



Comparison of Percutaneous Tibial Nerve Stimulation and Injection of Bulking Agent Methods in the Treatment of Fecal Incontinence

Fekal İnkontinans Tedavisinde Perkütan Tibial Sinir Stimülasyonu ve Dolgu Madde Enjeksiyonu Yöntemlerinin Karşılaştırılması

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ABSTRACT

Aim: Fecal incontinence is still a complex disorder in the daily practices of colorectal surgeons. Nerve stimulation and injection of bulking agent are two minimal invasive methods in the treatment of fetal incontinence. In the present study, the aim was to compare the short-term effectiveness of percutaneous tibial nerve stimulation (PTNS) and injection of bulking agent in the treatment of fecal incontinence.

Method: A total of 41 patients with fecal incontinence, who were treated with PTNS or bulking agent injection at İstanbul University İstanbul Faculty of Medicine, were enrolled in the study. Both groups were evaluated in terms of demographic data, the etiology of fecal incontinence, anorectal physiology test results, Wexner Fecal Incontinence Score and Modified Fecal Incontinence Quality of Life-Scale scores. The questionnaires were performed in the 12th month of the pre- and post-treatment periods.

Results: Of the patients, 24 (59%) were female, and 17 (41%) were male. The median age was 50 years (in between 25-71 years), and the mean body mass index was 27.7 kg/m² (in between 20-41 kg/m²). Twenty-two (54%) patients underwent PTNS; whereas, 19 (46%) patients underwent bulking agent injection. Both groups were found to be similar in terms of demographic data, pre-treatment fecal incontinence assessment and quality of life measurement. When the pre- and post-treatment fecal incontinence and the quality of life scores of the patients were evaluated, both methods were found to be efficient in the treatment of fecal incontinence (p<0.001). It has been experienced that these two techniques were equally effective when they were compared to each other (p=0.315 and 0.501).

Conclusion: Both techniques were effective in the treatment of fecal incontinence. The percutaneous tibial nerve stimulation is less invasive, whereas injection of bulking agent provides fewer hospital visits with faster improvement.

Keywords: Fecal incontinence, nerve stimulation, injection of bulking-agent

ÖZ

Amaç: Fekal inkontinans, halen kolorektal cerrahların günlük pratiği içinde kompleks bir sorun olmayı sürdürmektedir. Sinir stimülasyonu ve dolgu madde enjeksiyonu bu hastalığın tedavisi için kullanılan iki minimal invaziv tedavi yöntemidir. Bu çalışmamızda, fekal inkontinans tedavisinde, perkütan tibial sinir stimülasyonu (PTSS) ile dolgu madde enjeksiyonu yöntemlerinin kısa dönem sonuçlarını değerlendirmeyi amaçladık.

Yöntem: İstanbul Üniversitesi İstanbul Tıp Fakültesi'nde fekal inkontinans nedeniyle bu iki yöntemin uygulandığı 41 hasta çalışmaya dahil edildi. İki grup demografik veriler, fekal inkontinans etiyojisi, anorektal fizyolojik testler, Wexner Fekal İnkontinans Skoru ve Modifiye Fekal İnkontinans Yaşam Kalite Skoru açısından değerlendirildi. Anketler tedavi öncesi ve tedavi sonrası 12. ayda yapıldı.

Bulgular: Hastaların 24'ü (%59) kadın, 17'si (%41) erkekti. Ortalama yaş 50 (25-71) ve ortalama vücut kitle indeksi ise 27,7 kg/m² (20-41) idi. Yirmi iki (%54) hastaya PTSS uygulanırken, 19 hastaya (%46) dolgu madde enjeksiyonu yapıldı. Her iki grup demografik veriler, tedavi öncesi yapılan fekal inkontinans değerlendirme ve yaşam kalite ölçümü açısından benzeşik bulundu. Tedavi öncesi ve sonrası, inkontinans ve yaşam kalite ölçek skorları karşılaştırıldığında, her iki yöntem de fekal inkontinans tedavisinde etkin bulundu (p<0,001). Her iki yöntem kendi arasında karşılaştırıldığında, eşdeğer oldukları görüldü (p=0,315 ve 0,501).

