Dekompresija karpalnog tunela mikroinvazivnom ili klasičnom tehnikom: Randomizirana kontrolirana studija

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Journal article, Published version
Rad u časopisu, Objavljena verzija rada (izdavačev PDF)

Permanent link / Trajna poveznica: https://urn.nsk.hr/urn:nbn:hr:184:991147

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Download date / Datum preuzimanja: 2020-12-23

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Carpal Tunnel Release by Limited Palmar Incision vs Traditional Open Technique: Randomized Controlled Trial

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Aim. To compare a limited palmar incision for carpal tunnel release (CTR) with a traditional open technique, which is still considered the gold standard.

Methods. Seventy-two patients with a carpal tunnel syndrome were individually randomized into the trial (limited incision CTR) (n=36) and control group (traditional technique CTR) (n=36). In the trial group, skin incision parallel to the thenar crease was made up to 2.5 cm in length, under an operating microscope and endoscopic transillumination. Skin incision in the control group began at the distal border of the carpal ligament, followed the longitudinal crease of the palm, and crossed the base of the palm in a zigzag fashion. Three months after surgery, the patients were asked about symptomatic relief and intervals between the operation and return to their daily activities and work, and examined for scar tenderness and esthetic outcome. Distal motor latency, conduction velocity, scar length, scar width, and operation time were measured.

Results. There were no differences between the two groups in symptomatic relief and electrophysiological parameters. Intervals between the operation and return to daily activities (median 5 days, range 2-15) were shorter in the trial group than in the control group (median 10 days, range 2-21; p=0.001), as well as the intervals between the operation and return to work (median 15 days, range 5-45 vs median 30 days, range 10-60; p=0.001). Scar/pillar tenderness, scar length and width, esthetic outcome, and operation time were significantly better in the trial group.

Conclusion. Limited palmar incision CTR is as effective and safe as traditional CTR technique, but with better postoperative recovery and cosmetic results.

Key words: carpal tunnel syndrome; endoscopy; microsurgery; surgical procedures, minimally invasive

Carpal tunnel syndrome is the most common compressive neuropathy, and the median nerve decompression in the carpal region is the most frequent peripheral nerve surgery (1-3). Major textbooks of operative hand surgery, peripheral nerve surgery, and operative neurosurgical techniques recommend a traditional open-incision technique with longitudinal incision crossing the wrist flexion skin crease as highly effective approach in the treatment of carpal tunnel syndrome, with low percentage of complications (1-3). However, there are two main weaknesses of the traditional open carpal tunnel release. First, the scar is usually hypertrophic and sensitive, and a major source of complications (1,2). Second, the incision of the fascial convergence between the thenar and hypothenar is responsible for slower postoperative recovery (4). The challenge to perform carpal tunnel release without incising the fascial convergence and wrist crease has stimulated the development of several different endoscopic and microsurgical minimally invasive techniques (4-6). Anatomical studies showed that an endoscopic carpal tunnel release does not allow an adequate exploration of the thenar branch of the median nerve and decompression of its transligamentous variation (7). An endoscopic technique also endangers the ulnar and median nerves, branches of the median nerve, and communication between the two nerves both in the carpal tunnel and in the distal forearm (8-13). Some reports suggest that a minimally invasive open surgery could reduce a tissue trauma with the same effectiveness and safety as the traditional open carpal tunnel release (4-6). We conducted a randomized controlled trial to evaluate the limited palmar incision technique against the traditional approach.

Patients and Methods

Patients

According to the power analysis (14), an appropriate sample size required for each comparison group was 36 subjects. The trial and control groups were assumed to be of equal size. There was a 90% certainty that a clinically important difference
of 0.70 standard deviations would be detected between the
groups ( \( \alpha = 0.05; \beta = 0.90 \) )
Inclusion criteria were a typical medical history of carpal
tunnel syndrome, hypoesthesia of 256 Hz for vibration sense, dis-
tal motor latency greater than 5 ms, and/or a sensory nerve con-
duction velocity less than 30 m/\( \text{s} \). The exclusion criterion was
trauma-induced carpal tunnel syndrome.

Ethics Committee of the Pula General Hospital approved
the clinical trial. Each patient included in the study had been in-
formed before the surgery that he or she would undergo one of
the two equally efficient surgical techniques, and be allocated to
either the trial or control group.

Surgical Treatment

Patients in the trial group were operated on in regional an-
esthesia, using an operating microscope. Skin incision parallel to
the thenar crease was made in length up to 2.3 cm above the dis-
tal part of the transverse carpal ligament (Fig. 1). The ligament
was incised and the carpal tunnel decompressed in its distal part.
The incision of a proximal ligament part was performed subcuta-
neously with a flexed wrist. Both the distal part of the forearm and
the palm of the hand were transilluminated with a choledochos-
cope to control the completeness of decompression (5).

