

# Opportunistic Salpingectomy for Permanent Contraception: A Cross Sectional Study in Portugal

## Salpingectomia Profilática como Método de Contraceção Definitiva: Estudo Transversal em Portugal



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### ABSTRACT

**Introduction:** Opportunistic bilateral salpingectomy has been proposed as an ovarian cancer risk-reducing strategy namely as a means of tubal sterilization. We aimed to assess what were the procedures for interval and peripartum sterilization carried out nationwide, related motivational aspects and influential demographic or professional factors.

**Material and Methods:** Cross-sectional study based on an original survey sent to Obstetrics and Gynecology specialists and residents from across the country in 2019.

**Results:** Two hundred and twenty-five answers were obtained from 42 institutions (37 from the public sector). Laparoscopic tubal electrocoagulation (61%) was the most common procedure for interval sterilization followed by salpingectomy (28%). Major reasons pointed out for not performing salpingectomy were increased operative time (48.5%) and procedure not considered (45.5%). In some hospitals, the choice of salpingectomy depended on specific criteria namely surgical team decision. During cesarean-section, sterilization was most frequently performed using the modified Pomeroy technique (54%), followed by salpingectomy (32.5%), with a statistically significant prevalence in the north of the country. Sixty-nine percent of Portuguese Obstetrics and Gynecology residents and specialists consider that salpingectomy should be the procedure offered to women asking for definitive contraception.

**Discussion:** Although data are limited, salpingectomy at the time of cesarean delivery appears feasible and safe and this context might represent the best opportunity for intervention.

**Conclusion:** Opportunistic salpingectomy is not the most common sterilization procedure performed in Portugal, but it was considered the best choice to offer. Its benefits and risks should be discussed with women.

**Keywords:** Ovarian Neoplasms/prevention & control; Prophylactic Surgical Procedures; Salpingectomy; Sterilization, Reproductive; Surveys and Questionnaires

### RESUMO

**Introdução:** A salpingectomia profilática foi proposta como estratégia de redução do risco de cancro do ovário e método de contraceção definitiva. O objetivo deste estudo foi conhecer os procedimentos realizados a nível nacional para contraceção definitiva de intervalo e peri-parto, a opinião e motivações dos clínicos, e os fatores demográficos ou profissionais influentes.

**Material e Métodos:** Este é um estudo analítico transversal, baseado num questionário original enviado durante o ano de 2019 a especialistas e internos de Ginecologia-Obstetrícia a exercer em Portugal.

**Resultados:** Obtivemos 225 respostas provenientes de médicos a exercer em 42 hospitais (37 públicos). A laqueação tubar laparoscópica por electrocoagulação e corte (61%) foi o método mais frequentemente utilizado na mulher não grávida, seguido da salpingectomia (28%). Os principais motivos apontados para não realizar salpingectomia foram o aumento do tempo operatório (48,5%) e tratar-se de procedimento não equacionado (45,5%). Em alguns hospitais, a realização deste método dependia da decisão da equipa cirúrgica. No contexto *per-cesariana*, a técnica mais comum foi a de Pomeroy modificada (54%), seguida da salpingectomia (32,5%), com uma concentração no Norte do país com significado estatístico. A maioria (69%) dos participantes consideraram que a salpingectomia deveria ser o procedimento disponibilizado.

**Discussão:** Apesar da evidência científica ainda ser escassa, a salpingectomia *per-cesariana* parece exequível e segura, podendo representar a melhor oportunidade para intervenção no contexto da contraceção definitiva.

**Conclusão:** A salpingectomia profilática não é o procedimento de esterilização mais comum em Portugal, mas foi considerada como a escolha mais adequada. Os seus benefícios e riscos devem ser discutidos com as mulheres.

