GEORGIAN YOUNG ONCOLOGISTS

Educational collaboration opportunities and challenges

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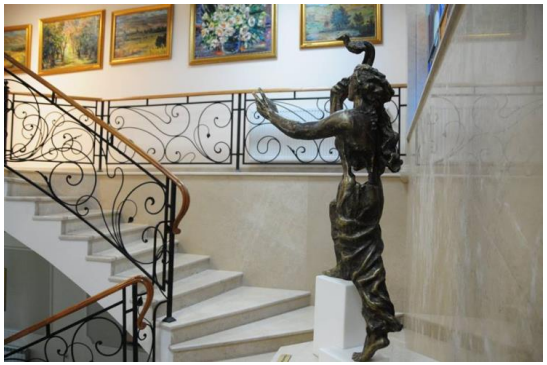
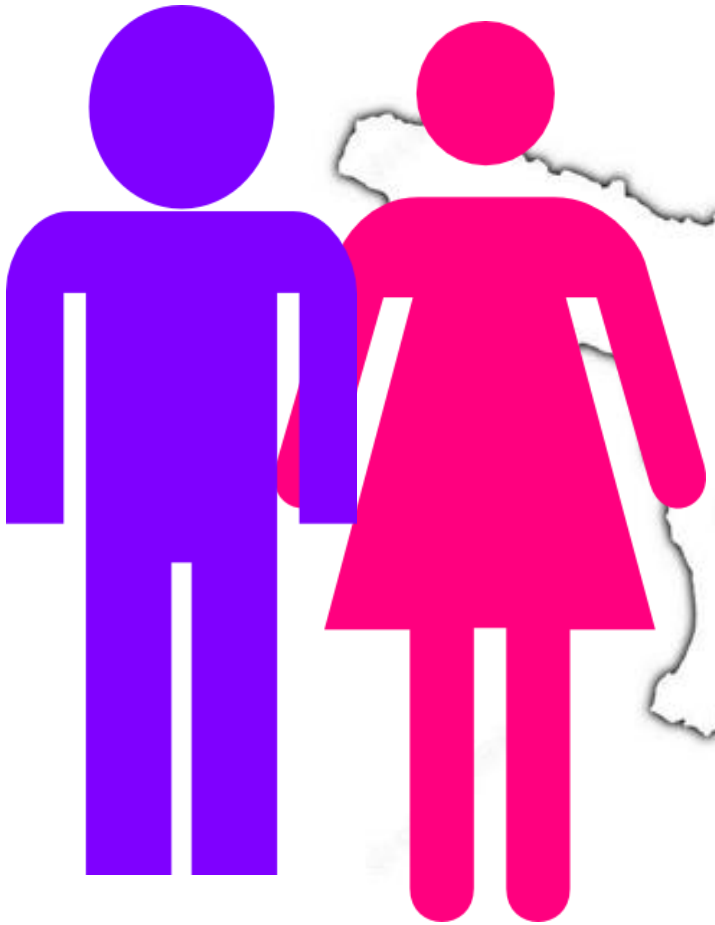
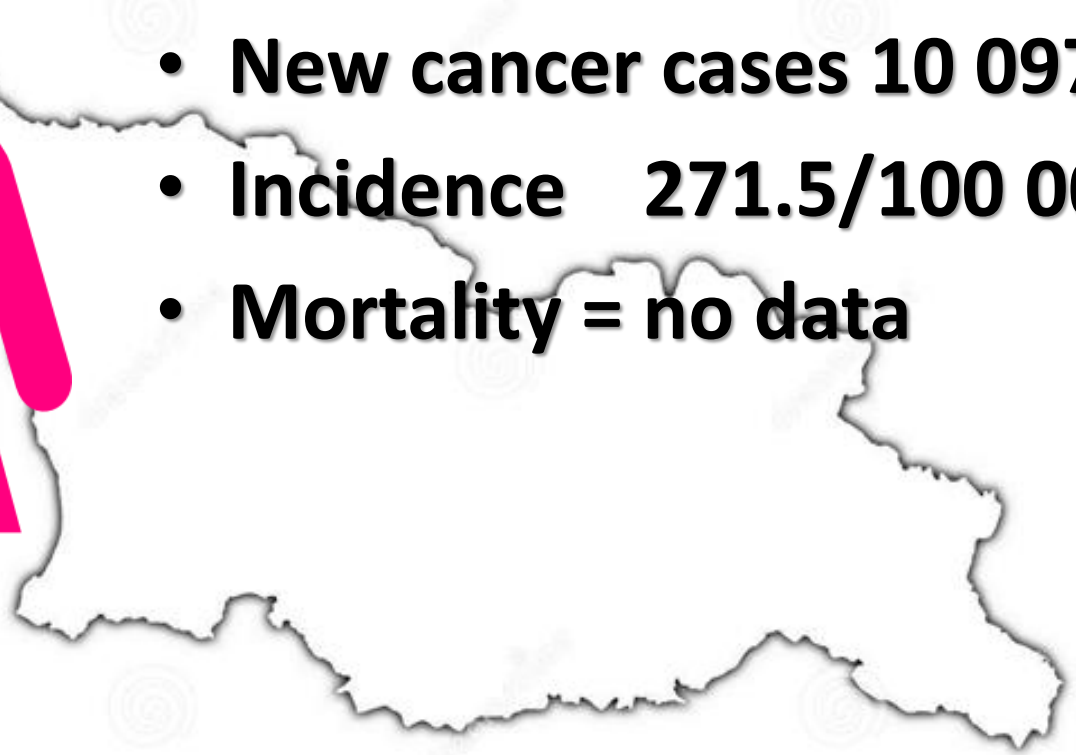


