INSTITUTE OF PHYSICS PUBLISHING PHYSICS IN MEDICINE AND BIOLOGY

Phys. Med. Biol. **51** (2006) 3347–3358 doi:10.1088/0031-9155/51/14/004

Evaluation of stray radiofrequency radiation emitted by electrosurgical devices

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Received 17 January 2006
Published 23 June 2006
Online at stacks.iop.org/PMB/51/3347

Abstract

Electrosurgery refers to the passage of a high-frequency, high-voltage electrical current through the body to achieve the desired surgical effects. At the same time, these procedures are accompanied by a general increase of the electromagnetic field in an operating room that may expose both patients and personnel to relatively high levels of radiofrequency radiation. In the first part of this study, we have taken into account the radiation emitted by different monopolar electrosurgical devices, evaluating the electromagnetic field strength delivered by an electrosurgical handle and straying from units and other electrosurgical accessories. As a summary, in the worst case a surgeon's hands are exposed to a continuous and pulsed RF wave whose magnetic field strength is 0.75 A m^{-1} (*E*-field 400 V m^{-1}). Occasionally stray radiation may exceed ICNIRP's occupational exposure guidelines, especially close to the patient return plate. In the second part of this paper, we have analysed areas of particular concern to prevent electromagnetic interference with some life-support devices (ventilators and electrocardiographic devices), which have failed to operate correctly. Most clinically relevant interference occurred when an electrosurgery device was used within 0.3 m of medical equipment. In the appendix, we suggest some practical recommendations intended to minimize the potential for electromagnetic hazards due to therapeutic application of RF energy.

1. Introduction

Electrosurgery allows both cutting and coagulation of tissue by passing a high-frequency, high-voltage electric current through the tissue being operated on. In monopolar electrosurgery three basic system components are needed: a power unit, an active electrode (electrosurgical handle) and a return electrode. Radiofrequency (RF) current flows from the electrosurgical unit (ESU) along a cable to the active electrode, then spreads through the patient's tissue,

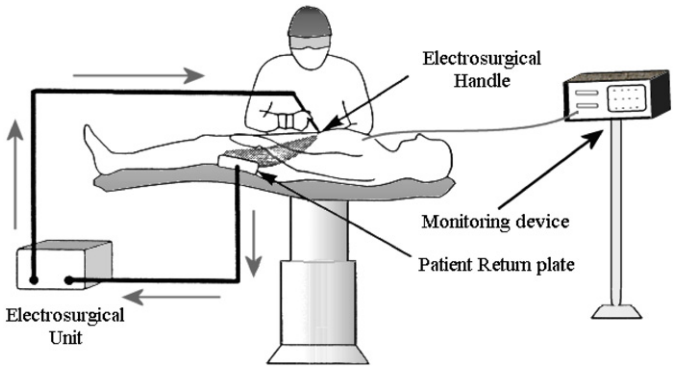

Figure 1. The principle of electrosurgery. A high-frequency current is conducted from a hand-held electrode with a small surface area, through the patient's body, to a neutral electrode (patient return plate) with a large surface area. The high current density close to the electrosurgical handle leads to the tissue heating necessary for coagulation and cutting purposes. Grey arrows indicate the current path.

to be collected and returned to the ESU by a patient plate electrode (return electrode). The desired surgical effect is achieved by concentrating the RF current (nominal frequency 300–400 kHz depending on the different electrosurgical units) via the active hand-held electrode in a small cross-section of the patient's tissue and safely dissipating the energy back to the ESU via a large area return electrode (see figure 1 for a schematic diagram). Also, newer electrosurgical devices are RF isolated and a dedicated isolation transformer isolates the unit's therapeutic current from its other circuits, preventing unwanted interactions with other patient-attached equipment. Defects in the insulation of the electrosurgical disposable accessories, or their improper use and incorrect positioning in operating room, can allow some RF energy to interfere with other life-support devices. Moreover, electrosurgical procedures are always accompanied by a general increase of the electromagnetic field in the operating room that could affect both surgeon and other physicians working in the immediate vicinity of the operating site. ESUs generate electric and magnetic fields near the electrosurgical handle and patient return plate that, even at low power levels, might approach or exceed the recommended limits for human exposure.

In the first phase of this paper, we describe the occupational exposure due to therapeutic application of radiofrequency energy. Measurements of electric and magnetic field strengths were made in areas near the electrosurgical unit and other accessories (hand-held electrode, patient return plate and cables) in order to determine typical and 'worst case' exposure levels of a surgeon and physicians who work in the vicinity of these equipments.

