ABSTRACT

Aim: Carpal tunnel release by opening the flexor retinaculum is considered a satisfactory treatment. However, in some patients, all the symptoms are not resolved. The objective of our study is to compare two surgical techniques.

Material and Methods: We have carried out a clinical, electromyographic and dynamometric evaluation of more than a hundred patients that received surgical treatment for Carpal Tunnel Syndrome, in a comparative analysis of the techniques used four weeks and ten years after surgery. Transverse ligament lengthening according to the Simonetta technique and mini-open decompression of the median nerve with an entire section of transverse ligament were compared.

Results: The Simonetta technique, in the immediate postoperative period as well as ten years after surgery, contributes to better results of manual function and grip strength, with a higher presence of numbness and tingling than decompression with complete section of the flexor retinaculum.

Conclusion: The technique of Simonetta is a surgical option to be considered for carpal tunnel syndrome. It does appear to result in less pillar pain and may be an option in heavy labourers who are willing to accept ongoing nerve symptoms, but it is not clear that this should be recommended over open decompression, unless this is in patients presenting perhaps with EMG negative disease, or minimally-mild positive nerve studies.

INTRODUCTION

Carpal tunnel syndrome is the most common compressive neuropathy of the upper extremity[1,7]. In general, surgery of this disease is the most frequent surgical intervention of the hand[2]. Despite its high incidence and prevalence in our society, uncertainty is still present at this time, regarding which can be the best way to diagnosis and treatment, or surgical technique used for this condition.

Treatment of this disorder by splitting the transverse ligament is considered a successful procedure. However, symptoms are not completely resolved in all cases[3]. Pain in the hypothenar and thenar areas corresponding to the end of the flexor retinaculum after its
entire section and persistent weakness of grip, have been described as common complications of classical decompression of the median nerve\[8-10\].

In order to reduce such complications, different techniques of ligament lengthening have been proposed\[11\]. We present the short and long-term evaluation of the Simonetta technique, including a comparison of its clinical, functional and electromyographic results with the mini-open decompression of the median nerve with complete section of the transverse ligament.

**PATIENTS AND METHODS**

We undertook a historical prospective cohorts study based on the evaluation of 117 patients who fulfilled the following inclusion criteria: (1) patients underwent surgery for carpal tunnel syndrome performed by the same specialist between the years 2002 and 2003; (2) pre-operative clinical diagnosis according to Graham’s criteria CTS-6\[12\], i.e. numbness and tingling in the median nerve distribution, nocturnal numbness, weakness and/or atrophy of the thenar musculature, positive Tinel’s sign, positive Phalen test, loss of two point discrimination; (3) positive electromyographic diagnosis before surgery (4) absence of re-interventions in later years. The presence of a previous carpal tunnel surgery was used as exclusion criteria.

During the time period studied, two different techniques were performed, due to introduction of the Simonetta technique in 2001, in the unit of hand surgery where this study took place. To make sure that selection bias was controlled, a randomized list of numbers of the surgeries expected to be performed in the period of time studied was created (numbers 1 to 122, referring to 122 surgeries). The first number generated from the randomized list was assigned the Simonetta technique; the second was assigned the technique with a complete section of the transverse ligament; and the third, the Simonetta technique, and so on in a consecutive manner. The software used to achieve this statistical generation was Microsoft Excel 1997. This method is commonly used in our institution when there is the possibility to study a new treatment in a comparative study.

Surgical procedures were performed as follows (Figure 1):

Mini-open decompression of the median nerve with entire section of the transverse ligament (FR division group: 58 patients): after the placement of the tourniquet of ischemia in the arm of the affected extremity, a palmar incision of 2.5 centimetres was made, following the ulnar edge of the nail of the fourth finger with the distal interphalangeal joint in a flexion of 90 degrees. The transverse ligament was cut completely, in a longitudinal way in its ulnar side. The medium palmar fascia was sutured and skin was closed with a re-absorbable suture of 5-0.

