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DRUG PROFILE



Evaluation of the Macy Catheter®: a rectal catheter for rapid medication and fluid administration

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ABSTRACT

Introduction: Health care providers are increasingly challenged to balance cost considerations for devices, drugs, and staffing all while continuing to provide excellent care. Patients in both the post-acute and acute care settings often require fluid and/or medication when their oral route is compromised and vascular access may not be warranted or immediately accessible. The rectum is an under-utilized administration point that can be accessed with speed and relative ease.

Areas Covered: Literature reviews of pharmaceutical, medical, and nursing references reveal current and historical science that validates the rectal route as a means of alternative administration for fluids and medications.

Expert Commentary: Historically the rectum has been used for medication and fluid delivery but in more recent times, use has waned due to many factors. The physiology of the rectum allows for rapid and reliable administration of a variety of medications as well as hydration. This serves as an introduction to a novel, simple, cost effective device that allows for discreet and painless rectal administration of fluids and medications when the oral route is compromised and/or intravenous access is difficult or unnecessary. This device is used in a variety of patients in many care settings.

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Macy Catheter; proctoclysis; rectal medication; rectal enema; rectal catheter

1. Introduction

Medication and fluid administration are paramount in health-care delivery both in the acute and post-acute settings. Although oral administration is the default route, it is not always appropriate. Intramuscular, sublingual (SL), or subcutaneous (SQ) routes can be considered for some medications and even fluids when the oral route is not an option, but very frequently fluid and medication delivery is administered intravenously at almost any cost. This includes invasive interventions such as central venous lines (CVLs) and intra-osseous (IO) access. Resorting to these invasive procedures increases the risk of infection and complications [1], and the intervention may not be warranted or necessary for patients presenting complaint or expected course of treatment.

In post-acute settings such as hospice, skilled nursing, and long-term care facilities, providers face challenges caring for patients who have a compromised ability to swallow and cannot take medications by mouth. For example, as hospice patients transition into the state of actively dying, clinicians need better options to quickly and effectively manage symptoms, such as terminal agitation and pain, without interrupting care and waiting for treatment when new medications and therapies are ordered and their arrival is delayed [2,3]. Furthermore, skilled nursing or long-term care facility patients may develop an acute condition like nausea, vomiting, or fever, which temporarily compromises the oral route and requires increased fluid administration or immediate medication delivery. Staff at these post-acute facilities may not be able to

or may have a difficult time starting peripheral intravenous (PIV) access. Alternative technology that is easily accessible and requires minimal training and skill to implement must be considered across both acute and post-acute markets.

2. Overview of the market

2.1. Acute care

The acute care setting provides services for all-comers: pediatrics, adults, and geriatrics. Current means to administer fluid or medications to patients vary as greatly as the patients themselves and the settings to which they present. Ideally, patients receive their fluids and medications orally (PO). However, healthcare must often be delivered under less than ideal circumstances. This may be related to patient condition, required therapy, setting, or any combination of these. A single versatile method for administration of fluids and medications that is easy to access and takes minimal expertise could help reduce cost and length of stay in situations where PIV access is not appropriate or desirable.

Patients in the acute care setting may also require administration of rectal medications for the relief of constipation or for disease management, i.e. lactulose to reduce ammonia or sodium polystyrene sulfonate (Kayaxelate) as part of a hyperkalemia protocol. Administration and patient retention of these medications can prove challenging for both the patient and provider.

The default alternative to oral medication and fluid is often PIV access, sometimes even despite evidence showing that this may not be the next best choice [4,5]. Proper technique by a skilled provider must be employed to minimize potential complications. Even with the best technique and a skilled provider, minor complications, including infiltration, phlebitis, and hematoma, are common. Major complications like tissue necrosis and compartment syndrome are also possible [6]. Current recommendations are that PIV catheters be replaced at least every 72–96 h or when clinically indicated [7], thus repeatedly requiring the use of these human and physical resources with every reinsertion.

When PIV fails, is unattainable, or if more aggressive or prolonged treatment is needed, a CVL may be the alternate choice for fluids and medications [7]. Increased cost and complications can be associated with CVL placement and use. Complications of CVL insertion and maintenance include vascular and pulmonary injury as well as thrombus formation and infection [1]. Cost includes the device plus the use of a higher-level provider and the need for multiple providers for insertion. To minimize complications, strict sterile procedures must be followed, and use of ultrasound guidance and after-placement quality monitoring are necessary. Payers such as Medicare and Medicaid will not reimburse providers for the therapy or cost of complications if strict guidelines are not followed and preventable complications arise [1,7,8].

IO access is a viable option for central access and aggressive fluid replacement. With the advent of new technology, IO is easily obtainable in adults and can provide many of the same benefits as CVL for a short period of time [8,9]. However, this therapy also requires a high-level provider, can only be used for 24 h before its site needs to be rotated, and involves a needle puncturing the skin and the bone.