Based on the previous results and considering that it is a widely held belief that devices emitting RF waves may interfere with the operation of an electronic equipment, we have analysed the potential effects of electromagnetic interference (EMI) with some life-support medical devices that are currently used in operating rooms. Many of them (e.g., ventilators and electrocardiographic devices) are directly connected to patient in order to detect very small physiological signals (typical values less than 1 mV). This intrinsic high sensitivity makes them particularly sensitive to electromagnetic disturbances that can be radiated during electrosurgery activities. This study has also become necessary seeing that during the past two years some reports of medical device failures from electromagnetic interference have been addressed to our department. The dominant effects that have been reported are malfunctions and irrecoverable cessation of monitoring in electrocardiographic (ECG) devices, and artefacts

or alarm conditions in cardiorespiratory monitoring devices. The most likely sources of those failures have been RF interferences from electrosurgical clinical use.

In the appendix of this work, we suggest some practical recommendations intended to minimize the potential for electromagnetic hazards due to therapeutic application of RF energy.

It should be noted that over the past few years the possibility of unwanted EMI with electronic medical equipment by radio waves coming from mobile telephones has been reported by a lot of authors in several countries; some hospital policies have been planned to address this risk. The interference with cardiac pacemakers (Kainz *et al* 2005, Souques 2004) and with ECG devices (Sweesy *et al* 2004) was analysed and the change in the performance of ventilators (Jones and Conway 2005, Tri *et al* 2001) and other common devices was evaluated (Lawrentschuk and Bolton 2004). However, electromagnetic (EM) radiation emitted by electrosurgery devices, the distribution of the electric and the magnetic field in an operating room, the occupational exposure and the simultaneous influence on the other life-support devices have not yet been investigated.

2. Materials and methods

Electrosurgical generators are able to produce a variety of electrical waveforms and as they change, so will the corresponding tissue effects. Depending on frequency and wave modulation, peak-to-peak voltage and current delivered by the unit, the surgeon is able to obtain the desiderated effects. The only variable that determines whether one waveform causes cutting effects and another produces a coagulum is the rate at which heat is produced. A continuous sine-shaped high-frequency current with peak voltages of 2000–2500 V produces high heat rapidly, causing quick cutting effects with little haemostasis. On the other hand, low modulated current (duty cycle about 10% on time) and extremely high voltage, with peak-to-peak voltages of up to 9000 V, cause intensive sparking effects between the active electrode and the tissue, producing less heat but leading to a coagulation effect.

In the first phase of this work, we have evaluated the RF radiation emitted by electrosurgical devices operating in both cutting and coagulation modes.

A preliminary experiment intended to measure the real EM field strength during a surgical intervention has been conducted in an operating room at the 'Ospedali Riuniti di Ancona' in Ancona, IT. After having covered the entire sensor of the probe with disposable plastic foil, it was positioned near the sterile operating site and close to the patient's return plate. With the source–detector distances minimized but constant for all trials, the maximum electric and magnetic field values delivered by an electrosurgical handle, and which strayed from an electrosurgical unit, were evaluated. These trials were repeated for three different types of electrosurgical procedures; a summary of the data obtained is given in table 1 along with information on the surgical techniques and powers used. Based on these preliminary measurements, tests were then performed in a controlled laboratory setting after having minimized reflections and the interference from external sources and other medical devices that are usually present in operating room (e.g., syringe pumps, fluorescent tubes and telephones).

Experiments were carried out on six different monopolar electrosurgical devices (three Valleylab Force FX and three ERBE Erbotom ICC350), all of which are currently used for the vast majority of electrosurgical applications. They were equipped with standard disposable electrosurgical handles (Valleylab type E2516) and blades of length 2.5 cm. A general summary of the generators' outputs according to different operating modes is provided in table 2.

Table 1. Electric and magnetic field strength measured in an operating room during three different surgical interventions.

