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Conceptualizing Risk and Effectiveness: A Qualitative Study of Women's and Providers' Perceptions of Nonsurgical Female Permanent Contraception

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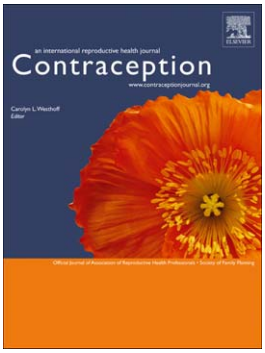

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Title

Conceptualizing risk and effectiveness: A qualitative study of women's and providers' perceptions of nonsurgical female permanent contraception

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Abstract

Objective: Novel approaches to nonsurgical permanent contraception (NSPC) for women that are low cost and require no incision or hysteroscope/surgical equipment could improve access to, and the acceptability of permanent contraception (PC). To better understand opportunities and limitations for NSPC approaches, we examined women's and OB/GYN providers' perceptions of NSPC in Portland, OR.

Study Design: Semi-structured, qualitative interviews were conducted with 40 women recruited from outpatient clinics with purposive sampling, and a focus group was conducted with 9 OB/GYNs in academic and community practice. Transcripts were coded and inductively analyzed with a grounded theory approach.

Results: The majority of women identified as white (67%) or Latina (25%). They had a median age of 31.5, and median number of children was one. Perspectives on NSPC were closely aligned with women's general attitudes towards PC; over half were considering PC for themselves or partners in the future. Most respondents valued multiple aspects of a nonsurgical approach, with themes of minimizing recovery time, invasiveness, risk, and avoiding hormonal contraception. Many assumed NSPC would be less effective than surgery, however, and felt a confirmation test would be necessary regardless of the failure rate. Providers welcomed efforts to expand contraceptive choice with NSPC, but would require long-term safety and efficacy data before recommending, and voiced concerns that NSPC's potential relative ease of administration could undermine the inherent seriousness of choosing PC.

Conclusions: Women’s and providers’ perceptions of NSPC hinged on the ways in which they conceptualized risk and effectiveness. While perceptions were generally favorable, confirmation of safety and effectiveness would be required for a new approach to be accepted.

Implications: This hypothesis-generating study elucidates women’s and provider’s perspectives on new methods of NSPC, and contributes to understanding their

perceptions of various types of risk. A technique to verify tubal occlusion would be needed for women and providers to accept NSPC.

Keywords

Sterilization, permanent contraception, contraceptive development, risk, perception, qualitative

Word count

3563 (Introduction 602, Methods 521, Results 1416, Discussion 1024); Abstract 300

1. Introduction

The global need for highly effective contraceptive methods far outstrips access to and utilization of these methods [1,2]. Although the continued development of female-controlled barrier methods and long-acting reversible contraception has expanded contraceptive choice and access, surgical female sterilization, or permanent contraception (PC), remains the most highly-utilized and effective method in the global setting. Over one-third of reproductive age women worldwide reply upon female PC [1,3]. In the United States, surgical female PC is the most commonly used method of contraception among parous women, and the most prevalent method among women aged 30 or older [4].

While female PC is highly prevalent, it is also the only method of contraception for women that requires a surgical procedure—whether that procedure is hysteroscopic, laparoscopic, or via laparotomy [5]. For some women, surgery may not be palatable or advisable. While surgical complications are very low in the U.S. [6], surgical risk exists. Globally, patient safety data for surgical sterilization are lacking, though catastrophic complications periodically surface in the media [7]. Cost to the medical system and insurance coverage also complicate access to surgical sterilization. Some women face barriers in accessing PC, which contributes to the risk of unintended pregnancy [8-11].

