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A qualitative study of ovarian cancer survivors' perceptions of endpoints and goals of care

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HIGHLIGHTS

- Concepts important to ovarian cancer survivors include communication with one's physician and expectations changing with position along the treatment continuum.
- While all survivors identify communication with one's physician as essential, only 14% reported having such communication prior to treatment decisions.
- Survivors prefer an individualized approach to care focusing on quality of life instead of chronologic increments of survival.

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ABSTRACT

Objectives. A survey of the Ovarian Cancer National Alliance revealed a communication gap between physicians and survivors. This qualitative study explored the space between perceptions in hopes of better defining treatment endpoints meaningful to treating physicians and their patients.

Methods. A focus group of ovarian cancer survivors (n = 22) was assembled via the survivor support network SHARE. A physician-guided session explored expectations of treatment, perceived outcomes, toxicity thresholds and decision making. The session was recorded, transcribed and coded. Common themes were identified and used to perform intra-case analysis by two independent reviewers.

Results. The main themes identified were barriers to communication, importance of frequent communication between patient and physician regarding goals, and expectations of treatment changing with position along the treatment continuum. One hundred percent of participants identified communication with their physician as an essential element in determining treatment course. However, only 14% reported having a discussion about goals, values and perceptions with their physician preceding treatment decisions. Participants reported that the terms progression free and overall survival held minimal significance for them and instead they preferred an individualized approach to care focusing on quality of life. Many women underreported side effects with reasons ranging from fear of dose reductions and additional tests to forgetting about symptoms due to anxiety.

Conclusions. An objective measure of treatment success meaningful to survivors, physicians and regulators is, at present, elusive and may not exist. Ideally, future trial design would place equal weight on quantitative and qualitative measures and include information about goals of treatment.

Introduction

Clinical trial endpoints have profound effects on late phase clinical trial design, interpretation, drug development, and regulatory approval of therapeutic agents. Selection of the optimal clinical trial endpoint is particularly provocative in ovarian cancer where long overall survival is observed even for those who present with advanced disease stages. This subject has been a source of recent discussion due to lack of new regulatory approvals as clinical trialists, regulatory bodies and industry debate the relative merits and shortcomings of different endpoints [1].

At the time of the initial diagnosis in patients with advanced cancer, many will seek aggressive therapy, hoping for extraordinary results. However, the expectations and goals of most patients will change over time [2,3]. Furthermore, what constitutes value in medical care can change dramatically, ranging from extension of life, to high quality life, tolerable side effects and communication with one's oncologist [4]. Overall survival and progression-free survival most commonly

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constitute the primary endpoints in ovarian cancer clinical trials [5]. However, as many ovarian cancer patients can achieve long overall survival, up to 100 months per a recent study [6], and goals of care will likely develop with time, some have suggested updated mechanisms of assessment in the clinical trial setting, for example instruments that assess quality of life and symptom control [7].

A survey of the Ovarian Cancer National Alliance entitled, "Endpoints in Clinical Trials: What do our patients consider important?" revealed a communication gap between physicians and survivors regarding this important issue [1]. This qualitative study will explore the space between perceptions in hopes of better defining treatment endpoints meaningful to treating physicians and their patients.

Methods

This study was approved by the New York University Langone Medical Center institutional review board. A single focus group was organized and held at the New York City headquarters of SHARE. SHARE is a 38-year-old nonprofit organization that enables informed survivors of ovarian and breast cancer to help women facing these diseases through its toll-free national helplines, in person support groups, educational programs and advocacy. Patient advocates from SHARE identified women who were previously known to the organization with a diagnosis ovarian cancer, primary peritoneal cancer or fallopian tube cancer who had completed front line treatment. These eligible women were contacted by email and invited to participate in a focus group discussion with the objective of better understanding the perceptions of ovarian cancer survivors regarding endpoints and goals of care. The invitation explained that the session would be recorded and used for the purpose of research, but that no identifying information would be obtained. Women were not offered any compensation for their participation.

