Medical Science

pISSN 2321–7359; eISSN 2321–7367

Effectiveness of feeding with standard formula of Ensure, Entrameal feeding and Hospital-prepared blended formulas in trauma patients admitted to ICU

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To Cite:
Shahri S, Mahmodiyeh B, Kamali A, Majd FK. Effectiveness of feeding with standard formula of Ensure, Entrameal feeding and Hospital-prepared blended formulas in trauma patients admitted to ICU. Medical Science, 2022, 26, ms1e1840.
doi: https://doi.org/10.54905/disssi/v26i119/ms1e1840

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Peer-Review History
Received: 12 November 2021
Reviewed & Revised: 14/November/2021 to 18/December/2021
Accepted: 21 December 2021
Published: 2 January 2022

Peer-review Method
External peer-review was done through double-blind method.

URL: https://www.discoveryjournals.org/medicalscience

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ABSTRACT

Introduction: In the present study, we decided to compare the effectiveness and economic efficiency of ensure, standard entrameal feeding and standard hospital gavage in trauma patients admitted. *Material and Methods*: In this double-blind clinical trial, 66 patients were randomly divided into three completely equal groups. Total protein level, arm circumference (MAC), and electrolyte levels were measured and the nutritional score and cost of each group were calculated. *Results:* The mean age of the three groups of ensure, standard entrameal feeding and hospital gavage were 35.05 (8.46), 34.05 (8.32) and 35.95 (11.55), respectively. The studied groups in terms of age, sex, sodium, potassium, magnesium and calcium were not significantly different. Total protein and MAC were not significantly different in the two groups of ensure, standard entrameal feeding (P = 0.998). A decreasing trend in NUTRIC Score was observed in all three groups, the most significant decrease was related to the anchor group, followed by intramylastic standard and hospital gavage (P <0.0001). In NUTRIC Score was observed in all three groups, where the most significant decrease was related to the ensure group, followed by standard entrameal feeding and hospital gavage (P <0.0001). *Conclusion:* The standard entrameal feeding was the same as ensure in terms of total protein and MAC, but imposes more complications and costs on the patient. Hospital gavage is not a good nutrition to provide patient's energy and protein.

Keywords: Gavage, intensive care unit, nutrition.

1. INTRODUCTION

Malnutrition is a common issue in the general population of hospitalized patients and is more common among patients admitted to ICU, but unfortunately these patients do not receive appropriate treatment (Westergren

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et al., 2008). Malnutrition is known to be a factor that increases the cost of hospitalization and treatment and can potentially worsen the therapeutic outcome of chronic diseases (Mogensen et al., 2015). Research has shown that the whole-body glycogen content is significantly reduced after 24 hours of not eating (Losser et al., 2010). In addition, not eating for more than 3 days in a healthy person induces insulin resistance (Peters et al., 2011). Protein is known to be a byproduct of glucose production. A 75 kg person loses 50% of their liver glycogen and 1% of their muscle mass within 24 hours after trauma and not eating (Singer et al., 2014). Therefore, the negative balance can lead to increased mortality. Lack of adequate nutrition in patients with long-term hospitalization in the ICU causes atrophy of body muscles and even heart muscle (Singer et al., 2010). On an international scale, the mortality of patients receiving a maximum of 10 kcal per kg of body weight per day is greatly increased compared to the expected normal mortality after the 7th day (Alberda et al., 2009).

Malnutrition in patients who were admitted to the ICU causes several complications in the systemic functioning of the individual. These changes include decreased immune responses, atrophy, and increased permeability of intestinal epithelial barriers, the latter of which cause infection and facilitates bacterial transmission. In addition, malnutrition slows wound healing, increases the risk of pneumonia, sepsis, and other conditions that ultimately lead to increased mortality, length of hospital stay, and treatment costs (de Souza Menezes et al., 2012). Therefore, it seems that nutritional support and elimination of nutritional deficiencies in these patients is a basic need. Standard Enteral Meal Powder, Ensure and hospital gavage are some of the foods used in ICU patients.

