

THE PRODIGY STUDY

TALKING POINTS

Medtronic

Study overview and methodology:

- PRODIGY is a mnemonic for **P**Rediction of **O**pioid-induced respiratory **D**epression **I**n patients monitored by capno**G**raph**Y**.
- PRODIGY is a Medtronic-sponsored, prospective, multi-center study to identify individuals at high risk for opioid-induced respiratory depression (OIRD). To our knowledge, this is the largest known such study using continuous capnography and pulse oximetry.
- PRODIGY is one of the first studies to assess clinical and economic evidence to support the use of continuous monitoring with capnography and pulse oximetry on the general care floor (GCF) of the hospital ward.
- The study analyzed 1,335 patients at 16 centers (9 in the United States, 4 in the European Union, 3 in Asia) from 7 countries. This allowed potential comparisons across different hospital settings and geographical regions.
- Continuous capnography and pulse oximetry data were collected using Microstream™ and Nellcor™ monitoring technology, with displays blinded and alarms silenced throughout the monitoring period.
- Respiratory depression episodes (RDEs) were detected using blinded, nonalarming continuous capnography and oximetry monitoring on the GCF, defined by one or more of the following:
 - $\text{etCO}_2 \leq 15$ or ≥ 60 mmHg for ≥ 3 continuous minutes
 - $\text{RR} \leq 5$ breaths per minute for ≥ 3 continuous minutes
 - $\text{SpO}_2 \leq 85\%$ for ≥ 3 continuous minutes
 - Apnea episode lasting > 30 seconds
 - Any opioid-related respiratory depression episodes (RDEs)
- RDEs for every patient were reviewed by a four-physician clinical events committee to confirm accuracy and authenticity.
- The initial study publication, "Respiratory Depression in Low Acuity Hospital Settings — Seeking Answers from the PRODIGY Trial," was published in the *Journal of Critical Care*. It reviewed respiratory compromise on the GCF and the study methodology.¹

- The primary publication, “Prediction of Opioid-Induced Respiratory Depression on Inpatient Wards Using Continuous Capnography and Oximetry: An International Prospective, Observational Trial,” has been accepted by *Anesthesia and Analgesia*.²

Based on the quantity and breadth of data collection, there will be many opportunities for secondary analyses and publication, including an assessment of the economic impact of respiratory compromise (RC) and an examination of how the type, dosage, and timing of opioid administration influences RC risk.

Key study takeaways:

- The study met its primary objective of deriving and validating a Risk Prediction Tool to identify adult patients receiving opioid medication on hospital GCFs at increased risk for OIRD.
- One or more RDEs were detected in 46 percent of the 1,335 GCF patients analyzed.²
- The new Risk Prediction Tool looks at five patient variables: age ≥ 60 by decade, sex, opioid naivety, sleep disorders, and chronic heart failure. Each variable is given a point value as noted in the chart below. This is the PRODIGY Risk Score.

Risk Factors	Scoring Criteria	Points	Score
Patient Age (years)	Age < 60	= 0 pts	
	Age 60–69	= 8 pts	
	Age 70–79	= 12 pts	
	Age ≥ 80	= 16 pts	
Sex	Male	= 8 pts	
	Female	= 0 pts	
Previous Opioid Use	Opioid naïve	= 3 pts	
	Previous opioid use	= 0 pts	
Sleep Disordered Breathing (SDB)	Known SDB or high STOP-BANG score	= 5 pts	
	No SDB or normal STOP-BANG score	= 0 pts	
Chronic Heart Failure (CHF)	Coexisting CHF	= 7 pts	
	No known CHF	= 0 pts	
Total PRODIGY Risk Score			

The PRODIGY Risk Score is divided into three risk levels: low risk (< 8 points), intermediate risk (≥8 to < 15 points), and high risk (≥15 points). For example, a 75-year-old male (12 points for age, 8 points for male gender) with a history of chronic heart failure (7 points) would receive a score of 27. This patient would be in the high-risk category.²

PRODIGY Risk Level

- Low risk of respiratory depression episodes for less than 8 pts
- Intermediate risk of respiratory depression episodes for 8–14 pts
- High risk of respiratory depression episodes for 15 pts or higher

Clinical and economic implications:

- The Risk Prediction Tool can serve as a guide to identify patients at the highest risk and guide early intervention using continuous capnography and pulse oximetry monitoring.
- Early identification and intervention in these high-risk patients have the potential to improve patient safety and decrease the economic and clinical burden of unplanned ICU admissions.
- Mean hospital length of stay was three days longer in patients with ≥1 RDE.²
- The average hospital cost for U.S. patients with 1 or more RDEs was significantly higher (\$4,446 on average) and the mean cost for “high-risk” scored patients with 1 or more RDEs was \$6,448 higher than for “high-risk” patients without RDEs.³

Respiratory compromise and opioid-induced respiratory depression (OIRD):

- Respiratory compromise (RC) is a common, costly, deadly — and preventable — condition^{4,5}
 - RC is the leading cause of ICU admissions⁶ and is one of the key contributing factors for code blues.^{7,8}
 - Patients with RC originating on the medical surgical floor are 29 times more likely to die than those experiencing it in other areas of care.⁴
- RC consists of respiratory insufficiency, failure, and arrest, and increases the likelihood of adverse outcomes and cost of patient care.^{4,5}
- OIRD is a significant cause of brain damage and death⁵, without any standardized risk prediction tools currently available.¹

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