Transverse ligament lengthening according to the Simonetta technique (Simonetta group: 59 patients): under the same perioperative, a palmar incision of 3 centimetres was made, following the ulnar edge of the nail of the fourth finger with the distal interphalangeal joint in a flexion of 90 degrees. After exposure of the flexor retinaculum, two parallel cuts were made ~0.5 centimetres apart in the middle third. The radial cut was extended to the proximal margin, while the ulnar cut was extended to the distal margin. The medium palmar fascia was sutured and the skin was closed using a re-absorbable suture of 5-0.

All surgeries were carried out under local anesthesia, without antibiotic prophylaxis, and a palmar splint was placed during the first fifteen days of the postoperative period.

The number of patients excluded from our study because of reoperation in later years was one (1.72%) in the case of decompression with complete section of the transverse ligament, and two (3.39%) in the case of patients who underwent lengthening of the flexor retinaculum. Another two patients assigned to the FR division group were excluded because of previous carpal tunnel surgery (3.29%).

In the year 2013, as in the pre-operative period and four weeks after surgery, patients were evaluated as follows

Clinical and functional assessment by using the Specific Questionnaire of Levine et al\[13\]. The Levine Symptom Score is determined by 11 questions regarding different attributes of pain, tingling and numbness with each answer scoring between 1 (normal) and 5 (most abnormal). The Levine Functional Score takes into account eight daily activities and indicates the ability to perform each one, from 1 (normal) to 5 (most abnormal). The results are expressed as a mean score of the questions answered.

Pillar pain assessment using two different methods\[14\]: (a) application of direct pressure on the thenar and hypothenar regions; (b)
leaning on a table with the patient’s weight on his/her hands placed on the table’s edge (“table test”). The patient stands approximately 40 cm from the foot of the table, then with elbows straight, leans over and places both hands on the edge of the exam table.

Dynamometric evaluation. Grip strength of studied hands was measured by an analogical dynamometer, with a graduated scale of 0 to 1 bars of pressure, at intervals of 0.05 bars (one bar is equivalent to 1.019 KgF/cm\(^2\)).

Electromyographic evaluation. The studies were performed using a Nicolet Viking Select (Madison, WI, USA) electromyograph. Surface recording and stimulation were used for all studies, collecting values of distal motor latency and sensory velocity conduction of the median nerve. The criteria of the American Electrodiagnosis Association were considered for gradation of carpal tunnel syndrome\(^1\). A sensory velocity of less than 48 meters per second, and a motor latency greater than 4.2 milliseconds for an interval of 7 centimetres, was considered a pathological cut-off value.

We were granted informed consent of all patients and permission from the Hospital Ethics Commission.

For statistical analyses, we used the calculation formula sample size for the comparison of means and percentages, the Chi-square and the Fisher’s Test for qualitative variables, and for quantitative variables the t-test of comparison of averages for paired or unpaired data, as well as the general linear model of repeated measures.

A sample size of 49 patients in each group was estimated as needed to detect a difference of 20% in the clinical and functional outcomes. Before analysing the values obtained, a normal distribution of the variables studied was verified, as well as the absence of differences between the two groups considered, depending on the surgical technique used, such as in epidemiological or clinical variables that could behave as confusion factors (Table 1).