		Measured values[b]					
		Patient plate		Handle		Cable	
Intervention	Power output[a]	A m^{-1}	V m^{-1}	A m^{-1}	V m^{-1}	A m^{-1}	V m^{-1}
Thyrotomy	Cutting: 80 W	1.12	381	0.17	325	1.37	294
	Coagulation: 80 W	3.24	325	0.29	358	2.18	362
Liver and abdominal	Cutting: 150 W	1.18	433	0.15	355	0.2	332
Surgery	Coagulation: 100 W	3.84	338	0.3	390	2.46	416
Mastotomy	Cutting: 200 W	1.32	456	0.25	381	1.73	345
	Coagulation: 100 W	3.77	334	0.28	397	2.53	414

[a] ERBE model Erbotom ICC350 electrosurgical unit.
[b] All data represent the maximum registered value over an acquisition time of 20 s.

Table 2. Electrosurgical units' output characteristics. All data are from manufacturers' technical sheets (ERBE 2006, Valleylab 2002).

Operating mode	Wave	Frequency (kHz)	Output voltage[a] (V)
Generator 1 (ERBE Erbotom ICC350)			
Cutting mode: High cut	Continuous sine shaped	330	570
Coagulation mode: Forced	Pulse-modulated alternating voltage	1000	2300
Generator 2 (Valleylab Force FX)			
Cutting mode: Pure	Continuous sine shaped	390	2300
Coagulation mode: Fulgurate	Damped sinusoidal burst cycle @ 57 kHz	390	6900

[a] Maximum peak-to-peak voltage at load resistance RL $= \infty$.

Measurements were conducted with a broadband radiation meter (PMM model 8053A) fibreoptically connected to two large cross-sectional area probes. Electric field strength was measured using a PMM model EP-330 isotropic probe while magnetic field strength was measured using a loop antenna (PMM model HP-032). During measurement procedures both probes and electrosurgical handle were positioned over a plastic tripod intended to minimize EM mutual interference. Two fibreglass arms held them mutually perpendicular at the same level, keeping 5 cm separation distance between the surgical blade and the centre of the probe. A schematic diagram of the experimental set-up is shown in figure 2.

All measurements were performed 'in air', averaging data over a 2 min period. Although this would not be a normal operating mode because every single action of cutting or coagulating is usually shorter than 20–30 s, it was used in order to obtain a stable reading on the measuring instrument. ESUs were powered during measurements by the use of the footswitch pedal and electric and magnetic field strength values were automatically corrected for their calibration values (correction factors in the specified frequency range: 0.03 dB for the *E*-field probe and 0.84 dB for *H*-field probe).

Tests started to evaluate EM field strength when the ESUs were operating in cutting mode. They were then repeated while the ESUs operated in coagulation mode. We initially set a low power output (80 W), which we then increased gradually, setting the same parameters used daily in electrosurgical procedures. We measured the EM field strength close to the electrosurgical handle and accessories (e.g., power unit, patient return plate and conducting

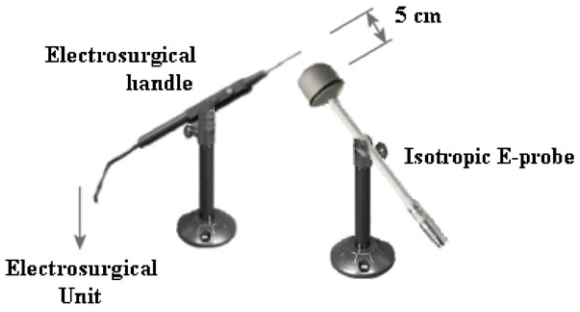

Figure 2. Diagram of the experimental set-up. The electrosurgical handle and *E*-field probe are arranged in a 90° geometry with a 5 cm separation distance between them. The electrosurgical handle is electrically connected (by a 2 m cable) to the power unit while the probe is fibreoptically connected to the radiation meter.

cables), paying particular attention to coiled cables. This practice that physicians usually do to reduce their excessive length creates an inductive bundle into the return circuit that may focus and boost the EM field, resulting in enhanced localized emission of high-frequency energy.

In the previous tests, electrosurgical accessories were identified as a source of locally intense electromagnetic fields. The intensity decreases rapidly with increasing distance, which should be carefully considered when evaluating unwanted coupling effects with a medical device. This is particularly true considering that electrosurgical units are increasingly likely to be used in close proximity to other medical devices, and RF conducting cables looped and left over them.

With this aim, we analysed the potential effects of electromagnetic interference with four samples of current model ventilators and four electrocardiographic devices from different manufacturers.

While the tests were under way an ESU was operated in coagulation mode (100 W output power) and an electrosurgical handle was used as a test RF source due to the very similar electric and magnetic strength values measured close to the handle and cables. First of all, we exposed each medical device to EM fields radiated during electrosurgical procedures, monitoring their screens and alarms while the electrosurgical handle was manoeuvred near them. Then we wanted to find out at which distance an influence on them might occur: the surgical handle was moved towards each medical device and was positioned at 30, 20 and 10 cm from all of their sides.

