SPA THERAPY AT THE DEAD SEA AREA FOR ANKYLOSING SPONDYLITIS

Sukenik S., Kudish S., Dubrowinski S., Flusser D. and Abu-Shakra M.

Soroka University Medical Center
Faculty of Health Sciences
Ben-Gurion University of the Negev
Beer-Sheva, Israel
Previous Studies At The Dead Sea Area

Inflammatory Arthritis

- Rheumatoid Arthritis
  - Clin Rheumatol 11:243, 1992
  - Harefuah 129:100, 1995
  - Rheumatol International (in press)

- Psoriatic Arthritis
  - J Rheumatol 21:1305, 1994
  - Isr Med Assoc J 3:147, 2001
Non-Inflammatory Arthritis

- Osteoarthritis
  Harefuah 129:100, 1995
  Isr Med Assoc J 1:83, 1999

- Fibromyalgia
  Clin Rheumatol 20:15, 2001
  Rheumatol International 20:105, 2001
Treatment Modalities At The Dead Sea

- Dead Sea water
- Thermo-Mineral springs
- Mud
- Physiotherapy
- Heliotherapy
Dead Sea

- The Lowest Spot On The Face Of The Earth – 400 m Below Sea Level
- Length – 50 km
- Width 17 km
- Terminal Lake
- One Of The Saltiest Lakes In The World
- Average Salinity 345 gr/l
Important Climatic Features

- World’s highest barometric pressure
- Low relative humidity (33-50%)
- High temperatures (summer 32-40°C, winter 20-32°C)
- Low rainfall
- Clear sunny skies
- High UVA/UVB ratio
- Pollen low atmosphere
- Oxygen-rich air – 6-8% more molecules per m³
Ideal Weather Conditions For Patients Suffering From Arthritis

- High barometric Pressure
- Low relative Humidity
- High Constant Temperatures

Summary Of Previous Studies

- Short term improvement in most of the clinical parameters
- Discordance between clinical and laboratory parameters
- Very few side effects
- Very few contraindications
- Cannot substitute conventional therapy but can complement it
Aim Of Present Study

To assess the efficacy of the unique climatic conditions at the Dead Sea versus balneotherapy.
Patients and Methods (1)

28 Pts – Ankylosing Spondylitis

**Inclusion Criteria**
- ACR diagnostic criteria for AS
- Active disease – back pain

**Exclusion Criteria**
- Psoriasis
- Malignancy
- End stage renal or liver diseases
- Mental disorders
- Spinal diseases
Patients And Methods (2)

Pts were randomly allocated:

Balneotherapy group – 14 pts

Daily Treatment with:

1. Mud packs – 39-40°c
2. Sulfur pool – 36-37°c
3. Dead sea water
Patients And Methods (3)

Climatic group – 14 pts

- No balneotherapy
- Sweet water pool

Duration of treatment: 2 weeks
Patients Assessments:
- 1-2 days prior to arrival
- End of treatment period (2 weeks)
- One month
- Three months

- All pts were assessed by a single rheumatologist
- Blinded to the mode of therapy
Parameter measured at each assessment:
- Bath AS disease Activity Index (=BASDAI)
- Physical examination
- Patient’s evaluation of disease:
  - VAS-pain severity:
  - VAS-limitation of movement
- SF-36: Quality of life Questionnaire
## Baseline Characteristics of study participants.

