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Neuromuscular Electrical Stimulation Therapy Effects on the Functional and Motor Recovery of the Upper Extremity in Patients after Stroke: A Randomized Controlled Trial

Nöromusküler Elektriksel Stimülasyon Tedavisinin İnme Sonrası Hastalarda Üst Ekstremite Fonksiyonel ve Motor İyileşme Üzerindeki Etkileri: Randomize Kontrollü Çalışma

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ABSTRACT

Introduction: This study aimed to investigate the effectiveness of passive neuromuscular electrical stimulation (NMES) combined with conventional rehabilitation program (CRP) in stroke patients in terms of enhancing the motor and functional recovery of the upper extremity (UE), improving spasticity, pain, and ability to engage in daily activities.

Methods: A total of 30 patients with hemiplegia were randomly distributed in two groups. The study group included 15 patients who received a CRP plus passive NMES applied to shoulder girdle muscles and wrist extensors. The control group included 15 patients who received only CRP. Assessments of the UE impairment were made at enrolment, midtreatment, end of treatment, and 2 months thereafter. Follow-up parameters were the Brunnstrom stage, UE parts of the Fugl-Meyer Assessment (FMA), Barthel index, visual analog scale (VAS) score, and Modified Ashworth scale (MAS).

Results: Statistically significant improvements were found in the Brunnstrom stages of the upper extremities and hands, FMA, and VAS score of the study group at the end of therapy and after 2 months. The FMA overall score improved significantly in the control group at the completion of treatment and after 2 months. MAS scores were higher in the control group at the end of therapy and 2 months afterward, but values did not significantly differ between groups.

Conclusion: CRP plus passive NMES treatment applied to shoulder girdle muscles and wrist extensors seems to be no

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Amaç: İnmeli hastalarda konvansiyonel rehabilitasyon programı (KRP) ile kombine edilen pasif nöromusküler elektriksel stimülasyonun (NMES); üst ekstremite (ÜE) motor ve fonksiyonel iyileşme, spastisite, ağrı ve günlük yaşam aktivitelere katılma becerisini iyileştirme açısından etkinliğini araştırmaktır.

Yöntemler: Otuz hemiplejik hasta randomize olarak 2 eşit gruba ayrıldı. Çalışma grubuna 20 seans KRP'ye ek olarak omuz kuşağı kasları ve el bilek ekstansörlerine pasif NEMS uygulandı. Kontrol grubuna ise sadece 20 seans KRP uygulandı. Değerlendirmeler tedavi başlangıcında, tedavi ortasında, tedavi sonunda ve tedavi bitiminden 2 ay sonra yapıldı. Sonuç ölçütleri olarak; Brunnstrom'un ÜE ve el evrelemesi, Fugl-Meyer Üst Ekstremite Motor Fonksiyon Skoru (FMA), Modifiye Ashworth skalası (MAS), vizüyel analog skala (VAS) ve Barthel indeksi kullanıldı.

Bulgular: Çalışma grubunda tedavi sonrasında ve 2 ay sonraki kontrol değerlendirmesinde üst ekstremite ve el Brunnstrom evrelemesinde, FMA ve VAS skorunda istatistiksel olarak anlamlı iyileşme görüldü. Kontrol grubunda FMA toplam skorunda tedavi sonu ve 2 ay sonraki kontrolde anlamlı düzeyde iyileşme saptandı. MAS skorları kontrol grubunda tedavi sonunda ve 2 ay sonra daha yüksekti, ancak değerler gruplar arasında anlamlı farklılık göstermedi.

Sonuç: İnmeli hastalarda KRP'sine eklenen omuz kuşağı ve el bilek ekstansörlerine uygulanan pasif NEMS'nin tek

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ABSTRACT

better than CRP alone, but passive NMES therapy is suggested to be used as an adjunct to neurological rehabilitation as it contributes to functional and motor recovery.

Keywords: Motor recovery, neuromuscular electrical stimulation therapy, rehabilitation, stroke, upper extremity

ÖZ

başına konvansiyonel programa üstün olmadığı görülmekle beraber fonksiyonel ve motor iyileşmeye katkıda bulunduğu için nörolojik rehabilitasyona yardımcı olarak kullanılması gerektiği kanaatindeyiz.

