Assessing the Efficacy of a New Protector Device (Pk1) on Dental Injury Associated with Laryngoscopy in a Randomized Clinical Trial

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ABSTRACT:
Background and Objective: Endotracheal intubation is routinely performed for airway maintenance in patients undergoing general anesthesia. Yet, dental injury during laryngoscopy remains one of the concerns that may cause gross aspiration resulting in morbidity. Therefore, various methods have been used to limit this complication, including tooth protectors, modifying blades, and designing new blades. But each have their own limitations. In this study, we aimed to assess the efficacy of a new protector device (PK1) on reducing dental injury during laryngoscopy.

Methods: This randomized clinical trial included 140 patients under general anesthesia. Two groups were studied, the first group was intervention group and the second one was control group. Each group consisted of 70 patients. At first the consent form was written by the patients, then PK1 was adjusted on the faces of intervention group after the patients laid on the operation room bed. The first step was that the protected and vertical arms were released and the device was located on the face and the mouth of the patient after positioning the patient’s head in Sniff position. Then, in order to diagnose the target of the device, the protected arms were fixed and the degree of vertical arms and the height of horizontal arms were changed as well. In the intervention group laryngoscopy was done by the help of PK1 and in the control group laryngoscopy was done with the same blades (Macintosh curved blades) without PK1. Intubation was performed by an expert anesthesia assistant and every contact with upper front teeth and grading of laryngoscopy with curved blades were recorded and compared between the two groups.

Results: In the intervention group, 2/70 (2.8%) dental contacts were reported, while the rate of dental contact was 30/70 (42.8%) in the control group (P-value= 0.0011). Moreover, laryngoscopy grading increased in the intervention group (48 patients vs. 0, respectively) (P-value= 0.0011) with no occurrence of unsuccessful intubation.

Conclusion: PK1 device is a safe, inexpensive, efficient tool for reducing dental damage during laryngoscopy.

Keywords: Tooth Injuries; Laryngoscopy; Anesthesia, General; Equipment and Supplies

[Introduction]
Endotracheal intubation is the routine method for airway maintenance in patients undergoing general anesthesia. One of the complications that may occur during general anesthesia is dental injury (1): 75% of which occurs during intubation, 16% during extubation, and 9% in recovery (2).
The commonest dental injury includes crown fractures, partial dislocations, and dislodgements (3), particularly seen in upper maxillary incisors (4, 5), which may cause mortality due to gross aspiration. It includes a frequent cause of medicolegal claims against anesthesiologists (6) and its incidence is reported to range from 0.1% to 12% in different studies (4). The wide range of its incidence might reflect the fact that it depends on various risk factors, which have been clarified by previous studies, including pre-existing dental pathology, like dental prosthesis and large decay (4, 7), which increases the risk up to 3.4 times (5), and unintentional force by the anesthesiologist in difficult intubation, which might be due to using incisal edges of the upper maxillary incisors as a fulcrum point (8).

As a result, studies have suggested precise dental examination before anesthetic procedure and have suggested the use of protector devices to reduce this complication (2, 9, 10). Some studies have designed dental shields to protect the teeth from trauma (11-13) or for fragile or loose teeth, or dental prostheses (14), while others have modified the existing blades (15-17) or have designed new blades (18) for better visualization and less dental contact. But the designed devices have some limitations, including the fact that some are only applicable for children and some cannot be applied in special cases, like opening mouth more than 3.5 cm. Therefore, we designed a new protector device (PK1) and aimed to assess its efficacy on reducing dental injury during laryngoscopy in the present study.

**[II] MATERIALS AND METHODS**

**Study design**

This randomized clinical trial (RCT) included 70 patients (sample size):

\[ n = \frac{Z^2 pq}{d^2} \]

\[ n = \frac{(2)^2(0.5)(0.5)}{(0.125)^2} = 70 \]

Previous studies have reported a variable frequency of this event, ranging from 1:8 to 1:1,900 patients. We considered \( \text{d}=1:8 \), \( z=2 \) (insurance interval = 95%), \( p=q=0.5 \) in ideal state.

N=70 who received general anesthesia in teaching hospitals of Shiraz University of Medical Sciences (Khalili and Shahid-Dastgheib Hospitals) in winter 2014. The intervention group consisted of 70 participants. All the patients were adult (over 18 years old) The patients were clarified about the details of the procedure and the difference between the two methods and entered the study voluntarily, as the patients had to cooperate to adjust the PK1 device on their face. All the steps of the procedure were explained to patients and the consent form was written by each patient.

Inclusion criteria comprised of patients who referred to Khalili and Shahid-Dastgheyb Hospitals and underwent general anesthesia and exclusion criteria comprised of patients with limited mandible movement, dislocated teeth, and having a possible reason for difficult intubation, in their examination by the specialist. PK1 is made of steel and has three parts: 1) the part fixing on the operating room’s bed, 2) a vertical part, and a 3) a horizontal part (protector part) (Figure 1).

