## **ORIGINAL ARTICLE**

# **Tracheotomy-Related Deaths**

A Systematic Review

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## **SUMMARY**

<u>Background:</u> Tracheotomies are frequently performed on ventilated patients in intensive care and sometimes lead to fatal complications. In this article, we discuss the causes and frequency of death associated with open surgical tracheotomy (OST) and percutaneous dilatational tracheotomy (PDT) on the basis of a review of the pertinent literature.

<u>Methods:</u> We systematically searched the PubMed, EMBASE, and Cochrane Library databases and the Karlsruhe Virtual Catalog for publications (1990–2015) on tracheotomy-related deaths in adults, using the search terms "tracheotomy" and "tracheostomy." 39 relevant dissertations were included in the analysis as well.

<u>Results:</u> 109 publications were included. Of the 25 056 tracheotomies described, there were 16 827 PDTs and 7934 0STs; for 295 tracheotomies, the technique used was not stated. 352 deaths were reported, including 113 in patients treated with PDT, 49 in those treated with OST, and 190 deaths related to a tracheotomy without specification of the method used. The frequency of death among patients with OST and those treated with PDT was similar: 0.62% for OST (95% confidence interval [0.47; 0.82]) and 0.67% for PDT ([0.56; 0.81]). The most common causes of death and their frequencies, as a percentage of all tracheotomies, were hemorrhage (OST: 0.26% [0.17; 0.40], PDT: 0.26% [0.19; 0.35]), loss of airway (OST: 0.21% [0.13; 0.34], PDT: 0.20% [0.14; 0.28]), and false passage (OST: 0.11% [0.06; 0.22], PDT: 0.20% [KI 0.15; 0.29]).

<u>Conclusion</u>: Bias in the data cannot be excluded, as these were not epidemiologic data and the documentation was found to be incomplete. The likelihood of a fatal complication seems to be the same with both tracheotomy techniques as far as can be determined from the available evidence. Tracheotomy-related deaths can be avoided in several ways: by thorough training under the leadership of experienced physicians, by the use of the World Health Organization's Surgical Safety Checklist regardless of where the tracheotomy is performed, and by the continuous vigilance of nursing staff.

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Department of Anesthesiology and Intensive Care Medicine, Emergency Medicine and Pain Therapy, Muncipial Hospital Dresden, Academic Teaching Hospital of the Technical University of Dresden: Dr. med. Nowak **T** racheotomies are among the most commonly performed procedures in mechanically ventilated intensive care patients; the two methods used are percutaneous dilatational tracheostomy (PDT) and open surgical tracheostomy (OST) (1). Every year, tracheotomy results in death or permanent disability of an estimated 500 patients in the United States alone (2). The aim of our review was to provide a literature analysis of the causes and incidence rates of tracheotomy-related deaths for both OST and PDT. We intended to study the more common complications of hemorrhage, false passage, and airway loss and to develop recommendations on how to prevent these events.

#### Methods

## Search strategy and case selection

Over a period of 5 years, a systematic analysis of the literature published between 1 January 1990 and 31 December 2015 was performed in the databases PubMed, EMBASE, Cochrane Library, and Karlsruhe Virtual Catalog (KVK), using the keywords "tracheotomy" and "tracheostomy." This review was conducted in accordance with the PRISMA guidelines (Preferred Reporting Items for Systematic Reviews and Meta-Analyses, www.pris ma-statement.org). The primary literature from meta-analyses and reviews as well as 39 German dissertations were also included in the analysis. Original articles published in French, Spanish, Italian, Dutch, or Russian, which were discovered by English-language summaries, were translated and included. Pediatric patients were excluded from the analysis. Independent plausibility checks were performed on each death from the perspectives of otorhinolaryngology (ENT) and anesthesiology/intensive care medicine (eFigure 1).

Information about age, sex, primary disease, indication for tracheotomy, tracheotomy technique (OST, PDT) and site of performance (intensive care unit, operating room, regular ward), time (perioperative [day of surgery] or postoperative [first postoperative day and following days]), complications, and causes of death was recorded, where available. Free-text descriptions of the deaths were collected. Forty cases with unclear causes of death from 19 publications were excluded (e1–e21) (*eFigure 1, eBox 1*).

#### TABLE 1

Overview of 363 complications among 352 tracheotomy-related deaths

	PI	ТС	0	ST	Method no	ot specified
		%			n	%
Hemorrhage Intraoperative (n = 10) Postoperative (n = 55)	9 35	7.4 29.1	1 20	1.9 37.0	0 0	0 0
Pneumothorax (n = 20)	15	12.4	5	9.3	0	0
Severe injury to posterior tracheal wall and tracheoesophageal fistula (n = 13)	9	7.4	3	5.5	1	0.5
Loss of airway Intraoperative (n = 14) Postoperative (n = 43)	11 22	9.0 18.1	3 14	5.5 26.0	0 7	3.7
Bronchospasm Intraoperative (n = 4)	4	3.3	0	0	0	0
Acute heart failure Intraoperative (n = 14)	8	6.6	3	5.5	3	1.6
Mediastinitis (n = 7)	7	5.8	0	0	0	0
Complications n.s. Complications total*	1 121	0.8 100	5 54	9.3 100	179 190	94.2 100
Total deaths	113		49		190	

n.s., not specified; OST, open surgical tracheostomy; PDT, percutaneous dilatational tracheostomy

\* 12 multiple fatal complications included

#### Data analysis

Descriptive analyses were performed using Microsoft Excel 2013. The results are reported as absolute values and percentages. All confidence intervals (CI) are stated at the 95% confidence level.

