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Systematic review of randomized clinical trials of surgical treatment for carpal tunnel syndrome

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Background: Carpal tunnel syndrome (CTS) is a common disorder for which several surgical treatment options are available. However, there is no consensus on the most effective method of treatment. The object of this systematic review is to compare the efficacy of the various surgical techniques in relieving the symptoms of CTS and promoting return to work and/or activities of daily living.

Methods: Computer-aided searches of Medline, EMBASE and the Cochrane Controlled Trials Register were conducted, together with reference checking. A rating system, based on the number of studies and their methodological quality and findings, was used to determine the strength of the available evidence for the efficacy of the treatment.

Results: Fourteen studies were included in the review. None of the alternatives to standard open carpal tunnel release (OCTR) seems to offer better relief of symptoms. There is conflicting evidence about whether endoscopic carpal tunnel release results in earlier return to work and/or activities of daily living.

Conclusion: Standard OCTR is still the preferred method of treatment for CTS. It is just as effective as the alternatives, but is technically less demanding, so incurs a lower risk of complications and of added costs.

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Introduction

Carpal tunnel syndrome (CTS) is caused by compression of the median nerve at the wrist which results in symptoms of pain, paraesthesia and hypoaesthesia in the hand. Conservative and surgical options are available to treat the condition. Surgery consists of dividing the transverse carpal ligament, thereby increasing the tunnel volume^{1,2} and reducing the pressure on the nerve³. In Denmark, the estimated cumulative incidence of operations for CTS is 0.61 per 1000 per year⁴. Various surgical techniques are available, however, there has been considerable discussion about which method is the most effective.

Until recently, open carpal tunnel release (OCTR) with a long palmar curvilinear incision was the standard procedure⁵. In addition to the transverse carpal ligament, the overlying structures from the skin to the median nerve are divided. Sometimes an epineurotomy is performed, parti-

cularly if the nerve sheath (epineurium) is thickened⁶. If there is scar tissue within the nerve, an internal neurolysis may be carried out to separate the involved fascicles from this fibrosis⁷. Endoscopic carpal tunnel release (ECTR) is a relatively new procedure. Its putative advantage is that, by dividing the transverse carpal ligament from within the carpal tunnel, the overlying structures are left intact. This may decrease postoperative morbidity and could potentially hasten return to work. Two techniques are commonly used for ECTR, the single-portal technique described by Agee *et al.*^{8,9} and the two-portal technique described by Chow^{10,11}. Since the introduction of ECTR various types of new incisions have been introduced for OCTR to try to reduce surgical trauma and hence recovery time¹².

The object of this systematic review is to compare the short- and long-term efficacy of the various surgical treatment options for relieving CTS symptoms and promoting return to work and/or activities of daily living.

Methods

Search and selection of studies

To identify publications, a search was made in Medline (January 1966 to March 2000), EMBASE (January 1988 to February 2000) and the Cochrane Controlled Trials Register (2000, issue 1), together with reference checking. A generic search for randomized clinical trials (RCTs)¹³ was combined with a specific search for CTS (using the keywords carpal tunnel syndrome, carpal tunnel, carpal syndrome and tunnel syndrome). To be included, a study had to meet the following criteria: (1) the study population consisted of patients with CTS; (2) different surgical techniques were compared; (3) the study was designed as a RCT; and (4) the results were published as a full report, written in Dutch, English, French or German. Studies were selected by two reviewers (A.A.M.G., R.J.P.M.S.) independently and disagreements were discussed to reach a consensus.

Assessment of methodological quality

Two reviewers (A.A.M.G., B.M.J.U.) independently assessed the methodological quality of the included studies and disagreements were resolved at a consensus meeting. The criteria that were applied have been recommended for systematic reviews in the field of musculoskeletal disorders¹⁴. This list of criteria was adapted for CTS with regard to prognostic indicators (c) and outcome measures (h) (Table 1). Moreover, as the intervention was surgery, the criteria 'care provider blinded' and 'compliance acceptable' were omitted from the original list. The criterion 'patient blinded' was applied only in studies comparing OCTR and OCTR with an additional procedure, because with those techniques similar incisions were made. The list contains criteria referring to internal validity, external validity and statistical considerations. Criteria could be scored as positive ('yes'), negative ('no') or unclear ('don't know'). Studies with a negative score for 'adequate randomization' (b1) were excluded from further analysis. The quality score of the studies was based on the number of positive scores for internal validity.

