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Clinical Study

Effect of intraoperative navigation on operative time in 1-level lumbar fusion surgery

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ABSTRACT

The use of intraoperative image guided navigation (NAV) in spine surgery is increasing. NAV is purported to improve the accuracy of pedicle screw placement but has been criticized for potentially increasing surgical cost, a component of which may be prolongation of total operative time due to time required for setup and intra-operative imaging and registration. In this study, we examine the effect of the introduction of O-Arm conical CT spinal navigation on surgical duration. We retrospectively analyzed consecutive freehand (FH) (n = 63) and NAV (n = 70) 1-level lumbar transpedicular instrumentation cases at a single institution by a single surgeon. We recorded setup and procedure time for each case. NAV was associated with significantly shorter total operative time for 1-level lumbar fusions compared to FH (4:30 +/− 0:42 hours vs. 4:53 +/− 0:39 hours, $p = 0.0013$). This shortening of total operative time was realized despite a trend toward slightly longer setup times with NAV. We also found a significant decrease in operative length over time in NAV but not FH cases, indicative of a "learning curve" associated with NAV. The use of NAV in 1-level lumbar transpedicular instrumentation surgery is associated with significantly shorter total operative time compared to the FH technique, and its efficiency improves over time. These data should factor into cost-effectiveness analyses of the use of NAV for these cases.

1. Introduction

Intraoperative image guided navigation (NAV) for spinal surgery involving transpedicular instrumentation was introduced 20 years ago in an effort to decrease the frequency of pedicle screw misplacement and resulting neurological morbidity. Numerous studies have demonstrated substantially improved accuracy of pedicle screw placement using spinal navigation when compared to freehand (FH) placement using anatomic landmarks alone (reviewed in [1]). Beyond improved accuracy, NAV can be used to verify the adequacy of spinal decompression and may tend to reduce operative blood loss [1,2]. Given these advantages, the use of NAV in spine surgery is increasing.

Early versions of three-dimensional navigation required intraoperative registration of anatomic or surface landmarks onto a preoperative scan, also known as "paired-point matching." However, registration accuracy in paired-point matching is largely dependent on identification of exact anatomic landmarks, and is thus relatively susceptible to operator error. The introduction of cone-beam CT allowed navigation based on CT images acquired intra-operatively, after surgical anatomy has been exposed, registered against fiducial markers that are fixed within the surgical field. When the images are acquired with the patient positioned on the operating room table after initial exposure, compared to navigation based on a preaquired scan, paired-point registration of individual vertebrae is not necessary, increasing the registration accuracy.

However, spinal NAV has been criticized for increasing total surgical cost, a component of which may be increased total operative time [3,4]. The effect of the use of spinal NAV on total operative time is unclear. Some authors have commented on the ease and rapidity of pedicle screw insertion with navigation [3,5], but whether the time saved on each screw insertion is sufficient to offset the time required for setup and intraoperative scanning is uncertain. Meta-analysis of the few studies examining total operative time did not support a significant difference between NAV and control cases, but these studies were limited to either cervical [6,7] or deformity [8] cases, with limited generalizability to 1-level lumbar fusion operations. Furthermore, although some have postulated a "learning curve" for the adoption of NAV technology in spine surgery [9], to our knowledge no study has reported data on how the length of operation changes with time after implementation of spinal NAV. In this study, we examine

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the effect of the introduction of O-Arm (Medtronic Sofamor Danek, Memphis, TN, USA) navigation on surgical duration of lumbar fusion procedures.

2. Methods

The study was approved by the Partners Healthcare Institutional Review Board (Protocol Number 2014P000053). All patient records used for the purposes of this study were anonymized and de-identified prior to analysis.

We retrospectively reviewed the duration of 1-level lumbar fusion surgeries before and after the introduction of intraoperative O-arm NAV. All surgeries were performed by a single surgeon at one institution. Starting 04/2012, every lumbar fusion was done with NAV. From surgical records, we obtained the time into the operating room, the surgical start and end times, and the number of levels fused, in 63 consecutive FH procedures and 73 consecutive NAV procedures. We also recorded reoperative versus *de novo* surgeries. From within this cohort, we excluded cases that included tumor removal.

The FH cases were conducted as follows: After obtaining the initial exposure, pedicle markers were inserted using standard anatomical landmarks, followed by verification with plain intraoperative radiograph in the antero-posterior (AP) and lateral planes. After pedicle screw insertion, a final set of radiographs (AP and lateral) was obtained to verify screw position.

The NAV cases were performed with an O-Arm intraoperative CT scanner. After obtaining initial exposure, a reference frame was affixed, typically on the caudal-most spinous process within the exposed surgical field. AP and lateral images were acquired to center the area of interest in the gantry. Axial images were obtained and transferred to a Stealth navigation station (Medtronic Sofamor Danek). After verification of the level and pedicle screw insertion with the aid of instruments with reference markers, another set of AP, lateral, and axial images was obtained to verify accurate placement of the screws, and in pertinent cases, the adequacy of the foraminal decompression.

