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Comparison of the effect of two methods of Casting and Splinting on Ankle Sprain-Induced Ligament injuries - A Randomized Clinical Trial

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Objective: **The prevalence of ankle sprain is 52.7-60.9 cases per 1000 people and is more likely to occur in young athletes. Forty percent of the patients experience impaired function for up to 6 months after the injury. The present study aimed to compare the two treatment methods of cast and splint immobilization to treat patients with first- and second-degree ankle sprain.** ***Methodology:*** **This clinical trial study performs on 120 patients with first- and second-degree ankle sprain. Patients randomly divide into two equal groups of 60 subjects. One group treat with a cast and the other one with a splint. At the beginning of the study and 2and six weeks after, the selected subjects were analyzed using SPSS 20 through descriptive and inferential statistics at the significance level of *p*>0.05.** ***Findings:*** **In this study, patients in the splint group were able to walk normally and swelling in the affected foot was reduced in the 2-week follow-up. Within this period, the ankle joint motion in both groups returned to normal. In comparison to the splint group, the patients in the cast group experienced less pain and needed less time to rest and return to daily activities.** ***Conclusion:*** **The study results showed that, in comparison with splinting, the casting was associated with less pain in a long time, less time to rest, and quicker return to daily activities, and therefore it was cost effective.**

INTRODUCTION

Ankle sprain and ligament injuries are common presentation in trauma patients that seen in ED. These injuries are commonly seen in active population. Forty percent of the patients experience impaired function for up to 6 months after injury (1). About 14% to 21% of all sports injuries are related to ankle sprain which accounts for 85% of the ankle injuries (2). The most common type of ankle sprain is the lateral type, which occurs as a result of the internal rotation of the foot when it is in the plantar flexion position (3).

Ankle ligament injuries are divided into 3 degrees: 1. Lack of ligament rupture which is associated with slight loss of function, pain, inflammation, ecchymosis, and proper weight bearing; 2. Relative rupture and somewhat reduced function, pain, inflammation, more ecchymosis, and difficult weight bearing; 3. Complete ligament rupture, loss of function, pain, inflammation, bruising, and not bearing weight. Joint stability is the first point in determining the type of ankle sprain treatment and is more important than the degree of injury. Complications of high degree injury include chronic instability, early osteoarthritis, chronic pain, and persistent disability. Recurrent unstable cases indicate subacute or chronic pathology. Various therapies have been suggested for ankle sprain. Ankle sprain is commonly treated with functional therapy, immobilization, and surgical intervention (4). Functional treatment refers to the complete immobilization of the joint, so that the joint is allowed to function fully or partially, which is started by PRICE (Protection, Rest, Immobilization, Ice, Elevation), and is continued by the use of lace-up ankle support (air cast), semi-rigid support, taping, and elastic bandage; among which the lace-up is significantly more effective in decreasing edema in the short term (1) and the elastic bandage has lower complications than taping and longer time to return to activity (sports and work), (1). In the first- and second-degree cases, the use of functional therapies is effective for a few days. In severe second-degree or third-degree sprains, 10-day immobilization with short cast or air cast splint, and the use of a cane for 2 to 3 weeks result in a faster recovery than tubular compression bandage. Patients are then followed up in the first 2 weeks by a general practitioner in mild cases and by an orthopedist in severe cases. The use of nonsteroidal anti-inflammatory drugs (NSAIDs), oral acetaminophen or opioid, and local topical diclofenac gel is effective in reducing pain and restoring movement (1, 14). As mentioned, a wide variety of treatments have been

