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UTILITY OF A MULTI-TARGET MEDICINE THAT BIO-REGULATES INFLAMMATION IN TREATMENT OF PSEUDOSCIATICA FOR PIRIFORMIS SYNDROME IN LONG DISTANCE RUNNERS

UTILIDAD DE UN MEDICAMENTO BIORREGULADOR EN EL TRATAMIENTO DE LA PSEUDOCIÁTICA POR UN SÍNDROME DEL PIRIFORME EN CORREDORES DE LARGA DISTANCIA

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SUMMARY

Background: The objective of the study is demonstrate if the inclusion of a bio-regulator drug for inflammation (Traumeel S®) in the medical-manual protocol recommended for the pyramidal syndrome, improves the clinic and shortens the functional recovery process in long distance runners.
Methods: Two groups of patients are studied (31/ 31), applying manual treatment with massage, miofascial liberation, post-isometric stretches and technics of muscular energy; and to the second group, the same protocol and weekly injections of Traumeel S®, in a 10 weeks follow up. The patient's pain is evaluated with four exploratory tests, and the subjective perception in a Visual Analogic Scale (VAS).
Results: 50% of the patients were male with mean age of 42.8 years (CI95% 41.6-44). In patients treated with Traumeel S® we observed: lower proportion of visits with pain (p< 0.0001), and an average of two visits less with pain (14 days) in all the evaluated test. Time until the disappearance of the pain in all the test, was significantly lower: median of survival, 6 weeks (CI95% 5.7-6.3), versus 8 weeks (CI95% 6.8-9.2) in the control group (p< 0.0001). The pain evaluation by the the patient was significantly better in the group treated with Traumeel S® (p<0.0001). No adverse events were observed.
Conclusion: We observe that the treatment with Traumeel S® reduces the time with pain in up to two weeks. Upon diminishing the inflammation in the sacro-iliac articulation, and in its tendinous insertion, we got a quicker resolution of the spasm and therefore of the clinical manifestations.

Key words: Piriformis muscle. Pseudosciatica. Inflammation. Long distance runners.

RESUMEN

Introducción y objetivo: El objetivo del estudio es demostrar si la inclusión de un medicamento biorregulador de la inflamación (Traumeel S®) en el protocolo médico-manual aconsejado para el síndrome piramidal, mejora la clínica y acorta el proceso de recuperación funcional en corredores fondistas.
Material y métodos: Se estudian dos grupos de pacientes (31/31), aplicándose al primero tratamiento manual con masaje, liberación miofascial, estiramientos post-isométricos y técnicas de energía muscular; y al segundo, el mismo protocolo junto a inyecciones semanales de Traumeel S®, en un seguimiento de 10 semanas. Se evalúa el dolor mediante cuatro pruebas exploratorias, y la percepción subjetiva del paciente en una EVA.
Resultados: Se analizó la evolución de 62 pacientes, 50% hombres con edad media de 42,8 años (IC95% 41,6-44). Observamos en los pacientes tratados con Traumeel S®: una proporción menor de visitas con dolor (p<0, 0001), y un promedio de dos visitas menos con dolor (14 días) en todos los test evaluados. El tiempo hasta la desaparición del dolor en todos los test, fue significativamente menor (mediana de supervivencia de 6 semanas (IC95% 5,7-6,3) frente a 8 semanas (IC95% 6,8-9,2) en el grupo control (p<0,0001). La valoración del dolor por el paciente fue significativamente mejor en el grupo tratado con Traumeel S® (p<0, 0001). No se observaron acontecimientos adversos.
Conclusión: Se demuestra que el tratamiento con Traumeel S® reduce el tiempo con dolor en hasta dos semanas. Al disminuir la inflamación en la articulación sacroilíaca, y en su inserción tendinosa conseguimos una resolución más rápida del espasmo y por tanto del cuadro clínico.

Palabras clave: Músculo piriforme. Pseudociática. Medicamento biorregulador. Inflamación. Corredores de larga distancia.

