Modeling the Effects of the Locked Pack Procedure to Prevent Guidewire Retention in a Clinical Setting

To the Editor:
We read with interest the study by Mariyaselvam et al.1 regarding the use of a locked pack (which required a guidewire to be inserted and lifted to open) to prevent guidewire retention after completion of central venous catheter insertion, and we commend them for their effort and this novel technique. The introduction of a locked pack will stimulate the search for a missed guidewire and, hence, its subsequent retrieval (if still inside the catheter). This will definitely reduce the occurrence of these rare events if the cause is retention of the whole guidewire, specifically due to operator distraction. From our experience of retained guidewires at our institution, a larger percentage of these incidents were due to other technical causes, such as breakage or inability to retract the guidewire.

In a retrospective study performed by our group, we reviewed 12,887 central venous catheter insertions over a 26-month period from 2011 to 2013.2 Of those insertions, eight involved guidewire retention. Of those eight cases, only two (25%) were caused by operator distraction. Five (63%) were due to retained fragment after guidewire breakage, and one case (12.5%) was due to inability to retract the guidewire because of impingement. Using our study data where the guidewire retention incidence was 1:1,611, we attempted to model the effects of the locked pack technique. If we remove two of the eight cases where guidewire retention was due to operator distraction, this yields a new incidence of guidewire retention: 1:2,148. Using a one-tailed z-ratio analysis, we can determine if this new ratio is significantly less. This new incidence rate is not significantly less than our initial rate of 1:1,611 (z = 0.204, P = 0.421).

Since our initial review, we have implemented an intense safety education program, and now immediate electronic confirmation of guidewire removal is required in patient charts. After reading the Mariyaselvam et al. manuscript, we reevaluated the incidence of retained guidewire through retrospective analysis of central venous catheter placements over a 26-month period from 2015 to 2017, and found three new instances of guidewire retention out of 7,558 insertions, yielding an incidence rate of 1:2,519. While this is still not a significant reduction (z = 0.319, P = 0.374), it is comparable to the reductions seen in our model implementation of the locked pack.

Competing Interests
The authors declare no competing interests.

References

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Retained Central Venous Guidewires: Are We Flushing Them Out?

To the Editor:
We read with interest the article by Mariyaselvam et al. highlighting a unique human factors approach to retained guidewires with their WireSafe kit. While the reported incidence of retained guidewires appears to be on the rise, it is currently running at approximately 0.03%.1-2 The Seldinger technique is the worldwide standard for insertion, but has the potential to result in guidewire retention. Adherence to checklists and training have been mainstays in the prevention of this complication. While checklists ensure awareness that a guidewire has been retained, they do not prevent the incident from occurring. The new WireSafe kit, with procedure completion parts in a locked box that use the guidewire as its “key,” is a novel idea and forces the operator to remove the guidewire to secure the line. However, it does not actually prevent the guidewire from being retained.

While the literature offers multiple causes for retained guidewires,1 the most common being operator distraction, an inadvertent guidewire retention during a central venous line insertion at one of our hospitals demonstrated that guidewires went from being potentially removable to completely retained as a result of flushing the catheter lumens at the end of the procedure. The guidewire does not completely occlude the lumen it passes through. This allows for aspiration of blood, which confirms placement in a vascular structure albeit with resistance. Indeed, this resistance should be a trigger for the operator to consider that the guidewire may still be within the lumen. However, it is easy to understand how this could be overlooked in a busy environment. A false assurance that the lumen is fully patent means that the lumen is then flushed. The guidewire is then pushed further into the patient’s vasculature and becomes inaccessible.
We would therefore like to suggest an addition to the WireSafe kit. We feel that the WireSafe kit may be enhanced by including preloaded “flush” syringes within the locked kit. This will ensure that the guidewire is always removed before the lumens are flushed. For those that prefer to prime the lumens of their central lines before insertion, perhaps a 3-ml preloaded, color-coded syringe clearly marked as “priming solution” could be included within the pack but outside of the locked kit. We believe a forced brake before flushing the central line lumen may prevent a removable guidewire from becoming a “lost” or retained one.

Competing Interests
The authors declare no competing interests.


References

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In Reply.
We would like to thank Camporesi et al. for their interest in the locked procedure pack (WireSafe) and our article. They are, of course, absolutely correct that the WireSafe is not intended to prevent guidewire breakage or malfunction; however, in our simulation it was shown to be highly efficacious in preventing clinicians simply forgetting to remove the whole guidewire.1 We see these as two separate problems requiring two separate solutions. Guidewire fracture or impingement due to kinking or unraveling needs to be addressed with improvements in manufacturing, materials, and operative technique. However, whole guidewire retention due to forgetfulness requires an understanding of human factors science and the inevitable fallibility of human operators, made worse by suboptimal working conditions. The well-recognized success of the energy, transportation, and other high-reliability industries use system changes and fail-safe forcing functions engineered into equipment design to prevent rare, but serious, errors and these are tested in a simulation setting. The incidence we quoted was from the article by Vannucci et al., referring to whole guidewire retention due to forgetfulness, and was 1:3,291.2 Interestingly, the incidence for “operator distraction” from the article by Omar et al. was almost identical at 1:3,221.3 These concordant figures would equate to approximately four forgotten guidewires everyday in the United States (an estimated 5,000,000 central venous catheters are placed annually). A recent article evaluating 391 cases from the U.S. Veterans Health Administration also supported the incidence of forgotten guide wires in the United States, and in addition, showed that 91% were whole—rather than fractured—guidewires.4 Regarding statistical significance for rare events in routine clinical practice, as discussed in our article, studies can seldom be powered to achieve significance.

Awareness and educational programs alone may have a higher cost and a more limited impact in the long term than design improvement. In the United Kingdom, the National Health Service England database contains 237 cases of forgotten whole guidewires (2004 to 2015).5 Despite being made a never event and increasing educational efforts in the National Health Service, the reported incidence has been increasing.5 Although immediate documentation of removal is commendable, we note that in one of the cases reported by Vannucci et al., guidewire removal was documented when it had, in fact, not been removed,2 and we have observed this occurring in the National Health Service.

We strongly disagree that comparable reductions would be seen by educational programs and improving documentation alone. Short-term improvements are often seen, but the negative effects of associated cost, increased cognitive load, creeping complacency, and warning fatigue blight these programs. An engineered (forcing function) safety solution delivers a sustained effect over time and if detected immediately, forgotten guidewires are normally amenable to bedside removal.

We also thank Drs. Kapoor and Mayall for their particularly perceptive letter addressing a loophole, about which we have agonized, relating to guidewires being flushed into the circulation. As described above, this would affect a small minority of these never events as the guidewire remains within the catheter at the time of the postoperative x-ray in the majority,5 and may migrate thereafter. Therefore, this should not discourage hospitals from using this solution. Our plan to use prefilled syringes was thwarted by the requirement of ethylene oxide, rather than gamma sterilization, by current packing companies; the former changes the pH and composition of saline in plastic sealed syringes. To prevent this, the WireSafe is sized to include a glass ampoule, an ampoule breaker, and a syringe with a filter needle, and we continue to try to influence packing companies to provide, and end users to request, these features. Additionally, we are aware of one company that is in the final stages of producing an ethylene oxide–compatible saline syringe, which we would endorse the use of within the WireSafe.

Competing Interests
Dr. Young has patented and is the inventor of the Venner WireSafe based on the locked pack described in this letter.