RESEARCH INSTITUTE OF CLINICAL MEDICINE (acad. F. TODUA CLINIC)
TBILISI, GEORGIA

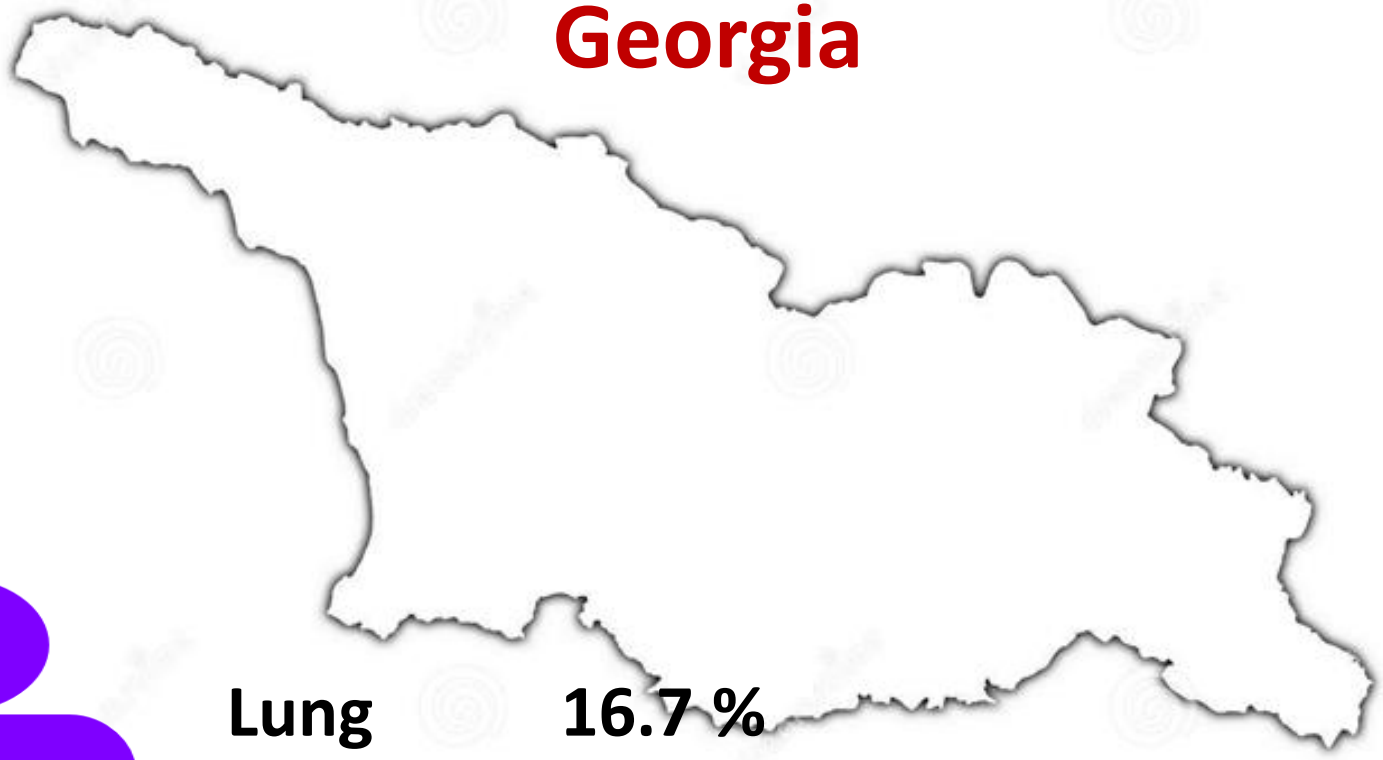
Cancer patients in Georgia

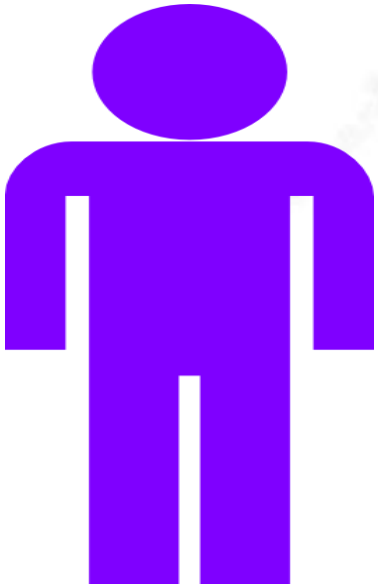




- New cancer cases 10 097
- Incidence 271.5/100 000
- Mortality = no data

Leading Sites of New Cancer Cases in Georgia

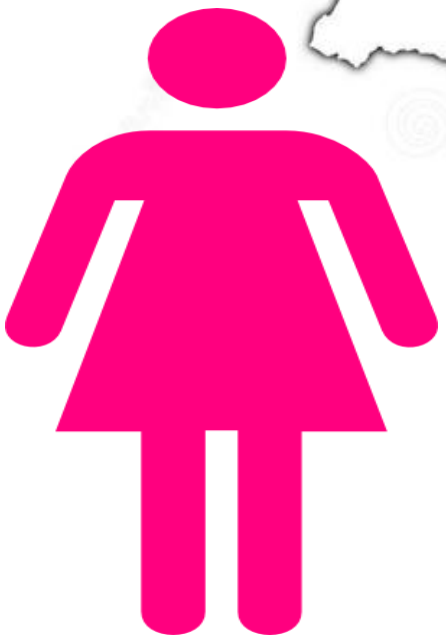




Lung	**16.7 %**
Prostate	**10.0%**
Bladder	**9.8 %**
Colorectal	**9.6 %**
Gastric	**6.9%**

NCDC. 2016

Leading Sites of New Cancer Cases in Georgia



Breast	33.5%
Thyroid	14.4%
Cervical	7.1%
Uterine	6.7%
Colorectal	6.5%

NCDC. 2016

Clinical Trials in Georgia

- Clear regulatory requirements
- Fast and smooth import/ export of study materials (no separate import/export license is required)
- International medical standards in management of many diseases
- High quality of data that is accepted by the FDA and proved by FDA inspections
- Motivated patients
- Political and social climate welcoming and supportive of clinical trials
- Very short start-up timelines