Data extraction

Data from the articles were extracted independently by two reviewers (A.A.M.G., D.v.G.) and recorded on a standard form. Information was collected on participants (age, sex, duration of symptoms, clinically and/or electrophysiologically confirmed CTS, number of patients treated bilaterally, number of patients or hands randomized), interventions

Table 1 Criteria for the assessment of methodological quality of randomized clinical trials evaluating the efficacy of surgical treatment options for carpal tunnel syndrome*

Patient selection	
a	Were the eligibility criteria specified?
b	Treatment allocation:
1	Was a method of randomization applied?
2	Was the treatment allocation concealed?
c	Were the groups similar at baseline with regard to the most important prognostic indicators?
Interventions	
d	1 Was the index intervention described explicitly?
	2 Was/were the control intervention(s) described explicitly?
e	Were co-interventions avoided or similar for all groups?
f	Was the patient blinded for the intervention?
Outcome measurement	
g	Was the outcome assessor blinded to the intervention?
h	Were the outcome measures relevant?
i	Were complications described?
j	Was the drop-out and loss to follow-up rate described and acceptable?
k	Timing follow-up measurements:
1	Was a short-term follow-up measurement performed?
2	Was a long-term follow-up measurement performed?
l	Was the timing of the outcome assessment similar for all groups?
Statistics	
m	Was the sample size described for each group?
n	Did the analysis include an intention-to-treat analysis?
o	Were point estimates and measures of variability presented for the primary outcome measures?

*All criteria were scored yes (+), no (−) or don't know (?). Criteria are related to internal validity (b1, b2, c, e, f, g, j, l, n), external validity (a, d1, d2, h, i, k1, k2) and statistics (m, o). Operation of the criteria is available from the authors on request

(surgical technique), outcome measures, timing of follow-up measurements, and results (point estimates and measures of variability, number of patients or hands). Although data on all reported outcomes were extracted, measures on symptoms (e.g. pain, percentage of patients with improved symptoms) were considered as primary outcomes, because these are of the greatest importance to patients^{15,16}. Also, time to return to work and/or activities of daily living was considered as the primary outcome measure, because this indicates how quickly the patient recovered. Information on complications was also recorded.

Statistical analysis

The quantitative analysis (meta-analysis) was limited to studies that were clinically homogeneous, i.e. for which the participants, interventions, outcome measures and timing of follow-up measurements were considered to be similar. Study results were combined using a fixed-effects model, or a random-effects model if the studies were statistically

Table 2 Methodological quality of randomized clinical trials evaluating the efficacy of surgical treatment options for carpal tunnel syndrome

