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Quantifying the Complications and Impact of Persistent Intubation Problems

Number of intubations

40 million intubations are performed a year in North America.

4 million (10%) of these intubations are performed in the pre hospital, emergency department and ICU. These are considered emergency intubations.

36 million intubations are performed in the operating room. These are considered non-emergent intubation.

Mortality Assumptions

30% baseline mortality for anyone needing an emergency intubation (roughly the general mortality in critically ill patents)

20% mortality for second major complication

Cost of Complications

Airway complication cost $15,000 (2014 CMS Data) to be conservative we will use $10,000.

Iatrogenic Pneumothorax cost 17,500-45,000 (Patient Safety in American Hospitals 2004)

Problems of Maneuverability

Multiple attempts to intubate (Difficult Intubations)

When an endotracheal tube cannot be placed in the first two attempts, the intubation is classified as a difficult intubation.

Difficult intubations make up 4% (1.44 m) of intubations in the Operating room and 10% (400,000) of intubations outside the operating room. (Mort,2004)

Complications and Mortality Associated with Multiple Intubation Attempts in the Pre-hospital, ED and ICU Settings.

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Mort et al. looked at complications associated with emergency intubations (ICU and ED) and demonstrated that major complications are markedly increased in difficult intubations (3 or more attempts to place the endotracheal tube.) (Figure 1)

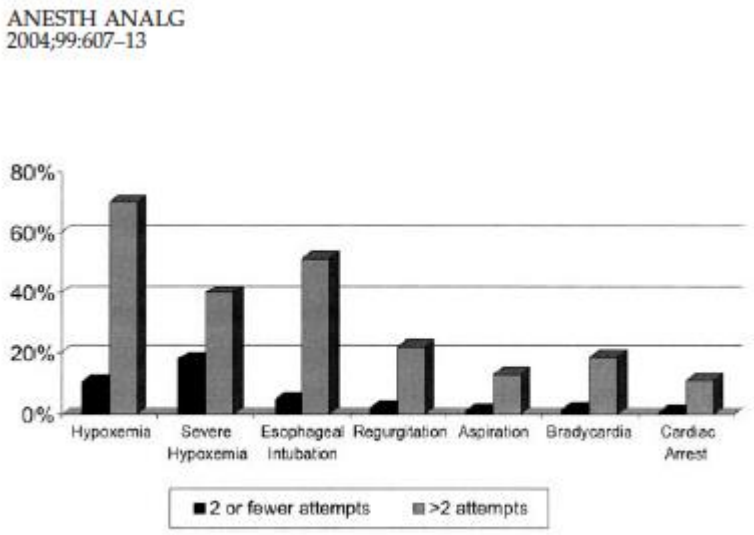

Figure 1. Graphic display of complications by intubation attempts.

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Let's quantify the sharp difference in major complication rates between difficult intubations (3 + attempts) and non-difficult intubations. (See Table 1)

Complication	Non-Difficult Intubation (1-2 attempts)	Difficult Intubation (3+ attempts)
Aspiration	0.8%	13%
Severe Hypoxemia	1.9%	28%
Esophageal Intubation	5%	51%
Cardiac Arrest	.7%	11%

Table 1 complication rates in non- difficult and difficult intubations (Mort)

More recently, a similar study by Sakles (2013) looked at intubations in the Emergency Department. Again, the tight relationship between multiple intubation attempts and a sharp rise in major complications was demonstrated. (See figure 2)

