Postoperative Monitoring:

The Good, Bad and Useless

Satya Krishna Ramachandran MD FRCA CCT DABA
Vice Chair of Anesthesiology for Quality, Safety and Innovation
BIDMC

Learning Objectives

1. Critically evaluate the reasons for monitoring patients
2. Discuss important studies relating to monitoring and clinical outcome prediction
3. Evaluate the accuracy of prediction of state change in sleep apnea monitoring and potential scientific impact.

Why Do We Monitor Patients?

1. Because it is medico-legally mandatory - i.e., SOC?
2. Because it makes sense?
3. Because it means something about the organ being monitored?
4. Because monitoring changes outcomes?

Why Do We Monitor Patients?

1. Because it is medico-legally mandatory - i.e., SOC?

Table 3. Consultant American Society of Anesthesiologists Membership Survey Summary

		Consultants *Percentage Response*				Membership *Percentage Response*			
Intervention or Linkage	Outcome	N	Agree (%)	Disagree (%)	Don't Know (%)	N	Agree (%)	Disagree (%)	Don't Know (%)
Continual assessment of airway patency, respiratory rate and SpO_2	Should be done	55	98.2	1.8	0.0	211	100.0	0.0	0.0
	Detects respiratory complications	55	98.2	1.8	0.0	211	98.1	0.0	1.9
	Reduces adverse outcomes	55	87.3	1.8	10.9	211	92.4	1.0	6.7

Why Do We Monitor Patients?

1. Because it is medico-legally mandatory - i.e., SOC?

Wrongful Death — Medical Malpractice — Settlement Amount: Confidential

Deceased sustained a severe global brain injury resulting from oxygen deprivation arising from the hospital's negligent failure to monitor the patient's blood oxygen level and to hook the patient up to a CPAP machine before sleeping, after the patient had undergone successful gastric bypass surgery. Patient had a previous medical history of moderate obstructive sleep apnea.

Established written hospital policies required that all post-operative patients with a known diagnosis of obstructive sleep apnea receive monitoring of blood oxygenation with continuous pulse oximetry. The patient required the use of a CPAP machine at bedtime or during daytime naps.

As a direct result of the hospital's failure to adhere to its written monitoring guidelines, the deceased was found unresponsive, cyanotic and not breathing at 5:15 p.m. by her surgeon who was making rounds. After testing, it was determined that the likely cause of death was obstructive sleep apnea.

The Decedent was survived by two sisters and two brothers.

Why Do We Monitor Patients?

1. Because it is medico-legally mandatory - i.e., SOC?

2. Because it makes sense?

Table 1. Comparison of Available Monitoring Modalities for Detection of Opioid-Induced Respiratory Depression in the Postoperative Period

Monitoring Modality	Sensitivity *	Specificity	Reliability	Response Time
$P_{et}CO_2$ (intubated)	High	High	High	Fast
S_pO_2 (no O_2 supplement)	High	Moderate-High	High	Fast
$P_{et}CO_2$ (unintubated)	High	Moderate-High[§]	Moderate	Fast
P_aCO_2	High	High	High	Slow
P_vCO_2	High	Moderate	High	Slow
$P_{tc}CO_2$	Moderate	High	Low-Moderate[‡]	Medium
S_pO_2 (with O_2 supplement)	Moderate	Moderate	High	Slow
Clinical assessment (skilled clinician)	Moderate	Moderate-High	Moderate	Slow
Respiratory rate (newer technology)	Moderate	Moderate[†]	Moderate	Medium
Tidal volume (unintubated)	Moderate	Moderate	Low	Medium
Chest wall impedance (for respir. rate)	Low-Moderate	Low[†]	Low	Medium
Clinical assessment (less skilled clinician)	Low-Moderate	Low-Moderate	Low-Moderate	Slow

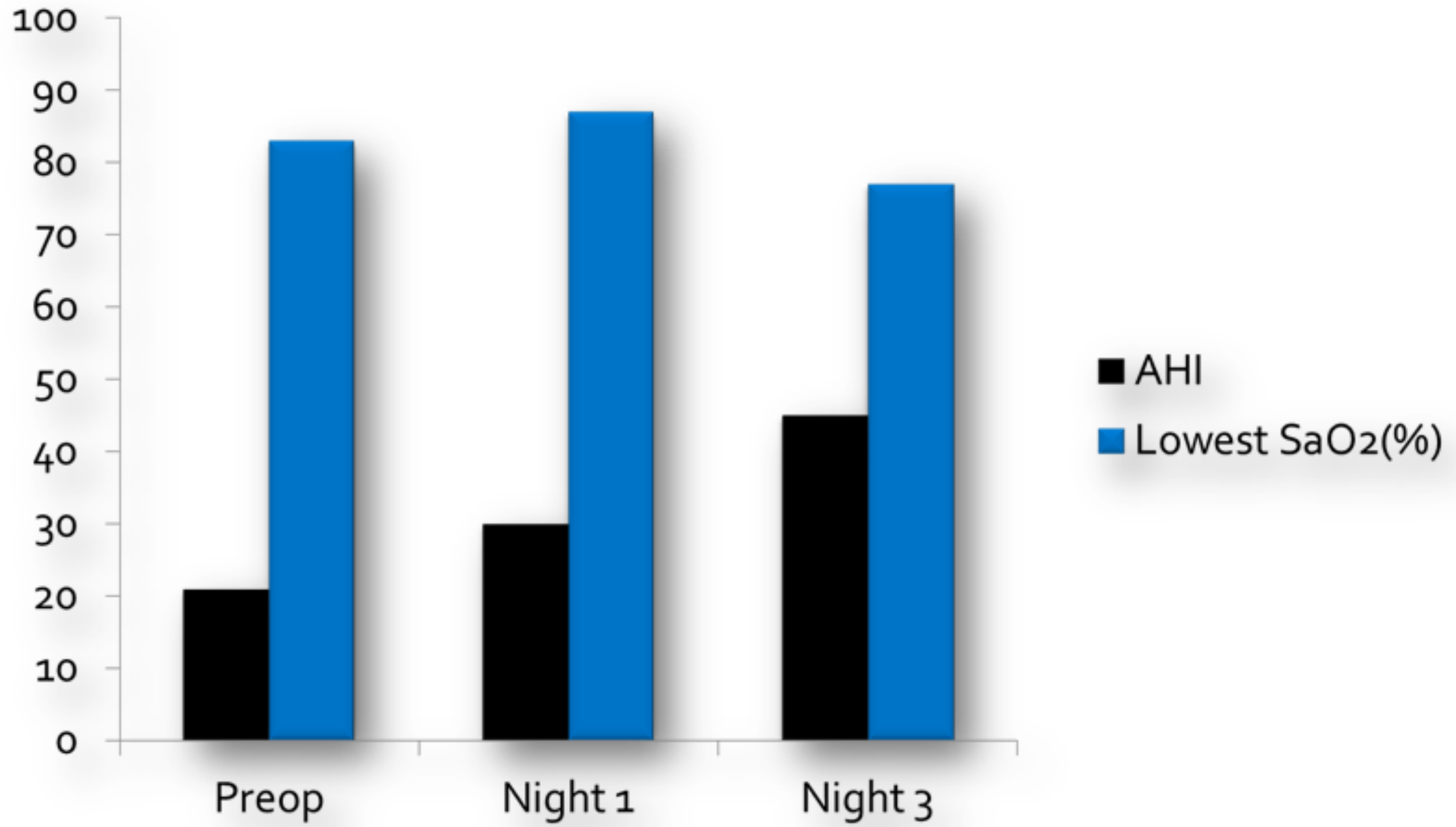
Why Do We Monitor Patients?

