OBJECTIVE: To evaluate the effectiveness of treatment with collar or physiotherapy compared with a wait-and-see policy in recent onset cervical radiculopathy.

DESIGN: Randomised controlled trial. SETTING: Neurology outpatient clinics in 3 Dutch hospitals. PARTICIPANTS: 205 patients with symptoms and signs of cervical radiculopathy of less than 1 month's duration. INTERVENTIONS: Treatment with a semi-hard collar and taking rest for 3 to 6 weeks; 12 twice-weekly sessions of physiotherapy and home exercises for 6 weeks; or continuation of daily activities as much as possible without specific treatment (control group). MAIN OUTCOME MEASURES: Time course of changes in pain scores for arm and neck pain on a 100-mm visual analogue scale and in the neck disability index during the first 6 weeks. RESULTS: In the wait-and-see group, arm pain diminished by 3 mm/week on the visual analogue scale (beta=-3.1 mm, 95% confidence interval [CI], -4.0 to -2.2 mm) and by 19 mm in total over 6 weeks. Patients who were treated with cervical collar or physiotherapy achieved additional pain reduction (collar: beta=-1.9 mm, 95% CI, -3.3 to -0.5 mm; physiotherapy: beta=-1.9, 95% CI, -3.3 to -0.8), resulting in an extra pain reduction.
compared with the control group of 12 mm after 6 weeks. In the wait-and-see group, neck pain did not decrease significantly in the first 6 weeks (beta=-0.9 mm, 95% CI, -2.0 to 0.3). Treatment with the collar resulted in a weekly reduction on the visual analogue scale of 2.8 mm (95% CI, -4.2 to -1.3), amounting to 17 mm in 6 weeks, whereas physiotherapy gave a weekly reduction of 2.4 mm (95% CI, -3.9 to -0.8) resulting in a decrease of 14 mm after 6 weeks. Compared with a wait-and-see policy, the neck disability index showed a significant change with the use of the collar and rest (beta=-0.9 mm, 95% CI, -1.6 to -0.1) and a nonsignificant effect with physiotherapy and home exercises.

CONCLUSION: A semi-hard cervical collar and rest for 3 to 6 weeks or physiotherapy accompanied by home exercises for 6 weeks reduced neck and arm pain substantially compared with a wait-and-see policy in the early phase of cervical radiculopathy. Trial registration Clinical trials NCT00129714.

SECTION 2: CRITICAL APPRAISAL OF VALIDITY

1. Number of patients starting each arm of the study?
   68 in the collar group, 70 in the physical therapy (PT) group, 66 in the control group.

2. Main characteristics of study patients (inclusions, exclusions, demographics, settings, etc.)?
   Acute (<1 month) cervical radiculopathy, age 18-75 years, arm pain with radiation distal to elbow, plus at least 1 neurologic finding (symptoms worse with neck movement, decreased deep tendon reflexes, sensory changes, muscle weakness)

3. Intervention(s) being investigated?
   Cervical collar vs PT vs placebo.

4. Comparison treatment(s), placebo, or nothing?
   Placebo

5. Length of follow-up?
   6 months

6. What outcome measures are used? List all that assess effectiveness.
   Neck pain, arm pain (visual analog scale [VAS]), disability (100-point scale).

7. What is the effect of the intervention(s)?
   (Tables 2 and 3 of original article)

8. What are the adverse effects of intervention compared with no intervention?
   Would be more costly to do PT or use collar vs nothing, but generally interventions were tolerated well.

9. Study addresses an appropriate and clearly focused question - select one
   Well covered

10. Random allocation to comparison groups
    Well covered
<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>11. Concealed allocation to comparison groups</td>
<td>Well covered</td>
</tr>
<tr>
<td>12. Subjects and investigators kept “blind” to comparison group allocation</td>
<td>Not applicable; not a blinded study.</td>
</tr>
<tr>
<td>13. Comparison groups are similar at the start of the trial</td>
<td>Well covered</td>
</tr>
<tr>
<td>14. Were there any differences between the groups/arms of the study other than the intervention under investigation? If yes, please indicate whether the differences are a potential source of bias.</td>
<td>Well covered</td>
</tr>
<tr>
<td>15. Were all relevant outcomes measured in a standardized, valid, and reliable way?</td>
<td>Well covered</td>
</tr>
<tr>
<td>16. Are patient-oriented outcomes included? If yes, what are they?</td>
<td>Pain, disability</td>
</tr>
<tr>
<td>17. What percent dropped out, and were lost to follow up? Could this bias the results? How?</td>
<td>About 10% in each group were lost to follow-up.</td>
</tr>
<tr>
<td>18. Was there an intention-to-treat analysis? If not, could this bias the results? How?</td>
<td>Apparently not addressed</td>
</tr>
<tr>
<td>19. If a multi-site study, are results comparable for all sites?</td>
<td>N/A</td>
</tr>
<tr>
<td>20. Is the funding for the trial a potential source of bias? If yes, what measures were taken to insure scientific integrity?</td>
<td>N/A</td>
</tr>
<tr>
<td>21. To which patients might the findings apply? Include patients in the study and other patients to whom the findings may be generalized.</td>
<td>Those with cervical radiculopathy.</td>
</tr>
<tr>
<td>22. In what care settings might the findings apply, or not apply?</td>
<td>Primary care, neurology, ER.</td>
</tr>
</tbody>
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23. To which clinicians or policy makers might the findings be relevant? Primary care.

