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# A Comparative Cadaver Study to Determine the Accuracy and Safety of Thoracic Pedicle Screw Instrumentation Based on Preoperative Computed Tomography Data Versus Free Hand Technique

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## 1. Introduction

The dorsal spine instrumentation with pedicle screw and rod construct has become widespread surgical procedure in treatment of degenerative spine disease, spinal deformity, trauma and tumours. The smaller diameter of thoracic pedicle and proximity of the spinal cord and great vessels increase the potential risk of screw malposition in thoracic spine especially on left side. Lateral, inferior and medial cortical breaches in thoracic pedicle can potentially yield severe clinical complication due to proximity of vital structures. Breach rates reported in the literature are as high as 40% overall and 55% in the thoracic spine. The incidence of neurological complications has been reported as up to 5%. The new and expensive technology such as three-dimensional (3D) computer assisted surgery(navigation) and computer-assisted fluoroscopy are not available in most places and requires high doses of radiation, surgical expertise, health care costs and steep learning curve. The conventional method, relying upon anatomical landmarks with liberal use of fluoroscopy (C arm), is the most commonly used technique around the world. Insertion inaccuracy and radiation exposure (for the patient, the surgical team, or both) remain drawbacks of this method. CT-guidance technique relies on the correlation of preoperative computed tomographic images with the actual surgical anatomy. These systems provide intraoperative information to the surgeon regarding instrumentation starting point, orientation, and size relative to anatomic dimensions. Few comparisons of image guidance to standard fluoroscopic techniques have been performed. In our hospital, we use fluoroscopy based free hand method without Pre Op CT assessment. The use of fluoroscopy method alone requires radiation exposure, surgical expertise. Recent reports claim that a fluoroscopy-guided system offered high accuracy and easy application. However, the superiority of either technique remains unclear in clinical application. This study will be done to analyse the accuracy of pedicle screws given by fluoroscopy method alone and Pre op CT guidance method with fluoroscopy in cadavers. We hypothesize that pre operative CT assessment will improve the accuracy of pedicle screw instrumentation using fluoroscopy method.

## 2. Aim of the Study

1. To ascertain the accuracy of pedicle screw insertion using both fluoroscopy and CT guided methods.

2. To evaluate whether CT guidance improves accuracy more than fluoroscopy which is traditionally done.

3. To correlate the pedicle screw violation in both methods in Post operative CT assessment.

4. To see whether Post operative CT assessment correlate well with morphological analysis in Cadavers.

5. To evaluate the breach rates in all thoracic pedicles and correlation with pedicle dimensions.

## 3. Materials and Methods

### 3.1. Study Design: Observational Study

The study utilized six cadavers (the cadavers were essentially trunks, with the extremities disarticulated and the head decapitated; but the spinal column with associated structures intact), which were sourced from the Department of Anatomy, S. C. B. Medical College and Hospital, Cuttack, Odisha, India. Due permission was taken from the institutional Ethics Committee (Institutional Ethics Committee Licence no. ( ). The cadavers were grouped into two groups (Gr-A and Gr-B), by first allocating an I.D. no. to it. Then Each I.D. no. was allocated a colour and a shape (i.e. Red fish, Blue star, yellow flower etc.). These shapes were cut out from coloured stiff plastic sheets and tied to the cadaver at multiple points by nylon suture, perforating the skin and deep subcutaneous tissue. Then, with the help of Microsoft Excel (version 2013), the id no's were typed in the first column randomly by the (second or third) author (Dr. Satyashree Ray), and then random numbers were created in the adjacent cells of the id no's, in the second column by the"=Rand()" function of the excel. Thus, The random nos were copied and the values were only pasted in the adjacent column cells. This is important because the random numbers change each time one clicks on the Excel sheet. After this step, the second column (column B) was deleted. Then the third column, which had now become the second, is sorted from smallest to largest number by the software ("sort" function). The software then asked permission to expand the selection. The permission was granted by clicking "o.k." and the software rearranged the I.D. no. associated with the random no's to occupy the position adjacent to the sorted configuration. Then the first three I.D. no's were allotted to group A and the second set of three I.D. no's were allotted to group B. The allotment was only known to the author, who did the allocation procedure. The surgeon and his assistant (not one of the Authors, Jyoti) were blinded to the information as to which cadaver belonged to which group. The Second author (Dr. Amit Das) knew of the allocation and was responsible for choosing the pedicle screw for group b (which had been CT scanner and the pedicle parameters were measured in radiant software and the results were tabulated in Excel in a proper format. But, Dr.amit das was not present during the operation. The appropriate screws were kept in plastic boxes and labelled as to the fact, it is meant for which vertebrae and whether it was for the left or right side. The decision of whether to use the provided screw or some other screw was left to The First author (Dr G. Amrit).

