Experiences and perceptions of women facing surgery of the ovaries; A qualitative study and development of the questionnaire complementing the consecutive sampling of biological tissue

Abstract

Indication for surgery of the ovaries includes both benign and malignant disorders. There is a paucity of studies regarding quality of life during the preoperative period before surgery of the ovaries. This study will apply semi-structured individual in-depth interviews with women about to have surgery at Department of obstetrics and gynecology at the University Hospital of Northern Sweden in Umeå to explore experiences and perceptions regarding quality of life, expectations, hopes and fears in that situation. Furthermore, the readiness to fill out a questionnaire will be explored. An existing questionnaire regarding known or suspected risk factors for ovarian cancer included in the "Consecutive sampling of ovarian tissue" will be further developed based on the qualitative analyses, validated and implemented. The possibilities of using a web-based design will be explored.

Purpose and aims

The purpose of this project is to explore women's experiences and perceptions on facing surgery of the ovaries as well as their views on answering a questionnaire, followed by developing a preoperative questionnaire.

The specific aims are:
1. To explore women's experiences and perceptions of the information given by health professionals at the time of diagnosis of an ovarian mass or other diagnosis leading to surgery of the ovaries, experiences and perceptions regarding risks and benefits of surgery in the short and long term, experiences and perceptions on having the ovaries removed and the meaning of hormonal loss, experiences and perceptions regarding possible altered identity as well expectations regarding sexual functioning after surgery, experiences and perceptions regarding the risk of malignancy and how to cope with the unknown result of surgery.
2. To explore the perceptions regarding filling out a questionnaire in the preoperative setting.
3. To develop and validate a questionnaire to complement consecutive sampling of biological samples from women having surgery due to an ovarian mass.

Survey of the field

Most ovarian disorders are benign, mainly benign neoplasms and functional ovarian cysts (1). Endometriosis is another gynecological disorder, and even though benign, it can have detrimental effect on quality of life (2). Endometriosis may in some instances indicate surgical treatment and removal of the ovaries or ovarian tissue (3). Of the gynecological malignancies, ovarian cancer carries the worst prognosis (4). Ovarian cancer is the eight most common cancer diagnosis worldwide with more than 295 000 cases a year (5) and an estimated 185 000 deaths per year (6). Ovarian cancer consists of a heterogenous group of malignant tumors that differs in morphology, etiology, molecular biology and prognosis (4). Because of the non-specific symptoms and the lack of reliable screening methods (7, 8),

approximately 60% of all ovarian cancers are diagnosed at a late stage (stage III and IV) (8). Overall, less than half of all women with ovarian cancer survive beyond five years after diagnosis, although the five-year survival rate is highly dependent on the cancer histotype and clinical stage at diagnosis (8).

Women with ovarian cancer faces high level of distress, especially women of younger age, diagnosed with more advanced disease, more physical symptoms and being newly diagnosed (9). The depression prevalence have been reported to be 25% during the pretreatment stage of ovarian cancer (10). Depression disorders in the general context of cancer have been associated with higher mortality rates (11, 12) and poorer quality of life (QoL) (13). There is an ongoing challenge how to best provide quality of care for cancer patients to optimize psychological and physical well-being (14). Women are reported to experience many difficulties during the diagnosis and treatment of an adnexal mass or ovarian cancer. Delayed diagnosis, lack of knowledge, uncertainty and side effects of the therapy have been described (15). A study of ovarian cancer survivals reported that system-based challenges such as treatment scheduling and waiting time were experienced as the most dominant issues with the health care system. The need to self-advocate or navigate the health system on one´s own when diagnosed with cancer have been reported as time-consuming, frustrating and exhausting (16). Patient- or nurse navigators who are well involved in each patients' medical situation and provides logistic and emotional support, may facilitate timely access to quality cancer care and improve patients QoL (17, 18). Increased medical advances in oncology with progress in survival time have led to a greater focus of cancer patients QoL (19). QoL have been defined by the World Health Organization (WHO) as the "individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" (20). There are several studies regarding QoL of women after a diagnosis, and during and after treatment, of ovarian cancer. However, there are only very few exploring women´s QoL during the phase of getting a diagnosis and pretreatment. In a recent study in Australia the theme "navigating uncertainty" summarized women´s general experiences, while four other themes highlighted significant areas where health care may be better aligned with women's preferences. These included "responsiveness in health care," "relational communication," "person-centered information," and "preparation for living beyond cancer treatment" (14). In a study from Canada in 2008 examining psychosocial experiences and support needs across the phases of epithelial ovarian cancer, the theme "extreme blunting" described women's experiences of the initial diagnosis as shocking and with absence of relevant information (21).

