Assessment of sleep characteristics using Fitbit Charge 4 in head and neck cancer patients undergoing palliative chemotherapy and radiotherapy: a prospective observational study

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Abstract

Background: Sleep disturbance is prevalent among cancer patients. The quantification of this sleep disturbance is missing, especially in palliative care settings.

Aim: The aim of this study was to study the sleep patterns of the patients undergoing palliative chemotherapy and radiotherapy for head and neck cancer (HNC) using a Fitbit Charge 4 sleep-tracking device.

Design: Prospective observational study.

Setting: A total of 110 HNC patients undergoing palliative chemotherapy and radiotherapy at a tertiary care teaching hospital in Central India.

Results: Forty-four percent of patients had a poor sleep score (less than 60). Average sleep duration was 218.66 ± 139.05 min; non-rapid eye movement (NREM) sleep duration 197.7 ± 115.91 (light NREM 171.36 ± 104 and deep NREM 23.36 ± 16.73); REM sleep duration was 30.44 ± 34.14 min. The Pittsburgh Sleep Quality Index was 10.23 ± 3.45, which indicated sleep deprivation over the past 1 month. Moderate levels of anxiety, depression, confusion, and distress existed in the cohort. Statistically significant but weak correlation existed between sleep score, anxiety, and depression. Strong correlation existed between distress score and sleep score. Confusion score did not have a significant correlation with sleep score.

Conclusion: HNC patients in palliative care settings were chronically sleep deprived. Sleep architecture was also disturbed. Moderate levels of anxiety, depression, confusion, and distress existed in the studied cohort; these psychosocial disturbances had a weak correlation with the sleep score and are likely to be multifactorial.

Trial registration: Institutional Ethics Committee number: IHEC-LOP/2020/IM0349. The study has been registered with clinical trial registry of India with registration number CTRI/2021/03/032400 (http://www.ctri.in).

Keywords: fitness trackers, head and neck neoplasms, palliative care, polysomnography, sleep

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Introduction

Sleep is a natural mechanism by which the body relaxes, restores, and repairs itself. A disturbed sleep has a wide variety of implications on the general well-being of the patient, especially mental well-being. In a cancer patient, etiology of sleep disturbance may be multifactorial. Not only do the physical symptoms due to cancer disrupt

sleep, but the treatment of these symptoms may also lead to sleep disturbance. Theoretically, insomnia may have an unprecedented impact on the outcome of cancer treatment; however, it is a much more difficult topic to study.

In this study, we have studied a cohort of head and neck cancer (HNC) patients who were undergoing in-hospital palliative chemotherapy, radiotherapy, or both. We studied this cohort for their sleep pattern, anxiety, depression, and confusion. For studying the sleeping patterns, we used a wrist-worn sleep-tracking device (Fitbit Charge 4). Fitbit Charge 4 uses an accelerometer that measures body movement and heart rate variability to determine the various stages of sleep. Compared to polysomnography, for total sleep duration, Fitbit Charge 4 has a sensitivity of 90% and specificity of 73%. For rapid eye movement (REM) sleep, sensitivity is 76% and specificity is 96%. For deep non-rapid eye movement (NREM) sleep, the sensitivity was 54% while specificity was 94%.[1] These sleep-tracking devices provide a variety of sleep-related data and have been considered appropriate for research purposes in a variety of noncancer settings.[2]

Aim and objective

The aim of the study was to study HNC patients for their sleeping patterns and to find whether the various sleep parameters have any relation to the existence of anxiety, depression, confusion, or distress.

To achieve this aim, we used Fitbit Charge 4 as the wrist-worn sleep-tracking device. The premium version of the Fitbit software provides data with respect to the total duration of sleep, duration of NREM and REM sleep, a sleep score (an algorithm-based score which corresponds to the quality of sleep). For quantification of anxiety and depression, we have used the Hospital Anxiety and Depression Score (HADS); confusion was quantified using the bedside confusion score and distress was measured using distress thermometer.

Materials and methods

This study is a prospective longitudinal single-blinded study and was performed as a postgraduate thesis in a tertiary care center in Central India. The study was jointly done by the Departments of Anesthesiology and Radiation Oncology. Approval of the Institutional Human Ethics Committee was obtained (2020/PG/July/05) and the study was registered in the Clinical Trials Registry of India (CTRI/2021/03/032400). The study was performed between December 2020 and December 2022.

