TITLE PAGE

Therapeutic results after ultrasound-guided Intratissue Percutaneous Electrolysis (EPI®) in the treatment of Rectus Abdominis-related Groin Pain in Professional Footballers: a pilot study.

Abstract

Background. Rectus Abdominis-related Groin Pain (RAGP) is one of the possible clinical patterns that determine pubalgia. RAGP is one of the typical clinical patterns in footballers and is due to the degeneration/tendinopathy of the distal tendon at the level of the two pubic tubercles. Intratissue Percutaneous Electrolysis (EPI) is a recent technique used in the treatment of tendinopathies.

Aim. The aim was to examine the therapeutic benefits of EPI by contrasting the two basic components that characterize RAGP: painful symptoms and resultant functional deficits.

Design. Consecutive Case Series

Setting. The therapeutic interventions were performed within the facilities of the "Friuli" Stadium, in Udine (Italy), the sporting venue of the Udinese Calcio Spa Football Club.

Population. Eight professional footballers at Udinese Calcio Spa Football Club.

Methods. The footballers underwent ultrasound-guided EPI treatment. No other type of treatment was combined with EPI. Pain was monitored with the Verbal Rating Scale, while functional deficit was monitored using the Patient Specific Functional Scale. The scales implementation took place before treatment, then 24 hours, 1 week, 1 month and 6 months after the end of treatment.

Results. Treatment with EPI produced a complete reduction of pain symptoms in one month and enabled excellent functional recovery for walking and jogging in one week; getting out of bed, running, jumping and kicking within one month from the end of the treatment.

Conclusions. Treatment with ultrasound-guided EPI has shown encouraging clinical results for RAGP. Data are preliminary: considering the limitations of this study more complex study designs are necessary to test the efficacy of the technique.

Clinical Rehabilitation Impact. This study introduces the EPI technique for the first time in the treatment of professional footballers suffering from RAGP. Its future use is proposed as a treatment solution, including complementary to conservative treatment.

Key words: Soccer, Groin Pain, Rectus Abdominis, Tendinopathy, Electrolysis, Ultrasonography

Introduction

Groin Pain (GP), also known as Athletic Pubalgia or Sportsman's Groin is an injury common in the world of football [1-3] but it represents a problem that is, still today, far from being solved. GP is generically defined as a painful syndrome in the pubic/inguinal area [4], which potentially limits sporting performance and in the worst-case scenario forces the footballer to withdraw from playing. This anatomical region is very complex [5-8]. As a consequence of this, identification of the primary etiological cause determining the symptoms is a task that can be complex because many clinical conditions fall within differential diagnosis [4,9-10]. For this reason it is often necessary to use instrumental surveys to detect possible anatomic abnormalities, particularly magnetic resonance imaging [11-14] and ultrasonography [15-16]. In fact there is no agreement in the literature on the definition or diagnostic criteria and a Gold Standard has not been identified. The diagnostic task can be so complex that often the term "Groin Pain" and its synonyms are used inappropriately as a final diagnosis, when they should instead at best describe its symptoms.

Contrary to this tendency, Hölmich [17] defined Rectus Abdominis-related Groin Pain (RAGP) as one of the possible clinical patterns that determine pubalgia. RAGP is one of the typical clinical patterns in footballers and is due to the degeneration/tendinopathy of the distal tendon/enthesis, at the level of the two pubic tubercles. The footballer experiences pain immediately above the pubic symphysis. The painful symptoms negatively affect certain daily activities and especially sporting activities. In this case clinical evaluation is often sufficient to arrive at a diagnosis: RAGP is in fact clinically characterized by pain on palpation of the distal tendon or enthesis at the level of the pubic symphysis and pain on abdominal contraction against resistance [4,17-19]. However, if determining an

