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Note from the editor

In the feature section of this newsletter, the area dealt with relates to “fighting breast cancer in the Middle East”. Three countries are described: Egypt, Iran and Israel. The article on this topic, by science writer Jenny Bryan, includes interviews by Prof. Hesham El Ghazaly (Egypt), Prof. Mohammad Akbari (Iran) and Prof. Bella Kaufman (Israel). Other countries in the Middle East, such as Iraq, Saudi Arabia, Syria, Jordan and Lebanon, as well as some North African countries, are not treated in this review.

The article is very informative on the efforts related to breast cancer prevention, early diagnosis and adherence to best care of the adjuvant setting. Less information is provided on availability of treatment options and on quality of life concerning patients with advanced disease. On this important topic, the personal story of Professor Bella Kaufman on being an oncologist in a large university hospital in Israel, and devoted to breast cancer care and research, as well as being a woman living with advanced breast cancer, is a relevant testimony. The issue of having access to new drugs is mentioned in her testimony, and is probably one of the most severe problems in breast cancer care and research in many Middle Eastern countries.

Breast cancer is a very common cancer in all Middle Eastern countries. Unfortunately, the political situation in the region is such that health issues in general, and breast cancer care and research in particular, are far from being a priority. With the population of Egypt (99 mil), Iran (77 mil), Israel (more than 8 mil) and other countries of the region such as Iraq (37 mil) and Saudi Arabia (33 mil), which are not mentioned in the interviews, breast cancer should receive more attention.

Presentation of newly diagnosed breast cancer in Middle Eastern countries occurs in earlier age (on average about ten years earlier) and at a more advanced stage than in Europe or the US. The incidence of breast cancer varies in the different countries and little is known about the distribution of genetic causes and lifestyle features contributing to these patterns. Research on BRCA 1 and 2 has been systematic only in Israel, but also in this country, information on other predisposition genes has been scarce. Considering the different incidence of breast cancer in Iran as compared with other countries in the Middle East, genetic and lifestyle studies might be a significant opportunity for a deeper understanding of the disease worldwide.

Besides the political situation and the unstable relationship among countries, little may be done to convince the various governments to address more attention to, and provide funding for clinical research in breast cancer.

Scarcé funding for clinical research in general is a major issue, even in Europe. Clinical research requires a sound structure and specifically trained personnel which is not easy to create, nourish and renew.

BIG has an important role in providing a platform on which clinical research could be fast and efficient allowing a more effective conduct of clinical trials within a network of countries across the world, thus competing with company-sponsored trials for yield and timing. An enhanced adherence of countries like those in the Middle East, where research is scarce and availability of innovative trials is rare, would be a significant step towards improving the condition of care for women with the disease. Furthermore, increased collaboration between the countries of the region on issues of prevention, care and research might be even more relevant for progress in the field and, maybe, for a peaceful coexistence too.

Establishing breast cancer registries, implementing mammographic and BRCA screening, extending treatment options and contributing to worldwide clinical trials are key priorities for the growing number of breast cancer specialists working across the Middle East.

Although there is considerable variation in the incidence and nature of the disease in the region, researchers are united in their desire to contribute to a better understanding of breast cancer and to improve outcomes for patients.

“We are entering a new era and, in the last five years, there has been much greater emphasis on research in the Middle East. We have plenty of ideas and we are expanding and integrating our research infrastructure, but it will only be possible to get the full flavour of breast cancer worldwide if countries of the Middle East take part in international studies,” says Professor Hesham El Ghazaly, Professor of Clinical Oncology and Head of the Medical Research Institute at Ain Shams University (MASRI), Cairo, Egypt.

MASRI, which opened officially in February 2018, brings together basic, animal, clinical and translational research, as well as bio-banking, in one building and is aiming to connect with all the 20-25 cancer research centres in Egypt. A unified plan is being developed to control breast and other cancers in the country, to avoid unnecessary duplication of research infrastructure, and to facilitate transfer of standardised data between centres, according to guidelines.

By raising standards in this way, it is hoped that cancer centres in Egypt will be able to play a more active role in international clinical trials, such as those coordinated by BIG.

“We already collaborate with researchers in Saudi Arabia, Algeria, the United Arab Emirates and Lebanon, but there is no umbrella organisation bringing together and augmenting all of the national breast cancer initiatives in the region,” says Professor El Ghazaly.

“We are trying to establish a better network of breast cancer research organisations, and also to use BIG as the umbrella for our research to enable us to collaborate at an international level.”

Professor Hesham El Ghazaly
Breast cancer is the most common form of cancer in women across the Middle East, with approximately 82,000 new cases each year in countries of the Middle East and North Africa (MENA), and over 30,000 deaths.

The disease typically occurs 10 years earlier than in women in western countries, with a median age of 48 years, and two thirds of women are under 50 when diagnosed. This compares with a median of 63 years in Europe and the US, with only 25-30% under 50 at diagnosis.

In some countries of the Middle East, breast cancer is diagnosed at a later stage, and this is generally attributed to lack of screening facilities or a reluctance to seek help. In a recently published survey with over 100 responses from oncologists working in MENA countries, more than 50% of participants reported that there was no efficient national or institutional breast cancer screening programme in their country.

ER+ tumours are generally less common in Middle Eastern than in western populations, though there is considerable variation. In Egypt and Iran, the proportions of women with ER+, HER2+ and triple negative disease are similar to those seen in Europe and the US. But research in Saudi Arabia has revealed a unique pattern in which 20% of women were found to have luminal A/B tumours, 17% HER2+, 10% with basal tumours, and 43% unclassified or penta-negative ones (i.e., ER-, PR-, HER2-, EGFR-, and cytokerin 5/6-).

Information about the frequency of BRCA mutations in women in the Middle East is limited, though high levels have been reported in women in Tunisia and in Ashkenazi Jewish women.

Inflammatory breast cancer is more common in Arab than in western populations, with rates of approximately 10% reported in Tunisia and Egypt.

As breast cancer is often diagnosed at a later stage in some countries of the Middle East, mastectomy is more commonly carried out than in western countries. However, in a recently reported study of over 3,000 women treated at a major cancer centre in Iran between 1998 and 2014, two thirds of breast tumours were stage 1/2 and breast conserving surgery was performed in approximately 60% of women.