The study participants included adult patients (18–60 years) with various types of HNCs who were undergoing palliative chemotherapy or radiotherapy in an in-hospital setting.

In the absence of any baseline data for sample size calculation, we considered a convenience sample of 110 patients to be adequate. The study participants had been enrolled after obtaining written informed consent.

Inclusion criteria: Adult patients having HNC on palliative chemotherapy/radiotherapy.

Exclusion criteria:

1. Less than 18 years age
2. Immediate postoperative patients
3. Patients apart from HNCs
4. Patient with preexisting (before diagnosis of cancer) history of sleep disturbance or hereditary sleep disturbance
5. Patient with advanced cardiopulmonary compromise (NYHA class 4)
6. Patients with a history of psychiatric illness mainly schizophrenia or other psychosis or neurosis
7. Patient unable to communicate or understand the assessment tools

Patients beyond the age range, immediate postoperative patients, cancers other than HNCs, preexisting sleep disturbances, or hereditary sleep disturbances before the diagnosis of cancer, patients with advanced cardiopulmonary compromise (NYHA class 4), patients with a history of psychiatric illnesses such as schizophrenia, neurosis, or other psychoses, and patients unable to communicate or understand the assessment tools were excluded from the study.

Upon admission demographic data was recorded, sleep-tracking device was applied to patient's wrist and HADS, and bedside confusion scores were recorded; the questionnaires were investigator administered. The quality of sleep over the

past 1 month was assessed using the Pittsburgh Sleep Quality Index (PSQI). Distress thermometer was used to assess the overall level of distress. Thereafter, the sleep-tracking device data was recorded daily for 3 days. Sleep-tracking devices usually work on actigraphy principle and tend to overestimate sleep in comparison to polysomnography. An additional incorporation of sensors for heart rate variability has led to improved results not only in defining sleep and awake states but also in defining individual stages of sleep.[3–5] If this aspect is taken into account, the actual sleep time may be lower than what was recorded by the sleep tracker. Fitbit is the sleep-tracking device that has been compared with polysomnography for its accuracy and has been found to have good sensitivity and specificity, hence we chose it for this study.

A PSQI of 5 or less was considered an indicator of good sleep. A bedside confusion score of 2 or more was taken as cut-off for the existence of delirium. A depression score of 5–9 indicated mild depression, 10–14 indicated moderate depression, 15–19 indicated moderately severe depression, and 20 or more indicated severe depression. An anxiety score of 8–10 indicated mild anxiety, 10–14 indicated moderate anxiety, and15–21 indicated severe anxiety. Distress thermometer was an 11-point Likert scale ranging from 0 to 10, where 1–3 meant mild distress, 4–6 meant moderate distress, and 7 or more indicated severe distress.

At the start of the study, participants received detailed counseling about the importance of wearing Fitbit devices consistently. This counseling session highlighted how accurate data collection could contribute significantly to the study's outcomes and health monitoring.

Compliance was actively monitored and ensured by the doctor on duty and the nursing officer on duty. These healthcare professionals regularly checked that participants were wearing their Fitbits as required.

The doctor and nursing officer provided continuous support to participants, addressing any issues or concerns they had with the Fitbit devices. This included assistance with device functionality and reminders to wear the device correctly.

To accommodate this, the questionnaires were made available in both English and Hindi. Participants were given the choice to select the language they were most comfortable with. For those who preferred Hindi, translated versions of the questionnaires were provided to ensure clarity and accuracy in their responses.

The data saturation was reached for this study.

Sample size calculation: Based on Green's method of sample size prediction for regression analysis $(N = 104 + X)_{14}$, a sample size of 110 is considered to be adequate; X being the number of dependent variables. Power of study would be 80% and level of significance would be 95%. Since six independent factors are under study (Psychological distress (HADS), Functional status (Eastern Cooperation Oncology Group (ECOG) status), Physical symptoms, Type of sedative medication, PSQI score, and Bedside confusion score), we consider a minimum sample size of 110 to be adequate.

Statistical analysis

All the data was analyzed using SPSS 16 software. For parametric data mean, standard deviation and 95% confidence interval limit were calculated. For finding the association between sleep characteristic data and other related data, Pearson correlation coefficient was used. Comparison of parametric data was done using an independent sample t test. A p value of 0.05 or less was considered significant.