		Internal validity								External validity						Statistics		Conclusion†					
Reference	Technique index intervention	b1	b2	c	e	f	g	j	l	n	score*	a	d1	d2	h	i	k1	k2	m	o	Symptoms ≤ 3 months	Symptoms > 3 months	Return to work or ADL
ECTR <i>versus</i> OCTR																							
Brown <i>et al.</i> ²⁷	Chow: extrabursal	+	–	+	+	+	+	+	+	+	7	+	+	+	+	+	+	–	–	+	Neutral		Positive
Benedetti and Sennwald ¹⁸ , Sennwald and Benedetti ¹⁹	Agee	+	+	+	+	?	+	+	–		6	+	+	+	+	+	+	–	+	+			Positive
Jacobsen and Rahme ²⁸	Chow: transbursal	?	?	+	+	–	+	+	+		5	+	+	+	+	+	+	+	+	+			Neutral
Erdmann ²⁹	Chow: extrabursal	+	?	+	?	?	?	+	+		4	+	+	+	+	+	+	+	–	–	Neutral	Neutral	Positive
Hoefnagels <i>et al.</i> ³⁰	Agee	?	?	+	+	?	+	+	–		4	–	+	+	+	+	+	–	+	+	Neutral		Neutral
Stark and Engkvist-Löfmark ³¹	Agee	?	?	?	+	?	+	+	+		4	–	+	+	+	+	+	+	+	–			Positive
Foucher <i>et al.</i> ³²	Agee	?	?	?	?	?	?	+	?		1	–	+	+	+	+	+	+	–	–			Neutral
OCTR: new <i>versus</i> standard incision																							
Nakamichi and Tachibana ³³	Short + US	+	?	?	+	+	+	+	+		6	+	+	+	+	+	+	+	–	+	Neutral	Neutral	
Brüser <i>et al.</i> ²⁰ , Richter and Brüser ²¹	Short incision	+	?	+	–	?	+	+	+		5	+	+	+	+	–	+	–	+	–	Neutral		Neutral
Citron and Bendali ³⁴	Ulnar L incision	?	?	+	?	?	+	+	+		4	–	+	+	+	+	+	+	+	–		Neutral	
OCTR with or without internal neurolysis																							
Mackinnon <i>et al.</i> ³⁵		+	+	+	+	+	+	+	+	?	8	+	+	+	+	–	–	+	+	+		Neutral	
Lowry and Follender ³⁶		+	?	?	+	+	+	+	+	–	6	+	+	+	+	+	+	–	+	+	Neutral		
Holmgren <i>et al.</i> ^{22,23}		?	?	?	+	?	?	+	+	+	4	+	+	+	+	–	–	+	–	–	Neutral	Neutral	
Open carpal tunnel release with or without epineurotomy																							
Leinberry <i>et al.</i> ³⁷		+	?	+	+	?	+	+	+	+	7	+	+	+	+	–	–	+	+	–		Neutral	

All criteria were scored yes (+), no (–) or don't know (?). Criterion f (patient blinded) was applied only when similar incisions were used. *Number of internal validity criteria scored positive. †Positive conclusion: index intervention significantly ($P < 0.05$) more effective than the control intervention(s) in relieving symptoms of carpal tunnel syndrome (3 months or less and more than 3 months) or promoting return to work and/or activities of daily living (ADL); neutral conclusion: no significant difference between index intervention and control intervention(s); blank: no outcomes on symptoms or return to work and/or activities of daily living, or no short- or long-term follow-up measurement. ECTR, endoscopic carpal tunnel release; OCTR, open carpal tunnel release; US, ultrasonography

heterogeneous. For studies that were clinically heterogeneous or did not present the data in sufficient detail to enable statistical pooling, a qualitative analysis was performed. In such cases a rating system was used consisting of four levels of evidence based on the number of studies, their methodological quality and their findings¹⁷: level 1 – strong evidence, provided by generally consistent findings in multiple high-quality RCTs; level 2 – moderate evidence, provided by generally consistent findings in one high-quality RCT and one or more low-quality RCTs, or by generally consistent findings in multiple low-quality RCTs; level 3 – limited or conflicting evidence, with only one RCT (either high or low quality) or inconsistent findings in multiple RCTs respectively; level 4 – no evidence (no RCTs).

Conclusions with regard to the findings of the studies were based on the statistical significance ($P < 0.05$) of the results of the outcome measures on symptoms and return to

work and/or activities of daily living, as assessed by the reviewers. Both short-term (3 months or less) and long-term (more than 3 months) results for symptom improvement were taken into consideration. The conclusion of a RCT was considered to be positive if the index intervention was significantly more effective than the control intervention(s), neutral if there were no statistically significant differences, and negative if the index intervention was significantly less effective than the control intervention(s). If at least 75 per cent of the studies had a similar score (either positive, neutral or negative), the findings were considered to be consistent. A RCT was (arbitrarily) regarded to be of high quality if at least five of the eight (or nine if patient blinding was included) internal validity criteria were scored as positive. A sensitivity analysis was performed to examine the results when high quality was defined as a positive score of 4 or more, or 6 or more for internal validity. The influence of considering findings to be consistent if at least

67 per cent of the studies had a similar score was also examined.

