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$TcPO_2$ changes are more pronounced than SpO_2 changes during simulated altitude changes in a hypobaric oxygen chamber: a nonrandomized controlled trial

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Abstract

Background: Hypoxia is a significant risk factor of hypertension. However, no studies have used transcutaneous tissue partial pressure of oxygen ($TcPO_2$) and partial pressure of carbon dioxide ($TcPCO_2$) monitors to measure the respective partial pressures in healthy individuals. Oxygen saturation (SpO_2) is often used for traditional monitoring of vital signs. This study investigated the changes in $TcPO_2$ and SpO_2 values during rapid changes in altitude. The trial was registered at ClinicalTrials.gov (registration no. NCT06076057).

Methods: Healthy adult volunteers were instructed to sit vertically in a hypobaric oxygen chamber, which ascended from 0 m to 2500 m at a uniform speed within 10 min. The Danish Radiometer TCM4 was used to measure $TcPO_2$ and $TcPCO_2$ with the ventral side of the upper arm as the measurement site. The Shenzhen Kerokan P0D-1 W pulse oximeter was used to measure heart rate and SpO_2, with values recorded once every 500 m.

Results: Altogether, 49 healthy volunteers were recruited between March 2023 and August 2023. With increasing altitude, $TcPO_2$ and SpO_2 decreased significantly ($P < 0.01$). During the ascent from 0 m, $TcPO_2$ began to change statistically at 500 m ($P < 0.05$), whereas SpO_2 began to change statistically at 1000 m ($P < 0.05$). At the same altitude, the difference in $TcPO_2$ was greater than the difference in SpO_2. At 1000 m, there were statistically significant changes in $TcPO_2$ and SpO_2 ($P < 0.001$). At altitudes >500 m, statistical significance was identified between $TcPO_2$ in both sexes ($P < 0.05$). Statistical significance in $TcPCO_2$ and heart rate was observed at the different elevations ($P < 0.05$).

Conclusion: In acutely changing low-pressure hypoxic environments, $TcPO_2$ changed more dramatically than SpO_2.

Keywords: Altitude change, Low-pressure oxygen chamber, Transcutaneous oxygen saturation, Transcutaneous partial pressure of oxygen

Introduction

An International Air Transport Association report has predicted 4.35 billion airplane trips worldwide by 2023. The cruising altitude range of airliners is maintained at approximately 8500–13,000 m.[1] Owing to various factors such as the machinery itself, passenger safety, and economic considerations, the cabin is artificially maintained at a pressure level equivalent to the oxygen content available in the atmosphere at an altitude of 2438 m (approximately 8000 ft) above sea level.[2,3] Under these conditions, healthy individuals have decreased blood oxygen levels.[4] The hypoxia challenge test can be used to assess the risk of hypoxia during a flight by simulating the hypoxic state. It is currently used in preflight hypoxia risk assessments in patients with chronic cardiopulmonary disease in some countries in Europe and the United States; however, no relevant literature reports in China have been published. Whether the body is hypoxic depends on the amount of oxygen transported by tissues and the ability of the oxygen reserves to meet the needs of aerobic metabolism. We need to identify patients who require timely preflight hypoxia risk assessments, provide them with respiratory support therapy, or arrange reasonable transportation for travel to avoid emergencies. Currently, scholars are exploring simple, feasible, noninvasive, or minimally invasive methods and indicators that can be used to predict flight-risk patients. Some scholars have used heart rate (HR) and HR variability,[5] to predict the risk of flight hypoxia. In addition, some scholars have reported that the risk of flight hypoxia can be assessed by combining the arterial oxygen saturation (SpO_2) level at rest and the lowest pulse oximetry level during the 6-minute walk test.[6]

The transcutaneous tissue partial pressures of oxygen and carbon dioxide, $TcPO_2$ and $TcPCO_2$, respectively, provide real-time and continuous responses to the oxygenation capacity of the body's tissues and play an important role in understanding the perfusion of the body's

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The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Table 1