Entrameal is the standard dietary formulation of gavage and weight gain supplement in adults, which is also used in patients admitted to the ICU. Standard entrameal compounds include concentrated protein, whey, calcium caseinate, maltodextrin, coconut oil, sunflower oil, lecithin, soy, carnitine, vitamin and mineral complex, enzyme complex, aspartame and oral flavoring (from: 2017). Another powder used is Ensure powder, which contains a special combination of unsaturated fats that are good for the heart, essential fatty acids (linoleic fatty acid and alpha-linolenic acid). Numerous studies have confirmed their role to improve the profile of blood lipid and reducing the risk of cardiovascular disease. Ensure powder contains protein, carbohydrates, vitamins A, B, C, D, E, K, sodium, potassium, calcium, magnesium, zinc, copper, iron and other minerals that is used in cases of weight loss, malnutrition, skeletal development, adolescent development as well as the main food in the ICU patients. Also, gavage solution is used for some patients admitted to the ICU where the cooked food mixture prepared manually in the hospital catering, is used.

Despite the cheapness of this type of compound, they are more likely to increase nosocomial infections due to the provision of a suitable environment for microbial growth (Hoffer and Bistrian, 2014). There are various methods and tools, none of which alone are effective for accurate and specific assessment of nutritional status; therefore, using several methods together can be useful in this regard (Guerra et al., 2014; Sungurtekin et al., 2008). In clinical nutritional evaluation, the patient's condition is examined in terms of physical appearance and the diagnosis of specific and non-specific symptoms that may reflect malnutrition. One of the tools used in clinical assessment of nutritional status is the comprehensive mental assessment method, which is a valid and reliable tool for determining malnutrition and has a good relationship with nutritional risk status in hospitalized patients (Kreymann et al., 2006). There are various stages in the nutrition of hospitalized patients, which include anthropometric measurements, clinical evaluation, evaluation of biochemical and laboratory indicators and evaluation of diet.

To widely evaluate the nutritional status of patients, using these steps together is useful and effective. Measurement of blood biochemical indices is another method of nutritional evaluation. Indicators such as albumin, prealbumin, total protein, transferrin, white blood cells, whole blood lymphocytes, hemoglobin, urea, creatinine, calcium, hematocrit, phosphorus, magnesium are considered to be affected by nutritional status. Measuring some anthropometric parameters and determining their changes can reflect the status of diet (Salehifar et al., 2008).

This study is aimed to evaluate the effectiveness of nutrition with standard formula (i.e., Entrameal and Ensure and hospital-prepared blended formulas) in trauma patients admitted to ICU due to economic efficiency.

2. MATERIAL AND METHODS

In this study, all patients who were admitted to the ICU during 2019 to April 2020 went under a double-blind clinical trial. We evaluated 66 patients by random sampling in three groups. In this study, neither the performer nor the statistical analyst knew the type of formulas. The patients in group A received Ensure powder, the second group (B) are patients who received standard Entrameal powder and the patients in the group C were given hospital gavage food. It should be noted that patients should not have TPN.

We first calculated the calories needed for these patients. To calculate the calorie requirement of patients, approximately 20 kcal per kg of patient weight was calculated. In case of fever, 13% was added to the calculated amount for each patient and 20% in case of burn. To evaluate the patients in each group, total protein level, mid arm circumference (MAC) and electrolyte levels (sodium,

potassium, magnesium and calcium) were measured and finally the patients' NUTRIC SCORE was calculated. Complications of each nutritional method, including diarrhea, vomiting, vomiting, and allergies, were evaluated. Finally, the cost for each patient was calculated according to the price of each nutritional supplement. Each of the above was evaluated on the first, eighth and fourteenth days and finally compared with each other.

Inclusion criteria were: 1) age 18 to 50 years, 2) need for nutrition through NG tube or gastrostomy or jejunostomy, 3) multiple trauma. Exclusion criteria included: 1) death, 2) intolerance to gavage for more than 24, 3) NPO recurrence of the patient for more than 24 hours, 4) Allergy to folate compounds, 5) History of diabetes, hyper or hypothyroidism and metabolic syndromes, 6) Allergy to milk proteins, 7) Gastrointestinal fistula, 8) Burn, 9) Kidney failure, 10) Liver failure

Statistical Analysis

SPSS statistical software version 22 was used for data analysis. Chi-score and t-test were used to compare the groups.

Ethical consideration

The ethical code is IR.ARAKMU.REC.1396.201.

