A Comparison of Plastic Single-Use With Metallic Reusable Laryngoscope Blades for Out-of-Hospital Tracheal Intubation

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Study objective: The objective of this study was to compare, in the emergency out-of-hospital environment, intubation success rates during the first laryngoscopy for 2 laryngoscope blade types: a metallic reusable and a plastic single-use.

Methods: An observational before-and-after study was conducted during 2 1-year periods. Adult patients were intubated by emergency physicians, anesthesiologists, or anesthesia nurses in the out-of-hospital setting with metallic reusable (first period) or a plastic disposable (second period) Macintosh 3 or 4 laryngoscope blades. Immediately after intubation, data were collected on success rate of intubation at the first attempt, intubation difficulty score, quality of laryngeal visualization, and the need for alternative airway techniques. To compare the 2 periods of the study, Wilcoxon's test was used for quantitative variables, and the χ^2 or Fisher's exact test was used for qualitative variables.

Results: Patients intubated with a metallic blade (594/1,177; 50.5%) and with a plastic blade (583/1,177; 49.5%) were included in the study. The first-attempt intubation success rate was higher in the metallic blade group (497/594, 84%) than in the single-use group (76%); difference 7% (95% confidence interval [CI] 3% to 12%) ($P<.002$). The incidence of difficult intubation, defined by an intubation difficulty score greater than 5, was lower (6% [95% CI 4% to 8%] versus 15% [95% CI 12% to 18%]) when metallic blades were used. A good laryngeal view (Cormack and Lehane classes I and II) was more frequently observed with metallic blade use (83% [95% CI 80% to 86%] versus 67% [95% CI 64% to 70%]). Alternative airway techniques such as the use of a Gum elastic bougie or an intubating laryngeal mask airway were more frequently used in the plastic blade period (12% [95% CI 10% to 14%] versus 4% [95% CI 2% to 6%]).

Conclusion: In out-of-hospital emergency care, the use of a plastic disposable laryngoscope blade decreased the success rate of tracheal intubation at the first attempt performed by emergency care providers. [Ann Emerg Med. 2007;50:258-263.]

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INTRODUCTION

Background

Emergency tracheal intubation, particularly in the out-of-hospital setting, can be difficult and has frequently been associated with significant complications.[1-5] The laryngoscope with a classic metallic reusable blade remains the standard device for tracheal intubation.

Recently, it has been emphasized that standard sterilization techniques for laryngoscope blades do not inactivate all infectious agents. Although several cases of prion transfer

Editor's Capsule Summary

What is already known on this topic

Metallic reusable laryngoscope blades are the standard device for tracheal intubation. Concerns about infectious disease transmission between patients prompted the manufacture of plastic, single-use blades; however, their effectiveness is unknown.

What question this study addressed

This 1,177-patient French out-of-hospital study compared intubation success rates achieved with standard metallic and disposable plastic laryngoscope blades.

What this study adds to our knowledge

Operators using metallic blades exhibited higher intubation success rates, fewer incidents of difficult intubation, and fewer uses of alternative airway technologies.

How this might change clinical practice

Laryngoscope blade composition may affect the effectiveness of airway management.

between patients have been reported after blood transfusion, the major infectious risk associated with laryngoscope blades remains for conventional microorganisms because of the frequent imperfections of the sterilization process.[6-8] There is therefore a theoretical risk of interhuman infectious transmission from reused laryngoscope blades that have had contact with infected tissue.[9] To completely avoid this risk, single-use devices are strongly recommended. However, there are few clinical studies that have assessed the effectiveness of single-use laryngoscope blades, and those that do exist have not been performed in the acute care environment.[10,11] Manikin studies have suggested that single-use plastic blades are less effective than reusable metallic blades and may make tracheal intubation more difficult.[12,13] A recent, inhospital study performed in patients who required rapid sequence induction also reported an increase in intubation difficulties when plastic blades were used.[14]

Importance

In emergency department and out-of-hospital care, single use disposable plastic laryngoscope blades are now available and may be used in daily practice because of the strong suggestion that single-use devices should be used when mucosal contact occurs. However, the effectiveness of the 2 types of blade has not been compared in the emergency setting. This is the first large study of plastic laryngoscope blade use in the out-of-hospital emergency context. If the plastic blades lead to a lower intubation success rate and make intubation more difficult, any theoretical benefits of avoiding rare infectious diseases are to be negated.

