Surgery 164 (2018) 931–934

Contents lists available at ScienceDirect

Surgery

journal homepage: www.elsevier.com/locate/surg

Hypothesis

Would women accept opportunistic (prophylactic) salpingectomy at the time of nongynecologic surgery to prevent development of ovarian cancer?

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ARTICLE INFO

Article history:
Accepted 27 March 2018
Available online 31 May 2018

High-grade serous ovarian carcinomas originate in the fallopian tube[1], and salpingectomy is associated with a considerable risk reduction for ovarian cancer.[2,3]

Numerous professional societies have recommended so-called opportunistic salpingectomy at the time of gynecologic surgery in appropriate women,[4,5] so nongynecologic procedures, such as laparoscopic cholecystectomy, might afford an opportunity for salpingectomy.

Introduction

Epithelial ovarian cancer is the most common cause of gynecologic cancer death and the fifth most common cause of cancer death in women behind breast, lung, colorectal, and pancreatic cancer .[1,6]Large-scale screening efforts have been unsuccessful,[7] and recently, the US Preventive Services Task Force (USPSTF) again recommended against screening for ovarian cancer in asymptomatic women without a high-risk hereditary cancer syndrome, because screening does not decrease mortality.[6] Progress against the development of this disease has been slow.[6,8]

Over the past 15 years, studies have shown that the cells from which most serous ovarian cancers likely originate from the fimbriae of the fallopian tubes.[1] This paradigm shift began in 2001 with the description of so-called dysplasias in the tubes of women at high familial risk of ovarian cancer who underwent prophylactic salpingo-oophorectomy.[9] These dysplasias are now called serous tubal intraepithelial carcinomas (STICs) and are considered the origin of most pelvic serous cancers.[1] Epidemiologic studies have shown that salpingectomy is associated with a decreased long-term risk for developing serous ovarian cancer.[2,3] Accordingly, since 2012, a number of professional societies beginning with the Society of Obstetricians and Gynaecologists of Canada have issued statements advocating opportunistic (prophylactic, incidental) salpingectomy at the time of elective gynecologic surgery or tubal sterilization.[4,5,10–12] The rationale for these recommendations is that the risks and complications of salpingectomy are low, the benefits are likely considerable, and salpingectomy at the time of other gynecologic procedures is easily performed. Opportunistic salpingectomy at the time of gynecologic surgery has gained considerable traction in the United States[13] and other countries.[4,5,11–15] A next step would be evaluating the possibility of opportunistic salpingectomy at the time of non-gynecologic surgery, such as cholecystectomy.

In a pilot study, we interviewed women scheduled for laparoscopic cholecystectomy (lap chole) to elicit potential concerns and acceptance of concomitant salpingectomy (salpingectomy was not actually offered). The goal of the study was to assess whether it would be worthwhile to plan a trial actually offering salpingectomy at the time of lap chole, specifically whether patients would be interested and could be recruited. The results of the interviews were used to develop a patient-reported outcome measure for women scheduled for lap chole who are to be offered elective salpingectomy.

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https://doi.org/10.1016/j.surg.2018.03.024

Methods

Interviews of women before elective lap chole

Women aged ≥45 years scheduled for elective lap chole for a benign indication were invited to an interview to elicit and address their attitudes, concerns, and potential acceptance of hypothetic concomitant salpingectomy at the time of their lap chole. Inclusion criteria were age ≥45 years and elective lap chole for benign disease; exclusion criteria were age <45 years, emergency cholecystectomy for acute cholecystitis, malignancy of the gallbladder, and a known BRCA mutation. Participants received oral and written information about the study and gave informed consent to be interviewed. The study protocol was approved by the ethics committees of the three participating institutions.

A qualitative research approach was used. A clinical psychologist (BB) who was not a member of the treatment team conducted in-depth, face-to-face interviews to obtain unbiased subjective perceptions and opinions from study participants. An interview guide was designed to cover the following topics: Attitudes, feelings and concerns about opportunistic salpingectomy; perception of ovarian cancer risk; perception of risk-reducing salpingectomy; fertility or the potential loss of fertility (sterilization); body image and femininity; and acceptance of operative strategies for prevention of ovarian cancer.

Interviews were initiated with written information on the concept of opportunistic salpingectomy at the time of lap chole. This information comprised the rationale for opportunistic salpingectomy (ie, probable risk reduction for ovarian cancer), the role of the fallopian tubes in reproduction, and the respective functions of the tubes and ovaries. Women were informed that ovarian cancer is a very real substantial problem in womenś health, but they were not provided specific figures regarding the magnitude of risk reduction or number-needed-to-treat. Study participants were informed explicitly that salpingectomy was not being offered and would not be performed during their operation.

