Transcutaneous oximetry: normal values for the lower limb

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Abstract

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Introduction: Current guidelines for transcutaneous oximetry measurement (TCOM) for the lower limb define tissue hypoxia as a transcutaneous oxygen partial pressure < 40 mmHg. Values obtained with some newer machines and current research bring these reference values into question.

Aim: To determine 'normal' TCOM values for the lower limb in healthy, non-smoking adults using the TCM400 oximeter with tc Sensor E5250.

Method: Thirty-two healthy, non-smoking volunteers had TCOM performed at six positions on the lower leg and foot. Measurements were taken with subjects lying supine breathing air, then with leg elevated and whilst breathing 100% oxygen.

Results: Room-air TCOM values (mean mmHg, 95% confidence interval (CI)) were: lateral leg 41.3, CI 37.8 to 44.7; lateral malleolus 38.6, CI 34.1 to 43.1; medial malleolus 43.9, CI 40.2 to 47.6; dorsum, between first and second toe 39.3, CI 35.9 to 42.7; dorsum, proximal to fifth metatarsal-phalangeal joint 46.4, CI 43.4 to 49.3; plantar 52.3, CI 49.6 to 55.1. Using the currently accepted value of less than 40 mmHg for tissue hypoxia, 24 of our 32 'healthy' subjects had at least one air sensor reading that would have been classified as hypoxic. Seventeen subjects had TCOM values less than 100 mmHg when breathing 100% normobaric oxygen.

Conclusion: Normal lower limb TCOM readings using the TCOM400 with tc Sensor E5250 may be lower than 40 mmHg, used to define tissue hypoxia, but consistent with the wide range of values found in the literature. Because of the wide variability in TCOM at the different sensor sites we cannot recommend one TCOM value as indicative of tissue hypoxia. A thorough clinical assessment of the patient is essential to establish appropriateness for hyperbaric oxygen treatment, with TCOM used as an aid to help guide this decision, but not as an absolute diagnostic tool.

Key words

Transcutaneous oximetry, hyperbaric oxygen therapy, wounds, patient monitoring, standards

Introduction

Transcutaneous oximetry measurement (TCOM) is the process of measuring the tissue partial pressure of oxygen through the skin. The technique was originally used in neonatology but has now become an essential component of wound assessment in hyperbaric medicine.[1] TCOM estimates tissue oxygenation non-invasively by measuring the diffusion of extracellular oxygen into a heated sensor on the skin. Confirmation of tissue hypoxia and demonstrated responsiveness of the tissue to oxygen in the area surrounding a wound allows selection of patients most likely to benefit from hyperbaric oxygen treatment (HBOT).[2] TCOM also provides useful information for patients requiring further vascular assessment and assists in determining amputation levels.[3]

Previous studies of TCOM in healthy individuals found values in the lower limb varied from 48 to 79 mmHg.[4–7] Values obtained with some newer machines and sensors bring these values into question. Reviews have defined lower limb hypoxia as a transcutaneous oxygen partial pressure ($P_{tc}O_2$) of less than 40 mmHg.[2,8,9] However, this single reference value may not be an accurate normal value for all points on the lower limb. A recent study found different 'normal' TCOM values for different areas of the upper limb.[10] As TCOM values are currently considered fundamental in determining suitability of patients for HBOT, it is essential to know normal reference values. The aim of this study was to establish normal TCOM values in various areas of the lower limb in healthy, non-smoking adult subjects.

