Iran Red Crescent Med J. 2019 May; 21(5):e90813. doi: 10.5812/ircmj.90813.

Published online 2019 May 26. **Research Article**

Dose-related Effect of Radial Extracorporeal Shockwave Therapy (rESWT) on Lateral Epicondylitis in Active Patients: A Retrospective Comparative Study

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Received 2019 February 18; **Revised** 2019 March 13; **Accepted** 2019 May 12.

Abstract

Background: Extracorporeal shock wave therapy is a noninvasive, safe, and well-tolerated treatment method which is increasingly used in the treatment of lateral epicondylitis. However, the gold standard treatment protocol is still controversial.
Objectives: This study aimed to investigate and compare the efficacy of two different pneumatic pressure levels of radial extracorporeal shockwave therapy (rESWT) in active patients with lateral epicondylitis, unresponsive to conservative treatment.
Methods: This retrospective comparative study was carried out in the Department of Orthopedics and Traumatology, Duzce University School of Medicine in 2018. A total of 330 patients with lateral epicondylitis unresponsive to conservative treatment were underwent rESWT during years 2010 - 2017. The patients were divided into two groups of 181 patients (group 1) with a total of 1500 impulses of 10 Hz frequency at 1 bar of air pressure during five treatment sessions at 1 week intervals, and 149 patients (group 2) with a total of 2000 impulses of 10 Hz frequency at 2 bars of air pressure during five treatment sessions at 1 week intervals. Functional and clinical outcomes were assessed just before the treatment, at six weeks and six months after treatment using the visual analogue scale (VAS) and the Quick-Disabilities of the Arm, Shoulder, and Hand (Q-DASH) score.
Results: The mean VAS score had significantly decreased in group 1 from 8.34 ± 1.22 to 2.59 ± 1.49 (P = 0.0001) and had also in group 2 from 8.56 ± 1.22 to 2.56 ± 1.76 (P = 0.0001). The mean Q-DASH score decreased significantly in both groups; from 58.92 ± 18.48 to 9.27 ± 5.85 (P = 0.0001), and from 65.36 ± 19.32 to 9.25 ± 6.28 (P = 0.0001) in group 1 and group 2, respectively. No significant difference was observed between the pretreatment VAS and the 6-month scores of groups 1 and 2 (P = 0.103). The mean difference in the Q-DASH pretreatment and 6-week scores and between the pretreatment and 6-month scores in group 2 were higher than those in group 1 (P = 0.011, P = 0.003).
Conclusions: Although both rESWT treatment regimens caused a decrease in pain and loss of function, the superior treatment protocol for rESWT appears to be five treatment sessions at 1-week intervals, with 2000 impulses per session and 2 bars. rESWT is a good option for treating lateral epicondylitis, as it is safe and effective and leads to no complications.

Keywords: Air Pressure, Elbow Extracorporeal Shockwave Therapy Hand, Lateral Epicondylitis, Ortopedics, Pain, Shoulder, Tennis Elbow, Traumatology, Visual Analog Scale

1. Background

Lateral epicondylitis is a tendinopathy involving eccentric overload and overuse at the origin of common extensor tendons in the elbow and affects 1% - 3% of adults annually (1, 2). Conservative treatments, such as modifications of activity, ice, non-steroidal anti-inflammatory drugs, physical therapy, ultrasound, injection therapies, extracorporeal shock wave therapy (ESWT), and surgical methods have been defined, but the gold-standard treatment remains unclear (2-6). ESWT is the first-line treatment choice for lateral epicondylitis unresponsive to conservative treatment and has a number of indications for musculoskeletal disorders (1, 2, 4, 7-10). The possible mechanism of action of ESWT in soft tissues is the release of angiogenesis-related growth factors, which promote the formation of new vessels and oxygenation to accelerate tissue healing (11-14). Despite good to excellent outcomes in most studies, no gold standard ESWT-use guidelines have been described for lateral epicondylitis. In addition, the type of machine, range of doses, localization of the patient, treatment frequencies, and the use of local anesthesia remain controversial (2, 4, 6). ESWT produces shock waves by

focusing electromagnetic, electrohydraulic, piezoelectric, and radial energy using a pneumatic pressure method (15, 16). Although both focused and radial ESWT have been used for lateral epicondylitis, they differ with respect to their generation devices, physical characteristics, and mechanisms of action. Compressed air generated by rESWT accelerates a projectile that strikes a fixed applicator, and the kinetic energy is converted into a shock wave delivered to the target tissue through the skin. These shock waves are conveyed radially into broad treatment areas (16).

rESWT, also referred as unfocused ESWT, is designed for more superficial treatments and is less painful and, as a result, does not require local anesthesia during treatment; therefore, it is a noninvasive, safe, and well-tolerated treatment method for lateral epicondylitis (17-19). However, there is no final consensus about the time interval between treatments, the number of impulses or shocks, the pneumatic pressure, or the frequency of the rESWT application (17-20).

