Prospective study: Early complications and short term neurologic outcome following posterior thoracolumbar pedicle screw fixations at two Ethiopian teaching hospitals, Addis Ababa, Ethiopia.

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ABBREVIATIONS

A.A: Addis Ababa.

AAU: Addis Ababa University.

ALERT: All African Leprosy Rehabilitation and Training Center.

CT: Computed Tomographic.

ER: Emergency Room.

HAI: Hospital Acquired Infection.

MCM: Myungsung Christian Medical Center.

MVA: Motor Vehicle Accident.

PSF: Pedicle Screw Fixation.

SSI: Surgical Site Infections.

TL: Tharaco-Lumbar.

UTI: Urinary Tract Infection

SNNP: Southern Nations, Nationalities and Peoples.

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ABSTRACT

BACKGROUND: Pedicle screw fixation is a well-known and increasingly performed technique to achieve fixation and fusion especially in thoracolumbar region. This technique is used for variety of indications. Despite technical advances in screw fixations complications can happen intraoperative or postoperative, and still PSF is associated with a risk of complication.

OBJECTIVE: To assess early complications and short term neurologic outcome following thoracolumbar pedicle screw fixations at two Ethiopian teaching hospitals.

METHODS: One year hospital-based prospective descriptive study was conducted on 68 patients that underwent posterior thoracolumbar pedicle screw fixation and fusion at ALERT and MCM hospitals from September 2019 to August 2020. To determine the existence and level of association between independent and dependent variables bivariate Pearson´s correlation analysis was done, and multiple regression analysis was also done to identify the existence of statistically significant association between independent variables and neurologic status at 3rd month.

RESULTS: 52 male and 16 female patients were included. The mean age was 31.79. Indications for hardware placement were trauma - 82.4 % (56 patients), degenerative and spondylolisthesis - 11.8% (8 patients), tumour - 2.9% (2 patients), infection - 1.5 % (1 patient), and one patient L2 screw fracture (previously PSF was done). A total of 351 screws were inserted. Most screws (76 screws - 21.7%) were inserted at the level of T12. Determined accuracy rate screws inserted was 88.0%, with screw malposition rate of 12%. Highest number of breech was found at the level of T12 - 9 breeches. Medial breech was the commonest (47.6 % of breeches, 20 screws), followed by anterior breech (38.09 %, 16 screws).

Intra-op complications happened for 16 patients (23.5%), 8 were intra-op CSF leak, 7 - intra-op pedicle fracture, and one nerve root injury. Early post-op complications that happened during hospital stay were one deep SSI, two UTI, three HAI, and five bed sores. Complications after discharge were two superficial SSI, two UTI, seven additional bedsores. Revision surgery was done for two patients (2.9%).

On neurologic evaluation at third month, 72.9% of patient (35 patients) were neurologically the same, 14.6% (7 patients) had some improvement, and 12.5% (6 patients) had significant improvement. The majority of patients 87.9% did not receive physiotherapy.

With 95% CI, only the presence of associated other site of injury (P=0.02) and lower extremity power status (P=0.02) have moderate correlation with the development of in-patient complications with r value of .404 and .362 respectively. On multiple regression analysis pre-op sensory level has a negative and significant effect on neurologic outcome at third month (standardized beta = . -1.690).

CONCLUSIONS: Trauma was the commonest indication for fixation. Based on our result finding posterior thoracolumbar pedicle screw fixations and fusions with can be done with acceptable complication rate and good recovery considering the limited resources. Since our follow-up period was only 3 month, we recommend further follow-up study of these patients for assessing late instrument related complications.

1. INTRODUCTION

1.1. Background and Statement of the Problem.

Pedicle screw fixation (PSF) is a well-known and increasingly performed technique to achieve fixation and fusion especially in thoracolumbar region. This technique is used for variety of indications including traumatic fractures, neoplastic, infectious, degenerative, and deformations associated with axial instability. PSF is also preferable and superior in biomechanical properties, fusion rate, early mobilization and versatility.[1]

PSF for spinal fixation were first described by King in 1944.[2] Dick, Roy-Camille, Steffee and Louis further develop and popularized this concept. [3, 4, 5, 6] Despite the technical advances in screw fixations, early complications following pedicle screw fixations can still happen either intraoperatively or postoperatively.[7]

Pedicle screw related complications includes infectious, post-op neurologic deficit, or implant failures like screw malposition, breakage or loss of correction. Nerve root irritation from medial angulation of the screw is also commonly reported. Rarely neurological, visceral, or vascular complications are also reported.[7]

