Investigating the Situation of Iranian Hospitals in Terms of Implementing Mandatory Patient Safety Standards: A Systematic Review

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Abstract

Background: Evaluate the patient’s safety status in Iranian hospitals using the Patient safety friendly hospital initiative (PSFHI) assessment tool provided by the World Health Organization. PSFHI assessment tool of 140 patient safety standards, they are classified as mandatory (20 standards), basic (90 standards) and advanced (30 standards). Mandatory standards are necessary criteria that hospitals must meet to register for PSFHI. The first stage of the patient safety program in Iran is to achieve the implementation of the mandatory standards to enter the patient safety friendly hospital program. We aimed to evaluate the patient’s safety status in Iranian hospitals in terms of implementing mandatory patient safety standards.

Methods: In this systematic review, articles were searched between 2001 and 2021 in Web of Science, PubMed, Scopus Google Scholar, and Iranian SID and Magiran databases. Keywords including patient safety, quality assessment, standards, patient safety friendly hospital, Iran were performed. These articles were evaluated independently by two researchers and the contradictions were discussed with the third author.

Results: Finally, 7 eligible studies were included in the study. The highest score (75%) was related to the fourth domain of safe environment and the lowest score with (47%) was related to the second domain of engaging and interacting with the patient and the community. The overall average of compliance with standards in all four areas was 70%.

Conclusion: Institutionalizing a patient safety culture, paying more attention to creating a culture to identify patients, educating staff and patients, and removing legal barriers, Increases the observance of mandatory patient safety standards in the Iran.

Keywords: Patient safety; Standards; Hospital; Iran

Introduction

Providing welfare services is an important part of the structure of a society. This makes the importance of proper and effective organization of such organizations more important for countries. Healthcare system is more special than other utilities (1). However, still the most important and
costly challenge facing health systems in other parts of the world is to ensure equal access to modern and guaranteed quality medical services due to lack of resources (2).

Hospital centers are one of the vital pillars of the health system in any country (3). In addition to the roles stated for hospitals, hospitals play a very important symbolic role for the public, reflecting the well-being of communities (4).

An important part of the quality of health care is patient safety (5) and it should be considered at all levels of the health system, especially organizations providing health services (6). Hospitals are one of the most important organizations providing health services and due to certain risks; observance of patient safety principles in it is very important (7).

One of the most important reasons for addressing the issue of quality in health services is the existence of safety problems in providing these services. On average in about 10% of all hospitalized patients, there are varying degrees injured (8) and estimated to be up to 75% of these errors are preventable. Unsafe care and medical services, in addition to inflicting suffering on humans, also incur heavy economic costs. In fact, between five and ten percent of health-related costs are due to unsafe clinical services that lead to patient harm. That the share of failure of systems and procedures is more than the role of individuals (9).

In health care systems, the problem of providing unsafe medical care is a widespread issue around the world. This can cause many side effects such as high morbidity and mortality and negatively affect the efficiency of hospitals (10). In this regard, in developed and developing countries, governments are trying to achieve an acceptable level of safety in hospitals (11).

Patient safety is a global challenge and should be a priority for any hospital board (12, 13). WHO defines the occurrence of patient safety as an accident that results in an unintended accident to a patient due to unintentional action, not due to the patient's general medical condition (14). A large number of patients are exposed to hospitals. They suffer from complications and injuries caused by providing services and it causes many problems for the patient (15). In developed countries, one in ten patients receiving hospital services. A person has a medical accident. However, this rate is much higher in developing countries. Deaths from medical errors in Canada, Australia and the United Kingdom. It is estimated about twenty thousand, eighteen thousand and forty thousand cases per year respectively. Several studies in the US and other countries have shown that medical errors are one of the biggest problems in health system (16-18). There are no documented statistics on medical errors related to patient safety in Iran but due to the increase in referral cases of people's complaints from doctors to the organization of the medical system or about twenty percent of medication errors by nurses over a period of three months The occurrence of such incidents can be considered important in Iran Health System (19).

Due to the large scope of medical errors in healthcare systems and related costs various approaches have been taken to deal with these errors and to improve patient safety, including a general approach to patient safety, a seven-step model to patient safety, and patient safety friendly hospitals (20). Patient safety friendly hospitals include a set of patient safety standards in the hospital. Implementation of these standards creates the possibility that patient safety as a top priority was admitted to the hospital and staff have the necessary commitment to patient safety (21).

