

Is an Ammeter Necessary to Determine Sterilization by Fulguration, Using Modern Electrosurgical Generator Unit?

Marcelo Ivo Campagnolo¹, Ricardo dos Reis^{1,2}, Ricardo F Savaris^{2,3*}, Marcele Oliveira dos Santos⁴ and Lúcia Maria Kliemann⁴

¹Programa de Pós-Graduação em Medicina: Ciências Médicas, Universidade Federal do Rio Grande do Sul, Porto Alegre, RS, Brazil

²Programa de Pós-Graduação em Medicina: Ciências Cirúrgicas, Universidade Federal do Rio Grande do Sul, Porto Alegre, RS, Brazil

³Departamento de Ginecologia e Obstetrícia, Universidade Federal do Rio Grande do Sul, Porto Alegre, RS, Brazil

⁴Departamento de Patologia, Universidade Federal do Rio Grande do Sul, Porto Alegre, RS, Brazil

Received May 21, 2017; Accepted June 30, 2017; Published December 29, 2017

ABSTRACT

Objective: To determine which mode and potency of electrocoagulation, using a modern electrosurgical generator, yields the smallest unobstructed area of the fallopian tubes.

Methods: In a cross-sectional study, tubes from 48 hysterectomies were evaluated. Tubes were randomly allocated to one of the following groups: A-25Wx5 sec, n=17; B-30Wx5 sec, n=17; C-35Wx5sec, n=18; D-40W, 5 sec, n=20; E-40W visual inspection (blanch, swells, collapse), n=16; F-50Wx5 sec, n=8. Bipolar electrocoagulation was applied in groups A to E, and unipolar electrocoagulation was performed in group F. Coagulation mode was used in all groups. Transversal histological sections of the isthmus segment of the fallopian tube were digitally photomicrographed and luminal area (mm²) was measured with ImageJ software. Kruskal-Wallis or ANOVA tests were used for statistics.

Results: Ninety-six fallopian tube sections were analyzed. Median [range] non-occluded area (%) of each group was: A= 0.12[0 to 3.96], B= 0.17[0.01 to 3.3], C= 0.33[0.03 to 4.61], D= 0.22[0 to 3.53], E= 0.27[0.01 to 1.45] and F=0.94[0.08 to 2.67]. No statistical significance was found (p=0.3 - Kruskal-Wallis test)

Conclusion: Different potencies of bipolar or unipolar, using a modern electrosurgical generator, yielded no significant difference among groups in the unobstructed area of fallopian tubes.

Keywords: Fallopian tube, Electrocoagulation, Tubal ligation, Tubal occlusion, Bipolar, Unipolar

Synopsis: In the coagulation mode, different coagulation modes > 25 W do not produce significant differences in the occluded area.

INTRODUCTION

Tubal ligation is an effective form of permanent female contraception. In the World, it is the most commonly used method of contraception, being the method selected by 19% of women aged 15 to 49 who are married or in union [1]. In the United States, it is the second most commonly used form of contraception [2]. Among the different methods of tubal ligation, the unipolar electrocoagulation has the lowest long-term failure rate, but has been associated with thermal injury to the bowel and is rarely used [3]. Laparoscopic bipolar coagulation is a safe technique and, according to the American College of Obstetricians and Gynecologists (ACOG) practice bulletin, at least 3 cm of the isthmus

portion of the fallopian tube must be completely coagulated [3].

Corresponding author: Ricardo F. Savaris, Rua Ramiro Barcelos 2350/1124 – Porto Alegre, Rio Grande do Sul, Brazil, 90035-903, Tel/Fax: 55 51 33598117; E-mail: rsavaris@hcpa.edu.br

Citation: Campagnolo M I, Reis R D, Savaris R F, Santos M O D, Kliemann L M. (2017) Is an Ammeter Necessary to Determine Sterilization by Fulguration, Using Modern Electrosurgical Generator Unit?. J Womens Health Safety Res, 1(1): 13-17.