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INTRODUCTION

The piriformis muscle originates in the anterior and lateral aspect of the sacrum, sacrotuberous ligament and sacroiliac joint capsule and is inserted in the upper surface of the greater trochanter with a round tendon. It gets out of the pelvis through the greater sciatic foramen, and if its size is large or it's spasmodic, it fills this gap and may compress the numerous vessels and nerves that go out of the pelvis next to it causing the "piriformis pseudo-sciatica". This muscle's action is mainly external rotation of the hip in neutral or extended position. But it's abductor when the hip is flexed at 90°. In the load movements we need the piriformis muscle to control the vigorous internal rotation of the hip, which is what happens when running, acting as a flywheel and compensating the deceleration when leaning on the ground.

The pyramidal syndrome presents a clinic that is similar to that of the back sciatic pain but the initial pain in hamstring and gluteal area don't usually reach beyond the twin area of the leg or popliteal area, rarely going down the leg and even more to the foot, which distinguishes this clinical setting from a real sciatica.

To explain the pyramidal syndrome etiology three possibilities have been described which, alone or acting simultaneously, would justify the clinical setting. On one hand, the anatomical compression of the sciatic and other nerves and vessels that come out along with it through the greater sciatic foramen, considering that it is stated that the nerve's cross may vary anatomically and occur over, under or through the piriformis muscle[1,2]. A second possibility might be myofascial pain referred by active trigger points within the piriformis muscle that would cause an excessive stress feedback and thus pain[3]. A third cause of pyramidal syndrome may be sacroiliac joint dysfunction or blockage, as it is a component that frequently accompanies it[2,4].

A minimum displacement of the sacroiliac joint could interact with myofascial trigger points and keep the injury[5]. In fact, the mentioned joint shows a high presence of mechanoreceptors[6] and it has been proven that the posterior sacroiliac ligament irritation is a major source of pain throughout the pelvic girdle[7]. In addition, the front rotation of the pelvis moves the contralateral sacrum to the affected piriformis muscle keeping its contracture, and if the mentioned sacroiliac joint dysfunction is not treated we wouldn't be dealing with the real source of the clinical setting and, after a merely symptomatic treatment, there would be recurrences[4].

In the case of recreational long-distance runners, strenuous exercise with rhythm changes and a prevailing tendency of hindfoot pronation and hip internal rotation along with the impact when running on hard surfaces (packed dirt or asphalt) would facilitate a pelvic overuse which can explain their high prevalence in clinical entities such as the ones analized in this study. Especially if, during week, their jobs involve seating during prolonged time (office, car, etc..), a very common situation in our environment.

The hypothesis this study tries to demonstrate is whether it is valid to treat a syndrome with eminently muscular nature by controlling the associated joint inflammation. Thus, a biological inflammation regulator is applied[8,9] to the muscle ends (sacroiliac joint and insertion tendon on the greater trochanter of the femur in the particular case of the piriformis muscle) and the aim will be to see if it implements the classic manual therapy applied exclusively to the muscle.

MATERIALS AND METHODS

Study Design

A retrospective observational study has been made on a sample of 256 patients (187 men and 69 women, all recreational runners with lower back or sciatic pain who, during the years 2008 and 2009, were under a monitoring protocol in our center, to study only those who presented pyramidal syndrome.

A sample of 62 cases was selected maintaining proportionality of gender, and was distributed

into two groups: one that had a bio-regulator treatment and another named control group.

Targeting of the study

The aim of this study is to compare the reduction of pain produced by the pyramidal syndrome between two groups of patients with or without bio-regulator treatment associated to the standard medical treatment during a monitoring period of 10 weeks.

The evaluation is done objectively by exploring four orthopedic tests that measure the presence or absence of pain in the exploration: Freiberg sign, sign Pace, shear test and the Fair test.

As secondary objective the patient's pain perception was evaluated using a visual analog scale (VAS), and at the end of the study the patient valued his satisfaction with the treatment by a VAS[10].

Patient selection criteria

The pathology under study is the pyramidal syndrome in non-professional long distance runners.

