CADTH COVID-19 PANDEMIC

COVID-19 CADTH HEALTH TECHNOLOGY REVIEW

Pulse Oximetry Monitoring in Patients at Risk of Hypoxia: An Ultra-Rapid Review of Clinical Utility and Guidelines

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To produce this report, CADTH used a modified approach to the selection, appraisal, and synthesis of the evidence to meet decision-making needs during the COVID-19 pandemic. Care has been taken to ensure the information is accurate and complete, but it should be noted that international scientific evidence about COVID-19 is changing and growing rapidly.

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Abbreviations

ABG	arterial blood gas
CHD	coronary heart disease
CHF	congestive heart failure
CI	confidence interval
COPD	chronic obstructive pulmonary disease
HR	heart rate
ICU	intensive care unit
LoA	limits of agreement
r	correlation coefficient
SaO2	arterial oxygen saturation
SD	standard deviation
SpO2	peripheral oxygen saturation
VSM	vital sign monitor

Research Questions

1. What is the clinical utility of pulse oximetry monitoring for the identification of asymptomatic hypoxia in patients with suspected or confirmed coronavirus disease?
2. What is the clinical utility of portable pulse oximetry devices in patients at risk of hypoxia?
3. What are the evidence-based guidelines regarding the use of pulse oximetry in patients at risk of hypoxia?

Key Findings

- No studies regarding the clinical utility of pulse oximetry monitoring for the identification of asymptomatic hypoxia in patients with suspected or confirmed coronavirus disease were identified. Four non-randomized studies in patients at risk of hypoxia for other reasons were included.
- Overall, evidence of limited quality (mostly from studies with high risk of bias) suggested that the studied portable pulse oximeters had comparable utility to hospital-grade pulse oximeters in patients at risk of hypoxia.
- No relevant evidence-based guidelines regarding the use of pulse oximetry in patients at risk of hypoxia were identified.

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE via OVID, PubMed, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were pulse oximetry and COVID-19, home use or portable use. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2017 and May 1, 2020.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Q1: Patients (any age) who are suspected of having or who have been diagnosed with coronavirus disease (COVID-19) Q2, Q3: Patients (any age) at risk of hypoxia
Intervention	Q1: Pulse oximetry monitoring Q2, Q3: Portable pulse oximeter monitors (e.g., for home use, self-monitoring, or in a non–hospital-based health care setting), or smartphone-based pulse oximeter monitors
Comparator	Q1: No pulse oximetry monitoring Q2: Alternative method of pulse oximetry monitoring (i.e., alternative setting or using an alternative device) Q3: Not applicable
Outcomes	Q1: Clinical utility (e.g., identification and treatment of asymptomatic hypoxia, early dyspnea, low oxygen saturation, or COVID pneumonia; hospitalization; ventilation; mortality) Q2: Clinical utility (e.g., oxygen saturation, early identification of hypoxia, prevention of severe hypoxia, hospitalization) Q3: Recommendations regarding pulse oximetry monitoring in an outpatient or home-based setting (e.g., which device to use, which settings, when they should be used)
Study Designs	Health technology assessments, systematic reviews, randomized controlled trials, non-randomized studies, guidelines

COVID-19 = coronavirus disease; Q = question.

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published prior to 2017.

Critical Appraisal of Individual Studies

The included publications were critically appraised by one reviewer using the Quality Assessment of Diagnostic Accuracy Studies 2 (QUADAS-2) checklist as a guide.[1]

Summary of Evidence

Quantity of Research Available

- Four non-randomized prospective equipment comparison studies were identified for this report.
- Additional references of potential interest are provided in Appendix 2.

Summary of Findings

Clinical Utility of Pulse Oximetry Monitoring in Patients with Suspected or Confirmed Coronavirus Disease

No relevant evidence regarding the use of pulse oximetry for the identification of asymptomatic hypoxia in patients with suspected or confirmed coronavirus disease (COVID-19) was identified.