**Palavras-chave:** Esterilização Reprodutiva; Inquéritos e Questionários; Neoplasias dos Ovários/prevenção e controlo; Procedimentos Cirúrgicos Profiláticos; Salpingectomia

### INTRODUCTION

Ovarian cancer is the most lethal gynaecological cancer in developed countries, showing an increasing incidence in recent decades and associated with 184,799 deaths worldwide in 2018.<sup>1</sup> Current secondary prevention strategies, namely including cancer antigen 125 (CA 125) level determination and gynaecological ultrasound, have not proved effective, leading to unnecessary interventions and compli-

cations, with no reduction in mortality.<sup>2-5</sup> High grade serous carcinoma (HGSC), the most common histological subtype, is mostly (> 70%) diagnosed in advanced stages (stages III and IV, according to the classification of the International Federation of Gynaecology-Obstetrics) and despite the evolution of chemotherapy treatments over the past 30 years, a 35% five-year survival rate remains unchanged.<sup>6,7</sup>

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Primary prevention strategies are recommended and prophylactic adnexectomy is recommended at age 35 or after having accomplished the patient's reproductive desire in the presence of a known breast cancer gene 1 (BRCA1) mutation (up to 60% lifetime risk of having HGSC) or at a later age in case that a mutation associated with a lower risk has been diagnosed.<sup>8</sup> A systematic and extensive histological analysis of the fallopian tubes of these patients has shown the presence of serous tubal intraepithelial carcinoma (STIC) and occult carcinomas in a high percentage of patients,<sup>9</sup> allowing the identification of a carcinogenesis sequence in which STICs are the precursor lesions that detach and implant in the ovary, giving rise to HGSC of the ovary, fallopian tube and peritoneum.<sup>6</sup> Subsequent studies have confirmed that the gene expression and immunohistochemistry profiles of HGSC are rather associated with the Müllerian epithelium (of the fallopian tubes) than the mesothelial epithelium (of the ovary surface).<sup>9,10</sup>

This new model of carcinogenesis with tubal origin has significant clinical implications namely regarding primary prevention, since low-risk patients are affected by most cases of ovarian HGSC (90% - 95%). Therefore, opportunistic salpingectomy has been recommended in 2010 by the British Columbia's Ovarian Cancer Research Program (OvCaRe group), i.e. tubal ligation in healthy women already undergoing pelvic surgery for another indication, in order to reduce the incidence of HGSC of the ovary, fallopian tube and peritoneum. A few more years will be required to assess the real impact of tubal removal on ovarian cancer incidence and mortality, but current evidence shows an absence of risk (mainly surgical<sup>6</sup> and decreased ovarian reserve)<sup>11</sup> and a favourable cost-effectiveness analysis.<sup>12</sup> For this reason, salpingectomy in addition to hysterectomy for benign pathology or as an alternative to tubal ligation is already recommended by international organisations, namely the American College of Obstetricians and Gynecologists (ACOG) and the Royal College of Obstetricians and Gynaecologists (RCOG).<sup>13,14</sup> The feasibility of opportunistic salpingectomy in peri-partum<sup>15-19</sup> or other non-gynaecological abdominal surgeries (e.g. laparoscopic cholecystectomy) and as a first risk-reducing strategy in women with BRCA1/2 mutation, which would allow delaying oophorectomy and reducing the risks of osteoporosis and cardiovascular disease associated with a premature failure of ovarian function, is still under assessment.<sup>20</sup>

The additional benefits of opportunistic salpingectomy include the reduced risk of surgical re-intervention for chronic pelvic pain, hydrosalpinx, pyosalpinx, tubo-ovarian abscess and ectopic pregnancy, in addition to its high contraceptive efficacy.<sup>21</sup> On the other hand, in the case of regret and desire for later motherhood, a surgical recovery of tubal function is not possible, leaving only the use of medically assisted procreation techniques.

In Portugal, opportunistic salpingectomy was assessed in 2020 by the Consensus on Contraception<sup>22</sup> as a definitive contraceptive procedure, as well as in the Consensus on Gynaecological Cancer<sup>23</sup> in the context of hysterectomy

with ovarian preservation or other intra-abdominal surgery. The national distribution of different female sterilisation procedures in non-pregnant women and in peripartum is unknown and may vary widely between and within clinics according to existing protocols, individual beliefs and knowledge of available evidence. In view of the above, this was the first Portuguese study aimed to assess its distribution and providing information on the grounds underlying the procedures. In addition, it was aimed to identify the demographic and professional factors underlying the conflicting opinions and possible barriers to salpingectomy.