Anahtar Kelimeler: Motor iyileşme, nöromusküler elektriksel stimülasyon tedavisi, rehabilitasyon, inme, üst ekstremite

Introduction

The most common cause of disability in the world is stroke and hemiplegia, which is the most severe disorder after stroke, resulting to an upper extremity (UE) dysfunction (1,2). More than 50% of patients with stroke are unable to use their affected hands and arms for daily activities (3). Therefore, the neuromuscular electrical stimulation (NMES) is a potentially beneficial treatment choice for motor enhancement. NMES reveals limb movements by applying an electrical current to weak muscles. Post-stroke rehabilitation combined with NMES effectively prevents muscle atrophy, increases muscle strength, reduces pain and spasticity, and facilitates motor re-learning (2). NMES may also be used to treat various disabilities at home, which is well tolerated by patients (4). Various types of applications are available; however, its use is limited in the field of rehabilitation (5). In practice, mostly non-implanted ones are used for stroke rehabilitation. Repeated muscle contractions occur without the patients' active participation during stimulation (6).

In this study, whether NMES combined with a conventional rehabilitation program (CRP) could improve the UE function to a greater extent than CRP alone in patients with hemiplegia was investigated.

Methods

From November 2015 to April 2016, a total of 30 patients with stroke, who was referred to our center for hospitalization to engage in 4-week therapy programs were recruited. Ethics committee approval was obtained for the research from the University of Health Sciences Turkey, İstanbul Training and Research Hospital Local Commission on Ethics (approval number: 736, date: 20.11.2015). Informed consent was obtained from patients who participated in this study.

Inclusion criteria includes age of 40-80 years old, absence stroke history, unilateral hemorrhagic, or thromboembolic stroke, time elapsed after stroke of 0-18 months, and hand and UE Brunnstrom stages between 1 and 4. Exclusion criteria includes non-fulfillment of the above inclusion criteria, decompensated heart failure, presence of implanted pacemaker, lower motor neuron lesion affecting the upper limbs, clinically active reflex sympathetic dystrophy syndrome, spinal cord injury, traumatic brain injury, severe cognitive deficit, and/or a neurological disorder such as epilepsy, Parkinson's disease, or multiple sclerosis.

The Brunnstrom approach is a technique that classifies patients into six phases based on muscle tone and synergy patterns. Therefore, after the stroke, the neurologic progress of each case was assessed, and the treatment method was planned with regard to the recovery degree defined via the current procedure. The examination was performed one by one for the UE, hand, and lower extremity. Elevated Brunnstrom degree represents good outcome (7). Motor evaluation was assessed with the UE motor subgroup score of the Fugl-Meyer Motor Assessment (FMA) (8). Turkish reliability and validity study of the FMA was done (9,10), which was developed to test the motor control in patients after stroke hemiplegia. The FMA is used clinically and in research settings to analyze disorder severity and motor enhancement, and prepare and evaluate therapy (8).

The Barthel index (BI) tests the independence level of patients in their daily activities (i.e., eating, taking a bath, dressing up, bowel and bladder control, toileting, transfer in a wheelchair, walking, and climbing the stairs). The index reveals the needed assistance for support. This evaluation method has been designed for patients undergoing stroke rehabilitation (11). The Turkish version of the BI was verified to be accurate and reliable by Küçükdeveci et al. (12). Score varies between 0 and 100, where 0-20 points indicate complete dependence, 21-61 advanced dependence, 62-90 intermediate dependence, 91-99 mild dependence, and 100 signifies complete independence.

The 5-point Ashworth scale is the most common scale used to determine muscle tone. The updated Modified Ashworth Scale (MAS) was developed by adding one grade (+1) to the original Ashworth scale (13). The MAS was used in our rehabilitation clinic.

Pain intensity was measured using a visual analog scale (VAS). VAS is widely used in health outcome research to quantify pain, which is normally described as a single 100 mm horizontal line anchored by 2 verbal descriptors (e.g., absence of pain; most severe pain ever felt). Increased pain is demonstrated by higher ratings (14).

