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Comparison of Disposable and Metallic Reusable Miller Blades for Tracheal Intubation in Children

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Abstract: Laryngoscopes are the potential cause of cross-contamination between patients. A considerable way to prevent this problem is to use of disposable laryngoscope's blades. This study was designed to evaluate laryngoscopic conditions in pediatrics with disposable and metallic Miller blades. One hundred and fifty two children scheduled for elective surgery aged 3-12 years were enrolled in this randomized, clinical trial. After induction of anesthesia, patients were randomly intubated with either disposable or metallic reusable Miller blade. During laryngoscopy and tracheal intubation, glottic view, brightness of laryngoscopic field, duration of laryngoscopy and satisfaction degree of anesthesiologists was recorded. All patients were successfully intubated. There was significant difference between disposable and metallic Miller blades with respect to brightness of laryngoscopic field. Grade I and II of laryngoscopy in metallic group was significantly different compared to disposable group (66 and 32% vs. 50 and 49%). There was no significant difference between disposable and metallic groups with respect to anesthesiologist satisfaction and duration of laryngoscopy. With respect to successful tracheal intubation of all patients in this trial and the usefulness of disposable laryngoscopes to prevent cross-contamination between patients, Topster disposable laryngoscope can be used under normal intubating conditions in pediatric patients.

Key words: Children, disposable laryngoscope, miller

INTRODUCTION

Laryngoscopes are potential sources of cross-infection (Neal *et al.*, 1995; Foweraker, 1995; Nelson *et al.*, 1985). Infectious agents which are found in the laryngoscopic devices, have the potential for devastating spread of the human immunodeficiency virus, hepatitis viruses B and C and transmissible non-conventional agents (Galinski *et al.*, 2003). With the discovery of variant Creutzfeldt-Jakob disease in tonsillar material, there has recently been an increase in the importance of laryngoscope blade as a source of cross-contamination (Goodwin *et al.*, 2006). Disinfection using moist heat is able to kill most organisms, but it may fail to kill bacterial spores. Chemical disinfectants also can be used, but microorganisms can often be detected on the laryngoscope blade after cleaning (Beamer and Cox, 1999; Ballin *et al.*, 1999; Roberts, 1973). To ensure decontamination, it is necessary to sterilize the laryngoscope in an autoclave. However, repeated sterilization in an autoclave can markedly reduce light intensity in fibrelight laryngoscopes (Bucx *et al.*, 1999; Skilton *et al.*, 1996). One report has shown that light intensity decreases by 37-100% after 200 sterilizations, meaning that some laryngoscopes become useless within a few months (Bucx *et al.*, 1999). Several surveys has shown that laryngoscopes are often not cleaned properly (Beamer and Cox, 1999; Ballin *et al.*, 1999; Roberts, 1973). One UK national survey of 237 hospitals shown that only 22% used an autoclave after each use of the laryngoscope and 18% did not use an autoclave at all. In addition, this survey reported that one third of operating theatre staff would not prepared to put a laryngoscope, which had been taken at random from a trolley in their departments and was ready for use, into their own mouth (Esler *et al.*, 1999). One 5th of the staff would not be prepared to do so even after sterilization of the blade in an autoclave. A considerable solution to prevent cross-contamination

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is to use disposable laryngoscope blades or disposable covers for laryngoscope blades. Many types of single-use blades are manufactured with different designs and materials. Disposable adult laryngoscopes have been investigated both in patients and in the laboratory with varying results but to our knowledge, there is not any survey investigating disposable laryngoscopes in pediatric patients.

Therefore, we designed this study to compare disposable and metallic Miller blades with respect to glottic view, brightness of laryngoscopic field, anesthesiologists' satisfaction and success rate of intubation in children.

MATERIALS AND METHODS

After obtaining institutional board review and parentral informed consent, 152 children, ages 3-12 years, with ASA physical status I and II in whom tracheal [illegible] were enrolled in this randomized clinical trial. Patients were not studied if they had any pathology of the neck or upper respiratory tract or were at risk of pulmonary aspiration of gastric contents, or with difficulty in mask ventilation. During preoperative evaluation, the patients were examined by an anesthesiologist for the view of the oropharynx according to Samsoon and Young (1987), modification of Mallampati score. Standard monitoring included electrocardiography, non-invasive blood pressure and pulse oxymetry (SpO_2). Before transferring the patients to the operating room, IV line was accessed using a 22 gauge catheter inserted in the surgical ward 45 min after application of EMLA cream. On the operating bed, all the patients were ventilated manually with a mask connected to the anesthesia-machine circuit system with 100% oxygen in the fresh gas flow. After pre-oxygenation, anesthesia was induced with 5 mg kg^{-1} sodium thiopental, 2 µg kg^{-1} fentanyl and muscle relaxation was induced with 0.5 mg kg^{-1} atracurium and anesthesia was maintained with a mixture of 50% N_2O and 1.5% isoflurane in oxygen. After anesthesia induction, sniffing position was applied to patients and 5 min later, the anesthesiologist performed laryngoscopy with either disposable (Topster, Taiwan) or metallic (Heine, Germany) blade, based on a computer-generated randomization scheme. A similar method was applied for laryngoscopies with the blade insertion from right and advanced posterior to the epiglottis. Laryngeal manipulation was not considered. Size of laryngoscope's blade was chosen based on anesthesiologist preferences and patients 'condition. On each laryngoscopy, the view of glottis was assessed and scored in 4 grades (Cormack and Lehane classification):