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suggested, either as functional therapy or as an immobilization treatment for ankle ligament injury following sprain (15, 16). In this regard, various studies have also been conducted to select the best treatment, which compared different functional treatments or functional and immobilization treatments. For instance, a study by MW Cooke *et al.* (2009) compared the three treatment methods of tubular double-layer compression bandage, below the knee cast, and air cast brace. Finally, below the knee cast and air cast brace were determined to be cost-effective treatments with more advantageous in short-term compared to bandages. In terms of pain, daily activities, exercise, and quality of life, below the knee cast was better than the others, and it was ultimately recommended that doctors should consider the compliance of patients in choosing a therapeutic approach (5). In another study, two methods of splint (as a type of immobilization) and compression bandage (as a type of functional therapy) were compared, and compression bandage was reported to be an easy and convenient method, which can be used for longer times by patients, while splinting was mentioned to be a cost-effective method given the reduced sick leave and a quick return to daily activities (6). In another study by Michel *et al.* in 2013, immobilization methods such as below the knee cast or boot in second- and third-degree acute ankle sprain in athletes for 5 to 10 days and continuation of immobilization resulted in better results, shorter recovery time, and reduced instability risk in long-term (7). In another study by Muhammad Naeem *et al.* in 2015, functional therapy was shown to reduce pain better than cast (8). As mentioned, no definitive treatment has been used for ankle sprain, while there are various treatments. Most studies have compared functional therapies or functional and immobilization treatments, but no study has compared the different immobilization methods. A review article by Ogilvie-Harris et al. in 1995 on ankle soft tissue injury related articles concluded that further studies are needed in the future to find the most effective method for treating ankle sprain (9). Two review articles on ankle sprain treatment with ultrasound therapy (5 clinical trials, 2011) and hyperbaric oxygen therapy (9 small trials, 2005) concluded that these methods are not effective and therefore not recommended (10). Despite the treatment, 10-30% of cases are associated with chronic complications, including functional or motion instability, chronic pain, and stiffness and swelling recurrence, often occurring in second-degree cases (1). Despite the high prevalence of ankle sprain, especially among young athletes, and the subsequent long disability, no definitive treatment is provided yet for ankle sprain, and various therapeutic approaches are employed so far. In addition, no study compared the ankle casting and splinting methods, and all studies focused on comparing a variety of functional therapies or comparing them with immobilization methods. In this regard, the authors decided to compare these two immobilization therapies, *i.e.* casting and splinting, which are common, since patients are willing to be treated through immobilization methods.

METHODOLOGY

This clinical trial (IRCT2016071528941N1) performs at the emergency departments of Imam Reza and Shahid Hasheminejad Hospitals of Mashhad. First, the study license obtains from the Ethics Council of Mashhad University of Medical Sciences (IR.MUMS.fm.REC.1394.533). Both treatments and study design explained for the patients and after accepting the study informed consent form completed by patients. The patient's specifications, including age, sex, comorbidity, mechanism of injury, and the involved foot record on questionnaire. The patients from a different city exclude from the study. Complete physical examinations performed, and the patients with other simultaneous injuries, neurological or musculoskeletal disorders, or any disabling disease excluded. The physical examination of the ankle and foot involved local tenderness, swelling, inflammation, ecchymosis, joint instability, and if possible, the ankle range of motion. In case of the presence of the ankle and foot Ottawa rules, a plain X-ray was requested to rule out a simultaneous fracture. The Ottawa ankle rules include pain and tenderness of the malleolus, inability to bear weight (4 steps) in the emergency department, and in the foot, pain, and tenderness at the base of the fifth metatarsus or the navicular bone, and the inability to bear weight (4 steps) in the emergency department. Then the patients visited by an emergency medicine specialist. Patients with a fracture or non-fractured cases classified as third-degree in the event of joint instability exclude from the study. The first- and second-degree injuries were studied. The subjects with less pain, swelling, ecchymosis, and proper weight bearing classified as first-degree, and cases with swelling, pain, more functional impairment and improper weight bearing as second-degree. Pain intensity score range from zero to 10using the Visual Analogue Scale (VAS). Finally, a total of 120 patients included in the study regardless of age, sex, first- or second-degree ligament injury, the number of sprains, involved foot, and the mechanism of injury, and randomly divided into two groups of 60 each. Both groups treat with RICE and NSAIDs for pain relief. One group treat with a short cast by an experienced person, and the second group receive a short ankle splint (Paxman). The patients recommended to continue a 10-day treatment course with cast or splint. The records at baseline included name, age, gender, underlying disease, mechanism of injury, sprain turn, pain intensity, foot involved (right or left), and the ankle range of motion. After recording these items and casting or splinting, the patients recall after two and six weeks. Each time, the pain in rest and activity, the difference in foot size, walking ability and the range of motion recorded. Also, the patients' rest and activity time, as well as the time they returned to normal activities, recorded during the follow-up.

We examine complete joint instability with anterior drawer, talar tilt, and external rotation tests. Due to the severe pain in acute phase of the disease these examinations perform in future visits. Patients classified as third-degree are excluded from the study.

Intervention

Short-term immobility of the ankle was randomly performed with a cast or splint in patients with ankle sprain.

Statistical Methods

The data analysis done with SPSS 20 through descriptive and inferential tests (paired *t*-test, Wilcoxon, Mann-Whitney, Chi-square and Kolmogorov Smirnov).

