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CLINICAL TRIAL STUDY

Dexamethasone *Versus* Magnesium Sulfate as an Adjuvant to Local Anesthetics in the Ultra-Sound Guided Injection of Piriformis Muscle for the Treatment of Piriformis Syndrome

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Abstract:

Background:

Piriformis Syndrome (PS) is an underdiagnosed cause of buttock, thigh and leg pain, most probably because it is thought to be a rare cause of sciatica. PS is widely believed to be myofascial in origin.

Materials and Methods:

This prospective, randomized, controlled, double-blind study was conducted at the pain management department. 50 patients aged from 20 to 60 years old were included in this study. The selected patients were randomly allocated into 2 groups containing 25 patients each; Group D received a total of 5 mL which included 2mL lidocaine 2%, 2mL (8 mg) dexamethasone and 1mL normal saline 0.9%, and Group M received a total of 5mL which included 2mL lidocaine 2%, 3mL magnesium sulphate (MgSO₄) (2.5%) . Patients demographic characteristics, baseline physical examination findings of the patients as well as the duration of pain were all recorded. Patients were re-assessed immediately after injection, 1 week, 1 month, and 3 months after the injection. Numeric Rating Scale (NRS) values were used at each evaluation time to assess the pain, while patients were in sitting, standing, and lying positions. All patients were assessed immediately and for 4 hours post-injection for any side effects related to the drugs used.

Results:

In the pre-injection time, immediately after and 1 week after injection, there were no statistically significant differences between groups D and M in pain values. While, on comparison between both groups, group M, was significantly better than group D, in NRS values 1 month and 3 months after injection. In group D, pain score values were significantly better immediately, 1 week, and 1 month after injection compared to the pre-injection values, while these values were not significantly different 3 months after injection compared with the pre-injection values. In group M, pain score values were significantly better immediately, 1 week, 1 month, and 3 months after injection compared to the pre-injection values.

Conclusion:

Magnesium sulfate was more effective, especially for long term pain relief (3 months) when compared to dexamethasone as they were used as adjuvants to lidocaine, if injected into the piriformis muscle (PM) guided by ultrasound in the management of PS refractory as initial conservative treatment.

Keywords : Magnesium sulfate , Dexamethasone , Lidocaine , Ultrasound guided injection , Piriformis syndrome , Numeric Rating Scale .

Article History

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1. INTRODUCTION

The PM function is to rotate the hip joint externally when the thigh is extended and to abduct the flexed thigh. PM originates from the ventral surface of the sacrum passing through the greater sciatic notch to be inserted into the greater

trochanter of the femur [1]. Piriformis Syndrome (PS) is known to be an underdiagnosed etiology of leg, thigh, and buttock pain, most probably as it is thought to be a rare etiology of sciatica [2]. The main causes of PS are [3]: 1) “proximal sciatic neuropathy” due to the injury of the proximal sciatic nerve by diseases inside the Piriformis Muscle (PM) like tumors, hematomas, fibrosis, or arteriovenous malformations; 2) compression of the sciatic nerve by the anatomical variations