<table>
<thead>
<tr>
<th>Variable</th>
<th>FR division Group</th>
<th>Simonetta Group</th>
<th>(p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>89.6%</td>
<td>83.05%</td>
<td>0.390</td>
</tr>
<tr>
<td>Male</td>
<td>10.4%</td>
<td>16.94%</td>
<td></td>
</tr>
<tr>
<td>Age (Average and standard deviation)</td>
<td>52.2 years (6.39)</td>
<td>49.1 years (6.63)</td>
<td>0.08</td>
</tr>
<tr>
<td>Body Mass Index (Average and standard deviation)</td>
<td>27.07 Kg/m(^2) (4.21)</td>
<td>27.08 Kg/m(^2) (4.43)</td>
<td>1.00</td>
</tr>
<tr>
<td>Manual worker</td>
<td>77.6%</td>
<td>81.4%</td>
<td>0.808</td>
</tr>
<tr>
<td>Previous wrist fractures</td>
<td>13.8%</td>
<td>10.2%</td>
<td>0.903</td>
</tr>
<tr>
<td>Local tumour antecedent</td>
<td>13.8%</td>
<td>15.3%</td>
<td>1.000</td>
</tr>
<tr>
<td>Trigger digit history</td>
<td>38.9%</td>
<td>19.6%</td>
<td>1.000</td>
</tr>
<tr>
<td>Diabetes</td>
<td>8.7%</td>
<td>9.8%</td>
<td></td>
</tr>
<tr>
<td>Rheumatoid Arthritis</td>
<td>3.4%</td>
<td>3.3%</td>
<td>1.000</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>3.5%</td>
<td>2.0%</td>
<td>0.614</td>
</tr>
<tr>
<td>Thyroid disorders</td>
<td>3.5%</td>
<td>5.9%</td>
<td>1.000</td>
</tr>
<tr>
<td>Preoperative oral corticoids therapy</td>
<td>25.8%</td>
<td>28.8%</td>
<td>0.828</td>
</tr>
<tr>
<td>Surgery over dominant hand.</td>
<td>93.1%</td>
<td>94.9%</td>
<td>0.712</td>
</tr>
<tr>
<td>Postoperative rehabilitation (ultrasound)</td>
<td>46.5%</td>
<td>49.1%</td>
<td>0.694</td>
</tr>
<tr>
<td>Rhizarthrosis grade I of Eaton</td>
<td>15.5%</td>
<td>20.5%</td>
<td></td>
</tr>
<tr>
<td>Rhizarthrosis grade II of Eaton</td>
<td>8.6%</td>
<td>6.8%</td>
<td>0.842</td>
</tr>
<tr>
<td>Rhizarthrosis grade III of Eaton</td>
<td>2.1%</td>
<td>2.3%</td>
<td></td>
</tr>
</tbody>
</table>

Statistically significant results \((p \text{ value <0.05})\).

**RESULTS**

No significant differences were registered between the groups studied for each evaluation in the preoperative period (Figure 2).

In relation to the outcomes recorded four weeks after surgery (Figure 3), favourable data was obtained and compared with the preoperative evaluation. Levine’s Clinical scale showed a higher improvement in the group of patients with entire section of the transverse ligament for questions referring to numbness and tingling sensations. In contrast, a higher improvement was found in the Simonetta group as far as weakness and functional scale (Tables 2 and 3). The preoperative grip strength of the operated hand was, on average, 0.525 bars (equivalent to 0.535 KgF/cm\(^2\)) (standard deviation 0.11) for the Simonetta group, and 0.494 bars (equivalent to 0.504 KgF/cm\(^2\)) (standard deviation 0.09) for the FR division group, without statistical differences between groups \((p=0.103)\). The dynamometric evaluation four weeks after surgery showed significant favourable data for the Simonetta
No differences in this respect were found (deviation 0.61). No differences in this respect were found (deviation 0.12) for patients undergoing ligamentoplasty and 0.375 bars (equivalent to 0.521 KgF/cm²) for the operated hand was 0.511 bars (equivalent to 0.521 KgF/cm²).

In the case of the electromyographic findings, the improvement in the operating zone was significantly higher in patients who underwent an entire division group. *: statistically significant results (p < 0.05).

The postoperative long-term grip strength (year 2013) of the Simonetta group were found in activities such as carrying bags, gripping a telephone receiver and opening jars. In the rest of the cases, the improvement in the long-term postoperative period regarding preoperative results was significantly higher in the FR division group; however, for question 7 (manual grasping and use of small objects?) the improvement experienced by the patients in the long-term follow-up period of 10.42 years for the Simonetta group (standard deviation 0.75) and of 10.28 years for the FR division group (standard deviation 0.61). No differences in this respect were found (p = 0.296).