RESULTS

There was no significant difference in any of the demographic characteristics between the two groups of casting and splinting ($p>0.05$). Walking was the most common mechanism of injury in both splinting and casting groups, (70.7% and 64.5%, respectively). Also, lateral malleolus was the most common site of ankle ligament involvement and tenderness in both groups. According to the Chi-square test, there was no difference in the ankle sprain side and the degree of injury between the two groups ($p=0.676$ and $p=1.0$, respectively).

The patients were followed up 2 and six weeks after the treatment, and some treatment quality variables compare in the two groups. Initially, the ability to walk investigates in both groups at baseline, and 2 and six weeks later. At baseline, 27 patients (46.6%) in the splint group

Table 1 Comparison of the patients' injury characteristics in the casting and splinting groups at baseline

Variable		Patients group		*p*-value
		Splint (n=58)	Cast (n=62)	
Involved foot	Right	24 (41.4%)	28 (45.2%)	* 0.676
	Left	34 (58.6%)	34 (54.8%)	
Injury mechanism	Fall	7 (12.1%)	8 (12.9%)	-
	Soccer	8 (13.8%)	4 (6.5%)	
	Walking	41 (70.7%)	40 (64.5%)	
	Volleyball	0 (0%)	9 (14.5%)	
	Mountain climbing	2 (3.4%)	1 (1.6%)	
Involved ligament	Medial malleolus	1 (1.7%)	0 (0%)	-
	Lateral malleolus	39 (67.2%)	47 (75.8%)	
	Medial foot	4 (6.9%)	1 (1.6%)	
	Lateral foot	4 (6.9%)	5 (8.1%)	
	Medial and lateral malleolus	5 (8.6%)	6 (9.7%)	
	Dorsal foot	4 (6.9%)	3 (4.8%)	
Tenderness site	Medial malleolus	1 (1.7%)	0 (0%)	-
	Lateral malleolus	37 (63.8%)	49 (79%)	
	Medial foot	4 (6.9%)	0 (0%)	
	Lateral foot	4 (6.9%)	4 (6.5%)	
	Medial and lateral malleolus	5 (8.6%)	6 (9.7%)	
	Dorsal foot	2 (3.4%)	0 (0%)	
Injury degree	1	19 (32.8%)	21 (33.9%)	* 1.0
	2	39 (67.2%)	41 (66.1%)	

* Chi-square test was used to compare the two groups.

Table 2 Comparison of ankle joint range of motion in two splinting and casting groups at baseline and 2- and 6-week follow-ups

Examination time	Ankle range of motion	Splint (n=58)	Cast (n=62)	*p*-value
Baseline	Normal	54 (93.1%)	58 (93.5%)	0.99*
	Reduced	4 (6.9%)	4 (6.5%)	
2-week follow-up	Normal	58 (100%)	62 (100%)	-**
	Reduced	0 (0%)	0 (0%)	
6-week follow-up	Normal	58 (100%)	62 (100%)	-**
	Reduced	0 (0%)	0 (0%)	

* Fischer's exact test used to compare the two groups.
** Due to the low sample size in the group, the results of the Chi-square test are not reliable.

Table 3 Comparison of the difference in the size of the affected and the healthy ankles in the two splinting and casting groups at baseline and the 2- and 6-week follow-up

Examination time	Studied index	Splint (n=58)	Cast (n=62)	*p*-value
Baseline	Mean (SD)	2.17 (1.6)	1.87 (1.54)	0.364*
	Median (Interquartile range)	2 (2)	2 (3)	
2-week follow-up	Mean (SD)	1.57 (1.08)	1.48 (1.26)	0.810*
	Median (Interquartile range)	2 (1.25)	2 (2.25)	
6-week follow-up	Mean (SD)	0.19 (0.54)	0.16 (0.58)	0.668*
	Median (Interquartile range)	0 (0)	0 (0)	

* The Mann-Whitney test used to compare the two groups.

