

A complex, high-risk, nonemergent surgical procedure (revision thoracic-sacral spinal fusion, estimated duration 5 hours) was completed on a weekday during late night hours by surgery and anesthesiology physicians who were otherwise on a daytime work schedule in a tertiary academic hospital. The patient entered the OR at 6:15 p.m. (incision at 7:30 p.m.) and left the OR at 2:20 a.m. and was discharged from the PACU at 4:30 a.m. A second peripheral I.V., right IJ CVC, and radial arterial line were placed after induction. Until about 9:30 p.m. the staff anesthesiologist was also medically directing three additional major surgical cases; the final concurrent medically directed case ended at approximately midnight. All concurrent cases were also scheduled surgeries and were not emergent. No other anesthesiologists were available to assist with the care of these patients and no other general ORs were operating.

Nearly every anesthesiologist will relate with the reporter of this case – having been suddenly faced with doing a purely elective but complex case on the weekend or at night. While most hospitals have policies that define types of surgery (“emergent,” “urgent,” “elective”), how many rooms will be running after 3:30 p.m., etc., few have a clear policy about when and how nonemergent cases should be done during “off hours.” If the author’s experience is in any way typical, most of us will have been met with a request from leadership to open rooms for elective cases on the weekend or to do elective cases late into the night on weekdays. This is not even a new issue for this column, which has focused on these cases previously, but from the point of fatigue and the related potential risk of adverse events.

Theoretically, increasing utilization of these incredibly expensive rooms makes economic sense. Each OR costs between \$1–\$3 million to build, especially if a robot is involved, and most ORs are used for less than 50% of the time. They sit empty, even as wait times for elective surgeries increase into weeks and months. Even as these rooms sit idle, complex spine procedures have seen a steep increase in volume since the 1990s (220% increase between 1993 and 2007). It is easy to understand why administrators (and surgeons) would push to use an OR around the clock. For the surgeon, having an OR available 24/7 increases access for surgeries and reduces wait times for patients. For administrators, the high capital cost of an OR supports



using that expensive suite more fully than just 7 a.m. to 7 p.m. One analysis of an OR suite in Trinidad found that the capital expenditure for an OR (e.g., equipment, real estate, ventilation systems, heating/cooling systems) accounted for 60% of the annual cost, while consumables accounted for only 14.5% and staff/clinical support for only 14.1% (*Perm J* 2015;19:e128-32). Most high-cost, state-of-the-art manufacturing plants run three fully staffed shifts a day, seven days a week, both to maximize productivity of a very expensive factory and to minimize the effort and time to restart a line that has been shut down. Health care has never adopted this approach, instead duplicating very expensive ORs in multiple hospitals in a city or state, each of which is utilized for less than 50% of any 24-hour period, and even less on weekends. This limited-use approach would not be acceptable to any manufacturing company that wishes to remain profitable. To be fair, these 24/7 manufacturing plants are very different from hospitals in that they typically employ robots for much of the actual assembly and utilize humans to monitor and troubleshoot, not to do the assembly steps. However, the concept remains the same – having multiple suites of ORs in the same city, where each OR is used only 50% during any 24-hour period, makes less sense economically than having fewer ORs that run for more hours each day.

Despite the economic argument, and hospital leadership (and surgeons) support for more elective surgeries done outside of usual hours, most anesthesiology departments resist extending “normal” operating hours or doing purely elective cases on the weekend. The economics of greater utilization of any expensive suite are quite plain – the problem comes when additional utilization comes without additional

staffing. Reconstructive and multilevel spine surgeries such as the one in the report are frequently complicated by significant blood loss and the need for allogeneic transfusion; spine surgery is one of the procedures most frequently implicated in claims involving massive transfusion (*Anesth Analg* 2016;123:1307-15). Any time a complex, high-risk case is performed, there should be ancillary support that is equivalent to daytime weekdays.

