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2011/06/03

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Abstract #1075

Phase II trial report of the new preoperative chemotherapy with S-1 and Docetaxel for advanced breast cancer.

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Misako Nakagawa, Mariko Misaki, Mayumi Ikeda, Masami Morimoto, Hirokazu Takechi, Yukikiyo Kawakami, Koichiro Kenzaki, Akira Tangoku

Background

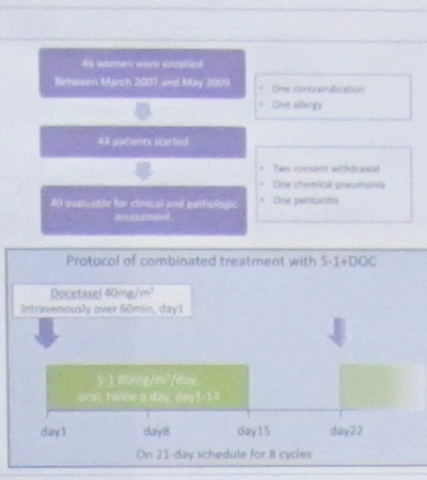
- A primary chemotherapy with anthracycline and taxanes is a gold standard regimen which realize pathological complete response (pCR) with 20%, but brings about serious side effects, i.e. heart failure, second malignancy. Therefore this regimen is difficult to use for poor risk patients.
- S-1 is a new oral anti-tumor drug. The combination therapy of S-1 and docetaxel (S-1+DOC) achieved significant response in patients with gastric cancer with minimal side effects.
- We reported the interim clinical results of the efficacy and toxicity of S-1 combined with docetaxel in ASCO 2009 (Abstract #1121). This is a final report of the study including tumor gene expression assay.

Endpoint

- Primary endpoint: Pathological complete response (pCR) rate
- Secondary endpoint: Breast conservative rate
- Tertiary for response: Safety

Methods

- Study design and ethics: Single-arm, phase II clinical trial. Approved by institutional review board with assent/consent.
- Study population: 44 patients with advanced breast cancer.
- Intervention: Docetaxel 40mg/m² intravenously over 60min, day1. S-1 80mg/m² orally, twice a day, day1-14. On 21-day schedule for 8 cycles.
- Pathological tumor response assessment: HE stained slides were prepared as 5mm tissue sections from the primary tumor. pCR was defined as no histologic evidence of invasive tumor cells in the surgical breast specimen.
- Gene expression profiling: Core needle biopsy frozen samples before chemotherapy. Total RNA was isolated from each of the frozen samples using RNeasy Mini Kit (Qiagen, Crawfords, CA). SupernaTM real time PCR (Life Technologies, Foster City, CA). Response-related 100 genes. Criteria for gene selection: P < 0.05 and fold change > 1.5.
- Surgery and postoperative treatment: Breast surgery (conservative whenever possible) and axillary dissection were mandatory. Adjuvant radio and hormonal therapy were administered according to institutional practice. *14 cycles and before surgery using RECIST criteria. *14 cycles and before surgery using RECIST criteria. *14 cycles and before surgery using RECIST criteria.



Results

Table 1. Baseline characteristics (n=44)

Characteristic	n (%)
Age	56.4 (64)
Median	56.4
Range	38-75
Menopausal status	
Premenopausal	11 (25)
Postmenopausal	33 (75)
Tumor diameter	
T1	4 (9)
T2	27 (61)
T3	13 (30)

Table 2. Response to treatment

Response	n (%)
CR	10 (23)
PR	21 (48)
SD	10 (23)
PD	3 (7)

Objective response rate (PR+CR) = 77.5%

Table 3. Breast conservative rates

Response	CR	PR	SD	PD
CR	10	8	0	0
PR	11	10	1	0
SD	1	0	0	0
PD	0	0	0	0

Table 4. Pathologic response by receptor and HER2 status

Receptor/HER2	CR	PR	SD	PD
ER and/or PgR	10	11	1	0
ER and/or PgR and HER2	1	0	0	0
ER and/or PgR and HER2	0	0	0	0