Pedicle screws can be inserted using imaging guided or using free hand techniques by using anatomic landmarks. Even though in the experienced hands pedicle screw fixation is a safe procedure for treating various diseases of the spine, minor differences in instrumentation technique may affect the outcome.[22] The introduction of different image-guided imaging systems has led to dramatic reduction in post-op screw malposition rates, and usage of these imaging guided screw insertions are recommended in difficult cases like scoliosis surgery, and revision surgeries.[8, 20]

Post-op surgical site infections following PSF may be superficial, or deep. Superficial infections usually manifested earlier than deep and hardware infections. Among the studied factors increased operative time was mainly associated with increased risk of post-op infections.[14] Old age, underlying medical conditions, multilevel fixations are also associated with increased risk of post-op complications.

Also there are no systematic Ethiopian studies published literatures done on the complications and risk factors for complications related to spine instrumentations. This study will assess early complications and risk factors related to PSF in our setup and complications can be compared with other series, adding some input to fill this gap

1.2. Significance of the Study.

Since the establishment of neurosurgical training program in 2006, PSF has been used for various indications in our setups. [9] Commonly indicated for traumatic spine injuries but also rarely for degenerative spine conditions, post-surgical management of spine infection, and post-spine tumor excision. Comparing to developed countries with a long years of experiences, spine fixations started to be experienced recently. And one of the aim of this study is to assess the overall complications and short-term post-op neurologic outcomes following thoracolumbar pedicle screw fixation that can be compared with studies published in the developed countries.

Mix up of different sizes and systems of screws on the same patient is also common due to shortage of screws. This study will also assess intra-op and post-op instrument related complications giving some input for assessing the safety such practices in these setup.

Rehabilitation centers are not widely available in our setups. This paper will also assess the rate of post-op physiotherapy for those in need, and give some input for further improvement of our rehabilitation centers and practices.

Late complications of screw fixation also described in many literatures, and the subject of this study can also be followed and studied for assessing late complications related to PSF in these setups.

2. LITERATURE REVIEWS

On a retrospective study between January 2008 and September 2012, the outcome of 146 patients undergoing surgery for spinal injury at MCM in Addis Ababa, Ethiopia were reviewed.[11] The mean age was 31.7 years, majority (88.4%) of patients were male. The most common cause of injury was MVA (54.1%), followed by falls (26.7%). 44 patients had associated injury. Before surgery 21.2% of patients had no neurological deficit, 46.6% had incomplete spinal cord injury and 32.2% had complete spinal cord injury. Posterior thoracolumbar fusion with pedicle screw fixation was done for 96 patients (65.8%). With the mean follow-up time of 22.9 months, 34.7% showed substantial improvement, and 42.9% had no neurological improvement. 22.5% had pressure wounds, 13.5% reported recurrent UTIs, 5.6% reported pneumonia, and only 1 patient (1.1%) reported a thromboembolic event. 46.4% received post-op physiotherapy.[11]

Institution-based retrospective study was conducted on surgical treatment outcome of traumatic TL fracture in 65 hospitalized patients from November 1, 2013-December 31, 2016 at Tibur Anbesa specialized hospital and ALERT, Addis Ababa, Ethiopia.[12] The mean age of the study participants was 29.11years. The time gap between injury and surgery was more than 48 hours for 63.1% and the median time gap between injury and surgery was 144 hours. Fall from height was the most common cause of injury. Thoracolumbar junction (T11 to L2) was the commonest site of trauma (72.3%). The predominant type of bony lesion in this study was burst fractures (38.5%), followed by fracture dislocation. Fracture pattern and initial sphincter function were found to be significantly associated with treatment outcome of traumatic thoracolumbar spine fractures.[12]

To identify and quantify the pedicle screw-related complications, 105 consecutive primary transpedicular lumbar and lumbosacral fusions (37 single-level fusions and 68 multiple-level fusions 2–7 levels), were analyzed (45 male and 60 female) retrospectively.[13] In 21 patients PLIF and in 7 patients ALIF was also performed. The mean age at the time of operation was 52 (range 18–79) years. In spite of antibiotic prophylaxis, they found a 4.7% deep infection rate, Culture results revealed Staphylococcus aureus in four cases and Staphylococcus epidermidis in one case. Screw misplacement was found in 6.5% of the screws, no a correlation between misplacement of the screw and neurological complications. In 13 patients (12.1%) 18 screws were found to be broken (3.4%), statistical analysis found significantly more broken screws in incompletely instrumented fusions and multilevel fusions, sacral fusions. We performed hardware removal for persistent pain in ten patients.[13]

