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Research Article

Comparison of the Efficacy of Corticosteroid and Local Anesthetic Injections Combined with Physiotherapy in Patients with Concomitant Pes Anserine Bursitis and Knee Osteoarthritis: A Prospective Randomized Study

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Abstract

Objectives: It was aimed to investigate the effects of local corticosteroid and local anesthetic injection in patients with concomitant pes anserine bursitis and knee osteoarthritis.

Methods: In this prospective randomized controlled study, 102 patients with knee osteoarthritis with pes anserine bursitis were divided into three groups: group I (physiotherapy + lidocaine), group II (physiotherapy + betamethasone dipropionate), and group III (physiotherapy: control). Evaluations were performed three times at the start of treatment, at day 15, and at week eight, using the Visual analog scale (VAS), Western Ontario and McMaster Universities Osteoarthritis index (WOMAC), and the Timed up and go (TUG).

Results: There was no difference in age, BMI, gender and baseline values in all three groups. There was a significant difference between the groups in pre and post treatment VAS and WOMAC scores ($p<0.05$). However, there was no difference between the groups in the post-test follow-up values ($p>0.05$). While betamethasone significantly decreased VAS and WOMAC scores, only WOMAC scores were decreased in the lidocaine group. There was no significant difference between the WOMAC scores of the lidocaine and betamethasone groups ($p>0.05$).

Conclusion: Corticosteroids and lidocaine are avaiable choices to relieve pain, our results show, corticosteroids are more effective. Consequently, steroids may be considered as a better option in patients with concomitant pes anserine bursitis and knee osteoarthritis.

Keywords: Corticosteroid, knee osteoarthritis, lidocaine, pes anserine bursitis

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Pes anserine is a component of the knee formed by the tendons of the sartorius, gracilis, and semitendinosus muscles; it resembles the foot of a goose, hence its Latin name.[1] Underneath this formation is found the bursa, which is located along the proximal medial tibia. Pes anserine bursitis, also called pes anserine pain syndrome, is a painful knee disorder that not only limits physical functioning, but also impairs the quality of life of a patient. Some

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predisposing factors have been implicated in the development of this syndrome, including obesity, diabetes mellitus, trauma, valgus deformity, and osteoarthritis of the knee.[2] The reported prevalence of pes anserine bursitis ranged between 2.5% and 20% in patients who presented with knee pain.[3]

Pes anserine bursitis is closely related to knee osteoarthritis. In a report, pes anserine pain (not synonymous with bursitis) was present in more than 90% of patients with knee osteoarthritis.[4, 5] Diagnosis is traditionally based on clinical grounds. However, some aspects of patient history and clinical examination may serve as helpful clues in diagnosis.

For instance, pain is aggravated when climbing stairs, during leg crossing, when getting up from a chair, and during active external rotation of the tibia. It should be noted, however, that not all patients who had pain and tenderness over the pes anserine bursa necessarily have pes anserine bursitis. Studies that utilized ultrasound or magnetic resonance imaging modalities to evaluate pes anserine bursitis have revealed lower prevalence rates than that previously reported.[3, 6] Knee osteoarthritis with pes anserine bursitis present with more pain, functional loss and disability than patients without pes anserine bursitis . Therefore, it is very important to choose effective treatment methods.[7]

Several treatment options with varying success rates have been tried, including nonsteroidal anti-inflammatory drugs, physiotherapy modalities, cold application with ice-packs, and injection of local anesthetics and/or corticosteroids.[8] Despite the relatively high frequency of this painful condition, surprisingly, only a few studies have evaluated the treatment strategies using the randomized controlled study design.[7, 9, 10] Although corticosteroids and local anesthetic injections are widely used in the treatment of joint and bursa diseases, there is no consensus on the physicians' choice of these treatment methods.[11] Corticosteroid injection treatments are inexpensive treatments that can be used effectively in the treatment of pes anserine bursitis.[7] However, the fact that it is an invasive method and the development of steroid-related side effects limits their use. Local anesthetic injections are the another invasive method and they are widely used in clinicle practice. However, the use of these agents is limited due to their side effects of the central nervous system and their toxicity.[12] The importance of this study is to determine the treatment method that is more effective and has the least side-effect profile among invasive interventions.