Baseline Characteristics

Variables	Frequency	Age	Height (m)	Weight (kg)	BMI (kg/m^2)
Total	49	23.5 ± 2.2	1.69 ± 0.09	64.2 ± 13.3	22.28 ± 3.48
Age groups					
Male	25 (51%)	23.0 ± 2.1	1.76 ± 0.06	70.9 ± 12.2	22.96 ± 3.61
Female	24 (49%)	23.0 ± 2.3	1.63 ± 0.06	57.2 ± 10.7	21.56 ± 3.26
t	—	−1.615	7.759	4.166	1.428
P	—	0.113	<0.001	<0.001	0.160
BMI groups					
<18.5	6 (12.2%)	22.8 ± 2.3	1.69 ± 0.06	49.2 ± 4.6	17.15 ± 0.72
18.5–24.9	33 (67.3%)	23.7 ± 2.3	1.68 ± 0.09	61.8 ± 10.2	21.65 ± 1.84
≥25	10 (20.4%)	23.0 ± 2.0	1.72 ± 0.08	81.1 ± 8.7	27.42 ± 1.94
F	—	0.644	0.621	24.819	68.860
P	—	0.530	0.542	<0.001	<0.001

Data are n(%) or mean ± SD.

BMI, body mass index.

microcirculation, the function of blood in transporting oxygen, and the function of the circulatory system.[7] $TcPO_2$ monitoring can be used to identify significant injuries, illnesses, and outcomes in patients admitted to the emergency department.[8] $TcPO_2$ and $TcPCO_2$ are often used to assess stress injury risk [9] in patients with respiratory and cardiac diseases, peripheral vascular diseases, and diabetes mellitus.[10–12] No studies have used $TcPO_2$ and $TcPCO_2$ to monitor changes in the partial pressures of oxygen and carbon dioxide during flights or rapid changes in altitude. SpO_2 is often used in traditional vital-sign monitoring. The fact that SpO_2 drops only at very low PO_2 values is also known from conventional blood gas analyses. Therefore, in the absence of large changes in oxygen levels in the body, SpO_2 does not reflect the timely changes in oxygen levels.

In conclusion, $TcPO_2$ and $TcPCO_2$ can reflect the oxygen supply capacity of tissues; however, no studies have used them in specific scenarios to monitor a healthy population. This study investigated the characteristics of $TcPO_2$ and $TcPCO_2$ under rapid changes in altitude and compared them with the commonly used index of SpO_2 to identify differences.

Materials and methods

Ethical statement

The trial was approved by the Ethics Committee on Scientific Research of Shandong University Qilu Hospital (ethical approval no. KYLL-202209-041) and registered at ClinicalTrials.gov (registration no. NCT06076057).

Study participants

The inclusion criteria were participants aged 19–30 years; with no history of coronary heart disease, hypertension, asthma, upper respiratory tract infections, decompression sickness, anemia, or ear disorders; no entry into highland areas within 2 years; and no medication taken during the trial period. All the study participants provided written informed consent.

Participants with severe heart disease and arrhythmia, organ failure, evident generalized edema, dermatosis, generalized skin breakdown, and limb vascular disorders were excluded from the study.

Methods

During the operative procedure, general information of the participants, including age, sex, height, weight, history of illness, and current physical complaints, was collected. Prior to test initiation, gas correction was performed, and the electrodes were worn by the volunteers according to the prescribed procedure, with the wearing site uniformly on the ventral side of the forearm. The values were monitored for 15 to 20 min to stabilize before proceeding. Healthy adult volunteers entered the hypobaric oxygen chamber, sat vertically, and ascended from 0 m to 2500 m at a uniform speed within 10 min. The Danish Radiometer TCM4 was used to measure $TcPO_2$ and $TcPCO_2$ with the ventral side of the upper arm as the measurement site. The Shenzhen Kerokan P0D-1 W pulse oximeter was used to measure the HR and SpO_2 values, with the values recorded once every 500 m. During the course of the test, the participants stopped immediately