Widespread interest in a simple, safe, nonsurgical approach to PC led to the promotion of quinacrine in many developing countries in the 1980s and 90s [12-14]. Concerns about toxicities and efficacy, as well as the politicization of the method, have all limited long-term prospects for this method [15,16]. The Essure® micro-insert system for female sterilization is marketed as nonsurgical [17], and has expanded women's options for PC where it is offered. However, this procedure requires the use of a hysteroscope, a surgical endoscope that requires a trained surgeon, and placement of permanent coil inserts. While there are no incisions, this approach remains too resource intensive for many settings. For the purposes of this paper, hysteroscopic sterilization is not considered a new method of nonsurgical permanent contraception (NSPC).

New, nonsurgical PC methods are currently in development. One such method, polidocanol, is a prototype agent for NSPC designed to be administered transcervically as a foam via a small balloon catheter. Polidocanol is a sclerosing agent that has been used

for years as a treatment for varicose veins [18]. In preclinical trials in non-human primates, this agent has shown promise as a safe and effective PC method [19,20].

The development of a new contraceptive method that is acceptable and appealing to women requires insight into potential user perspectives. Contraceptive users' responses to their options can be characterized as a "complex interplay between a woman, a technology, and a service delivery environment" [21]. While there is some historical data on the user acceptability of NSPC, it is limited to studies of quinacrine in low resource settings [14,22]. There exist no data on perceptions of NSPC in the U.S. or Europe. Traditional acceptability studies have been criticized for not taking into account the broader context of women's lives, including their levels of reproductive autonomy. Women often cannot accurately predict their preferences about specific hypothetical methods in isolation from other factors [21]. Given that an NSPC method is not yet available, we designed a study to qualitatively explore women's, men's, and women's healthcare providers' perspectives on NSPC. We focused on gaining nuanced perceptions of PC, surgery, and responses to new methods, rather than on whether a specific method would be "acceptable" to a particular population. We aimed to inform the contraceptive development process, and generate hypotheses for future research on NSPC. In this paper, we examine perceptions of NSPC among women and women's healthcare providers in Portland, OR.

2. Methods

This mixed-methods study incorporates qualitative interviews with married/partnered women, a focus group with obstetrician-gynecologists (OB/GYNs), and a survey with men. The study, conducted in Portland, OR from July-October 2013, was approved by the institutional review board at Oregon Health & Science University (OHSU). Findings from the male survey are presented elsewhere, as are findings from a parallel study conducted in eastern Maharashtra, India in early 2014.

2.1 Semi-structured interviews

Semi-structured interviews were conducted with 40 married/partnered women. Inclusion criteria were age 18-45, in a relationship with a man and theoretically "at risk

for pregnancy" (has not undergone female PC/hysterectomy), pregnant or having at least 1 child, and English or Spanish-speaking. Women were recruited in person from two outpatient women's health and primary care clinics: the OHSU Center for Women's Health in Portland, OR, and the Virginia Garcia Memorial Health Center in Hillsboro, OR. Interviews were conducted in English or Spanish. Participants were identified via a combination of purposive/quota and convenience sampling. Quotas included at least 10 women identifying as Latina, and no more than 50% pregnant participants. The sample size was determined based on the number expected to allow for theoretical saturation, or the point at which no new conceptual insights are generated [23]. Two experienced female study staff members who were trained in qualitative methods, and one of whom was bilingual in English and Spanish, conducted all interviews. Demographic information was collected via closed-ended questions at the outset of the interview. Interview themes included contraceptive decision-making, perceptions of permanent contraception and surgery, and responses to new contraceptive methods including NSPC; see figure 1 for representative content. Participants received a $50 gift card upon completion of the interview.

2.2 Focus group discussion (FGD)

A single FGD was conducted with nine OB/GYNs practicing in the Portland area. Participants were recruited by email and represented both community and academic generalist practice. An introductory script with a general description of polidocanol was read to participants, and is included in figure 1. Two authors facilitated the FGD and did answer basic questions about polidocanol, though placed emphasis on the concept of NSPC rather than the specific method. The FGD focused on providers' perspectives on surgical sterilization, and new contraceptive technologies in development, such as NSPC. The FGD was audio-recorded and transcribed.

