TubeClear®

Enteral Access Clearing System

An Active Device for Restoring Patency in Clogged Small Bore Feeding and Decompression Tubes, Case Report Series

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Abstract

Feeding tubes are used to deliver enteral nutrition (EN) to patients unable to ingest nutrients and medications orally and therefore at risk of malnutrition and dehydration.

Unfortunately, the long and narrow inner lumens of small bore feeding tubes used to deliver enteral nutrition and medication to patients often clog for various reasons including, delivery of high viscosity medications, chemical reactions between feeding formula and medication, or by inadequate tube maintenance. Clogged feeding tubes can cause patients to go extended periods without nutrition and medication, and attempts to unclog tubes strain valuable nursing resources. Traditional methods to clear clogged feeding tubes are often unsuccessful, potentially leading to hospitalization, invasive procedures for tube replacement, and patient discomfort. The TubeClear® System, an FDA-cleared medical device, was developed to restore patency in clogged feeding tubes while the tube remains in the patient. The system is comprised of a reusable Control Box that actuates a single-use Clearing Stem. The Clearing Stem inserts into the feeding tube and its tip moves backwards and forwards to mechanically disrupt and ultimately clear the clog. This case series documents twelve cases in which the TubeClear System was used to clear clogged feeding tubes. All cases were completed by a single licensed healthcare practitioner and were 100% successful without any issues reported by the practitioner and/or patients. The ability to quickly clear clogged feeding tubes while the tube remains in the patient will save healthcare resources, and ease the burden on patients and caregivers.

Introduction

Small bore feeding tubes, also known as enteral access devices, are used to provide essential nutrition and medication to patients at risk of malnutrition and dehydration due to an inability to ingest orally.[1] An estimated 7M feeding tubes are placed each year in the U.S. alone.[2-4] Clogging is one of the most frequent mechanical complications of feeding tubes.[1,6] Tubes are more likely to become clogged when powdered, crushed, acidic, or alkaline medications or blenderized feeding formulas containing particulates are delivered through the small inner lumen, or when tubes are not routinely flushed following feedings.[5] Reported clogging rates vary, ranging from 9 - 35%.[1,5-10] Clogging of nasoenteral (NE) and nasogastric (NG) feeding tubes are considered to be underestimated and underreported, actual rates are likely much higher.[6] Based on a 25% clogging rate, US medical facilities treat an estimated 1.75M clogged feeding tubes annually.

Feeding tube occlusions create hassles and frustration for practitioners and anxiety and discomfort for patients. The lapse in nutrition and medication regimen may also negatively impact recovery.[11] Standard techniques for restoring tube patency in the past included enzymes, Coca-Cola, and meat tenderizer. Today, commercially available manual brushes and stylets exist, in addition to enzymes or clearing with syringe flushes.[5,12,13] Attempts to clear obstructions using these techniques are time-consuming to healthcare practitioners and often result in tube replacement still being required. Among other common medical procedures, patients rank NE/NG tube insertion to be one of the most painful.[14-16] Replacing a feeding tube may cause additional patient safety risks, associated medical costs, and additional pain and discomfort to the patient. The most common way to place NE feeding tubes, blind insertion at patient bedside, has a reported 0.5 - 16% malposition rate.[6] Malpositions into the trachea may cause pneumothoraxes and possibly death. Several methods exist for verifying accurate placement with the most reliable being radiography.[6] However, this exposes patients to additional radiation and medical costs. The approximate cost of an abdominal x-ray to confirm tube placement averages $280,[17] with 1 - 3 views required to confirm tube placement. Taking into account nursing time, tube replacement, radiographs and other miscellaneous costs, the capability to unclog a feeding tube while it remains in the patient, could represent substantial savings to a medical facility not to mention reduced pain and discomfort to the patient.

