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Women's preferences for permanent contraception method and willingness to be randomized for a hypothetical trial☆,☆☆,★

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ABSTRACT

Objective: To understand women's preferences for permanent contraception by salpingectomy or tubal occlusion following standardized counseling and evaluate the practicality of a future randomized trial.
Study design: We invited pregnant and non-pregnant women planning permanent contraception at the University of California, Davis (UCD) and University of Tennessee (UT) Obstetrics and Gynecology clinics to participate. We enrolled women when they received routine counseling and signed procedure consent. Participants received standardized information sheets reviewing permanent contraception options based on pregnancy status then completed an anonymous survey with questions about demographics, method preference, and willingness to participate in a hypothetical randomized trial comparing salpingectomy and tubal occlusion. We evaluated predictors for salpingectomy preference using multivariable analysis.
Results: From July 2015 to October 2016, we enrolled 75 women at UCD and 63 women at UT. Overall, respondents preferred salpingectomy (63.0%); among the 47 women not currently pregnant at both sites, 40 (85.1%) preferred salpingectomy, most commonly because of higher efficacy. Although population characteristics differed significantly between the sites, only UCD site (aOR 4.2; 95% CI 1.9, 9.4) and non-pregnancy status (aOR 4.2; 95% CI 1.6, 10.8) predicted preference for salpingectomy in the multivariable model. Most participants (n=84, 60.9%) would not be willing to be randomized to a theoretical trial comparing salpingectomy and tubal occlusion procedures.
Conclusion: Among a diverse group of women from two different areas in the U.S. given a choice of permanent contraception methods, salpingectomy is preferred over tubal occlusion. Most women planning a permanent contraceptive procedure would not agree to a randomized comparison of these methods.
Implications statement: Salpingectomy, which offers theoretically higher efficacy and potentially greater ovarian cancer protection compared to tubal occlusion, is preferred by the majority of patients and should be offered to all women seeking permanent contraception. Differences in method choices less likely reflect the patient population and more likely the counseling provided.

1. Introduction

In the United States, approximately 21.8% of women rely on female permanent contraception to prevent pregnancy [1]. Surgical options for female permanent contraception include tubal occlusion, partial or total salpingectomy or transcervical sterilization. The U.S. Collaborative Review of Sterilization (CREST) study, a prospective analysis of outcomes with postpartum partial salpingectomy and laparoscopic occlusion procedures, included procedures performed from 1978 to 1987 [2]. During this time, surgical technology was less advanced than today with relatively poor visualization and lack of sophisticated instrumentation. Thus, during this time, surgeons rarely performed salpingectomy.

Recent attention within the medical community has focused on salpingectomy for permanent contraception, bolstered primarily by evidence suggesting a reduction in ovarian serous adenocarcinoma risk [3]. Although a benefit of salpingectomy as compared to alternative procedures is a presumed 100% efficacy for pregnancy prevention [4], this factor has garnered less attention. Female tubal occlusive permanent contraception procedures are estimated to reduce a woman's lifetime risk of ovarian cancer by 24% to 34% [5,6]; however, women undergoing salpingectomy have a 64% risk reduction for serous epithelial ovarian

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Table 1
Demographic information of women planning female permanent contraception at UC Davis (July 2016–October 2017) and UT (July 2016–June 2017)