The clinical criteria required for selecting patients was:

- Pseudo-sciatic's clinic.
- Significantly positive palpation to pain (higher than or equal to 8 cms. on the VAS) in three points of reference: sacroiliac Fortin point (2), any of the two piriformis trigger points according to Travell and Simons (3) and the trigger point of the insertion into the greater trochanter of the femur (3);
- Five orthopedic tests. Four of them had to be painful during exploration: The Freiberg sign to forced internal rotation in supine position, the Pace sign[11] to resisted abduction and external rotation in sitting, the posterior shear test of the sacroiliac[12] with knee and hip flexion and pressure on the femoral shaft in supine position and Fair test[13] with hip and knee flexion, adduction and internal rotation in supine position. The fifth test, the straight leg raise test to look for the Lasègue sign[14], should not be painful, since the compression produced by the piriformis muscle is of dynamic or active nature and this is a test of passive nature.

Information was collected about the patient's data on the first consultation regarding sex, age and affected side.

Protocolized monitorings are weekly up to a total of 10 weeks, during which an exploration of the four orthopedic tests is performed: Freiberg sign, Pace sign, back shear test and the Fair test. All measurements were taken by the same examiner.

At each visit and before the clinical examination, each patient valued their pain using a visual analog scale (VAS) on a 100 mm line, where the level 100 is "the highest possible pain" and 0 is "no pain at all", the patient valued his pain with a vertical mark[10].

Treatment

The target population (n = 62) was randomly distributed into two proportional groups (control group and study group), consisting each of 31 patients, who received 10 treatment sessions in 10 weeks (1 session per week).

The first group or "control group" was given as therapy a massage on the pelvi-trochanteric muscles and lumbar region, myofascial release with deep strokes from the side of the sacrum to the greater trochanter, post-isometric muscle pyramidal muscle stretching and muscular energy technique, the latter to normalize the sacroiliac dysfunction associated to piramydal syndrome[4,14].

The second group or "study group" was given the same physical therapy treatment as the control group plus, at the end of each weekly session, 4 ml intradermal injections of an inflammation biotherapic modulator (Traumeel S®)[8,9,15,16] on three points of the sacrum lateral border below

the posterior superior iliac spine of the hip bone and on the trigger point of the trochanteric insertion of the piriformis muscle. The procedure is done with a 27Gx1 "0.40x25 mm needle and a double-body syringe of 5 ml., making a subcutaneous wheal with an inclination to the skin plane of 45° and then entering into intradermal level perpendicularly to the mentioned plane.

Therefore, in each of the four referenced points around 1ml of the aforementioned biotherapy is deposited. The choice of injected form of the drug for this clinical setting is crucial to prove the study main hypothesis: Local treatment of muscle origin and insertion can lead to a spasm, and thus pain, decrease in this clinical setting.

The criteria for stopping treatment are the common in clinical practice, if the patient has local or general intolerance to the treatment or decides to suspend it due to other reasons. The selected cases successfully completed all 10 weeks of protocol treatment.

All patients put off their sport activity during the study and were only advised to perform a static and painless self-stretching of the piriformis muscle three times a day, after instructing them and checking its correct practice.

Statistical analysis

We performed a descriptive analysis with frequency distribution for qualitative variables and calculation of usual measurements (arithmetic mean, standard deviation, minimum and maximum, and the 95% confidence interval) for continuous variables. Comparisons between variables were analyzed using the Chi^2 test for proportion comparison or the Wilcoxon test when comparing two periods and the Student t test to compare baseline between treatment groups and sex for the VAS values. The ANOVA mixed factorial (split-plot) test was applied with the Bonferroni or Games Howell corrections for multiple comparisons when comparing the VAS of the treatment groups in the 11 monitoring visits.

The survival analysis of Kaplan Meier as well as the Cox regression analysis were also applied in order to study the pain remission time for each exploratory test. Significance level was set at 0.05. The statistical analysis software was SPSS 14.0.

RESULTS

Complete data from 62 patients were obtained for all selected variables for the study, during the 10 weeks of retrospective monitoring, so there was no deviation from the study plan.

Demographics

50% of the patients were male (31/62). The average age differed significantly between men and women ($p < 0.0001$), aged 45 (95% CI 43.1-46.8) and 40.7 years (CI 95% 39.4-42) respectively, with an age difference of 4,2 years (95% CI 2-6.4) being lower in women. Selected patients were between 37 and 53 years old (42.8 on average).