SQ and nasogastric (NG) routes are other alternatives for fluid and medication administration for acute care patients. In fact, the American Academy of Pediatrics recommends the NG route should PO fluid challenges fail for the pediatric patient with acute gastroenteritis (AGE) [4]. SQ fluid administration in the emergency department (ED) has also been shown to be simple and effective when compared to IV fluid administration [10]. These methods are not routinely used for a variety of reasons, including trauma to the patient and comfort level of the provider [5]. These also bear risk of infection, extravasation, and infiltration.

2.2. Post-acute

In the post-acute environment, including sectors such as hospices, palliative care, skilled nursing facilities, and long-term care facilities, it is critical to quickly manage changes in a patient's condition. In the post-acute environment, maintaining care in the setting of patients' choice, often their home, is a patient satisfier and often the most economical care environment. If symptoms are unable to be managed in the home or nursing care facility, patients are often transferred to an ED or hospital for continuing care. This increases the cost and care burden of patients and families.

Similar to acute care, the preferred choice for medication administration in the post-acute setting is PO. However, when the oral route is not an option due to patient condition, alternative routes of medication administration must be considered. Alternative routes of medication administration for the post-acute patient when the oral route fails include SL, rectal suppository or microenema, SQ, intravenous (IV), transdermal, epidural, and intrathecal [3]. These alternatives pose certain challenges due to the coordination of supplies, nursing time, and care required to maintain them. For example, when a physician order is obtained for an IV in the home, there is often a delay in delivering the required supplies and medications needed for IV access, placement, and medication administration [3]. Moreover, skilled nursing facilities or long-term care facilities may not be staffed or equipped to care for a patient requiring continuous IV treatment [3].

In both the acute and post-acute markets, a reliable and easy alternative for medication administration that can be placed and maintained by any provider in any setting would offer an ideal solution for provider and patient.

Alternative routes to PO and IV, such as the rectal route, are currently used in both the post-acute and acute marketplaces. Alternative routes have the potential to grow as healthcare continues to search for the most economic and effective option that has a positive impact on patient outcomes. With the advent of new technology, the rectal route can serve as the first-choice alternative for fluid and medication administration in many circumstances.

Jannin et al. provide a 21st-century review of the rectal route as a viable and reliable administration route with a long history of use and current underutilization for medication administration [11]. They highlight the usefulness in vulnerable populations such as pediatrics, geriatrics, and those unable to take PO due to the level of consciousness or vomiting. There is no current best practice guideline for the means by which to achieve this [12].

The focus of the current rectal access technology is not for medication and fluid administration but for drainage and containment of stool. Although some have clearance for administration of medication, these kits are intended primarily for outflow and collection of fluid. The retention balloon size, frequently using 45 ml of fluid, can cause pressure ulcers and even hemorrhage [13]. The kits can also be quite pricey. Because of these limitations, some providers manipulate devices available in their setting, such as Foley catheters or NG tubes, to administer retention enemas and other rectal medications [12]. These makeshift methods are not Food and Drug Administration (FDA) indicated for the administration of fluids and medications. These improvised methods lead to the inconsistent delivery of fluids and medications and require repeated access, as they are not indwelling. These improvisations generally lack a retention balloon, causing leakage of fluid and medication. Additionally, they pose a workflow challenge as the provider searches for adaptable parts such as clamps or connectors.

3. Introduction to the device: Macy Catheter: Hospi corporation

The Macy Catheter's FDA indication is to provide rectal access for the administration of fluids and medications. Fluids and medications are administered via the 14Fr silicone catheter's one-way valve medication administration port (Figure 1, labeled MC). The catheter is held in place by a water-filled 15 ml balloon that sits in the distal third of the rectum against the rectal sphincter (Figure 2, illustration *in situ*). The balloon inflation port only connects with a luer syringe, thereby eliminating the chance for a misconnection error with the medication administration port, which has an enteral-only connection. A trained provider inserts the Macy Catheter with a procedure similar to, but quicker and easier than, urinary catheter placement [3,14,15]. The device enables the immediate initiation of therapy and facilitates effective symptom management, especially for those patients with difficult

vascular access. Common patients who benefit from the device are those experiencing pain, agitation, nausea, vomiting, dehydration, or constipation.