**3.2. Statistical Analysis**

Data were analysed by using Statistical Package for the Social Sciences (SPSS) version 19. Quantitative data were described as mean and standard deviation (SD). Nominal variables were presented as numbers and percentages. Chi-square test was used for cross tabulation of categorical data. P value ≤0.05 was considered statistically significant.

**3.3. Results**

In our study, there were 33 vertebrae (N=66 Pedicles, right and left) in each group [Gr-A and Gr-B, N (Total =132 pedicles)]. The distribution of the parameters as described below needed to be assessed as to whether they have little evidence to have non-Gaussian distribution or departed significantly from Gaussian distribution. The software programme JASP [1] and Jamovi [2] were used for statistical analysis. A Shapiro-Wilk test was done on the Data sets to test the foregoing hypothesis. The distribution of Pedicle width, Pedicle angle and Pedicle length as measured by RadiAnt DICOM Viewer software [2] (right and left side of Vertebra) in the Group-B cadavers, deviated significantly from normality; except for Pedicle width on the right side (Group-B) and Pedicle angle (Group-B) [Not enough evidence of distribution being non-normal at .05 level of significance]. As most distributions deviated from normality, a decision was made to use non-parametric tests for determining the statistical significance of the difference of median of the above parameters on both sides in the vertebra in Group B and utilize median and IQR to summarize the data. The median diameter of the pedicle width (rt) is 5.72 mm (4.85, 6.59) and the median pedicle width (lt) is 5.5mm (4.62, 7.04). The median pedicle angle and the median pedicle length of the right side are 17.6 degrees (15.4, 20.3) and 16.9mm (15.1, 18.2) respectively. The same preceding parameters on the left side are 19 degrees (17.3, 21.5) and 17.5 mm (15.2, 18.4) respectively. The median sagittal diameter and median sagittal angle are 9.44 mm (8.55, 10.7) and 4.3 degrees (2.8, 5.6) respectively. Wilcoxon sign rank test was conducted to know if there is any statistically significant difference in the Pedicle width in the vertebra of the right and left side in Group B and it showed that there is no significant difference in the pedicle width at .05 level of significance (W=241.5, Z=0.519, p=0.61). Similarly when Wilcoxon signed rank test was conducted on the pedicle angle and pedicle length on the right and left side of the vertebra in group B the result showed that there is a significant difference in the former at .05 level of significance (W=144.5, Z=2.43. p=.02) but no statistical difference in the latter at .05 level of significance (W=178, Z=1.61, p=.11). The Percentage Frequencies and actual frequencies of pedicle breach of pedicle screw as inferred from post-procedure CT scanning in Group A and Group B are given in Table no.2. A Chi-square test was conducted to determine if the breach of the pedicle screw (as determined in the CT scans with the help of RadiAnt software [3] has any association with the Cadaver groups (group-A and Group-B) and the association was significant at .05 level of significance [ $\chi$ 2 (1, N=132) =4.4, p=.04]. But with Yates correction, the association is not significant at a .05 level of significance [ $\chi$ 2 Yates (1, N=132) =3. 64, p=.06]. As Yates's correction is overtly conservative, we will accept the result of the first chi-square test (without Yates's correction) [4]. This implies that the preceding Cadaver groups have evidence to be associated with the frequency of breach and no breach at a .05 level of significance and the relative risk of breach in group B to group A is 0.5. Therefore as evident from this experiment, the Group B (in which CT scan was done before pedicle screwing procedure and pedicle screws chosen accordingly) had 50% less chance of Pedicle breach compared to Group A (as evident from Post procedure CT scanning). This means there is a 50% reduction in pedicle breach as inferred from the dissection of vertebrae in both groups post procedure. The NNT as calculated from the contingency table no -1 is approximately 5. This means that for one patient to benefit from the kind of intervention as adopted in group B, 5 patients need to be treated. This value is a bit larger than the value as inferred from the dissection procedure. The reason being more breaches of pedicle screws being discovered in the dissection method in Group A, which were not evident in the CT scan, post procedure and thereby increasing risk reduction value as calculated from the contingency table data of breach sta from dissection procedure. The percentage frequency of breach of the pedicle screw as inferred from dissection of the vertebrae after the procedure in group A and group B is given in table no.1 .A Chi-square test was conducted to determine if the breach of the pedicle screw has any association with the Cadaver groups (group-A and Group-B) and the association was significant at .05 level of significance [$\chi 2$ (1, N=132) =27.3, p=1.75x10 -6 ]. The effect size as measured by Phi Coefficient was 0.455, which signifies the strength of the association. The relative risk of a breach in group B to group A is 0.33. Therefore as evident from the physical dissection of vertebrae, the Group B (in which CT scan was done before pedicle screwing procedure and pedicle screws chosen accordingly) had 30 % lower risk of Pedicle breach compared to Group A(as evident from Post procedure CT scanning. This means there is a 70 % reduction in pedicle breach as inferred from the dissection of vertebrae in group B post procedure. The NNT as calculated from the contingency table no -1 is approximately 3. This means that for one patient to benefit from the kind of intervention as adopted in group B, 3 patients need to be treated (This is quite encouraging).

