An Orthopedic Surgeon, A Bike Wreck, and Stopping the Cycle of Opioid Use

OnMedicalGrounds

PODCAST 1

[00:04] Dr. Jill Sellers:
Welcome to the *On Medical Grounds* podcast. I'm Jill Sellers, your host. *On Medical Grounds* is a casual, friendly place where you can find an authentic audible blend of timely scientific and medical knowledge. We talk with experts about their experiences and knowledge, the utilization of new therapies, and challenges within the world of healthcare. Select podcasts offer continuing medical education credits for those of you needing an additional why you should listen. We provide perks to all posted podcasts by linking content so you can drink in more if you so choose.

[00:40] Dr. Jill Sellers:
Our guest today is Dr. Stephen Southworth. Dr. Southworth is a board certified orthopedic surgeon who specializes in hip and knee replacement. He has a Master of Science Degree from the University of South Carolina, a medical degree from the Medical College of Ohio and an MBA from the University of Tennessee. Dr. Southworth currently practices in Tupelo, Mississippi, and is affiliated with North Mississippi Medical Center and North Mississippi Ambulatory Surgery Center. I will provide a link to his full bio in the show notes. Welcome, Dr. Southworth.

[01:14] Dr. Stephen Southworth:
Jill, it's great to be with you again.

[01:16] Dr. Jill Sellers:
You and I have worked on a few medical education projects over the years, such as webinars, videos, and publications, including our most recent publication in *Clinical Therapeutics* titled "*Narrative Summary of Recently Published Literature on Intravenous Ibuprofen*." I'm going to link to that in the resources, in the show notes. I have to say through all these projects, you are one of the nicest and smartest people I have had the pleasure of working with. And just for the record, your wife did not tell me to say that. In addition, you and I share something else in common. We both, unfortunately, broke bones in 2020, just a few weeks apart during the pandemic. You got hit by a car. Isn't that right?

[01:57] Dr. Stephen Southworth:
Yes, last summer, June of 2020. It was a beautiful Saturday afternoon. I was out on my bike, just on city streets. I did indeed get hit by a van that turned into me. Fortunately, it was a low rate of speed. It was the kind of impact that an emergency room doctor would call a T-bone kind of injury. Although I didn't instantly know it at that time, the bumper hit and created a tibial plateau fracture on my left leg. And I ended up on the hood of the vehicle with my left forearm kind of impaled on the edge of the hood and split laceration down to muscle. Some very nice bystanders helped me get down in a log roll fashion. The EMS packaged me up. Cervical collar, spine board, IV, and then took me to the emergency department of the 650-bed hospital where I work seven days a week.

[02:54] Dr. Stephen Southworth:
Anyway. I'm going through my evaluation and treatments and I'm getting my CT scans and my lacerations are being sewn up. My leg is being mobilized after CT. And I have to say I did not get any kind of opioid or narcotic. I didn't get any antiemetic because I didn't get any opioid. I didn't get ketorolac. I did get intravenous ibuprofen. I got 800 milligrams of ibuprofen with a rapid infusion in my IV. And that is all I needed for pain control for those few hours and to get me home because ibuprofen has a 10 milligram morphine equivalency with none of the opioid side effects. So, although we're talking today about ibuprofen, I've also been a patient of it.

[03:44] Dr. Jill Sellers:
I'm curious. Did you have to request that or is that automatically what they gave you?

[03:48] Dr. Stephen Southworth:
It's not automatic.

[03:49] Dr. Jill Sellers:
Yeah.

[03:50] Dr. Stephen Southworth:
But being a physician there, they gave me choices.

[03:54] Dr. Jill Sellers:
Mm-hmm (affirmative). Well, your story's very exciting. Mine wasn't as exciting. I wasn't given choices of pain management. I was clumsy and just slipped on some wet concrete steps and broke my second, third and fourth metatarsals on my right foot. So anyway, suffice it to say, we've both had our orthopedic issues this year. And the treatment of our pain obviously varied. Speaking of pain management, let's get to our topic today. When did the use of opioids for pain management become an opioid crisis?