As in western countries, availability of newer breast cancer treatments in the Middle East depends on financial constraints. Results from the recent MENA survey showed that, while the older generation chemotherapy agents were available at most centres, the availability of newer agents was limited, with lapatinib used in 40% of centres, eribulin at 11%, ixabepilone at 7.7%, pertuzumab at 10.1%, and trastuzumab emtansine at 6.2%.

In Israel, where some of the pivotal early research on HER2 was carried out, a wide range of treatments is available at hospitals across the country. But, despite humanitarian initiatives by Israeli physicians, treatment opportunities are much more limited in Gaza and the West Bank.

In the large Iranian study, 89% of patients were prescribed adjuvant therapy, and over 90% received external radiotherapy, with a small proportion receiving intraoperative radiotherapy. However, only 7% received trastuzumab.

Overall survival from breast cancer varies across the Middle East, but national rates of 77%, 80% and 71% have been reported in Egypt, Israel and Iran, with higher rates in specialist cancer centres.
Breast cancer priorities in Egypt

In Egypt, breast cancer is the most common cancer in women and makes up 34% of all cancers, with approximately 39,000 new cases per year.

“With 100 million people living in Egypt, we have the largest population in the Middle East and have increasing numbers of women presenting with breast cancer. However, as a low-income economy, it is difficult to collect all the data together.”

About eight per cent of women are diagnosed with inflammatory breast cancer, and there is ongoing research into a possible viral link to the disease. Early onset breast cancer (EOBC) in women under the age of 40 has been reported to be more common, more aggressive and with worse outcomes in women from Egypt and areas of North Africa than in other countries, and a recent study compared risk factors, phenotype and genotype in patients in Egypt, Algeria, Morocco and Tunisia with those in France, where the incidence of EOBC is increasing.7

The research, reported by Professor El Ghazaly and collaborators, showed that North African women were older at menarche, had more children, more frequent breastfeeding, a higher body mass index and lower use of oral contraception than French women. Tobacco and alcohol consumption were higher in the French patients and a family history of breast or ovarian cancer was more common.

Interestingly, in a sub group of women without a family history of breast cancer, there was a higher rate of BRCA1/2 in North African than in French women. Researchers suggested this may be explained by the lower penetrance of breast cancer in North Africa due to differences in genetics or environmental modulators between the two populations or to the fact that, for cultural reasons, North African families are less likely to talk about breast cancer and so patients were less likely to be aware of relatives who had the disease.

Professor El Ghazaly explains that education campaigns and mobile mammography units are helping to raise public awareness of breast cancer in Egypt, and progress has been made in decreasing the stage at which the disease is typically diagnosed closer to that seen in western countries. However, only about 200,000 women have been screened to date, there is a continuing need for education in Egypt about the value of clinical examination for earlier detection of breast cancer.

A new five-year prevention strategy developed by the National Committee Against Cancer in Egypt is focusing on all aspects of cancer care, from early detection to treatment, research and palliative care. Professor El Ghazaly explains that the intention is to develop prevention guidelines for implementation at all facilities where breast cancer is treated in the country, in collaboration with representatives from the World Health Organisation (WHO) and the Union for International Cancer Control (UICC), and possibly the U.S. National Institutes of Health (NIH).

Early onset and triple negative disease are important priorities for researchers in Egypt but, as in most countries, funding is a major challenge, with little money available from government. Most clinical trials are sponsored by pharmaceutical companies, though it is hoped that more of the money generated from such research can be channelled into supporting institutional and investigator-led studies.

“Breast cancer research is slightly fragmented in Egypt, because we have a complicated health system with services including government, university, private and insurance hospitals and NGOs. We are trying to connect our research through our professional organisations and the Breast-Gynecological International Cancer Society, and to get more external funding for broader based studies, including from European and US research organisations, such as ASCO,” says Professor El Ghazaly.

The good news is that, in recent years, Egyptian clinicians, especially the younger doctors, have become more interested in carrying out research - basic, translational and clinical -, and collaborative research projects are springing up across the Middle East.

Professor El Ghazaly suggests that, if BIG scientists could mentor breast cancer researchers in Egypt and other countries of the Middle East, this would be mutually beneficial:

“All the members of BIG will benefit from this because our patient genotypes will be included in clinical trials, which doesn’t happen at present. We already know that expression of epidermal growth factor receptor varies between non-small cell lung cancer populations in Asia compared to Caucasian populations, and this affects suitability for targeted treatment. It is very likely that similar variations exist with breast cancer and this could have important implications for future prevention and treatment of breast cancer.”

Breast cancer in Israel: focusing on BRCA mutations

With 4,500 new cases per year, breast cancer is the most common form of cancer diagnosed in Israel. The incidence (100 per 100,000 women) is like that of western countries, reflecting similarities in lifestyle, and is higher than other countries in the Middle East. Thanks to a national screening programme for women over 50, most cases are diagnosed at an early stage (I and II), and only 3-4% are diagnosed with stage IV disease.

However, as Professor Kaufman points out, the breast cancer profile in Israeli does differ significantly from that in western countries for the frequency of BRCA mutations. Amongst the 50-60% of women in Israel who are Ashkenazi Jews, approximately 2.5% have a BRCA mutation, which means that there are some 40,000 carriers in Israel.

There was a lower rate of BRCA1 mutation in North African than in French patients (7% vs. 15%, p=0.02), though there was no significant difference in the rate of BRCA2 mutations (8% vs. 6.6% respectively, p=0.58). The results of the study did not support the suggestion that EOBC was more aggressive in North African women, and it was concluded that the worse prognosis in these patients was due to more advanced stage at diagnosis.

Interestingly, in a sub group of women without a family history of breast cancer, there was a higher rate of BRCA1/2 in North African than in French women. Researchers suggested this may be explained by the lower penetrance of breast cancer in North Africa due to differences in genetics or environmental modulators between the two populations or to the fact that, for cultural reasons, North African families are less likely to talk about breast cancer and so patients were less likely to be aware of relatives who had the disease.

Professor Kaufman, who founded and leads the Israeli Consortium for Hereditary Breast Cancer, collaborated in a recent study to identify the most effective way to screen Ashkenazi Jewish women for three common BRCA 1 & 2 mutations.8 This showed that, amongst unaffected women aged 25 and over, and without known familial mutations, proactive recruitment to population screening had clear advantages over self-referral.

