Discussions

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Disclosure slide

- Research grant from Taiho Pharmaceutical Co. Ltd.

Poster Discussion Session

Breast Cancer, 56PD

Quality of life in TSU-68 study: Combination of docetaxel and TSU-68, an oral antiangiogenic agent, in patients with metastatic breast cancer previously treated with anthracycline

B. Sohn, S. Kim, J. Ahn, K. H. Jung, K. Lee, J. Ro, S. Im, Y. Im, H. Song, H. Park, H. Chung

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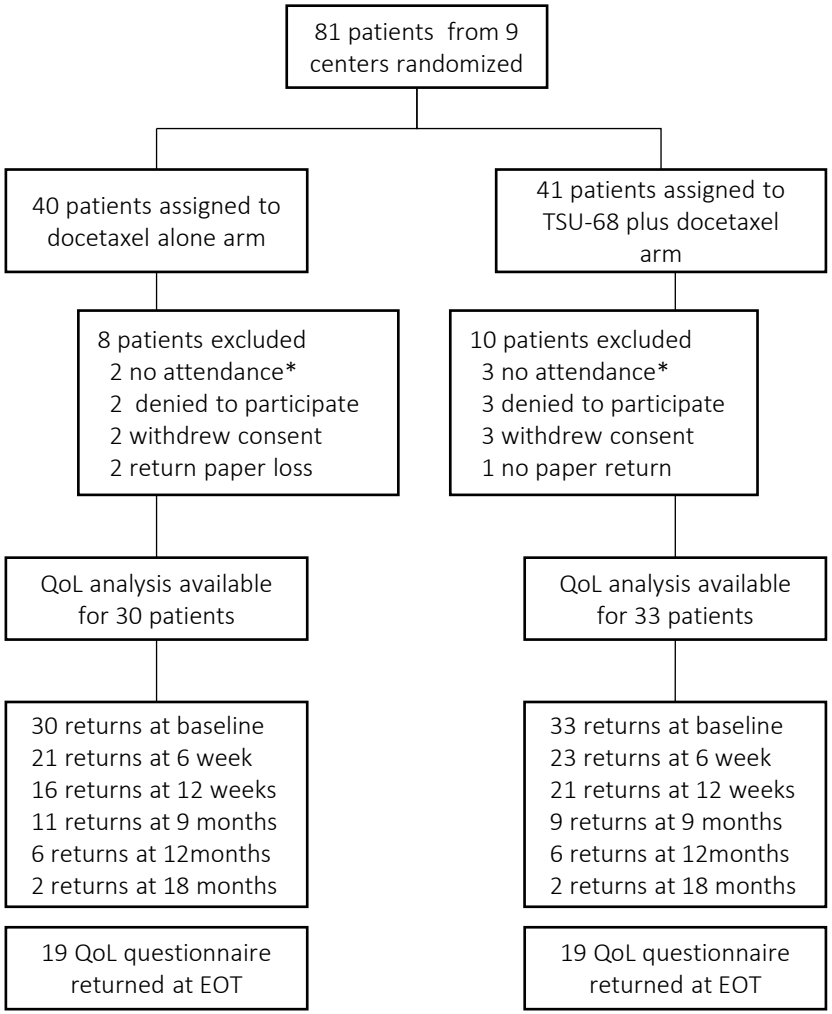


*Two center did not participated in collateral QoL study.

In main study (Kim SB, Invest New Drugs. 2014), no differences in PFS, response rate, and OS, has been seen between two treatment groups. However, in the subgroup analysis, TSU-68 plus docetaxel was associated with better OS than docetaxel alone in anthracycline-resistant patients (HR=0.3; 95%CI=0.1–0.8; p=0.02).

- QoL questionnaires were collected at each scheduled visit time until disease progression /withdrawal.
- The last QoL questionnaire was collected as “QoL at the end of treatment (EOT)”
- Because serial QoL assessments were discontinued, few patients completed the questionnaires after 12 months, therefore the analyses were done only for the visit up to 12 months.