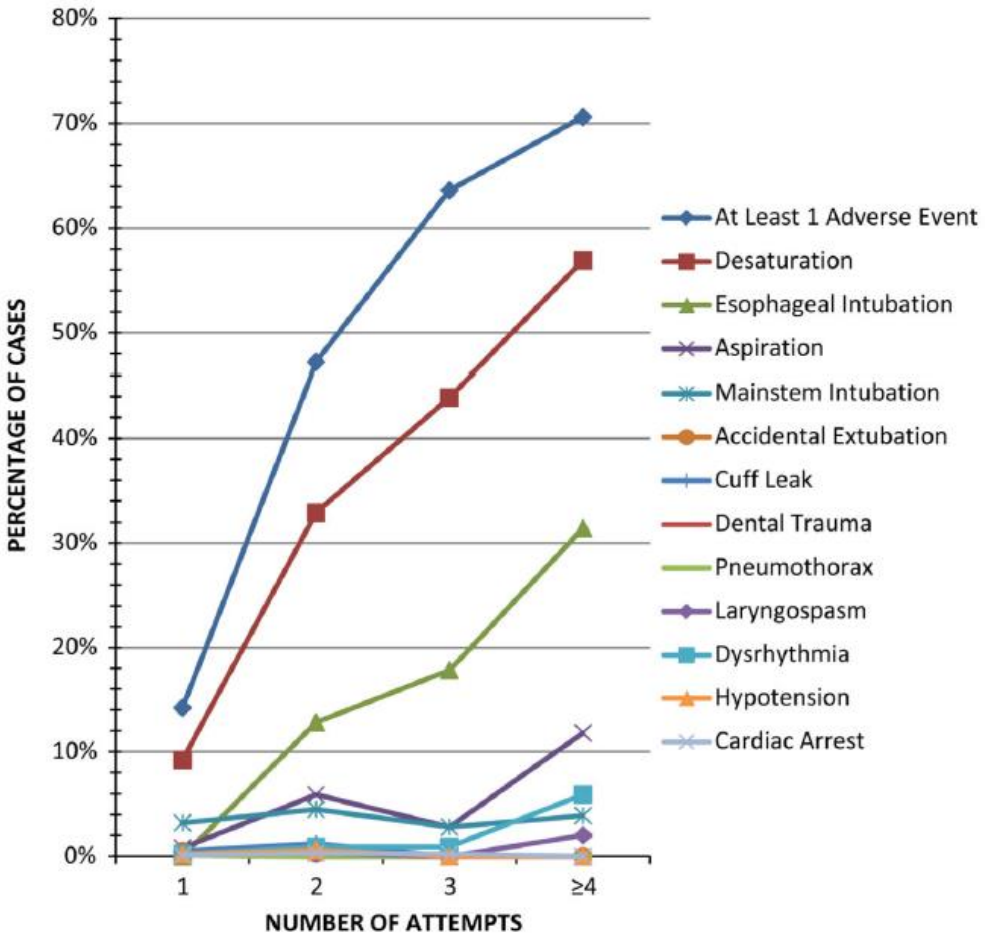

Figure 1.
Incidence of one or more adverse events and incidence of specific adverse events versus number of attempts.

Figure 2. Complication rates with multiple intubation attempts (Sakles 2013)

Both studies demonstrate the tight relationship of multiple intubation attempts and major complications, hence the overriding importance of intubating patients on the first attempt.

A nice lecture on ED and ICU intubations, complications, and importance of first pass attempts is available here:

https://www.youtube.com/watch?v=yDfw95e2Qkc

Why can't the patient be intubated on the first attempt?

Reasons for first intubation attempt failure are well understood and generally fall into two categories: 1) failure to visualize the entrance to the trachea, and 2) failure to be able to direct the endotracheal tube into the trachea.

The first cause, failure to visualize the trachea, has largely been solved with the advent of the video laryngoscope. We now no longer have to move the tongue and lower jaw out of the way to see the vocal cords. We can see around the corner and see the entrance to the trachea. This corner, however, has created a new problem, we can see where we would like to place the tube, however the 'corner' creates a steep angle making it difficult to bring the tube up into the tracheal entrance! This problem is well documented in the literature and widely understood by those intubating on a day to day basis. Studies demonstrate that inability to get the tube into the trachea despite a good view of the tracheal entrance makes up 54.7% of first attempt failures with video laryngoscopy. (Sakels 2011)

Key Point: The Through-The -Cords articulating boogie solves this problem as the articulating tip provides the fine maneuverability and control for easily entry into the trachea. If you can see where you want to be, the Through-The -Cords articulating boogie can get your tube there! This ability has the potential to make 55% of multiple intubation attempts disappear, effectively making 55% of associated major complications disappear.

