

Importance of Clinical Relevance in Clinical Trials

To the Editor:—We read with interest the article by Santoni *et al.*¹ Maintaining manual in-line stabilization for direct laryngoscopy in patients with known or suspected cervical spine injury is a practice which would benefit from further research. However, we believe the protocol design in this study has limited the clinical relevance of the data generated.

The authors designed a prototype pressure-sensing laryngoscope blade specifically for this study. The protocol for intubation in this study was regulated by limitations of these pressure sensors. The research team prohibited external laryngeal manipulation and prohibited use of a stylet. Use of bougie was not mentioned. Both external laryngeal manipulation and use of stylet/bougie are accepted techniques to assist intubation when laryngoscopy is difficult, and are part of the difficult airway algorithm.^{2,3} Both of these techniques are commonly used in patients with suspected cervical spine injuries.⁴

The approach used in the study, which does not represent normal clinical practice, resulted in an increased burden of risk to the patients in this study (three failed intubations and one dental trauma in ten subjects), so that the trial was abandoned. The clinical benefit of a study in humans needs to be balanced against the risk assumed by the subjects. It would be valuable to repeat the study in a more realistic clinical setting, allowing clinicians to intubate the patient

in whatever manner they are used to, and using intubation aids as required. It would be interesting to see if manual in-line stabilization still resulted in a doubling of applied pressure in that scenario.

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Balancing the Force of Direct Laryngoscopy with Manual In-Line Stabilization

To the Editor:—Manual in-line stabilization (MILS) is employed during direct laryngoscopy in patients with known or potential cervical spine instability to try to stabilize the spine. A recent article by Santoni *et al.* evaluated how MILS affected the pressure against the tongue and jaw during direct laryngoscopy.¹ Pressure was measured with sensors attached to the upper surface of a Macintosh 3 blade. In nine anesthetized paralyzed patients, institution of MILS increased the pressures during laryngoscopy almost two-fold, as compared with pressures measured without MILS. Although MILS is intended to stabilize the cervical spine during laryngoscopy, the authors proposed that “secondary increases in pressure application with MILS have the potential to increase pathologic cranio-cervical motion.”

In the absence of MILS, upward and forward force exerted on the airway will be transmitted in some part to the cervical spine and the spine will move, as Dr. Todd and his group have demonstrated.² The force will also compress the tongue, contributing to exposure of the vocal cords with laryngoscopy.³ However, it is not clear how much movement-generating force, if any, will be applied to the spine if MILS is instituted as described. Santoni *et al.* explain that MILS is performed by an assistant holding the patient's occiput and applying “forces equal and opposite to those created by the anesthesiologist.”¹ One might expect that matching laryngoscopy force with an equal and opposite force would result in no net force on the head, thus reducing the force

and movement of the cervical spine, as compared with the situation with no MILS. In fact, Santoni *et al.* list the goal of the MILS as preventing or minimizing head and neck movement.

How MILS actually works in practice is another issue. The assistant performing the task is guided by feel without any measurement of force. Thus, MILS may not balance the force of laryngoscopy and may not minimize movement. The Santoni group may be correct that MILS does not accomplish the objective. *However, they only measured the pressure on the laryngoscope and did not evaluate the force exerted by MILS.* Thus, they do not know what the net force was and cannot say one way or another from this body of research whether MILS had the potential to reduce or increase the craniocervical motion.

The observation that MILS worsened glottic visualization, a finding also reported by other investigators, is interesting and could be an outcome of the way the MILS was executed. The increased force on the tongue with MILS should lead to greater compression of the tongue, increase the space in the airway and, if anything, improve the glottic view rather than impairing it. In a study examining simulated cervical spine precautions, we showed several years ago that having an assistant hold a patient's head firmly against the table during laryngoscopy significantly reduced the amount of head extension necessary to expose the vocal cords compared to the state with no head stabilization.⁴ We suggested that less head extension was needed because the downward pressure on the head allowed the laryngoscopist to lift more forcibly and achieve greater displacement of the tongue from the field of view. Some additional factor must be operative in the Santoni study to worsen the view with MILS. Perhaps the main effort of the assistants was to resist head

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extension, rather than balance the upward force of laryngoscopy. Limited head extension would make laryngoscopy more difficult and could contribute to higher grade views. In our 1991 paper, the assistants did not oppose head extension.

We congratulate Santoni *et al.* on their highly relevant study. The degree to which MILS is beneficial in patients with potential cervical spine injury is an important and timely issue.⁵ The application of physics and engineering principles to medical problems will help answer clinical questions such as this. We would welcome further research about how laryngoscopy and MILS impact the forces exerted on the spine and airway, and how best to implement MILS.