Evaluation of indicators of patient safety friendly hospitals leads to the analysis of the current situation and development measures are formulated. These indicators are classified into three areas of mandatory, basic and advanced indicators. Standards that are mandatory criteria for recognition as friendly hospital patient safety is essential to be fully realized. The basic indicators are the minimum standards that the hospital must follow for patient safety. Advanced indicators are requirements that the hospital, depending on its capacity and resources, meet in order to achieve them in order to strengthen safe services. Indicators of safe clinical services include the general areas of safety aspects of clinical care, the system of re-
ducing the risk of acquired infections due to health care, the safety of blood and blood products, the safe drug system and the complete medical records system. These indicators provide an operational framework for evaluating patient care in the hospital (22, 23).

In recent years, good successes have been made in Iran to improve patient safety, which can establish clinical governance, patient safety friendly hospitals, accreditation of hospitals according to codified standards cited (10). The first stage of the patient safety program in Iran is to achieve the implementation of the required standards to enter the patient safety friendly hospital program. Patient safety assessment has advantages for hospitals and shows the observance and commitment of hospitals in response to the expectations of society evaluating patient safety standards encourages an important way to show weaknesses and improvements in achieving standard goals (24). The ultimate goal of evaluation is to improve the level of patient safety in hospitals and consequently, the community is protected from hospital injuries and the reduction of unwanted complications in the hospital environment. Therefore, considering that no comprehensive study has been done so far, the purpose of this study was to evaluate the patient's safety status in Iranian hospitals in terms of implementing mandatory patient safety standards.

Therefore, the present study was designed as a systematic review to answer the question of what is the status of implementation of mandatory patient safety standards in Iranian hospitals.

Methods

Study Design and Search Strategy
This study was done based on check list of a systematic review and meta-analysis or PRISMA (25). A comprehensive and systematic search of articles was conducted between 2001 and April 2021. Due to the vastness of patient safety studies and the large number of studies and according to the purpose of the study, which is to check the status of the implementation of mandatory standards for patient safety in Iran. Therefore, the search keywords are as follows. The search protocol defined by using the main Keywords "patient safety", "quality assessment", "standards", "patient safety friendly hospital" and "Iran". The above keyword combinations were searched in all three sections of title, abstract and keyword (Title-Abs-Key). The search strategy was considered appropriate to the site being searched. Search sites are Web of Science, PubMed, Scopus and The Google Scholar database was searched separately for the first 100 items. Persian sites and medical science articles bank, search reference of SID researcher, Magiran were identified. For related articles, manually searching reference lists of articles were also searched.

Eligibility criteria
Criteria for entering articles were 1- Studies have been done only in Iran. 2- Time: The period for publishing studies from 2001 to April 2021. Exclusion criteria were 1- Studies conducted to measure safety culture, safety atmosphere, and patient safety from the perspective of the treatment staff or with self-made questionnaires or anything that examined patient safety from a perspective other than patient-friendly hospital standards was removed. The final criterion for the inclusion of studies in the present study was the use of a patient safety friendly hospital questionnaire. 2- Because assessing the patient's safety status in Iranian hospitals has been a priority of this study and examining the safety status of hospital patients is a more comprehensive discussion than examining errors and that treatment errors are a small part of the patient's safety debate. Especially from the perspective of a patient-friendly hospital, they do not fully reflect the patient's safety status. Therefore, studies that examined patient safety solely by examining treatment errors or adverse events were also excluded. 3- Studies that examined the implementation of mandatory patient safety standards in the entire hospital were included in the study. Otherwise, if they had reviewed other standards or were per-
formed in a part of the hospital, were excluded from the study.

**Study Selection and Data Extraction Process**
Examples of this study were all articles published in domestic and foreign journals, congressional and conference abstracts, books, dissertations, and reference sites. Patient safety studies that examined hospitals for compliance with safety-friendly standards and entered the study in Persian and English, published in domestic and foreign magazines and patient safety status of Iranian hospitals were evaluated in terms of implementation of the mentioned standards. After the search, the findings related to each of the searched databases were stored separately and in separate groups in EndNote software. Duplicate titles were then removed and considering the inclusion and exit criteria, the title and abstract of the remaining articles in each group were read and related articles were isolated. In the next step, the full text of the relevant articles was read and completely relevant studies were identified.

