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Isolated Nail Lichen Planus– an expert consensus on treatment of the classical form

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60

61 **Abbreviations used:**

62 LP: lichen planus

63 NLP: nail lichen planus

64 JAK: janus kinase

65 IFN: interferon

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**70 ABSTRACT**

71 Lichen planus is a benign inflammatory disorder of unknown etiology that may affect the  
72 skin, mucosae, scalp and nails. When the nails are affected, **it may lead to permanent**  
73 **destruction with severe functional and psychosocial consequences.** Therefore, prompt  
74 diagnosis and early treatment are essential, even in mild cases. There are currently no  
75 guidelines for the management of nail lichen planus and the published literature on  
76 treatment is limited. The aim of this paper is then to provide practical management  
77 recommendations for the classical form of nail lichen planus, especially when restricted  
78 to the nails. Topical treatment has poor short-term efficacy and may cause long-term side  
79 effects. Instead, intralesional and intramuscular triamcinolone acetonide should be  
80 considered first line therapies. Oral retinoids are second line choices, and  
81 immunosuppressive agents may also be considered.

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**85 CAPSULE SUMMARY**

- 86 • Nail lichen planus may cause significant discomfort and permanent nail  
87 destruction, so prompt treatment is essential.
- 88 • Intralesional triamcinolone acetonide is the first-line treatment, but systemic  
89 corticosteroids, retinoids, and immunosuppressive agents may also be considered.

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## 93 INTRODUCTION

94 Lichen planus is a benign inflammatory disorder of unknown etiology that may affect  
95 the skin, mucosae, scalp and nails<sup>1,2</sup>. Nail involvement affects adults more than  
96 children<sup>3,4</sup>. Fingernails are more commonly affected than toenails. Different clinical  
97 presentations have been recognized<sup>5,6</sup> but, in this paper, we will only discuss the  
98 management of the the classical variant, especially when restricted to the nail unit.

99 The longitudinal pattern of nail plate ridging and fissuring is quite characteristic of this  
100 variety of NLP. Onycholysis and nail bed hyperkeratosis may also be present. Dorsal  
101 pterygium, anonychia and nail bed atrophy are, instead, less frequent. In most cases the  
102 diagnosis of NLP is clinical, but in questionable cases, a biopsy is necessary with site  
103 selected according to clinical examination findings<sup>8</sup>.

104 Nail involvement in LP may be severe and **can rapidly worsen with irreversible**  
105 **scarring as a potential outcome**. This causes significant discomfort to patients, affecting  
106 their quality of life. Therapeutic medications with proven efficacy are limited, and  
107 **treatment is notoriously challenging, with high rates of failures, relapses and recurrences**.  
108 **If NLP is not properly and promptly treated, improvement can be difficult to achieve**<sup>9</sup>.

109 No guidelines exist for the treatment of NLP and there is no medication with a specific  
110 indication for its treatment. Moreover, no validated scoring system exists to objectively  
111 assess the efficacy of prescribed medications. Treatment of the nail unit in general is  
112 notoriously challenging, because delivery of topical drugs is difficult, mildly effective  
113 and time-consuming and clinicians are often reluctant to prescribe systemic treatments  
114 when the disease is localized only to the nails thus limiting potential therapeutic options.

115

## 116 MATERIALS AND METHODS

117 A literature search in the PubMed database has been performed and a total of 21 papers  
118 were collected<sup>10-30</sup> (Table 1 – supplemental material). Due to the limited literature, we  
119 evaluated papers with cases of isolated NLP, but also papers with LP affecting the nails  
120 and other body areas. However, since the purpose of this paper was to review efficacy of  
121 treatment, we believe that it should be evaluated independently if it was the more  
122 appropriate option to choose.

123 The authors were then invited to participate in a survey to:

### 124 *1. Define the severity of clinical presentation;*

125 NLP severity has been defined as MILD: thinning, longitudinal ridging, distal splitting  
126 less than 3mm in length, onycholysis less than 25%, no nail bed hyperkeratosis (Fig.1A);  
127 MODERATE: partial fissuring, longitudinal grooves, distal splitting between 3 and 5  
128 mm, onycholysis between 25% and 50%, mottled erythema of the lunula, subungual  
129 hyperkeratosis (Fig.1B); SEVERE: complete fissuring, deep grooves, splitting more than  
130 5 mm, onycholysis more than 50%, diffuse erythema of the lunula (Fig.1C). Pterygium  
131 and anonychia belong to this last stage, but since they do not respond to any treatment,  
132 they will not be discussed afterwards. We agreed not to create a numeric score because in  
133 NLP the dystrophy is too diffuse and cannot be assessed in quadrants as in nail psoriasis.