Copyright: ©2017 Campagnolo M I, Reis R D, Savaris R F, Santos M O D, Kliemann L M. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

The use of inline ammeter is not recommended or mentioned by the Brazilian Health Ministry, by the Brazilian Federation of Gynecologists and Obstetricians (FEBRASGO), or by the Argentinian Health Ministry. Therefore, it is necessary to provide evidences if the current practice of tubal ligation without inline ammeter, using the bipolar mode in a modern electrosurgical generator, deliver enough energy to collapse the lumen of the fallopian tube. The objective of this study is to verify which mode and potency of electrocoagulation, using a modern electrosurgical generator, attains adequate sterilization without the use of an ammeter.

MATERIAL AND METHODS

The institutional review board of Hospital de Clínicas de Porto Alegre and of the Hospital Femina de Porto Alegre approved this cross-sectional study. Inclusion criteria consisted in women with normal fallopian tubes that would be submitted to surgery. From April 2010 until December 2011, consecutive women scheduled for hysterectomy or tubal ligations were asked to permit use of the product of the hysterectomy for this study. Women who did not give written consent, those who had gynecologic cancer, hydrosalpinx, isthmic segment of the fallopian tube < 3cm, or abnormal anatomy of the fallopian tube were excluded. The procedures were done by one of the authors (MIC), or by another surgeon previously instructed about the protocol. During the procedure, each tube was randomly allocated to one of the following groups: A-25W x 5 sec; B-30W x 5 sec; C-35W x 5sec; D-40W, 5 sec; E-40W visual inspection (blanch, swells, collapse); F-50W x 5 sec. Randomization list was generated by a computer software. The randomized list was kept in sequenced sealed envelope, which was opened at the beginning of the surgery. All groups used the coagulation mode, because cutting mode is not possible in bipolar electrocoagulation. Bipolar electrocoagulation was applied in groups A to E, and unipolar electrocoagulation was performed in group F.

Electrocoagulation was performed in the coagulation mode using the WEM Model SS-501S electrosurgical generator (WEM Equipamentos Eletrônicos Ltda, Ribeirão Preto, SP, Brazil) with the Bipolar (Ref. 14.1048, EDLO, Canoas, RS, Brazil), or the unipolar forceps (Ref. 12231, Rhosse, Ribeirão Preto, SP, Brazil). Bipolar coagulation of the tubes was performed on an auxiliary table after the uterus was removed. Due to the characteristics of unipolar system, electrocoagulation of the fallopian tubes was performed before the removal of the uterus. Unipolar coagulation was considered as a control and was limited to 8 samples.

Fulguration of the tubes was performed on three contiguous areas, at least 3cm in length, as recommended in the literature [7].

Histology and analysis of the occluded area

Coagulated tubes were resected and fixed in formaldehyde 10% for histological analysis and embedded in paraffin. Paraffin blocks were cut 4 µm thick and were stained with hematoxylin and eosin. Four transversal sections were obtained from each block and analyzed by microscopy. The section with the highest thermal injury, according to Soderstrom et al. [5], was chosen for digital photomicrography. Digital pictures were taken using an Olympus BX51 microscope (Olympus Optical Co., Tokyo, Japan) connected to a digital color camera/Q-Color 5 (Olympus). Images were obtained with a 4X objective UPL an FI (resolution: 2.75µm), at a size of 2560x1920 pixels (resolution: 1mm = 590 pixels), under standard lighting conditions.

ImageJ analyses

In order to reduce bias, each slide was coded and the open lumen area (mm²) and percentage were blindly analyzed for the outcomes: luminal area (mm²) and percentage of area open in the lumen. These outcomes were analyzed with ImageJ software (ImageJ v1.43j; National Institutes of Health, Bethesda, MD, USA available at <http://rsbweb.nih.gov/ij/>). Briefly, a circle was drawn around the lumen of the fallopian tube. The outside area was cleared and the image was converted into 8 bits. The image was adjusted for a threshold, using a dark background. Next, the region of interest (ROI manager) was activated and saved in a file. From the ROI manager, the software calculated the total and relative open area of the section.

Sample size, statistical analysis and ethical issues

Sample size was calculated based on data previously published [5] and using the formula described in the literature [7]. The following parameters were used: an alpha error of 0.05, power of 0.8, total occlusion of the lumen (100%) using bipolar coagulation at 35 W, a reduced occluded area (85%) with lower potencies, and a standard deviation of 10. These figures yielded a sample size of a minimum of 8 cases in each group.

