Colorectal Delivery Device

Organization
Mercy Research
Division of Product Development & Informatics (PD&I)

Industry:
Healthcare/medical

Researchers:
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Status of Intellectual Property:
Issued US Patent No. US9402968

Next Steps:
Prototype optimization
Preclinical testing
Clinical studies

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Wanted

Experienced leader to finalize development and commercialization in coordination with the Mercy Research Product Development team

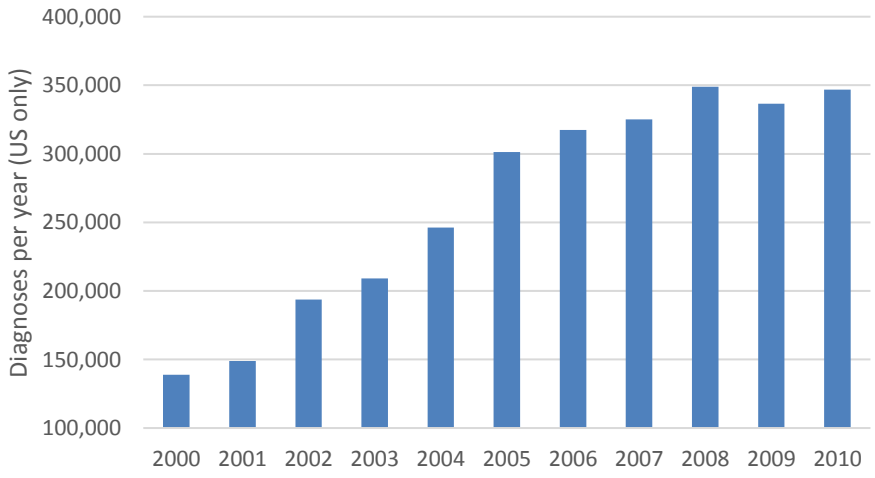
Customer Problem

Clostridium difficile is one of the most common hospital-acquired infections, and is increasingly a frequent cause of morbidity and mortality among elderly hospitalized patients. *C. difficile* infection (CDI) can lead to diarrhea, sepsis and even death. Current treatment methods rely on oral antibiotics. For severe and/aggressive cases, IV antibiotics or other therapies are delivered concomitantly with oral antibiotics. However, for recurring cases and/or patients who are unable to swallow oral medications, physicians often resort to topical treatment using a retention enema with IV vancomycin. This is off-label use of the IV drug, is frowned upon by the FDA, and has shown mixed results in published case studies. Reasons for failure include limited topical coverage of colonic tissues by the drug, inability of the antibiotic to reach the transverse colon, and limited exposure time.

Potential Market Uses

The Colorectal Delivery Device (CDD) has been designed to provide therapeutic foam to areas of the colon, achieving targeted topical therapy for a diseased colon and enhanced disease treatment. The advantage of this device is its ability to deliver a foam medication into the descending colon as well as past the splenic flexure and into the transverse area of the colon. Compared to enemas, a foam application has been documented to reach the upper limits of the diseased area and provide better tolerability and an easier application for patients. In addition, foam has been shown to remain present for approximately 4 hours to provide greater exposure to the diseased areas versus an enema. This low pressure foam application will provide a uniform and more extensive dispersion of medication onto the colonic mucosa for greater coverage of medication to the desired site.

Market Size



Innovation

The device is composed of a canister that holds both the propellant and biocompatible foam solution. The canister also contains a drug delivery port, allowing the clinician to add the appropriate medication for a specific treatment or therapy. The device also includes a valve assembly to allow for a controlled release while also preventing accidental discharge during setup and application of the foam. To provide accurate positioning of the device during patient use a balloon mechanism is provided to regulate the degree of insertion to enhance patient safety.

The use of a low-pressure therapeutic foam directly to the localized area will result in a safety profile that does not have any systemic effects from the result of high dose antibiotics or other medications. Also, the canister system will often allow for the loading of less expensive forms of medication to help lower the direct cost of treatment. Initially, the indications for this device would be expected to target infections and inflammatory conditions within the colon.

Stage of Development

A working prototype has been developed and initial *in vitro* data has been gathered to demonstrate pressure safety and distribution of medication within a simulated human model colon. The CDD is designed to not allow for over pressurization and pressure levels are well below insufflation rates used in standard G.I procedures. The propellant used in this device is CO2 which is naturally absorbed into the bloodstream during administration.

In addition to the working prototype, we have initiated preclinical testing preparation using a third-party cGLP laboratory. The studies expected to prepare the product for clinical testing include cytotoxicity determination of the foam carrier, with and without drug, rectal irritation testing, travel distance of the foam carrier in the intestinal tract, and pharmacokinetic dosing measurements.

Competitive Advantages

Traditional treatment options for intestinal infection of *C. diff* rely on administration of the antibiotic metronidazole for mild to moderate illness, and vancomycin for more severe or recurring cases. A relatively recent addition to the options for antibiotic treatment is fidaxomicin, which is an orally-administered antibiotic with minimal systemic effects.

Alternative treatments that are currently in various investigational phases include vaccine-like biologic treatments, such as vaccination with *C. diff* toxoid monoclonal antibodies, fecal transplants, adjunct drugs to vancomycin or metronidazole to reduce recurrence of *C. diff* infection, and new probiotic formulations to replenish the natural flora of the colon.

The proposed colorectal drug delivery device utilizes the known efficacy of antibiotic therapy, but minimizes systemic effects by delivering medication directly to the site of infection. The colorectal drug delivery device would also provide effective treatment at a drastically lower price than other investigational treatment options – especially biologic treatments, as these can easily cost many hundreds or thousands of dollars per administration. The proposed device therefore represents a potentially safe, cost-effective and efficacious therapy for *C. diff* infection.