#### **Results**

Our search strategy identified 109 publications (eTable 1) (e22-e119). We found 71 different freetext descriptions of tracheotomy-related deaths (eTable 2) (e22-e119) in 40 case studies (37%), 35 case reports (32%), 12 dissertations (11%), 12 case-control studies (11%), 6 randomized controlled trials (RCTs) (5%), 3 structured questionnaires (3%), and 1 review with additional own cases (1%). In 12 of 39 dissertations with a total of 4765 OSTs and 4437 PDTs, 13 patients died. The 109 publications comprised 25 056 tracheotomies, including 16 827 PDTs, 7934 OSTs, and 295 tracheotomies without information about the technique used. Altogether, 352 tracheotomy-related deaths were documented in 21 countries, thereof 113 along with PDT, 49 along with OST, and 190 without information about the technique used (Tables 1 and 2, eFigures 1 and 2).

#### Hemorrhages

Altogether, 65 fatal hemorrhages were reported (*Table 3*), thereof 38 (58.5%) brachiocephalic trunk hemorrhages where death occurred in 3 cases during the perioperative period (e15, e66, e98) and in 28 cases between day 1 and day 117 (e64), with a mean of 24

days. In 7 cases, no information about the time of death was provided (*eBox 2*).

#### False passage-related complications

In 32 patients, 44 serious complications resulted from false passage, thereof 35 along with PDTs and 9 along with OSTs (*Table 4, eBox 2*).

#### Loss of airway

Twenty-seven authors reported loss of airway of mixed etiology as cause of death; 33 cases during or after PDT and 17 during or after OST. In 7 cases, no information about the tracheotomy technique and the pathomechanisms was provided (*Table 5, eBox 2*).

#### Discussion

#### Tracheotomy-related deaths

Worldwide, tracheotomies are commonly performed procedures. In Germany, a total of 37 793 temporary tracheostomies and 16 733 permanent tracheostomies were performed in 2015 (e120).

PDT has been promoted as a quick and easy procedure in numerous publications, but warnings have also been issued (3). Tracheotomy-related deaths are described as rare events of diverse etiology (4–8, e101). Das et al. (2) reported results of a US-survey identifying an estimated 1000 serious incidents and events annually related to tracheotomies and 500 incidents resulting in death or permanent disability. It is challenging to identify special types of deaths in the literature because the search term "death" is almost

#### TABLE 2

References regarding tracheotomy-related deaths associated with open surgical tracheostomy (OST) vs. percutaneous dilatational tracheostomy (PDT)

First author/comment	OST	PDT
Dulguerov 1999 (18) Meta-analysis OST versus PDT 1986–1996	17/10 000	55/10 000
Kearny 2000 (e72) Single center retrospective review PDT 1990–1998	n.s.	0.6%
Oliver 2007 (17) Meta-analysis OST versus PDT (1999–2006)	0.16%(1/628)	0.58%(3/522)
Kost 2005, 2008 (5, 6) Evaluation PDT versus OST 1988–2003	0–2%	0–0.5%
Mallick 2010 (20) Review tracheostomy in critically ill patients 1981–2008 (studies have demonstrated a procedural mortality rate approaching zero)	n.s.	n.a.
Dennis 2013 (e38) Single center retrospective review PDT 2001–2011	n.s.	0.16%
Simon 2013 (e101) Review PDT 1985–2013	n.s.	0.17%
Brass 2016 (8) Review PDT versus OST 1990–2011 (no evidence of a reduction in mortality with the use of a percutaneous technique)	n.s.	n.s.
Results of our review 1990–2015		
Total	0.62% Cl: [0.47; 0,82]	0.67% Cl: [0,56; 0,81]
Deaths due to false passage	0.11% Cl: [0.06; 0.22]	0.20% CI: [0.15; 0.29]
Deaths due to loss of airway	0.21% Cl: [0.13; 0.34]	0.20% CI: [0.14; 0.28]
Deaths due to hemorrhage	0.26% Cl: [0.17; 0.40]	0.26% Cl: [0.19; 0.35]

CI, confidence interval; n.s., not specified

always related to the outcome of studies. After analysis of data from a US database of more than 113 653 tracheotomies, Shah et al. concluded in 2012 that it is impossible to determine from these data whether the mortality is due to tracheotomy complications (9).

We started our analysis of fatal complications in 1990 because from that time PDT, as described by Ciaglia (10), has gained worldwide acceptance. The analysis of 71 free-text descriptions identified 4 key areas (*eTable 2*):

- Procedure-related deaths
- Complication-related deaths
- Deaths related to tracheal cannulas
- The term death as a neutral statement.

Therefore, we suggest to use the term "tracheotomy-related death," in keeping with van Heuern et al. (e60) and Shah et al. (9). With this neutral term, all causes are covered.

#### Perioperative hemorrhage

Tracheal hemorrhage can be life-threatening, even if the actual blood loss is low. With flexible bronchoscopy, even small amounts of blood can significantly reduce visibility in the surgical field. In addition, the suction capacity of flexible endoscopes is lower than that of rigid endoscopes. This concerns the amount of blood and the time factor and is of vital importance especially in patients with respiratory failure. Due to the dead space in the airways, intratracheal hemorrhage of 150-200 mL results in hypoxia, long before circulation is affected. Taking this into consideration, the discussion in the literature about "major bleeding" or "minor bleeding," with various amounts suggested to define clinically relevant hemorrhages, appears pointless, as demonstrated by the following 4 examples: 50 mL (e115), more than 100 mL (e10), more than 5 ccm (11), "major bleeding: surgical intervention or transfusion" (12). Apart from bleeding associated with tracheo-innominate fistula (TIF), not the defined amount of blood lost is important, but the question to where the blood flows. While relevant external bleeding requires primary revision surgery, internal bleeding should trigger the algorithm to immediately secure the airway. Here, monitoring gas exchange is critical and determines the time window for the steps to be taken. Tracheotomy-related deaths