Comparison between two groups (Two sample t test & ANCOVA)

- Docetaxel+TSU-68 showed higher score than Docetaxel only*.
  - FACT-B total score at 12 months (p=0.03)
  - FACT-G score at 12 months (p=0.02)
  - FWB score at 6 week (p=0.045)
  - Anticipation (Expectation) score at 6 week (p=0.04)
  - Frustration (Anxiety) score at EOT (p=0.02)

- However, by analysis of covariance (ANCOVA) adjusted with baseline score and anthracycline resistance, there were no difference between two groups at each scheduled visit time & at the end of treatment.
- Although there were positive changes over time in Docetaxel+TSU-68 group, these changes did not show a statistical difference.

*In poster, numbers are expressed in red color in tables
†In poster, “adjusted P value” is expressed in figures

Comparison within treatment group (one sample t test & GEE)

- Longitudinal changes in Docetaxel+TSU-68*
  - PWB: physical well being score at EOT (p=0.005)
  - SWB: social well being score at 12 week (p=0.04)
  - EWB: emotional well being score at 6 &12 week (p=0.009 & p=0.028) and score at 9&12 months (p=0.032 & p=0.005)
  - FWB: functional well being score at 6 week (p=0.008)
- Longitudinal changes in Docetaxel only*
  - BPOMS: profile of mood state score at 6 week (p=0.006)
  - FACT-G total score at EOT (p=0.020)

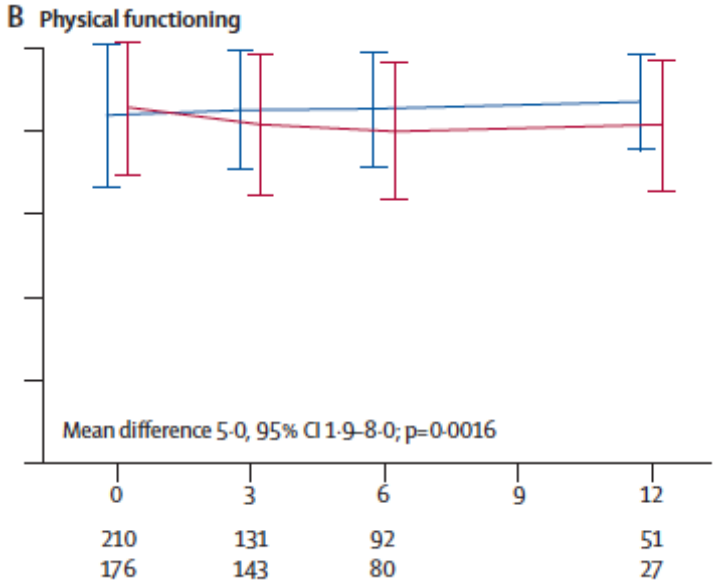
- Although there is a tendency of positive changes over time in Docetaxel+TSU-68 group, the small positive changes does not meet minimal important difference (MIB, FACT-G: 6, FACT-B: 8, FACT-B TOI: 6, BCS: 3).

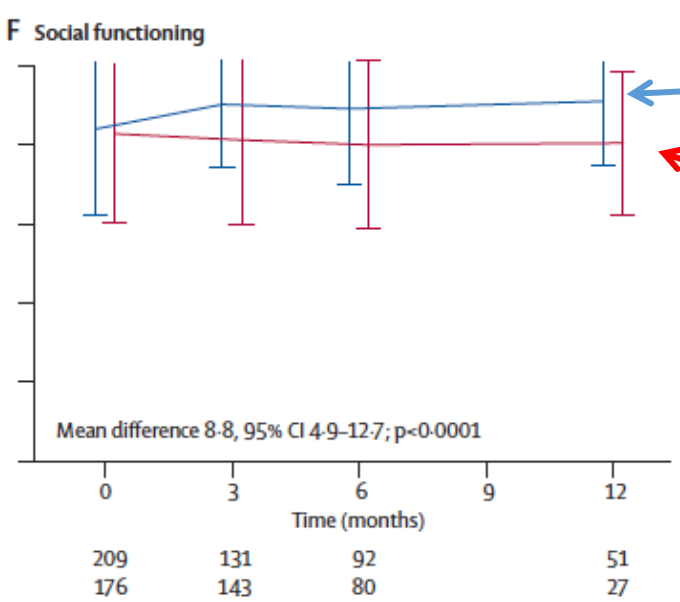
*In poster, it appears blue colored number in tables

†All the p-value of QoL scores by GEE was P > 0.05. Data are shown in figures.