Goals of This Investigation

The objective was to compare, in the emergency out-of-hospital environment, tracheal intubation success rates after the first attempt at laryngoscopy with 2 laryngoscope blade types: a reusable metallic and a plastic single-use.

We hypothesized that there would be a lower intubation success rate using a single-use plastic blade than with a metallic reusable blade.

MATERIALS AND METHODS

Study Design

A prospective, observational, before-and-after study was conducted in a single university out-of-hospital emergency medical unit (Service de Médecine d'Urgence et de Réanimation) in France during 2 periods: before (September 2003 to August 2004) and after (September 2004 to August 2005) the introduction of plastic single-use laryngoscope blades. The change to disposable blades was not undertaken specifically to conduct a research study. During the study period, the collected data were self-reported by the operators.

Setting and Selection of Participants

The Service de Médecine d'Urgence et de Réanimation, equipped with 5 mobile ICUs, covers a suburb of Paris with a population of 1.3 million and with approximately 10,000 medical emergency out-of-hospital interventions per year.

Each mobile ICU team is made up of at least 3 individuals: an ambulance driver, an anesthesia nurse, and a senior physician specializing in either emergency medicine (>90%) or anesthesiology. Nurses joining the Service de Médecine d'Urgence et de Réanimation require 4 years of operating room anesthesia experience, whereas physicians must have completed more than 90 successful tracheal intubations during a 3-year period. In this study, 50 out-of-hospital emergency care providers performed all tracheal intubations (27 senior emergency physicians, 5 senior anesthesiologists, and 18 specialist nurses). During the 2 study periods, the operators were the same.

All adult patients (18 years or older) who were intubated in the out-of-hospital setting during the 2 periods were included in the study. The study was performed according to French Ethics law (Loi Huriet), and because the study did not involve deviation from our standard clinical practice, informed consent was not required.

Interventions

Before the introduction of plastic laryngoscope blades into routine practice, the operators had 1 hour of manikin training. Airway management is standardized in our out-of-hospital unit. For patients with spontaneous cardiac activity who require intubation, rapid sequence intubation is performed if there is no evident contraindication for succinylcholine use. After facemask preoxygenation, orotracheal intubation is attempted 1 minute after bolus injection of succinylcholine (1 mg/kg). Sedation is

not administered to patients in cardiac arrest. The Sellick maneuver is routinely applied. Patients at risk of cervical spine injury are intubated with manual in-line immobilization. In case of impossible standard laryngoscopy-assisted intubation, a 2-step predefined difficult airway management algorithm is followed. In the first step, direct laryngoscopy is maintained and external laryngeal manipulation carried out while tracheal access is attempted with the use of a Gum Elastic Bougie (Eschmann tracheal tube inducer; Sims Portex, Hythe, United Kingdom). If this fails, the second step uses blind tracheal intubation with the Intubating Laryngeal Mask Airway (ILMA, Fastrach, Laryngeal Mask Company, Henley-on-Thames, United Kingdom). Failed intubation is defined as 3 successive failures at tracheal access. When facemask ventilation is impossible or severe hypoxemia occurs during the airway management process, cricothyroidotomy is carried out. All emergency physicians staffing the service receive theoretical and practical instruction on the specific techniques recommended for airway management. All ambulances were equipped with Macintosh metallic laryngoscope blades (Heine Classic+; Heine Optotechnik, Germany) during the first year and with Macintosh plastic disposable blades (Bioblad, Rüsch, Germany) during the second year of the study. Two sizes (3 and 4) were available.

