

PRESCRIBING PATTERN, TOLERABILITY AND EFFICACY STUDY (4 WEEKS) OF THE NOVEL DRUG "XIAPEX"



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Objectives

Xiapex is a novel drug under observation from the Italian Medicine Agency (AIFA), an innovative and expensive drug. The drug is allowed by law to be given for three times on the same palmar fascia for 4 weeks.

Aim

Xiapex utilization monitoring during a 10 month period of marketing.

Methods or Study Design

From the AIFA database were obtained the eligibility criteria for the Xiapex treatment such as:

- the joint involved in the treatment (*metacarpophalangeal, MP, or proximal interphalangeal, PIP*)
- degree of contracture (*between 20 and 50 for MP; between 15 and 40 for PIP*)
- prior surgical intervention (*only aponeurotomy or fasciotomy*)

Clinical data of 24 patients (P) were available from the doctor as well as data on tolerability and efficacy of the drug after 4 weeks of treatment.

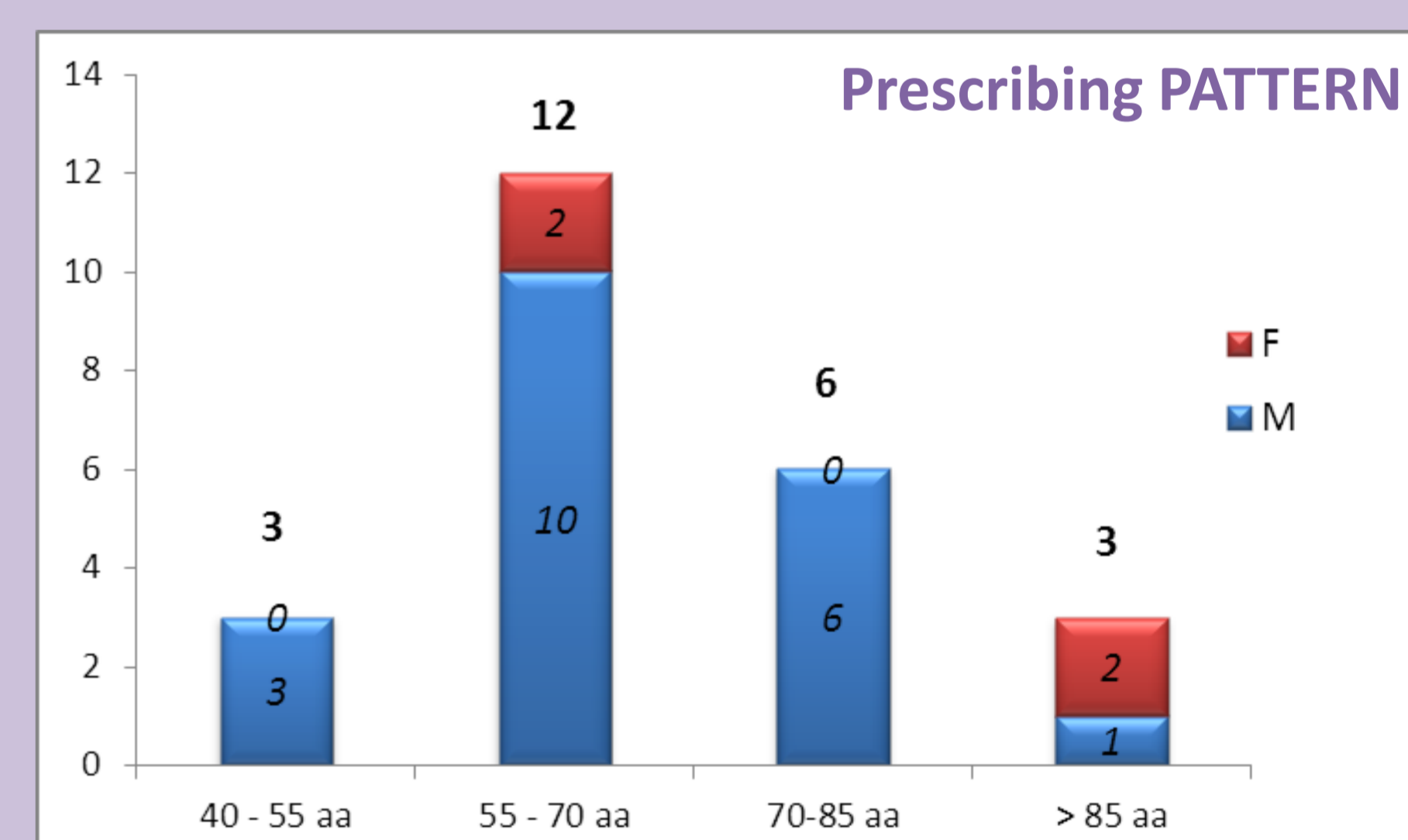
2 Eleggibilità Dati Clinici Eligibility criteria_Clinical dates

Si prega di fare riferimento al RCP di Xiapex

http://www.ema.europa.eu/ema/index.jsp?url=/pages/medicines/human/medicines/002048/human_med_001423.jsp&mid=WC0b01ac058001d124

Xiapex è indicato nel trattamento della contrattura di Dupuytren in pazienti adulti con corda palpabile

