Trials that fail to show advantages of 3D navigation in spine surgery—is it the technology or the trial?

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Ruatti *et al.* (1) have published a randomized study comparing computer-navigated and conventional pedicle screw placement. It was a single-center study although with six different surgeons. The procedures were also divided into open and percutaneous, although allocation was not randomized and presumably was up to the surgeon. The percutaneous group also included vertebroplasty/ kyphoplasty procedures, in addition to screw placement. The outcome measures were: (I) screw malposition rates; (II) screw insertion time; and (III) radiation exposure.

For open procedures, the authors found a lower screw malposition rate with navigation than without (5% vs. 17%). However, the converse was true for percutaneous procedures; navigation yielded a higher malposition rate (24% vs. 5%). Screw insertion time per vertebra (2 screws) was longer in the navigated group for both open (16.33 vs. 7.33 min) and percutaneous (21 vs. 8 min) procedures. For open procedures, radiation exposure was higher with use of navigation (0.21 vs. 0.1 mSv). However, for percutaneous procedures, while radiation exposure increased for both navigated and conventional groups, it was relatively lower with use of navigation (0.6 vs. 1.62 mSv). All differences were found to be significant.

This commentary will be divided into two parts: one on the study itself and the other on the results/findings. Regarding the study, while randomized controlled trials (RCTs) are considered the highest level of evidence in appraising the literature, there are rules and guidelines in the design and conduct of an RCT (2,3). First, a power calculation should be made based on results of previous studies and assumptions made by the authors. This allows authors to estimate how many patients are needed in each group in order to have a certain level of confidence in detecting a difference if one exists, and therefore, also an estimate of how long study recruitment would take (2,3). Second, parameters for randomization should be explicitly stated (2,3). In a study such as this, reasonable parameters would include: approach (open vs. percutaneous), region of spine (lumbar vs. thoracic), and number of levels. This would help minimize the bias created by known variables or potential confounders. In this study, I suspect such measures were not taken because there were significantly more screws placed in the conventional group compared to the navigated group (382 vs. 174), indicating that more multilevel procedures were done without navigation. Lastly, (I) a CONSORT diagram that outlines the flow of the study from identification of qualified candidates to enrollment, treatment, and then each follow-up time point; (II) study funding source; and (III) clinical trial registration numberare now considered standard for reporting of RCTs.

Regarding interpretation of study findings, it is interesting that the authors' findings do not point to navigation either being clearly superior or inferior, even though they found significant difference with every comparison they have made. With open screw placement, navigation is more accurate but also gives more radiation. On the other hand, with percutaneous screw placement, navigation gives relatively less radiation but is less accurate. With either approach, navigation seems to take a lot more time than conventional technique.

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To a large extent, radiation exposure is determined by the number of shots the surgeon takes/asks for during the procedure. While baseline image acquisition is a necessity for all navigated cases, subsequent images could be affected by surgeon factors including their status in the learning curve. Although the paper stated that 3 of the 6 surgeons had experience >20 years and the other 3 had experience >2 years, the more appropriate pieces information are: number of years experience using navigation to place screws, number of years experience placing percutaneous pedicle screws, and number of years experience using navigation to place percutaneous screws. The same point could be made regarding pedicle screw insertion time.

A more disturbing finding, however, is what the authors found in regards to accuracy rates. While it may be true that the authors employed a very strict criterion for screw placement accuracy, thus increasing their malposition rates to include misplacements that are unlikely to be clinically important, a 24% rate for navigated percutaneous screws is unacceptable especially if the non-navigated group only had a 5% rate. Certainly, this difference cannot be explained by strict criteria, as the same criteria would have been applied in assessing screws in both groups. Furthermore, this finding seems to go against the findings of many other researchers who have found higher screw placement accuracy with use of navigation, and particularly with intraoperative 3-D navigation. The question has to be asked therefore whether this finding may be related to the particular equipment/systems used for this study, and not necessarily generalizable to other similar systems in the market; or, whether this was mainly user dependent, meaning the surgeons, admittedly or not, may still have been going through their respective learning curves during the period of study. Perhaps a way to help find out would be for the authors to further analyze their results by surgeon. If all six surgeons had similar rates, then it more likely is the system/equipment that leads to inaccuracy; on the other hand, if there is wide variability in surgeon rates, then it must be the learning curve. Either way, caution should be exercised in making strong general statements regarding the pros and cons of computer navigation in spine surgery.

In summary, although this study was well-intentioned, conducted as a level I study, looked at all truly relevant outcome measures, and is a welcome addition to the growing literature on computer navigated spine surgery (4-11), interpretation of its findings should also be taken in conjunction with multiple other well-performed studies on this subject.

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None.

Footnote

Conflicts of Interest: The author has no conflicts of interest to declare.

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