The most frequently affected side is the right (47/62) in 75.8 % of cases. However we found differences between men and women, being more frequently affected the right side in men (29/31, $p=0.001$), whereas in women there is not such a clear predisposition (18/31).

Homogeneity in baseline VAS and exploratory tests

Basal homogeneity was studied on those variables that could affect the response to treatment. The two study groups were homogeneous in age, both men and women.

The patient's VAS value for pain at the beginning of the treatment makes no difference between men and women nor between both treatment groups.

All patients showed pain in the four evaluated orthopedic tests at the initial examination.

Monitoring results of the 10-week exploratory tests

Results were evaluated in three ways, first with the evaluation of the proportion of monitoring

time during which patients felt pain. Secondly we measured on how many examinations, on average, patients experience pain during the monitoring.

Finally, we measured how long it takes the patient to feel pain in every performed test, and in all tests, using survival analysis until each test and all together were negative.

Proportion of time under pain

We evaluated the proportion of monitoring examinations on which patients suffered pain out of a total of 341 visits in each treatment group, resulting from multiplying 31 patients in each group by 11 visits including the initial visit.

Since all patients completed the 10 visits it was not necessary to perform a weighting of this ratio per patient. We observed a higher proportion of time under pain in the control group patients, compared to the group treated with Traumeel S®, in all evaluated tests the absolute risk reduction is: in the treatment group by 8.5% of the time with less pain in the sign of Freiberg, 22.8% in the sign of Pace, 21.1% in the shear test, and 17.9% in the Fair test (Table 1).

Number of examinations under pain weighted per patient

We observed statistically significant differences between the two treatment groups, in the number of examinations on which patients had pain on all performed explorations. The number of examinations under pain turned out to be significantly lower in all patients in the group treated with Traumeel S®, an average of two fewer examinations with pain during the evaluation of all tests, that is, up to 14 fewer days with pain (Table 2).

Time to pain remission

We evaluated the time to pain remission in each of the four tests and on the whole, by means of the Kaplan Meier survival analysis and the comparison of survival curves between the two treatment groups by the Lorg Rank (Mantel-Cox) test. We conducted a Cox regression analysis to evaluate the age and sex covariates of the patients together with the treatment group. The results for these two variables evidence that they have no influence on the response to treatment in a statistically significant way.

As described in Table 3, significant differences were observed in the survival curves of all tests

TABLE 1.
Proportion of time with pain in the four orthopedic tests

Orthopedic test	Control		Traumeel		
	Examinations	%	Examinations	%	p
Freiberg	90	26.4%	61	17.9%	P=0.007
Pace	172	50.4%	94	27.6%	P<0.0001
Shear	240	70.4%	168	49.3%	P<0.0001
Fair	257	75.4%	196	57.5%	P<0.0001
Total examinations	341	100%	341	100%	

TABLE 2.
Number of examinations with pain in the four orthopedic tests

Orthopedic test	Control		Traumeel		
	Examinations	IC95%	Examinations	IC95%	p
Freiberg	2.9	2.1-3.7	1.96	1.7-2.3	P=0.026
Pace	5.5	4.5-6.6	3	2.5-3.5	P<0.0001
Shear	7.7	6.9-8.6	5.4	4.8-6	P<0.0001
Fair	8.3	7.6-9	6.3	5.8-6.9	P<0.0001

except the Freiberg test. Survival medians in both groups and their respective confidence intervals of 95% are described. The results of the multivariate analysis were significant for treatment group in the Pace test (p = 0.01), shear test (p = 0.0001), Fair test (p = 0.002) and for all tests combined (p = 0.002). Freiberg test did not differ between the two groups of patients.

Figure 1 shows the survival pain curve evaluated in all orthopedic tests.

Pain VAS

We performed a variance analysis for two factors (moment of evaluation and treatment) and repeated measures on a split-plot type factor. We found that in both treatment groups the patient's pain is significantly reduced from the initial visit to 10 monitoring weeks after (p <0.0001). The difference between the two treatment groups turns statistically significant after two weeks of monitoring (p = 0.015) taking as a starting point similar values in the basal visit in both groups (p = 0.213). The difference between both groups reaches its peak at six weeks of monitoring, up to 17.8 mm (95% CI 10.2-25.4) being the value of pain always higher in the control group. Figure 2 depicts the evolution of the value of pain evaluated by the patient in the two treatment groups.

