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COMPARISON BETWEEN EXTRACORPOREAL SHOCK WAVE THERAPY AND LOCAL CORTICOSTEROID INJECTION IN THE TREATMENT OF CHRONIC PLANTAR FASCIITIS WITH A CALCANEAL SPUR: A RANDOMIZED CONTROLLED STUDY

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Objective: To compare the effectiveness of extracorporeal shock wave therapy (ESWT) and local corticosteroid injection (LCI) in the treatment of chronic plantar fasciitis with a calcaneal spur.

Materials and Methods: A total of 56 patients with chronic plantar fasciitis were included in this randomized controlled study. The presence of a calcaneal spur was shown radiologically in all patients. Patients were randomly assigned to two groups: the first group were treated by three sessions of ESWT at weekly intervals. Second group were treated by ultrasound guided corticosteroid injection. The patients were evaluated using the visual analog scale (VAS)-pain and Foot Function Index (FFI). Evaluation was done at pretreatment, at 4 and 12 week.

Results: There were significant improvements in VAS and FFI scores at 4 and 12 weeks compared with pretreatment scores in both groups (all $p < 0.05$). The reduction in VAS and FFI Pain scores in LCI group was significantly greater than in ESWT group ($p<0.05$). In both groups, there were no significant differences in VAS and FFI scores at 12 weeks compared with 4th week scores.

Conclusion: ESWT and LCI are effective treatments for chronic plantar fasciitis with a calcaneal spur. LCI seems to be more effective for improving pain compared to ESWT.

Keywords: Extracorporeal shock wave therapy, local corticosteroid injection, chronic plantar fasciitis, calcaneal spur, pain

1. INTRODUCTION

Plantar fasciitis (PF) is the most common cause of plantar heel pain (Aldridge, 2004 , Tu & Bytomski, 2011). The overload injury of the proximal plantar fascia is the main reason of PF (Wrobel et al., 2016). The presence of other risk factors like obesity, structural and biomechanical factors accelerates the injury (Alvarez-Nemegyei & Canoso,2006, Roxas,2005). A diagnosis of plantar fasciitis is based on the patient's history and physical examination (Goff &Crawford, 2011). Patients complain of heel pain that is worse with the first steps after rest (Aldridge, 2004). Physical examination presents with tenderness at the medial tubercule of the calcaneus (Roxas, 2005). Diagnostic imaging methods can show the involvement of anatomic structures. Ultrasonography and magnetic resonance imaging are used to investigate the plantar fasia and plain film x-rays are used to show calcaneal spurs (McMillan et al.,2009). Chronic damage on the plantar fascia ligament causes a calcaneal spur to where the plantar fascia attaches to the calcaneus (Agyekum & Ma, 2015). The calcaneal spur is a bony outgrowth from the calcaneal tuberosity and is seen in 45–85% of the patients with PF (Kirkpatrick, Yassaie& Mirjalili, 2017)

PF with a calcaneal spur is considered a self-limiting clinical condition but resolution can take months to years (Tu & Bytomski, 2011, Roxas, 2005). Plantar heel pain often causes severe discomfort and effects patients' daily lives (Rosenbaum, DiPreta & Misener, 2014). Patients prompt to search treatment before the pain resolves because of the effect of heel pain on activities of daily living (Luffy et al.,2018). Treatment of plantar fasciitis is typically conservative. First-line therapies include relative rest, activity modification, stretching, strengthening exercises, ice massage, and use of anti-inflammatory or analgesic medications,orthotic devices. Chronic cases are recalcitrant and do not respond to routine conservative treatment (Crawford&Thomson,2003, Goff &Crawford, 2011). LCI and ESWT are treatment options for more recalcitrant cases (Goff &Crawford, 2011, Luffy et al.,2018, Tu&Bytomski, 2011). LCI is commonly used in the treatment of chronic plantar fasciitis because of its rapid effectiveness, easy availability, and low cost (Goff & Crawford ,2011, Lapidus & Guidotti FP,1957). ESWT is preferred for the treatment of PF because it is noninvasive and its recovery time is fast (Crawford&Thomson ,2003 , Dedes et al.,2019).