**3.4. Discussion**

Pedicle screw fixation has become the backbone of various spine surgeries starting with fractures, deformity correction, neoplastic lesion and almost all pathologies of spine. Even in expert hands the rate of pedicle screws misplacement may range from 5 to 41% in the lumbar spine and 3 to 55% in the thoracic spine.13,14,15,16,17 When we consider the magnitude of medial pedicle violation, a value of more than 4 mm put the medial neural structures under high risk of injury. A value up to 4mm is considered low risk for damage to medial neural structure and breach below 2 mm is considered in the ‘‘safe zone’’ in terms of neural damage.13 Despite those measurements there is no consensus in the literature regarding the safe zone for pedicle screw placement. So, until studies absolutely prove the safe zone concept, the pedicle screws must ideally be completely contained within the pedicle without any breach.18 The techniques used to insert pedicle screws can be broadly divided into free hand technique and imaging guided technique. The free hand technique can be further divided into drill guided and pedicle gear shift probe technique. The imaging guided technique can be further divided into fluoroscopic assisted, intraoperative navigation and robotic assisted technique.18 Each of the techniques have its advantages and disadvantages. 2D fluoroscopy gives an idea about both entry point and trajectory. While some literatures have reported the accuracy of fully contained pedicle screws from 28% to 85%, a few literatures have reported it to be around 68.1% with the use of intraoperative fluoroscopy.19,20 3D fluoroscopy merges many serial pictures to give a three-dimensional picture which increases the accuracy to 95.5%. Intraoperative navigation surgery also called computer-assisted surgery combine markers and preoperatively acquired images to guide the surgeon with real time anatomy of patient. But the disadvantage is that if the patient’s posture changes due to any activities intraoperatively or even due to breathing movements of the patient than the real time picture does not confirm with actual anatomy of patient. Before any procedure using navigation, the instruments need to be registered for optical or electromagnetic tracking. Any deviation in this tracking reduces the accuracy of screw placement. The latest robotic assisted technique, promises increased accuracy, decreased potential surgical complications, and reduced intraoperative radiation exposure. Ejovi Ughwanogho et. al. divided the pedicle screws into three types of optimal screw, acceptable screw, and potentially unsafe screw. Optimal screw is the one which has its central axis in the plane of pedicle and axis of the pedicle with the tip completely within the vertebral body. Acceptable screw is the one whose majority of shank is outside the central axis of the pedicle, but not potentially unsafe. Potentially unsafe screw is defined as the screw where the central axis of the screw traversed the spinal canal, left anterior/lateral vertebral body perforation where it risks the aorta, or any screw repositioned or removed after the post-operative computed tomography scan.21 With computed tomography guided technique 74% screws were found optimal, 23% screws were acceptable and only 3% screws were potentially unsafe but in case of non-navigated technique the number of screws in each group were 42%, 49% and 9% respectively. It was further found that with the use of navigation the likelihood of a potentially unsafe screw was reduced by almost 3.8 times. Without the use of navigation, the risk of medial wall breach and the risk of intra-operative removal of screw were around 7.6 times and 8.3 times higher as compared to with the use of navigation. All the three incidences were found potentially significant as indicated by their p values [21]. The use of intraoperative navigation definitely benefitted the accuracy