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Research article

Effect of radiofrequency denervation on pain severity among patients with cervical, thoracic or lumbar spinal pain: A clinical retrospective study

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HIGHLIGHTS

- Radiofrequency ablation (RFA) method emerges as a very successful treatment method in patients who do not have an operative pathology but who suffer from chronic pain.
- Especially, considering the persistent outpatient clinic admissions of patients with persistent low back pain, RFA is a "rescuer" position for most clinicians.
- The clinical relief of the patients for two years is one of the most critical data clearly demonstrating the long-term success of the procedure.

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ABSTRACT

Background: Low back pain is the leading cause of job-related disabilities. The zygapophyseal (facet) joint has been identified as a cause of spinal pain in 15%–45% of individuals. Radiofrequency ablation (RFA) to the facet joints of the lumbar, cervical and thoracic regions and discussion of the 2-year follow-up results will provide additional data and contribute to understanding the long-term effectiveness of RFA.

Methods: Patients with cervical, thoracic or low back pain, not accompanied by radicular pain and without primary and/or metastatic disease in the spinal region during radiological evaluation were retrospectively analysed. A total of 1274 patients aged >18 years who had clinical follow-up for at least 1 year and had back pain for >6 months were included in the study. The RFA groups were compared within themselves before and after the application. Moreover, patients who received RFA were compared with those who did not receive RFA (controls). The visual analogue scale and quality-of-life scores of the patients were evaluated. Periodic clinical follow-ups revealed changes in neurological status.

Results: Of the 774 patients who underwent RFA, 156, 184 and 434 patients had pain in the cervical, thoracic and lumbar and lumbosacral regions, respectively. The control groups consisted of 108, 122 and 270 patients, respectively. No significant difference in any of the baseline demographic variables was observed between the groups ($p > 0.05$). A significant improvement was found in both visual analogue scale and quality-of-life scores when compared before and after RFA application within the groups. In addition, a significant improvement was found in the RFA group compared with the control group.

Conclusions: As far as we know, this is the first comparative study of RFA involving the cervical, thoracic and lumbar spinal regions. RFA made it possible to obtain satisfactory results in all three regions. With its increasing popularity and frequency of use, new indications for RFA may emerge.

1. Introduction

Back pain occurs in 70%–85% of the general population, and 12%–30% of adults have a specific cause for their back pain [1]. Low back pain (LBP) is the leading cause of job-related disabilities [2]. The zygapophyseal (facet) joint (FJ) has been identified as a cause of spinal pain in 15%–45% of individuals [3]. It is also known that the joint is a highly functional anatomical structure in segmental spinal movement. Fluid increase and oedema secondary to inflammation in the FJ are induced by recurrent irritative factors. Degenerative changes in FJs can

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cause abnormal strain and stress and increase the load on the FJs. Positive response to pain with local anesthetic blockade at the location of nerve supply supports facet arthropathy as the cause [4].

Therapeutic interventions for FJ pain include intra-articular steroid injections, extracorporeal shockwave therapy, surgical treatment, medial branch nerve blocks and medial branch nerve radiofrequency ablation (RFA) [5, 6]. RFA is an injection procedure that is used to treat several conditions, including chronic spinal pain. Although this minimally invasive procedure can be performed around or inside the joint, the main target is the external branches of the recurrent sensory nerve. Thus, effective pain control can be achieved [7]. Two medial branches of the primary dorsal rami of the spinal nerves, which innervate the FJ at the pathological level, are targeted with RFA [8]. The orientation and route of the medial branch varies depending on its location in the spinal canal. For example, unlike the lumbar segment, the course of the medial branch may vary according to the thoracic segment [9].

Radiofrequency waves that are passed through an insulated needle ablate the pain-causing nerve and eliminate the transmission of pain signals to the central nervous system. The needle tip must be at the correct location for the intervention to be effective. Despite publications about the results of RFA, controversy about its results continues [10, 11, 12].

This study aimed to retrospectively present the clinical results of a 2-year follow-up of RFA applied to all spinal regions.

2. Materials and methods

In this study, all procedures performed were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all participants included in the study. Ethics committee approval was obtained from Kırıkkale University Non-invasive Research Ethics Committee (No. 20/03-19, Date: 08/09/2018).

