Is Free Hand Technique for Pedicle Screw Insertion Safe in Setup Lacking Advance Navigation System?

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ABSTRACT

Objective: To determine the safety of pedicle screw fixation of the spine by free hand technique in terms of screw malposition and screw related post-operative complications.

Methods: This descriptive study was conducted in Orthopedic department Lady Reading Hospital Peshawar Pakistan from 23rd April 2017 to 23rd March 2020.Patients of either gender and age operated with pedicle screw fixation of the spine by free hand technique using universal entry point were included. Post-operative radiographs of the spine were utilized for screw position. Patients with malposition radiographic screws and those with screw related post-operative complications were screened with CT scan of the spine. CT based position of the pedicle screw was classified as per Zhang classification as type 0 (good), type 1 (Acceptable), type 2 (Unacceptable) and type 3 (Grievous). Revision surgery was performed for symptomatic pedicle screws and type 2 and type 3 malposition screws.

Results: The total number of patients enrolled in our study were 96. Mean age was 34.20±9 years (range 10 to 70 years). Male patients were 45(46.9%) and female 51(53.1%). Total number of screws were 717 with maximum number of screws (n=425, 59.27%) in lumbar spine followed by thoracic spine (n=250, 34.87%) and sacral spine (n=42, 5.86%). Radiologically 684(95.40%) screws were within the pedicles and patients were without any symptoms while 33(4.6%) screws were malposition. CT scan classified 29(4.0%) malposition screws as type 1 but the patients were asymptomatic. Only 3(0.4%) screws in two patients were symptomatic type 2 and revision was done. No screw related vascular or visceral complication was reported.

Conclusion: Free hand technique of pedicle screw fixation using universal entry point is a safe and reliable method in the absence of advance navigation system. Thorough knowledge of the spine, anatomy of the vertebrae and surgeon's experience are however mandatory for safe placement of pedicle screw with free hand technique.

Keywords: Accuracy, Free hand technique, Fluroscopy, Navigation system, Pedicle Screw, Safety, Spine.

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INTRODUCTION

Pedicle Screws and rod fixation is a modern technique of internal fixation in traumatic, degenerative and deformity of the spine for obtaining rigid fixation, biological union and minimizing complication of pseudoarthrosis.[1] Although there are various techniques of pedicle screw insertion but focusing on the safe zone of insertion to avoid iatrogenic injury to the spinal cord or nerve roots is of paramount importance.[2] Free hand technique, fluoroscopic, CT guided and computer assisted navigation system are various methods for pedicle screw insertion.[3,4] CT guided and computer assisted navigation system has high accuracy rate.[5] CT guided insertion of pedicle screws however has hazard of radiation exposure.[6] Computer assisted and robotic

techniques are technically demanding, more time consuming and expensive hence not feasible to use in developing countries.[7] Many surgeons use anatomical land marks for inserting pedicle screws with free hand technique but there are some variations in all techniques resulting in variable accuracy.[8] Many studies [9,10] reported that free hand technique is a safe, accurate and reliable method of pedicle screw insertion for fixing traumatic, degenerative and deformities of the spine. A systematic review[11] revealed a surgical time of 257.7 minutes and a complication rate of 1.6% of pedicle screw insertion utilizing per operative image guided system versus surgical time of 226.8 minutes and complication rate of 1.7% with free hand technique.

Our hospital lacks advanced navigation system for pedicle screw insertion and we used free hand technique using universal entry point and fluoroscopic control. The objective of our study was to determine the safety of pedicle screw fixation of the spine by free hand technique in terms of screw malposition and screw related post operative neurological, vascular or visceral complications

METHODS

This descriptive study was conducted in Orthopedic department Lady Reading Hospital Peshawar Pakistan from 23rd April 2017 to 23rd March 2020. Patients of either gender ad age with transpedicle screw fixation for trauma, deformity and degenerative spine were included. Patients with tumours, metastasis, infection and revision surgery were excluded. The study was approved by the Ethical Committee of our hospital. Informed written consent was taken from all participants. In the included subjects complete history, physical examination and investigations(AP and lateral Radiographs of the spine and MRI) were done and patients were prepared for pedicle screw fixation.

