Novel Device For Removal of Blood Clot Obstructions in Drainage Tubes

Scott M. Thompson

General Surgery,
Department of Surgery,
Mayo Clinic College of Medicine,
200 First Street SW,
Rochester, MN 55905;
Department of Radiology,
Mayo Clinic College of Medicine,
200 First Street SW,
Rochester, MN 55905

Cornelius A. Thiels

General Surgery,
Department of Surgery
Mayo Clinic College of Medicine,
200 First Street SW,
Rochester, MN 55905

Johnathon M. Aho¹

Division of General Thoracic Surgery,
Department of Surgery,
Mayo Clinic College of Medicine,
200 First Street SW,
Rochester, MN 55905;
Department of Physiology and Biomedical Engineering,
Mayo Clinic College of Medicine,
200 First Street SW,
Rochester, MN 55905
e-mail: aho.johnathon@mayo.edu

Medical drains frequently become obstructed requiring removal or re-intervention. Currently, there is no widely accepted practice for maintaining drain patency. A simple device to remove obstructions from medical drains may have significant benefit. We manufactured a prototype drain clot extractor (DCE) for extracting obstructions. Fresh nonanticoagulated swine blood was instilled within drainage tubes of 16, 20, and 32 French ($n=2$ for each size) to generate a 4 cm blood clot. The operator was then equipped with a 0.035 in. guidewire (GW) and given 2.5 min to attempt removal while blinded. Similarly, the operator was equipped with the DCE. Volumes removed were determined by volume displacement and by drain size and method of removal. Comparison of DCE to GW by analysis of variance and means comparison using Tukey were used for statistical analysis. The DCE facilitated mechanical removal of obstructions for 16, 20, and 32 French drainage tubes. Volumes removed: 16 French (GW mean 10% volume, DCE mean 70% volume $p=0.02$); 20 French (GW mean 12.5% volume, DCE mean 75% volume $p=0.01$); 32 French (GW mean 37.5% volume, DCE mean 100% volume $p=0.01$). DCE volume removal had no dependence on drain size ($p>0.05$). This device may have utility for reducing morbidity from early drain discontinuation or replacement. Further in vivo and clinical studies are needed to determine the safety, feasibility, and efficacy of this device as tool for removing medical drainage obstructions. [DOI: 10.1115/1.4035128]

¹Corresponding author.

Manuscript received May 9, 2016; final manuscript received October 16, 2016; published online December 21, 2016. Assoc. Editor: Michael Eggen.

Introduction

Medical drainage tubes and feeding tubes are commonly used in modern clinical practice for a variety of diagnostic, therapeutic, and palliative indications. Drainage and feeding tubes come in a variety of sizes and can be placed either surgically, endoscopically, or via interventional techniques and are being increasingly utilized to minimize the morbidity associated with surgical complications, for diagnostic purposes or for enteral nutrition. In the management of pathologic fluid collection, it is essential that drains remain functional, as an obstructed drain can cause significant morbidity. Unfortunately, these drains frequently become partially or completely obstructed which may predispose a patient to infection and worsen their clinical condition. Prior studies have shown that drains are an independent risk factor for surgical site infection, and preventive interventions, such as drain antisepsis, decrease the risk of bacterial colonization and subsequent infections [1,2]. Fibrinolytic therapy combined with DNase has been suggested for the unclogging of drainage tubes in patients with pleural space infections [3], but is not routine in postsurgical drains.

However, if the drain is obstructed, this increases the risk and therefore a nonfunctional drain must be replaced or removed. Although the need for operative replacement of a drain is becoming increasingly rare, interventional drain interrogation and replacement requires a significant amount of resources and cost. In addition, these interrogations require specialized equipment and places patients at risk of complications. Therefore, a technique for maintaining drain patency and relieving obstruction may improve patient outcomes and reduce resource utilization.

Despite that drain complications are a common occurrence, there is minimal literature on optimal management and to our knowledge there is no commercially available device for returning drain patency after an obstruction has occurred. A simple device to remove obstructions from catheters, potentially at the bedside, may have significant benefit. In addition to being cost-effective, safe, and easy to use, this device would need to be able to de-clot a wide variety of drain sized for both patients with short- and long-term drainage catheters. We describe a catheter for extracting obstructions from medical drainage tubes and present initial feasibility experiments on potential applications across a variety of medical drainage tubes.