FDA indicated to stay in place for up to 28 days, and thus respects patient privacy, as there is no need for repeated rectal access or repositioning of the patient after initial placement [3]. The Macy Catheter is smaller and softer than typical formed stool in the rectum. It is designed to be easily expelled with defecation. If expelled with, or removed for, a bowel movement, the Macy Catheter can be immediately reinserted by clinicians or caregivers trained on this simple procedure. Fluids and medications can be administered as frequently as needed to manage patient conditions via the medication administration port, which is secured to a patient's leg or abdomen. Medications delivered to this portion of the rectum partially avoid the first-pass effect through the liver. With this initial bypass of the liver, more of the substance is available in the

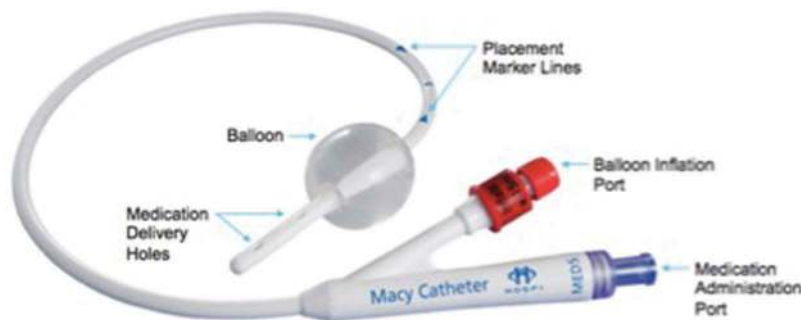


Figure 1. Labeled Macy Catheter. Reproduced with permission from Hospi Corporation.

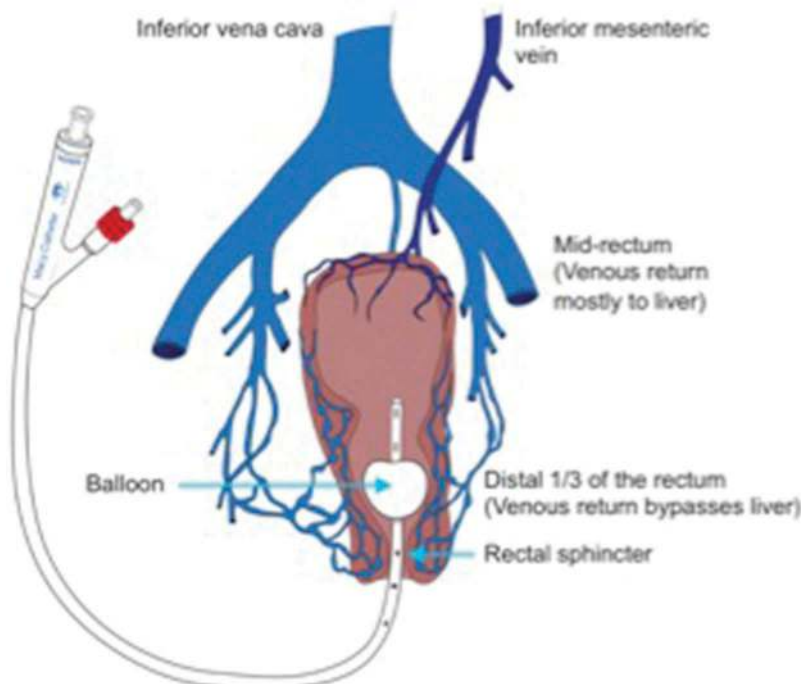


Figure 2. Illustration of Macy Catheter *in situ*. Reproduced with permission from Hospi Corporation.

bloodstream, allowing greater bioavailability for some medications compared with the oral route [2].

Insertion of the Macy Catheter is a 5-minute non-sterile procedure. Learning to insert and use it is a very quick and easy process. Training requirements are based on the specific policies and protocol of the healthcare setting and medical oversight, but typically consist of a live or recorded presentation, followed by a skills assessment. Clinician training takes less than 30 min to complete. Initial insertion of the Macy Catheter is ordinarily performed by a Registered Nurse (RN) or Licensed Practical Nurse (LPN)/Licensed Vocational Nurse (LVN). Education on maintenance and reinsertion is also given to other care providers, including family.

Although simple to use and very safe, the Macy Catheter is contraindicated in cases where the rectal mucosa is compromised, including recent bowel surgery (less than six weeks), rectal lesions, or tumors. It should not be used if there is active rectal bleeding or frequent liquid stools [16]. Patients should be monitored for possible adverse effects as well. The Macy Catheter is designed with a much smaller retention balloon than stool containment systems (15 ml vs. 45 ml), so pressure necrosis is unlikely and no cases have been reported. Other possible adverse outcomes that could occur would include perforation, obstruction, infection, leakage, or temporary loss of sphincter tone [16].

