

Bartels R, Verhagen W, et al. Prospective Randomized Controlled Study Comparing Simple Decompression versus Anterior Subcutaneous Transposition for Idiopathic Neuropathy of the Ulnar Nerve at the Elbow: Part I. Neurosurgery 2005;56:522-530.

Design: Randomized clinical trial

Population/sample size/setting:

- 152 patients (94 men, 58 women, mean age 47) undergoing surgery for ulnar neuropathy at the elbow in the Netherlands
- Inclusion criteria included signs and symptoms (sensory disturbance in ulnar aspect of hand and/or weakness of ulnar muscles) for at least 3 months, with EMG abnormalities of motor nerve conduction velocity and compound action potential amplitude
- Exclusion criteria included previous surgery on symptomatic side, trauma of the elbow, neurologic symptoms in the arm because of other causes (e.g., stroke), or involvement of opposite arm

Main outcome measures:

- Randomized to simple decompression (n=75) or ulnar nerve anterior subcutaneous transposition (n=77)
- Mean duration of simple decompression was 13.7 minutes; for transposition mean duration was 31.3 minutes
- After surgery, both groups had a gradual improvement
- Success was defined as either complete resolution of symptoms, or as sometimes having tingling and/or elbow pain
- Success at 1 year was reported in 49/73 (67%) of simple decompression patients and in 54/74 (73%) of anterior transposition patients: a non-significant difference in outcome
- SF-36 and the Dutch version of the McGill Pain Questionnaire were administered and both scores improved over time, with no differences between groups (data not shown)
- 18 failures were reported, defined as worsening of paresthesias or weakness; 8 failures were in decompression group and 10 in transposition group; 13 underwent reoperation (6 in decompression and 7 in transposition group)
- Complications were reported less frequently in the simple decompression group (7 in the decompression and 23 in the transposition group); most common complication was loss of sensation around scar (2 in decompression and 14 in transposition group)

Authors' conclusions:

- Surgery for entrapment ulnar neuropathy at the elbow can be highly effective
- Simple decompression is as successful as anterior transposition, but has fewer complications and shorter operative time
- Simple decompression is favored over the more complex procedure

Comments:

- As the authors concede, the follow-up examination was done by the surgeon who did the surgical procedure and the pre-operative examination
- Randomization done by a computer-generated list, but this is not clearly concealed prior to patient enrollment
- The methods section reports that an independent blinded neurologist evaluated a random sample of 30 patients during follow-up, but the findings of that neurologist are not reported and the bias from non-blinding cannot be excluded
- The text reports that success was reported in 49 of 75 decompression and 54 of 77 transposition patients; however, because of loss to follow-up (Figure 1 and Table 4), the correct denominators are 73 and 74 patients respectively
- It is true that the SF-36 and McGill Pain Questionnaire scores, completed prior to the follow-up visits, are not biased by lack of blinding, but the scores are not reported
- Follow-up is nearly complete, and the flow diagram in Figure 1 is clear, with appropriate power calculations and good descriptions of inclusion and exclusion criteria
- Loss of sensation around the scar was more frequent in the transposition group, but the extent of the sensory loss and its functional consequences are not reported

Assessment: Inadequate to support conclusions about the comparative effectiveness of the two operations (concealment of allocation not clear, blinded subgroup of patient examinations not reported)