- Quality of Life is crucial in cancer treatment, particularly in patients having metastatic disease.
- Analysis on the balance between benefits and risk, and QoL should be incorporated in new drug development.

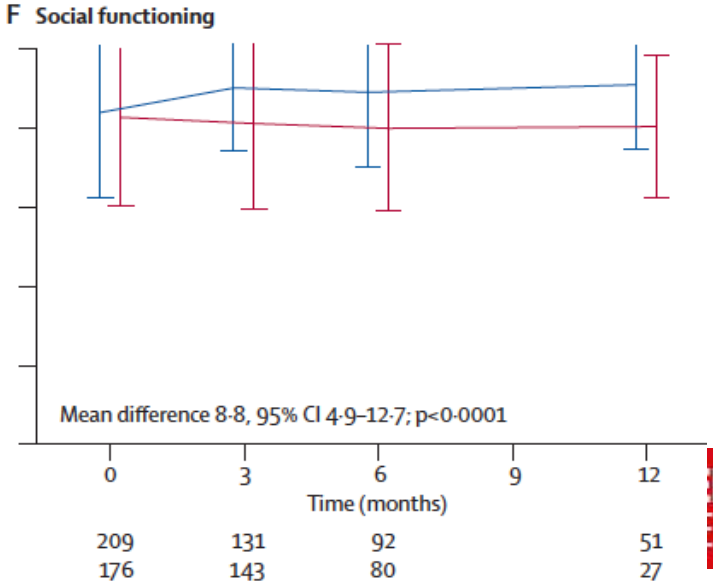
QoL: Oral FU (S1) versus Taxane in MBC





S1

Taxane



Taxanes versus S-1 as the first-line chemotherapy for metastatic breast cancer (SELECT BC): an open-label, non-inferiority, randomised phase 3 trial

Tsutomu Takashima, Hirofumi Mukai, Fumikata Hara, Nobuaki Matsubara, Tsuyoshi Saito, Toshimi Takano, Youngjin Park, Tatsuya Toyama, Yasuo Hozumi, Junji Tsurutani, Shigeru Imoto, Takanori Watanabe, Yoshiaki Sagara, Reiki Nishimura, Kojiro Shimozuma, Yasuo Ohashi, for the SELECT BC study group

Summary

Background Oral fluoropyrimidines are used for the first-line treatment of metastatic breast cancer to avoid severe adverse effects, although firm supporting evidence is lacking. We aimed to establish whether S-1 is non-inferior to taxanes in this setting.

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Questions

- It would be interesting to see a difference between different medical platforms and background.
- What and how we can assess the balance between therapeutic efficacy and QoL?

Poster Discussion Session

Breast Cancer, 57PD

Multicenter observational study of fulvestrant 500 mg in postmenopausal Japanese women with ER positive advanced or recurrent breast cancer after prior endocrine treatment (SBCCSG29 study)

K. Kimizuka , K. Inoue, S. Nagai, T. Saito, S. Nakano, K. Futsuhara, H. Yamada, T. Sakurai, S. Kaneko, S. Hata, M. Kurosumi

