January 22, 2020

IrriGREAT: Automated continuous fluid irrigation system

Brief Innovation Description

Continuous fluid irrigation is extensively used in endoscopic surgery to expand the surgeon's operative field, clear bleeding from the surgical site, and improve visualization. Continuous fluid irrigation is also a routine component of inpatient and emergency room patient care in the management of gross hematuria (blood in the urine). In this scenario it is used to prevent painful clot urinary retention. The most common way of administering irrigation is via a passive gravity-fed system that relies on nurses to diligently monitor and switch irrigation bags, as well as titrate the inflow rate (Figure 1). In a busy clinical setting, bags running dry can result in complications and significant discomfort for patients. We have developed a device to automate this system. This device addresses a large unmet need for a very common clinical problem. It is a device that is widely scalable and has the potential for world-wide commercialization.

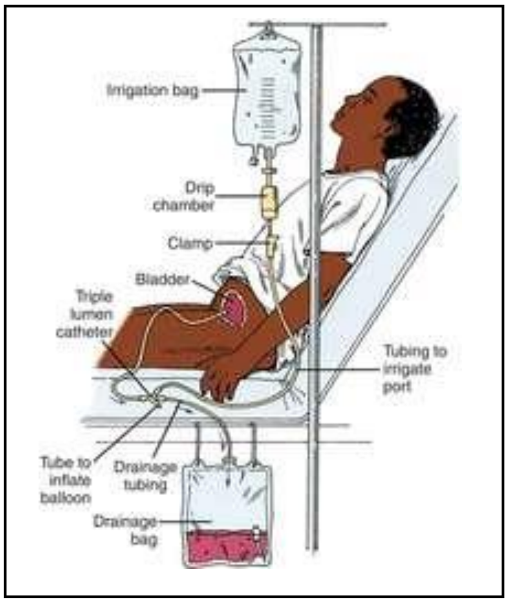

Figure 1: Continuous bladder irrigation (https://medical-dictionary.thefreedictionary.com/continuous+bladder+irrigation)

Detailed Description

Currently available methods of administering continuous irrigation intraoperatively, or on the hospital ward, are via either a rudimentary but low-cost system (the common gravity-fed, nurse work-intensive system described above) or a rarely-used higher fidelity system with significantly higher cost (the Thermedx® FluidSmart™ system). The Thermedx® system, is a large standalone device that takes up floor space in the operating room (approximately 2 sq ft), and requires additional space for storage. In a small operating room such a device can be cumbersome and intrusive. The device must be plugged into an electrical outlet, possibly limiting its placement in the operating room. In addition, the system can only interchange two irrigation bags before requiring reloading. Most importantly, the system is not compatible with standard saline/glycine irrigation bags or standard tubing used in the operating room, and uses costly consumable proprietary tubing and bags. This has hampered this device's integration into practice, and thus the gravity fed-system remains the most common system used.

There is currently no middle-ground device on the market. We have designed a device that automates the existing gravity-fed system and is compatible with current standard hospital equipment (Figure 2). This is a small-profile mechatronic device that can be "clicked onto" existing gravity-fed systems, and will be able to switch between four irrigation bags. What is unique about our design is that it is compact, easy to install and use, and has minimal footprint (which is key in today's crowded ORs and emergency rooms). Also, because it automates the most common way irrigation is currently being administered, it will be very easy to integrate the device into practice.

In addition, a we have designed a second palm-sized device (which works in tandem with the first device) which is able to completely automate continuous bladder irrigation for the management of hematuria, by titrating the inflow fluid rate based on effluent colour (the more bloody the effluent, the faster the inflow, and conversely). This is a completely portable device and will be the first such device on the market. It offers a streamlined solution for one of the most common clinical problems being managed in the emergency room and on the hospital wards worldwide.

Figure 2: IrriGREAT intraoperative irrigation palm sized device

Impact

Gross hematuria (blood in the urine) is a very common presenting complaint in emergency rooms world-wide. The large majority of patients with significant gross hematuria require the initiation of continuous bladder irrigation (CBI). This is the management of choice for this condition, and, in the majority of cases, is the only intervention needed until the bleeding subsides. Patients can run continuous bladder irrigation in the emergency room for hours up to days. Patients for whom bleeding does not settle in the ER are admitted to hospital for a longer duration of CBI. During these long durations of irrigation treatment, 3 L normal saline irrigation bags must be continuously monitored and changed by nurses. If an irrigation bag runs dry, the patient can develop blood clots within the bladder within minutes. This leads to blockage of the catheter and painful urinary retention. In this scenario blood clots must be are manually irrigated through the catheter (by a nurse, or more commonly by a urologist) at the bedside, with only the use of topical urethral anesthetic. Both clot urinary retention, as well as manual clot irrigation, can be excruciatingly painful for patients. The irrigation process can take up to one hour, and is performed by forcefully administering saline and suctioning the urethral catheter to remove clots. If the clot is too organized, or if the patient is not tolerating the manual irrigation well, the patient is placed on the emergency operating room list for the procedure to be done under anesthetic using rigid instruments. Such complications are extremely common and easily preventable with automation of the current irrigation system. Such as system will reduce potential complications and associated discomfort for patients, will reduce hospital stays, will decrease transfusion rates, and will prevent the need for emergency OR procedures.