1. Because it is medico-legally mandatory - i.e., SOC?

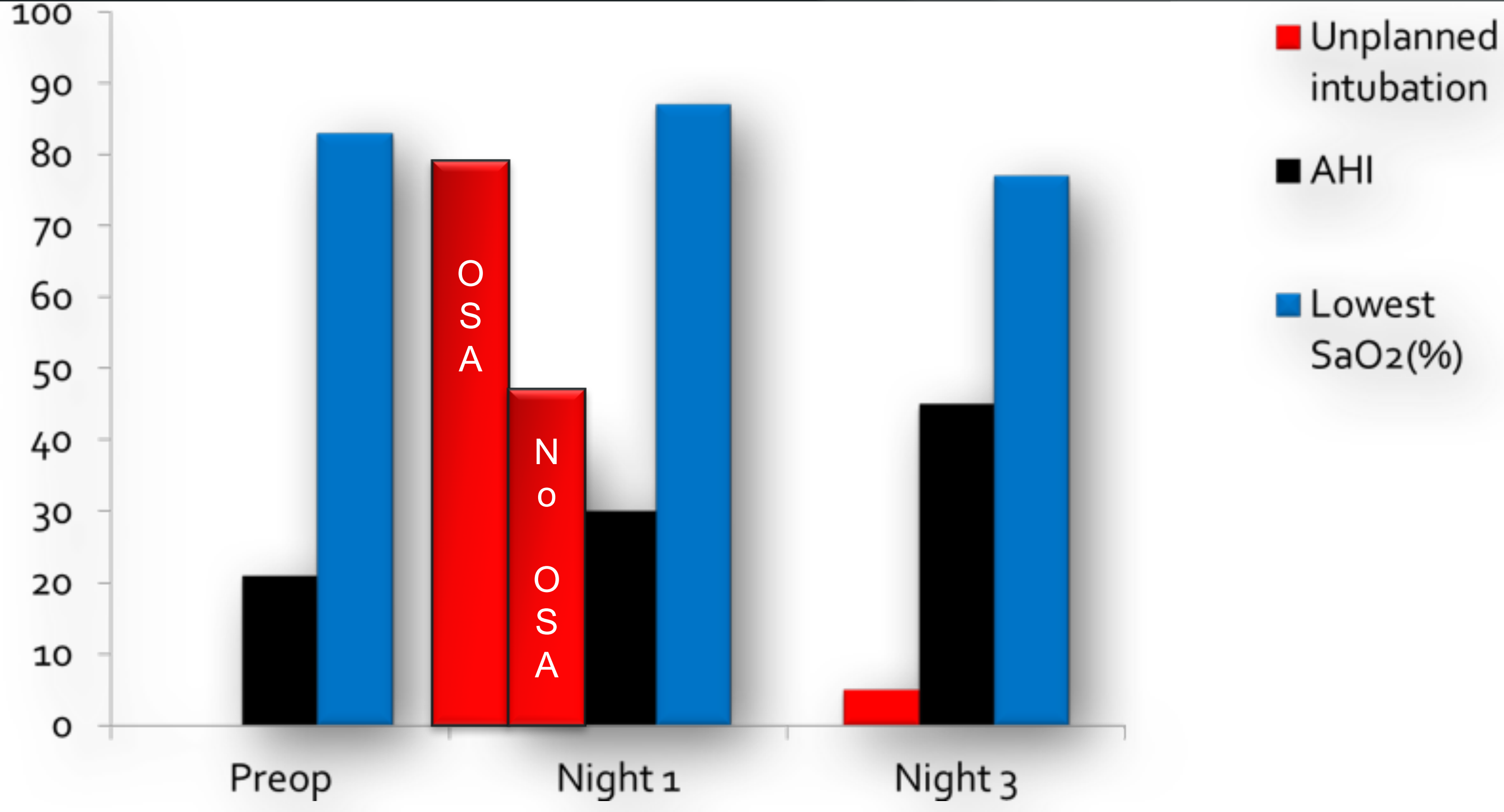
2. Because it makes sense?

3. Because it means something about the organ being monitored?

Postoperative SDB course



Relationship Between SDB & Postoperative Respiratory Failure



Why Do We Monitor Patients?

1. Because it is medico-legally mandatory - i.e., SOC?

2. Because it makes sense?

3. Because it means something about the organ being monitored?

4. Because monitoring changes outcomes?

Why Do We Monitor Patients?