Although other rectal devices are currently on the market, those approved for fluid and medication introduction are primarily focused on stool collection and do not have a dedicated delivery port for this purpose. Other methods currently employed to administer fluids or medications rectally do not have a retention balloon (NG tubes, red rubber catheters) or require repeated direct access to the rectum (Toomey syringe). Although there are other methods of achieving rectal fluid and medication administration, Macy Catheter's medication delivery port with a one-way self-closing valve (preventing backflow or leakage) and retention balloon make this a novel device. These features address the issues associated with rectal access and administration, including retention, ease of access, patient comfort, and dignity.

4. Science and research

4.1. Historical

Research topics related to the science surrounding the Macy Catheter provide evidence for the need and the effectiveness of such a device. The rectal route for medication administration has long been seen as a viable option [11], and micro-enema delivery offers rapid release with predictable results [2]. There is a wide variety of classes of medications that have been proven effective when given rectally, including analgesia – both narcotic and non-narcotic – antiemetics, and antibiotics [17,18].

Fluid administration via the gastrointestinal tract is the gold standard for the treatment of AGE. The Centers for Disease Control and American Academy of Pediatrics recommend oral rehydration then NG [4]. A 2006 Cochrane Collaboration revealed that 1 in 25 children fail oral rehydration and highlighted that NG and IV can both be quite traumatic. Both

come with risk and require skilled providers for administration [5,19]. In 2012, Barker performed a meta-analysis of 82 articles on alternatives to IV therapy for children with AGE and highlighted that none included proctoclysis [5]. Case study and research have shown effective hydration with proctoclysis for adults. It has been reported to be simple, effective, cost-efficient, and a useful alternative when other means of fluid administration are not available or warranted [20,21]. Historical studies have shown adults to tolerate approximately 300 ml fluid per hour [20]. Murphy described the simple and effective use of proctoclysis in the early 1900s, and these successes with rectal fluid administration involved the use of elaborate setups with metal tips, rubber hoses, and electric heaters [22].

4.2. Current/ongoing

As the Macy Catheter is a new device, research and data specific to its use and outcomes are ongoing and just emerging. Reports in the literature specific to the Macy Catheter have revealed several commonalities across all patient populations/markets. The Macy Catheter offers a quick and easy access route [12,14], patients find it comfortable [3,23], it facilitates rapid symptom control [12,14,23], and a variety of medications have been proven effective [12,14,23]. The Macy Catheter has been shown to be cost effective and is easy to use [3,15,24].

5. Cost considerations

Cost comparison of the Macy Catheter with other more commonly used fluid and medication delivery routes is challenging. Each published cost analysis of fluid and medication delivery systems combines different varied factors to total cost: the device itself, additional physical supplies, labor time, and cost of labor/level of the provider to initiate. Additionally, when considering the cost of any fluid or medication delivery system, it may be prudent to consider the frequency at which the device will need to be reinserted or changed, the potential for and cost of complications, as well as the cost of the fluid or medication administered via that route. Table 1 lists several of these factors for comparison. The Macy Catheter may provide a more cost-effective fluid and medication route for both acute and post-acute care patients when one considers that the Macy Catheter can be placed quickly by any trained healthcare provider into a non-sterile, natural orifice; it can be left in place up to 28 days and complications are unlikely. Either sterile or non-sterile fluids, such as water or Pedialyte®, have been used for rehydration, and the medications to be administered are pills crushed and administered via microenema. All of these considerations suggest the Macy Catheter is a lower-cost intervention for medication and fluid delivery. As the Macy Catheter matures in the market, more data for cost analysis should become available.

Tangible evidence of the cost savings the Macy Catheter can provide was published by one hospice agency, which has been utilizing the catheter in their inpatient units since 2015. They reported much of their cost saving from a switch from parenteral medications, which are more costly, to less-expensive oral

Table 1. References [1,6–10, 13, 16, 25–27]. IV: intravenous, SQ: subcutaneous, IO: intra-osseous; CVL: central venous line.

Device	Providers needed for insertion	Insertion technique	Time needed for insertion	Additional equipment/supplies	Dwell time	Reported complications
Macy Catheter	1 Trained Healthcare Professional	Non-sterile	~2 min	Water, sterile, or non-sterile fluid	28 days	None reported
IV	RN or MD, possible additional 1–2 holding help (Peds)	Aseptic	~ 5–30 min	Dressings, possibly veinfinder or ultrasound, lidocaine, sterile fluids	72–96 h	Infiltration, extravasation, hematoma, nerve palsy, infection
SQ (Hydration)	RN or MD plus holding help (Peds)	Aseptic	~2–3 min	Hyaluronidase, sterile fluids	48 h	Infection, extravasation
IO	RN or MD	Aseptic	~ 2 min	Specialty dressing/securement device, lidocaine, sterile fluids	24 h	Infection, extravasation, compartment syndrome
CVL	MD, RN, possibly US Tech	Sterile, with extensive draping	~15–80 min	Sterile draping, ultrasound, X-ray, sterile fluids	Varies based on type of line used	Infection, thrombosis, pneumothorax, hemorrhage
Bowel Management Systems	RN, possibly holding help	Non-sterile	(no available time references)	Lubricant	29 days	Pressure ulcer, hemorrhage

medications delivered in microenema form via the Macy Catheter. In 2017, this same hospice agency implemented a set of guidelines instructing clinicians to use the Macy Catheter as the first-line alternative when a patient is unable to swallow and the SL route is ineffective. These changes led to a projected net savings in 2017 of \$92,302 [24].