Sonuç: Her iki teknik, fekal inkontinansın tedavisinde etkin bulunmuştur. PTSS daha az invazivken, dolgu madde enjeksiyonu ile daha hızlı düzelmeye elde edilmekte ve hasta geliş sayısı daha az olmaktadır.

Anahtar Kelimeler: Fekal inkontinans, sinir stimülasyonu, dolgu madde enjeksiyonu



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Introduction

Fecal incontinence (FI) can be briefly described as involuntary loss of gas, liquid or solid stool due to anal sphincter dysfunction or damage. Congenital or acquired disorders, such as spina bifida, anorectal abnormalities and many colorectal diseases, can precipitate FI.¹ The prevalence of FI ranges from 1.4% to 18%.^{1,2,3,4}

FI is not only a physical health problem, as patients often isolate themselves from the community and are affected psychologically, socially and financially. Conservative treatments, such as irrigation enemas, dietary manipulation, constipating medication, and pelvic floor exercises, are the first-line treatment, yet the overall success rate of these methods is low.^{5,6} Major surgical procedures for FI, such as sphincteroplasty, graciloplasty and the implantation of an artificial sphincter, have high complication rates, and the results are unsatisfactory.^{7,8,9,10} Therefore, colorectal surgeons seek new treatment methods that are less invasive and have more acceptable complication rates. One such method is sacral nerve stimulation (SNS), which was first used by Matzel et al.¹¹ for FI in 1995 and later performed by several centers with satisfying results.¹² In the early 2000s, percutaneous tibial nerve stimulation (PTNS), which is less expensive, invasive and more practical than SNS, was developed. The effectiveness of PTNS has been shown in the treatment of urinary incontinence, and promising results were obtained in treating FI.^{13,14}

Shafik¹⁵ was the first to inject a bulking agent to treat FI; since then, various injectable materials have been produced and used for FI, and positive results have been published.¹⁶

The purpose of the current study was to evaluate and compare the results of two different methods [PTNS and polyacrylonitrile injection (PI)] that have been used to treat FI.

Materials and Methods

The current study is a retrospective analysis of 41 patients who were diagnosed with FI and underwent PTNS or PI treatments between December 2013 and March 2014. All patients were older than 18 years of age and had at least a 6-month duration of FI (gas, liquid or solid stool). Conservative methods (dietary manipulation, constipating medication, weight loss, Kegel exercise) were unsuccessful in these patients. After undergoing physical examinations and providing detailed medical histories, the patients were informed of treatment options and provided their consent. Prospectively collected data included demographic data, etiology of FI, results of anorectal physiological and radiology tests (endoanal ultrasound, anal manometer studies), and the results of the Wexner FI Score (WFIS) and

Modified FI Quality of Life Scale (MFIQLS) questionnaires. The WFIS and MFIQLS questionnaires were answered before and 12 months after the end of treatment. This study has been approved the Ethic Committee of İstanbul University Faculty of Medicine (no: 2015/778).

Technique

The PTNS procedure was performed on an outpatient basis using the neuromodulation system (Urgent[®] PC) without an antibiotic prophylaxis and local anesthesia. The system utilizes a 9 V battery and provides an electrical current ranging from 0 to 9 mA, a fixed pulse width of 200 microseconds and a fixed frequency of 20 Hz. The electrode needle was inserted 4 cm above and 2 cm posterior to the medial malleolus at a 60° angle, and an adhesive surface electrode pad was placed on the arch of the same foot at the same time (Figure 1). After both electrodes were connected to the stimulator, the current was slowly increased until the motor and/or sensory responses were elicited. Plantar flexion of the large toe or fanning of the other toes was accepted as a motor response, and a tingling sensation or a feeling of needles on the foot was accepted as a sensory response. When the motor or sensory response was not obtained or if pain occurred, the device was switched off and the procedure was repeated until the correct needle position was found. After the current location of the needle was confirmed, the stimulator was set at the highest level that could be tolerated by the patient. The total duration of each treatment session was 30 minutes, and treatments were performed once per week for ten weeks.