The TubeClear® System was developed by Actuated Medical, Inc. (AMI; Bellefonte, PA) to efficiently and effectively clear clogs in feeding tubes while the tube remains in the patient.[18] In 2012, the TubeClear System received 510(k) clearance by the FDA (K121571) for the clearing of clogged 10 - 18 Fr nasogastric (NG) feeding tubes. In 2013, the indications for use were expanded to include 10 - 18 Fr nasoenteral (NE), gastrostomy (G) and jejunostomy (J) tubes (K131052). The TubeClear System is comprised of a reusable Control Box to which a single-use Clearing Stem is attached (see **Figure 1**). The Clearing Stem is inserted into the patient's feeding tube by the healthcare practitioner. While the practitioner holds the stationary Clearing Stem Sheath, the motor in the Control Box causes the Clearing Stem Tip to move backwards and forwards against the obstruction to mechanically disrupt and dislodge the clog and restore patency. This report discusses six (6) clogged feeding tube cases (**Table 1**) in detail and six supplemental cases that were cleared using TubeClear at a large central Ohio academic medical center. As shown in **Table 1**, the average time to remove the occlusion was 14 minutes with 100% success/efficacy and no safety issues reported by the practitioner or patient.

Figure 1: TubeClear® Control Box with attached Clearing Stem.
The device is FDA-cleared for use in restoring patency to clogged NG, NE, G, and J feeding tubes.

Methods

In this study, twelve (12) cases using the TubeClear System are discussed. All twelve (12) cases were cleared by a single licensed critical care clinical nurse specialist over an 11-month time period (May 2013 - April 2014). Six (6) cases are discussed in detail, while six (6) supplemental cases are generally described. All of these patients were admitted to a large academic medical center with a primary cardiac diagnosis. Of the six (6) detailed cases, the median patient age was 62 years with an average weight of 72.2 kg and height of 1.78 m. Five (5) of the patients were treated with 10 Fr (109 cm length) and one was treated with a 14 Fr small bore feeding tube. For all cases, prior to utilizing the Clearing Stem, the hospital standard for flushing the small bore feeding tube was implemented (i.e., flushing with at least 20 ml of saline/water) and the clog was verified. Following clog verification, the healthcare practitioner then explained to the patient how they would proceed in trying to unclog the tube, before continuing with the procedure.

Based upon the feeding tube's length and diameter, the appropriate Clearing Stem was selected. For cases subsequently described, the Clearing Stem model used was NE-1043 (length: 109 cm), compatible with 10 - 18 Fr feeding tubes. The Clearing Stem is composed of a plastic sheath covering a wire with a permanently bonded depth control collar along its length. This collar is designed to stop the Clearing Stem's progression before the Clearing Stem exits the distal end of the feeding tube. The proximal end of the Clearing Stem is magnetically connected to the Control Box for stability. The Control Box motor moves the wire backward and forward. The distal Clearing Stem wire tip is specially designed to be flexible while maintaining the mechanical integrity to chip away at the clog. Prior to inserting the Clearing Stem into the feeding tube, a water-soluble lubricant was applied to the distal Clearing Stem tip. The TubeClear System and saline flushes were alternated in use until the occlusion was successfully cleared. The Clearing Stem was removed to enable the administration of the saline flushes. Patency restoration was confirmed following an easily administered 20 ml saline flush. Following each clearing attempt, the practitioner completed a survey form that captured key outcomes related to the procedure. A case summary from the survey sheets appears in **Table 1**. All data was collected as part of a product evaluation, and was not part of a clinical trial.

Case 1:

A 58-year-old female, weighing 122 kg, presented with a 10 Fr small bore nasoenteral tube that was clogged approximately 2 hours prior to the next medication administration time, in January 2014. Prior to the clog being detected, medication was being passed through the tube. The practitioner was able to successfully remove the occlusion using a NE-1043 Clearing Stem (109 cm length) with a total procedure time of 10 minutes following an easy insertion and manipulation of the Clearing Stem. No issues were reported during the procedure, and the patient did not note any type of discomfort.

Case 2:

A 66-year-old male, weighing 67.9 kg, height 1.91 m, presented with a clogged 10 Fr small bore nasoenteral tube in February 2014. Prior to clogging, feeding formula and medication was being administered. The patient's tube had been placed seven (7) days prior to clogging. The practitioner was able to successfully restore tube patency using a NE-1043 Clearing Stem with a total procedure time of 20 minutes following an easy insertion and manipulation of the Clearing Stem. No issues were reported during the procedure, and the patient tolerated the procedure well.

Case 3:

A 48-year-old female, weighing 71.1 kg, height 1.63 m, presented with a clogged 10 Fr small bore nasoenteral tube in February 2014. The patient had the tube placed ten (10) days prior to clogging and was used for feedings and medication administration. The practitioner was able to successfully remove the occlusion using a NE-1043 Clearing Stem, requiring a total procedure time of 20 minutes. The Clearing Stem was easily inserted and manipulated. The patient was not responsive during the procedure; no issues were reported during the procedure.

