Evaluation of a new laryngoscope blade (Manipal throat packing blade) for throat pack insertion

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Abstract

Background and aims: Insertion of a throat pack using a Macintosh laryngoscope after placing an oral Ring, Adair and Elwyn (RAE) tube fixed to the lower lip in the midline invariably results in the lateral movement of the tongue or the tube requiring repositioning. The aim was to design a laryngoscope blade that would produce minimal movement of the endotracheal tube or the tongue during the insertion of throat pack and compare it with the Macintosh laryngoscope blade.

Material and Methods: A laryngoscope blade similar to the Doughty’s blade of Boyle Davis mouth gag with a groove in the center of the blade was initially designed. This was made of polyvinyl chloride to enable 3-D printing. Specifications given were modified after trial and error including addition of a flange. A bench study was then done to compare the Macintosh blade with the Manipal blade with and without flange. Forty anesthesia postgraduates and staff familiar with airway management inserted throat pack with each blade in random order in a manikin already intubated with an oral RAE tube and their impressions were noted.

Results: The RAE tube remained in the midline after throat packing in 97.5 and 95% with Manipal blade with and without flange as compared to 52.5% with Macintosh blade. Ease of use was affected by the lack of sturdiness of the new blades. The light was good. Most people found both blades better or the same as the Macintosh blade.

Conclusion: The Manipal laryngoscope blade with and without flange are both associated with the minimal lateral movement of the endotracheal tube and are easy to use. Their sturdiness must be improved.

Keywords: Endotracheal tube displacement, laryngoscope blade design, throat pack

Introduction

The insertion of an oropharyngeal pack is a requirement for many surgeries in the nose and throat under general anesthesia, e.g., surgeries such as adenoidectomy, tonsillectomy, cleft palate and lip repair, and orofacial surgeries. Insertion of throat pack is done after induction of general anesthesia and oral endotracheal intubation. To facilitate the surgery and the use of the throat gag used by the surgeons, an oral Ring, Adair and Elwyn (RAE) endotracheal tube is used. The tube is fixed at the center of the lower lip. Subsequently, when a Macintosh blade is used to insert the oropharyngeal pack, the part of the tube over the tongue tends to move to the left side as the flange of the Macintosh blade is designed to push the tongue to the left side. An extra effort needs to be used to ensure that the tube remains in the center or if it has moved to the side, the tongue needs to be pulled back to the right using a finger or even a Magill’s forceps.

This study was aimed to design a new laryngoscope blade that would fit onto the handle of a conventional laryngoscope and would permit insertion of a throat pack without any movement of the endotracheal tube or the tongue. We hypothesized that...
a blade with a groove in the center would hold the tube in place. The blade would have to be inserted along the tongue in the center of the mouth (rather than from the right angle of the mouth as is done with the Macintosh laryngoscope), and so, we took the Doughty’s blade of the Boyle’s Davis mouth gag as a guide. In addition, the blade needs to help keep the mouth open. The objective of this blade was to aid hassle-free throat pack insertion, and so, needed to give a good view of the pharynx, not necessarily the larynx. We then added a flange to our design to keep the jaws separated. The local workshop and the biomedical engineering department were contacted to design and get a 3-D print of the prototype. The new blades (with and without flange) were then used for the bench trial on a manikin.

The primary objective was to check whether the tube remained in the midline after throat packing using the new blade. The secondary objectives were to compare the ease of use of the blade and its sturdiness in comparison with the Macintosh blade.

Material and Methods

The methodology involved deciding on a suitable design, suitable material, making the blade, and then, testing the blade on a manikin.

Design

Description of the initial design: The Macintosh laryngoscope blade design was not satisfactory. The design of Doughty’s blade of the Boyle’s Davis mouth gag used by the otolaryngologist is available with a groove that is designed to hold the tube in place during surgery such as tonsillectomy. We thought that a similar design on the laryngoscope blade is likely to be helpful for our purpose. We approached the local workshop to make a laryngoscope blade (Manipal throat pack blade) with a design similar to the Doughty’s blade of Boyle’s Davis mouth gag. We instructed that it must be modified further to hold a bulb and wiring similar to a Macintosh size 3 blade.