#### TABLE 3

#### Fatal hemorrhage

Fatal hemorrhages (n = 65)	PI	PDT		OST		n.s.	
		%		%	n		
Intraoperative (n = 10)	9	20.5	1*	4.8	0	)	
Postoperative (n = 55)	35	79.5	20	95.2	0	)	
<b>Total</b> (n = 65)	44	100	21	100	0	)	
Anatomical variations as a contributing factor (n = 9)	7		2		0	)	
Fatal brachiocephalic trunk hemorrhages							
Intra-/perioperative (n = 3)	2	8	1*	7.7	0	)	
Postoperative (n = 35)	23	92	12	92.3	0	)	
Total (n = 38)	25	100	13	100	0	)	

n.s., not specified; OST, open surgical tracheostomy; PDT, percutaneous dilatational tracheostomy \* identical case

> reported in the literature remind us of the importance of these considerations which should, of course, go without saying. Likewise, changing from flexible endoscopy to rigid endoscopy is part of the emergency treatment, if indicated.

> Intraoperative hemorrhages resulting in death (*Table 3*) occur typically with PDT, including cases of false passage with fatal bleeding. Ayoub et al. (e23) described deaths resulting from variations in vascular anatomy and highlighted the need to constantly be aware of this possibility. This is underscored by 9 cases with fatal outcome reported in the literature. Preoperative ultrasonography of the neck with visualization of the large blood vessels, the thyroid and the course of the trachea as part of a preoperative checklist is recommended (13).

#### Postoperative hemorrhage

Postoperative hemorrhages after tracheotomies can be life-threatening, as the neck region is rich in blood vessels. Halum et al. (e58) analyzed postoperative hemorrhages, the most common complication, up to the first week after tracheotomy. Later bleeding events may disappear from the sight of intensivists and shift via the path of rehabilitation facilities to the nursing domain. In our review, higher rates of postoperative hemorrhages occurred with OST compared to PDT, in terms of the total number of fatal complications with each technique—PDT versus OST (*Table 1*). Kearny et al. (e72) found postoperative hemorrhage to be the most common complication with 2.2%.

## Brachiocephalic trunk hemorrhage—tracheo-innominate fistula

Performing tracheotomies below the level of the 4<sup>th</sup> tracheal ring is dangerous because of the vascular anatomy in this area. Thus, it is critical to accurately

establish the patient's external and internal anatomy by means of preoperative examination, ultrasonography and endoscopy of the trachea. Tracheoinnominate fistula (TIF) has been regarded as a rare, but often fatal complication for many years (e34). In case of severe hemorrhage, rigid tracheobronchoscopy is the method of choice, as it offers better visibility and significantly greater suction capacity for blood in a short period of time (e121). In addition, endotracheal intubation with targeted tamponade of the bleeding source with the tube's cuff can be performed at any time via a rigid endoscope (7) (*Table 3*).

#### False passage

A false passage may have fatal consequences, regardless of the type of tracheotomy. Tracheotomies below the level of the 4<sup>th</sup> tracheal ring may be fatal. In 13 cases, it caused a TIF with fatal hemorrhage. These bleeding events occurred more frequently with PDT, performed with and without flexible endoscopy, indicating that PDT with endoscopy does not provide adequate orientation. Furthermore, 10 fatal cases of pneumothorax and 5 cases of tracheoesophageal fistula (TEF) occurred with PDT with and without flexible endoscopy. Not every false passage leads to a fatal outcome. Van Heuern et al. (e60) reported that primarily false passage is to be expected in 0.5 to 2% of cases treated with PDT. Marx et al. (e84) reported false passages in 1.2% and Kearny et al. (e72) in 0.7% of cases treated with endoscopically controlled PDT. According to our analysis of complications, false passage-related fatal outcomes are to be expected in 0.20% of cases with PDT and in 0.11% of cases with OST. Even though these incidences may appear low, they represent 25 deaths which could have been prevented, as demonstrated by the retrospective analysis. After OST, 7 patients had false passage-related fatal outcomes. With intensive care medicine being such a sensitive field, there appears to be even more reason to categorize PDT as a high-risk procedure (e100). The term high risk describes best the nature of complications that occasionally occur. The same applies to OST. The analysis of the cases of tracheotomyrelated deaths clearly shows that tracheotomy is not a procedure to be performed by beginners. Intensive training in anatomy and the techniques of PDT and OST under the guidance of experienced ENT specialists, surgeons and intensivists is vital, given the 32 deaths identified in our review (Table 4). With flexible endoscopy not always providing the best possible orientation, rigid endoscopy with mechanical ventilation via the endoscope was introduced as an alternative PDT technique to prevent serious complications (14).