The efficacy of ESWT and LCI in the treatment of chronic PF has been investigated and has shown in the literature. Although there are some studies comparing the efficacy of ESWT and LCI in the treatment of PF (Erden et al.,2021, Eslamian et al.,2016, Hocaoglu et al., 2017, Lai et al.,2018, Porter &Shadbolt ,2005, Saber et al.,2012, Serbest et al.,2013, Yucel et al.,2010, Xu et al.,2020), it is not known if one treatment is clearly superior over other. In the presence of a calcaneal spur, ESWT may be considered for the first treatment choice, since it reduces the length of the spur (Hayta et al.,2017,Yin et al.,2014). Therefore, in this study, we aimed to evaluate and to compare the efficacy of ESWT and LCI on pain and functional status in the treatment of chronic PF with a calcaneal spur.

2. MATERIALS AND METHODS

2.1.Research and Publication Ethics: Ethical approval was obtained from the Education Planning Board of The Physical Therapy and Rehabilitation Trainig and Research Hospital (29/04/2015-1789)

2.2. Patients: A total of 66 patients with chronic heel pain evaluated in the physical therapy and rehabilitation outpatient clinic. The inclusion criteria of the study were having unilateral heel pain more than 12 weeks, presence of a calcaneal spur radiologically examined and unsuccessful conservative treatment consisting of NSAI drugs, orthotic devices (heel cups, arch supports) and stretching exercises. The exclusion criteria were presence of inflammatory diseases and neurological conditions, pregnancy, previous ESWT or LCI to the foot, previous trauma to the foot (fracture, rupture of tendon). Considered the inclusion and exclusion criteria only 60 patients were eligible for study and they were randomly assigned to ESWT and LCI group. During the 12 week follow -up, 4 patients from LCI group had to remove from study because they did not complete the collection of results. At last 30 patients in ESWT group and 26 patients in LCI group completed the collection of results and were included the final analysis (Fig 1). A written informed consent was obtained from each patient. The study was conducted in accordance with the principles of the declaration of Helsinki. The demographic and clinical data of the patients were recorded. Group 1 patients were treated with three sessions of ESWT (Medical Italia ESWT, 2400 shock waves with 3 bar intensity and 12 Hz frequency) at weekly intervals. The ESWT without local anesthetic was applied to the point of maximal terderness in the medial calcaneus. Group 2 patients were treated by ultrasound guided corticosteroid injection. All patients were injected by the same physiatrist under aseptic conditions, using 40 mg methyl-prednisolone. The needle (27- gauge) was inserted with a medial oblique approach (perpendicular to the long axis of the ultrasound transducer) and advanced under continuous ultrasound guidance into the proximal plantar fascia. During ESWT and LCI procedures, patients were in a prone position with ankle joints in a neutral position. Patients did not receive medical treatment, did not use a splint or did not do exercises (stretching exercises) during the treatment periods. The pain levels of the patients were determined using the Visual Analogue Scale (0-10) and Foot Functional Index (FFI) Pain scores. Activity limitation and disability levels were questioned using FFI activity limitation and FFI disability scores. Evaluation was done at pretreatment, at 4 and 12 week.

2.3. Study Design

This study was designed as a randomized controlled trial. We use a computer-generated randomization program to assign the patients to the ESWT or LCI groups. Same investigator blinded to group allocation performed the baseline, 4-week and 12-week evaluations.

2.4. Sample Size

Sample size was calculated with assumed difference of at least 1.2 units due to the change of VAS scores in 4-week evaluation between the treatment groups. A total sample size of 54 (27 study participants and 27 controls) was necessary for a 2-sided test with statistical power of 0.95 and a type I error of 0.05. A post hoc power analysis revealed that the trial had a power of > 0.99. The data of assumed difference of 1.2 were applicable to our pilot study. Sample size and power analysis calculations were performed using G*Power Software Package (version 3.1.4).

2.5. Outcome measures

2.5.1. Visual Analog Scale (VAS)

The VAS-pain consists of a 10 cm horizontal line, with the left extreme indicating zero (no pain) and the right extreme indicating 10 (unbearable pain). Patients were asked to mark the point on the line according to the pain they experienced within the last week (Johnson 2001).

