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Actigraphic Assessment of Sleep Quality in Patients Before and After Lumbar Facet Denervation by Radio Frequency

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Abstract: We looked at the correlation between pain severity levels and sleep graphic analysesin patients with lumbar degenerative narrow canal disease before and after facet blockage by the percutaneous radio frequency method, using an actigraphy bracelet. Thirty patients were included in the study. Before the operation and in the first week and first month afterwards, we used an actigraphy device to provide objective analysis data alongside a number of methods of measurement which relied on subjective data.
A comparison was made between the objective actigraphic analyses and the subjective tests before the blockage and in the first week and first month afterwards. A statistically significant correlation was found between the analyses and the tests ($p<0.005$).
In these kinds of study, evaluating sleep disturbance along with pain yields objective results. The results obtained, which conformed to each other, showed that quality of life improved in a shortime. The actigraph is beneficial in this regard.
Keywords: Actigraphy, choronic pain, facet blockage, lumbar degenerative diseases, radiofrequancy denervation, sleep disturbance.

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Introduction

Chronic back pain is a commonly encountered disease. It is caused in approximately 70% of cases by degenerative lumbar disease (Evren *et al.,* 2005; Hurley *et al.,* 2010; Hartwell *et al.,* 2014).This is a clinical picture deriving from degenerative changes in the intervertebral disk, corpus, intervertebral foramen, facet articulations, lamina and ligaments (Marin *et al.,* 2006; O'Donoghue *et al.,* 2009; Patel *et al.,* 2014). It is noticeable that after the complaint of back pain, the second most frequent complaint of between% 68 and 75% of patients with degenerative lumbar disease is said in the literature to be sleep disturbance (Evren *et al.,*

2005; Marin *et al.*, 2006; Şendir *et al.*, 2007; Hurley *et al.*, 2010; Utku *et al.*, 2010). It was shown in a study carried out on hospitalized patients that the most important factor which disturbed their quality of sleep was pain (Şendir *et al.*, 2007). In another study, a significant correlation was found between the intensity of back pain and the level of disturbance of sleep quality. It was shown that the quality of sleep improved after treatment for the reduction or relief of pain (Evren *et al.*, 2005; Şendir *et al.*, 2007; O'Donoghue *et al.*, 2009; Hurley *et al.*, 2010; Utku *et al.*, 2010; Hartwell *et al.*, 2014).

In patients with degenerative lumbar disease, migration of proinflammatory cytokines such as prostaglandin E, serotonin, bradykinin, histamine, interleukin 6 (IL-6), interleukin 10 (IL-10), and GABA because of the pain sensitizes the nociceptors. Action potentials spread along the axon as a result of activation of peripheric nociceptors and reach the cell body in the dorsal root ganglion. Here, the neurotransmitters substance P and calcitonin gene-related peptide (CGRP) are produced in the cell ribosomes, and are secreted from the nerve endings making synapses in the second-rank noci-responsive neurons in the spinal cord. After that, they activate the neurokinin receptors (NK-1R) in the dorsal horn cells of the spinal cord and produce a new action potential. This newly produced action potential signal is sent to the neospinothalamic or paleospinothalamic tractus, from there to the middle brain, and to the thalamic, hypothalamic and limbic structures of the brain. From these places, it is spread to many deep and cortical pathways in the brain and results in wide and serial stimulation. This pain stimulus causes a sensorial and emotional response, which includes sleep disorders, which are relevant to our topic (Smith and Haythornthwaite, 2004; Campbell *et al.*, 2013; Hartwell *et al.*, 2014).

In a recently published article (2), Campbell *et al.*, (2013) showed by positron emission tomography (PET) that endogenous opioid peptides bound strongly to Mu Opioid Receptors (MOR) especially in the prefrontal cortex, primary and secondary somatosensorial cortex, insula, thalamus and anterior cingulate regions of the brain in healthy volunteers in whom supraspinal dysfunctional pain had been created. In the same study, changes were shown by PET and functional MRG in the same cerebral regions in signals of metabolic activity and oxygen levels according to the level of pain applied. In this study, hypoactivation in the dorsolateral prefrontal cortex was shown by PET and functional MRG when pain was accompanied by complaints of sleep disturbance and a reduction in sleeping time. In these studies, it was emphasized that in the treatment of pain and in the assessment of diseases causing pain such as fibromyalgia, peripheral neuropathic pain and rheumatoid arthritis, this should be taken into account in sleep disorders (Campbell *et al.*, 2013; Onat *et al.*, 2013).