Professor Bella Kaufman, who founded and leads the Israeli Consortium for Hereditary Breast Cancer, in the Middle East, this would be mutually beneficial:

“All the members of BIG will benefit from this because our patient genotypes will be included in clinical trials, which doesn’t happen at present. We already know that expression of epidermal growth factor receptor varies between non-small cell lung cancer populations in Asia compared to Caucasian populations, and this affects suitability for targeted treatment. It is very likely that similar variations exist with breast cancer and this could have important implications for future prevention and treatment of breast cancer.”

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Women who were actively recruited for screening tended to be older and have a family history that was less suggestive of breast cancer than those who self-referred. Of the 1.2% of women who were BRCA carriers, 40% had no significant family history. 90% of participants would recommend general BRCA screening for Ashkenazi Jewish women.

“We are now doing a feasibility study to work out the best way to put these findings into practice for screening the Ashkenazi Jewish population for BRCA,” says Dr Kaufman. She explains that 60-70% of women with BRCA mutation breast cancer have triple negative disease, so there is concerted research in this area, which includes collaborations with research groups in the UK.

“We are initially testing for three founder BRCA mutations that we have in our Ashkenazi population, which is a lot easier and quicker than BRCA testing in other groups. In the last five years, we have also been building our tissue biobanks and are aiming to have primary tumour and metastatic samples or liquid biopsies for all our patients,” she says.

Alongside the considerable challenge of BRCA mutation-positive breast cancer in Israel is the problem of extending screening and treatment to Jewish women in the most conservative communities and to Arab women.

Professor Kaufman explains that, initially, it was impossible even to mention cancer to the most orthodox Jewish women, but after many years of education by women doctors and a lot of activity by the Israeli Cancer Association who take mobile mammogram units to Arab villages, considerable progress has been made.

“We now see similar uptake for screening in Arab women as in the rest of the population, though there is still some way to go with the ultra-ultra orthodox communities,” she says.

Women with breast cancer in Israel have access to the full range of treatments at low cost through a national health system, and the National Health Basket, similar to the National Institute for Health and Care Excellence (NICE) in the UK, meets twice a year to decide if new therapies should be made available.

As a result of earlier diagnosis and availability of new generation treatments, there is a continuing improvement in breast cancer survival in Israel, with overall mortality now standing at less than 20%.

For the future, Professor Kaufman believes that research should focus on issues that are most relevant to the country’s breast cancer population, notably those with hereditary breast cancer. She would like to see an epidemiological study of prevention and screening as well as translational research on BRCA tumours, and a growing role for Israeli researchers in phase I studies of new drugs.

“We need to focus on our strengths—we have the brains and the infrastructure, and you cannot be an oncologist if you are not optimistic!”

“I am optimistic that we can move ahead with our research and continue to improve the outlook for women with breast cancer in Israel—and hopefully across the Middle East.”

Professor Bella Kaufman

References

Egypt celebrates Breast Cancer Awareness Month

Throughout the month of October, countries around the world joined together to raise awareness about the importance of routine screening and early diagnosis for breast cancer.

In Egypt, the Breast Gynaecological International Cancer Society (BGICS) team led an awareness campaign called “PINK October ENTE AKWA”. This theme comes to life through the authentic, inspirational stories of individuals, as told by the brave women who have faced breast cancer, and the loved ones who support them throughout the difficult journey.

Covered by more than 50 international media outlets and newspapers targeting patients, caregivers and healthcare professionals, this successful campaign reached millions of people and caregivers, a sizeable percentage of the Egyptian population.

The campaign included a programme aimed to promote healthy living through exercise and nutrition, and to encourage women to get screened in the fight against breast cancer in both urban communities and the heartlands.

Additionally, the opportunity was offered to perform free bilateral breast screening using ultrasound. To get more women performing breast exams more often, BGICS encourages the free usage of their cheeky and informative leaflets, slideshows, posters, and more.

An important element of the campaign was designed to build the self-esteem of women already affected by breast cancer, through a practical approach to the appearance-related side effects of the disease. This included workshops to help women learn about cosmetic techniques and alternative hair fashion, and to have the opportunity to meet and communicate with other women undergoing cancer treatment.

The Breast Cancer through Art initiative consisted of contributions by artists and focused on how we deliver messages through art and painting. During Wear it Pink, the closing ceremony of the campaign, approximately one thousand pink ribbons were distributed. Chaired by Prof El Ghazali and involving other public figures and eminent speakers in the field of oncology and nutrition, the aim was to emphasise the key messages of the entire campaign, namely to encourage people to take positive and definitive action towards eradicating breast cancer by raising awareness about common risk factors, prevention and different screening methods available, as well as the importance of a balanced diet and an active lifestyle in maintaining optimal health.

Meet the experts

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“They didn’t have the privilege to meet an oncologist, they got all information from me. [...] They are all on this rollercoaster with me.”

However, how Bella focuses on the positive aspects of this difficult time of her life is truly admirable. She could not be more surrounded and supported by her family, friends and colleagues.

Her interactions with patients have changed, as she now feels able to better understand what the disease really means for them. Some of them know about her disease, others do not. In certain cases, she uses her story to encourage patients and share hope, optimism and advice. Other times, she is the one who gets inspired by them. “All meetings usually end with a hug now”, she says.

Bella’s condition triggered the launch of a compassionate programme for metastatic breast cancer patients in Israel called PALBOCICLIB, which has already benefitted 60 patients. She was the first patient.

Dr Bella Kaufman’s testimonial

On 2-4 November 2017, breast cancer specialists, patient advocates and journalists gathered at the 4th ESO-ESMO International Consensus Conference for Advanced Breast Cancer (ABC) in Lisbon, Portugal, to develop guidelines for the management of patients with ABC and raise awareness on the needs and challenges of this group.

During the opening session of the congress, Dr Bella Kaufman, Head of the Breast Cancer Unit at the Chaim Sheba Medical Center in Tel Aviv, Israel, gave a moving lecture, sharing with the attendants some insight into her life with metastatic breast cancer.

An oncologist with over 25 years’ experience, Bella was diagnosed with metastatic breast cancer in 2013.

Coping with the many changes in her life since the diagnosis – no longer being able to plan ahead or commit to any invitations, getting used to her new appearance, among others – Bella also feels disoriented, crossing back and forth from patient’s bed to doctor’s desk. She knows the data, the path and the outcome, and she admits sometimes being enveloped with deep sadness and a sense of pessimism. This knowledge is her best advantage as well as toughest disadvantage.