Results

Search and selection of studies

Twenty-one publications met the inclusion criteria, 20 of which were found in Medline. Searching EMBASE resulted in the identification of one additional publication. Data from two studies were published twice (in German and in English), so the data from both sets of two papers were combined^{18–21}. The same was done for a trial in which the short- and long-term results were reported separately^{22,23}. Four studies were excluded from further analysis because the patients were not adequately randomized^{8,24–26}. Fourteen studies were finally included in the review.

Methodological quality

The two reviewers initially agreed on 90 per cent of the assessments of methodological quality. Disagreement, as a result of reading (65 per cent) and interpretation (35 per cent) errors, was resolved at the consensus meeting. *Table 2* shows the scores. The studies scored positive on one to eight of the eight (or nine) internal validity criteria. Eight of the 14 studies were of high quality. Many studies reported on randomized treatment allocation, but failed to describe the exact procedure (b1) or state whether the method of randomization was concealed (b2). Information on the blinding of the outcome assessor (g) was often not provided. Furthermore, many studies presented the data inadequately (o).

Efficacy of the surgical treatment options

Data from the trials were not pooled statistically because many studies did not present the outcomes in such a way that this pooling was possible (as reflected by the negative scores on criterion o shown in *Table 2*). Furthermore, the studies were clinically heterogeneous with regard to study population (different eligibility criteria), interventions (different surgical techniques), outcome measures (different symptoms measured, different definition of time to return to work) and timing of follow-up measurements. Therefore, all conclusions with regard to the efficacy of the surgical treatment options were based on the strength of the available evidence according to the predefined rating system. The conclusions of the studies with regard to symptoms (short- and long-term follow-up) and return to work and/or activities of daily living are shown in *Table 2*.

Table 3 presents the study characteristics (participants, interventions, results for symptoms and return to work and/or activities of daily living, complications).

Endoscopic versus open carpal tunnel release

Three high-quality^{18,19,27,28} and four low-quality^{29–32} studies were identified. Different types of ECTR were applied, but the results were combined because all the techniques divide the transverse carpal ligament from within the carpal tunnel and differ only in the way in which this is achieved. Three studies evaluated the short-term effects on symptoms (one of high quality²⁷ and two of low quality^{29,30}); all concluded that ECTR was equally effective as OCTR. With regard to the long-term results for symptoms, no differences between the groups were found in one low-quality study²⁹. Four studies^{18,19,27,29,31} concluded that patients returned to work and/or activities of daily living earlier after ECTR, while the other three studies^{28,30,32} found no difference. In summary, there is moderate evidence that in the short term (level 2), and limited evidence that in the long term (level 3), ECTR and OCTR provide similar degrees of symptom relief; there is conflicting evidence (level 3) that ECTR results in earlier return to work and/or activities of daily living.

Open carpal tunnel release: new versus standard incision

Two high-quality studies^{20,21,33} and one low-quality study³⁴ were found. Although the three studies used different types of new incision, they were considered to be more or less similar because the purpose of all these new types of incision is to provide an alternative to ECTR, by reducing postoperative morbidity (as with ECTR) while also releasing the transverse carpal ligament (partly) under direct vision (as in OCTR). The two high-quality studies^{20,21,33} concluded that there were no differences between the groups with regard to relief of symptoms in the short term (1.5–3 months). Long-term follow-up measurements (0.5–2 years) in one high-quality³³ and one low-quality³⁴ study also showed no differences between the groups in terms of symptom relief. Only one high-quality study^{20,21} examined the time to return to work, but no difference in effect between the two types of incision was found. There is, therefore, strong evidence that in the short term (level 1), and moderate evidence that in the long term (level 2), OCTR with a new type of incision is equally effective in relieving CTS symptoms as OCTR with a standard incision. Furthermore, there is limited evidence (level 3) that time to return to work is similar for both types of incision.