The complications of 648 consecutively inserted pedicle screws (140 - thoracic and 508 lumbar) were studied on a prospective study on 91 patients. [14] The study was relied on pre and postop radiograph for assessment of screw misplacement. To determine intra and interobserver reliability, the main author (observer 1) and two senior spinal fellows evaluated 111 pedicle screws from AP and lateral radiographs on 2 separate occasions, even if there was no significant difference between the observers for either 1st or 2nd evaluation of pedicle screws. The overall complication rate of pedicle screw instrumentation was 13%. Intraoperative complications consisted, pedicle fractures (two pedicles in one patient), Cerebrospinal fluid leak (two cases), Screw misplacement (three cases), one patient had sensory L5 root changes, this settled within 3 weeks. Postoperative complications consisted of: Deep wound infection (five cases), Screw loosening (two cases, Screw-rod disconnection due to technical error (one case). And increased operative time was significantly associated with increased infection rate. [14]

Forty-seven patients with degenerative lumbar scoliosis undergoing decompression and fusion with pedicle screw instrumentation were evaluated retrospectively with a minimum “2 years” follow-up. The operations were performed by 2 surgeons at 2 institutions. Patients with a history of hypertension, diabetes, heart disease, pulmonary disease, gastrointestinal disease, and kidney disease were considered to have medical comorbidities. They categorized complications as early perioperative (3 months after surgery) and late (complications happened after 3rd month). There were 14 early perioperative complications and 18 late complications. Logistic regression analysis showed that excessive intraoperative blood loss was the most significant risk factor for the development

of early perioperative complications. Early perioperative complications also occurred more frequently in patients older than 65 years, and patients who had arthrodesis of more than 5 vertebrae. Sex, smoking, number of medical comorbidities, and operative time were not associated with the development of early complications. [15]

Different scales used in literatures as a tool for assessing screw positions. Gertzbein scale is the most widely used scale, in which cortical breaches are described by the extent of extra cortical screw violation. (16) This scale has four grades (graded 0-3), Grade0 = fully contained within a pedicle with no evidence of cortical breach, Grade1 = < 2mm, Grade 2 = 2-4mm, and Grade 3 being >4 mm cortical breach. Gertzbein and Robbins, in their series of 67 patients analyzes 167 pedicular screws, reported two minor neurological complications that spontaneously resolved. [16]

A later study by University of Michigan Medical Center; Youkilis et al. slightly altered this classification to specify three different grades: Grade 1 screws did not show evidence of pedicle breach, Grade 2 screws breached 2 mm or less, and Grade 3 screws were those that breached more than 2 mm. Grade II and Grade III screws were considered true cortical violations. In this review of the 224 image-guided thoracic pedicle screws, there was 19 cortical violations (8.5%), and statistical analysis revealed a significantly higher rate of cortical perforation in the mid-thoracic spine (T4–T8, 16.7%; T1–T4, 8.8%; and T9–T12, 5.6%), the use of image-guided techniques was recommended for the placement of thoracic pedicle screws at this levels. [17]

Placement of pedicle screws can be done on free-hand (reliant on pre-operative imaging and intra-operative anatomical landmarks) or assisted with either fluoroscopy or stereotactic navigation technology, designed to decrease the breach rate and improve pedicle screw placement accuracy. High accuracy rates reported with each of these three core techniques. However, due to differing definitions of breach and varying radiographic analyses, it is extremely difficult to compare studies side-by-side to determine which techniques are superior. Screws placed in the mid-thoracic spine and/or in spines with significant deformity should be guided stereotactically to ensure accuracy. [18]

A meta-analysis investigating studies published between 1990 and 2009 demonstrated that 89.2% of 7533 pedicle screws were placed accurately. Between studies, assessment of screw accuracy varies significantly, which adds difficulty when interpreting and comparing them. [19]

Another meta-analysis with 130 studies involving a total of 37,337 pedicle screws by Kosmopoulos and Schizas, specifically looking at accuracy of pedicle screw placement with different found a mean misplacement rate of 8.7%.[20] 7,533 pedicle screws were summarized with 6,721 screws accurately inserted into the pedicles (89.22%). The median, minimum and maximum accuracies of literatures that used intra-op 2D floroscopy was found to be 86.51%, 72.73%, and 96.05% respectively.

