones are limited to 2 W), so the resulting influence on brain tissue may indeed be lower. Higher frequencies also reduce the depth of penetration of the EMF, so that deeper nervous structures would be reached by a lower

From the ENT Department (M.M., V.C., L.S., A.M., L.C.) and Department of Neurology (P.M.), University of Verona, Verona, Italy; and the Department of Computer and Systems Science (S.R.), University of Pavia, Pavia, Italy.

Editor's Note: This Manuscript was accepted for publication February 22, 2013.

The authors have no funding, financial relationships, or conflicts of interest to disclose.

Send correspondence to Marco Mandalà, MD, PhD, ENT Department, University of Verona, Piazzale L. A. Scuro, 10; 37134 Verona, Italy. E-mail: marcomand@hotmail.com

DOI: 10.1002/lary.24103

intensity EMF, whereas structures closer to the skin would absorb a greater amount of energy.

Despite the rapid and widespread diffusion of Bluetooth technology, its possible effects on the auditory function in humans have not yet been investigated. The recently published experimental evidence that exposure to cell phone EMFs deteriorates CNAPs in humans[5] motivated us to expand the previous study and investigate whether the same effect may be observed while wearing a Bluetooth headset connected to a mobile phone.

MATERIALS AND METHODS

The cohort reported here is a patient-based clinical population seen between April 2010 and November 2010. The study was conducted at the Department of Otolaryngology (tertiary referral center) of the University of Verona (Verona, Italy). All participants were affected by unilateral definite Ménière's disease (MD) according to the criteria of the American Academy of Otolaryngology–Head and Neck Surgery.[9] A complete audiological and neuro-otological evaluation with pure-tone audiometry, speech audiometry, impedance audiometry, auditory brainstem response (ABR), electrocochleography, eye-movement bedside examination, vestibular evoked myogenic potentials, and caloric testing was performed in all subjects. Normal 1.5 T brain magnetic resonance imaging findings were obtained preoperatively in all patients. All participants had also received medical therapy (diuretics, betahistine, low salt diet) for at least 6 months without any improvement.

Fifteen patients met the entry criteria, but three patients were not enrolled in the study due to profound hearing loss in the ear to be operated on. Twelve patients underwent retrosigmoid vestibular neurectomy (VN) to treat definite unilateral MD while being monitored with CNAPs to assess direct mobile phone exposure or, alternatively, the EMF effects of Bluetooth headsets.

All patients signed a written informed consent. Ethics approval was obtained from the University of Verona Ethics Committee.

Readers interested in details of the surgical procedure and intraoperative monitoring techniques are referred to our previous publication.[5] The experimental setting is briefly described here. A retrosigmoid craniotomy with a diameter of 3 to 4 cm was carried out, and the dura was opened. The eighth nerve was exposed after cerebellar retraction and arachnoid dissection. CNAPs recording from the proximal portion of the cochlear nerve (CN) was performed using a Teflon, insulated, silver electrode wire (type Ag 7/10; Medwire Corporation, Mt. Vernon, NY) with a small cotton wick sutured on its tip. Alternating click stimuli at 31 pulses/s were provided using a Walkman-type earphone at 100 to 120 dB (sound pressure level [SPL]) depending on the hearing of the patient. After 100 repetitions, the recorded potentials were filtered, amplified, and averaged with the Medelec Synergy N-EP evoked potentials system (CareFusion, Gort, Ireland). CNAPs latency of the first negative peak (N1) and the normalized absolute amplitude of N1 were evaluated in all subjects. ABRs were also recorded in all subjects at the same time as CNAPs.

Six randomly assigned patients were exposed to the EMFs produced by a mobile phone (Nokia 6310i; Nokia, Keilalahdentie, Finland) over the craniotomy, whereas in the other six subjects, a Bluetooth headset (BH-213; Nokia) was positioned in the same place and connected to the same mobile phone lying approximately 50 cm away. The distances from both the Bluetooth headset and the mobile phone antenna to the CN were measured in every trial.