The efficacy and safety of ESWT were also clearly supported by the studies in database (1, 2, 4). On the other hand, even if there are many studies comparing the different rESWT regimens, there is no scientific evidence for rESWT that any regimen is superior or inferior for patients with lateral epicondylitis (2-5). For example, a rESWT regimen that employs 2000 pulses of 10 Hz frequency at a 1.8 bar of air pressure at each session at three once weekly sessions was compared with sham rESWT in a double-blind, randomized, placebo-controlled study. The authors concluded that rESWT does not seem to be effective in patients with lateral epicondylitis (21). On the other hand, another study with different rESWT regimens in which the total number of shocks was 2500, the pressure was 2 bars: 1500 shocks of 5 Hz frequency followed by 500 shocks of 10 Hz frequency were applied locally on the lateral epicondyle and 500 shocks of 2 bars pressure and 5 Hz frequency were compared respectively. The authors concluded that rESWT could be recommended in the treatment of lateral epicondylitis (22).

2. Objectives

The purpose of this study was to investigate and compare the efficacy of two different rESWT pneumatic pressure levels in active patients with lateral epicondylitis unresponsive to conservative treatment.

3. Methods

This retrospective comparative study examined 433 consecutive patients who underwent rESWT by the same physician from January 2010 to December 2017 for lateral epicondylitis in the Department of Orthopedics and Traumatology, Duzce University School of Medicine in 2018. The study was performed in accordance with the guidelines of the declaration of Helsinki ethical principles for medical research involving human subjects and approved by the Noninvasive-Clinical Ethical Committee of the Medical School of Duzce University, Duzce, Turkey in 2018 (no. 2018/42) and written informed consent was obtained from all patients.

A total of 330 of these patients who met the inclusion criteria were included in this study. Patients who had symptomatic isolated lateral epicondylitis, 18 - 60 years of age, with a follow-up period of at least 6 months and who underwent regular ESWT for at least 5 weeks (1 session/week) were included. Patients < 18 or > 60 years old, with a thrombosis, a fracture of the elbow or forearm, acute inflammation in the treatment area, tumor in the treatment area, pregnant, blood-clotting disorder (hemophiliacs), cervical radiculopathy or ipsilateral extremity entrapment neuropathy, bilateral lateral and ipsilateral medial epicondylitis, using corticosteroids, and those who received platelet rich plasma or an autologous blood injection in the last 6 weeks were excluded. According to these criteria; 103 patients were excluded due to cervical radiculopathy or ipsilateral extremity entrapment neuropathy (n = 18), patients < 18 or > 60 years old (n = 63), inflammation in the treatment area (n = 3), platelet rich plasma or an autologous blood injection in the last 6 weeks (n = 19).

Demographic data, including the total number of patients, mean age, percentage of male and female patients, mean duration of symptoms, percentage of involvement of the dominant extremity, and lesion side were recorded.

The lateral epicondylitis diagnosis was verified in all cases before the treatment by clinical tests, i.e., painful local palpation at the humeral lateral epicondyle and exacerbated pain at the lateral epicondyle with resisted wrist extension and a fully extended elbow. The indications for ESWT included persistence of pain, loss of function, and unresponsiveness to conservative treatment such as rest, ice, sling, and pharmacological therapies (systemic and/or local non-steroidal anti-inflammatory drugs).