Table 4 Comparison of the pain severity score between baseline and the 2- and 6-week follow-ups in the two groups of splinting and casting

Variable	Studied index	Splint (n=58)	Cast (n=62)	*p*-value
Baseline *vs.* 2-week follow-up, rest	Mean (SD)	3.64 (2.37)	4.90 (2.26)	0.003*
	Median (Interquartile range)	4 (3)	4.5 (2.25)	
Baseline *vs.* 2-week follow-up, activity	Mean (SD)	2.52 (2.33)	3.82 (2.13)	0.001**
	Median (Interquartile range)	2 (2)	3.5 (3)	
Baseline *vs.* 6-week follow-up, rest	Mean (SD)	6.16 (1.79)	7.02 (1.64)	0.009**
	Median (Interquartile range)	6 (3)	7 (2)	
Baseline *vs.* 6-week follow-up activity	Mean (SD)	5.76 (1.81)	6.92 (1.87)	0.001*
	Median (Interquartile range)	6 (2)	7 (2.25)	
2-week follow-up rest *vs.* 6-week follow-up, rest	Mean (SD)	3.24 (1.74)	3.10 (1.69)	0.206**
	Median (Interquartile range)	3 (3)	3 (2)	

2-week follow-up activity *vs.* 2-week follow-up activity	Mean (SD)	2.52 (1.95)	2.11 (2.10)	0.645
	Median (Interquartile range)	2.5 (3.25)	2 (4)	

* Independent *t*-test was used.
** The Mann-Whitney test was used.

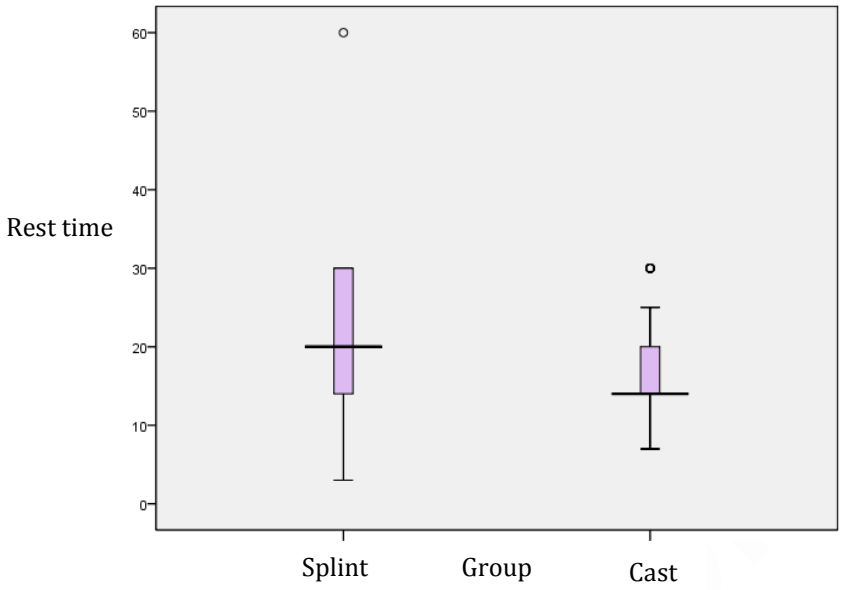

Figure 1 Comparison of the rest time between the cast and splint groups

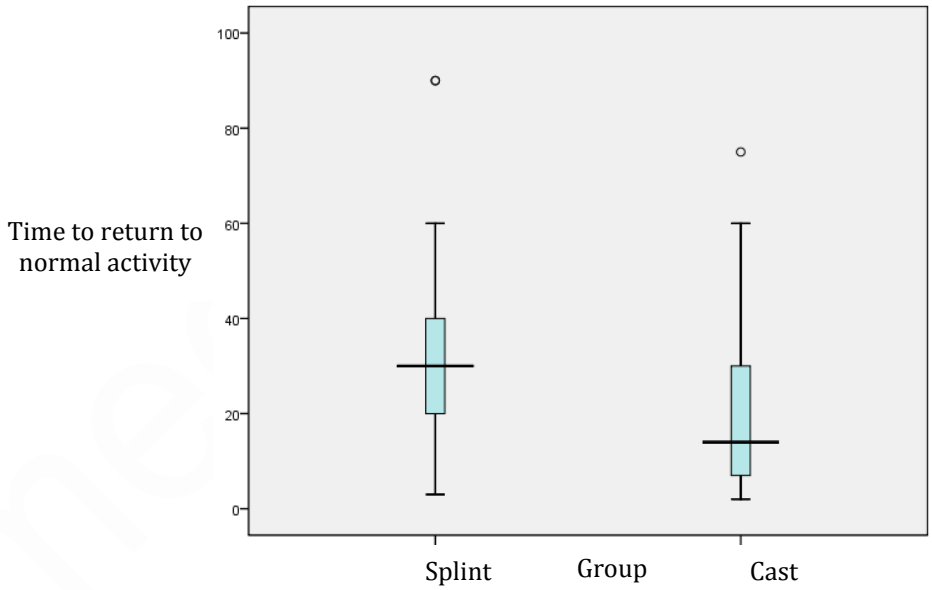

Figure 2 Comparison of the time to return to normal activity between the two groups of cast and splint