The Official Journal of the Anesthesia Patient Safety Foundation

apsf www.apsf.org NEWSLETTER

Fall 2011

"No Patient Shall Be Harmed By Opioid-Induced Respiratory Depression"

[Proceedings of "Essential Monitoring Strategies to Detect Clinically Significant Drug-Induced Respiratory Depression in the Postoperative Period" Conference]

Matthew B. Weinger, MD, and Lorri A. Lee, MD,
for the Anesthesia Patient Safety Foundation

The APSF believes that clinically significant, drug-induced respiratory depression in the postoperative period remains a serious patient safety risk that continues to be associated with significant morbidity and mortality since it was first addressed by the APSF in 2006.[1] The APSF envisions that *"no patient shall be harmed by opioid-induced respiratory depression in the postoperative period,"* and convened the second multidisciplinary conference on this serious patient safety issue in June of this year in Phoenix, AZ, with 136 stakeholders in attendance. The conference addressed "Essential Monitoring Strategies to Detect Clinically Significant Drug-Induced Respiratory Depression in the Postoperative Period."

Does Monitoring Change Outcomes?

Two step rule:

1. Monitoring changes treatment

2. Treatment changes outcomes

Four Potential Ways to Use Monitoring Data

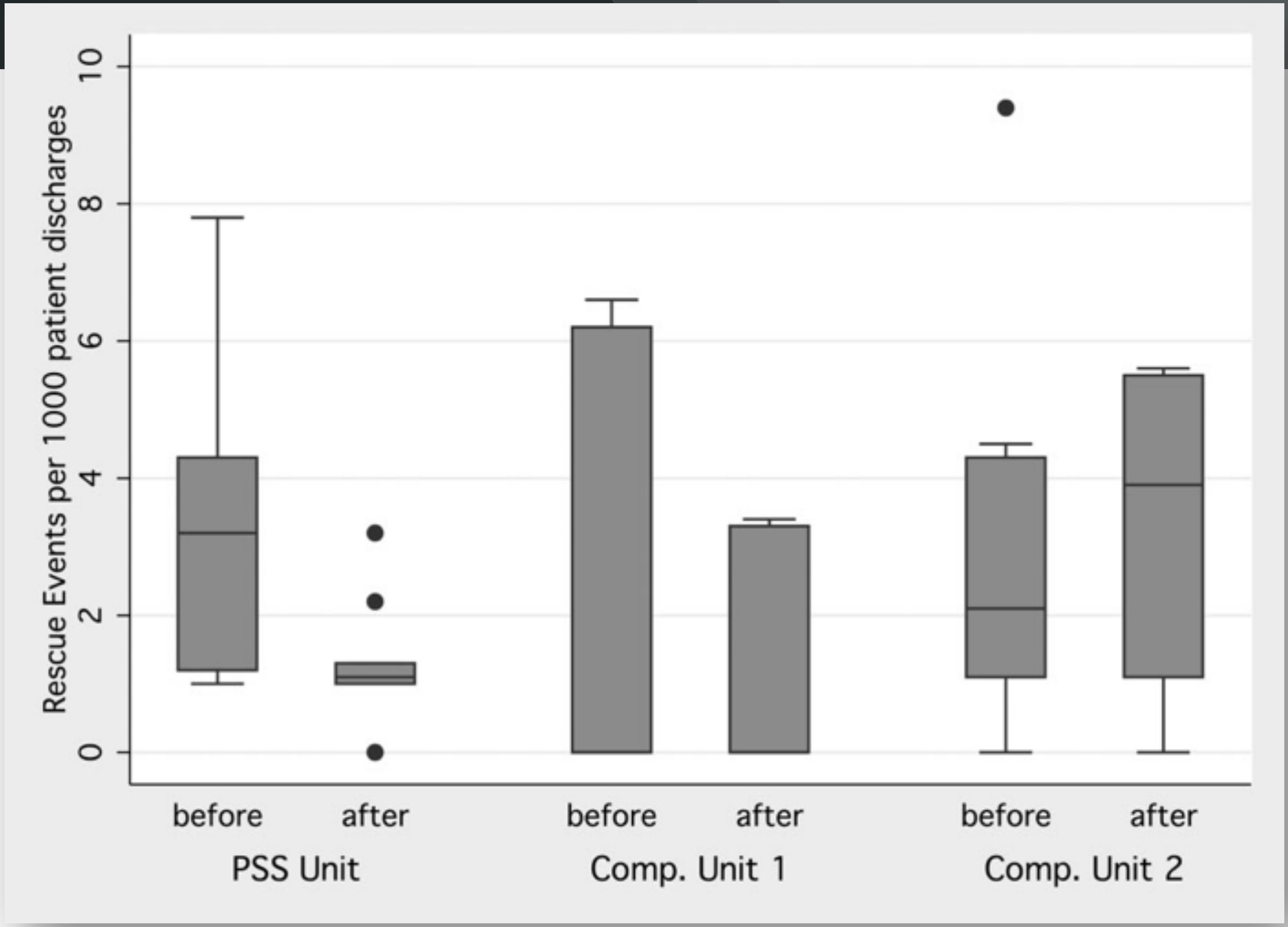
- By classifying **real-time step change in state of health** (physiological to pathological state)
- By **predicting real-time step change in state of health** (physiological to pathological state)
- By classifying **subtle, transient change in physiological state**, where the relationship with specific disease process is known
- By predicting **subtle, transient change in physiological state**, where the relationship with specific disease process is known

Four Potential Ways to Use Monitoring Data

- By classifying **real-time step change in state of health** (physiological to pathological state)

Capturing Real-Time (Retrospective) Step Change

Threshold Based Surveillance System



PLOS | ONE

RESEARCH ARTICLE

Retrospective observational evaluation of postoperative oxygen saturation levels and associated postoperative respiratory complications and hospital resource utilization

Satya Krishna Ramachandran[1] *, Aleda Thompson[2], Jaideep J. Pandit[3], Scott Devine[4], Amy M. Shanks[2]

Early Postoperative (PACU) Pulse Oximetry and Outcomes?

- Derive the best measures of desaturation:
  - Consider the measures as surrogates of a certain clinical phenotype
- Several dimensions of desaturation
  - Depth - nadir
  - Duration - under threshold? Under median?
  - Area under the curve
  - Oxygen therapy?

Central tendency measure. The median SpO_2 value for each sliding window (5 minute window, q1-minute) was first calculated. On a per patient basis, the median of all sliding window medians was defined as the median SpO_2 value in PACU. All median data were transformed into a dichotomous measure of central tendency of desaturation by determining the population spread of these data, and identifying the 10^{th} centile of desaturation medians, since lower median values likely signify greater respiratory risk. For this dataset, the median SpO_2 threshold was defined as <94% using this methodology.