SECTION 3: REVIEW OF SECONDARY LITERATURE

1. DynaMed excerpts (Cites this study only)


3. Bottom line recommendation or summary of evidence from DynaMed (1-2 sentences) Cites this study, most of the rest of the discussion is about surgery.

4. UpToDate excerpts


6. Bottom line recommendation or summary of evidence from UpToDate (1-2 sentences) Recommends cervical collars or PT, but notes there are no RCTs to support this.

7. PEPID PCP excerpts

1. Initial treatment options comprise rest, cervical immobilization, anti-inflammatory drugs (nonsteroidal and steroidal), pain relievers (including muscle relaxants and antiepileptics), and physical therapy (strength of recommendation [SOR]: B, cohort studies)
   - As many as 60% of patients who fail initial treatments report long-term pain relief with epidural corticosteroid injections (SOR: C, case series)
   - Surgery to reduce nerve compression can improve pain and function, but has risks (SOR: B, 1 randomized, controlled trial [RCT] and cohort studies)
   - The natural course of cervical radiculopathy may be spontaneous resolution of symptoms within 5 years in 75% of cases (SOR: B, retrospective cohort studies)

Evidence Summary

1. FAST TRACK: As many as 60% of patients who fail initial treatments report long-term pain relief with epidural corticosteroid injections

2. Initial treatments for cervical radiculopathy encompass:
   - Rest
   - Cervical immobilization
   - NSAIDs
   - Analgesics (including muscle relaxants and antiepileptics)
   - Physical therapy

3. Because few RCTs of these treatment options have been conducted, recommendations are based primarily on cohort studies and clinical experience

4. Analgesia: Try anticonvulsants last
   - No clinical trials have been published that look specifically at rest, immobilization, or oral analgesics for cervical radiculopathy
     - A Cochrane review of studies of anticonvulsants for treating acute and chronic pain found none that focused on cervical radiculopathy
     - The review concluded that "surprisingly few trials show analgesic effectiveness of anticonvulsants," and "anticonvulsants should be withheld until other interventions have been tried."

5. Physical therapy seems to help
   - No RCTs of physical therapy for cervical radiculopathy have been reported
     - However, a case series of patients treated specifically for cervical radiculopathy found that 10 of 11 patients who underwent physical therapy (including manual therapy, cervical traction, and strengthening exercises) were improved - defined as a
A self-report of being “quite a bit better” at 6-month follow-up

However, the inclusion criteria of these studies weren’t limited to cervical radiculopathy, limiting the applicability of the results. The 3 RCTs showed no advantages (2 studies) or modest advantages (1 study) for cervical traction over placebo or standard physical therapy without traction. Each study defined improvement differently, but most patients in all groups showed improvement.

Epidural steroids appear effective

Epidural corticosteroid injections have demonstrated success in both retrospective and prospective studies. One case series of cortisone epidural injections reported 60% of patients (12 of 20) had good or excellent response at long-term follow-up (mean follow-up=21.2 months; range=2–45 months). Six of the 20 patients proceeded to surgery.

Another series of 32 patients who had failed conventional treatment showed a 62% response - defined as “good or excellent” pain relief - to epidural steroid injection at 14 days. At 6 months, 53% continued to report good or excellent pain relief. No significant side effects occurred. The 44% of patients who didn’t report success also didn’t report any further deterioration.

Surgery can relieve pain, but has risks

Laminectomy to reduce nerve compression may alleviate pain and improve function, but it has risks. Surgical procedures for cervical radiculomyelopathy have reported death rates of 0% to 1.8%; nonfatal complications occurred in 1% to 8% of patients.

A Cochrane review found only 1 RCT (N=81) that compared surgery with conservative treatment (physiotherapy and the cervical collar). Twenty patients crossed over to another treatment, including 3 surgical patients who improved before surgery and 11 who did postop physiotherapy. Patients were still analyzed by intention to treat, however.