In our study to reduce selection bias multiple observers have collected the data and motivated subjects have been enrolled to prevent loss of follow-up.

Results

The study lasted for 18 months; out of the 110 patients, 57% were male. Squamous cell carcinoma was the most common histopathological type (100/110). The most common symptoms were pain (60/110) followed by difficulty in swallowing (42/110), decreased appetite (37/110), and decreased sleep (32/110). Of the patients, 43% were taking oral morphine; 35% patients were on paracetamol and tramadol combination; 10% were taking antidepressants. As per Fitbit classification of sleep score, a sleep score of 90–100 is considered excellent; 80–89 is good; 60–79 is fair and less than 60 is poor. A total of 11 patients had a sleep score of 21–30; 6 had 31–40;

Table 1. Showing the demographic parameters in study population.

Parameters	Unsegregated *N* = 110	Group 1 *N* = 42	Group 2 *N* = 68	Statistical results	
	Mean ± SD	Mean ± SD	Mean ± SD	95% CI for difference of mean	*p* Value
Age (years)	54.76 ± 11.41	52.76 ± 8.129	56 ± 12.94	−7.65 to 1.18	0.149
Weights (kg)	54.65 ± 8.50	54.45 ± 8.267	54.78 ± 8.706	−3.65 to 2.99	0.844
Duration of illness (months)	8.30 ± 3.77	8.69 ± 3.672	8.06 ± 3.672	−0.84 to 2.10	0.397
ECOG	2.76 ± 0.63	2.62 ± 0.623	2.85 ± 0.629	−0.47 to 0.01	0.060

The patients have been segregated into two groups based on the sleep score. Group 1 denoted patients with sleep score 60 or more, Group 2 denotes patients with sleep score less than 60. Independent sample student *t* test was applied.
ECOG, Eastern Cooperation Oncology Group.

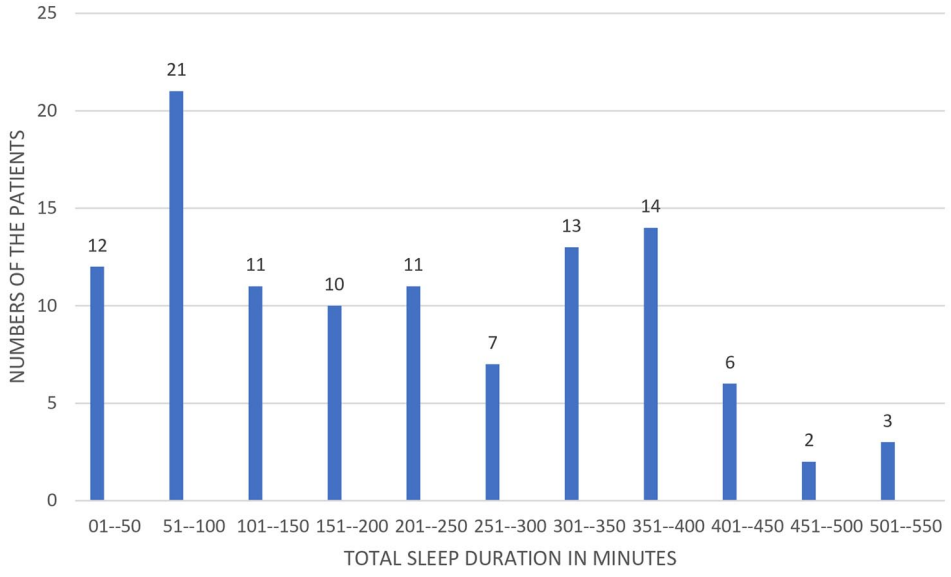

Figure 1. Bar diagram showing frequency of total sleep duration among the studied cohort.

23 had 41–50; 32 had 51–60; 13 had 61–70; 15 had 71–80; 4 had 81–90; and 6 patients had 91–100.

For the purpose of statistical analysis, we divided the patients into two groups based on the mean sleep score; those having a mean sleep score of more than 60 (non-poor sleep score) were denoted as group 1, and those having a sleep score of less than 60 (poor sleep score) were denoted as group 2. The consolidated and segregated demographic data are shown in Table 1. The two groups were comparable in age, weight, duration of illness, and ECOG functional status. Distribution of patients as per their sleep score is shown in Figure 1.