RAGP diagnosis tends to be simple, the main problem of how to treat it remains. In the literature there is a dearth of studies that evaluate the effectiveness of specific conservative treatment for RAGP (see reviews [20,21]); basically because it has never been considered as a separate clinical pattern in its own right. RAGP is in fact relatively rare compared with other clinical patterns [17], therefore the lack of specific treatment protocols is not surprising. Discussion concerning the effectiveness of conservative treatment in Groin Pain in general however is open. Conservative treatments generally involve: rest or limitation of activity; manual therapy for restoring the range of motion of the hip and normalisation of muscle stiffness and tone; all active exercises aimed at improving the stabilising capacity of the pelvic muscles (core stability) and recovery of muscular strength [20-26]. Nevertheless, the limits of treatment protocols are, on the one hand, their length and, secondly, the high possibility of recurrence. The duration of treatment may in fact even fluctuate between 13-20 weeks. These time-frames are inconceivable, since a professional footballer's absence from his activities has a significant economic and strategic impact. In addition to this, the recurrence rates are far from negligible. The tendency for the condition to become chronic along with the long recovery times are provoking renewed interest in the search for quicker, more effective therapeutic solutions that also substantially limit the possibility of recurrence.

Intratissue Percutaneous Electrolysis (EPI) is a recent technique used in the treatment of tendinopathies [27-29]. The EPI technique consists of the production of a galvanic current inside the tendon, using an acupuncture applicator. Galvanic current is produced in a solution of salt water through a chemical reaction. Salt (NaCl) and water (H_2O) are decomposed in their chemical constituent elements. They then form new substances such as NaOH. The NaOH is extremely important as it is highly caustic and destroys collagen and mixed substances in the area of the damaged tendon. EPI is a basic technique using a chemical process of non-thermal electrolytic ablation that induces a highly-controlled inflammatory response. When only treating the degenerated tendon tissue, EPI should be combined with the use of ultrasound to identify the structural alteration with absolute precision (ultrasound-guided EPI). Until now, no study has

reported on the effects of treating RAGP with ultrasound-guided EPI. Consequently, the aim of the present study was to examine the therapeutic benefits of ultrasound-guided EPI by contrasting the two basic components that characterize RAGP: painful symptoms and resultant functional deficits. The primary hypotheses of the authors were that treatment with EPI can lead to rapid reduction of the symptoms and recovery of optimal sports performance in a timescale that is acceptable to a professional footballer (no greater than one month from the end of treatment). According to the authors these possible clinical and functional outcomes would be the result of local tissue release induced by the EPI intervention, via the removal of anomalous deposits of collagen (fibrosis) around the tendinous insertion.

Materials and Methods

Subjects

Eight elite professional soccer players (mean ± SD; age 26.8 ± 4.4 years; height 184 ± 8.9 cm; weight 81.6 ± 9.6 kg) from the first team of Udinese Football Club during the seasons 2011-2014 participated in the current study (design: consecutive case series). The footballers were included in the study when a diagnosis of RAGP was confirmed and when the symptoms should have been present for at least 48 hours, where conservative therapy had not led to a substantial improvement. The footballers were excluded from the study when: the diagnosis of RAGP was being strongly debated (difficulty in interpretation of clinical signs); it involved pain on palpation of other structures in the vicinity of the pubic symphysis (inclusion of the adductor longus, the pubic ligament, fibrocartilage disc); there were no signs of degeneration of the tendon/enthesis upon ultrasound examination; other concomitant pathologies were detected (using MRI); the presence of a general or local contraindication to EPI was found [27,29]. The recruitment process initially envisaged clinical evaluation (identification of the primary clinical pattern) followed immediately

by ultrasound evaluation (identification of the degenerated tendinous portion of the Rectus Abdominis on the pubic tubercles). The final part of the assessment involved the registration of VRS and PSFS values. This would be followed by MRI. If the exam confirmed RAGP as the primary disease the footballer was included in the study. All participants were informed of the experimental risk and gave written informed consent. The University Human Research Ethics Committee granted the ethics approval for all of the experimental procedures.

Instrumentation

The ultrasound examination was carried out using a ultrasound GE Logiq S7 expert (GE Healthcare, Milwaukee, WI) with a 50 mm linear footprint matrix probe (5-15 MHz). The EPI technique was applied using a specifically developed medically certified (Directive 93/42/EEC) device (EPI® Advanced Medicine Barcelona, Spain).