What does this persistent problem of entering the tracheal look like in clinical practice?

Below is a link to what this problem looks like via Youtube:

https://www.youtube.com/watch?v=BvpUI7vOpDw

This is a compilation of intubations with a video laryngoscope; some easy and some struggling. Notes especially cases 9 and 13. These best demonstrate the struggle to enter the trachea which can end in multiple attempts and major complications. All attempts shown in this compilation were ultimately successful, however it is important to keep two keep in mind the trauma to the vocal cords and people are unlike to post a failed airway.

In contrast, this is a link to one of several hundred extremely difficult airway managed by Dr. Runnels using an articulating introducer.

https://www.youtube.com/watch?v=fu_LW9prlFs

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Number of complications in the emergency intubation setting (ICU, ED, Prehospital).

Major complication rates associated with multiple intubation attempts in the setting of emergency intubations allow estimate of the number of complications expected in the US every year. 55 percent of difficult intubations result from inability to direct the tube into the trachea. The TTC articulating introducer solves this problem and should result in 55% fewer difficult intubations as well as 55% fewer major complications associated with multiple intubation attempts.

Tables 2 and 3 demonstrate the calculated number of expected complications associated with current intubation technology and the expected complication reduction when using a TTC articulating stylet. Table 2 uses Mort's complication rates, and table 3 uses Sakles complication rates.

Major Complication	Complication Rate	Current Number of Complications	Complications expected with TTC Articulating Bougie	Total Major Complications Reduced
Aspiration	13%	52,000	23,400	
Severe Hypoxemia	28%	112,000	50,400	
Esophageal Intubation	51%	204,000	91,800	
Cardiac Arrest	11%	44,000	19,800	
Total Major Complications		**412,000**	**185,400**	**208,120***

Table 2. Complications -difficult emergent intubations (400,000/year) Mort

Major Complication	Complication Rate	Current Number of Complications	Complications Expected with TTC Articulating Bougie	Total Major Complications Reduced
Aspiration	5.9%	63,956	28,792	
Severe Hypoxemia	37.8%	409,752	184,464	
Esophageal Intubation	15.8%	171,272	77,104	
Cardiac Arrest	0.1%	2,916	1,952	
Total Major Complications		649,316	292,312	**337,208***

Table 3. Complications in difficult emergent intubations (400,000/year) Sakles

**Note that the reduction in major complications is not simply complications with and without the TTC articulating bougie. Some patient's complications are still present in those intubated on the first attempt.*

With 55% higher first attempt success rate, the overall difficult intubation rate for emergency intubations effectively drops from 10 % to 4.5%. Table 4 shows what this decrease looks like in terms of absolute numbers of major complications eliminated, costs savings, and lives saved using the average of the Mort and Sakles data.

Difficult intubation Rate	Total Major Complications All Emergent intubations	Cost of Complications ($10,000/complication)	Deaths (Mortality20%)	
10%	530,000	$5,300,000,000	106,000	
5.4%	238,000	$2,380,000,000	47,600	
Reduction	**292,000**	**$2,920,000,000**	**58,400**	

Table 4. Impact of TTC articulating introducer on major complications, costs, and deaths.

By solving the persistent problem of 'Inability to direct the ETT into the tracheal entrance' Through The Cords articulating introducers can reduce the absolute number of major complications by 292,000 in the ED and ICU alone! This reduction in major complications can lead to a cost savings of nearly 3 billion dollars a year and save nearly 60 thousand lives!

Assumptions of cost and mortality of a major airway complications used here are very conservative, we believe these are both much higher.