2.5.2. Foot Function Index (FFI)

The FFI is an index to evaluate the impact of foot pathology on pain, disability and activity

limitation. The FFI is divided into 3 subgroups that address pain, disability and activity limitation. It consists of 23 items including nine items for the pain subgroup, nine items for the disability subgroup, and five items for the activity limitation subgroup. Each item is recorded using a 10-point Visual Analog Scale (VAS). The values calculated for each three subgroup. The pain subgroup of the FFI consists the pain that occurs with the first steps in the morning and pain when standing or walking (Budiman-Mak, Conrad & Roach, 1991).

2.6.Statistical analysis

Analysis was performed by using SPSS 20.0 (SPSS Inc., Chicago, IL). Shapiro-Wilk test was used to assess the distribution of continuous variables. Data were presented as mean±SD for continuous variables; as median (minimum-maximum) for discrete variables, and number and percentage for categorical variables. Comparisons between the ESWT and LCI groups were evaluated with Kruskal-Wallis test for mean values, Mann-Whitney U test for median values and chi-square test for categorical variables. The Friedman test was used to assess the effectiveness of the treatment methods comparing baseline, 4-week and 12-week follow-up values. A p value of < 0.05 was accepted as significant

3. RESULTS

The comparisons of demographic and pretreatment clinical characteristics of the groups are given in Table 1. According to this; there were no significant differences between the groups in any of these parameters ($p> 0.05$). The majority of the patients was females in both groups. The mean of age was 52.33 ± 9.61 in ESWT group and 49.73 ± 11.01 in LCI group. The mean of BMI was 31.73 ± 5.02 kg/m^2 in ESWT group and 32.91 ± 8.24 kg/m^2 in LCI group. Diabetes mellitus (DM) was seen in 8 patients in ESWT group and in 11 patients in LCI group. The effectiveness of treatments in outcome measures at 4 and 12 weeks was shown in Table 2. Both groups reported significant improvements in VAS and FFI scores (FFI Pain Score, FFI Disability Score, FFI Activity Limitation Score) at 4 and 12 weeks compared with pretreatment scores (all $p<0.05$). According to pretreatment values, the changes in outcome scores (Δ) with treatments are demonstrated in Table 3. The reduction in VAS Pain and FFI Pain scores in LCI group was significantly greater than in ESWT group at 4th week and at 12th week ($p <0.05$). In both groups, there were no significant differences in VAS and FFI scores at 12th week compared with 4th week scores. None of the patients developed complications after LCI or ESWT.

4. DISCUSSION

In the present study, we investigated results of ESWT and LCI applied to patients with chronic PF with a calcaneal spur. Although significant improvements were observed in pain and disability scores in both groups, the reduction in pain scores in LCI group was significantly greater than in ESWT group. Our results indicated that LCI is more effective in PF for improving pain compared to ESWT in the short term.

PF is a painful condition which can cause significant discomfort and disability (Aldridge, 2004). It is important to find the most effective method of treatment because of the effect of heel pain on activities of daily living. There are different treatment options for PF, but there is no consensus on the most effective treatment in the literature (Leão et al.,2020). ESWT and LCI are two popular treatments for patients who are unresponsive to other conservative treatment methods (Li et al.,2018).

Previous studies comparing the efficacy of ESWT and LCI for treatment of chronic PF had diverse outcomes (Erden et al.,2021, Eslamian et al.,2016, Hocaoglu et al., 2017, Lai et al.,2018, Porter &Shadbolt ,2005, Saber et al.,2012, Serbest et al.,2013, Yucel et al.,2010,

Xu et al.,2020). In 2005, Porter et al. (Porter&Shadbolt, 2005) revealed LCI was more efficacious than ESWT in the treatment of PF. However, Lai et al. (Lai et al.,2018) found that ESWT was more efficient than LCI on chronic PF on the pain level outcome at 12th week. Some randomized controlled trials showed both ESWT and LCI improved pain and functional ability in PF but inter-group differences were not statistically significant (Eslamian et al.,2016, Saber et al.,2012 , Yucel et al.,2010). In our study both groups reported significant improvements in pain, activity and disability scores at the 12-week follow-up and there was a significant difference in terms of pain improvement between groups. The patients in the LCI group had a significantly better pain relief than the ESWT group.

