Are women with intrapartum tubal ligation more likely to regret?

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POWERED BY ENTOG

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ABSTRACT

Tubal ligation is a long-time surgical method of definitive female contraception based on the blockage of the tubal lumen and further iatrogenic tubal infertility. Despite being a very efficient method, it requires a surgical procedure and it's considered a definitive method, given that reversal and restoration of tubal patency is a complicated procedure with low rates of success, thus requiring most of the women with pregnancy desire to resort to IVF. Nowadays there are other highly effective, reversible and long-acting minimally invasive method, such as intrauterine devices or subcutaneous implant. However, tubal ligation is still a frequent procedure.

Rates of tubal ligation are highly variable within and between countries and especially between different cultures. Also, the rates of regret are highly variable depending on many factors such as age, marital status, parity and outcome of pregnancies.

This is a multicentric international observational cross sectional study. The research question is whether there are differences in regret rates between elective and intrapartum tubal ligation. A cohort study will be conducted, based on telephone structured interviews to women who had undergone this procedure 10 to 15 years before.

KEYWORDS

Contraception; Sterilization, Tubal Ligation; Regret Rates

ACRONYMS AND ABBREVIATIONS

ENTOG	European Network of Trainees in Obstetrics and Gynecology
EU	European Union
HFEA	Human Fertilization and Embryology Authority
IUD	Intrauterine Device
IVF	In Vitro Fertilization
IVI	Instituto Valenciano de Infertilidad
RM	Reproductive Medicine
UNESCO	United Nations Educational, Scientific and Cultural Organization

INTRODUCTION

Tubal ligation is an old surgical method of definitive female contraception. It is indicated when women choose definitive contraception or in medical situations in which a pregnancy represents an unacceptable risk to the patient's life or leads to high risk unfavorable maternal-fetal outcome.[1] According to Portuguese Legislation, voluntary sterilization can only be performed in women over 25 years of age, who unequivocally express and in writing, willingness to submit to the intervention of definitive contraception.[2]

Tubal ligation can be performed in the immediate postpartum period by laparotomy during cesarean section or by infraumbilical minilaparotomy in the first 48 hours after vaginal delivery. The surgical techniques most frequently used in these situations are bilateral partial salpingectomy using the Pomeroy technique or the Kroener technique.[1,3] Tubal ligation can also be performed electively, by laparoscopy or minilaparotomy, through total or partial salpingectomy, through ring ligation or through electrosurgery, destroying and sectioning the fallopian tube. Laparoscopy is the route of choice, with laparotomy and minilaparotomy being the most used in peri-partum sterilizations. [1,3]

Regarding the effectiveness of this contraceptive method, the Pearl index for bilateral tubal ligation is 0.5-1.8%, with a failure rate (considering all available techniques) less than 1%.[1,3] The risks associated with this procedure include those inherent to surgery, namely those associated with general anaesthesia and laparotomy / laparoscopy, but also an increased risk of ectopic pregnancy. This contraceptive method does not provide protection against sexually transmitted infections, nor does it allow control of the menstrual pattern. [1]

Despite being a very efficient method, it requires a surgical procedure and it's considered a definitive method, given that reversal and restoration of tubal patency is a complex procedure with low rates of success. As a non-reversible method, the possibility of regret is a major concern. Women who intend to restore fertility have one of two options: restoration of tubal patency or IVF.

Nowadays there are other highly effective, reversible and long-acting minimally invasive methods, such as the levonorgestrel-releasing or copper intrauterine device or the subcutaneous implant. [1]

Regret rates vary widely, depending not only on the country, region or culture, but also on other factors, such as age, marital status, parity and outcome of pregnancies.[1] According to different authors, the rate of regret after the procedure varies from 2 to 28% .[1,5,6,7]

A quite common practice is to perform tubal occlusion techniques during caesarean section. Pregnancy and delivery are emotional and extremely important moments in any woman's life. The decision to undergo a tubal ligation in such circumstances may not be thoroughly reflected. On the other hand, deferred and elective sterilization, proposed in the context of Family Planning medical appointment, may reflect a more weighted choice and be associated with a lower rate of regret after the procedure. It is not clear, however, whether there is a statistically significant difference between the rates of regret after peripartum tubal ligation and after elective tubal ligation.[8]

AIMS

The main aim of this study is to compare rates of regret after elective or intrapartum tubal ligation

This study also aims to address:

- Risk factors for tubal ligation regret;
- How likely would women choose this method again;
- What would be women's first choice if they were able to choose a new method.

