Sirs,

Osteoarthritis (OA) represents the most prevalent form of chronic articular disease, leading progressively to severe physical impairment, disability and reduced quality of life in middle-age and elderly people (1). Among OA pharmacological therapies, glucosamine crystalline sulfate (GlcN-S) has shown efficacy in the improvement of OA-related pain and functional impairment (4). Recent data show mud packs application as a therapeutic option able to improve function, perceived pain and quality of life in knee OA patients (5-7).

In a previous randomised, controlled, crossover study we reported that combined treatment providing mud-bath therapy and glucosamine crystalline sulfate (GlcN-S) has a positive and safe role in improving pain, function and quality of life in knee OA after six months (7).

The present study is an extension of the previously reported investigation on knee OA treatment (7).

At the end of this phase, all OA patients discontinued any treatment and we observed them after 6 months (T12), during which patients did not use any treatment for OA. At T12 visit, for each patient, we collected data including personal history, physical examination with recording of measures of OA severity and activity: knee circumference measurement, active knee flexion ROM. Pain intensity, OA severity and activity were also evaluated by the use of the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index, Lequesne algo-functional Index, and visual analogue scale (VAS). The Health Assessment Questionnaire (HAQ) was used for the evaluation of functional status and the 28-item General Health Questionnaire for the evaluation of somatic symptoms (GHQ-28) (Ox ford) was used for the evaluation of functional status of the Western Ontario and McMaster Universities; VAS: visual analogue scales; HAQ: Health Assessment Questionnaire; GHQ-28: 28-item General Health Questionnaire.

When analysing separately data in the two groups of the study, no differences were found in the comparison between them at each study time. In a recent randomised, controlled, crossover study we have reported that combined treatment providing mud-bath therapy and GlcN-S has a positive and safe role in improving pain, function and quality of life in mild/moderate knee OA (7).

Aim of the present study has been to evaluate the persistence of this improvement after 6 months of discontinuation of all treatments for OA.

Results of the present extension study report that mud-bath therapy and oral GlcNS after 6 months of their discontinuation in patients with knee OA show sustained clinical efficacy.

In particular, when comparing basal (T0) data with results obtained at T12, for all the considered values, patients maintained the statistically significant improvement after the 6 months of treatment.

Data derived from this extended period of observation following a previous RCT suggest that the association of GlcN and mud-bath therapy has a positive role in maintaining stable improvement of pain, function and quality of life in knee OA patients.

In conclusion, the association of GlcNS and mud-bath therapy after 6 months of their discontinuation in patients with knee OA show sustained clinical efficacy. This beneficial effect could be related to the peculiar physicochemical properties of Ichia natural mineral water and mud. These could represent an important therapeutic opportunity for OA patients, in combination with GlcNS, and should be taken into account in further studies.

F. CASO*, MD, PhD
L. COSTA*, MD, PhD, Assist. Prof.
A. DEL PUENTE*, MD, PhD, Assist. Prof.
D. SORBO*, MD
R. PELUSO*, MD, Assist. Prof.
R. SCARPAN1, MD, Assoc. Prof.

1Rheumatology Unit, Department of Clinical Medicine and Surgery, University Federico II, Naples, Italy;
2Orthopaedic Unit, Rizzoli Hospital, Bologna, Italy; 3Julio Gasolinno Thermal Study Centre, Ischia, Italy.

*F. Caso and L. Costa contributed equally to this article.

Address correspondence to:
Raffaele Scarpa, MD, Rheumatology Unit, Department of Clinical Medicine and Surgery, University Federico II, via S. Pansini 5, 80131 Naples, Italy; E-mail: rscarpa@unina.it

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References


Table I. Indices of osteoarthritis activity, pain intensity, osteoarthritis severity, quality of life, psychological status at baseline (T0), at 6-month (T6) and at twelve-month (T12) visit of patients included in the study.

<table>
<thead>
<tr>
<th></th>
<th>T0</th>
<th>T6</th>
<th>T12</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active knee flexion ROM (grade)</td>
<td>12.47 ± 22.08</td>
<td>13.64 ± 16.58</td>
<td>13.83 ± 15.47</td>
<td>0.0001</td>
</tr>
<tr>
<td>Active knee extension ROM (grade)</td>
<td>3.49 ± 2.21</td>
<td>5.64 ± 1.86</td>
<td>5.22 ± 1.95</td>
<td>0.0002</td>
</tr>
<tr>
<td>Knee circumference measurement (cm)</td>
<td>41.49 ± 6.77</td>
<td>38.43 ± 5.96</td>
<td>38.08 ± 5.96</td>
<td>0.013</td>
</tr>
<tr>
<td>WOMAC OA index</td>
<td>33.55 ± 22.08</td>
<td>18.50 ± 16.73</td>
<td>14.40 ± 11.56</td>
<td>0.0001</td>
</tr>
<tr>
<td>LEQUESNE algo functional index</td>
<td>11.24 ± 4.85</td>
<td>6.50 ± 4.57</td>
<td>6.42 ± 4.32</td>
<td>0.0001</td>
</tr>
<tr>
<td>VAS</td>
<td>42.22 ± 21.98</td>
<td>25.42 ± 19.85</td>
<td>21.89 ± 14.23</td>
<td>0.0001</td>
</tr>
<tr>
<td>HAQ</td>
<td>0.76 ± 0.61</td>
<td>0.54 ± 0.34</td>
<td>0.30 ± 0.33</td>
<td>0.0001</td>
</tr>
<tr>
<td>GHQ28</td>
<td>1.94 ± 0.48</td>
<td>1.57 ± 0.52</td>
<td>1.64 ± 0.49</td>
<td>0.005</td>
</tr>
</tbody>
</table>

ROM: range of motion; WOMAC: Western Ontario and McMaster Universities; VAS: visual analogue scales; HAQ: Health Assessment Questionnaire; GHQ-28: 28-item General Health Questionnaire.

*p-value in the Comparison between values at T0 and T12.