Table 2 depicts the data derived from the sleep-tracking device. In the cohort, the mean duration of sleep was 218 ± 139 min, total sleep duration in group 1 was significantly higher than in group 2. The duration of REM sleep was just 30 ± 34 min and was significantly higher in group 1. The duration of NREM sleep which included light and

Table 2. Showing various study parameters.

Parameters	Unsegregated *N* = 110	Group 1 (*N* = 42)	Group 2 (*N* = 68)	Statistical results	
	Mean ± SD	Mean ± SD	Mean ± SD	95% CI for difference in mean	*p* Value
Confusion score[a] (2)	2.72 ± 1.40	2.60 ± 1.63	2.81 ± 1.23	−0.80 to 0.37	0.470
Distress score[b]	5.58 ± 1.64	4.33 ± 1.58	6.35 ± 1.13	−2.53 to −1.50	0.000*
Depression score[c] (11)	11.06 ± 3.89	10.19 ± 4.05	11.60 ± 3.72	−2.91 to 0.08	0.064
Anxiety score[d] (11)	13.05 ± 3.72	12.02 ± 3.73	13.69 ± 3.60	−3.08 to −0.246	0.022*
PSQI[e] (5)	10.23 ± 3.45	7.19 ± 2.63	12.10 ± 2.41	−5.88 to −3.94	0.000*
Actual sleep time (min)	218.66 ± 139.05	260 ± 124.39	193.09 ± 142.29	14.16 to 119.8	0.013*
REM sleep (min)	30.44 ± 34.14	42.50 ± 33.52	23.04 ± 32.59	6.63 to 32.27	0.003
NREM sleep (min) (light + deep) sleep time	197.7 ± 115.91	216.95 ± 99.36	181 ± 123.75	−8.82 to 80.73	0.097
(a) Light sleep time (min)	171.36 ± 104	188.90 ± 91.31	160.53 ± 111.86	−12.29 to 69.04	0.170
(b) Deep sleep time (min)	23.36 ± 16.73	28.05 ± 16.42	20.47 ± 16.38	1.19 to 13.95	0.020*

[a]Bed side confusion score ⩾2 is considered as a confused state; [b]Distress score of 5 or more is abnormal; [c]Depression score ⩾11 is abnormal; [d]Anxiety score ⩾11 is abnormal; [e]PSQI score more than 5 is considered sleep disturbed.
*Indicates that a *p* value is less than 0.05 and is significant.
PSQI, Pittsburgh Sleep Quality Index.

deep sleep time was 197 ± 116 min and was comparable between the two groups; out of this, deep sleep time constituted a very small fraction.

The sleep quality over the past 1 month was assessed using the PSQI scale; the PSQI score in the cohort was 10.23 ± 3.45. In group 1, it was 7.19 ± 2.63; in group 2 it was 12.1 ± 2.4 (*p* value <0.001).

The bedside confusion score was high in both groups, it was comparable in both groups. Depression score indicated existence of moderate depression in cohort, the depression score was comparable in both groups. Moderate anxiety also existed in the cohort and the anxiety score was significantly higher in group 2. Moderate distress existed in the cohort and the distress score was significantly higher in group 2.

Correlation analysis as shown in Table 3 indicates that in-hospital sleep score had a high correlation with PSQI. Similarly, the distress score had a high and statistically significant correlation with sleep score. The correlation between sleep score and other scores, except confusion score was statistically significant but was weak. Apart from the sleep score, other sleep parameters do not correlate well with the anxiety, depression, and confusion scores. Binary status of opioid intake correlated weakly with the sleep score, confusion score, and distress score (Table 3).

Discussion

In this study, we prospectively studied the sleep pattern of HNC patients undergoing palliative chemotherapy and radiotherapy using a wrist-worn sleep-tracking device. We have found that sleep scores generated by wrist-worn sleep-tracking devices (Fitbit Charge 4) had a good correlation with PSQI. These patients were sleep deprived, both in quantity and quality. Stages 3 and 4 of NREM sleep and REM sleep were grossly reduced. These patients had moderate levels of anxiety, depression, confusion, and distress. Distress score was strongly correlated with the sleep score. Anxiety and depression had a weak but statistically significant correlation with the sleep score; confusion score seemed to be

Table 3. Table showing Pearson correlation coefficient between sleep score and other outcome parameters.