In our prospective, randomized controlled trial, 30 patients who met the inclusion criteria were randomized into two groups by order of hospitalization. The study group included 15 patients who received CRP (range-of-motion, stretching, strengthening, mobilization, Bobath, Brunnstrom exercises, positioning, splinting, and walking training) plus passive NMES, whereas the control group included 15 patients who received CRP only. The wrist extensor muscles (extensor digitorum communis and extensor carpi ulnaris), deltoideus, and supraspinatus were stimulated with superficial electrodes in the study group. A portable two-channel neuromuscular stimulator (Globus-Genesy model 1200, Treviso, Italy) was used. The frequency of the stimulus was set between 20 and 50 Hz. The current amplitude was adjusted to a suitable amount for the patient (0-100 mA). The position of the electrode on

the supraspinatus was 1.5 cm above the midpoint of the spine of the scapula; the site of electrode settlement for the posterior deltoid was two finger widths down to the posterior edge of the acromion. The negative electrode was located just above the wrist crease for the wrist extensors, and the positive electrode was affixed to an area near the lateral epicondyle. Stimulation therapies were performed 5 days a week for 20 min for 4 weeks in the study group. Assessments of UE impairment were made at enrolment (week 0), midtreatment (week 2), end of treatment (week 4), and 2 months thereafter.

Statistical Analysis

Data were analyzed using the Statistical Package for the Social Sciences software v. 22.00 for Windows (SPSS Inc., Chicago, IL, USA). Categorical data are expressed as numbers with percentages for descriptive analyses, whereas continuous data are expressed as means with standard deviations (SDs). The normality of distributions was verified using the Kolmogorov-Smirnov test.

Within- and between-group differences were investigated. Wilcoxon's signed rank test was used to compare non-normally distributed variables, and the Paired Sample t-test was used to compare normally distributed variables both pre- and post-treatment between two groups. Between-group comparisons were made using the Mann-Whitney U test, the unpaired t-test was used for continuous variables, and the chi-square test or Fisher's exact test (as appropriate) was used for categorical variables. The cut-off for statistical significance in all analyses was 0.05.

Results

Demographic characteristics and clinical parameters are presented in Table 1. No statistically significant finding was found in any demographic feature between groups ($p>0.05$). In the study group, statistically significant improvements were found in the Brunnstrom stages of the UE and hand; the FMA arm, coordination, and total scores; and the VAS at the completion of treatment and 2 months later ($p<0.05$) (Table 2, 3). The FMA total score improved significantly in the control group at the completion of the treatment and after 2 months (Figure 1). MAS values of the shoulder, elbow, and wrist were higher in the control group at the end of the therapy and two months thereafter (Table 4). However, no statistically significant differences were found between two groups in terms of follow-up parameters ($p>0.05$). In addition, no significant difference was found between groups in the mid- and post-treatment and 2-month control in Brunstrom UE stage, Brunstrom hand stage, BI, and VAS parameters, which were assessed by repeated measures analysis ($p>0.05$). MAS shoulder values gradually decreased in the study group while it increased gradually in the control group (Figure 2-4).

Table 1. Demographic and clinical characteristics of patients

		Study group (n)	Control group (n)
Sex (male/female), (n)		8/7	7/8
Age (years) (mean ± SD)		67.5±8.5	70.0±6.8
Marital status, n (%)	Married	10 (66.7)	9 (60)
	Divorced	5 (33.3)	6 (40)
Job, n (%)	Self-employed	3 (20.0)	2 (13.3)
	Housewife	7 (46.7)	7 (46.7)
	Retired	4 (26.7)	4 (26.7)
	Worker	1 (6.7)	2 (13.3)
Education, n (%)	Illiterate	5 (33.3)	3 (20.0)
	Primary school	8 (53.3)	6 (40.0)
	Secondary school	1 (6.7)	4 (26.7)
	High school	1 (6.7)	2 (13.3)
Plegic side, n (%)	Right	8 (53.3)	7 (46.7)
	Left	7 (46.7)	8 (53.3)
Dominant side, n (%)	Right	14 (93.3)	14 (93.3)
	Left	1 (6.7)	1 (6.7)
Comorbid diseases, n (%)	Diabetes	4 (26.7)	6 (40.0)
	Hypertension	13 (86.7)	13 (86.7)
	Ischemic heart disease	3 (20.0)	7 (46.7)
	Hyperlipidemia	0 (0.0)	2 (13.3)
Smoking, n (%)		2 (13.3)	2 (13.3)
Stroke type, n (%)	Thromboembolic	13 (86.7)	12 (80.0)
	Hemorrhagic	2 (13.3)	3 (20.0)
Transient ischemic attack		2 (13.3)	5 (33.3)
Time to commencement of rehabilitation		4.2±4.5	3.5±2.2