Another study that compared the effectiveness of ESWT and LCI for PF showed that VAS scores were decreased statistically significantly in both groups, however LCI provided significantly greater decrease in pain according to ESWT (Serbest et al.,2013). In a recent study, Erden et al. (Erden, 2021) found a significant decrease in terms of pain in all patients in their study. However, the reduction in pain scores in LCI group is significantly more than in ESWT group. In the mentioned studies pain was evaluated only by VAS. In our study we also evaluated the pain levels by FFI Pain scores. Like mentioned studies, in our study the reduction of pain scores in the LCI group was significantly greater than the ESWT group.

Some studies, in patients with PF showed the superiority of ESWT over LCI (Hocaoglu et al., 2017, Xu et al., 2020). Xu et al. (Xu et al.,2020) found an improvement in pain and function in both groups, but clinical improvements were not maintained in the LCI group at the 3-month follow-up. Hocaoglu et al. (Hocaoglu et al.,2017) also found significant improvements in VAS and FFI scores in both groups but posttreatment improvements were not maintained in the LCI group at 1 month. The authors of studies mentioned above revealed that ESWT was superior to LCI due to its longer duration of action (Hocaoglu et al, 2017, Xu et al.,2020). In our study both ESWT and LCI remained effective at the 12-week follow-up. We observed that patients had an improvement in pain and function in both groups at the 4-week follow-up. Posttreatment improvements were also maintained at the 12-week follow-up. We considered that ultrasound-guided LCI can effectively treat PF and remains at 12 weeks after injection. The use of ultrasound-guided injection of corticosteroid may be associated with long-term effects.

In the meta-analysis of Li et al. (Li et al., 2018), ESWT and LCI showed similar functional outcomes in patients with PF. They reported that the pain relief was related to energy intensity levels of ESWT. The high-intensity ESWT had superior pain relief, followed by LCI, and low-intensity ESWT in their study. In our study LCI was superior to ESWT in terms of pain reduction. We performed median energy ESWT for three-sessions. Since most of the studies were conducted with three-session ESWT, we preferred three-session ESWT in our study. We considered that LCI can reduce pain in patients with PF, especially when performed with ultrasound guidance.

The main limitation of this study was the lack of long-term follow-up. Patients were followed up for 12 weeks. We don't know the long-term functional outcomes of patients. Second limitation of this study includes its small size. Another limitation of this study is x-ray and ultrasound examination was not done after treatments. We did not known the radiologic changes of spur and plantar fascia on objective evaluation. Also no control group was used to exclude placebo effects of ESWT and LCI. Further research using a larger sample size with control group and long period of follow is suggested.

The studies comparing the efficacy of ESWT and LCI in the treatment of chronic PF reported contradictory results. The variations in the literature are likely due to multiple factors including the treatment protocol and delivered energy level of ESWT and the use of

ultrasound-guided injection of corticosteroid. We conclude that both ESWT and LCI seem to be effective on pain and foot functions in the treatment of chronic PF with a calcaneal spur. However LCI was superior to ESWT in terms of pain reduction in PF. In PF, the main complaint of the patients is the pain that effects their activities of daily living. Therefore, LCI may be the first treatment option according to our results.

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Table 1. Comparison of demographic and pretreatment clinical characteristics of the groups

	ESWT group (n=30)	LCI group (n=26)	P value
Age (year) mean±SD	52.3 ± 9.6	49.7 ± 11.0	0.34
BMI(kg/m^2) mean±SD	31.7 ± 5.0	32.9 ± 8.2	0.51
Sex, n (%)			0.12
Female	24 (80)	16 (61.5)	
Male	6 (20)	10 (38.5)	
Educational level, n (%)			0.21
Illiterate	2 (6.7)	0 (0)	
Primary school	14 (46.7)	9 (34.6)	
High school-university	14 (46.7)	17(65.4)	
Work status, n (%)			0.86
Housewife	12 (40)	12 (46.2)	
Working	12 (40)	10 (38.5)	
Retired	6 (20)	4 (15.4)	
Diabetes mellitus, n (%)	8 (26.7)	11 (42.3)	0.21
Walking activity, n (%)	17 (56.7)	19 (73.0)	0.09
VASmorning pain Median (min-max)	8.5 (0-10)	10 (2-10)	0.26
VASpain Median (min-max)	8 (4-10)	8 (6-10)	0.22
FFI Scores , mean±SD			
FFIpain	74.5 ± 14.9	77.3 ± 15.7	0.51
FFIdisability	57.2 ± 20.8	49.9 ± 8.3	0.17
FFIactivity limitation	30.7 ± 22.9	24.1 ± 19.9	0.26