[04:24] Dr. Stephen Southworth:
It really took off, at least in the United States, about 20 years ago. In 2001, the Veterans Administration and the American Pain Society both opined that pain should be measured as if it was a vital sign. The Joint Commission, which was formerly called the Joint Commission on Accreditation of Healthcare Organizations, also opined that pain should be indeed a vital sign. So a fifth vital sign, so to speak, was born. The other four vital signs, of course being breathing, heart rate, blood pressure, and body temperature. This fifth vital sign kind of created a real conflict for hospitals and healthcare providers who are impacted in reputation, employability, Medicare reimbursement by patient satisfaction scores.

[05:10] Dr. Stephen Southworth:
This fifth vital sign set up hugely conflicting and adverse incentives for all involved. For example, pain scores and patient satisfaction scores ranked on customer surveys can influence reimbursement by CMS in a subsequent year. And there may be a perceived pressure to over-prescribe, although it might not be in the patient's best interest pharmacologically speaking. If reimbursement is tied to satisfaction, and satisfaction in the perspective of some patients is a prescribing habit, then that can lead to an adverse incentive. The other four vital signs can be measured objectively by an observer, such as a nurse, an EMT, a doctor, and so forth. But this fifth vital sign of pain can only be reported by the patient and cannot be independently

validated. And additionally, there are very great variations in how people report pain. Attempts have been made to create pain scales, like the 0 to 10 scale or the smiling face to the crying face scale often used for young children, but these measurements often are not reproducible. Variations in pain perception and reporting vary with age, gender, ethnicity, prior disease experience and so forth.

[06:23] Dr. Stephen Southworth:
I've had patients report to me that their pain is a 10, which should be a near death almost unconscious state of suffering, all while they could barely look up from their phone. And yes, before you ask, there are some pain medication recipients, hopefully not many, but some who participate, politely speaking, in the abuse and diversion of controlled medications. And I want to clarify something before going any further. Opioids are very important. They're safe. They're effective. They're completely legitimate when they're used in the right setting and in the right way. They have no cardiac or renal risk profile when used properly. And I'm not advocating against their use to alleviate suffering. But minimizing the dependence on opioids, however, is a worthy goal, especially when adjuncts or alternatives are available. Opioid monotherapy used to be a mainstay of treatment. And we can still use opioids when needed, but augment to minimize their adverse effects.

[07:22] Dr. Jill Sellers:
I agree that there is a time place and purpose for the use of opioid medications, yet knowing when and how to minimize their use is important. I'm curious. What was the tipping point that finally got the attention of healthcare providers and others that we had an opioid problem in the United States?

[07:42] Dr. Stephen Southworth:
Well, I can only speak to the United States' data. But over the past 20 years, the annual number of deaths from motor vehicle accidents has been surpassed by drug overdose deaths, most of those are opioid overdoses. And to be clear about it, most of the opioid overdose deaths are from synthetic or prescribed opioids. They're not street opioids like heroin. This crisis has been triggered by a number of interwoven issues that have resulted in a national storm. The adverse incentives in satisfying the difficult to measure fifth vital sign have created a conflicting situation for all involved. Patients, physicians, pharmacists, surgeons, nurses, EMTs, healthcare systems overall, just everybody.

[08:26] Dr. Stephen Southworth:
So patients who interact with the healthcare system are surveyed. Surveys are a good and healthy way to measure the needs of a consumer and how they're being met. However, the survey results can and do influence payments that healthcare systems can receive in the following year. When it comes to alleviating suffering, we should use every tool at our disposal that satisfies the patient consumer and is humane. Therefore, if there is a perceived unmet need, such as lack of pain management and that unmet need is reflected in the survey, the healthcare system financially suffers. At the same time in 2001 and after, pharmaceutical companies that produce opioids responded to this fifth vital sign mandate. And opioids were marketed more intensely as a new opportunity for pain management in market segment for their medication.

[09:20] Dr. Stephen Southworth:
The Washington Post and other investigators have identified emails that sadly ignore the increasing opioid dependency rate as long as the market kept growing. Healthcare professionals have known for many

years about opioid demand, the concerns for abuse and diversion and all of the negative consequences of inappropriate opioid use. And where has ground zero been? The most opioid afflicted areas in the United States have been West Virginia, South Carolina, Kentucky, and Tennessee, the heart of Appalachia, which includes some of the nation's poorest and most vulnerable people, both economically and in terms of addiction potential. So now, the pendulum is swinging away from opioid monotherapy. Driven by the diversion, abuse, and opioid related death statistics, the government has finally started to act against the problems that we as healthcare professionals have struggled with for decades.

