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Ultrasound, Fluoroscopic-Guided Caudal, Lumbar Epidural Steroid Injections and Blinding Paraspinal Lumbosacral Steroid Injections in Patients with Low Back Pain with Radiculopathy

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Abstract

Background and Aims: Low back pain (LBP) is considered one of the most common health conditions in the world right now, and it affects many individuals throughout different stages of their lives. Chronic LBP (CLBP) was estimated to be between 5% and 10%, defined as LBP that lasts for 12 weeks. The most common causes of CLBP with radiculopathy are lumbar disc prolapse (LDP) and degenerative facet osteoarthropathy (DFO); the aim of this study is to investigate the efficacy of ultrasound (US) guided, fluoroscopy (FL) guided, Caudal Epidural Steroid Injection (CESI), lumbar epidural steroid injections (LESI), and blinding lumbosacral steroid injections (LSPSI) in patients with CLBP with radiculopathy. **Patients and Methods:** This is a randomized prospective study that was conducted at the department of rheumatology at Al Azhar University Hospital in Egypt between November 2020 and August 2021. A total of 100 patients with refractory CLBP with radiculopathy were enrolled in the study. Consequently, they were divided into 2 groups: the first consisted of fifty patients with CLBP and radiculopathy caused by LDP, as determined by lumbosacral magnetic resonance imaging (MRI), and the second group consisted of fifty patients with refractory low back pain and radiculopathy caused by DFO, as determined by lumbosacral plain x-rays and lumbosacral MRI. The following procedures were performed: US-guided CESI, FL-guided CESI, FL-guided LESI, US-guided LESI, and blinding LSPSI. **Results:** In the LDP group, there is a statistically signifi-

cant difference between considered spinal nerve roots as regards Visual Analogue Scale (VAS) (at 2 months). Likewise, a statistically significant difference was found between blinding LSPSI and US-Guided LESI with respect to VAS (baseline) and VAS (2 months) (P-value = 0.018 and 0.003, respectively). Statistically significant differences were reported in VAS (2 months) for both FL-guided LESI and FL-guided CESI groups. Considering the VAS of studied spinal nerve roots in the DFO group, there is a statistically significant difference between the examined spinal nerve roots with respect to Oswestry Disability Index (ODI) (2 months). Similarly, there is a statistically significant difference in VAS (2 months) between US-guided LESI and para-spinal roots and FL-guided LESI and para-spinal roots (P-value = 0.038 and 0.021, respectively). Additionally, there is a statistically significant difference between the US-guided CESI, FL-guided CESI, FL-guided LESI, and spinal nerve roots with respect to ODI (at 2 months). (P-value = 0.033, 0.025 and 0.005, respectively). **Conclusion:** US is excellent in guiding CESI and LESI and should be the preferred alternative when FL is not provided, with a similar treatment outcome compared to FL-CESI and LESI.

Keywords

Fluoroscopic-Guided, Caudal and Lumbar Epidural Steroid Injections, Ultrasound-Guided, Low Back Pain, Radiculopathy, Lumbar Disc Prolapse, Degenerative Facet Osteoarthropathy

1. Introduction

Low back pain (LBP) is a common health condition that affects many people. The global activity-limiting LBP prevalence in 2015 was 7.3%, which means 540,000,000 people at a time were affected [1]. In Egypt, a high proportion of LBP patients in ambulatory clinics were seeking medical care. In one study, it was estimated at 53.2% [2].

Chronic LBP (CLBP) was estimated to be between 5% and 10%, defined as LBP that lasts for 12 weeks. CLBP is caused by the complex, biological, psychological, and social interactions of various factors. Moreover, CLBP is mainly associated with co-morbidities such as depression and anxiety, which pose a therapeutic difficulty [3]. The most common cause of radicular pain is lumbar disc prolapse (LDP) [4]. Another common cause of LBP is degenerative facet osteoarthropathy (DFO). DFO is a clinicopathological construct that involves inflammation of the synovial facet joints, resulting in mechanical or chemical stimulation of the facets and, consequently, CLBP [5]. Facet joint operations are therefore commonly performed, such as intra-articular facet joint steroid injections, medial branch blocks, and medial branch nerve denervation [6]. The methods of CLBP management continue to grow. The initial assessment is important not only for correct diagnosis, but also for pain severity and functional disability assessment. This enables the health professional to define the extent of the

problem in a management strategy [7].