Adverse reactions and withdrawals

No patient abandoned the treatment and the degree of satisfaction was high in both groups (93% of the patients in the control group and 96% in the study group described it as "very good" or "good") (Table 4). It should be emphasized, as well, that no patients in the study group had any adverse reaction to administered medication.

DISCUSSION

Although some authors speak about a low prevalence and incidence of the pyramidal syndrome, the truth is that in sports and especially long distance runners is not uncommon. It is well demonstrated in the study given that 62 of the 256 runners who came to our clinic with sciatic, lumbar or pseudo-sciatic symptoms presented it. Therefore, in the studied group, it would be interesting consider it not as an exclusion diagnosis but as an additional possible cause of pelvic pain.

In the treatment of pyramidal syndrome it is crucial to keep in mind the overlapping etiology that leads to maintained muscle spasm of the piriformis. Many authors have advocated the classic muscle infiltration with local anesthetic and corticosteroids as a solution, which appears to be more effective if it's guided and in the perisciatic[17]. Other authors firmly prefer the injection of botulinum toxin[11].

There are also defenders of dry needling of the muscle of using only local anesthetic but in the two specific trigger points[3]. And in the approach to infiltration, the proposed method was infiltration with corticosteroids of the piriformis muscle near the lateral border of the sacrum[13]. It should be noted that all previous treatments aim to achieve infiltration or direct needling of the muscle fibers, with substances or procedures that are not without risk. As first line treatment of the clinical setting, stretching of the muscle has

TABLE 3. Time to disappearance of pain. Survival median by number of examinations

Orthopedic test	Control		Traumeel		Log Rank
	Median	IC95%	Median	IC95%	(Mantel-Cox)
Freiberg	2.9	2.1-3.7	1.96	1.7-2.3	P=0.026
Pace	5.5	4.5-6.6	3	2.5-3.5	P<0.0001
Shear	7.7	6.9-8.6	5.4	4.8-6	P<0.0001
Fair	8.3	7.6-9	6.3	5.8-6.9	P<0.0001
(All tests)	8	6.8-9.2	6	5.7-6.3	p<0.0001

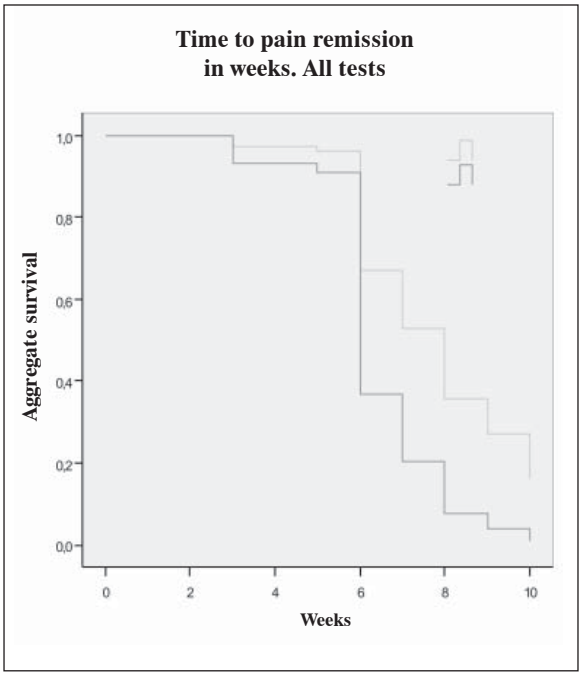


FIGURE 1. Cumulative survival curve for the disappearance of pain in all tests, by treatment group