To our best knowledge, no study in the literature has compared the efficacy of local anesthetic and corticosteroid injections combined with physiotherapy in the treatment of pes anserine bursitis. Thus, we aimed to compare the treatment efficacies of physiotherapy+ local anesthetic injection, physiotherapy + local corticosteroid injection and physiotherapy alone in this randomized controlled study involving patients with concomitant osteoarthritis and pes anserine bursitis.

Methods

Study Design and Setting

This study is a single-center, prospective, randomized, single-blinded (outcome assessor) trial in which lidocaine injection and corticosteroid injection combined with exercise were compared in patients with concomitant knee osteoarthritis and pes anserine bursitis. This study was performed between March 2019 and March 2020 in accordance with the Helsinki Declaration and with permission from the ethical committee of Bolu Abant Izzet Baysal University (Clinical Research Ethics Committee decision no: 2017-145, date: 14.12.2017). All participants signed a written informed consent before being enrolled in this study.

Study Participants

Patients who were diagnosed with concomitant knee osteoarthritis and pes anserine bursitis and who met the inclusion criteria were included in this study. The inclusion criteria were as follows: having stage II–IV knee osteoarthritis with pes anserine bursitis, showing symptoms for more than 3 months, and aged 40–70 years. Primary knee osteoarthritis was diagnosed according to the American College of Rheumatology criteria[13] and graded based on the Kellgren–Lawrence radiological classification. Pes anserine bursitis diagnosis was made based on clinical findings. Patients who had undergone knee operations, had an inflammatory rheumatic disease, had diabetes mellitus, had a history of knee trauma, had a meniscus tear, had valgus/varus deformity, and had received injection treatment for pes anserine bursa during the preceding year were excluded. None of the study participants were allowed to use nonsteroidal anti-inflammatory drugs or other analgesics during the study period.

Interventions

The study participants underwent a physiotherapy program that included one-time 15-minute cold therapy using ice packs and a closed-kinetic chain quadriceps strengthening program consisting of isometric quadriceps exercise and eccentric quadriceps exercises with heel slides, and squats. These exercises were repeated 10 times a day, 7 days per week, for a total of 8 weeks. The patients were instructed to sit down with a towel placed beneath their knees and to

press their knees against the towel while stretching their knees. Then, they were asked to maintain this position for 10 s and return to the starting position slowly thereafter. The patients who were randomized to the lidocaine (group I) and corticosteroid injection (group II) groups were injected with 1 cc of 20 mg lidocaine (Jetokain, Edaka İlaç AŞ, Turkey) and with 1 cc of 5 mg + 2 mg betamethasone dipropionate/sodium phosphate (Diprospan, Merck Sharp Dohme Inc., USA), respectively, combined with a physiotherapy program. Group III was the control group, which just received physiotherapy (ice packs and exercises). The injections were applied to the most tender point in the pes anserine region using the soft tissue infiltration technique only once at the commencement of the treatment period. All injections were performed by the same physician.

Randomization

The 254 patients who attended the physiotherapy and rehabilitation outpatient clinics in our hospital during the study period were screened for suitability for inclusion in this study. Of these patients, 152 were excluded either based on the exclusion criteria or because they refused to participate. Finally, 102 patients were randomized into one of the three parallel groups randomization was performed with a sequential order list using the Microsoft Excel© 2003 (Microsoft, Redmond, WA) random number production function, as follows: group I (physiotherapy + lidocaine), group II (physiotherapy + betamethasone dipropionate), and group III (physiotherapy: control) (Fig. 1).

Outcome Measures

The primary outcome measured was treatment efficiency, which was evaluated using the visual analogue scale (VAS), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and Timed Up and Go (TUG). The VAS, WOMAC, and TUG evaluations were performed at the start of the study (baseline evaluation) and then repeated on day 15 and at the end of the 8-week study period. Measurements were performed by one of the investigators who was blinded to the patients' group assignments. All adverse effects related to the study interventions were recorded on day 15 and on week 8 of the assessments.