In relation to Levine’s Questionnaire, favourable data was obtained from most patients ten years after surgery, with a global average value between lack of affectation and the slightest discomfort. For questions 6, 8 and 9 of the clinical scale (numbness and paresthesias), the improvement experienced by the patients in the long-term postoperative period regarding preoperative results was significantly higher in the FR division group; however, for question 7 (manual weakness), it was significantly higher in the Simonetta group.

In the case of the functional score, significant differences in favour of the Simonetta group were found in activities such as carrying bags, gripping a telephone receiver and opening jars.

The long term postoperative results of Levine’s Questionnaire (Figure 4), pillar pain and grip strength referred to an average follow-up period of 10.42 years for the Simonetta group (standard deviation 0.75) and of 10.28 years for the FR division group (standard deviation 0.61). No differences in this respect were found (p = 0.296).

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Table 4: Electromyographic data: differences between groups.

<table>
<thead>
<tr>
<th></th>
<th>S. pre</th>
<th>F. pre</th>
<th>p</th>
<th>S 4w</th>
<th>F 4w</th>
<th>p</th>
<th>S 10y</th>
<th>F 10y</th>
<th>S 4w</th>
<th>F 4w</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>SV (meters/second)</td>
<td>37.41</td>
<td>37.74</td>
<td>0.81</td>
<td>40.15</td>
<td>44.72</td>
<td>50.02</td>
<td>6.98</td>
<td>11.61</td>
<td>42.56</td>
<td>48.02</td>
<td>0.00*</td>
</tr>
<tr>
<td>ML (milliseconds)</td>
<td>5.04</td>
<td>4.95</td>
<td>0.95</td>
<td>4.75</td>
<td>4.26</td>
<td>11.01</td>
<td>0.69</td>
<td>0.19</td>
<td>4.07</td>
<td>0.09</td>
<td>0.00*</td>
</tr>
</tbody>
</table>

Diagnosis:
- Normal: 0%
- Mild: 18.6%
- Moderate: 61.1%
- Severe: 20.3%

Statistically significant results (p < 0.05).

Figure 4: Clinical and Functional Scales of Levine's Questionnaire: 1: normal – 5: most abnormal. S: Simonetta group; F: Flexor Retinaculum division group. 10 y: ten years after surgery.
The decrease in grip strength compared with the preoperative evaluation was significant in the latter group ($p=0.001$), but was not in the Simonetta group ($p=0.715$). Results in grip strength showed significant differences between groups in the long term ($p=0.000$).

No differing results were registered between the evaluation four weeks after surgery, and the values obtained in the long term in relation to Levine’s Questionnaire and the dynamometric evaluation. No significant changes between groups were registered when comparing both postoperative evaluations.

The presence of pillar pain ten years after surgery was registered in no patients when it was assessed by direct pressure of the thenar and hypothenar areas. In the case of the “table test” assessment, no patients of the Simonetta Group had a positive result, while one patient with an entire section of the transverse ligament (1.72%), without statistical differences, ($p=0.49$).

In the case of the long term electromyographic evaluation, the follow-up period was 10.49 years for the Simonetta group (standard deviation 0.63) and 10.67 years for the FR complete section group (standard deviation 0.72), without statistical differences between either ($p=0.259$). Findings in 2013 showed positive differences in most patients compared to the pre-operative data. However, the improvement in the parameters of sensory conduction velocity and distal motor latency of the median nerve in patients who underwent an entire section of the transverse ligament was higher than in the Simonetta group. The same may be said about electromyographic diagnosis, i.e. the mild carpal tunnel syndrome was most frequent in patients who underwent ligamentoplasty, and normal in patients with a complete section of flexor retinaculum. In addition, changes between the four week postoperative evaluation to the long term assessment were significantly favourable in the case of the FR group compared with the Simonetta group (Table 4) (Figure 5).

