

ECPC Metastatic Breast Cancer Roundtable

October 29, 2020

Welcome & Introductions

Antonella Cardone welcomed the participants to the roundtable. She introduced ECPC as a co-leader in the roundtable and ECPC's main project, the Transforming Breast Cancer Together Initiative. All participants and panelists also briefly introduced themselves.

Roundtable Participants

Moderator: Dr. Fatima Cardoso, ABC Global Alliance

Panelists:

- Antonella Cardone, ECPC
- Charis Girvalaki, ECPC
- Suepatra May-Slater, PRECISIONheor

Participants:

Name	Organization	Country
Sabine S. Spitz	Europa Donna Austria	Austria
Assia Konsoulova	Women for oncology - Bulgaria	Bulgaria
Mariela Vasileva-Slaveva	Women for oncology - Bulgaria	Bulgaria
Ana Tecic Vuger	Croatia OncoWay	Croatia
Magdaléna Vošalíková	Alliance of Women with Breast Cancer	Czech Republic
Olga Rozsivalova	The Alliance of Women with Breast Cancer	Czech Republic
Renate Haidinger	Brustkrebs Deutschland e.V. (German Breast Cancer Association)	Germany
Sylvia Brathuhn	Women selfhelp Cancer	Germany
Helen Forristal	Marie Keating Foundation	Ireland
Clare Busuttil	Europa Donna Malta	Malta
Roberta Ventura	ABC Global Alliance	Portugal
Roswitha Britz	Fecma (Spanish Federation Of Breast Cancer)	Spain
Susanne Dieroffhay	Swedish Breast Cancer Association	Sweden
Carla Whitbread	firça - strength against cancer	United Kingdom

Surrogate Survival Endpoints

During the roundtable discussion, Dr. Cardoso defined the terms endpoint, outcome, and surrogate. She noted that an endpoint is a way of measuring efficacy or QoL and is used to measure the effect of a treatment. She shared an analogy of height's relationship to increments of measurement. The outcome is height, but centimeter or inches is the endpoint used to assess height. She also noted that a surrogate is an endpoint that is approximate. In clinical trials, if the endpoint is difficult to measure or requires too much time (takes too long) to measure, surrogates are utilized as a proxy for a treatment's effectiveness. She noted for the audience that not always there is a good correlation between the surrogate and the actual endpoint (for example not always progression free survival is correlated with overall survival).

Charis Girvalak reviewed the literature review findings on surrogate survival endpoints for the audience and Dr. Cardoso then posed to the panel participants specific questions followed by group discussion and observer comments that prompted further discussion, as noted below.

- Discussion Question 1: How can we better educate patients about **surrogate survival endpoints**?
 - The language around surrogate survival endpoints is considered “obtuse”. Participants noted the critical need to simplify the terms, language, and definitions for: surrogate, endpoint, and survival. These terms are daunting to experienced breast cancer advocates, and even more confusing for “normal” breast cancer patients who often can’t even cope well with their diagnosis, let alone these complex terms.
 - One panel participant highlighted that the fact that many patients do not want to “take in” these words, as they are struggling to cope with just the idea that they have metastatic breast cancer.
 - Another participant currently undergoing treatment shared that she did a lot of research on her diagnosis and thought surrogate survival endpoint was “a lot to take in” and had to look it up in the dictionary repeatedly to get an objective definition.
 - Another participant also struggled with the term when she first heard it. Patients struggle to understand what an endpoint is to begin, with and adding “surrogate” makes it an even more complex term. It is important to talk to patients with plain language

- Discussion Question 2: How do patients **interpret progression-free survival**?

Dr. Cardoso noted that when explaining the concept of PFS to patients is the time during which the tumor under control, not growing. Is that important? Yes, if the growth of tumor is linked to symptoms and by controlling it you control the symptoms. It also depends on the toxicity of the treatment; the toxicity cannot be higher than the disease symptoms. Despite having “survival” in the name it is not always related to extending survival.

- Panel participants concurred with one participant’s suggestion to rename progression-free survival to a simpler easier to understand term, because patients only hear the word "survival."
- Discussion Question 3: In the absence of overall survival data for a given therapy, **which endpoints become most important to patients** when thinking about treatment benefit?
 - The participants generally agreed that while QoL is important, it is not the same for all patients. Participants noted that patients valued being able to work, spend time with their children, maintain their normal daily routine, living an independent life, and managing side effects to the degree possible.
- Discussion Question 4: Now that patients are living longer with mBC, **what other patient relevant aspects should be considered and measured as an endpoint** to explain the impact of treatment and disease on patients’ day-to-day lives?
 - Participants noted that typical clinical trial endpoints (i.e. the effects/outcomes of a certain treatment or action) that are important to patients are often related to QoL, however as previously noted, QoL is not the same for all patients and throughout the cancer journey.
 - One participant noted that although the clinical definition of stable disease or PFS may be whether or not the tumor was shrinking - to patients, it does not matter if the tumor was shrinking. Patients prefer stable disease and QoL rather than shrinking of tumor.
 - The participants reiterated that for patients, quality of life is about the ability to preserve their normal functioning of day to day life and to be able to go to work, spend time with family and manage daily activities of life without impact of side effects.

