A FASTER AND DEEPER **RESPONSE TO HYPOXIA**

Ulf Borg, Director of Clinical Science,
Department of Medical Affairs, Medtronic

OBJECTIVE

The objective of this study[1] was to characterise the dynamic response of the INVOS™ system compared to Nonin QUANOX™*, CASMED FORE-SITE ELITE™*, and Masimo Root™* O3™* NIRS monitors during an induced hypoxic state in an animal model.

METHODOLOGY

Three juvenile Yorkshire cross swine, weighing 14–17 kg, were enrolled in this nonblinded, non-randomised, prospective study. Animals were placed in an induced hypoxic state and data was collected at 15-second intervals. Fourteen to 15 runs were completed on each animal and a total of 44 runs were collected. During each run, one adult sensor from the INVOS™ system and one adult sensor from either CASMED, Nonin, or Masimo system were placed on the cranium simultaneously. Cerebral oxygenation values from both devices and oxygen levels were recorded at the same 15-second intervals. SpO_2 levels were measured concurrently and used for comparison. A 20% reduction from baseline was chosen given relevance of this as an intervention threshold from previous work.[2]

RESULTS

The mean difference in time to reach 80% of baseline relative to the INVOS™ cerebral oximeter was significantly slower for Masimo and CASMED cerebral oximeters (mean time = +183 seconds, p=0.0002 and +151 seconds, p=0.0008, respectively). The Nonin cerebral oximeter took 25 seconds longer to reach the 80% threshold but was not significantly different from the INVOS™ cerebral oximeter (p=0.6053). The magnitude of response was greater with the INVOS™ system compared to competitors. At ten minutes, the INVOS™ system was 26 percentage points lower than the CASMED system and 21 percentage points lower than the Masimo system (p<.0001 and p=0.0041, respectively). The INVOS™ system was 10 percentage points lower than the Nonin system but was not statistically significant (p=0.304). Finally, when SpO_2 values declined to a critical level (45 to 47 percentage points decrease from baseline), the INVOS™ system demonstrated the largest mean reduction (-37% from baseline, followed by the Nonin, CASMED, and Masimo systems at −30%, −17%, and −14%, respectively). Both the INVOS™ system and Nonin system had statistically greater reductions than either the Masimo or CASMED systems (p<0.0001).

CONCLUSION

The INVOS™ 5100C cerebral oximeter demonstrated faster times to 80% of baseline, greater magnitude proportional tracking with SpO_2 levels over time, and a magnitude more consistent with SpO_2 at a specified level than either the Masimo Root™* O3™* system or CASMED FORE-SIGHT ELITE™* cerebral oximeters. While Nonin EQUANOX™* system was not found to be statistically different than the INVOS™ system, all the same trends were observed.

The acute hypoxia model used in the study demonstrated a difference in performance related to speed of reaction, magnitude of reaction, and correlation to SpO_2 in a transition from normal oxygen saturation to a deeply hypoxic state. The INVOS™ monitoring system demonstrated a unique response as compared to the other monitors tested.

The study was designed to assess performance under a clinically relevant scenario and intervention threshold. Previous studies have shown that intervention based on an 80% of baseline threshold has resulted in improved patient outcomes.[3,4] The 80% threshold was thus used in this study given its proven clinical relevance while monitoring with the INVOS™ system.[5,6]

Figure 1 demonstrates the speed in which INVOS™ system responded to induced hypoxia. The INVOS™ system reached the 80% threshold first, followed by the Nonin EQUANOX™* system (25 seconds later), CASMED FORE-SIGHT ELITE™* cerebral oximeter (151 seconds later), and finally the Masimo Root™* O3™* system, which was the slowest (183 seconds later).

The INVOS™ system demonstrated a faster response time (based on statistical mean difference) when hypoxia was induced in the test subject

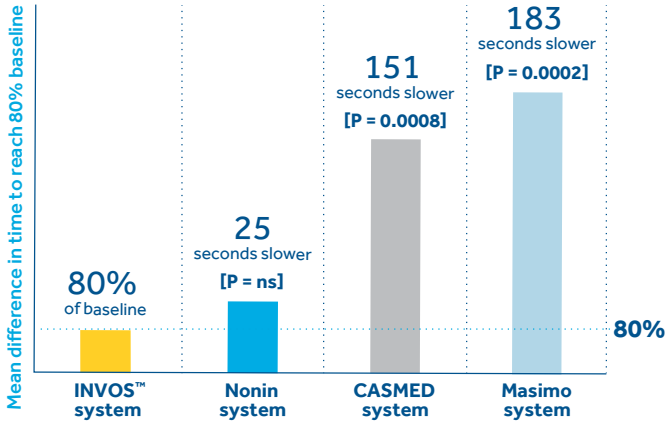

Figure 1. The INVOS™ system reached 80% threshold faster than the competitors.