Case 4:

An 85-year-old male, weighing 68 kg, height 1.7 m, presented with a clogged 10 Fr small bore nasoenteral tube in February 2014. The patient had the tube in place for only 2 - 3 hours prior to clogging following potassium administration. The practitioner was able to successfully remove the occlusion using a NE-1043 Clearing Stem with a total procedure time of 15 minutes following an easy insertion and manipulation of the Clearing Stem. The patient described a tickling sensation but no discomfort or additional issues were reported.

Case 5:

A 67-year-old male, weighing 79.9 kg, height 1.7 m, presented with a clogged 14 Fr nasoenteral tube in early April 2014. The tube was being used to deliver nocturnal feeds to the patient and clogged 2 days after placement. The practitioner was able to successfully clear the occlusion using a NE-1043 Clearing Stem with a total procedure time of 5 minutes following an easy insertion and manipulation of the Clearing Stem. The patient did not note any type of discomfort and no issues were reported during the procedure.

Case 6:

A 56-year-old male, weighing 91 kg, height 1.96 m, presented with a clogged 10 Fr small bore nasoenteral tube in April 2014. The patient had the tube in place for only 2 hours prior to clogging following delivery of feeding formula and aspirin (acetylsalicylic acid, ASA). The practitioner was able to successfully clear the occlusion using a NE-1043 Clearing Stem with a total procedure time recorded to be 10 - 15 minutes (13 minutes was recorded in Table 1 for computing average). The insertion and manipulation of the Clearing Stem was noted to be easy. The patient did not note any type of discomfort and no issues were reported during the procedure.

Supplemental Cases: *Patients (n=6) ranged in age and gender and tube placement information was not readily available. The practitioner was able to successfully clear all occlusions using a NE-1043 Clearing Stem with total procedure times ranging from 5 - 30 minutes. The insertion and manipulation of the Clearing Stem was noted to be easy. The patients did not note any type of discomfort and no issues were reported during the procedure.*

Discussion

Through this case series the TubeClear System was used safely and effectively, restoring patency to clogged small bore feeding tubes. The practitioner's experience using the device has been extremely positive. The device did not cause discomfort to the patients, and clogs were removed in an average of 14 minutes. The ability to clear the occlusions while the tube remains in the patient, avoiding the need to replace the tube and the associated risks, costs, and patient discomfort is a significant advantage of the technology.

Enteral nutrition via a feeding tube is often indicated when a patient is unable to swallow food or medication. When a feeding tube clogs, patients can experience extended time without nutrition or medication which can negatively impact health and recovery.[11] Valuable nursing time is consumed due to the limited options for clearing a clogged tube. The TubeClear System overcomes a major obstacle in critical-care medicine – clearing clogged feeding tubes. Clearing the potential 1.75M clogged and sluggish tubes in the U.S. alone every year, instead of removing and replacing the tube, saves significant healthcare resources, and eases the burden on both the patient and staff. Further investigation would be beneficial to critical care, high acuity, and progressive care units of the cost-savings and efficacy of the TubeClear System.

Table 1: The TubeClear System Case Series Summary Table.

Case	Sex	Age (yr)	Tube Size (Fr)	Time Lapsed from Tube Placement to Clog Appearance	Last Substance Passed Prior to Clogging	Total Procedure Time (minutes)	Patency Restored?
1	F	58	10F	-	medication (Protonix® (Pantoprazole))	10	Yes
2	M	66	10F	7 d	tube feed & meds (Protonix® (Pantoprazole))	20	Yes
3	F	48	10F	10 d	tube feed & meds (Protonix® (Pantoprazole))	20	Yes
4	M	85	10F	2 - 3 hrs	potassium	15	Yes
5	M	67	14F	2 d	nightly tube feeds	5	Yes
6	M	56	10F	2 hrs	tube feed / aspirin (ASA)	13	Yes
Median		**62**				**Mean 14 Std. Dev. 6**	
Supplemental Patients (n=6) ranged in age and gender. Tube placement information was not readily available at the time of document preparation.							

Information on the Author

Marcia Belcher is a retired licensed critical care clinical nurse specialist with 42 years of critical care experience.

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