[10:16] Dr. Jill Sellers:
I will link to the government action information you just mentioned in the show notes for our listeners. Dr. Southworth, when did you decide that a change needed to be made in how to manage patients pain, peri and post-operatively?

[10:29] Dr. Stephen Southworth:
Well, change is healthy, and disruptive change can be even better. In 2007, the concept of another NSAID for post-op pain management came along. And I was approached as a principal investigator for a study that used intravenous ibuprofen for a single site adult surgery where the wound should be closable. And I was intrigued. The study was a double-blinded, placebo-controlled, multicenter trial conducted on three continents. In the data analysis, it became clear that there was a statistical significance between study subjects who received intravenous ibuprofen versus those who had received placebo.

[11:06] Dr. Stephen Southworth:
The ibuprofen patients had better or lower visual analog or so-called VAS scores postoperatively, and they consumed less opioids in the recovery phase after surgery. And that study has been replicated among several other study segments, which have included women undergoing abdominal hysterectomy, older adults undergoing total joint arthroplasty adults undergoing laparoscopic cholecystectomy, children having tonsillectomy, burn patients, PrAMA patients, et cetera. With the accumulating data from each of these studies, it is become even clearer that IV NSAIDs improve the patient experience for those undergoing surgery or dealing with a significant injury in less perceived pain, less metabolic stress, and less or no opioid use.

[11:58] Dr. Stephen Southworth:
Opioid use has many potential adverse effects. And if we can lessen or avoid opioid use totally, the adverse effect profile of the opioid is decreased or eliminated. I was convinced that IV ibuprofen has a vital role in pain management after our first large trial of over 300 subjects that was published in 2009. The consistent supporting data from all the subsequent trials have only strengthened the case for the use of intravenous ibuprofen.

[12:27] Dr. Jill Sellers:
It sounds like you envisioned that IV ibuprofen could change the way pain is managed in surgical patients. So, has it?

[12:35] Dr. Stephen Southworth:
Well, since it became a commercially available in 2009, intravenous ibuprofen has significantly aided our comfortable, no narcotic or minimal narcotic surgery experience goal for patients undergoing elective

surgery. In addition, we now know that preoperative dosing just before surgery does not increase the bleeding risk unlike some other NSAIDs. There's a frequently a sense of anxiety or fear when a patient is facing a surgery or an invasive procedure. Educating the patient prior to the procedure is important for them to know that we're going to be addressing their anticipated pain concerns even before the scalpel touches the skin. And patients generally like the idea of multiple pain alleviating agents, of multimodal analgesia being available to them. Regional anesthesia, field blocks, NSAIDs, ice, immobilization and splinting for post-op injuries, or ice elevation and early mobilization and joint replacement procedures, these are just a few examples.

[13:37] Dr. Stephen Southworth:
In non-elective surgeries or with injuries that don't necessarily immediately require surgery, intravenous ibuprofen allows us to ease or eliminate pain without opioid monotherapy, particularly in the emergency room setting when the patient has an ongoing evaluation. IV ibuprofen has the equivalents of morphine analgesia, but none of the risk of respiratory depression. In the multiple trauma patient or the burn patient for example, where a patient may be going back to the OR for a series of procedures over days or weeks, IV ibuprofen has no dependency, no tolerance buildup, no propensity towards ileus, no increased bleeding risk and no increased need for transfusions or wound wash outs.

[14:24] Dr. Jill Sellers:
It seems to me the biggest hurdle other than alleviating patients' anxiety related to pain management may be to convince your colleagues that IV ibuprofen is worth a try. So tell me about the challenges and successes of using IV ibuprofen in your practice.

[14:40] Dr. Stephen Southworth:
It's been 14 years since we published our first 300 plus patient trial of randomized placebo controlled double-blinded multicenter data showing IV ibuprofen as minimizing opioid use in the perioperative experience. And I still have some of those same patients in my practice who now, as they age, need other procedures like joint replacement. So some of those patients who were in this study, and again, this study was double-blinded, so without going back and looking, I don't know and the patient doesn't know if they received ibuprofen or placebo, but some of them will ask in advance if they can have that same treatment that eased their pain back in 2007 or 2008. They were aware that it was a study drug then, but now we can assure them that it is available without being in a study and it can be used as long as they have no exclusion criteria. The primary challenge has been overcoming the patient's expectation that opioids are the first choice, which is untrue.

