



Cryoultrasound therapy in the treatment of chronic plantar fasciitis with heel spurs. A randomized controlled clinical study

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Background. Plantar fasciitis is one of the most common causes of pain in the inferior heel and is very frequent in some running sports. It affects up to 10% of general population and accounts for 11% to 15% of all foot pain symptomatology. Several treatments have been suggested, but there is no evidence supporting a specific conservative management strategy.

Aim. Evaluation of the efficacy of combined cryoultrasound therapy on chronic plantar fasciitis with heel spurs resistant to pharmacological and instrumental therapies.

Design. Single-blind randomized clinical trial.

Population. 102 consecutive patients affected by chronic plantar fasciitis with painful symptomatology for at least 6 months, intensity of pain higher than 5 on the VAS score, presence of heel spurs, use of plantar orthoses and ineffectiveness of previous therapies.

Methods. The patients were randomized into two groups: Group A treated with cryoultrasound therapy and Group B with cryotherapy. Our protocol was based on 10 daily treatments, lasting 20 minutes. Each participant was evaluated using VAS score before (T0) the treatment and 3 months (T1), 12 months (T2) and 18 months (T3) after. Effectiveness index was calculated from T1 to T3.

Results. Both treatments have been found effective. The difference in pain intensity on the VAS scale between the two groups at T2 was 4.35 points in favor of Group A (IC 95% 3.75; 4.95; P<0.001), reaching the primary end point. The difference in pain intensity on the VAS scale between the two groups at T1, T2 and T3 was 3.00, 4.35 and 4.81 respectively, showing a statistically significant difference between VAS aver-

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age scores at all follow-ups in favor of Group A. Scores of at least 66% at the effectiveness index were only achieved in Group A (P values <0.001).

Conclusion. Cryoultrasound therapy could be an efficient treatment option for chronic plantar fasciitis.

Clinical Rehabilitation Impact. Cryoultrasound therapy promises an effective and long-lasting clinical improvement in patients with chronic plantar fasciitis, granted its high therapeutic efficiency, patients' satisfaction, its limited cost and its short and repeatable protocol of use.

KEY WORDS: Fasciitis, plantar - Heel spur - Musculoskeletal diseases - Cryotherapy - Ultrasonic therapy.

Plantar fasciitis is one of the most common causes of pain in the sole of the foot and the inferior heel.¹ On an annual basis it affects more than 2 million persons in the USA alone.²

It is often characterized by severe pain when taking the first step in the morning. This affects up to 10% of general population,³ and it is estimated to account for 11% to 15% of all foot symptomatology.^{4, 5} This disease is very common in sportsmen and professional athletes, and affects in particular runners (accounting for nearly 10% of total injuries),

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basketball, soccer, football and rugby players and other athletes, who practice sports in which the lower limbs are heavily used.⁵⁻⁷

Plantar fasciitis is a degenerative condition caused by repetitive partial tearing of the plantar fascia with associated chronic inflammation,⁷ which leads up to the onset of pain and functional changes in gait.⁸⁻¹⁰ The anatomical shortening causes mechanical stimulation, leads to chronic bone traction and the ensuing development of bony plantar heel spurs.^{3, 8} Despite their high incidence in this disease, heel spurs may not be directly associated with heel pain¹¹ and have no negative prognostic significance.^{12, 13}

The etiology of plantar fasciitis remains uncertain and is probably multifactorial.¹⁴ Several risk-factors such as obesity, occupations that require prolonged standings, traumas, improper shoes, anatomic and structural abnormalities, foot over-pronation and aberrant foot biomechanics (*e.g.*, pes planus, pes cavus, shortening of the Achilles tendon), reduced ankle dorsiflexion and age are all closely related to the onset of this disease.^{4, 13-16}

In runners, its onset appears to be associated with overuse, incorrect or unregulated training and improper or excessively worn footwear.^{3, 17} When pain occurs in sedentary adults, it is often related to poor intrinsic muscle strength and poor force attenuation, secondary to an acquired pes planus, and aggravated by a decrease in the body's healing capacity.^{2, 3, 17, 18}

Informing the patient about this pathology should be the starting point of the treatment: complete rest is needed until full recovery, restoration of a correct gait function and pain is relieved.^{19, 20} In order to achieve this, several physical and rehabilitative treatments may be used: conservative care, such as electrical modalities (*e.g.*, TENS, TECAR therapy), taping, stretching, soft tissue therapy/massage, therapeutic ultrasound, laser therapy, cryotherapy, magnetotherapy, night splints, orthotics; injections and medications (corticosteroids, anti-inflammatory drugs and NSAIDs, mesotherapy); extracorporeal shock wave therapy.^{7, 15, 20, 21}