6. Clinical profile and post-market findings

The catheter was developed in response to a clinical need for a rapid-access, cost-effective technology to administer medications and fluids quickly when patients start to lose the ability to swallow and SL medications are no longer effective. In 2013, the first patent for the Macy Catheter was issued, and FDA 510K Clearance for the Macy Catheter was received in February 2014.

With a strong foothold in the hospice market, as of 2018, the Macy Catheter is utilized in both the acute and post-acute settings across the United States. Additionally, the Macy Catheter is EU (Europe) CE Marked and CAN (Canada) Licensed.

7. Conclusion

Fluid and medication delivery is an essential part of patient care in both acute and post-acute settings. It is necessary to have a reliable alternative method for delivery of fluids and medications when the oral route is unavailable and when IV is not warranted or easily accessible. The Macy Catheter provides a quick, easy, non-sterile alternative delivery route through a natural orifice that is lower-risk, cost-effective, and could be a patient preference over repeated IV sticks if the patient is given the option.

8. Expert commentary

Rectal administration of fluids has been documented since 1909 with the original experiments on proctoclysis being reported by Murphy. Unfortunately, this method of fluid delivery was cumbersome and not readily available [22]. Over the years, the popularity of rectal administration of fluids and medications has waxed and waned for a multitude of factors,

including difficulty in administration techniques, dosage form availability, and social acceptance [11].

The rectum itself is pH neutral, 7–8. It has a small surface area, 200–400 cm², compared to that of the small intestines with 200 m². Circulation through the rectum is performed by three vessels: the superior, middle, and inferior rectal veins (see Figure 2). The lower two avoid first-pass metabolism, increasing the bioavailability of drugs that do not need to be activated by processes in the liver [28,29].

Placed in the distal one-third of the rectum, the Macy Catheter can serve as an alternate route to deliver fluids and certain medications to a variety of patients when IV therapy may not be necessary. Most healthcare staff, with minimal training, can insert it quickly and safely. The fact that the catheter can stay in place for 28 days makes it an ideal tool for administering maintenance therapies in the post-acute setting. In the acute care setting, this is especially alluring considering IO devices can only stay in place for 24 h, CVL placement opens a patient up for central line acquired bacterial infections (CLABSI), and the infection rates increase in PIVs left in longer than the recommended Centers for Disease and Control Prevention (CDC) guidelines [1,9,14,15].

The rectal route of administration has been given consideration in the post-acute care setting because it serves a variety of functions, including pain management, agitation control, fever management, antibiotic administration, and simple fluid administration [29]. The Macy Catheter expands upon current rectal medication administration techniques by doing away with the usual suppository, which often requires extensive custom compounding, increased inventory, and frequent obtrusive visits between the patient and nursing staff. In the past, oral solutions and suspensions have been administered via the rectal route. The bioavailability of these medications is variable and has been inherently less than their oral counterparts. Multiple physiological factors play a role in the lack of absorption and bioavailability: lack of villi, dwell time, and reduced fluid volume capacity. Characteristics of the medication itself also play an important role in overall bioavailability. Solutions given rectally seem to be similar to their oral counterparts and possibly superior to oral and rectal suspensions. Mechanical loss of the drug may also decrease availability [30]. The Macy Catheter focuses on using microenemas – crushed

medications diluted in 1–20 mL of fluid – as the primary means of drug delivery [28]. Microenema solutions of some medications can achieve a bioavailability similar to their oral, IM, and IV counterparts by the elimination of first-pass effect with absorption of the drug in the lower two-third of the rectum [29–31]. These microenemas are unlikely to induce defecation and were considered much more comfortable for patients compared to suppositories in a recent study of healthy volunteers [23,28,29]. If the Macy Catheter is expelled with a bowel movement, a trained provider can easily reinsert it [16]. In comparison, loss of a PIV line may require a post-acute care facility to send the patient to an acute care facility for line replacement and possible admission to the hospital at great cost to the patient and facilities [1,14].