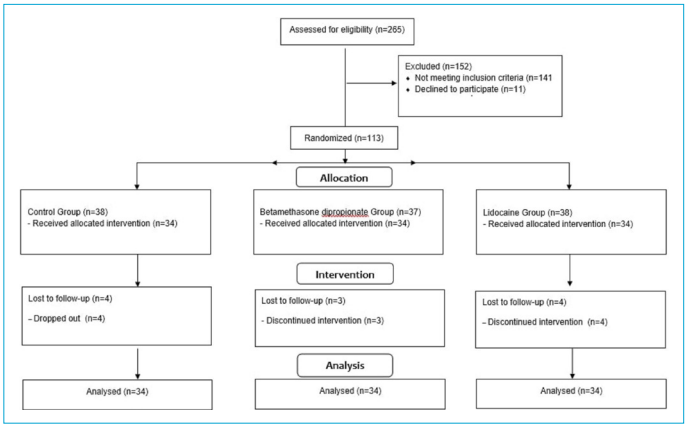

Figure 1. Flow chart of study.

VAS: We used paper-based VAS to evaluate the baseline severity and changes in the intensity of pain induced by the interventions in our study cohort. The VAS was devised by Hayes and Patterson and is used to rate pain. Subjects self-report the intensity of their pain by placing a mark at a certain point along a 10 centimeter-long line.[14] One end of the scale (0 cm) represents "no pain" and the other end (10 cm) represents "worst pain experienced."

WOMAC Osteoarthritis Index: The WOMAC is a self-administered questionnaire comprising 24 items covering three domains, namely, pain, stiffness, and physical functional disability.[15] The subscales for pain, stiffness, and physical functional disability comprise 5, 2, and 17 questions, respectively. All subscales consist of five choices ranging from zero ("not present") to 4 ("very severe"). We used the WOMAC version that was validated in a Turkish cohort.[16] The patients were asked to complete all questions by themselves, and then we calculated the global WOMAC score for each participant.

TUG: While sitting in an arm-supported chair, the patient walks up to a point three meters away at the fastest speed he can walk. The walking time is recorded in seconds and the average speed is evaluated according to the age group.[17]

Sample Size Calculation and Statistical Analysis

Power analysis: Sample size per the recommendations of Wang et al.[18] At 80% test power and $\alpha<0.05$ with an effect size of 0.164, at least 31 patients were needed for each group. Power analysis was performed with G*Power (Heinrich-Heine-Universität Düsseldorf) according to the study of Choi et al.[19]

Kolmogorov-Smirnov test was used to check the normality assumptions of the data. Parametric variables were compared using one-way ANOVA and two-way repeated-measures ANOVA for group-time interactions and time interaction of each group, respectively. A p-value < 0.05 was accepted as statistically significant. SPSS 16.0 software package (IBM, Armonk, NY, USA) was used for data analysis.

Results

A total of 102 patients who met the inclusion criteria were randomly allocated to to one of the following groups: group I (physiotherapy + lidocaine, n=34), group II (physiotherapy + betamethasone dipropionate, n=34), or group III (physiotherapy alone:control, n=34). The demographic

characteristics of the study groups are shown in Table 1. The groups were comparable in terms of age, BMI, and sex distribution. At the baseline evaluation, no significant differences for the results were observed among the groups (p=0.058). Also, the three groups were comparable in terms of VAS (p=0.094) and WOMAC (p=0.070) scores (Table 2).

The TUG results did not significantly differ from the baseline values in any of the interventions. The VAS scores significantly differed between groups, as determined by one-way ANOVA (F(2.99) = 7.361, p=0.001) (Table 3). Post hoc analysis revealed that betamethasone dipropionate significantly reduced the VAS scores compared with the control. Although the lidocaine injection also reduced the mean VAS scores, these results did not significantly differ from those obtained in the control subjects (p=0.468). Moreover, no significant difference was observed between the betamethasone and lidocaine groups in terms of VAS score reduction (p=0.069) (Table 4). As regards the WOMAC scores, the three groups significantly differed as determined by one-way ANOVA (F(2.99) = 11.087, p<0.001). Post hoc analysis revealed that the WOMAC score was reduced signifi-

Table 1. Demographic characteristics of the study groups

	Lidocaine (n=34) X±SD		Betamethasone (n=34) X±SD		Control (n=34) X±SD		f	p
Age (years)	58.5±7.45		62.17±6.67		60.26±7.82		2.137	0.123
BMI (kg/m^2)	31.01±3.62		31.71±3.39		29.45±4.14		2.785	0.224
	n	%	n	%	n	%	χ^2	p
Gender								
Female	29	85.3	31	91.2	25	73.5	3.953	0.139
Male	6	14.7	3	8.8	9	26.5		

χ^2: Chi-Square F: One-way Anova test, BMI: Body mass index, p<0.05.

