Change in saturation oxygen and hemodynamic responses by adding intrathecal dexmedetomidine *vs*. sufentanil to bupivacaine in patients undergoing dynamic hip screw operation: a randomized clinical trial

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Abstract

Sufentanil (SUF) and dexmedetomidine (DEX) are used as bupivacaine in the spinal technique that providing stable hemodynamic conditions with least side effects. This study aimed to compare the change in saturation oxygen and hemodynamic responses after intrathecal DEX and SUF as adjuvants to bupivacaine in patients undergoing dynamic hip screw. This clinical trial was conducted with 80 patients referring to Valiasr Hospital, Arak, Iran, who were randomly assigned to two groups (n = 40): DEX group (8 mg bupivacaine with 5 µg DEX) and SUF group (8 mg bupivacaine with 2.5 µg SUF). The pain severity was lower in DEX group at different hours and the systolic pressure and diastolic blood pressure were lower in DEX group than in SUF group after surgery. Saturation oxygen was generally lower and more stable in DEX group but there was no significant difference between two groups. The incidence of sensory and motor block was lower in DEX group than in SUF group, but the duration of assessment of sensory block was lower in SUF group than in DEX group. DEX relieves pain up to 24 hours postoperatively. Nevertheless, Care should be taken to avoid the DEX induced shivering in patients. The study was approved by Ethical Committee of Arak University of Medical Sciences by IR.ARAKMU.REC.1395.32 code on April 25, 2016 and was registered in Iranian Registry of Clinical Trials by code number: IRCT2017050220258N45 on August 4, 2017.

Key words: adjuvants; bupivacaine; dexmedetomidine; intravenous; spinal anesthesia; sufentanil

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Introduction

Neuraxial block is a common method for administering anesthesia, involving spinal anesthesia as a type of neuraxial anesthesia. Neuraxial blocks cause a sympathetic block, motor block, analgesia or anesthesia. Therefore, the spinal block is reported as a common anesthetic method for patients undergoing lower limb orthopedic surgery, such as dynamic hip screw (DHS) operations.[1,2] Postoperative pain control is a substantial problem in spinal anesthesia, because of using only local anesthetics with a relatively short duration of action. Hence, early analgesic interventions are required postoperatively. Various adjuvants, such as clonidine, midazolam, have been studied to enhance spinal anesthesia,[3,4] while opioids added to the local anesthetic solution can cause itching, suppression, or reduced respiratory rate.

Sufentanil (SUF) is 10 times more potent than fentanyl, producing minimal hemodynamic changes when used with bupivacaine (BUP) in the spinal technique,[5] while dexmedetomidine (DEX), a newly α2-receptor selective sympathomimetic drug (α2 agonist), is being evaluated as a neuraxial adjuvant, providing stable hemodynamic conditions, adequate intraoperative and prolonged postoperative analgesia with least side effects,[6-9] which was approved by the U.S. Food and Drug Administration as a short-term sedative for mechanically ventilated patients in Intensive Care Unit. Based on human studies, 5 µg of DEX with BUP has been suggested to produce the postoperative analgesic effect of spinal anesthesia with minimal side effects.[7,10] However, the efficacy of DEX and SUF combined with isobaric BUP is assessed. Nevertheless, we did not find any study comparing the effect of DEX added to hyperbaric BUP, as well as hyperbaric SUF added to BUP. Therefore, this study aimed to compare the mean change in saturation oxygen (SaO_2) and hemodynamic responses by adding intrathecal DEX *vs*. SUF to BUP in patients undergoing DHS operation.

Subjects and Methods

Subjects

A total of 80 patients undergoing DHS for hip fracture in the Valiasr Hospital (Arak, Iran) were recruited between September 2016 and April 2017. Sample size was determined using power 80% and α error 0.05%. Patients were randomly divided into two groups ($n_1 = n_2 = 40$) including DEX and SUF by block randomization method. The inclusion criteria were as follows: counting consenting to participate in the trial, aged 20–60 years, candidate for DHS fixation, lack of breastfeeding, no liver, kidney, and cardiopulmonary disorders and diabetes, non-addiction, no long-term use of analgesic drugs, neurological drugs, antiepileptic, no history of allergy or contraindication for BUP or DEX. Exclusion criteria were patient unwillingness. A preoperative examination was performed for each patient and, thereafter, they were nil per os, full name for

8 hours. They received baseline monitoring, including pulse oximetry, electrocardiography, full name and non-invasive blood pressure, upon arrival to the operating room. Ringer's lactate solution 10 mL/kg was infused prior to induction of spinal block. The writing and editing of the article was performed in accordance with the CONsolidated Standards Of Reporting Trials (CONSORT) Statement.

