Rational uses of Electro-Surgery and our Policy: Safe Practice, Safe Surgery

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The electrosurgical generator or the diathermy unit has been described as the most hazardous device used on a daily basis in the operation theater. So, professional and rational use is very essential. An apparently simple irrational application may give rise to unforgivable and life threatening catastrophic events. Though surgeon may not place the diathermy equipment to the patient in surgical setup, but it is the ultimate unavoidable responsibility of a surgeon to do safe use of this potentially hazardous device in our day to day common surgical practice. And therefore, every surgeon must be aware of the basic principle and the critical events of electro-surgery. Moreover, every hospital should have a local policy which must be strictly adhere to. The ultimate objective of this RCT is to evaluate such a safety checklist compatible to our clinical setup to triumph in the very complicated field of electro-surgery. The findings of this study reveals that the rate of critical events is significantly lower in the experimental groups of this RCT (where there was an application of ES checklist) in contrast to the control groups (where no such safety checklist was used). Moreover, the expenditure of additional 3 minutes for the ES checklist to be filled up for each surgical patient has the significant potential to reduce the number of critical events and ensure safe practice.

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Introduction

The basic knowledge and proper understanding of electro-surgery is essential to have safe practice in the theatre. It is quite strange that how does it work? How can we pass high voltage at a relatively high current through patients without killing our patients? The key factor that allows the use of electro-surgery is that the current from the generator is high frequency alternating current. Low frequency current which alters fifty times per second or at fifty Hartz leads to neuromuscular stimulation and potential cardiac arrest. Electrosurgical generator delivers a much high frequency around 4 hundreds to 5 hundreds Kilo-Hertz and it is this that prevents neuromuscular stimulation and allows the current to pass safely through the body. There are two methods of applying electro-surgery: Monopolar and Bipolar.[1, 2]

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We will deal firstly with the Monopolar electro-surgery. Having established that the high frequency AC prevent neuromuscular stimulation. Now why the clinical effect achieved at the tip of the instrument and not at the patient's eternal electrode? This comes down to a simple matter of surface area and current concentration. The power is concentrated over a tiny surface area at the tip of the electrosurgical instrument. Yet dissipated over an area thousands times greater at the patient's eternal electrode. This causes a negligible heating effect. It is important to appreciate that despite of many things, the pad or the patient's eternal electrode does not earth the patient. The pad nearly completes the circuit back to the electrosurgical generator. It is not an earthling device.[1, 2, 3, 4]

Most electrosurgical generators in the UK are isolated circuit; however, if the system we are using is not an isolated one, we must take special care to ensure the patient's eternal electrode is properly applied throughout the operation. The major potential hazard with the older style grounded generator is that the current flowing through the patient will not preferentially look for the patient's eternal electrode to complete the circuit. It is equally having flow back to the earth, therefore, should the patient's eternal electrode becomes detached from the skin, the current may leave the body by any number of alternative route, for example, the operating table or the ECG electrodes causing burn at these points due to current concentration.[4]

The proper placement of pad is a very crucial event for safe practice. We should ensure that a well vascularized muscle mass is chosen and that we avoid areas of vascular insufficiency, irregular body contour and bony prominence and also consider the incision site and the prep area, patient's position and other equipment on the patient. Another safety feature of electrosurgical generator is the presence of interrogation circuit whereby the electrosurgical generator constantly check how well the patient's electrode is applied by measuring impedance across the pad. Should the pad begins to peel off the skin, the impedance rises and output from the generator shuts down until the patient's electrode is properly reapplied. There are different modes of electro-surgery those we commonly we aware of: cutting, blend, coagulation and spray or fulguration. There are two important differences between these modes: the time the current is actually supplied by the generator and the voltage.[1, 2, 4]

Current leakage is a very dangerous phenomenon where special attention is required. More worryingly, the electrosurgical cables are commonly wrapped around the metal instrument in the theatre; current leak will energized the instrument which if in contact with the patient's skin has the potential to cause a full thickness burn. A very practical example might be the tip of a towel clip to secure the drapes, having cable wrapped around it and then coming into contact of the patient's skin causing full thickness burn.