Surgical Technique

All the surgeries were performed under general anaesthesia with patient prone on radiolucent operating table. Through a midline longitudinal incision of appropriate length posterior elements were exposed. The pedicle screws in cervical, thoracic and lumbosacral spine were passed by free hand technique utilizing universal entry point proposed by Zhang.[12] We adopted this technique because it was easier to learn, taught and adopted. In this technique the junction of the lateral margin of superior articular process and lateral mass for cervical spine and transverse process for thoracic and lumbosacral spine was identified. The entry point(Universal Entry Point) for pedicle screw was 1mm caudal and medial to this junction point for cervical spine,2 mm for thoracic spine and 3 mm for lumbosacral spine(average 2 mm for all).The axial and sagittal trajectories were perpendicular to the axial and sagittal planes of the laminae of isthmus. This universal entry point is located at 1 o'clock and 11 o'clock on the axial view of the pedicle. The cortical bone at the entry point was breached with an awl. The pedicle was cannulated to an appropriate depth with the help of a blunt gearshift keeping in mind the axial and sagittal trajectory. A feeler with a ball-ended tip was inserted to confirm any pedicle breach. An appropriate size pedicle screw was inserted after probing and tapping.

After recovery from anaesthesia patients were assessed clinically for any screw related neurological, vascular and visceral complications and AP and lateral radiographs were ordered. The radiographic assessment of screw placement was performed by two senior Orthopaedic surgeons who were not part of the study team. Patients with malposition radiographic screws and those with screw related post operative complications were screened with CT scan of the spine for confirmation of screw malposition. CT based position of the pedicle screw was classified as per Zhang[12] into four types as follows:

I. Type 0 (Good): The pedicle screw was inside the medullary canal of the pedicle
II. Type 1 (Acceptable):Minimal(< 2 mm) perforation of the pedicle cortex was noted.
III. Type 2 (Unacceptable):The pedicle was perforated(2 to 4 mm) or less than half of the diameter of the pedicle screw was outside the pedicle cortex.
IV. Type 3 (Grievous):The pedicle was perforated(> 4 mm) or more than half of the diameter of the pedicle screw was outside the pedicle cortex.

Symptomatic pedicle screws and type 2 and type 3 pedicle screws were revised. Patients were regularly followed in OPD for one year. The data was analyzed with the help of SPSS version 27. Frequency and percentage was calculated for qualitative variables while quantitative variables were represented as mean and standard deviation. A comparison of screws that were inside the pedicle with those that had breached the pedicles was done and *P* value calculated with Chi-square test. P value < 0.05 was considered significant. The data was presented in table where necessary.

RESULTS

The total number of patients in our study were 96. Mean age of the patients were 34.20±9 years (range 10 to 70 years). Majority(53.1%,n=51) of our study participants were female while males were 45(46.9%). Total number of screws were 717 with maximum number of screws (n=425,59.27%) in lumbar spine followed by thoracic spine (n=250,34.87%) and sacral spine (n=42,5.86%).Traumatic spine fixation accounted for 43 (44.8%) patients followed by 27(28.1%) cases of degenerative spine disease and 26(27.1%) cases of spine deformity. We found that radiologically 684(95.40%) screws were within pedicles and patients were without any symptoms while 33(4.6%) screws were malposition. (P value < 0.05) Out of these 33 screws 22(66.6%) screws were in the thoracic spine while 11(33.3%) screws were in the lumbar vertebra. CT scan classified 29(4.0%) malposition screws as type 1 but the patients were asymptomatic. Only 3(0.4%) thoracic screws in two patients had caused neurological deficit (type 2) and revision was done with restoration of neurology. No screw related vascular or visceral complication was reported.

DISCUSSION

In our study the pedicle screw malposition rate with free hand technique was 4.6%. We found variable rates of pedicle malposition rate in literature.(table I).