Methods

Briefly, the device is a deployable catheter that is able to bypass obstructions in a low-profile manner, Fig. 1(a)). The device consists of inner and outer shafts, which are coaxially oriented together (12 French). The inner shaft moves by deployment by the operator relative to the outer shaft. This movement articulates a series of nitinol baskets which in a collapsed state are the size of the catheter, but when deployed can range in size from 12 to 40 French to fit the drainage tubing lumen. The catheter can accommodate guidewires of 0.035 in. for guidance if required. Briefly, the method of insertion into the drain lumen in a collapsed state allows the catheter to be directed past the obstruction (using or not using a guidewire) and then once past the obstruction, deployed and withdrawn facilitating mechanical removal of the obstruction. The device may be deployed repeatedly until the obstruction is removed.

To generate conditions suitable for initial in vitro testing, fresh swine blood was instilled within chest tubes of 16, 20, and 32 French ($n=2$ for each size) and clamped to generate a 4 cm long tubular clot of diameter equal to the internal diameter of the drainage tube which was allowed to form over 24 h and desiccate to simulate an obstruction. The volume of the clot was calculated based on the internal drain diameter and length which were measured using calipers.

The operator was then given a 0.035 in. guidewire and presented with the distal end of the drain tubing. The distal end of the catheter was concealed to blind operator to the simulated in vivo proximal portion of 16 cm to simulate clinical conditions and

given 2.5 min to attempt removal of the debris (Fig. 1(b)). The volume of clot removed was then determined by volume displacement in a 10 ml test tube which was then recorded. Similarly, under blinded conditions and a 2.5 min time constraint, the operator was equipped with the obstruction extractor device (Fig. 1(c)). Volume removal was calculated by displacement in the same manner. Volumes of removed obstruction were then calculated and compared. Comparison of DCE to GW by analysis of variance and means comparison using Tukey between DCE and GW and drain size were used for statistical analysis. All analyses and figures were generated using Graphpad Prism 7.

Results

The volume of obstruction was calculated according to the following table:

Drain size	Internal diameter	Clot length	Clot volume
16 French ($n = 2$)	3.9 mm, 3.9 mm	40.6 mm, 39.8 mm	0.49 cc, 0.48 cc
20 French ($n = 2$)	4.3 mm, 4.3 mm	41.2 mm, 39.8 mm	0.6 cc, 0.58 cc
32 French ($n = 2$)	7.2 mm, 7.2 mm	42.6 mm, 38.5 mm	1.73 cc, 1.57 cc

The device performed favorably compared to mechanical removal using a 0.035 in guidewire with nearly complete removal of obstructions with the device for 16, 20, and 32 French drainage tubes in comparison to the guidewire technique, Fig. 1(d).

16 French (Guidewire removed mean 10% of obstruction volume, drain clot extractor removed mean 70% of obstruction volume $p = 0.02$)

20 French (Guidewire removed mean 12.5% of obstruction volume, drain clot extractor removed mean 75% of obstruction volume $p = 0.01$)

32 French (Guidewire removed mean 37.5% of obstruction volume, drain clot extractor removed mean 100% of obstruction volume $p = 0.01$)

There was no dependence on drain size and volume removed by DCE all $p > 0.05$.

Discussion

Using the prototype device, we have demonstrated a technique for the mechanical removal in vitro blood clots from drainage tubes. The device presented consists of a collapsible basket catheter that allows the obstruction to be bypassed in a collapsed state, then deployed and removed to mechanically remove the obstruction. Although production cost is approximately \$100 (U.S.), it is expected that the device cost could easily be offset by the potential cost saving if additional procedures are avoided.

In these preliminary tests in the laboratory, we have compared our results with the catheter device to the most contemporary technique for obstruction removal using a 0.035 in guidewire with results favoring our device. It is possible that this device may be able to be used for mechanical removal of debris by bedside

(a)

(c)

(b)

(d)

Guidewire vs. Drain Clot Extractor Obstruction Remover

Fig. 1 (a) Distal working end of the obstruction removal device in the deployed state, (b) 0.035 guidewire in a 32 French chest tube, with incomplete removal of the obstruction, (c) obstruction removal device collapsed in 32 French chest tube, and (d) Percentage of obstruction removal for 16, 20, and 32 French chest tubes using 0.035 guidewire (GW) compared to obstruction removal device (DCE)

practitioners as most drainage tubes indicate how much length is present before the proximal drain fenestration. If one were to use a standard, noncollapsible brush, the obstruction may be pushed further into the drain or cause further impaction of the obstruction.