Evaluation Protocols

All the soccer players were evaluate before treatment ('pre'); at 24 hours ('post24h'), 1 week ('post1w'), 1 month ('post1m') and 6 months ('post6m') after the end of treatment. An ultrasound examination was carried out to pinpoint the area of degeneration of the distal tendon or of the enthesis of the Rectus Abdominis. In order to document the clinical evolution of RAGP, The Verbal Rating Scale (VRS) was chosen for pain assessment, while the Patient Specific Functional Scale (PSFS) was used for functional evaluation. VRS is a commonly used scale for the assessment of pain in adults. It is an eleven-point numeric pain scale with 0 representing one extreme: "no pain", and 10 representing the other pain extreme: "the worst pain imaginable" [30]. This scale was chosen due to the fact that it is particularly valuable in the follow-up to the pain intensity measurements [31]. VRS values were recorded for: Palpation of the distal tendon/enthesis at the level of the two pubic tubercles (VRSpal); Abdominal contraction against resistance (VRScont). PSFS is an individualized functional outcome scale used to evaluate changes in disability over time [19,32]. PSFS requires

athletes to identify at least three activities that they are having difficulty with or are unable to perform. The athlete rates each activity on a 0 ("unable to perform activity") to 10 ("able to perform activity at same level as before injury or problem") scale. PSFS have been modified by the authors, who selected the activities to be measured, or rather those generally impaired by RAGP. PSFS values were recorded for the following activities: getting out of bed (PSFSbed), walking (PSFSwalk), jogging (PSFSjog), running (PSFSrun), jumping (PSFSjump), kicking (PSFSkick). VRS [31] and PSFS [33] show high test–retest reliability for evaluation of the pain and functional level for chronic diseases/syndromes such as rheumatoid arthritis, low back pain and lateral epicondylitis.

Treatment

The patient was made to lie down in the supine position. Subsequently, the pubic and suprapubic areas were thoroughly disinfected using isopropyl alcohol. For the treatment an EPI® device capable of generating galvanic current was used. The device parameters (intensity and duration of the current) were set at 3 mA for 4 seconds [27,29]. The device was connected to an acupuncture needle (0.25x30mm). At each session, the same operator, who is an expert in the use of ultrasound guided EPI, carried out 3 applications at the level of the tendinous degeneration. The anatomical area to be treated with EPI was precisely identified through the concurrent use of ultrasound (see Figure 1). No other type of treatment was combined with EPI. The number of sessions of EPI for each athlete was ~4 ranged from 2 to 6 sessions. The mean duration (±SD) of the treatment was 18.62±14.72 ranged from 4 to 45 days (median: 13 days). Treatment is considered completed when the player is subjectively satisfied with the therapeutic results and is able to practice his sport activity without symptoms that condition his performance.

Statistical Analysis

Variables are presented as the mean (± SD), and the estimated precision is indicated with 90% confidence limits (CL). In addition to the analyses for statistical significance (i.e., paired t-tests), possible differences between scores or interval times for the same player were analysed (pairwise

comparisons) for practical significance using magnitude-based inferences.[34] The data were log-transformed prior to the analysis to reduce non-uniformity of error. The standardised differences or effect sizes (90% confidence interval) between the scores and interval times were calculated. The threshold values for the Cohen effect size (ES) statistics were: trivial (0.0 – 0.19), small (0.2 – 0.59), moderate (0.6 – 1.1), large (1.2 – 1.9) and very large (> 2.0).[35-36] Probabilities were also calculated to establish whether the true (unknown) differences were lower, similar or higher than the smallest worthwhile difference (0.2 multiplied by the between-subject standard deviation, based on Cohen's effect size principle). The quantitative chances of higher or lower differences were evaluated qualitatively as follows: <1%, almost certainly not; <5%, very unlikely; <25%, unlikely/probably not; 25–75%, possibly/possibly not; >75%, likely/probably; >95%, very likely; >99%, almost certainly.[35-36] A substantial effect was established as >75%. If the likelihood of higher or lower differences was >75%, the true difference was assessed as clear (substantial).[37-38]