Multiple methods of treatment are provided, such as surgical procedures, prudent methods, and interventional therapies, which continue to increase at an uncontrollable pace at increasing costs. In addition to pain reduction to improve function and quality of life, chronic pain treatment should include a rehabilitation program [8].

While many studies examined the benefit of epidural injections (EI) for LBP, particularly if radiculopathy is the cause of pain, other studies disputed their effectiveness. EI can be performed by interlaminar, transforaminal, or caudal approaches with local anesthetes, steroids, or a combination of both. In addition to improving function and mobility, epidural steroid injections (ESI) are commonly given to alleviate pain, which can cause healing [9]. Even though it requires typically significant quantities of injectate, caudal epidural steroid injection (CESI) is regarded as the most secure and least demanding modality with little risk of coincidental dural puncture and is a beneficial modality in post-surgery syndrome [10].

We aimed to investigate the efficacy of ultrasound (US) guided, fluoroscopy (FL) guided, Caudal Epidural Steroid Injection (CESI), lumbar epidural steroid injections (LESI), and blinding lumbosacral blind injections (LSPSI) in patients with CLBP with radiculopathy.

2. Patients and Methods

Study design and data collection

- This is a randomized prospective study that was conducted at the department of rheumatology at Al Azhar University Hospital in Egypt between November 2020 and August 2021. Of the 164 adults with refractory CLBP with radiculopathy screened for entry into this study, those who met the inclusion criteria were selected. Conversely, those who did not meet the inclusion criteria or met the exclusion criteria were excluded. Consequently, 100 patients with refractory CLBP with radiculopathy fulfilling the criteria for inclusion were divided into 2 groups:
- ***Group* (*I*):** Fifty patients with refractory CLBP and radiculopathy as a result of LDP as determined by lumbosacral magnetic resonance imaging (MRI) were divided into five subgroups:
  - **Subgroup (1):** Ten patients were treated with a US-guided Caudal Epidural Steroid Injection (CESI).
  - **Subgroup (2):** Ten were treated with an FL-guided CESI.
  - **Subgroup (3):** Ten patients were treated with FL-guided lumbar Epidural Steroid Injection (LESI).
  - **Subgroup (4):** Ten patients were treated with a US-guided LESI.
  - **Subgroup (5):** Ten patients were treated with blinding LSPSI.
- ***Group* (*II*):** Fifty patients with refractory CLBP and radiculopathy due to DFO were divided into five subgroups based on lumbosacral plain x-rays and lumbosacral MRI findings:

- **Subgroup (1):** ten patients were treated with a US-guided CESI.
- **Subgroup (2):** ten patients were treated with an FL-guided CESI.
- **Subgroup (3):** ten patients were treated with an FL-guided LESI.
- **Subgroup (4):** ten patients were treated with US-guided.
- **Subgroup (5):** ten patients were treated with a blinding LSPSI.

Inclusion criteria

Patients with CLBP with radiculopathy analyzed by routine clinical assessment and MRI, aged between 18 and 65 years, in whom conservative treatment (medical treatment and physiotherapy) failed for more than 6 weeks and who refused surgery or were unfit for surgery, are included.

Exclusion criteria

The study excluded patients with vertebral fractures, spinal inflammatory disease, spinal infection, bleeding tendency, tumors, cauda equina syndrome, spinal canal stenosis, post-laminectomy surgery, osteoporosis, primary scoliosis, vertebral crack, pregnancy, diabetic, and hypertensive patients.

Clinical examination

All patients are exposed to a full history and clinical assessment, including a musculoskeletal examination of all the joints with stress on lumbar spine examination.

Laboratory assessment

Blood samples were taken and analyzed for complete blood count, erythrocyte sedimentation rate, prothrombin time, focus, INR, fasting blood glucose, Ca, liver capacity tests, kidney function tests.

Imaging

An X-ray and an MRI of the lumbosacral spine were done as a baseline evaluation for all patients.

Outcome measures

Patients were surveyed at baseline, 1 week, 1 month, and 2 months after the injection.

Visual Analogue Scale (*VAS*) [11]

Made up of a continuous horizontal line. This line is 100 mm long. The score is anchored by (0 score = no pain) at one end and (100 score = worst imaginable pain) at the other end to measure the intensity of pain.