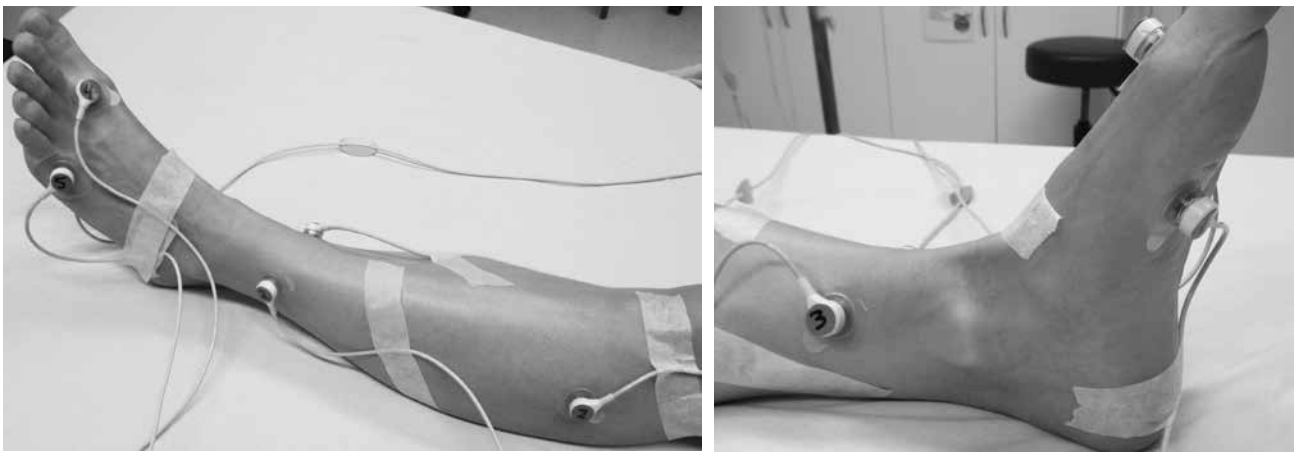
Methods

Ethics approval for this study was granted by the Human Research Ethics Committee of the Townsville Hospital and Health Service (HREC/12/QTHS/209). Thirty-two (16 male, 16 female) healthy volunteers were recruited from the hospital staff and general population to participate in the study. Exclusion criteria included subjects younger than 18 years old; current or former smoker; known cardiovascular disease including treated or untreated hypertension; significant respiratory disease or any other significant medical condition. Subjects with only one leg, significant scarring, or a skin condition on the lower limb, were also excluded. As subjects were required to have a plastic hood placed over their head to receive oxygen during part of the study, severe claustrophobia was a further exclusion criterion.

All participants were given a study information sheet and informed consent was obtained. Subjects refrained from consuming food or caffeine or performing heavy exercise

Figure 1

Transcutaneous oximetry measurement: placement of the six sensors on the lower limb
Sensor 1 – 10 cm distal to the lateral femoral epicondyle
Sensor 2 – 5 cm proximal to the anterior aspect of the lateral malleolus
Sensor 3 – 5 cm proximal to the centre of the medial malleolus
Sensor 4 – Dorsum of the foot between the 1st and 2nd metatarsal heads away from any obvious veins
Sensor 5 – Dorsum of the foot proximal to the head of the 5th metatarsal
Sensor 6 – Plantar 1st metatarsal area (proximal to the fat pad at the base of the great toe)



for two hours prior to participating in the study. The study was performed at sea level. Subjects were placed in a supine position on a hospital bed with their head slightly raised on one pillow for the duration of the study. They were offered a blanket for comfort and to limit any vasoconstrictive effects of being cold. The room temperature was maintained between 22.0 and 22.5^{O}C (the ambient temperature recommended by the TCOM manufacturer). The participants rested quietly while the sensors were placed.

Basic demographic data were collected including height and weight. Oxygen saturation and blood pressure were measured on both arms. Dorsalis pedis and posterior tibial pulses were recorded for both legs. Ankle brachial index (ABI) and toe pressures were also measured.

Participants were randomized to have six sensors placed on either their right or left leg (Figure 1). The sensor sites were prepared by shaving hair if necessary, wiping clean, rubbing with an alcohol swab and drying with gauze. One sensor was positioned 10 cm distal to the lateral femoral epicondyle and two sensors were each placed 5 cm proximal to the lateral and medial malleoli. Two sensors were placed on the dorsum of the foot attempting to avoid large superficial vessels, one between the first and second metatarsal heads and the second proximal to the fifth metatarsal-phalangeal (MTP) joint. The final sensor was placed on the plantar aspect of the foot proximal to the first metatarsal-phalangeal joint. The leads were secured in place with tape to prevent pull on the sensors. Subjects were requested to keep talking to a minimum during the study.