In the treatment of patients with degenerative lumbar disease, drugs, physiotherapy options and surgical treatment options are available. One of the treatment options for suitable patients is the minimally invasive method of percutaneous lumbar facet denervation, which does not involve the risks of general anesthesia and serious surgery.

Percutaneous lumbar facet denervation is not an alternative to classical surgery treatment. However, it is a method of treatment for pain which may sometimes be preferred by patients as an addition to drug and physiotherapy methods for patients with back pain but without neurodeficits in situations where there are indications for surgery but where surgery may carry a high risk. After performing percutaneous lumbar facet denervation, we compared by means of various tests the changes in pain and sleep disturbance between before the blockage operation and in the first week and first month after it, and the aim of the study was to evaluate the effects on the quality of life of the patients. We used an actigraphy bracelet

(Figure 1) to provide objective data, and examined the correlation between pain severity levels of the sleep graphics and analyses in pre- and post-blockage patients, and evaluated the conformity between the subjective tests and the actigraphy measurement analyses (Figure 2).

Material and Methods

This was a prospective study planned jointly by Şifa University Medical Faculty and the Neurosurgery and Psychiatry clinics of Buca Government Hospital. We obtained the approval of Şifa University Ethics Committee, dated 30.5.2014, Reference No: 144-50. The characteristics of patients with a complaint of back pain who formed the study group were as follows: 1-no neurological deficit found in neurological examination, and surgery not considered for reasons of the complaint of back pain, but complaints not relieved by drug therapy or physiotherapy; 2-a diagnosis by radiological methods or MRI of lumbar degenerative disease such as lumbar degenerative narrow canal, scoliosis, old vertebral collapse fractures, or lumbar degenerative disk hernia; 3-being in a mental state to cooperate. Thirty patients between the ages of 40 and 60 years who met these criteria and for whom facet blockage by the minimally invasive percutaneous radiofrequency method had been recommended were included in the study. The Informed Voluntary Consent Form (conforming to the Regulation on Clinical Research) concerning the study was read to the patients, and signed by the patient's next of kin and by the doctor. Before intervention on the patients started, their sociodemographic characteristics including age, gender, smoking and alcohol, tea and coffee consumption habits, drug or substance dependence, other psychiatric or metabolic diseases, past operations and socio-economic level were recorded. Before blockage and in the first week and first month after blockage, the following assessments were made of the patients.

1. Visual Pain Scale (VPS): This is used to assess pain complaints in patients with back pain. The meaning of the numbers 0 to 10 arranged along a 10 cm line was explained to patients. They were asked to show the number on the line which best expressed their pain (Sayar *et al.,* 2002; Yılmaz and İskesen, 2007; Boysan *et al.,* 2010; Yılmaz *et al.,* 2012; Campbell *et al.,* 2013; Onat *et al.,* 2013).

2. Oswestry Disability Index (ODI): The self-completed questionnaire contains ten topics concerning intensity of pain, lifting, ability to care for oneself, ability to walk, ability to sit, sexual function, ability to stand, social life, sleep quality, and ability to travel. Each item is evaluated between 0 and 5. A higher total score indicates greater disability (Sayar *et al.,* 2002; Littner *et al.,* 2003; Yılmaz and İskesen, 2007; Boysan *et al.,* 2010; Yılmaz *et al.,* 2012; Onat *et al.,* 2013).

3. Pittsburgh Sleep Quality Index (PSQI): This was developed by Buysse et al. with the aim of assessing sleep quality, amount of sleep and sleep disturbances. The scale consists of 19 questions scored from 0 to 3. It contains seven sub-items using self-reporting to assess sleep quality, delay in going to sleep, length of sleep, adequacy of continuous sleep, sleep disturbance, the use of sleeping medication, and dysfunction within the day. A high score indicates poor sleep quality (Littner *et al.,* 2003; Martin and Hakim, 2011; Uluğ and Yılmaz, 2012; Campbell *et al.,* 2013; Onat *et al.,* 2013; Tekeoğlu *et al.,* 2013).