Opioids, nonsteroidal anti-inflammatories, benzodiazepines, antidepressants, corticosteroids, antibiotics, anti-seizure, and anti-psychotic have all been studied using rectal administration [29]. Antibiotics are of particular interest since fever and sepsis are some of the main causes long-term care facility patients are admitted to EDs since the nursing staff are not generally allowed to place invasive lines in these facilities. With more research, it is plausible that protocols could be put in place for post-acute care nursing staff to administer antibiotics rectally with gentle fluid rehydration when infection is first spotted. This would hopefully prevent the development of sepsis and septic shock and thus reduce admission to acute care facilities.

A variety of patients can reap the benefits of the Macy Catheter, including both the elderly and pediatric populations. In the United States, the FDA clearance does not state specific age, size, or weight for use. Clinical judgment should dictate appropriate placement. The catheter is 14fr, not much larger than a rectal thermometer. Roberts and Hedges' Clinical Procedures in Emergency Medicine and Acute Care states: *'IV access in small children may be very difficult to obtain and frightening to the child. In these situations, the option of rectal administration may outweigh the benefits of IV drug therapy. Patients who refuse parenteral drug administration may also benefit from rectal delivery, as well as those with nausea and vomiting or the inability to swallow'* [32]. This definitive textbook of emergency procedures specifically highlights the use of the Macy Catheter for rectal access.

There have been various case reports and studies reporting the use of the Macy Catheter in both the acute and post-acute settings [3,12, 14–16, 23, 24, 33]. As more clinicians are introduced to this modality, they should begin to see the versatility and advantages of having this alternative medication route. Patients who are agitated could have the Macy Catheter quickly and easily placed to offer a safer, needle-free route for repeated medication administration. The catheter remains secured to the patient's thigh or lower abdomen, is not directly visible, and does not impede the use of their hands. This makes it less likely to be forcibly or accidentally removed by the patient. Even if the patient did dislodge the catheter, there would be no trauma and body substance exposure for the caregiver would be limited. Or consider patients with difficult vascular access; they could have the Macy Catheter as a secondary line in addition to PIV. Maintenance fluids or medications could be administered via PIV. Adding the Macy Catheter

provides an additional access route for medications not able to be administered via PIV [34]. Antibiotics are another area of interest for acute facilities. When a patient presents in septic shock, it is often difficult to obtain IV access due to the patient's fluid status. It then becomes a race against the clock to have a skilled physician place a CVL, administer fluids and antibiotics, and control the fever to meet Centers for Medicaid and Medicare Services (CMS) requirements. With the Macy Catheter, one nurse could begin to place an IV line as another places the Macy Catheter and starts either fluids or antibiotics to both treat the patient and meet CMS requirements, including those mandated by the Surviving Sepsis Campaign. Unfortunately, data is limited with regard to micro-enema antibiotics, and prospective research is needed in this area [31,35].

9. 5-Year view

The Macy Catheter has the potential to make significant contributions to patients and the healthcare system due to its simple configuration, ease of administration, and low risk of adverse effects. It helps address the important clinical question: 'what is the optimal way to administer fluids and medications to a patient whose oral route is compromised and for whom IV access is difficult or not indicated?' With the ability to instill a variety of medications and fluids, the device can cover a multitude of disease states in both the acute care and post-acute care settings [14,15,29].

Protocols put in place at long-term care facilities will decrease the number of patients who need to be sent to acute care for line placement, rehydration therapy, and symptom control by expanding the use of the rectal route. Especially in the elderly with do not resuscitate (DNR) requests, antibiotics and pain management could be started at home or in the facility. This could, in turn, reduce the number of hospital-acquired infections, inappropriate intubations, and CMS 'fallouts' and reduce the number of patients who develop septic shock prior to arrival at an acute care facility. More research is needed to quantitatively justify the cost of the catheter and to prove that certain protocols reduce readmission rates.

In the event of a catastrophic natural or man-made disaster, the Macy Catheter could provide rapid and cost-effective hydration and medication administration for mass casualties. Owing to the non-sterile technique and ease of insertion, the Macy Catheter requires little skill to insert and maintain, especially in situations when sterile conditions are not practical and sterile formulations for parenteral administration are not accessible.

Eventual device configurations and regulatory approvals could make the Macy Catheter available via retail pharmacy by prescription. For common conditions such as constipation and hyperemesis gravidarum, the catheter would provide a quick and easy solution to administer fluids or medications at home. This would facilitate rapid and effective symptom management, avoiding an unnecessary admission to an acute care facility.

Current research objectives also include increased determination of optimal drug dosing, dilutions, and adjuvants, via pharmacokinetic studies, to increase confidence in prescribing the plethora of drugs that can be administered as microenemas. Research containing results of the impact of protocols for the use of the catheter and specific pharmacokinetic data for various active pharmaceutical ingredient formulations are both obtainable within the next five years.