Table I: Review of literature showing percentage of malposition pedicle screws with free hand Technique.

S. No	Name of Author	Year of Study	Percentage of malposition pedicle screws with free hand Technique
1	Kim YJ9	2004	6.2%
2	Fisher et al13	2006	33.8%
3	Schizas C14	2007	11.6%
4	Karapinar L15	2008	5.8%
5.	Mod H10	2009	9.3%
6.	Samdani et al16	2010	12.1%
7.	Parker SL17	2011	9%
8.	Silbermann J18	2011	5.9%
9.	Su P19	2012	6.5%
10.	Hojo Y20	2014	14.8%
11.	Fennell VS21	2014	4%
12	Vijayeswaran N22	2019	4%
13	Junaid M 2	2019	3.4%
14.	Zhang ZF12	2020	1%
15.	Our study	2020	4.6%

The possible reasons for these variations are the individual differences in free hand techniques, surgeon's experience, spine pathologies and segment of the spine involved. Hojo and Ito[20] demonstrated that free hand pedicle screw fixation of cervical spine had a higher malposition rate in patients with rheumatoid arthritis (26.8%) than with spondylotic (16.6%) and traumatic spine(11.2%).These authors advocated the use of image guidance for accurate placement of pedicle screws in cases of rheumatoid arthritis and spondylotic pathologies of the cervical spine. Accurate placement of pedicle screws with free hand technique can be difficult in deformity correction of the spine as the superior articular process and transverse process are usually abnormal in size and distorted in shape due to deformity and rotation rendering exact entry point extremely difficult.12 Rajan [23] in his series of 100 screws noted a cortical breach in 12% in free hand group and 10% in free hand supplemented with intra operative fluoroscopy. The results were however not statistically significant. The average number of fluoroscopic shots for passing each screw was 7 minutes. Each screw inserted with free hand technique without fluoroscopy consumed 2 minutes less that inserted under C-arm. This difference in time consumption was however statistically significant.

In our study majority (66.6%, n=22) of the malposition screws were in the thoracic spine followed by lumbar spine (33.3%,n= 11). Fischer *et al*[13] reported 33.8% malposition rate of pedicle screw

in thoracic spine and Schizas[14] documented 11.6%.Free hand pedicle screw fixation of the upper and middle thoracic vertebra is challenging because of many factors. These include smaller size of the thoracic pedicle, smaller diameter of the spinal canal, variations in pedicle axis and angle of pedicle body, fear of fracturing the pedicle and adherence of the thoracic viscera to the anterior longitudinal ligament.[24]

Only 3(0.4%) thoracic screws in two patients had caused neurological deficit (2 to 4 mm medial cortical breach, type 2) in our study for which revision was done and neurology was restored. Studies [25,26] had demonstrated that no neurovascular complications occurred when pedicle screw perforation was less than 2 mm. Neurological complications due to malposition pedicle screws were only manifested when more than 4 mm of medial pedicle wall had been perforated.[27] Kim[9] has proposed that if there are no abnormal electrophysiological signals a medial cortical breach within 2 mm is considered as a Definitive Safe Zone,2 to 4 mm is Probable Safe Zone while 4 to 8 mm is Questionable Safe Zone. Gertzbein[28] believed that medial breach within 4 mm (grade 0 to 2) is within safe zone while beyond 4 mm (grade 3) is dangerous.

Descriptive design, small sample size and no cervical cases were the possible limitations of our study. We recommend further studies to confirm our results.

CONCLUSION

Free hand technique of pedicle screw fixation using universal entry point is a safe and reliable method in the absence of advance navigation system. Thorough knowledge of the spine, anatomy of the vertebrae and surgeon's experience are however mandatory for safe placement of pedicle screw with free hand technique. Adjuvant techniques like intraoperative fluoroscopy, navigation and neurophysiological studies when available must be used to enhance the accuracy of pedicle screws and to avoid complications.

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