[15:39] Dr. Jill Sellers:
Yes, I imagine that piece of education is vital for alleviating surgery related stress for the patient. How has pain management evolved since you began as an orthopedic surgeon?

[15:51] Dr. Stephen Southworth:
We've moved away from opioid monotherapy as I've mentioned previously. I've been able to eliminate totally the use of ketorolac from my practice. Haven't used it in over a decade. Although ketorolac is effective for pain, it has some very undesirable features. First, it's a strong platelet binder. It absolutely increases bleeding in surgeries and injuries. Secondly, it's a highly Cyclooxygenase 1 or a COX-1 drug, so it can potentially interfere with the healthy prostaglandins, the ones that protect gastric mucosa and are

essential for healthy renal function. Even at low and moderate dosing, ketorolac can cause an acute renal insult. With the elimination of ketorolac, we've reduced transfusion rates and eliminate the episodes of NSAID associated renal injury. Also, reducing pain with a multimodal approach for injuries and surgeries has helped shifting a lot of inpatient stays and procedures to the outpatient arena. It helps eliminate emergency room bounce backs for unmet pain, has helped to minimize or totally eliminate opioid side effects when the opioid use is either decreased or not used at all.

[17:06] Dr. Jill Sellers:
I'm sure some of your colleagues were and/or will be hesitant to eliminate opioids from their pain management regimen. Do you have any advice for those considering the use of IV ibuprofen in managing their patients' pain?

[17:21] Dr. Stephen Southworth:
I do. First, don't take my word for anything. [inaudible 00:17:24] about intravenous ibuprofen from the published literature, there's an ever-growing mountain of evidence accumulating for the past 14 years, and from researchers around the globe serving many different patient population segments. Second, leverage the concept of multimodal analgesia. Using multiple agents and techniques eliminates the likelihood of adverse effects or overdependence on any one modality. And it's better for the patient. It's better for the outcome. It's better for the healthcare institution and in the long run, it's better for the population. Third, spend a moment preoperatively, preferably in the relaxed office setting, alleviating the patient's anxiety about the concept of pain and the use of the multimodal analgesia techniques and letting them know that you are their anti-pain advocate.

[18:15] Dr. Stephen Southworth:
Fourth, and this one is aimed mostly at orthopedists, trauma surgeon, sports medicine surgeons, plastic surgeons, et cetera. It's important to address the correct and incorrect information about short-term NSAID use and long-term fracture healing. The anecdotal opinions and retrospective reviews of two and three decades ago have not been validated in the recent literature. Using intravenous ibuprofen for 24 to 48 hours in a fracture surgery patient or a joint replacement patient has no influence on the recruitment or efficiency of osteoblasts weeks later. Fifth, understand the power of bioavailability. Oral administration of a medication will never equal IV administration in terms of plasma concentration. And some mechanisms of action depend upon that concentration. Only at peak doses does IV ibuprofen cross the blood-brain barrier, a level we will not achieve by tablet formulation.

[19:18] Dr. Stephen Southworth:
Sixth, preemptive multimodal analgesia will exceed catch-up techniques. If peripheral nociceptors are not medicated before the surgery and when the scalpel touches the skin, nociceptors will still fire even if a patient is under general anesthesia, but the patient just simply doesn't perceive it until the emergence from the anesthetic. However, pre-medicated nociceptors have a higher threshold for firing. So, prevention of pain always beats catching up on pain. Seventh, it's important to use opioids where indicated and avoid them where they're not indicated. Opioid induced hyperalgesia is becoming better understood, and it has negative effects of long-term opioids on fracture healing mechanisms that are just as important as avoiding as the longterm NSAID effects on fracture healing.

[20:11] Dr. Stephen Southworth:
Lastly, I would recommend that they study pain and its various components. Opioids have no antipyretic effect, no local analgesia. They do make people prone to constipation. They act only in the central nervous system and they have no anti-inflammatory effect whatsoever. But the vast majority of injury pain or postoperative pain is inflammatory in nature. And an opioid has no anti-inflammatory action, whatsoever. NSAIDs, however, are very effective at reducing the redness, swelling, heat, and inflammatory achiness of the incision and fracture pain. I know this from experience and as a prior fracture and post-op patient myself.