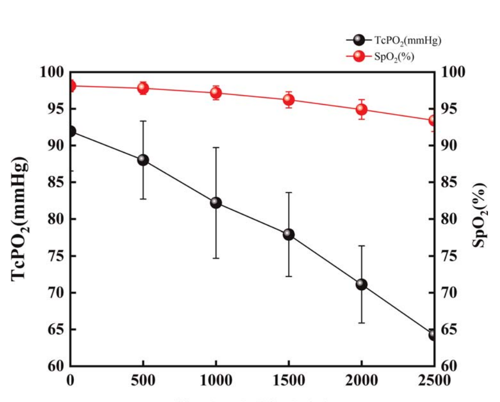

Figure 1. Comparison of trends in $TcPO_2$ and SpO_2 at different altitudes. SpO_2, oxygen saturation; $TcPO_2$, transcutaneous oxygen partial pressure.

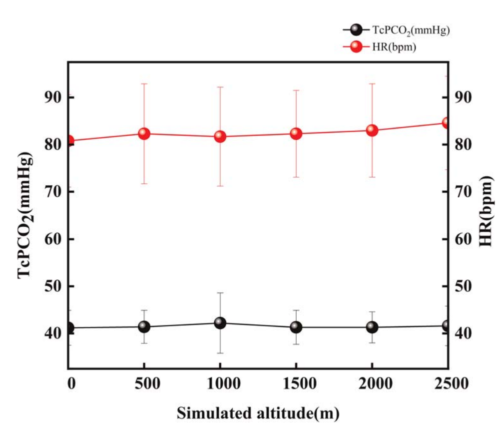

Figure 2. Comparison of trends in $TcPCO_2$, HR at different altitudes. HR, heart rate; $TcPCO_2$, transcutaneous carbon dioxide partial pressure.

Table 2

Measurements of $TcPO_2$, $TcPCO_2$, HR, and SpO_2 at Different Simulated Altitudes

Simulated Altitudes (m)	$TcPO_2$ (mmHg)	$TcPCO_2$ (mmHg)	HR (bpm)	SpO_2 (%)
0	91.9 ± 5.4[*†‡§‖]	41.2 ± 3.7[‖¶#**††]	80.8 ± 9.8[‖¶#**§]	98 (98,99)[‖¶†‡§]
500	88.0 ± 5.3[†‡§‖‡‡]	41.4 ± 3.5[**††‖#§§]	82.3 ± 10.6[#**††§§‖‖]	98 (97,98)[‡§‖#§§]
1000	82.8 ± 5.5[*‡§‖‡‡]	42.4 ± 3.5[‖¶**††§§]	81.7 ± 10.5[‖¶**††§§]	97 (97,98)[§‖¶**‡‡]
1500	77.7 ± 5.2[*†§‖‡‡]	41.3 ± 3.6[‖¶#††§§]	82.3 ± 9.2[‖¶#††§§]	96 (95,97)[*§‖#‡‡]
2000	71.1 ± 5.3[*†‡‖‡‡]	41.3 ± 3.3[¶#**‖§§]	83.0 ± 9.9[¶#**‡‡‖‖]	95 (94,96)[*†‡‡‡‖‖]
2500	64.6 ± 4.7[*†‡§‡‡]	39.5 ± 2.5[*†‡§‡‡]	84.6 ± 9.9[†‡¶††‡‡]	93 (92,95)[*†‡††‡‡]
F	1346.088	11.860	3.088	224.470
P	<0.001	<0.001	0.010	<0.001

Data are mean ± SD.

$TcPO_2$, $TcPCO_2$, and HR values were mean ± SD; SpO_2 values were median (interquartile spacing).

*Values are significantly different when compared with 500 m ($P < 0.05$).

†Values are significantly different when compared with 1000 m ($P < 0.05$).

‡Values are significantly different when compared with 1500 m ($P < 0.05$).

§Values are significantly different when compared with 2000 m ($P < 0.05$).