**Reporting Quality Assessment**

After determining the relevant studies in terms of titles and content to evaluate the quality of documents compiled evaluation checklist. The purpose of each research, study method, data collection tool, measurement status of variables, study target group and analysis status were analyses with twelve questions (26). One point was awarded for each question. In this checklist, the minimum acceptable score of eight was considered. Finally, the articles that received the lowest score were selected for inclusion in the study and relevant information was extracted. Moreover, in the screening stage, the studies were reviewed and screened by two people.

**Data collection tools and data extraction and analysis**
The tools used in this systematic review included article quality evaluation checklists and data mining checklists. Data extraction checklist included the general characteristics of the study (year of study, type of tool, hospital type). This form was designed in the form of an Excel file and completed by two separate evaluators. The details of the extracted studies are given in (Table1).

**Table 1: General characteristics of articles resulting from systematic review**

| Row | Reference | Place and time | Type of tool | Type of hospital |
|-----|-----------|----------------|--------------|-----------------|
| 1   | Mohammadkarim Bahadori (27) | Iran-2013 | PSFHI | Private |
| 2   | Saeed Asefzadeh (28) | Iran-2013 | PSFHI | Teaching Hospital |
| 3   | Zohra Mazhari (29) | Iran-2014 | PSFHI | General Hospital |
| 4   | Alireza Jabbari (24) | Iran-2015 | PSFHI | General Academic hospital |
| 5   | Hassan Babamohamadi (30) | Iran-2016 | PSFHI | General Academic hospital |
| 6   | Firoozeh Bairami (31) | Iran-2016 | PSFHI | General Academic hospital |
| 7   | Hossein Habibzadeh (32) | Iran-2019 | PSFHI | General Academic hospital |

Differences between the two assessments were resolved through a group discussion in the presence of the team leader. This checklist was approved by the team leader and someone outside the team. Finally, after extracting the data, the information of the evaluated hospitals was reported as mean and standard deviation based on the available parameters.

Overall, 410 articles were identified in a systematic review. One hundred and fifty-one studies...
were omitted due to duplicate studies without full text. Overall, 181 articles due to irrelevant studies in terms of title and abstract, sixty-five articles due to irrelevant study criteria and six studies were excluded due to not achieving the quality limit. After reviewing the inclusion and exclusion criteria and qualitative evaluation, finally seven eligible studies were conducted between 2000 and 2021. All seven studies were conducted in different cities of Iran, including Tehran, Isfahan, Semnan, Urmia and Rasht. Two studies were conducted in 2013, one study in 2014, one study in 2015, two studies in 2016 and one study in 2019 (Fig. 1).

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**Results**

**Results percentage of compliance with mandatory patient safety standards by main area in seven Iranian studies**

Mandatory standards: Area one: Governance and leadership - Area two: Involvement and interaction with the patient and the community - Area three: Safe and evidence-based clinical services - Area four: Safe environment.

The highest score (75%) is related to the fourth area of safe environment, which is the level of compliance with the standards in good condition. The lowest score with (47%) is related to the second area of engaging and interacting with the patient and the community, which indicates that hospitals in this area are in a weak position in meeting the standards in the relevant area. The lowest score with (47%) is related to the second area of engaging and interacting with the patient.
and the community, which indicates that hospitals in this area are in a weak position in meeting the standards in the relevant area (Table 2).

Table 2: Average percentages in general in all studied hospitals in Iran (27,32)

| Area  | Number of hospitals | Minimum | Maximum | Mean   | Std. Deviation |
|-------|---------------------|---------|---------|--------|----------------|
| Area one | 34                  | .4400   | .9444   | .702285| .1354040       |
| Area two | 34                  | .0000   | 1.0000  | .478412| .1783654       |
| Area three | 34                 | .0850   | .8660   | .683079| .1681688       |
| Area four | 34                  | .0000   | 1.0000  | .757776| .2446575       |
| Total  | 34                  | .3420   | .8881   | .709038| .1386093       |

The highest average rate of compliance with mandatory patient safety standards is 83% in study number three, which indicates the good condition of the studied hospitals in complying with and implementing the standards. The lowest rate of compliance with the standards with an average of 55% in study number 7, which indicates the average status of compliance with and implementation of mandatory patient safety standards (Table 3).

