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# Evaluation of a Novel Adjunct to Facilitate Tracheal Intubation

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Tracheal intubation using video-laryngoscopy with hyper-angulated blades (VDL-HA) necessitates the concomitant use of a rigid metal stylet with unwanted consequences including difficulty guiding the stylet into the trachea.[1] Often, VDL improves the view of the glottis but does not facilitate intubation.[2] We have developed and tested the prototype of an adjunct with a flexible tip that aids its tracheal placement, a flexible intubation aid (FIA)[3] (Figure). It is more malleable than a stylet but stiffer than a standard bougie. The angle of tip flexion is controlled using the handle. The endotracheal tube (ETT) is preloaded onto the bottom of the handle, which is conically shaped and designed to hold a 15 mm connector. It can be released with minimal force.

## METHOD

After approval by the local research evaluation panel, anesthetists experienced in VDL, but not involved in developing the FIA, participated in video-recorded device testing on a manikin. After watching a 75-second training video, they immediately did four tasks: (1) laryngoscopy using MacIntosh blade, (2) intubation using VDL-HA with metal stylet, (3) intubation using VDL-HA with standard bougie, and (4) intubation using VDL-HA with a previously unused FIA. The primary outcome was device performance in aiding intubation compared with other adjuncts. Secondary outcomes were ease of insertion, ease of railroading the ETT, overall device performance, and time to intubation (TTI: from laryngoscopy blade entering the mouth to complete removal). Outcomes were measured on participant-rated 5-point scales except TTI (determined using videos). For the primary outcome, ordinal data were converted into binary data ("much easier" and "easier" indicating FIA superiority, other options indicating nonsuperiority). Expecting 90% of users to favor the FIA, a sample size of six was calculated for the evaluation.[4] For the primary outcome, the null hypothesis was set as "no difference in performance of FIA compared with other adjuncts." The binomial test was used to calculate the 1-tail *P*-value. TTI comparisons were made using the Wilcoxon signed-rank test.

## RESULTS

Eight anesthetists (female:male 5:3, median consultant experience 15 years) participated. Five preferred VDL-HA in difficult intubation scenarios, two preferred channeled VDL and one preferred the flexible scope. The median Cormack-Lehane score for MacIntosh laryngoscopy on the manikin was two (range 1-3, mode 2).

FIA performance was superior to the metal stylet and standard bougie (Table). Median TTI was 61 seconds, 116.5 seconds, and 59.5 seconds using stylet, bougie, and FIA, respectively, with no significant difference when using FIA compared with bougie ($P$ = .24) or stylet ($P$ = .87). FIA insertion into the larynx and trachea was scored as "very easy" (by seven and five participants, respectively) or "easy" (by one and

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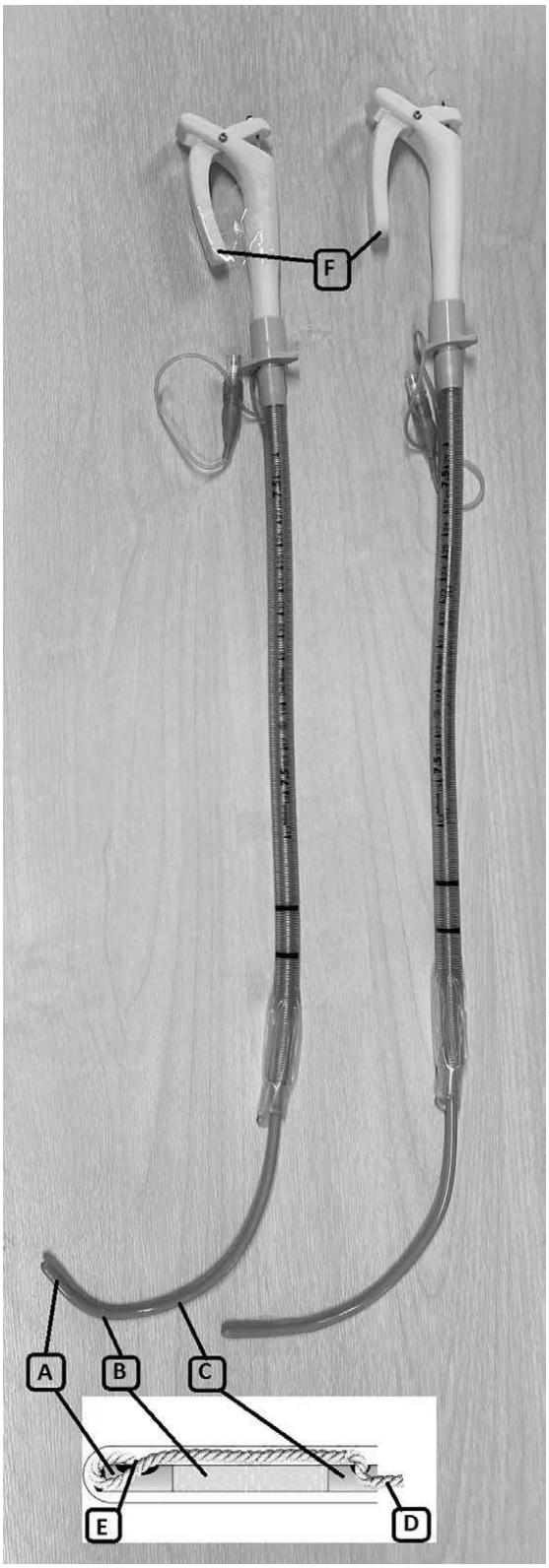