In all cases, we assessed the number of levels fused, total case length (defined as the interval between time into the room and time out of the room), case setup time (defined as the time interval between time into the room and surgical start time), and total operative time. Statistical analysis was carried out with a two-tailed Student's t-test to compare these various parameters between NAV and FH cases.

3. Results

We identified 73 NAV and 63 FH consecutive cases for analysis. Of these, we excluded three NAV cases because they included tumor removal. Ultimately, we analyzed data from 70 NAV and 63 FH cases between 03/2006–05/2015. Of these, 25 (35.7%) NAV cases and 16 (25.4%) FH cases were re-operations (Pearson's chi-Squared, $p = 0.1982$).

The total operative time, defined as the time from entry into room to end of procedure, was calculated for each case. The mean +/– standard deviation total time of FH cases (n = 63) was 4:53 +/– 0:39 hours, and NAV cases (n = 70) was 4:30 +/– 0:42 hours ($p = 0.0013$) (Fig. 1).

Total operative time is a composite of setup time (time from entry into room to start of procedure) and procedural time (time from start of procedure to end of procedure). We studied the effect of NAV on these time components individually. We found no significant difference in setup time between NAV and FH cases (NAV: 0:52 +/– 0:08 hours vs. FH: 0:50 +/– 0:12 hours, $p = 0.2319$). Procedure time was significantly shorter in NAV cases (NAV: 3:39 +/– 0:41 hours vs. FH: 4:04 +/– 0:37 hours, $p = 0.0003$) (Fig. 1).

To determine whether re-operation modified the effect of NAV, we separated the data based on whether the procedure was a re-operation at the fused level. *De novo* NAV cases (n = 45) were significantly shorter than *de novo* FH cases (n = 47); (4:25 +/– 0:46 hours vs. 4:54 +/– 0:40 hours, respectively, $p = 0.0015$). Re-operative 1-level fusion cases were not significantly different in total operative time between the two groups (NAV: [n = 25], 4:40 +/– 0:33 hours vs. FH: [n =16], 4:51 +/– 0:39 hours, $p = 0.3679$).

Prior reports have postulated a learning curve in the adoption of new technology, including NAV. To identify evidence for such a learning curve in our data, we examined the trend in operating length over time. Among FH cases, there was no significant trend in total operating time across the length of time spanned by the cohort (03/2006–02/2012). Among NAV cases, there was a significant negative linear trend in total operative length ($p < 0.0001$) (Fig. 2). When we separated total operative length into setup and procedure times, we found negative trends over time for both setup and procedure time.

4. Discussion

As the use of NAV in neurosurgery increases, its impact on surgical outcomes, complication and reoperation rates, cost, and operative time will need to be examined. For common neurosurgical operations, such as transpedicular lumbar instrumentation procedures, changes in cost and operative length can have profound implications on resource expenditures across the healthcare system. NAV using the O-arm conical CT system has been previously reported to enable superior accuracy of pedicle screw placement compared to FH techniques based on identification of anatomical landmarks. Nevertheless, some have criticized NAV for spinal surgery for increasing cost and operative time. Although there has been some published data on the effect of implementation of NAV technology on operative time, to our knowledge there are no reports that ask this question explicitly with respect to 1-level lumbar fusion procedures.

In this study, we sought to determine the effect of NAV on operative time in transpedicular lumbar instrumentation procedures. We found that total operative time (including both setup and procedure time) was significantly lower with the use of NAV compared to FH surgery by a mean of 23 minutes for 1-level lumbar fusion cases ($p = 0.0013$).

We hypothesized that NAV would be more useful in re-operative cases, in which surgical anatomy may be distorted or tissue planes may be scarred or obliterated, making the identification of anatomic landmarks more difficult. Thus, we analyzed the effect of NAV separately for re-operative and *de novo* cases. Surprisingly, we found that NAV significantly shortened total operative time for *de novo* cases. Although we did not find a statistical difference between NAV and FH techniques among re-operative cases, we were likely underpowered to detect statistical significance for re-operations. We believe that a larger sample size of re-operative cases with NAV and FH techniques would have demonstrated a benefit of NAV on operative time.

We sought to distinguish between setup and procedure time in the analysis of the effect of NAV. Use of NAV is thought to prolong setup time because of the need for positioning of NAV equipment, ensuring operating room personnel are prepared, organizing additional sterilized equipment required for NAV use, and other extra preparatory steps. However, we found no significant difference between setup time in NAV and FH cases (Fig. 1). The use of NAV may prolong procedure time because of the time required to scan and register the patient intra-operatively, after the surgical anatomy is adequately exposed. Conversely, NAV