In all subjects, CNAPs were first recorded with the phone in standby mode for 2 minutes (T0) and then continuously monitored for 5 minutes of active call, with the CN directly exposed to either the Bluetooth headset EMF or the mobile phone EMF (T1). The phone was set in active call by answering a phone call from a landline. The volume was set at a medium level. The surgical setting minimized the possibility of auditory stimulation, because the external auditory canal was closed by both the earphone and three sterile surgical drapes. All of these conditions contributed to significantly reduce the possible effect of direct acoustic stimulation from the mobile phone or Bluetooth device. To provide a quantitative assessment of environmental noise level evaluation (operating room) and product noise testing (mobile phone and Bluetooth headset), sound level measurements were performed with a Svan 948 professional phonometer and SV22 microphone (Svantek s.r.l., Melzo (MI), Italy). At the end of the exposure, the potentials were recorded for 10 minutes, and surgery was then continued with the VN.

Three months after surgery, an audiometric evaluation was performed using pure-tone audiometry to assess the extent of hearing preservation. Differences between the Bluetooth group and the mobile phone group were tested using Fisher exact test and Student *t* test, or Wilcoxon rank sum test, as appropriate.

CNAP recordings at time T0 and at the end of the 5-minute exposure (T1) were compared between the two study groups (Wilcoxon rank sum test). The Friedman test, in combination with Dunn's multiple comparison test, was used to assess the effects of 5 minutes of EMF exposure by comparing the data collected at each minute during the 15 minutes of CNAPs recording with that recorded at T0. Such comparison was performed independently in both the direct mobile phone- and the Bluetooth-exposed subjects. An analysis of variance (ANOVA) test was performed to investigate the differences in environmental sound levels among the different conditions tested.

RESULTS

Demographic data of the populations exposed to direct mobile phone or Bluetooth EMFs are reported in Table I. CNAP measurements showed stability and reproducibility at T0. A typical three-phase response was obtained with a predominant negative peak (N1) generated by the depolarization wave propagation (Fig. 1).

Direct mobile phone EMF exposure showed a significant decrease in CNAP amplitude and an increase in latency in all subjects (Friedman test, $P < .0001$). A post hoc test (Dunn's multiple comparison test) indicated that significant changes in CNAPs were present from 2 minutes after the beginning of exposure to 5 minutes and 6 minutes after its end for amplitude and latency, respectively ($P < .05$).

The Bluetooth EMF-exposed population showed no statistically significant effect on the latency and amplitude of CNAPs ($P > .05$; Friedman test) during the entire monitoring period (Fig. 1). No significant changes could be detected with V wave latency of the ABR recordings in both study groups ($P > .05$; Friedman test). Changes in wave I and III of the ABR could not be analyzed statistically due to their inconsistency in the recordings. The

TABLE I.
Demographic Data, Latency, and Amplitude Variations at the End of the 5-Minute Exposure for the Direct Mobile Phone EMF-Exposed Group and the Bluetooth EMF-Exposed Group.

Group	Number of Subjects	Mean Age (yr)	Sex (M/F)	Latency Shift at the End of 5-Minute Exposure (ms)	Normalized Amplitude Reduction at the End of 5-Minute Exposure (%)
Bluetooth EMF exposure	6	48.8 ± 16.8	2/4	0.03 ± 0.06	97 ± 4
Mobile phone EMF exposure	6	58.1 ± 21.6	3/3	0.46 ± 0.23	27 ± 11
Statistical analysis (*P* value)		.4267*	.5582†	.0068*	.0001*

*Wilcoxon rank sum test.
†Fisher exact test.
EMF = electromagnetic field.

3-month audiological follow-up showed no changes ($P > .05$, Wilcoxon test) in hearing threshold when comparing the mean pure-tone average (PTA) of the whole population before (41 ± 14 dB hearing level [HL]) and after surgery (51 ± 16 dB HL).