**Figure.** The FIA in neutral and maximal tip-flexed positions. An enlarged sketch of the internal mechanism at the tip is shown: angle of tip flection can be controlled depending on how hard the handle (F) is squeezed. This pulls on a cable (D) moving through a rod (C). The rod connects distally to a flexible portion (B). This in turn attaches to a small rigid portion more distally (A). The cable moves through two apertures and curves after exiting portion A, to be welded onto itself at point E. Letting go of the handle returns the tip to neutral position. FIA indicates flexible intubation aid.

three participants respectively). Advancement of ETT over FIA was rated "easy" by five participants, "some difficulty" by two, and, "a lot of difficulty" by one. The median rating of the overall performance of FIA was 8 of 10.

Seven participants left a comment, forming three opinion clusters: the FIA improves views and feels less traumatic to soft tissues compared to the stylet, environmentally friendly materials should be considered in its manufacture, and pediatric sizes would be useful.

Observing the videos, all participants obtained good views of the glottis with VDL-HA. Using the metal stylet, two participants who do not use VDL-HA, could not insert it in the trachea. Conversely, both inserted the FIA into the trachea and railroaded the ETT over it successfully. Two participants displaced the ETT while withdrawing the stylet. In one case, this caused extubation. This difficulty did not happen with the FIA. One participant changed the shape of the stylet three times to achieve tracheal insertion. Two participants did not attempt intubation using VDL-HA with standard bougie, saying it would be futile. Two others changed the shape of the bougie to match the blade curvature and used it successfully. Other participants also changed the bougie shape but were unsuccessful. Using the FIA, two participants had difficulty railroading the ETT for intubation because they had inserted the FIA too far into the trachea or did not rotate the ETT to help advancement.

## DISCUSSION

The FIA prototypes, tested on a manikin using VDL-HA by experienced anesthetists, compared favorably against the rigid metal stylet and standard bougie. The participants had watched a short training video, with no opportunity for device handling or practice, indicating that using the FIA is highly intuitive. These findings support in vivo testing of the FIA. We would hypothesize that it is less likely to cause airway trauma compared with a metal stylet and faster TTI will be achieved with minimal practice. ■

### DISCLOSURES

**Name:** Roxaneh Zarnegar, MBBS.
**Conflicts of Interest:** R. Zarnegar is named inventor on the device patent.
**Name:** Irving Caplan, BSc.
**Conflicts of Interest:** I. Caplan is named inventor on the device patent.
**Name:** Giovani Fossati, Masters, Enterprise Engineering.
**Conflicts of Interest:** G. Fossati is named inventor on the device patent.
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**Table. Results of Comparison Between the FIA and a Standard Bougie or Metal Stylet Presented As Raw Data and After Conversion to Binary Data ("Much Easier" and "Easier" Indicating FIA Superiority and All Other Options Indicating Nonsuperiority)**

| Primary outcome comparisons | Ratings on 5-point scale | | Binomial test 1-tail *P* | |
|---|---|---|---|---|
| How FIA compared with the metal stylet in aiding intubation | Made it much easier | 4 | FIA superiority | 7 |
| | Made it easier | 3 | FIA nonsuperiority | 1 |
| | Was no different | 0 | *P* = .035 | |
| | A little harder | 1 | | |
| | Made it much harder | 0 | | |
| How FIA compared with the ordinary bougie in aiding intubation | Made it much easier | 4 | FIA superiority | 8 |
| | Made it easier | 4 | FIA nonsuperiority | 0 |
| | Was no different | 0 | *P* =.004 | |
| | A little harder | 0 | | |
| | Made it much harder | 0 | | |

Values are number of participants giving the score.
Abbreviation: FIA, flexible intubation aid.



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