‖Values are significantly different when compared with 2500 m ($P < 0.05$).

¶Values are not significantly different when compared with 500 m ($P > 0.05$).

#Values are not significantly different when compared with 1000 m ($P > 0.05$).

**Values are not significantly different when compared to 1500 m ($P > 0.05$).

††Values are not significantly different when compared with 2000 m ($P > 0.05$).

‡‡Values are significantly different when compared with 0 m ($P < 0.05$).

§§Values are not significantly different when compared with 0 m ($P > 0.05$).

‖‖Values are not significantly different when compared with 2500 m ($P > 0.05$).

HR, heart rate; SD, standard deviation; SpO_2, oxygen saturation; $TcPCO_2$, transcutaneous carbon dioxide partial pressure; $TcPO_2$, transcutaneous oxygen partial pressure.

if they experienced symptoms of discomfort such as tinnitus, dizziness, headache, dyspnea, or chest pain.

Sample size calculation: For comparison of the same index at different altitudes, group comparison of the same index at the same altitude, and comparison of measurement data in multiple groups using repeated-measurements analysis of variance (ANOVA), set 2-sided $\alpha = 0.05$, effect size $f = 0.25$, and the power is 0.95, in this study, the maximum grouping is 3 groups, and the number of the measurements is 6 times, in order to obtain a larger sample size, the correlation coefficient of intra-group is 0, and the nonsphericity correction is $1/(6 - 1) = 0.2$. Using G*Power 3.1 software (Franz Faul, Universität Kiel, Germany) for calculations, the total sample size was 210, and the number of repeated measurements was 6 times, so $210/6 = 35$ people, and the number of experimental subjects was 35. Considering factors such as refusal or withdrawal, additions were calculated at 20%; the calculated sample size was $35/(1 - 20\%) = 44$ cases, and 49 cases were finally included.

Statistical analysis

The IBM SPSS Statistics (version 26.0; IBM Corp, Armonk, NY, USA) software was used for data processing and analysis. Categorical information is expressed as n (%), and measurement information conforming to normal distribution is expressed as means ± standard deviations (SD), the independent-sample *t* test was used for continuous variables categorized by gender, and repeated-measures ANOVA was used to compare the data across different elevations. Measures that were not normally distributed were expressed as medians (interquartile ranges); the Friedman test was used to compare the data across different elevations. Post hoc 2 × 2 comparisons were performed using the Bonferroni correction method and Nemenyi test. Differences were considered statistically significant at $P < 0.05$. Graphs were created using Origin 2021 software (Origin Lab Corporation, Northampton, MA, USA).

Results

Baseline characteristics

From March 2023 to August 2023, 49 volunteers were eligible for inclusion in the study. All the volunteers completed the entire process and did not experience significant injuries or unintended effects. Table 1 summarizes the characteristics of the 49 volunteers.

Comparison of $TcPO_2$, $TcPCO_2$, HR, and SpO_2 measurements at different altitudes

A significant decrease in $TcPO_2$ and SpO_2 was observed with increasing altitude (Fig. 1), with a slight overall decrease in $TcPCO_2$

Table 3

Comparison of the Variability of $TcPO_2$ and SpO_2

Variables	δ	CV
$TcPO_2$		
0 m	29.27	5.9%
500 m	28.27	6.0%
1000 m	29.74	6.6%
1500 m	27.38	6.7%
2000 m	27.57	7.4%
2500 m	22.36	7.3%
SpO_2		
0 m	0.651	0.8%
500 m	0.707	0.9%
1000 m	0.889	1.0%
1500 m	1.219	1.2%
2000 m	1.802	1.4%
2500 m	2.247	1.7%

δ, variance. CV, coefficient of variation; SpO_2, oxygen saturation; $TcPO_2$, transcutaneous oxygen partial pressure.