Table 3 Characteristics of randomized clinical trials evaluating the efficacy of surgical treatment options for carpal tunnel syndrome

Reference	Participants	Intervention	Results*			
			Symptoms ≤ 3 months	Symptoms > 3 months	Return to work or ADL	Complications
ECTR <i>versus</i> OCTR Brown <i>et al.</i> ²⁷	Mean age 56 years, 68% female, mean duration of symptoms 24 months; clinical and electrophysiological CTS; idiopathic CTS; 24 of 145 patients treated bilaterally	(1) ECTR: two-portal extrabursal Chow technique (<i>n</i> = 84 hands) (2) OCTR (<i>n</i> = 85 hands)	Improvement in symptoms (paraesthesia, numbness) in 99% (1) and 98% (2) after 12 weeks (difference 1% (95% c.i. -3 to 5%))	No data given	Median 14 (1) and 28 (2) days (significant difference between groups)	Significantly more scar tenderness in (2) <i>versus</i> (1) after 12 weeks (no significant difference after 3 and 6 weeks). No significant difference between groups in pillar tenderness at 3, 6 and 12 weeks; 1 partial transection of superficial palmar arch, 1 digital nerve contusion, 1 ulnar nerve neuroparaxia and 1 wound haematoma in (1)
Benedetti and Sennwald ¹⁸ , Sennwald and Benedetti ¹⁹	Mean age 53 years, 79% female, mean duration of symptoms 9 months; clinical and electrophysiological CTS; idiopathic CTS	(1) ECTR: one-portal Agee technique (<i>n</i> = 25 patients) (2) OCTR (<i>n</i> = 22 patients)	No data given	No data given	Mean 24 (1) and 42 (2) days (significant difference between groups)	1 conversion to OCTR and 1 transient neuroparaxia in (1); 1 painful hypertrophic scar and 1 reflex sympathetic dystrophy in (2)
Jacobsen and Rahme ²⁸	Mean age 46 years, 72% female, clinical and electrophysiological CTS; idiopathic CTS; 3 of 29 patients treated bilaterally	(1) ECTR: two-portal transbursal Chow technique (<i>n</i> = 16 hands) (2) OCTR (<i>n</i> = 16 hands)	No data given	No data given	Mean 17 (1) and 19 (2) days (no significant difference between groups)	3 transient numbness on radial side of ring finger in (1); 1 prolonged wound secretion in (2)
Erdmann ²⁹	Mean age 53 years, 73% female, mean duration of symptoms 24 months; clinical and electrophysiological CTS; not only idiopathic CTS; 34 of 71 patients treated bilaterally (25 patients 1 hand ECTR, 1 hand OCTR simultaneously)	(1) ECTR: two-portal extrabursal Chow technique (<i>n</i> = 53 hands) (2) OCTR (<i>n</i> = 52 hands)	Significantly more improvement in pain in (1) <i>versus</i> (2) after 1, 2 and 4 weeks, but no significant difference between groups after 3 months	No significant difference in pain between groups after 6 and 12 months	Mean 14 (1) and 39 (2) days (only patients not having simultaneous operation on both hands) (significant difference between groups)	1 ulnar nerve paraesthesia and 1 incomplete release in (1); 1 wound infection, 1 scar tethering and 5 scar hypertrophy in (2)

Table 3 (continued)