and 11 patients (17.7%) in the cast group are able to walk completely. In contrast, six patients (10.3%) in the splint group and 13 patients (21%) in the cast group are unable to walk. The other participants are relatively able to walk. Given the small number of people in the groups, the Chi-square test results are not reliable. Therefore, a new variable defines and compare through combining the relative walking ability group and the walking inability group in the 2- and 6-week follow-ups. After the combination of the relative walking ability and the walking inability groups, no significant difference observes between them in the 2-week follow-up (p=0.044). It means that the patients treated with splint are significantly more likely to walk completely in the 2-week follow-up compare with the patients treated with a cast. However, there was no significant difference between the two groups in the 6-week follow-up (p=0.106). The treatment trend of the patients in the splint group in the 2- and 6-week follow-ups showed a significant improvement in these patients compared to the baseline ($p \leq 0.001$). As the results of the patients in the splint group, the treatment trend in the patients in the cast

group are appropriate regarding their ability to walk, and a significant improvement compared with the baseline (p<0.001).

Ankle joint range of motion

No significant difference was found between the two groups in the ankle joint motion limitation at baseline (p=0.99). In the 2- and 6-week follow-ups, all patients of the cast and splint groups returned to the normal range of motion.

The ankle joint range of motion in the patients treated in the splint group in the 2- and 6-week follow-ups was significantly better than baseline (p<0.001). However, no difference observes between the results during the 2- and 6-week follow-ups (p=0. 1), showing that 2-weeks treatment with splint is sufficient to improve the ankle joint range of motion and there is no need for further treatment. Similar to the results of the splint group, there was a significant improvement in the ankle joint range of motion in the 2- and 6-week follow-ups compared with baseline in the cast group (p<0.001). Also, there was no difference between the results of this variable when comparing the 2- and 6-week follow-ups (p=0.1). These results also confirm that 2-week follow-up with splint is sufficient to return the range of ankle joint motion to normal.

The difference in the size of the involved and the healthy ankles

There was no significant difference in the size of the involved and healthy ankles between the two groups at baseline and 2- and 6-week follow-ups (p>0.05).

The difference in the size of the involved and healthy ankles in the splint group was significant at the 2-week follow-up compared to the baseline (p=0.014). This variable was not significant in the cast group (p=0.152). However, it was significantly improved in both groups at the 6-week follow-up as compared with the baseline and the 2-week follow-up in both groups (p<0.001). These results show that the 2-week follow-up is not enough to observe the positive outcomes of the treatment with the cast regarding of the ankle size improvement; whereas, a significant improvement observed after using the splint for two weeks. However, if either of the two treatments used, it is recommended to continue the treatment for up to 6 weeks to achieve a higher recovery.

Pain severity score

The patients in the cast group had a greater pain than the splint group at baseline (6.45±1.75 versus 7.27±1.58, p=0.008). In the 2-week follow-up, no significant difference observes in the pain score, both during the activity and rest (p=0.103 and p=0.233, respectively). However, in the 6-week follow-up, the patients in the cast group experiences significantly less pain than the splint group (0.35±0.87 versus 0.69±1.03, p=0.026). To further investigate this variable, the pain score at baseline compare with the pain score in the 6-week follow-up, and the pain score in the 2-week follow-up compare with the pain score in the 6-week follow-up during the rest and activity between the two groups. The pain severity score significantly decreased in the cast group during the 2- and 6-weeks follow-ups specially in the active state compared to the baseline (2-week follow-up: 3.82±2.13 versus 2.52±2.33 in the active state, p<0.001, and 4.90±2.26 versus 3.64±2.37 in the resting state, p=0.003; 6-week follow-up: 6.92±1.87 versus 5.76±1.81 in the active state, p=0.001, and 7.02±1.64 versus 6.16±1.79 in the resting state, p=0.009). However, there was no significant difference in pain reduction between the 2- and 6-weeks follow-ups in the two groups (the active state: p=0.645 and in resting state: p=0.206).

