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Neurolysis versus anterior transposition of the ulnar nerve in cubital tunnel syndrome: a 12 years single secondary specialist center experience

--Manuscript Draft--

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Abstract:	<p>Background Various conservative treatments and surgical techniques have been reported in the literature as efficient and feasible measures to treat the cubital tunnel syndrome. However, there has been no consensus on the best management of the syndrome, and uniform standardised guidelines have not yet been accepted or introduced. With our study, we present our experience on the clinical efficacies and outcomes of the surgical techniques of neurolysis alone and neurolysis associated with ulnar nerve anterior transposition at the elbow joint in patients with neuropathic symptoms due to cubital tunnel syndrome.</p> <p>Materials and methods A total of 107 patients with cubital tunnel syndrome were retrospectively enrolled,</p>

	<p>surgically treated and followed up in our study. The cohort was divided into two groups: 41 patients treated only with neurolysis of the ulnar nerve (Group 1), and 66 patients treated with neurolysis and anterior transposition (Group 2). Of the participants, 35 were women and 72 were men. The average age was 54 years. Significant comorbidities were preoperatively diagnosed in 26 patients. Conservative measures had been considered, followed by surgical management if appropriate. A pre-op electromyography (EMG) was performed for all patients. All surgical procedures were performed by the same surgical team. A postoperative follow-up was carried out and the findings were recorded. The "McGowan" and "Wilson and Krout" classifications and the DASH score were used. A satisfaction questionnaire was administered to all patients postoperatively at 2 weeks).</p> <p>Results Ulnar nerve neurolysis and anterior transposition surgery were all successfully performed. Overall complications were postoperative haematoma (8%) and wound problems (5%). In 6% there was recurrence of symptoms. In 11% there was no improvement of symptoms. Pre-op McGowan classifications for groups 1 and 2 were 0% and 0% (grade 0), 21% and 24% (grade 1), 46% and 44% (grade 2), and 33% and 34% (grade 3), respectively. The post-op McGowan classifications were 34% and 37% (grade 0), 39% and 40% (grade 1), 23% and 20% (grade 2), and 4% and 3% (grade 3), respectively. The post-op Wilson and Krout classifications were 45% and 46% (excellent), 26% and 28% (good), 19% and 15% (fair), and 10% and 11% (poor), respectively. The DASH score means for groups 1 and 2 were 14.8 and 15.2, respectively. A negative Froment's sign was present in 73.2% and 71.2%, respectively. In Group 1, the post-op satisfaction questionnaire scores were 0 for one patient, 1 for four patients, 2 for seven patients, 3 for ten patients, 4 for twelve patients and 5 for seven patients. In group 2, the post-op satisfaction questionnaire scores were 0 for three patients, 1 for nine patients, 2 for twelve patients, 3 for fifteen patients, 4 for eighteen patients and 5 for nine patients.</p> <p>Conclusions In our experience, the surgical technique to treat the cubital tunnel syndrome most efficiently and feasibly has not yet been established in terms of indications and outcomes. This is supported by the data present in the international literature. Good and similar results were obtained with neurolysis alone and neurolysis associated with anterior transposition of the ulnar nerve (in line with the international data). In conclusion, more high-quality studies of greater statistical power are needed to provide a consensus on the surgical indications and techniques to treat the cubital tunnel syndrome and to establish internationally standardised guidelines.</p>
<p>Response to Reviewers:</p>	<p>COMMENTS TO THE AUTHOR:</p> <p>The article still needs revisions. - Paper and abstract still require a thorough revision of the English language that is essential for publication, as already suggested. According to your suggestion the paper was professionally revised to improve the English language</p> <p>-A 2-year recruitment period was specified in materials and methods. The title of the article is about a 12-year experience. There is an inconsistency. Please explain The study was retrospective so in a 2 year recruitment period we reviewed patients treated in a 12 year period.</p> <p>- Line 53: "We fully informed all the subjects about the characteristics of the study and they gave their consent." What do you mean? It seems tha you wrote a description of a prospective study. Is this a retrospective one? The patients were informed that their data were used for the study, as we usually do also in retrospective studies</p> <p>- "The anterior subcutaneous transposition procedure of the ulnar nerve was performed in addition to the simple neurolysis in presence of osteophytes, valgus deformity of the elbow and dynamic instability at the diagnostic manoeuvres." Did you always perform anterior transposition in subjects with osteophytes and valgus deformity? Or only after intraoperative evaluation? Please clarify Only after intraoperative evaluation as reported in the Materials and Method section</p> <p>-line 50: write " Groups" we modified in the text</p> <p>- Lines 55-57: were the associated pathologies treated at the same time, for example snapping triceps? how? Please specify in the paper, as already suggested we added the associated lesions paragraph in the text</p>