Duration of desaturation. The cumulative time in minutes below median SpO_2, expressed as number of minutes per hour of PACU SpO_2 monitoring was calculated. All duration data were transformed into a dichotomous measure of duration of desaturation by determining the population spread of these data, and identifying the 90^{th} centile of desaturation duration, since longer desaturation periods likely signify greater respiratory risk. For this dataset, the desaturation duration threshold was defined as the cumulative time ≥18 minutes per hour of SpO2 <94% using this methodology.

Nadir desaturation measure. The minimum SpO_2 in PACU was chosen as the lowest value either documented as a manual entry by PACU nurse during room air exposure for five minutes or captured during all continuous monitoring periods starting from the first recording of SpO_2 through to PACU discharge. All nadir desaturation data were transformed into a dichotomous measure of nadir desaturation by determining the population spread of these data, and identifying the 10^{th} centile of each patient's desaturation nadirs, since lower nadir values likely signify greater respiratory risk. For this dataset, the nadir SpO_2 threshold was derived as <89% using this methodology.

Duration of oxygen therapy in PACU. As PACU nurses were expected to treat desaturation with patient arousal and supplemental oxygen therapy, we assumed that longer oxygen exposure times were at least in part, indicative of ongoing desaturation issues needing this intervention. This variable was derived as the fraction of PACU time that the patient had documented oxygen therapy. The derived fraction was converted into an ordinal variable with <25%, 25–49%, 50–74% and 75–100% forming the categories that describe longer oxygen requirements in PACU. For this dataset, these durations were derived as <30 min, 31–60 min, 61–90 min and >90 min using this methodology.

Table 6. Secondary outcomes on matched dataset.

	Oxygen treatment duration>30 minutes (N = 18,677)	Oxygen treatment duration≤30 minutes (N = 18,677)	p-value
Total Charges			
Charge (median, 25th, 75th centile)	12,532 [8,683 to 21,690]	10,874 [7,661 to 18,190]	<0.001
Day of Surgery Charges			
Charge (median, 25th, 75th centile)	9,749 [5,001 to 15,076]	8,672 [4,623 to 13,370]	<0.001
Surgery Charges			
Charge (median, 25th, 75th centile)	6,075 [0 to 10,508]	6,205 [0 to 10,162]	<0.001
Respiratory Charges			
Charge (median, 25th, 75th centile)	0 [0 to 370]	0 [0 to 125]	<0.001
Hospital Length of Stay (median, 25th, 75th centile)	0 [0 to 1]	0 [0 to 1]	<0.001
Early PRC			
Reintubation [n(%)]	34 (0)	15 (0)	0.007
Ventilatory support [n(%)]	551 (3)	131 (1)	<0.001

All data are reported as either frequency (percent) or median [25th percentile to 75th percentile], as appropriate.

Four Potential Ways to Use Monitoring Data

- By classifying **real-time step change in state of health** (physiological to pathological state)

- By **predicting real-time step change in state of health** (physiological to pathological state)

Predicting Future Step Change Integrated Monitoring System (IMS)

- An IMS (BioSign; OBS Medical, Carmel, Indiana) used heart rate, blood pressure, respiratory rate, and peripheral oxygen saturation by pulse oximetry to develop a single neural networked signal, or BioSign INDEX (BSI)
- Data were analyzed for cardiorespiratory instability according to BSI trigger value and local MET activation criteria.
- Tarassenko and Pinsky

What Did IMS Change?

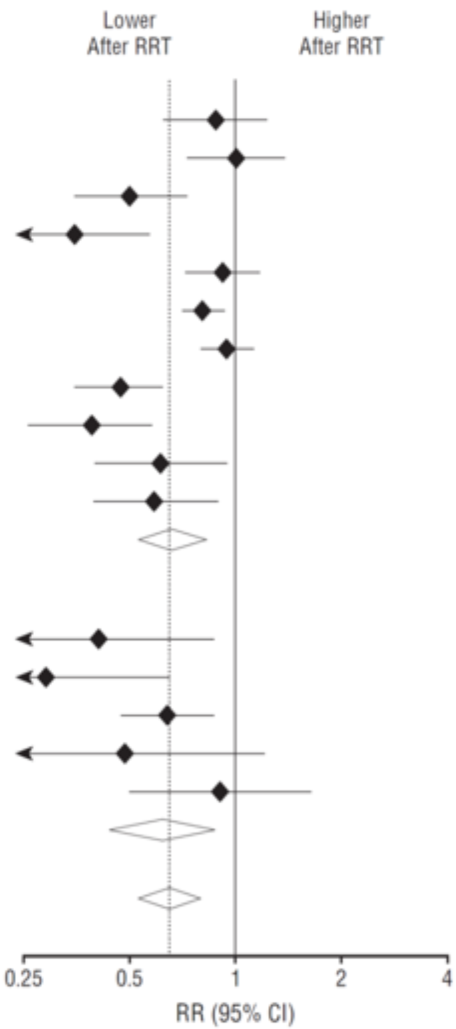
- 18, 248 hours of continuous monitoring
- 111 MET activation criteria events caused by cardiorespiratory instability in 59 patients
  - All MET events were detected by BSI in advance (mean, 6.3 hours) in a bimodal distribution (6 hours and 45 minutes; 100% sensitivity)
  - But MET activation for this cause occurred in only 7 patients (6% PPV for MET activation; NNT/NNP not calculated)

Rapid Response Teams

A Systematic Review and Meta-analysis

Paul S. Chan, MD, MSc; Renuka Jain, MD; Brahmajee K. Nallmothu, MD, MPH; Robert A. Berg, MD; Comilla Sasson, MD, MS