Patient Preferences and Treatment Decision Making

Charis Girvalaki, reviewed the literature review findings on patient preferences and treatment decision making in mBC for the audience and Dr. Cardoso then posed to the panel participants specific questions, followed by group discussion and observer comments that prompted further discussion, as noted below.

- Discussion Question 1: How can **patient-physician dialogue be improved** regarding treatment options and alignment around treatment goals?
 - Most participants agreed that physicians do not ask what the main concerns of the patients are. The treatment and the disease itself, might take time, and the clinical encounter time is limited. Thus, it is important for the physician to know what the patient needs are at that time.
 - The breast cancer nurse can play an important role in patient-physician dialogue. To some participants, the nurse can explain the treatment options better, which allows physicians the time to talk about other important points during the appointment. There are many benefits in breast cancer nurses eliciting patient needs and preferences.
 - One participant mentioned aligning patient expectations with the physician upfront. Some patients may expect their physician to tell them about all their options other than oncology drugs, such as Traditional Chinese Medicine, to help with their diagnosis.
 - An oncologist commented that discussions around treatment goals are not a one-step process and discussions have to happen at different levels, with caregivers and nurses, etc.
 - There is a need for additional physician training when communicating with patients. Some participants noted their physician's body language (sitting down, standing up, etc.) when discussing metastatic disease.

- Discussion Question 2: What patient **needs, expectations, or desires** are currently not addressed by health care providers and/or health systems?

Dr. Cardoso commented that patients should actively define treatment goals and doctors should provide treatment options.

- Overall, participants expressed that the patient-physician relationship needs improvement. Participants wish to be respected by the physician and involved in decision-making.
- Participants noted the critical need for care providers to accept and respect the patient perspective. One participant stated "We are professional patients that need to be listened to."
- The patient care team must look at the patient as a whole person, and bring a holistic view of understanding the patient as an individual, not just treating the cancer.

- One participant noted that providers should “treat patients as people” who have own individual needs, desires, concerns.
 - Another participant noted that some patients expect the oncologist to have “all the answers” and play the role of the dietician, counselor, and other roles that they may not be able to play.
 - The participants noted that long term and late emerging side effects of treatments are rarely discussed and needs to be given more attention in the patient-physician dialogue – often the focus is on the “now” as opposed to what may occur in the future.
 - Finally, one patient noted that treatment impact on the brain (e.g. cognitive side effects) are often not addressed by providers.
- Discussion Question 3: What **barriers** do patients continue to face in communicating their desires and expectations for treatment?
 - Provider respect and empathy/understanding for patients is often considered a barrier. Physicians need to show that they respect the patient and accept the patient’s views.
 - One patient noted that fear is a major issue, as sometimes patients do not want to ask questions about treatment because they are afraid of the answers.
 - Physicians should explain palliative care in a simple and humane fashion.
 - In the clinical encounter, patients aren’t given adequate time or opportunity to express their fears or desires with their care team and may often fear doing so.
 - The time the patient spends with the physician is crucial, and physicians need to invest time in the consultation and follow up discussions, even if that is addressed with the patient by other members of the care team.
 - One of the participants recommended making a list of questions, and Dr. Cardoso noted that questions should be listed in order of priority in case not everything is discussed. The participants emphasized that it is important to not be afraid ask someone questions and for help, and make follow-up appointments if needed.
 - Some patients would like the oncologist to provide more holistic care – not just “giving the drug”, but considering all the other aspects and factors that can support patients.
 - It was widely suggested that patients attend appointments with members of their support network including partners, children, or friends. However, it was also noted that in the presence of others, it may be difficult for the patient to freely discuss treatment options and prognosis. It is better for patients to discuss QoL with the physician without the presence of a guest.
 - Participants noted that the coronavirus pandemic – and the limits it has placed on the presence of patient’s support partners - has provided an

opportunity to rethink the patient-physician dialogue within the context of cancer treatment.

Quality of Life and Symptom Burden

Charis reviewed the literature review findings on quality of life and symptom burden in mBC for the audience and Dr. Cardoso then posed to the panel participants specific questions, followed by group discussion and observer comments that prompted further discussion, as noted below.

- Discussion Question 1: How do **patients define QoL**?
 - Participants suggest that whatever the patient identifies as a QoL impact needs to be followed up on in health assessment measures repeatedly. Physical, social, psychological, and financial implications/costs should be integrated into quality of life assessments, as they are all important to the patients.