Her husband and children, with whom she often shares unfiltered information about her medical case, are not spared. While she always tries to protect her patients and their families from the emotional ups and downs, she has not found a way to do that for herself and her loved ones yet.

Bella concluded her talk by giving some tips to the attendance, wearing her “patient” shoes: “Remember, their disease is not their life. Our patients’ lives extend beyond their disease, so ask them, and share the joy and happiness that happen in their lives”.

“Where was that wall, that safety net? […] Once my world was a lot clearer. There was my side and theirs, the doctor and the patient. But no longer.”

Professor Bella Kaufman
In February 2018 a new BIG HQ structure was implemented. Why is this important?

CS: Just as it is important to periodically “refresh” BIG’s governance to meet the demands of a growing organisation and changing environment, it is essential to adapt BIG’s HQ structure to be able to do the same. Our restructuring aims on the one hand to be more streamlined, while at the same time to enable a dynamic, younger generation with deep scientific and clinical trials expertise to lead BIG HQ and support the organisation.

To Carolyn Straehle: You were present at the start of BIG. Two decades later, what achievement(s) make(s) you feel most proud of?

CS: It’s difficult to single out specific achievements, though I do feel proud to have played a significant role in building an organisation with international renown and contributing to an important social cause. When I joined BIG in 1999 as its first employee, the organisation was still an early-phase experiment that could well have failed. Along the way, there have been numerous challenges, but through persistence, hard work and doing my best to forge and maintain positive bonds between the great many individuals who contribute to BIG, as well as to establish a professional headquarters structure, much more has been achieved than I would ever have imagined almost 20 years ago.

To Theodora Goulioti: As incoming CEO at BIG HQ, what is your vision for the future of BIG as an organisation and of BIG HQ?

Theodora Goulioti: For nearly 20 years, BIG – by bringing together like-minded academic research groups and their world-class experts dedicated to finding cures for breast cancer through global research and collaboration – has been conducting international clinical trials and research programmes, many of which have been practice-changing. My vision for the future of BIG as an organisation is to continue working very closely with our member groups to further optimise breast cancer treatment, particularly in the areas that remain under-explored in the treatment journey of the patients with breast cancer but that are fully complementary to new drug development and translational research. To that purpose, we have recently established several working groups involving experts from throughout the BIG network. As for BIG HQ, Carolyn Straehle who has been with BIG since day 1, was able to build a team of highly motivated and talented people who work every day with the patient at heart.

“My vision is to further nurture this team and work even more closely with the headquarters of our member groups to ensure that we provide optimal support to breast cancer research and ultimately to those affected by the disease.” Theodora Goulioti

“With an expanded BIG Executive Board representing more disciplines and greater geographic representation, and involving both senior and earlier-career experts, BIG should be well poised to continue to run studies and programmes making a difference to people affected by breast cancer.” Carolyn Straehle

What does BIG HQ contribute to BIG as an organisation?

CS: Because the member groups of BIG are all independent entities – and quite diverse ones at that – it is important to have a strong, professional, and neutral management “hub” at the centre. One role that we have always had is to facilitate the communications between BIG groups, whether by organising scientific meetings or conducting surveys of interest about different studies and programmes. Over the years, though, we’ve increasingly contributed to the scientific and operational development and conduct of studies. And, importantly, we ensure that BIG’s academic principles, which are at the core of our mission, are maintained across our studies despite interacting with a great number of different partners.
In the PD-L1 positive population, the treatment yielded an objective response (ORR) rate of 15% and a disease control rate (DCR) of 25%. In the subgroup of PD-L1 positive patients with at least 5% or more TILs present in the metastatic lesion, the ORR was 39% and DCR was 47%, suggesting that quantification of TILs can contribute to identify patients who will benefit from this treatment. No responses were observed in the PD-L1 negative cohort. Three patients continued treatment beyond one year without disease progression. Pembrolizumab in combination with trastuzumab was very well tolerated, with mild or moderate fatigue the most commonly reported adverse event (21%). Four immune-adverse events were reported, two of them in the one patient (all resolved) who continued in complete remission after 2 years.

These results were presented by Dr. Sherene Loi. Dr. Loi concluded that immune evasion is a likely mechanism of resistance to trastuzumab since the majority of patients had low TILs in their metastatic lesion. She encouraged attendees to focus further research in immune-oncology for metastatic HER2+ patients on combinations with effective anti-HER2 therapy, especially in patients with low TILs.

A press release with the detailed study results was issued jointly by BIG and IBCSG and is available on the BIG website, in the scientific section.

SOFT and TEXT (BIG 2-02/BIG 3-02): ovarian suppression reduces recurrence for young breast cancer patients

At SABCS researchers presented a combined analysis of the SOFT and TEXT trials after a median follow-up of 9 years, which supports the first findings published in the New England Journal of Medicine in 2014.

Indeed, the results confirm that exemestane, compared to tamoxifen, significantly improves patient outcome when used concomitantly with trastuzumab.

An update of the SOFT trial after 8 years of follow-up was also presented and showed that adding ovarian suppression to tamoxifen significantly decreased the relative risk of disease-free survival events by 24% compared to tamoxifen alone. The clinical benefits were most pronounced in women younger than 35 with a relative risk reduction of 44%.

While the follow-up of the 5,738 participating patients continues, SOFT and TEXT together have already provided practice-changing results, giving doctors a new post-operative treatment option for young women with hormone-sensitive early breast cancer who may have a higher risk of cancer recurrence after surgery.

A press release was issued jointly by IBCSG and BIG and is available on the BIG website.

SOLD (BIG 1-10) supports standard one-year trastuzumab treatment

Synergistic drug combinations could lead to shorter treatments which have several advantages for patients and society, i.e. fewer toxicities and costs.

SOLD enrolled 2,176 patients from 63 centres in 7 countries. The REACT (BIG 1-03): no benefit from anti-inflammatory celecoxib in primary breast cancer patients

A phase III multicentre double-blind randomised trial of celecoxib versus placebo in primary breast cancer patients

The REACT trial first opened to recruitment in 2007 and completed recruitment in November 2012. In total 2,639 patients entered the trial: 1,825 from the UK (68 sites), and 814 from Germany (91 sites). Following 2 years of treatment with celecoxib, patients were followed-up 6-monthly for 1 year and then annually for up to 10 years.