Oswestry Disability Index (*ODI*) [12]

It is a self-administered questionnaire with ten sections, each of which is scored on a 0 - 5 scale, with 5 representing the most disability. It is made up of ten short-term sectors. The index is calculated by dividing the total possible score by the sum of the individual scores, then multiplying the result by 100 and expressing it as a percentage. As a result, the denominator for each of the unanswered questions is reduced by 5.

The investigators who assessed the baseline data and outcome measures were blind to the treatment procedures, and one investigator oversaw intervention in each of the two groups.

Intervention

- *US-Guided CESI and LESI*: All the injection procedures were performed in an outpatient clinic setting. We used the TOSHIBA XERIO with a linear probe at 12 MHz as the US instrument. The injection of the treatment drug was a mixture of 0.5% lidocaine (2 mL) and 2 mL of triamcinolone acetonide (40 mg/1 ml) [13].
- *FL-Guided CESI and LESI*: All injections were carried out in a specialised room equipped with an FL device in the operating room. We used an FL GS 1004 device with an ALLURA XPER FD 20 system (Philips, Holland) that included an X-ray tube housing assembly, an X-ray tube, a beam limiting device, and an image receptor. The injection of the treatment drug was a mixture of 0.5% lidocaine (2 mL) and 2 mL of triamcinolone acetonide (40 mg/1 ml) [13].
- *Blinding LSPSI*: This application was performed about 2 cm lateral to the spinous process at the L4-5 level (the line joining the superior aspect of the iliac crests posteriorly, Tuffier's lines) and 2.5 cm lateral to the spinous process with a 3 - 5 cm depth at the L5-S1 level. The injection of the treatment drug was a mixture of 0.5% lidocaine (2 mL) and 2 mL of triamcinolone acetonide (40 mg/1 ml) [13].

Statistical analysis:

Data collected in the history of Microsoft Excel software was coded, entered, and analysed for basic clinical examinations, laboratory studies, and outcome measures. SPSS (Social Science Statistical Package) version 25 (IBM, Armonk, NY, USA) has compiled and analysed the collected data on IBM-compatible computers. Depending on the type of quality data, the quantitative continuous group is represented by average ± SD as number and percentage. The tests used were the following: Independent t-test samples, Chi-square test, one-way Variance Analysis (ANOVA) and Post Hoc test. A significant P-value < 0.05 has been considered.

3. Results

A total of 100 patients with refractory CLBP with radiculopathy participated in the study, 62% of whom were females. Their age ranged from 19 - 60 years (41.43 ± 10.61) in the LDP group and 41 - 60 years (42.69 ± 10.48) in the DFO group (mean, 42.69 ± 10.48), and the disease duration ranged from 2 - 12 (7.7± 3.4) in the LDP group and 2 - 19 (5.82 ± 2.53) in the DFO group (**Table 1**).

Regarding the LDP group, there is no significant difference in VAS between studied spinal nerve roots (at baseline, after 1 week, 2 weeks, and 1 month), while there is a statistically significant difference between considered spinal nerve roots as regards VAS (at 2 months). Likewise, a statistically significant difference was found between blinding LSPSI and US-Guided LESI with respect to VAS (baseline) and VAS (2 months) (P-value = 0.018 and 0.003, separately). Statistically significant differences in VAS (2 months) were found between blinding

Table 1. Demographic findings of the study population.

Variables	LDP Group (n = 50)	DFO Group (n = 50)
Age range (mean ± SD), years	19 - 60 (41.43 ± 10.61)	29 - 62 (42.69 ± 10.48)
Sex		
Female	29 (58%)	33 (66%)
Male	21(42%)	17 (34%)
Disease duration range (mean ± SD), years	2 - 12 (7.7 ± 3.4)	2 - 19 (5.82 ± 2.53)
BMI range	19.5 - 42 (29.9 ± 6.4)	25 - 29.9
Normal (18 - 25)	7	5
Overweight (>25 - 30)	29	23
Obese (>30)	14	22

LSPSI and both FL-Guided CESI and LESI (P-value = 0.017 and 0.005, respectively) (Table 2).