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In Reply:—We thank both Dr. Loane and colleagues, and Drs. Hastings and Delson for their thoughtful comments regarding our study of manual in-line stabilization (MILS).¹

Loane *et al.* criticize our study on two levels. Because we did not allow the use of intubation aids, such as a stylet, bougie, or external laryngeal manipulation, Loane *et al.* suggest that our findings have little clinical relevance. They further suggest, because we did not allow the use of intubation aids, our study placed patients at increased and/or unnecessary risk of injury. When we designed our study, we decided to prohibit the use of airway aids to ensure that all of the forces of intubation would be reflected by the pressure values obtained by the instrumented laryngoscope blade. Had we done otherwise, any number of variable and nonquantified forces could be applied during intubation, which would preclude a valid test of our primary hypothesis. However, when making this decision, we were well aware that MILS would impair glottic view and that intubation would likely be more difficult in some patients. Nolan *et al.* had previously reported that 5 of 74 patients (7%) of patients could not be intubated with MILS without the use of airway aids.² Accordingly, we included two elements in our study design to increase patient safety. First, we employed very stringent enrollment criteria to ensure that only patients who appeared easy to intubate and to have a low risk of intubation-related complications were eligible. Second, all intubations were performed by experienced faculty anesthesiologists. We anticipated that with these extra safety precautions all patients would be successfully intubated, even with MILS. Contrary to our expectation, in two of nine patients (22%), MILS precluded successful intubation, with one of these two patients experiencing a minor dental injury. This certainly begs the question of why, in our study, MILS so greatly increased intubation difficulty. This is an important question that we address in our response to Drs. Hastings and Delson. Nevertheless, because MILS so greatly increased intubation difficulty, we stopped our study after the preplanned interim analysis. We decided that the patient-related risks of continuing outweighed the statistical benefits of continuing. Therefore, we think we took appropriate steps, both in the design and conduct of our study, to minimize patient risk.

Our study made two key observations. First, even in patients who were otherwise easy to intubate, and even with experienced anesthesiologists, MILS often severely impaired glottic visualization and greatly increased intubation difficulty. Second, when confronted with a difficult intubation, anesthesiologists responded by applying much greater lifting pressures with the laryngoscope. As we review in the Discussion section of our article,¹ cadaver studies show external stabilization methods that result in impaired glottic visualization—such as MILS³—

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increase pathologic motion at the unstable segment. Increased pathologic motion at the unstable segment can only be explained by an increase in net force across the unstable segment, with the laryngoscope serving as the instrument by which that force is applied. Accordingly, our study calls into question whether MILS actually decreases the risk of cervical cord injury with intubation. In contrast, the risks of MILS are abundantly clear. Based on our experience, we now consider MILS to almost automatically put patients into the difficult airway pathway. Accordingly, we agree with Loane *et al.* that having several airway aids immediately available is necessary and, in fact, may often be required to successfully intubate the patient when MILS is employed. From our perspective, these observations and conclusions are highly clinically relevant.

Drs. Hastings and Delson correctly point out that we did not measure the net force applied to the cervical spine during intubation. We agree that if the forces of laryngoscopy are perfectly counterbalanced by the assistant who applies MILS, cervical spine movement should be zero. However, two cadaver studies indicate that *external* stabilization methods do not appear to entirely offset the increased forces applied *internally* when glottic view is impaired. In cadavers with unstable spines, external stabilization methods that impair glottic view—either MILS³ or a cervical collar⁴—increase pathologic motion at the unstable segment; this can only be explained by increased force across the unstable segment.

Drs. Hastings and Delson suggest that our findings may have been influenced by the method by which MILS was performed. We think that they are certainly right. It is ironic that although MILS is currently considered to be a standard of care, there is no standard for how MILS is to be performed. There is no formal description of how MILS is to be performed in the current Advanced Trauma Life Support manual other than “during intubation, the neck must be maintained in neutral position.”⁵ When described at all, MILS techniques vary widely among studies. Our MILS technique was based on the descriptions of Nolan *et al.* (“The aim of [MILS] is to prevent cervical spine movement by the application of equal and opposite forces to those generated by the intubator”)² and Heath *et al.* (“The patient’s neck [is] immobilized by . . . holding the sides of the neck and mastoid processes, thus preventing any movement of the neck during . . . laryngoscopy”).⁶ Accordingly, we applied MILS to prevent any appreciable movement of the head or neck and, quite specifically, to prevent craniocervical extension during intubation. Although anesthesiologists applied increased pressure to airway tissues, increases in tissue displacement were often not sufficient to obtain a line of sight (Grade 3 or 4 glottic view in five of nine patients). Because of recent concerns