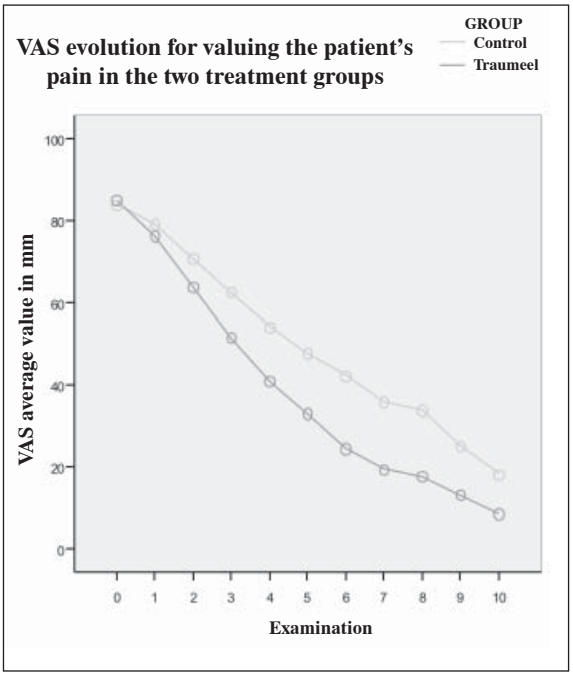


FIGURE 2. Evolution of the VAS of pain appreciated by the patient in both treatment groups

Degree of satisfaction	Control		Traumeel	
	N	%	N	%
Very good (9-10)	27	87	29	93.6
Good (7-8)	2	6.5	1	3.2
Average (5-6)	2	6.5	1	3.2
Bad (3-4)	0	0	0	0
Very bad (0-2)	0	0	0	0
Total	31	100	31	100

TABLE 4.
Patient's degree of satisfaction with treatment ("Score of 0 to 10")

proven to be very effective, in the field of physical therapy, being its effect apparently increased with the simultaneous application of coolant spray (fluoromethane, ethyl chloride) or by using ice, in order to neutralize more effectively the trigger points[3].

Massage, myofascial relaxation techniques and stretching, initially smooth and analytically on the fibers affected then extended throughout the gluteal muscles, have been well described for years and seem to be effective if applied correctly and without pain in order not to generate more spasm[19,20]. To approach a possible dysfunctional origin of the sacroiliac joint some osteopathic techniques have been described, such as strain-counterstrain of Jones, or Mitchell muscle energy techniques, being more rare the application of joint mobilization with impulse or thrust[16]. Finally, surgery is reserved for cases that are impossible to revert by any of these treatment methods and may, most likely, correspond to isolated entrapment etiologies without sacroiliac influence myofascial taut bands that could cause a feedback in the clinical setting from its trigger point[1].

Conservative physical therapy appears to be effective (27 of 31 improved in 10 sessions, in the control group) and proves that it should be the first-line treatment in this syndrome. Likewise, this conservative treatment could be improved by adding injections of a bio-regulator drug (Traumeel S®) to decrease inflammation in the sacroiliac area and trochanter muscle, as it has been demonstrated in this study (29 of 31 already had clear improvement after 8 sessions in the study group).

It is also possible that, apart from acting on the muscular component, which is already done here with manual medical techniques, in the therapeutic approach of this syndrome may be crucial to take care of the inflammation by quieting the sacroiliac mechanoreceptors and the tendon receptors to prevent the muscular spasm from persisting, thus originating new recurrences. The physiological mechanism that justifies it is the medullar facilitation that stops feeding the spasm by cancelling the aberrant gamma efferents. This is especially important if strenuous efforts continue as it happens in sports, even the recreational type. Further research is required to demonstrate the results of our study in a double blind clinical study, to achieve the maximum level of scientific evidence.