Start up timelines

- Document preparation/ agreement negotiation: 2 weeks
- Local Ethics committee approval: 2 weeks
- Regulatory approval: 3 weeks
- Total timeline: 6-7 weeks

Clinical Trials at RICM

- **2008**- First Clinical Trial (ICH-GCP compliance in clinical trials was adopted)

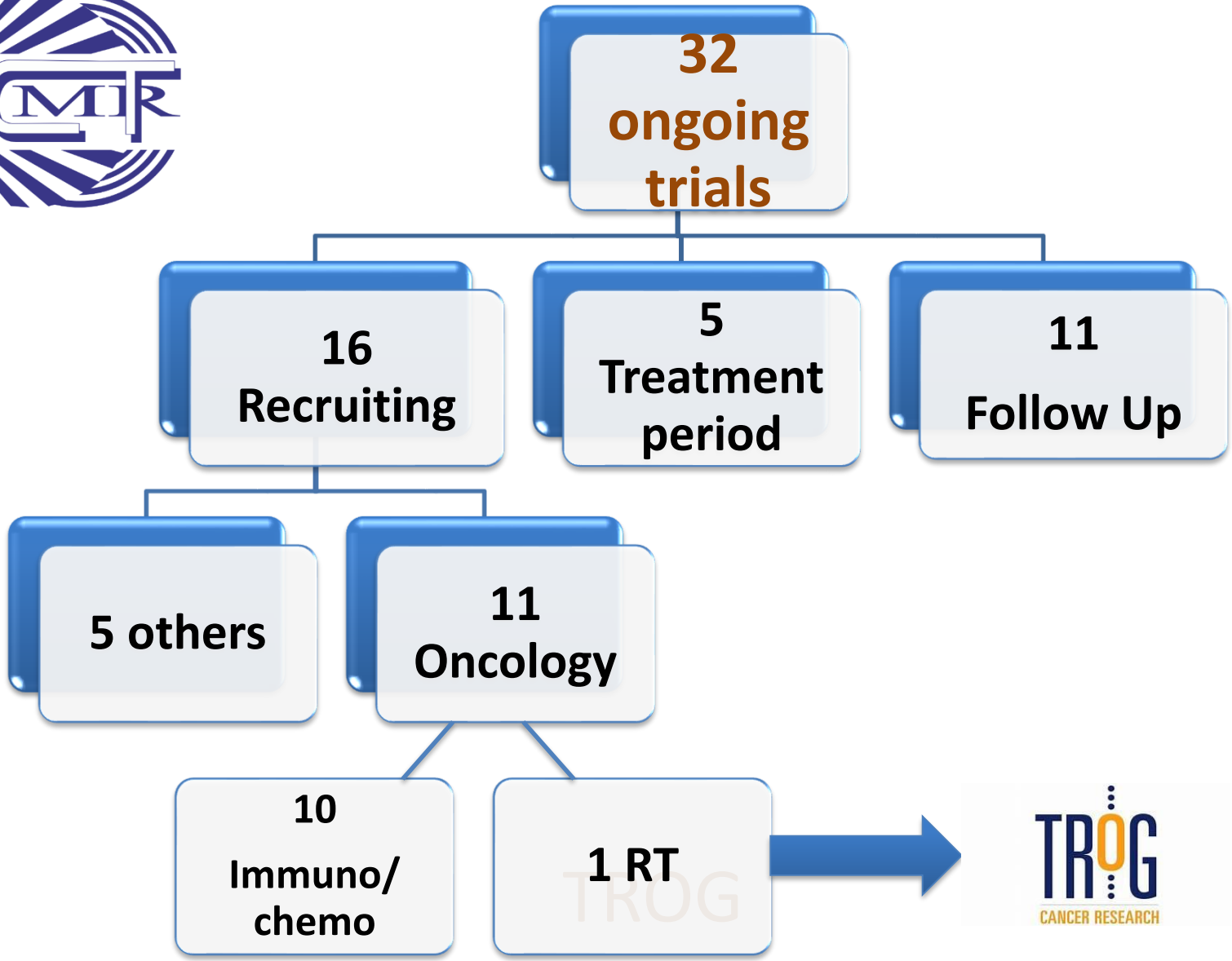
- **2011**- Department of Clinical research was founded