Prior to the convening of the focus group, a voluntary and anonymous questionnaire was distributed by email to women who had indicated intention to participate in the focus group. This questionnaire included personal demographic questions (e.g. age, ethnicity, profession), disease-related questions (e.g. cancer diagnosis, cancer stage, number of recurrences, current disease status) and questions about treatment goals and quality of life priorities.

All participants signed a written release for the use of study audio recordings. The moderator reviewed the release documentation and verbally confirmed informed consent from each participant prior to starting the focus group. The focus group was arranged in a circular pattern to encourage discussion [8]. A moderator guide containing open-ended questions was prepared by the authors and used by the physician moderator (Supplementary material I). Assistant moderators were present to ensure recording was functioning, take notes and observe interactions and behaviors. Techniques such as reflection (e.g., "Let me repeat what you said") were used to clarify statements [9]. Participants were assigned numbers and stated their number prior to speaking on each occasion to facilitate future transcription. The session lasted 90 min. Immediately following the session the moderator and assistant moderators debriefed.

The focus group session was audio-recorded and transcribed in entirety. The narrative logs were ordered chronologically, as suggested by Bogdan [10]. Iterative review of the transcripts and coder triangulation were used to thematically analyze the data. Members of the research team individually reviewed the transcript and created an inclusive list of master themes. Two independent readers then coded the transcripts. A third reader reviewed then coded transcripts for inter-rater agreement. Disagreements were then discussed and resolved. Numerous category codes were generated and used to organize the data [11]. Common themes that emerged from the data were coded and used to illuminate patterns and hypotheses. General coding schemes included setting/context codes, participant perspective codes, event codes, strategy codes and relationship codes [10]. Any deviation from these patterns was documented and explored. Finally, the patterns that emerged from this data were compared to the findings of prior studies on related topics.

Results

Twenty-two women completed the pre-focus group questionnaire and participated in the focus group. The median age of participants was 66 (range 39–71). Three participants (14%) were initially diagnosed with stage one disease, 17 (77%) with stage three disease and two (9%) with stage four disease. Thirteen women (59%) reported a history of disease recurrence. The median number of recurrences was one and ranged from one to nine. Four participants (18%) reported that they were receiving treatment at the time of the focus group. Ten women (45%) reported experiencing side effects either from treatment or disease at the time of the focus group. Four participants (18%) reported having previously participated in a clinical trial (Table 1).

The first part of the focus group included three yes versus no questions asked to the entire group. Participants answered by raising their hands. The first question was, "has your physician had a discussion about your goals, values and perceptions during treatment planning?" to which three participants (14%) answered yes. The second question was "should a discussion about your goals, values and perceptions be included when determining treatment plans?" to which 22 participants (100%) answered yes. The third question was, "have you been able to communicate your goals and values to your physician?" to which 15 women (68%) answered yes.

Table 1
Participant demographics.

Age (median, range)	64 (47–72)
Age at diagnosis (median, range)	55 (39–71)
Ethnicity	
Caucasian	19 (86%)
African American	2 (9%)
No answer	1 (5%)
Profession	
Health care	9 (41%)
Business/sales	4 (18%)
Retired	4 (18%)
Unemployed	2 (9%)
Other	3 (14%)
Cancer diagnosis	
Ovarian cancer	21 (95%)
Fallopian tube caner	1 (5%)
Primary peritoneal cancer	0 (0%)
Cancer stage	
I	3 (14%)
II	0 (0%)
III	17 (77%)
IV	2 (9%)
Recurrent disease	
Yes	13 (59%)
No	9 (41%)
Number of recurrences (median, range)	1 (1–9)
Currently receiving treatment	
Yes	4 (18%)
No	17 (77%)
No answer	1 (5%)
Currently experiencing unresolved side effects of treatment or disease	
Yes	10 (45%)
No	5 (23%)
No answer	7 (32%)
Prior participation in clinical trial	
Yes	4 (18%)
No	16 (73%)
No answer	2 (95%)
BRCA status	
BRCA 1/2 mutation positive	6 (27%)
BRCA 1/2 mutation negative	11 (50%)
BRCA 1/2 mutation unknown	5 (23%)