- Discussion Question 2a: Which **factors have the strongest impact on QoL** (e.g., type of treatment, being free of progression, route of administration, etc.)?
 - Psychologically patients must accept the disease and prepare for changing circumstances. Oncologists often explain this aspect to patients. One participant shared that she now carries medication when going for a walk, in case she has back pain.
 - Pain control and sleep control have strongest impact on QoL, no matter the line of therapy. They cause significant impact on patients' daily life and are difficult for them to tackle.
 - Patients having multiple treatment appointments in silos, rather than together, impacts QOL.

- Discussion Question 2b: How do patients **consider tradeoffs between symptoms and staying progression-free**, as mBC patients are living longer with the disease?
 - An oncologist participant commented that we cannot always achieve OS, and QoL is an acceptable primary endpoint given that it is an especially important endpoint for patients with mBC.
 - To patients, management of side effects is key. Patients highlighted pain as a key symptom to manage. However, all symptoms are important to avoid, and it is not necessarily about choosing between vomiting and diarrhea, for example.

The following discussion questions (2c and 3) were included in the presentation but were not explicitly addressed by the moderator, as these were embedded in previous responses.

- Discussion Question 2c: Which **symptoms are patients willing to experience** to remain progression-free?

- Discussion Question 3: Which **symptoms are most important to minimize** to maintain quality of life?

- Discussion Question 4: Which **dimensions related to QoL** (e.g., physical, psychosocial, functional ability) **should population health decision makers integrate** in HTA considerations?
 - Participants agreed that decision makers should include all four dimensions (physical, psychosocial, functional ability, and financial) in HTA considerations.

- Discussion Question 5: How important is **mode of treatment administration** (e.g., an oral therapy vs. an intravenous therapy) and related QoL when considering treatment options? Why?
 - Participants gave mixed reactions to mode of treatment administrations. Most preferred oral therapy because they feel less restricted (i.e. able to travel) and oral therapies require less frequent visits to the clinic, particularly if distance is an issue.
 - Distance to clinic was a significant consideration because patients may have to travel further or more frequently for an IV infusion. In addition, there is a common misperception that IV therapy is more efficacious.
 - Lastly, for some patients, frequent engagement with the system (e.g. visits to the clinic for IV infusion) can provide reassurance for patients.

In some countries, providers may receive greater reimbursement for prescribing IV therapies, thereby incentivizing them to recommend this form of treatment over oral therapies.

- Discussion Question 6: What is **missing from treatments today** that may improve a patient's tolerability for treatment?
 - During this pandemic, many patients are not able to visit the clinic with members with support partners, due to clinic access restrictions. This has been particularly problematic when patients are alone and being given bad news.

- Participants noted the critical need for better management of side effects and associated wrap around care. Dr. Cardoso noted that 90% of mBC side effects can be successfully managed with available therapies and interventions. However, a comprehensive approach to management is needed, including:
 - Educating patients about potential side effects
 - Preventing potential side effects through prophylaxis
 - Ensuring that providers actively reduce dosage if side effects are experienced, and that patients do not fear reductions in dose as reducing a dose does not necessarily reduce efficacy.
 - Development of a guide with tips on what to anticipate and recommendations on how to manage side effects would be very beneficial for patients.

Caregiver Burden

Charis reviewed the literature review findings on caregiver burden in mBC for the audience and Dr. Cardoso then posed to the panel participants specific questions followed by group discussion and observer comments that prompted further discussion, as noted below.

- Discussion Question 1: How do patients account for **the impact of a therapy to caregivers** at different points in the treatment journey?
 - Participants noted that caregivers are burdened by worry about the patient and their concerns, while patients themselves do not want to be an additional psychological burden to caregivers.
 - While caregivers may want what is best for the patient, they may also not be able to handle or process news about the patient's health or a poor prognosis. This places an enormous emotional toll on the patient as well.
 - Many of the panel participants shared their caregivers concerns about their own cancer course.
- Discussion Question 2: Are there **other impacts** on caregivers that are not reflected in the summary?
 - Participants noted the critical need to develop resources to support caregivers, such as educational materials or mental health support resources.
 - Further, there should be a recognition that there are patients who simply don't have caregivers, who also require support.
 - Providers need to provide support services to caregivers as well, (e.g. referrals to counseling/psycho-oncologists) because caregivers need to be

able to look after themselves too, if they are to effectively care for the patient.

- Most caregivers do not tell their employers that they are caregivers and will often suffer at work because their employers or colleagues are unaware about their circumstances or not sympathetic to their circumstances.
- Caregivers experience distress and often need to repress their own feelings about the burden they are experiencing.
- Caregivers may have responsibilities to more than one person.
 - One patient shared that her husband is her primary caregiver but is often caring for both of their elderly parents.