	Sleep score	Anxiety score	Depression score	PSQI	Confusion score	ECOG	Distress score
Sleep score	1	−0.248	−0.261	−0.864	−0.112	−0.205	−0.838
p Value		0.009*	0.006*	<0.001*	0.243	0.032*	<0.001*
Distress score	−0.838	0.294	0.296	0.752	0.201	0.186	1
p Value	<0.001*	0.002*	0.002*	0.000*	0.035*	0.052	
Depression score	−0.261	0.375	1	0.143	0.052	0.132	0.296
p Value	0.006	0.000		0.137	0.590	0.168	0.002
ECOG	−0.205	0.095	0.132	0.234	0.381	1	0.186
p Value	0.032	0.325	0.168	0.014	0.000		0.052
Opioid intake	−0.31	0.08	−0.16	−0.41	0.21	−0.12	0.21
p Value	0.002*	0.13	0.21	<0.001*	0.04*	0.12	0.04*

*A *p* value of less than 0.05 is statistically significant.
ECOG, Eastern Cooperation Oncology Group; PSQI, Pittsburgh Sleep Quality Index.

independent of the sleep score. ECOG physical status also had a weak but statistically significant correlation with sleep score.

Normally an individual sleeps for approximately 6–8 h and this sleep has various stages. Sleep begins with stage 1 NREM, which lasts approximately 1–7 min and constitutes 2%–5% of the total sleep duration. Stage 2 NREM follows stage 1 NREM and lasts for 10–25 min and constitutes 45%–55% of the total sleep duration. Stage 2 is characterized by sleep spindles and K-complexes. While sleep spindles are important for memory consolidation, K-complexes are associated with a burst of sympathetic nerve activity, which causes an increase in heart rate and blood pressure.[6,7] Stage 3 and 4 NREM, also called slow wave sleep (SWS) lasts only for a few minutes and constitutes 13%–23% of the total sleep duration.

In this study, we have found that sleep was grossly reduced (3.6 ± 2.3 h); the PSQI score which assesses sleep quality over past 1 month also indicated sleep deprivation. Wrist-worn sleep trackers tend to overestimate sleep duration, implying that actual duration of sleep is even lesser.[3–5]

Although a change in ambiance (being in a hospital ward, away from home setting) may be a significant contributor to acute sleep deprivation,[8] we speculate that its contribution in the studied cohort was less significant as the patients were sleep deprived even in the home setting. A previous polysomnography-based study ($N = 17$) showed that HNC patients have a high prevalence (76%) of obstructive sleep apnea before primary resection[9] and after surgery, 12% have sleep apnea.[10] Since most of the patients were receiving palliative treatment for HNC, the chances of Obstructive sleep apnea (OSA) are likely to be high. OSA disturbs the temporal stability of NREM and REM sleep, manifesting as shorter and more frequent bouts, without changing the "summary" polysomnography (PSG) metrics such as stage percentages and total sleep duration.[11]

In this study, we have found that stage percentages were also disturbed, hence something more than OSA must be at play.

Another important contributor to disturbed sleep is the physical symptoms. A high percentage (55%) of the patients had pain as the most common symptom and almost 75% of patients were using weak or strong opioids. Only 10% of patients were using antidepressants. The correlation between opioid intake status and sleep score was weak but statistically significant. This result suggests that opioid intake may play an important role in sleep disruption. Opioids have been found to significantly reduce REM sleep and SWS by

decreasing adenosine levels in the prefrontal cortex. It is no secret that when patients do not get a restorative sleep they are more likely to experience physical symptoms such as pain, leading to a self-perpetuating cycle of pain and insomnia.[12–14]

Corticosteroids which are also commonly used in cancer care also reduce the stage 4 NREM and REM sleep cycle while increasing the duration of stage 2 NREM sleep. Alpha-2 delta ligands such as pregabalin and gabapentin increase the duration of stage 3 and 4 NREM and may be useful adjuncts in pain management in cancer patients.[15]

Light NREM (Stages 1 and 2) is characterized by K-complexes, which have been associated with sympathetic stimulation. Deep NREM (stages 3 and 4) is associated with parasympathetic predominance. Sympathetic overactivity due to disruption of NREM sleep architecture can partially explain high anxiety in the cohort.[16]

REM sleep which normally constitutes 20%–25% of the total sleep time was significantly lower in the studied cohort (~14%). Since, stages 3 and 4 of NREM and REM sleep are important for the maintenance of emotional well-being and memory consolidation, the existence of moderate depression and confusion can be partially explained by the lack of it.[17]

Distress as measured on a distress thermometer is multifactorial; patients deprived of good quality sleep are more likely to experience distress.