The PI (Gatekeeper[®]) treatment was also performed as an outpatient procedure. Under mild anesthesia, the patients were placed in the lithotomy position. Before the injection, all patients received fleet enemas and 1 g of intravenous ampicillin sulbactam for prophylaxis. After the perianal area was cleaned with an antiseptic solution, four small incisions were performed at 3, 6, 9 and 12 o'clock 2 cm beyond the anal verge (Figure 2). Then, the introducer, which is composed of a metal guide and the prosthesis, was inserted



Figure 1. The nerve stimulation device and inserted needle

into the intersphincteric area (or defect) through the skin incisions. The bulking agent was implanted after confirming the location of the sheath with endoanal ultrasound intraoperatively, and it was checked postoperatively. The implant was intended to be positioned closer to the anal verge vertically. After the procedure, the patients were kept under observation for four hours.

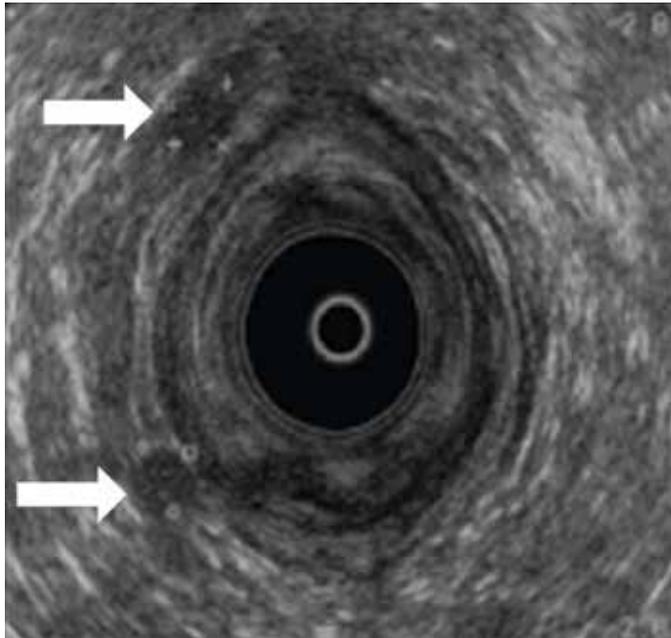


Figure 2. An endoanal ultrasound photo during the polyacrylonitrile injection implantation

The collected data were analyzed with the Statistical Package for Social Sciences (SPSS, Chicago, IL, USA) software version 15.0 for Windows. Chi-squared tests, student's t-tests and Mann-Whitney U tests were used for the analysis, and $p < 0.05$ was considered statistically significant.

Results

Forty-two patients [17 (41%) males and 24 (59%) females] were enrolled in the study. The mean patient age was 50 years (range, 25-71 years), and the mean body mass index was 27.7 kg/m^2 (range, $20\text{-}41 \text{ kg/m}^2$). Twenty-two (54%) of the patients underwent PTNS, and 19 (46%) underwent PI. The demographic data and etiologic factors are shown in Table 1. Twenty-one female patients (88%) had a history of vaginal delivery, and 10 of these women had given birth 3 times or more (47%). Only one woman reported an episiotomy. Of the rectal cancer patients, one patient had undergone a transanal local excision, and 13 had undergone low anterior resection.

Decreased resting and squeezing pressures were found in the anal manometry studies for both groups. Endoanal ultrasound revealed combined internal and external anal sphincter incompleteness in 29 patients, whereas the external anal sphincter was normal in 12 patients (Table 1). The mean pre-procedure WFIS was 13.6 ± 5.2 in the PTNS group and 12.9 ± 6.4 in the PI group. The mean MFIQLS was 32.8 ± 1.3 and 30.5 ± 1.4 in the PTNS and PI groups, respectively ($p > 0.05$). When the patients were reevaluated after treatment, a significant improvement was observed

Table 1. The demographic data, pre-treatment test results and etiologic factors

	PTNS (n=22)	PI (n=19)	p
Age (year)	49 (25-71)	51 (23-71)	0.63
Female/Male	15/7	10/9	0.27
BMI (kg/m^2)	27.2 (20-41)	28.6 (21-39)	0.46
WFIS before treatment	13.6 ± 5.2	12.9 ± 6.4	0.73
MFIQLS before treatment	32.8 ± 1.3	30.5 ± 1.4	0.74
Resting pressure (mmHG)	41 ± 17	47 ± 17	0.422
Squeeze pressure (mmHG)	72 ± 4	84 ± 5	0.179
Only internal sphincter defect	5 (23%)	7 (36%)	
Internal and external sphincter defect	17 (77%)	12 (64%)	0.328
Etiology			
Surgery for benign anorectal disease	5 (23%)	5 (26%)	
Surgery for rectal neoplasm	7 (31%)	7 (37%)	
Spinal surgery	4 (2%)	0	
Vaginal delivery	12 (80%)	8 (80%)	
The average number of births	3 (1-11)	3 (2-6)	