Data are presented as n (%) for categorical variables and means ± SDs for continuous variables.
n: Number of patients, SD: standard deviation

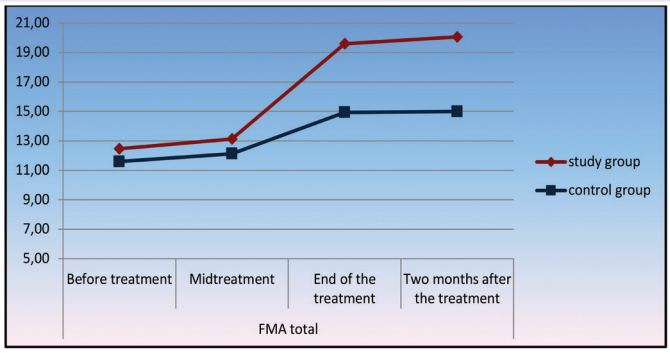

Figure 1. Fugl-Meyer Motor Assessment total score

FMA: Fugl-Meyer Motor Assessment score

Discussion

In this trial, all stroke patients had stable baseline values of all scores prior to treatment. After 20 sessions of UE rehabilitation combined with NMES, improved clinical values were observed in the study group and were sustained to the 2-month follow-up. Spasticity worsened in the control group. However, no statistically significant differences were found between groups.

NMES is widely used in the recovery of patients who had sustained neurological injuries such as stroke, spinal cord injuries, or other neurological disorders including paralysis and paresis. NMES has been used for joint mobility, joint contracture reduction, edema reduction, circulation improvement, atrophy prevention, muscle strength and

Table 2. Motor function assessment

		Fugl-Meyer				
(Mean ± SD)		**Upper extremity**	**Wrist**	**Hand**	**Coordination**	**Total**
Before treatment	Study group	9.0±6.8	0.9±1.9	1.6±2.8	0.7±1.5	12.5±13.1
	Control group	8.9±8.5	0.4±1.3	1.8±3.4	0.5±1.2	11.6±13.1
2. week (midtreatment)	Study group	9.6±7.0	1.0±1.9	1.6±2.8	0.7±1.5	13.1±13.3
	Control group	9.2±9.1	0.6±1.5	1.8±3.3	0.5±1.2	12.1±14.1
4. week(end of the treatment)	Study group	**13.0±8.7***	1.8±2.8	1.7±2.7	**1.5±2.0***	**19.6±17.3***
	Control group	10.1±9.0	1.3±2.0	1.3±2.1	0.5±1.2	**14.9±15.4***
2 months after the treatment	Study group	**13.3±9,4***	2.0±3.2	1.7±2.6	**1.5±2.1***	**20.1±18.1***
	Control group	10.56±9.0	1.3±1.9	0.9±2.0	0.5±1.1	**15.0±15.2**

*p<0.05, SD: standard deviation

Table 3. Assessment of motor recovery, functional status, and pain

		Brunnstrom stage		Barthel index	VAS shoulder	VAS wrist
(Mean ± SD)		**Upper extremity**	**Hand**			
Before treatment	Study group	1.8±0.9	1.5±1.1	47.7±30.7	4.0±2.2	1.7±2.6
	Control group	1.7±1.2	1.8±1.2	29.7±32.1	5.6±2.8	3.7±2.9
2. week (midtreatment)	Study group	2.1±1.1	1.7±1.1	49.3±31.8	4.1±2.1	**1.5±2.1***
	Control group	1.8±1.1	1.9±1.2	31.3±31.9	5.6±2.1	3.9±2.8
4. week (end of treatment)	Study group	**2.1±1.3***	**2.4±1.8***	**56.0±32.8***	**3.2±1.9***	**1.5±1.7***
	Control group	1.9±1.3	2.2±1.5	36.0±32.5	5.3±1.8	3.9±2.8
2 months after the treatment	Study group	**2.5±1.4***	**2.5±1.9***	**58.0±30.3***	**3.8±2.0***	**1.1±1.4***
	Control group	1.9±1.3	2.0±1.4	33.7±32.2	6.2±2.0	4.5±3.3