Results

Table I summarizes the mean values of VRS and PSFS. By comparing the average values for VRSpalp and VRScont recorded pre-treatment with those recorded at 'post24h', a substantial decrease was observed in the values by 52.51% and 56.88% respectively. It is *almost certain* that the differences between the average values are substantial (see Table II). The percentage differences were calculated as the difference between average values over a given time interval, divided by the average value recorded before treatment. An additional improvement of symptoms was observed at 'post1w' for both tests, with a total reduction of the VRSpalp and VRScont values by 87.17% and 95.78%. The differences between the 'pre' and the 'post1w' values are substantial (*very likely* and *likely* respectively): 96% and 94% that the differences are effectively substantial (see Table II). The average VRS values at 'post1w' were very low but only at 'post1m' all footballers were completely asymptomatic. No substantial differences were recorded between 'post1w', 'post1m' and 'post6m' values for the VRS variables.

As regards the level of functionality, the lowest PSFS values were recorded for PSFSbed, PSFSjump and PSFSkick (see Table I). At 'post24h' the values improved by 116.67%, 141.67% and 200% respectively, with an *almost certain* substantiality of the differences between the values. An additional functional improvement was obtained at 'post1w' for the three tests (moderate ES for PSFSbed and PSFSkick, small for PSFSjump). In this case the substantiality of the differences between 'post24h' and 'post1w' values is *almost certain* for PSFSbed and PSFSkick, *very likely* for PSFSjump (100%, 99% and 97% that the differences are effectively substantial). The maximum level of functional performance was achieved at 'post1m'. PSFSrun, PSFSjog and PSFSwalk were the least compromised activities at the pre stage. At 'post24h', functional recovery of 72.22%, 29.63% and 23.28% respectively was observed: the substantiality of the differences was *very likely* for PSFSrun, *likely* for the other two activities (98%, 93% and 94% that the differences were effectively substantial); an additional functional improvement was obtained between 'post24h' and 'post1w' (small ES for PSFSrun and PSFSjog, moderate ES for PSFSwalk): the footballers had recovered maximum functionality of jogging and walking at 'post1w', PSFSrun in the three subsequent weeks. All footballers had recovered the maximum level of sports performance at 'post1month'. No substantial differences were recorded between 'post1w', 'post1m' and 'post6m' values for the PSFS variables.

Discussion

The aim of the present study was to examine the therapeutic benefits of ultrasound-guided EPI by contrasting the two basic components that characterize RAGP: painful symptoms and resultant functional deficits. The primary hypotheses of the authors were that treatment with EPI can lead to rapid reduction of the symptoms and recovery of optimal sports performance in a timescale that is acceptable to a professional footballer (no greater than one month from the end of treatment). The main findings of this study were that treatment with EPI ensured substantial reduction of the

symptoms, eliminating the symptoms completely in 1 month. It also provided complete functional recovery for walking and jogging in 1 week, for get out of bed, running, jumping and kicking between 1 week and 1 month from the end of treatment.

For both clinical tests, VRSpalp and VRScontr, a substantial improvement of the symptoms (very large effect size) was observed between the pre-treatment and follow-up measurements recorded. Considering that no other type of treatment was combined with EPI (such as rest, NSAID or traditional physical therapy), it is legitimate to believe that the therapeutic effect can possibly be attributed to the EPI intervention. It can definitively be stated that all footballers were almost pain free 1 week after the end of treatment (mean (±SD) values: 1.25±2.12 and 0.38±0.74, respectively) and the proposed clinical tests were completely negative for the subsequent measurements. These data seem to confirm the initial hypothesis according to which EPI intervention can promote a rapid reduction of the symptoms of RAGP. The study design does not however allow for a definitive conclusion to be reached on this. These results, in the hypothetical situation where EPI is confirmed as effectively being the primary therapeutic factor, could be attributed to the direct ablation by EPI [28]. The intervention in fact induces focal tissue release via the removal of fibroses and degenerated components, consequently optimising the biomechanics of tendons, as described in the studies on the therapeutic benefit of EPI in the treatment of patellar tendinopathy [27,29].