3. RESULTS

Table 1 shows the demographic information of patients in three groups. In this study, the three groups were not significantly different from each other in terms of any of the electrolytes, Ca, Mg. The information of which is given in Table 2.

Table 1 Demographic information of patients

Group		Sex (%)	Age (SD)
Ensure	Female	11 (50%)	35.05(8.46%)
	Male	11 (50%)	
Standard Entrameal	Female	10 (44.5%)	34.05 (8.32)
	Male	12(54.5%)	
Hospital Gavage	Female	11 (50%)	35.95 (11.55)
	Male	11 (50%)	

Table 2 Electrolyte and mineral information of patients

Electrolyte	Day	Group	Mean(SD)	P value
Na	First	Ensure	139.73(2.95)	0.723
		Standard Entrameal	139.95(2.85)	
		Hospital Gavage	138.55(2.24)	
	Eighth	Ensure	140.14(2.05)	
		Standard Entrameal	140.09 (1.97)	
		Hospital Gavage	139.32(2.78)	
	Fourteenth	Ensure	141.18(3.35)	
		Standard Entrameal	140.27(1.86)	
		Hospital Gavage	139.73 (3.86)	
K	First	Ensure	4.15 (0.52)	0.097
		Standard Entrameal	3.86 (0.52)	
		Hospital Gavage	4.11 (0.45)	
	Eighth	Ensure	4.11 (0.51)	
		Standard Entrameal	4.04(0.48)	
		Hospital Gavage	4.05(0.32)	
	Fourteenth	Ensure	4.23 (0.48)	
		Standard Entrameal	4.114(0.45)	
		Hospital Gavage	4.16(0.42)	
Ca	First	Ensure	8.68 (0.37)	0.283

		Standard Entrameal	8.72 (2.85)	
		Hospital Gavage	8.5 (0.44)	
	Eighth	Ensure	8.63 (2.05)	
		Standard Entrameal	8.59 (0.41)	
		Hospital Gavage	8.54 (0.41)	
	Fourteenth	Ensure	8.47 (1.07)	
		Standard Entrameal	8.71 (0.49)	
		Hospital Gavage	8.45 (0.44)	
Mg	First	Ensure	2.19 (0.14)	0.498
		Standard Entrameal	2.13 (0.19)	
		Hospital Gavage	1.86 (0.32)	
	Eighth	Ensure	2.15 (0.18)	
		Standard Entrameal	2.17 (0.21)	
		Hospital Gavage	1.83 (0.25)	
	Fourteenth	Ensure	2.20 (0.15)	
		Standard Entrameal	2.16 (0.16)	
		Hospital Gavage	1.85 (021)	

Total protein

Total protein changes in the three groups on the first, eighth and fourteenth days were significantly different (P = 0.0001). These changes had an increasing trend in the standard Entrameal and Ensure groups and a decreasing trend in the hospital gavage group. These changes are shown in Table 3 and 4. No significant difference was observed between the two groups of Entrameal and Ensure (P = 0.998). There was a significant difference between the standard Entrameal or Ensure group with hospital gavage (P = 0.001).

Table 3 Total protein changes

Electrolyte	Day	Group	Mean (SD)	P value
Total Pr	First	Ensure	5.08 (0.60)	0/0001
		Standard Entrameal	5.12 (0.64)	
		Hospital Gavage	5.01 (0.41)	
	Eighth	Ensure	5.52 (0.59)	
		Standard Entrameal	5.55 (0/7)	
		Hospital Gavage	4.80 (0/43)	
	Fourteenth	Ensure	5.90 (0/56)	
		Standard Entrameal	5.85 (·/69)	
		Hospital Gavage	4.72 (0.45)	
MAC	First	Ensure	29.05 (2.03)	0.097
		Standard Entrameal	29.08 (3.13)	
		Hospital Gavage	27.64 (2.61)	
	Eighth	Ensure	30.03 (2.09)	
		Standard Entrameal	30.00 (3.21)	
		Hospital Gavage	26.36 (3.02)	
	Fourteenth	Ensure	31.12 (2.21)	
		Standard Entrameal	31.05 (3.27)	
		Hospital Gavage	29.95 (2.61)	
Nutric Score	First	Ensure	3.75 (0.86)	0.0001
		Standard Entrameal	3.52 (1.02)	
		Hospital Gavage	3.84 (1.01)	
	Eighth	Ensure	1.45 (0.65)	
		Standard Entrameal	2.42 (0.81)	