Further instructions to the workshop were as follows: The proximal part of a ‘Manipal throat pack blade’ must fit onto the handle like a conventional Macintosh laryngoscope blade [Figure 1]. The shaft part of it must be smooth and curved with a radius of curvature of about 60°. About 3 cm from the proximal end (handle end), the shaft of the blade must have an oblong opening followed by a groove up to the tip of the blade to hold a 6–8.5 mm internal diameter (ID) endotracheal tube. The left edge of the groove on the blade must have an attachment for placement of a laryngoscope bulb, two-thirds of the distance from the proximal end similar to a Macintosh blade. The following dimensions were proposed:

- Length: 10 cm, 2 cm at the base where it fixes on to the laryngoscope handle. The part that is inserted into the mouth would be 8 cm long (7 cm + 1 cm taper).
- Width: ~2 cm at the base and 2.5 cm at about 1 cm from the tip, and then, round off to 2 cm at the tip.

Material

Since the blade was still in the designing stage and would be initially tested only on a manikin, the ease of making the blade was more important than its suitability for use in humans. Moreover, multiple modifications were expected. The biomedical engineering department decided on polyvinyl chloride (PVC) as a suitable material and opined that the design can be 3-D printed using this material. The production would be easy and inexpensive. This could be used for preliminary testing in manikins to see if the design and its utility are satisfactory. At this stage, it was noticed that the base (the proximal part that fits onto the handle) of the Macintosh laryngoscope blade has a spring mechanism. This was not possible to replicate with the 3-D printing using PVC.

On preliminary use of the prototype, we found that the strength of the new laryngoscope blade [Figure 2a] was not adequate for laryngoscopy. It broke at the joint while attempting laryngoscopy. To improve the strength of the blade, we decided to modify the blade by removing the opening in the groove. Design 2 of the new Manipal throat pack blade is shown in Figure 2b.

The strength of the blade of Design 2 was adequate for performing throat pack insertion but provision for a light source had to be made. A LED bulb was attached to the blade on the palatal surface about 2 cm proximal to the tip of the blade on the left side of the groove. This bulb had wires and screws connected to the handle of the Macintosh blade.
containing batteries. Thus, the new blade could be attached to the Macintosh handle and the electrical circuit could be completed similar to a regular Macintosh blade [Figure 2c].

This blade (Manipal throat pack blade without flange) was further modified to include a flange (Manipal throat pack blade with flange) which would help to keep the mouth open and ensure maximum space during insertion of the pack [Figure 2d]. The electrical wires were placed beside the flange.

**Bench trial**
A bench trial was conducted on an intubation manikin with 20 anesthesia residents and 20 anesthesia staff experienced in airway management by using the newly designed laryngoscope blade. This trial was not registered in Clinical Trial Registry of India (CTRI) because it was a bench study on manikins.

The Institutional Ethics Committee’s (IEC) approval was obtained (IEC approval number and date: IEC 880/2018 dated 12th Dec 2018).

The trachea of a standard adult intubation manikin was intubated with an 8 mm oral RAE tube and the tube was fixed to the lower lip in the midline. Figure 3a–c shows the views obtained with a Macintosh laryngoscope blade, Manipal throat pack blade without flange, and Manipal throat pack blade with flange.

The postgraduates and staff were asked to insert a standard size throat pack with each of the three blades, the Macintosh size 3 blade, the Manipal throat pack blade without flange, and the Manipal throat pack blade with flange in random order (using lots). The nature of the study did not allow concealment or blinding. They were instructed not to use it to visualize the glottis but only the pharynx. The ease of the throat pack insertion, time taken to insert it, and their perceptions about the new blade in comparison with the regular Macintosh blade were noted down. Since we were observing the time to insert the throat pack, we wanted to standardize the size of the pack as well as how it was handed over to the laryngoscopist. Hence, a standard length of rolled dry gauze was used for packing using Magill’s forceps. The pack was given to the staff and postgraduates bunched up into four bunches (to ensure uniformity and comparability). Once the throat pack insertion was completed with one blade, the pack was completely removed and reinserted with the other blades in a similar manner. The participants were required to answer a questionnaire regarding their evaluation of the blades after their participation.

The sample size calculation was based on the lateral movement of the endotracheal tube. In a small pilot study involving 12
anesthesia residents, the lateral movement of the endotracheal tube (ETT) was noticed by 5/12 participants (41.6%) during the throat pack insertion in the manikin using a standard Macintosh laryngoscope. If we assume that at least 20% improvement should be provided with the new blade, with a 95% confidence interval, a minimum sample size of 24 participants was required.

Results

A total of 40 volunteers: 20 anesthesia consultants and 20 anesthesia residents, participated in the study. All of them had an experience of at least 1 year with endotracheal intubation and insertion of throat packs. The responses to the questionnaire are tabulated in Table 1.