Table 3: Average percentages by study code

| Code study | Area one | Area two | Area three | Area four | Total |
|------------|----------|----------|------------|-----------|-------|
| 1          | N        | 1        | 1          | 1         | 1     |
| Mean       | .666600  | 1.000000 | .800000    | 1.000000  | .777800 |
| Std. Deviation | .305500 | .500000  | .714267    | .500000   | .750000 |
| 2          | N        | 3        | 3          | 3         | 3     |
| Mean       | .888833  | .500000  | .714267    | .500000   | .750000 |
| Std. Deviation | .055500 | .071500  | .019346    | .0433013  |       |
| 3          | N        | 5        | 5          | 5         | 5     |
| Mean       | .562400  | .433200  | .781600    | .816400   | .836400 |
| Std. Deviation | .026838 | .057265  | .019346    | .0164408  |       |
| 4          | N        | 10       | 10         | 10        | 10    |
| Mean       | .781280  | .563290  | .773230    | .803960   | .776950 |
| Std. Deviation | .095929 | .070345  | .085489    | .0813633  |       |
| 5          | N        | 4        | 4          | 4         | 4     |
| Mean       | .662950  | .491775  | .641650    | .660700   | .614250 |
| Std. Deviation | .026651 | .083962  | .069552    | .0433591  |       |
| 6          | N        | 7        | 7          | 7         | 7     |
| Mean       | .641429  | .357143  | .630000    | .928571   | .637143 |
| Std. Deviation | .175634 | .125698  | .121987    | .1508547  |       |
| 7          | N        | 4        | 4          | 4         | 4     |
| Mean       | .694500  | .375000  | .416250    | .500000   | .552750 |
| Std. Deviation | .096033 | .311804  | .577350    | .2005050  |       |
| Total      | N        | 34       | 34         | 34        | 34    |
| Mean       | .702285  | .478412  | .683079    | .757776   | .709038 |
| Std. Deviation | .135404 | .178365  | .168168    | .2446575  | .1386093 |
The highest average rate of compliance with mandatory patient safety standards with 83% in five hospitals in Semnan (30), which shows the good condition of the studied hospitals in complying with and implementing mandatory patient safety standards and the lowest rate of compliance with standards with an average of 55% in four selected hospitals in Isfahan, which indicates the average status of compliance and implementation of mandatory patient safety standards in this city (24) (Table 4).

Table 4: Average percentages by study location

| Place   | Area one | Area two | Area three | Area four | Total |
|---------|----------|----------|------------|-----------|-------|
| Isfahan | N        | 4        | 4          | 4         | 4     |
| Mean    | .694500  | .375000  | .416250    | .500000   | .552750 |
| Std. Deviation | .0960330 | .1443376 | .3118048   | .5773503  | .2005050 |
| Rasht   | N        | 7        | 7          | 7         | 7     |
| Mean    | .641429  | .357143  | .630000    | .928571   | .637143 |
| Std. Deviation | .1756349 | .2439750 | .1256981   | .1219875  | .1508547 |
| Semnan  | N        | 5        | 5          | 5         | 5     |
| Mean    | .562400  | .433200  | .781600    | .816400   | .836400 |
| Std. Deviation | .0268384 | .0675552 | .0572652   | .0193468  | .0164408 |
| Tehran  | N        | 14       | 14         | 14        | 14    |
| Mean    | .796136  | .580921  | .762507    | .752829   | .771236 |
| Std. Deviation | .1014354 | .1534065 | .0703276   | .0193468  | .0164408 |
| URMIA   | N        | 4        | 4          | 4         | 4     |
| Mean    | .662950  | .491775  | .641650    | .660700   | .614250 |
| Std. Deviation | .0266511 | .0274840 | .0839629   | .0695529  | .0433591 |
| Total   | N        | 34       | 34         | 34        | 34    |
| Mean    | .702285  | .478412  | .683079    | .757776   | .709038 |
| Std. Deviation | .1354040 | .1783654 | .1681688   | .2446575  | .1386093 |

The highest average rate of compliance with mandatory patient safety standards is 80% in 2014, which indicates the good condition of the studied hospitals in complying with and implementing the standards this year. The lowest level of compliance with standards with an average of 61% in 2018, which represents the average state of implementation of standards compliance and patient safety requirements this year, which shows a downward trend (Table 5).