4. Beck Depression Index (BDI): This was developed by Beck et al. to measure the severity of the symptoms of depression. It consists of 21 items which are scored from 0 to 3 (Sayar *et al.,* 2002; Yılmaz and İskesen, 2007; Boysan *et al.,* 2010; Uluğ and Yılmaz, 2012; Yılmaz *et al.,* 2012; Campbell *et al.,* 2013; Onat *et al.,* 2013).

5. Insomnia Severity Index (ISI): This was developed to evaluate the severity of insomnia, and is a measurement tool with a high degree of validity and reliability. It consists of seven items, scored from 0 to 4. Possible total scores vary from 0 to 28. Self-reporting and statements of the partner are used to measure difficulty getting to sleep, difficulty remaining asleep, early waking, satisfaction with sleep pattern, disruption of daily functionality, awareness of sleep-derived disruption and the level of stress caused by the problem (Sayar *et al.,* 2002; Boysan *et al.,* 2010; Uluğ and Yılmaz, 2012; Yılmaz *et al.,* 2012; Campbell *et al.,* 2013; Onat *et al.,* 2013; Tekeoğlu *et al.,* 2013).

6. Quality of Life Index (SF-36 QOL): This is the most commonly-used scale to measure quality of life and was developed to measure the quality of life especially in patients with physical illnesses. It can measure positive as well as negative aspects of health. Its clearest advantage is that it measures physical function and related abilities. The scale consists of 36 items with eight measurement dimensions: physical function (10 items), social function (2 items), role restrictions relating to physical problems (4 items), role restrictions relating to emotional problems (3 items), mental health (5 items), energy/vitality (4 items), pain (2 items), and general perceptions of health (5 items). The scale depends on self-reporting. These eight scales can be aggregated into two summary measures: the Physical (PCS) and Mental (MCS) Component Summary scores (SF-36-PCS,Sf-36-MCS) (Sayar *et al.,* 2002; Yılmaz and İskesen, 2007; Uluğ and Yılmaz, 2012; Yılmaz *et al.,* 2012; Onat *et al.,* 2013; Tekeoğlu *et al.,* 2013).

7. Use of the Actigraph bracelet: the Actigraph (Actiwatch 2 Philips Respironics Co Inc, USA) is a light, portable and sensitive instrument in the form of a wristwatch which can detect and record motor activities (Figure 1). Recorded data can be downloaded to a computer and assessed and analyzed using an actigraphy program (Figure 2). It provides objective information with which to measure and evaluate sleep continuity or sleep disruption. Its advantages include its practicality of use and the fact that is does not necessitate a stay in hospital. Its use in academic studies has been accepted by the American Sleep Association, and standards for its use have been created (Littner *et al.,* 2003; Lichstein *et al.,* 2006; Gironda *et al.,* 2007; Martin and Hakim, 2011; Madsen *et al.,* 2013).We told our patients that the device was to do with sleeping well, and gave them information to relieve any worries they had regarding it. The actigraph device remained continuously attached to the wrist on the patient's non-dominant side for three days before the radio frequency denervation operation, for three days one week after the operation, and for three days one month after the operation. Our use of the Actigraphy bracelet for three-day periods is in accordance with the criteria accepted by the American Sleep Association (Marin *et al.,* 2006).

We used the Actigraphy devices in the main sleep period to measure the values which are used as an objective standard in the measurement of sleep-insomnia quality, which include the parameters of total time spent in bed (TBT), total sleep time (TST), effective sleep percentage (Sef) (night sleep time/time spent in bed x 100), frequency of waking after sleep and time spent awake(WASO), time of going to bed, time of going to sleep, delay in first going to sleep (OL), and the length of periods spent awake during the night sleeping period (Awake).

The Actigraph is an accelerometer which can measure people's motor movements over a long period which can sense forces of as low as 0.01 G. It has the capacity to sense movement of up to 32 microdeflections a second (32 Hz) (Lichstein *et al.,* 2006; Gironda *et al.,* 2007; Morgenthaler *et al.,* 2007; Patel *et al.,* 2014; Trudeau *et al.,* 2015). Data is stored in the

device's memory as 30-second epochs. After transfer of data to a computer and assessment by an actigraphy program, daily actograms are produced. Percutaneous facet denervation was performed in cases of degenerative lumbar disease under local anesthetic in operating room conditions by means of radio frequency pulses of 120 seconds at 42ºC targeting the medial branches and facet joints of the dorsal roots, accompanied by fluoroscopy. The operation was performed a total of 53 times, once on each lesion, on 30 patients.