Department of clinical research

- ✓ 46 multi central, international clinical trials from 2011 till 2018
- ✓ 6-7 new trials per year
- ✓ 17 completed studies
- ✓ 2 FDA Inspections – Result : NAI
- ✓ Service provider for all Georgian sites in 21 studies: *14 Radiology, 3 Lab, 2 Endoscopy, 1 Oncogenetics, 1 RT*

Phase I Trials from 2007

- Phase I trials in oncology- 23
- Ongoing- 3



Phase II-III trials in oncology

* Department of clinical research

All staff are members of Association of clinical research professionals(ACRP) and annually attending meetings

___ACRP supports clinical research professionals through membership, training and development.

____ACRP's vision is that clinical research is performed ethically, responsibly, and professionally everywhere in the world. ACRP's mission is to promote excellence in clinical research.

SCIENCE

On the base of the Institute are functioning:

- ❑ Department of Medical Radiology and Endoscopy,
- ❑ Postgraduate scientific courses for PhD degree,
- ❑ Residency programs in Radiology, Oncology and Radiation Therapy
- ❑ Computed and Magnetic Resonance Tomography Training Center
- ❑ Doctors qualification training Center

Since its foundation 85 theses for the degree of PhD were defended; more than 300 radiologists have been trained here. Number of scientists of the Institute have been awarded State and National prizes, 21 inventions received patents.

A number of scientists of the Institute has been awarded 4 State, 5 National and 9 prizes of the National Academy of Georgia.

GEORGIAN
YOUNG
ONCOLOGISTS

Georgian Group of Young Oncologists

GEORGIAN YOUNG ONCOLOGISTS

To Share Knowledge

Education


E PACE OF ONCOLOGY
CALCIUM GLUCONATE AND MAGNESIUM SULFATE IN
OXALIPLATIN-BASED
BACKGROUND


Neo-adjuvant Hormonal Therapy For Locally Advanced Breast Cancer
Lika Katsiafashvili, Margarita Katcharava, Mariam Zhvania, Sophio Kobakhidze, F. Todua
Research Institute of Clinical Medicine, Consilium Medicis
Background
Methods
Results
Primary Endpoint
Long Term Survival

Research and Trials

Annals of Oncology 27 (Supplement 6): vi149–vi206, 2016
doi:10.1093/annonc/mdw370.52

gastrointestinal tumours, colorectal

504P **Calcium gluconate and magnesium sulfate in preventing neurotoxicity in patients receiving oxaliplatin-based combination chemotherapy-capeOX**

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Background: Oxaliplatin in combination with Capecitabine (CapeOX) is widely used chemotherapy regimen in the treatment of colorectal (CRC) and gastric (GC) cancer both in the adjuvant and metastatic setting. Oxaliplatin-induced peripheral neuropathy (OXA-IPN) is the major cause of treatment delay, dose reduction and cessation of oxaliplatin-based therapy. Evidence regarding the role of calcium(Ca) and magnesium (Mg) prophylaxis to prevent oxaliplatin-related neurotoxicity is conflicting. This study is a prospective randomized study to evaluate the effect of Ca/Mg infusion on prevention or amelioration of oxaliplatin neuropathy in patients with CRC and GC treated with CapeOX.