Table 5: Average percentages by year of hospital evaluation

| Assessment year | Area one | Area two | Area three | Area four | Total |
|-----------------|----------|----------|------------|-----------|-------|
| 2012            | N        | 1        | 1          | 1         | 1     |
| Mean            | .666600  | 1.000000 | .800000    | 1.000000  | .777800 |
| Std. Deviation  | .310303  | .120303  | .120303    | .120303   | .120303 |
| 2013            | N        | 21       | 21         | 21        | 21    |
| Mean            | .718133  | .458710  | .657490    | .787600   | .687643 |
| Std. Deviation  | .173533  | .173533  | .173533    | .173533   | .173533 |
| 2014            | N        | 8        | 8          | 8         | 8     |
| Mean            | .684812  | .458250  | .756350    | .697750   | .804000 |
| Std. Deviation  | .1727303 | .0616690 | .0674458   | .1644043  | .0518625 |
| 2018            | N        | 4        | 4          | 4         | 4     |
| Mean            | .662950  | .491775  | .641650    | .660700   | .614250 |
| Std. Deviation  | .0265511 | .0274840 | .0839629   | .0695529  | .0433591 |
| Total           | N        | 34       | 34         | 34        | 34    |
| Mean            | .702285  | .478412  | .683079    | .757776   | .709038 |
| Std. Deviation  | .1354040 | .1783654 | .1681688   | .2446575  | .1386093 |
Discussion

The results of this study were examined in four areas (leadership and management of nine standards, involvement and interaction with the patient and the community of two standards, safe and evidence-based clinical services of seven standards, safe environment of two standards) that hospitals were evaluated and scored according to these standards.

Based on the results of this review, the average level of compliance with mandatory patient safety standards in Iranian hospitals was at an average level of 70%. Considering that obtaining 100% of the required standards in all the studied dimensions is necessary to achieve the minimum level of patient safety friendly hospital. Therefore, the necessary goals in this regard should be in the strategic and operational planning of hospitals to achieve fully the standards in the four axes under consideration. Moreover, by employing technical officials and expert patient safety coordinators with experience and experience in this field in hospitals and sufficient attention of the management team is needed to discuss the full implementation of standards and provide sufficient funding to do so.

According to the results of the present systematic study, the average level of compliance with mandatory patient safety standards in Iranian hospitals was in the axis of governance and leadership with 70% in the average situation. In Lebanese hospitals, teamwork and managerial support for patient safety scored the most points, which is consistent with the present study (19). The results of this axis are also consistent with Forouzan's research. The findings of this study showed the expectations and performance of the department head in order to improve patient safety; it has been evaluated as moderate (33). In order to increase the safety of the patient in this axis, put patient safety programs in hospital operational and strategic plans as a top priority, appoint a qualified staff member with the necessary authority to be responsible for the patient safety program, Regular performance of patient safety management visits by senior hospital managers, and it is necessary to hold regular meetings of the mortality committee in Iranian hospitals. Therefore, in order to improve the safety of the patient in this group, it is necessary to include patient safety programs in the operational and strategic plans of the hospital and to hire qualified and skilled technical staff.

According to our results, the domain of patient and public involvement with a mean score of (47%) which indicates that hospitals in this area they are in a weak position in complying with the standards in the relevant axis. The results of this dimension are consistent with the study of Christine et al. In their study, communication problems and lack of proper identification of patients are among the factors that affect patient safety (34). The results of the present study and unfavorable and low status, awareness reported patient satisfaction, which may be due to patients' low awareness of their rights (35). Our findings are approved with another study (36) which found that hospital status according to patient safety standards in this domain was at a low level (42.3%) and in another patient and public involvement (25%) had met the lowest standards (37). In order to achieve desired status in patient and public involvement domain, developing comprehensive programs and practical researches to hospital make available health notice for its patients and caregivers to authorize them to share in taking the right decisions about their care, seems necessary.