2.3 Data analysis

Interviews and the FGD were audio-recorded, transcribed, and where applicable, translated into English. Interview transcripts were analyzed with an inductive approach using principles of grounded theory [23,24]. After reading all raw transcripts,

investigators reached consensus on initial codes and created a working code book. After twenty transcripts were independently coded in NVivo (QSR International Version 10, 2012), two investigators compared their coding line-by-line, added additional codes when necessary, and resolved coding discrepancies prior to resuming the coding process. NVivo was used to group codes and categories during the axial coding process and memo-writing. The research team then met to further refine the categories and concepts that emerged from the memos, reaching theoretical saturation on the concepts of interest. The FGD transcript was manually coded, and content was analyzed for themes and variant views. Informal member checking was subsequently performed.

3. Results

3.1 Semi-structured interviews

Interview participants had a median age of 32, with a range of 23-42. The majority identified as white (67%) or Latina (25%). 70% were married, and had a median of 1 child. Of the 40 participants, half were pregnant, and half had a college or graduate degree. See Table 1 for participant characteristics.

3.1.1 Attitudes towards permanent contraception:

Most of the interview participants (23 out of 40) were considering or planning future use of PC. Of these, 10 were considering vasectomy, 9 were considering tubal sterilization, and 4 were considering either/both. All but a few respondents expressed support for PC as a personal choice when asked "What do you think about permanent contraception?" Yet, most placed conditions on when PC is appropriate, such as age, relationship status, level of certainty and number of children a woman already has:

> *"If the woman makes it with the understanding that it's permanent...and she's at the proper age where she can, like, 20 might be a little too young for that choice…"*

Most women (75%) supported PC in the immediate post-partum period; those who did not were concerned about compromised decision-making, regret, and the stress of

surgery. Finally, 20% (8/40) of women expressed the view that their male partners should "take his turn" in contraceptive responsibility by undergoing vasectomy.

3.1.2 Interest in NSPC

Perceptions of NSPC were closely aligned with women's general attitudes towards PC. Most respondents expressed interest in multiple aspects of a nonsurgical approach. In particular, most assumed it would be less invasive than surgery and that NSPC would likely avoid risks associated with anesthesia.

> *"Uh, just that it's not surgical. Any surgery has a risk, basically, for infections…or anesthesia is a serious thing, so that's pretty much the appeal. I know everything has risk, but, maybe less of a risk."*

Several women also mentioned reduced recovery time with a nonsurgical procedure as a major advantage; they anticipated that a less invasive procedure would allow for less missed work, less pain, and less "down time" as parents.

> *"Well, the recovery time…I mean if it's nonsurgical I'm assuming there's not that big of a recovery period. So, to me that would be very appealing…."*

Others brought up various benefits of NSPC, including the likelihood of reduced cost, an outpatient venue, avoiding hormonal contraception due to perceived side effects, and increased accessibility at a public health level. Regarding the latter, one participant hypothesized that a simpler, nonsurgical method would be cheaper and require less input from the healthcare system.

3.1.3 Risk, effectiveness, and confirmation

Risk emerged as a multifaceted concept in the interviews: conceptualizations of risk ranged from safety concerns about new contraceptive methods, to surgical risk, to concerns about regret, to contraception failure and pregnancy risk. Regarding new methods of contraception, including NSPC, women's perspectives revolved around their

conceptualizations of risk. The majority of participants had safety and side effect concerns about new methods, often filtered through past experience with hormonal contraception. For example, one 23-year old participant explained:

> *"I think it's [development of new contraceptive methods] fantastic because you have many choices, but sometimes those choices are not technically the greatest ones for you or ones that you particularly like... I mean I struggled for the longest time to find one that worked for me... I did the depo and I gained so much weight, and it messed with my self-esteem."*

In general, women stated interest in new methods, but didn't want to be an early adopter. Negative media exposure, such as TV advertisements targeting IUD complications, were cited several times as instilling skepticism and heightened sense of risk with respect to contraceptive methods:

> *"I would want to hear a little bit about…how long those trials have been and how long it's been researched, 'cause there's lots of things that have been out on the market, you know, for a good five/ten years that they're discovering later have some nasty side effects."*

The weighing of risks and benefits was a main theme in women's decision-making around PC. Risks related to PC may not be 'worth it' when considering the length of anticipated benefit. One 36 year-old participant put it this way:

> *"Because right now I have a 3-year birth control [method] and if there was something like a 5 or 10 year, I'd probably just get that and then wait for menopause. Because I'm old enough where it wouldn't be 30 years. And it's such a minor thing that I probably wouldn't bother with a surgery."*

The risk of pregnancy, or of contraceptive failure, was another risk women prioritized. While several respondents spoke of concern for surgical PC failure, most women perceived surgical PC as inherently more effective than a nonsurgical procedure:

> *"Well, it (NSPC) sounds safer…But it kind of also sounds less effective."*

> *"Um, I mean, it'd be less - I assume it'd be less costly, which would be nice. But...you know, if it's non surgical I'd also want to know, like, how are you really able to see what you're doing and has this been tested before, on what? …and what are the probabilities of it, you know, not working, because it's not surgical."*

When asked if it would be important to have a confirmation test done if a given method of PC were 99% effective, the majority of our sample strongly felt that it was necessary to come back for a confirmation test regardless of the stated efficacy of the method. While some (9/40) said that 99% effectiveness was "good enough," several had the expectation that surgical PC should have a 0% failure rate:

> *"Yeah, I would wanna make sure everything was safe...uh...that there's no chances at all...[of pregnancy] …Especially if it's supposed to be permanent."*

3.2 Focus group discussion

In general, providers welcomed efforts to expand contraceptive options with NSPC. Most commented on the challenges of providing highly effective contraception among patient populations who are wary of hormonal methods and "foreign bodies" such as implants and IUDs. In the same vein, once it was explained that polidocanol foam dissipates in the body, providers felt such a method would be more acceptable to some patients than placement of an IUD or implant. The majority of the providers felt that avoiding surgery when possible was in everyone's interest.

Participants emphasized the need for long-term (which they defined as 5-10 years) data on safety and efficacy of any new method, and had questions about the specifics of a nonsurgical method's physiology and the need to confirm tubal occlusion.

Particularly in the absence of long-term follow up data, participants felt strongly that confirmation of tubal occlusion would be necessary, though did point out the inconsistency that despite knowledge of surgical PC failure, it is still not standard of care to confirm tubal occlusion after tubal ligation. A few providers also spoke to their observations that patients tend to perceive surgery as the most effective method, and thus may prefer surgical PC.

Providers described the difficulties they faced in presenting new methods to patients. One participant commented that 'selling' a new method "[requires] overcoming some skepticism…and then really being able to articulate it well to patients." Another OB/GYN noted her experience after she began offering Essure® as an office procedure:

> *"At first when the concept came out [Essure®], I thought it was ridiculous when we have so many other better methods. Why would you want to go through that? But after doing so many cases, I think it is a very good option."*

When asked if they foresaw ethical issues with NSPC, some providers expressed concern that the relative ease of a nonsurgical method could undermine the inherent seriousness of choosing permanent contraception – concern "that the population could be confused about the procedure…that they wouldn't take it as seriously, maybe." Two other participants commented,

> *Participant 1: "My worry would be that it's so simple that those who - that there would be a temptation to minimize the gravity of something permanent…or just making that conversation a little too brief because if all I need to do is put this little tube in and go [motions] and squirt, then –"*
>
> *Participant 2: "Yeah, a 15 minute appointment for their permanent sterilization!"*

The importance of counseling patients regarding PC was emphasized in the discussion. Providers described counseling for surgical sterilization as "ritualized," with multiple steps and an expectation that each patient is extensively counseled about risks and

alternatives. As one provider summarized, "the counseling needs to be the same [for NSPC] as it is for surgical [PC]."

