

Post Traumatic sufferings and Tendinopathies of sports people

A new methods for the local pharmacological administration.

Dr. Buselli P, Dr. Spaggiari PG
Azienda Ospedaliera della Provincia di Lodi, Lodi, Italy

Introduction

In the sports practice it is quite common that acute traumatic syndromes and Tendinopathies may compromise the sport performance.

This kind of local problems are commonly treated with various kind of Physical therapies with administration of drugs in either a general way and directly onto the area of the trauma.

All about the preparation of the topical principles and Iontophoresis matters depends on the real possibilities of transdermal delivery of the topical principles.

Needles or systems using pressure introduce problems belonging to the undesired accumulation of the drug in one spot, to its systemic diffusion, to the sanguinities of the act itself with the inescapable lesion on the Dermis.

Due to this, the availability of a Transdermal delivery System able to deliver drug cocktails is of a certain interest.

Materials and methods

Data regarding a group of 37 sports patients have been collected. These patients were affected by either post-Traumatic pathology or tendinopathy. They have been monitored during the therapy time until two weeks after therapy. All the patients responding to the following criteria have been excluded:

- Allergies to the used drugs
- Acute Infections of soft-tissues
- Presence of cartilage from accretion

The protocol included a preliminary clinical evaluation (T.1) repeated at the end of the therapeutic cycle (T.2) and after two weeks from that (T.3).

Data about the VAS (Visual Analogic scale 0 – 10 score) scale patient’s pain perception and data about the local pain perception to a pressure stimulus following the Fisher ‘s pressure Algometry creteria (1 – 6 Kg/cm²) have been collected.

The procedure included the administration of a cocktail of drugs (troxerutin Carbazochrome 1,5 cc, 2% Mepivacaine chlorohydrate, 1cc, Diclofenac sodium 1 mg, 10% Bisodium Calcium edetate 2cc – diluted in 10cc Nacl solution) in 4 consecutive times/day for contusional traumas and the administration of a cocktail of drugs (4% Betamethasone phosphate 1mg, Diclofenac sodium 1 mg, 2% Mepivacaine chlorhyate, 10% Bisodium Calcium edetate 2cc – diluted in 10cc Nacl solution) in 6 times/day in alternative days for Tendinopathies.

To administer the cocktail of drugs the Transderm Ionto System from Mattioli Engineering Italia SpA has been used.

The application is carried out by means of a preliminary controlled microdermabrasion and then the application of a film containing the active principles to deliver .

This film will be transdermally delivered by means of particular electrical pulses.

Results

The total results outline is shown in the table below (**dv1/2** is the difference between the values of t.1 and t.2 evaluations, and , in the same way, between dv2/3 and dv1/3 evaluations).

Pathology	M.F.	Age	vas1 tF.1	vas2 tF.2	dv1/2	dtF.1/2	vas3 tF.3	dv2/3	df2/3	Dv1/3	df1/3				
			P	P	P	P	P	P	P	P	P				
Total	2710	27,57	6,96	1,68	4,65	3,25	< 0,0001	< 0,0001	4,07	3,55	<0,001	ns	< 0,0001	< 0,0001	
			4,89	0,97	0,53	1,59	1,29				1,89	1,48			
Tendinopathies	206	28,19	7,07	1,52	5,07	2,98	< 0,0001	< 0,0001	4,71	3,21	ns	ns	< 0,0001	< 0,0001	
			5,11	0,97	0,53	1,36	1,07				1,74	1,37			
Contusion	7	4	26,73	6,82	2,01	4,59	3,53	< 0,0001	<0,005	3,77	3,98	ns	ns	< 0,0001	< 0,005
			4,73	0,87	0,43	1,50	1,60				1,69	1,67			

The administration of drugs through the Transderm Ionto System has been carried out in a very easy and comfortable way. No problems have been encountered neither during nor after the administration session.

Patients didn’t reported neither uncomfortable feelings nor electrical pulses perceptions.

FOR EDUCATIONAL PURPOSES ONLY

In some subjects some adverse reactions to drugs have been reported, previously not known.

These cases had to stop the treatment and they have been excluded from the final study.

Discussions

The whole clinical parameters variations indicate a statistically significant answer (Avg).

The single groups analysis reduces the statistically total figure as a direct dependency of the observed cases reduction.

The average improvement does not expire with the pharmacological administration but it still lightly improves after 2 weeks from the end of the treatment .

The single groups analysis shows some differences in the average tendency of the recorded clinical data. Particularly the lower answer of the rotulea tendino pathies group of patients has been noticed.

This have to be addressed to the clinical study definition and , in part , to technical aspects that this study introduced and required some modifications to the transdermal delivery head probe .

Conclusions

As a conclusion, this experience confirms that the pharmacological therapy administered by Ultrapeel® Transderm® Ionto System, through microdermabrasion and electrical pulses , appears to be a methodology of a clear clinical interest.

This methodology has been proven to be effective and reducing recovery time and getting to a better acceptability Versus other pharmacological administration means.

The costs involved with this methodology appears to be interesting for both single and reduced number of sessions.

The Transderm® Ionto System has got FDA clearance since December 2003 (N° K032968).

Bibliography

1. Crawford F. Thomson C. Interventions for treating plantar heel pain (Cochrane Review). The Cochrane Library, Issue 2, 2004.
2. Fisher AA Pressure algometry over normal muscles. Standard values, validity and reproducibility of pressure threshold. Pain, 30(1987): 115-126.