Clinical Utility of Portable Pulse Oximetry Devices in Patients at Risk of Hypoxia

Four non-randomized prospective studies,[2-5] reported findings on the clinical utility of different types of portable pulse oximetry monitors. All the studies were published in 2019, and one each was conducted in Israel,[3] South Africa,[4] Turkey,[5] and the US of America.[2] One of the studies evaluated smartphone-based oximeters,[5] two assessed wrist-sensor oximetry,[2,3] and one investigated a portable fingertip pulse oximeter.[4] A summary of the study characteristics is available in Table 2 in Appendix 1.

Smartphone-based oximeters

The study by Tayfur and Afacan[5] evaluated the effectiveness of a smartphone-based pulse oximeter to accurately measure arterial oxygen saturation (SaO_2) compared with a conventional hospital vital signs monitor (VSM) device. The gold standard arterial blood gas (ABG) analysis was the reference for SaO_2 measurement in the study. A total of 101 patients presenting at a tertiary care centre and the emergency service with indications of chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), acute dyspnea, pneumonia, and multiple trauma were selected by convenience sampling to participate in the study. Data about patients' demographics and baseline characteristics were not reported.

- Analysis of results showed that the mean difference (MD) in SaO2 was as follows:

  Conventional hospital VSM versus ABG

  - MD = -1.04% (95% CI: -1.299 to -0.780);
  - r = 0.936 (95% CI: 0.907 to 0.957; P < 0.0001)

  Smartphones-based oximeter versus ABG

  - MD = -0.67% (95%CI: -0.845 to -0.494);
  - r = 0.968 (95% CI: 0.952 to 0.978; P < 0.0001)
- The authors concluded that "the HR and SaO2 values obtained by smartphone were found to be consistent with the measurements of the reference devices."[5] However, there was no direct comparison between the smartphone-based oximeter and the VSM, and the study had a high risk of bias necessitating caution with such interpretation.

Key Limitations (high risk of bias):

- Convenience sampling (i.e., non-consecutive enrolment of patients) may have resulted in selection bias that can make the results unreliable. In addition, patients with a variety of conditions were enrolled but it is unclear if the study participants were sufficiently representative of each of these conditions; therefore, it is unclear to whom the results are generalizable.
- Potentially relevant patients (such as those requiring urgent care, with a high degree of hypothermia, or those were unable to adapt to the measurements with a device due to conditions such as unconsciousness or confusion) were excluded from entering the study, which may have resulted in overestimation of diagnostic accuracy.[1]
- The application of devices and all measurements in the study were undertaken by health professionals. It is unknown if similar outcomes would have been obtained if the measurements were performed by patients or members of the general public with limited knowledge of, or experience with, smartphone measurements.

Wrist-sensor oximeters

The study by Guber et al.[3] evaluated the accuracy and precision of a wrist-sensor pulse oximeter in measuring peripheral oxygen saturation levels (SpO_2) and pulse-rate compared with a fingertip pulse oximeter in 15 healthy volunteers and 23 patients with chronic lung diseases enrolled at the pulmonary department of a medical centre. Both devices were FDA approved. The patients' group comprised eight patients with COPD, six with asthma, five with sarcoidosis, and four with other unspecified conditions. The mean age (standard deviation) was 60.4 (9.83) years and 51.5 (15.52) for the healthy volunteers. All the study participants were simultaneously tested using the two devices, placed on the same hand, respectively. Measurements were taken before and after a 6-Minute walk test (6-MWT), which is a test used to assess aerobic capacity. Readings were recorded with participants in a sitting position and while standing. The SpO_2 and pulse-rate data from both devices were collected simultaneously and passively using Bluetooth technology and used in the analysis. It must be noted that separate data for each group for the before and after 6MWT measurements were not available for independent verification. Instead, measurement pairs (one per device) for the full analysis set of patients and healthy volunteers were combined, preventing a comparison of the devices in different participant groups.