Statistical analyses were performed using the Rstudio software version 0.98.501 via R Language. The variables were investigated using visual (histograms, probability plots) and analytical methods (Kolmogorov-Simirnov/Shapiro-Wilk test) to determine whether or not they were normally distributed. Descriptive analyses were presented using means, standard deviations and minimum-maximum for variables parameters (Oswestry, PSQI, ISI, BDI, SF-36-PCS, SF-36-MCS, VPS, TBT, TST, OL, Sef, WASO, Awake Time). Since the variables were not normally distributed, nonparametric tests were conducted to compare these parameters. The Wilcoxon test was used to compare the change in these parameters between pre-op, 1 week post-op and 1 month post-op. The Mann-Whitney U test was used to compare these parameters between males and females. In investigating the associations between non-normally distributed variables, the correlation coefficients and their significance were calculated using the Spearman test. A p-value of less than 0.05 was considered to show a statistically significant result.

Results

Thirty patients were included in the study, 17 (56.7%) of whom were male and 13 (43.3%) female. The mean age of the males was 54 years, and that of the females 52. According to their own statements, all patients had sleep disturbance as well as complaints of back pain. Thirteen of the patients had pain on the left side, eleven on the right, and six bilaterally. In general, canal narrowing related to lumbar degenerative disease was present at the L4-L5 + L5-S1 levels. None of the patients had any neurological deficit other than severe pain and neurogenic claudication. Descriptive statistics relating to the subjective and objective analysis parameters are given in Tables (Tables 1, 2 and 3). In order to increase the reliability and correctness of the statistics in our study, we used a patient population of between 40 and 60 years of age whose sleep periods and sleep quality were more homogeneous.

Table 1. Descriptive Statistics of Parameters for Pre-Op

Parameters	Mean	Std. Deviation	Minimum	Maximum
Oswestry_0	91.16	4.85	82.00	100.00
PSQI_0	11.06	1.68	5.00	14.00
ISI_0	21.46	3.08	11.00	28.00
BD_0	45.86	9.66	13.00	56.00
SF-36-PCS_0	23.28	4.72	18.19	41.55
SF-36-MCS_0	28.31	5.96	18.60	39.25
VAS_0	8.98	0.39	8.00	10.00
TBT_0	608.74	147.32	330.00	970.00
TST_0	404.60	115.86	187.00	745.00
OL_0	79.93	56.25	18.50	294.50
Sef_0	65.45	9.71	33.49	82.37
WASO_0	53.12	36.85	5.92	138.33
Awake_0	53.34	28.00	8.33	153.25

Table 2. Descriptive Statistics of Parameters for 1 Week Post-Op

Parameters	Mean	Std. Deviation	Minimum	Maximum
Oswestry_1	15.96	8.07	6.00	40.00
PSQI_1	4.82	0.94	4.00	9.00
ISI_1	7.16	1.54	4.00	12.00
BD_1	15.64	5.22	2.00	24.00
SF-36-PCS_1	41.37	4.29	32.50	51.15
SF-36-MCS_1	42.56	4.56	33.10	51.70
VAS_1	2.02	0.43	1.00	3.00
TBT_1	544.80	118.61	287.00	858.00
TST_1	442.76	88.77	244.00	713.00
OL_1	40.86	28.65	2.33	120.50
Sef_1	82.87	5.20	71.79	92.93
WASO_1	39.91	30.59	9.67	176.25
Awake_1	40.23	19.05	11.67	110.00

Table 3. Descriptive Statistics of Parameters for 1 Month Post-Op

Parameters	Mean	Std. Deviation	Minimum	Maximum
Oswestry_2	4.62	3.86	0.00	20.00
PSQI_2	2.70	1.30	0.00	5.00
ISI_2	2.78	1.75	0.00	8.00
BD_2	6.50	4.51	0.00	20.00
SF-36-PCS_2	51.39	4.78	40.75	65.50
SF-36-MCS_2	48.92	2.95	43.50	54.45
VAS_2	1.39	0.46	1.00	2.00
TBT_2	531.30	113.37	384.00	889.00
TST_2	461.82	101.69	319.00	885.00
OL_2	24.32	17.05	2.75	84.32
Sef_2	87.63	4.61	80.06	99.47
WASO_2	36.33	27.88	8.06	122.75
Oswestry_2	4.62	3.86	0.00	20.00

Comparison of the subjective test parameters and the objective actigraphy parameters is presented in Tables (Tables 4, 5 and 6). All results relating to the recovery of patients were statistically significant, with $p<0.05$.

