Multicenter Phase II study of a frozen glove to prevent docetaxel-induced onycholysis and cutaneous toxicity for the breast cancer patients

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Discussion

During our study, the nurses had listened to the influence on pt’s life and described on her medical records. Patients complained on her life and mental activity, such as daily activity (14 pts), beauty (12 pts), housework (8 pts), hobby (3 pts), work, damage on her body image and physical depressive symptom (37 pts) and so on.

Avoid these unfavorable symptom, it seems to be important to reduce the toxicity of her exposure portion, expressly on hands.

Our data suggests that the FG may be useful to achieve the planned chemotherapy, similarly according to the previous report by Scotte (Fig.1)

Conclusions

FG significantly reduces the nail toxicity associated with docetaxel and is a safety tool on supportive care management for breast cancer patients. This should be provided in general practice widely to improve a patients QOL.
**Background**

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We have learned from the questionnaire survey of description and hearing type that the onycholysis and skin toxicity occur in approximately 90% of patients treated with docetaxel (DTX) on hands and 65% on feet. Besides neurotoxicity and edema, these adverse events cause the worse quality of life (QOL) assessment because of the exposure, public noticed site.

According to the report that the Elasto-Gel frozen glove (FG) was effective for the prevention of DTX-induced onycholysis and skin toxicity (Fig. 1, Scott F. JCO, 2005), we have planned to reanalyze the efficacy and safety of FG for Japanese breast cancer pts by the multicenter, prospective phase II study.

**Patients and Methods**

Patients receiving DTX 75 mg/m² alone or in combination chemotherapy more than 4 cycles were eligible for this case-control study.

Each patient on the case group wore an FG for a total of 90 minutes on the both hands (Fig. 2). Her feet were not protected.

The control data was obtained by the questionnaire survey from the pts who had not used FG during the chemotherapy.

Onycholysis and skin toxicity were assessed at each cycle by National Cancer Institute Common Toxicity Criteria and documented by photography (Table 1). This study had accomplished by multidisciplinary approach by nurses, pharmacists, and doctors

Wilcoxon matched-pairs rank test was used.

**Results**

Between March 2006 and May 2007, 70 pts on case and 52 pts on control were evaluated (Table 2).

Table 2

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>No. of Patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>70 180%</td>
</tr>
<tr>
<td>Sex</td>
<td>Female</td>
</tr>
<tr>
<td>Performance Status</td>
<td>92 29</td>
</tr>
<tr>
<td>Previous Treatment</td>
<td>1 1</td>
</tr>
<tr>
<td>Treatment Line</td>
<td>Pre-Operational Breast</td>
</tr>
<tr>
<td>Comorbidities</td>
<td>Single agent</td>
</tr>
<tr>
<td>Duration of therapy</td>
<td>4</td>
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</tbody>
</table>

Median age were similar for each group, 52 [29-74 years] on case and 51 [25-73 years] on control.

Onycholysis were significantly lower in the FG-protected hands compared with the control hands (p=0.0001) (Fig. 3). Onycholysis was grade (G) 0 in 41% vs 8%, G1 in 54% vs 74%, and G2 to 3 in 4.3% vs 80% on the FG-protected hands and the control hands, respectively (Fig. 3).

For the feet, there was no difference in frequency between pts on case and on control (Fig. 4).

We analyzed the frequency of the skin toxicity by the combination the data of hand-foot skin reaction, desquamation, hyperpigmentation and induration/fibrosis into phenomenon to compare with the historical control data. The frequency of the skin toxicity was not significantly lower in the FG-protected hands (Fig. 5).

Although one pt (0.1%) experienced discomfort due to cold intolerance, there were no serious adverse events caused by FG.