## MATERIAL AND METHODS

This was a cross-sectional analytical study, including data obtained by applying an original 28-item questionnaire (see Appendix 1: [https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/14033/Apendice\\_01.pdf](https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/14033/Apendice_01.pdf)) to a sample of gynaecology and obstetrics registrars and consultants working in mainland Portugal and the autonomous regions. It was carried out online through the Google Forms platform and was available from 10 August 2019 to 30 November 2019.

Prior to its implementation, the adequacy to the objective of the study was tested through a pilot test involving gynaecology and obstetrics consultants and registrars working in our department. The questionnaire was subsequently disclosed throughout the different public departments of gynaecology and obstetrics and was disseminated nationwide by the Portuguese Network of Trainees in Obstetrics and Gynaecology (PONTOG), the Portuguese Society of Gynaecology (SPG) and Facebook® social networking.

No approval by the local ethics committee was required given the absence of interventions and use of patient data. The participants' informed consent was ensured at response submission since it was clearly informed at that stage that by submitting the questionnaire these would be consenting to the use of their data for statistical analysis. IBM SPSS Statistics® version 25 (SPSS Inc., Chicago, Illinois, USA) software and chi-square test were used, in addition to Fisher's exact test (comparison of groups regarding nominal variables), Mann-Whitney test, Kruskal Wallis test (comparison of two or more groups regarding continuous variables with non-Gaussian distribution) and Spearman's correlation test (analysis of the relationship between two ordinal and/or continuous variables with non-Gaussian distribution). Statistical significance was considered for  $p$ -values < 0.05. The analysis of the recommended procedure offered to patients was performed per public institution and per participant regarding all the remaining questions.

## RESULTS

A total of 225 responses were obtained (see Appendix 2: [https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/14033/Apendice\\_02.pdf](https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/14033/Apendice_02.pdf)) from gynaecology and obstetrics consultants and registrars working in 42 hospital institutions: 37 public hospitals (213 responses) and five private hospitals. The demographic and

professional characterisation of the participants is shown in Table 1; 84% of the national public departments were represented (distribution shown in Fig. 1), including all A1, A2 and B1-type departments. A positive correlation was found between the number of responses and the department typology (correlation coefficient = 0.432;  $p$ -value = 0.008), with higher number of responses obtained from larger departments.

The recommended surgical technique made available in 61% of the hospitals to patients seeking permanent contraception was laparoscopic tubal ligation, followed by laparoscopic salpingectomy (28%) and laparoscopic tubal ligation with Yoon rings, laparotomy for tubal ligation and laparotomy for salpingectomy with lower representation (Fig. 1). There were no statistically significant differences between the respondent departments as regards region, department type, training suitability and availability of surgical reversal of tubal ligation.

When questioned about the possibility of salpingectomy being an option, 47% of the respondents have described that it could be a surgical option to be recommended in their hospital, depending on specific criteria (Table 2) from which the available surgical team (65%) stood out. It is worth mentioning that the patient's preference was mostly described in 'other options' item. Most of the respondents (84%) have described not knowing the rate of salpingectomy vs. ligation in their hospital. Only 15% of the respondents have described that salpingectomy was not among the surgical options recommended in their hospital (Table 3), mostly due to an increased surgical time (49%) and to the fact that it was not considered as an option (46%).

As regards disclosed information to women seeking permanent contraception, only 37% of the respondents have considered that any information on the advantages and disadvantages of salpingectomy vs. ligation was systematically provided in their hospital, as well as the patient's choice