Table 4

Comparison of Changes in $TcPO_2$ with Changes in SpO_2

Groups	$TcPO_2$ (mmHg)	SpO_2 (%)	*t*	*P*
500–1000 m	–0.06 ± 0.02	–0.01 ± 0.01	–16.234	<0.001
1000–1500 m	–0.06 ± 0.02	–0.01 ± 0.01	–15.549	<0.001
1500–2000 m	–0.08 ± 0.02	–0.01 ± 0.01	–20.595	<0.001
2000–2500 m	–0.09 ± 0.03	–0.02 ± 0.01	–19.063	<0.001

Data are mean ± SD.

SpO_2, oxygen saturation; $TcPO_2$, transcutaneous oxygen partial pressure.

and increase in HR (Fig. 2). $TcPO_2$ and SpO_2 differed significantly between altitudes ($P < 0.001$), and in the post hoc comparison, during the ascent from 0 m, $TcPO_2$ began to change statistically at 500 m ($P < 0.05$), whereas SpO_2 began to change statistically at 1000 m ($P < 0.05$) (Table 2). At the same altitude, the differences in $TcPO_2$ were larger than the differences in SpO_2 (Table 3). To further explore whether changes in $TcPO_2$ differed from changes in SpO_2 during changes in altitude, several heights were selected, for example, 500 and 1000 m; the $TcPO_2$ and SpO_2 data of everyone were standardized, and the difference between the 2 heights data was divided by the data standardization at the first height. This yielded statistical significance between the change in $TcPO_2$ and the change in SpO_2 ($P < 0.001$), which was greater than that in blood SpO_2 (Table 4).

Comparison of $TcPO_2$ and SpO_2 by sex at different altitudes

Statistical significance in $TcPO_2$ was observed between sexes at altitudes >500 m ($P < 0.05$) (Table 5); the $TcPO_2$ of females was generally higher than that of males (Fig. 3). The statistical significance was more significant at higher altitudes (2500 m, $P < 0.001$) (Table 5). Only at simulated altitudes of 1000 m and 1500 m was there statistical significance in SpO_2 between the sexes ($P < 0.05$) (Table 5), and females had slightly higher SpO_2 than males (Fig. 3).

Comparison of $TcPO_2$ and SpO_2 at different altitudes in different body mass index subgroups

According to the body mass index (BMI) grouping standard of the World Health Organization [13] and the characteristics of the study population, the study population was divided into 3 groups as follows: BMI <18.5 group (6 people), BMI = 18.5–24.9 group (33 people), BMI ≥25 group (10 people). $TcPO_2$: Muchly's $W = 0.172$, $P < 0.001$, did not meet the spherical test. Therefore, the corrected Greenhouse-Geisser results prevailed. The main effect of elevation was significant, $F = 801.770$, $P < 0.001$, partial $\eta^2 = 0.946$; the main effect of BMI grouping was not significant, $F = 1.331$, $P = 0.274$, partial $\eta^2 = 0.055$; the interaction effect of elevation and BMI subgroup was not significant, $F = 1.667$, $P = 0.144$, partial $\eta^2 = 0.068$. SpO_2: Muchly $W = 0.294$, $P < 0.001$, did not meet the spherical test. Therefore, the corrected Greenhouse-Geisser results prevailed. The main effect of elevation was significant, $F = 207.223$, $P < 0.001$, partial $\eta^2 = 0.818$; the main effect of BMI grouping was not significant, $F = 0.596$, $P = 0.555$, partial $\eta^2 = 0.025$; and the interaction effect of elevation and BMI subgroup was not significant, $F = 0.800$, $P = 0.582$, partial $\eta^2 = 0.034$ (Table 6).

