

Performance of Pronto-7 Noninvasive Hemoglobin Pulse CO-Oximeter in a Dark Skinned Population

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Introduction

The Masimo Pronto-7 Rainbow 4D Pulse CO-Oximeter (Masimo Corporation, Irvine, CA) has received FDA clearance and CE certification for the non-invasive measurement of total hemoglobin concentration (SpHb). The technology has been evaluated in published studies for hospitals and emergency room settings in mostly light skin pigmented subjects but not in populations with predominantly dark skin pigmentation. We undertook this study to compare the performance of the device in subjects with dark skin pigmentation against lighter pigmented subjects.

Methods

Following IRB approval 136 adult subjects were recruited from cataract surgery medical mission in Durban, South Africa and 51 subjects from a health fair in Southern California. Subject skin tone was determined using the Massey and Martin NIS Skin Color Scale (1 being Light skin pigmentation to 10 being Dark skin pigmentation). Demographic information such as age, gender, ethnicity and dominant hand was also collected along with the noninvasive hemoglobin readings from the Pronto-7 device (software version 2.3.1.6). Reusable finger sensors (rev F) were placed following manufacturer's directions for use, with the subject's non-dominant ring finger as first choice for placement. The appropriate sensor size (small, medium or large) was determined using the included finger caliper. Proper optical shielding of the sensor was also used. During testing, subjects were advised to remain quiet and motionless to reduce the chance of motion interference artifacts. The number of repeat measurements was recorded. If after 5 attempts a reading could not be obtained, the test was categorized as a "failed attempt". Repeat measurements and failed attempts are reported as a number and as a percentage value. Unpaired T test was used for statistical comparison. $P < .05$ was considered statistically significant.

Results

The Pronto-7 was able to obtain SpHb readings in the vast majority of subjects of both light and dark skin pigmentation. Although there was a higher percentage of repeated measurements and failed attempts in the darker pigmented subjects compared to lighter pigmented subjects, the differences were not significant ($p = 0.54$ and 0.17 respectively).

Discussion

The data presented here indicate that the Masimo Pronto-7 non-invasive Spot Check device for SpHb performs with acceptable reliability in a population with darker skin pigmentation. The percentages of failed or repeated attempts to obtain a hemoglobin concentration value in light and dark skinned subjects were not statistically significant.

Figure 1

	All Subjects	Massey Scale 1-5	Massey Scale 6-10
Number of Subjects	186	82	104
Age Range (avg.), yrs.	18- 91 (61.5)	18-90 (57.0)	23-91 (64.8)
Hemoglobin Range (avg.), g/dL	9.8 - 17.4 (13.2)	9.8 - 17.4 (13.2)	10.3 - 16.4 (12.8)
Repeat Readings (>1) (%)	21 (11.2)	6 (7.3)	15 (14.4)
Failed Attempts (%)	12 (6.4)	3 (3.6)	9 (8.6)