Table 1 – Characteristics of the study population

Participants (225)	n (%)	Public departments	n (%)*	n (%)†
<b>Age</b>		<b>Region</b>		
25 - 30	44 (19.6)	Northern	12 (32.4)	58 (27.2)
30 - 35	58 (25.8)	Central	6 (16.2)	64 (30.0)
35 - 40	43 (19.1)	Lisbon and Tagus Valley	13 (35.1)	70 (32.9)
40 - 45	18 (8.0)	Southern (Alentejo and Algarve)	4 (10.8)	12 (5.6)
45 - 50	7 (3.1)	Autonomous regions	2 (5.4)	9 (4.2)
50 - 55	14 (6.2)			
55 - 60	24 (10.7)	<b>Typology</b>		
60 - 65	15 (6.7)	A1	5 (13.5)	68 (31.9)
65 - 70	2 (0.9)	A2	8 (21.6)	46 (21.6)
		B1	16 (43.2)	65 (30.5)
<b>Gender</b>		B2	8 (21.6)	34 (16.0)
Female	180 (80.0)			
Male	45 (20.0)	<b>With training capability</b>		
		Yes	32 (86.5)	197 (92.5)
<b>Experience</b>		No	5 (13.5)	16 (7.5)
Registrars	68 (30.2)			
Consultants	157 (69.8)	<b>Availability of tubal ligation reversal</b>		
		Yes	5 (13.5)	52 (24.4)
<b>Involvement in Family Planning consultations?</b>		No	32 (86.5)	161 (75.6)
Yes	127 (56.4)			
No	98 (43.6)			
<b>Involvement in DF? ‡</b>				
Yes	166 (73.8)			
No	59 (26.2)			
<b>Involvement in caesarean deliveries?</b>				
Yes	211 (93.8)			
No	14 (6.2)			

\* Per total of public departments – 37; † Per total of participants – 213; ‡ DC - Definitive contraception