Reference	Participants	Intervention	Results*			
			Symptoms ≤ 3 months	Symptoms > 3 months	Return to work or ADL	Complications
Hoeftnagels <i>et al.</i> ³⁰	Mean age 51 years, 74% female, mean duration of symptoms 21 months; clinical and electrophysiological CTS	(1) ECTR: one-portal Agee technique (<i>n</i> = 87 patients) (2) OCTR (<i>n</i> = 91 patients)	76% free of tingling in both groups after 1 week, and no significant difference in symptom severity score between groups after 3 months	No data given	More than 4 weeks' absence from work in 16% (1) and 13% (2) (difference 3% (95% c.i. -7 to 14%))	Significantly less postoperative pain in (1) versus (2) after 1 week; 1 conversion to OCTR, 1 broken knife left in operation wound and 1 increased numbness in fingertips in (1)
Stark and Engkvist-Löfmark ³¹	Mean age 53 years, 55% female, mean duration of symptoms 29 months; 15 patients clinical and electrophysiological CTS, 5 patients only clinical CTS; idiopathic CTS; all patients (<i>n</i> = 20) treated bilaterally	(1) ECTR: one-portal Agee technique (<i>n</i> = 20 hands) (2) OCTR (<i>n</i> = 20 hands)	No data given	No data given	Mean 20 (1) versus 30 (2) days (significant difference between groups)	1 subcutaneous haematoma and 1 loss of strength and mobility in the wrist in (1); 2 loss of strength and 1 swollen/stiff fingers in (2)
Foucher <i>et al.</i> ³²	Only clinical CTS; 2 of 249 patients treated bilaterally	(1) ECTR: one-portal Agee technique (<i>n</i> = 54 hands) (2) OCTR (<i>n</i> = 69 hands) (3) OCTR with anterior ligamentoplasty type I (<i>n</i> = 59 hands) (4) OCTR with anterior ligamentoplasty type II (<i>n</i> = 69 hands)	No data given	No data given	No significant difference in time to return to work between groups (all 17 days)	1 algodystrophy and 2 conversions to OCTR in (1)
OCTR: new versus standard incision Nakamichi and Tachibana ³³	Mean age 58 years, 100% female; clinical and electrophysiological CTS; idiopathic CTS	(1) OCTR with short incision (1.0–1.5 cm) with ultrasonographic assistance (<i>n</i> = 50 patients) (2) OCTR (<i>n</i> = 53 patients)	No significant difference in symptoms (numbness and paraesthesia) between groups after 3, 6, 13 weeks	No significant difference in symptoms (numbness and paraesthesia) between groups after 6, 12, 24 months; 86% (1) and 89% (2) free of symptoms after 24 months (difference -3% (95% c.i. -16 to 10%))	No data given	Significantly more scar pain and tenderness in (2) versus (1) after 3, 6, 13 weeks; no other complications
Brüser <i>et al.</i> ²⁰ , Richter and Brüser ²¹	Mean age 54 years, 78% female, mean duration of symptoms 41 months; clinical and electrophysiological CTS; idiopathic CTS	(1) OCTR with short incision (2.5 cm) (<i>n</i> = 38 patients) (2) OCTR with long incision (4.5 cm) (sometimes with epineurotomy) (<i>n</i> = 42 patients)	No significant difference in night symptoms, tingling and numbness between groups after 1, 2, 3, 6 weeks	No data given	Median 21 (mean 17.6) versus 18 (18.8) days (no significant difference between groups)	No significant difference in scar tenderness and tenderness of radial and ulnar pillars after 1, 2, 3, 6 weeks

Table 3 (continued)