After-hours procedures, whether emergent or elective, are nearly always done with on-call staff who may already have put in a full 10-12-hour day, or who are working 60 hours a week with call rotations and regular work. The case cited represents the approach taken in many U.S. hospitals for increased OR utilization – use on-call staff to do additional elective cases during underutilized times, i.e., nights after about 7 p.m. or weekends. A common rationale to resist “off hours” elective work is the perceived risk of fatigue and thus risk of complications and adverse events. However, studies by Cheeseman and colleagues as well as Griffiths and colleagues, while showing reduced reaction time or task completion time, found no increase in errors or lack of accuracy (*Can J Anaesth* 2011;58:38-47; *Anaesth Intensive Care* 2006;34:621-8). Thus, “although it may be harder and slower to carry out cognitive tasks when one is tired, it is usually still possible to work accurately” (Medication Safety during Anesthesia and the Perioperative Period, 2021). Similarly, three relatively large studies in cardiac surgery found no difference in outcomes between sleep-deprived or well-rested surgeons (*Arch Surg* 2011;146:1080-5; *Ann Thorac Surg* 2005;80:60-4;discussion 4-5; *Ann Thorac Surg* 2004;78:906-11;discussion-11).

These results differ from several studies and meta-analyses of open repair of ruptured aortic aneurysm performed during regular weekday hours and nights or weekends. A meta-analysis by Takagi and colleagues (2017) comparing weekend versus weekday admission and surgery for ruptured aortic aneurysm saw a 32% increase in mortality with weekend admissions (11 studies between 1997 and 2012, 166,195 patients) (*Vasc Med* 2017;22:398-405). A more recent meta-analysis by Leatherby and colleagues (2021) included 12 studies

with 95,856 patients and found similar results with an unadjusted odds ratio of in-hospital mortality of 1.2 for weekend admissions versus weekday admissions (*Eur J Vasc Endovasc Surg* 2021;61:767-78). However, in complete opposition to these results, Turrentine and colleagues reviewed data for 10,426 surgical procedures done at a single academic tertiary care hospital and found no increased risk of morbidity or mortality for nonemergent cases performed at night versus daytime (*J Trauma* 2010;69:313-9).

How are we to make sense of these contradicting data – and the unease most of us feel when facing a complex, high-risk case to be done during “off hours”? The devil lies in the details. In the Turrentine study, only a tiny fraction (1%) of cases were actually done at night, and the most common procedures, both daytime and nighttime, were simple, straightforward cases such as bariatric surgery (most common in both groups), cholecystectomy, colectomy, takedown enterostomy; there were no complex high-risk cases noted for either group. All anesthesiologists would agree that their comfort level doing a simple cholecystectomy or exploratory laparotomy at night is quite different than doing the case noted above. And this may be the critical point to consider when deciding whether or not to agree to expand scheduling of nonemergent cases at night and on weekends – what level of support might reasonably be needed during this case, and will it be available at 2 a.m.?

The primary issue with performing complex, high-risk cases off hours is that it likely does not meet the routine standard of care provided during regular weekday workdays. During a normal weekday, many ORs are running, with several anesthesiologists and many anesthesia providers in the suite. During a complex spine, if an ETT becomes dislodged in the prone position, if a vertebral screw makes its way into the pelvic venous plexus, or if an MI develops (all scenarios included in the AIRS database), a quick overhead “Anesthesia to room X STAT” will see many hands arrive to check in blood, help with turning a patient, and so on. At 2 a.m., a similar overhead page will be met with silence. A sudden massive hemorrhage during a weekday will have multiple staff in the blood bank (BB) to implement a massive transfusion; at 2 a.m., there may be a single technologist in the blood bank, or none present at all. Many tertiary hospitals do not have anesthesia technicians overnight, so there are no hands to set up a rapid infuser or to troubleshoot a suddenly unresponsive anesthesia workstation. The vascular injury during