Finally, we have to remember not to use any alcohol based solution when utilizing the electro-surgery. The electrosurgical current has the ability to set such solution alight and cause a full thickness burn as a result. It is very important to highlight that the flame of burning alcohol would not even be seen under bright theatre lightings but very silently would cause a full thickness burn.[3, 5]

Another crucial aspect is the issue of pace maker. Electrosurgical current can creates voltage in the pace maker lead which can cause a heating effect at the point of contact with the endocardium; leading to failure of the pace maker. If the patient has a pace maker, it is wise to use bipolar electro-

surgery. If this is not practical, the patient's eternal electrode should be sited so that current does not pass through the heart or the pace maker lead and the power setting should be kept low. In case of laparoscopic surgery, special attention must be paid to the issue of direct coupling, insulation failure, capacitive coupling & ramping, as most often any injury caused in this way remains the scope of the field of the laparoscopic vision and go completely unnoticed by the surgeon at the time of surgery.[1, 3, 5]

Heinrick's safety pyramid

Developed in 1931, Heinrick's safety pyramid theorized that unsafe acts or near misses lead to minor injuries & over time to a major injury. The accident pyramid proposed that for every 300 near misses, there are 29 minor injuries and 1 major injury.[6, 7, 8]

With this in mind, in this RCT here we have designed a locally compatible, less time consuming Electro-surgical Safety Checklist (ES Checklist) for our clinical setup to combat with these common mistakes with the routine use of diathermy unit in theater. In this ES Checklist, there are 20 individual codes for all 3 principal steps.

A) Sign in (Before skin incision)

Before the surgery to be started, the OT nurse will read this part (part A) of the ES Checklist loudly in presence of the whole surgical team & with the implied consent of the chief surgeon, will place tick mark for code 1 to 15. Then the chief surgeon will deliver his brief verbal instructions and the OT nurse will place tick mark for code 16.

B) Time out (before skin/ port closure)

Just before the closure of access, the OT nurse will read the part B of the ES Checklist loudly in presence of the whole surgical team & with the implied consent of the chief surgeon, will place tick mark for code 17 & 18.

C) Sign out (immediate after the procedure)

Just after the procedure, before the patient is carried out of the theatre, the trainee surgeon will fill-up the part C of the ES Checklist with brief instruction of the chief surgeon.

Finally, it is the fundamental unavoidable responsibility of the chief surgeon to review the whole checklist briefly but accurately before leaving the theatre.

Electrosurgical safety checklist

Name of institute: ---------- **Department: ----------**

ES Reg. no: ----------

A) ***Sign in (Before skin incision)***				
			Code	***Remarks***
• Patient confirmation		√ **or** ×	**1**	
	Identity			
	Age			
	Date of birth			
	Reg. no			
• Surgical profile confirmation		√ **or** ×	**2**	
	N/O procedure			
	Indication			
	Incision			
	Anaesthesia			

• Patient's body is free of		√ **or** ×	**3**	
	Jewelry	√ or ×		
	Any metal	√ or ×		
• Incompatible devices		√ **or** ×	**4**	
	Pace maker	√ or ×		
	ECG lead	√ or ×		
	Others			
• Patient plate confirmed		√ **or** ×	**5**	
• Appropriate patient plate size confirmed		√ **or** ×	**6**	
• Hand piece confirmed		√ **or** ×	**7**	
	Monopolar	√ or ×		
	Bipolar	√ or ×		
• Anticipated mode confirmed		√ **or** ×	**8**	
	Mode	Range	Average	
	Cutting			
	Coagulation			
	Blend			
	Spray/Fulguration			
• Diathermy cable is not wrapped around		√ **or** ×	**9**	
	Towel clip	√ or ×		
	Any instrument	√ or ×		
• Diathermy paddle confirmed		√ **or** ×	**10**	
• Earthling, if present		√ **or** ×	**11**	
• Interrogation circuit, if present		√ **or** ×	**12**	
• Insulation confirmation		√ **or** ×	**13**	
• Skin preparation		√ **or** ×	**14**	
	Alcoholic	√ or ×		
	Non-alcoholic	√ or ×		
• Selective laparoscopic equipment			**15**	
	All metal	√ or ×		
	All plastic	√ or ×		
	Hybrid	√ or ×		
• Brief verbal instructions		√ **or** ×	**16**	

B) ***Time out (before skin/ port closure)***				
Remarks	***Code***	***Status***		
	17	√ **or** ×	• Special attention (checkup)	
	17 (a)	Checked/NA	Operative site	
	17 (b)	Checked/NA	Haemostasis	
	17 (c)	Checked/NA	Viscera	

	17 (d)	Checked/NA	Wall	
	17 (e)	Checked/NA	Ports	
	17 (f)	Checked/NA	Other	
	18	√ **or** ×	• Device disconnected	
C) ***Sign out (immediate after the procedure)***				
			Code	***Remarks***
• Electrosurgical record		√ **or** ×	**19**	
Haemostatic procedure, hand piece used, mode used, any critical events etc.		Special postoperative attention: Name of the recorder: Identification: Signature: Date: Time:		
• Specific record of critical event & the possible cause		√ **or** ×	**20**	