In 2017, 10 years after the first patient was recruited, another key milestone of the trial was reached. As the year began, the trial approached a median follow-up of 9 years, and the coordinating teams in the UK (International Collaborative Cancer Group) and Germany (German Breast Group) worked to collect and clean data for the primary analysis.
The results of the study’s primary analysis were presented in an oral session at SABCS by Prof. Charles Coombes. The primary aim of this study was to assess the effect of two years of adjuvant therapy with the COX-2 inhibitor celecoxib compared with placebo in patients with HER2-negative breast cancer. The study observed no benefit of celecoxib to patients receiving this treatment, but further exploratory studies focusing on the ER-positive subgroup of patients are ongoing.

Work in 2018 will focus on the submission of the peer reviewed manuscript. This will be the first major trial to examine COX-2 antagonists in this setting. Work is also ongoing between our partners to get several translational projects up and running, with the aim of identifying key biomarkers for the COX-2 response.

The next step for Dr. Fatima Cardoso, co-principal investigator of the study, and her colleagues, is to find a pharmaceutical partner willing to conduct a therapeutic clinical trial for men affected by the disease.

A press release, issued jointly by BIG and EORTC, is available on the BIG website.

R. C. Coombes & J. M. Bliss & S. Lobl

The International Male Breast Cancer Programme (BIG 2-07): 1 out of 3 men does not receive adequate treatment

The International Male Breast Cancer Programme is run simultaneously in Europe, in the US and South America and consists of three different parts. Firstly, a retrospective collection and analysis of clinical data and biological samples from 1,822 male breast cancer cases between 1996 and 2010. The results of which were recently published in Annals of Oncology[1] and show that male and female breast cancers are definitely different in terms of histology and grading. The study also indicates that the quality of care of male patients is inferior to that of the opposite gender.

At SABCS 2017 researchers presented the results of a RNA sequencing analysis performed on 152 tumour samples from this retrospective registry[2]. Their findings support the results reported by a Swedish group in 2012[3], suggesting that there is a breast cancer subtype occurring exclusively in men that needs to be characterised better.

They also presented findings of the second part of the programme, a prospective registry of newly diagnosed patients built over a period of 30 months and concluded in February 2017. With over 550 male breast cancer patients recruited, including 75% in Europe, 20% in the US and 5% in other countries, the investigators showed that, through an international collaborative effort, they were able to set up a well-structured and functional research network ready to run a clinical trial that could generate meaningful results in this rare disease setting[4].


Other BIG trial updates

**ABCeSG**

**ABCeSG 42 / BIG 14-03 PALLAS – ABCeSG’s network still ahead in recruitment**

The global trial PALLAS (Palbociclib Collaborative Adjuvant Study) compares the CDK4/6-inhibitor palbociclib given in combination with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone for male and female patients with hormone receptor-positive (HR+)/ human epidermal growth factor receptor 2 (HER2)-negative early breast cancer. The global cap of 1,000 patients with breast cancer stage IIA was reached in September 2017, and by now all participating countries have received full approval, which means that more than 200 sites are activated and ready for enrolment.

The Austrian Breast & Colorectal Cancer Study Group (ABCeSG), legal sponsor of this study for the BIG network, acknowledges that thanks to the efforts of so many collaborators around the world, global enrolment is ahead of schedule – more than 60% of the targeted sample size has already been randomised, and the enrolment goal will likely be reached in 2018.

This success comes from the hard work of all PALLAS enthusiasts as well as the remarkable efforts of ABCeSG/s/ BIG’s partners worldwide.

“In 2018, we will activate all pending sites and work towards our goal to complete enrolment together with our US colleagues. In addition to finishing accrual, we will increasingly focus on data quality and proper reporting as well as documentation”, says Michael Gnant, MD, Coordinating Investigator for PALLAS and president of the ABCeSG.

**BCT-ANZ**

**ANZ 1601 / BIG 16-02 - EXPERT**

The EXPERT clinical trial is the first large-scale randomised trial that will investigate the use of a multigene expression panel (PAM 50-based Prosigna® assay) to enable safe and individualised de-escalation of adjuvant breast radiation in early breast cancer. In a first for BCT-ANZ (Breast Cancer Trials), it will be the international co-lead group in collaboration with BIG, and the aim is to recruit 1,170 participants globally. The EXPERT study chair is Professor Boon Chua.
Postmenopausal women with hormone receptor-positive breast cancer who took the aromatase inhibitor (AI) anastrozole for extended 2 years after 5 years of adjuvant endocrine therapy received an equal benefit compared to those who took anastrozole for 5 additional years. These results suggest that the shorter duration of treatment is as effective as 5 years, but protects patients from harmful side effects.

“Extended adjuvant treatment with aromatase inhibitors has been demonstrated to improve disease-free survival of postmenopausal women with this subtype of breast cancer. However, the optimal duration of extended AI is still being investigated. Because this treatment leads to prolonged side effects and impacts quality of life, it is important to establish how long the treatment should be given.”

The trial’s primary endpoint was disease-free survival. Secondary endpoints included overall survival, contralateral breast cancer, fractures, and toxicity.

There was also no significant difference in overall survival. Bone fractures were more likely in the 5-year group, suggesting that a longer duration of anastrozole treatment may be a risk factor for fractures. Michael Gnant said the trial results suggest that clinicians should consider a 2-year course of anastrozole sufficient for most patients: “I believe that these trial results should be implemented into daily practice at once. This result can help save a lot of unnecessary side effects for many women around the world.”

Maybe future translational research using data and biomaterial from the patients in the ABCSG 16 study could be useful to characterise potential molecular factors that influence patients’ response to extended anastrozole.
Breast cancer in older patients

Breast cancer is an ageing-related disease. The average age for breast cancer diagnosis is approximately 60 years, and over 40% of all breast cancers diagnosed are in women aged 65 years or older. It is anticipated that by the year 2030 approximately 20% of the population will be aged over 65 years.

The EORTC-75111-10114 study is an example of how studies with new therapies can be conducted in the elderly population. The study entitled “Pertuzumab and trastuzumab (PH) versus PH plus metronomic chemotherapy (PHM) in the older HER2+ metastatic breast cancer population” is an open-label multicentre randomised phase II selection trial of the EORTC Elderly Task Force and Breast Cancer Group. The first results of the trial were presented at the San Antonio Breast Cancer Symposium™, December 5-9, 2017. Abstract # 725, Spotlight Session 3, Thursday 7 December 2017, San Antonio, TX, USA.