Patients were randomly placed in one of two groups; group 1: 181 patients with five treatment sessions at one-week intervals and 1500 impulses/session at 1 bar, and group 2: 149 patients with five treatment sessions at one-week intervals and 2000 impulses/session at 2 bars. The treatments were performed by the same physician with 10 years of experience using the Swiss Dolorclast Master® ESWT machine (EMS SA, CH-1260, Nyon, Switzerland) calibrated regularly, which produces radial shockwaves. For the application of rESWT, the shoulder of the patient in the sitting position was brought to 45° of abduction, the el-

bow was flexed to 90° with the forearm in neutral supination and, after applying a sufficient amount of ultrasound gel to the epicondylar area with maximum pain-sensitivity, radial shock waves were applied using a standard 15 mm applicator with small circular motions but without local anesthesia. No pain relieving medication was given to the patients; however, a cold pack was applied for 20 min after rESWT, if needed.

3.1. Outcome Measurements

Functional and clinical outcomes were assessed just before the treatment and at six weeks and six months after treatment using the visual analogue scale (VAS), and the Disabilities of the Arm, Shoulder and Hand (Q-DASH) score. VAS is a scale and is useful for measuring pain that is believed to range across a continuum of values and cannot easily be directly measured. The simplest VAS is a straight horizontal line of fixed length, usually 100 mm. The Q-DASH is an abbreviated version of the original DASH outcome measure. In comparison to the original 30 item DASH outcome measure, the Q-DASH only contains 11 items. It is a questionnaire that measures an individual's ability to complete tasks, absorb forces, and severity of symptoms. The Q-DASH tool uses a 5-point scale from which the patient can select an appropriate number corresponding to his/her severity and function level. Like the original version, the Q-DASH score ranges from 0 (no disability) to 100 (severest disability).

3.2. Statistical Analysis

Statistical analyses were performed using the Number Cruncher Statistical System (NCSS) 2007 Statistical Software (Keysville, UT, USA) program for Windows. Besides standard descriptive statistical analysis (mean and standard deviation, median, interquartile range), the variables indicate a normal distribution. Unpaired *t*-test was used in the comparison of groups, repeated one-way analysis of variance was used for the time comparison of variables, post Hoc Newman Keuls multiple comparison test was utilized in the comparison of time subgroups, the variables do not indicate a normal distribution, Mann Whitney-U test was used in the comparison of groups and Chi-square test was performed during the evaluation qualitative data. A P value < 0.05 was considered significant.

4. Results

A total of 330 patients who met our eligibility criteria were included; 181 of these patients (130 [71.82%] females and 51 [28.18%] males) whose mean age was 42.72 ± 7.14 (17 - 60) years were in group 1 and 149 patients (94 [51.93%] females and 55 [30.39%] males) whose mean age was 43.11 ± 7.71 (22 - 60) years were in group 2. The right elbow was affected in 110 (60.77%), and the left elbow was affected in 71 (39.23%) patients in group 1 and the right elbow was affected in 96 (64.43%) and the left elbow was affected in 53 (35.57%) patients in group 2. The mean symptom durations were 8.07 ± 3.54 (2 - 18) months in group 1 and 8.62 ± 4.59 (2 - 20) months in group 2. No significant difference was observed between mean age, sex, affected side, dominant side, or mean symptom duration of groups 1 and 2 ($P > 0.05$) (Table 1). By the final follow-up, the mean VAS score had decreased significantly in group 1 from 8.34 ± 1.22 to 2.59 ± 1.49 ($P = 0.0001$) and had significantly decreased in group 2 from 8.56 ± 1.22 to 2.56 ± 1.76 ($P = 0.0001$). The mean Q-DASH score decreased significantly in group 1 from 58.92 ± 18.48 to 9.27 ± 5.85 ($P = 0.0001$) and had decreased significantly in group 2 from 65.36 ± 19.32 to 9.25 ± 6.28 ($P = 0.0001$) (Tables 2 and 3, Figure 1). No significant differences were observed between the VAS pretreatment and that at 6 months in groups 1 and 2 ($P = 0.103$). The mean difference in the Q-DASH pretreatment and 6-week scores and the pretreatment and 6-month scores in group 2 were significantly higher than those in group 1 ($P = 0.011$, $P = 0.003$) (Table 4). No complications such as pain, irritation, swelling or localized bleeding, petechiae, or hematomas were reported.