Methods: Patients with CRC or GC undergoing adjuvant or palliative therapy with CapeOX were randomly assigned to Ca/Mg (1g Ca gluconate+ 1g Mg sulfate pre- and post-oxaliplatin) or placebo group. 133 oxaliplatin-naive CRC/GC patients were enrolled (112 CRC, 22 GC) who received at least one cycle of CapeOX. Patients were randomized to receive (Ca/Mg group; n = 78) or not receive (control group; n = 55) Ca gluconate and Mg sulfate infusion. The primary end point was the percentage of patients with grade 2 or greater sensory neurotoxicity (sNT) at any time during or after oxaliplatin-based therapy by National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE; version 3) criteria.

Results: A total of 636 cycles of CapeOX were administered, median 5 and 4,5 cycles for Ca/Mg and control group respectively. Overall 82% (109) patients experienced at least Grade 1 acute sNT. Severities for control and Ca/Mg group patients, respectively were Grade 1, 33% and 41%; Grade 2, 11% and 10%; Grade3, 3% and 8%; Grade 4 2% and 0%. The incidence rates of grade 2 or worse neurotoxicity were 23% and 29% for Ca/Mg and control arms, respectively ($p = 0.434$)

Conclusions: Calcium/Magnesium did not substantially decrease oxaliplatin-induced neurotoxicity. Our study does not support using calcium/magnesium to protect against oxaliplatin-induced sNT.

Clinical trial identification: Trial has not protocol number Release date- 05.05.2016

Legal entity responsible for the study: Georgian Group on Young Oncologists

Funding: Georgian Group on Young Oncologists

Disclosure: All authors have declared no conflicts of interest.

Contents lists available at ScienceDirect

The Breast

journal homepage: www.elsevier.com/brst

Breast cancer subtypes in young adult women in Georgia

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BREAST CANCER SUBTYPES IN YOUNG ADULT WOMEN IN GEORGIA

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BACKGROUND

Breast cancers are increasingly recognized as heterogeneous disease based on expression of receptors for estrogen (ER), progesterone (PR), and human epidermal growth factor receptor 2 (HER2). There are four main subtypes of breast cancer with differing tumor characteristics including hormone receptor status (ER and PR positive or negative) and expression status of the HER2 gene. These subtypes have different risk factors, diagnostic descriptions, treatment options, and prognoses.

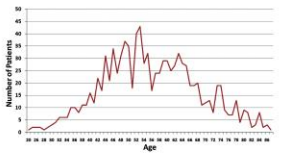
Few data exist on the frequency of molecular subtypes in young and older women. Here, we characterize the incidence of BC patients by molecular subtypes and age.

In Georgia, the incidence of registered new breast cancer cases on 2015 was 1743.There is no data of breast cancer subtypes in cancer-registry. The purpose of this study is to compare the distribution of the breast cancer subtypes in young and elderly breast cancer patients. Our study is the first in Georgian population to detail subtype specific breast cancer occurrence among young adults (YAs) aged 20 to 39 years. We also identified subtypes in different age groups and compared distribution of breast cancer subtypes in all age groups.

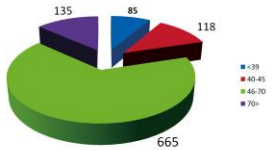
METHODS

Breast cancers during the period 2013 to 2015 including ER and PR status (as hormone receptor (HR) status) and HER2 status, was obtained from the Georgian main histopathology laboratories all over the country. We analysed 1003 women with breast cancer included 85 women aged 20 to 39 years (YA's), 118 women aged 40 to 45 years (older premenopausal), 665 women aged 46-70 (postmenopausal) and 135women older than 70 years (elderly group) at diagnosis. Incidence rates were calculated by subtype (triple-negative; HR + /HER2 - ; HR + /HER2 + ; HR - /HER2 +), and differences in subtype characteristics by age groups were evaluated.