Table 2. Comparison of the baseline scores of the study groups

	Lidocaine (n=34) X±SD	Betamethasone (n=34) X±SD	Control (n=34) X±SD	f	p
TUG	11.29±1.74	12.29±2.05	11.35±1.77	2.982	0.058
VAS	7.23±1.07	7.52±1.28	6.94±0.91	2.417	0.094
WOMAC	29.52±10.5	35±12.33	29.67±10.05	2.725	0.070

TUG: Timed up and go; VAS: Visual Analog Scale; WOMAC: Western Ontario and Mcmaster Universities Osteoarthritis Index; F: One-way Anova test.

Table 3. Comparison of the TUG, VAS and WOMAC scores of the study groups at the baseline, 15th day and 8th week of the study.

	Baseline	15th day of the study	8th week	f	p
TUG					
Lidocaine	11.29±1.74	10.29±1.62	10.64±1.68	1.448	0.240
Betamethasone	12.29±2.05	11.17±1.58	11.11±1.8		
Control	11.35±1.77	10.64±1.72	11.08±1.81		
VAS					
Lidocaine	7.23±1.07	5.08±1.13	5.02±1.19	7.361	0.001
Betamethasone	7.52±1.28	4.79±1.83	4.73±1.89		
Control	6.94±0.91	5.2±1.12	5.32±1.22		
WOMAC					
Lidocaine	29.52±10.5	20.61±7.36	20.58±7.6	11.087	<0.001
Betamethasone	35.0±12.33	23.34±11.12	22.1±10.8		
Control	29.67±10.05	23.91±8.9	24.35±8.93		

TUG: Timed up and go; VAS: Visual Analog Scale; WOMAC: Western Ontario and Mcmaster Universities Osteoarthritis Index; F: Two-way repeated-measures ANOVA test, p<0.05.

Table 4. Post hoc results of VAS and WOMAC scores between groups

	Mean Difference (SE)	Confidence intervals (%95 CI)	p
VAS			
Lidocaine- Betamethasone	-0.58 (0.26)	-1.211/0.035	0.069
Lidocaine-Control	0.41 (0.26)	-0.211/1.035	0.263
Betamethasone -Control	1.001 (0.26)	0,376/1,623	0.001
WOMAC			
Lidocaine- Betamethasone	2.73 (1.25)	-0.239/5.710	0.493
Lidocaine-Control	-3.14 (1.25)	-5.710/0.239	<0.001
Betamethasone -Control	-5.88 (1,25)	-8.857/-2.907	0.002

Tukey post hoc analysis was used to changes over time; VAS: Visual analog Scale; WOMAC: Western Ontario and Mcmaster Universities Osteoarthritis Index; p<0.05.

cantly both by the lidocaine injection and betamethasone injection compared with the control (p=0.001 for both). Contrarily, no difference was observed between the lidocaine and betamethasone dipropionate groups in terms of WOMAC score reduction (p=0.078) (Table 4). The WOMAC subgroup analysis revealed that there was a significant difference in the pain (p=0.019) and stiffness (p=0.008) scores, and the difference was at the 15th day in favor of the corticosteroid group (Table 5).

From day 15 to week 8, the groups did not significantly differ in terms of TUG (F(2.99) = 4.923, p=0.090), VAS (F(2.99) = 8.024, p=0.101), and WOMAC scores (F(2.99) = 12.000, p=0.820) (Table 6).

Discussion

The main finding of the present study was that, compared with the control, the betamethasone injection significantly reduced pain, stiffness, and physical functioning based on the VAS and WOMAC scores of the patients with concomitant osteoarthritis and pes anserine bursitis. The lidocaine injection reduced WOMAC scores at a magnitude equal to that of betamethasone; however, it did not result in a significant change in the VAS scores compared with the controls. The favorable effects of the injections were evident on day 15 of the treatment and continued to remained so at week 8. We did not observe any significant adverse events related to the study interventions.