### 134 *2. Define when systemic treatment is preferred or indicated;*

135 “Few-nail disease” should be defined as a disease affecting 3 nails or less. However, we  
136 do not impose the threshold of the 3 nails for the initiation of a systemic treatment, but  
137 we indicate it as a suggestion. Quality of life of patients, in fact is an important factor to  
138 take into account when prescribing a treatment because dystrophy involving the first 3

139 digits might have significant functional consequences even if the severity of the disease is  
140 mild, justifying systemic treatments.

141 *3. Define the number of months necessary to evaluate the first results of treatment and*  
142 *the number of months over which a treatment is judged unsuccessful;*

143 There are no data on nail growth in NLP. Normally the nail growth rate is 2-3 mm/month  
144 for fingernails and 1- 2 mm/month for toenails<sup>31</sup>, **therefore a minimum of 3 to 6 months is**  
145 **necessary to evaluate the results of treatments.**

146 *4. Define the percentage of success of a treatment;*

147 No improvement or worsening is a disease reduction of 0%; minimal improvement is a  
148 disease reduction of  $\leq 25\%$ ; mild improvement is a disease reduction of 26-50%;  
149 moderate improvement is a disease reduction of 51-75%; great improvement is a disease  
150 reduction of 76-99%; clinical cure is a disease reduction of 100%.

151

## 152 **RESULTS**

153 After reviewing the literature<sup>10-30</sup>, it is clear that treatment of NLP is challenging.  
154 Prospective studies with long term follow up have never been performed and evidence-  
155 based studies are not even feasible because the pathogenesis of NLP and molecular  
156 targets for drug development are unknown. Most of the reported papers are single case  
157 reports or expert opinions where detailed data on disease localization and severity are  
158 lacking. This provides an incorrect evaluation of treatment efficacy and indications. Not  
159 all patients, and not even all affected nails, responded to the given therapy; not all  
160 patients responded in the same way and the first prescribed successful treatment was,  
161 sometimes, not effective in case of recurrences. It was impossible to predict which patient

162 respond to treatment and which will not. In general, due to a faster growth rate and  
163 reduced thickness, fingernails responded better and quicker than toenails: however, the  
164 **thumb responded less and more slowly.**

165 According to the authors' experience, however, effective treatment options exist and  
166 include intralesional and systemic treatments (Fig. 2). Topical treatment is not instead  
167 recommended due to limited drug penetration and potential side effects related to the  
168 long-time application<sup>32</sup>. Environmental exposures that may worsen the disease, and delay  
169 the response to treatment, should always be limited or avoided.

170

## 171 **DISCUSSION**

172 According to the literature and to the authors' experience, early treatment is always  
173 recommended for NLP and the wait and see approach is generally not advisable due to  
174 the dystrophic nature of the disease and the unpredictable course.

175 It is very important to suppress inflammation to treat NLP<sup>33,34</sup> and the first-line therapy  
176 should always be triamcinolone acetonide. The intralesional route of administration is  
177 considered an optimal targeted therapy, as the drug is delivered to the site of  
178 inflammation, namely the nail matrix or nail bed with numerous advantages if properly  
179 performed.

180 When the nail matrix is affected, injections are quite tolerable for patients, even for  
181 older children (at least >14 years old). Ethyl chloride spray, "talkesthesia" and the  
182 concomitant use of vibrating devices can be utilized instead of digital block anesthesia.  
183 Even 20 nails can be treated in one office visit in few minutes. Injections in the nail bed  
184 are instead too painful without a digital block anesthesia.



185 While adverse events<sup>35-37</sup>, including atrophy, are possible, there is strong consensus  
186 that they are minimal or even non-existent when this technique is used with appropriate  
187 training<sup>38</sup>. Hematomas and transient numbness of the distal digit are, instead, more  
188 frequent.

189 As with nail psoriasis<sup>39</sup>, there is not enough evidence regarding the optimal dosage,  
190 dilution, number and frequency of injections, and maximum duration of treatment.