BMI:Body Mass Index VAS:Visual Analog Scale FFI: Foot Function Index ESWT: Extracorporeal Shock Wave Therapy LCI: Local Corticostreoid Injection SD: Standard Deviation

Table 2. The effectiveness of treatments in outcome measures

	ESWT group	p	LCI group	P value
VASpain		**< 0.001[a]**		**< 0.001[a]**
Pretreatment	8.0 ± 1.6		8.5 ± 1.4	
4 week posttreatment	4.0 ± 2.6	**< 0.001[c]**	2.2 ± 2.1	**< 0.001[c]**
12 week posttreatment	1.3 ± 1.7	1[c]	1.3 ± 1.7	0.28[c]
FFI pain		**< 0.001[a]**		**< 0.001[a]**
Pretreatment	74.5 ± 14.9		77.3 ± 15.7	
4 week posttreatment	34.5 ± 25.5	**< 0.001[c]**	22.1 ± 20.0	**< 0.001**
12 week posttreatment	33.7 ± 29.7	1[c]	13.6 ± 20.8	0.43[c]
FFI disability		**<0 .001[a]**		**< 0 .001[a]**
Pretreatment	57.2 ± 20.8		49.9 ±18.3	
4 week posttreatment	34.5 ± 25.5	**< 0.001[c]**	11.7 ± 15.2	**< 0.001**
12 week posttreatment	33.7 ± 29.7	1[c]	6.3 ± 11.7	0.43[c]
FFIactivitylimitation		**< 0.001[b]**		**<0 .001[a]**
Pretreatment	30.7 ± 22.9		24.1± 19.9	
4 week posttreatment	11.4 ± 17.6	**0.003[c]**	3.87± 9.12	**< 0.001[c]**
12 week posttreatment	10.1 ± 17.9	< 1[c]	1.5±5.95	1[c]

VAS:Visual Analog Scale FFI: Foot Function Index ESWT: Extracorporeal Shock Wave Therapy LCI: Local Corticostreoid Injection a: 4 week posttreatment compared with pretreatment and 12 week posttreatment compared with pretreatment are significant p<0 .001 b: 4 week posttreatment compared with pretreatment p= 0.003. 12 week posttreatment compared with pretreatment p<0 .001 c= comparisons with last follow up visit

Table 3. Comparisons of changes in outcome measurements between the groups			
	ESWT group Mean±SD	**LCI group** Mean±SD	**P value**
VAS pain			
Pretreatment – 4 week posttreatment	-4 ± 2.6	-6.3 ± 2.2	**0.003**
Pretreatment – 12 week posttreatment	-4.3 ± 2.93	-7.2 ± 2.0	**< 0.001**
4 week posttreatment – 12 week posttreatment	-0.3 ± 2.1	-0.9 ± 1.7	0.21
FFI pain			
Pretreatment – 4 week posttreatment	40.0 ± 27.7	55.1 ± 22.7	**0.03**
Pretreatment – 12 week posttreatment	40.8 ± 30.2	63.6 ± 24.0	**0.003**
4 week posttreatment – 12 week posttreatment	0.7 ± 21.0	8.4 ± 17.9	0.15
FFI disability			
Pretreatment – 4 week posttreatment	34.4 ± 25.8	38.2 ± 17.3	0.51
Pretreatment– 12 week posttreatment	34.4 ± 27.7	43.6 ± 20.2	0.15
4 week posttreatment – 12 week posttreatment	0.0 ± 14.4	5.4 ± 14.3	0.16
FFI activity limitation			
Pretreatment – 4 week posttreatment	19.33 ± 21.4	20.30 ±17.3	0.85
Pretreatment – 12 week posttreatment	20.55 ± 23.3	22.67 ±20.5	0.72
4 week posttreatment – 12 week posttreatment	1.22 ± 6.2	2.37 ±7.6	0.53