The presence of pes anserine bursitis increases the severity of walking disability in knee osteoarthritis, and the severity of this disability is often linked to pain.[7, 20] However, in our study, the TUG results in both injection groups did not differ from the results obtained in the control group. The anti-inflammatory effect of betamethasone and the analgesic effect of lidocaine both reduce pain. Although the corticosteroid injection significantly improved the VAS scores, this improvement was not manifested in terms of functionality, suggesting that additional rehabilitation procedures are needed to achieve improvements in daily life activities.

Several treatment options are available to patients with pes anserine bursitis, although little evidence-based data

Table 5. Comparison of the subsection of WOMAC scores

	Baseline	15th day of the study	8th week	F	p
Pain					
Lidocaine	5.79±2.59	3.26±1.67	3.32±1.77	4.104	0.019
Betamethasone	7.23±2.93	4.73±2.31	4,67±2,26		
Control	6.14±2.32	4.47±1.84	4.58±1.95		
Stiffness					
Lidocaine	2.2±1.24	1.73±1.05	1.73±1.05	5.748	0.008
Betamethasone	3.26±1.52	2.47±1.05	2.,41±0.98		
Control	2.32±1.09	2.0±0.85	2.0±0.85		
Physical Function					
Lidocaine	21.7±7.64	15.94±5.5	15.97±5.64	0.036	0.699
Betamethasone	24.5±8.82	16.79±7.9	16.52±7.63		
Control	21.14±7.29	17.38±6.67	17.7±6.83		

WOMAC: Western Ontario and Mcmaster Universities Osteoarthritis Index F: Two-way repeated-measures ANOVA test, p<0.05.

Table 6. Post hoc results of VAS and WOMAC scores within group interaction

	Mean Difference (SE)	Confidence intervals (%95 CI)	p
VAS			
Lidocaine			
1-2	2.147 (0.18)	1.681/2.613	0.001<
1-3	2.206 (0.20)	1.687/2.725	0.001<
2-3	0.059 (0.10)	-0.201/0.318	0.989
Betamethasone			
1-2	2.735 (0.21)	2.189/3.281	0.001<
1-3	2.794 (0.24)	2.166/3.422	0.001<
2-3	0.059 (0.11)	-0.222/0.339	0.954
Control			
1-2	1.735 (0.14)	1.362/2.109	0.001<
1-3	1,618 (0.15)	1.219/2.016	0.001<
2-3	-0.118 (0.09)	-0.350/-0.115	0.632
WOMAC			
Lidocaine			
1-2	8.912 (0.98)	6.434/11.389	0.001<
1-3	8.941 (1.06)	6.264/11.618	0.001<
2-3	0.029 (0.26)	-0.690/0.631	0.998
Betamethasone			
1-2	11.647 (0.94)	9.271/14.023	0.001<
1-3	12.088 (1.12)	9.244/14.932	0.001<
2-3	0.441 (0.39)	-0.547/1.430	0.805
Control			
1-2	5.765 (0.70)	3.995/7.534	0.001<
1-3	5.324 (0.68)	3.601/7.406	0.001<
2-3	-0.441 (0.26)	-1.099/0.217	0.301

Tukey post hoc analysis was used to changes over time, Osteoarthritis Index, p<0.05. 1: Measurements at baseline, 2: Measurements on the 15th day, 3: Measurements in the 8th week, VAS: Visual analog Scale, WOMAC: Western Ontario and Mcmaster Universities.

demonstrate their efficacy. Patients are initially treated with rest, cryotherapy, physiotherapy, and systemic non-steroidal anti-inflammatory medications. Local injection of a corticosteroid and a local anesthetic is also a treatment option in patients who do not respond to an initial treatment.[8] Moreover, one recent study has proven the efficacy of extracorporeal shock wave therapy.[20]