The self-limiting nature of this disorder should be taken into account when choosing the most suitable management strategy.⁵ Plantar fasciitis will usually respond to conservative treatments,⁷ even though only a few high quality, randomized, controlled trials support the efficacy of the aforementioned therapies.^{5, 21, 22}

The practical guideline developed by the American College of Foot and Ankle Surgeons states that the most reasonable approach is to start with patient-directed, low risk and minimal cost intervention, such as regular stretching of calf muscles and plantar fascia, soft tissue massage, avoidance of barefoot walking and flat shoes, use of plantar orthoses and heel cushions, and limitation of prolonged physical activities.¹ The use of non-steroidal anti-inflammatory drugs may be reasonable in the initial treatment of the acute phase and corticosteroid injections may provide short-term relief.^{1, 5} More expensive and invasive treatments may be a second-line option for those patients who have experienced no improvement. Surgery should be reserved to patients for which conservative measures have previously failed.^{1, 5}

A further possible treating option is the use of therapeutic ultrasound. Such therapy exerts an analgesic and anti-inflammatory effect and is one of the most advised physiotherapeutic treatments for plantar fasciitis, when in association with regular stretching exercises.^{3, 8}

Recently, cryoultrasound therapy has been tested for musculoskeletal and musculotendinous disorders. This new technology combines the benefits of therapeutic ultrasound with those of cryotherapy.^{23, 24} This therapy relies on the synergy between these two different techniques, which strengthen each other, avoiding possible complications caused by the thermal heating effect of the ultrasounds and improving the mechanical and biological therapeutic effects of ultrasound therapy.²⁴

The aim of this randomized and controlled single-blind trial with active control group is to evaluate the clinical efficacy of cryoultrasound therapy, in comparison to cryotherapy alone, in patients affected by chronic plantar fasciitis with heel spurs, resistant to conservative therapies. Our null hypothesis was that cryoultrasound therapy and cryotherapy alone have identical clinical efficacy after the 12-month follow-up on plantar fasciitis patients, in terms of pain reduction and patient's satisfaction.

Materials and methods

This single-blind RCT enrolled 102 consecutive patients affected by chronic plantar fasciitis.

The patients were informed in detail with an

Characteristics		Group A	Group B	P value (95%; CI)
Patients, N.		42	42	
Age, mean±SD, (range), years		54.7±9.9 (38-75)	54.3±8.7 (40-72)	0.85 (-3.7; 4.5)
Gender, N.	Male	24	26	
	Female	18	16	
Side, N.	Right	22	23	
	Left	20	19	
VAS, mean±SD, (range), cm		7.6±1.4	7.3±1.2	0.30 (-0.3; 0.8)

CI: confidence interval; N.: number; SD: standard deviation; VAS: visual analogue scale.

At the end of the treatment, patients were advised to continue using plantar orthoses, to avoid sports, long walks and intense physical activities for 12 months at least.



Figure 1.—Cryoultrasound treatment.

Outcomes and follow-up

Symptoms of all patients were evaluated before (T0) the treatment and 3 months (T1), 12 months (T2) and 18 months (T3) after the treatment by the same physician, who was not aware of what group each patient belonged to.

The self-assessment of the level of pain was recorded on the 10 cm horizontal VAS scale, with 0 cm corresponding to “no pain” and 10 cm corresponding to “the worst pain possible”. The VAS scale has proven a reliable and sensitive scale for pain and has been widely used in clinical studies.²⁵⁻²⁷

From T1 to T3 the effectiveness index was calculated and analyzed: (VAS score at T0 - VAS score at follow-up/VAS score at T0 x 100).²⁴

This index allowed us to classify the results at 3, 12 and 18 months after the treatment in:

- not improved;
- slightly improved (effectiveness index from 1% to 40%);

- improved (index between 41-65%);
- significantly improved (66% to 85%);
- recovered (86% to 100%).

Statistical analysis

The primary end point was defined as the difference of 2.5 points between the Group A and the Group B in the intensity of pain reported by the patient and recorded on the VAS scale 12 months after the end of the treatment. The first secondary end point was defined as the difference between the two groups in the intensity of pain reported by the patient and recorded on the VAS scale 3, 12 and 18 months post treatment. The second secondary end point was defined as the difference between groups in the percentage of patients who achieved a score of at least 66% at the effectiveness index (significantly improved + recovered) 3, 12 and 18 months after the treatment.