The surgery group showed greater pain improvement at 3 months, as assessed by visual analogue scale (0-100), than the physiotherapy group (mean difference [MD]=−14; 95% confidence interval [CI], −27.84 to −0.16) and the cervical collar (MD=−21; 95% CI, −33.32 to −8.68). At 1 year, however, no difference was seen between surgery and physiotherapy (MD=−9; 95% CI, −23.39 to 5.39) or between surgery and the cervical collar (MD=−5; 95% CI, −18.84 to 8.84).

PEPID citation/access data


9. PEPID content updating

1. Do you recommend that PEPID get updated on this topic?
Yes, there is important evidence or recommendations that are missing.

If yes, which PEPID Topic, Title(s):
cervical radiculopathy

2. Is there an EBM Inquiry (HelpDesk Answers and Clinical Inquiries) as indicated by the EB icon that should be updated on the basis of the review?
Yes, there is important evidence or recommendations that are missing.

If yes, which Evidence Based Inquiry (HelpDesk Answer or Clinical Inquiry), Title(s):
Which treatments are effective for cervical radiculopathy?
11. Citations for other excerpts

12. Bottom line recommendation or summary of evidence from Other Sources (1-2 sentences)

Section 4: Conclusions

1. Validity: How well does the study minimize sources of internal bias and maximize internal validity? Give one number on a scale of 1 to 7 (1=extremely well; 4=neutral; 7=extremely poorly)

2. If 4.1 was coded as 4, 5, 6, or 7, please describe the potential bias and how it could affect the study results. Specifically, what is the likely direction in which potential sources of internal bias might affect the results?

3. Relevance: Are the results of this study generalizable to and relevant to the health care needs of patients cared for by "full scope" family physicians? Give one number on a scale of 1 to 7 (1=extremely well; 4=neutral; 7=extremely poorly)

4. If 4.3 was coded as 4, 5, 6, or 7, please provide an explanation.

5. Practice changing potential: If the findings of the study are both valid and relevant, does the practice that would be based on these findings represent a change from current practice? Give one number on a scale of 1 to 7 (1=definitely a change from current practice; 4=uncertain; 7=definitely not a change from current practice)

6. If 4.5 was coded as 1, 2, 3, or 4, please describe the potential new practice recommendation. Please be specific about what should be done, the target patient population and the expected benefit.

This seems to be standard practice, and this article provides the evidence for that practice.

I'm not sure what people are currently doing (are they following the recommendations from UTD, etc)?
7. Applicability to a Family Medical Care Setting:
Is the change in practice recommendation something that could be done in a medical care setting by a family physician (office, hospital, nursing home, etc), such as a prescribing a medication, vitamin or herbal remedy; performing or ordering a diagnostic test; performing or referring for a procedure; advising, educating or counseling a patient; or creating a system for implementing an intervention? Give one number on a scale of 1 to 7 (1=definitely could be done in a medical care setting; 4=uncertain; 7=definitely could not be done in a medical care setting)
8. If you coded 4.7 as a 4, 5, 6 or 7, please explain.

9. Immediacy of Implementation: Are there major barriers to immediate implementation? Would the cost or the potential for reimbursement prohibit implementation in most family medicine practices? Are there regulatory issues that prohibit implementation? Is the service, device, drug or other essentials available on the market? Give one number on a scale of 1 to 7 (1=definitely could be immediately applied; 4=uncertain; 7=definitely could not be immediately applied)
10. If you coded 4.9 as 4, 5, 6, or 7, please explain why.

11. Clinical meaningful outcomes or patient-oriented outcomes: Are the outcomes measured in the study clinically meaningful or patient oriented? Give one number on a scale of 1 to 7 (1=definitely clinically meaningful or patient oriented; 4=uncertain; 7=definitely not clinically meaningful or patient oriented)
12. If you coded 4.11 as a 4, 5, 6, or 7 please explain why.

13. In your opinion, is this a Pending PURL? Give one number on a scale of 1 to 7 (1=definitely a Pending PURL; 4=uncertain; 7=definitely not a Pending PURL)
Criteria for a Pending PURL:
- Valid: Strong internal scientific validity; the findings appears to be true.
- Relevant: Relevant to the practice of family medicine
- Practice changing: There is a specific identifiable new practice recommendation that is applicable to what family physicians do in medical care settings and seems different than current practice.
- Applicability in medical setting:
- Immediacy of implementation

I think we need to do a poll of some kind to determine current practice and practice-changing potential.

SECTION 5: EDITORIAL DECISIONS
1. FPIN PURLs editorial decision (select one) Pending PURL Review—Schedule for Review
2. Follow up issues for Pending PURL Reviewer
3. FPIN PURLS Editor making decision Kate Rowland
4. Date of decision
5. Brief summary of decision