- The average time from onset of symptoms to surgery is 25.4 days. In the text it is specified that all patients have performed conservative therapy for 3 months. There is an inconsistency. Please explain
This is a mistake, the correct time is 95.4 days, we corrected in the text

- Did you performe mc Gowan score pre and postoperatively? In a previous revision you wrote that you performed it at 3 months but in the results there are preoperative values. Clatify all this information about study design also in methods.
we performed the mcGowan pre and post operatively, we clarify in the text

- Line 110: in the results you reported Froment sign. Please explain in the text why you used this sign and report references.
We added the reference 2 and the explanation in the text

- line 128: please eliminate 2 after dot
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- Lines 168- 178: please format like the other paragraphs
we changed according to your suggestion

- line 181: please write "of"
we changed according to your suggestion

- Please format the reference 2 in the bibliography like the other references, as already suggested
we changed according to your suggestion

-All corrections suggested in the text should be reported in the abstract, that is still unclearwe changed according to your suggestion

Neurolysis versus anterior transposition of the ulnar nerve in cubital tunnel
syndrome: a 12 years single secondary specialist center experience

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1 **INTRODUCTION**

2 Various conservative treatments and surgical techniques have been reported in the literature as efficient and
3 feasible treatments for the cubital tunnel syndrome. However, there is no consensus on the best management
4 of the syndrome, and uniform standardised guidelines for both conservative and operative treatment have not
5 yet been accepted.

6

7 **BACKGROUND**

8 Patients with repetitive upper limb activities, prolonged postures in flexion of the elbow (sleeping, driving,
9 typing, talking on the phone, etc.), and congenital laxity of the retinaculum (ligament and fascia of Osborne)
10 are more susceptible to symptomatic compression and/or hypermobility of the ulnar nerve at the elbow.
11 Other possible causes of cubital tunnel syndrome are post-traumatic elbow deformity and reduced
12 dimensions of the cubital tunnel (due to osteophytes, ganglions, osteochondromas, elbow synovitis,
13 Struthers' ligament, hypertrophic medial head of the triceps and epitrochleoanconeus) [1].

14 The main symptoms of the syndrome include ring and little finger paraesthesia (intermittent or constant),
15 hypoesthesia of the ulnar aspect of the hand and clumsiness with poor control of the grip. Signs include
16 intrinsic hand muscle weakness, positive Wartenberg and Froment's sign, atrophy of the first commissure,
17 weak flexor digitorum profundus of the little finger, positive Tinel's sign at the elbow, and positive
18 electromyography and nerve conduction studies [2,3].

19 Management consists of conservative and surgical options. The former are usually implemented for 3 months
20 and the results reviewed before taking any further surgical action. Conservative measures include splinting at
21 night-time, nerve-gliding exercises and the avoidance of postures or repetitive flexion movement of the
22 elbow (as they were shown to be potentially useful in non-severe cases) [4].

23 Surgical options include simple neurolysis, neurolysis with anterior transposition (subcutaneous,
24 intramuscular, submuscular), and medial epicondylectomy. However, there is no complete agreement in the
25 literature about the best surgical procedure [5].

26 Moderate-quality evidence indicates that simple decompression and decompression with anterior
27 transposition are equally effective based on clinical, neurophysiological and imaging characteristics [6,7,8].
28 However, the decompression with transposition is associated with more deep and superficial wound
29 infections than the simple decompression [6]. Poor outcomes are associated with advanced age, lower nerve
30 conduction velocity and lower action potential amplitude. These results suggest that anterior subcutaneous
31 transposition of the ulnar nerve is effective and safe for the treatment of moderate to severe cubital tunnel
32 syndrome, and that initial severity, advancing age and electrophysiological parameters can affect treatment
33 outcome [5].

34 The aim of the present study is to evaluate the clinical efficacy and outcomes of neurolysis with or without
35 anterior transposition of the ulnar nerve in patients with neuropathic symptoms due to cubital tunnel
36 syndrome.