Significance and scientific novelty

There is a lack of qualitative studies regarding the views and perceptions of women with a known ovarian mass, or other diagnosis of the ovaries, about to have surgery. To our knowledge, this will be the first qualitative study within this area carried out in a Swedish setting. As an ovarian mass might be diagnosed as ovarian cancer with poor prognosis, this time period might be stressful and frightening for the affected woman. The results of this study will increase knowledge about women's experiences and perceptions in the preoperative period, and thereby have the potential to support positive changes regarding the quality of information and care as well as increased quality of life for women waiting for an ovarian surgery.

Project description

Study design

This project includes both semi-structured in-depth interviews as well as further development, validation and design of a pre-operative questionnaire. Further, several issues concerning an implementation of a web-based version of the questionnaire will be explored. If a web-based version is found feasible, it will be implemented.

Material and methods

I. In-depth interviews

For aim one and two, semi-structured individual in-depth interviews will be carried out. Eligible participants for this study will be women waiting for surgery of the ovaries at Department of obstetrics and gynecology, University Hospital of Northern Sweden, Umeå. The participants will be selected using purposive sampling, i.e. aiming for variation in age, education and indication for ovarian surgery. Women who do not speak Swedish will be excluded. Before participation in the interview each eligible participant will be individually approached by a research nurse or operation coordinator and receive oral and written information before filling in a consent form. The participant will also be informed that she may disrupt her participation at any time during the study and that participation will not affect any health care procedures. Women approving to participate in the study will have the ability to choose the place of the interview, for example at the woman's home, at the hospital or any other public location. During the interview a researcher conducting the interview will be present, and in some cases an observer. Women not living in Umeå, although waiting for surgery there, will in some cases have the possibility to be interviewed by telephone. Each interview will be digitally recorded and will take an estimated 60-90 minutes. Participant recruitment and data collection will continue until level of saturation, i.e. when no new information arises about the phenomenon under study (22). The study will apply emergent design if needed.

Thematic interview guide

An interview guide has been composed and will be pre-piloted among 2-3 women waiting for surgery. The aim of pilot testing the interview guide is to confirm the relevance and the coverage of the content in order to identify the possible need to make modifications of the questions before the start of the major study (23).

The following key domains are included in the interview guide.

Key domains
Women´s experiences and perceptions of: • The initial contact with healthcare before the decision of surgery of the ovaries • Earlier reproductive health in relation to the diagnosis of an ovarian mass or other indication for ovarian surgery (contraceptives, pregnancies and outcomes, menopausal hormone, sexuality) • The information given by health professionals about the diagnosis

- Waiting for surgery of the ovaries with special focus on the risk of malignancy (when indicated)
- What the health care could have done to improve/ease the waiting time
- Pros and cons of having this surgery
- How the operation will affect the female role regarding health, sexuality and lack of hormones, and the relationship to a possible partner
- The quality of life before and after the decision of surgery of the ovaries
- Answering a questionnaire regarding reproductive history
- Other topics related to waiting for surgery of the ovaries, that the participants want to discuss

Data analysis

The digitally recorded interviews will be transcribed verbatim in Swedish. The text materials will then be coded, categorized in sub-categories that will be aggregated in categories, and an overarching theme will be sought. Analysis will be performed through qualitative manifest and latent content analysis inspired by Graneheim and Lundman (24). Trustworthiness will be increased by triangulation, for example parallel coding of the same materials by different researchers followed by discussion to reach consensus on codes and their interpretation (25). Representative quotations will be sought for each sub-category and presented in English in the final paper.