- The investigators reported that no significant oxygen desaturations were observed during the 6-MWT.
- The mean SpO2 for the wrist-sensor pulse oximeter was 96.45% compared with 97.18% for the fingertip pulse oximeter reference.
- The precision rate of 2.28% met the pre-specified root mean-squared-error threshold of less than 3% for accuracy.
- The investigators concluded that the wrist-sensor pulse oximeter was both accurate and precise for SpO2 and pulse measurements during daily activities of pulmonary patients and was not inferior to standard devices for spot-checking or short period examinations.[3]

Key Limitations (High Risk of Bias):

- Both participants with known disease and a control group without the condition were enrolled, which may exaggerate the diagnostic accuracy.[1]
- The method of recruiting patients to participate in the study was unknown.
- Separate data not available for patients and healthy volunteers for an independent assessment of how the devices performed in these two groups.

- On applicability, 83.8% of study participants found the wrist-sensor pulse oximeter comfortable to use compared to 38.9% for the fingertip pulse oximeter reference device. However, 97.3% of the participants scored display clarity and readability as good or very good for wrist-sensor pulse oximeter compared to 100% for the reference device.

The study by Harris et al.[2] assessed the accuracy of an FDA-approved wrist-sensor pulse oximeter in measuring SaO_2 in infants under 12 months of age compared with a conventional hospital-grade pulse oximeter. ABG analysis using co-oximetry was the reference in the study. A total of 24 infants with baseline oxygen saturation less than 90% due to cyanotic coronary heart disease (CHD) were enrolled from a pediatric cardiac critical care unit and a neonatal intensive care unit (ICU). As part of their clinical care, all the patients already had an indwelling arterial line that could be used to obtain an arterial blood sample for ABG and the hospital-grade pulse oximetry. The wrist-sensor pulse oximeter was placed on a thumb, big toe, or mid-foot of an extremity to avoid signal interference and hypo-perfusion-related artifact from the hospital device and the arterial line.

- The results of the analysis were as follows:
  - Co-oximetry (Gold standard)
    - Mean (SD) SaO_2 = 72% (9%).
  - Wrist-sensor pulse oximeter
    - Mean (SD) SaO2 = 76% (8%).
    - The reading was higher than the co-oximeter by an average of 4.0% (90% CI, 2.3 to 5.7).
  - Conventional Hospital-grade pulse oximetry
    - Mean (SD) SaO2 = 80% (8%).
    - The reading was higher than the co-oximeter by an average of 7.4% (90% CI, 5.4 to 9.5).
- The investigators concluded that when the wrist-sensor pulse oximeter when placed appropriately on the finger, toe, or thumb was, at least, as accurate as the hospital device.[2]

Key Limitations (Low Risk of Bias)

- There was an applicability concern about the tested wrist-pulse oximetry device (Masimo WristOx2 3150). This device was not a regular consumer item that can be purchased off the shelves of a local store. To buy one, an interested party needs to contact a designated vendor that vets an application to decide whether to fulfill an order.

Fingertip pulse oximeter

The study by Smith and Hofmeyr[4] evaluated the agreement between a portable fingertip pulse oximeter and a conventional bedside hospital pulse oximeter in measuring SpO_2 and pulse-rate in adult surgical patients who presented for elective or emergency surgery. A total of 220 patients were recruited by convenience sampling. The fingertip and conventional bedside pulse oximeter probes were applied to the same hand, and simultaneous measurements were obtained with both devices in all patients. The analysis was performed using a Bland-Altman approach to determine bias, precision, and limits of agreement (LoA), with the acceptable level for LoA pre-specified at 3%. In addition to an overall assessment that included data from all patients, a subgroup analysis was

conducted, assessing patients with baseline SpO_2 ≥93% (normal) and those with SpO_2 <93% (hypoxemic) separately.