Characteristic	TOTAL*	Prefers salpingectomy	Prefers tubal occlusion	P Value†
	N=138	*n*=87	*n*=49	
Site				<0.001
UC Davis	75 (54.3%)	59 (67.8%)	16 (32.7%)	
UT	63 (45.7%)	28 (32.2%)	33 (67.3%)	
Age (years)	31.0±5.9	33.1±6.1	28.6±4.6	0.002
18–25	30 (21.7%)	14 (16.1%)	16 (32.7%)	
26–30	37 (26.8%)	23 (26.4%)	13 (26.5%)	
31–35	31 (22.5%)	16 (18.4%)	14 (28.6%)	
36–40	28 (20.3%)	23 (26.4%)	5 (10.2%)	
≥41	12 (8.7%)	11 (12.6%)	1 (2.0%)	
Race				0.18
Caucasian	101 (73.2%)	61 (70.1%)	39 (79.6%)	
African-American	19 (13.8%)	10 (11.5%)	8 (16.3%)	
Asian	4 (2.9%)	4 (4.6%)	0	
American Indian/Native Alaskan	2 (1.4%)	2 (2.3%)	0	
Other‡	12 (8.7%)	10 (11.5%)	2 (4.1%)	
Ethnicity				0.78
Hispanic	19 (13.8%)	13 (14.9%)	6 (12.2%)	
Non-Hispanic	114 (82.6%)	72 (82.8%)	40 (81.6%)	
Missing data	5 (3.6%)	2 (2.3%)	3 (6.1%)	
Marital status				0.034
Single	55 (39.9%)	29 (33.3%)	24 (49.0%)	
Married	64 (46.4%)	49 (56.3%)	15 (30.6%)	
Divorced	13 (9.4%)	6 (6.9%)	7 (14.3%)	
Separated/widowed	6 (4.3%)	3 (3.4%)	3 (6.1%)	
In heterosexual relationship	120 (87.0%)	78 (89.7%)	42 (85.7%)	0.64
Education Level				0.014
<11 years	19 (13.8%)	8 (9.2%)	10 (20.4%)	
12 years or GED equivalent	33 (23.9%)	19 (21.8%)	13 (26.5%)	
Some College	54 (39.1%)	31 (35.6%)	23 (46.9%)	
College	19 (13.8%)	17 (19.5%)	2 (4.1%)	
Graduate/professional	12 (8.6%)	11 (12.6%)	1 (2.0%)	
Other	1 (0.7%)	1 (1.1%)	0	
Employment				0.29
Full time	64 (46.4%)	44 (50.6%)	20 (40.8%)	
Part time	17 (12.3%)	11 (12.6%)	6 (12.2%)	
Student	3 (2.2%)	3 (3.4%)	0	
Unemployed	24 (17.4%)	10 (11.5%)	12 (24.5%)	
Homemaker	29 (21.0%)	18 (20.7%)	11 (22.4%)	
Other	1 (0.7%)	1 (1.1%)	0	
Income (annual household, thousands)				0.006
<10	27 (19.6%)	10 (11.5%)	16 (32.7%)	
10+ to 30	34 (24.6%)	22 (25.3%)	12 (24.5%)	
30+ to 50	25 (18.1%)	16 (18.4%)	9 (18.4%)	
50+ to 70	14 (10.1%)	9 (10.3%)	5 (10.2%)	
70+ to 90	8 (5.8%)	5 (5.7%)	3 (6.1%)	
90+ to120	9 (6.5%)	9 (10.3%)	0	
120+	15 (10.9%)	14 (16.1%)	1 (2.0%)	
Missing data	6 (4.3%)	2 (2.3%)	3 (6.1%)	
Smoking status				0.24
Smoker	30 (21.7%)	16 (18.4%)	13 (26.5%)	
Non-smoker	107 (77.5%)	71 (81.6%)	35 (71.4%)	
Missing data	1 (0.7%)	0	1 (2.0%)	
Gravidity				0.14
0	3 (2.2%)	3 (3.4%)	0	
1	7 (5.1%)	7 (8.0%)	0	
2	28 (20.3%)	17 (19.5%)	10 (20.4%)	
3	43 (31.2%)	25 (28.7%)	17 (34.7%)	
4	23 (16.7%)	17 (19.5%)	6 (12.2%)	
>5	33 (23.9%)	18 (20.7%)	15 (30.6%)	
Missing data	1 (0.7%)	0	1 (2.0%)	
Parity				0.42
0	6 (4.3%)	5 (5.7%)	1 (2.0%)	
1	42 (30.4%)	26 (29.9%)	15 (30.6%)	
2	54 (39.1%)	36 (41.4$)	17 (34.7%)	
3	17 (12.3%)	11 (12.6%)	6 (12.2%)	
4	15 (10.9%)	9 (10.3%)	6 (12.2%)	
>5	2 (1.4%)	0	2 (4.1%)	
Missing data	2 (1.4%)	0	2 (4.1%)	
Prior miscarriage	44 (31.9%)	28 (32.2%)	16 (32.7%)	0.96
Prior ectopic pregnancy	4 (2.9%)	4 (4.6%)	0	0.13
Prior abortion	20 (14.5%)	14 (16.1%)	6 (12.2%)	0.54
Prior unintended pregnancy	67 (48.6%)	41 (47.1%)	25 (51.0%)	0.55

and primary peritoneal carcinoma compared with women who have tubal occlusion or no permanent contraception procedure [7]. Furthermore, recent studies have shown no increased surgical risks with salpingectomy compared to occlusive procedures during laparoscopy, except for a minimal increase in operative time [8,9], or during cesarean delivery [10]. Use of salpingectomy for permanent contraception is increasing during laparoscopic sterilization and cesarean delivery [11,12] and ACOG has acknowledged salpingectomy as an effective method of contraception that may provide ovarian cancer risk reduction [13].