37

38 **MATERIALS AND METHODS**

39 **Patients**

40 From April 2014 to April 2016, 107 patients with cubital tunnel syndrome were retrospectively enrolled in
41 our study. Our cohort was divided into two groups: group 1, with 41 patients who were treated solely with
42 neurolysis of the ulnar nerve at the elbow; and group 2, with 66 patients who were treated with neurolysis
43 and anterior transposition of the ulnar nerve.

44 Preoperative electromyography (EMG) was performed for all patients. The EMG criteria for the diagnosis of
45 cubital tunnel syndrome were used (Table 1) [9].

46 **Inclusion criteria:** patients with symptomatic cubital tunnel syndrome recalcitrant to conservative treatment.
47 No restrictions in terms of aetiology were applied.

48 **Exclusion criteria:** associated compression at the Guyon canal, associated cervical radiculopathy, associated
49 thoracic outlet syndrome, all forms of neuropathies, and severe systemic or local comorbidities.

50 The groups were homogeneous for the baseline features of the patients enrolled. Out of all patients, 35 were
51 women and 72 were men. The average age of the patients was 54 years.

52 The study protocol was approved by the hospital's Ethical Review Board, and it was conducted in
53 accordance with the principles of the Declaration of Helsinki and its amendments. We fully informed all the
54 subjects about the characteristics of the study, and they gave their consent.

55 The types of cubital tunnel syndrome encountered in our study were: idiopathic, 58%; post-traumatic, 27%
56 (fractures, dislocations, traumatic wounds, burns); arthritis, 6%; valgus deformity of the elbow, 5%; benign
57 neoplasia, 3% (lipoma, neurofibroma, others); and medial triceps snapping syndrome, 1%.

58 Among the two groups, 26 patients were diagnosed with significant comorbidities such as diabetes, arthritis
59 and autoimmune diseases. All these patients were, however, under appropriate management and treatment
60 and fit for surgery at the time.

61 All patients were seen 2 weeks postoperatively for wound check, removal of sutures and clinical assessment,
62 and again at 3 months for clinical assessment. Further follow-up appointments were organised only for the
63 cases who did not benefit at all from the surgical procedure or did not achieve significant improvements of
64 the symptoms.

65 A full clinical examination of the ipsilateral elbow, forearm, wrist and hand was also performed, both pre-
66 and postoperatively for all patients. The clinical examination included the Froment's sign in order to test the
67 ulnar nerve [2].

68 The average waiting time from the onset of the neuropathic symptoms to the surgical procedure was 95.4
69 days. We took into consideration the international management recommendations and used the suggested
70 conservative measures, when appropriate, before deciding to start the surgical management. These
71 conservative strategies included (for a period of 3 months) splinting at night-time, nerve-gliding exercises
72 and the avoidance of postures or repetitive flexion of the elbow (as they were shown to be potentially useful
73 in non-severe cases) [4].

74 All patients included in the study were previously subjected to conservative treatment that had failed.
75 Twenty-seven patients were surgically treated within 3 months from the onset of the symptoms, 30 patients
76 within 3 to 6 months, 31 patients within 6 to 12 months and 19 patients after 12 months.

77 Neurolysis of the ulnar nerve was used as the sole surgical technique when there was intraoperative evidence
78 of nerve compression resolved by neurolysis at the level of the epitrochlear groove. The anterior
79 subcutaneous transposition of the ulnar nerve was performed in addition to the simple neurolysis in the
80 presence of osteophytes, valgus deformity of the elbow or dynamic instability with the diagnostic
81 manoeuvres.

82 The clinical evaluation was performed 3 months after surgery with the following scales: the McGowan
83 classification system (clinical classification with regard to the sensory function of the injured ulnar nerve
84 both pre- and postoperatively) [10], the Wilson and Krout classification (postoperative results in terms of
85 sensory and motor function within 3 months from the operation) [11] and the DASH score (Disabilities of
86 the Arm, Shoulder and Hand score as a primary outcome measure of the surgical procedures) [12].

87 The DASH questionnaire was administered to all patients postoperatively in clinic (at 12 weeks) to assess
88 their satisfaction in terms of the improvement of symptoms.