Intervention

This study was double-blind clinical trial and anesthesiologist, surgeon and patient were unaware about medication in patients of each group. The pharmaceutical combination was prepared by two anesthesiology assistants who were masked for patients' assignment. Injection of medication conducted during 15 minutes, and after medication injection, the patients took at supine position while wearing an oxygen mask (4 L/min). In DEX group, patients were administered with 8 mg BUP (Astrazenca Co., Kombrij, UK) and 5 µg DEX (Hospira Co., Lake Forest, IL, USA); and in SUF group, patients were administered with 8 mg BUP and 2.5 µg SUF (Daru-Pakhsh Co., Karaj, Iran). If hypotension (more than 20% of baseline) occurred 10 mg ephedrine was injected, and this was recorded in the patient's record. If heart rate (HR) < 50 beats/min, atropine 0.5 mg was administered. The side effects such as nausea, vomiting, itching, and respiratory depression were recorded.

Measurements

Vital signs including blood pressure, HR, and SaO_2 were recorded before sensory block and after the patient took a supine position. Recording of vital signs were continued every 2 minutes, until the block was assessed. Moreover, the vital signs registered in recovery room and on the ward every 15 minutes until the end of surgery. Finally, the mean of vital signs and trend of them were compared between two groups. Pinprick test[11,12] is performed for sensory block level once every 2 minutes with a 23G needle until the block was assessed. Motor block was evaluated by Modified Bromage score[13]: 0, inability to raise extended leg against resistance (no weakness); 1, inability to raise extended leg (just able to move knee); 2, inability to flex knee (able to move feet); and 3, inability to move leg or foot. On achieving T8 sensory blockade level, surgery was allowed. Testing was then conducted every 10 minutes until the point of two segment regression of the block was observed. Further testing was performed every 20 minutes until the recovery of S2 dermatome was achieved. Besides those listed above, the time to reach this highest sensory level, time to S1 level sensory regression were recorded in the patient's record. Pain scores were postoperatively recorded by using visual analog scale[14] between 0 and 10, every 1, 2, 6, 12, and 24 hours post-operation. If visual analog scale > 4, 1 g intramuscular injection of Apotel alone was given as rescue analgesia, then Apotel received was also recorded in 24 hours. Finally, two groups were compared for the no-vital signs, the duration and onset of sensory and motor block, analgesic dose and time, and pain intensity.

Ethical consideration

Informed consent was obtained from each patient before study. Moreover, the study protocol was approved by Ethical Committee of Arak University of Medical Sciences by IR.ARAKMU.REC.1395.32 code on April 25, 2016 and was registered in Iranian Registry of Clinical Trials by code number: IRCT2017050220258N45 on August 4, 2017.

Statistical analysis

Data were analyzed in using Statistical Package for Social Sciences (SPSS) version 20 (IBM SPSS Inc., Chicago, IL, USA), with descriptive statistics including mean, standard deviation, standard error, frequency and percentage. Moreover, two groups were compared with chi-square, independent *t*-test and repeated measurement analysis of variance. Statistical level was considered at 0.05.

Results

Baseline comparison of patients with dynamic hip screw operation in the dexmedetomidine and sufentanil groups

This randomized double-blind randomized clinical trial was conducted with 80 patients undergoing DHS, who referred to Vali-Asr Hospital and, afterwards, were randomly assigned into two groups, DEX and SUF, whose mean age was 61.25 ± 2.19 and 59.20 ± 3.25 years, respectively. No statistically significant difference was seen in age between both groups ($P \geq 0.05$) while the mean weight was 70.00 ± 5.01 kg and 75.8 ± 8.47 kg in the DEX and SUF groups, respectively ($P = 0.036$). Moreover, no statistically significant difference was seen in weight ($P \geq 0.05$) and sex ($P > 0.05$) between the two groups. **Figure 1** shows the CONSORT flow diagram of patients.