A total of 1274 patients with cervical, thoracic or LBP, among 38336 patients who applied to the outpatient clinic between January 2017 and August 2018, were retrospectively analysed. The patients who had cervical, thoracic or LBP not accompanied by radicular pain and who did not have primary and/or metastatic disease in the spinal region in radiological evaluation and who have at least 2 years of follow-up were included this study. RFA was applied to 774 of 1274 patients, whereas the rest comprised the control group. Individuals aged <18 years were not included in the study. Other inclusion criteria were pain resistant to conventional therapy, including nonsteroidal anti-inflammatory drugs (NSAID), muscle relaxants and physical therapy and a baseline visual analogue scale (VAS) [13] score of at least 4. The exclusion criteria were as follows: patients with severe root compression findings on imaging modalities, neurological deficits on physical examination, severe radicular symptoms or neurogenic claudication findings, and patients with previous nerve stimulation such as dorsal root stimulation and peripheral nerve stimulation.

The patients were diagnosed following detailed neurological and radiological imaging examinations to determine the location of pain. Tenderness of the paraspinal region and pain and tenderness on palpation in all FJ locations are one of the most important neurological findings. In addition, spinal flexion–rotation and extension movements were applied to all patients along with the Valsalva manoeuvre. All patients underwent standardised physical examination provocation tests. Direct radiography, computed tomography and magnetic resonance imaging (MRI) were performed on all patients. The hyperintensity seen in T2 sequences, especially in the FJs, was considered if it corresponds to the pain area on palpation. However, despite the controversial role of imaging modalities in determining the degree of FJ pain, they have an important role in excluding other pain-causing pathologies. For each patient, the location of the RFA application was determined based on neurological examination and MRI findings, and RFA was applied to a single level in a single session in the RFA group.

The patients were divided into three groups according to their pain locations: cervical, thoracic and lumbar. For each group, control groups (500 patients) were formed from patients who did not receive RFA treatment. Appropriate NSAID treatment was initiated for the control group for approximately 3–4 weeks. How long and in which effectiveness NSAIDs will benefit varies for each individual. In cases of acute low back pain, relief is usually observed within the first 3 weeks. For this reason, during this period, NSAID use in a dose and duration that will show sufficient pain relief is sufficient for most of the patients [14]. Since it would be difficult to create a patient group with chronic LBP who did not use any medication as a control group, a control group was formed from patients using only NSAIDs. In addition, the patients who comprised the control group were not started on any additional medications (antidepressants containing painkillers, other opioid drugs, etc.), and patients using other drugs were not included in the study.

Given the multitudes of RFA articles on a single spinal region in the literature, this study aimed to summarise and compare the entire spinal block in a single article. The results were not evaluated as a whole, and each spinal region was evaluated separately.

Demographic data, body mass index (BMI), VAS scores, quality-of-life scores and information on pre-procedural NSAID use were obtained. VAS, which is a subjective measuremet system that has been approved for use for both acute and chronic pain, and is created by scoring patients from 1 to 10. Pre-procedural VAS pain scores were documented before the RFA procedure (pre-VAS) and after the RFA at the following time points: 3 months, 6 months, 1 year and 2 years. Quality-of-life was assessed using the SF-36 Health Survey [15]. It holds eight subscales categorised into two scores. The scores are then transformed into a scale ranging from 0 (reflecting poor quality-of-life) to 100 (reflecting excellent quality-of-life). The scores were documented before RFA after RFA at the following time points: 3 months, 6 months, 1 year and 2 years.

The patient's anamnesis, recorded during routine clinical follow-ups, was compared with the initial complaints and analyzed. Compared to the preoperative period, the patient was examined for improvement in both his physical examination and symptoms, and patients whose clinical symptoms improved were recorded as benefiting from the operation. The cases in which the VAS score decreased by two levels or more after the RFA application were also recorded as improved. The groups that received RFA were compared within themselves before and after RFA. In addition, patients who received RFA were compared with patients who did not receive RFA (control group). Some of the illustrative cases in this series are shown in Figure 1.