#### Loss of airway

Loss of airway (*Table 5*) is a widely feared adverse event; it can occur in 5 situations:

- With PDT, the standard maneuver of withdrawing the endotracheal tube (ETT) to the level of the glottis may lead to dislocation of the tube into the hypopharynx. This type of loss of airway is a specific problem of PDT, with and without flexible endoscopy (15, e100). To secure the airway, rigid endoscopy was suggested as an alternative PDT technique (14, e41).
- The intraoperative creation of a false passage during PDT was described as early as 1992 (e113).
- Postoperative dislocation of the tracheal cannula after PDT with failed reinsertion is caused by the curtain phenomenon. During cannula change, the thyroid, muscular or adipose tissue may shift and cover the tracheostomy, impeding re-insertion of the cannula. In case of difficult airway, it may be impossible to quickly reintubate the patient. Higher accidental decannulation rates after PDT were reported compared with OST (16). However, similar courses with fatal outcome occurred with OST as well (e11, e20, e50, e74, e103). A stoma without securing suture to the trachea has the same potential risks as a stoma created by PDT, due to the curtain phenomenon (e74).
- Tracheal cannula obstruction by blood clot or mucus plug do occur, regardless of the method used (e38, e43, e45, e92, e106, e116).
- Accidental decannulation may lead to fatal outcomes (e50, e112, e115).

#### Incidence of tracheotomy-related deaths

The exact reasons for the differences between the incidences of tracheotomy-related deaths reported by various authors are unknown; possible factors include differences in scope as well as small patient samples (17) and reference to procedures performed many years ago when other surgical techniques were used (18) (Table 5). Compared with other papers, our review is based on the largest number of deaths and the largest number of tracheotomies performed. Consequently, it is difficult to precisely state the incidence of tracheotomy-related deaths. In our analysis presented here, the death rate is 1.4% (352 deaths on 25 056 tracheotomies). However, it is very likely that this rate may be over- or underestimated; thus, it should not be considered as being representative of the true rate. Death statistics report similar rates for PDT and OST; however, one limitation is that for 190 deaths no information on the technique used for tracheotomy was available, besides the lack of epidemiological data. Our review did not confirm the reported finding of higher operative mortality with OST compared to PDT (3% versus 0%) (19). This finding was flawed because for PDT references from the current literature were selected, while for OST references from the literature published between 1969 and 1981 were used which do not reflect

#### False passage-related fatal complications

False passage (n = 32) and its consequences (n = 44) $^{*1}$	PDT		OST		n.s.	
and its consequences (n = 44)".		%* <sup>2</sup>		(%)* <sup>2</sup>		(%)
Intraoperative bleeding (n = 6)	5	11.3	1	2.3	(	)
Postoperative bleeding (n = 17)	12	27.3	5	11.3	(	)
Pneumothorax (n = 12)	10	22.7	2	4.6	(	)
Tracheoesophageal fistula (TEF) (n = 6)	5	11.3	1	2.3	(	)
Loss of airway (n = 3)	3	6.8		0	(	)

n.s., not specified; OST, open surgical tracheostomy; PDT, percutaneous dilatational tracheostomy; \*<sup>1</sup> multiple complications included

\*2 related to 44 events

#### TABLE 5

#### Loss of airway with fatal outcome

Loss of	PI	PDT		OST		.S.
airway (n = 57)						%
Intraoperative (n = 14)	11	33.3	3	17.6	0	0
Postoperative (n = 43)	22	66.7	14	82.4	7	100

n.s., not specified; OST, open surgical tracheostomy;

PDT, percutaneous dilatational tracheostomy

today's OST techniques and generally improved safety standards. Likewise, the assumption that the majority of meta-analyses demonstrate reduced procedure-related mortality for PDT (20) is not tenable, as it conveys a false sense of security for PDT. The mortality rates we found for PDT (0.67%; 95% CI [0.56; 0.81]) und OST (0.62% [0.47; 0.82]) are based on the total number of 16 827 PDTs and 7934 OSTs. From the perspective of medical law, it should be noted that, according to the currently available data, the risk of tracheotomy-related death appears to be the same for both techniques as they are practiced today.

#### Limitations

Our review found numerous documentation shortcomings. We identified 190 tracheotomy-related deaths where no information about the method of tracheotomy used had been recorded. Time-of-death data were missing in 196 cases, while information about the place of tracheotomy and the place of death (intensive care unit, operating room, regular ward) was not available in 242 cases. Gender data were missing in 136 cases, while in 216 cases information about gender was reported (125 men, 91 women). The primary disease was documented in 203 deaths, but was missing in 149 deaths. In 40 cases, autopsy results were reported as part of quality assurance protocols and in 7 cases autopsy was refused. In 305 deaths, no information about whether an autopsy had been performed was available. The true number of tracheotomy-related deaths is difficult to determine. It is reasonable to assume that some fatal outcomes remain unreported. Publication bias is obviously an issue as not every death is published in the literature. Numerous tracheotomy-related studies, addressing a broad range of questions, have been conducted, but complications were not documented; thus, a number of deaths may remain unrecognized. Additional unreported cases may occur when in studies tracheotomy-related deaths are included under "deaths and survivals" without further comment. Brass et al. (8) confirmed that numerous studies are flawed by shortcomings and inaccuracies, resulting in a low level of evidence for certain aspects of tracheotomy-related mortality.

#### Conclusion

From the perspective of medical law, it should be noted that, according to the currently available data, the risk of tracheotomy-related death appears to be the same for both techniques as they are practiced today. Performing tracheotomies below the level of the 4<sup>th</sup> tracheal ring is dangerous due to the vascular anatomy in this area. It is recommended to use rigid tracheobronchoscopy in cases of severe hemorrhage because of the good visibility and high suction capacity for blood offered by this method. Rigid endoscopy should be available whenever surgical procedures involving the trachea, including PDT, are performed. Tracheotomies should not be performed by inexperienced surgeons. Extensive knowledge of the anatomy and the techniques of PDT and OST is crucial, as is training by experienced ENT surgeons, general surgeons, and

## **KEY MESSAGES**

- The incidence of tracheotomy-related deaths is similar for percutaneous dilatational tracheostomy and open surgical tracheostomy.
- Hemorrhage, loss of airway, and false passage are the most common causes of tracheotomy-related deaths.
- For the future, more extensive and complete documentation of tracheotomy-related deaths is desirable to enable better quality management.
- The prevention and control of complications leading to tracheotomy-related deaths should be taken into consideration when tracheal procedures are planned and aftercare is provided—encouraged is, for example, the systematic use of a checklist, such as the WHO's Surgical Safety Checklist.

intensivists. To improve tracheotomy quality management and care and to prevent fatal complications, tracheotomy-related deaths should be given more attention in the future, e.g. by publishing case reports (21). Given the successful reduction of perioperative mortality and positive experiences with interdisciplinary communication prior to surgical procedure, it appears advisable to recommend the use the WHO's Surgical Safety Checklist for tracheotomies as well, regardless of the place where they are performed (13).