O	Diagnosi	Contrattura di Dupuytren con corda palpabile
O	Mano (viene compilato in automatico)	Destro Sinistro
O	Articolazione coinvolta <i>Involved joint</i>	Metacarpofalangee (MP) Interfalangea prossimale (PIP)
E	Grado di gravità	Basso o moderato Alto
E	Contrattura (gradi) (A) <i>Degree of contracture</i>	... controllo: 20° ≤ MP ≤ 50° oppure 15° ≤ PIP ≤ 40°
O	Trattamento chirurgico <i>Surgical intervention</i>	Si No
O	Se sì, indicare quale:	Aponeurotomia <i>Aponeurotomy</i> Aponeurectomia (oppure Fasciectomia) <i>Fasciotomy</i>
O	Indicare il risultato dell'intervento	Lesioni nervose Parziale risoluzione del problema Problemi nella guarigione della ferita Rigidità Recidiva della contrattura di Dupuytren
O	Precedente trattamento corticosteroide	Si No
O	Altri trattamenti già effettuati	...
O	Il paziente presenta inoltre: <i>Concomitant conditions</i>	Diabete mellito <i>Diabetes</i> Alcolismo <i>Alcoholism</i> Tabagismo <i>Tabagism</i> Epilessia <i>Epilepsy</i> Ipercolisterolemia <i>Hypercholesterolemia</i> Cirrosi epatica <i>Cirrhosis</i> Infezioni da HIV <i>HIV infection</i> Nessuna delle condizioni sopra <i>None</i>



Results

PRESCRIBING PATTERN

Age range of P was from 40 to 90 years. Of that 4 were women and 20 men.

CONCOMITANT CONDITIONS

- 19 P not present other disease
- 2 P diabetes
- 2 P hypercholesterolemia
- 1 P tabagism

MAIN ISSUE

22 P had a metacarpophalangeal contracture. In particular:

- 11 P with a contracture score of 30
- 2 P with a score of 35
- 7 P with a score of 40
- 2 P with a score of 50.

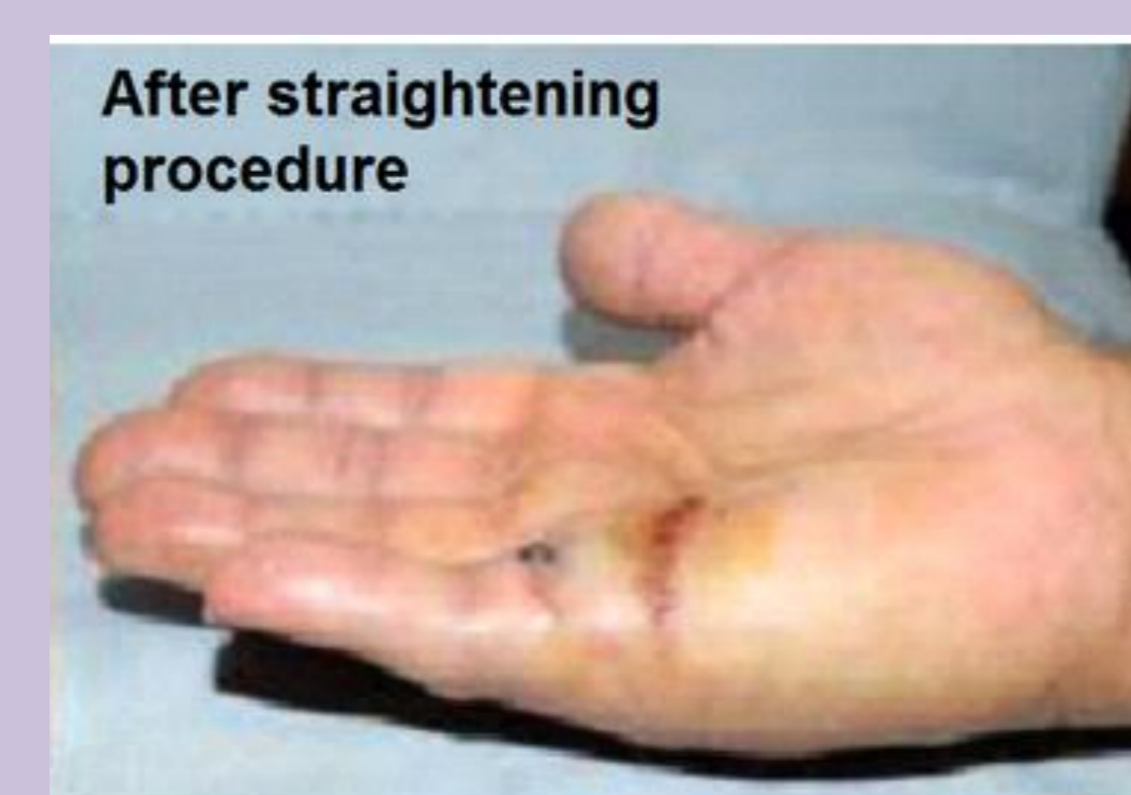
2 P had a proximal interphalangeal contracture. In particular:

- 1 P with a score of 35
- 1 P with a score of 40.

Only 2 P had previous surgical intervention (fasciotomy).

Discussion

All the 24 P treated once was sufficient to resolve the Dupuytren's contracture (specifically the remaining residual delta of muscular contraction was trascurable). Only minor, modest and short side effects were observed such as *skin rash* at the armpit, *light skin abrasions* and *echymosis*.



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