GraphPad Prism version 6 for Macintosh (GraphPad Software, Inc., San Diego, California, USA) was used for statistical analysis of the variables, using the Kruskal-Wallis test. $AP < 0.05$ considering significant. This study was submitted and approved by *Comitê de Ética em Pesquisa* – Hospital de Clínicas de Porto Alegre and Grupo Hospitalar Conceição.

RESULTS

Fifty-nine women were invited to participate in the study, and 11 were excluded (6 had a short isthmic segment; 5 had abnormal anatomy of the fallopian tube). Forty-eight women, i.e., 96 fallopian tubes, were submitted to bipolar or unipolar coagulation. Characteristics of the population are depicted in **Table 1**. No significant difference was observed among groups, either in total or relative area due to the high

variability (**Figure 1**). Although not significantly different from the other groups, the highest mean occluded area of the fallopian tube was obtained in group E (40 W visual inspection). In average, this method did not occluded 8.3% (95%CI: 5.4 to 16.5) of lumen of the fallopian tube. The

mean $\pm$ SD time of coagulation for each grasp in group F (40 W visual) was 3.8 ± 1 seconds. The highest open area was obtained with the unipolar method 29.5% (95%CI: 13.5 to 45.5).

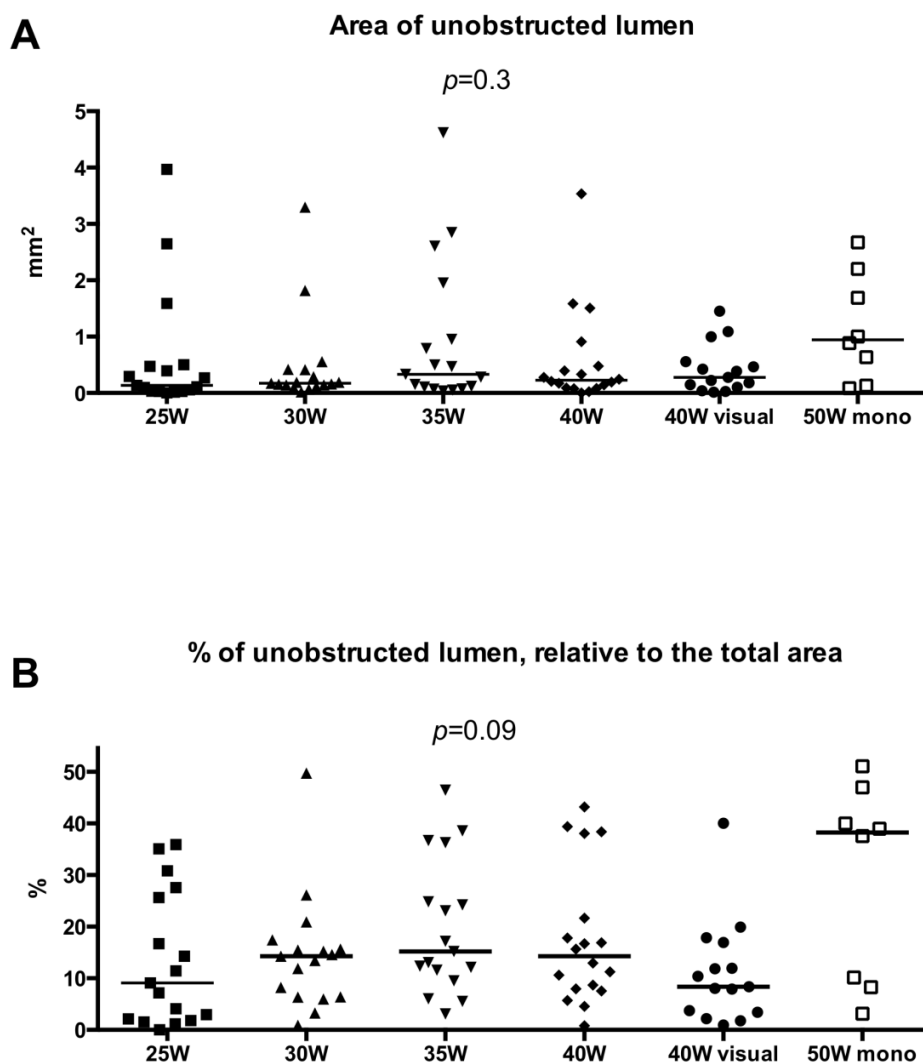


Figure 1. A- Unobstructed area in mm² of the fallopian tube after unipolar (50W mono) or bipolarcoagulation using different wattages.B- Percentage of the lumen that remained open after bipolar or unipolar electrocoagulation. Bar represent median. Kruskal-Wallis test was used for statistical analysis.