Most interviews took place on the day before elective lap chole. The interviews took 30 and 60 min and were taped. The recorded conversations were transcribed verbatim by the clinical psychologist who performed the interviews, and the transcripts were used for the content analysis. Inductive content analysis was carried out to identify categories for each interview.[16] Issues assigned to each category were converted into questions with a 4-point Likert response format.

Participants

Twenty-three women (age 45–72 years, mean 56) scheduled for elective lap chole were approached; 20 agreed to participate, 2 declined to be interviewed, and 1 was excluded because of problems with the language. Of the 20 participants, 7 worked in the social or health care sectors, 5 were office workers, 4 were workers, 2 were farmers, and 2 were child caregivers. Median parity was 2 (range, 0–4). Fourteen of the 20 women had a history of gynecologic surgery (conization $n=2$, curettage $n=6$, hysterectomy $n=6$, and 1 each after a unilateral salpingectomy, a bilateral salpingo-oophorectomy), and tubal sterilization). Two patients had a previous diagnosis of cancer, and 16 had a family history of cancer. None had a known BRCA mutation.

Results

Attitudes, feelings and concerns about opportunistic salpingectomy

Nineteen of the 20 participants indicated that they were open to the idea of opportunistic salpingectomy at the time of lap chole; 17 thought it a good idea, and two would want to consider it further. Twelve would agree to the opportunistic salpingectomy

Table 1
Attitudes, perceptions, and concerns regarding opportunistic salpingectomy at the time of elective laparoscopic cholecystectomy (lap chole) in 20 women.

Category	Items	N
Attitudes, feelings, concerns	Positive attitude, salpingectomy is a good idea	17
	Would think about it	2
	No concerns	11
	Negative attitude	1
Acceptance	Would accept salpingectomy at the time of lap chole	12
	Would probably accept but would want more time to think about it	7
	Would refuse	1
Body image, femininity	Mindful care for oneś body	10
	I trust my instincts	11
	Low health consciousness	2
	Losing my fallopian tubes would not change the way I feel about my body	14
	Concerned that losing my fallopian tubes might affect me psychologically	2
Risk perception	I havenť thought or been concerned about ovarian cancer	9
	I am concerned about ovarian and other cancers	7
	Reducing my risk of ovarian cancer would be reassuring	15
Fertility, sexuality	Fertility and having children is important	17
	Salpingectomy would not affect my femininity	17
	Salpingectomy would not affect my sexuality	16
	Salpingectomy would be a good option for contraception	15
Other issues	Interested in more information about ovarian cancer	7
	Would search the internet	3
	Would discuss with a gynecologist	15
	Would discuss with personal physician/ gynecologist	8
	Would discuss with family	5
	Would discuss with a psychologist	2
Time frame	Information 1 week before lap chole adequate	11
	Information 2 weeks or more weeks before lap chole	7
Costs	Should be covered by insurance	14
	Might be willing to pay	6

straightaway. Eleven of the 20 participants had no concerns regarding removal of the tubes. One participant would refuse opportunistic salpingectomy (Table 1).

Acceptance of opportunistic salpingectomy

Twelve of 20 participants would accept opportunistic salpingectomy at the time of their scheduled lap chole, 7 would need more time for making a decision but would not be averse, and one would refuse salpingectomy (Table 1).

Body image and femininity

Five of 20 women raised the importance of appearance; half of the responses (10 of 20) fell under the topic "mindful care for one's own body." Eleven patients reported that they trusted their instincts when making decisions. Two women did not show a distinct health consciousness. Fourteen participants thought that absence of the fallopian tubes would make no difference regarding body image, but two thought it might influence mental well-being (Table 1).

Ovarian cancer risk perception and risk-reducing salpingectomy

Nine participants had not thought about ovarian cancer and did not consider themselves informed about the disease. Seven women had concerns about ovarian cancer and would consider the reduction of risk to be reassuring (Table 1).

Fertility or the potential loss of fertility

Seventeen of 20 participants reported that fertility and having a family were very important. After completed childbearing, 7 women thought that infertility as a consequence of salpingectomy would not be a problem for them. Seventeen and 16, respectively, thought salpingectomy would not have an impact on femininity or sexuality and would welcome salpingectomy for contraception (Table 1).