10. Key issues

- A variety of patients in different care settings need an alternative delivery route for fluid and medication when the oral route is compromised and venous access is not practical, not warranted, or difficult to obtain.
- The Macy Catheter is the first FDA indicated rectal catheter for on-going administration of fluid and medications. It can remain in place for up to 28 days. Insertion of the catheter is a quick, painless, non-sterile procedure, which can be performed by a trained healthcare provider.
- The simplicity, speed and versatility of the Macy Catheter make the rectal route a viable first line alternative for fluid and medication delivery when the oral route is compromised. The Macy Catheter can be used for a variety of patient conditions across the entire lifespan.

11. Information resources

General information about the Macy Catheter: www.macycatheter.com

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Declaration of interest

KM C Macygin is a paid consultant for Hospi Corporation, makers of the Macy Catheter. M Goldsmith is a paid employee of Hospi Corporation. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

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References

Papers of special note have been highlighted as either of interest (*) or of considerable interest (***) to readers.

1. Kornbau C, Lee KC, Hughes GD, et al. Central line complications. *Int J Crit Illn Inj Sci.* 2015;5(3):170–178.
2. Warren DE. Practical use of rectal medications in palliative care. *J Pain Symptom Manag.* 1996;11(6):378–387. PubMed PMID: 107386050.
3. Paez K, Gregg M, Massion CT, et al. Promoting excellence in symptom management case series: case study: a new intervention for rapid end-of-life symptom control in the home setting. *J Hosp Palliat Nurs.* 2016;18(6):498–504. PubMed PMID: 00129191-201612000-00005.
- **Case study shows rapid relief of terminal symptoms using the Macy Catheter.**
4. King CK, Glass R, Bresee JS, et al. Managing acute gastroenteritis among children: oral rehydration, maintenance, and nutritional therapy. *MMWR Morb Mortal Wkly Rep.* 2003;52(RR-16):1–16.
5. Barker LT. In the child with gastroenteritis who is unable to tolerate oral fluids, are there effective alternatives to intravenous hydration? *Ann Emerg Med.* 2012;60(5):607–608. PubMed PMID: 22560467.
6. Kagel EMM, Rayan GMM. Intravenous catheter complications in the hand and forearm. *J Trauma.* 2017;56(1):123–127.
7. O'Grady N, Alexander M, Burns LMT, et al. Guidelines for the prevention of intravascular catheter-related infections, *Am J Infection Control.* 2011;39(Suppl.1) S1eS34. .
8. Dolister M, Miller S, Borron S, et al. Intraosseous vascular access is safe, effective and costs less than central venous catheters for patients in the hospital setting. *J Vasc Access.* 2013;14(3):216–224.
9. Petitpas F, Guenezan J, Vendeuvre T, et al. Use of intra-osseous access in adults: a systematic review. *Crit Care.* 2016;20(102). PubMed PMID: 27075364; eng. DOI:10.1186/s13054-016-1277-6
10. Mace SE, Harb G, Friend K, et al. Cost-effectiveness of recombinant human hyaluronidase-facilitated subcutaneous versus intravenous rehydration in children with mild to moderate dehydration. *Am J Emerg Med.* 2013;31(6):928–934. PubMed PMID: 00001832-201306000-00007.
11. Jannin V, Lemagnen G, Guerolt P, et al. Rectal route in the 21st century to treat children. *Adv Drug Deliv Rev.* 2014;73(Supplement C):34–49.
- **Review showing rectal route as viable and underused, especially in pediatrics but with application for many patient types.**
12. Macygin KM, Lee J, Lam A, et al. Safe and effective administration of lactulose retention enema in the ED using specialized rectal medication administration catheter. *Am J Emerg Med.* 2018;36:489-523.
- **Case report of Macy Catheter for administration of Lactulose retention enema.**
13. Sparks D, Chase D, Heaton B, et al. Rectal trauma and associated hemorrhage with the use of the convatec flexi-seal fecal management system: report of 3 cases. *Dis Colon Rectum.* 2009;53:346–349.
14. Honasoge A, Lyons N, Hesse K, et al. A novel approach for the administration of medications and fluids in emergency scenarios and settings. *J Visualized Exp.* 2016 Nov 09;(117). PubMed PMID: 27911381; PubMed Central PMCID: PMC45226138. DOI:10.3791/54622
- **Multimedia publication with case studies, protocols and in depth discussion of possible uses for the Macy Catheter.**
15. Lyons N, Nejak D, Lomotan N, et al. An alternative for rapid administration of medication and fluids in the emergency setting using a novel device. *Am J Emerg Med.* 2015 Aug;33(8):1113 e5–6. PubMed PMID: 25662805.
- **Case report of early uses of Macy Catheter.**
16. Hospi Corporation. Macy Catheter instructions for use. In: Hospi corporation N. California; 2013. editor.
17. van Hoogdalem EJ, de Boer AG, Breimer DD. Pharmacokinetics of rectal drug administration, part I: general considerations and clinical applications of centrally acting drugs. *Clin Pharmacokinet.* 1991;21(1):11–26. PubMed PMID: 00003088-199121010-00002.
- **Literature Review of common medications administered rectally**
18. van Hoogdalem EJ, de Boer AG, Breimer DD. Pharmacokinetics of rectal drug administration, part II. Clinical applications of peripherally acting drugs, and conclusions. *Clin Pharmacokinet.* 1991;21(2):110–128.