In the LDP group, there is no statistically significant difference in ODI (at baseline, after 1 week, 2 weeks, 1 month, and 2 months), but there is a statistically significant difference between US-Guided LESI and spinal nerve roots as regards ODI (2 months) (P-value = 0.015), and between FL-Guided CESI and spinal nerve roots as regards ODI (2 months) (P-value = 0.032) (Table 3).

In the DFO group, there is no statistically significant difference in VAS (baseline, after 1 week, 2 weeks, 1 month, and 2 months), while there is a statistically significant difference between the examined spinal nerve roots with respect to ODI (2 months). Similarly, there is a statistically significant difference in VAS (2 months) between US-guided LESI and para-spinal roots and FL-guided LESI and para-spinal roots (P-value = 0.038 and 0.021, respectively) (Table 4). There was no statistically significant difference between contemplated spinal nerve roots as regards ODI (at baseline, after 1 week, 2 weeks, and 1 month), while there was a statistically significant difference between contemplated spinal nerve roots as regards ODI (at 2 months) (P-value = 0.04).

Statistically significant differences in ODI (1 month) were found between FL-Guided CESI and para-spinal roots and FL-Guided CESI and para-spinal roots (P-value = 0.037 and 0.028, respectively).

Additionally, there is a statistically significant difference between the US-guided CESI, FL-guided CESI, FL-guided LESI, and spinal nerve roots with respect to ODI (at 2 months) (P-value = 0.033, 0.025 and 0.005, respectively) (Table 5).

4. Discussion

In this research, we aimed to assess US, FL-guided, CESI, LESI, and blinding LSPSI in patients with CLBP and radiculopathy.

Table 2. VAS comparison of the studied spinal nerve roots in the LDP group.

		Spinal nerve roots in LDP group					F	P-value
		US-Guided LESI (n = 10)	FL-Guided LESI (n = 10)	US-Guided CESI (n = 10)	FL-Guided CESI (n = 10)	Blinding LSPSI (n = 10)		
Baseline VAS	Mean	6.9	7.8	7.3	7.5	8.2	1.74	0.157 NS
	±SD	0.9	0.9	1.6	1.1	1.2		
VAS at 1 week	Mean	3.2	4.0	3.0	3.2	3.8	0.77	0.546 NS
	±SD	1.4	1.2	2.3	1.7	0.9		
VAS at 1 month	Mean	1.9	2.4	3.0	1.9	3.2	1.18	0.332 NS
	±SD	1.4	2.9	1.6	1.1	1.2		
VAS at 2 months	Mean	1.9	2.5	3.4	2.1	4.6	3.45	0.015 S
	±SD	1.3	3.0	2.0	1.5	1.0		

	Para-Spinal root comparisons			
	P1	P2	P3	P4
Baseline VAS	0.018 S	0.453 NS	0.095 NS	0.192 NS
VAS at 1 week	0.393 NS	0.775 NS	0.256 NS	0.393 NS
VAS at 1 month	0.106 NS	0.316 NS	0.801 NS	0.106 NS
VAS at 2 months	0.003 S	0.017 S	0.163 NS	0.005 S

F: F value of ANOVA test; S: P-value < 0.05 is considered significant; NS: P-value > 0.05 is considered non-significant.

Table 3. ODI comparison of the studied spinal nerve roots in the LDP group.

		Spinal nerve roots in LDP group					F	P-value
		US-Guided LESI (n = 10)	FL-Guided LESI (n = 10)	US-Guided CESI (n = 10)	FL-Guided CESI (n = 10)	Blinding LSPSI (n = 10)		
Baseline ODI	**Mean**	61.0	58.4	47.6	57.3	55.9	1.01	0.411 NS
	±SD	19.2	11.7	22.9	12.4	9.3		
ODI at 1 week	**Mean**	35.0	32.5	25.5	30.2	29.3	1.19	0.327 NS
	±SD	10.0	6.6	12.4	9.9	11.7		
ODI at 1 month	**Mean**	26.6	24.8	22.1	19.9	24.8	0.61	0.655 NS
	±SD	7.4	12.5	13.1	9.2	9.9		
ODI at 2 months	**Mean**	16.1	14.3	27.0	19.6	29.0	2.5	0.055 NS
	±SD	6.0	14.3	18.2	11.3	12.3		

	Para-Spinal root comparisons			
	P1	P2	P3	P4
Baseline ODI	0.478 NS	0.728 NS	0.251 NS	0.845 NS
ODI at 1 week	0.223 NS	0.491 NS	0.414 NS	0.846 NS
ODI at 1 month	0.707 NS	1.0 NS	0.573 NS	0.309 NS
ODI at 2 months	**0.032 S**	**0.015 S**	0.733 NS	0.114 NS

F: F value of ANOVA test; S: P-value < 0.05 is considered significant; NS: P-value > 0.05 is considered non-significant.