2.1. FJ injection procedure

All procedures were supervised and/or performed by the same neurosurgeons. Participants were positioned prone on a radiolucent fluoroscopy table. Non-invasive blood pressure monitoring and a pulse oximeter were placed. Except in rare circumstances, sedation was not administered. All prognostic injections were performed with superficial local anaesthetic and fluoroscopic guidance. Individuals with bilateral pain received bilateral blocks, whereas those with unilateral pain received single one-sided blocks. The lumbar, thoracic or cervical spine was prepared with chlorhexidine and draped in a sterile manner. A standard conventional RFA technique was followed.

Each stage of the procedure was controlled by placing the C-arm fluoroscopy in the antero-posterior or oblique position, depending on the patient's anatomical structure, and the area to be injected was clearly revealed. The entry point was determined lateral to the midline, on the medial edge of the transverse process, targeting the area where it joins the superior articular process, and local anesthesia was applied using 1% lidocaine after sterile preparation. After reaching the target point, 150 mm long electrode with 10 mm normal or angled tip was used for RFA. If the angled tip was used, the convex surface of the tip was used after

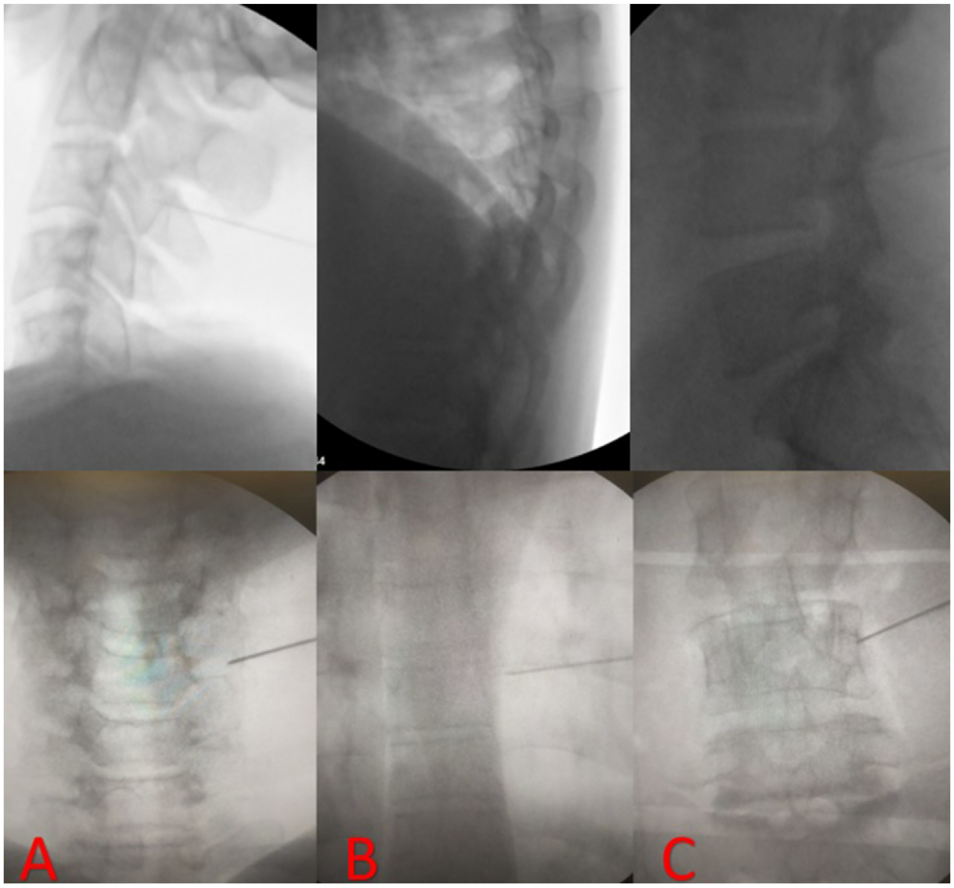


Figure 1. Cervical (C5-6, A), thoracic (T4-5, B) and lumbar (L4-5, C) radiofrequency ablation procedure with facet denervation in different patients with fluoroscopy.

reaching the medial branches in order to maximize the efficiency of the RFA procedure. In order to further enlarge the lesion area, the cannula should be deepened from this point and an angulation of 180° should be performed on the lower part of the posterior foraminal wall.