The sample size calculation is based on the primary endpoint, 29 patients per group were needed to detect the difference of 2.5 points in the VAS score, an estimated standard deviation of 2.5, a level of significance of 5% and a power of 98%. Assuming a drop-out rate of 15%, at least 33 patients per group were required. The characteristics of the patients were described using the average and the standard deviation for continuous variables and by percentage for categorical variables. The continuous variables were examined to confirm normal distribution. The difference between and within the groups was analyzed using the parametric Student's t test for independent data and paired data, respectively. The Fisher's Exact test was performed to compare the percentages of patients who achieved a score of at least 66% at the effectiveness index in the Group A with those in the Group B 3, 12 and 18 months after the treatment. All analyses were performed on the basis of the principle of the intention to treat. A P value <0.05 was considered significant. The confidence interval (CI) at 95% was also calculated. All analyses were performed with SPSS software for Windows (version 20.0, SPSS, Chicago, IL, USA).

Results

We noticed that the treatment used in our study had no side effects nor complications and we also had a high patients' compliance.

Four patients were lost at follow-up after 18

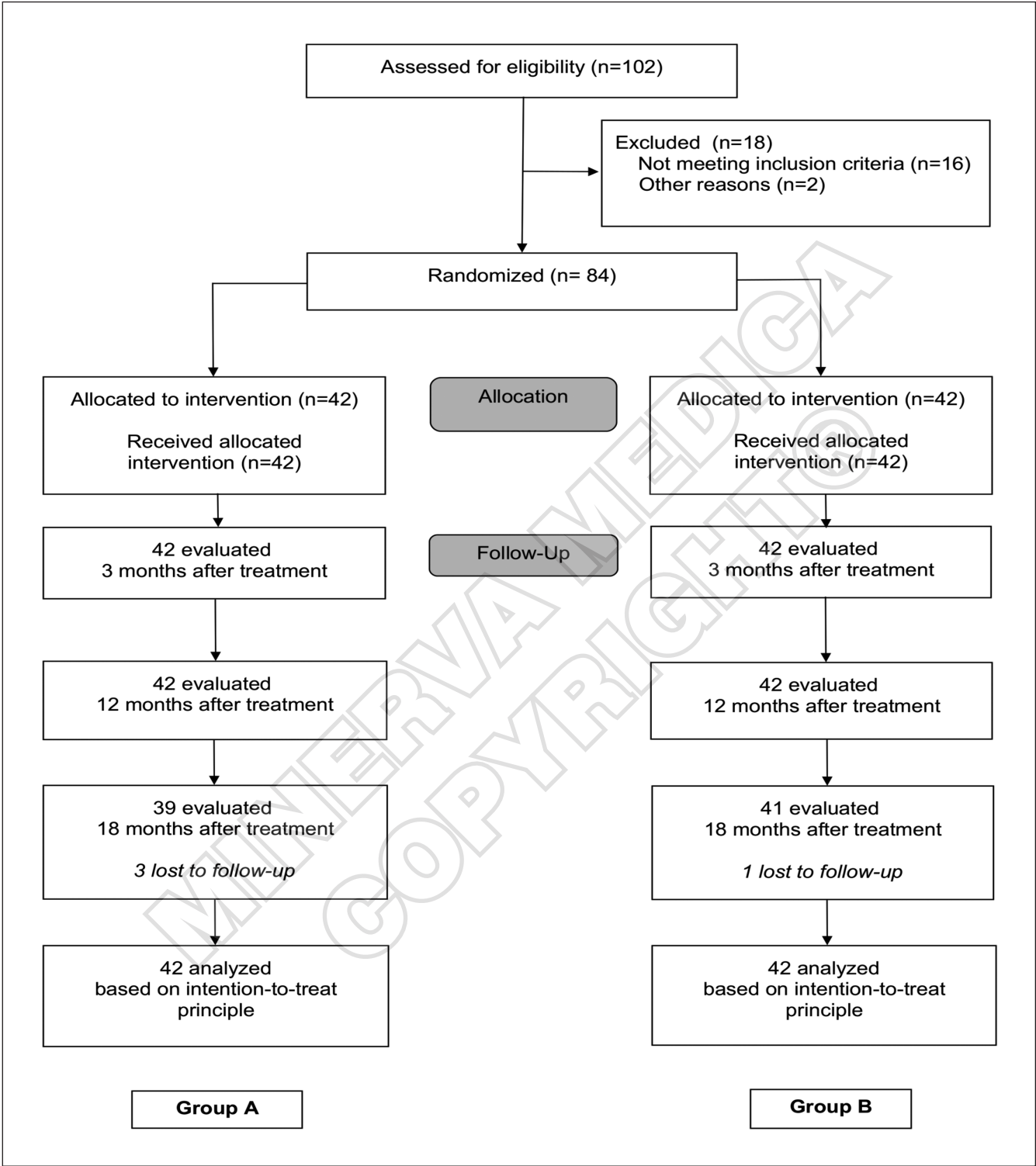


Figure 2.—Consort flow diagram.