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of the PM itself; 3) “post-traumatic PS” as a trauma of the gluteal region might lead to injury of the sciatic nerve due to the formation of scar tissue in PM as well as nearby tissue; 4) chronic buttock pain initiated by the musculoskeletal diseases of PM like myofascial pain or pinching of the sciatic nerve by PM during some leg and thigh movements. However, in many of the cases, PS is thought to be myofascial in etiology [4]. In about 50% of the cases of the PS, there is a history of trauma to PM, which is often mild and might happen many months before symptoms occur. The sciatica and buttock pain that is initially due to trauma might cause inflammation, spasm, and hypertrophy of the muscle itself. Inflammatory mediators, such as histamine, serotonin, prostaglandin, and bradykinin are released from the inflamed muscle and cause irritation of the underlying sciatic nerve leading to inflammation–irritation–spasm–pain cycle. The inflamed, spastic, or stretched PM might cause compression of the sciatic nerve between the muscle and the iliac bone [3]. Management of PS starts with conservative pharmacotherapy using nonsteroidal anti-inflammatory (NSAID) drugs, skeletal muscle relaxation drugs, and anti-neuropathic pain drugs in conjunction with physiotherapy, which emphasizes on stretching of the PM to treat the underlying pathology [5]. In case of failure of this conservative regimen to treat PS after 3 months, the treatment is then proceeded with invasive treatment like local injections of PM, which might be a diagnostic tool as well a therapeutic intervention [6]. The results of local anesthetic injections into the PM are acceptable as a diagnostic tool for PS through the excellent and almost immediate pain relief caused by it [6]. In order to increase the safety and the accuracy of the injection technique of the PM, different devices, such as nerve stimulator, electromyography, magnetic resonance imaging (MRI), computed tomography (CT), fluoroscopy, and ultrasounds (US), have been used to guide the PM injection [7 - 11]. US guidance is considered an effective alternative technique for needle placement during PM infiltrations. Modern US equipment provides excellent soft-tissue visualization; identify bony landmarks, vessels and nerves; and gives us real-time visualization of needle pathway towards the intended targets [12]. Compared to fluoroscopy, electromyography, CT, and MRI, US has no contraindications, produce no ionizing radiation, does not require contrast, and is well tolerated by patients [13]. Local anesthetics with or without corticosteroids (CS) might be injected into the PM to alleviate the pain of PS [14]. Although magnesium sulphate has no direct analgesic effect, it prevents calcium ions influx into the cells by blocking NMDA receptors post-synaptically, which leads to its anti-nociceptive effect, mainly in neuropathic pain conditions. Furthermore, this anti-nociceptive effect is believed to be due to its prevention of central sensitization produced by peripheral tissue damage. NMDA receptors regulate the cellular influx of Na^+ and Ca^{2+} , and the outflux of K^+ . These voltage-dependent ion channels are blocked non-competitively in the resting state by the magnesium ions [15]. Glucocorticoids decrease pain by preventing prostaglandins synthesis, which causes inflammation, and a decrease in vascular permeability that leads to tissue edema. Glucocorticoids are also strong lipophilic molecules that can pass the blood-brain barrier. Researches have proved that corticosteroid receptors are present in the central and peripheral

nervous systems and are responsible for growth, differentiation, development, and plasticity of nerves [16]. In particular, steroids have been found to decrease spontaneous discharge in injured nerves, which decreases neuropathic pain [17]. In this study, we aimed to compare the effect of dexamethasone versus magnesium sulfate as an adjuvant to local anesthetics in the ultra-sound guided injection of PM for the treatment of PS.

2. PATIENTS AND METHODS

This randomized, prospective, controlled, double-blinded study was conducted at Fayoum University Hospital in the pain management department from April 2018 to May 2019. After obtaining approval from the university ethical committee and written informed consent from the patients, 50 patients aged from 20 to 60 years old were included in this study. Inclusion criteria were:

1- Patients diagnosed with PS of myofascial origin with unilateral hip and/or thigh and leg pain with positive FAIR (flexion, adduction, internal rotation) test and local tenderness and/or trigger points in the PM.

2- Failure of appropriate conservative treatment in the form of pharmacotherapy and physiotherapy to alleviate pain of PS after 3 months from the start of treatment.

Exclusion criteria included patients with motor and neurological deficiencies other than PS, such as limited hip and/or lower limb motion range, operative history in the lumbar and/or pelvic regions, pregnancy, history of allergy to the drugs used in the study, history of recent anticoagulation use, infection at the site of injection, and clinical or radiological evidence of lumbosacral disc prolapse, spondylolisthesis or metastasis in the lumbosacral vertebrae. Baseline assessments were done by a physician who was blinded to the study groups. A well-detailed history, including duration of PS pain, factors aggravating pain, factors alleviating pain, history of trauma, and past medical history were recorded. Physical examinations of the lumbosacral region, hip joint, and the sacroiliac joint were performed carefully to exclude any other causes of pain rather than PS. During the neurological examination, muscle power, cutaneous sensation, deep tendon reflexes (knee and ankle reflexes), and abnormal reflexes were recorded. Aggravation of pain and/or its radiation on palpation of the PM on the symptomatic side and reproduction of pain with maneuvers like performing downward pressure on the ipsilateral flexed knee with maximum adduction and internal rotation of the ipsilateral flexed hip in the lateral decubitus position (FAIR test) [18], forceful internal rotation of the extended thigh on the affected side in the supine position (Freiberg’s maneuver) [19], active abduction of the thigh on the affected side in the lateral decubitus position (Beatty’s maneuver) [20], and active abduction of both thighs against resistance in the seated position (Pace’s maneuver) [21], were recorded. At the end of the physical examination, in cases when other causes of sciatica could not be excluded, x-ray and/or MRI of the lumbosacral spine and hips were performed. All patients received US-guided injection of the PM by the same physician who was unaware of the study groups. The selected patients