	Control Group		Intervention Group			
	Patients, No.	Deaths, No.	Patients, No.	Deaths, No.	Weight, %	RR (95% CI)
Adult Studies						
Bristow et al (hospital 1 vs 2)[20]	13059	66	18338	69	7.29	0.88 (0.62-1.23)
Bristow et al (hospital 1 vs 3)[20]	19545	99	18338	69	7.64	1.00 (0.73-1.37)
Buist et al[28]	19317	73	22847	47	6.97	0.50 (0.35-0.73)
Bellomo et al[27]	21090	63	20921	22	5.71	0.35 (0.22-0.57)
Kenward et al[33]	53500	139	53500	128	9.71	0.92 (0.72-1.17)
DeVita et al[29]	143776	930	55248	290	8.54	0.81 (0.71-0.93)
Hillman et al[31]	56756	93	68376	90	9.28	0.94 (0.79-1.13)
Jones et al[30]	16246	66	104001	198	8.00	0.47 (0.35-0.62)
Dacey et al[13]	5667	44	17090	52	6.57	0.39 (0.26-0.58)
Baxter et al[12]	7820	43	11271	38	6.20	0.61 (0.40-0.95)
Chan et al[9]	24193	147	24978	77	6.58	0.59 (0.40-0.89)
Overall Adult (I^2=80.5%, P<.001)	**380969**	**1763**	**414908**	**1080**	**82.49**	0.66 (0.54-0.80)
Pediatric Studies						
Brilli et al[36]	16255	25	9615	6	0.25	0.41 (0.00-0.86)
Sharek et al[35]	22037	53	7257	5	2.50	0.29 (0.10-0.65)
Zenker et al[14]	22561	181	11682	60	7.72	0.64 (0.47-0.87)
Hunt et al[38]	7504	16	7503	8	2.45	0.49 (0.18-1.20)
Tibballs and Kinney et al[37]	104780	20	138424	24	4.58	0.91 (0.50-1.64)
Overall Pediatric (I^2=10.2%, P=.35)	**173137**	**295**	**174481**	**103**	**17.51***	0.62 (0.46-0.84)
Overall (I^2=73.9%, P<.001)	**554106**	**2058**	**589389**	**1183**	**100.00**	0.65 (0.55-0.77)

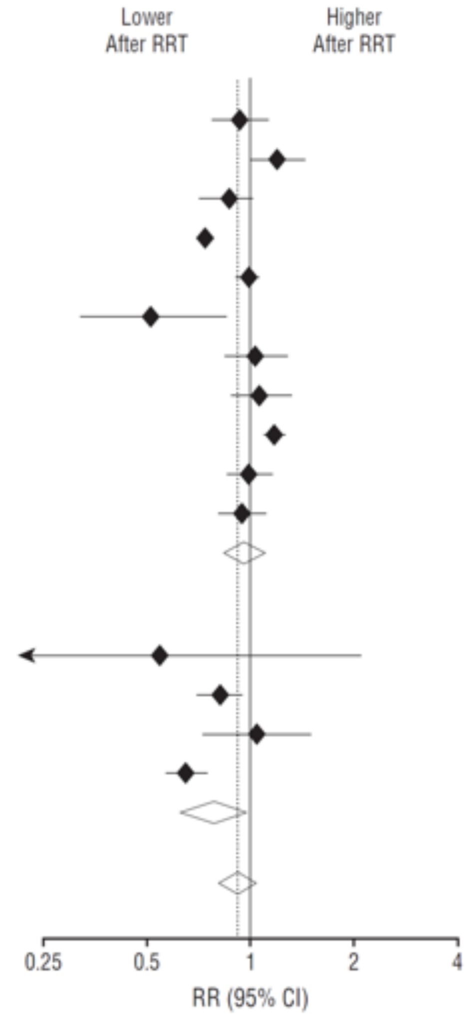


Rapid Response Teams

A Systematic Review and Meta-analysis

Paul S. Chan, MD, MSc; Renuka Jain, MD; Brahmajee K. Nallmothu, MD, MPH; Robert A. Berg, MD; Comilla Sasson, MD, MS

	Control Group		Intervention Group			
	Patients, No.	Deaths, No.	Patients, No.	Deaths, No.	Weight, %	RR (95% CI)
Adult Studies						
Bristow et al (hospital 1 vs 2)[20]	13 059	240	18 338	243	7.17	0.93 (0.77-1.12)
Bristow et al (hospital 1 vs 3)[20]	19 545	295	18 338	243	7.28	1.20 (1.00-1.43)
Buist et al[28]	19 317	380	22 847	393	7.31	0.87 (0.71-1.01)
Bellomo et al[27]	21 090	302	20 921	222	8.51	0.74 (0.70-0.79)
Kenward et al[33]	53 500	1070	53 500	1054	8.36	0.99 (0.91-1.07)
Priestley et al[34]	1336	76	1456	73	3.54	0.52 (0.32-0.85)
Hillman et al[31]	56 756	67	68 376	72	6.85	1.03 (0.84-1.28)
Dacey et al[13]	5667	123	17 090	398	6.96	1.07 (0.88-1.32)
Jones et al[30]	25 334	873	100 243	4070	8.43	1.18 (1.10-1.27)
Baxter et al[12]	7820	279	11 271	400	7.65	0.99 (0.86-1.16)
Chan et al[9]	24 193	780	24 978	773	7.56	0.95 (0.81-1.11)
Overall Adult (I^2=91.4%, P<.001)	**247 617**	**4485**	**357 358**	**7941**	**79.62**	0.96 (0.84-1.09)
Pediatric Studies						
Brilli et al[36]	16 255	11	9615	3	0.10	0.55 (0.00-2.10)
Sharek et al[35]	22 037	547	7257	158	7.62	0.82 (0.70-0.95)
Zenker et al[14]	22 561	97	11 682	53	4.86	1.05 (0.73-1.50)
Tibballs and Kinney et al[37]	104 780	459	138 424	398	7.80	0.65 (0.57-0.75)
Overall Pediatric (I^2=66.0%, P=.03)	**165 633**	**1114**	**166 978**	**612**	**20.38**	0.79 (0.63-0.98)
Overall (I^2=90.3%, P<.001)	**413 250**	**5599**	**524 336**	**8553**	**100.00**	0.92 (0.82-1.04)



Can Monitoring Harm?