89

90 Table 1

EMG CRITERIA FOR DIAGNOSIS OF CUBITAL TUNNEL SYNDROME
1. Absolute delay of ulnar nerve conduction at the elbow
2. >10 m/s reduction of velocity conduction (VCM and VCS) at the elbow
3. >20% reduction of action potential (MAP and SAP) at the elbow
4. Absence of sensorial signals
5. Evidence of muscle atrophy

91 Statistical analysis

92

93 The Statistical Package for Social Sciences (SPSS) version 13 was used for calculations. All the data were
94 analysed by a single-blinded researcher. Computed P values were two-sided, and $P < 0.05$ was used to
95 determine statistical significance. The Wilcoxon–Mann–Whitney test for two independent samples was
96 performed in order to evaluate differences between groups for numerical variables. The Pearson chi-square
97 was performed in order to evaluate differences between groups for categorical variables.

98

99 **Surgical technique**

100 The patient was placed in the supine position. A surgical incision was made at the medial epicondyle, the
101 ulnar nerve was identified and the neurolysis was performed distally and proximally up to the Osborne
102 ligament. The nerve was evaluated during the flexion and extension of the elbow. If the nerve appeared free
103 from adhesions, only the neurolysis was performed; if the ulnar nerve was not sliding, the anterior
104 transposition was then performed.

105

106 **Associated lesions**

107 For the treatment of triceps snapping syndrome, surgery included a partial resection of the medial triceps
108 edge. In posttraumatic cases, surgery included the previous hardware removal and/or valgus correction.
109 Benign neoplasia was removed in the 3% of cases involved.

110

111 **RESULTS**

112 The most recent international surgical guidelines for ulnar nerve neurolysis with or without anterior
113 transposition were followed, and all surgical procedures were successfully performed (open surgery).

114 Overall complications were very limited, with no difference between the two groups ($P > 0.05$). They
115 included postoperative haematoma in 8% of the cases and wound problems in 5% of the cases. Recurrence of
116 the symptoms was recorded in 6% of the patients at the final follow-up. In 11% there was no
117 improvement of symptoms.

118

119 **Group 1**

120 The preoperative McGowan classification was grade 0 for no patients, grade 1 for 21% of the patients, grade
121 2 for 46% of the patients and grade 3 for 33% of the patients. The postoperative classification was grade 0
122 for 34% of the patients, grade 1 for 39% of the patients, grade 2 for 23% of the patients and grade 3 for 4%
123 of the patients (Table 2).

124 The postoperative Wilson & Krout classification was recorded as excellent in 45% of the cases, good in 26%
125 of the cases, fair in 19% of the cases and poor in 10% of the cases (Table 3).

126 The recorded DASH scores ranged from a minimum of 0 to a maximum of 77.4, with a mean of 14.8.

127 Postoperatively, the Froment's sign was negative in 30 cases (73.2%) and positive in 11 cases (26.8%).

128 The postoperative satisfaction questionnaire score was 0 for one patient, 1 for four patients, 2 for seven
129 patients, 3 for ten patients, 4 for twelve patients and 5 for seven patients.

130

131 **Group 2**

132 The preoperative McGowan classification was grade 0 for no patients, grade 1 for 22% of the patients, grade
133 2 for 44% of the patients and grade 3 for 34% of the patients. The postoperative classification was grade 0
134 for 37% of the patients, grade 1 for 40% of the patients, grade 2 for 20% of the patients and grade 3 for 3%
135 of the patients (Table 2).

136 The postoperative Wilson & Krout classification was recorded as excellent in 46% of the cases, good in 28%
137 of the cases, fair in 15% of the cases and poor in 11% of the cases (Table 3).

138 The recorded DASH scores ranged from a minimum of 0 to a maximum of 78.6, with a mean of 15.2.

139 The postoperative Froment's sign was negative in 47 cases (71.2%) and positive in 19 cases (28.8%).

140 The postoperative satisfaction questionnaire score was 0 for three patients, 1 for nine patients, 2 for twelve
141 patients, 3 for fifteen patients, 4 for eighteen patients and 5 for nine patients.