WFIS: Wexner Fecal Incontinence Score, MFIQLS: Modified Fecal Incontinence Quality of Life Scale, BMI: body mass index, PTNS: percutaneous tibial nerve stimulation, PI: polyacrylonitrile injection

in both groups according to both the WFIS and MFIQLS (Table 2).

After treatment, according to the WFIS, 15 patients (68%) improved in the PTNS group and 10 patients (53%) improved in the PI group ($p=0.315$). In terms of the MFIQLS, 15 patients (69%) in the PTNS group and 11 patients (57%) in the PI group showed improvements ($p=0.501$).

When the WFIS of patients was evaluated only in the way FI episodes, 15 (68%) patients in the PTNS group and 10 (53%) patients in the PI group subjectively reported that their number of incontinence episodes was reduced by more than 50% ($p=0.274$).

For both groups, we did not encounter with any complications in peri- and postoperative periods.

Discussion

In current study, we compared two minimally invasive treatment options for FI. Our study is the first study comparing the effect of these two treatment modalities over a heterogeneous patient group. Regardless to etiology, both PTNS and PI were found to be effective in the treatment of FI.

There is no clear data about the exact incidence of FI. A study from the United States showed that FI affected 8.3% of the population, which is approximately 18 million people.¹⁷ FI decreases a patient's quality of life, causes socio-economic problems, and isolates the patients from the community; in addition, the related health care costs increase every year.¹⁸ Initial treatments, including conservative methods such as irrigation enemas, dietary changes (dietary manipulation) and constipating medication, are inadequate for most cases. In addition to their high complication rate, major surgical procedures, such as sphincteroplasty, graciloplasty and artificial sphincter implantation, do not provide satisfactory results.^{5,6,7,8,9,10}

SNS, which is initially used to treat urinary incontinence, was first used by Matzel et al.¹¹ to treat FI, and a success rate of up to 75% has been reported in subsequent studies.¹⁹ However, this invasive procedure requires two surgeries under general or local anesthesia and has specific morbidities.^{20,21} PTNS is cheaper and less invasive than SNS; PTNS can also be performed without anesthesia with similar success rates.^{20,22} The therapeutic effect of nerve stimulation treatment is not well known. One theory is that this therapy activates myelinated α and β sensory fibers and thereby

Table 2. Wexner Fecal Incontinence Score and Modified Fecal Incontinence Quality of Life Scale results before and 12 months after the end of the treatments (*P: Pretreatment; **A: After treatment)

	WFIS-P	WFIS-A		MFIQLS-P	MFIQLS-A	
PTNS	13.6±5.2	7.4±5.8	$p<0.001$	32.8±1.3	45±1.5	$p<0.001$
Gatekeeper	12.9±6.4	7.8±5.8	$p<0.001$	30.5±1.4	40.7±1.2	$p<0.001$
All patients	13.3±5.7	7.6±5.7	$p<0.001$	31.9±1.3	43.2 ±1.3	$p<0.001$

WFIS-P: Wexner Fecal Incontinence Score-pre procedure, WFIS-A: Wexner Fecal Incontinence Score-after procedure, MFIQLS-P: Modified Fecal Incontinence Quality of Life Scale-pre procedure, MFIQLS-A: Modified Fecal Incontinence Quality of Life Scale-after procedure, PTNS: percutaneous tibial nerve stimulation

Table 3. The results of percutaneous tibial nerve stimulation trials (*Cleveland Clinic Florida Fecal Incontinence Score, **St. Mark's Continence Score, ***Wexner Fecal Incontinence Score)