DISCUSSION

The new feature of modern electrosurgical generators, where constant electronic adjustments provide constant power through different tissue changes, leads us to investigate if total fulguration of the fallopian tube could be achieved without the use of an inline ammeter.

In this study, we used different potencies and modes and we were not able to find any statistical difference among

groups. The bipolar mode, independently of the wattage used, yielded a median occluded area of over 85%, while the 40 W with visual inspection provided around 92% of occlusion (**Figure 1**). These data are in accordance to those published in the literature [5]. The bursts of high-peak voltage desiccate the outer layers of the tube too quickly and prevent deep penetration by the electrons delivered. This high-peak voltage may explain the lowest coagulation area (around 61%) obtained with unipolar coagulation, which used 50W. Nevertheless, it is possible to achieve complete

coagulation of the lumen with bipolar mode, using ≥ 25 W for 5 seconds (**Figure 1**).

Table 1. Baseline characteristics of the studied population.

Parameter	Group of fulguration settings						<i>P</i> ⁱ
	25W ^a	30W ^b	35W ^c	40W ^d	40W ^e	50W ^f	
Age ^g	40.7(8)	37.6(7.7)	43.6(8.8)	37.1(8.2)	40.4(8.3)	40(4)	0.5
Gestations ^g	3.2(1.5)	2.9(1.5)	2.8(1.2)	3.3(0.9)	2.8(1.2)	1.5(1.7)	0.3
Parity ^g	3.2(1.5)	2.8(1.6)	2.5(1.3)	3.1(1.3)	2.6(1.1)	1.5(1.7)	0.4
Ethnicity ^h							
Caucasian	3	9	5	3	6	2	
non-caucasian	11	2	3	5	2	2	
Tubes from							
Abdom hysteretic	5	4	4	3	0	8	
Vaginal hysteretic	3	3	6	4	6	0	
BTL-Abdomen	8	10	7	12	9	0	
BTL-Vaginal	1	0	0	0	1	0	
BSO	0	0	1	1	0	0	
Total of tubes	17	17	18	20	16	8	

^a 25 W x 5 sec - bipolar

^b 30 W x 5 sec - bipolar

^c 35 W x 5 sec - bipolar

^d 40 W x 5 sec - bipolar

^e 40 W visual inspection - bipolar

^f 50 W x 5 sec - unipolar

BTL: bilateral tubal ligation

Abdomhysterec.: abdominal hysterectomy

BSO: bilateral salpingo-oophorectomy

^g numbers are given as mean(standard deviation)

^h Each fallopian tube of a patient was randomized to a different group.

ⁱ ANOVA

Based on our findings, it is possible to identify that total occlusion of the fallopian tube is feasible without the use of inline ammeter, which is incorporated with most bipolar generators in the US [8]. The importance of inline ammeter lies on the recognition that the fallopian tube is totally coagulated [5]. This recommendation is based from a review of 2267 procedures done before 1987, where failures on tubal ligation were observed [6]. In 1989, Soderstrom *et al.*, using 5 tubes derived from hysterectomy, demonstrated that bipolar system using 35 W in the coagulation mode yielded

complete coagulation of the fallopian tube. Likewise, using 20 tubes, complete coagulation of the fallopian tube was obtained with 25 W in the cutting mode. These results were based on a Kepplinger and Valley lab generators [5].

Modern electrosurgical generators have electronic adjustments, which provide constant power through different tissue changes, and can offer up to 40W. In addition, these new modern electrosurgical generators do not offer “pure cut” in the bipolar mode, thus the use of an inline ammeter is

necessary to indicate when the current through the fallopian tube has ceased flow.