Due to the weakness of this axis, the mandatory standards of patient safety in Iranian hospitals, in order to improve this axis, the patient should be adequately explained to the patient about any invasive treatment and diagnostic measures, all risks, benefits and possible side effects of the procedure and with the presence of a nurse the patient signs the consent form. To do this completely, hold briefing sessions for physicians treating patients for full explanation to the patient it is necessary to receive any service. It is also necessary to ensure the correct identification
of patients and its identification in all stages of patient treatment and medical records staff and nurses in our wards must complete training courses to identify properly patients in the hospital. Inattention to patient identification in hospitals has been pointed out and misdiagnosis is still cited as a significant problem in hospitals, which poses serious risks to the patient's health and incurs large costs for the health care system (38).

According to the results of the present study, the average level of compliance with mandatory patient safety standards in Iranian hospitals in the dimension of safe and evidence-based clinical services with an average of Average 68% is in the average situation. The performance of hospitals in the domain of safe evidence-based clinical practices was also acceptable. This domain mainly refers to the safety standards in laboratory, radiology, and infection control units, which play a significant role in patient safety. In particular, healthcare-related infection is a major threat to patient safety, leading to patient disability, death, and additional care provision.

The observance of the standards of this group in Shahid Beheshti Hospital with good performance was shown, which is not consistent with the present review study (39). Mousavi’s study assessed the status of compliance with infection control standards as relatively safe, which is consistent with the results of this study (40). In order for this axis to grow, measures such as the need for infection prevention and control programs in all Iranian hospitals, including an organizational chart, an operational plan, a guide and a manual, should be available. Hospitals must ensure proper cleaning, disinfection and sterilization of all equipment with special emphasis on high-risk units. All Iranian hospitals must follow valid guidelines, including WHO guidelines on safe blood and blood products and it is vital that the hospital ensures that essential medicines are provided 24 h a day.

According to our results, the average level of compliance with mandatory patient safety standards in Iranian hospitals is related to the fourth area of safe environment with the highest average (75%), which is the level of compliance with the standards in good condition. In this research, the axis of safe environment includes safe waste management system. Hospital waste has a high potential for risk for patients, hospital staff, and the public. Principled management of hospital waste necessitates continuous control and monitoring of elements such as production, storage, collection and transportation, decontamination and disposal of this waste.

Medical waste management and related wastes in selected hospitals of Guilan, Isfahan and Kohgiluyeh and Boyer Ahmad the condition of the studied hospitals in the stage of separation, packaging and collection and storage of waste was assessed as relatively good, which is consistent with the results of our study (41). Moreover, the good performance of the operating room in this group, which indicates the desirability of the drug system, and waste management in the study hospital, which is consistent with the present review, study (39). To grow this axis and to achieve 100% compliance with standards, measures such as waste segregation adherence of hospitals to the guidelines of the WHO is necessary to eliminate the management of sharp and winning waste. An effective implementation of patient safety initiatives may depend on the legal infrastructure and enforcement of standards by hospital management, creating an organizational responsiveness to expectation of patients, creating a safety culture in hospitals and participation of patients and their families.

**Conclusion**

The overall status of mandatory patient safety standards in all Iranian hospitals is moderate, in order to implement patient-friendly standards, the required patient safety standards must be implemented 100%. Due to the importance and necessity of observing patient safety in medical centers, it is necessary to review the principles in the management and structure of medical centers and more attention Hospital management team. To achieve a good level of all aspects of the protocol, patient safety goals should be considered at
the level of strategic planning in hospitals, and provided sufficient funding for the implementation of these standards. Paying attention to the patient's safety culture and improving it, carrying out regular managerial visits patient safety and attention to the management of medical equipment in the axis of governance and leadership, the use of correct patient identification system and taking measures to Informed participation of patients and companions in the axis of attracting participation and interaction with the patient and the community, attention to clinical errors, especially drug errors, and issues related to blood and blood products in the field of safe and evidence-based clinical services and implementation of safe waste disposal management system in the axis of safe environment it can improve the patient's level of safety and achieve faster and more effective patient safety standards and improve the patient's safety conditions. The mandatory patient safety standards play important role in improving patient safety using leadership, safety practices and creating good working conditions and environment for the staff. So, focus on these standards is essential in improving the patient safety in hospitals in Iran.

Journalism Ethical considerations

Ethical issues (Including plagiarism, informed consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc.) have been completely observed by the authors.

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Conflict of interest

The authors declare that there is no conflict of interest.

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