Information regarding women's preference for permanent contraception method and factors influencing such decision is lacking. Further, while experts suggest that randomized trials are needed to support the validity of salpingectomy to reduce the incidence of ovarian cancer [14], the practicality of conducting such trial has not been studied. To better understand the method preferences of women seeking permanent contraception, factors that influence their choice, and the practicality of a randomized trial that would include women seeking permanent contraception, we conducted a survey study at two academic institutions for women planning a permanent contraception procedure.

2. Materials and methods

We performed an anonymous survey study at two academic institutions, the University of California Davis (UCD) between July 2015 and October 2016, and the University of Tennessee (UT) between July 2015 and June 2016. UCD started offering salpingectomy as part of routine permanent contraception counseling in February 2014 whereas UT had not initiated this counseling as routine prior to the study. We included a convenience sample of women planning permanent contraception as a post-partum procedure (enrolled while pregnant) or unrelated to pregnancy. We excluded women <18 years of age, pregnant women receiving counseling and consent while an inpatient, and women unable to read or understand the study materials in English. The institutional review boards at both institutions reviewed the study and considered it exempt.

We relied on providers in the medical offices to offer the survey to women immediately after they received routine surgical counseling and signed the state or federally-mandated consent form. Willing participants received a packet containing a one-page study explanation, standardized permanent contraception information sheets specific for pregnant or non-pregnant women (online Appendices A and B), an anonymous survey (online Appendix C), and an envelope in which to seal the completed survey. Participants placed sealed envelopes in a locked drop-box; study staff retrieved the envelopes intermittently.

The information sheets (online Appendices A and B) used in the study were those developed for routine clinical counseling by the Division of Family Planning at UCD based on available information at the time of the study. These sheets reviewed available permanent contraception methods including the associated risks of surgery, failure rates and potential ovarian cancer risk reduction. For pregnant women, these methods included postpartum tubal occlusion and tubal occlusion or salpingectomy at time of cesarean delivery; for non-pregnant women, these methods included transcervical, laparoscopic salpingectomy and laparoscopic tubal occlusion. The survey collected demographic information, sterilization method preference and why, and the subject's theoretical willingness to participate in a randomized control trial. We used questions from a previously used UCD Family Planning research office survey to collect the demographics information and pre-tested the questions specific to the planned study outcomes on reproductive age clinic staff. Two authors (AP, KS) reviewed all surveys at their respective institutions. We categorized free text answers based on themes.

We compared differences in patient demographics between the two sites and between the choice of salpingectomy groups using Pearson's chi-squared test for categorical variables and Wilcoxon two-sample test for continuous and ordinal variables. Multivariable logistic regression required a backward model selection because of the relatively small number of responses in comparison to the numbers of variables of interest. We used the results of univariate tests for association in choice of salpingectomy in the model selection process, including those variables with $p<.15$ in backward selection and retaining those variables with $p<.05$ in the final multivariable model. We excluded respondents who did not provide an answer regarding method preference from the univariate and multivariable analyses but did include these subjects in evaluation of willingness to be randomized in a trial comparing salpingectomy with tubal occlusion. We performed all statistical analyses using SAS® software version 9.4 (SAS Institute, Cary, NC) and considered $p<.05$ as significant.

3. Results

We enrolled 138 participants, 75 at UCD and 63 at UT, and included all 138 surveys collected in the analysis. Participant characteristics based on preferred contraception method are presented in Table 1. The population characteristics differed substantially by site with notable differences including that women at UCD compared to UT were older (33.1 vs. 28.6 years, $p<.0001$), less likely Caucasian (62.7% vs. 85.7%, $p=.0015$), more educated (81.3% with above high school level vs. 38.1%, $p<.0001$) and less likely currently pregnant (57.3% vs. 74.6%, $p=.023$) (online Appendix D).