To the best of the author's knowledge, this is the first study that has objectively measured sleep, and its quality in patients having HNC and who are under palliative treatment. The findings of the study highlight the special needs of patients having cancer. A disturbed sleep indicates the need for better symptom management and taking steps to make a treatment plan that is more holistic (incorporate ways to mitigate the spiritual, psychological, and social aspects of cancer management). The high incidence of sleep deprivation suggests need for better awareness among patients and caregivers with regard to sleep hygiene and various non-pharmacological ways of sleep improvement. Hospital wards keeping cancer patients should have a more comfortable ambiance, which prevents sleep disruptions for one reason or the other.

This pioneering study objectively assessed sleep and its quality in HNC patients undergoing palliative care, emphasizing their unique needs. Using Fitbit software, we gathered data on sleep duration, NREM and REM sleep, and a quality-based sleep score. This cohort was also evaluated for sleep patterns, anxiety, depression, and confusion. Fitbit's accuracy, compared favorably to polysomnography, along with its strong sensitivity and specificity, drove its selection as the preferred sleep-tracking device for this study.

Limitation of the study

The results of the study are for patients with head and neck malignancies only. Since the symptom complex and factors disturbing sleep in cancer of other regions are different, the sleep pattern may be different. Since most of the patients included in the study cohort were of lower socioeconomic status, there is a possibility that the results may vary as per the socioeconomic status. Sample size was small, a larger, multicentric study can validate the results of this study. Since algorithm of different sleep-tracking devices is different, the results may vary if a different device is used. For more generalizable results, a larger polysomnography-based study is the way forward, although feasibility of such a study will be an issue.

Conclusion

Based on the findings of this study, we can conclude that in patients undergoing palliative chemotherapy and radiotherapy for head and neck malignancies, pain is the most common physical symptom.

Wrist sleep-tracking devices have a strong correlation with validated and extensively used PSQI questionnaires; wrist-worn sleep-tracking devices can be a useful tool in tracking sleep-related issues even in palliative care settings. The quality of sleep in general is poor, duration of sleep is grossly inadequate; however, the composition of the sleep as determined by the REM/NREM ratio is less disturbed.

A significant proportion of patients are delirious and have coexisting anxiety and depression; these entities do not have any meaningful correlation with sleep score and hence are unlikely to improve with pharmacological and non-pharmacological interventions for improving sleep.

These patients have a high distress level and inadequate sleep seems to be an important contributor to overall distress, sleep improving interventions are likely to reduce the level of overall distress in the patients.

In patients undergoing palliative chemotherapy and radiotherapy for head and neck malignancies, the quality of sleep is poor and duration of sleep is grossly inadequate. However, the composition of the sleep as determined by the REM/NREM ratio is less disturbed and does not have any significant correlation with anxiety, depression, confusion, and distress scores.

Declarations

Author's note

We declare that the manuscript has been read and approved by all the authors that the requirements for authorship as stated for publication in the *Saudi Journal of Anesthesia* have been met, and that each author believes that the manuscript represents honest work.

Ethics approval and consent to participate

The study has been conducted according to the World Medical Association Declaration of Helsinki. The study has been approved by the Institutional Human Ethics Committee. Written informed consent had been obtained from the study participants.

Consent for publication

Not applicable.

Author contributions

Anuj Jain: Conceptualization; Data curation; Formal analysis; Funding acquisition; Investigation; Methodology; Project administration; Resources; Software; Supervision; Validation; Visualization; Writing – original draft; Writing – review & editing.

Jha Suryavanshi: Conceptualization; Data curation; Formal analysis; Funding acquisition; Investigation; Methodology; Project administration; Resources; Software; Supervision; Validation; Visualization; Writing – original draft; Writing – review & editing.

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Competing interests

The authors declare that there is no conflict of interest.

Availability of data and materials

The data file has been as provided as Supplemental Material. The data can be accessed from the Supplemental Material.

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Supplemental material

Supplemental material for this article is available online.

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