191 According to the authors, triamcinolone acetonide should be injected in a concentration  
192 of 2.5, 5 or 10 mg/ml according to disease severity. If lower concentrations vials are not  
193 commercially available, dilutions of 10 mg can be made with 1% lidocaine without  
194 epinephrine or sodium chloride. A volume of 0.1 ml per nail plate quadrant is enough and  
195 the solution should be slowly injected with a 30 Gauge needle. The needle should be  
196 inserted till a loss of resistance and then the liquid injected until blanching of the area is  
197 observed<sup>38</sup>. An insulin syringe with a built-in needle or a Luer lock syringe are the best  
198 for injections under pressure, frequent when injecting within the nail unit. Different  
199 techniques of injection are shown in Fig. 3<sup>40,41</sup>. Needle-less injecting instruments (port-o-  
200 jet or dermo-jet) are not supported by the authors due to the potential risk of splash back  
201 of blood and the scarce manageability of the existing instruments on a small and convex  
202 structure like the nail unit.

203 Injections should be repeated every 4 to 5 weeks, for a minimum of 4 to 6 months to  
204 appreciate results. If improvements are seen, it is appropriate to continue until there is  
205 marked or complete improvement and then taper for few months. Tapering is best  
206 performed by extending the period between injections (once every 6 to 8 weeks). If no

207 clinical response is achieved after 6 sessions, another treatment modality should be  
208 evaluated, and tapering is not necessary.

209 Intramuscular triamcinolone should be considered as an adjunct to intralesional  
210 administration in case of severe disease, especially if more than 3 nails are affected, in  
211 any presentation. Intramuscular triamcinolone is also recommended if intralesional  
212 injections are not feasible because the patient is affected by nail bed LP, the physician  
213 lack of expertise, or if the patient refuses them. It should be done even if there is one or  
214 few nails affected as stated before.

215 A dose of 0.5-1 mg/kg every month for at least 3 to 6 months is suitable for both  
216 children and adults, with dosages of 1 mg/kg/month advised during the active treatment  
217 phase (at least for the first 2-3 months and especially in severe cases). Caution must be  
218 taken due to systemic side effects even if they are quite rare. Underlying conditions such  
219 as diabetes, glaucoma and osteoporosis should always be ruled out. Bone protection with  
220 calcium and vitamin D should also be discussed<sup>42</sup>. Treatment is continued until there is  
221 marked or complete improvement and then tapered with dosage reduced to half of the  
222 therapeutic dose. If no clinical response after 6 months is achieved, change of treatment  
223 should be considered and tapering is not necessary.

224 Oral steroids might be also an option, however, they may cause unwanted side effects  
225 due to the required high dosages kept daily for many months<sup>43</sup>. For this reason, the  
226 authors discourage their use in NLP.

227 For patients, who refuse or who have contraindications to steroids, oral retinoids can  
228 be a valid option. Acitretin 0.2 - 0.3 mg/kg a day<sup>44</sup> or alitretinoin 30 mg/day<sup>10-12</sup> are  
229 known to be effective in patients with cutaneous and oral LP, but their role in treating

230 NLP is less known. Known side effects of retinoids include nail softening and  
231 brittleness<sup>45</sup> which are unwanted in NLP affected patients that already suffer from nail  
232 fragility. Thus, low dosages of acitretin are always recommended, lower than those used  
233 for nail psoriasis (0.3 – 0.4 mg/kg a day)<sup>39</sup>. Dose adjustments may be however needed  
234 over time, because side effects may occur (usually 2-18 weeks after starting treatment).  
235 Retinoids are also well known to accelerate nail growth, and this is the mechanism by  
236 which they probably improve matrix NLP<sup>46</sup>. The desquamative effect of retinoids can  
237 instead improve the typical hyperkeratosis of nail bed LP.

238 Alitretinoin is known to have fewer side effects than acitretin, higher anti-  
239 inflammatory properties and a better regulation of keratinocytes differentiation and  
240 proliferation<sup>47</sup>. Moreover, alitretinoin seems to reduce the susceptibility of the epidermis  
241 to friction, another factor that negatively influences nail growth in NLP. Unfortunately,  
242 alitretinoin is not available in every country.