When making measurements, the medical devices were connected to the appropriate patient signal simulator for their proper operation. We used a Metron ECG simulator to provide a repetitive electrocardiographic pattern (the protocol we employed included eight different ECG patterns and voltages) and a Metron ventilator tester to simulate healthy adult lungs.

3. Results

3.1. Stray RF radiation

An electromagnetic field's structure in close proximity to an RF emitting source is highly inhomogeneous and does not have a plane-wave character. In this region, called the near-field or Fresnel region, electric and magnetic fields' vectors are not mutually perpendicular to the direction of propagation and both fields vary considerably from point to point. To fully

Table 3. Magnetic field strength emitted by electrosurgical units in both cutting and coagulation operating modes. All data represent the mean of three independent measurements averaged over a 2 min period. Total measurement uncertainty is about ±10%.

		Magnetic field strength (A m^{-1})						
	Power output (W)	Handle	Patient plate[a]	Patient plate[b]	Power unit[a]	Power unit[b]	Cable[a]	Cable (coiled)[a]
ESU 1	100	0.18	1.11	0.2	0.6	0.2	1.4	1.6
Cutting mode	120	0.2	1.15	0.3	0.6	0.22	1.6	1.9
	200	0.25	1.3	0.4	0.7	0.22	1.7	2.2
Coagulation mode	80	0.3	3.2	0.5	0.38	0.18	2.2	2.5
	100	0.3	3.8	0.6	0.4	0.2	2.5	2.9
ESU 2	100	0.5	2.7	0.5	0.8	0.5	2.9	3.2
Cutting mode	150	0.55	3.0	0.6	0.9	0.5	3.3	3.6
	200	0.6	3.2	0.6	1.1	0.8	3.5	3.9
Coagulation mode	80	0.45	4.5	0.8	0.5	0.45	1.2	1.45
	120	0.75	5.8	1.0	0.6	0.55	1.5	1.9

[a] Source–detector distance = 5 cm.
[b] Source–detector distance = 50 cm.

Table 4. Electric field strength emitted by electrosurgical units in both cutting and coagulation operating modes. All data represent the mean of three independent measurements averaged over a 2 min period. Total measurement uncertainty is about ±10%.

		Electric field strength (V m^{-1})							
	Power output (W)	Handle	Patient plate[a]	Patient plate[b]	Power unit[a]	Power unit[b]	Cable[a]	Cable (coiled)[a]	Cable (coiled)[b]
ESU 1	100	350	400	51	190	32	300	330	38
Cutting mode	150	360	435	58	220	37	330	380	40
	200	380	450	59	230	39	350	410	44
	250	400	500	68	250	34	420	480	46
Coagulation mode	80	360	320	55	220	38	360	420	45
	100	400	330	68	260	42	400	470	46
ESU 2	100	120	400	88	160	55	230	280	35
Cutting mode	150	130	450	90	160	57	280	330	38
	200	190	470	95	167	55	350	420	40
Coagulation mode	80	170	280	80	160	54	200	245	40
	120	190	310	87	171	55	207	250	45

[a] Source–detector distance = 5 cm.
[b] Source–detector distance = 50 cm.

characterize the RF environment, it is necessary to determine both electric and magnetic field strengths. Table 3 presents the magnetic field strength measured while ESUs were operating in cutting and coagulation modes, while a general summary of electric field strength is provided in table 4. Measured values are arranged in horizontal groups in terms of different operating modes, and rows in each group present data in terms of increasing emitting power. Data have been collected for a 2 min period, then they were averaged, assuming a Gaussian distribution, and rounded off. The measurement uncertainty caused by systematic errors can be quantified as ±10% of the indicated field strength (for frequencies up to 300 MHz), which was estimated

Table 5. Summary of electromagnetic interference from RF energy emitted by an electrosurgical unit.

Device	Manufacturer	Model	EMI effect	EMI observed (two samples of each model)
Electrocardiographic	Bionet Co	Cardiocare	No detectable noise	0 (0%)
	Remco	Cardioline Delta3P	Artefacts and disruption of critical function	2 (100%)
Ventilator	Nellcor Puritan Bennett	840	Increased the displayed tidal volume	1 (50%)
	Siemens	Servoventilator 300	No detectable noise	0 (0%)

with a level of confidence of twice the standard deviation, as stated in the probes' calibration certificate.