Pain comparison of patients with dynamic hip screw operation in the dexmedetomidine and sufentanil groups

As seen in **Figure 2**, the pain severity (visual analog scale) was same between two groups at the baseline, but it was lower in DEX group at different hours, while analgesia was observed in each patient of DEX group and approximately 80% of those in SUF group at the 1st hour post-operation. A statistically significant difference was seen in pain severity between both

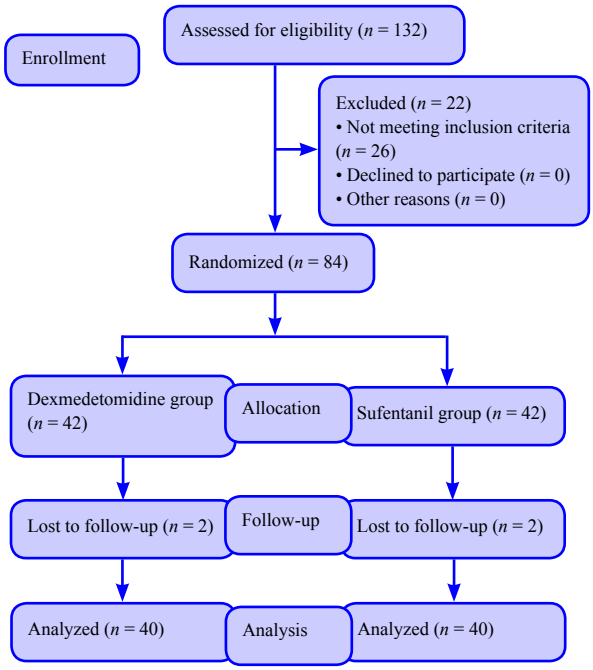

Figure 1: CONsolidated Standards Of Reporting Trials (CONSORT) flow diagram of patients.

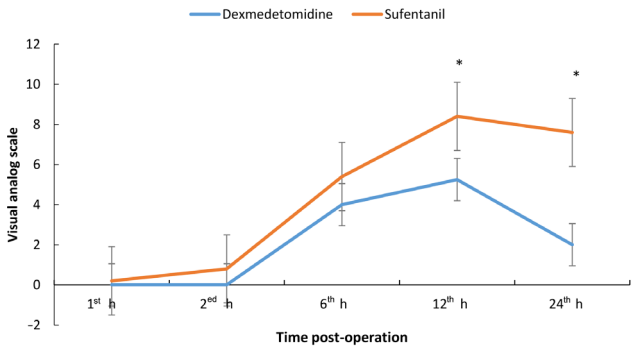

Figure 2: Postoperative assessment of pain in patients with dynamic hip screw operation of dexmedetomidine and sufentanil groups.
Note: Pain was evaluated by visual analog scale. Data are expressed as the mean ± SD, and were analyzed by repeated measurement analysis of variance followed by independent *t*-test. *$P < 0.05$, *vs.* dexmedetomidine group.

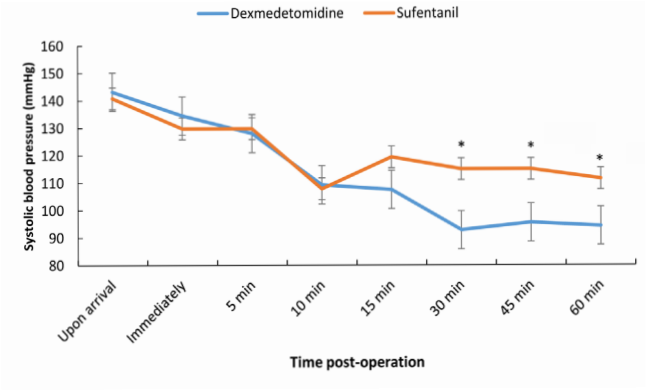

Figure 3: Systolic blood pressure at different time points after surgery in patients with dynamic hip screw operation of dexmedetomidine and sufentanil groups
Note: Data are expressed as the mean ± SD, and were analyzed by repeated measurement analysis of variance followed by independent *t*-test. *$P < 0.05$, *vs.* dexmedetomidine group.

groups ($P = 0.003$) and no pain was observed in all subjects of DEX group and analgesia. In 60% of those in SUF group, at the 2nd hour post-operation, with no difference in pain score between the two groups ($P < 0.001$). At the 6th hour, DEX group had less pain. Statistically significant differences were found in pain score between both groups at 12 and 24 hours with same *P* values ($P < 0.001$), and lower pain score was observed in DEX group. The repeated measurement test showed a statistically difference in pain score between both groups ($P < 0.001$). However, the trend of pain was increasing in SUF ($P = 0.032$), while this trend was not significant in DEX group ($P = 0.126$).