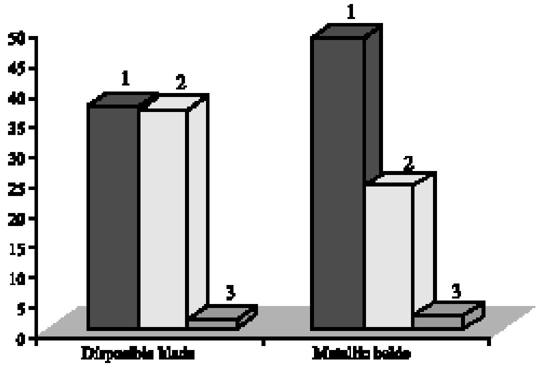

Fig. 1: Laryngoscopic view (based on Cormack and Lehane grading system): most of the glottis seen, only the posterior extremity of the glottis seen, no part of the glottis seen and neither the glottis nor epiglottis seen

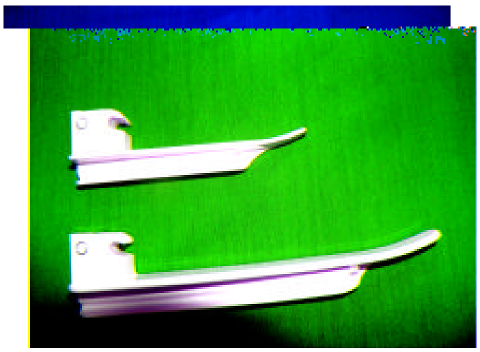

Fig. 2: Topster disposable laryngoscope

most of the glottis seen, only the posterior extremity of the glottis seen, no part of the glottis seen and neither the glottis nor epiglottis seen (Fig. 1). The brightness during laryngoscopy was also assessed using a visual analogue scale (VAS). The scale, a 10 cm line, was used for this purpose, with the word 'darkest ''on the left side of the line and 'brightest 'on the right side. Duration of tracheal intubation was described as the time from entering the laryngoscope into the oral cavity until passage of tracheal tube via the vocal cords. Self-reported anesthesiologist satisfaction was also described as favorable, acceptable and bad. Success of intubation was confirmed by capnograph and auscultation of symmetric bilateral ventilation. If arterial oxygen saturation was decreased below 85%, laryngoscopy was terminated and after enough oxygenation of patient, laryngoscopy was repeated. In addition, any problem associated with the use of the laryngoscope such as damage to the blade or loss of light during laryngoscopy was recorded (Fig. 2).

With duration of laryngoscopy and tracheal intubation as our primary outcome, we did not find any pediatric data with the Topster Miller blade. Respecting a pilot study on 84 patients using $\alpha = 0.05$ and $\beta = 0.1$, sample size of 76 patients per group was calculated ($n = 2 (1.96+0.84)^2 \times 340/25 = 75.72$).

Data were expressed as simple count or mean [±SD] and compared by analysis of variance (ANOVA), Fisher's exact test, or Chi square test where appropriate. Statistical calculations were performed using SPSS version 12.0. $p<0.05$ was considered significant.

RESULTS

There were 152 patients studied (68 male and 32% female) and no patient was excluded or lost from the study. There was no difference between groups with respect to sex, age and weight (Table 1) and Mallampati score (Table 2). All patients were intubated successfully. In no patient did any problem occur, for example, inadvertent loss of light during laryngoscopy, damage to the blade or dental injury. Glottic view of grade I and II significantly different between groups (66 and 32% with metallic blade VS 50 and 49% with disposable blade). There was no significant difference between groups with respect to duration of intubation ($p = 0.931$) (Table 1). The metallic laryngoscope produced brighter field than the disposable laryngoscope and the difference was significant ($p<0.01$) (Table 2). For user satisfaction during laryngoscopy, we did not find any significant difference between disposable and metallic blade ($p = 0.1$) (Table 3).