	Hospital Gavage	3.09 (0.87)
Fourteenth	Ensure	0.23 (0.43)
	Standard Entrameal	1.57 (0.69)
	Hospital Gavage	2.57 (0.75)

Table 4 Changes in the Ensure and Standard Entrameal groups

Total pr		P value
Ensure	Standard Entrameal	0.998
	Hospital Gavage	0.001
Standard Entrameal	Ensure	0.998
	Hospital Gavage	0.001
Hospital Gavage	Ensure	0.001
	Standard Entrameal	0.001
MAC		P value
Ensure	Standard Entrameal	0.996
	Hospital Gavage	0.0001
Standard Entrameal	Ensure	0.996
	Hospital Gavage	0.0001
Hospital Gavage	Ensure	0.0001
	Standard Entrameal	0.0001
Nutric Score		P value
Ensure	Standard Entrameal	0.004
	Hospital Gavage	0.0001
Standard Entrameal	Ensure	0.004
	Hospital Gavage	0.007
Hospital Gavage	Ensure	0.0001
	Standard Entrameal	0.007

MAC variable

Table 4 shows the MAC changes in the three groups on the first, eighth and fourteenth days that the MAC changes in the three groups were significantly different (P = 0.0001). These changes showed an increasing trend in the standard Entrameal and Ensure groups, and a decreasing trend in the hospital gavage group. No significant difference was found in terms of MAC between Entrameal and Ensure groups (P = 0.996). Furthermore, the Entrameal or Ensure with hospital gavage were significantly different (P = 0.0001).

Nutric score

The nutritional score changes are shown in Table 4. Nutritional score changes in the first, eighth and fourteenth days were significantly different in the three groups (P = 0.0001). This score revealed a decreasing trend in all three groups, but the Ensure group showed a significantly faster decreasing trend than the standard enteral feeding group (P = 0.004). The Ensure group had a significantly faster decreasing trend than the hospital gavage group (P = 0.0001). The standard enteral feeding group also had a significantly faster decreasing trend than the hospital gavage group (P = 0.007).

Cost variable

Table 5 and figure 1 shows the average and standard deviation of the cost of each group in terms of Iranian toman in three groups. Significantly, the hospital gavage group, ensure feeding group and standard enteral feeding group had the lowest mean cost (P = 0.0001), respectively.

Table 5 Mean and standard deviation of cost in three study groups

P-value	SD	Mean	Group
0.0001	105324.221	221583.455	ensure feeding group
	183268.225	320892.091	standard enteral feeding group
	44227.276	98632.636	hospital gavage group