Methods

This research study was conducted as a Randomized Controlled Clinical Trial (RCT) among the patients of elective surgery in Khulna Medical College Hospital, Bangladesh from a period of 02.02.2010 to 02.02.2014. A total number of 360 hospital admitted patients within the age of 20 to 50 years were included as the study population. Among these patients, 300 patients underwent elective open abdominal surgery and the rest 60 patients underwent laparoscopic cholecystectomy. The 300 patients of open abdominal surgery were divided into group A (Control group) and B (Experimental group). On the other hand, the 60 patients of laparoscopic cholecystectomy were divided into group C (Control group) and D (Experimental group). The proposed Electro-surgical Safety Checklist (ES Checklist) was only applied to group B and D of study population. Simple random sampling was used as the sampling method for this research study.

Results

This RCT was conducted among the indoor patients of General Surgery wards of Khulna Medical College Hospital, Khulna with an ultimate view to evaluate an electro-surgical safety checklist compatible to our clinical setup. In the study, on the basis of simple random sampling, a total 360 patients were selected first on the basis of selection criteria which were basically divided into 4 groups (A, B, C & D). The age and sex distribution of the study population on both groups is described in table I.

Table I: Age and sex distribution of both groups of study population

Age in years	*Group A*	*%*	*Mean±SD*	*Group B*	*%*	*Mean±SD*
			(Open surgical group, n_1=300)			
20 - 30	21	14	38±2.1	39	26	37±1.5
31 – 40	82	54.7		67	44.7	
41 – 50	47	31.3		44	29.3	
Total	***150***			***150***		

Age in years	*Group C*	*%*	*Mean±SD*	*Group D*	*%*	*Mean±SD*
			(Laparoscopic surgical group, n_2=60)			
20 - 30	03	10	39±1.8	00	00	41±1.9
31 – 40	12	40		13	43.3	
41 – 50	15	50		17	56.7	
Total	***30***			***30***		

Table II suggests that among the patients of group A, the total number of critical events was 85 (56.7%) & on the contrary, it was 20 (13.3%) in case of group B. Again, in case of group C & D, it was 43.3% & 10% respectively.

Table II: Critical events in both groups of study population

Critical events	*Group A*		*Group B*		
			(Open surgical group, n_1=300)		
	No	***%***	***No***	***%***	***p value***
Adverse events	03	02	00	00	0.05
Near miss	21	14	03	2	
No-harm events	61	40.7	17	11.3	
Total	***85***	***56.7***	***20***	***13.3***	

Critical events	***Group C***		***Group D***		
			(Laparoscopic surgical group, n_2=60)		
	No	***%***	***No***	***%***	***p value***
Adverse events	01	3.3	00	00	0.5
Near miss	01	3.3	00	00	
No-harm events	11	36.7	03	10	
Total	***13***	***43.3***	***03***	***10***	

Table III: Critical events in both groups of study population

Average time consumption	Group B	Group D	
	minutes	minutes	p value
Sign in	01	1.5	
Time out	01	0.5	0.5
Sign out	1.5	01	
Average total time	03	03	

As stated earlier, ES checklist was applied only to group B & D. The average time required for all three principal steps is depicted in table 3 which points out that it was within the range of 0.5 to 1.5 minutes for each individual step. And the total time for all three steps was on an average 03 minutes for each Group (B & D).

When the results of this RCT, in term of critical events were plotted on diagram & expressed in Heinrick's pyramid, the following images were obtained (Figure 1 & 2).

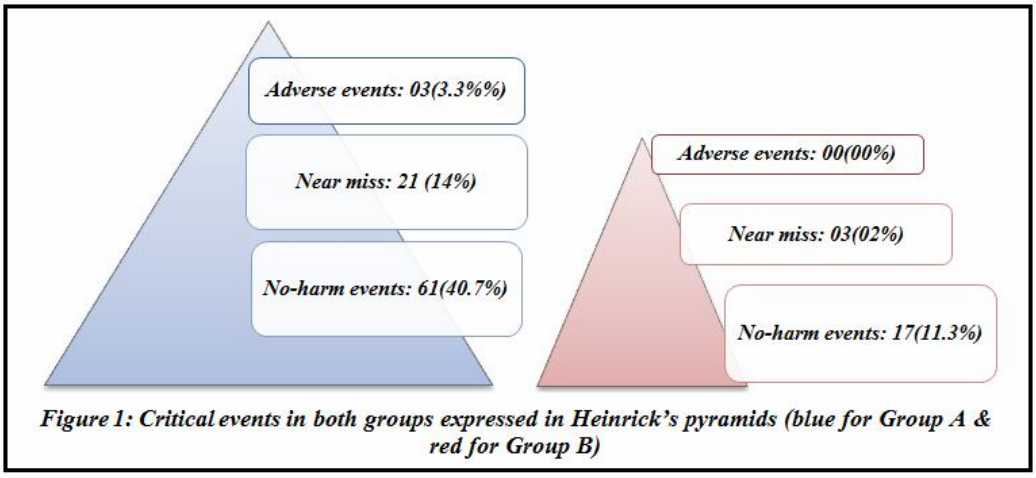

Figure 1: Critical events in both groups expressed in Heinrick's pyramids (blue for Group A & red for Group B)