Unfortunately, we have no reliable numbers to extrapolate complications in the remaining 36 million intubations performed in the Operating Room. However, we know that 4% of these are difficult intubations (1,440,000 difficult intubations per year). As these are elective intubations in a highly controlled setting, with properly prepared patients, and highly skilled anesthesia providers, the complications associated with difficult airways is surely less, but still present. Nonetheless, 55% fewer difficult intubations will result in the same magnitude of reduction in complications, deaths, and associated costs inside the operating rooms as well.

In addition, the time to complete the intubation is greatly reduced leading to cost savings.

Complications Associated with Lack of Depth Control

Once an introducer or an endotracheal tube is placed into the trachea, depth matters! The trachea in adults is between 8 and 10cm long, after that it divides into the right and left main bronchus which supply oxygen to each lung. Device tip travel beyond the trachea into the right or left bronchus can have life threatening consequences. Direct damage to the bronchi and lungs such as pneumothorax, lacerations, and perforations can and do occur.

In the case of endotracheal tubes, if the tube passes through the trachea and into a bronchus physiologic as well as physical damage can occur. Placing an endotracheal tube too deep, past the trachea and into a bronchus is called an endobronchial intubation. In this situation oxygen is only delivered to one lung, only half of the blood passing through the lungs has oxygen available to pick up. This leads to low oxygen content or hypoxemia in the blood. Less oxygen is available to be delivered to tissues which can lead to organ damage and death. In addition, the breath volume that should be delivered to both lungs, is now delivered to only one lung. This can result in high pressure in the ventilated lung which can cause trauma to the lung tissue, pneumothorax and death. In addition, the non-intubated lung can also collapse and consolidate leading to further damage.

It is difficult to imagine the provider stress in emergent intubations. The overriding drive is to place the tube or introducer into the trachea. How deep into the trachea is too often a secondary concern.

Endobronchial intubations.

Schwartz and others have documented a 15% endobronchial intubation rate in emergent intubations. Unfortunately, little is known about how often or how long this goes unrecognized or how often this lead to real tissue damage. What we do know is the consequences of endobronchial intubations. In the ICU setting endobronchial intubation is associated with a significant increase in mortality. (Zwillich, 74) found that a endobronchial intubation lowered survival in the ICU from 64% to 45% and was strongly associated with pneumothoraxes and tension pneumothoraxes as well as immediate hypotension.

Davis found that hypoxemia in patients with closed head injuries increased mortality from 22% to 41%. (Davis, 2004)

Chi found that prehospital hypoxemia increased mortality of patients with brain injury from 20% to 37%. (Chi, 2006)

Endobronchial intubations make up 2% of adult malpractice claims and 4% of pediatric claims against anesthesiologists. (Caplan 1990, ASA Closed claims)

Extrapolation of endobronchial intubations in based on 4m emergency intubations are presented in table 5 below.

	Endobronchial intubation rate	Endobronchial intubations	Cost of complications at $10,000 per	Deaths
Emergency intubations 4m	**15%**	**600,000**	**$6,000,000,000**	**30,000**

Table 5 Impact of endobronchial intubations on the emergency setting.

Our Color-zoned depth control system has the potential to eliminate these complications

Airway Introducer Trauma

If placed too deep into the bronchus and lungs, airway introducers or bougie can cause lacerations and pneumothorax. (The common name for airway introducers is 'bougie"). This became apparent recently in the anesthesia literature when the old style, (reusable and soft), Gum Elastic bougie was replaced by stiffer plastic,

single use bougies. Reports of injury with stiffer, single use bougies, began to surface. Studies demonstrated that much more force could be transmitted to the lung though the stiff shaft of the single use bougie; well above the force needed to puncture a pig lung! (Marson, 2014) This resulted in the call to take care to never let the tip pass through the trachea into the bronchus or small airways!

Key Point: A further call was issued to redesign the bougie so that depth of insertion can be easily controlled. As of yet no redesign has taken place!