Discussion

As the altitude increased, and the barometric pressure decreased, the supply of oxygen to the tissues decreased.[14] At higher altitudes, the lower barometric pressure makes it difficult for oxygen to diffuse into the vascular system, which can lead to oxygen deprivation or hypoxia, known as hypoxic hypoxia.[15] Pulmonary ventilation studies have been conducted in low-pressure chambers at various simulated altitudes.[16–18] However, ventilation tests may not be effective discriminators. Higher altitudes lead to lower PaO_2 levels[19] and have a significant effect on SpO_2,[20,21] which is supported by the results of this study. In the present study, $TcPO_2$ demonstrated a strong sensitivity to changes in tissue oxygen, with a decrease of

Table 5

Comparison of $TcPO_2$ and SpO_2 by Sex at Different Altitudes

Variables	Male	Female	*t*/*U*	*P*
$TcPO_2$ (mmHg)				
0 m	90.6 ± 5.1	93.3 ± 5.5	–1.752	0.086
500 m	86.5 ± 4.7	89.6 ± 5.6	–2.085	0.043
1000 m	81.0 ± 4.5	84.8 ± 5.8	–2.570	0.013
1500 m	75.7 ± 4.2	79.8 ± 5.5	–2.964	0.005
2000 m	69.1 ± 4.5	73.2 ± 5.3	–2.932	0.005
2500 m	62.3 ± 3.5	67.0 ± 4.7	–4.004	<0.001
SpO_2 (%)				
0 m	98 (97.5,98)	98 (98,99)	–0.931	0.352
500 m	98 (97,98)	98 (97,99)	–1.909	0.056
1000 m	97 (96,97)	97 (97,98)	–2.247	0.025
1500 m	96 (95,96)	97 (96,97)	–3.029	0.002
2000 m	94.6 ± 1.3	95.2 ± 1.3	–1.386	0.172
2500 m	93.2 ± 1.4	93.6 ± 1.6	–0.992	0.326

Data are mean ± SD or median (IQR).

$TcPO_2$ and SpO_2 in 2000 m and 2500 m values were mean ± SD; SpO_2 in 0 m, 500 m, 1000 m, and 1500 m values were median (interquartile spacing). SD, standard deviation; SpO_2, oxygen saturation; $TcPO_2$, transcutaneous oxygen partial pressure.

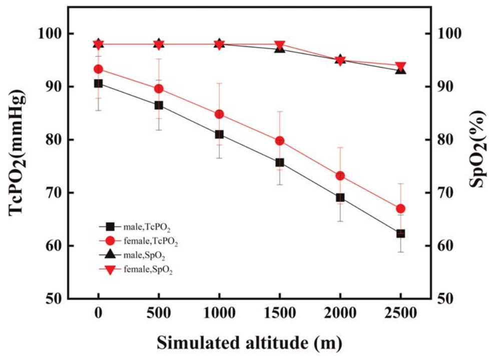

Figure 3. Comparison of $TcPO_2$ and SpO_2 by sexes at different altitudes. SpO_2, oxygen saturation; $TcPO_2$, transcutaneous oxygen partial pressure.

6–7 mmHg for every 500-m increase in altitude. At 500 m, $TcPO_2$ began to decrease significantly, whereas SpO_2 decreased gradually without a significant downward trend until it reached 95%. The $TcPO_2$ varied significantly not only between altitudes, but also between individuals at the same altitude (Table 3), indicating that the mean value at this altitude fluctuated by 10 mmHg. Moreover, these individuals were young and approximately the same age, which reflects individual differences. SpO_2 did not reflect large individual differences.

In the present study, statistical significance in $TcPO_2$ was observed between the sexes at the same altitude. $TcPO_2$ and SpO_2 were higher, and interindividual differences were more pronounced in females than in males. The decrease in $TcPO_2$ was more pronounced in males than in females at increasing altitudes, and SpO_2 was less pronounced in this respect. These differences may be related to differences in lung function indices between sexes. A previous study reported sex differences in lung function, which may be related to fat distribution.[22] Higher waist-to-hip ratios have been demonstrated to be associated with gas exchange[23]; men tend to have more thoracic and abdominal fat than women, and higher thoracic obesity is associated with lower expiratory reserve volume.[24] Overall, these 2 studies support the hypothesis of sex-related differences. These findings are consistent with those of previous studies.[25]

Although a previous study stated that the release of fat may affect $TcPO_2$ values, the current study revealed a difference in the $TcPO_2$ values between different BMI subgroups, indicating that the $TcPO_2$ values of people who were slightly thinner and overweight were lower than those with normal weight. However, the P value was >0.05, which was not statistically different, and this may be related to the fact that after grouping by BMI, the number of people in the groups was small. Further studies are required with larger sample sizes.

