AIOM LAZIO in TEXAS

The SequerPlus Study

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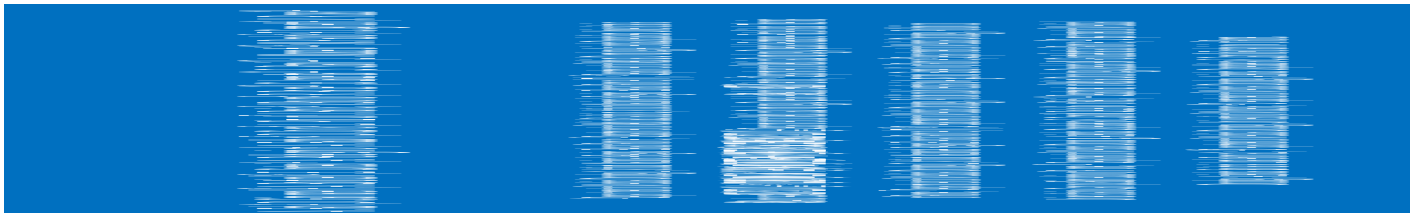
SEQUERPLUS: a Multicenter Real Practice Observational Study Investigating the endocrine-based Therapies Sequential Approach in Hormonal Receptor Positive (HR+) HER2 Negative (-) Metastatic Breast Cancer (MBC).



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12 Oncological Centers of Lazio

First collaborative study of AIOM Lazio

Despite the sequential ET is recognized as the preferred approach for HR+/HER2- MBC, **no data** from clinical trials support the choice between the different sequential strategies

Sequential HT
the evolution during the “era”

Individual Considerations:

- Desire for time without treatment change
- Toxicity
- Access
- Cost

No CDK inhibitor: Total PFS 24 months

Adapted from Ingrid Mayer, MD, ASCO, 2017

SEQUERPLUS STUDY

OBJECTIVE

To identify the optimal sequence of endocrine therapies according to real practice experience before CDK 4/6 inhibitors introduction.

PRIMARY END-POINT

Progression Free Survival (PFS) according to first, second and later lines of endocrine-based therapies.

METHODS AND MATHERIALS

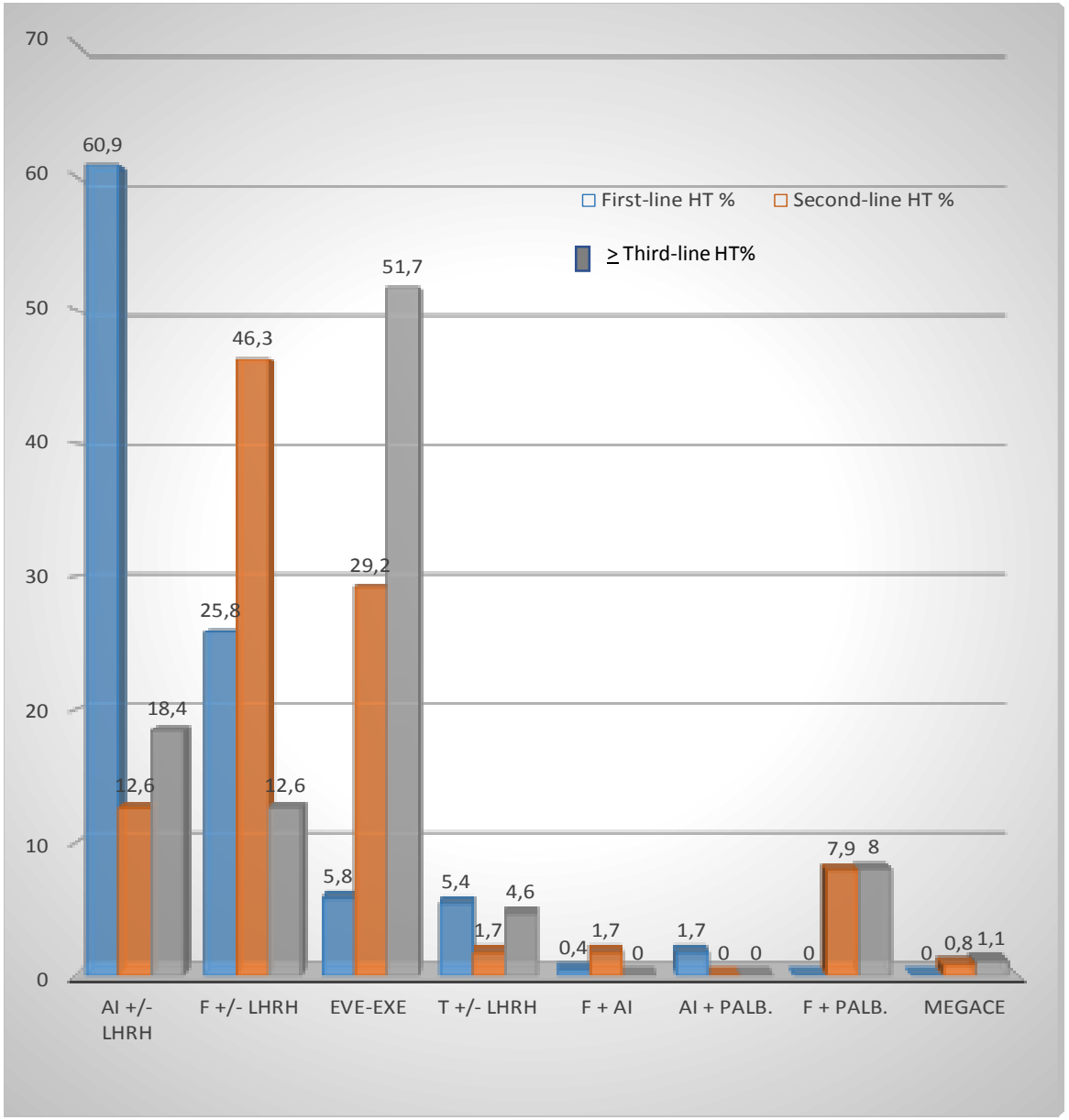
The prognosis of 240 patients with hormonal receptor positive metastatic breast cancer treated with at least two sequential endocrine-based lines of treatment from 2006 to 2017 in twelve cancer centers of Lazio was retrospective analyzed.