Unfortunately, inline ammeters are not sold in Brazil, and the only orientation given by the Brazilian Health Ministry on tubal ligation is that the procedure should be performed with bipolar mode [9]. This lack of details could be related to the evolution of the electrosurgical generator units. New electrosurgical generators have a computer-controlled tissue feedback response system that senses tissue impedance and corrects the energy flow [10]. In addition, the report that bipolar coagulation system was highly effective for bilateral tubal ligation, if a segment of ≥ 3 cm was coagulated [4], may contribute to the lack of details given by the Brazilian Health Ministry, and from other institutions, such as the Argentinian Health Ministry [11] and the Brazilian Federation of Gynecologists and Obstetricians (FEBRASGO) [12].

The strengths of this study are the calculated sample size and the use of ImageJ software to quantify the unobstructed area of the fallopian tube. ImageJ provides an unbiased quantification of the open area, and this approach seems to be superior to visual inspection. Initially, we used the histological grading described by Soderstrom et al. [5], but the high inter- and intraobserver variation (data not shown) led us to use the ImageJ software. Hopefully, this method can be the gold standard to quantify the open lumen.

The main weakness of the study is its lack of external validity. Just one electrosurgical generator was used, so no extrapolations can make to other models. Another aspect is the degree of thermal injury. The histological analysis was done after the electrocoagulation was performed. It has been shown that complete occlusion may take up to 8 weeks to occur [13]. Therefore, our data may underestimate the real rate of the tubal occlusion.

This study brings new data about the unipolar occlusion rate that was thought to be the best method for tubal occlusion. In addition, it provides evidence that new generators can cause total occlusion of the fallopian tube. New settings for tubal fulguration, such as lower wattage and longer time may, be sought to reach the best occlusion rate without using an inline ammeter.

In summary, the modern electrosurgical generator used herein yielded similar degree of damage on the fallopian tube independently of the mode and potency used. These results may help to develop guidelines in places with low resource.

ACKNOWLEDGEMENT

Fundação de Incentivo a Pesquisa e Ensino (FIPE) – Hospital de Clínicas de Porto Alegre.

REFERENCES

1. United Nations (2011) World contraceptive use, 2011.
2. Zite N, Borrero S (2011) Female sterilisation in the United States. *Eur J Contracept Reprod Health Care*. 16: 336-340.
3. ACOG (2013) Practice bulletin no. 133: benefits and risks of sterilization. *Obstet Gynecol*. 121: 392-404.
4. Hulka JF, Reich R (1994) Sterilization techniques: Hulka JF, Reich H, editors. Textbook of laparoscopy. 2nd. Philadelphia: W.B. Saunders Co.
5. Soderstrom RM, Levy BS, Engel T (1989) Reducing bipolar sterilization failures. *Obstet Gynecol*. 74: 60-63.
6. Julious SA (2004) Sample sizes for clinical trials with normal data. *Stat Med* 23: 1921-1986.
7. Hoffman BL, Schorge JO, Schaffer JJ, Halvorson LM, Bradshaw KD, Cunningham FG, et al. (2014) Minimally Invasive Surgery. *Williams Gynecology*.
8. Peterson HB, Xia Z, Wilcox LS, Tylor LR, Trussell J (1999) Pregnancy after tubal sterilization with bipolar electrocoagulation. U.S. Collaborative Review of Sterilization Working Group. *Obstet Gynecol* 94: 163-167.
9. Brazil, Health Ministry. Secretary of Health policies (2002) Technical area of women's health. Family planning: technical manual/Secretary of policy of health, Technical area of Women's health]. Standards and Technical manual.
10. Advincula AP, Wang K (2008) The evolutionary state of electrosurgery: where are we now? *Curr Opin Obstet Gynecol* 20: 353-358.
11. Trumper E, Provenzano B, Prigoshin P (2009) Health Ministry of the Nation (Argentina)-Scientific document-tubal ligation.
12. Poli MEH, Mello CR, Machado RB, Pinho Neto JS, Spinola PG, Tomas G, et al. (2009) FEBRASGO - Manual of Contraception. *Femina* 37: 459-492.
13. Tucker RD, Benda JA, Mardan A, Engel T (1991) The interaction of electrosurgical bipolar forceps and generators on an animal model of fallopian tube sterilization. *Am J Obstet Gynecol* 165: 443-449.