On the other hand, the uncertainty caused by random errors is the standard deviation of the mean of the three independent measurements: it ranges from $\pm 0.8\%$ to $\pm 1.5\%$ of the indicated field strength value. This implies that the total uncertainty affecting our measurements, calculated as the mean squared error of both independent contributors of error, cannot be less than $\pm 10\%$.

The previous results have documented that electrosurgical procedures give rise to fairly high electric and magnetic fields in operating rooms: measured EM field values in areas near equipment were generally in the range of 160–260 V m^{-1} for the electric field (0.4–1.1 A m^{-1} for the magnetic field), depending on the different operation modes. At 0.5 m distance from the ESU electric field strength fell to 32–57 V m^{-1} while the magnetic field strength was still in the range 0.2–0.8 A m^{-1}.

Relatively intense electric fields have been reported within a few cm of the electrosurgical handle and slightly higher near the patient return pad. Maximum readings obtained were as high as 400 V m^{-1} (close to the electrosurgical handle) and 500 V m^{-1} (close to the patient return pad) when the ESU was operating in cutting mode (250 W output power).

Of particular relevance to prevent the potential EM interference with other electrical devices is the observation that a strong electric field has also been measured near every electrosurgical accessory: cables and the power unit should both be considered important as possible interference sources. In particular, the highest readings were associated with coiled cables: data obtained at a distance of 5 cm were as high as 480 V m^{-1} and 3.9 A m^{-1}.

Regarding magnetic field strength in general, the highest readings were associated with the coagulation operating mode (5.8 A m^{-1}, mode: Fulgurate—120 W output power). This is because the ESU's peak-to-peak coagulation voltage is higher than the cutting voltage and because it is not a continuous sinusoid, but a series of bursts of a damped sinusoidal voltage that may induce transient current.

3.2. Electromagnetic interference

Table 5 presents the observed EM interferences by therapeutic use of RF energy. The categories of equipment tested, the different manufacturers and models are summarized in the first three columns, while the last two columns describe the clinically observed EMI effects and the percentage of their incidence.

In a controlled laboratory setting no detectable noise or changes in the shape of the electrocardiographic wave were seen either on the ECG's display or on printed

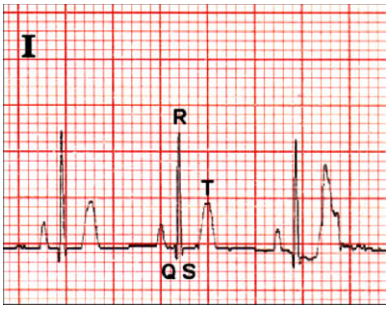

Figure 3. Lead I electrocardiographic tracing generated by a patient signal simulator. Three consecutive QRS complexes are shown: the last one after having positioned the hand-held electrode in close proximity to the ECG device. EMI caused the elevation of the ST segment and depression of the R wave.

(This figure is in colour only in the electronic version)

electrocardiographic tracing when the hand-held electrode was placed $\geqslant$30 cm from it. On the other hand, when it was placed 20 cm or closer, significant artefacts were detected in both Remco's devices. Failures of the ECG algorithm occurred, like the straight upward ST-segment elevation, shown in figure 3.

This interference could have serious clinical consequences because the ST elevation above the baseline, combined with an alteration in the normal 1:1 relationship between two consecutive R waves, is the earliest ECG sign of a heart attack like myocardial infarction or transmural ischaemia (Drew *et al* 2004). When the hand-held electrode was placed at 10 cm or closer to the electrocardiograph device the inhibition was complete; no output signal was detected and both the ECGs stopped working.

It should be noted that they returned to normal operation after the hand-held electrode was moved away, and also that the primary settings and monitoring parameters, such as filter setting, signal amplitude and the recorder sweep speed changed.

No detectable noise was seen on either Bennet's ECG display or tracing, so they seem to be well protected against EMI.

Regarding RF interference with electronically controlled ventilators, the investigation showed that only one (Puritan Bennett 840) increased the displayed tidal volume from 370 to 520 ml, and the high respiratory rate alarm sounded when the hand-held electrode was placed $\leqslant$10 cm from it. On the other hand, interference was not observed when the active electrode was positioned close to the pneumatic section instead of the electronic panel.