Descriptive statistic is reported using the median (Interquartile range, IQR) or frequency. Progression Free Survival (PFS) curves were estimated with the Kaplan-Meier method and compared with the log-rank test. Analysis were performed by SPSS version 21.0 (SPSS Inc., Chicago, IL).

Patients' characteristics	Number	%
Median Age	64 years	IQR: 55-72,6
Menopausal status	184	76,7
Surgery of Primary Tumor	222	92,5
Positive Nodal Status	111	62,7
Stage IV	38	15,8
Recurring Stage IV	202	84
NeoAdjuvant Chemotherapy	53	26,2
Adjuvant Chemotherapy	132	65,4
Adjuvant Hormonaltherapy	169	83,7
Time to Progression from the end of adjuvant hormonal therapy		
< 12 months	137	57,1
□ months	103	42,9
Number of metastatic sites		
1	148	61.7
2	53	22.1
3	20	8.3
>=4	19	7,9
Metastatic type		
Bone-soft tissue-nodes	167	69,6
Only Visceral	28	11,7
Visceral and soft tissue	45	18,8
Metastatic site		
Local recurrence	18	7,5
Contralateral breast	11	4,6
Nodes	50	20,8
Bone	167	69,6
Only bone	108	45,0
Lung	41	17,1
Liver	19	7,9
Brain	4	1,7
Other	26	10,8

240 pts

HT utilizzata nelle linee sequenziali di trattamento



For **the I-Line** setting the **AI** was chosen as first-line therapy in 146 (60.9%) pts and **FLV** in 62 (25.8%) pts and **EVE-EXE** in 13 (5.8%) pts.