<table>
<thead>
<tr>
<th></th>
<th>Balneology group N=14</th>
<th>Climatic group n=14</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong> Male</td>
<td>12</td>
<td>14</td>
<td>0.48</td>
</tr>
<tr>
<td>Female</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td>49.7 ± 12.0</td>
<td>46.1 ± 13.4</td>
<td>0.46</td>
</tr>
<tr>
<td><strong>Disease duration</strong></td>
<td>17.1 ± 13.3</td>
<td>18.6 ± 12.2</td>
<td>0.77</td>
</tr>
<tr>
<td><strong>Use of medication</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain killers</td>
<td>7 (50%)</td>
<td>4 (28.6%)</td>
<td>0.22</td>
</tr>
<tr>
<td>Narcotics</td>
<td>0</td>
<td>1 (7.1%)</td>
<td>0.5</td>
</tr>
<tr>
<td>NSAIDs</td>
<td>9 (64.3%)</td>
<td>8 (57.1%)</td>
<td>0.5</td>
</tr>
<tr>
<td><strong>Routine physical therapy</strong></td>
<td>1 (7.1%)</td>
<td>0</td>
<td>0.5</td>
</tr>
<tr>
<td><strong>Initial BASDAI</strong></td>
<td>4.9 ± 2.0</td>
<td>6.1 ± 1.5</td>
<td>0.07</td>
</tr>
<tr>
<td><strong>Initial VAS for pain</strong></td>
<td>6.7 ± 2.2</td>
<td>6.4 ± 2.4</td>
<td>0.75</td>
</tr>
<tr>
<td><strong>Initial VAS limitation in movement</strong></td>
<td>6.3 ± 2.4</td>
<td>7.1 ± 1.6</td>
<td>0.28</td>
</tr>
<tr>
<td><strong>Initial morning stiffness (minutes)</strong></td>
<td>46.3 ± 32.9</td>
<td>74.3 ± 48.6</td>
<td>0.1</td>
</tr>
</tbody>
</table>
### BASDAI scores at the four assessments by treatment group. Average ± SD

<table>
<thead>
<tr>
<th></th>
<th>Balneotherapy group n=14</th>
<th>Climatic group n=14</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study initiation</strong></td>
<td>4.86 ± 1.98</td>
<td>6.10 ± 1.47</td>
</tr>
<tr>
<td><strong>End of treatment at Dead-Sea area</strong></td>
<td>3.96 ± 1.58</td>
<td>4.16 ± 2.18 *</td>
</tr>
<tr>
<td><strong>One month follow-up</strong></td>
<td>4.83 ± 1.59</td>
<td>4.67 ± 1.56 *</td>
</tr>
<tr>
<td><strong>Three months follow-up</strong></td>
<td>4.77 ± 1.67</td>
<td>4.86 ± 1.96</td>
</tr>
</tbody>
</table>

BASDAI: Bath Ankylosing Spondylitis Disease Activity Index

* P < 0.05 – in comparison to pretreatment values
### Results of VAS Scores for Pain and for Movement Limitation. Average ± SD

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<thead>
<tr>
<th></th>
<th>Balneotherapy group n=14</th>
<th>Climatic group n=14</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pain</td>
<td>Movement</td>
</tr>
<tr>
<td><strong>Study initiation</strong></td>
<td>6.7 ± 2.2</td>
<td>6.3 ± 2.4</td>
</tr>
<tr>
<td><strong>End of treatment at Dead-Sea area</strong></td>
<td>4.4 ± 2.2 *</td>
<td>5.9 ± 2.2</td>
</tr>
<tr>
<td><strong>One month follow-up</strong></td>
<td>5.2 ± 2.5 **</td>
<td>5.9 ± 1.8</td>
</tr>
<tr>
<td><strong>Three months follow-up</strong></td>
<td>5.1 ± 2.7 *</td>
<td>6.1 ± 2.0</td>
</tr>
</tbody>
</table>

**VAS:** Visual Analog Scale (Scale 1-10)

* P < 0.05
** P < 0.01
### BASDAI Scores at The Four Assessments of All Patients

**ALL PATIENTS (28)**

<table>
<thead>
<tr>
<th>Time Point</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study initiation</td>
<td>5.48 ± 1.82</td>
</tr>
<tr>
<td>End of treatment</td>
<td>4.06 ± 1.87 (<em>) (</em>)</td>
</tr>
<tr>
<td>One month follow-up</td>
<td>4.75 ± 1.55</td>
</tr>
<tr>
<td>Three months follow-up</td>
<td>4.81 ± 1.78</td>
</tr>
</tbody>
</table>

* * P < 0.01 – in comparison to pretreatment value
Results of selected physical examination tests, regardless of treatment group (n=28). All values are in centimeters, Average ± SD

<table>
<thead>
<tr>
<th>Assessment period</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wall-occiput distance</td>
<td>10.5 ± 8.7</td>
<td>10.2 ± 8.7</td>
<td>10.5 ±8.8</td>
<td>11.1 ± 9</td>
<td>0.78</td>
</tr>
<tr>
<td>Chest expansion</td>
<td>3.5 ± 4.7</td>
<td>3.3 ± 1.5</td>
<td>3.3 ± 1.2</td>
<td>3.6 ± 2.4</td>
<td>0.97</td>
</tr>
<tr>
<td>Finger 3-floor distance</td>
<td>35.2 ± 11.4</td>
<td>31.5±11.5</td>
<td>34 ± 13.5</td>
<td>33.8 ±12.3</td>
<td>0.21</td>
</tr>
<tr>
<td>Schober test</td>
<td>2.0 ± 1.3</td>
<td>3.1 ± 2.4</td>
<td>2.6 ± 1.2</td>
<td>2.4 ± 1.3</td>
<td>0.014</td>
</tr>
</tbody>
</table>