A frequent and persistent problem

The Joint Commission's Sentinel Event database* includes reports of 98 alarm-related events between January 2009 and June 2012. Of the 98 reported events, 80 resulted in death, 13 in permanent loss of function, and five in unexpected additional care or extended stay. Common injuries or deaths related to alarms included those from falls, delays in treatment, ventilator use and medication errors; all were traced back to alarm system issues. Alarm-related events are recognized as underreported and occur in all health care settings. Ninety-four of the reported events occurred in hospitals, with the majority of those events occurring in telemetry, intensive care,

In addition, the U.S. Food and Drug Administration's (FDA) Manufacturer and User Facility Device Experience (MAUDE) database reveals that 566 alarm-related patient deaths were reported between January 2005 and June 2010, a figure that is considered by industry experts to underrepresent the actual number of incidents.

Countering Alarm Fatigue vs. System Failures

- Countered by widening thresholds and introducing delays
  - SpO2 threshold of 80% alerts in 0.67% of patients
    Vs. 6.25% alert rate at a SpO2 threshold of 90%
  - The PPV of IMS is <10% despite extending delay to 4 out of 5 min period.
- System failures are extensive/common
  https://www.ecri.org/Documents/PA_PSRS/2008.03_Supplement.pdf

Four Potential Ways to Use Monitoring Data

- By classifying **real-time step change in state of health** (physiological to pathological state)
- By **predicting real-time step change in state of health** (physiological to pathological state)
- By classifying **subtle, transient change in physiological state**, where the relationship with specific disease process is known

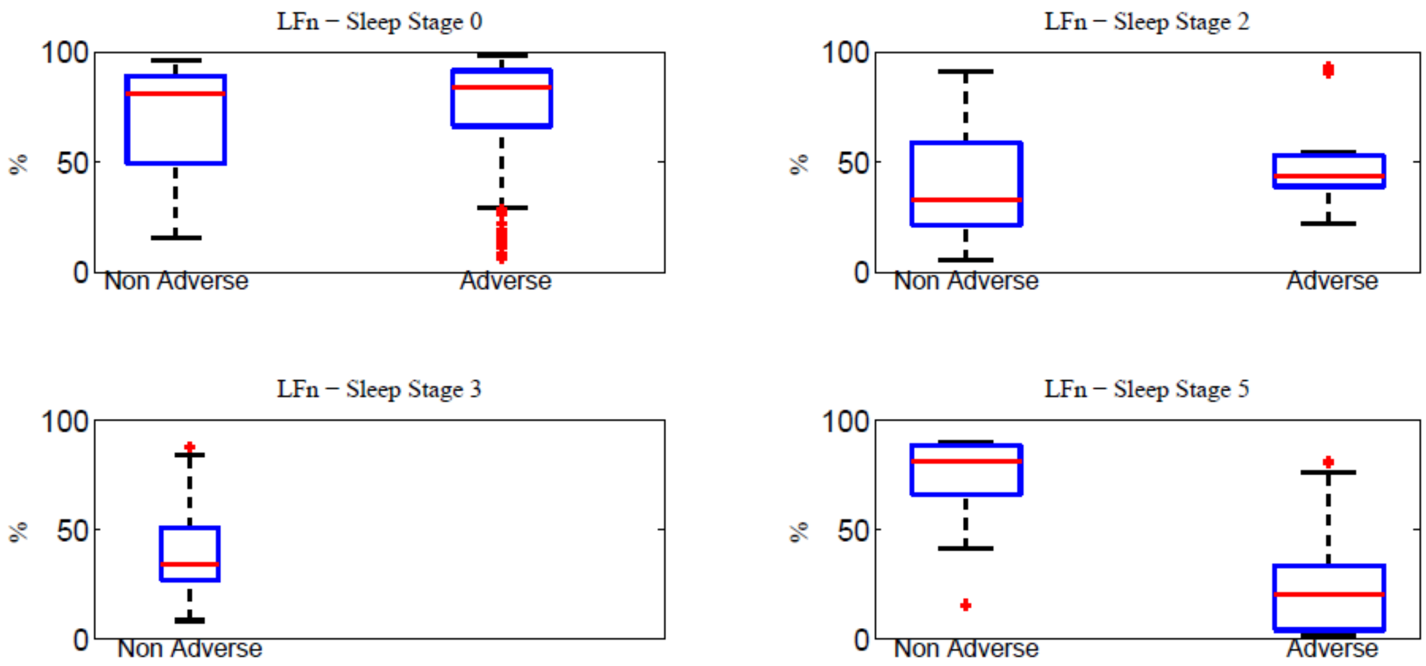
OSA and Pulse Oximetry

- Episodic airway obstruction with ‘subtle’ desaturation epochs
  - Reproducible
  - Exacerbated by exposure to anesthesia and surgery
- Public health implications
  - Disease and mortality burden
  - Costs
- Treatment modalities unsatisfactory - event insensitive?
  - CPAP
  - Weight loss
  - Surgery