Data Collection and Processing

The following data were recorded by the senior physician of the mobile ICUs on a data sheet immediately after intubation: age; sex; known or estimated weight and height; Glasgow Coma Scale score; history of ear, nose, and throat neoplasia or surgery; facial trauma; cervical immobilization; circumstances of intubation (eg, cardiac arrest, coma caused by self-poisoning, coma caused by neurologic disease, respiratory distress, trauma, shock or analgesia). For each patient, the intubation difficulty score (number of tracheal intubation attempts, number of operators who attempted intubation, alternative techniques used, glottic exposure [as defined by the Cormack and Lehane class]),[15] intensity (normal or increased) of lifting force applied during laryngoscopy, necessity for external laryngeal manipulation, and position of the vocal cords were recorded (Table 1).[16] A difficult intubation was defined by an Intubation Difficulty Scale score greater than 5. The use of the Gum elastic bougie, intubating laryngeal mask airway, or cricothyroidotomy was also recorded. All the data were then managed in an anonymized personal computer database.

Table 1. Intubation difficulty score.[16]

Parameter	Score
Number of attempts >1	N_1
Number of operators >1	N_2
Number of alternative techniques	N_3
Cormack and Lehane class 1	N_4
Lifting force required	
Normal	$N_5=0$
Increased	$N_5=1$
Laryngeal pressure	
Not applied	$N_6=0$
Applied	$N_6=1$
Vocal cord mobility	
Abduction	$N_7=0$
Adduction	$N_7=1$
IDS=sum of scores	N_1–N_7

IDS, Intubation Difficulty Scale score.

Outcome Measures

The primary outcome was the intubation success rate at first laryngoscopy. Secondary outcomes included glottic view, the incidence of difficult intubation, and the need for alternative airway techniques.

Primary Data Analysis

In a previous study performed in our unit, we showed that intubation success rate during first laryngoscopy was about 83% with metallic reusable blades.[17] We hypothesized that intubation success rate during first laryngoscopy with plastic blades would be less than 75%. With a power of 0.9 and for a type I error α of 0.05, we required 540 patients to be recruited to each group. Our unit performs 550 to 600 intubations a year. We therefore decided to compare 2 consecutive 1-year periods.

Categorical data are reported as numbers (%) and quantitative data as medians with 25th to 75th percentiles. To assess the impact of blade type on the success rate of the first attempt at intubation, patients intubated with metallic reusable blades and those intubated with plastic single-use blades were compared using univariate analysis. χ^2 Test was used to compare qualitative variables. The 95% confidence interval (CI) of the difference of proportions between groups was calculated. All statistical tests were 2 tailed, and $P<.05$ was considered significant. Data were analyzed with SAS software, version 9.1.3. (SAS Institute, Inc., Cary, NC).

RESULTS

One thousand one hundred ninety-three patients were recruited into the study. Six hundred four (50.5%) were intubated with a metallic reusable blade and 589 (49.5%) with a single-use plastic blade. Because of missing data, intubation difficulty score could not be calculated for 10 patients intubated with a metallic blade and 6 intubated with a plastic blade. The median number of intubations by operator was 12 (range 5 to 31) during the first period and 12 (range 6 to 28) during the second period. Patient characteristics in the 2 periods of the study are shown in Table 2. First-attempt intubation had a higher success rate in the metallic blade group (497/594; 84%; 95% CI 81% to 87%) than in the plastic blade group (445/583; 76%; 95% CI 73% to 80%) ($P<.002$) (Table 3). The difference in the first-attempt success rate between the groups was 7% (95% CI 3% to 12%). Glottic exposure was better with the use of metallic blades, and difficult intubation, defined by an intubation difficulty score greater than 5, was nearly 3 times more frequent when plastic blades were used (Table 3). Last, the

Table 2. Patient characteristics.