The most common indication in surgical practice is placement of a drain in the postoperative wound bed to facilitate dead space closure. While it is unclear if there is any meaningful benefit compared to dead space obliteration using suture, drain use is common [4]. The most common debris encountered in the drain is often desiccated blood from the wound bed, which is the condition we attempted to replicate as reasonably as possible.

Medical practitioners often use drains and tubes to remove fluid or air collections from a body cavity or organ space in a variety of clinical conditions. However, the drainage of fluid via a synthetic tube is complicated by the body's robust response to foreign objects and the heterogeneous nature of the fluids that are drained from the body. The protein, debris, and other solid materials contained in these fluids commonly accumulate and obstruct drain tubing. This can lead to incomplete drainage fluid collections and subsequent patient harm. Although obstruction is anecdotally more common among smaller lumen tubes, large bore tubes are also subject to obstruction. The current standard of care for obstructed or partially obstructed tubes is either removal or replacement. In our study, the DCE device did not have a difference in efficacy when controlling for drain size, which is a consideration given that larger drains are technically more challenging to replace using an interventional approach. When removal is not yet an option, the replacement of these tubes carries further morbidity and cost to the patient and is not always feasible. Currently, there is no solution to remove this debris, and the drain itself has to be replaced, typically under radiological guidance. Thus, there exists a critical need to provide a simple bedside solution to obstructed drainage tubes.

Conclusion

Further in vivo and clinical studies are needed to determine the safety, feasibility, and efficacy of this device as tool for removing medical drainage obstructions. However, pilot data suggest that this type of device has significant potential for improving outcomes for a relatively rarely discussed, but potentially morbid complication, the clogged medical drainage tube.

Acknowledgment

Dr. Aho is supported by Department of Surgery Innovation Accelerator Funding (Mayo Clinic) and a grant from the National Heart, Lung, and Blood Institute, T32 HL105355. These funders had no role in the design or conduct of the study; collection, management, analysis, or interpretation of the data; or preparation, review, or approval of the article. Mayo Foundation has a financial interest in technologies developed by Dr. Aho. Dr. Aho reports patent disclosures for multiple technologies which he does not receive royalty.

References

- [1] Degnim, A. C., Scow, J. S., Hoskin, T. L., Miller, J. P., Loprinzi, M., Boughey, J. C., Jakub, J. W., Throckmorton, A., Patel, R., and Baddour, L. M., 2013, "Randomized Controlled Trial to Reduce Bacterial Colonization of Surgical Drains After Breast and Axillary Operations," *Ann. Surg.*, **258**(2), pp. 240–247.
- [2] Barbadoro, P., Marmorale, C., Recanatini, C., Mazzarini, G., Pellegrini, I., D'Errico, M. M., and Prospero, E., 2016, "May the Drain be a Way in for Microbes in Surgical Infections?," *Am. J. Infect. Control*, **44**(3), pp. 283–288.
- [3] Rahman, N. M., Maskell, N. A., West, A., Teoh, R., Arnold, A., Mackinlay, C., Peckham, D., Davies, C. W. H., Ali, N., Kinnear, W., Bentley, A., Kahan, B. C., Wrightson, J. M., Davies, H. E., Hooper, C. E., Lee, Y. C. G., Hedley, E. L., Crosthwaite, N., Choo, L., Helm, E. J., Gleeson, F. V., Nunn, A. J., and Davies, R. J. O., 2011, "Intrapleural Use of Tissue Plasminogen Activator and DNase in Pleural Infection," *N. Engl. J. Med.*, **365**(6), pp. 518–526.
- [4] Aho, J. M., Nickerson, T. P., Thiels, C. A., Saint-Cyr, M., and Farley, D. R., 2016, "Prevention of Postoperative Seromas With Dead Space Obliteration: A Case-Control Study," *Int. J. Surg.*, **29**, pp. 70–73.