Change in HRV - Sympathovagal Control Pattern

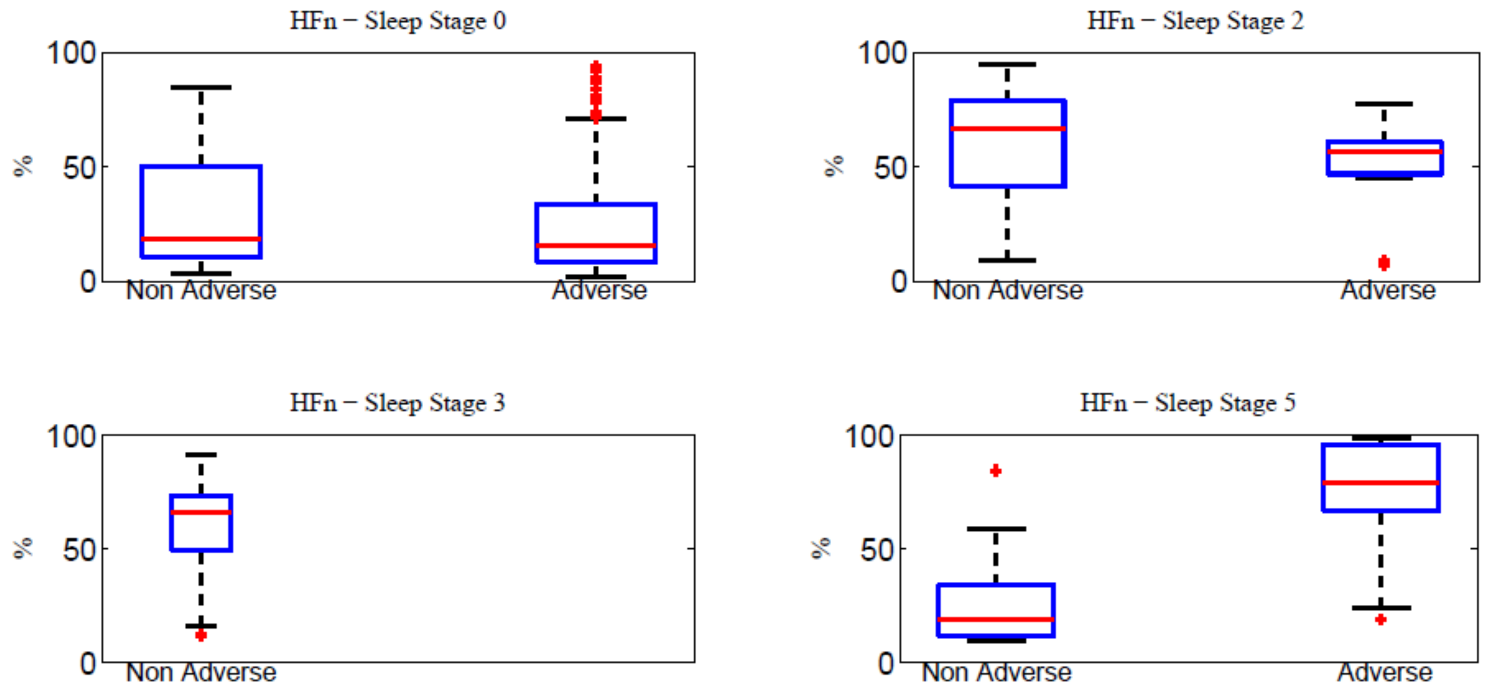
- Case control retrospective design
  - 20 patients with early post-extubation respiratory/airway failure
  - 20 matched controls for age decile, gender, AHI, surgical specialty
- PSG data from formal in-lab study within 1 year of event (before or after)
- HRV metrics derived from whole night ECG analysis
- Time series data split into 1-min segments, classified under sleep stages, OSA vs CSA events and cumulative distribution

Sympathovagal Balance Across Sleep Stages



(b) Box plots for LF_n of the spectral oscillations for RR intervals during undisturbed in stages 0 (upper left), 2 (upper right), 3 (lower left), and 5 (lower right)

REM related Vagal Predominance in Adverse Outcome



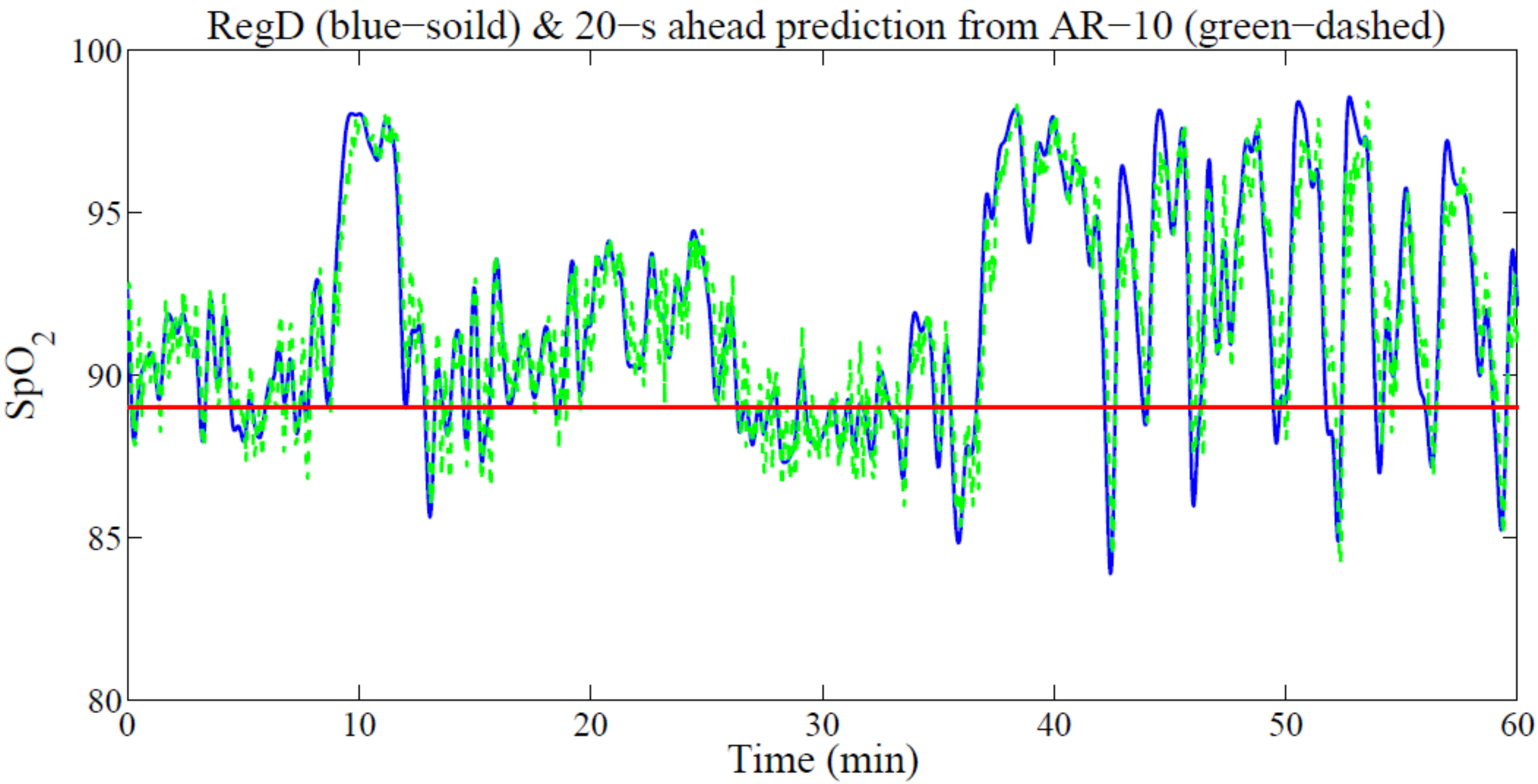
(c) Box plots for HF_n of the spectral oscillations for RR intervals during undisturbed in stages 0 (upper left), 2 (upper right), 3 (lower left), and 5 (lower right)

Four Potential Ways to Use Monitoring Data

- By classifying **real-time step change in state of health** (physiological to pathological state)
- By **predicting real-time step change in state of health** (physiological to pathological state)
- By classifying **subtle, transient change in physiological state**, where the relationship with specific disease process is known
- By predicting **subtle, transient change in physiological state**, where the relationship with specific disease process is known

Why Predict SpO_2 Signal Values in OSA?