Reference	Participants	Intervention	Results*			
			Symptoms ≤ 3 months	Symptoms > 3 months	Return to work or ADL	Complications
Citron and Bendall ³⁴	Mean age 52 years, 83% female; only clinical CTS; not only idiopathic CTS	(1) OCTR with ulnar L incision (<i>n</i> = 23 patients) (2) OCTR with standard incision (<i>n</i> = 27 patients)	No data given	95% (1) and 88% (2) free of symptoms after 12 months (difference 7% (95% c.i. -9 to 22%))	No data given	No significant difference in pillar pain between groups. Significantly more recovery in scar sensitivity in (1) versus (2); 1 delayed wound healing in each group
OCTR with or without internal neurolysis						
Mackinnon <i>et al.</i> ³⁵	Mean age 59 years, 81% female; clinical CTS only; idiopathic CTS; 4 of 59 patients treated bilaterally	(1) OCTR with internal neurolysis (<i>n</i> = 29 patients/31 hands available for evaluation) (2) OCTR (<i>n</i> = 30 patients/32 hands)	No data given	Improvement in symptoms in 81% (1) and 88% (2) after 12 months (difference - 7% (95% c.i. -25 to 11%))	No data given	No data given
Lowry and Follender ³⁶	Clinical and electrophysiological CTS; severe CTS; 9 of 41 patients treated bilaterally	(1) OCTR with internal neurolysis (<i>n</i> = 25 hands) (2) OCTR (<i>n</i> = 25 hands)	Excellent or good clinical response (pain, sensory deficit, complications) according to neurologist in 67% (1) and 65% (2) after 3 months (difference 2% (95% c.i. -26 to 29%))	No data given	No data given	4 persistent incisional pain, 1 hand swelling and 1 adhesive capsulitis in (1); 3 persistent incisional pain and 1 causalgia in (2)
Holmgren <i>et al.</i> ^{22,23}	Mean age 50 years, 69% female; clinical and electrophysiological CTS	(1) OCTR with internal neurolysis (<i>n</i> = 24 patients?) (2) OCTR (<i>n</i> = 24 patients?)	No significant difference in pain, paraesthesia and hypoaesthesia between groups after 3-4 weeks	89% free of symptoms in both groups after 6 months and 86% (1) versus 75% (2) after 3-4 years (difference 11% (95% c.i. -15 to 36%))	No data given	No complications ascribable to internal neurolysis
OCTR with or without epineurotomy						
Leinberry <i>et al.</i> ³⁷	Mean age 65 years, 59% female, mean duration of symptoms 32 months; clinical and electrophysiological CTS; not only idiopathic CTS; 6 of 44 patients treated bilaterally	(1) OCTR with epineurotomy (<i>n</i> = 25 hands) (2) OCTR (<i>n</i> = 25 hands)	No data given	56% (1) and 60% (2) free of symptoms (pain, altered sensibility, paraesthesia, loss of manual dexterity) after 1 year (difference - 4% (95% c.i. -31 to 23%))	No data given	No data given

ADL, activities of daily living; c.i., confidence interval; CTS, carpal tunnel syndrome; ECTR, endoscopic carpal tunnel release; OCTR, open carpal tunnel release. **P* < 0.05 was considered significant

Open carpal tunnel release with or without internal neurolysis

Two high-quality studies^{35,36} and one low-quality study^{22,23} were included. One of the high-quality studies³⁶ examined the clinical response 3 months after operation and found no significant difference between the groups. The low-quality study^{22,23} also found no difference in improvement of symptoms between the groups in the short term (3–4 weeks). One high-quality³⁵ and one low-quality^{22,23} study also found equal relief from symptoms in both groups in the long term (6 months and 4 years, respectively). There is, therefore, moderate evidence (level 2) that division of the transverse carpal ligament with internal neurolysis does not improve short- or long-term symptom relief.

Open carpal tunnel release with or without epineurotomy

Only one high-quality study³⁷ was identified. The follow-up measurement after 1 year revealed no significant difference in improvement of symptoms between the groups, indicating limited evidence (level 3) that adjuvant epineurotomy offers no additional benefit in long-term symptom relief compared with OCTR alone.

Sensitivity analysis

Changing the cut-off point of the quality score to four or more, and to six or more positive criteria, resulted in 13 and six high-quality studies respectively (*Table 2*). If high quality is defined as at least six positive criteria, the level of evidence for ECTR resulting in earlier return to work and/or activities of daily living compared with OCTR will rise from conflicting evidence (level 3) to strong evidence (level 1). When consistent findings are defined as 67 per cent of the studies reporting the same conclusion instead of 75 per cent, the level of evidence for ECTR resulting in earlier return to work and/or activities of daily living compared with OCTR also rises from conflicting evidence (level 3) to strong evidence (level 1).

Complications

All studies comparing ECTR with OCTR reported complications. It seems that ECTR gives more transient nerve problems (e.g. neurapraxia, numbness, paraesthesia) and OCTR more wound problems (e.g. infection, hypertrophic scar, scar tenderness). In a few cases ECTR had to be abandoned and OCTR was performed instead. There seems to be no difference in pillar pain between OCTR with

a new or a standard incision; however, in two studies^{33,34} more scar pain and tenderness was found with the standard incision, although in the third study^{20,21} this was not confirmed. No conclusions can be drawn with regard to differences in complications between OCTR and OCTR with an additional procedure (internal neurolysis or epineurotomy). This is due to the fact that only one study reported complications³⁶, one merely stated that there were no complications ascribable to internal neurolysis^{22,23} and the two other studies provided no information on complications^{35,37}.