This 80-patient study attempts to find out if HER2-targeted regimens with minimal toxicity for the elderly population might delay, or even completely obviate, the use of conventional taxane chemotherapy. Overall survival for patients with HER2-positive breast cancer is clearly improved with a combination of taxanes and agents that specifically target HER2. Classic chemotherapy including taxanes, however, is often accompanied with side effects that can adversely affect health-related quality of life in older patients.

The main objectives of EORTC trial 75111-10114 are to evaluate the efficacy, as measured by progression-free survival at 6 months following treatment with pertuzumab combined with trastuzumab or pertuzumab combined with trastuzumab plus metronomic chemotherapy, in elderly patients with metastatic breast cancer. Metronomic chemotherapy uses low doses of chemotherapy drugs to minimise toxicity. This EORTC trial includes older patients with histologically proven HER2-positive invasive breast cancer who did not receive prior chemotherapy for metastatic disease.

Prof. Hans P.M.W. Wildiers, Universitair Ziekenhuis Leuven – Campus Gasthuisberg, Chair of the EORTC Cancer in the Elderly Task Force and Coordinator of this study, says: “With these well-tolerated, new targeted therapies, we hope to control tumour growth for few years so that toxic chemotherapy can be delayed or even omitted, since older patients can also die from other age-associated diseases rather than breast cancer.”

This EORTC (European Organisation for Research and Treatment of Cancer) trial is led by the EORTC Patients in the Elderly Task Force in collaboration with the EORTC Breast Cancer Group and is supported by an educational grant from Roche.

GBG clinical trials

So far, immune-checkpoint inhibitors have been tested mainly in metastatic triple-negative breast cancer (TNBC), either as monotherapy or in combination with chemotherapy, and some encouraging activity has been seen. Therefore, GBG (German Breast Group) initiated a neoadjuvant phase II trial of sequential nab-paclitaxel followed by epirubicin and cyclophosphamide with or without the checkpoint inhibitor durvalumab, a fully human anti-PD-L1 antibody, in patients with early TNBC aiming to increase the rate of pathologic complete responses (pCR). The GeparNuevo study randomised a total of 174 patients between June 2016 and September 2017 from 28 sites in Germany, with initial results expected later in 2018.

With regard to the chemotherapy backbone, all patients in the GeparNuevo trial received the nanoparticle albumin-bound paclitaxel (nab-paclitaxel) at a dose of 125 mg/m². This decision was taken based upon the results of GeparSepto: in this GBG phase III trial, nab-paclitaxel was shown to increase the pCR rate in TNBC compared with conventional solvent-based paclitaxel (Untch et al. Lancet Oncol. 2016). Recently, the long-term outcomes of GeparSepto demonstrated a significant improvement in terms of disease-free survival as well as when patients received nab-paclitaxel as part of the anthracycline/taxane-based sequential chemotherapy regimen (HR=0.69, 95% CI [0.54-0.89]; log rank p=0.0044). Interestingly, significant interaction between the treatment group and K67 status was observed, suggesting that neoadjuvant nab-paclitaxel treatment also generates long-term benefit in tumours with lower proliferation rates (Schneeweiss et al. SABCS 2017; oral presentation GS3-05).

Another GBG trial, presented as a poster discussion at the 2017 SABCS meeting, was MALE, the first phase II trial conducted exclusively in male breast cancer in Germany (Reinisch et al. SABCS 2017; poster discussion PD7-10). Patients were randomly assigned to receive tamoxifen alone, tamoxifen plus a GnRH analogue, or exemestane plus a GnRH analogue for a total duration of 6 months, and consecutive changes in hormonal parameters were assessed. In addition, the MALE trial offered a unique opportunity to address important translational research questions, such as the role of cytochrome P450 polymorphisms involved in tamoxifen metabolism and hormone receptor activity and aromatase expression in tumour tissue. A total of 56 patients (53 in the adjuvant and 3 in the metastatic setting) were enrolled between October 2012 and June 2017 from 24 sites in Germany. The first results after 3 months of (neo)adjuvant or metastatic antihormonal therapy showed the expected changes in hormonal parameters, with a significant reduction of estradiol levels in both the tamoxifen plus GnRH analogue arm and in the exemestane plus GnRH analogue arm in comparison with tamoxifen alone. The three different therapy strategies were well tolerated with no new safety concerns.
The term "real world study" suggests that all other studies are not real world, which is not completely true. However, classic randomised controlled phase III studies are characterised by very specific and sometimes tight inclusion and exclusion criteria that do not reflect the general (and "real-world") breast cancer population. In addition, assessments done in clinical trials are usually stricter than in everyday clinical practice. Still, "real world" data can provide important health information about patients in the social context of their day-to-day lives. Therefore, the PADMA trial, an international, prospective, randomised, open-label, multicentre, controlled phase IV low intervention trial, is seeking to mirror everyday clinical practice and to investigate in a more realistic context whether first-line therapy with palbociclib plus endocrine treatment is superior to chemotherapy +/- endocrine maintenance therapy. This trial will evaluate two approved approaches for the treatment of hormone receptor-positive, HER2-negative metastatic breast cancer. The aim of the trial is to establish a superior but also patient-preferred treatment approach for this specific situation (Loibl et al. SABCBS 2017; poster OT3-05-04).

References:


GEICAM

Clinical trials are not the limit; the time has come for cooperative groups to serve as real-world data providers and to ensure maximum standards in research quality.

Epidemiological studies and real-world data

It has been well recognised by the whole scientific community that in research in general, and in cancer research in particular, standard clinical trials cannot be the only source of new evidence. In the highest performing research institutions, clinical trials involve less than 20% of patients and that figure decreases in other environments. Hence, we can deduce that the majority of patients do not produce usable information. In this regard, well-organised repositories of information from routine practice are now progressively being considered of paramount importance. These non-interventional (observational) cohort studies allow us to acquire deep knowledge about the current clinical scenarios of patients treated outside of clinical trials, the real prognosis of different patient subgroups, the off-trial use of established therapies, patient and healthcare professional preferences, toxicity data from routine use cohorts, among many other topics. All this information is highly valuable for innovative clinical trial design and, if properly gathered, could form the basis for novel structures for drug approval and reimbursement. This is particularly important for sustainability in highly demanding environments, such as the way oncology has evolved.