were randomly allocated using computer-generated method and opaque sealed envelopes into 2 groups containing 25 patients each according to the study drugs; Group D received a total of 5 mL, which included 2mL lidocaine 2%, 2mL (8 mg) dexamethasone, and 1mL normal saline (0.9%), and Group M received a total of 5mL, which included 2mL lidocaine (2%), 3mL magnesium sulphate (MgSO₄) (2.5%). US piriformis injections (using Sono Scape A5; Shinzhen, China) were performed with the patients in prone positions. A pillow or towels was placed between the bed and the patient's inguinal area helping to increase the pelvic tilt, this allowed better visualization of the PM with the US probe. With a sterile US transducer cover and sterile US gel, a 6-to-1-MHz curvilinear transducer was put in a transverse orientation to first identify the sacral cornua and was then moved towards the greater trochanter until the lateral edge of the sacrum was observed. The transducer probe was then moved further laterally until the greater trochanter of the femur and ilium were both observed. The PM appeared as a hyperechoic band lying between the lateral edge of the sacrum medially and the greater trochanter of the femur laterally emerging through the greater sciatic notch and deep to the gluteus maximus muscle. The sciatic nerve appeared as an oval-shaped hyperechoic structure lying deep to the PM. Either a 21- or 23-gauge long needle (3.5 inches) was used for injection purposes. The 21-gauge needle was preferred because it is more rigid (compared with the 23-gauge needle); therefore, excessive bending of the needle was less likely to occur during the procedure. The medial-to-lateral in-line approach was recommended when performing the ultrasound-guided piriformis muscle injection [22].

In group D, the solution was injected in the fascial plane between the PM and the underlying sciatic nerve while visualizing the hypoechoic injectate lifting the thin hyperechoic sheath away from the relative hypoechoic muscle of the piriformis body. In group M, the solution was injected in the PM itself, where the needle was simply advanced through the piriformis sheath into the muscle belly to be injected at the point of maximum tenderness. In this case, US provided a mean of depth control to avoid needle passage through the PM into the pelvis. During an intramuscular injection, the injectate may collect as a bolus or track laterally between the multiple slips of the PM.

2.1. Measured Parameters

1- Patients demographic characteristics including age, sex, height, and weight were assessed and compared between both groups.

2- Baseline physical examination findings of the patients, such as duration of pain, side of pain, site of pain, history of trauma, presence of bad sitting habits (sitting on unilateral hard object), tenderness or radiating pain on deep palpation of PM, FAIR test, Beatty test, Pace test, and Freiberg test were recorded and compared between both groups.

3- Patients were reassessed immediately after injection (first evaluation), one week (second evaluation), 1 month (third evaluation), and 3 months (fourth evaluation) after the injection by a physician who was not aware of the study groups. Numeric Rating Scale (NRS) values were used at each

evaluation time to assess pain while patients were in sitting, standing, and lying positions (primary outcome measures). A 0-10 numeric rating scale NRS was used to evaluate pain.

4- All patients were assessed immediately and 4 hours post-injection for any side effects related to the drugs used, such as hyperglycemia (random blood glucose level > 200mg/dL in patients whose baseline random blood glucose level was < 140mg/dL), gastritis, hypotension (20% decrease in the patient's mean arterial blood pressure compared to the baseline), hypertension (20% increase in the patient's mean arterial blood pressure compared to the baseline), sedation, bradycardia (heart rate < 60 beats per minute) and poor reflexes (knee and ankle reflexes) (secondary outcome).