All TCOM assessments were performed by the same technician using the TCM400 Transcutaneous (tc) pO_2 Monitoring System with tc Sensor E5250 (Radiometer Medical ApS, Bronshoj, Denmark) which can record $P_{tc}O_2$ data from six tc E5250 sensors simultaneously. The electrode temperatures were pre-set to 44^{O}C and atmospheric and zero-point electrode calibrations were performed as per the manufacturer's recommendations. A humidity correction factor was calculated from the room temperature, saturated water vapour pressure and relative humidity, and input into the machine according to the TCM400 operator's manual.[11] The TCM400 displays $P_{tc}O_2$ values in units of mmHg.

We used the TCOM protocol described by Sheffield, which has been used historically in hyperbaric medicine to identify tissue hypoxia and responsiveness to hyperoxia.[12,13] Initial normobaric, room-air readings from all sensors were recorded after a minimum 20-minute equilibration period that allowed all sensors to stabilize.[4] The leg was then elevated 45° above its resting level and placed on a foam wedge, with sensor readings recorded after 5 minutes. The leg was returned to the horizontal position for a minimum 5-minute period allowing all sensor readings to re-stabilize, and another set of readings were recorded to ensure TCOM had returned to baseline. The subjects then breathed 100% oxygen at a flow rate of 15 L·min^{-1} for 10 minutes via a clear plastic hood with a soft neck seal, with sensor readings recorded at the end of the 10-minute period, once stabilized (a pilot study demonstrated that 10 minutes was sufficient to reach stable levels). All sites were inspected for thermal injury. All collected data were de-identified and entered

Table 1
Demographic and baseline characteristics of the 32 subjects; means and SD or number (n) shown;
* $P < 0.05$ for difference between male and female

Variable	Males (n = 16)		Females (n = 16)		All (n = 32)	
Age (years) *	45.1	(10.6)	53.8	(12.3)	49.4	(12.1)
< 50 years old (n)	5		10		15	
Body mass index (kg·m^{-2})	27.2	(2.9)	27.2	(3.8)	27.2	(3.3)
Normal weight (BMI = 20–25) (n)	3		4		7	
Overweight (BMI > 25–30) (n)	11		9		20	
Obese (BMI > 30) (n)	2		3		5	
Systolic BP (L) (mmHg) *	124	(7)	117	(9)	121	(9)
Systolic BP (R) (mmHg)	124	(8)	120	(11)	122	(10)
Diastolic BP (L) (mmHg) *	80	(9)	72	(6)	76	(9)
Diastolic BP (R) (mmHg)	76	(6)	73	(6)	74	(6)
SpO_2 (L) (%) *	97.4	(1.0)	98.4	(1.1)	97.9	(1.2)
SpO_2 (R) (%)	97.7	(1.1)	98.3	(1.0)	98.0	(1.1)
Heart rate (beats·min^{-1})	68	(9)	65	(14)	66	(12)
Ankle brachial index	1.09	(0.07)	1.08	(0.07)	1.09	(0.07)
Toe brachial index	0.78	(0.11)	0.78	(0.15)	0.78	(0.13)
Toe systolic BP (mmHg)	98.5	(15.4)	94.6	(17.7)	96.5	(16.5)

into a pre-formatted Excel spreadsheet. These data were then exported into Stata Statistical Software: Release 11 (StataCorp LP, College Station, TX, USA) for analysis.

ANALYSIS

The primary outcome of this study was a determination of the normal range of TCOM readings when measured at various places on the leg of healthy, volunteer subjects. Based on previous reports of mean normal TCOM readings ranging from 52 to 70 mmHg with a standard deviation of approximately 10 mmHg,[4–7] our sample size of 32 subjects was intended to allow us to estimate mean TCOM readings with a 95% CI of ± 3.5 mmHg. Having 16 male and 16 female subjects also provided 80% power (with $\alpha = 0.05$) to detect a 10 mmHg difference in mean TCOM readings of males versus females using Student's t-test.