*P<0.05, SD: standard deviation, VAS: visual analog scale

Table 4. Spasticity assessment using the MAS

	Modified Ashworth scale			
(Mean ± SD)		**Shoulder**	**Elbow**	**Wrist**
Before treatment	Study group	1.2±1.1	0.9±0.7	1.0±2.7
	Control group	0.7±0.7	0.7±0.7	0.8±0.7
2. week (midtreatment)	Study group	1.1±0.7	0.9±0.7	0.9±0.7
	Control group	0.9±0.8	0.9±0.7	0.9±0.9
4. week (end of the treatment)	Study group	1.1±0.6	1.0±0.7	0.8±0.6
	Control group	1.2±0.8	**1.2±0.7***	**1.1±0.6***
2 months after the treatment	Study group	0.9±0.7	1.0±0.7	0.7±0.6
	Control group	**1.5±1.0***	**1.3±0.7***	**1.3±1.0***

*P<0.05, SD: standard deviation, MAS: modified Ashworth scale

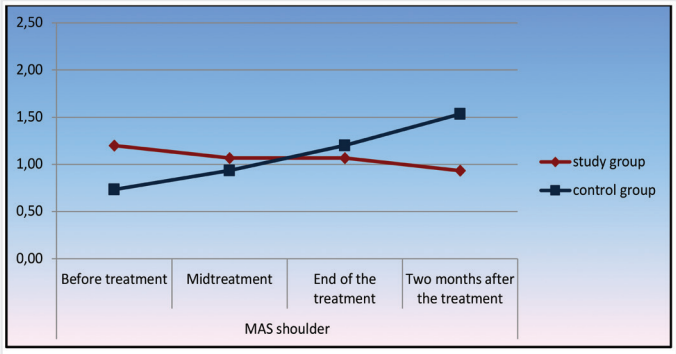

Figure 2. Modified Ashworth Scale shoulder

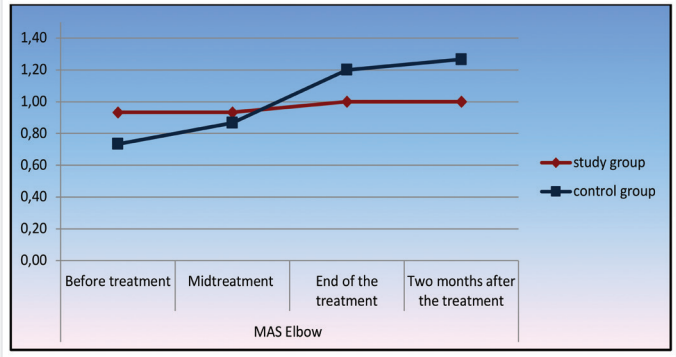

Figure 3. Modified Ashworth scale elbow

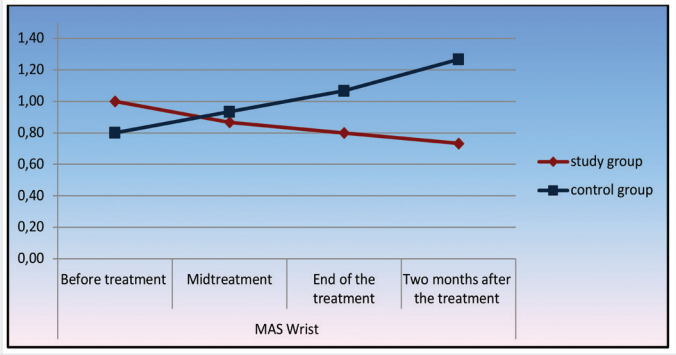

Figure 4. Modified Ashworth scale wrist

sensory perception improvement, spasticity reduction, discomfort reduction, and gait disorders correction (15). Peripheral impacts of NMES include increased strength of contraction, increased muscle mass, transformation from glycolytic type 2 muscle fibers to oxidative type 1 muscle fibers, and vasodilatation by arterial response regulation (16,17).