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Figure 2 demonstrates the magnitude of response to hypoxia of the INVOS™ system in relation to the competitors. The INVOS™ system responded 10% lower than the Nonin system, 21% lower than the Masimo system, and 26% lower than the CASMED system. A response that is more proportional to the physiological change may result in interventions appropriate for the change compared to that of a stable shallow response.

Figure 3 demonstrates the correlation between SpO_2 values and mean rSO_2 values. SpO_2 values were decreased to 55%, an extremely hypoxic state. This figure illustrates that when SpO_2 levels reached 55% (a 45% reduction from baseline), the INVOS™ system mean rSO_2 % values decreased 37% from baseline, followed by Nonin system (30% reduction), CASMED system (17% reduction), and Masimo system with the least decrease (14% reduction from baseline).

The INVOS™ system demonstrated a greater response to hypoxia at 10 minutes

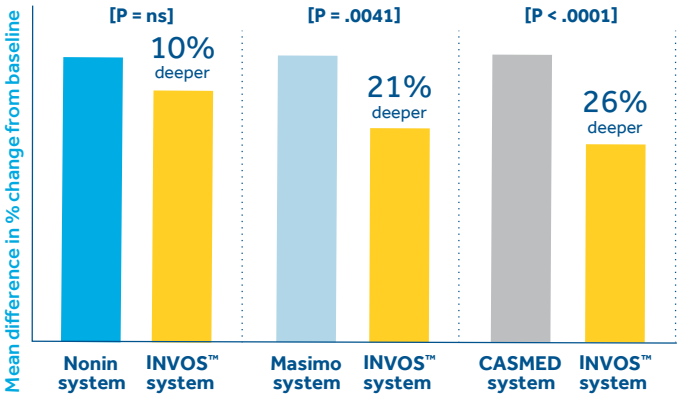

Figure 2. The INVOS™ system's mean depth of response was greater than all tested devices after hypoxia was induced for 10 minutes. Differences between INVOS™ system and Masimo and CASMED systems were statistically significant. Although the same trend was seen between the INVOS™ and Nonin systems, the difference is not statistically significant.

The INVOS™ system demonstrated a higher % change from baseline when SpO_2 values reduced

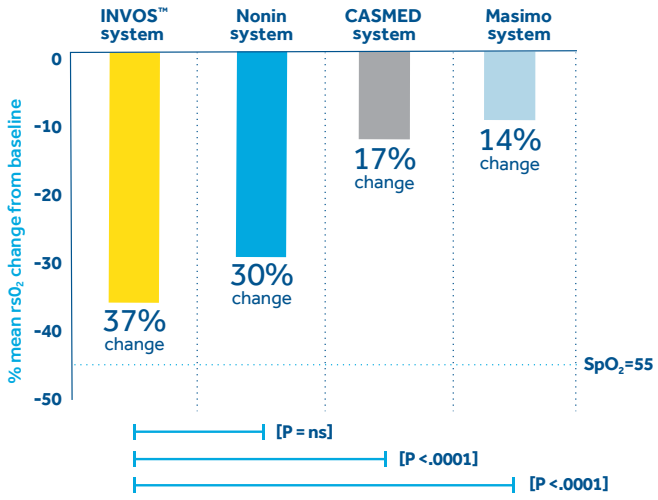

Figure 3. The INVOS™ system mean rSO_2% correlated more closely to the change in SpO_2 at a value of 55% indicating that the change in the INVOS™ system reflected a clinically relevant event.

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Medtronic Australasia Pty Ltd
2 Alma Road
Macquarie Park, NSW 2113
Australia
Tel: +61 2 9857 9000
Fax: +61 2 9889 5167
Toll Free: 1800 668 670

Medtronic New Zealand Ltd
Level 3 - Building 5, Central Park Corporate Centre
666 Great South Road
Penrose, Auckland 1051
New Zealand
Fax: +64 9 918 3742
Toll Free: 0800 377 807

medtronic.com.au
medtronic.co.nz