CRITERIA FOR RESEARCHERS RECRUITMENT

INCLUSION CRITERIA:

- Candidates must be residents or specialists in Obstetrics and Gynecology.
- Candidates must work in a department that regularly performs tubal ligations and that are able to consult patient records.

FAVORABLE ASPECTS:

- From different countries

EXCLUSION CRITERIA:

- None

METHODS

Study Design

Cohort prospective study

Reference Population

Women submitted to tubal ligation – intrapartum and elective tubal ligation –, who are currently between 50 and 55 years old.

Subject Inclusion/exclusion criteria

- INCLUSION
    - Women submitted to tubal ligation, who are currently between 50 and 55 years old
- EXCLUSION
    - Patients who refuse to participate.
    - Patients impossible to contact by telephone (who do not answer, whose phone number is wrong).

Intervention and Follow-up

Each researcher will search for patients that fulfil the criteria of inclusion.

A structured interview will be given to all researchers who will call (phone call) patients and perform the interview (*Annex*).

COLLECTION OF SAMPLES AND INFORMATION

Sample gather protocol and objective of sample collection

Answers to the interviews as well as patients' clinical data (see in independent variables) will be stored in an excel/SPSS database.

Preservation

The answers will be stored in an electronic database that only researchers will have access to.

STATISTICAL METHODOLOGY

The database will be rigorously defined with the variables destined to be analyzed according to the objectives set. The necessary information will be collected.

Finally, and prior to the statistical study, an exploratory data analysis will be carried out to review the quality of the information extracted.

Study Variables

Exposure measures (Independent) / Other variables

CODE	TYPOLOGY	DESCRIPTION
AGE_TL	Discrete numeric	Age (at TL date)
AGE_NOW	Discrete numeric	Age (current)
NAT	Categorical	Nationality
EDU	Discrete numeric	Education (at TL date)
MARIT	Categorical	Marital Status at TL date (single, married, divorced, separated, widow)
GESTA	Discrete numeric	Number of gestations (at TL date)
DELIV	Discrete numeric	Number of vaginal deliveries (at TL date)
CES	Discrete numeric	Number of cesarean sections (at TL date)
COMP_PERIP	Categorical	Peripartum complications (yes/no)
OFFS	Categorical	Offspring death (yes/no)
TIME_TL	Discrete numeric	Time elapsed between last delivery and TL
REAS	Categorical	Reason that led to the option for TL ("*Illness"*; *"I had all the children I wanted; "My partner had all the children he wanted; "financial reasons"; "Other")*
TYPE_TL	Categorical	Type of TL (intrapartum/elective)
COMP_LT	Categorical	Postoperative complications specifically due to LT (yes/no)

Outcome measures (Dependent)

CODE	TYPOLOGY	DESCRIPTION
Q1	Categorical	*"Do you regret having performed a tubal ligation?"* (yes/no)
Q2	Categorical	*"After TL, was there any moment you wanted to have more children?"* (yes/no)
Q3	Categorical	"*Did you change your partner after LT?"* (yes/no)
Q4	Categorical	*"How likely would you be to choose this method if it was today?"* (yes/no)
Q5	Categorical	*"If you were able to choose again, which of the following methods would you choose?"* (pill, IUD, implant, condom)
Q6	Categorical	"*Have you tried or undergone any kind of reproductive treatment after TL?*" (yes/no)
Q6A	Categorical	(If answer to Q6 is yes) *"Which of the following procedures did you undergo?*" (IVF/ restoration of tubal patency)
Q7	Categorical	*"Did you get pregnant after tubal ligation?"* (yes/no)

Sampling method and sample size

Sample selection will be carried out by simple random sampling, recruiting individuals at random from the population that has the characteristics of interest (women undergoing peripartum or elective tubal ligation, who are currently between 50 and 55 years old).

Assuming a 28% of maximum regret rate and a difference of 10% between groups, the estimated sample size with a confidence interval of 95% and 80% of power with be around 350. So, in order to have a representative population, we aim to get data from 500 patients, around 250 in each group.