Already years ago, GEICAM (Spanish Breast Cancer Group) identified its large capabilities for real-world data (RWD) gathering and the chance to become a key generator of highly valuable RWD platforms in breast cancer in Spain, thanks to its broad coverage of the Spanish territory with almost 800 breast cancer investigators working in 184 institutions all around the country. In this issue, GEICAM shares two of its ongoing prospective registries.

RegistEM Study. GEICAM/2014-03. A prospective registry study with unresectable locally advanced or metastatic breast cancer patients.

RegistEM is a prospective, multicentre non-interventional cohort study designed to develop a registry for advanced breast cancer. Targeted for inclusion are patients recently diagnosed with advanced disease, either after a recurrence or as first diagnosis.

The primary objective of this study is to observe the real distribution of the different breast cancer subtypes in the unresectable locally advanced or metastatic disease settings.

The secondary objectives include analysing multiple variables related to patient outcome and treatments. This study will recruit approximately 1,400 patients with the different breast cancer subtypes (approximately 978 luminal, 252 HER2-positive, and 170 triple negative). The recruitment period is 3 years from January 2016 to December 2018. As of the end of December 2017, 40 sites have been participating, and 619 patients already included.


Designed as a non-interventional (NIS), multicentre, retrospective cohort study, the primary objective of ALAMO IV is to study the demographic, clinical and anatomic-pathological characteristics of new cases of breast cancer diagnosed from 2002 to 2005 in Spanish hospitals.

ALAMO IV will collect data from around 12,000 new cases diagnosed during a 4-year period (2002-2005). 42 hospitals are participating in this study. As of 27 December 2017, 4,223 patients have been included. It is estimated that recruitment will finish in December 2018.
In 2017 LACOG (Latin American Cooperative Oncology Group) launched the largest ever prospective breast cancer registry in Latin America (LATINABREAST study), which will include approximately 4,500 new cases of breast cancer from 31 centres in Argentina, Brazil, Colombia, Chile, Cuba, Guatemala, Mexico, Peru and Uruguay.

The first patients are expected to be enrolled in the beginning of 2018, with the objective of generating real world data, stemming from symptoms and diagnosis to treatment and outcome, as well as identifying the gaps in access to optimal cancer care.

**LACOG**

International TAXIS / SAKK 23/16 breast cancer trial scheduled for 2018

The removal of all lymph nodes in the armpit through conventional axillary dissection has been standard care for all patients with breast cancer for almost a century. In the 1990s, the sentinel lymph node procedure, which involves the selective removal of the first few affected lymph nodes, was introduced into clinical practice. Today, conventional axillary dissection is still performed on many women with breast cancer that has spread to the nodes. Regrettably, this also causes morbidity in the form of lymphedema, impaired shoulder mobility, sensation disorders and chronic pain in as much as one-third of all women undergoing the procedure.

In the TAXIS trial, SAKK (Swiss Group for Clinical Cancer Research) aims to evaluate the optimal treatment for breast cancer patients in terms of surgery and radiotherapy. Specifically, the trial will investigate the value of tailored axillary surgery, a new technique that aims to selectively remove positive lymph nodes. Tailored axillary surgery combines the removal of palpably suspicious nodes with the sentinel procedure. During the procedure, the successful removal of the initially biopsied and clipped lymph node metastasis is confirmed by specimen radiography. Selective imaging-guided localisation of the clipped lymph node for targeted removal is encouraged. According to Prof. Dr. Walter P. Weber, Chair of Breast Surgery at Basel University Hospital and TAXIS Coordinating Investigator, tailored axillary surgery is a promising procedure that is expected to significantly decrease morbidity in breast cancer patients by avoiding surgical overtreatment.

TAXIS is one of several large international studies currently investigating axillary treatment and will be conducted within the SAKK network of breast centres together with international collaborations. Patient accrual is expected to open in July 2018, first in about 20 Swiss centres. These will enroll a minimum of 750 patients, with an additional 750 patients being enrolled abroad. TAXIS has the potential to establish a new worldwide treatment standard with fewer side effects and better quality of life, while keeping the same efficacy as radical surgery.

This important phase III trial will be conducted with generous support from The Rising Tide Foundation, Stiftung Krebsforschung Schweiz, Krebsliga beider Basel, and Fond’Action.

**SAKK**

Extended adjuvant bisphosphonate treatment over 5 years in early breast cancer does not improve disease-free and overall survival compared to 2 years of treatment: phase III data from the SUCCESS A study


According to a recent meta-analysis, adjuvant bisphosphonate treatment in patients with early breast cancer leads to improved survival and a reduced rate of recurrences in the bone, particularly in postmenopausal patients, and is therefore recommended by numerous international guidelines in this setting (EBCTCG, Lancet 2015). Within the SUCCESS A study, two different treatment durations were evaluated: the safety and efficacy of adjuvant bisphosphonates, as well as their potential impact on the persistence of circulating tumour cells (CTCs).

In this 2x2 factorial design phase III study, 3,754 patients with high risk, node-negative and node-positive early breast cancer were randomised between two anthracline-taxane based chemotherapy regimens. In a second randomisation, patients were assigned to 2 versus 5 years of adjuvant zoledronate treatment, with a dose of 4 mg i.v. every 3 months for 2 years, followed by 6-monthly administration thereafter in the 5-year arm. CTC analyses were performed before systemic treatment, after chemotherapy, and after 2 and 5 years of follow-up respectively. 2,987 patients were available for the current analysis.

Univariate Kaplan-Meier analysis for adapted disease-free survival (DFS) and overall survival (OS) did not demonstrate any difference between 2 and 5 years of adjuvant bisphosphonate treatment, with a p-value of 0.83 and 0.71, respectively. Furthermore, multi-variable Cox regression analysis adjusting for prognostically relevant factors did not show any significant difference between patients receiving 5 or 2 years of zoledronate treatment (DFS: hazard ratio [HR] 0.97, 95% confidence interval [CI] 0.75 – 1.25, p = 0.81; OS: HR 0.98, 95% CI 0.67 – 1.42, p = 0.90). No difference could be shown for bone recurrences as first distant recurrence, nor according to the menopausal status of the patients.