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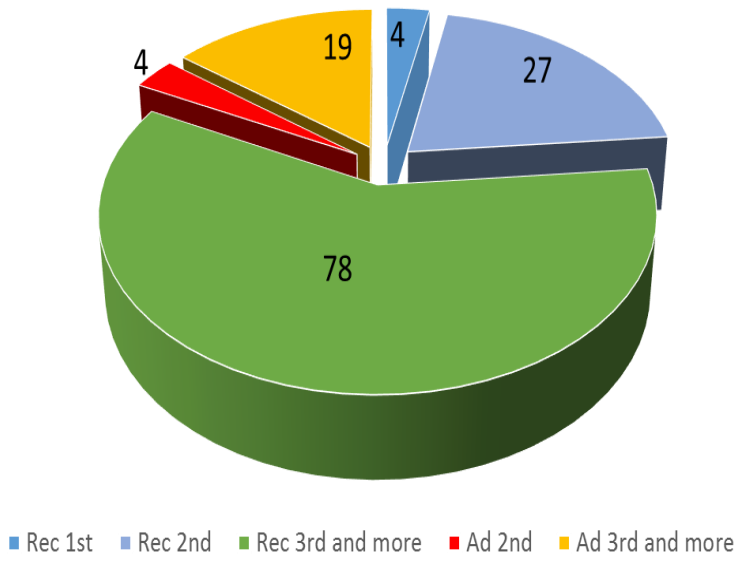
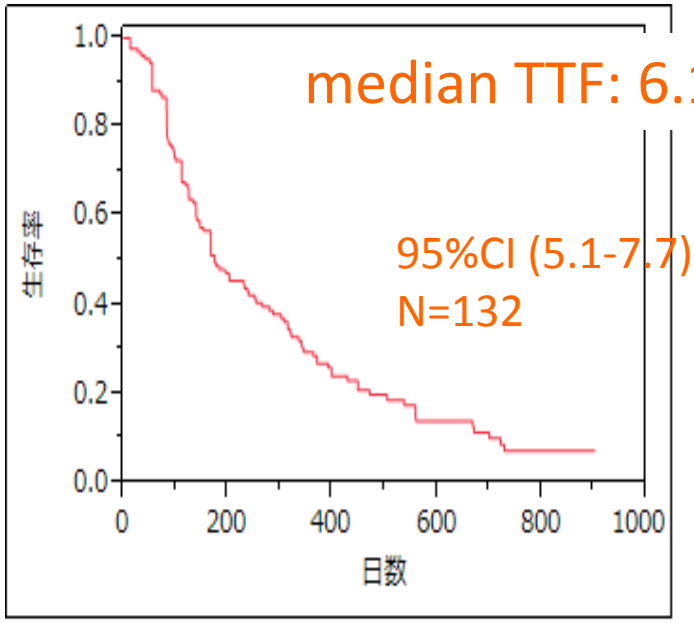
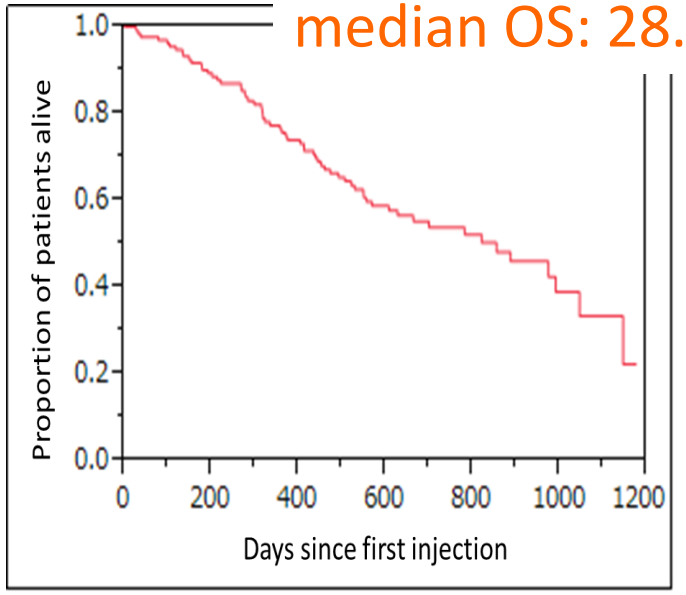
Line of the Fulvestrant treatment



TTF



OS



ORR and CBR

		RR(%)	CBR(%)
Total patients	132	12.9	45.5
1st + 2nd	38	15.8	47.4
3rd + more	94	11.7	44.7