TABLE II.—Mean VAS score at baseline and 3, 12, 18 months after the end of treatment in both groups.

	Baseline	3 months (T1)			12 months (T2)			18 months (T3)		
	Mean±SD	Mean±SD	Δ ^w (95%CI)	P value	Mean±SD	Δ ^w (95%CI)	P value	Mean±SD	Δ ^w (95%CI)	P value
Group A	7.57±1.36	3.26±2.3	4.31 (3.64 to 4.97)	<0.001	2.17±1.77	1.09 (0.70 to 1.49)	<0.001	1.57±2.06	0.60 (0.22 to 0.97)	0.002
Group B	7.29±1.15	6.26±1.06	1.03 (0.71 to 1.33)	<0.001	6.52±0.83	-0.26 (-0.47 to -0.06)	0.014	6.38±0.94	0.14 (-0.05 to 0.33)	0.135
Δ ^B (95%CI)	0.28 (-0.26 to 0.83)	3.00 (2.29 to 3.70)			4.35 (3.75 to 4.95)			4.81 (4.11 to 5.50)		
P value	0.303	<0.001			<0.001			<0.001		

VAS: visual analogue scale; SD: standard deviation; Δ^w: within-group difference; CI: confidence interval; Δ^B: between-group difference.

months, 3 in the Group A, one in the Group B (Figure 2). However, on the basis of the intention-to-treat, the data for these 4 patients were included in our analysis. Both treatments have been found effective (Table II).

Main outcome measure

The difference in pain intensity recorded on the VAS scale between the two groups 12 months after the treatment was 4.35 points (95% CI 3.75; 4.95; P<0.001), reaching the primary end point. This difference was in favor of Group A.

The VAS average values at baseline and the differences between and within groups at various follow-ups after the end of the treatment are shown in Table II.

Secondary outcome measure

Considering the first secondary end point, the difference in pain intensity recorded on the VAS scale between the two groups at 3, 12 and 18 months after the treatment was 3.00, 4.35 and 4.81, respectively. The results showed a statistically significant difference between average scores of the VAS of the two groups at all follow-up time points in favor of Group A (Table II).

Considering the second secondary end point, scores of at least 66% at the effectiveness index were only achieved in the Group A in the follow-ups at 3, 12 and 18 months. Significant differences between the two groups were observed at all follow-up time points in favor of the Group A (all P values <0.001) (Table III).

TABLE III.—Results of effectiveness index at 3, 12, 18 month follow-up in both groups.

Effectiveness Index, %	Group A	Group B	P value ^a
3 month follow-up			
Not improved	2.4%	26.2%	
Slightly improved	23.9%	71.4%	
Improved	30.9%	2.4%	
Significantly improved	30.9%	—	<0.001
Recovered	11.9%	—	
12 month follow-up			
Not improved	2.4%	35.7%	
Slightly improved	4.8%	64.3%	
Improved	16.6%	—	
Significantly improved	59.5%	—	<0.001
Recovered	16.7%	—	
18 month follow-up			
Not improved	4.8%	23.9%	
Slightly improved	4.8%	76.1%	
Improved	4.8%	—	
Significantly improved	38.1%	—	<0.001
Recovered	47.5%	—	

^a Fisher's Exact test.

Discussion

Plantar fasciitis leads to a significant disability, presents frequent relapses and a long recovery time, especially in athletes.^{1, 2, 5, 8, 18, 19, 28}

Martin *et al.*¹⁵ and Crawford and Thomson²¹ have shown a variable success rate for nonsurgical and conservative treatments.^{1, 5, 15, 21} The clinical outcome for most patients is typically favorable^{1, 5} and about 90% of patients is successfully treated with conserv-

ative and nonsurgical measures within 1 year.^{1, 5, 7, 19, 29} Only 5% of patients, presenting chronic and recurrent pain, is treated surgically.^{1, 5, 15, 19, 21}

Despite evidence of the effectiveness of therapeutic ultrasound being limited by the relative lack of prospective studies,^{5, 16, 30-32} it is currently often used with benefit in the treatment of plantar fasciitis (Speed; D'Andréa Greve *et al.*).^{7, 8, 22, 33, 34} The studies by Zanon and Imamura demonstrated its success in association with regular stretching exercises,^{8, 35, 36} Dyson *et al.*,³⁷ Byl *et al.*,³⁸ and Binder *et al.*,³⁹ in the tissue repair and soft tissue lesions treatment, Ebenbicher *et al.*⁴⁰ in calcific tendonitis therapy and Robertson-Baker⁴¹ and van der Windt *et al.*⁴² for musculoskeletal disorders.