	Reduction more than 50% in FI episode	Median FI score			Mean number of FI episodes			Defer defecation (min)		
		Before	After	p	Before	After	p	Before	After	p
Govaert et al.* ²² (n=22)	63.4% (n=14)	11.6±3.5	5.9±3.9	0.001	19.6±21	3.6±4.8	0.029	N/A	N/A	
Hotouras et al.* ²² (n=100)	N/A	12.8±3.7	9.1±4.4	0.001	5 (0-35)	1 (0-27)	0.001	1 (0-15)	5 (0-25)	0.001
George et al.** ²⁶ (n=11)	81% (n=9)	19 (3)	12.7 (2.1)	N/A	8.2 (5.2)	1.8 (0.8)	0.044	1.9 (0.9)	6.7 (5.2)	0.010
Boyle et al.* ³⁰ (n=31)	71% (n=31)	13 (5-20)	7 (0-20)	0.001	4 (0-30)	0 (0-27)	0.001	1 (0-15)	5 (0-25)	0.001
de la Portilla et al.** ²⁵ (n=16)	44% (n=7)	13.2±4.1	9.1±5	0.001	8.5 (3-19.5)	3.5 (0-15.2)	0.001	N/A	N/A	

FI: Fecal incontinence, N/A: not applicable

inhibits C-fiber transmission to the thalamus. Increasing the contractions of the anal sphincter by stimulating efferent somatic nerves is another proposed mechanism. Although electrical stimulation increasing the anal canal pressure has been demonstrated in experimental studies, some clinical trials have shown that electrical stimulation does not affect anal sphincter pressure.^{5,6,23}

There is no consensus concerning the optimal treatment plan (frequency and duration) for PTNS. The session duration is usually 30 minutes, and the session frequency varies between once or twice per week and every other day, with the total treatment duration ranging from 6 weeks to 3 months.^{22,24,25,26} We used a protocol of 30-minute sessions per week and a total of 10 sessions because a substantial portion of patients lived far from the clinic.

Previous studies of PTNS have revealed that the procedure reduces the frequency of FI episodes by more than 50%. PTNS also improves the FI score and prolongs the time of deferring defecation in most patients (Table 3). Furthermore, improvements in patient quality of life have been observed.^{22,24,25,26,27} Consistently, PTNS also improved the FI score and quality-of-life values in our study. In addition, 15 (68%) patients experienced more than 50% reduction in the number of FI episodes. Transcutaneous nerve stimulation (TNS) has shown equivalently successful results as PTNS;^{28,29} but George et al.²⁶ found no difference between TNS and the control group. We have no experience with transcutaneous TSS in our clinic.

Shafik¹⁵ first used injectable bulking agents (Teflon) to treat FI with success rates of between 45.4% and 63.4%. Following this publication, various materials, such as autologous fat, collagen analogs, and silicon, have been used and demonstrated positive results.^{30,31} Although this method has been used for 20 years to treat FI, the optimal agent, quantity of the agent, injection technique, injection area and number of injections have not been clearly defined.³²

In our study, thin, solid polyacrylonitrile cylinders, first used by Ratto et al.,³² were used as an implant material. This implant is thin and long (21 mm-1.2 mm) during the implantation and becomes shorter and thicker (17 mm-7 mm) within 24 hours after implantation (Figures 3a and 3b). As noted above, the application area and the method of injection vary according to the health center and the surgeon. Some centers perform the injection under general anesthesia, and other centers prefer sedoanalgesia. Some surgeons use endoanal ultrasound during the injection, whereas others use the guidance of digital examination.^{33,34} We performed the procedure with endoanal ultrasound (when available), with the patients under sedation. According to the literature, the bulking agent injection is usually used for internal sphincter dysfunction and rarely for patients with combined

sphincter defects.^{31,33,34,35} Injection to the sub-mucosal area allows the procedure to be performed with a digital rectal examination without an ultrasound device.³⁵ In the prospective randomized study conducted by Tjandra et al.,³¹ the success rate was significantly higher when the procedure was performed with endoanal-US guidance. The authors did not observe any differences between the two groups in terms of complications and or implant migration, but they found that the implants were placed more superficially when the injection was performed with the digital examination.³¹ However, sub-mucosal injection is associated with more pain, infection and implantation erosion.^{31,34,36} The positioning of the implant near the anal verge rather than the anorectal junction seems to be important for maintaining a sufficient anal high-pressure zone. Ratto et al.³² did not observe any complications in patients treated with PI. We also did not observe any complications among our study groups but prosthesis migration and perianal abscess were reported after PI application in a previous case report.³⁷