Characteristics	Metallic Blades, n=594	Plastic Blades, n=583
Sex, No. (%)		
Women	230 (39)	233 (41)
Men	364 (61)	338 (59)
Body mass index, kg/m^2, median (25th-75th percentiles)	24.7 (22–27)	24.8 (22–27)
Age, y, median (25th-75th percentiles)	59 (42–75)	55 (42–71)
Circumstances of intubation, No. (%)		
Cardiac arrest	278 (47)	231 (40)
Respiratory distress	48 (8)	57 (10)
Trauma	38 (6)	43 (7)
Coma caused by self-poisoning	81 (14)	102 (18)
Coma caused by neurologic disease	100 (17)	108 (19)
Analgesia	12 (2)	6 (1)
Shock	37 (6)	32 (5)
History of ENT disease, No. (%)	13 (2)	8 (1)
Facial trauma, No. (%)	29 (5)	34 (6)
Cervical immobilization, No. (%)	60 (10)	71 (12)
Medications used, No. (% of patients with SCA)		
Succinylcholine	308 (98)	352 (100)
Etomidate	280 (89)	301 (86)
Thiopental	22 (7)	27 (7)
Ketamine	14 (5)	24 (7)
Blades size used, No. (%)		
3	421 (71)	385 (66)
4	173 (29)	198 (34)

ENT, Ear, nose, and throat; *SCA,* spontaneous cardiac activity.

Table 3. Intubation process characteristics.

Characteristics	Metallic Blades, n=594	Plastic Blades, n=583
Cormack and Lehane class, No. (%, 95% CI)		
I	374 (63,59–67)	251 (43,39–47)
II	116 (20,17–23)	140 (24,21–27)
III	40 (7,5–9)	101 (17,14–20)
IV	64 (10,9–13)	91 (16,13–19)
Intubation success rate at first laryngoscopy, No. (%, 95% CI)	497 (84,81–87)	445 (76,73–79)
IDS, median (25th-75th percentiles)	1 (0–2)	2 (0–4)
IDS >5, No. (%, 95% CI)	35 (6,4–8)	86 (15,12–18)
Uses of GEB, No. (%, 95% CI)	22 (4,2–6)	50 (9,7–11)
Uses of ILMA, No. (%)*	1 (0.2)	17 (3)
Impossible intubations, No. (%)*	1 (0.2)	1 (0.2)

IDS, Intubation difficulty score; *GEB,* gum elastic bougie; *ILMA,* intubating laryngeal mask airway.
*95% CI not calculated.

need for alternative airway techniques in cases of difficult laryngoscopy was higher during the plastic-blade period (Table 3). There did not appear to be a learning effect after the introduction of plastic blades.

LIMITATIONS

This study has several limitations. The first and major limitation is its nonrandomized and unblinded design, with the possibility of confounding factors accounting for the observed differences. It is possible that operators were biased against the plastic blade, and this may have influenced their intubation practice or data completion. Moreover, the self-reporting data process might have biased some results. However, our medical team has not changed during the study, and our standard operating procedures were also identical during the 2 parts of the study. No improvement in intubation success rate over time was observed during the second period, suggesting that there was no learning effect with the plastic blades.

The second limitation is related to the study environment. In the out-of-hospital environment, many patients are intubated when lying on the ground,[18] which may provide a worse laryngoscopic view than in hospital emergency intubation, and our results may not be valid for inhospital practice. However, a recent study performed in the operating room has reported similar results.[14]

The third limitation is failure to comprehensively record all intubation-related complications. It may have been useful to analyze the incidence of respiratory and cardiovascular complications during use of the 2 types of blade.

We cannot demonstrate that a higher intubation success rate at the first attempt improves outcome, because we have not designed this study with survival or morbidity endpoints. We can only speculate that higher numbers of intubation attempts are associated with a higher complication rate, which has been reported elsewhere.[2]

The fourth limitation is that we have assessed only 1 type of plastic blade. Currently, there are several different single-use plastic laryngoscope blades available that may have slightly different characteristics. However, the plastic blade we used has been reported to have one of the best performances when compared with others in a manikin study.[13] Similarly, our results cannot be extrapolated to plastic straight blades. Last, we cannot totally exclude the possibility that small changes in the epidemiology of patients were a source of bias. During the second year of the study, there were more intubations carried out on patients in coma and fewer cardiorespiratory arrests.