Hemodynamic comparison of patients with dynamic hip screw operation in the dexmedetomidine and sufentanil groups

Based on *t*-test, a statistically significant difference was seen between two groups in 15, 30, 45 and 60 minutes after surgery ($P < 0.05$) and the mean of systolic blood pressure (SBP) showed lower SBP in DEX group. However, the SBP was not statistically significant between two groups until the 10th minute after surgery ($P > 0.05$). As seen in **Figure 3**, SBP was initially same between two groups, but difference of SBP between two groups was increased from the 10th minute after surgery. The SBP is increased in SUF group than DEX to a large extent and then reduced subsequently. The repeated measurement test showed a decreasing trend in SBP at DEX group ($P < 0.001$), but this trend was not significant in SUF group ($P = 0.165$).

As can be seen in **Table 1**, there was significant difference in diastolic blood pressure at 10, 15 and 30 minutes between two groups ($P < 0.05$), while it was not statistically different before 5th and after 45th minute of surgery ($P > 0.05$). As shown in **Table 1**, significant difference was observed in HR at 5, 15, and 30 minutes ($P < 0.05$) and the mean of HR was lower in DEX group.

As seen in the **Figure 4**, SaO_2 is generally lower in DEX group, while no statistically significant difference between SaO_2 in all minutes ($P > 0.05$) and statistically similar in SaO_2. Moreover, there was no significant trend in SaO_2, while the mean of SaO_2 in DEX group was more stable than in the SUF group.

As depicted in **Table 2**, the onset of sensory and motor block

Table 1: Diastolic blood pressure (mmHg) and heart rate (beats/min) at different time points after surgery in patients with dynamic hip screw operation of dexmedetomidine and sufentanil groups

Time post-operation	Dexmedetomidine	Sufentanil	*P*-value
Diastolic blood pressure			
Upon arrival (baseline)	76.25±9.72	77.40±7.45	> 0.05
Immediately	76.25±9.72	76.40±6.36	0.935
5 min	68.75±11.53	69.00±8.37	0.912
10 min	70.00±3.58	64.80±9.82	0.002
15 min	63.75±4.19	71.40±11.17	0.001
30 min	56.25±4.19	71.40±11.17	0.01
45 min	62.50±8.39	62.22±4.70	0.875
60 min	62.50±8.39	63.50±4.38	0.506
Heart rate			
Upon arrival (baseline)	80.47±5.84	80.47±6.11	0.665
Immediately	81.25±5.70	83.40±7	0.24
5 min	82.67±3.72	88.60±7.70	< 0.001
10 min	82.47±8.97	82.95±7.62	0.153
15 min	77.37±5.86	87.60±14.23	< 0.001
30 min	75.25±12.38	80.40±10.43	0.048
45 min	75.82±6.63	76.00±14.09	0.944
60 min	78.57±4.50	76.22±7.69	0.101

Note: Data are expressed as the mean ± SD, and were analyzed by repeated measurement analysis of variance followed by independent *t*-test.

was lower for DEX group than SUF ($P < 0.001$). Moreover, the duration of assessment of sensory block was lower in the SUF group than DEX ($P < 0.001$). More Apotel was used in SUF group than in DEX group ($P < 0.001$). However, no statistically significant differences were in hypotension, nausea and vomiting, itching, incontinence drop in HR and headache ($P > 0.05$), but in shivering in DEX group ($P < 0.001$).