5. Discussion

Over the past three decades, ESWT has been widely used to treat soft tissue pathologies and other musculoskeletal disorders, such as plantar fasciitis, lateral epicondylitis, calcific tendonitis, nonunion, myositis ossificans, avascular necrosis, and chronic Achilles tendonitis (1, 15, 19-23). However, the mechanism of action of ESWT has not been

Table 1. Summary of Patient Demographics and Clinical Characteristics[a]

	Group 1 (N = 181)	Group 2 (N = 149)	P Value
Age	42.72 ± 7.14	43.11 ± 7.71	0.634[b]
Sex			0.495[c]
Male	51 (28.18)	55 (30.39)	
Female	130 (71.82)	94 (51.93)	
Affected side			0.391[c]
Right	110 (60.77)	96 (64.43)	
Left	71 (39.23)	53 (35.57)	
Dominant extremity			0.091[c]
Right	167 (92.27)	141 (94.63)	
Left	14 (7.73)	8 (5.37)	
Symptom durations	8.07 ± 3.54	8.62 ± 4.59	0.218[d]

[a] Values are expressed as mean ± SD or No. (%).
[b] Unpaired *t*-test.
[c] Chi Square test.
[d] Mann Whitney U test.

Table 2. Comparison of Mean VAS and Q-DASH Score from Pretreatment at 6 Weeks and 6 Months[a]

		Group 1 (N = 181)	Group 2 (N = 149)	P Value[b]
VAS				
	Pretreatment	8.34 ± 1.22	8.56 ± 1.22	0.094
	6th weeks	6.22 ± 1.52	6.71 ± 1.53	0.004
	6th months	2.59 ± 1.49	2.56 ± 1.76	0.879
	P Value[c]	0,0001	0,0001	
Q-DASH				
	Pretreatment	58.92 ± 18.48	65.36 ± 19.32	0.002
	6th weeks	26.34 ± 8.58	26.99 ± 8	0.481
	6th months	9.27 ± 5.85	9.25 ± 6.28	0.984
	P Value[c]	0.0001	0.0001	

Abbreviations: Q-DASH, quick-disabilities of the arm, shoulder and hand score; VAS, visual analogue scale.
[a]Values are expressed as mean ± SD.
[b]Unpaired *t*-test.
[c]Repeated One-Way ANOVA.

Table 3. Newman Keuls Multiple Comparison Test

	VAS		Q-DASH	
	Group 1	Group 2	Group 1	Group 2
Pretreatment	0.0001	0.0001	0.0001	0.0001
Pretreatment - 6th weeks	0.0001	0.0001	0.0001	0.0001
Pretreatment - 6th months	0.0001	0.0001	0.0001	0.0001
6th weeks - 6th months	0.0001	0.0001	0.0001	0.0001

Abbreviations: Q-DASH, quick-disabilities of the arm, shoulder and hand score; VAS, visual analogue scale.

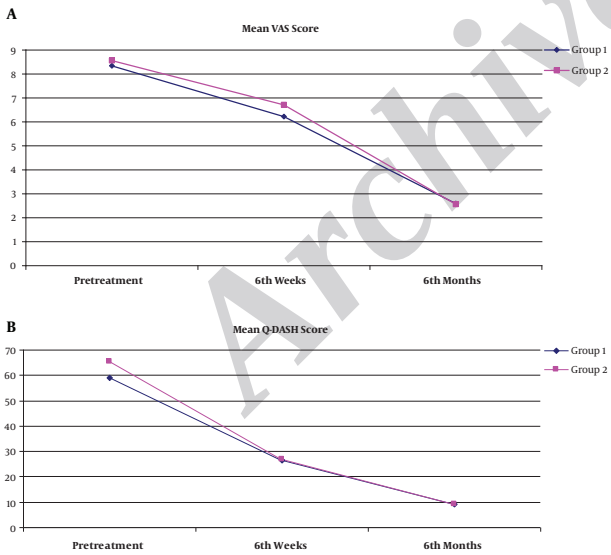

Figure 1. A, mean VAS score from pretreatment at 6 weeks and 6 months; B, Mean Q-DASH score from pretreatment at 6 weeks and 6 months

fully demonstrated. Several animal studies have examined the role and therapeutic effects of ESWT (11-14). Orhan et al. performed a comparative histological and biomechanical study in a rat model of Achilles tendon injury treated with ESWT (500 shocks, 15 kV) and a control group. They reported that new vessel formation increased, fewer adhesions developed, and mechanically stronger tissue was obtained (11). Hsu et al. reported that collagen synthesis increased, new vascularization was accelerated, and tensile strength of the tissue increased when ESWT was applied at 0.29 mJ/mm^2 in a rabbit patellar tendinitis model (13). In addition, Wang et al. showed that low-energy shock waves (0.12 mJ/mm^2, 500 shocks) accelerated the formation of new vessels when applied to the noble tendon-bone junction, and this effect continued for 12 weeks (14).