Table 4. VAS comparison of the studied spinal nerve roots in the DFO group.

		Spinal nerve roots in the DFO group					F	P-value
		US-Guided LESI (n = 10)	FL-Guided LESI (n = 10)	US-Guided CESI (n = 10)	FL-Guided CESI (n = 10)	Blinding LSPSI (n = 10)		
Baseline VAS	**Mean**	8.2	8.6	7.7	7.9	7.8	0.72	0.580 NS
	±SD	0.9	0.8	2.1	1.1	1.4		
VAS 1 week	**Mean**	3.8	4.5	3.4	3.7	4	1.01	0.414 NS
	±SD	1.1	1.2	1.3	1.5	1.3		
VAS 1 month	**Mean**	2.2	2.5	2	1.9	2.2	0.34	0.844 NS
	±SD	1.0	1.4	1.1	1.6	0.9		
VAS 2 months	**Mean**	2.1	1.9	2.4	2.4	3.8	1.76	0.153 NS
	±SD	1.9	1.7	1.4	2.0	1.9		
		Para-Spinal root comparisons						
	P1		**P2**		**P3**		**P4**	
Baseline VAS	0.513 NS		0.193 NS		0.870 NS		0.870 NS	
VAS at 1 week	0.730 NS		0.390 NS		0.303 NS		0.605 NS	
VAS at 1 month	1.0 NS		0.590 NS		0.719 NS		0.590 NS	
VAS at 2 months	**0.038 S**		**0.021 S**		0.085 NS		0.085 NS	

F: F value of ANOVA test; S: P-value < 0.05 is considered significant; NS: P-value > 0.05 is considered non-significant.

Table 5. ODI comparison of the studied spinal nerve roots in the DFO group.

		Spinal nerve roots in the DFO group					F	P-value
		US-Guided LESI (n = 10)	FL-Guided LESI (n = 10)	US-Guided CESI (n = 10)	FL-Guided CESI (n = 10)	Blinding LSPSI (n = 10)		
Baseline ODI	**Mean**	63.8	54.2	54.6	55.4	58.4	0.6	0.661 NS
	±SD	16.9	11.4	20.4	18.4	12.0		
ODI at 1 week	**Mean**	27.5	25.7	23.3	25.7	32.8	0.82	0.519 NS
	±SD	13.2	10.6	15.6	10.9	11.3		
ODI at 1 month	**Mean**	22.7	21.2	19.7	20.3	31.3	1.72	0.161 NS
	±SD	13.4	9.2	10.2	10.7	13.0		
ODI at 2 months	**Mean**	31.2	17.9	23.4	22.5	39.0	**2.7**	**0.04 S**
	±SD	18.3	17.0	10.6	14.1	18.2		
		Para-Spinal root comparisons						
	P1		**P2**		**P3**		**P4**	
Baseline ODI	0.461 NS		0.566 NS		0.604 NS		0.682 NS	
ODI at 1 week	0.347 NS		0.209 NS		0.095 NS		0.209 NS	
ODI at 1 month	0.1 NS		0.055 NS		**0.028 S**		**0.037 S**	
ODI at 2 months	0.279 NS		**0.005 S**		**0.033 S**		**0.025 S**	

F: F value of ANOVA test; S: P-value < 0.05 is considered significant; NS: P-value > 0.05 is considered non-significant.

Our study showed no statistically significant differences in age, BMI, gender distribution, and disease duration between the groups studied. These results are in agreement with Won *et al.* [14] who reported non-significant differences in age, BMI, sexual distribution, and duration of illness among the groups studied.