PSFSkick, PSFSbed, PSFSjump were found to be the activities most compromised by RAGP. With these activities the footballers reported a substantial functional improvement at the end of treatment (large effect size), more or less sufficient for the footballer to consider the treatment satisfactory. Intuitively, the functional improvements were the consequence of the reduction of the pain symptoms described above and, hypothetically, by the indirect reparative action of EPI. EPI in fact made it possible to optimise the local healing process, especially if there was adequate subsequent mechanical stimulation of the tendon treated [27,29]. Therefore, with the requirement to complete the process, with timescales that tend to be long for tendon tissue, it is possible that substantial

functional recovery would not be achieved immediately. In possible agreement with the above, an increase of performance was also observed between 'post24h' and 'post1w' (small/moderate effect size) while complete recovery of performance was achieved in the three subsequent weeks, confirming the initial hypothesis that elevated levels of sports recovery is possible in short timescales via EPI intervention (treatment lasted 18.62±14.72 days; median: 13 days) and the excellent levels of less than one month from the end of treatment. As regards the other three activities evaluated (PSFSwalk, PSFSjog and PSFSrun) the improvements were quantitatively less consistent, most likely because the functional deficits were not so marked at the beginning of treatment. As regards functional recovery, without a control group, it is not possible to draw definitive conclusions.

In addition to what has been presented, it should be emphasised that none of the players have never suspended their sporting activities (training or match) during the treatment: the latter aspect is certainly important, as it shows how EPI, in addition to being a helpful technique for RAGP, does not impact on the strategic choices of the club.

Treatment with EPI has led to a rapid reduction in symptoms and shorter functional recovery times than those expected by the various Groin Pain conservative treatment protocols: the duration fluctuates between 4-20 weeks [21,35-36]. Considering the review by Jansen et al. [21] regarding treatment of longstanding GP in athletes, abdominis tendinopathy (possibly synonymous with RAGP) was taken into consideration in a single article on the 45 analysed. In this work carried out by Martens et al. [39] (1987) recovery times were 3 months in the first group (treatment: conservative managment; 36% excellent or good results) and 10-14 weeks in the second group 2 (treatment: surgery; 53%-72% excellent results). There is evidence that the methodological differences make for a speculative comparison between the results of this study (which does not consider RAGP as an isolated disease but associated with adductor tendinopathy) and with the others presented in the review (primarily because the diagnoses were different).

In general, the success of EPI treatment for tendinopathies is due to the fact that this technique has been shown to induce significant recovery of the degenerated tissue from a structural point of view, thus optimizing the physiological healing process [27-29].

RAGP is an overuse injury, so the prolonged stress on the structure over time determines the degeneration. In addition to this, the tendinous tissue, compared with muscle tissue, has a low metabolic rate, which corresponds to slow healing [40]. The loss of the tendons' adaptive capacity with respect to external stimuli is therefore an altogether predictable characteristic. Complete healing is, for these reasons, often very difficult to achieve in the short term and consequently creates the preconditions for chronic tendinopathy. It is no coincidence then that almost all symptomatic athletes suffering from GP present with chronic degenerative changes [41].

It is assumed, therefore, that conservative treatment demonstrates such high recurrence rates because it only produces a functional recovery of the degenerated tendon through the reduction of symptoms, but lacks the ability to induce a structural recovery thereof. The lessening of symptoms does not correspond to healing of the degenerated tendon tissue and relapse remains a distinct possibility. This is the typical condition of injuries resulting from overuse, in which the symptoms vary in an unpredictable manner, in relation to time, discounting that conservative treatment may have a significant impact in the long term [42].

EPI however offers the possibility of removing the degenerated parts of the tendon and optimising the healing process in terms of time and recovery quality. This study introduces the EPI technique for the first time in the treatment of professional footballers suffering from RAGP. Its future use is proposed as a treatment solution, including complementary to conservative treatment. It is hoped, therefore, that in the future the therapeutic efficacy of this technique in the treatment of tendinopathy will be confirmed by other studies.