Rating	Pain Level
0	No Pain
1-3	Mild Pain (nagging, annoying, interfering little with daily activities)
4-6	Moderate Pain (interferes significantly with daily activities)
7-10	Severe Pain (disabling; unable to perform daily activities)

2.2. Sample Size

Based on data from a previous study, 21 patients per group helped achieve 81% power to detect the differences between both group means which is 5.0 and that the mean of group 2 is 3.0 with the estimated group standard deviation of 2.0 and 2.0 and with a significance level (alpha) of 0.05 using a two-sided two-sample t-test [23]. PASS 11 was used to calculate sample size.

2.3. Data Analysis

SPSS version 22 (IBM Corp., Armonk, New York, USA) was used for statistical analysis. Normally distributed numerical data are presented as mean \pm standard deviation, and differences between the groups were compared using the independent Student's *t*-test. Chi-square test was used for categorical data. Intragroup data at different follow-up time points (each re-evaluation time point was compared with the pre-injection baseline findings) were evaluated using a paired Student's *t*-test. All statistical tests were two-tailed, with *P* < 0.05 being considered statistically significant.

3. RESULTS

The differences in demographic data of the patients in both groups D and M such as age, sex, height, and body weight, were not statistically significant (p-value >0.05) (Table 1). The comparison between both groups was not statistically significant (p-value >0.05) as regards the pain characteristics, including the pain duration, pain side, pain character as local or radiating pain, history of trauma, presence of incorrect sitting positions, such as sitting crossed-legged or squatting for long periods of time, presence of tenderness and/or radiating pain on deep palpation of PM, and the presence or absence of FAIR test, Beatty test, Pace test and Freiberg test (Table 2). In the pre-injection time, immediately after and 1 week after injection, there were no statistically significant differences between groups D and M as regards pain values measured using NRS in standing, sitting and lying positions (p-value >0.05) (Table 3). While, the comparison between both groups

were significantly better in group M and D on comparing NRS values 1 month and 3 months after injection in standing, sitting and lying positions (p-value<0.05) (Table 3). In group D, the NRS values were significantly better immediately, 1 week, and 1 month after injection compared to the pre-injection values (p-value<0.05), while these values were not significantly different 3 months after injection, compared with the pre-injection values (p-value >0.05) (Table 3). In group M, the comparison of NRS values was significantly better immediately, 1 week, 1

month, and 3 months after injection compared to the pre-injection values (p-value < 0.05) (Table 3). Some patients in group D developed side effects in the form of hypertension (2 patients), hyperglycemia (3 patients), and gastritis (1 patient) (Table 4). While in group M, 1 patient developed hypotension and 1 patient experienced minimal sedation (Table 4). The comparison between both groups regarding the incidence of side effects was not significant (p-value >0.05) (Table 4).

Table 1. Demographic data

Spaces added	Group D (n=25)	Group M (n= 25)	P-value
Age (years) (Mean ± SD)	42.69 ± 11.3	43.13± 7.2	0.4
Sex (M/F) (Number of patients)	12/13	14/11	0.34
Height (cm) (Mean ± SD)	148.15 ± 10.8	150.7 ±9.4	0.12
Weight (kg) (Mean ± SD)	81.54 ± 9.2	80.41± 8.6	0.64

Data are presented as mean ± SD or number of patients
p-value > 0.05 is considered statistically non-significant

Table 2. Pain characteristics and physical findings of the patients.

	Group (D) N=25	Group (M) N=25	P-value
Duration of pain (days) (mean ± SD)	150 ± 45.7	148.23± 33.2	0.6
Side of pain (right/left)	11/14	12/13	0.393
Local/radiating pain	15/10	14/11	0.776
History of trauma (+/-)	20/5	19/6	1
Bad sitting habits (+/-)	17/8	16/9	1
Tenderness with deep palpation of PM (+/-)	25/0	25/0	1
Radiating pain with deep palpation of PM (+/-)	21/4	20/5	1
FAIR test (+/-)	23/2	22/3	1
Beatty test (+/-)	18/7	19/6	1
Pace test (+/-)	15/10	16/9	1
Freiberg test (+/-)	14/11	13/12	1

Data are presented as mean ± SD or number of patients
p-value > 0.05 is considered statistically non-significant between both groups

Table 3. Pain values measured by NRS in both groups.