VAS: Visual Analog Scale FFI: Foot Function Index ESWT: Extracorporeal Shock Wave Therapy LCI: Local Corticosteroid Injection SD: Standard Deviation

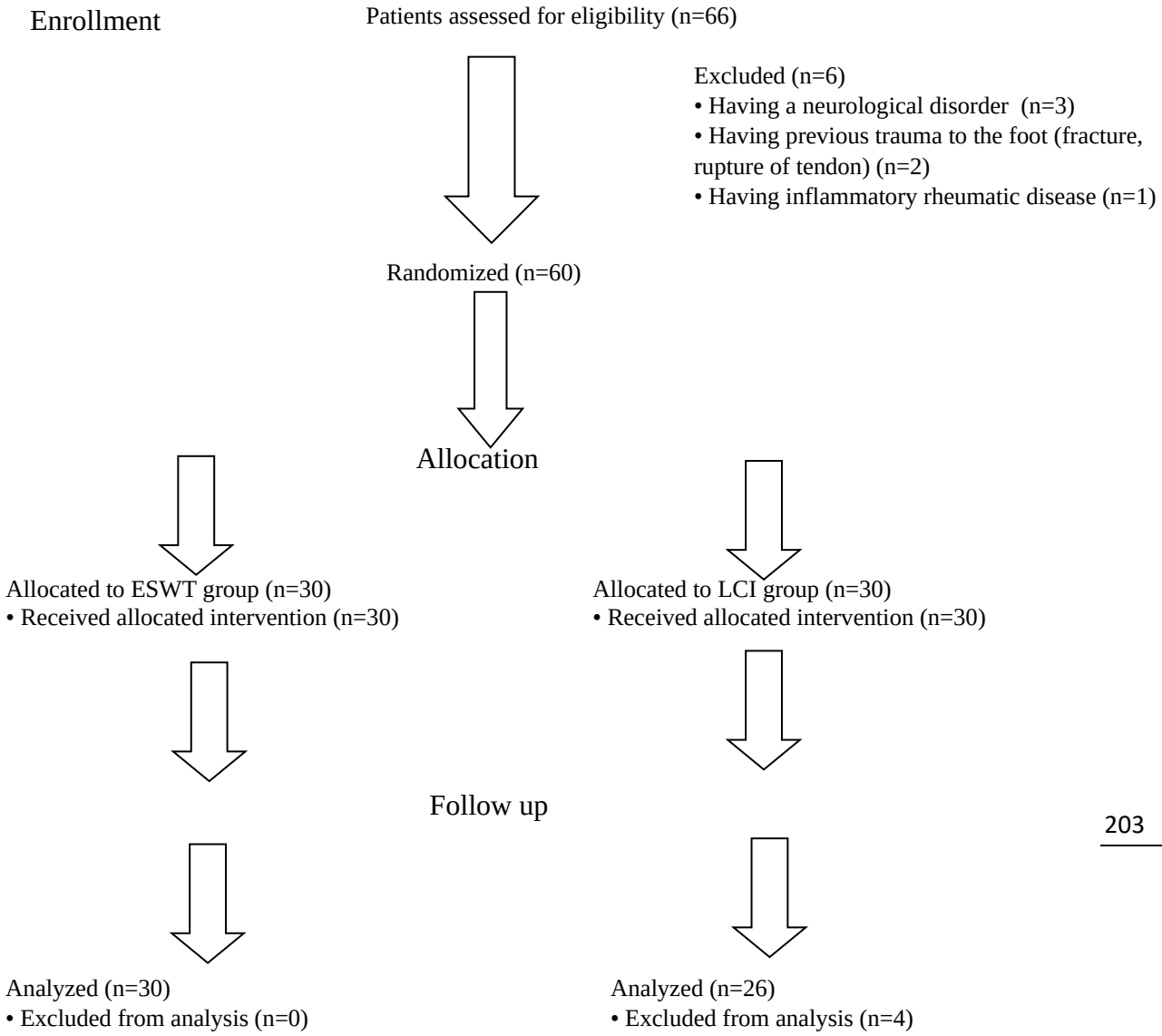

Figure 1. Flow diagram for randomized subject enrollment in this study (ESWT: Extracorporeal Shock Wave Therapy LCI: Local Corticosteroid Injection)