Demographic characteristics of male and female subjects were compared using Fisher's Exact Test or Student's t-test as appropriate. Descriptive statistics are reported for TCOM readings at each of the six sensor sites: mean and 95% confidence interval (CI) for the mean are reported when data are normally distributed; median, inter-quartile range and approximate 95% CI for the median are reported for non-parametric data. Differences between mean TCOM measurements for males and females were compared using t-tests when data were normally distributed, and using the Wilcoxon rank sum test for non-parametric data. Correlations between baseline perfusion measures of systolic blood pressure (SBP), diastolic blood pressure (DBP), oxygen saturation (SpO_2) and toe SBP in the randomized limb and the observed room-air and on-oxygen TCOM readings at each sensor site were evaluated using linear regression or Spearman's rank correlation for normal and non-parametric data respectively, with Bonferroni correction for multiple comparisons.

Results

Demographic and baseline data are shown in Table 1. The subjects ranged in age from 22 to 80 years. Female subjects were older than male subjects (mean age, 53.8 vs. 45.1 years); mean left-sided systolic blood pressure, diastolic blood pressure and oxygen saturation also differed statistically between female and male subjects, but these differences were clinically irrelevant. Baseline measures of perfusion were clinically unremarkable in all subjects.

The surface-air TCOM readings for each sensor site were normally distributed, both in the aggregate and for males and females separately. The leg-elevated and on-oxygen TCOM readings were not normally distributed. The mean, 95% CI and minimum and maximum values for the room-air sensor readings are shown in Table 2. Female subjects had higher room-air TCOM readings at the lateral leg sensor (44.8 versus 33.7 mmHg, $P = 0.04$), otherwise there were no differences in the mean room-air TCOM readings for female and male subjects. The median, inter-quartile range, 95% CI for the median, and minimum and maximum values for the leg-elevated and on-oxygen sensor readings are shown in Table 3. Female subjects had higher leg-elevated TCOM readings than male subjects at the lateral leg sensor site (median 39.5 vs. 32.0, Wilcoxon Rank Sum test, $P = 0.04$); there were no significant differences in the leg-elevated and on-oxygen TCOM readings for female and male subjects at any of the sensor sites (Wilcoxon Rank Sum test, all $P \geq 0.05$, data not shown). No evidence of skin injury was found.

Table 2
Mean and 95% confidence interval (95% CI) for TCOM readings for each sensor breathing room air (mmHg); * $P = 0.04$

Sensor	Male (n = 16)	Female (n = 16)	All (n = 32)
Lateral leg*			
Mean (95% CI)	37.7 (32.6–42.8)	44.8 (40.6–49.0)	41.3 (37.8–44.7)
Range	13–51	29–59	13–59
$n < 40$ mmHg	9	3	12
Lateral ankle			
Mean (SD)	41.0 (33.5–48.5)	36.2 (31.3–41.0)	38.6 (34.1–43.1)
Range	13–61	12–48	12–61
$n < 40$ mmHg	8	10	18
Medial ankle			
Mean (SD)	43.9 (37.8–50.1)	43.8 (39.4–48.2)	43.9 (40.2–47.6)
Range	13–65	29–58	13–65
$n < 40$ mmHg	5	4	9
Dorsum, 1st & 2nd toe			
Mean (SD)	41.0 (36.8–45.2)	37.6 (32.2–42.9)	39.3 (35.9–42.7)
Range	24–53	21–59	21–59
$n < 40$ mmHg	8	8	16
Dorsum, 5th toe			
Mean (SD)	45.8 (41.4–50.1)	47.0 (42.9–51.1)	46.4 (43.4–49.3)
Range	21–60	34–59	21–60
$n < 40$ mmHg	4	3	7
Plantar, 1st MTP			
Mean (SD)	53.3 (48.8–57.8)	51.4 (48.2–54.6)	52.3 (49.6–55.1)
Range	39–70	37–63	37–70
$n < 40$ mmHg	2	1	3

Figure 2 displays graphically the room-air TCOM readings for all study subjects at all sensor sites, showing several TCOM readings below 40 mmHg, particularly for the proximal sensors. Twenty-four of the 32 subjects had at least one room-air TCOM reading below 40 mmHg. Sixteen subjects had at least one on-oxygen sensor reading less than 100 mmHg (Table 3). Eleven had multiple readings less than 100 mmHg: eight with two sensors, two with three sensors and one with four sensors. Of the 31 on-oxygen sensor readings less than 100 mmHg, all but four of these same sensors (in three subjects) had also exhibited decreases in TCOM of at least 10 mmHg with leg elevation. None of the sensors recorded very low (i.e., TCOM < 30 mmHg) on-oxygen readings. The average change with leg elevation in those sensors with on-oxygen TCOM < 100 mmHg was -13.5 mmHg, with the biggest change being -24 mmHg and the smallest being -5 mmHg. We were unable to discern a pattern to either the decrease with leg elevation and initial values or to the response to oxygen and initial values.