Scalability

Our innovations are widely scalable. The intraoperative automated irrigation component can be used by many surgical specialties, including urology, orthopedics, and gynecology. In urology the common procedures which use irrigation include: transurethral resections of prostate (TURPs), GreenLight laser surgery for BPH, transurethral resections of bladder tumors (TURBTs), ureteroscopy and percutaneous nephrolithotomy (PCNL) for treatment of kidney stone disease, and many others. Within orthopedics, irrigation is extensively used during arthroscopic surgery, and in gynecology for vaginoscopy and related procedures. In North America there are more than 2 million surgical procedures performed each year that require intraoperative irrigation. As minimally invasive surgical techniques further develop and gain popularity, we expect these numbers to further increase, increasing potential sustainability of our products.

With respect to the automated continuous bladder irrigation system, the scalability and sustainability potential is even greater. Continuous bladder irrigation is not just used in post-operative urology patients but is widely used in the emergency room and on hospital wards across all medical specialties for the management of hematuria. The market potential is great, as more than 5 million patients require continuous bladder irrigation in North America every year.

Continuous Bladder Irrigation	**Treatments / year**
North America Total	**>5,000,000**
Operating Room Irrigation	**Procedures / year**
Urology	1,000,000
Orthopedics	750,000
Gynecology	300,000
North America Total	**>2,000,000**

Figure 3: IrriGREAT market potential

Potential to generate revenue and profit

Our innovation has a great potential for generating revenue and profit. We estimate that we will be able to price a full device (including the intraoperative irrigation component and CBI component) at $5,000. To put this into context, an emergency operation and hospital admission will likely cost upwards of $50,000. If only one surgery can be prevented with this device, the cost of 10 devices will be recovered immediately.

The current cost of materials to make a prototype device is approximately $200. This cost will go up slightly for the final version to be used in clinical testing. But we anticipate the cost to go down again with production scale-up to approximately $50/unit.

Most average-sized hospitals will likely want to supply their emergency rooms with at least 5 units, their operating room with at least 5 units, and the hospital wards with about 10 units. There are currently approximately 8,000 hospitals in North America (1,500 hospitals in Canada and 6,500 hospitals in United States). If we are able to target 1% of this market, we can potentially generate up to $8 million dollars in sales revenues.

80 hospitals (1% of North American market)*20 units/hospital*$5,000/unit = $8 million in sales

Intellectual Property

We have been working closely with Hill & Schumacher (a firm highly recommended by the University of Toronto IP Office) to complete our US patent application for our devices. The first draft should be available for review this week and will be circulated to the inventors for editing and approval. We anticipate that the patent submission will occur within the next two weeks.

Financials

Projected financial need to bring first generation device ready for market are as follows:

Engineering expertise salary
(1 recent engineering graduate staff, 1 senior engineering consultant): 1 additional year…………….$50,000
Materials and electronic components
(for 5 fully functioning units for clinical testing):……………………………………………………………….………. $5,000
Clinical Trials (anticipated start time Summer 2020):
Clinical Trial #1 (Intra-operative device): summer medical student (data gathering)………………………$5,500
Clinical Trial #2 (Continuous bladder irrigation device): summer medical student (data gathering)..$5,500
Clinical Trial research coordinator
(ethics approval, consent/document preparation, regulatory paperwork):…………………………………. $5,000
Health Canada approval:……………………………………………………………………………………………………….. $15,000
FDA approval (type 2 risk category device): ………………………………………………………………………………$50,000
Patenting costs:…… $20,000
Legal costs: ………$3,500

Total estimated cost:………$159,500

We anticipate that with a $100,000 we will be able to get this device very close to market ready.

Project's management team

The Principal Investigator, Dr. Monica Farcas is a urologic surgeon at St. Michael's Hospital with subspecialty training in endourology and endoscopic surgery. She has a research background in engineering (holding both an undergraduate and a graduate degree in engineering). Her primary academic research focus is bringing innovative engineering designs to medical applications (with a specific focus on the development of small marketable devices). To this end she is currently involved in the design and prototyping of a number of small medical devices aimed at improving efficiency in the operating room. As she is trained both as a surgeon and an engineer, she has a unique and practical viewpoint, as well as a unique combined skill set. Her ultimate goal is to maximize the use of these skills in order to bring innovations that will improve medical and surgical care for her patients. Her collaborative team consists of a principal engineer with extensive knowledge in health care innovation, Dr. Brian Carrillo. He is the past Director of Research and Development for one of the most successful startup corporations developed at the University of Toronto in conjunction with MARS innovation, OtoSim™. The corporation was started six years ago by a University of Toronto ENT surgeon and continues to bring millions of dollars in revenue each year. The remainder of the team consists of biomedical engineering students, an undergraduate medical student, a urology resident physician, and a nurse educator.