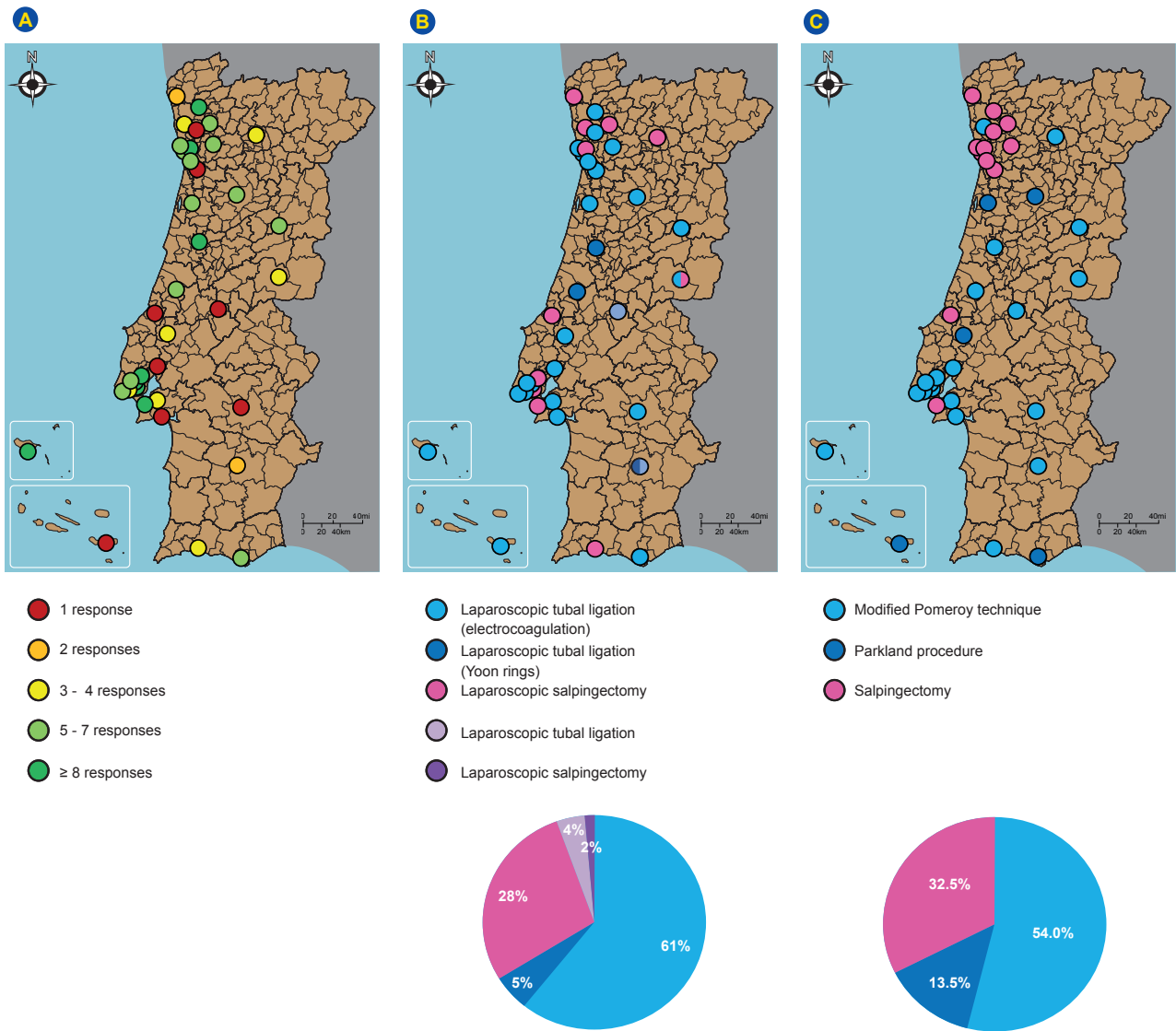


Figure 1 – Distribution of the number of responses (A), the procedure that was offered to non-pregnant mothers (B) and at the time of caesarean section (C), per institution.

Table 2 – Criteria for opportunistic salpingectomy when not filed

Criteria*	n (%)
Over 35 years of age	8 (7.5)
Associated pathology as contraindication to pregnancy	24 (22.6)
Social case	12 (11.3)
Three or more children	9 (8.5)
Family history of ovarian cancer	41 (38.7)
Known BRCA mutation with delayed oophorectomy	33 (31.1)
Depends more on the surgical team than any specific criterion	69 (65.1)
Other (added by respondents):	11 (10.4)
Patient's preference	6
Surgical proposal	2
At the time of caesarean section	2
Associated gynaecological pathology	1

\* This was only answered by the respondents (105) who have described that salpingectomy was considered as an option, with specific criteria– more than one option could have been selected

between both procedures. This rate was reduced to 31% in pregnant mothers. The patient's selection (salpingectomy or ligation) was described by 34.5% of the respondents as included in the informed consent. There were statistically significant differences in the systematic disclosure of the abovementioned information between hospitals where salpingectomy was performed vs. those where laparotomy was performed [non-pregnant women were informed in 78.1% vs. 22.7% of these hospitals, respectively ( $p$ -value < 0.001) while pregnant women were informed in 53.2% vs. 29.3% ( $p$ -value = 0.012)].

Female sterilisation at the time of caesarean section was carried out according to the patient's choice in all the institutions, as described by all respondents, when previously required during pregnancy, with an overall estimated rate between 5% and 10%. Modified Pomeroy technique was recommended (Fig. 1) in 54% of hospitals, followed by salpingectomy in 32.5% and Parkland technique in 13.5%. There were statistically significant differences in salpingectomy during caesarean section between the Northern region and the rest of the country (83% vs. 8%,  $p$ -value < 0.001).

When assessing whether salpingectomy would be an option during caesarean section, 46% of the respondents have considered that it depended on the surgical team and 31% that it was not an option in their institution. The main reasons for this (Table 3) included the fact that it was not considered as an option (57%), an increased surgical time (42%) and the fear of complications (36%). From the 141 respondents who have carried out a salpingectomy during caesarean section in their hospital, 97% were not aware of any surgical complication directly related to this procedure.

The complications described by the remaining respondents included unspecified haemorrhage (two cases), intra-operative haemorrhage requiring hysterectomy during caesarean section (one case) and haemoperitoneum (one case).

In case that pregnant women had previously expressed a desire for definitive contraception, in whom a vaginal delivery was expected, only in two public hospitals within the Lisbon and Tagus Valley region (by salpingectomy and tubal ligation by a modified Pomeroy technique, respectively) a definitive contraception by umbilical mini-laparotomy was offered to patients within the same hospital stay.

Salpingectomy was the major definitive contraception procedure that should be offered to patients, according to 69% of the respondents. Tubal ligation was chosen by 15% of these and 10% said they had no opinion. Twelve respondents have preferred to specify alternative options, including providing the patient with additional information and shared decision (6), assessment of the patient's clinical context (2), placement of levonorgestrel-releasing intrauterine device (2), further study requirement (1) and vasectomy (1). There were no statistically significant differences between the participants as who would choose to offer salpingectomy vs. tubal ligation regarding gender, clinical experience (registrars vs. consultants), family planning consultation, definitive contraceptive surgery or caesarean section, region of the country, type of department, training skills of the department or availability of surgical reversal of tubal ligation. Regarding the respondent's age, there was a younger age distribution of participants who selected salpingectomy ( $40.4 \pm 11$ ) vs. those who selected ligation ( $45.7 \pm 12.3$ ) ( $p$ -value = 0.038).