Table 1: Patients and clinical data

	Groups		
Characteristics	Disposable blade	Metallic blade	p-value
Sex (male/female)	55/21	53/23	0.05
Age (month)	61.52±26.77	65.35±32.56	0.05
Weight (kg)	19.09±8.92	18.42±7.79	0.05
Duration of intubation (sec)	18.81±11.26	18.97±11.06	0.05
*VAS	6.98±0.82	8.01±0.79	0.001

Data are expressed as mean±SD; * visual analogue score

Table 2: View of the oropharynx according to Samsoon and Young (1987) modification of Mallampati score

	Groups	
Mallampati score*	Disposable blade	Metallic blade
Class 1	56	52
Class 2	19	22
Class 3	1	2
Class 4	0	0

Data were expressed as number of patients; *p>0.05; Class 1: Full visibility of tonsils, uvula and soft palate; Class 2: Visibility of hard and soft palate, upper portion of tonsils and uvula; Class 3: Soft and hard palate and base of the uvula are visible; Class 4: Only hard palate visible

Table 3: Self-reported anesthesiologist satisfaction of laryngoscopy with either Topster disposable or metallic blades

Anesthesiologist satisfaction	Disposable blade	Metallic blade
Favorable	38	48
Acceptable	24	22
Bad	14	6

Data were expressed as number of patients; No significant difference exists between 2 group ($p = 0.10$)

DISCUSSION

There has recently been a large increase in the number of disposable blades on the market. Variant Creutzfeldt-Jakob disease resulting from a prion infection is the most important factor encouraging anesthesiologists to use disposable laryngoscopes (Kitamoto *et al*., 1991). Prions may be found in lymphoreticular tissue during the asymptomatic incubation period (Hill *et al*., 1999). Hirsch *et al*. (2005) showed that 30% of laryngoscope blades were contaminated with lymphocytes after intubation. Prions resist routine sterilization (Caesar and Scott, 2004) and without the use of single-use equipment or blade sheaths, there is a risk of passing prion infection from patient to patient. There has, therefore been a move to single use laryngoscope blades; not only for tonsillectomies, but also for routine use (Blunt and Burchett, 2003). Disposable blades do not have the same physical characteristics as metallic ones. Shape, size, light sources and stiffness are different between blade types. Many surveys have been performed to evaluate clinical performance of these laryngoscopes. Assai *et al*. (2001) reported that one single-use plastic laryngoscope blade (Vital View) 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 single-use blades did not perform as well as metal reusable blades (Goodwin *et al*., 2005; Evans *et al*., 2003; Anderson *et al*., 2006). Amour *et al*. (2006) compared in hospital patients intubated with disposable 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*. (2006) during first laryngoscopy was higher with metallic blades and complications related to the intubation process were more frequently observed in patients intubated with disposable blades. Jabre *et al*. (2007) conducted a similar study and showed that in out-of-hospital emergency care, the use of a disposable laryngoscope blade decreased the success rate of tracheal intubation at the first attempt performed by emergency care providers.

To our knowledge, this is the first study evaluating disposable laryngoscopes in pediatric patients. Goodwin *et al*. (2006) examined 11 disposable Miller 1 blades (pediatric size) in laboratory environment. They showed significant difference in flexibility between metal and disposable blades in 3 different axes of force. They also compared the blades' light intensity and angle of light emission, finding up to an eightfold difference in the level of illumination.

There are 2 major concerns about clinical performance of disposable laryngoscopes in children. The first one is the success rate of tracheal intubation. With regard to this point, we did not have any failure of intubation with disposable blades and all patients in both groups were successfully intubated. The second important point is the duration of laryngoscopy and tracheal intubation. This is so important especially in children because functional residual capacity is smaller in children compared to adults and children are more prone to hypoxemia during laryngoscopy for tracheal intubation, thus we should shorten the duration of laryngoscopy in children as much as possible. As we show, we did not find any significant difference between disposable and metallic laryngoscope in our study with regard to duration of laryngoscopy. Respecting these 2 important concern for clinical use of disposable laryngoscopes in children, we found no significant difference compared to metallic laryngoscope, so it was not surprising that in our study, anesthesiologists was overally satisfied with the use of disposable laryngoscopes and the little differences in favorable description of anesthesiologists satisfaction could be probably due to lesser brightness of laryngoscopic field with disposable compared to metallic laryngoscopes.

In Topster disposable laryngoscopes, light is transmitted indirectly by means of a prismatic beam to glottic area. This can reduce brightness during laryngoscopy and affect laryngoscopic quality. We had several limitations in our study. The first one was the necessity of shortening the duration of laryngoscopy in children to prevent hypoxemia, which could be a stress factor for anesthesiologist during laryngoscopy. The second and most important limitation is its unblinded design, with the possibility of confounding factors accounting for the observed differences. Moreover, the self-reporting data process might have biased some results. Our third limitation was that we have assessed only one type of disposable blade. Currently, there are several different single-use laryngoscope blades available that may have slightly different characteristics and then we cannot extrapolate our results to other Miller disposable blades. In this study, we assessed the performance of Topster disposable laryngoscope only in elective pediatric patients with normal airways and thus in difficult intubations or emergency setting; however, we feel that it is logistical to maintain conventional metallic laryngoscopes in reserve.

CONCLUSION

Our study indicates that in routine pediatric anesthesia and with experienced hands, Topster` Miller disposable blades can be regarded as equal to nondisposable metallic blades. We recommend that every new disposable laryngoscope blades should be compared with metallic reusable blades before their routine clinical use.

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