- The MD between the hospital device and fingertip oximeters are summarized below:
  - Overall analysis
    - MD = 0.55% (95% CI, -0.73 to -0.36).
    - Upper LoA = 2.16% (95% CI, 1.84 to 2.47) and
    - Lower LoA = -3.25% (95% CI, -3.56 to -2.94).
  - Subgroup with SpO2 ≥93% (normal)
    - MD = -0.20% (95% CI, -0.38 to -0.01)
    - Upper LoA = 2.20% (95% CI, 1.88 to 2.53)
    - Lower LoA = -2.60% (95% CI, -2.92 to -2.27)
  - Subgroup with SpO2 <93% (hypoxemic)
    - MD = -1.57% (95% CI, -1.92 to -1.22)
    - Upper LoA = 0.99% (95% CI, 0.37 to 1.59)
    - Lower LoA = -4.13% (95% CI, -4.73 to -3.53)
- The investigators concluded that the accuracy of the tested fingertip pulse oximeter was comparable to that of a conventional hospital-grade bedside pulse oximeter in perioperative patients with normal blood oxygen saturation (SpO2 ≥ 93%). However, the accuracy of the portable fingertip pulse oximeter deteriorated with progressive hypoxemia (SpO2 < 93%).

Key Limitations (high risk of bias):

- Convenience sampling may have resulted in selection bias that can make the results unreliable, and it is unclear to whom the results are generalizable.
- The exclusion criteria prevented potentially relevant patients, such as those who had infectious diseases with a high risk of transmission from entering the study. Inappropriate exclusions are known to result in overestimation of diagnostic accuracy.[1]
- The studies were conducted in a tertiary care setting with the application of devices, and all measurements, undertaken by health professionals. It is unknown if similar outcomes would be obtained if the measurements were performed by patients or members of the general public.

Guidelines Regarding the Use of Pulse Oximetry in Patients at Risk of Hypoxia

No relevant evidence-based guidelines regarding the use of pulse oximetry in patients at risk of hypoxia were identified.

Conclusions

No studies regarding the clinical utility of pulse oximetry monitoring for the identification of asymptomatic hypoxia in patients with suspected or confirmed coronavirus disease were identified. All identified evidence was from studies with patients at risk of hypoxia for other reasons.

Four non-randomized prospective equipment comparison studies[2-5] provided evidence for this report. Given that signal measurement by the devices being compared needs to be from the same person for a credible comparison, the non-randomized study design does

not appear to be an important limitation. However, three of the four included studies were deemed to be at high risk of bias for other reasons.

One of the studies evaluated a smartphone-based pulse oximeter,[2-4] two assessed wrist-sensor oximeters,[2,3] and one investigated a portable fingertip pulse oximeter.[4]

The smartphone-based oximeter was tested for effectiveness of measuring blood oxygen saturation in patients with COPD, CHF, acute dyspnea, pneumonia, and multiple trauma.[5] Data from this study[5] (with a high risk of bias) suggested that the smartphone-based oximeter had similar effectiveness in measuring SaO_2 compared to a conventional hospital-grade VSM or the gold standard ABG analysis, though direct statistical comparisons between the smartphone and hospital-grade VSM SaO_2 results were not provided. However, the convenience sample method and inappropriate exclusion criteria with the potential to deny entry of relevant patients into the study were sources of significant unreliability of the reported findings.

The evidence from one study[3] with a high risk of bias involving healthy volunteers and patients with chronic lung disease suggested that the accuracy and precision of the tested wrist-sensor pulse oximeter were comparable to that of the reference fingertip pulse oximeter in measuring SpO_2. Sources of uncertainty included the unknown method of recruitment and potentially exaggerated accuracy finding due to enrolling participants with known disease and a control group without the condition. Evidence from another study[2] with a low risk of bias suggested that the tested wrist-sensor pulse oximeter was at least as accurate as the hospital-grade device in measuring SaO_2 in infants under 12 months of age with baseline oxygen saturation less than 90% due to CHD. An important limitation of the study was that it was conducted in infants with a specific baseline oxygen saturation level. Therefore, the generalizability of the findings in other populations is unknown.