Participants’ remarks

Manipal throat pack blade without flange has good light. There is no displacement of ETT as ETT is inside the groove of the blade and there is less chance of trauma and pressure to the upper airway especially the upper lip and upper incisors. However, they also opined that the Manipal throat pack blade without flange is not very strong and should be made of more sturdy material (preferably steel). The space to introduce the pack is less with this design. The handle-to-blade attachment was loose and so the light tended to flicker—interfering with the packing (no locking mechanism). Packing close to laryngopharynx around the glottis was difficult.

About 67.5% of the respondents opined that a flange would be helpful. The Manipal throat pack blade with flange was similar with good light and visibility with no displacement of ETT as ETT is inside the groove of the blade. There was a greater space for maneuvering inside the oral cavity. The throat packing was easy with this new blade with flange. However, this also needed to be sturdier, preferably steel. The handle-to-blade attachment was loose and so the light tended to flicker—interfering with the packing (no locking mechanism) similar to the blade without flange.

Discussion

The insertion of an oropharyngeal pack is a requirement for many surgeries in the nose and throat under general anesthesia. When a Macintosh blade is used to insert the oropharyngeal pack, the part of the RAE tube inside the mouth tends to move to the left side. The present study was undertaken to see if a laryngoscope blade can be designed to avoid this problem. The Doughty’s blade of Boyle’s Davis mouth gag was initially chosen as a prototype, hoping that the endotracheal tube can be firmly held in the midline while the packing is done. The plan was to design and print a prototype blade using a 3-D printer because this would be cheap, and hence, alterations could be easily made after the trials. A steel prototype would require a mold to make it and was more complex. In addition, the plan was to have a blade that would fit onto the handle of a standard Macintosh laryngoscope blade. This handle has a spring mechanism in its area of contact with the blade. This was difficult to replicate.

Polyvinyl chloride was the material used for 3-D printing. The initial design given had a groove in its distal half whereas there was an opening in its proximal half. This blade was very brittle and could not withstand force. It was clear that the blade would be stronger without the opening. Hence, the opening was omitted in the next design.

The second design was satisfactory to insert the throat pack as it could hold the tube well in the midline. The challenge was to provide a light for the packing. The spring mechanism on the original Macintosh laryngoscope could not be replicated in the 3-D printing. Hence, a small LED bulb had to be attached to the posterior surface with wires and battery. This was assigned the name Manipal throat pack blade without flange.

The initial users (in the pilot study) commented that they missed the flange similar to the one present on the Macintosh blade. A flange would hold the jaws apart and provide more space to insert the throat pack. The next version was printed with a flange incorporated in it. This flange was designed

Table 1: Responses to the questionnaire used to record the assessment of the throat pack blade by the participants

| Question                                                                 | Macintosh blade (%) | Manipal throat pack blade without flange (%) | Manipal throat pack blade with flange (%) | P      |
|-------------------------------------------------------------------------|---------------------|---------------------------------------------|------------------------------------------|--------|
| The endotracheal tube remained in the midline after the throat pack placement-Yes | 52.5                | 97.5                                        | 95                                       | 0.000  |
| Ease of use of the laryngoscope blade for throat pack insertion-Grade 1   | 52.5                | 80                                          | 47.5                                     | 0.006  |
| Did you feel that the throat pack blade material is sturdy enough for the purpose? Yes | 100                 | 40                                          | 27.5                                     | 0.000  |
| How would you rate the new blade in comparison to a Macintosh blade? Better Same | 60                  | 45                                          | 45                                       | 0.273  |
| Better Same                                                             | 32.5                | 37.5                                        | 17.5                                     |        |
to be only half as long and wide as the flange on a regular Macintosh blade. This was called the Manipal throat pack blade with flange.

Thus, there were three blades to compare: Macintosh blade, Manipal throat pack blade without flange, and Manipal throat pack blade with flange. There were 40 participants in the study, who randomly inserted a standard throat pack using these three blades in random order in a manikin already intubated with a 6 mm ID oral RAE tube.

Although we had 20 faculty and 20 residents trying out the new blades, there was no intention to compare the expertise of both groups. They were all experienced in endotracheal intubation and throat pack insertion is a fairly simple task. Since the blades were new and had not undergone any trial, it was appropriate that a bench study is done before attempting to use them in the patients. Moreover, the material used was not medicalgrade plastic. Sterilizing the equipment would have been difficult.