Rest time

The results of the Mann-Whitney test showed that the patients in the splint group needed more resting time (22.14±9.13 vs. 17.66 ±6.38, p<0.001).

Time to return to normal activity

Mann-Whitney test results showed that the patients in the splint group needed more time to return to the normal activities (31.72±19.44 *vs.* 19.60±14.74, p<0.001).

DISCUSSION

The study results showed that ankle sprain can be treated with casting better than splinting. At the end of the study, it observed that in those patients treated with short foot cast (compared to the split group), walking ability significantly improved and pain intensity greatly reduced. In addition, these people needed less time to rest, and less time to return to work. In a study by Mohammad Naeem *et al.* in 2015, functional treatment was shown to be better than casting in reducing pain (8). In a meta-analysis by Kerkhoffs *et al.*, no differences found between supportive care and the casting (11). However, no study investigated the extent of pain relief among different immobilization methods. Regarding the time to return to work, Michel *et al.* in 2013 showed that the use of immobilization methods resulted in a shorter recovery time (7). Leanderson *et al*. reported that casting below the knee, as compared to functional methods, was more cost-effective given the less need for being at home. It was also obviously better in terms of pain reduction, daily activities, exercise, and quality of life (6). In this study, we also found that casting reduces long-term pain and results in a quicker return to daily activities. No studies have compared the effects of immobilization methods. Walking was the most common mechanism of injury in both groups. In a study conducted by Gulzar in 2013, walking was also the most common cause of ankle sprain (12). As documented in previous studies, lateral malleolus and ligaments were the most common sites of injury in ankle sprain (12, 13), and no difference was found in the injured side and degree of injury between the two groups. In terms of walking ability at baseline, patients in the cast group were less able to walk than the splint group; however, they were significantly improved in the 2- and 6-week follow-ups. In the both splint and cast groups walking ability significantly improve during the treatment; but there was no significant difference between the two groups. This result suggests that both casting and splinting can improve the patients' walking ability with no significant difference. The ankle joint range of motion at baseline was similar in both groups with no significant difference between them in the 2- and 6-week follow-ups, but according to the results, two weeks treatment was very effective and adequate in both groups to improve the ankle joint range of motion, and longer treatment did not result in further change. Regarding the ankle swelling, there was no difference between the two groups at baseline and the 2- and 6-week follow-ups, but swelling was significantly decreased after two weeks in the splint group. That is while no significant impact seen in the caster group. Therefore, it can be concluded that splint has a greater role in reducing swelling, and it would be better to spend a longer time to reduce swelling in both treatment methods. At baseline, the pain severity was higher in the cast group than in the splint group. Casting caused a greater reduction in the pain score than the splint group in the 2- and 6-week follow-ups, and there was a significant difference between the two groups. This finding suggests that casting was more effective in reducing pain compared to

splinting. Ultimately, this study showed that treatment with casting required a shorter resting time and the patients returned to work sooner.

CONCLUSION

In comparison to splinting, the casting associated with more pain relief, shorter resting time, and quicker return to daily routine. So, the casting is more cost-effective and more suitable specially in patients with pain, and the splinting is associated with further reduction in swelling and should considered in cases of high swelling. But in general, it is better to select the ankle sprain treatment type according to the patients and their desire for the treatment method. Also, in all methods, the use of analgesics and rest, as well as subsequent follow-up, should be taken into account.

Limitations

Inappropriate compliance of patients with the use of splint or cast as the treatment modalities was one of the limitations in this study, and most patients, especially patients with more pain, tended to use the cast. Nevertheless, we used both methods randomly regardless of the patients' desire and encouraged them to use any of the methods. The inability to adequately supervise the use of splint or cast by the patients during the treatment course was another limitation. Also, some patients dissatisfied with the cast weight given the type of plaster used, which sometimes led to the treatment discontinuation. One of the strengths of the present research was the lack of repetition of similar studies, and a large number of patients with ankle sprain made the study fully feasible. The tendency of the majority of patients to use immobilization methods also led to a better implementation of the research project.

Suggestions

It seems that the use of lighter plaster can be associated with more satisfaction and acceptance by patients. The possibility of routine follow-up of patients with an ankle sprain in the emergency departments can provide better feedback in the patient and therapist due to its high prevalence. It is also better to select the treatment type according to the willingness and compliance of each patient.

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Cast, splint, ligament damage, sprain, ankle

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Conflict of interest

The authors declare that there is no conflict of interest regarding the publication of this manuscript.

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