Discussion

Based on our results at baseline measurements, no statistically significant difference was found in age, weight, and gender

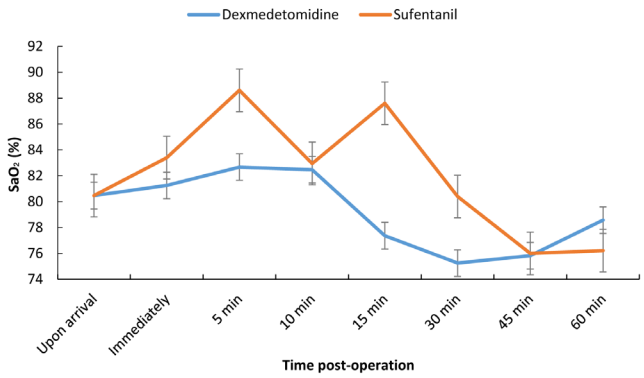

Figure 4: Saturation oxygen (SaO_2) at different time points after surgery in patients with dynamic hip screw operation of dexmedetomidine and sufentanil groups.
Note: Data are expressed as the mean ± SD, and were analyzed by repeated measurement analysis of variance followed by independent *t*-test.

Table 2: Comparison of the onset and secondary of sensory and motor block in patients with dynamic hip screw operation of dexmedetomidine and sufentanil groups

Variable	Dexmedetomidine	Sufentanil	*P*-value
Onset of sensory block (s)	16.00±25.78	20.00±35.43	0.312
Onset of motor block (s)	115.0±83.66	216.0±12.51	< 0.001
Sensory block assessment (min)	15.00±4.17	12.40±1.98	< 0.001
Motor block assessment (min)	10.50±3.61	10.00±5.28	0.061

Note: Data are expressed as the mean ± SD, and were analyzed by repeated measurement analysis of variance followed by independent *t*-test.

between both groups and two groups were same. Analgesia was observed in each patient of DEX group and approximately 80% of those in the SUF group at the first hour postoperative, decreased to 60% in the second at 2 hours after the surgery, while pain was less in the first group at 6, 12, and 24 hours after the surgery. There was significant difference in the incidence of side effects between two groups. Only, shivering was higher in DEX group. A statistically significant difference was between both groups, 15, 30, 45, and 60 minutes after surgery, while SBP was lower in the group and diastolic blood pressure showed a statistically significant difference both group at the 10, 15 and 30 minutes. HR was less in DEX group. With no statistically significant difference in SaO_2 between both, the onset of sensory block in DEX group was lower. The duration of the sensory block assessment was lower in SUF group than DEX group. More Apotel was used in the SUF group than in DEX group.

Safari et al.'s study[5] evaluated the effect of adding DEX to intrathecal BUP in addicted patients undergoing lower limb surgery and showed that analgesia duration in DEX group was longer than the control group. When added to BUP in spinal anesthesia, DEX can increase the duration for BUP in addicted patients.[5] Their study results were consistent with ours. Another double-blind randomized study by Nayagam et al.,[15] was compared the intrathecal fentanyl and DEX added to low dose BUP for spinal anesthesia in lower abdominal surgeries and showed that no statistically significant differences in the time to reach T10 segment block between the groups. Since DEX facilitates the spread of the block and provides longer postoperative analgesia, it is superior to fentanyl. Moreover, all patients were hemodynamically stable and both groups show no statistically significant difference in side effects.[15] In our study, the analgesia was higher in DEX group. The onset time of the motor block was lower in DEX group, while the duration of sensory block assessment was lower in the SUF group than the other group. Among complications, shivering was higher in DEX group which had lower HR. The difference between their and our results is likely due to the different surgery sites and the number of subjects across both studies, as well as the type of opioids used in our study.