In relation with recidivism, as it was exposed previously, the number of patients excluded from our study because of reoperation in later years was one (1.72%) in the case of decompression with complete section of the transverse ligament, and two (3.39%) in the case of patients who underwent lengthening of the flexor retinaculum. Those patients were re-operated with an open entire section of the transverse ligament, in a time of 22 months after surgery in the case of the FR division group, and in a mean postoperative time of 18.6 months in the case of the Simonetta group. (sd: 5.4).

The rate of patients treated occasionally with oral painkillers ten years after surgery was of 15.7 % in the case of the Simonetta group and 7.2 % in the case of FR division group.

**DISCUSSION**

A short and long-term evaluation of the transverse ligament lengthening according to Simonetta has been exposed. Few studies have examined this technique[8,16]. In fact, in an extensive review of the literature we failed to find an immediate postoperative evaluation together with long-term outcomes. Dias et al[9] showed in their study of 52 patients over 25 weeks of follow-up, no advantage of this technique over the complete section of the transverse ligament regarding the recovery of neurological symptoms, functional outcomes and postoperative pain.

In our evaluation, no differences were registered in relation to pillar pain between groups in the postoperative long term. However, rates favourable to the transverse ligament lengthening showed four weeks after surgery is data to be taken into account in surgery of carpal tunnel syndrome[14]. This syndrome is characterized by the usual triad of pain, stiffness and tumefaction that lead to limited functionality.

Netcher et al[17] described that transverse ligament lengthening constitutes a surgical alternative to the open conventional decompression of the median nerve and, as it displays the advantages of avoiding the volar displacement of the nerve. In addition, a greater evolution of time free of symptoms has been described for this kind of technique, where the transverse ligament is conserved or reconstructed after its initial section[17]. However, we consider that the optimal size of the resulting bandelet during the ligament lengthening and the exact crossing of the cuts in the flexor retinaculum to guarantee a satisfactory decompression of the median nerve remain to be determined.

We have been able to show significant differences in some items of Levine’s Questionnaire when comparing the two studied techniques that were maintained at the two postoperative periods studied: a greater clinical improvement (numbness, tingling) in patients who underwent surgery with a complete section of the transverse ligament, and a greater functional improvement (grip strength and performing of daily activities) in the group of patients operated on according to the Simonetta technique. Savornin et al[18] described a review of surgery for carpal tunnel syndrome, as well as a telephone survey of 78 patients that had undergone treatment with a complete section of the transverse ligament. After twenty four months of follow-up, one third of the patients stated that they experienced a decrease in grip strength.

In relation to this finding, we have found favourable dynamometric data in the group of patients with the transverse ligament conserved. This result seems to correspond to the best referred values of functional capacity observed in our evaluation, for example, in habitual activities like carrying a grocery basket or holding a telephone receiver and opening bottles. This data has special relevance in our sample of patients, where a clear predominance of manual workers was presented.

The differences found in the electromyographic diagnosis four weeks after surgery and in 2013, in favour of the patients operated on with an entire section of the transverse ligament, as well as in the parameters of distal motor latency and sensory conduction velocity of the median nerve, suggest that this technique is able to maintain a better decompression of the medium nerve than with the use of ligament lengthening according to Simonetta.

Independently of the surgical technique for median nerve decompression, nowadays it may be considered an interesting option using microscopic devices that permit a better visualization and assessment of the epineural adhesions and coagulation of the flexor retinaculum after be incised and avoiding epineural fibrotic scarring.

In summary, the technique of Simonetta is a surgical option to be considered for carpal tunnel syndrome. It does appear to result in less pillar pain, better results of manual force and may be an option in heavy labourers who are willing to accept ongoing nerve symptoms. It is not clear that this technique should be recommended over mini-open decompression with entire section of the transverse ligament, with exception of patients presenting perhaps with EMG negative disease, or minimally-mild positive nerve studies.

**ACKNOWLEDGMENTS**

All patients gave written informed consent to be included in this study, and the study was authorized by the local ethical committee and performed in accordance with the ethical standards of the 1964 Declaration of Helsinki as revised in 2000. There are no conflicts of interest with regard to the present study.
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