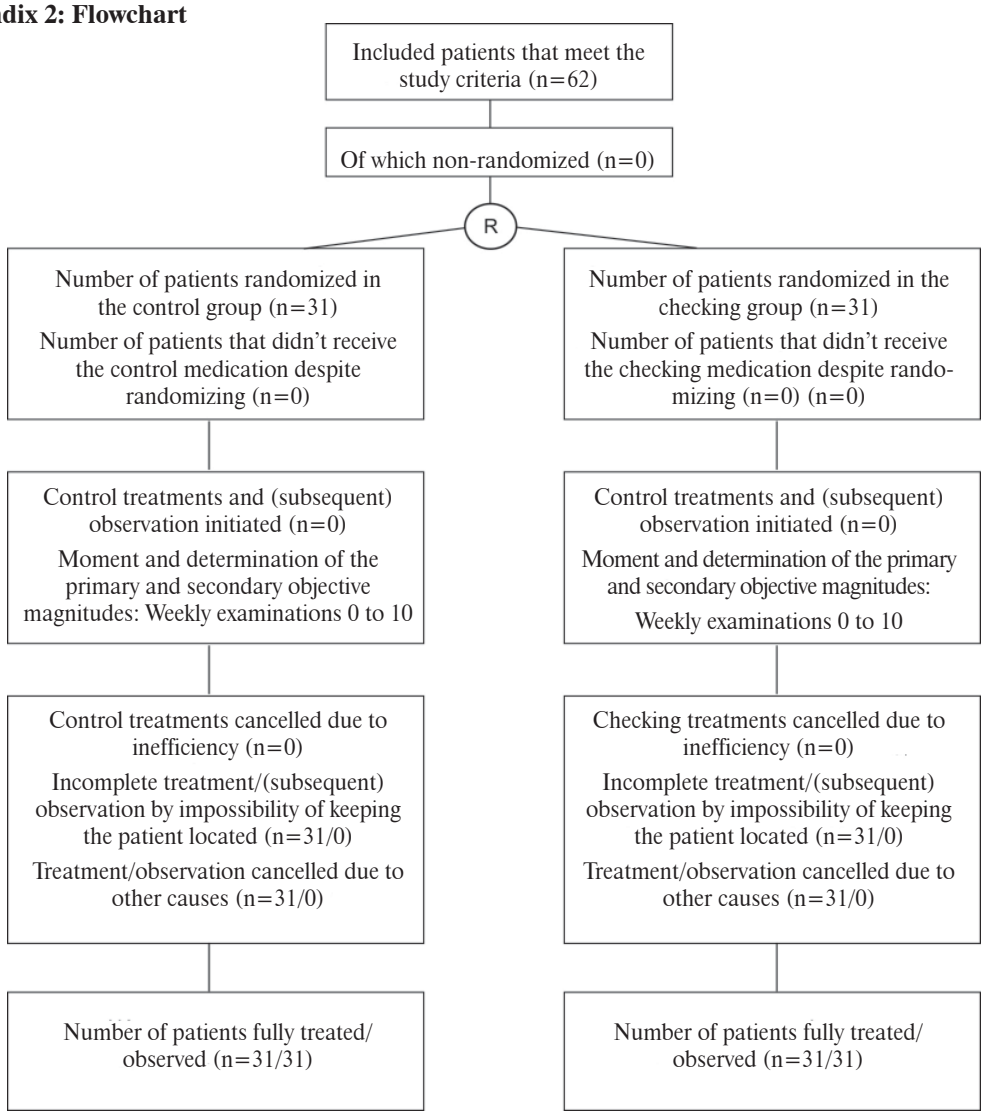
CONCLUSIONS

- **P**yramidal syndrome is not as uncommon in recreational or popular long distance runners as in the rest of the population.
- The treatment chosen in the first place is the conservative one, being the medical manual approach very effective.
- The aforementioned conservative treatment has been significantly improved with the application of injections of a multi-target medicine that bio-regulates inflammation.
- The use of this biotherapy had as important advantage the absence of adverse reactions, compared to the well-known ones presented on NSAIDs.

Appendix 1: Traumeel S® components

Extract source	Volume in each vial (2,2 ml.)
Arnica montana	2.2×10^{-2} µl
Calendula officinalis	2.2×10^{-2} µl
Achillea millefolium	2.2×10^{-3} µl
Chamomilla recutita	2.2×10^{-3} µl
Symphytum officinale	2.2×10^{-6} µl
Atropa belladona	2.2×10^{-2} µl
Aconitum napellus	1.3×10^{-2} µl
Bellis perennis	1.1×10^{-2} µl
Hypericum perforatum	6.6×10^{-3} µl
Echinacea angustifolia	5.5×10^{-3} µl
Echinacea purpurea	5.5×10^{-3} µl
Hamamelis virginiana	2.2×10^{-2} µl
Mercurius solubilis	1.1×10^{-6} µl
Hepar sulfuris	2.2×10^{-6} µl

Appendix 2: Flowchart



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