Q&A: Fighting Infection With Innovation

Recently, TYRX, Inc. announced that it received U.S. Food and Drug Administration (FDA) 510(k) clearance to market AIGISRx® ST, an antibacterial product for the surgical repair of damaged or ruptured soft tissue. *Surgical Products* spoke with Daniel Lerner, MD, a cardiologist and chief medical officer at the company about the new development, and why it works to help surgeons and surgical staff in their fight against hospital-acquired infection (HAI).

***Surgical Products*:Can you provide some background into the antibacterial technology used in the new AIGISRx® ST product? What does this new patch contain that allows it to fight infection?**

Dr. Lerner: The AIGIS patch contains a combination of two antimicrobial agents: minocycline and rifampin. These two antibiotics are generics, but the combination is proprietary. It was developed by an infectious disease doctor at Baylor University, Rabih Darouiche. He developed this antibiotic combination more than 10 years ago and it has been used on multiple medical devices, including central venous catheters, hemodialysis catheters, CSF shunt catheters and penile implants. There are multiple randomized controlled trials of this antibiotic combination for preventing medical device-related infections that in aggregate have included more than 1,400 patients. The research demonstrates that this antibiotic combination is effective at preventing HAIs of medical devices.

***Surgical Products*: Why did the company decide to expand this technology to gastrointestinal surgeons and general surgeons? What needs were you looking to meet?**

Dr. Lerner: It’s clear that in today’s medical environment, surgical site infection is a large unmet clinical need. We currently market a product used with pacemaker and ICD implantation. That was a compelling application for us because those infections are associated with significant morbidity, cost and mortality.

Surgical infections in the general surgery realm are very similar in their fingerprint

in that surgical site infections are rare. Usually in general surgery, surgical site infections are in the 3 to 4 percent range. However, when they occur, they're very catastrophic for the patients because it means that the benefit of the surgery can be diminished. The patient usually needs a sustained course of antibiotics, and in some cases, the surgery may even need to be repeated.

So, the feeling at the company was that given that the general surgery case load in this country is quite large—approximately three million cases/year—that this was an area where the company's technology and innovation could have a particularly relevant impact.

***Surgical Products*: Are there certain infections in which this patch is particularly helpful in preventing?**

Dr. Lerner: The combination of minocycline and rifampin is a very broad spectrum antibiotic combination, that is, it has effectiveness against a broad spectrum of pathogens. The majority of surgical site infections are caused by two classes or organisms— Coagulase-negative staphylococci species and *Staphylococcus aureus*.

People are usually familiar with *Staph. aureus* because it can present with two general patterns of antibiotic susceptibility. One is susceptible to the antibiotic methicillin, and can be treated with less sophisticated forms of antibiotics. The other is resistant to methicillin, and is referred to as methicillin-resistant *Staphylococcus aureus* (MRSA). MRSA is a pathogen that is problematic because it requires more sophisticated antibiotic coverage. It turns out that MRSA is susceptible to the antibiotic combination of minocyclin and rifampin, and so one of the innovations that the AIGISRx® ST offers is local, sustained delivery of an antibiotic that MRSA is not resistant to. . The majority of the antibiotics are released within the first 72 hours, but antibiotic release can occur out to seven days.

***Surgical Products*: What types of surgical procedures does this patch benefit?**

Dr. Lerner: These devices, as they are cleared by the FDA, are indicated for preventing colonization of the mesh when it's used to perform a repair. So, where these antibiotics are accepted is in preventing an infection of the operative site that is due to colonization of the mesh. This is a problem that is obviously a concern for surgeons because they would like to have the cleanest field possible when they do the surgery.

This product has been cleared by the FDA for soft tissue repair, and that includes hernia repair. TYRX has a relationship with Bard around the use of this type of product for hernia repair, and in addition to hernia repair, this product would be useful anywhere that soft tissue repair is done in a surgical application. So if there is a weakness in a wall, or in any other soft tissue, this device would be FDA-cleared for that application.

***Surgical Products*: Why is a product like this particularly important for soft**

tissue procedures? Why are patients undergoing these procedures susceptible to infection?

Dr. Lerner: Surgical site infections are problematic because they incur a significant cost to the health care system and are associated with morbidity and mortality. There are certain types of procedures in medicine that carry a finite risk of a surgical site infection, and that's a risk that can be mitigated, but current technologies don't allow it to be totally eradicated. That risk is increased by some patient characteristics, like diabetes, and also by some aspects of procedures that are conducted in typically less clean areas of the body tend to have a greater risk.

For example, procedures like inguinal hernia repair occur in parts of the body that tend to have a higher likelihood of contamination. These surgical site infections, which are to be expected at a certain rate with surgical procedures, can also be increased by either characteristics of the patient or characteristics of the procedure.

***Surgical Products*: What causes infections in these procedures?**

Dr. Lerner: The main cause is contamination of the operative field and that most often occurs from the patient's own skin flora. Human skin is colonized by pathogens that include the staphylococcus species that cause surgical site infections most commonly.

During preparation of the patient's skin, it's possible for some of these colonizing bacteria to enter into the surgical site, and that is believed to be the most common cause of surgical site infections. So, it's helpful if any antibiotics used in these procedures have activity against Staph aureus and, particularly in today's environment, against MRSA.

***Surgical Products*: Until now, what has been the solution for surgeons to fight infection in these procedures? Are their other antibacterial materials for soft tissue repair available?**

Dr. Lerner: It has been most common to administer intravenous antibiotics at the beginning of the procedure. In some types of procedures, this can be very effective as the sole means of infection prophylaxis. However, there are meta-analyses of published studies that show for particular classes of soft tissue infection, for example, some types of hernia repair with mesh, that the intravenous antibiotics can have a minimal impact on reducing infection. So, an adjunctive form of antibiotic therapy might have value in that setting.

What do you see for the future as this product is used more often in ORs? How do you think this product will help improve care for patients?

Dr. Lerner: Hospital-acquired infections are such an important area. Our focus now is to develop effective methods to use drug-device technology to reduce hospital-acquired infections.

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