II. The questionnaire

For the third aim, the previous questionnaire (Dnr 09-108/2016-470-32M) addressing medical information of known or suspected importance to gynecological cancer, will be updated and suitable results from the in-depth interviews will be used to form additional questions. The previous questionnaire is already used as a complement to the consecutive sampling of biological samples from women having surgery due to an ovarian mass or other indication for surgery of the ovaries. In the first step, approximately 4-5 women who have answered the previous questionnaire will be asked to be interviewed about the formulation and content of each question. In the next step, a new questionnaire will be developed based on the comments of the previous questionnaire and related results gained from the in-depth interviews. Collaboration with expertise in questionnaire design at Umeå University is established. Validation of the questionnaire will be performed by comparing the variables with relevant health data registers. The new questionnaire will also be validated with interviews of women waiting for gynecologic surgery as well as experts i.e. gynecologists working at the Department of obstetrics and gynecology at the University Hospital of Northern Sweden in Umeå and sub-specialist in gynecologic pathology, Department of Medical Biosciences, Pathology, Umeå University. Further validation methods might be applied.

Additionally, the technical, organizational, legal and economic issues regarding the use of a web-based version of the questionnaire will be explored, and a web-based version will be developed and implemented if feasible.

Ethical consideration

An ethical approval will be sought before the initiation of the study. Informed consent will be the foundation for participation. The research team are aware that some questions in the interview guide may be sensitive, and participants can choose not to answer if they prefer. For both the in-depth interviews and the questionnaire, the results will be presented on an aggregated level. When individual quotations will be used to illustrate findings, identifying characteristics will not be presented.

The questionnaire will not include any identifying characteristics such as name or personal number. Instead, the questionnaire will be labeled with an identification number in order to link the data to the biological samples. The questionnaires will be stored at a safe location in accordance with national regulations. Participants will be able to take part of the results of this study through the manuscript or published paper.

Timeline for research activities

Project	Activity	2019 December	2020 Spring	2020 Fall	2021
In-depth interviews	Develop plan, ethical approval	x	x		
	Interviews		x		
	Coding and interpretation		x		
	Publishing manuscript			x	
	Present at conference				x
Develop questionnaire	Detailed plan and ethical approval	x	x		
	Design		x		
	Validation		x		
	Implementation			x	
	Explore the possibility of a web-based questionnaire		x		

Project organization/resources

Annika Idahl: MD, Associate professor of obstetrics and gynecology. Experienced researcher regarding ovarian cancer epidemiology as well as academic clinical trials. Experience in qualitative methods. PI of the study. Conception and design. Analyzing and critically revising manuscripts. Exploring possibilities for a web-based questionnaire.

Sophia Holmlund: Midwife, PhD. Experience in qualitative and epidemiological methods as well as development of questionnaires. Conception and design. Performing interviews. Analyzing and drafting manuscripts. Validation of questionnaire. Exploring possibilities for a web-based questionnaire.

Ewa Rolfsman: Associate professor at Department of Applied Educational Science. Experienced researcher in questionnaire design and validation methods. Development and validation of questionnaire.

Ann Lalos: Senior professor at Department of Clinical Sciences, Obstetrics and Gynecology. Experienced researcher in infertility, abortion, gynecological cancer and sexuality. Experience in qualitative methods. Conception and design. Critically revising manuscripts.

Eva Lundin: MD. Professor at Department of Medical Biosciences, Pathology. PI of the study "Ovarian cancer – markers for early diagnosis and prognosis" including the questionnaire that will be updated and validated in this study. Conception and design of the questionnaire.

Ulrika Ottander: MD, Associate professor of obstetrics and gynecology. Experienced researcher regarding ovarian cancer and gynecological surgical procedures. Conception and design of the questionnaire.

Equipment

In the research group, all necessary equipment is available.

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