	Group D (n=25)			Group M (n=25)			P-value**		
	In Standing position	In Sitting position	In lying position	In Standing position	In Sitting position	In lying position	In Standing position	In Sitting position	In lying position
Pre injection	6.7± 0.34	6.9 ± 0.33	7.01± 0.35	6.86 ± 0.45	6.66 ± 0.25	6.76 ± 0.37	0.178	0.07	0.16
Immediately post injection	2.1 ± 0.93	2.24 ± 0.83	2.28 ± 0.73	1.6 ± 0.79	1.84 ± 0.85	2±0.64	0.105	0.093	0.135
p-value*	0.024*	0.03*	0.02*	0.04*	0.042*	0.02*			
Post injection 1 week	1.94 ± 0.24	2.02 ± 0.66	2.25 ± 0.84	1.57 ± 0.34	1.8± 0.76	1.9± 0.94	0.52	0.185	0.171
p-value*	0.004*	0.01*	0.02*	0.007*	0.045*	0.024*			
Post injection 1 month	4.9± 0.38	4.33 ± 0.43	4.4 ± 0.36	1.37± 0.15	1.02± 0.35	1.3 ± 0.30	<0.001**	<0.001**	<0.001**
p-value*	0.04*	0.025*	0.014*	0.023*	0.008*	0.026*			

(Table 1) cont....

	Group D (n=25)			Group M (n=25)			P-value**		
	In Standing position	In Sitting position	In lying position	In Standing position	In Sitting position	In lying position	In Standing position	In Sitting position	In lying position
Post injection 3 months	6.68 ± 0.29	6.46 ± 0.14	6.7 ± 0.23	1.98 ± 0.26	2.45 ± 0.39	2.5 ± 0.42	<0.001**	<0.001**	<0.001**
p-value*	0.56	0.64	0.34	0.04*	0.03*	0.01*			

Data presented as (mean ± SD). SD=Standard deviation.

P* < 0.05 is considered significant for intra-group comparison (comparing each post-injection assessment with the pre-injection baseline assessment)

P** < 0.05 is considered significant for comparison between groups.

Table 4. Side effects that occurred in both groups

	Group D (n=25)	Group M (n=25)	P-value
Hypotension	0	1	1
Hypertension	2	0	0.49
Hyperglycemia	3	0	0.235
Gastritis	1	0	1
Sedation	0	1	1
Bradycardia	0	0	1

Data are presented as number of patients

p-value > 0.05 is considered statistically nonsignificant between both groups

4. DISCUSSION

PS represents an important cause of buttock and lower limb pain in patients presenting to pain management clinics [24]. When clinically indicated, injections into the piriformis sheath or muscle belly can provide diagnostic information and facilitate recovery [24]. Management of PS begins with conservative pharmacotherapy using NSAIDs, skeletal muscle relaxation drugs, and anti-neuropathic pain drugs and in conjunction with physiotherapy, which emphasizes on stretching of the PM to treat the main pathology [5]. If no significant improvement is achieved after 3 months of conservative therapy, then injection of the PM can be considered, which might be a diagnostic tool for PS through therapeutic success [6]. Benzon *et al.* and Hanania *et al.* described many different injection techniques for the treatment of PS. For example, injections inside the muscular belly, the peri-sciatic nerve infiltration, or injections inside the medial side of the muscle or into the lateral aspect [25, 26]. There are still no conclusive studies about which of the techniques is superior. Many different solutions have been tried in the injection management of PS as local anesthetics, corticosteroids, glucose 12.5%, and botulinum toxins with different outcomes [27]. This may be attributed to the different pathophysiological theories that may contribute to PS. Local anesthetics exert their mechanism of action as antinociception by their sodium channel blocking and membrane stabilizing effects. While corticosteroids act as anti-inflammatory, and anti edematous drugs by the inhibition of phospholipase A2 reducing arachidonic acid and prostaglandin synthesis, they also have an anti-nociceptive effect [28]. MgSO4 is known to have a muscle relaxant effect, its mechanism of the muscle relaxation effect is shown as a result of competition with calcium ion (Ca2+) for membrane channels and also due to its presynaptic inhibition of acetylcholine (ACh) release from the neuromuscular junction [29]. Although magnesium has no direct analgesic effect, it inhibits calcium ions entering cells by blocking NMDA receptors, which causes an anti-nociceptive