142 No statistical differences were found between the two groups for all clinical tests evaluated.

143

144 Table 2

MC GOWAN CLASSIFICATION				
	NEUROLYSIS		ANTERIOR TRANSPOSITION	
	PRE OPERATIVE	POST OPERATIVE	PRE OPERATIVE	POST OPERATIVE
Grade 0	0%	34%	0%	37%
Grade I	21%	39%	22%	40%
Grade II	46%	23%	44%	20%
Grade III	33%	4%	34%	3%

145

146 Table 3

WILSON AND KROUT CLASSIFICATION (POST-OPERATIVE)

	NEUROLYSIS	ANTERIOR TRANSPOSITION
Excellent	45%	46%
Good	26%	28%
Fair	19%	15%
Poor	10%	11%

147

148

149 **DISCUSSION**

150 Different surgical procedures have been proposed for the treatment of ulnar entrapment neuropathy at the
151 cubital tunnel. In 1957, Osborne proposed that ulnar nerve palsy was caused by compression [8,10]. He
152 reported the existence of a band of fibrous tissue bridging the head of the flexor carpi ulnaris. This band lies
153 directly over the ulnar nerve. He noticed that it was slack during elbow extension but tight with flexion. The
154 division of this band (Osborne's fascia) was deemed enough to relieve the symptoms. Feindel and Stratford
155 in 1958 proposed the same theory of compression of the ulnar nerve in the cubital tunnel [14]. Anterior
156 transposition and neurolysis are the commonest procedures performed globally [15–18]. Many authors report
157 worsening of symptoms after anterior transposition [19–21]. This may be attributed to devascularisation of
158 the nerve by obliteration of the epineural vessels [22–24]. This, however, was not experienced at our
159 institution. In neurolysis, the ulnar nerve is left in its original position without the risk of segmental
160 ischaemia due to ligation of segmental blood vessels [25]. Several authors have suggested that simple
161 decompression may be as beneficial to the patient's symptoms as anterior transposition and may have fewer
162 complications [13,14,20,26].

163 When reviewing the collective literature of case series and expert opinions, the results were variable and, of
164 course, opposing opinions were found on the preferred technique.

165 In our experience, the most definitively effective and feasible surgical technique to treat the cubital tunnel
166 syndrome has not yet been established in terms of indications and outcomes. This is supported by the data in
167 the international literature [17,24,27,28,29]. Good and similar results were obtained with both neurolysis
168 alone and neurolysis associated with anterior transposition of the ulnar nerve (in line with the international
169 data). These studies suggest that neurolysis is at least as effective as transposition. There is, however, no
170 clear evidence that either procedure is more effective than the other in reducing local elbow pain.

171 Comparing our results with the current literature is not easy, because there are many different clinical scales,
172 and different authors utilised different evaluation systems.

173 Until recently, the only prospective study comparing these two approaches was by Adelaar et al. [30]. The
174 study was designed primarily to assess the importance of preoperative clinical and electrical factors, in
175 addition to the surgical technique, in determining outcomes. They compared three different surgical
176 techniques in 32 patients. The surgical groups were highly unequal in size and follow-up was relatively short,
177 but overall, transpositions were thought to fare better (1/7 after neurolysis as opposed to 7/30 after
178 transposition were considered to have a good outcome). According to our study, the differences in outcome
179 were not statistically significant, and nonsurgical factors were deemed more important in determining the
180 overall outcome.

181 Gervasio et al. [31] produced the first recognised randomised, prospective study in January 2005.
182 Methodologically, the study was very sound with independent and blinded neurological assessment of
183 patients before and after surgery. However, it was exclusive to those patients classified as having severe
184 (Dellon grade 3) cubital tunnel syndrome. Clinically, functionally and electrophysiologically, the outcomes
185 between the two 35-patient groups were essentially identical.

186 In March 2005, the second recognised prospective, randomised study was published. Bartels et al. [32]
187 compared simple decompression with subcutaneous transposition for idiopathic neuropathy. The study was
188 relatively large with 152 patients assessed. Their results also strongly indicate that simple decompression and
189 subcutaneous transposition are equally effective methods of treatment. The transposition group had a higher
190 complication rate. The authors therefore favoured simple decompression because of its surgical simplicity
191 and reduced complication rate.

192 The results of this study seem indicate that the final outcomes are more related to the severity of the
193 compression rather than the duration of the symptoms. Moreover, the surgical procedure must be guided by
194 the aetiology of the ulnar nerve compression. More specific and standardised clinical or radiological
195 indications are needed to clarify the grey area between the two surgical techniques.

196 In conclusion, this study showed that both neurolysis and transposition are safe procedures with a
197 postoperative improvement of clinical and functional scales. However, the transposition is historically
198 associated with more postoperative complications, and it must be performed in addition to the simple
199 neurolysis only in the presence of osteophytes, valgus elbow deformity and dynamic instability with the
200 diagnostic manoeuvres [33].

201

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