The patients from control group were also operated on in
regional anesthesia. Operating loupes with x2.5 magnification
were used and the carpal tunnel was released by Evermann tech-
nique (Fig. 1). The incision began at the distal border of the
transverse carpal ligament, followed the longitudinal crease of
the palm in a “zigzag” fashion ulnar to the longitudinal axis of
the ring finger, and continued into the forearm. In the proximal por-
tion of the incision, the forearm fascia was isolated and divided
longitudinally. The median nerve was identified and protected.
The transverse carpal ligament was divided along the ulnar aspect
of the median nerve to protect the median motor branches (1-3).
The thenar branch of the median nerve was exposed and, if its
course was transligamentous, a further decompression was per-
formed (1-3).

Primary Endpoints

Three months after surgery, patients with covered scar re-
region were sent to the first independent investigator, physiatrist or
neurologist (NB or LPR). Data on sensibility, thumb abduction,
distal motor latency, conduction velocity, and satisfaction with
the operative outcome were labeled with code numbers, and en-
tered into the database by the third independent investigator
(VMI).

Secondary Endpoints

During the same visit, the second independent investigator, a
medical student (II), asked the patients about the time elapsed be-
tween the surgery and their return to daily activities and work, ac-
cording to their own appraisal. The student examined the incision
region for scar and radial or ulnar pillar tenderness, measured scar
length and width, and assessed cosmetic appearance of the scar
using grades 1 to 5. The neurosurgeon (MFS) annotated the dura-
tion of operations.

Masking and Follow-up

The patients were included into the study by the first inde-
pendent investigator (NB or LPR), according to the inclusion and
exclusion criteria and their own consent. Selected patients were
referred to the second independent investigator (II), who random-
ized them into two groups using a 10-number-per-block random-
ization. The two surgical procedures were concealed in enve-
oples. The envelopes were consecutively numbered according to
the number assigned to each patient included in the study. The
type of operation was unknown to a patient and to the surgeon
until after the patient had given the written consent. Each pa-

tient’s medical records were labeled with patient’s record num-
ber and forwarded to the third independent investigator (VMI)
for statistical analysis. Three months after surgery, investigators inde-
dependently checked primary and secondary endpoints.

Statistical Analysis

The following observed parameters were used in the statis-
tical analysis of differences between the groups: electrophysio-
logical findings (distant motor latency and sensory nerve conduc-
tion velocity), hand function (return to daily activities and return
to work), cosmetic results (scar length, scar width, and esthetic
outcome), and operation time. The differences were calculated
with the one-way analysis of variance (1W-ANOVA) and, if sig-
nificant, post hoc comparisons using independent sample t-test
were performed. Chi-square test was used for comparisons be-
tween the two groups in frequency distribution of scar and ulnar
or radial pillar tenderness.

Results

Between September 9, 1997 and January 30, 2001, 72 patients entered in the study (Table 1). Eight
patients were excluded because their carpal tunnel syndrome was caused by trauma. Patients in the trial
group were operated on using the limited incision technique for carpal tunnel release. There were 5
men and 31 women in the trial group (mean age, 54.2±8.9 years). Patients from the control group
(mean age 52.5±9.7 years; 13 men and 23 women) were operated on using traditional open technique
for carpal tunnel release. Each patient suffered pain and paresthesia in the distribution of the median
nerve. The pain was more intensive at night or after specific activities.

Three months after surgery, patients from both
groups derived the identical symptomatic relief out-
come (Table 2). Furthermore, there were no signs of

Figure 1. Anatomical relation of the median and the ulnar
nerves, the median nerve branches, and its variations are
crucial in surgical incisions placement. Left: incision in the
traditional open carpal tunnel release. Right: incision in the
limited palmar carpal tunnel release. T – palmar cutaneous
branch of the median nerve (Taleisnik branch), M – ul-
ner-to-median nerve communication in the distal forearm
(Marinacci communication), B – superficial palmar com-
munication between the ulnar nerve and the median nerve
(Berrettini branch), and RC – a communication between
motor branch of the median nerve and the deep branch of
the ulnar nerve (Riche-Cannieu anastomosis).

Figure 1.
Superficial palmar communication between the me-

The trial and control group (Table 2). There was no significant difference in the postoperative electrophysiological findings between both groups. There was no significant difference in the distal motor latency (ms) and sensory nerve conduction velocity (m/s).

Electrophysiological findings (mean ±SD):
- Distal motor latency (ms): 4.12 ±0.90 for the trial group and 4.08 ±0.80 for the control group.
- Sensory nerve conduction velocity (m/s): 41.86 ±8.50 for the trial group and 43.67 ±9.00 for the control group.

Comparison between the trial and control group as a measure of the efficacy and safety of limited incision carpal tunnel release technique.

Table 2. Symptomatic relief and electrophysiological comparison between the trial and control group.