In the first week, 1 month, and 2 months after injection, we have seen very statistically significant improvements in VAS and ODI versus before injection in the two groups. This indicates an improvement in the pain and function after 2 months of injections in both groups, although statistically significant differences in these parameters were not present between 1 week versus 1 month or 1 month versus 2 months versus after injection. The results of this study are consistent with Park *et al.*'s previous observation [15]. CESI, as denoted by VAS and ODI improvements after injecting vs. before injecting, showed significant improvements in pain and function in the US and FL CESI.

Current results showed that the US and FL-guided CESI subgroups VAS-ODI varied non-statistically within 1 week, 1 month, and 2 months following the injection of both LDP and DFO. This is well in line with the results of Akkaya *et al.* [16] and Hazra *et al.* [17] who reported that the CESI guided by the US and FL has not improved statistically significantly with respect to pain and function, which was denoted by VAS and ODI improvement after injections.

The benefits of US include its ease of use, lack of radiation, and ability to be used in virtually any clinical setting.

Most importantly, US can provide real-time and continuous needle guiding images without exposing patients to radiation. Power Doppler imaging was used to identify the blood vessels. Using the US, a needle trajectory that avoids blood vessels and other structures can be chosen from the start [18].

The current results show that regarding the VAS and ODI subgroups in the US Guided and FL Guided LESI, there was not a statistically significant difference at 1 week, 1 month, or 2 months after injection into the LDP and DFO groups. This is well in line with the results of Yang *et al.* [19] who said that Pain and function did not statistically improve with US and FL guided LESI, despite VAS and ODI improvement after injections.

The current results show that at week 1 and 2 months after injection in the LDP and DFO groups, the LESI and CESI subgroups as VAS and ODI were not statistically significantly different. This is consistent with the findings of Elashmawy *et al.* [20] who stated that there was no significant statistical improvement in pain and function between US and FL-guided LESI as indicated by VAS and ODI improvement following injections. However, the clinical advantages for transforaminal lumbar epidural steroid injection (TFESI) are improved than for CESI probably because TFESI had the capability to directly deliver the drugs to the target area.

The current results indicated that the LESI, CESI, and blinding LSPSI subgroups VAS and ODI had a non-statistically significant difference at 1 week and 1 month after injection in the LDP groups, while the differences between the blinding LSPSI and other subgroups VAS were substantial at 2 months after the

LDP group was injected.

At the end of our two-month study, all parameters showed clinically significant improvements. In cases where injections did not improve, secondary failure after injection improvements for 1 month, and a tertiary failure after injection improvements for 2 months, the procedure could fail, and there could be different receptor reactions to the steroid that affect the results. There may be several possible reasons for the failure of the procedure [20].

The disease's duration prior to injection could influence the outcome of the procedure. Our analysis concluded that this factor had the greatest impact, and the relationship was defined. We discovered that shorter disease duration (5 years) was preferable to longer disease duration (>5 years). Several studies have shown that chronically symptomatic patients are liable for worse results than acute ones. The longer the symptoms lead to more chronic inflammation, which may not react to the steroids [21].

Nonetheless, there are some limitations to this study. First, our sample size is relatively small, which may limit our ability to generalize our findings. Second, we did not repeat the injections in accordance with the North American Spine Society Guidelines [22]. However, recent research suggests that some patients may benefit from repeated injections [23]. Third, a follow-up MRI of the patients may be beneficial in assessing changes in disc morphology and the potential effects of the injection.

5. Conclusion

Prior to being considered for employable intercession, LESI provides an elective and powerful methodology in the management of LBP. LESI is pitifully prescribed over CESI because of its non-critical better clinical impact, possibly because LESI can deliver drugs directly into the target region. When compared to FL-directed CESI and LESI, the US is not inferior and less difficult to perform in directing CESI and LESI, and the US should be the preferred option when FL is not available.

Data Sharing Statement

The datasets used in this work are available upon reasonable request from the corresponding author.

Ethical Approval and Consent to Participate

The study was conducted under the Declaration of Helsinki. Ethics committee approval was received for this study from the ethics committee of Al Azhar University School of Medicine (No. 2020753-1) in October 2020. All participants were assigned informed consent after a clear explanation of the study process and possible side effects.

Authors' Contributions

All authors contributed to data analysis, composing, or revising the paper, giving

final approval of the published version, agreeing to the submitted journal, and agreeing to be accountable for all parts of the work.

Conflicts of Interest

The authors declare no conflicts of interest.

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