Table 3 – Reasons for not carrying out an opportunistic salpingectomy

Reasons in non-pregnant women*	n (%)
This was not considered	15 (45.5)
No advantages when compared to ligation	3 (9.1)
No reversal of the procedure (unavailable tubal ligation reversal)	4 (12.1)
Absence of surgical training for laparoscopic salpingectomy	4 (12.1)
Fear of early menopause	1 (3.0)
Increased surgical time	16 (48.5)
Salpingectomy involves a more invasive approach	10 (30.3)
<b>Other (an update was not required)</b>	<b>1 (3.0)</b>
Reasons at the time of caesarean section†	n (%)
Absence of advantages when compared to tubal ligation	4 (5.8)
No surgical reversal	7 (10.1)
Absence of surgical training for the procedure	6 (8.7)
Fear of complications	25 (36.2)
Increased surgical time	29 (42.0)
This was not considered as an option	39 (56.5)
Other (surgical team)	1 (1.4)

\* This was only answered by the respondents (33) who have described that salpingectomy was not part of the surgical options offered in their hospital – more than one option could have been selected; † This was only answered by the respondents (69) who have described that salpingectomy at the time of caesarean section was not part of the surgical options offered in their hospital have answered – more than one option could have been selected

## DISCUSSION

Despite the presence of long-term contraceptive methods that are almost as effective as tubal ligation, many Portuguese women still prefer a surgical method for definitive contraception. Even though this choice may be used for a potential decrease in the risk of ovarian cancer, although it should not be encouraged for this purpose.

This was the first study carried out in Portugal showing the national distribution of definitive contraception procedures, as well as the perspectives underlying their implementation. Unlike surveys carried out in other countries,<sup>24-31</sup> this study was only focused on the assessment of permanent contraception procedures and does not address the context of hysterectomy for benign pathology, in which opportunistic salpingectomy is already more widespread. This allowed the development of a more targeted and concise questionnaire, aimed at maximising the participation.

In studies that separately assessed opportunistic salpingectomy in the context of definitive contraception, different rates were found in different countries between non-pregnant women and at the time of a caesarean section: 42% and 25% (Australia 2015);<sup>29</sup> 13.3% and 12.5% (France 2016);<sup>26</sup> 71% and 64% (Austria 2016)<sup>27</sup> and 52.8% and 36.8% [United States of America (USA) 2016].<sup>24</sup> Only in the USA was the vaginal postpartum setting (whose representation is significant within the American continent) also assessed and a 26.4% rate of salpingectomy was found. These wide variations may have been influenced by several external factors, including the way the questions were formulated or the population analysed. For instance, in Austria, where the highest utilisation rates were found, respondents were heads of department (no anonymity) and were allowed to select several options simultaneously.<sup>27</sup> In turn, the lowest rates of use found in France were related to a preference for the use of an Essure® device for tubal occlusion (a less invasive method, although currently discontinued).<sup>26</sup> The fact that the publications date from 2015 - 2016 may still involve an important outdated of the rates (in the USA only 7.2% of physicians had described in 2013 a preference for salpingectomy as an interval definitive contraception).<sup>30</sup>

Only one study assessed the reasons for carrying out a salpingectomy in the specific context of definitive contraception (USA 2016).<sup>24</sup> The most commonly described reason (by 91% of participants) was to reduce the risk of ovarian, fallopian and peritoneal cancer and the main concerns included an increased operative time (described by 36%, 29% and 31% of respondents, depending on whether it was performed during interpregnancy interval, during caesarean section and postpartum) and the risk of complications (by 25%, 48% and 44% respectively). No statistically significant differences were found in demographic and occupational factors between respondents offering salpingectomy vs. ligation.