Statistical data analysis

A descriptive analysis (numerical and graphical) will be carried out, according to the type of the variable:

- For quantitative variables, the usual summary statistics will be used (maximum, minimum and quartiles, and measures of dispersion such as the mean and standard deviation). Graphically, the data will be represented by histograms and box-and-whisker plots or bar diagrams, depending on whether the quantitative variable is continuous or discrete.

- For categorical variables, tables of frequency and proportions will be provided along with 95% confidence intervals. Graphically, bar charts will be used to represent the data.

Objectives assessment

In case comparative analysis has to be undertaken, depending on the distribution of continuous variables, parametric (t-tests) or non-parametric (Mann-Whitney test) will be used to compare continuous variables between the 2 groups. For comparison of proportions, the Chi-square test will be used. To carry out multivariate analysis, linear or logistic regression will be used, for continuous or categorical dependent variables respectively.

STUDY PLAN

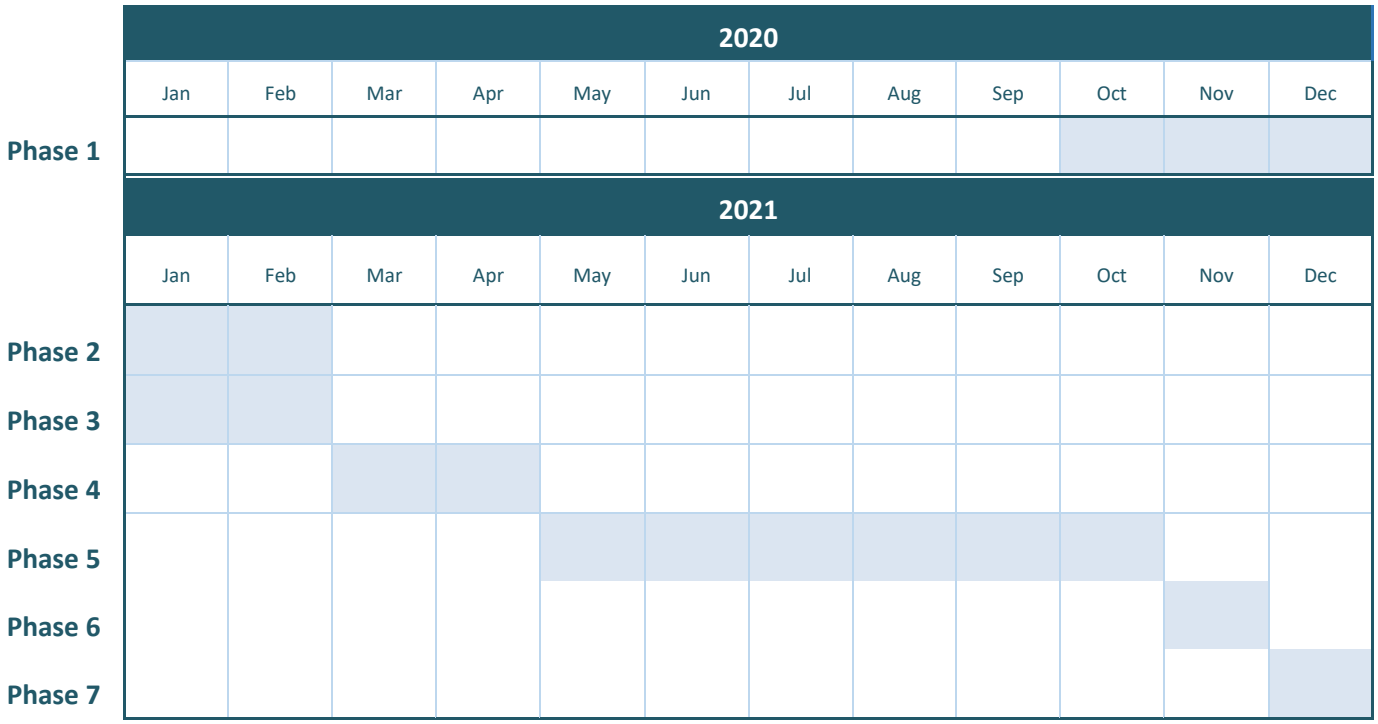
This study will be divided in the following phases:

1. Phase 1: elaboration of the protocol
2. Phase 2: Submission to ENTOG multicentre research groups.
3. Phase 3: Evaluation and approval by the ENTOG executive committee
4. Phase 4: Publication of the protocol and recruitment of researchers.
5. Phase 5: Acquisition of data
6. Phase 6: Description of the results and elaboration of the paper and/or presentation.
7. Phase 7: Publication of the final work.