Overall, women preferred salpingectomy ($n=87$, 63.0%) to tubal occlusion ($n=49$, 35.5%). The women who preferred salpingectomy most commonly cited superior pregnancy prevention ($n=53$, 60.9%) as the single most important reason for picking their chosen method, followed by ovarian cancer risk reduction ($n=29$, 33.3%). Among the 49 women who preferred tubal occlusion, the primary reason included a mix of responses including fewer incisions ($n=13$, 26.5%), shorter procedure ($n=13$, 26.5%), and "possibly reversible" ($n=11$, 22.4%). Of note, 2 (1.4%) women did not include a preference, and 5 (5.7%) women who chose salpingectomy and 13 (26.5%) women who chose tubal occlusion did not include a reason. When evaluating only the 47 non-pregnant respondents, 40 (85.1%) preferred salpingectomy.

Predictors of choice for salpingectomy are presented in Table 2. Individual patient characteristics (gravidity, prior ectopic pregnancy, employment, income level, marital status, education and age) did not predicted likelihood of preference for salpingectomy. Predictors for salpingectomy preference were location and pregnancy status: women at UCD (aOR 4.2; 95% CI 1.9, 9.4) and non-pregnant women (aOR 4.2; 95% CI 1.6, 10.8) more likely preferred salpingectomy.

Most participants ($n=84$, 60.9%) would not be willing to be randomized to a hypothetical trial comparing salpingectomy and tubal occlusion procedures. Of those not willing to participate, only 58 (67.9%) provided a reason for their choice, which included wanting choice of method ($n=30$, 35.7%), wanting only their chosen method ($n=24$, 28.6%), and not wanting to participate ($n=4$, 4.8%). The only characteristics that significantly predicted willingness to be randomized were age ($p=.04$) and gravidity ($p=.03$); however, neither of these factors demonstrated a specific trend that would help target women more likely to enroll in such a study (Table 3).

Notes to Table 1:
Data are presented as mean ± standard deviation or n (%).
UC Davis, University of California, Davis; UT, University of Tennessee; GED, General Equivalency Degree.
* Two women with missing data for preference of permanent contraception are included in the total population but not in the sub-category analysis.
† *P* values were determined using Pearson's chi-squared test for categorical variables and two-sample t-test for continuous variables.
‡ Women chose "other"; this category does not include Hawaiian/Pacific Islander.

Table 2
Univariate and multivariable predictors of choice of salpingectomy by women planning permanent contraception procedure (N=138)

Characteristic	Classification	Number of subjects	Preference for salpingectomy	Univariate p-value	Order of Effect removed*	Multivariable p-value	aOR (95% CI)
Gravidity	0	3	3 (100%)	0.11	1	0.96	--
	1	7	7 (100%)				
	2	27	17 (63.0%)				
	3+	98	60 (61.2%)				
Prior ectopic	Yes	4	4 (100%)	0.14	2	0.97	--
	No	130	83 (63.9%)				
Employment	Employed	84	58 (69.1%)	0.12	3	0.67	--
	Other	52	29 (55.8%)				
Income	<50,000	85	48 (56.5%)	0.006	4	0.77	--
	≥50,000	46	37 (80.4%)				
Marital status	Married	64	49 (76.6%)	0.004	5	0.55	--
	Other	72	38 (52.8%)				
Education	< Grade 12	18	8 (44.4%)	0.10	6	0.68	--
	Grade 12/GED	32	19 (59.4%)				
	>Grade 12	86	60 (69.8%)				
Age	<25	30	16 (53.3%)	0.01	7	0.10	--
	>25 to 30	36	13 (36.1%)				
	>30 to 35	30	14 (46.7%)				
	>35 to 40	28	5 (179%)				
	>40	12	1 (8.3%)				
Site	UCD	75	59 (78.7%)	<0.0001	--	<0.0001	4.2 (1.9, 9.4)
	UT	61	28 (45.9%)				
Currently pregnant	Yes	88	47 (53.4%)	<0.001	--	0.003	4.2 (1.6, 10.8)
	No	47	40 (85.11%)				

Data missing for gravidity (n=3), prior ectopic (n=4), income (n=7), education (n=2), age (n=2), employment (n=2), site (n=2), marital status (n=2), and pregnancy status (n=3).
UC Davis, University of California, Davis; UT, University of Tennessee; GED, General Equivalency Degree; CI, Confidence Interval.
* Order of backward selection for logistic regression model, including univariate variables with p<.15. Univariate tests for other demographic factors (race, ethnicity, in heterosexual relationship, parity, prior miscarriage, prior abortion, and prior unintended pregnancy) with p>.15.