Table 5. Analysis of downregulating genes between Responder and Non-responder

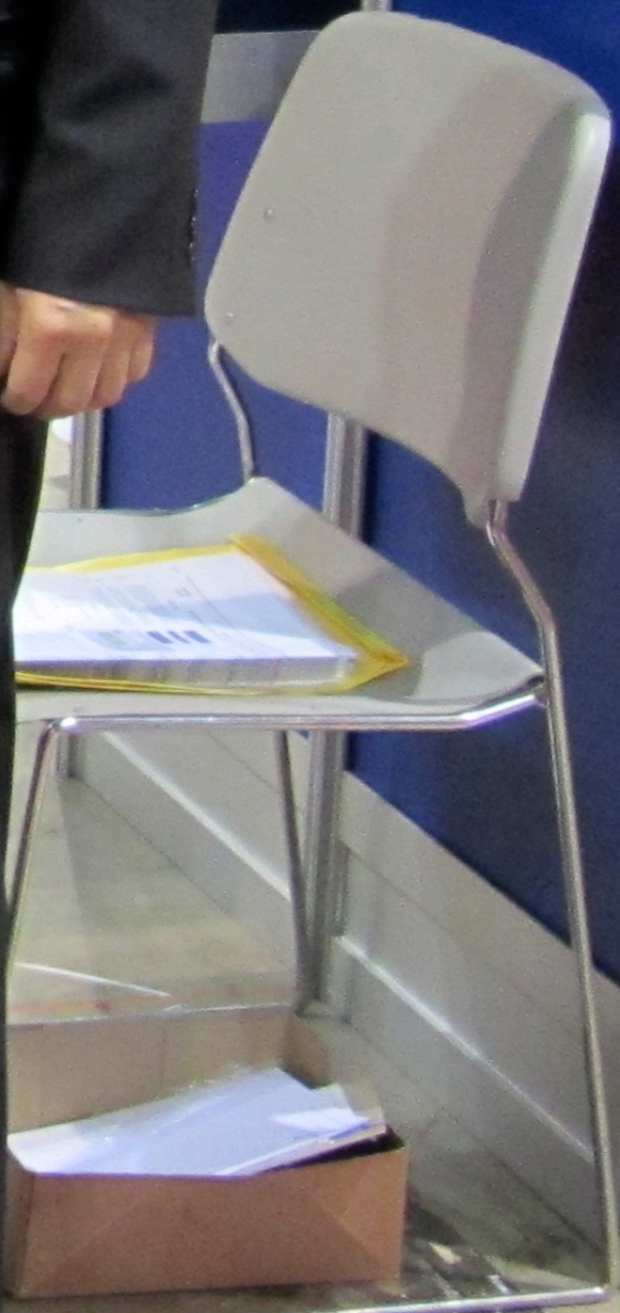
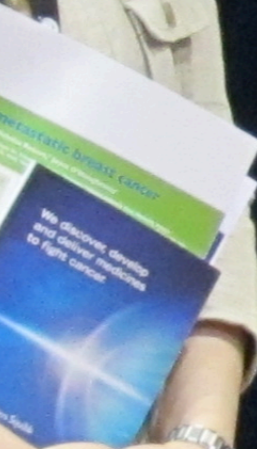
Gene	FC	P-value	FC	P-value
CDKN1A	0.508	0.0002	1.976	0.0002
CDKN1B	0.506	0.0002	1.976	0.0002
CDKN1C	0.506	0.0002	1.976	0.0002
CDKN2A	0.506	0.0002	1.976	0.0002
CDKN2B	0.506	0.0002	1.976	0.0002
CDKN2D	0.506	0.0002	1.976	0.0002
CDKN2E	0.506	0.0002	1.976	0.0002
CDKN3	0.506	0.0002	1.976	0.0002
CDKN4	0.506	0.0002	1.976	0.0002
CDKN5	0.506	0.0002	1.976	0.0002
CDKN6	0.506	0.0002	1.976	0.0002
CDKN7	0.506	0.0002	1.976	0.0002
CDKN8	0.506	0.0002	1.976	0.0002
CDKN9	0.506	0.0002	1.976	0.0002
CDKN10	0.506	0.0002	1.976	0.0002
CDKN11	0.506	0.0002	1.976	0.0002
CDKN12	0.506	0.0002	1.976	0.0002
CDKN13	0.506	0.0002	1.976	0.0002
CDKN14	0.506	0.0002	1.976	0.0002
CDKN15	0.506	0.0002	1.976	0.0002
CDKN16	0.506	0.0002	1.976	0.0002
CDKN17	0.506	0.0002	1.976	0.0002
CDKN18	0.506	0.0002	1.976	0.0002
CDKN19	0.506	0.0002	1.976	0.0002
CDKN20	0.506	0.0002	1.976	0.0002