It was easy to get the blades printed and they were relatively inexpensive. The LED light was much brighter than the bulb on a Macintosh blade. The scatter or spread of the light was also wide, and thus, the view of the throat was much better than a Macintosh blade.

However, they had their downside. It was not possible to get the wires concealed in the body of the blade. The blades were not very strong and tended to break when any extra force was exerted on them during the retraction of the tongue (in the manikin). For this reason, the participants had to be instructed to be gentle with these blades. This was one reason why some participants scored the Macintosh blade higher than the new blades.

Most participants found the Manipal blade with flange to be very useful and opined that the endotracheal tube did not move from where it was fixed during or after packing. In patients, the tissues will be softer and it remains to be seen whether the advantage is confirmed in them.

There are hardly any studies published in the literature on throat pack insertion. Karmarkar, et al.\textsuperscript{[1]} did an analytical pilot study prospectively to compare the flange slide pack technique (FSPT) using the Macintosh laryngoscope blade with conventional laryngoscopy-guided throat packing. They found that the FSPT was faster. However, in a patient who is already intubated and is being ventilated, the time taken to pack may not matter much. A few extra seconds would not be clinically significant at all. In the present study, it was the movement of the endotracheal tube that was in focus. There are no studies on modifications of the laryngoscope blade design to address difficulties with throat packing. This is the first such study.

All the new blades have a groove in the center to hold the tube. The first prototype had a cut in the blade which reduced its strength, and hence, the second version was without a groove. The third version had a flange added to keep the mouth open and facilitate pack insertion by creating more space. Whether a cut is needed or not in a stainless-steel version will need to be evaluated when they become available. Further research can be with the stainless-steel versions.

Athanassoglou et al.\textsuperscript{[2]} published a review article on the pros and cons of anesthetist-inserted throat packs. They recommended that the surgeon and not the anesthetist insert the throat pack. Essentially, this was to avoid the ‘forgotten throat packs’. They also published a protocol for the insertion and removal of throat packs. In such cases where the problem occurred, the complications occurred not because of the throat packs themselves but a failure to remove them at the end caused airway obstruction and even a death consequent to it. This would amount to negligence. An editorial in Anaesthesia in 2018 by Bailey et al.\textsuperscript{[3]} was titled, ‘Have we reached the end for throat pack inserted by anesthetists?’ This too was focusing on the ‘forgotten throat packs’. The Royal College of Anaesthetist’s guidelines of 2019 for provision of anesthesia services for ENT surgery also dissuaded anesthetists from inserting throat packs.\textsuperscript{[4]}

In our hospital, it is routine for an anesthetist to insert the throat pack and its removal is also the anesthetist’s responsibility. A ribbon gauze is used for packing and whenever possible, the tip of the throat pack is taped alongside the endotracheal tube. A label to that effect is taped on to the face and a board with boldly written words ‘Throat pack is in’ is displayed. The removal of the throat pack is confirmed before the removal of that board and a note of the same is made in the patient’s case notes. There has not been an incident related to the throat pack in the last 30 years at this hospital. In that context, anesthetists continue to insert throat packs in patients who need it, and thus, the new Manipal blade still remains relevant at our hospital and anywhere else where such practice is still present.

The only complication anticipated with the use of the new blades is their fragility. This is primarily because of the material used to make them. Currently, it is made of 3-D printable material and breaks easily when an extra force is used. A medical-grade stainless steel version of the same would be helpful to overcome this problem. The blade should also be autoclavable for use in patients (similar to the Macintosh blades). The design of the new blade, especially with the
flange, is very easy to use. Further, all the new blades have a groove in the center to hold the tube. The prototype had a cut in the blade which reduced its strength. Whether a cut is needed or not in stainless-steel versions will need to be evaluated when they become available. Further research can be with the stainless-steel versions.

Conclusions

The use of the Macintosh laryngoscope blade to insert a throat pack results in the lateral movement of the tube nearly 50% of the time while both the Manipal laryngoscope blade with and without flange are associated with minimal lateral movement of the endotracheal tube. The Manipal throat pack blade with flange is significantly easier to use for this purpose as compared to either the Macintosh blade or Manipal throat pack blade without flange. Neither of the new blades is sturdy. The overall impression about the prototype Manipal throat pack blade with and without flange is that they are both better or at least similar to the Macintosh blade for throat pack insertion. However, the material needs to be stronger and a steel version with light incorporated inside it is likely to be useful.

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Conflicts of interest
There are no conflicts of interest.

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