Table 4. Comparison of Mean Changes VAS and Q-DASH Score from Pretreatment at 6 Weeks and Pretreatment at 6 Months[a]

		Group 1 (N = 181)	Group 2 (N = 149)	P Value[b]
VAS				
	Pretreatment - 6th weeks	2.12 ± 1.28	1.85 ± 1.32	0.052
	Pretreatment - 6th months	5.75 ± 1.61	6 ± 1.77	0.103
Q-DASH				
	Pretreatment - 6th weeks	32.59 ± 19.65	38.38 ± 20.92	0.011
	Pretreatment -6th months	49.66 ± 19.43	56.11 ± 20.16	0.003

Abbreviations: Q-DASH, quick-disabilities of the arm, shoulder and hand score; VAS, visual analogue scale.
[a]Values are expressed as mean ± SD.
[b]Mann Whitney U test.

The clinical applications of ESWT vary in musculoskeletal disorders but are currently focused on the radial (19, 24). Most clinical studies have reported that rESWT has potential advantages, such as a larger treatment area, less need for specific focusing, no requirement for additional local anesthesia, and low cost (17, 18). In addition, an overview of the physical principle differences of rESWT are pressure, pulse duration, pressure field (radial, divergent), penetration depth (small, superficial) and effects on tissue (16, 19, 25).

However, despite good to excellent outcomes in most studies, there are no gold standard guidelines described for rESWT use in lateral epicondylitis (17, 18, 22, 26). The type of machine, range of pneumatic pressure, localization of the patient, treatment frequencies, and use of local anesthesia remain controversial (19, 25). In this present study, we compared the clinical results of two patient groups who were diagnosed with lateral epicondylitis and treated with two different rESWT protocols (five treatment sessions at 1-week intervals, with 1500 or 2000 impulses/session and 1 or 2 bars, respectively) using the Swiss Dolorclast Master® ESWT machine, which produces radial shockwaves. Based on the results of this study with two different regimes, the rESWT can be used in the treatment of lateral epicondylitis.

Although low, medium and high energy is mentioned in the literature, there is no final consensus on the definition (4, 20). For example, Speed et al. defined low, medium, and high energy flux densities as: < 0.10 mJ/mm^2, 0.1 - 0.20 mJ/mm^2, and > 0.20 mJ/mm^2 (20). On the other hand, Rompe et al. evaluated 0.08 mJ/mm^2 as low energy and 0.08 - 0.28 mJ/mm^2 as medium energy (4). Different treatment protocols and ranges of pneumatic pressure or devices are often used for rESWT treatment of musculoskeletal disorders (17-19). Several studies have concluded that radial shock wave therapies are a noninvasive, safe, and well-tolerated treatment method for lateral epicondylitis (17, 18, 22, 24). Herein, we performed a comparative retrospective single-center study with a large number of patients using two different pneumatic rESWT pressures and a 6-month follow-up.

Similarly, several studies have shown that different rESWT treatment protocols for lateral epicondylitis produce good to excellent clinical outcomes over short or long-term follow-ups with different treatment protocols (17, 18, 22, 26). For example, Spacca et al. performed a comparative prospective randomized controlled single blind study of rESWT and a control group for 6 months; 31 patients underwent rESWT (2000 pulses, 4 - 10 Hz, 1 - 1.2 bar, once/week, four sessions) another 31 underwent rESWT (15 - 20 pulses, 4 - 10 Hz, 1 - 1.2 bar, once/week, four sessions). They reported that rESWT decreased pain and functional impairment and was a safe, effective therapy for treating lateral epicondylitis (17). In addition, Yang et al. randomized 30 patients into the following lateral epicondylitis treatments: 15 rESWT (2000 pulses, 10 Hz, individual pneumatic pressure, once/week, three sessions) and 15 subjects who underwent only physical therapy with a 24-week follow-up. Their findings were similar to those of Spacca et al. (18). Another study compared 30 patients treated with rESWT and 30 patients who underwent ultrasound therapy and found that the rESWT group had significantly improved pain or reduced pain and improved function at the 8-week follow-up (26). In the present study, despite the short follow-up time, our outcomes were concordant with previously published reports. The mean clinical and functional outcomes after 6 months showed significant improvements in the VAS and Q-DASH scores compared to the preoperative status ($P < 0.05$) at both rESWT doses.