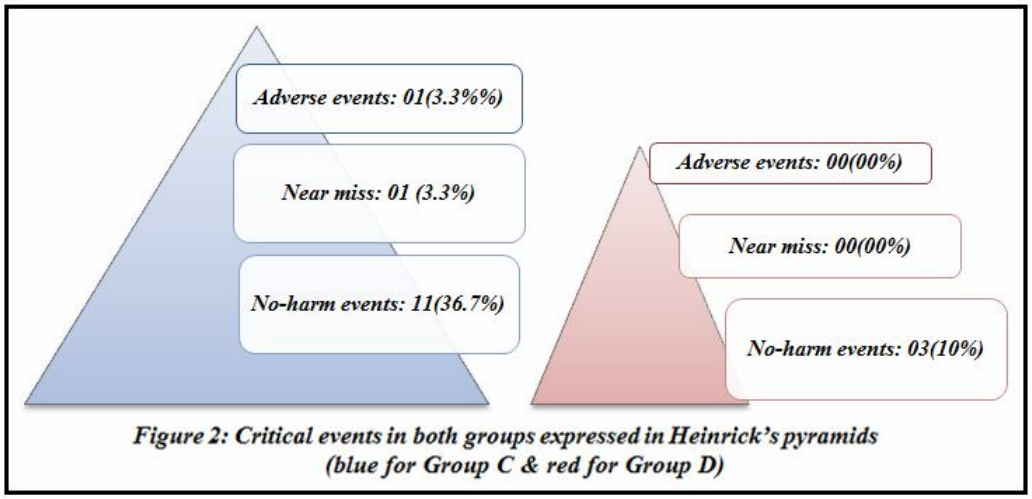

Figure 2: Critical events in both groups expressed in Heinrick's pyramids (blue for Group C & red for Group D)

Discussion

Electro-surgical complications are potentially common hazards in routine surgical practice which usually starts at unavoidable simple noticed or unnoticed minor mistakes of the members of the surgical team and finishes up at dangerous catastrophic ending or outcomes. As stated in the theory of Heinrick's safety pyramid, for every 300 near misses, there are 29 minor injuries & 01 major injury[6, 8], so if we can reduce the number of the minor events at the base of the pyramid, only then we can be able to control the shape as well as the top of the pyramid where the major events are situated. And the strategy of using ES checklist mentioned in this RCT is very directed to that specific goal.

The findings of this study reveals that the rate of critical events in group A, B, C & D are 56.7%, 13.3%, 43.3% & 10% respectively (Table II). It is important to note here that the rate of critical events is significantly lower in the experimental groups of this RCT (group B & D, where there was an application of ES checklist) in contrast to the control groups (group A & C, where no such safety checklist was used). Moreover, the rate of major critical events was found to be nil in case of application of ES checklist in the control groups (Table II, figure 1 & 2). The actual point of fact here is that application of ES checklist in control groups (group B & D) reduced the number of no harm events & near misses, therefore, ultimately reduced the number of major events (figure 1 & 2). So, if the base of the pyramid can be controlled, it is quite probable to have an auto-control at the top. And ES checklist is quite specific to such goal.

Another important aspect of this RCT is that there was an average consumption of additional 01 minute (0.5 to 1.5 minutes) for each of the three principal steps of ES checklist than the traditional application of routine electro-surgery without any safety checklist and the average time required for all three principal steps was found to be 03 minutes (table 3). In other words, the expenditure of additional 03 minutes for the ES checklist for each surgical patient has the significant potential to reduce the number of critical events in the very complicated field of routine electro-surgery.

Conclusion

To sum up the key fact- the electrosurgical generator is the most hazardous device used in the operation theatre on a daily basis. So, safe practice and rational use is essential & for which there is no easy alternative to a locally compatible, less time consuming Electro-surgical Safety Checklist in any clinical setup. And this RCT is an initial approach to settle this unsettled issue in our surgical practice.

Recommendation

Here, by this RCT, we would like to seek the kind attention of World Health Organization (WHO) & other policy making bodies of Health to conduct studies in large scale regarding this burning issue to give a definitively reliable & universally acceptable shape of this initial step to a final unequivocal conclusion.

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