243 In case of improvement, retinoids are continued until cure and only then the drug  
244 dosage is progressively reduced. If no clinical response after 6 months is achieved, a  
245 change of treatment should be considered, and tapering is not necessary. According to the  
246 authors' experience, however, mild to moderate cases however respond to retinoids much  
247 better than severe ones.

248 Azathioprine 100mg/day, cyclosporine 3-5 mg/kg/day or mycophenolate mofetil 1000  
249 mg/twice a day can be considered, as monotherapy or as an adjunctive-to-steroid therapy  
250 in severe case with poor response to steroids. Their efficacy is not well studied for NLP  
251 and the authors support their use only as a 3<sup>rd</sup> option. However, it should be noted that  
252 patients that do not respond to a first-line therapy are unlikely to respond to other

253 treatments. These patients should be in any case followed over time and provided by  
254 comprehensive nail care instructions, including, but not limited to, mechanisms of  
255 trimming their dystrophic plates, avoidance of overaggressive manicuring, as well as  
256 optimal moisturization of the nails.

257 The use of hydroxychloroquine and methotrexate is not supported as they are thought,  
258 by our group, to be ineffective. Biologics are not included in our list as there is minimal  
259 experience on their usage for NLP: they should be used off label, as the other drugs, but  
260 the costs are by far more expensive.

261 A future potential therapy may be tofacitinib, an inhibitor of the enzymes JAK 1 and 3,  
262 upregulated in LP. Pro-inflammatory cytokines and the IFN $\gamma$  pathway are thus inhibited  
263 and CD8+ T-cell recruitment reduced<sup>48</sup>. Tofacitinib has never been evaluated in patients  
264 with NLP, but it has been studied in scalp LP patients resistant to conventional  
265 treatments, resulting in an 80% clinical improvement, either as monotherapy or as  
266 adjunctive therapy<sup>49</sup>. Further studies are however necessary because the costs are high.

267

## 268 CONCLUSION

269 To conclude, NLP should always be treated and regardless of treatment chosen, a long  
270 term follow-up for all affected patients is advisable because relapses are common.

271 This paper underlines the importance of early treatment as the course of the disease is  
272 unpredictable and often aggressive. Triamcinolone acetonide, both intralesional and  
273 intramuscular are first line therapies. Oral retinoids are second line choices, and  
274 immunosuppressive agents may also be considered.

275

276 **FIGURE LEGENDS**

277 Fig.1 – NLP mild form (A): note longitudinal ridging and splitting limited to the distal  
278 portion of the plate. Onycholysis is mild and nail bed hyperkeratosis is absent. NLP  
279 moderate form (B): partial fissuring, longitudinal grooves, distal splitting between 3 and  
280 5 mm. Mottled erythema of the lunula can be roughly observed in the 2<sup>nd</sup> fingernail.  
281 Onycholysis is more marked and nail bed hyperkeratosis can be observed in the thumb.  
282 NLP severe form (C): complete fissuring and splitting more than 5 mm, onycholysis  
283 more than 50%, diffuse erythema of the lunula.

284 Fig.2 – Clinical treatment algorithm according to the number of nails involved, the  
285 severity of the disease and the location of the inflammation. Different shades of blue  
286 indicate the 1<sup>st</sup> to the 3<sup>rd</sup> option selected according to authors' experience (not all  
287 treatments are approved by the regulatory authorities of all countries).

288 Fig.3 – Intralesional matrix and bed injection techniques - *De BERKER*<sup>40</sup> (A): 2  
289 injections in the proximal nail fold, 1 injection per side, starting 2 millimeters proximal to  
290 the cuticle (nail matrix LP); 2 injections under the nail plate starting from the lateral  
291 folds, 1 injection per side (nail bed LP). *RICHERT* (personal data) (B): 3 injections (fan-  
292 like) starting from the median part of the proximal fold to reach the proximal matrix and  
293 its lateral horns (nail matrix LP); 3 injections (fan-like) under the nail plate from the  
294 hyponychium to reach the whole bed (nail bed LP). *GROVER*<sup>41</sup> (C): 1 injection starting  
295 2mm proximal to the proximal nail fold and advancing roughly up to the middle (nail  
296 matrix LP); 1 injection with the needle inserted slightly more medially and advanced  
297 towards the center of the nail bed. If the syringe is in parallel axis to the finger, the risk to  
298 encounter the bone is higher (nail bed LP). [Graphic designer: Florence Richert]