Figure 2
Distribution of TCOM readings at each sensor site on the lower limb on room air (< 40 mmHg is currently regarded as hypoxic)

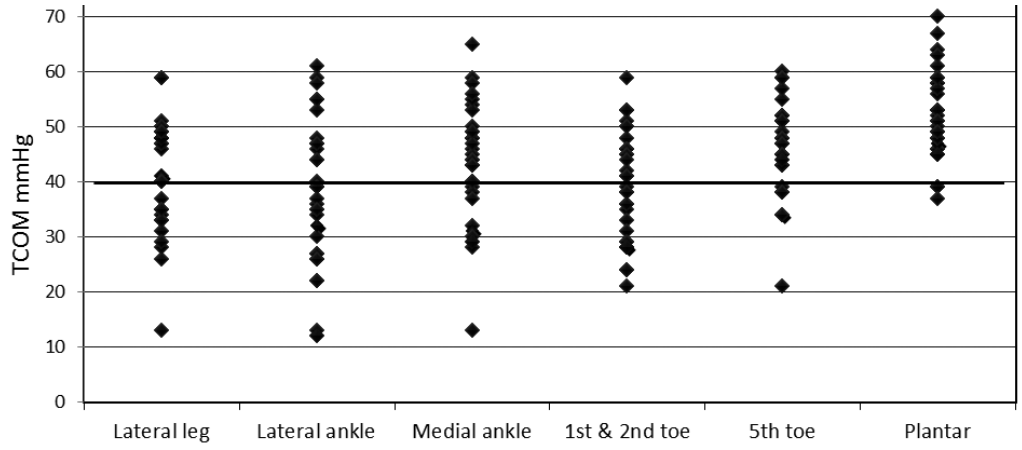


Table 3
Median (inter-quartile range) and 95% confidence interval (95% CI) for TCOM readings for each sensor; subject breathing room air with leg elevated and subject breathing 100% oxygen with leg level (mmHg).

Sensor	Room air, leg elevated	100% oxygen, leg level
Lateral leg		
Median (IQR)	34.5 (27.5–40.0)	241.5 (203.5–307.5)
95% CI	31.0–40.0	207.0–279.5
Range	4–55	130–366
$n \geq 10$ mmHg drop	8	n/a
$n < 100$ mmHg, oxygen	n/a	0
Lateral ankle		
Median (IQR)	29.0 (12.5–34.5)	200.0 (158.0–279.0)
95% CI	14.0–32.5	164.0–241.0
Range	1–44	53–337
$n \geq 10$ mmHg drop	23	n/a
$n < 100$ mmHg, oxygen	n/a	2
Medial ankle		
Median (IQR)	31.5 (25.5–36.5)	213.5 (158.5–275.0)
95% CI	27.0–36.0	176.0–269.5
Range	6–60	55–389
$n \geq 10$ mmHg drop	20	n/a
$n < 100$ mmHg, oxygen	n/a	1
Dorsum, 1st and 2nd toe		
Median (IQR)	27.5 (16.0–34.5)	137.5 (72.5–195.5)
95% CI	17.5–30.0	101.0–180.5
Range	1–47	45–384
$n \geq 10$ mmHg drop	27	n/a
$n < 100$ mmHg, oxygen	n/a	10
Dorsum, 5th toe		
Median (IQR)	33.0 (24.0–40.0)	132.0 (86.5–179.5)
95% CI	25.5–38.0	94.5–168.5
Range	4–55	51–307
$n \geq 10$ mmHg drop	26	n/a
$n < 100$ mmHg, oxygen	n/a	11
Plantar, 1st MTP		
Median (IQR)	43.5 (38.0–50.0)	162.0 (113.0–210.5)
95% CI	40.5–50.0	124.0–190.5
Range	26–62	69–246
$n \geq 10$ mmHg drop	12	n/a
$n < 100$ mmHg, oxygen	n/a	7