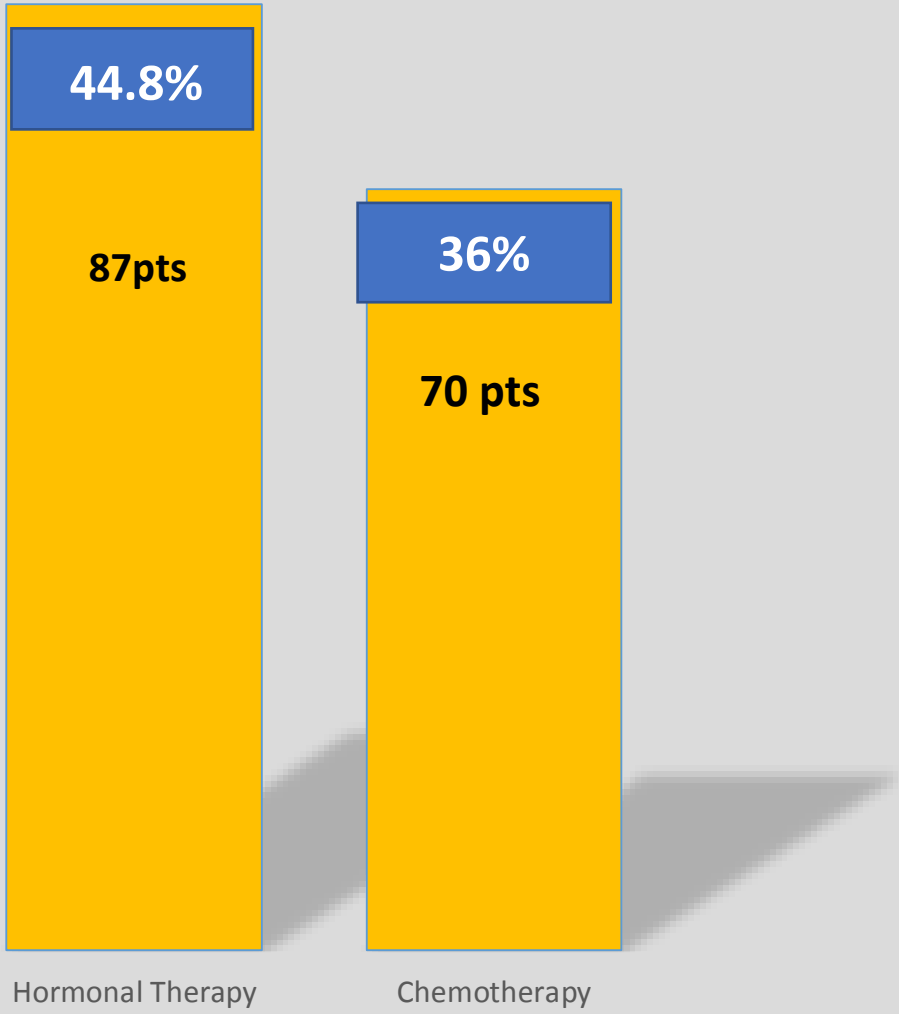
For the **II-Line** setting **FLV** resulted the most favourite option in 111 (46.2%) pts and **Eve-Exe** combination in 70 (29.2%) pts and **AI** in 30 (12.5%) pts.

For the **III-Line** setting **Eve-Exe** resulted the most favourite option in 123 (51.7%) pts and **AI** in 45 (18.4.%) pts and **FLV** in 30 (12.6%) pts.

Sequenze Utilizzate in RWE (Lazio)