Pneumothorax rates in emergent intubations are documented to be 0.1% (Martin 2011) Bougies are used in 12.9 % of all emergent intubations and 51% of all difficult emergent intubations. In the operating room bougie use rates are documented to be 4%.

Table 6 extrapolates these rates to absolute number of pneumothoraxes.

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Setting	Pneumothorax use rate	Number of bougies used	Pneumothoraxes	Cost of Complications	Deaths
Emergency intubations 4,000,000	12.9%	516,000	516	$8,772,000 - $23,220,000	96
OR intubations 36,000,000	4%	1,440,000	1440	$24,480,000 - $64,800,000	270
All Intubations		**1,956,000**	**1956**	**$33,525,000 - $88,020,000**	**366**

Table 6. Bougie Associated Pneumothorax extrapolation

An intragenic pneumothorax carries a 18.7% mortality and associated cost of $17,000-$45,000 per incident. (Health grades 2004) Malpractice settlements average $143,250 in 1999 dollars. (Caplan 1990, ASA Closed claims) Iatrogenic pneumothorax is now a CMS Never-Never event in the setting of central line placement! It could easily become a Never-Never event in the setting of airway management as well.

What does this persistent problem of lack of depth control look like in clinical practice?

A quick review of Youtube demonstrations of bougie use demonstrates a general lack of awareness of this danger. Note also how difficult it is to determine tip depth at the level of the vocal cords via current incremental introducer marking systems even when used with a video laryngoscope.

https://www.youtube.com/watch?v=r2rDhnpjseg - Watch the end of the bougie in comparison to the video screen before and after the endotracheal tube is advanced.

https://www.youtube.com/watch?v=62T4K-_9b4E - Note the comment "It is better to have it too deep than too shallow"

https://www.youtube.com/watch?v=BoTv2-TqBcA - Note that none of the reason given for having someone hold the end of the bougie while advancing is never, "Avoiding injury to trachea and lungs"!

In the Emergency intubation setting it is difficult to know how many pneumothoraxes are caused by boogies and how many are caused by endobronchial intubations, however lack of depth control in the trachea is a contributory factor in many of these pneumothoraxes.

Airway Exchange Catheter Complications

Airway exchange catheters are used in 108,000 endotracheal tube exchanges per year in North America. Use of these catheters carry a 1.5% pneumothorax rate and a 13.8% failed airway exchange. (Mclean 2013) Lack of depth control of the exchange catheter in the trachea lies at the heart of both complications. If the tip is too deep, a pneumothorax or lung damage can result either because of direct trauma by the tip, or barotrauma as a result of ventilation through the catheter with the tip in the one bronchus. If the tip is too shallow, it can come out of the trachea leading to the inability to pass the ETT back into the trachea. Table 7 extrapolates complications and deaths from these complications.

Complication	Complication rate	Number of complications	Costs of Complications	Deaths
Pneumothorax	1.5%	1,620	$27,540,000 - $72,900,000	303
Failed Airway	13.8%	14,900	$149,000,000*	2980**
Totals		**16,520**	**$176,540,000 - $221,900,000**	**3,283**

Table 7 Airway Exchange Complications and Deaths

*assumes $10,000 / major airway complication

**assumes 20% mortality associated with failed intubation in the setting of a critically ill patient

Total Value of Preventable Complications

Where we have reliable numbers, we have calculated the total cost savings complications TTC airway tools are capable of preventing. (Table 7) Keep in mind that these cost savings represent only complications from 4,000,000 emergency intubations (ICU and ED). As we have no reliable numbers for complications in the 36,000,0000 Non-Emergent intubations (OR) this number surely underestimates the real cost savings.

Type of complications	Savings From Prevented Complications
Difficult Intubation Complications	$2,900,000,000
Endobronchial intubations	$6,000,000,000
Bougie Complications	$33,000,000 - $87,000,000
Exchange Catheter Complications	$176,000,000 -$222,000,000
Total Savings Form Prevented Complications In the ICU and ED	**$9,000,000,000**

Table 7 Tally of savings from prevented complications