Breast Cancer by age
(1003 patients)



Distribution by age groups

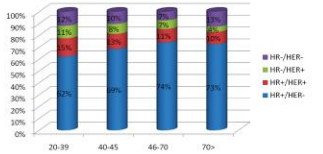


RESULTS

The incidence of BC in YA's was 8,5%. The most common BC subtype was HR +/HER2- among all age groups, and HR - /HER2 + was the least; however, the relative contribution of each subtype varied within age categories. In young adults (YA's) HR + / HER2 - was the most commonly diagnosed subtype (62 %), followed by HR + /HER2 +(15%), triple-negative (12%) and HR - /HER2 + (11%). Statistically no significant difference of BC subtypes was observed in age groups.

HR + /HER2 - subtype was lesser in YA's than in elder population (62% vs 73%), but statistically non-significant (p=0.19) and there was not significant difference in prognostically "unfavorable" subtypes (HR- /HER2+ and triple-negative) (23 % vs 17%) (p=0.134; (CI) 95%: 0.09 to 1.71). Surprisingly no difference of Triple-negative BC was observed in YA and elderly groups (12% vs 13%).

Proportion of Breast Cancer Subtype by age groups



CONCLUSION

The distribution of breast cancer subtypes among young adults (YAs) didn't vary from that observed in older women. Our study results seem to be in contradiction with other studies previously reported in literature. Future studies should consider whether distribution of breast cancer subtypes influences long-term survival in young compared with older women..

Key words: Breast cancer, Young adults, triple-negative.

1. Primary Surgery followed by Chemotherapy versus definitive concurrent Chemoradiotherapy in locally advanced non-small-cell lung cancer (LAD-NSCLC)

Ivane Kiladze, Vladimer Kuchava, Natia Joxadze , Lika Katselashvili, Tamar Melkadze (Tbilisi, GE)

2. Optimal chemotherapy regimen for concurrent chemoradiation in locally advanced unresectable non-small-cell lung cancer

Natia Jokhadze, Ivane Kiladze, Lika Katselashvili, Margarita Kacharava, Natalia Jankarashvili,Irakli Zumbadze, Nugzar Kalandarishvili, Tamar Melkadze, Elene Gogua (Tbilisi, GE)

Clinical Trials in Oncology

Field	Phase	N of Patients	Start date End date
Breast Cancer	III	6	2004-2006
Breast Cancer	I	10	2005-2006
Breast Cancer	II	28	2006-2007
Breast Cancer	II	26	2006-2007
Solid Tumors	I	3	2007-2008
Acute Myeloid Leukemia	I	12	2007-2010
Lung Cancer	II	5	2008-2010
Lung Cancer	II	6	2008-2009
Solid Tumors	II	17	2008-2009
Breast Cancer	II	13	2008-2010
Breast Cancer	II	36	2009-2011
AML	III	4	2010-2011
Lung Cancer	III	12	2010-2012
Lung Cancer	III	4	2010-2012

Field	Phase	N of Patients	Start date End date
GI and Breast Cancer	III	5	2012-2012
Breast Cancer	Bioeq.	23	2012-2012
Breast Cancer	III	65	2009-ongoing
GI and Breast Cancer	Gioeq.	18	2012-ongoing
Lung Cancer	III	Initial	2014
Breast Cancer	III	Initial	2014
Breast Cancer	III	Initial	2014
NHL	III	Initial	2014
GI	III	Initial	2014
Pancreatic Cancer	II	Initial	2013
Thoracotomy	II	11	2013
HEC	II	21	2013
MEC	II	17	2014
Breast Cancer	II	3	2014

Clinical Trials in Oncology (cont.)

Field	Phase	N of Patients	Start date End date
Breast Cancer	III	11	2014-ongoing
Breast Cancer	III	8	2014-ongoing
Breast Cancer	II	11	2014-2015
Breast Cancer	II	5	2014-2015
Colon	II	6	2014-ongoing

Thank you for your attention