1	AI (+ LHRH)	FLV	EVE-EXE
2	FLV	EVE-EXE	AI
3	EVE-EXE	AI O CDK4/6	FLV O CDK4/6

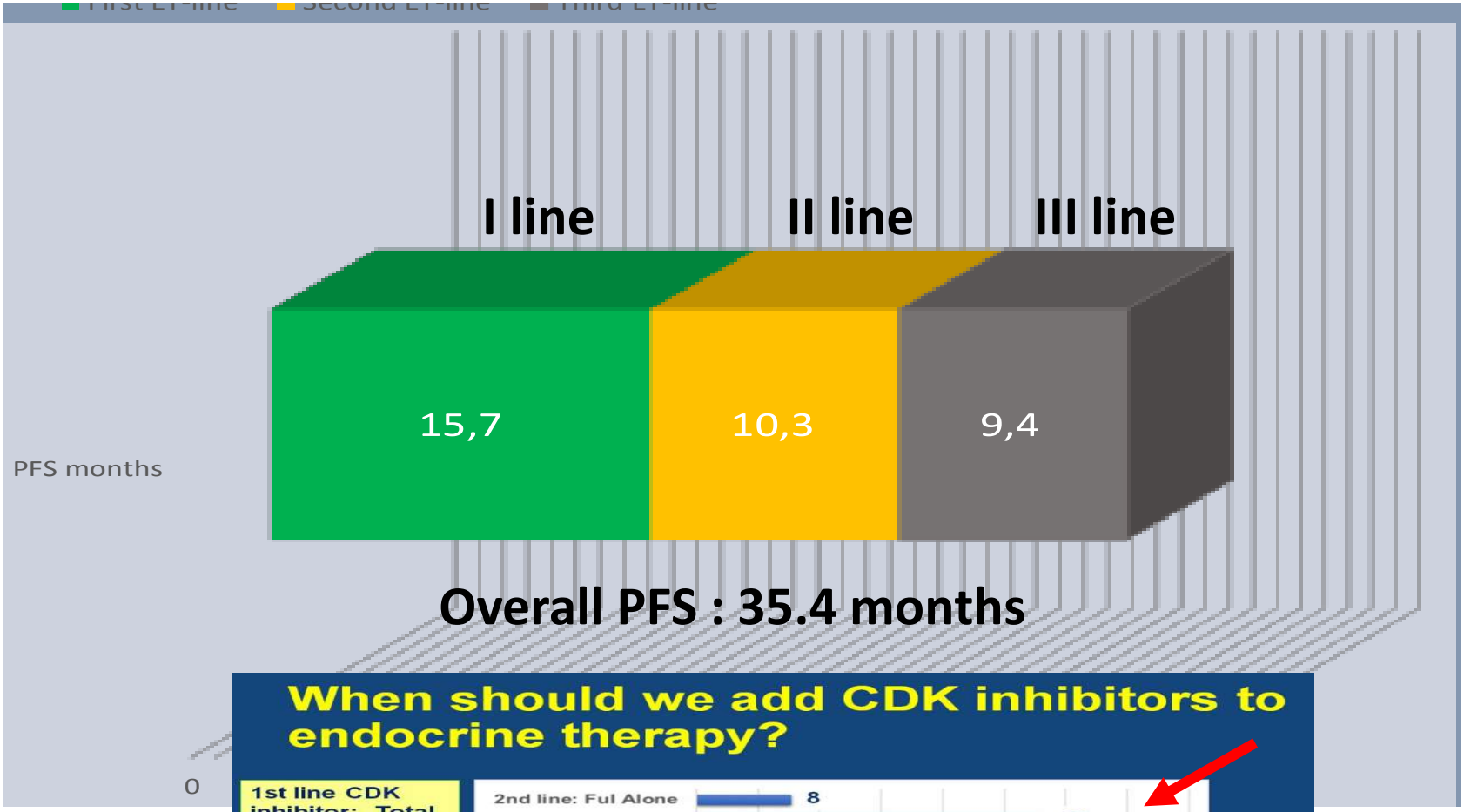
Descriptive analysis of the main therapeutic options in third-line setting

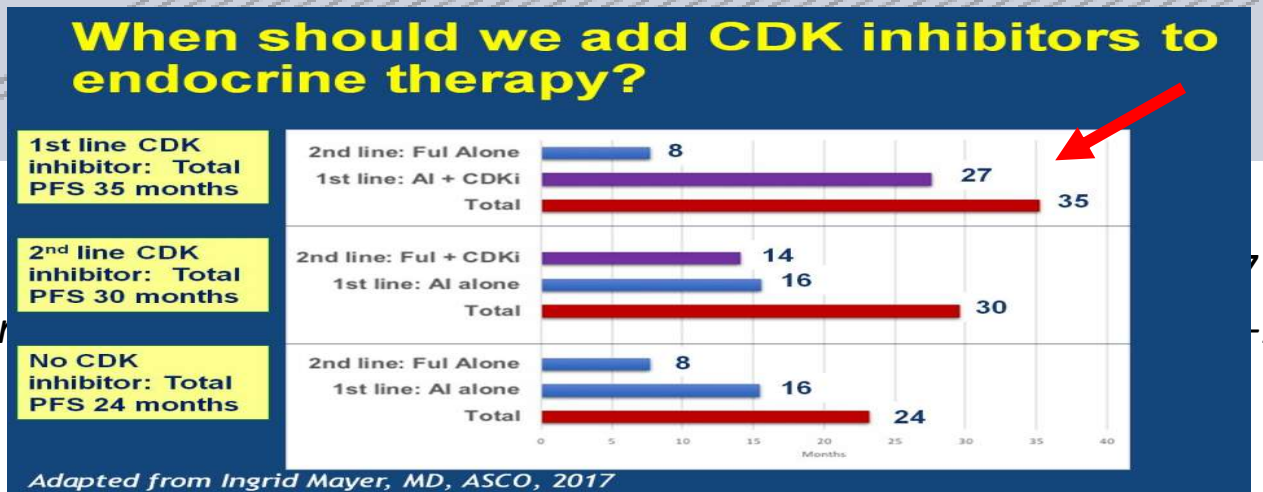


At the time of cut-off analysis, 46 (19.2%) pts still on II line of treatment; 44.8% , 36% pts respectively received HT or chemotherapy for their disease progression; the remainig 11 (4,6%) and 26 (10.7%) pts were dead or lost to follow-up, respectively (Fig.2).