Despite the high prevalence of pes anserine bursitis, it is notable that there is a paucity of data in the literature regarding the optimal treatment for this condition.[20-22] A few randomized controlled studies on this condition have been carried out. However, this limited number of studies have yielded conflicting results regarding the efficacy of corticosteroid injection. Vega-Morales and colleagues conducted a randomized controlled study wherein they stratified patients into lidocaine + methylprednisolone injection and distilled water + lidocaine injection groups.[10] All participants were prescribed with diclofenac during the study period. The authors evaluated the efficacy of local steroid injections based on WOMAC scores within 4 weeks. The study revealed that methylprednisolone was not superior to the placebo. Using a randomized controlled study, Sarifakioglu et al. compared the treatment efficacy of physiotherapy and corticosteroid injection in patients who had concomitant knee osteoarthritis and pes anserine bursitis. The treatment efficacy was assessed based on VAS, WOMAC, and on TUG week 8 of treatment. They found that corticosteroid injection and physiotherapy demonstrated similar efficacies.[7] In a prospective interventional study without a control, Yoon et al. evaluated the efficacy of local corticosteroid injection based on VAS and WOMAC scores.[23] The corticosteroid injection significantly decreased the VAS and WOMAC scores. Meanwhile, our results showed that both VAS and WOMAC scores increased significantly on day 15 and on week 8 compared with the baseline values in all three groups.

To our best knowledge, this study is the first to evaluate the treatment efficacies of local corticosteroid and local anes-

thetic injections in the context of physiotherapy in patients who had knee osteoarthritis and pas anserine bursitis. Local corticosteroid injection was somehow more effective than local lidocaine injection because it reduced both the VAS and WOMAC scores of the treated subjects relative to those of the control subjects. However, both injection methods equally reduced the WOMAC scores, although the local anesthetic injection did not influence the VAS scores compared with the control. Furthermore, the treatment effect remained strong until week 8.

This study is the first to conduct a head-to-head comparison of the local injection of a corticosteroid and a local anesthetic. Our results showed the superiority of the local anesthetic or corticosteroid injections over physiotherapy alone. For the power analysis, we recruited a sufficient number of patients so we can conduct an assessment at 80% power. We evaluated the efficacy of the treatments using three scales, namely, VAS, WOMAC and TUG , at two distinct time points. Moreover, we determined whether the injections could retain their treatment effects for up to 8 weeks.

Limitations

First, we diagnosed pes anserine bursitis based only on clinical grounds. Therefore, some of our patients might not have pes anserine bursitis despite the suggestive clinical findings. Second, the WOMAC scale was originally devised to evaluate the pain, stiffness, and physical functional status of osteoarthritis patients. Given that the patients were not allowed to use analgesic and anti-inflammatory drugs, despite the improvements in pes anserine-related pain with the treatment, the patients might have continued to experience pain due to their osteoarthritis. This factor should be kept in mind when interpreting the present results. Third, we did not use an ultrasound-guided technique while performing the injections; unguided injections have considerably lower success rates compared with the guided injections.[24, 25] We used tissue infiltration technique aiming at the most tender area over the bursa; however, there is no guarantee that adequate amounts of the investigated drugs were injected into the bursa in all instances.

Conclusion

Pes anserine bursitis shouldn't be missed out in knee osteoarthritis patients, complaining of pain. Although corticosteroids and lidocaine are avaiable choices to relieve pain, our results show, corticosteroids are more effective. Consequently, steroids may be considered as a better option. The main contribution to literature is that injection of steroids are more potent than local anesthetics, exercise and cold compression. Although our study showed acceptable to evaluate treatment differences, we suggest that randomized studies recruiting more subjects and utilizing objective diagnostic modalities are a conspicuous research requirement to increase the evidence-based treatment data.

Disclosures

Ethics Committee Approval: Bolu Abant Izzet Baysal University Clinical Researches Ethics Committee, Decision number: 2017/145, Date: 14/12/2017.

Peer-review: Externally peer-reviewed.

Conflict of Interest: None declared.

Authorship Contributions: Concept – M.F.Y., R.K., E.Y.; Design – M.F.Y., E.Y.; Supervision – M.F.Y., R.K., E.Y.; Materials – M.F.Y., E.Y., M.A., Ş.B.T.; Data collection &/or processing – M.F.Y., R.K., Z.A., Ş.B.T.; Analysis and/or interpretation – M.F.Y., R.K., E.Y., Z.A.; Literature search – M.F.Y., M.A., Z.A.; Writing – M.F.Y., R.K., E.Y.; Critical review – M.F.Y., R.K., E.Y.

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