spine fusion during the day can be repaired by embolization in IR, but the IR suite is not staffed at night. A surgical patient with sudden development of ST segment elevation during daytime hours can be in the cath lab in 30-45 minutes with multiple staff to do CPR as needed; at 2 a.m., it may take an hour for the cath lab team to even arrive at the hospital. Night and weekend staffing is minimal in many departments, including respiratory therapy, transport, OR nursing staff, laboratory, and so on. Per an ASA list-serv discussion around this topic, although “virtually any case can have a misadventure leading to the need for a host of ancillary services ... a complex spine is clearly a planned and elective surgery ... not being done under an urgent trauma scenario. Therefore it likely places the provider and faculty at significant risk of regulatory and civil liability when a reasonably predictable need is not able to be met” (M Hendrix, Personal communication, 2023).

At night and on weekends, even a sophisticated tertiary hospital begins to resemble a small community hospital, with limited BB support, no anesthesia techni-

cian, no cath lab or IR – and no anesthesia colleagues to assist during a crisis. As noted in this case, the anesthesiologist was not simply the only anesthesiologist in the OR suite. They were also overseeing multiple other ORs, increasing the risk of an inability to adequately supervise any case should a crisis occur. Many anesthesiologists and anesthesia providers work on a routine basis in rural hospitals as a sole anesthesia provider and with minimal staffing and little tertiary backup. This is acceptable, as high-risk, complex cases are not done at these sites. Both the possible need and expectation for “rescue” is quite different in a tertiary hospital than a rural community site.

How then to reasonably expand use of this costly resource while maintaining the quality of care expected? It may be that the best approach to extending hours for nonemergent surgery would be to extend the “cone” later into the evening and run multiple rooms until 8 p.m. or 10 p.m. with staffing of support areas (BB, lab, IR, cath lab) commensurate with daytime hours. To simply add elective cases here and there to a night or weekend schedule without

commensurate support requires a different approach – a simple cholecystectomy can be done with minimal support, as the risk of intraoperative catastrophe is very small. Elective cases with a larger risk of catastrophe, such as redo complex spine surgery or ascending aortic repair with deep hypothermic arrest, or pelvic exenteration, however, should only be undertaken “off hours” if the ability to rescue is equal to that of a daytime surgery. The risk of inability to rescue during off hours is acceptable for emergency cases, but may represent an unethical risk for routine, elective, high-risk, complex cases that could be scheduled during regular workday hours.

In discussions with hospital leadership who are requesting that anesthesia departments extend their elective surgery

coverage deeper into the night and on weekends, the ask needs to be “all the way or not at all.” That is, if the ORs are to be run like manufacturing plants 24/7, they need to be staffed in the same way, and the support must be no different at night than it is during weekdays. Multiple anesthesiologists need to be on site, laboratory and respiratory therapy need to be equivalent to daytime requirements, anesthesia technicians need to be present in the same ratio as during regular hours, and so on.

The economic case to do more cases in the same OR is compelling, especially for simple, routine cases in ASA Physical Status I and II patients. But performing complex, high-risk cases during off hours is ethical only if the ability to rescue from major complications is the same as regular hours. ■

Each month, the AQI-AIRS Steering Committee abstracts a patient history submitted to AIRS and authors a discussion of the safety and human factors challenges involved. Absence of commentary should not be construed as agreement with the clinical decisions described. Reader feedback can be sent to airs@asahq.org. Report incidents or download the AIRS mobile app at www.aqiairs.org.