Adverse events as of 2 years after the start of zoledronate treatment were more frequent in the 5-year arm (all grade adverse events 46% vs. 27%; grade 3/4 toxicity 7.6% vs. 5.1%).

**SUCCESS**

There was no significant difference in the prevalence of persisting CTCs as determined 5 years after adjuvant chemotherapy, which was the case in 10.5% of the patients with extended treatment and 7.2% of patients with 2-year treatment.

In summary, at this early point in time, our study showed no difference in adapted DFS or OS between 5 years and 2 years of adjuvant zoledronate treatment in high-risk patients with early breast cancer after adjuvant chemotherapy, irrespective of menopausal status. 5 years of zoledronate treatment was associated with an increased frequency of adverse events. The similar prevalence of CTCs 5 years after adjuvant chemotherapy is in accordance with the survival analysis. Therefore, 5 years of adjuvant zoledronate treatment should currently not be considered in these patients in the absence of decreased bone density.

**Literature**

In the second half of 2017, the BIG website was revamped. This stemmed from the need to improve the responsiveness of the website, to adapt to an ever-evolving technological world, where information is consumed mostly on mobile devices.

In parallel, we wanted to update BIG’s messaging as well as improve user experience overall. This is why the new BIG website is split into two sections: a fundraising section and a scientific section, each catering to a specific audience.

The scientific section contains information about the clinical trials and research programmes conducted under the BIG umbrella, brief presentations about the member groups that make up the BIG network, a database of peer-reviewed publications from BIG studies, and news relevant to the scientific community. This is also where the BIG Members’ Area may be found, a password protected area where BIG members can find confidential information related to BIG meetings and other useful documents.

In the fundraising section, users can find information about how to support BIG and its trials, the importance of clinical trials, general information about the organisation and upcoming fundraising events.

The Breast International Group (BIG) is a not-for-profit organisation for academic breast cancer research groups from around the world. Founded by leading European breast cancer experts in 1999, BIG now constitutes a network of 59 groups and data centres based in Europe, Latin America, the Middle East, Asia and Australasia. These entities are tied to several thousand specialised hospitals and research centres worldwide. About 30 clinical trials and several research programmes are run or are under development under the BIG umbrella at any one time. BIG also works closely with the US National Cancer Institute and the North American Breast Cancer Group, so that together they act as a strong interacting force in the breast cancer research arena.

www.BIGagainstbreastcancer.org

The 59 breast cancer research groups of the BIG network

| ABCSG | Breast-Cancer & Colorectal Cancer Study Group |
| ACOG | Arbeitsgemeinschaft Gynäkologische Onkologie Breast Study Group |
| AROGNECO | Association de Recherche dans les Cancers du Sein pour l’Etude des Cancers Ovoïdes et du sein |
| BCT ANZ (formerly ANZBTCG) | Breast Cancer Trials - Australia & New Zealand |
| BDPCG | Breast Disease Professional Committee of CMEA (China) |
| BGCS | Breast-Gynaeological International Cancer Society |
| BIGA | Breast Intergroup of Eastern India |
| BIGCC | Breast Cancer Co-operative Group of Canada |
| BovanEurOnc | Breast Cancer Intergroup (formerly Nordic Bov) |
| CTCG | Canadian Cancer Trials Group |
| CEGO | Central European Oncology Group |
| CT-IB | Cancer Trials Ireland |
| CTRA | Cancer Therapeutics Research Group |
| DBCG | Danish Breast Cancer Cooperative Group |
| EORTC BCG | European Organisation for Research and Treatment of Cancer, Breast Cancer Group |
| FBCG | Finnish Breast Cancer Group / Suomen Rintatyöryhmä |
| GBD | Francan Breast Intergroup |
| GARC | Grupo Argentino de Investigación Clínica en Oncología |
| GBS | German Breast Group |
| GC BC | Georgian Cancer Study Group |
| GEPCO | Groupo de Estudios Clínicos Oncológicos Panamena |
| GECAM | Spanish Breast Cancer Group |
| GCCH | Chilen Cooperative Group for Oncologic Research |
| GOUGC | Grupo Oncologico Cooperativo de Uruguay |
| GHO | Italian Oncology Group for Clinical Research |
| GOGO | Gruppo Oncologico Nord-Ovest |
| HBS | Helicentric Breast Surgical Society |
| HACOG | Helicentric Cooperative Oncology Group |
| HRC | Hong Kong Breast Oncology Group |
| HOBG | Hellenic Oncology Research Group |
| IGBCG | Icelandic Breast Cancer Group |
| ICBG | International Breast Cancer Study Group |
| ISBG | Israeli Breast Group |
| IRIS | International Breast Cancer Intervention Studies |
| ICRC | International Collaborative Breast Cancer Group |
| ICNAR | Indian Co-Operative Oncology Network |
| JBCRG | Japan Breast Cancer Research Group |
| KCSG | Korean Cooperative Oncology Group |
| LACOG | Latin American Cooperative Oncology Group |
| MICHELANGELO Fonda | Fondazione Michelangelo |
| NBO | Norwegian Breast Cancer Group |
| NCRI BCGS | National Cancer Research Institute - Breast Cancer Clinical Studies Group |
| SABG | Swedish Association of Breast Oncologists |
| SAKK | Swiss Group for Clinical Cancer Research |
| SBCG | Sheba Breast Collaborative Group |
| SKMCH | Shaukat Khanum Memorial Cancer Hospital & Research Centre |
| SLO | Société Luxembourgeoise d’Oncologie |
| SOLST | SUCCESS - Study Group |
| SBDCO | Swedish Breast Cancer Group |
| TCCG | Tawam Cooperative Oncology Group |
| TDC | Trans Tasman Radiation Oncology Group |
| TCCS | Thai Society of Clinical Oncology |
| UCBC | Uncancer Breast Group |
| WSG | Westdeutsche Studiengruppe |
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Boobs Art is an itinerant exhibition of 50 to 200 themed posters articulated around the art of the breast, which has been an inexhaustible source of inspiration throughout history.

Showcasing the most significant works of creators, the exhibition also highlights remarkable postoperative tattoos and astounding awareness campaigns.

This expo is available to be hosted by companies wishing to show they care about their employees and their families all while supporting Breast Cancer awareness.

If you know of a company to contact, simply tell us:

Serge.Schmitz@BIGagainstBC.org