The basal CNAPs (T0) latency and amplitude measurements for the two tested populations showed no statistically significant differences (Table I; $P > .05$, Wilcoxon test). When comparing CNAP recordings at the end of EMF exposure (T1) between the Bluetooth and mobile phone populations, the results showed statistically significant differences in terms of latency ($P = .0068$; Wilcoxon test) and amplitude ($P < .0001$; Wilcoxon test) (Table I).

Between the two populations, no statistically significant differences were found in the distance measured from the Bluetooth headset and the mobile phone antenna to the CN (62 ± 7 mm vs. 64 ± 12 mm; $P = .7317$; *t* test). In the Bluetooth-exposed subjects, the antenna of the mobile phone was kept 51 ± 9 cm away from the surgical field.

The mean environmental sound level observed in the operating room during the procedure was 49.7 ± 2.3 dB SPL. No statistically significant differences could be observed among the various conditions tested: no mobile device in the operating room, mobile phone in standby mode or activated and lying around 6 and 50 cm away, and Bluetooth headset in standby mode or activated and lying around 6 cm away ($P > .05$; ANOVA test).

DISCUSSION

The present paper expands on a previous investigation on CNAP deterioration induced by cell phone EMFs in humans[5] and shows that when using the same surgical protocol, the EMFs produced by a Bluetooth device have no short-term effect on the exposed acoustic nerve. On the other hand, the present work confirms the deterioration of CN conduction due to mobile phone EMF exposure, as recently described.[5]

The outcomes of the present study show that, contrary to the finding that the latency and amplitude of CNAPs are very sensitive to EMFs produced by the tested 900 MHz mobile phone, the EMFs produced by a common Bluetooth device do not induce any significant change in CN activity. In addition, the EMFs generated by a mobile phone kept 50 cm away from the exposed CN also do not affect CNAPs. This condition is similar to the everyday life situation, where a cell phone is kept in a jacket pocket while using a Bluetooth headset. These observations confirm that the bioactivity of mobile phone EMFs is related to their intensity, frequency, and/or

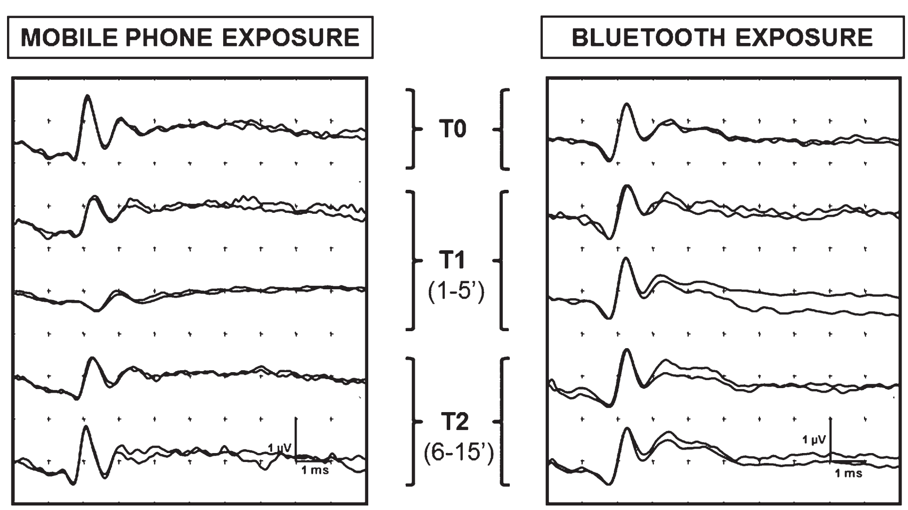

Fig. 1. Series of cochlear nerve compound action potentials (CNAPs) recorded in one of the patients submitted to direct mobile phone electromagnetic field (EMF) exposure and one subject exposed to Bluetooth EMF. CNAP recordings obtained before, during, and after EMF exposure are shown. A significant reduction in amplitude and increase in latency may be seen in the direct mobile phone EMF-exposed group. No significant changes in amplitude and latency could be detected in the Bluetooth EMF-exposed population. T0 = before EMF exposure; T1 = during EMF exposure; T2 = after EMF exposure.

distance from the antenna[10] and bear important safety implications.