The device was set after the patient laid on the operation room bed, after taking IV supply and monitoring the patient. The first step was that the fixing part was attached to the operating room’s table (bed), then the vertical part was attached to the fixing part, and the patient’s head was positioned in Sniff position. Then, estimate the angle of the vertical part and height of the horizontal part with face and mouth of patient. Then change the angle of vertical part far from patient’s mouth and face. Then general anesthesia was induced by intravenous administration of 0.05 mg.kg midazolam, 1-2µg/kg fentanyl, 4-5 mg/kg thiopental, and 0.5 mg.kg atracurium. The patient was ventilated by face mask then.

Before laryngoscopy, vertical and horizontal parts were put back to the patient’s face and mouth and laryngoscopy was performed by assistant putting the blade on the horizontal part of the device to prevent contact with upper teeth. The
laryngoscopy was performed by Macintosh curved blades. In the intervention group laryngoscopy was done by the help of PK1 and in control group laryngoscopy was done with the same blade and same method without PK1. After laryngoscopy and tracheal intubation process an expert anesthesia, the vertical and horizontal arms were removed and disconnected from the fixing part. The tracheal tube was then fixed. Control group consisted of 74 patients with the same characteristics and the same inclusion/exclusion criteria. In this group laryngoscopy was done without PK1 but with the same method of anesthesia. During the procedure, every contact with upper front teeth and grading laryngoscopy with curved (Macintosh) blades were recorded and compared between the two groups.

**Ethical considerations**

The protocol of the study was approved by Shiraz University of Medical Sciences. The design and objectives of the study were explained to all participants and written informed consent was obtained from those who were willing to participate in the study and they were clarified that they were free not to participate in the study.

**Statistical analysis**

Continuous variables are presented as mean (SD) and qualitative variables are reported through frequencies (percentage). Comparison was performed using Chi-square test. Statistical analysis was performed using SPSS 19.0 software (SPSS Inc., Chicago, IL, USA). P-values less than 0.05 were considered statistically significant.

[III] **RESULTS**

In the intervention group, 2/70 (2.8%) dental contacts were reported, while the rate of dental contact was 30/70 (42.8%) in the control group (p-value=0.0011). Moreover, laryngoscopy grading increased in the intervention group (48 patients vs. 0, respectively) (p-value=0.0011), with no occurrence of unsuccessful intubation. But most of the 48 cases needed pressure on cricoid cartilage.

[IV] **DISCUSSION**

The results of the current study indicated significantly fewer dental contact in the intervention group that indicates the superiority of PK1 device although increased grading was compensated by cricoid pressure. The importance of dental injury during laryngoscopy and the limitations of some previously described devices motivated us to design a new protector device. Some of the previously designed devices are not applicable for all patients (13) and some are only applicable for children (17), but the PK1 device could be safely used for all ages (because of the thin steel shaft) and in all cases. Besides, the device is adjustable from 0-180° and can be used in different situations, like patients suffering from rheumatoid arthritis, or patients with previous head and neck fractures, who need special movements, as changing the patient’s positioning during anesthesia is very hazardous. The protector part is sterilizable. So one of this device can be used for most of the patients because it is reusable. On the other hand the protector part is inexpensive and can be changed and replace a new sterile one for each patient. Thus, the wide range of motion of the PK1 device can help such patients, although all patients in the present study were positioned in supine and sniff position, as we only aimed to examine normal patients. Moreover, the PK1 device is applicable in patients who need proper support in upper jaw, like patients suffering from cleft palate, which does not require McGill forceps and another assistant, as routinely performed for patients suffering from cleft palate. Similarly, some studies have designed and assessed different devices for reducing dental injury. Monaca et al have compared five tooth protectors and have reported dental shields useful for reducing dental injury, but rather large and expensive (11). But the PK1 device is inexpensive and easy to use. Lee and colleagues compared the Callander modification of Macintosh blade, in
which the flanged was partially removed, with Macintosh blade and have concluded reduced risk of teeth contact by Callander modification (15). Zangankhah and colleagues have added another modification to Callander blades (GSH) and have reported reduced chance of hitting the upper teeth (18). Other studies were in favor of angulated blades like McCoy and the Belscope that are reported to have better visibility, less force applied to the handle, and higher tooth-device distance (19). Itoman and colleagues compared metal and plastic blades and concluded fewer dental fracture by plastic laryngoscope blades and better performance of metal blades in difficult intubations (20). The strengths of the current study included comparing the device with a control group, which reduces the bias induced by confounding factors, which have not been considered in previous studies, and the limitations of the current study included lack of possibility of blinding the patients or the anesthesiologist, as the patients should have been aware of all details of each procedure, due to the Ethics of the study. Besides, there were no follow-up for patients in the present study. Other variables could also been considered, like patients’ satisfaction and anesthesiologist’s view.

[V] CONCLUSION
As the results of the present study indicated, the PK1 device is a safe, efficient, inexpensive device for reducing dental injury during laryngoscopy, which can be used for all age groups, has a wide range of motion that enables the anesthesiologist to change the device instead of patient in hazardous cases, and is applicable in patients with cleft palate.

REFERENCES
Assessing The Efficacy of A New Protector Device (PkJ) on Dental Injury Associated with Laryngoscopy in A Randomized


Figure 1.

![Figure 1](image1.jpg)

Figure 2.

![Figure 2](image2.jpg)