A comparison of patch testing with nickel sulfate in TRUE Test and in petrolatum at 2.5% and 5% concentrations

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Despite the European Union (EU) Nickel Directive introduced in 2009, nickel contact allergy is still frequent and represents a health concern in the EU (1). Therefore, it is important to evaluate test methods and concentrations (2). Nickel sulfate 2.5% pet. is included in the International Contact Dermatitis Research Group (ICDRG) baseline patch test series. In other baseline series, such as the European and the Swedish, nickel sulfate 5% pet. is included, or alternatively nickel sulfate 200 μg/cm² in TRUE Test. The aim of this study was to compare the performance of nickel sulfate in TRUE Test with nickel sulfate 2.5% pet. and 5% pet..

METHODS
This study was a part of a larger multicenter ICDRG study comparing nickel sulfate 2.5% pet. and 5% pet. The results of this multicenter study have not yet been published. Between January 2020 and August 2020, a total of 192 patients were patch tested consecutively with the baseline series at the Department of Dermatology and Allergy Centre, Odense University Hospital, Denmark. The baseline series consists of the TRUE Test panels 1-3 (SmartPractice Aps, Hillerød, Denmark) and a panel of additional allergens in Finn Chambers on Scanpor tape (SmartPractice, Phoenix, AZ, USA) to complete the European baseline patch test series. Simultaneously, all patients were tested with nickel sulfate 2.5% and 5% pet. from the same batch (Chemotechnique Diagnostics, Vellinge, Sweden) using 8 mm Finn chambers and a dose 20 mg of the patch test preparation. The patch tests were applied on the upper back for 48 hours under occlusion and read on day (D) 3 and D7, according to the current European Society of Contact Dermatitis (ESCD) guidelines. Positive reactions were graded +, ++, ++++, while doubtful reactions +? were dismissed as nonallergic. Relevance of the positive reactions was not taken into account in this study.
RESULTS

Out of the 192 patients, 69 (36%) had a positive reaction to either one of the nickel preparations. For TRUE test, 21 (30% of total positives) had a positive reaction with most of the reactions being ++ (57%). For nickel sulfate 2.5% pet., the number of total positive reactions was 20 (29% of total positives) with a majority of ++ reactions (60%). Testing with nickel sulfate 5% pet. resulted in 28 positive reactions (41% of total positives), mostly + reactions (46%) and ++ reactions (43%) (Table 1).

DISCUSSION

This study compared nickel sulfate in TRUE Test with nickel sulfate in 2.5% pet. and 5% pet. A difference in positive reactions between the three test concentrations was found in favor of nickel sulfate 5% accounting for most of the positive reactions (41% of the positive reactions). Nickel sulfate in TRUE Test and nickel sulfate 2.5% pet. gave comparable test results. No irritant reactions were found.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

REFERENCES

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<th>Ni, Nickel.</th>
<th>Total Negatives (n)</th>
<th>?+</th>
<th>+</th>
<th>++</th>
<th>+++</th>
<th>Total positives (n)</th>
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</thead>
<tbody>
<tr>
<td>Ni 200 µg/cm² (TRUE test)</td>
<td>152</td>
<td>19</td>
<td>6</td>
<td>12</td>
<td>3</td>
<td>21</td>
</tr>
<tr>
<td>Ni 2.5% pet.</td>
<td>150</td>
<td>22</td>
<td>5</td>
<td>12</td>
<td>3</td>
<td>20</td>
</tr>
<tr>
<td>Ni 5% pet.</td>
<td>141</td>
<td>23</td>
<td>13</td>
<td>12</td>
<td>3</td>
<td>28</td>
</tr>
</tbody>
</table>

**TABLE 1** Grading of patch test results (n=192).