In most patients, a curved 18-gauge 100-mm RFA cannula with a 10-mm active tip (BMC RF Cannula, Baylis Medical, Canada) was used and steered to the correct location. Some patients, because of body habitus, did require a longer cannula. The final cannula positioning was confirmed. We performed motor stimulation using one electrode at a time to prove the absence of motor fibre recruitment or paraesthesia in the limb before thermal lesioning (at 2 H and 2 V). The thermal lesion was then started at 80 °C for 90 s. The target temperature was monitored to ensure that appropriate temperatures were reached. After the thermal lesion was created, the motor test was repeated first. Afterwards, anteroposterior, lateral, and oblique views were taken with C-arm fluoroscopy, final controls were performed, and the electrodes were removed. After the procedure for each level, 0.5% bupivacaine and 40 mg/mL methylprednisolone acetate mixture were injected in a total of 1 cc.

2.2. Statistical analysis

All statistical analyses were performed using IBM SPSS 20.0 software (IBM Corp., Armonk, NY, USA). Data are reported as the mean ± SD for normally distributed continuous variables and as number and percentage for dichotomous variables. Data were compared between the groups using the chi-square test for categorical data and the t-test or analysis of variance (or the Kruskal–Wallis test as a nonparametric alternative) for continuous data. A two-tailed $p < 0.05$ was considered to indicate significant differences.

3. Results

Of the 1274 patients who were included in the study and 774 patients underwent RFA, 156 had pain in the cervical region, 184 in the thoracic region and 434 in the lumbar and lumbosacral region. The control groups consisted of 108, 122 and 270 patients, respectively. There were 581 (46.1%) male patients and 693 (53.9%) female patients with a mean age of 40.03 ± 15.26 (range, 19–75) years at initial symptom onset. No family history of vascular malformations, spinal trauma or surgery was noted for any patients at presentation. Cervical or thoracic LBP without radicular pain was the most common symptom in most of the patients. The median interval between symptom onset and date of diagnosis was 7.9, 6.5 and 5.4 months in the lumbar, thoracic and cervical groups, respectively.

In the RFA group, 277 (63.5%) patients in the lumbar, 46 (25%) in the thoracic and 65 (41.6%) in the cervical group were on NSAIDs, respectively. No significant difference was found in the clinical relief between those who used NSAIDs and those who did not use NSAIDs before the procedure ($p > 0.05$). In addition, no significant difference was found in the BMI of all three groups ($p > 0.05$).

Appropriate NSAID treatment was initiated for the control group in approximately 3–4 weeks. No mortality was observed in the study. No patient reported any side effects or complications from the RFA procedure at any follow-up time points. However, when the motor response was checked during the procedure, motor responses in the form of tremors and contraction in the relevant extremity were obtained in 10 patients in the cervical, 7 in the thoracic and 5 in the lumbar region. Thereupon, the entrance location was changed, and the process was completed without any complications.

The baseline demographic and procedural characteristics by localisation are summarised in Table 1. No significant difference in any of the baseline demographic variables was observed between groups ($p >$

Table 1. Summarized data of patients with spinal pain.

	Cervical	Thoracic	Lumbar	Control
Number of Patients	156	184	434	C-108, T-122, L-270
Gender (male/female)	80/76	90/94	168/266	243/257
Mean Age	35.33 ± 9.23	40.04 ± 10.84	45.77 ± 19.67	40.26 ± 7.21
Symptom duration, months	5.4	6.5	7.9	7.2
Follow up, months	24.2	24.7	25.1	24.8
Pre-procedural NSAID use	65	46	277	500
BMI (kg/m^2)	22.77 ± 5.51	26.85 ± 8.22	29.85 ± 7.72	27.47 ± 6.51
Pre VAS score	7.1 ± 1.72	7.2 ± 2.14	7.8 ± 2.86	7.5 ± 2.17
Post VAS score, months (3rd/24th)	2.0 ± 0.52/2.9 ± 0.71	2.1 ± 0.61/3.0 ± 0.34	2.2 ± 0.41/3.1 ± 0.64	5.7 ± 0.51/6.1 ± 0.44
Early clinical follow-up (Improve/Stable)	141/15	166/18	394/40	97/403
Last clinical follow-up (Improve/Stable)	134/22	157/27	372/62	78/422

0.05). Table 1 shows the changes in VAS scores after intervention. In all three RFA groups, a significant decrease in the VAS score was observed at the 3-month control. The p values in the lumbar, thoracic and cervical groups were $p = 0.001$, $p = 0.018$ and $p = 0.026$, respectively. When compared with the NSAID alone (control) group, a significant difference was observed in all three RFA groups ($p < 0.05$).