The effects of intravenous DEX on the hyperbaric BUP spinal anesthesia was assessed by Dinesh et al.[16] and their results showed that intravenous DEX significantly prolongs the duration of sensory and motor block. Moreover, if intravenous DEX be used as an adjuvant to BUP for spinal anesthesia, the occurrence of bradycardia is significantly higher, while DEX provides excellent intraoperative sedation and postoperative analgesia.[17] The Dinesh et al.[17] findings are in line with our results. Hassani et al.[18] observed that adding SUF to BUP can lead to hemodynamic stability similar of fentanyl in patients. SUF, *vs*. fentanyl, provides prolonged duration of analgesia, facilitate the spread of the sensory block, increase average SPO_2 levels, and decrease overall side effects, while, DEX had more analgesia and a prolonged duration of the anesthetic block in our study. The cause of this difference can be traced to different drugs used in two studies. Moreover, Kim et al.'s study[1] evaluated the effects of intrathecal DEX on low-dose BUP spinal anesthesia in elderly patients undergoing transurethral prostatectomy and suggested that the peak block level was in both groups receiving and non-receiving DEX, with a faster onset time to the peak block and a prolonged duration of sensory block and postoperative analgesia in the recipient group. Their results are consistent with our results. Jung et al.'s study[19] randomized 60 adult patients into 3 groups receiving BUP which normal saline, DEX 0.25 μg/kg), DEX 0.5 μg/kg was added 5 minutes after BUP injection to assess the effects of single-dose intravenous DEX on hyperbaric BUP spinal anesthesia. That study showed that the duration of motor and sensory anesthesia was observed to be significantly increased in DEX 0.5 μg/kg group while the sensory block regression time significantly rises in DEX 0.25 and 0.5 μg/kg groups. Onset time, peak block level, sedation level, and incidence of hypotension and bradycardia needing treatment did not differ among the groups.[19] Their results were consistent with ours.

The intrathecal DEX with intrathecal magnesium sulfate used as adjuvants to BUP investigated in 90 patients by Shukla et al.'s study and they concluded that a faster onset of anesthesia and prolonged duration in the group receiving DEX, while a delayed onset of anesthesia in those receiving magnesium sulfate, and a prolonged than the control group and lesser than DEX group. All three groups were similar in hemodynamic properties, with no significant side effects observed.[20] DEX had better block assessment, in our study. Motiani et al.[21] in a randomized controlled trial compare the intrathecal SUF versus fentanyl for lower limb surgeries and showed a faster onset and prolonged duration of sensory block in groups receiving SUF and fentanyl. The duration of complete and effective

analgesia is significantly prolonged in the fentanyl and SUF with BUP recipients than the recipients of BUP alone.[21] Our results are not in line with theirs and DEX was better, possibly due to different adjuvants: SUF *vs*. DEX in ours and SUF vs. fentanyl in Poonam Motiani study, though the latter shows fentanyl efficacy, our study suggests that DEX is more effective than SUF. Moreover, another double-blind, prospective study, was evaluated the effect of low-dose DEX or clonidine on the characteristics of BUP spinal block was evaluated on 60 patients in the 3 groups receiving clonidine-BUP, DEX - BUP, and BUP. They showed that all groups were observed to be similar for SaO_2, HR, and sedation level intraoperatively and postoperatively, while DEX and clonidine provides a similar duration of motor and sensory block, that their results are not consistent with ours in which DEX prolonged the duration of sensory block and the duration of analgesia.

In conclusion, DEX relieved pain up to 32 hours postoperatively in patients undergoing DHS. Moreover, less Apotel was used in DEX group caused shivering in patients, which should be carefully considered when being used. The onset of sensory and motor block and the duration of sensory block assessment were shorter in DEX group and SUF group, respectively. HR is generally lower in DEX group. Lastly, we suggest that a study be conducted with further subjects, aimed at comparing the three drugs DEX, clonidine, and SUF.

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Author contributions
Study conception: BY, AK, HM; data collection: HM; data acquisition and data analysis: HM: data interpretation: BY, AK. All authors approved the final version of the manuscript for publication.

Conflicts of interest
There is no conflict of interest.

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Institutional review board statement
The protocol of study was approved by the Ethical Committee of Arak University of Medical Sciences with IR.ARAKMU.REC.1395.32 approved on April 25, 2016. In addition, it was registered in Iranian Registry of Clinical Trials with IRCT2017050220258N45 on August 4, 2017.

Declaration of patient consent
The authors certify that they have obtained patients consent forms. In the form, patients have given their consent for the images and other clinical information to be reported in the journal. The patients understand that their names and initials not be published and due efforts will be made to conceal their identity.

Reporting statement
The writing and editing of the article was performed in accordance with the CONsolidated Standards Of Reporting Trials (CONSORT) Statement.

Biostatistics statement
The statistical methods of this study were reviewed by the biostatistician of Arak University of Medical Sciences, Iran.

Data sharing statement
Datasets analyzed during the current study are available from the corresponding author on reasonable request.

Plagiarism check
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Peer review
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