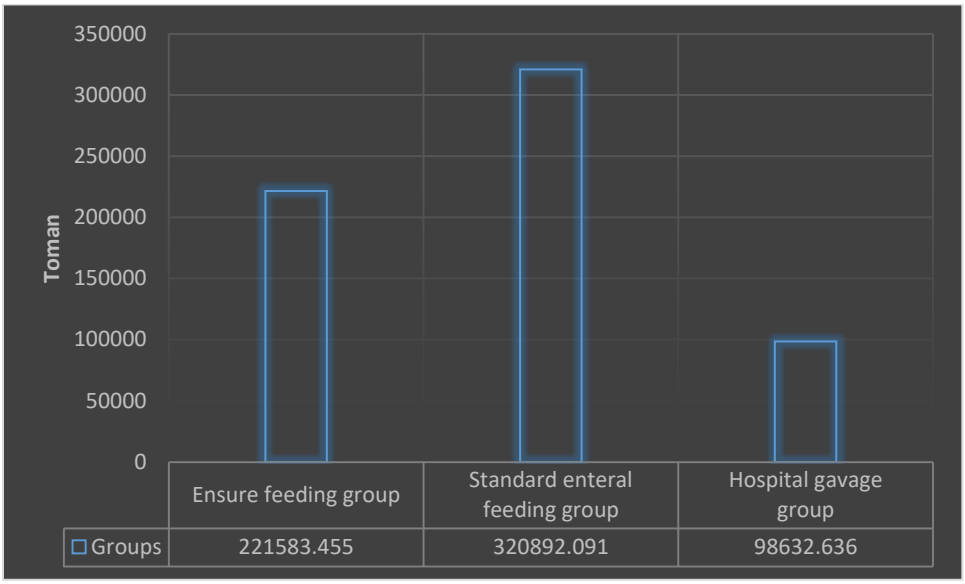

Figure 1 The cost of each group in terms of Iranian Toman in three groups

Complications

Ensure group had no side effects at any time. The results showed that 5 patients had diarrhea and 1 patient had diarrhea and vomiting on the first day in the standard Entrameal group; on the eighth day, 5 people also had diarrhea. In the hospital gavage group, 2 people showed vomiting on the first day, while 3 and 2 people patients exhibited vomiting and diarrhea on the fourteenth day, respectively.

4. DISCUSSION

In the present study, the mean and standard deviation of age in the three groups of standard enteral feeding, and hospital gavage were 35.05 ± 8.46, 34.05±8.32 and 35.95± 11.55, respectively, which did not show a significant difference (P = 0.805). Ensure group consisted of 11 (50) women and 11 (50) men. The standard Entrameal group consisted of 10 (45.5) females and 12 (54.5) males and the hospital gavage group consisted of 11 (50) females and 11 (50) males. No significant difference was found between all groups (p = 0.914). These findings show that the results of the study are not affected by a specific age group or gender.

In the present study, changes in sodium and potassium were not significantly different in the three groups (P = 0.723 and P = 0.097). This indicates that none of these foods have altered the body's major electrolytes (sodium and potassium) during these 14 days. These supplements do not cause beneficial or harmful changes in these electrolytes in the body. It is worth noting that sodium chloride is one of the compounds used in the two powders of Ensure and standard Entrameal (from: 2017) and usually hospital gavages are monitored for sodium chloride compounds and salt as needed in all three of these solutions (Salehifar et al., 2008). Therefore, it can be concluded that these three solutions have not made significant changes relative to each other. However, no similar study has been performed to evaluate sodium chloride in patients for two weeks; thus, the results of previous studies cannot be compared with the present study.

Changes in calcium and magnesium as two vital minerals for the human body during the study were not significant in the three groups (P = 0.498 P = 0.238). In other words, these three types of compounds were not superior over each other in compensating patients' blood calcium for 14 days. Of course, the lack of changes can also be attributed to the short duration of the study because the two standard powders of Ensure and standard Entrameal provide acceptable and suitable sources of calcium for the body (from: 2017). However, no significant difference was found in the consumption of gavage compared to the other two powders in terms of these micronutrients. But these results are different from the study of Hosseini Mousavi and his colleagues (Jazayeri et al.,

2018), where they standard nutritional powders were compared with the hospital-prepared blended formulas. They found that in the standard enteral feeding group, the mean blood calcium of patients increased (3.82 to 4.28) after one week of using and did not change in the blended formulas which are prepared in the hospital (from 4.16 to 4.17) ($p < 0.0001$).

In the present study, the total blood protein of patients for 14 days in enteral feeding group and ensure group was significantly higher than hospital gavage. On the other hand, the blood protein of patients undergoing gavage during these two weeks was not only variable but also reduced ($p < 0.0001$). No significant change was found between the two groups of enteral feeding and ensure during 14 days of treatment ($p = 0.998$). In other words, the both supplements were not superior after 14 days of treatment and had the same effect on total protein changes. The results of our study on total protein were consistent with a study conducted by Hosseini Mousavi et al., (2018) where they showed a significant increase in albumin after one week in patients receiving Standard enteral feeding ($p < 0.0001$). On the other hand, the average albumin in the blood of ICU patients has increased after one week of using the hospital-prepared blended formula, but it has not increased to the level of the standard enteral feeding (hospital-prepared blended formula: 2.93 to 3.94; standard enteral feeding 2.96 to 4.61).