4. Discussion

This study is the first to explore perceptions of new methods of nonsurgical permanent contraception among a sample of women and OB/GYNs in the U.S., and contributes to the small body of literature on NSPC. Interview participants, the majority of whom identified as future users of PC, expressed a strong interest in a nonsurgical PC method. The concepts of risk and effectiveness framed women's and FGD respondents' perceptions of NSPC, as well as their responses to PC and new contraceptive methods more generally.

Various risk perception theories have been developed to try to understand the ways in which people judge and react to risk, with a vast attendant literature [25]. Many health-related behaviors are studied with the lens of risk perception, such as perceived HIV risk and sexual behavior [26]. While the risk perception literature around contraception is relatively sparse, the concepts are widely applied: Demographic Health Surveys globally feature women's fears of contraceptive side effects [27,28]; a recent cohort study found that women underestimate the effectiveness of intrauterine contraception and overestimate health risks [29]; and many populations at risk for unintended pregnancy are also at risk for misinformation around risks associated with unprotected intercourse and contraceptive use [30,31]. In our study, women's risk perception of NSPC was shaped by past contraceptive experiences, perceptions of PC, and how the risk of pregnancy was balanced against those of method use. It is important to note here that women generally did not use the word "risk" except to describe surgical and anesthesia-related risks. Many women expressed risk perceptions in the form of concern, worry, and the weighing of benefits and harms. We did not exclude women whose partners have undergone vasectomy, as technically they are still "at risk" for pregnancy. We did not find any specific variant views among the three women in this category, but it is possible that these participants may have found NSPC less relevant to their lives, and less likely to share engaged perceptions.

Our participants held surgical PC to a different metric than barrier or reversible contraception—that is, they expected surgical PC to be permanent, or 100% effective. In light of most participants' belief that surgical PC represented the pinnacle of contraceptive effectiveness (though no information regarding the efficacy of surgical or nonsurgical PC was provided), many assumed a nonsurgical approach to PC would be less effective. Thus, women, as well as providers, almost universally felt a confirmation of tubal occlusion would be necessary. We hypothesize that some women may simply feel more secure with a confirmation test if offered, and that the knowledge that one has had surgery for PC affects risk perception. It is also possible that women and providers alike are more confident when the tubes are visualized and occluded surgically, despite known surgical sterilization failure [32]. Transcervical approaches may inspire less assurance given that they may not be immediately effective and the interruption of the tube cannot be seen. In the context of some participants' choice of less effective methods despite identifying as family complete, their concern about a potential <1% failure rate of NSPC seemed particularly uncoupled from their present pregnancy risk perception. NSPC is designed for high- and low-resource settings alike, but a novel, low-cost, accurate confirmation test will be essential, as the hysterosalpingogram is not a practical approach in many communities around the world [33].

Provider FGD participants highlighted two characteristics of NSPC that raised their concern: the ease of performing the procedure seemed to be at odds with the inherent seriousness—the permanence—of a permanent method. They emphasized the need for the counseling around NSPC to reflect the seriousness and permanence of the method—and that the informed consent procedures for NSPC will need to be as "ritualized" as they are for surgical PC. In other words, providers felt that the counseling process for NSPC should not be abbreviated even if the procedure were simpler, safer, and cheaper.

Our findings must be interpreted in light of several limitations. Our sample is not representative of women and OB/GYNs in Portland or the broader U.S. Indeed, the majority of our sample was white and 50% had a college or graduate degree, which does not reflect the demographics of women most likely to opt for PC nationally [34]. While the sample size was appropriate given standards in qualitative research [35], it may have

been beneficial to have purposively sampled women with lower educational attainment, as well as women identifying as Asian and African-American. Also, we did not address perceptions of immediate versus delayed efficacy of PC in detail, and this should be explored in future research. Given the preliminary and hypothesis-generating goals of the study, we conducted only one FGD with OB/GYNs; it is possible that additional FGDs would have yielded varying insights. Social desirability bias is also a consideration; it is possible that participants felt inclined to show a positive interest in NSPC given the face-to-face interaction with interviewers. Finally, we asked women to comment on their perceptions of NSPC, which is not yet available. Though our questions were centered on characteristics of NSPC, rather than on specifics of the method, women were still asked to consider NSPC in the hypothetical. Women's responses to a physically available method may have been different [21].