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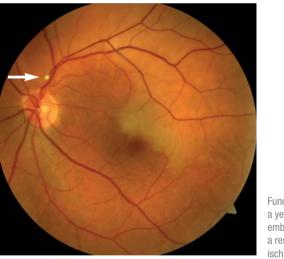
Supplementary material For eReferences please refer to: www.aerzteblatt-international.de/ref1617

eFigures, eBoxes, and eTables: www.aerzteblatt-international.de/17m0273

## **CLINICAL SNAPSHOT**

## Sudden Visual Shadow in a 70-Year-Old Man

A 70-year-old man complained of shadow vision in one eye since the morning. He was concerned about a possible retinal detachment. Fundoscopy revealed occlusion of the superior temporal artery by a cholesterol embolus and resulting ischemic edema of the affected areas of the retina. The main causes of retinal artery occlusion are atherosclerosisassociated thrombosis, embolism from the carotid circulation, giant-cell arteritis, and embolism from the heart. After evaluation for risk factors, this patient was given rheologic treatment. The source of his embolism was identified as atherosclerotic plaques in the internal carotid artery.



Fundoscopy reveals a yellow cholesterol embolus (arrow) and a resulting area of ischemia

A vascular surgical intervention was not indicated. He was treated over the long term with ASA 100 mg/day. The sudden appearance of a shadow in the visual field is always an indication for an emergency ophthalmologic examination.

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#### **Conflict of interest statement**

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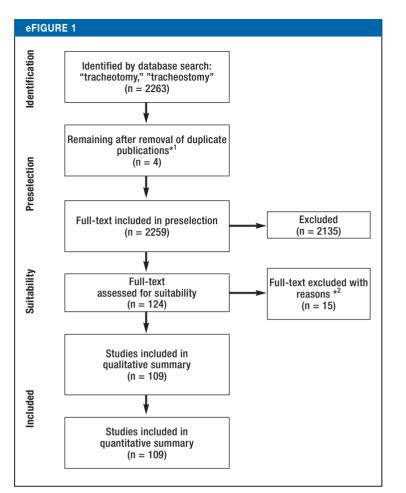
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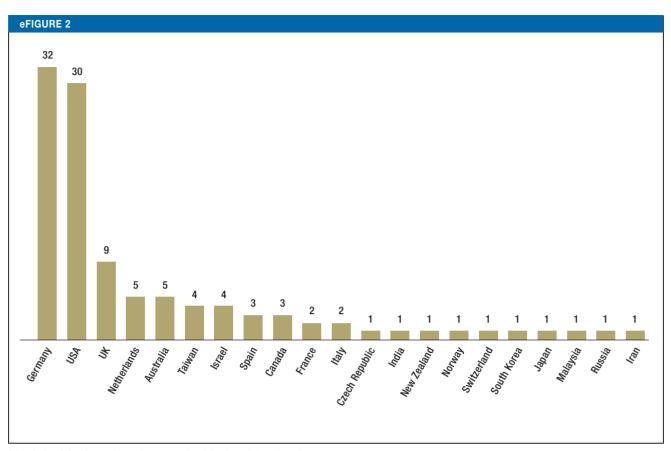
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#### **Flowchart of publication selection**

- OST, open surgical tracheostomy; PDT, percutaneous dilatational tracheostomy
- \*<sup>1</sup> 4 duplicate publications with 11 deaths
- \*<sup>2</sup> 8 publications with 10 deaths: PDT-related death not clear
- 2 publications with 3 deaths: OST-related death not clear
- 4 dissertations with 7 deaths: Tracheotomy-related death not clear
- 1 publication with 9 deaths: Not differentiated between brain damage and tracheotomy-related death



Included publications with tracheotomy-related deaths, origin and number

## eBOX 1

## Supplementary information: Methods

Forty individual deaths were excluded from 15 publications and 4 duplicate publications for the following reasons (*eFigure 1*) (e1–e21):

- The connection between death and tracheotomy was not clear in 8 publications on percutaneous dilatational tracheostomy (PDT) with 10 deaths (e1–e9) and 2 publications on open surgical tracheostomy (OST) with 3 deaths (e10, e11), as well as in 3 dissertations on PDT with 4 deaths (e12–e14) and 1 dissertation on OST with 3 deaths (e15).
- Four duplicate publications were excluded with 3 PDTrelated deaths (e3 and e17, e16 and e18) and 8 tracheotomy-related deaths where the surgical method was not specified (e19, e20).
- The borderline between severe irreversible brain damage and death was not clearly recognizable in 9 cases (e21).