TCOM levels were not explained by other measures of perfusion: there was a small but statistically significant ($\beta = 0.25$, r-square = 0.308) positive correlation between toe SBP and room-air TCOM at the sensor on the dorsum of the foot proximal to the fifth MTP joint, otherwise there were no significant associations between any of the perfusion measures and the observed TCOM at any sensor, whether on room air, with the leg elevated or breathing 100% oxygen.

Discussion

TCOM is a non-invasive method of estimating tissue oxygenation and the results are used to assist selection of appropriate patients for HBOT. The current normal reference value of 40 mmHg in non-diabetic patients may not be an accurate reference by which to define hypoxia for all locations on the lower limb. Using this value to define hypoxia, about half of the readings between the first and second toes and those of the lateral ankle would have been classified as hypoxic. There was no sensor site for which all of our subjects had values above 40 mmHg, and 24 of the 32 recorded a room-air TCOM below 40 mmHg for at least one sensor site. TCOM values on room air were less than 20 mmHg at four sites in three subjects and, therefore, could have been misclassified as evidence of critical limb ischaemia.[8] However, all four sites responded to oxygen with values above 100 mmHg, suggesting the possibility of

a diffusion barrier contributing to their low room-air values rather than critical ischaemia. Further, the use of multiple electrodes ensures that data from a single electrode is not used in isolation.

Incorrectly classifying patients as having hypoxic tissue may lead to some patients receiving HBOT unnecessarilly. Unfortunately, a more conservative reference value is not a complete solution. A reference value of 34 mmHg (one SD below the mean recorded in our study) would still lead to classification of 9% of our room-air sensor readings as hypoxic. Clinical practice guidelines for TCOM have been developed to assist the clinician;[8] however, our results reaffirm that clinical history and physical examination remain mandatory in selecting appropriate patients for HBOT.

Our study recorded no room-air TCOM values greater than 70 mmHg, although higher values have been reported in earlier studies.[5,6,14,15] A possible explanation for the difference in our results compared to previous studies is that the TCOM400 monitoring system may measure tissue oxygenation differently, as newer sensors have different technical specifications.[16] As discussed with Radiometer, the TCM400 electrode temperature is controlled by two thermistors in the electrode head. These must be in agreement with each other to within less than 0.6^{O}C. If they are not, then a temperature error is flagged and it is not possible to use that electrode. The specifications for the TCM400 state that temperature accuracy is described as better than ± 0.1^{O}C.

Recent lower limb studies using the TCM400 continue to be guided by earlier normal values.[17–20] Also, previous studies have focused on patients with vascular disease or diabetes, with no healthy control arm to define normal values. One previous study used a standardized sensor position, the first inter-metatarsal space, and found mean values of 55 (± 9.92) mmHg in a group of diabetic patients and mean values of 56 (± 8.8) mmHg in non-diabetic patients.[17] These values are again somewhat higher than those we observed at the same sensor site in healthy, non-smoking subjects, mean 39 (± 9.8) mmHg. We are unaware of any studies evaluating measurement validity for different TCOM machines measuring at the same anatomical site.

It has been common practice to place a sensor on the anterior chest wall as a central reference that is reported to provide information regarding the cardio-respiratory status of the patient. In an earlier TCOM study, we found that the chest sensor reading was below that of at least one arm/hand sensor reading in more than three-quarters of our healthy subjects, with one subject's room-air chest sensor value being 13 mmHg, with arm/hand sensor readings ranging between 38 and 63 mmHg.[10] The same has been found in other studies and a recent expert consensus statement confirms that a percentage of patients have an abnormally low chest TCOM reading and the value of this site as a central reference is questionable.[8,17] Given the unreliability of the chest sensor as a reference site, we did not use it in this study and chose to focus all sensors on the lower limb.

