Frozen socks use in the prevention of docetaxel induced nail and skin reaction: results of a case - control study

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ABSTRACT

Background: Nail and skin disorder of the hand occurs in about 50 % of patients (pts) treated with docetaxel [2]. No data exists on nail and skin toxicity (NST) of the foot after D. We investigated the efficacy and safety of an Elastic-Gel™ (Alkion, France) flexible frozen sock (FS) for the prevention of D - induced NST.

Methods: Cancer pts receiving D at 75 to 100 mg/m² (1 hour infusion q 3 w) alone or in combination chemotherapy were eligible for this matched case - control study. Each patient wore a FS for a total of 90 minutes (min) on the right foot (15 min before to 15 min after D - infusion). Left foot, acted as control, was not protected by FS. NDT were assessed at each cycle by NCI - CTC v 3 criteria and documented by photography. Comfort in socks wearing was assessed by ad hoc scale. Wilcoxon matched - pairs rank test was used to determine the magnitude of difference between two matched groups.

RESULTS: 49 pts were evaluated. Median age: 64 yrs; M/F: 37/12; ECOG PS ≤2. All pts were treated with docetaxel as an one - hour intravenous infusion every 3 weeks. No prior treatment with taxanes. No adjustment for multiplicity of tests was performed. Analyses of toxicities were carried out on the per - protocol population defined as the totality of included patients, which use the FS at least on time at the first cycle.

No differences were observed in term of time to occurrence of nail and skin toxicity between protected and unprotected feet: 105 vs 107 and 101 vs 103 days, respectively. The impact on the time to nail toxicity occurrence of some confounders as the ECOG PS, sex, number of cycles and dose of docetaxel was studied using multivariate Cox regression analysis (forward stepwise selection).

No adjustment for multiplicity of tests was performed.

CONCLUSIONS

Less toxicity of the feet vs hands
► nail: 21 % vs 81 %. skin: 6 % vs 54 %.
► No significant efficacy on skin toxicity: 6% vs 2% (p = 0.18).
► Significant sock protection on nail toxicity
► no toxicity on protected foot (p = 0.002).

REFERENCES


ACKNOWLEDGMENTS

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SARL.

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STUDY DESIGN

The present matched, case - control, phase 11 study was designed to assess the efficacy and safety of cold therapy in the prevention of docetaxel - induced onycholysis and skin toxicity of the foot.

Patients enrolled in this prospective study were undergoing treatment for a variety of tumor types with docetaxel. Between 70 - 100 mg/m² as an one - hour intravenous infusion every 3 weeks, either alone or in combination with other cytotoxic agents.

No prior treatment with taxanes.

The absence of skin and nail disorders at the start of chemotherapy.

Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2.

Patients provided written informed consent before inclusion.

Patients were excluded if they had Raynaud's syndrome, distal cold intolerance, and peripheral neuropathy (grade≤ 2). All analyses of toxicities were carried out on the per - protocol population defined as the totality of included patients, which use the FS at least on time at the first cycle.

No differences were observed in term of time to occurrence of nail and skin toxicity between protected and unprotected feet: 105 vs 107 and 101 vs 103 days, respectively.

No adjustment for multiplicity of tests was performed.

RESULTS

Nail toxicity of the foot after docetaxel treatment

Patient characteristics (per - protocol population, n=48)

<table>
<thead>
<tr>
<th>CHARACTERISTICS</th>
<th>CONTROL FOOT (n=48)</th>
<th>PROTECTED FOOT (n=48)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>Male</td>
<td>36 (75)</td>
<td>30 (65)</td>
</tr>
<tr>
<td>Female</td>
<td>24</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>median (range)</td>
<td>62 (36 - 80)</td>
<td>62 (36 - 80)</td>
</tr>
<tr>
<td>ECOG</td>
<td>0</td>
<td>22 (46)</td>
<td>14 (29)</td>
</tr>
<tr>
<td>performance</td>
<td>1</td>
<td>20 (42)</td>
<td>12 (25)</td>
</tr>
<tr>
<td>2</td>
<td>6 (12)</td>
<td>8 (17)</td>
<td>0.43-0.89</td>
</tr>
<tr>
<td>Type of tumor</td>
<td>Prostate</td>
<td>25 (52)</td>
<td>23 (48)</td>
</tr>
<tr>
<td>Lung (non - small cell)</td>
<td>10 (21)</td>
<td>11 (23)</td>
<td>0.72-0.99</td>
</tr>
<tr>
<td>Other</td>
<td>9 (19)</td>
<td>6 (13)</td>
<td>0.14-0.53</td>
</tr>
<tr>
<td>Duration of cycles</td>
<td>Median</td>
<td>12 (6 - 22)</td>
<td>13 (6 - 22)</td>
</tr>
<tr>
<td>Number of cycles</td>
<td>Median</td>
<td>5 (1 - 14)</td>
<td>5 (1 - 14)</td>
</tr>
<tr>
<td>Cumulative dose (mg)</td>
<td>Median</td>
<td>120 (100 - 200)</td>
<td>120 (100 - 200)</td>
</tr>
</tbody>
</table>

Nail toxicity

Grade 0: no toxicity on protected foot
Grade 1: partial loss of nail(s) (onycholysis) or pain in nail beds interfering with function.
Grade 2: partial loss of nail(s) (onycholysis) or pain in nail beds interfering with function, or complete loss of nail(s).
Grade 3: partial loss of nail(s) (onycholysis) or pain in nail beds interfering with function.
Grade 4: dissatisfied: 1 = not satisfied; 2 = satisfied; 3 = very satisfied.

COMFORT ASSESSMENT

Global comfort: 0 = not satisfied; 1 = satisfied; 2 = very satisfied.
Cold tolerance: 0 = no complaints; 1 = mild complaints; 2 = severe complaints.

No differences were observed in term of time to occurrence of nail and skin toxicity between protected and unprotected feet: 105 vs 87 and 101 vs 103 days, respectively.

The impact on the time to nail toxicity occurrence of some confounders as the ECOG PS, number of cycles and dose of docetaxel was studied using multivariate Cox regression analysis (forward stepwise selection).

No adjustment for multiplicity of tests was performed.

STUDY DESIGN

Statistical Design

Analyses of toxicities were carried out on the per - protocol population defined as the totality of included patients, which use the FS at least on time at the first cycle.

Two - sample Wilcoxon matched - pairs rank test adjusted for use was used as the main method to determine the statistical signifi-
cance of difference between the incidence of nail and skin toxicities between FS - protected and unprotected feet.

Kaplan-Meier method was used to estimate differences in time to toxicity occurrence (patients were censored if no toxicity occurred at the end of chemotherapy or during follow-up).

The impact on the time to nail toxicity occurrence of some confounders as the ECOG PS, number of cycles and dose of docetaxel was studied using multivariate Cox regression analysis (forward stepwise selection).

No adjustment for multiplicity of tests was performed.

REFERENCES


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