- **Literature Review of common medications administered rectally**
- 19. Hartling L, Bellemare S, Wiebe N, et al. Oral versus intravenous rehydration for treating dehydration due to gastroenteritis in children. *Cochrane Database Syst Rev.* 2006. PubMed PMID: 00075320-100000000-03260. DOI:10.1002/14651858.CD004390.pub2
- 20. Bruera E, Pruvost M, Schoeller T, Montejo G, et al. Proctoclysis for hydration of terminally ill cancer patients. *J Pain Symptom Manage.* 1998;15(4):216–219. PubMed PMID: CN-00686341.
- **Clinical trial of proctoclysis.**
- 21. Tremayne V. Emergency rectal infusion of fluid in rural or remote settings. *Emerg Nurse.* 2010;17(9):26–28. PubMed PMID: 00008410-201002000-00018.
- **Out of hospital case report of proctoclysis including procedure.**
- 22. Murphy JB. Proctoclysis in the treatment of peritonitis. *J Am Med Assoc.* 1909 Apr;L11:1248–1250.
- **First known report of proctoclysis.**
- 23. Lam YWF, Lam A, Macy B. Pharmacokinetics of phenobarbital in microenema via Macy Catheter versus suppository. *J Pain Symptom Manage.* 2016 June 01;51(6):994–1001.
- **Study reporting pharmacokinetics of phenobarbital given microenema via Macy Catheter vs. suppository**
- 24. Latuga N, Gordon M, Farwell P, et al. Improving care and decreasing costs: utilizing the macy catheter for end of life symptom management. [White Paper] Hospice of Buffalo, editor. 2017.
- **White paper discussing cost benefit of Macy Catheter.**
- 25. Arthur AG JM, Thomas SH. Subcutaneous fluid administration: a potentially useful tool in prehospital care. *Emerg Med Int.* 2012;2012:1–5.
- 26. Noble-Adams R. Dehydration: subcutaneous fluid administration. *Br J Nurs.* 1995;4(9):488–494.
- 27. ConvaTec. Directions for use 2014 [9/1512017]. [cited 2017 Oct 1]. Available from: <https://marketingworld.convatec.com/MarketPortCore/MediaFile/DownloadByApplication?applicationToken=dc038e44b0b0ee4d8616f7b6880b24551bfecf237645a04fb5b76ab792a36858&itemId=ed29ea89-2b5d-4886-9d58-d06bb1c76f74&mediaFileId=6b64a991-e977-42e4-a473-df2d8431bda7&forceDownload=true>
- 28. De Boer AG, De Leede LG, Breimer DD. Drug absorption by sublingual and rectal routes. *Br J Anaesth.* 1984;56(1):69–82.
- 29. Davis MP, Walsh D, LeGrand SB, et al. Symptom control in cancer patients: the clinical pharmacology and therapeutic role of suppositories and rectal suspensions. *Support Care Cancer.* 2002 Mar 01;10(2):117–138.
- 30. Eller MG, Wright C, Della-Coletta AA. Absorption kinetics of rectally and orally administered ibuprofen. *Biopharm Drug Dispos.* 1989;10(3):269–278.
- 31. Davis S, Burnham W, Wilson P, et al. Use of adjuvants for enhancement of rectal absorption of cefoxitin in humans. *Antimicrob Agents Chemother.* 1985;28(2):211–215.
- 32. Behar S. Alternative methods of drug administration. In: editor, Roberts JR. Roberts and Hedges' clinical procedures in emergency medicine and acute care. 7th ed. Philadelphia (PA): Elsevier; 2019.
- 33. Markota A, Fluher J, Rectal SA. Instillation of cold fluids for targeted temperature management after cardiac arrest: a case report [case-report]. *Ther Hypothermia Temp Manag.* 2017 July 14. DOI:10.1089/ther.2017.0018.en
- 34. Nabil N, Miner DJ, Amatruda JM. Methimazole: an alternative route of administration. *J Clin Endocrinol Metabolism.* 1982;54(1):180–181.
- 35. Bergogne-Berezin E, Bryskier A. The suppository form of antibiotic administration: pharmacokinetics and clinical application. *J Antimicrob Chemother.* 1999;43(2):177–185.