The main researcher and the senior researchers are involved in all of the phases of this study.

Recruited researchers will be involved in phases 4 and 5. These researchers will also review the final version of the work, and may be called to actively participate in phase 6 and 7 if needed.

TIMELINE



ETHICAL CONSIDERATIONS

This Research Project respects the fundamental principles of the Declaration of Helsinki, the Council of Europe Convention on Human Rights and Biomedicine, the UNESCO Universal Declaration on the Human Genome and Human Rights, as well as the requirements ofnational requirements in the field of biomedical research, as required by Organic Law 3/2018, of December 5, on Protection of Personal Data and guarantee of digital rights and bioethics and the Good Standards of Clinical Practice.

The personal data will be treated according to Regulation EU 2016/679 of the European Parliament and of the Council of April 27, 2016 concerning the protection of natural persons with regard to the processing of personal data and the free circulation of such data.

There isn't any kind of identification of the subjects, either real or coded identification, so anonymity is guaranteed.

FINANCIAL SUPPORT

No funding is expected to be needed.

Side costs, such as costs related to interviews (phone calls for instance) are to be covered by each specific researcher.

PUBLICATION

Submission for potential publications in scientific journals, presentations at scientific events and / or publication / presentation in other social media are expected.

However, it is still not possible to assert the specific journals, platforms or events.

REFERENCES

1. 1. Sociedade Portuguesa da Contraceção. 2020. "*Consensos Sobre Contraceção*".
2. Decreto-Lei nº 3/84, publicada em Diário da República em 1984-03-24, Artigo nº 10 "Esterilização Voluntária".
3. Cochrane Database of Systematic Reviews. 2016. *"Techniques for the interruption of tubal patency for female sterilisation"*
4. Lashen H. 2010. "*Tubal sterilization. In: The Fallopian Tube in Infertility and IVF Practice."* Cambridge University Press; 113–22
5. Shreffler KM, et al. 2016. "*Reasons for tubal sterilisation, regret and depressive symptoms*". J Reprod Infant Psychol; 34:304–13.
6. Chi IC, Jones DB, et al. 1994. "I*ncidence, risk factors, and prevention of poststerilization regret in women: An updated international review from an epidemiological perspective.*" Obstet Gynecol Surv; 49:722–32
7. Jahanian Sadatmahalleh S, et al. 2018. "*Evaluation of influencing factors on tubal sterilization regret: A cross-sectional study*". Int J Fertil Steril; 12:200–6.
8. Fernandes AM, et al. 2006. "*Laqueadura intraparto e de intervalo*". Rev Assoc Med Bras;52:323–7.

ANNEX

INERVIEW GUIDE

Phone number (contact):_____

Age (at TL date): _____ **Age (current): _____**

Nationality:_____ **Education (at TL date): _____**

Marrital status (at TL date): (__) Single (__) Married (__) Divorced (__) Separated (__) Widow

Obstetric History: Nr. of pregnancies: __ | Nr. of deliveries: __ | **Vaginal**: __ | **Cesarean: ___**

Peripartum complications: (__) yes (__) no

Offspring death: (__) yes (__) no

Time elapsed between last delivery and TL: ____

Reason that led to the option for TL:

(__) "*Illness"*

(__) "*I had all the children I wanted"*

(__) "*My partner had all the children he wanted"*

(__) "Financial reasons"

(__) "*Other":* _____

Type of TL: (__) intrapartum (__) elective

Postoperative complications specifically due to LT: (__) yes (__) no

Questão	**YES**	**NO**
Q1 – *Do you regret having performed a tubal ligation?*		
Q2 – *After TL, was there any moment you wanted to have more children?*		
Q3 – *Did you change your partner after LT?*		
Q4 – *How likely would you be to choose this method if it was today?*		

Q5 – *If you were able to choose again, which of the following methods would you choose?*		*"Pill"*
		"IUD"
		"Implant"
		"Condom"

	YES	**NO**
Q6 – *Have you tried or undergone any kind of reproductive treatment after TL?*		

Q6A (If answer to Q6 is **YES**) **–** *Which of the following procedures did you undergo?*		*"In Vitro Fertilization"*
		"Restoration of tubal patency"

	YES	**NO**
Q7 – *Did you get pregnant after tubal ligation?*		