On the other hand, Salehifar et al., (2008) showed consistent results on protein deficiency in hospital gavage solutions by analyzing the protein, lipid, and carbohydrate contents of the gavage solution in the ICU of Imam Khomeini Hospital, Sari, Iran. In addition, they assessed 30 patients admitted to the ICU for at least 5 days. The daily metabolic needs of the patients were calculated using the Harris-Benedict equation and calculated calorie and protein values were comparison with the required amount. They found that the protein and energy contents of gavage solutions were 16 and 32.5%, respectively. Therefore, they stated that the hospital-prepared gavage solution prepared in the hospital was not sufficient to meet the calories and protein needed by patients. These solutions need to be prepared in such a way that they have an acceptable content of carbohydrates, lipids and proteins, or to prepare them with standard enteral nutritional solutions.

In the present study, the changes in MAC were significant in three groups ($p < 0.0001$) and this parameter increased in the two groups of standard entrameal feeding and ensure groups for 14 days; however, its changes showed a decreasing trend in the hospital gavage group. The two groups of standard entrameal feeding and ensure were not significantly different in terms of MAC changes ($p = 0.996$). In other words, the two groups of standard entrameal feeding and ensure were consistent in terms of MAC changes. Although the two groups of standard entrameal feeding and ensure were consistent in terms of MAC elevation and provision of protein, but they are significantly better than hospital gavage. No study was found to compare these three formulas in terms of protein and MAC for comparison. As shown by Hosseini Mousavi et al., (2018), the benefit of standard formula was higher in comparison to the combined formulas prepared in the hospital (hospital gavage) for patients admitted to the ICU and physicians are advised to use it.

In the present study, changes in NUTRIC Score in all three groups had a decreasing trend over 14 days. The largest decreases in this parameter were in the ensure group (from 3.75 to 0.23), followed by the standard entrameal feeding (from 3.52 to 1.57) and the gavage group (from 3.84 to 2.54), respectively. These changes were quite significant ($p < 0.0001$), indicating the high efficiency of ensure in lowering the nutric score. From these data, it can be seen that ensure and standard entrameal feeding are better combinations in meeting the nutritional needs of patients than the hospital gavage. Ansure significantly reduced the nutritional score compared to standard entrameal feeding ($p < 0.0001$), indicating a better performance of ensure in meeting the nutritional needs of patients and reducing their nutritional score. In this regard, no study has been found to compare at the global and Iranian levels. Regarding the side effects of these formulas, no side effects have occurred at any time in the Anshour group.

In the standard entrameal feeding group, on the first day, 5 people developed diarrhea, followed by diarrhea and vomiting (1 patient). In the second time, 5 people have diarrhea, which can be attributed to the time required to tolerate the formula. In our study, it can be stated that standard entrameal feeding was associated with diarrhea after one week of use. In the hospital gavage group, 2 people showed vomiting in the first time. In the third time, 3 people had vomiting, followed by diarrhea (2 patients). In this group, complications of diarrhea and vomiting were seen after using hospital gavage. The incidence of diarrhea and vomiting in the hospital gavage group has been reported previously by Nachvak Seyyed et al., (2018), where 4.7% of patients developed diarrhea after using the hospital formula and another 4.7% vomited, and a total of 12 Percentage of gastrointestinal complications. Another 4.7% developed vomiting, and a total of 12 percent had gastrointestinal upset. A total of 12% had gastrointestinal upset.

In the current study, the cost of hospital gavage was significantly lower than all groups, followed by ensure and standard entrameal feeding ($p < 0.0001$). Due to better performance, less nutritional side effects of anchovies and similarity of performance of the two ensure and standard entrameal feeding groups in terms of total protein and MAC, ensure will be economically beneficial. Among the three dietary formulas, ensure powder is the best option for treatment of patients who were admitted to the ICU in terms of complications, reduction of nutritional score and cost.

5. CONCLUSION

Standard entrameal feeding was the same in terms of total protein and MAC, but it causes more complications and is more expensive. Hospital gavage was not found to be a good nutrition to provide patient's needs such as energy and protein.

Consent for publication

All authors declare that they have consented for publication.

Authors' contributions

All authors contributed to the design of the study, as well as data collection and analysis, and the writing of the manuscript. All authors read and approved the final manuscript.

Acknowledgments

We would like to thank all the esteemed personnel of the intensive care units (neurology, neurosurgery and surgery ICUs) and the clinical base of Valiasr Hospital in Arak who helped us in this project.

Funding

This study has not received any external funding.

Conflict of interest

The authors declare that there are no conflicts of interest.

Data and materials availability

All data associated with this study are present in the paper.

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