A review of bulking agent injection studies revealed that improvements in FI score, FI frequency and quality of life are unrelated to injection techniques and area.^{31,33,34,36} In the study by Ratto et al.,³² FI episodes and FI scores decreased from 7.1 to 1.0 and from 12.7 to 5.1, respectively. In addition, the authors reported significant increases in the deferral of defecation time, general health and quality-of-life scores. In our study, which included internal sphincter deficiency and combined sphincter defects (internal and external sphincter), unlike previous studies, a significant reduction in FI episodes, decrease in WFIS and increased quality-of-life scores were obtained. Furthermore, 10 patients (52%) reported a reduction of the FI frequency.

Damaser et al.³⁸ observed in their experimental animal study that anal canal pressure can be enhanced with nerve stimulation, and Matzel et al.³⁹ observed increases in the anal squeeze pressure and rectal sensitivity through SNS. However, in many studies, the anorectal physiological test results, which were performed after the treatment, did not change despite clinical improvements.^{5,22} Despite the significant clinical improvement in the PTNS group, in their randomized trial, George et al.²⁶ reported that

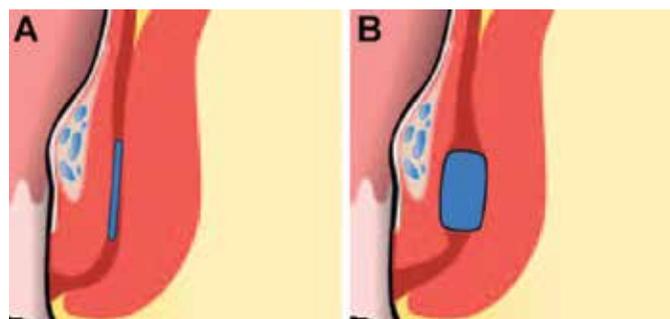


Figure 3. a) and b) Views of Gatekeeper a) shortly after the injection and b) 24 hours after the injection

there was no significant difference between the PTNS and placebo group in terms of anorectal physiological tests. Moreover, some data have indicated that post-treatment results are not related to the pretreatment anal manometer tests and anal ultrasound results.³⁰ Similarly, there are conflicting data in terms of anorectal physiological tests after bulking agent implantation. In a study that used PI, no change in the post-treatment anorectal physiological tests was observed.^{16,31,32,33,34} We also believe that anorectal physiological tests are not necessary to assess a patient's symptoms after treatment and that a patient interview suffices.

Alternative treatments must be considered for the patients who did not improve with these techniques. Better results have been reported after a second injection.¹⁶ Because of decreasing electrical resistance, stimulating the sacral nerve from its proximal end with SNS can be considered in patients who do not benefit from PTNS.⁶ A study from the UK reported that 68% of the patients who did not recover with PTNS had better results with SNS.⁴⁰

We did not randomize our patients. It was our main limitation about this study. Due to the duration of PTNS treatment, patients were asked to choose the practicable option for them. The other limitation of this study was that anorectal physiological tests were not performed after treatment and that the patients were evaluated through questionnaires and clinical outcomes.

In conclusion, both methods PTNS and PI are influential treatment options for FI secondary to isolated or combined sphincter deficiency regardless to etiology. The two methods showed similar positive effects on FI episodes, decreased WFIS and improved patient quality of life. As PTNS becomes more prominent (because it is less invasive), PI is in a favorable position because of its short-term effectiveness and fewer required hospital visits. In patients who report inadequate responses after the initial procedure, we believe that these techniques complement one another and need not be considered alternative treatments.

Ethics

Ethics Committee Approval: Ethic Committee of İstanbul University Faculty of Medicine (no: 2015/778), Informed Consent: Obtained.

Peer-review: External and Internal peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: Metin Keskin, Evrim Yılmaz, Emre Balık, Türker Bulut, Concept: Metin Keskin, Emre Balık, Türker Bulut, Design: Metin Keskin, Emre Balık, Türker Bulut, Data Collection or Processing: Metin Keskin,

Evrım Yılmaz, Analysis or Interpretation: Metin Keskin, Bora Karip, Emre Balık, Literature Search: Metin Keskin, Emre Balık, Türker Bulut, Writing: Metin Keskin, Bora Karip, Alper Şahbaz.

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