Safety profile

	AE(G1-4)	> G3
Any adverse event	48	3
Injection site reaction	12 (9.1%)	0
Hot flushes	9 (6.8%)	0
Joint disorders	7 (5.3%)	0
Fatigue	7 (5.3%)	0
Headache	2 (1.5%)	0
Nausea	2 (1.5%)	1
Constipation	2 (1.5%)	0
Others*	7 (5.3%)	*2

(*duodenal ulcer, cellulitis)

Subsequent post-Fulvestrant therapy

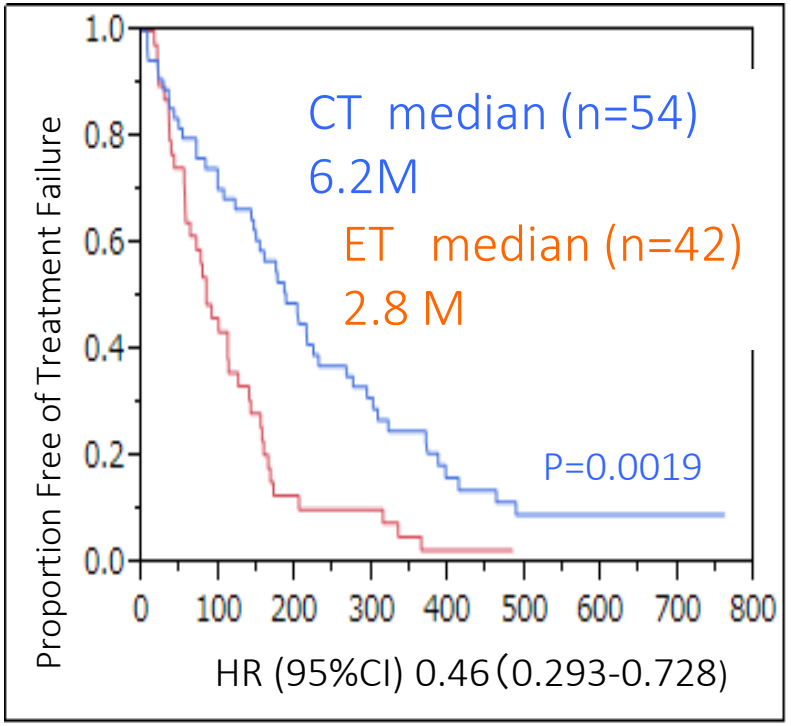
Chemotherapy (CT) 54 (56%)

Endocrine therapy (ET) 42 (43%)

Clinical response

		RR(%)	CBR(%)
Total	97	18.6	32.0
ET	42	2.4	12.2
CT	54	31.2	46.3
ET+mTORi	1		

TTF stratified by post-Fulvestrant therapies



Real-world data of fluvestrant therapy for metastatic breast cancer patients

- Median TTF:

  1st + 2nd line 6.4M

  3rd line 5.9M

- Median OS: 29M

Stratification by subsequent therapy, Median TTF

- Chemotherapy: 6.2M
- Hormonal therapy: 2.8 M

It is useful for comparison, when new drug data come.

Question

- What and how we can monitor, collect and analyze real-world data from metastatic breast cancer practice?

Poster Discussion Session

Breast Cancer, 58PD

Comparison of efficacy of neoadjuvant chemotherapy FEC 100 and docetaxel 75 versus AC and docetaxel in locally advanced breast cancer – a randomised clinical trial

Dr Dhanraj, Dr Biswajith, Dr Swaruparani, Dr Smita, Dr Sunu Cyriac, Dr Bhavana B, Dr Kadambari
(Puducherry, India)