## eBOX 2

## Supplementary information: Results

#### • Hemorrhage

During percutaneous dilatational tracheostomy (PDT), fatal intraoperative hemorrhages occurred in 9 cases (e25, e59–e61, e71, e88, e93, e97, e98). With open surgical tracheostomy (OST), one fatal intraoperative hemorrhage caused by false passage with incorrectly low tracheotomy above the 6th tracheal ring and immediate fatal brachiocephalic trunk hemorrhage was reported (e15). Postoperatively, arterial hemorrhages occurred in 50 cases and venous hemorrhages in 5 cases; in 10 cases, no information was provided. In 17 cases, postoperative hemorrhages occurred because the tracheotomies were performed too low. Anatomical variants as cofactors in fatal hemorrhages were reported in 9 cases, of these in 2 cases with OST (e41, e104) and 7 cases with PDT (e48, e63, e88, e93, e98, e112, e117). These variants comprised 3 high brachiocephalic trunks (e41, e63, e112), 1 atypical course of the subclavian artery (e98), 1 thyroid ima artery (e104), 1 variant of a large vein (e48), 1 altered anatomical situation after thyroid surgery for goiter (e93), 1 significant tracheal displacement due to pulmonary fibrosis (e88), and 1 cervical rib with aneurysm of brachiocephalic trunk (e117). In addition, the following rare sources of bleeding were described: combination of arterial and venous hemorrhage from the jugular vein and the brachiocephalic trunk, lying on top of each other (e63), common carotid artery (e72), thyroid ima artery (e104), jugular vein (e15, e48, e63), and tracheal stent treatment after tracheotomy with late bleeding complication caused by tracheo-innominate fistula (TIF) (e55). In one case, TIF was promoted by sepsis (e77) (Table 3).

#### False passage-related complications

False passage was the cause of 6 intraoperative hemorrhages, 5 occurred along with PDT (e25, e41, e61, e88, e93) and one with OST (e15); severe false passage–related postoperative hemorrhages occurred in 17 cases. In 13 of these cases, tracheotomy was performed too low, between the 4<sup>th</sup> and 12<sup>th</sup> tracheal ring, resulting in TIF with fatal bleeding. Pneumothorax was reported in 10 cases with PDT (e28, e30, e34, e44, e57, e65, e70, e88, e93) and 2 cases with OST (e47, e89). Severe multiple injuries related to false passage were described in 12 cases with PDT (e30, e44, e71, e72, e88, e117) and in one case with OST (e47). In 5 cases, false passage primarily caused a tracheoesophageal fistula (TEF) (e30, e42, e57, e68, e72); in 3 of these cases the complication occurred despite the use of flexible endoscopy (e30, e57, e68) and in one case TEF occurred with OST (e47) (*Table 4*).

#### Loss of airway

Loss of airway during or after tracheotomies was reported as cause of death in 57 cases, in 33 of these cases during or after PDT and in 17 cases during or after OST. In 7 cases, no information about the tracheotomy technique and the pathomechanisms was provided. PDT was performed with flexible endoscopy in 5 cases and without flexible endoscopy in 6 cases. Flexible endoscopy did not prevent dislocation of the endotracheal tube *(Table 5)* (e10–e12, e19, e27, e28, e33, e35, e38, e43–e45, e49, e52, e72, e74, e84, e86, e92, e100, e103, e106, e108, e112, e113, e115, e116). Failed re-intubation was reported as the cause of death in 11 patients (e10, e12, e35, e38, e52, e100, e106, e108). Four deaths with additional neck and laryngeal emphysema, infection-related neck swelling, or extreme obesity were reported (e 50, e112, e115). Two deaths were related to cannula dislocation, resulting from inadequate sedation (e44). Loss of airway due to cannula dislocation after PDT was reported in one patient with trisomy 21 (e33) *(Table 5)*.

## eTABLE 1

## Publications with tracheotomy-related deaths

		Number of OSTs <sup>*1</sup>	Number of PDTs <sup>*2</sup>	Number of tracheotomies with method not specified (n.s.)	Deaths
Allen (e22)	1992		100		1* <sup>2</sup>
Aust (e17) Knipping (e18)	2007 2016		(2) 58		(2* <sup>2</sup> ) 2* <sup>2</sup>
Ayoub (e23)	2007		1		1* <sup>2</sup>
Barba (e24)	1995	21	27		1* <sup>2</sup>
Barranco (e25)	2016		1		1* <sup>2</sup>
Bauer (e26)	2006	2			2* <sup>1</sup>
Bause (e27)	1999		1		1* <sup>2</sup>
Berrouschot (e28)	1997		76		2* <sup>2</sup>
Brendel (e29)	2005		130		1* <sup>2</sup>
Büsch (e30)	2006	63	290		1* <sup>2</sup>
Byhahn (e31)	2005		474		2* <sup>2</sup>
Chiu (e32)	2005		107		1* <sup>2</sup>
Cobean (e33)	1996		65		1* <sup>2</sup>
Cokis (e34)	2000		1		1* <sup>2</sup>
Cole (e35)	1994	25	55		1* <sup>2</sup>
Cordes (e36)	2015	151			1* <sup>1</sup>
Das (2)	2012			177	177
Dempsey (e37)	2010		572		2* <sup>2</sup>
Dennis (e38)	2013		3162		5* <sup>2</sup>
Dost (e39)	1999		2		2* <sup>2</sup>
Drage (e40)	2002		1		1* <sup>2</sup>
Klemm (e41)	2008	1	1		1* <sup>1</sup> 1* <sup>2</sup>
Douglas (e42)	1999		1		1* <sup>2</sup>
El Solh (e43)	2007	427	· ·		4* <sup>1</sup>
Escarment (e44)	2000		162		2* <sup>2</sup>
Fikkers (e45)	2004		342		1* <sup>2</sup>
Fikkers (e46)	2003	1	3		1* <sup>1</sup> 3* <sup>2</sup>
Franz (e47)	1990	25	5		1* <sup>1</sup>
Freeman (e48)	2001	40	40		1* <sup>1</sup>
Friedman (e49)	1993	UT UT	100		1*2
Friedman (e50)	1996	27	26		3*1
Geng (e51)	1990	390	20		2* <sup>1</sup>
Gilbey (e52)	2012	370	1		1* <sup>2</sup>
Goldenberg (e19) Goldenberg (e20)	2000/ 2002	1130			8* <sup>1</sup> (8* <sup>1</sup> )
-		(1130)	2		(8 <sup>-7</sup> )
Grant (e53)	2006	74	3		3** 1* <sup>1</sup>
Griggs (e54)	1991	74	153		1^1
Grundmann (e55)	1999	1			1*1 1*1
Gupta (e56)	2014	1			•
Hamilton (e57)	2007		1		1*2
Halum (e58) Hazard (e59)	2012 1991	972 24	203 22		7 1* <sup>1</sup> 1* <sup>2</sup>