[20:53] Dr. Jill Sellers:
Yes, me too. Now, IV ibuprofen, the brand name of Caldolor is now available in a ready to use container. Can you comment on the utilization of this product in the perioperative setting? Has it made administration more efficient?

[21:09] Dr. Stephen Southworth:
To be totally truthful, it has made no difference to me whatsoever since I'm not the pharmacist or the pharmacy tech and I'm not the one that had to prepare the product for administration. It has, however, made a difference in the emergency room for personnel helping trauma patients without risking bleeding and without reducing respiratory drive in the injured patient which opioids can potentially do. Caldolor ready to use has also made for more efficiencies in the pre-op holding area where elective surgery patients receive the intravenous medication just before surgery, and also for more efficiency in the OR itself. So the anesthesiologist or CRNA doesn't have to wait for mixing time to administer the medication. Its also reduced demand on floor nurses giving post-op dosing when the mixing delay is eliminated.

[21:59] Dr. Jill Sellers:
It is amazing how eliminating just a few steps with one medication can positively impact workflow in patient care. I want to switch gears just for a moment and talk about changes in orthopedic surgery. Tell me some of what's been going on there. I have a few more questions about when the pandemic hit.

[22:19] Dr. Stephen Southworth:
Sure. Sure. Well, these are just a few, but some common ones. Fluoroscopic assisted fracture reductions, minimal incision surgery, microscopic visualization of small structures, arthroscopic procedures, computer assisted navigation techniques, multimodal analgesia, and moving inpatient interventions to outpatient status by maximizing these techniques. These are some very common ones.

[22:46] Dr. Jill Sellers:
When the pandemic hit, how did that affect your practice? And then, did the number of surgeries decline?

[22:54] Dr. Stephen Southworth:
Yeah, it's been an interesting year, hasn't it?

[22:56] Dr. Jill Sellers:
Yes.

[22:58] Dr. Stephen Southworth:
The number of elective procedures declined for a number of reasons. First, in some of the US states, including my own, elective inpatient procedures were postponed for weeks or a few months to minimize the consumption of personal protective equipment or PPE, because that was needed to care for the most ill of the COVID-19 patients. Second, a lot of patients wanted to just avoid the hospital environment totally out of fear of catching COVID-19, although in-patient risk was quite minimal for personnel taking appropriate protective precautions. And I have to say that I have felt safer in the hospital than I did at the grocery store this past year based on the public's adherence or lack of adherence to distancing, masking, and hand washing protocols.

[23:47] Dr. Stephen Southworth:
Thirdly, even though I'm at a very large healthcare facility, it's a 650-bed hospital at the center of a seven hospital hub and spoke system, it was inevitable that some healthcare professionals would either have to quarantine from a presumed COVID-19 exposure or actually become ill. We have approximately 6,500 employees in our system and we could tolerate a few persons being quarantined. However, as the pandemic progressed, the numbers climbed, paralleling the progression of the world. And we became quite strained when we were losing 100 or 200 or even more employees for a 10 to 14 day period at a time, particularly if that employee had a critical pandemic related role like respiratory therapist, nurse, ICU physician, infectious disease specialist, or so forth.

[24:41] Dr. Stephen Southworth:
Injuries, however, did not decline. While elective cases dropped off, fractures still had to be treated. We did move more fracture cases to the outpatient setting when circumstances permitted as long as it did not risk patient care. Outpatient surgery does not keep the patient in the hospital or at least no longer than 23 hours. So PPE consumption is less as is the employee burden. When our State Department of Health provided appropriate weekly guidance based on illness trends, we gradually resumed surgery for patients requiring elective procedures, but the emphasis on the outpatient setting remained. This was a trend that predated COVID-19. The pandemic just accelerated it.

[25:25] Dr. Jill Sellers:
What impact will this shift to ambulatory or outpatient surgery have on your ERAS protocol?