Assessment 1 was performed immediately before leaving for the Dead-Sea area, Assessment 2 was performed immediately before leaving the Dead-Sea area, Assessment 3 and 4 were performed one and three months after completion of therapy, respectively.
Results of the SF-36 questionnaire. Values are on a scale between 0 and 100, higher score represent better health. Average ± SD.

<table>
<thead>
<tr>
<th></th>
<th>Balneotherapy group n=14</th>
<th>Climatic group n=14</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>before</td>
<td>after</td>
</tr>
<tr>
<td>Limitations in physical activities</td>
<td>33.6 ± 23.7</td>
<td>46.4 ± 25.3</td>
</tr>
<tr>
<td>Limitation in everyday activities</td>
<td>26.8 ± 31.7</td>
<td>33.9 ± 28.8</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>27.9 ± 19.3</td>
<td>42.1 ± 18.6 *</td>
</tr>
<tr>
<td>General health perception</td>
<td>18.2 ± 22.2</td>
<td>16.1 ± 15.6</td>
</tr>
<tr>
<td>Levels of psychological stress and anxiety</td>
<td>47.6 ± 38.6</td>
<td>54.8 ± 31.0</td>
</tr>
<tr>
<td>Limitations in social activities</td>
<td>34.8 ± 24.1</td>
<td>40.2 ± 18.5</td>
</tr>
<tr>
<td>Emotional role</td>
<td>55.1 ± 21.9</td>
<td>50.6 ± 20.6</td>
</tr>
<tr>
<td>Energy levels and fatigue</td>
<td>37.1 ± 15.2</td>
<td>43.4 ± 21.9</td>
</tr>
</tbody>
</table>

* p=0.03 compared with value before treatment
Summary

- Significant improvement (p<0.05) in BASDAI lasting one month was observed only in the climatic group.
- The addition of balneotherapy did not show any beneficial effects (except for pain).
- SF-36 questionnaire – no significant improvement in both groups.
Previous Studies

Tishler et al, Clin Rheumatol 1995; 14:21

Uncontrolled Pilot Study
14 pts treated with
- Hot spring water
- Mud packs

Duration: 2 weeks
Results:

Significant Improvement:
- Morning stiffness
- Finger to floor distance
- Overall well-being
- Reduction in use of NSAID’s

Improvement began after one week
last – three months
Previous Studies (2)
Hashkes P. – Scand J Rheumatol 2002; 31:172

Duration – 4 weeks
53 pts
Mode of therapy-climatotherapy + different modalities of balneotherapy + physiotherapy
Uncontrolled
No follow-up examinations
Results:

60% (32/53) – Responders

Responders:
At least 20% improvement in 3 of the following 4 criteria:

- Morning stiffness
- Pain intensity
- Patient global assessment
- Bath as functional index

A. S. males responded more often than females
Previous Studies (3)

Tubergen et al – Arthritis Care and Research 2001; 45:430
Tubergen et al – Arthritis Rheum 2002; 47:459

120 pts – randomized, prospective controlled Study

<table>
<thead>
<tr>
<th>Group</th>
<th>Number of Patients</th>
<th>Intervention</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>40 pts</td>
<td>3 weeks-SPA therapy</td>
<td>At Bad Hofgastein, Austria</td>
</tr>
<tr>
<td>Group 2</td>
<td>40 pts</td>
<td>3 weeks-SPA therapy</td>
<td>At Thermalbad, Arcen, Netherlands</td>
</tr>
<tr>
<td>Group 3</td>
<td>40 pts (control)</td>
<td>Standard treatment at home</td>
<td></td>
</tr>
</tbody>
</table>

After intervention weeks
All patients - weekly group physical therapy for 40 weeks
Results:

- Combined SPA – exercise therapy (group 1,2) is superior to standard therapy (group 3)

- Beneficial effects at least 40 weeks

- Favorable cost – effectiveness and cost – utility ratios
Thanks
Thank You!