First author (reference)	Year	Number of OSTs <sup>*1</sup>	Number of PDTs <sup>*2</sup>	Number of tracheotomies with method not specified (n.s.)	Deaths
van Heuern (e60)	1996		147		1* <sup>2</sup>
Heyse (e61)	1999		209		1* <sup>2</sup>
Hill (e3) Toursarkissian (e16)	1996 1994		215 (141)		1* <sup>2</sup> (1* <sup>2</sup> )
Herzhoff (e62)	2005	303			1* <sup>1</sup>
Hoiting (e63)	2010		2		2* <sup>2</sup>
Hung (e64)	2007	1			1* <sup>1</sup>
Hutchinson (e65)	1991		1		1* <sup>2</sup>
Hürter (e66)	2000		1		1* <sup>2</sup>
Ivatury (e67)	1992		61		1*2
Joosten (e68)	1996		53		1* <sup>2</sup>
Kapadia (e11)	2000	79			1* <sup>1</sup>
Kapural (e69)	1999	1			1* <sup>1</sup>
Klein (e70)	2007		207		1* <sup>2</sup>
Klemm (e71)	1998		1		1* <sup>2</sup>
Kearny (e72)	2000		827		5* <sup>2</sup>
Krusche (e73)	1992	200			3*1
Lee (e74)	2015	205			3* <sup>1</sup>
Letzsch (e75)	2006	50	1		1* <sup>2</sup>
Lim (e76)	2000	50	261		2* <sup>2</sup>
Lu (e77)	2005		1		2* <sup>2</sup>
Lubnin (e78)	2015	100	2		2** 1* <sup>1</sup> 1* <sup>2</sup>
Lukas (e79)	2003	408	87		1*2
Maeda (e80)	2002		1		1*2
Malthaner (e81)	1998				1* <sup>2</sup>
Marelli (e82) Martinez (e83)	1990 2009		61	118	1
	1996		254	110	1* <sup>2</sup>
Marx (e84) Mäser (e85)	2004		200		1*2
Massick (e86)	2004	114	50		1*2
Muhl (e87)	1995	117	14		1* <sup>2</sup>
McCormick (e88)	2005		1187		3*2
McGuire (e89)	2003	1			1* <sup>1</sup>
Mourelo (e90)	2015	7	13		1
Norwood (e91)	2000		422		1* <sup>2</sup>
Oggioni (e92)	1995		57		1* <sup>2</sup>
Páez (e93)	2005		38		2* <sup>2</sup>
Pandit (e94)	2006		501		1* <sup>2</sup>
Porter (e10)	1999	58	12		1* <sup>2</sup>
Rassekh (e95)	2015	14	8		1* <sup>1</sup>
Rosolski (e96)	2006		1		1* <sup>2</sup>
Ryan (e97)	2003		1		1* <sup>2</sup>
Schäfer (e12)	2007		100		2* <sup>2</sup>
Schubert (e15)	1993	1964			2* <sup>1</sup>
Shlugman (e98)	2003		1		1* <sup>2</sup>

First author (reference)	Year	Number of OSTs <sup>*1</sup>	Number of PDTs <sup>*2</sup>	Number of tracheotomies with method not specified (n.s.)	Deaths
Shrager (e99)	1994		400		1* <sup>2</sup>
Sollid (e100)	2008		4		4* <sup>2</sup>
Simon (e101)	2013		1873		3* <sup>2</sup>
Soubirou (e102)	2002		1		1* <sup>2</sup>
Stam (e103)	2015	1			1* <sup>1</sup>
Stein (e104)	1997	124	100		1* <sup>1</sup>
Stoeckli (e105)	1997	36	47		1* <sup>1</sup>
Suh (e106)	1999		95		2* <sup>2</sup>
Sutarski (e107)	2006	76	112		1* <sup>2</sup>
Tabaee (e108)	2005	14	29		1* <sup>2</sup>
Tan (e109)	2004		352		1* <sup>2</sup>
Tewarie (e110)	2015		265		5* <sup>2</sup>
Thompson (e111)	2001		300		1* <sup>2</sup>
Uhlig (e112)	2010		162		2* <sup>2</sup>
Wang (e113)	1992		7		1* <sup>2</sup>
Wang (e114)	2009		1		1* <sup>2</sup>
Walz (e115)	1998		337		2* <sup>2</sup>
Wease (e116)	1996	204			1* <sup>1</sup>
Zehlicke (e117)	2007		1		1* <sup>2</sup>
NCEPOD (e118)	2014	669	1530		4/1* <sup>1</sup>
Hasanloi (e119)	2014	30	30		1* <sup>1</sup>
Number of publications: 109		7934	16 827	295	49* <sup>1</sup> /113 <sup>*2</sup> 190 n.s.