In this way, the subjective tests and the actigraphy analyses were found to conform with each other. Strong correlations were seen in correlation coefficients (cc) particularly at the end of the first month between TBT and PSQI (cc: 0.371), TBT and ISI (cc: -0.474), TBT and BDI (cc: -0.404), and TST and BDI (cc: -0.370) (Tables 8, 9 and 10). As can be seen in Table 7, no significant difference was found between males and females in any of the study parameters in any of the three periods (Table 7).

Table 4. Comparision of Parameters between Pre-Op and 1 Week Post-Op

Parameters	P-value
Oswestry	0.0001
PSQI	0.0001
ISI	0.0001
BD	0.0001
SF-36-PCS	0.0001
SF-36-MCS	0.0001
VAS	0.0001
TBT	0.032
TST	0.066
OL	0.0001
Sef	0.0001
WASO	0.037
Awake	0.012

Table 5. Compare of Parameters between PreOp and 1 Month Post-op

Parameters	P-Value
Oswestry	0.0001
PSQI	0.0001
ISI	0.0001
BD	0.0001
SF-36-PCS	0.0001
SF-36-MCS	0.0001
VAS	0.0001
TBT	0.007
TST	0.013
OL	0.0001
Sef	0.0001
WASO	0.015
Awake	0.0001

Table 6. Compare of Parameters between 1 Week Post-op and 1 Month Post-op

Parameters	P-Value
Oswestry	0.0001
PUKI	0.0001
USI	0.0001
BD	0.0001
SF-36-PCS	0.0001
SF-36-MCS	0.0001
VAS	0.0001
TBT	0.325
TST	0.206
OL	0.001
Sef	0.0001
WASO	0.451
Awake	0.099

Table 7. Compare of Parameters between Woman and Man

	PreOp	Post Op-1 Week Later	Post Op-1 Months Later
Parameters	**p-Values**		
Oswestry	0.150	0.169	0.148
PUKI	0.439	0.599	0.716
USI	0.098	0.894	0.296
BD	0.751	1.000	0.207
SF-36-PCS	0.953	0.279	*0.049*
SF-36-MCS	0.596	0.723	0.254
VAS	0.655	0.287	0.284
TBT	0.716	0.437	0.602
TST	0.376	0.415	0.687
OL	0.398	0.961	0.776
Sef	0.216	0.814	0.575
WASO	0.860	0.350	0.350
Awake	0.929	1.000	0.953

Figure 1. Device of wrist actigraph

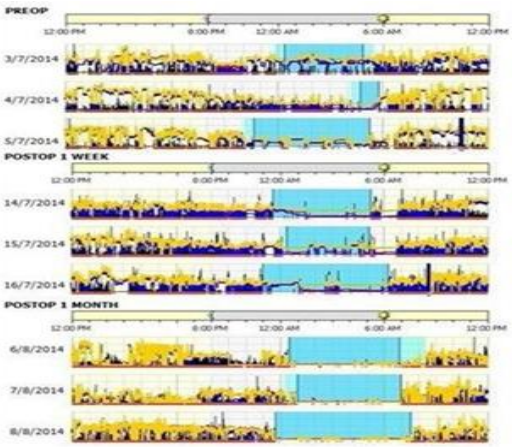

Figure 2. Actogram examples of our study patients

These results show that in examining patients' recovery, quality of life and sleep quality, the test results relying on patients' subjective criteria were in accord with the objective actigraphy analysis parameters.

Discussion

Polysomnography (PSG) is the gold standard for sleep testing according to the American Sleep Association study. Actigraphy analysis can be used as an alternative instead PSG , with the acceptance and approval of the American Sleep Association and organizations conducting academic studies (Clete *et al.*, 2001; Sayar *et al.*, 2002; Littner *et al.*, 2003; Morgenthaler *et al.*, 2007; Martin and Hakim, 2011; Onat *et al.*, 2013). Use of the method has spread because it is easy to apply and cheap.