All of the described effects were temporary and not critically disruptive, with the equipment self-restoring to normal display function within a couple of seconds.

4. Conclusions

Human exposure to time-varying EM fields results in energy absorption in tissues that depend on the frequency involved and on the body's position in the field (ICNIRP 1998).

In operating rooms we are dealing with electrosurgical devices operating in the frequency range 300–400 kHz (wavelength 700–1000 m) and with a separation distance between the radiofrequency source and the body that is less than one-tenth of the field's wavelength. A surgeon normally keeps the hand-held surgical blade very close to their chest during surgical operations, so the upper part of their body can suffer exposure under reactive near-field

Table 6. Reference levels for both occupational and general public exposure to time-varying electric and magnetic fields in the 0.1–1 MHz frequency range (ICNIRP 1998).

Exposure	E-field strength (V m^{-1})	H-field strength[a] @ 330 kHz (A m^{-1})	@ 390 kHz (A m^{-1})	@ 1 MHz (A m^{-1})
Occupational	610	4.8	4.1	1.6
General public	87	2.2	1.8	0.73

[a] $1.6/f$ A m^{-1} for occupational exposure and $0.73/f$ A m^{-1} for general public exposure. f (in MHz) represents the different electrosurgical output frequencies.

conditions. This is the region of EM field, closest to the radiating source, that contains mostly the radiated EM energy.

Scientific literature (Jokela *et al* 1994) reports that near-field exposure can result in high local energy absorption mainly due to the electric field induced by current flowing along the antenna (electrosurgical blade), and strongly dependent on the separation distance between the RF source and the body. Under these conditions, significant thermal damage can occur in high-watercontent tissues near the surface of the head or body: maximum energy absorption is expected in tissues such as the eye and the testis.

Table 6 summarizes reference levels for both occupational and general public exposure to time-varying EM fields as they have been suggested by ICNIRP (1998) and recently stated in Directive 2004/40/Ec of the European Parliament (2004). The ICNIRP's exposure guidelines set the maximum electric field limit between 0.065 and 1 MHz at a strength of 610 V m^{-1} for occupational exposure and 87 V m^{-1} for general public exposure. On the other hand, magnetic field limits should be accorded to the frequencies of different fields, using the following equations: $1.6/f$ (A m^{-1}) for occupational and $0.73/f$ (A m^{-1}) for general public exposure (f expressed in MHz). For purposes of demonstrating compliance with the reference levels, both electric and magnetic fields should be analysed and considered separately.

Regarding personnel exposure, this study demonstrates that stray radiation emitted by the electrosurgical handle never exceeds the reference levels. In the worst case, the surgeon's hands are exposed to a continuous RF wave whose magnetic field strength is 0.6 A m^{-1} (E-field 400 V m^{-1}) in cutting operating mode and little higher (H-field 0.8 A m^{-1}; E-field 400 V m^{-1}) in coagulation operating mode.

On the other hand, regarding the patient's surveillance, we have demonstrated that they can suffer relatively high levels of exposure to RFs; both electric and magnetic field general public reference levels are usually exceeded in the body region where the return plate is applied. This exposure is amply justified because the patient undergoes a surgical operation, and a location for the return plate must be chosen that is close enough to the operative site and, at the same time, far away from any needle electrodes. Considering that in this frequency range leakage current and RF stray fields generally flow on the body's surface, the interaction of time-varying current and the needles' small tissue contact area may cause high current density at the site of contact, increasing the risk of a skin burn.

This study also demonstrates that every electrosurgical accessory as a part of an electric circuit becomes an RF source itself; particularly high electric field intensity has been observed in very close proximity to them. The maximum E-field strength reported was 500 V m^{-1} at a distance of 5 cm from both the patient return pad and coiled cables when the ESU was operating in cutting mode (250 W output power).

Another important point to observe is that coiling electric cables and fastening them with metal clips or forceps introduces an inductance into the return circuit that focuses and boosts the RF radiation, resulting in enhanced and localized emission of EM fields ('hot spots'). We observed a significant increase (about +20%) in both electric and magnetic field strength close to coiled electric cables compared to the extended ones.