Only a few studies have supported the conclusion that rESWT is no more effective than placebo for lateral epicondylitis (21, 27, 28). Capan et al. evaluated the pain, grip strength, and functional results after rESWT vs. placebo. The authors compared 28 patients who underwent rESWT (2000 pulses, 10 Hz, 1.8 bar, once/week, three sessions) to 28 who underwent sham rESWT without applicator contact. The patients were evaluated with the VAS, the Roles and Maudsley scale, and the patient-rated tennis elbow evaluation for pain and function. They concluded that rESWT was not more effective in reducing pain or improving function or grip strength than a placebo after a 3-month follow-up (21). Similarly, Haake et al. evaluated pain, grip strength, and functional results of ESWT vs. placebo. Those authors compared 165 patients who underwent ESWT (2000 pulses, 0.07 - 0.09 mJ/mm^2, once/week, three sessions) to 137 who underwent placebo-ESWT without applicator contact. The patients were evaluated with a VAS, the Roles and Maudsley scale, and the patient-rated tennis elbow evaluation for pain and function. They concluded that ESWT was ineffective for reducing pain and improving function and grip strength compared to the placebo after a 12- month follow-up (27). Our results are different from the study conducted by Capan et al. using rESWT because of differences in the treatment protocol, follow-up period, and the evaluation tests. In addition, considering that our results are different from those of Haake et al., different ESWT devices were used, with different treatment protocols and evaluation tests.

Some minor complications have been discussed in the literature with limited reports associated with ESWT treatment such as pain, irritation, swelling, localized bleeding, petechiae, or hematomas (29). These data were not confirmed by our study in which there were no reported complications.

A few limitations of our study should be mentioned. First, it was a retrospective design and examined short-term outcomes. In addition, there were substantial differences in rESWT use such as clinical conditions, study design, technology and devices, treatment protocols, and the follow-up period. However, that this was a single medical center study with a large number of patients with the same diagnosis, treated with a standard protocol by a single physician with 10 years of experience; furthermore, the same radial shockwave-generators were used to evaluate the patients after a considerable follow-up time.

5.1. Conclusions

Although both rESWT treatment regimens decreased pain, the rESWT treatment protocol of five treatment sessions at 1-week intervals, with 2000 impulses per session and 2 bars was superior to five treatment sessions at 1-week intervals with 1500 impulses/session, and 1 bar. Taken together, this study was conducted in a single hospital in a single country but it has a large series of patients. Although it is assertive to take a general conclusion, according to our results; rESWT is a successful treatment in terms of patient satisfaction and pain relief at both rESWT pneumatic pressure levels. For this reason, rESWT constitutes a safe and effective option for treating lateral epicondylitis, without complications. Further prospective-multicenter

studies with a large number of patients are needed to optimize the rESWT treatment protocol for use during a long-term follow-up.

Footnotes

Authors' Contribution: The idea of research, hypothesis generation, planning the methods, biological materials reagents referred patients, hypothesis generation, and critical review: Mehmet Arican; supervision and responsibility for the organization and course of the project, and manuscript preparation: Mehmet Arican, Yalçın Turhan; responsibility for conducting experiments, management of patients, organizing and reporting data: Mehmet Arican, Zekeria Okan Karaduman; analysis, presentation and logical explanation of results: Yalçın Turhan; literature check: Yalçın Turhan; responsibility for creation of the entire or a substantial part of the manuscript: Zekeria Okan Karaduman.

Conflict of Interests: The authors have not received financial payments or other benefits from any commercial entity and all of them declared no conflict of interest during preparation and publication of this manuscript.

Ethical Approval: The study was performed in accordance with the guidelines for declaration of Helsinki ethical principles for medical research involving human subjects and approved by the Noninvasive-Clinical Ethical Committee of the Medical School of Duzce University, Duzce, Turkey in 2018 (no. 2018/42).

Funding/Support: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Patient Consent: Written informed consent was obtained from all patients.

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