The main limitations of the present study are: simple study design (case series – pilot study); low patient number (only with "isolated RAGP": the inclusion/exclusion criteria were expressly strict); no control group: As the participants were members of the same football club no control group was included. The primary risk was the discovery of the existence of the two groups and the two interventions by the participants. This would have given rise to negative conduct such as leaving or requesting a change of treatment or heavily distorting the results of the proposed treatment (especially in terms of patient reported outcome); no treatment protocol validation (EPI was established recently). In the context of Groin Pain a possible development would be to evaluate the clinical results obtainable with the ultrasound-guided EPI in the treatment of Adductor Longus-related Groin Pain, which is the most frequent clinical pattern in soccer players.

Conclusion

Conclusions. Treatment with ultrasound-guided EPI has shown encouraging clinical results for RAGP. Data are preliminary: considering the limitations of this study (case series with no control group), more complex study designs are necessary to test the efficacy of the technique.

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Titles of tables and figures

Table I. The VRS and PSFS values (mean ± SD)

Table II. Summary statistics for different times evaluation

Fig.1 An author inserts the acupuncture applicator (asterisks) at the distal insertion of the Rectus Abdominis (longitudinal section). Using ultrasound, the needle can be seen and guided so as to reach the precise area to be treated.

Table I. The VRS and PSFS values (mean ± SD)

Variables	*pre*	*post24h*	*post1w*	*post1m*	*post6m*
VRSpal	9.75±0.71	4.63±2	1.25±2.12	0.00±0.00	0.00±0.00
VRScon	9±1.07	3.88±2.53	0.38±0.74	0.00±0.00	0.00±0.00
PSFSbed	3±1.85	6.50±1.41	9.75±0.71	10±0.00	10±0.00
PSFSwalk	7±2.33	8.63±1.60	10±0.00	10±0.00	10±0.00
PSFSjog	6.75±2.12	8.75±1.16	10±0.00	10±0.00	10±0.00
PSFSrun	4.50±2.45	7.75±1.16	9.75±0.71	10±0.00	10±0.00
PSFSjump	3±2.45	7.25±1.58	9.75±0.71	10±0.00	10±0.00
PSFSkick	2.25±1.91	6.75±1.16	9.50±0.93	10±0.00	10±0.00

Table II. Summary statistics for different times evaluation

Variables	pre vs. post24h ES (Magnitude of difference)	*Qualitative assessment*	pre vs. post1w ES (Magnitude of difference)	*Qualitative assessment*	post24h vs. post1w ES (Magnitude of difference)	*Qualitative assessment*
VRSpal	9.36 ± 3.69 (0/0/100)	*Almost Certainly*	14.01 ± 12.05 (4/0/96)	*Very Likely*	3.68 ± 6.61 (11/2/87)	*Likely*
VRScon	7.82±3.36 (0/0/100)	*Almost Certainly*	15.48±16.31 (6/0/94)	*Likely*	7.75±16.31 (10/0/90)	*Likely*
PSFSbed	1.41±0.51 (100/0/0)	*Almost Certainly*	2.14±0.60 (100/0/0)	*Almost Certainly*	0.80±0.25 (100/0/0)	*Almost Certainly*
PSFSwalk	0.57±0.4 (94/5/1)	*Likely*	0.95±0.60 (98/2/0)	*Very Likely*	0.38±0.30 (85/15/0)	*Likely*
PSFSjog	0.73±0.59 (93/6/1)	*Likely*	1.07±0.60 (99/1/0)	*Almost Certainly*	0.34±0.22 (87/13/0)	*Likely*
PSFSrun	0.94±0.53 (98/2/0)	*Very Likely*	1.43±0.66 (100/0/0)	*Almost Certainly*	0.48±0.21 (98/2/0)	*Very Likely*
PSFSjump	1.34±0.67 (99/1/0)	*Almost Certainly*	1.85±0.65 (100/0/0)	*Almost Certainly*	0.49±0.24 (97/3/0)	*Very Likely*
PSFSkick	1.61±0.84 (99/1/0)	*Almost Certainly*	2.45±0.65 (100/0/0)	*Almost Certainly*	0.69±0.31 (99/1/0)	*Almost Certainly*