For purposes of preventing unwanted EM interference with implanted devices it should be noted that over the past few years there has been a concern that EM waves from some RF devices could interfere with the operation of implanted pacemakers (Kainz *et al* 2005, Souques 2004), that could cause them to malfunction. The US Food and Drug Administration (FDA) has planned some policies to address this risk, requiring pacemaker manufacturers to test their devices for susceptibility to electromagnetic interference. Even though pacemakers have been recently designed to be immune to very intense electric fields (200 V m^{-1}) and electromagnetic shielding has been incorporated, the preceding results suggest an increase in risk not only for the patient but also for all the physicians attending to them if they are wearers of active implanted devices. The potential risk of unintended interference is greater for the surgeon because the hand-held active electrode is usually held very close to the thorax during the surgical procedures.

Regarding unintended EMI with medical devices, we have demonstrated that the hand-held electrode placed near some commercially available ventilators and ECG devices caused malfunctions and significant artefacts. In this frequency range, a 10 cm distance between any electrosurgical accessory and the electrocardiographic device is sufficient to inhibit its normal functions. Although the possibility of interference cannot be entirely described by the previous observations, it should be noted that electric field strength measured at 0.5 m from the sources usually exceeds both the immunity level of 7 V m^{-1} recommended by the US Food and Drug Administration (FDA) and the minimum immunity level of 3 V m^{-1} recommended by the 1993 revision of the International Electro-Technical Commission (IEC) Standard IEC 60601-1-2 for medical electrical equipment. All observed effects were temporary and testing was not standardized between studies. It is of concern that both kinds of devices (50% of ECGs tested and 25% of ventilators) were susceptible to clinically relevant electromagnetic interference. Additionally, a lot of factors may affect the severity of interference in electrical equipment (e.g., the ESU's power output, coupling effects, distance, orientation, earthing and other factors); many potential problems can be easily resolved by ensuring an adequate separation distance between the RF sources (power unit and cables) and the medical devices.

For purposes of preventing unwanted EM interference, the ESU should be used in such a way that a separation distance of at least 50 cm is normally maintained between any electrosurgical accessory and a medical device.

5. Future developments

Efforts should be made to establish meaningful correlation between therapeutic application of RF energy and unwanted electromagnetic interference on medical electrical equipment that might be encountered in an operating room, as well as to identify which device is much more susceptible to interference and to determine the minimum distance at which it may occur.

In addition, medical device manufacturers are expected to 'harden' their products against RF electric fields that are much more intense than the 3 V m^{-1} level specified in the previous standards and to provide the user with instructional material to caution against RF interference.

For example, a clear warning label as well as instructional information on minimum required distances for compliance would be an acceptable means of ensuring that an ESU is used safely.

Appendix

Based on the previous results and considering that we cannot avoid using electrosurgical equipment on patients with the operators in close proximity, the overall suggestions and recommendations intended to minimize the potential for electromagnetic hazards during electrosurgical procedures can be summarized as follows:

- Advise operating room staff and clinicians of the risk of potential interference produced by the RF surgical equipment that may influence the operation of the other patient-attached equipment.
- Special attention should be paid to ensure that all sources of RF energy are kept at a sufficient distance from any life-support or monitoring medical device. Considering that electromagnetic radiation is governed by the inverse square law, we suggest placing the power unit and all other accessories at least 0.5 m away from them.
- Do not allow electrosurgery cables to lay over or contact the cables of a medical device.
- Avoid coiling and fastening electrical cables with forceps or metal clips. This practice, usually undertaken to reduce their excessive length, produces regions of field intensification ('hot spots'). The electrical cables should be positioned in such a way so as to avoid contact with other medical devices and other leads.
- Whenever possible, use the lowest power output setting for the intended purpose.
- Do not use subcutaneous needle electrodes for monitoring evoked potentials. Due to their small tissue contact area they may collect RF leakage current, leading to burns at the site. Conventional ECG electrodes should be positioned away from the current pathway through the body, farther from the active site than the patient return plate.
- For patients and physicians holding cardiac pacemakers or other active implants there is a limited possibility of interference by therapeutic application of RF energy. These fields dissipate rapidly with distance, so 'prudent avoidance' would mean staying perhaps 0.5 m away from the ESU and any other accessories.
- Always employ ESUs and accessories that meet the specific reference standards: in Europe they should have a CE mark (Medical Devices Directive 93/42/EEC) and comply with the IEC 60601-2-2/1998 (3rd edn) standard, while in the US conformance to the ANSI/AAMI HF18 standard is required. Ensure that electrosurgery cables are rated above the corresponding maximum peak output voltage of the ESU.
- Regular preventative maintenance and inspections are recommended to ensure the correct calibration of the system and to prevent any degradation in performance.

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