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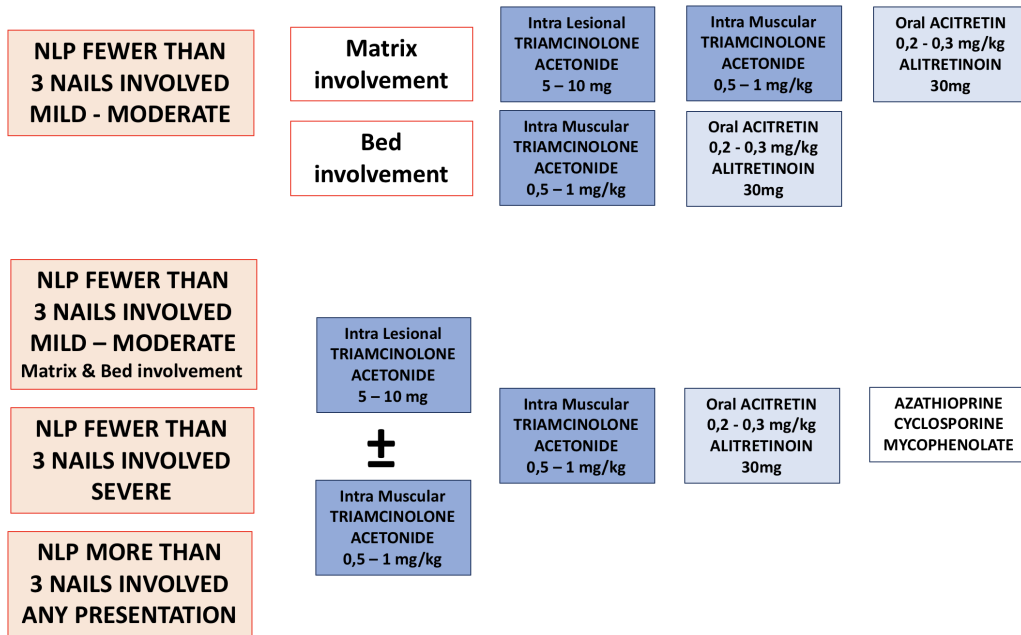
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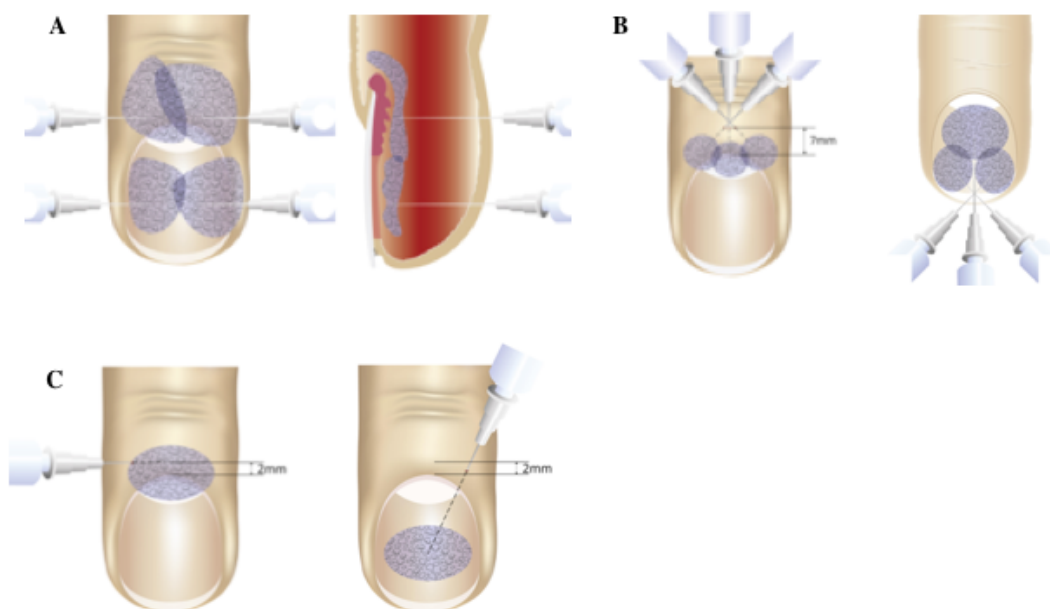
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