Characteristics of studies

Characteristics of included studies

Porter 2015

| Methods | Location: The Canberra Hospital, Canberra  
Design: Randomized controlled trial  
Method of randomisation: Randomization was performed using a single toss of a coin  
Assessor blinding: No blinding  
Study period: April 2009 to May 2010  
Follow-up: 2 years  
Intention-to-treat: There were no outliers in either group |
| --- | --- |
| Participants | There were 21 patients in the LARS group, 11 male and 10 female, mean age 26.1 years (range 16 – 43). There were 20 patients in the MBG group, 10 male and 10 female, mean age 24.0 years (range 16 – 41).  
Inclusion criteria:  
(1) Chronic instability (> 3 months) of ATFL and CFL  
(2) Medically fit  
(3) Physically active  
(4) Failed non-operative treatment  
(5) Skeletally mature  
(6) Signed, informed consent  
Exclusion criteria:  
(1) Previous ankle surgery  
(2) MBG contra-indicated  
(3) Ankle fracture  
(4) Diastasis  
(5) MCL laxity  
(6) >90 kg body mass  
Loss to follow-up: No patients lost. |
| Interventions | MBG procedure: Anatomic repairment of the lateral ankle ligaments with three double-bodied suture anchors  
LARS procedure: Anatomic reconstruction of the lateral ankle ligaments with LARS AC 30 DB synthetic ligament  
Both groups underwent the same post-operative rehabilitation programme.  
Assigned: 20/21  
Analysed: 20/21 |
| Outcomes | (1) The foot and ankle outcome score (FAOS)  
(2) Complications: Irritation of the peroneal tendons, wound complications, pseudoaneurysm |
| Notes |  |

Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Randomization was performed using a single toss of a coin</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Single toss of coin used, but further concealment protection not mentioned</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias)</td>
<td>High risk</td>
<td>Blinding was not possible, LARS procedure required two additional incision</td>
</tr>
<tr>
<td>Bias</td>
<td>Risk</td>
<td>Details</td>
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<tr>
<td>Blinding of outcome assessment (detection bias)</td>
<td>High</td>
<td>Blinding was not possible, LARS procedure required two additional incision</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low</td>
<td>There was no loss to follow-up</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>High</td>
<td>Additional outcome measure used but not described in the method section</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear</td>
<td>There was insufficient information to judge the risk from other sources of bias</td>
</tr>
</tbody>
</table>

Footnotes