Evidence from one study[4] with a high risk of bias involving adult perioperative patients suggested that the tested fingertip pulse oximeter in measuring SpO_2 was as accurate as a conventional hospital-grade bedside pulse oximeter if the patients had normal blood oxygen saturation level (SpO_2 ≥93%); however, the accuracy declined with progressive hypoxemia (SpO_2 <93%). The convenience sample method used to recruit study participants was a source of significant uncertainty, as discussed previously in this report.

Overall, the evidence suggested that portable pulse oximeter devices had comparable utility to non-portable devices. Smartphone technology is evolving rapidly with expected improvement in applications with each new version, and there are different kinds of wrist-sensor and fingertip pulse oximeters, meeting different performance standards. As pulse oximetry technology continues to evolve, future studies using appropriate methodology will be required to determine the clinical utility of the different available monitors.

No relevant evidence-based guidelines regarding the use of pulse oximetry in patients at risk of hypoxia were identified.

References

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2. Harris BU, Stewart S, Verma A, et al. Accuracy of a portable pulse oximeter in monitoring hypoxemic infants with cyanotic heart disease. *Cardiol Young.* 2019;29(8):1025-1029.
3. Guber A, Epstein Shochet G, Kohn S, Shitrit D. Wrist-sensor pulse oximeter enables prolonged patient monitoring in chronic lung diseases. *J Med Syst.* 2019;43(7):230.
4. Smith RN, Hofmeyr R. Perioperative comparison of the agreement between a portable fingertip pulse oximeter v. a conventional bedside pulse oximeter in adult patients (COMFORT trial). *S Afr Med J.* 2019;109(3):154-158.
5. Tayfur I, Afacan MA. Reliability of smartphone measurements of vital parameters: a prospective study using a reference method. *Am J Emerg Med.* 2019;37(8):1527-1530.

Appendix 1: Characteristics of Included Publications

Table 2: Summary of Characteristics and Findings of Included Studies

Author, Year, Country	Design	Type of device(s) tested	Reference Standard	Population	Outcomes measured	Findings	Conclusion	Assessment
								Risk of bias
Guber et al. (2019)[3] **Israel**	A prospective, single-arm, single-centre, open-label clinical study. Readings were done in a resting position, as well as before and after 6MWT	FDA-approved wrist-sensor pulse oximeter (Oxitone-1000)	FDA-approved fingertip pulse oximeter	A total of 38 adult (≥18 years) participants – 23 patients with chronic lung disease (COPD, asthma, sarcoidosis, other) and 15 healthy volunteers. The patients were either outpatients in the pulmonary clinic, or ambulatory patients undergoing a pulmonary rehabilitation program	SpO_2 measurements-– Accuracy, and Precision were assessed	The mean SpO_2 for the wrist-pulse oximeter was 96.45% compared to 97.18% for the fingertip pulse oximeter reference. The precision rate of 2.28% met the Arms -Root mean-square-error threshold (< 3%) for accuracy.	The wrist-sensor pulse oximeter device was as accurate and precise as the fingertip pulse oximeter used as reference for the measurements SpO_2 and pulse during daily activities of patients with lung disease, and for spot-checking or short period examinations.	High
Harris et al. (2019)[2] **USA**	A single-centre prospective non-randomized study	A wrist-pulse oximetry device (WristOx2 3150) compared with a conventional hospital pulse oximeter device (Masimo LCNS	Arterial oxyhemoglobin saturation measured by co-oximetry.	A total of 24 infants under 12 months of age with baseline oxygen saturation less than 90% due to cyanotic CHD presenting at a pediatric cardiac critical care unit, and neonatal ICU	Arterial oxygen saturation	The mean (SD) saturation by the different devices are as follow: *Co-oximetry reference standard* 72% (9%). *Wrist-pulse oximetry* device 76% (8%).	"From this, we conclude that the study device when appropriately placed on the finger, toe, or thumb is at least as accurate as the hospital device as	Low