<table>
<thead>
<tr>
<th>Primary endpoints</th>
<th>Surgical technique used for carpal tunnel release</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic relief after the procedure (No. of patients):</td>
<td></td>
</tr>
<tr>
<td>complete</td>
<td>limited incision</td>
</tr>
<tr>
<td>near-complete</td>
<td>31</td>
</tr>
<tr>
<td>complications</td>
<td>5</td>
</tr>
<tr>
<td>Electrophysiological findings (mean ±SD):</td>
<td></td>
</tr>
<tr>
<td>distal motor latency (ms)</td>
<td>4.12 ±0.90</td>
</tr>
<tr>
<td>sensory nerve conduction velocity (m/s)</td>
<td>41.86 ±8.50</td>
</tr>
</tbody>
</table>

Table 3. Secondary endpoints served to measure the invasiveness of surgery.

<table>
<thead>
<tr>
<th>Secondary endpoints</th>
<th>Surgical technique used for carpal tunnel release</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hand function</td>
<td></td>
</tr>
<tr>
<td>return to daily activities (days)*</td>
<td>limited incision</td>
</tr>
<tr>
<td>return to work (days)*</td>
<td>15 (5-45)</td>
</tr>
<tr>
<td>Cosmetic results</td>
<td></td>
</tr>
<tr>
<td>scar length (mm)*</td>
<td>2.3 ±0.2</td>
</tr>
<tr>
<td>scar width (mm)*</td>
<td>1.6 ±0.5</td>
</tr>
<tr>
<td>esthetic outcome /1-5#</td>
<td>3 (3-5)</td>
</tr>
<tr>
<td>Tenderness</td>
<td>3/36</td>
</tr>
<tr>
<td>Operation time (min)*</td>
<td>9.5 ±1.1</td>
</tr>
</tbody>
</table>

Results are expressed as mean ±SD.

*Results are expressed as median (range).

#Grades used for assessment: 1 – unsatisfactory, 2 – fair, 3 – good, 4 – very good, and 5 – excellent.

For almost 50 years, open technique for carpal tunnel release has been a reliable approach for surgeons to relieve symptoms of carpal tunnel syndrome. Recently, some endoscopic and minimally invasive surgical techniques have been developed to decrease the invasiveness of the surgery (4-6). In last few years, there has been intense debate over the “optimal” technique for carpal tunnel release (4,15,16). Lee and Strickland (4) reported very promising results of limited palmar incision technique they used on a series of 525 patients. Shapiro (6) published similarly good results on a series of 482 patients who underwent microsurgical carpal tunnel release. In this trial, we compared the traditional open technique as a gold standard with a microscopic limited incision technique for the first time, and showed that both techniques were equally effective and safe. However, parameters such as intervals between the surgery and return to daily activities and work, scar and pillar tenderness, scar length, scar width, esthetic outcome, and operation time were significantly better in patients who underwent limited palmar incision for carpal tunnel release. Therefore, this approach can be recommended as a less invasive surgical technique.

Our study had at least two weaknesses. First, the group of patients included into trial was small, because the study was conducted in the county hospital where the frequency of surgeries of entrapment neuropathies was relatively low. Power analysis showed that 36 patients per group was the lowest possible number that gives valid results. The second limitation was that, when the trial was planned, we did not predict that worker’s compensation would have such a great influence on the interval between the operation and return to work. Patients who had carpal tunnel release done through limited palmar incision and had worker’s compensation returned to work significantly later, which caused great overlap between the trial and the control group results and made them less confident (15).
Lee and Strickland (4) introduced a limited palmar incision technique to preserve a fascial convergence between the thenar and the hypothenar and to avoid skin incision crossing wrist crease. These two anatomical structures are the most important for quick postoperative recovery. They used a skin incision up to 1.5 cm in length over the distal part of the carpal ligament. The division of the distal part of the carpal ligament is performed under direct vision, whereas the proximal part of the ligament is blindly divided by a specially designed “carpal tunnel tome”. Shapiro (6) described the microsurgical technique with an incision up to 1 cm longer, which allowed the division of the whole ligament under direct vision. The proximal end of the incision is at least 5 mm away from the wrist crease and the convergence between the thenar and the hypothenar is still partially preserved, which are the goals of the minimally invasive technique (15). We preferred incision under direct vision to prevent nerve branch injury, which is the first complication of carpal tunnel release and occurs due to numerous anatomical variations (7,12,13). Furthermore, the thenar branch can be explored and further decompressed, only under direct vision (1,2).

An incomplete section of the ligament is the second commonest complication and may occur when the operative field is not widely opened (4,5,11,15,18). Franzenzi at al (5) described the use of transillumination in a minimally invasive carpal tunnel release using a modified Painé retinaculatome to secure a completeness of ligament transaction. For transillumination we used a choleodoscope available in our operating theater because the price of a single-use retinaculatome with light is around US$100, whereas the surgery itself costs US$10.

Our next step will be the comparison between limited incision and an endoscopic technique for carpal tunnel release. Endoscopy is a rapidly developing technique, but today still connected with serious problems? We hope that in time the endoscopy will carry less risk of complications, which will allow us to do further research for the benefit of our patients.

Acknowledgement

This study was supported by Croatian Ministry of Science and Technology grant No. 0062076 to Dr Marin F. Stančić.

References


Received: September 28, 2001
Accepted: January 15, 2002

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