of pedicle screw placement, which was found to be statistically significant, but the same significance could not be replicated in terms of neurological complications, rate of spinal fusion after surgery, post-operative pain relief and objective benefit when assessed using various health outcome scores [22]. A further advance technique after navigation is Robotic surgery. The robot guides the surgeon with the proper trajectory for screw placement in terms of sagittal and coronal orientation based on a preoperative plan where all the measurements were done using computer software. It does not replace the surgeon and has advantage in patients with difficult anatomy and increases the feasibility, accuracy, and efficiency of the fixation [23]. The patient’s normal vertebral anatomy was assessed by doing a preoperative CT scan with robotic surgery protocol and the data was registered in the computer. The robot follows the data and guides the surgeon for screw insertion. The robot might or might not use intraoperative navigation depending upon its manufacturer [24]. The use of robotic guided technique to insert pedicle screw results in about 83.4% when compared to 76% accuracy using freehand technique. The number of non-misplaced screw as per Gertzbein-Robin scale was about 93.4% in robot assisted versus 88.9% in the free hand technique [25]. Though the figure in terms of percentage of screws looks higher in the robotic group many studies could not conclude that the figures are actually statistically significant [26,27]. So, apart from robotic surgery the various other techniques include the freehand fluoroscopy-guided technique and intraoperative image-assisted computer navigation techniques, including isocentric C-arm (Iso-C) 3D (3-dimensional) navigation, computed tomography (CT) navigation, O-arm navigation, CT-magnetic resonance imaging co-registration technology, and a 3D-visual guidance technique etc which were developed by different manufacturers [28,29,30]. Our study was conducted at a tertiary care Government institute where the modern techniques of 3D fluoroscopy, navigation, O arms or robot are not available. The pedicle screw fixation is done using intraoperative fluoroscopy (C-arm) assisted technique which is followed in most of the set-ups. We found 74.72% accuracy in our study which is comparable with the result found in other studies and the number of significant misplaced screws were around 6% with no postoperative neurological or vascular deficit in any of the patients. There was significant postoperative improvement in patients with incomplete spine injury Grade B to E as per SNCSCI classification or ASIA grading.

## 4. Conclusion

The use of intraoperative fluoroscopy (C arm) to confirm the starting point and the trajectory of pedicle screw placement is widely practised in most of the orthopaedics and spine centres. Some centres have started using advanced techniques like intraoperative image-assisted computer navigation techniques, including isocentric C-arm (Iso-C) 3D (3-dimensional) navigation, computed tomography (CT) navigation, O-arm navigation, CT-magnetic resonance imaging co-registration technology, 3D-visual guidance technique and Robot guided systems. The superiority of those modern equipment over the traditional free hand technique and free hand with C arm assistance has not been clearly proven in various studies available in literatures. So, till the use of advanced equipment become widespread, in expert hands the current technique can be relied upon for both accuracy and safety of pedicle screw placement which can benefit a major part of patients with spinal pathologies with less economic burden. Further studies must be carried out to establish the practical benefit of different techniques which can guide the policymakers to choose the appropriate system to cater to the need of patient population.

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