In recent years, actigraphy analysis has started to be used in pain studies in addition to studies of sleep disorders and sleep quality. In a study published in 2014, Hartwell *et al.*, (2014)

showed that pain was an important factor affecting sleep, and showed objectively by the use of actigraphy analysis parameters the improvement in sleep after drug treatment. In the same study, it was concluded that with drug treatments for pain, there was statistically significant conformity between actigraphic TBT, TST, Sef, OL, WASO, Awake analysis parameters and the subjective tests which are still used today (Hartwell *et al.,* 2014).

Similarly, there are several studies which have found conformity between subjective tests and actigraphy analysis in the results of drug treatment for pain of fibromyalgia, osteoporosis, rheumatoid arthiritis, chronic backache, shoulder pain and chest pain (Sayar *et al.,* 2002; Littner *et al.,* 2003; Lichstein *et al.,* 2006; Onat *et al.,* 2013; Patel *et al.,* 2014).There are recent studies in different fields in the literature in which actigraphy analysis has been used in the assessment of surgical cases. An article by Madsen *et al.,* in (2013) considered 32 studies out of 143, which were found to have suitable criteria, in which sleep disturbances were assessed using actigraphy analysis. They reached the conclusion that subjective tests and actigraphy analysis were statistically in conformity, and emphasized that the lack of studies in a relative field of neurosurgery was a shortcoming (Madsen *et al.,* 2013).

The methods, time periods and analysis parameters of actigraphic use in our study were in conformity with the actigraphic use (Marin *et al.,* 2006) time periods and parameters of the 32 recent studies evaluated by Madsen *et al.,* (2013). In these studies, parameters were generally taken continuously for three days before surgery, and in the first week and first month afterwards. In studies on the use of actigraphy in cardio-vascular surgery, actigraphy was used for seven consecutive days and healthy control group studies were conducted (Yılmaz and İskesen, 2007).

Percutaneous facet denervation by radio frequency causes reversible damage to sinovertebral sensory nerves. It is reported in the literature that the effects of denervation last for between one and six months (Shealy, 1975; Cohen and Raja, 2007; Chao *et al.,* 2008; Cohen *et al.,* 2009). We studied the effects of pain therapy by percutaneous facet denervation using radio frequency in lumbar degenerative diseases on pain, quality of life and sleep disorder by actigraphy parameters which provide objective data and subjective tests, and we found no parallel study in the literature. We also examined whether the results were in accordance with each other. Because the aim of our study was to compare the data of cases from before blockage with that from one week and one month after blockage, there was no control group in our study. As in other studies, the statistically positive results of the subjective tests and the data parameters of the actigraphy analysis in our study and their conformity to each other were found to be significant (Littner *et al.,* 2003; Lichstein *et al.,* 2006; Yılmaz and İskesen, 2007; O'Donoghue *et al.,* 2009; Yılmaz *et al.,* 2012; Onat *et al.,* 2013; Patel *et al.,* 2014).

It is generally agreed in the literature that there is no statistically significant difference relating to the effect of gender on sleep quality (O'Donoghue *et al.,* 2009; Onat *et al.,* 2013). O'Donoghue *et al.,* (2009) and Madsen *et al.,* (2013) in separate studies supported by the American Sleep Association, both suggest that further research is needed (Şendir *et al.,* 2007; O'Donoghue *et al.,* 2009; Utku *et al.,* 2010; Yılmaz *et al.,* 2012; Madsen *et al.,* 2013; Onat *et al.,* 2013). No statistical difference relating to gender was found in our study.

We evaluated the contribution to quality of life in patients on whom the minimally invasive procedure of percutaneous lumbar facet radio frequency denervation had been performed for lumber degenerative narrow canal, and this provided us with objective results in our assessment of sleep disturbances and sleep quality. The positive results on quality of life of

the subjective tests based on the statements of patients and their relatives and the actigraphy analyses which provided us with objective data and the conformity between them show that the denervation procedure is beneficial in the short term. Our study makes a new contribution to the literature and supports other studies. As the number of similar scientific studies increases, it will be possible to make a more reliable assessment.

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