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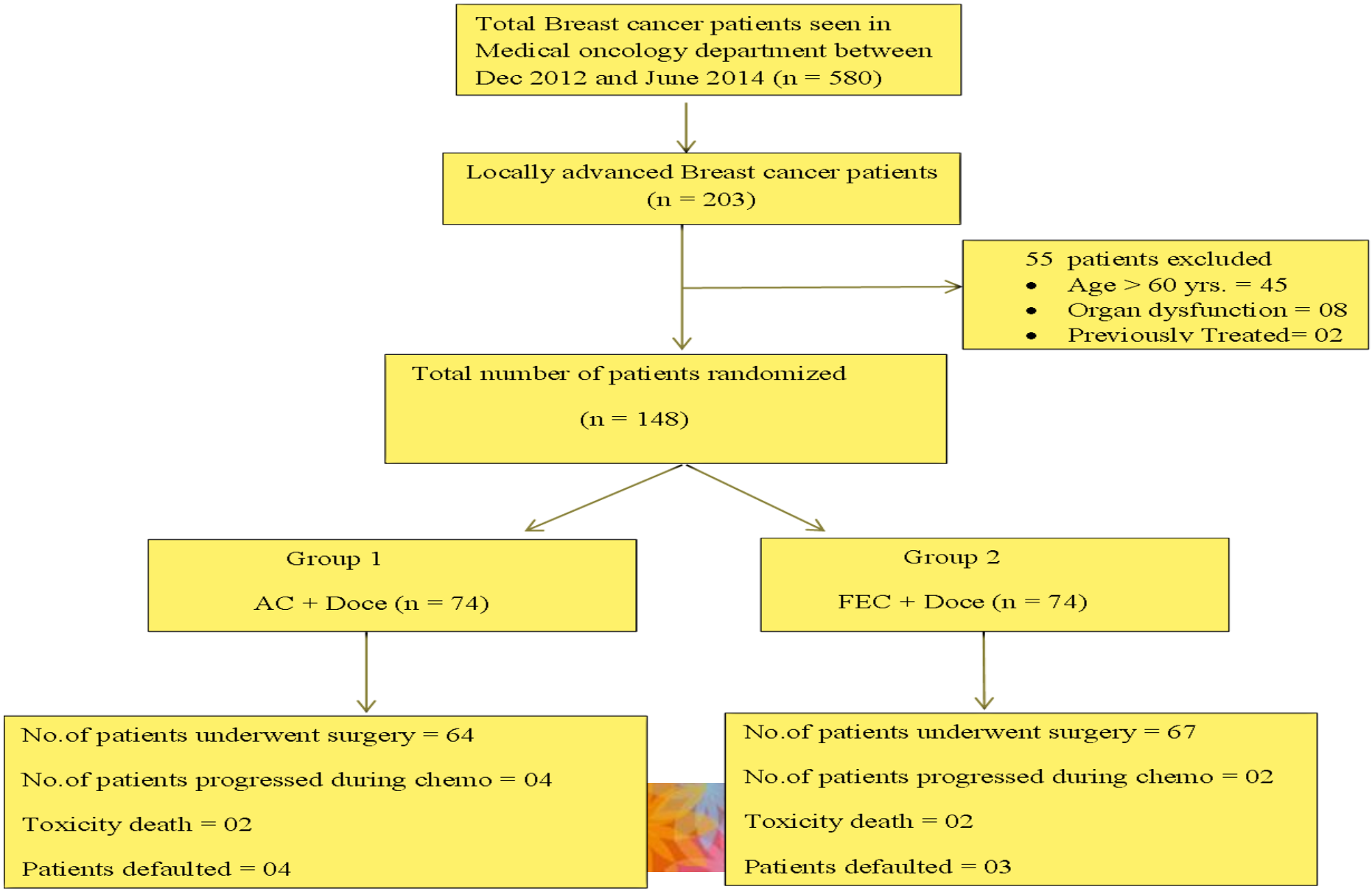
Consort Diagram

Figure 1: Consort diagram of the study population



- NACT followed by surgery and radiotherapy with or without hormonal therapy
- The primary objective was to assess and compare the pCR and toxicity profile.
- Approximately 90% of patients completed NACT and underwent surgery.
- The pCR rates were 31% in group 1 and 34% in group 2.
- Grade 3 & 4 toxicities such as neutropenia and febrile neutropenia were significantly higher in group 1 as compared to group 2.
- Also hand-foot syndrome was significantly high in group 1
- After a mean follow up of 21.4 months, no PFS difference was detected (82.4% vs. 85.1%).
- OS outcomes were similar as well (95.6% and 97.9%).

Questions

- It is comparable with postoperative adjuvant results.
- What type of trial should be considered next?