DISCUSSION

To our knowledge, our study is the first to assess plastic laryngoscope blades in the out-of-hospital environment. We report that the intubation success rate during the first laryngoscopy is higher with metallic reusable blades.

Emergency intubation, particularly when carried out in the out-of-hospital environment, carries a high risk of pulmonary aspiration and desaturation. A recent study has confirmed that the occurrence of periods of desaturation during out-of-hospital intubation are associated with poor outcome in head-injured patients.[19] Intubation conditions may also be more difficult for patients intubated while lying on the ground.[18] Considering these factors, it is not surprising that the difficult intubation rate

is often reported as higher in out-of-hospital care than inhospital.[16] When strict sedation protocols are applied, difficult intubation rates range between 5% and 12% in out-of-hospital medicine.[20,21] Several factors associated with out-of-hospital difficult intubation have been reported, including type of sedation used, facial trauma, obesity, and a history of ear, nose, and throat disease. In this study, we have identified a new factor that might significantly influence success of the intubation process.

The main motivation for the use of disposable devices is related to the risk of disease transmission between patients. Several cases of prion transfer between patients have been reported after blood transfusion, and it is well known that laryngoscopes can become contaminated with blood during use.[8] Therefore, single-use devices are an obvious solution to the problem. However, plastic blades do not have the same physical characteristics as metallic ones. Shape, size, light sources, and stiffness are different between blade types.[13] Most of the operators involved in this study believed that stiffness of the plastic blades was less than that of metallic ones and might be the main factor influencing the quality of laryngoscopy.

There are few clinical data concerning single-use plastic laryngoscope blades. Asai et al[11] reported that one single-use plastic laryngoscope blade assessed in 100 patients was easy to use and had similar performance to a reusable metal laryngoscope blade. In contrast, other manikin studies demonstrated that some plastic single-use blades did not perform as well as metal reusable blades. A recent study reported results similar to ours. Amour et al[14] compared inhospital patients intubated with plastic or metallic blades. All the patients included in this study were intubated after rapid sequence intubation. The intubation success rate reported by Amour et al[14] during first laryngoscopy was higher with metallic blades, and complications related to the intubation process were more frequently observed in patients intubated with plastic blades. Although we have not extensively recorded intubation-related complications, we speculate that more frequent intubation attempts are associated with more frequent complications, as reported recently by Mort.[1-3] We believe that in the emergency setting, in which the patient may be hypoxemic, factors increasing the time to intubation during rapid sequence intubation should be avoided at all costs.

New disposable devices, especially airway devices, should be properly assessed before introduction into clinical practice. In particular, new disposable laryngoscope blades should be compared with metallic reusable blades before their clinical use because, as previously observed with laryngoscope blades and the Gum elastic bougie, disposable devices are not necessarily as effective as reusable ones.[22,23] New airway devices that fail to match the standard of established equipment can increase clinical risk and should be avoided. The use of unproven single-use laryngoscope blades and also other single-use airway devices must be questioned.

In Retrospect

If we had to design another comparative study between the 2 types of blade, we would perform a randomized study. We would also record in detail complications occurring during the intubation process. An excess of intubation-related complications with the use of disposable blades would reinforce the results we observed.

In summary, we report that in the absence of other changes in practice, training, or equipment, the transition to disposable laryngoscope blades in our out-of-hospital system was associated with lower first-attempt endotracheal intubation success.

The number of intubation attempts and the need for alternative airway techniques were also higher with disposable device use. Although the nonrandomized character of our study limits the power of our findings, these observations must alert practitioners to the potential hazards associated with the use of new disposable devices.

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