194 pts progressive after II Line (80%)

PFS post progression & Global PFS with sequential HT





Among 194 pts *(44.8%) received further* *-10.9).*

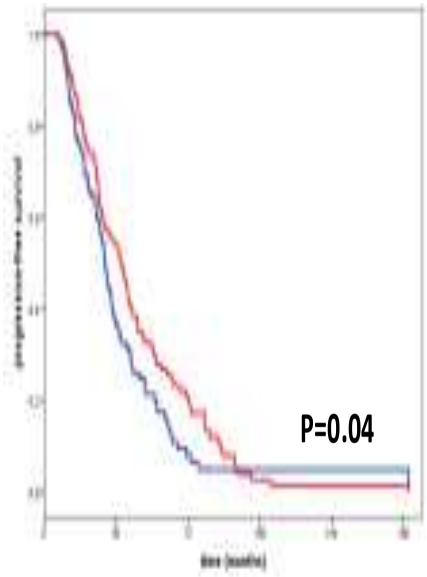


Fig.4 PFS according to time to progression from adjuvant hormonal therapy [illegible] months from the end of adjuvant HT; red line: >12 months from the end of adjuvant HT.

therapy (ET).

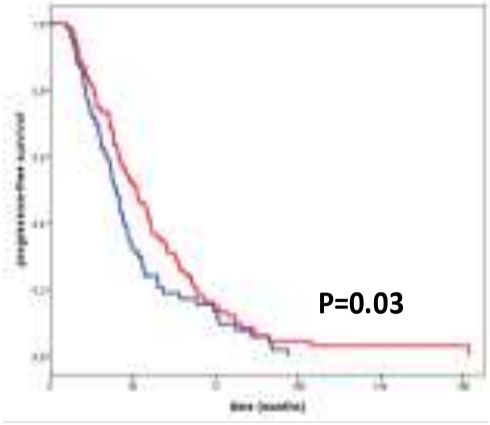


Fig.5 PFS according to the number of metastatic sites. Blue line: > 1 metastatic sites; red line: single metastatic site.

Conclusions & Caveats

1. The sequential use in first and second-line setting of endocrine therapies for HR+/HER2- MBC improves median PFS up to 35.4 months and OS up to 10.5 yrs.
2. According to real practice experience the optimal sequences could be AIs followed by F and F followed by Eve-Exe.
3. A role for these compounds should be redefined in the light of recently introduction of CDK 4/6 inhibitors in combination with AIs or F for the first or later lines.

The Role of RWE in the Community

FDA uses RWD and RWE to monitor postmarket safety and adverse events and to make regulatory decisions.

The health care community is using these data to support coverage decisions and to develop guidelines and decision support tools for use in clinical practice.

Medical product developers are using RWD and RWE to support clinical trial designs (e.g., large simple trials, pragmatic clinical trials) and observational studies to generate innovative, new treatment approaches.

Le Banche Dati Sanitarie: uno strumento di RWE per le Aziende Farmaceutiche

Operare attraverso la RWE per:

- Integrare le informazioni disponibili nei trial clinici
- Ottenere le informazioni su sotto-popolazioni nella reale pratica clinica
- Avere una visione completa ed identificare i costi “reali” del “treatment journey”
- Valutazione delle possibilità di accesso al mercato
- Supportare il valore economico del prodotto

Stakeholders

- Ministero
- AIFA
- Regioni
- ASL/AO
- Clinici
- Farmacologi
- Pazienti
- Aziende Farmaceutiche

Studio SequERPlus AIOM Lazio

Arruolamento per Centro Partecipante: update al 15 Gennaio 2018: 273 pazienti

Centro	*Referente*	*Collaboratori*	*Totale Pazienti*
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Bel Colle - Viterbo	Agnese Fabbri	Daniele Alesini	28
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Roma Regina Elena OM2	Vici Patrizia	Laura Pizzuti	16
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Thanks to :

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Diana Giannarelli
Statistician
Regina Elena National Cancer Institute - Rome

Elisabetta Bozzoli
Data Manager
Regina Elena National Cancer Institute - Rome

Aiom Lazio Direttivo

2015 - 2017

2017 - 2019