A Prospective Study Evaluating Intra-Articular Hyaluronic Acid (1ml) for Ankle Osteoarthritis

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Study performed at the department of Orthopaedics, University of British Columbia
Disclosure

I, Alastair Younger declare that in the past 3 years:

I have received support from the following companies:
Zimmer, Bioventus, Cartiva, Acumed, Wright medical, Synthes, Ferring.

I have done consulting work for the following companies:
Zimmer, Ferring, Acumed, Wright medical

I have done speaking engagements for the following companies:
Zimmer, Acumed, Wright Medical

I hold individual shares in the following:
Cambie Surgery Centre, Specialist Referral Clinic, Footbridge Centre for Integrated Foot Care
Introduction

• Ankle osteoarthritis can cause disabling symptoms and some patients favor non operative treatment.
• Surgery is performed once non operative treatment has failed
• Patients may require relief of symptoms while awaiting surgery particularly in the working age group
• We assessed Durolane® (NASHA non-animal hyaluronic acid) for treatment of ankle osteoarthritis.
Methods

• Single arm prospective study
• Powered for 29 patients
• Follow up 6, 12, 18, 26 weeks
• Injection +/- imaging
• Outcome = VAS and AOS
• Adverse events recorded
• Use of rescue medication
• Statistics – 95% confidence intervals

• Inclusion criteria:
  • Modified Kellgren Lawrence 2 or 3
  • Isolated ankle arthritis
  • Able to come off all medication
  • 19 to 85 years of age
  • BMI < 35
  • No surgery on the index ankle within 12 months
Results

• 37 enrolled
• Two lost to follow up – one dropped out due to pain
• The primary end point was met with a least square reduction of pain by 40% from baseline
• The greatest improvement was seen at 12 weeks
• Rescue medication was used most at 6 weeks
• Adverse events were usually minor and not related to the study device
• 6 patients had injection site pain or joint pain
• One patient withdrew from the study as a result of injection site pain
Patient demographics and baseline characteristics (full analysis set, N=37).
SD, standard deviation

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean (SD) or n (%)</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>60.9 (11.7)</td>
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<tr>
<td>Male gender</td>
<td>21 (56.8%)</td>
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<tr>
<td>Body weight (kg)</td>
<td>81.3 (16.6)</td>
</tr>
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<td>Body mass index (kg/m²)</td>
<td>27.3 (4.1)</td>
</tr>
<tr>
<td>Ankle OA VAS pain score: study ankle</td>
<td>50.1 (14.5)</td>
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<td>Kellgren-Lawrence radiographic grade</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>5 (13.5%)</td>
</tr>
<tr>
<td>III</td>
<td>32 (86.5%)</td>
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</table>
Results - AOS

Ankle OA VAS pain score (mean ± SD)

- Baseline: 50.1 ± 14.5
- Week 6: 29.7 ± 18.1
- Week 12: 24.4 ± 18.4
- Week 18: 30.5 ± 20.1
- Week 26: 32.3 ± 19.9

Percentage change from baseline in ankle OA VAS pain score (mean ± SD)

- Week 6: -39.8 ± 33.0
- Week 12: -49.7 ± 35.4
- Week 18: -37.0 ± 39.4
- Week 26: 34.1 ± 37.7
Summary

• In conclusion, this prospective, cohort study shows promise for viscosupplementation with NASHA in the treatment of ankle OA. A single injection provided symptomatic relief for up to 26 weeks and although one patient reported pain and withdrew from the study, the procedure was well tolerated. We would support further investigation of NASHA for the treatment of ankle OA and a randomized controlled trial would be merited.
References

[23]
References (cont)