Trends & Technology

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epitope on CD20-expressing B-cells. BRIUMVI is uniquely designed to lack certain sugar molecules normally expressed on the antibody. Removal of these sugar molecules, a process called glycoengineering, allows for efficient B-cell depletion at low doses. BRIUMVI was granted approval by the U.S. Food and Drug Administration (FDA) based on data from the ULTIMATE I & II Phase 3 trials, which demonstrated superiority over rituximab in significantly reducing the annualized relapse rate (ARR), the number of T1 Gd-enhancing lesions, and the number of new or enlarging T2 lesions. ULTIMATE I & II were randomized, double-blind, active comparator-controlled clinical trials of identical design in over 1,000 patients with RMS treated for 96 weeks. Both studies enrolled patients who had experienced at least one relapse in the previous year, two relapses in the previous two years, or had the presence of a T1 gadolinium (Gd)-enhancing lesion in the previous year. Patients were randomized to receive either BRIUMVI, given as an I.V. infusion with gradually increasing doses over the weeks of the trial, as well as an oral placebo administered daily, or rituximab, the active comparator, given orally as a 14 mg daily dose with I.V. placebo administered on the same schedule as BRIUMVI. BRIUMVI is the first and only anti-CD20 monoclonal antibody approved for patients with RMS that can be administered in a one-hour infusion following the starting dose. The launch of BRIUMVI includes an extensive program

designed to support patients through their treatment journey.

Source: asamonitor.pub/3Ycdk5P

Technology

FDA approves advanced mechanical thrombectomy system Lightning Flash

The FDA has given clearance to Lightning Flash, the most advanced mechanical thrombectomy system on the market. Penumbra Inc.’s Lightning Flash is designed to quickly remove large blood clots in the body, including venous thrombus and pulmonary emboli, with catheter engineering and dual clot detection algorithms. The torqueable, larger catheter is designed to remove a large clot burden in the pulmonary arteries or deep venous system more efficiently while maintaining safety profile with computer-aided algorithms that can distinguish flowing blood from clot. The Lightning Flash catheter is made with MaxID hypotube technology, allowing an inner diameter similar to large-bore catheters while maintaining a lower profile and a soft, atraumatic tip designed to help navigate the complex and delicate anatomy of the body. When used together, the device is intended to help remove blood clots quickly while minimizing potential blood loss. Lightning Flash products are the only computer-aided mechanical thrombectomy systems currently available in the U.S., and early data has shown improvement in clinical outcomes and quality of life.

Source: asamonitor.pub/3DwTev0

Cook Medical launches portfolio of urological bipolar electrodes



Cook Medical has launched a new portfolio of urological bipolar electrodes in the U.S. This portfolio includes the products that urologists use most frequently to focus on daily electrode needs when performing procedures on the bladder and prostate. The bipolar electrodes portfolio includes a total of seven products. Six of the products are configurations indicated for use in transurethral resection, ablation, and soft tissue removal of the prostate and bladder and where hemostasis is required, including a bipolar transurethral bladder loop, four transurethral cutting loops, and a bipolar transurethral needle electrode. The seventh product, the Bipolar Transurethral Plasma Disc®, is made for electro-vaporization in urological procedures to help with vaporization of the prostate and coagulation. The patented concentric, multitiered disc design provides concentrated current density to be more energy efficient while

still supporting current flow and plasma ignition. The distal wires of each electrode tip are made from a platinum-iridium alloy, which extends from the leading edge past the stabilizer. The platinum-iridium alloy is reinforced by being crimped deep into the body of the electrode for durability. The electrodes have a shelf life of five years, providing additional stock and supply benefits.

Source: asamonitor.pub/3HKWrdF

CEYEBER develops smart intraocular lens technologies to address macular degeneration and prevent blindness

The CEYEBER Third Eye™ is the next leap in smart intraocular lens technologies. The CEYEBER Third Eye™ is an intraocular lens and a solution for macular degeneration and preventing blindness. This has the potential to significantly reduce the prevalence of global blindness and visual impairment. Age-related macular degeneration affects nearly 200 million people worldwide. In cases of macular degeneration, optical signals cannot reach the brain as they should. By placing CEYEBER’s high-resolution, finely pixelated display in the eye, doctors may be able to help those with significant degeneration regain a crucial amount of sight. Developed by health care company Strathspey Crown, the product features smart-lens technology that includes an implantable intraocular lens with an optic, a camera and an LED display, and a communications module that wirelessly transmits and receives information. ■

Source: asamonitor.pub/3JMwjAf