Historically as part of routine TCOM assessment, the leg is elevated for five minutes.[3,21,22] A drop of 10 mmHg is considered indicative of significant vascular disease and decreased healing in amputations.[23,24] Two recent vascular studies have examined this using the TCM400. One study found a drop of less than 10 mmHg in diabetic and non-diabetic patients with severe limb ischaemia; however, their starting values were in the low teens and these patients would have been identified as having severe disease without the added leg elevation.[18] The other study used the 10 mmHg drop with elevation to stratify their patients. Ninety-two per cent of patients in the equivocal TCOM range for healing of 20–40 mmHg, with a drop on elevation of > 10 mmHg, failed to heal whereas 80% of patients who had ≤ 10 mmHg drop on elevation healed.[20] However, a drop of 10 mmHg has also been found in healthy subjects.[7] In our study, the response to elevation varied by sensor site with the distal sites more responsive to leg elevation (Table 3). In total, all except one of our subjects had TCOM decrease ≥ 10 mmHg for at least one sensor site when their leg was elevated; this brings into question the use of this manoeuvre in assessing patients during TCOM and, therefore, it is no longer used in our unit.

Expert consensus is that in normal subjects breathing 100% oxygen at normobaric pressure, TCOM on the leg should always increase to a value ≥ 100 mmHg.[8] In this study, on-oxygen TCOMs below 100 mmHg were recorded at every sensor site except the most proximal site (Table 3). This lack of response to normobaric oxygen was most pronounced at the most distal sensor sites. With oxygen administration, TCOM increased by as little as 25 mmHg at the lateral ankle and medial ankle sensor sites, and by as little as 11 mmHg at the site between the first and second toe. There was one subject whose on-oxygen TCOM increased only 6 mmHg at the fifth toe site, and another subject whose on-oxygen TCOM did not increase at all at the plantar site.

While some of these observations might represent random measurement errors, they are too persistent throughout our data. The lateral and medial ankle sites and the dorsum of the foot are not straight-forward measurement sites. Suitable sensor sites were dictated by the availability of flat surface areas where a fixation ring could be applied, but the sites we used are clinically relevant. These sites are dominated by bones and superficial blood vessels. It is feasible that our low values and lack of response to 100% normobaric oxygen could be explained by the influence of de-oxygenated blood in the surrounding vessels.

The normal procedure in Australia is an oxygen challenge using a head hood not a non-rebreather (NRB) mask. We

have just completed another study comparing oxygen flow rates using the hood and the mask (Blake DF, unpublished observations). The hood at 15 L·min^{-1} performed better than 15 L·min^{-1} with a NRB mask. The maximum oxygen concentration in the hood is 98%, reached within approximately six minutes. Of note, the TCOM values with the hood were 50 to 90 mmHg higher than with the NRB mask.

Our study has limitations. The conventional view is that the sole of the foot is not a good measurement site because of the thickened skin and low TCOM values not being representative of the tissue below the keratin layer.[9,25] Neuropathic ulcers are common in this area, and results from our previous study, showing that the palmar surfaces of the hand have high values and low dispersion, led us to include the plantar site in this study.[10] Only three subjects had room-air TCOM values lower than 40 mmHg at this site, although it had a poorer response to oxygen. Including this site in clinical practice and undertaking further studies may be worthwhile.

Our study was also limited in that we used only one TCOM machine. Further studies comparing normal values on different machines and sensors may help elucidate the differences and variability in our values from those quoted in the literature. Finally, our study speaks only to the specificity of lower limb TCOM values in healthy, disease-free non-smokers; we cannot comment on the sensitivity and specificity of TCOM in other patient groups.

Conclusions

Normal lower limb TCOM readings using the TCOM400 oximeter with tc E5250 sensors may be lower than 40 mmHg, the currently accepted definition of hypoxia, but consistent with the wide range, 10 to 40 mmHg, found in the literature. Because of the wide variability in TCOM at the different sensor sites we cannot recommend a single TCOM value as indicative of tissue hypoxia. Using comparative TCOM on the contralateral leg might be better for identifying 'abnormal' tissue and the expected effect of an oxygen challenge; however, many patients may have bilateral disease. A thorough clinical assessment of the patient is essential to establish appropriateness for HBOT, with TCOM results used to help guide this decision and not as an absolute until normal baseline values have been fully validated.

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