The profound differences between the specifications of GSM cell phones and Bluetooth devices in terms of transmission power are a probable explanation for the experimental findings of this study. The Nokia 6310i is a GSM phone. Its manufacturer's SAR specifications claim a value of 0.82 W/kg in 10 g of tissue (European standard) when tested during 900 MHz operation. Under these conditions, the European regulations[11] allow for a maximum SAR of 2 W/kg, and the transmission power is limited to a maximum of 2 W. On the other hand, the Nokia BH-213 is a Bluetooth device with a transmission range up to 10 m and operating at 2.4 GHz, complying with Bluetooth class 2 device regulations, and it therefore has a maximum transmission power of 2.5 mW. The SAR of Bluetooth devices is usually so low that it is rarely reported by the manufacturer, although a recent publication by the Swiss Federal Office of Public Health[12] has measured SARs of Bluetooth headsets in the range .001 to .004 W/Kg. In sum, the absence of measurable effects of exposure to Bluetooth EMFs appears to be explained by the much lower transmission power of Bluetooth headset devices, which is nearly three orders of magnitude lower than that of the tested cell phone.

A further finding of this study that deserves attention is the lack of measurable effects on CNAPs during exposure to the cell phone EMFs when the distance to the cell phone is increased to about 50 cm. In fact, the near field EMF produced by the cell phone antenna quickly decreases with increasing distance, with terms inversely proportional to the square and the cube of distance, so that its intensity is dramatically reduced at the distances used here.

Taken together, these findings indicate that the alternative offered by a Bluetooth headset coupled with a cell phone kept in a pocket or on a table is generally safer in terms of EMF effects on the nervous system and therefore represents a viable solution for safer operation.

The main limitation of the present study is represented by the experimental model used to investigate the effects of EMFs on CNAPs. In fact, the craniotomy exposes the CN directly to the EMF source, thereby eliminating the attenuation provided by the biological structures that are normally interposed between the antenna (Bluetooth headset or cellphone) and the CN, such as skin, skull, fat, muscle, blood, and grey and white matter that have different SAR values.[13]

Using a mathematical model of the human head, it was recently suggested that the strength of the internal field and the SAR value decay exponentially with increasing depth in the head, so that they are higher in the vestibular than in the auditory region.[14] Considering that in an intact head, the CN lies at a depth of about 6 cm, the modeling findings in Parazzini[15] show that the EMFs reaching the CN could be attenuated by at least 80% with respect to those in the immediate proximity of the antenna. Therefore, our surgical procedure exposes the CN directly to a well-defined EMF, eliminating all of the complexity and variability of modeling EMF distribution and SAR in the human head tissues, and allows a direct measurement of the effects of EMF exposure on the function of the CN. Our procedure evaluates the effects of an EMF stimulation that is significantly higher than that occurring under normal conditions.

Another major limitation of the study is represented by the fact that average auditory function in Ménière's disease subjects is below normal, whereas we obviously were not able to test normal subjects in the same conditions, and thus our study could not define if Bluetooth exposure would be detrimental in normal patients. Furthermore, a number of mobile phones and Bluetooth devices are currently on the market with different EMF characteristics, whereas we had the opportunity to test our patients with only one of these. On the other hand, the international regulations allow class 2 Bluetooth devices to provide a maximum transmission power of only 2.5 mW, which was also the nominal maximum output of the tested device; the possibility of a different effect of different Bluetooth device models seems to us unlikely.