n.s., not specified; OST, open surgical tracheostomy; PDT, percutaneous dilatational tracheostomy The figures in brackets represent duplicate publications with exclusion of the numbers. \*<sup>1</sup> OST \*<sup>2</sup> PDT

## eTABLE 2

ree-text descriptions of tracheotomy-related deaths (first authors)				
Description	First author (reference)			
"death related to the procedure"	Angel (15), Barba (e24), Chiu (e32), Klein (e70), Sollid (e100), Tabaee (e108)			
"mortality directly related to the procedure"	Brass (8)			
"procedure-related death"	Allen (e22), Kearny (e72)			
"lethal complication"	Ayoub (e23)			
"exitus letalis"	Bauer (e26), Geng (e51), Schubert (e15), Joosten (e68)			
"Todesfall im Zusammenhang mit Tracheotomie" [death in connection with tracheotomy]	Bause (e27), Klemm (e71)			
"patient died"	Berrouschot (e28), Drage (e40), Friedman (e50), Hazard (e59), Hung (e64), Hutchinson (e65), Kapural (e69), Lim (e76), Lu (e77), Massick (e86), Maeda (e80), Rassekh (e95), Shlugman (e98), Stoeckli (e105), Wang (e114)			
"Tod" [death]	Brendel (e29), Franz (e47), Uhlig (e112), Walz (e115)			
"woman died"	Byhahn (e31)			
"death"	Cobean (e33), Cole (e35), Cordes (e36), Dulguerov (18), El Solh (e43), Fikkers (e46), Freeman (e48), Hasanloi (e119), Kost (5), Lukas (e79), Marelli (e82), NCEPOD (e118), Pandit (e94), Stam (e103), Suh (e106), Tan (e109), Thompson (e111), Toursarkissian (e16), Wang (e114) Walz (e115), Wease (e116)			
"event death"	Das (2)			
"patients died as a result of their complications"	Dempsey (e37)			
"complications resulted in deaths"	Dennis (e38), Escarment (e44)			
"Komplikationen nicht überlebt " [did not survive complications]	Dost (e39)			
"deaths were directly attributed to the tracheotomy" and "mortality directly attributed to the tracheotomy"	Goldenberg (e19), Goldenberg (e20), Lee (e74)			
"cause of death directly related to the procedure"	Gilbey (e52)			
"death related to technique"	Griggs (e54)			
"Patient verstarb" [patient died]	Grundmann (e55), Herzhoff (e62), Hürter (e66), Krusche (e73), Letzsch (e75), Schäfer (e12), Schubert (e15), Zehlicke (e117)			
"Todesfall" <i>[fatality]</i>	Mäser (e85)			
"she died"	Hamilton (e57), Ryan (e97), Malthaner (e81)			
"one of them died"	Fikkers (e45)			
"dying from the event"	Halum (e58)			
"eingriffassoziierter Todesfall" [procedure-related death]	Heyse (e61)			
"death tracheostomy-related"	van Heuern (e60)			
"procedure-related mortality"	Hill (e3)			
"death directly related to the performance of percutaneous tracheostomy"	Ivatury (e67), McCormick (e88)			
"death at the time of accident"	Kapadia (e11)			
"Tod durch" <i>[death by],</i> "Tod wegen" <i>[death due to]</i>	Koitschev (4)			
"mortality"	Kost (5, 6)			
"death associated with the procedure"	Marx (e84)			
"procedural mortality"	Mallick (20)			
"death rate for PDT"	Norwood (e91)			

Description	First author (reference)
"decesso riscontrato in relazione alla procedura" [procedure-related death], "decessi" [death]	Oggioni (e92)
"muerte" [death]	Páez (e93)
"leading to death"	Porter (e10)
"tracheotomy-related complication and death"	Shah (9)
"intraprocedural death"	Shrager (e99)
"fatality occurring", "fatality due", "being fatal", "proved fatal", "resulted in perioperative death"	Oliver (17)
"operative mortality"	Cheng (19)
"fatal erosive hemmorhage"	Klemm (e41)
"fatal bleeding", "pitfalls of PDT"	Hoiting (e63)
"le patient est décédé" [patient deceased]	Soubirou (e102)
"fatalities due to PDT", "PDT-related fatalities"	Simon (e101)
"haemorrhage flooded both lungs"	Cokis (e34)
"treatment be withdrawn"	Douglas (e42)
"cannula-related complications in ward", "ward deaths"	Martinez (e83)
"Blutaspiration mit Todesfolge" [aspiration of blood resulting in death]	Muhl (e87)
"three fatalities"	Grant (e53)
"Reanimation eingestellt" [cardiopulmonary resuscita- tion discontinued]	Rosolski (e96)
"Blutung, die zum Tode führte" [hemorrhage led to death]	Stein (e104)
"letale Blutung" [fatal hemorrhage]	Sutarski (e107)
"death possibly attributable to the technique of tracheostomy creation"	Freeman (e48)
"perioperative death", "postoperative death"	Friedman (e49)
"complications included death"	Higgins (16)
"a fatal complication observed"	Mourelo (e90)
"resulting in cardiac arrest"	McGuire (e89)
"metastasis as major late complication"	Aust (e17)
"occurrence of tracheostomy metastases"	Knipping (e18)
"infection-related in-hospital mortality"	Tewarie (e110)
"смерть" [death]	Lubnin (e78)

PDT, percutaneous dilatational tracheostomy