Discussion

Our standard regimen of primary chemotherapy (E, F, anthracycline and cyclophosphamide) + docetaxel (pCR rate 20%) but brings about serious side effects, i.e. heart failure, second malignancy. Therefore this regimen is difficult to use for poor risk patients.

S-1+DOC had higher pCR rate (77.5%) than standard regimen (20%).

Our study has several limitations. First, the number of patients was small. Second, the study was retrospective. Third, the study was not randomized. Fourth, the study was not controlled. Fifth, the study was not blinded. Sixth, the study was not double-blind. Seventh, the study was not multicenter. Eighth, the study was not international. Ninth, the study was not long-term. Tenth, the study was not follow-up.



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Abstract #1075
Effectiveness of the new program...

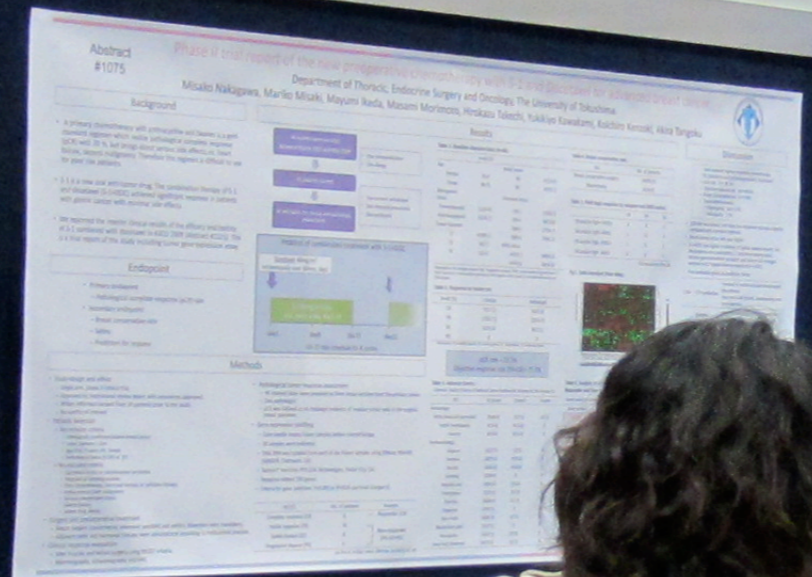
Department of Thoracic, Endocrine Surgery and Oncology, The University of Medicine
Misako Nakagawa, Mariko Mizuki, Naoyuki Tsuda, Masaru Morimoto, Hiroaki Saito, Takuro Kawahara, Kazuo Inoue, Akihiro...

Background:
The new program...

Methods:
We conducted a...

Results:
The results of the...

Conclusion:
The new program...



Three women in business attire are engaged in a conversation. One woman is wearing a pink shirt and black skirt, another a patterned top and black skirt, and the third a black suit. They appear to be discussing the poster board.

A woman with dark hair, wearing a light-colored jacket and a patterned skirt, stands with her back to the camera, looking at the poster board.

Two men in suits are looking at the poster board. One man is holding a camera up to take a photo of the poster. The other man is standing next to him, looking at the poster.

Two women are standing and talking. One woman is wearing a light-colored jacket and dark pants, and the other is wearing a dark jacket and dark pants. They are looking towards the poster board.