Author, Year, Country	Design	Type of device(s) tested	Reference Standard	Population	Outcomes measured	Findings	Conclusion	Assessment Risk of bias
		saturation sensor)				The reading was higher than the co-oximeter by on average 4.0% (90% CI, 2.3 to 5.7). *Hospital device* 80% (8%). The reading was higher than the co-oximeter by on average 7.4% (90% CI, 5.4 to 9.5).	currently used. However, it is concerning that the 90% CI of arterial oxygen saturation minus pulse oximeter saturation for both sensors crossed the threshold of 5%, which has been previously described as the clinically acceptable range for managing patients with cyanotic heart disease."[2] p. 1027	
Smith and Hofmeyr (2019)[4] **South Africa**	A single-centre prospective study	A portable fingertip pulse oximeter	A conventional bedside pulse oximeter	220 adult surgical patients in a hospital/theatre environment in a tertiary-level institution	Peripheral oxygen saturations (SpO_2) and pulse rates	The MD between the hospital device and fingertip oximeters were as follows: *Overall* MD = 0.55% (95% CI, –0.73 to –0.36). Upper LoA = 2.16% (95% CI, 1.84 to 2.47) and Lower LoA = –3.25% (95% CI, –3.56 to –2.94).	"This pragmatic study demonstrated that a fingertip pulse oximeter was accurate (within 3% SpO_2) in perioperative patients with normal oxygenation ($SpO_2 \geq 93\%$) compared with a bedside pulse	High

Author, Year, Country	Design	Type of device(s) tested	Reference Standard	Population	Outcomes measured	Findings	Conclusion	Assessment
								Risk of bias
						Patients with SpO_2 ≥93% (normal) MD = –0.20 (–0.38 to –0.01) Upper LoA = 2.20 (95% CI, 1.88 to 2.53) Lower LoA = –2.60 (95% CI, –2.92 to –2.27) *Patients with SpO_2 <93% (hypoxemic)* –1.57 –1.92 to –1.22) Upper LoA = 0.99 (95% CI, 0.37 to 1.59) Lower LoA = –4.13 (95% CI, –4.73 to –3.53)	oximeter. As in previous studies, accuracy deteriorated with progressive hypoxemia. A measurement of < 93% on the portable device is cause for concern and should prompt further investigation and management of hypoxia if necessary."[4] p. 158	
Tayfur and Afacan (2019)[5] **Turkey**	A single-cohort, open prospective study	Smartphone-based (Samsung Galaxy S8)	An ABG device compared to a conventional hospital VSM device used at the emergency care centre	A total of 101 patients with indications of COPD, CHF, acute dyspnea, pneumonia, and multiple trauma presenting at a tertiary care centre and the emergency service.	Arterial oxygen saturation	The MD in SaO_2 compared to the ABG reference, was as follows: *For the hospital VSM* MD = –1.04% (95% CI, –1.299 to –0.780);	"The HR and SaO_2 values obtained by smartphone were found to be consistent with the measurements of the reference devices."[5] p. 1527	High

Author, Year, Country	Design	Type of device(s) tested	Reference Standard	Population	Outcomes measured	Findings	Conclusion	Assessment
								Risk of bias
						r = 0.936 (95% CI, 0.907 to 0.957; P < 0.0001), *For the smartphones-based oximeter* MD = –0.67% (95%CI, –0.845 to –0.494); r = 0.968 (95% CI, 0.952 to 0.978; P < 0.0001)	"In the current study, the mean differences between VSM HR and smartphone HR and VPM SaO_2 and smartphone SaO_2 were in favour of smartphone measurements."[5] p.1529	

6MWT = 6-minute walk test; ABG = arterial blood gas; CHD = coronary heart disease; COPD = chronic obstructive pulmonary disease; r = correlation coefficient; CHF = congestive heart failure; CI = confidence interval; ICU = intensive care unit; HR = heart rate; LoA = limits of agreement; MD = mean difference; SD = standard deviation; SaO_2 = arterial oxygen saturation; SpO_2 = peripheral oxygen concentration; VSM = vital sign monitor.

Appendix 2: Additional References of Potential Interest

References Excluded for Lack of Comparator Devices

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