Thus, although the detection principle is different, it can more effectively reflect the oxygen supply of blood or tissue by noninvasive, real-time monitoring compared with the traditional monitoring of vital signs. Blood SpO_2 is generally used, although we observed that it often changes when the body is abnormal; the $TcPO_2$ at the tissue level of oxygen supply is reduced, and SpO_2 in the blood does not decrease significantly, which can provide an early warning.

Limitations

A limitation of this study is that $TcPO_2$ and $TcPCO_2$ monitors may cause unavoidable systematic errors in the oxygen chamber. Nevertheless, the values were still informative for the same-altitude scenarios. Considering age concentration and average age, the study participants were relatively young, which is another study limitation; other age groups can be introduced for comparison in subsequent studies.

Conclusion

Transcutaneous tissue partial pressure of oxygen has been shown to promptly reflect changes in the tissue partial pressure of oxygen

Table 6

Comparison of $TcPO_2$ and SpO_2 at Different Altitudes in Different BMI Subgroups

Variables	BMI < 18.5	BMI = 18.5–24.9	BMI ≥ 25	F	P	Partial η^2
$TcPO_2$ (mmHg)						
0 m	88.3 ± 2.4	93.1 ± 4.9	90.3 ± 7.2			
500 m	84.7 ± 1.0	88.9 ± 4.9	87.2 ± 7.3			
1000 m	79.5 ± 2.7	83.6 ± 5.4	82.2 ± 6.5			
1500 m	75.3 ± 2.9	78.4 ± 5.2	76.9 ± 6.2			
2000 m	69.5 ± 2.4	71.5 ± 5.5	70.9 ± 5.8			
2500 m	63.8 ± 2.8	65.2 ± 5.1	63.3 ± 4.3			
Altitude				801.770	<0.001	0.946
BMI				1.331	0.274	0.055
Altitude × BMI				1.667	0.144	0.068
SpO_2 (%)						
0 m	97.8 ± 0.8	98.2 ± 0.8	98.0 ± 0.8			
500 m	97.7 ± 1.0	97.9 ± 0.8	97.5 ± 0.7			
1000 m	97.0 ± 1.3	97.2 ± 0.9	97.0 ± 0.9			
1500 m	96.0 ± 1.8	96.4 ± 1.0	95.8 ± 1.0			
2000 m	94.8 ± 1.8	94.9 ± 1.3	94.8 ± 1.1			
2500 m	93.8 ± 1.7	93.5 ± 1.5	92.9 ± 1.4			
Altitude				207.223	<0.001	0.818
BMI				0.596	0.555	0.025
Altitude × BMI				0.800	0.582	0.034

Data are mean ± SD.

$TcPO_2$ and SpO_2 values were mean ± SD.

BMI, body mass index; SD, standard deviation; SpO_2, oxygen saturation; $TcPO_2$, transcutaneous oxygen partial pressure.

during changes in altitude, better reflecting individual differences and allowing for noninvasive real-time monitoring.

Conflict of interest statement

The authors declare no conflict of interest.

Author contributions

Li Y, Chen L, Luan X, and Ma D participated in research design. Li Y, Chen L, Fu Z, and Wang Z participated in the writing of the paper. Li Y and Fu Z participated in the performance of the research. Chen L, Sun S, and Hu T contributed new reagents or analytic tools. Li Y, Fu Z, and Wang Z participated in data analysis.

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Ethical approval of studies and informed consent

All procedures performed in this study involving human participants were in accordance with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The trial was approved by Ethics Committee on Scientific Research of Shandong University Qilu Hospital (no. KYLL-202209-041, 2022.11.29). Written informed consent was obtained from all participants included in the study.

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