4. Discussion

In this convenience sample of women recruited from two academic medical centers, we found that few women planning permanent contraception would be willing to participate in a hypothetical randomized trial comparing salpingectomy and tubal occlusion. Further, the majority of women counseled using a standardized information sheet expressed a preference for salpingectomy over tubal occlusion or a partial salpingectomy procedure. While there are many differences in populations between the two sites, the only statistically significant different demographic factors that also significantly predicted choosing salpingectomy were site, marital status, and pregnancy status. Pregnant women were less likely to desire salpingectomy compared to women seeking permanent contraception unrelated to pregnancy. Given that about 50% of women who consent for post-partum permanent contraception change their mind [15], this finding may be more related to the uncertainty around permanent contraception itself.

For non-pregnant women, these findings suggest that the differences in the population characteristics are less relevant to method choice than the differences in counseling from providers at the sites. While both sites provided the same informational sheets to subjects, counseling came from their provider and was not standardized. The two sites differed in their experience with offering salpingectomy routinely; the higher interest among UCD patients is likely reflective of the providers already integrating this counseling prior to the study. The UT results demonstrate the initial impact when such counseling starts. Regardless, patients at both sites preferred salpingectomy.

Importantly, most women at both locations, despite varying demographic characteristics, stated they would not want to be randomized in a hypothetical trial comparing permanent contraceptive techniques. Most women would decline participation for reasons primarily related to autonomy (wanting choice of method or only chosen method). A randomized trial in women having hysterectomy would evaluate salpingectomy vs. non-removal whereas a trial in women seeking permanent contraception would evaluate salpingectomy vs. occlusion/partial removal. These are two different types of studies, especially because occlusion provides some ovarian cancer prevention benefit [5,6]. For a trial of women seeking permanent contraception, based on a 64% ovarian cancer risk reduction [7] and a 10% lost to follow-up rate, approximately 2200 women per group would be required. Our 61% refusal rate implies approximately 7200 women planning sterilization would need to be approached to enroll an appropriately powered trial. The CREST trial, a non-randomized long-term follow-up study, enrolled 10,863 women over 8 years [2] at a time when 27.5% of contracepting women used female permanent contraception [16]. The incidence of new procedures each year has declined substantially; given the much

Table 3
Associations of participant demographics* with willingness to be randomized to a hypothetical study randomizing women to permanent contraception method.

Characteristic	TOTAL	Percent willing	p-value†
	N=138	n=54 (39.1%)	
Age (years)			
18–25	30 (21.7%)	15 (50.0%)	.04
26–30	37 (26.8%)	15 (40.5%)	
31–35	31 (22.5%)	16 (51.6%)	
36–40	28 (20.3%)	6 (21.4%)	
≥41	12 (8.7%)	2 (16.7%)	
Gravidity			.04
0	3 (2.2%)	3 (100%)	
1	7 (5.1%)	0	
2	28 (20.3%)	9 (32.1%)	
3	43 (31.4%)	20 (46.5%)	
4	23 (16.8%)	7 (30.4%)	
5+	33 (24.1%)	15 (45.5%)	
Missing data	1 (0.7%)	0	

Data are presented as n (%).
* All demographics in Table 1 analyzed; only significant variables presented in this table.
† Pearson's chi-square test.

lower rate (21.8%) today [1], a randomized trial would likely take much more than 10 years just to enroll and may not be feasible.

Regardless, a more important factor revealed by the women in this study is that the greater efficacy from tubal removal is more relevant than the potential for greater ovarian cancer protection. Even though both factors are pertinent, we must acknowledge that for our patients, removal of the entire tube is preferable for contraceptive purposes. For those women who prefer occlusive procedures because of the potential for reversal, better counseling overall is needed.

Strengths of this study include multicenter data collection in a diverse group of women in two different areas in the U.S. The lack of standardized counseling across sites allows greater generalizability. However, as a convenience sample using an anonymous survey, we do not know the total number of women at the sites who could have completed the survey or how many women who completed or did not complete the survey actually had a permanent contraceptive procedure. Additionally, given the anonymous nature of the survey, we could not assess if the woman's health history impacted the provider counseling or the answers to her survey. Although we did collect household income information, we did not collect insurance information which may have been important to include in our analyses.

In conclusion, when patients received structured counseling about all permanent contraception options that identified salpingectomy as more effective than tubal occlusion, more than 60% had significant interest in salpingectomy. Regardless of women's preferred approach to permanent contraception, most would refuse to participate in a randomized trial. As a result, a randomized controlled trial comparing salpingectomy to tubal occlusion for permanent contraception would be difficult to complete.

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