Ongoing studies using different experimental conditions and devices on animal models aim to clarify the physiological and pathological substrate of the effect of exposure to different EMFs on the cochlear and facial nerve.

CONCLUSION

To the best of our knowledge, this study, for the first time, provides information regarding the differences of short-term effects of Bluetooth headset and mobile phone EMFs on the auditory nervous structures through intraoperative monitoring. Latency and amplitude of CNAPs are very sensitive to EMFs produced by mobile phones, whereas the EMFs produced by a common Bluetooth device do not induce any significant change in cochlear nerve activity. The conditions of exposure, therefore, differ from those of everyday life, in which various biological tissues may reduce the EMF affecting the cochlear nerve. Nevertheless, these novel findings may have important safety implications.

BIBLIOGRAPHY

1. Hardell L, Carlberg M, Soderqvist F, Mild KH, Morgan LL. Long-term use of cellular phones and brain tumours: increased risk associated with use for ≥10 years. *Occup Environ Med* 2007;64:626–632.
2. Hardell L, Carlberg M. Mobile phones, cordless phones and the risk for brain tumours. *Int J Oncol* 2009;35:5–17.
3. Kwon MS, Hamalainen H. Effects of mobile phone electromagnetic fields: critical evaluation of behavioral and neurophysiological studies. *Bioelectromagnetics* 2011;32:253–372.
4. Kaprana AE, Chimona TS, Papadakis CE, et al. Auditory brainstem response changes during exposure to GSM-900 radiation: an experimental study. *Audiol Neurootol* 2010;6:270–276.
5. Colletti V, Mandala M, Manganotti P, Ramat S, Sacchetto L, Colletti L. Intraoperative observation of changes in cochlear nerve action potentials during exposure to electromagnetic fields generated by mobile phones. *J Neurol Neurosurg Psychiatry* 2011;82:766–771.
6. Kaputa D, Price D, Enderle JD. A portable, inexpensive, wireless vital signs monitoring system. *Biomed Instrum Technol* 2010;44:350–353.
7. Jones RP, Conway DH. The effect of electromagnetic interference from mobile communication on the performance of intensive care ventilators. *Eur J Anaesthesiol* 2005;22:578–583.
8. Hardell L, Sage C. Biological effects from electromagnetic field exposure and public exposure standards. *Biomed Pharmacother* 2008;62:104–109.
9. Committee on Hearing and Equilibrium. Guidelines for the diagnosis and evaluation of therapy in Meniere's disease. American Academy of Otolaryngology, Head and Neck Foundation, Inc. *Otolaryngol Head Neck Surg* 1995;113:181–185.

10. Panagopoulos DJ, Chavdoula ED, Margaritis LH. Bioeffects of mobile telephony radiation in relation to its intensity or distance from the antenna. *Int J Radiat Biol* 2010;86:345–357.
11. International Commission on Non-Ionizing Radiation Protection. Guidelines for limiting exposure to time-varying electric, magnetic, and electromagnetic fields (up to 300 GHz). *Health Phys* 1998;74: 494–522.
12. Swiss Federal Office of Public Health. Bluetooth. BAG Web site. January 30, 2007. Available at: http://www.bag.admin.ch/themen/strahlung/00053/00673/03571. Accessed January 24, 2013.
13. Kwon MS, Jaaskelainen SK, Toivo T, Hamalainen H. No effects of mobile phone electromagnetic field on auditory brainstem response. *Bioelectromagnetics* 2010;31:48–55.
14. Parazzini M, Tognola G, Franzoni C, Grandori F, Ravazzani P. Modeling of the internal fields distribution in human inner hearing system exposed to 900 and 1800 MHz. *IEEE Trans Biomed Eng* 2007;54:39–48.
15. Parazzini M. Interactions Between Radio Frequency Electromagnetic Fields Produced by Mobile Phones and the Auditory System: Biological Effects and Numerical Dosimetry [PhD dissertation]. Milan, Italy: Polytechnic University of Milan; 2004.