What else would be relevant?

Seven of 20 participants were interested in more general information about ovarian cancer and 3 indicated they would now search the internet. Fifteen patients would like to discuss salpingectomy with a physician before the procedure, and 8 would like to talk to their family doctor or their personal gynecologist. Five indicated they would discuss this with their family.

Time required to make a decision regarding salpingectomy

Eleven of 20 participants indicated that 1 week would be a sufficient amount of time to consider and decide whether to undergo salpingectomy at the time of lap chole; 7 women would prefer 2 weeks or more. Nine women indicated they would accept salpingectomy straightaway.

Costs

Fourteen of 20 women thought that any cost of salpingectomy at the time of lap chole should be covered by their insurance (Austria has a public health care system that covers almost all disease-related medical procedures without co-payments). Six women thought they might be willing to pay for the additional procedure.

The results of the in-depth interviews were used to develop a 29-item, patient-reported outcome measure (PROM) to assess women's attitudes to elective opportunistic salpingectomy at the time of lap chole. This PROM is now being validated in a larger sample.

Discussion

Lap chole is a common operation in women and also affords a potential possibility for opportunistic salpingectomy. The results of the semi-structured interviews of women ≥45 years scheduled for elective lap chole suggest that most such women are open to the possibility of concomitant salpingectomy. The motivation was decreasing their risk for ovarian cancer; contraception was welcomed by women <50 years. This study was conceived as a precursor to a planned feasibility study of opportunistic salpingectomy at the time of elective lap chole.

Clearly, removing reproductive tract organs in patients with indications for operations of the hepatobiliary tract will require careful and comprehensive counselling and informed consent. Women will have to be informed about the rationale for the procedure and the magnitude of the possible benefit; about possible additional operative risks; about the elective nature of the procedure; about what the tubes do (as opposed to what the ovaries do); that salpingectomy means definitive sterilization but not onset of menopause; and about any additional costs that may have to be covered by the patient. The risks of salpingectomy at the time of gynecologic surgery is low[12,13] but may be greater when performed with lap chole. Consent is all the more important, because salpingectomy is unrelated to the indication for lap choleand is anatomically remote from the gallbladder. Despite these considerations, the women we interviewed were open to the idea, and most patients indicated that they would request salpingectomy if it were offered.

While opportunistic salpingectomy at the time of gynecologic surgery has been shown to be safe and easily performed, [12] we have found no reports of opportunistic salpingectomy at the time of non-gynecologic procedures. Because of technical factors, such as patient positioning and port placement, salpingectomy at the time of lap chole may not be as straightforward as salpingectomy at the time of pelvic surgery. Salpingectomy at the time of lap chole or other non-gynecologic procedures may have a non-negligible risk of severe complications (for example, hemorrhage, a bowel injury at the time of salpingectomy in a patient with a history of previous surgery or sigmoid diverticulitis). Salpingectomy at the time of non-gynecologic surgery is, however, a potential opportunity to decrease the risk of developing a potentially lethal disease (as well as providing reliable long-term contraception).

Ours was a pilot study with limitations. The number of patients was small. It was an interview study regarding a hypothetic question. No patient actually underwent salpingectomy. Responses may have been different if salpingectomy was actually offered, and patients were asked to decide. Furthermore all interviews were conducted by a single psychologist. Responses may have been different if women were approached about opportunistic salpingectomy in the course of routine clinical practice as opposed to a research setting. Women with a lower rate of previous gynecologic surgery may be less inclined to think about a further gynecologic procedure. Costs will differ in different health care systems where responses may be different if patients had to pay for the procedure. Finally, the patients were not given the estimated risk of severe complications or the expected risk reduction of developing ovarian cancer.

In conclusion, our interviews suggest that informed women >45 years scheduled for elective lap chole are likely to consider or request elective salpingectomy at the time of their lap chole if this were offered to them. Opportunistic salpingectomy at the time of non-gynecologic surgery appears to be an avenue worth pursu-

ing in an effort toward primary prevention of ovarian cancer. Offering an opportunistic salpingectomy at the time of non-gynecologic surgery would require a calculation of the risk/benefit ratio and would face a number of organizational and other challenges in clinical practice. The next step is a clinical feasibility study, which has been initiated as the salpingectomy at the time of elective cholecystectomy (SaLCHE) Trial (ClinicalTrials NCT03171467). This trial is studying acceptance, technical feasibility, time requirements, and complications.

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