Cryotherapy is generally considered to be a basic component of most injury management strategies.⁴³ A review by Bleakley *et al.*⁴⁴ proved the effectiveness of cryotherapy in reducing edema and short-term pain and the study of Knobloch *et al.* also demonstrated its benefits on tendonitis.⁴⁵

Some new researches have shown that the association of cryotherapy and therapeutic ultrasound offers advantages in comparison to CO₂ laser therapy or TECAR therapy in treatment of tendon injuries and musculoskeletal diseases.^{23, 24}

This controlled and randomized study was performed to compare the therapeutic efficacy of combined cryoultrasound therapy and cryotherapy in patients affected by chronic plantar fasciitis with heel spurs.

In order to avoid any bias, our selected patients used insoles regularly and presented heel spurs, as their absence could have been a confounding factor in the data analysis, because of their high incidence in this pathology.^{11, 12}

Both treatments improved pain perception and showed a statistically significant decrease in the VAS score, even though differences in pain intensity on the VAS scale between the cryoultrasound group and the cryotherapy group were soon noticeable, reaching 4.35 points (95% CI 3.75; 4.95; $P < 0.001$) at the 12-month follow-up as per our primary end point. Improvement was extensive and continuous in the cryoultrasound group, whereas in the control group we noticed a slight improvement in values only in the first stage (T1), while afterwards pain symptomatology did not improve significantly. This trend was also confirmed by the values at the 18-month follow-up and the effectiveness index

analysis, which showed a more beneficial effect of combined cryoultrasound therapy on pain on the short, medium and long term.

Nonetheless, not all Group A patients reached acceptable values: at T1 14 patients (33.3%) had VAS scores higher than 5; among them, 3 patients (7.1%) had high VAS scores also at T3. A satisfying analgesic therapy should keep pain at a mild intensity rating, with values lower than 4.5 on VAS scale; over this threshold pain could interfere heavily with daily activities and quality of life.^{25, 33} The majority of patients in Group A reached this goal immediately at the first check-up (T1), in which the average VAS score was 4.3; this value then dropped to 1.6 at the 18-month follow-up. On the contrary, patients in Group B never reached these scores, which remained high.

We can infer from these data that excellent results can be obtained in treating plantar fasciitis when cryotherapy is used in association with therapeutic ultrasound. The head of the ultrasound device, placed on the affected area, causes an immediate vasoconstriction, which is followed by a strong superficial vasodilatation and a decrease in deep muscle perfusion. The simultaneous use of cryotherapy causes a decrease in deep tissue temperature, thereby increasing the density of the tissue itself. The combined use of these two therapeutic techniques determines a direct compensation of their side effects and both an additive and synergetic result on their therapeutic effects. Cryoultrasound creates an exogenous-endogenous thermotherapy, in which cryotherapy counterbalances ultrasound's side effects, improving the mechanical and biological effects on tissue regeneration and remarkably decreasing the thermic effect.

The results of our study protocol on plantar fasciitis agree with those in other studies, in which Cryoultrasound has been employed in treating traumatic and acute inflammatory pathologies.^{23, 24, 40} A limit of our study is the evaluation of subjective pain alone, without instrumental data or imaging (*e.g.*, echography or RM). Moreover further clinical studies are necessary to confirm the results of our study also on other musculoskeletal disorders. In order to correctly evaluate this therapeutic approach, it would also be useful to conduct trials versus placebo, with control groups treated with no therapy at all. In our study, as a matter of fact, it was not possible to realize the role cryotherapy and therapeutic ultrasound each assumed.

Furthermore, cryotherapy does not present many contraindications except for advanced vascular diseases, osteoporosis with increased bone turnover, local bleeding or skin lesions and the presence of metal fragments such as orthopedic fixation devices.

We can therefore conclude that, thanks to the synergetic action of ultrasounds and cryotherapy, Cryoultrasound could be an efficient treatment option for chronic and recalcitrant plantar fasciitis, granted its high therapeutic efficiency, patients' satisfaction, its limited cost in comparison to other physical therapies and its short and repeatable protocol of use.

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Received on April 9, 2013.

Accepted for publication on September 30, 2013.

Epub ahead of print on October 30, 2013.