Discussion

Search and selection of studies

The search was restricted to Medline, EMBASE, the Cochrane Controlled Trials Register and trials published as a full paper, written in Dutch, English, French or German. Therefore, some studies might have been missed, which may have led to bias. Unpublished studies and studies that were presented only in abstract form are more likely to have non-significant results^{38,39}. Furthermore, trials with significant results are more likely to be published in English⁴⁰.

Methodological quality

There is no consensus on which criteria should be used to assess the methodological quality of RCTs. However, criteria that are regarded as being most important in reducing bias, concealment of allocation and double blinding are included in the list used for this review⁴¹. The other criteria in the list are generally accepted methodological criteria that are also included in most of the other available lists⁴². In fact, the focus was on the quality of the reporting. It is possible that a trial did meet a particular criterion, but that for the sake of conciseness this aspect was not described in detail in the publication. One drawback of combining information on different study characteristics into a sum-score for methodological quality is that a positive score on one criterion may compensate for a negative score on another. Therefore a sum-score could conceal methodological shortcomings and variation in methods between studies⁴³.

Efficacy analysis

Owing to relatively small study populations (half of the studies had 20 to 30 patients in each group) clinically relevant differences in outcomes between treatment options could remain undetected. Statistical pooling would have

increased the power, but it was decided not to pool the data and to perform a qualitative analysis, based on levels of evidence, instead. It is therefore possible that some smaller differences between treatment groups may have been missed. These were not statistically significant in the individual trials, but would have become statistically significant if the data had been pooled. Still, this does not seem likely on reviewing the data from the trials, because the differences that were not statistically significant were mostly so small that they were also not clinically relevant.

The strength of the evidence for the efficacy of an intervention is based partly on the methodological quality of the studies. The difference between high- and low-quality studies in this review was based on an arbitrarily chosen cut-off point, and varying this point leads to a different conclusion with regard to the efficacy, as was noted for ECTR resulting in earlier return to work and/or activities of daily living compared with OCTR. No consensus has yet been reached on how to assess the strength of the available evidence and so the levels of evidence used in this review are, to some extent, arbitrary. It was decided to apply this rating system because it has good face validity, is simple and explicit, and has already been applied in several reviews on the effectiveness of various treatment options for low back pain^{17,44}.

None of the alternatives to standard OCTR (i.e. ECTR, OCTR with a new type of incision, and OCTR with internal neurolysis or epineurotomy) seems to offer better relief from CTS symptoms in the short or long term. There is conflicting evidence for ECTR resulting in earlier return to work and/or activities of daily living than OCTR, but the evidence becomes strong when the assumptions for the rating system are changed slightly.

The American Academy of Neurology recommends OCTR for the surgical treatment of CTS, a guideline based on so-called 'moderate clinical certainty'⁴⁵. On the basis of the results of the present review, OCTR would also be recommended because the alternatives do not provide better relief from symptoms. The only possible advantages of ECTR would be fewer wound problems and earlier return to work and/or activities of daily living. Possible disadvantages are higher complication rates (nerve problems) and costs. Overall complication rates seem to be similar for OCTR and ECTR when reviewing the published studies⁴⁶. However, it should be noted that, although the complication rates may be similar, many difficult cases are immediately excluded from ECTR, for example patients needing an adjuvant procedure (e.g. synovectomy in the case of inflammatory arthritis) and patients with space-occupying lesions or with stiff (arthritic) wrists^{29,47}. A cost-effectiveness study concluded that the two techniques have similar total costs, but that ECTR is

more costly if the difference between the techniques in mean time to return to work is less than 21 days⁴⁸. Of the four studies included in this review that found a difference in time to return to work^{18,19,27,29,31}, only one reported a difference of more than 21 days²⁹.

Conclusion

Standard OCTR is still the preferred method of treatment for CTS because, while it is just as effective as the alternatives, it is technically less demanding and so incurs a lower risk of complications and added costs.

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