MARKET SNAPSHOT

What You Lose When You Don't Snooze

Maria Shepherd • Data Decision Group

ore than 70 million Americans suffer from sleep disorders and of those, more than 18 million have obstructive sleep apnea (OSA).1 OSA is caused by a blockage in the throat, generally associated with a collapse of the soft tissue. With each episode of apnea, the brain partially or fully wakes the sleeping patient as an alert to continue breathing. The interval between breaths can last from seconds to minutes, and these intervals can happen more than 30 times per hour.² If left untreated, OSA can trigger high blood pressure, and other cardiovascular co-morbidities that touch almost every disease state addressed by the medical device industry.3

Why it's Important in Orthopedic Surgery

OSA is prevalent among surgical patients. A retrospective 2011 study⁴ reviewed orthopedic surgery patient records (n=527) to determine incidence and risk factors for post-op hypoxemia and complications in OSA patients. In this study, 33 percent of the patients developed hypoxemia and 11 percent developed hyporcarbia, an abnormally high level of carbon dioxide in the bloodstream.

Risk factors for hypoxemia were hypercarbia, use of bronchodilators, a body mass index greater than 35, and estimated blood loss of more than 250 millileters. Patients with hypoxemia had significantly

more respiratory interventions, longer hospitalizations and a higher risk of wound infections. Severe hypoxemia was associated with significantly more interventions than mild hypoxemia.

Hypoxemia Rates in OSA Patients by Surgery Type

Post-operative hypoxemia in OSA patients is associated with adverse outcomes. This study measured the incidence of hypoxemia (none, any, mild, severe) by surgery type with the outcomes seen in Chart 2.⁶ The mean and standard deviation for duration of each episode was 143±178 minutes—greater than two hours, on average, per episode. This is an enormous



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TABLE 1.

Adverse Outcomes Associated with Hypoxemia in OSA Surgery Patients¹⁰

	No Hypoxemia	Any Hypoxemia	Mild Hypoxemia	Severe Hypoxemia
Need for CPAP	27%	36%	35%	38%
Increased intensity of care	15%	45%	36%	70%
Higher wound infection rates	0%	3%	4%	2%
Increased hospital length of stay (days)	4.4+/-2.3	6.0+/-5.2	6.0+/-5.9	5.9+/-2.3

cost to the healthcare system. The authors noted most institutions do not have sufficient resources for intensive monitoring of all post-operative OSA patients and that every hypoxemic episode was serious enough to warrant clinical intervention. It has been estimated that each institution would need to spend at least \$25,000 annually to provide a high level of monitoring of post-operative OSA patients.⁷

Adverse Outcomes Associated with Hypoxemia in OSA Surgery Patients

In this study, patients with hypoxemia episodes experienced an increase in adverse outcomes as seen in Table 1.9

Impact on the Healthcare System

Like diabetes, an effect treatment for OSA could have a significant ripple effect across the healthcare system. Orthopedic device companies should consider the opportunity to find treatments that address this complex disease state during orthopedic surgery. This is not a far-fetched concept if we think out of the box and consider other successful examples to treat device-related complications. A good analogy is the development of anti-microbial coated catheters to reduce infection rates in catheter based interventional procedures. While the jury is still out on current efficacy rates of these treated catheters, technology will improve and prevail, and ultimately catheter based infection rates will decrease. OSA is a significant opportunity for innovators in our industry because orthopedic patients with OSA are an at-risk and underserved market. 💠

References:

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7. Gross JB, et. al. Practice guidelines for the perioperative management of patients with obstructive sleep apnea: A report by the American Society of Anesthesiologists Task Force on Perioperative Management of patients with obstructive sleep apnea. Anesthesiology. 2006; 104:1081-1093

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9. Liu S., et. al. Postoperative hypoxemia in orthopedic patients with obstructive sleep apnea HSSJ (2011) 7:2-8 10. Ibid

Readers are invited to submit market data and trend questions to Maria Shepherd. Periodically, selected questions will be presented in this column, with answers from Maria. Send your questions to mshepherd@ddecisiongroup.com.

Maria Shepherd has 20 years of leadership experience in medical device/life-science marketing in small startups and top-tier companies. After her industry career, including her role as vice president of marketing for Oridion Medical where she boosted the company valuation prior to its acquisition by Covidien, director of marketing for Philips Medical and senior management roles at Boston Scientific Inc., she founded Data Decision Group. Data Decision Group provides whitespace research and critical data to support medical device decision making. The firm quantitatively and qualitatively sizes opportunities, evaluates new technologies, provides marketing services and assesses prospective acquisitions. Shepherd has taught marketing and product development courses, and is on the board of the MSBiV Medtech Investment Committee and can be reached at (617) 548-9892 or at mshepherd@ddecisiongroup.com.