The clinical relief at the end of the third month was noticeably good. The difference between the clinical relief after month 3 and that after months 3, 12 and 24 was not significant ($p > 0.05$). However, a minimal increase in VAS scores was noted at the end of month 12. Participants' VAS scores were comparable at months 12 and 24. Although no significant difference was found, the increase in VAS scores indicates that the procedure provided short-term relief in all three regions.

Detailed quality-of-life scores for the groups are shown in Table 2. In the quality-of-life scores, a significant improvement was found among the RFA groups after the procedure. In addition, a significant difference was noted between the RFA group and the control group ($p < 0.001$).

4. Discussion

Radiofrequency applications and their benefits have been extensively reviewed in the literature. They have become a frequently used method in soft tissue lesions, cardiac lesions orthopaedic applications and ablation of liver and kidney tumours. The radiologic diagnosis of spinal diseases has become much more precise with advances in spinal imaging using MRI, which is especially correlated with CT with reconstruction images. Thus, the RFA method has begun to be used frequently in spinal region pathologies [16, 17, 18, 19].

Repetitive stress or trauma results in osteoarthritis, which in turn causes inflammation and build-up of joint fluid. FJ inflammation appears to be one of the major causes of pain in the spinal area. Neck pain or LBP, which is very common in clinical practice, was significantly relieved with FJ interventions [20, 21, 22]. RFA has emerged as a very successful treatment method in patients who do not have an operative pathology or who have concomitant diseases that would make operation risky but who suffer from chronic pain [23, 24]. The economic burden of LBP on the country's economy and the failure of most surgeries to alleviate back pain creates a vicious circle. Thus, in addition to the positive clinical results of RFA, its economical nature is among its advantages [25].

Optimising pain management and patient selection, preventing complications and detailing clinical studies have been dependent on understanding the mechanism of RFA application. With the ablation and creation of the electromagnetic field, the RFA method can achieve the desired effectiveness. By reaching high temperatures, it creates coagulation necrosis, burns the painful nerve and can significantly alleviate the patient's pain. Thanks to the electromagnetic field it creates, it can manage neuroinflammation, pain pathway and gene expression (C-Fos, CGRP, ATF3). It can also regulate endogenous opioids and regenerative

Table 2. Quality of life in groups according to clinical follow-up.

Mean Scores for SF-36	Cervical	Thoracic	Lumbar	Control
Physical functioning (Pre/3rd/24th)	79.27/91.12/90.42	81.32/92.08/91.17	80.24/92.91/91.77	81.71/81.9/80.08
Role limitation caused by physical health (Pre/3rd/24th)	73.12/89.66/88.15	75.27/90.85/89.87	76.29/91.34/90.27	75.63/75.9/74.85
Body pain (Pre/3rd/24th)	54.79/80.97/80.05	55.49/81.92/80.78	55.72/81.99/81.57	55.98/56.1/55.74
General health (Pre/3rd/24th)	64.53/77.86/76.93	66.79/78.53/77.63	65.79/79.32/78.23	67.03/67.3/66.95
Vitality (energy/fatigue) (Pre/3rd/24th)	55.21/63.80/62.45	56.87/64.21/63.88	55.89/64.61/64.28	56.92/57.1/56.84
Social functioning (Pre/3rd/24th)	80.42/90.12/89.03	81.55/90.46/89.25	81.78/91.13/89.67	82.56/82.6/82.01
Role limitation caused by emotional problems (Pre/3rd/24th)	89.67/95.47/94.17	91.31/95.56/94.63	90.91/95.87/94.42	91.82/92.2/92.11
Emotional well-being (Pre/3rd/24th)	66.24/73.68/72.57	67.39/74.84/73.78	68.01/75.27/74.51	67.91/68.2/68.30
Physical component score (PCS) (Pre/3rd/24th)	43.43/51.17/49.67	44.53/50.32/49.87	45.17/51.02/49.95	44.88/44.9/44.81
Mental component score (MCS) (Pre/3rd/24th)	52.97/55.82/54.73	53.67/56.88/55.76	53.52/56.71/55.61	53.44/53.6/53.51

A statistically significant difference was found in the quality of life of the groups treated with RFA compared to the pre-op period. There was also a statistically significant difference compared to the control group receiving appropriate NSAID treatment ($p < 0.001$). Scores represent the level of functioning and range from 0 (poor) to 100 (excellent).

mechanisms and act on spinal cord cells by minimising microglial activity (and neurotransmitters such as BDNF, PI3K and p-ERK) [26].