NSPC, while still theoretical, has the potential to transform the safety and accessibility of PC. In addition to the basic science, research on women's, men's, and providers' perceptions of a given method is critical to the contraceptive development process. We found that perceptions of NSPC among both women and providers hinged on how they weigh various risks and perceive the effectiveness of a given contraceptive method. Future research on NSPC must include the perceptions of a more diverse group of women, both nationally and internationally. One particular area of interest is the role of confirmation tests of tubal occlusion, and how to balance risk of PC failure with costs, including inconvenience. Furthermore, prior to rolling out a new nonsurgical method, strategies for patient counseling and informed consent specific to NSPC must be developed. Such research must incorporate hypothesis-driven research on perceptions and preferences that will inform eventual clinical trials.

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Figure 1: Representative content from study instruments

Interview Guide: Attitudes towards sterilization & surgery
What do you think about permanent contraception? [Probe: Do you have concerns about permanent contraception ("tubes tied" and sterilization)?
What do people in your community say about permanent contraception? [Probe: your friends, partner, family members?]
What do you think about having a sterilization surgery (getting your "tubes tied") at the time of delivery?
Have you had surgery before? What kind of surgery? What do you think makes something surgical?
Currently, permanent contraception requires a surgical procedure. Are you comfortable with the idea of surgery for permanent contraception? [Probe: do you have specific concerns regarding surgery? Is there anything about surgical sterilization that is appealing to you?]
Interview Guide: Attitudes and features of new contraceptive technology
If a safe and effective method of permanent contraception could be provided without the need for surgery, would this interest you? [PROMPT: what specifically would interest you about such a method and why? What questions and concerns would you have?]
How do you react when you hear about a new method of contraception being available? [Probe: Are you interested in trying it right away? Are you hesitant…?]
Currently, a special exam can demonstrate if a permanent contraceptive surgery has completely blocked the tubes, but this requires a pelvic exam and an X-ray. If a method of permanent contraception were 99% effective, would it be important for you to come back for a confirmation test visit? [Probe: If the method were 90% effective, would your answer differ?]
Focus Group Guide: Introductory script
"A nonsurgical method of permanent contraception is in development. The technique would be office-based, and similar to the placement of an IUD. This method would use a catheter similar to those used during an HSG for transcervical delivery of a sclerosing foam. There would be no need for specialized equipment or ultrasound. Anesthesia would not be required."

Table 1: Participant Characteristics

Interviews: Married/partnered women (n = 40)	
	No. participants (%)
Mean age (median, range)	33 (32, 23-42)
Race/ethnicity	
White	27 (67%)
Latina	10 (25%)
Native American	3 (8%)
Education	
High school or less	8 (20%)
Some college	12 (30%)
College degree	15 (37%)
Graduate degree	5 (13%)
Marital status	
Married	28 (70%)
Unmarried	12 (30%)
Religion	
Catholic	14 (35%)
Protestant	10 (25%)
Mormon	2 (5%)
Jewish	2 (5%)
Buddhist	1 (3%)
None	11 (27%)
Currently pregnant	20 (50%)
Median live children (range)	1 (0-4)
Number of children *0-1* *2* *3 or more*	 25 (63%) 8 (20%) 7 (17%)
Fertility intention	
More children desired	8 (20%)
No more children desired	28 (70%)
Unsure	4 (10%)
Current FP method (n = 20)	Condoms 1, oral contraception 1, DMPA 1, implant/IUD 8, vasectomy 3, none 5, missing 1
Focus Group: Obstetrician/Gynecologists (n = 9)	
Practice type *Academic* *Private group* *Solo*	 6 2 1
Median years in practice, including residency	13 (mean 16, range 4-42)
Sex	Female 8, Male 1