- Airway events precede desaturation in a dose dependent manner
- Some evidence that deep desaturation episodes carry greater threat
  - Ventricular arrhythmias
  - Some evidence that treatment reduces arrhythmia risk
- Finite inputs for single output (MISO modeling)
  - Previous SpO2 values and system tendency to desaturation
  - Sleep state
  - Medications


RegD (blue−soild) & 20−s ahead prediction from AR−10 (green−dashed)
SpO2
Time (min)
100
95
90
85
80
0
10
20
30
40
50
60

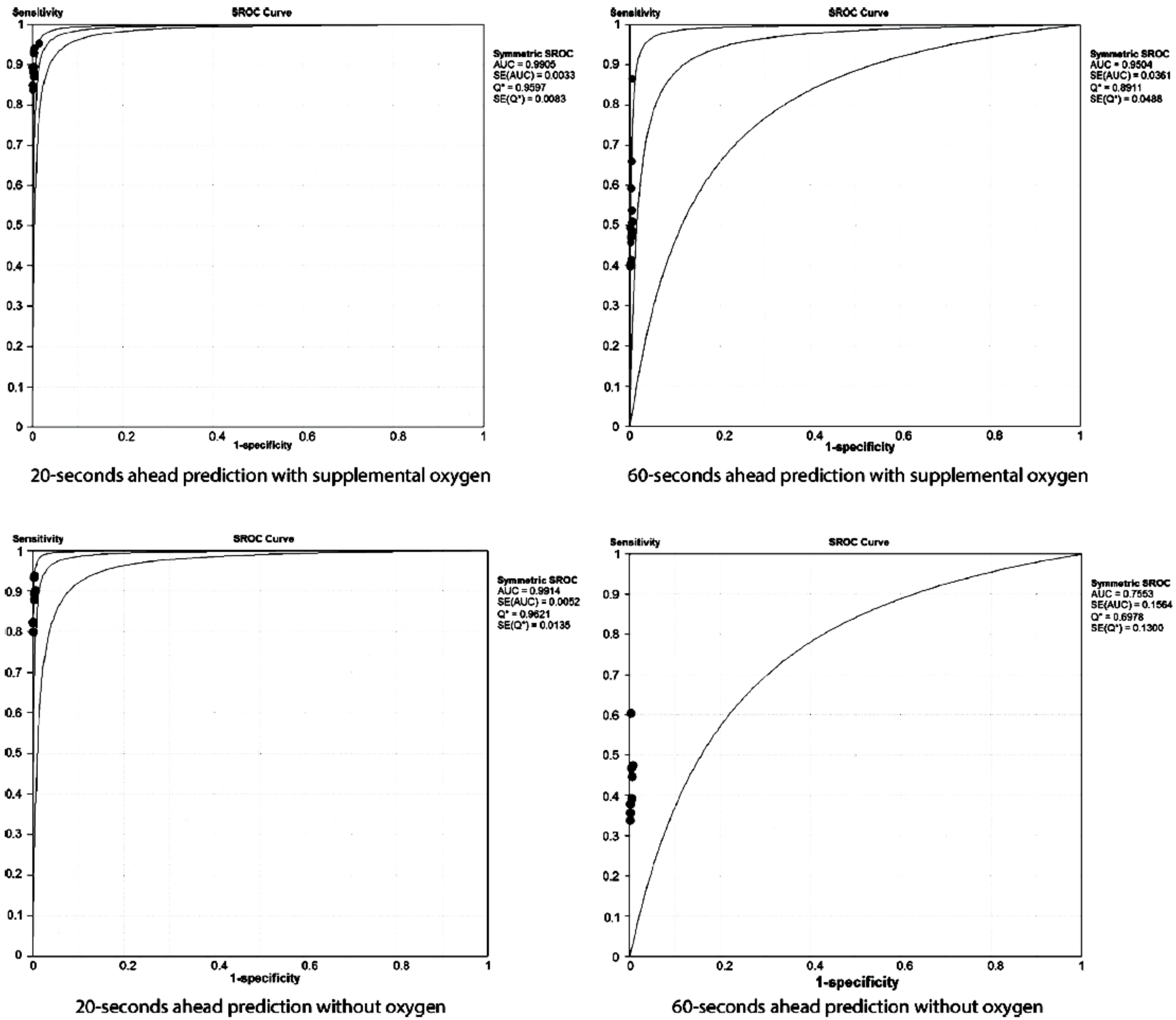


Fig. 2 Summary receiver operating characteristic *curves* for accuracy of prediction of critical desaturation events over the two 20s and 60s predictions across oxygen treatment groups

Oxygen treatment ENHANCED the ability of the model to predict SpO2 values 60-seconds ahead of time

Apnea Prediction?

Table 2. Comparison of Performance over the Testing Data Set between the Proposed Algorithm (with Two Classification Methods) and Two Previous Studies

Algorithm	TPR (%)	TNR (%)	PPV (%)	ACC (%)	AUC (%)
AICPV	85.5	79.8	72.2	82.0	82.7
AICPV w/ GMM	94.7	90.3	88.2	92.2	92.5
Várady et al.	63.5	66.6	35.0	66.0	65.1
Fontenla-Romero et al.	70.2	64.5	13.6	64.9	67.3

Summary

1. Critically evaluated the reasons for monitoring patients
2. Challenging to link monitoring with clinical outcomes
3. Prediction of events may have potential clinical impact.