MacVicar et al. reported that RFA treatment success was defined as at least 80% relief of pain for at least 6 months and required no other healthcare for back pain [27]. For the cervical region, Lord et al. observed a significant reduction in pain following RFA to the cervical medial branch [28]. Multiple studies have demonstrated that dual concordant medial branch with higher rates of relief (80%–100%) have been shown to have the best outcomes [29].

Although Manchikanti et al. showed some benefits of RFA treatment to the lumbar medial branch [4], the results of other studies are consistent with clinical trials and systematic reviews that have shown negative evidence for the therapeutic value of facet blocks [30, 31]. If the treated FJs are the source of the pain, the patient may begin to notice longer-lasting pain relief from denervation 2–5 days after the injection [32]. In our study, a minimal increase in VAS scores was observed at the end of the first year. However, no significant difference was found in VAS scores at the end of the second year. The finding that there is no worsening in the quality-of-life and VAS scores reveals that the long-term results of RFA are satisfactory if applied correctly. However, in contrast to the literature, good results were obtained in our study independent of the preoperative VAS score [7]. Consistent with the literature, a significant decrease in VAS scores was found in the early results, but at the end of the second year, no significant difference was found [7].

Postoperatively, a significant improvement was noted in both VAS scores and quality-of-life scores compared to the preoperative status and the control group. The clinical relief of patients after 2 years is one of the most critical data, clearly demonstrating the long-term success of the procedure.

In the literature, patients who respond well to the RFA procedure are those who have high preoperative VAS scores and use low-dose NSAIDs [7, 33, 34]. However, in our study, no pre-procedure demographic data (including NSAID use) were related to the clinical relief seen in the postoperative period. Despite its frequent use and extensive discussion in the literature, the success rates of RFA in different spinal regions could not be clearly revealed. In all three groups, we think that RFA gives satisfactory results in facet-induced pain in the spinal region, since a significant improvement was found in the quality-of-life and VAS scores. Moreover, the statistical ratios and final figures obtained were comparable for all regions.

In clinical practice, RFA is used with increasing frequency. Considering that numerous clinic outpatients had persistent LBP, RFA is considered a ‘rescuer’ by many clinicians. We think that our study is valuable given the small number of studies on the cervical and thoracic regions and the low number of samples in these studies.

The success of RFA has been demonstrated in patients with severe spinal stenosis or pathological FJ cysts and patients who do not require surgery after examination and imaging modalities [35, 36]. If sufficient soft tissue is coagulated, patients can experience lasting clinical relief of their symptoms and improvement in spinal motion.

5. Limitations

The retrospective design of this study is one of the most important limitations. Prospective randomised controlled trials and sample enlargement will yield more valuable results. Given the retrospective nature of this study, forming the control group was challenging. Moreover, causality could not be established without a formal randomised controlled trial. Multi-centre randomised trials are needed to ascertain the best way to diagnose FJ pain, confirm the efficacy of RFA and determine which patients benefit the most.

6. Conclusion

We believe this study provides new information by showing the effectiveness of RFA in three spinal regions and making comparisons between the groups. Our study revealed the efficacy of RFA on the cervical, thoracic and lumbar spinal regions for the first time in the literature, and satisfactory results were obtained in all three regions, which will lead to new indications and increased use of RFA treatment.

Declarations

Author contribution statement

Mehmet Huseyin Akgul: Conceived and designed the experiments; Performed the experiments; Contributed reagents, materials, analysis tools or data.

Mehmet Yigit Akgun: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

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Data availability statement

Data will be made available on request.

Declaration of interests statement

The authors declare no conflict of interest.

Additional information

No additional information is available for this paper.

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