Does systemic administration of parathyroid hormone after non-instrumented spinal fusion surgery improve fusion rates and fusion mass in elderly patients compared to placebo in patients with degenerative lumbar spondylolisthesis?

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Few studies have investigated the effects of parathyroid hormone (PTH) therapy on fusion in patients undergoing spinal arthrodesis.

Early studies showed a more robust fusion mass with PTH after spinal fusion surgery.

But the efficiency of PTH on non-instrumented posterolateral spinal fusion surgery remains unclear.
Parathyroid hormone therapy

Teripartide: A potential solution?

Could PTH have a positive impact on outcomes of non-instrumented arthrodesis?
A prospective, randomized, double-blind and placebo-controlled clinical trial

Comparing PTH to placebo (saline)

A single center study conducted in accordance with the CONSORT guidelines.
Intervention

The patients injected themselves once a day in 3 months.

20 µg Teriparatide
or
Placebo (identical pen injection devices with saline).

On the day before surgery the patients were instructed by a research nurse in proper injection techniques.
Timeline and data collection

The patients were randomized, by a pharmacist, in blocks of 10 to spinal decompression and posterolateral fusion surgery, with or without subsequent treatment with PTH in a 1:1 fashion.

Enrolment, surgery and follow-up were completed between May 2013 and April 2017.
Assessment of fusion

The fusion status was evaluated from the CT scans performed at 12 months follow up.

- Fusion quality: Area \( \text{Houndsfield, HU} \)
- Fusion volume
- Fusion classification: “A reversed Glassmann”
Figure 1 CONSORT Flow diagram showing the flow of participants through each stage of the study

446 Patients assessed for eligibility

Excluded (n=345)
- Not meeting inclusion criteria (n=159)
  - Declined to participate (n=46)
  - Other reasons (n=110)
  - Pen no. 101 date expired (n=89)

Randomized (n=101)

Allocation

Allocated to the PTH group (n=50)
- Did not complete intervention
  - Surgery cancelled (n=2), Cerebral insult (n=1), Anesthetic nausea (n=1)

Allocated to the control group (n=51)
- Did not receive complete intervention
  - Anesthetic nausea (n=1), Re-operated (n=1)

Follow-Up

5 were lost to follow-up (n=45)
- (Mors caused by traffic accident n=1, Re-operated n=1)

Lost to follow-up (n=49)
- (Transport complications n=1, Re-operated n=1)

Analysis

Analysed (n=43)
- Discontinued the intervention (Risk of elevated level of blood calcium) (n=2)

Analysed (n=47)
- Discontinued (Risk of elevated level of blood calcium) (n=1)

12 months

Complete to analysis (n=41)

Complete to analysis (n=46)
# Study population

## Overall patients characteristics

<table>
<thead>
<tr>
<th></th>
<th>PTH</th>
<th>Placebo</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of patients</td>
<td>41</td>
<td>46</td>
<td>0.582</td>
</tr>
<tr>
<td>Male, N (%)</td>
<td>11 (27)</td>
<td>7 (15)</td>
<td>0.182</td>
</tr>
<tr>
<td>Age, Mean (SD)</td>
<td>71 (1.01)</td>
<td>70 (0.88)</td>
<td>0.452</td>
</tr>
<tr>
<td>Body Mass Index, kg/m², Mean (SD)</td>
<td>27.48 (4.18)</td>
<td>26.56 (3.06)</td>
<td>0.242</td>
</tr>
<tr>
<td>Former Smokers, N (%)</td>
<td>1 (2.3%)</td>
<td>2 (4.3%)</td>
<td>1.000</td>
</tr>
</tbody>
</table>
# Fusion - quality and volume

<table>
<thead>
<tr>
<th>Fusion materials quality and volume</th>
<th>PTH group</th>
<th>Control group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>41</td>
<td>46</td>
<td>0.582</td>
</tr>
<tr>
<td>Total number of surgical levels, N</td>
<td>47</td>
<td>52</td>
<td>0.832</td>
</tr>
<tr>
<td>One level</td>
<td>35 (85)</td>
<td>40 (87)</td>
<td>0.830</td>
</tr>
<tr>
<td>Two levels</td>
<td>6 (15)</td>
<td>6 (13)</td>
<td>1.000</td>
</tr>
<tr>
<td>Fusion mass (areal x HU) per level, mm², Mean (SD)</td>
<td>16350.3 (10836.10)</td>
<td>17538.9 (15980.18)</td>
<td>0.689</td>
</tr>
<tr>
<td>Mean volume of the fusion materials per level, mm³, Mean (SD)</td>
<td>44.89 (30.96)</td>
<td>43.07 (28.89)</td>
<td>0.777</td>
</tr>
</tbody>
</table>
## Fusion - classification

### Fusion rates grading

<table>
<thead>
<tr>
<th>Grade</th>
<th>PTH group</th>
<th>Control group</th>
<th>Fused: Yes or No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Solid bilateral fusion, N (%)</td>
<td>2 (4.9)</td>
<td>10 (21.7)</td>
<td>Yes</td>
</tr>
<tr>
<td>2 Solid unilateral fusion, N (%)</td>
<td>10 (24.4)</td>
<td>7 (15.2)</td>
<td>Yes</td>
</tr>
<tr>
<td>3 Partial bilateral fusion, N (%)</td>
<td>11 (26.1)</td>
<td>8 (17.4)</td>
<td>No</td>
</tr>
<tr>
<td>4 Partial unilateral fusion, N (%)</td>
<td>9 (22)</td>
<td>12 (26.1)</td>
<td>No</td>
</tr>
<tr>
<td>5 No fusion N (%)</td>
<td>9 (22)</td>
<td>9 (19.6)</td>
<td>No</td>
</tr>
</tbody>
</table>

P-value = 0.165
Conclusions

PTH treatment was well tolerated but did not provide additional benefits regarding clinical outcome or in achieving a solid fusion after surgical arthrodesis, compared with placebo at 12 months.

Disclosures:
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