[25:31] Dr. Stephen Southworth:
Well, we maximize everything we can to complete the safe perioperative experience while reducing the likelihood of return to the ER or office for pain control. As long as patients, and just as importantly, as long as their significant others and caregivers understand that multimodal analgesia combined with preoperative education of what to expect, what to look for, how to elevate [inaudible 00:25:53], when, where, and how to apply ice, how to safely mobilize, when to make a phone call, when to plan that office visit, when to return to work, when to use an NSAID either with or without acetaminophen and when to stop either or both, these are very important. As long as patients and families understand these things and that the outpatient experience can actually be safer than the inpatient experience because inpatient is where all the sick people are, then maximizing ERAS augments all of those expectations.

[26:27] Dr. Jill Sellers:
How does the hospital inpatient setting differ from the outpatient or ambulatory surgical setting with respect to reducing reliance on opioids and managing a patient's pain?

[26:39] Dr. Stephen Southworth:
Well, interestingly, most of our early IV ibuprofen studies were hospital-based. In my particular hospital, there is a protocol that requires all IV medications to be pump administered. And it kind of takes almost an act of Congress to change those protocols. So, IV ibuprofen in my institution is given in approximately a 20 minute infusion. But right across the street at the Ambulatory Surgery Center, which is still part of the very same large healthcare system, that pump requirement does not exist. So at the Ambulatory Surgery Center, patients can get a pre-operative dose of IV ibuprofen in a five to 10 minute infusion. IV ibuprofen is never given as a bolus, but the administration time has definitely shortened. This maximizes bioavailability and peak plasma concentration of the medication so the peripheral nociceptors, peripheral nerves, and brain's pain center are maximally medicated before surgery.

[27:39] Dr. Jill Sellers:
How important is IV ibuprofen in your pain management protocol? And when do you do administer it?

[27:46] Dr. Stephen Southworth:
My pain management protocol has made IV ibuprofen really the central and first agent used, both pre and post-operatively for the inpatient. Other medications, and opioids in particular, have become the adjunct when needed, not vice versa as it was prior to the concept of multimodal analgesia. When we utilize this protocol, the patient is not groggy, they're not sedated, they have less risk or no risk of an ileus. They're more likely to get up and move and exercise, to work with a physical therapist, to walk, to do their leg lifts, to do their heel slides, et cetera. Faster mobility is always good for every organ system. It's better for the patient. It minimizes Atelectasis. It promotes shorter inpatient stays and it leverages outpatient success. For elective surgery patients, IV ibuprofen is given in the pre-op holding area just before proceeding to the OR.

[28:41] Dr. Stephen Southworth:
If the patient is staying in the hospital, I use a six hour dosing plan as long as the patient has an IV or saline lock excess. In all cases, I stopped the IV ibuprofen at 48 hours post-op and never exceed 3,200 milligrams total in a 24 hour period, which equates to 800 milligram dosing every six hours. For trauma and fracture patients, IV ibuprofen can be given in the emergency department or in the pre-op holding area. Patients admitted with injuries without the need for immediate surgery, IV ibuprofen is the first agent and other modalities are maximized. Splinting, ice, elevation, early mobilization as long as it does not risk fracture stability. And opioids are really now the second tier agent.

[29:32] Dr. Stephen Southworth:
For outpatient surgery, patients receive a single dose of IV ibuprofen in the pre-op holding area. They undergo their procedure and then they're home in two to three hours. And they're instructed prior to surgery that they can use oral ibuprofen every six hours for up to two days for fractures after the surgery, but at two days they've got to stop the NSAID. They may have an opioid prescription, but I've had patients not fill it. Some of them even will bring back the unused paper prescription to me when they come back for their X-ray check or for their wound check in the office.

[30:05] Dr. Jill Sellers:
And I think that is absolutely incredible from the pharmacy perspective that I have a totally different view of that, you know? But I appreciate patients who take responsibility for their health, understand the risk of

medication use, and do not want to subject themselves to potential problems with medications. Thank you, Dr. Southworth for being here and educating us on IV ibuprofen and its important role in surgical patient pain management. It has been very educational. And I, personally, appreciate surgeons like you who are concerned about not only pain management, but the drugs used to manage pain. So thank you.

[30:44]] Dr. Stephen Southworth:
It's my honor.

[30:47] Dr. Jill Sellers:
And thank you for listening to the *On Medical Grounds* podcast. Instructions for processing your continuing medical education credits and the resources that were referred to in this podcast are linked in the show notes. In addition, be sure to click the subscribe button to be alerted when we post new content.