The reasons for salpingectomy were not assessed in this study, as it was focused on the assessment of any constraints, although this would be a relevant information. Sal-

pingectomy was mostly selected by non-pregnant women in 42% of the hospitals in the Northern region and during caesarean section in 83% of the hospitals. This disparity may suggest the presence of some other reason for salpingectomy during caesarean section, apart from reducing the risk of cancer as, if this were the reason, a similar rate would be assumed in non-pregnant women. It is possible that salpingectomy during caesarean section was already the traditional technique used in this region, either because there was no biological purpose for the tube after ligation or because it was considered to be an even more effective technique than ligation.

As regards the reasons not to perform a salpingectomy, an 'alternative that was not considered' option was given by 45.5% of the respondents in interpregnancy interval and by 56.5% during caesarean delivery. On the other hand, 'no advantages when compared to lactation' was selected by only 9.1% and by 5.4% of the respondents within this context, showing that the fact that salpingectomy is not considered is not due to a lack of professional updating and that drawing attention to this issue may make a difference.

When considering interval definitive contraception, a 10-minute increase in operative time by performing salpingectomy has been described,<sup>13</sup> not ruling out salpingectomy for this purpose. On the other hand, the concern that the peripartum characteristic vascular engorgement could lead to an increased surgical risk is not based on any evidence. In a retrospective cohort study involving 10,741 women, a 10-minute increase in caesarean section time and a similar blood loss was described for salpingectomy when compared to ligation.<sup>15</sup> Similar results have been obtained in randomised controlled prospective studies.<sup>16,17,19</sup> In our study, only 3% of the respondents with experience of performing peripartum salpingectomy were aware of any bleeding complications and these did not lead to any change in the preference vs. ligation.

Since more than half of the sterilisation procedures are described in peripartum,<sup>18</sup> caesarean section seems to be the ideal setting to increase the use and potential effect of opportunistic salpingectomy, taking advantage of a surgery based on an obstetric indication in pregnant mothers having previously expressed the desire for definitive contraception. In this sense, a more in-depth knowledge of the experience of the Northern region could contribute to greater safety in the disclosure of peripartum salpingectomy to the rest of the country. Peripartum vaginal sterilisation, a context in which opportunistic salpingectomy appears to be equally safe, is not a common practice in Portugal and unavailable for any intervention.

The limitations of this study include those related to survey-based studies, due to a limited value of data as it depends on the perception of the participants. The combination of closed-ended questions, allowing for a quantitative analysis, with the possibility of adding new information in open-ended responses - another option, whenever considered relevant by the respondents, are a strength of the study. This is particularly important considering that all

questions were compulsory.

Regarding the participation rate, the disclosure methodology prevented from any accurate assessment of how many physicians had access to it. However, this methodology simultaneously allowed for a disclosure throughout most of the public departments in the country while maintaining the respondent's anonymity (since it was not addressed to the department board), an apparently representative demographic distribution of the national reality and aimed at the professionals involved in family planning consultations and definitive contraception surgeries, a desirable situation since these have a more comprehensive knowledge of the department reality and are involved in the decision making process. In this way, it was possible to analyse the data by public service and by participant, as well as to obtain information on the procedures carried out in the hospitals (with an excellent agreement between elements of the same department) and on the most adequate procedures. This study is unique in this sense, showing two aspects that cannot be presumed to coincide. An 84% response rate per public department in the worst-case scenario (since it is not possible to ensure that the questionnaire has effectively reached B2-type departments, from which no response was obtained) should also be considered as a strength of the study.

## CONCLUSION

A less-than-desirable rate of opportunistic seems to exist in Portugal. The implementation of protocols may be a way of ensuring that salpingectomy does not stop being considered, as professionals seem to be informed and are receptive to change.

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This study also highlights the need to improve counseling in order to allow the participation in decision making of women or pregnant mothers seeking definitive contraception and selecting between tubal ligation and opportunistic salpingectomy, taking advantage of a reduction in the risk of ovarian cancer.

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## HUMAN AND ANIMAL PROTECTION

The authors declare that this project complied with the regulations that were established by the Ethics and Clinical Research Committee, according to the 2013 update of the Helsinki Declaration of the World Medical Association.

## DATA CONFIDENTIALITY

The authors declare that they have followed the protocols of their work centre on the publication of patient data.

## CONFLICTS OF INTEREST

The authors declare that there were no conflicts of interest in writing this manuscript.

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