In previous studies, NMES was usually applied to the wrist extensors (18-20). Chuang et al. (21) found that therapeutic electrical stimulation of the supraspinatus and posterior deltoid muscles showed to effectively reduce shoulder subluxation and pain, increase muscle force, and promote shoulder stabilization in patients who are hemiplegic. Therefore, in the present study, application of both distal and proximal regions is preferred since the shoulder and hand are functional units in UE rehabilitation (2,21).

In literature, NMES application was seen used more often in the first year after stroke (6). In our study, the time to start rehabilitation was 4.2±4.5 months in the study group and 3.5±2.2 months in the control group, in accordance with the literature. The number of sessions and application time were also compatible with that of the literature.

NMES improves the motor and functional status of patients who had stroke. Hsu et al. (22) reported that NMES enhances UE function. Authors compared three groups over 4 weeks: 30 min of stimulation per day, 60 min per day combined with a regular rehabilitation program, and a control group (the regular rehabilitation program alone). They concluded that at least 10 h of NMES combined with regular rehabilitation may enhance the recovery of UE function in patients who had stroke during the early period (22). Rosewilliam et al. (23) recruited patients who had stroke with no UE function, and demonstrated that repetitive NMES for 30 min (on- and off-periods: 15 s) applied twice each working day for 6 weeks can trigger repeated wrist extension and improved wrist function. Boyaci et al. (18) investigated the effects of active and passive NMES; a sham control group was included. No statistically significant differences were found between the active and passive NMES groups in any parameter evaluated at the end of the treatment (18). In our study, after 20 sessions of UE rehabilitation coupled with NMES, enhanced follow-up parameters (Brunnstrom, FMA, BI) showing motor function were observed in the study group and were sustained for 2 months, but this result was not found statistically significant.

A higher MAS scores cause disruption of synergistic muscle activity. Patients who had stroke usually develop compensatory movements when using their paretic UE. Decreased MAS values of the elbow, wrist, and finger joints strengthen the coordination of muscles. In addition, the flexibility of the proximal and distal joints aids proper hand-grip and release (3). However, effect of NMES on spasticity is still controversial. Passive stretching of the extensor muscles of the forearm in addition to NMES significantly reduces spasticity (20). Santos et al. (24) showed that NMES applied to the flexor and extensor muscles of the wrist decreases spasticity in patients who are hemiplegic. Sahin et al. (20) evaluated the effectiveness of superficial electrical stimulation on spasticity of the wrist flexor muscles following stroke and reported that NMES along with wrist extensor muscles stretching was more efficient than stretching alone in terms of reducing spasticity. In the present study, MAS values of the shoulder, elbow, and wrist were significantly higher in the control group at the completion of therapy and after 2 months.

In a study investigating the effectiveness of NMES treatment on shoulder pain in patients with chronic hemiplegia, NMES was applied for 6 hours a day for 6 weeks. At the conclusion of the report, a substantial reduction in pain was found (25). In a randomized controlled trial consisting of 90 patients, NMES was applied to the wrist and finger extensors for 30 min a day for 6 weeks. As a result, important advancement in the level of pain was reported (26). In our study, substantial improvement was observed in the VAS score in the study group at completion of therapy and after 2 months.

Conclusion

CRP plus passive NMES treatment of the shoulder girdle and elbow extensor muscles seems to be no better than CRP alone, but we

suggest that NMES should be used as an adjunct during neurological rehabilitation programs because NMES contributes to functional and motor recovery and decrease spasticity and pain. The type of treatment (active or passive) and duration of stimulation maximizing the effects of NMES remain to be further investigated.

Ethics Committee Approval: Ethics committee approval was obtained for the research from the University of Health Sciences Turkey, İstanbul Training and Research Hospital Local Commission on Ethics (approval number: 736, date: 20.11.2015).

Informed Consent: Informed consent was obtained from patients who participated in this study.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions: Surgical and Medical Practices - B.K., E.A., N.S.Ç., S.Ç., K.A., F.U.; Concept - B.K., E.A., N.S.Ç., Y.P.D., S.Ç., K.A., F.U.; Design - B.K., E.A., N.S.Ç., S.Ç.; Data Collection or Processing - B.K., S.Ç., K.A., F.U.; Analysis or Interpretation - B.K., E.A., N.S.Ç., Y.P.D., F.U.; Literature Search - B.K., E.A., Y.P.D., K.A.; Writing - B.K., E.A., Y.P.D.

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