effect, especially in neuropathic pain [15]. In this study, injections were done at the peri-sciatic nerve site (in the fascial plane between the PM and the underlying sciatic nerve) and the injectate was mainly local anesthetic plus steroids to treat the neuropathic pain resulting from the inflammation, edema, and the irritation of the sciatic nerve (group D). While in group M, the injections were done at the piriformis muscle belly itself at the point of maximum tenderness where both local anesthetics and MgSO4 were injected to treat the spasm and hypertrophy of PM, which is believed to be one of the main pathologies associated with PS. Comparing with the pre-injection NRS values in sitting, standing and lying positions; these values were significantly improved in both groups D and M immediately after injection and at 1week assessment after injection, also the comparison between both groups was statistically insignificant during these assessment times. 1 month after injection, NRS values started to rise in group D but still significantly better than the pre-injection values in the same group, while NRS values were still significantly better in group M compared with the pre-injection values in the same group and they were also significantly better compared with the values of 1 month assessment in group D.

3 months assessment after injection, NRS values in group D were high enough that patients asked for nonsteroidal anti-inflammatory and anti-nociceptive drugs, while in group M; NRS values were significantly better compared with the pre-injection values in the same group and also compared to the values of 3 months assessment after injection in group D. These findings were in agreement with the findings of Tugce *et al.* [23], who studied the differences between local anesthetics (LA) and local anesthetic plus corticosteroid (CS) injections in the management of PS in their double-blinded, randomized, prospective and controlled trial done in 2014, and they found that LA injections for the PS were believed to be clinically effective. However, the addition of steroids to local anesthetics did not show additional benefits, which ensured the idea that PS is mainly muscular in origin and responds better to both LA

and LA+CS injections as it responded well to MgSO₄ injections into the PM belly in this study. Porta M. performed a comparative study between botulinum toxin type A (BTX-A) and methylprednisolone injections for the treatment of myofascial pain syndrome (MPS) and pain from chronic muscle spasm, including PS [27], they found that the decrease in pain score between baseline and 30 days after injection was greater in the BTX-A group compared to the corticosteroid group. At 60 days after injection, the pain severity score for the BTX-A-treated patients was statistically significantly lower than the pain score for the corticosteroid-treated population. Furthermore, the decrease in pain score in the BTX-A group at 60 days after injection was greater than the decrease at 30 days, whereas the effect of the corticosteroid had begun to wane. These results indicate the superior efficacy of BTX-A over conventional corticosteroid injections in patients suffering from myofascial pain syndrome. These findings were in agreement with the findings of this study as pain scores improved significantly in LA plus steroid group immediately, 1 week after injection, but they started to rise again 1 month and 3 months after injection. While in group LA plus MgSO₄, pain scores were significantly better immediately, 1 week, 1 month, and 3 months after injection. MgSO₄ and BTX-A have similar effects, but different mechanisms of actions in producing muscle relaxation as MgSO₄ competes with calcium ion (Ca²⁺) for membrane channels and pre-synaptically inhibits acetylcholine release from the neuromuscular junction [29]. While BTX-A acts by binding pre-synaptically to high-affinity recognition sites on the cholinergic nerve terminals and decreasing the release of acetylcholine, causing a neuromuscular blocking effect [27]. BTX-A is considered a highly expensive drug compared to MgSO₄, also repeated injections of BTX-A into the muscle can lead to muscle atrophy in the long term [27]. In this study, the incidence of side effects was less in MgSO₄ group (1 patient developed hypotension and 1 patient developed sedation out of 25 patients). While in the dexamethasone group, there were higher incidences of side effects (1 patient developed gastritis, 2 patients developed hypertension, and 3 patients developed hyperglycemia out of 25 patients).

CONCLUSION

Magnesium sulfate was found to be more effective, especially for long term pain relief (for 3 months) when used as additive to lidocaine on performing PM injections, guided by ultrasound compared to dexamethasone in the management of PS refractory as initial conservative treatment with fewer side effects.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was approved by the scientific research ethics committee of Al- Fayoum University, Faiyum, Egypt, under approval No. R118. .

CONSENT FOR PUBLICATION

All patients participated on a voluntary basis and gave their informed consent.

AVAILABILITY OF DATA AND MATERIALS

Not applicable.

FUNDING

None.

CONFLICT OF INTEREST

The author declares no conflict of interest, financial or otherwise.

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