A recent CT analysis, retrospective analysis of freehand thoracic pedicle screws placed by neurosurgery residents demonstrated a 15% breach rate of thoracic pedicle screws when placed by neurosurgery residents, a rate that is comparable to reported accuracies, there was no clinically evident neurovascular complications and it was suggested that under appropriate supervision neurosurgery residents can safely place freehand thoracic screws with an acceptable breach rate. [21]

On a large study published on 2011 by Department of Neurosurgery; Johns Hopkins University, with "7-years institutional experience" with placement of pedicle screws in the TL spine, a total of 964 patients received 6816 free-hand pedicle screws Degenerative/deformity disease was the commenset indications for fixation (51.2%), followed by spondylolisthesis (23.7%), tumor (22.7%), trauma (11.3%), infection (7.6%), and congenital (0.9%). Mean age was 56.1 (6 15.0) years. Most patients presented with mechanical back pain in 522 patients (50.0%), followed with myelopathy (43.3%), with radiculopathy (40.2%), motor-associated symptoms (45.5%), sensory-

related symptoms (10.5%), with bowel or bladder dysfunction (9.2%). Breach was defined as more than 25% of the screw diameter residing outside the pedicle or vertebral body, a total of 115 screws (1.7%) in 87 patients (9.0%) had a breach on post op evaluation. Breach occurred more frequently in the thoracic than the lumbar spine (2.5% and 0.9%, respectively), with T4 (4.1%) and T6 (4.0%) had the highest breach rate, whereas L5 and S1 had the lowest breach rate. Image-guided assistance was recommended when placing screws between T4 and T6. Breach was more often lateral (61.3%) than medial (32.8%) or superior (2.5%). The mean (6 SD) length of hospitalization after surgery was 10 (6 12) days. Perioperative complications included 45 durotomies (4.3%) with intraoperative CSF leak, 23 surgical site infections (2.2%), and 14 pulmonary emboli (1.3%). Eight patients (0.8%) underwent revision surgery to correct misplaced screws. [22]

Hundred patients underwent transpedicular screw within 4 years period on Turkish retrospective study published on Cukurova Medical Journal on 2018. [23] Mean age of the patients was 49 years, 57 patients being male. A total of 692 transpedicular screws were applied for 45 patients (45%) with traumatic TL fractures, 18-spinal tumor, 17-spondylolisthesis, 11-spinal stenosis, 7-spinal infections, and 2-LDH. And of these total screws most (75 screws) were inserted for L2 pedicle, 82 screws (11.85%) were evaluated as malposition, and graded according to Gertzbein classification in which 20 screws were grade 1, 44 screws were grade 2 and 18 screws were grade 3. Medial and lateral perforation was common (39 and 38 patients respectively) than anterior and inferior perforations. There was a tendency of screw malpositions in the thoracic levels most frequently seen as medial pedicle wall perforations (Of the 39 patients who had medial malpositions, 24 screws were at the thoracic levels). 7 patients had post-op wound infection, 4 patients had dural tear and cerebrospinal fluid (CSF) fistula and Revision surgery was done for 5 patients had root compression related to screw malposition. [23]

On a Prospective study conducted in India, 30 patients who underwent free hand posterior thoracic instrumentation from May 2015- May 2016, was analyzed. [24] The mean age was 39 years. The etiologic diagnoses were - spinal trauma-22, spinal tuberculosis-05, spinal deformity-02, and spinal tumour-01. Screws were evaluated by two observers, and of a total of 168 polyaxial titanium screws were inserted, 24screws (14.28%) of screws were malpositioned, and 3 screws (1.78%) considered to have critical medial breach of more than 2 mm perforation. By performing multiple regression analysis the commonest perforation was lateral wall perforation (6.54%), followed by medial perforation and commonest pedicle having perforation was at level of T9 (29.10% of perforations), followed by T7 (25.00%). In 3 patients sudden give away was felt during gear shift probing and a breach confirmed on palpation/probing and the screw was re directed intraoperative, none of these redirected screws showed breach on the postoperative evaluation. [24]

At a single teaching hospital, Iran, a retrospective study on accuracy and complications of pedicle screw insertion for lumbar and thoracolumbar fractures conducted on 2013. (25) A total of 216 pedicle screws inserted with 15 months period on 52 patients. 34 were males, mean age 32.6±5.8 years), most screws inserted at level of T-12 (38), followed by T-11 (36). The mean duration of surgery was 197±34 minutes. The overall length of stay at hospital was 10.9±4.8 days. The results based on Gertzbein and Robbins scale was graded A (n=43 [19.9%]), B (n=89 [41.2%]), C (n=62 [28.7%]), D (n=21 [9.7%]), and E (n=1 [0.5%]). Grade A and B considered clinically acceptable, and for grade C, D, and E screw malposition was considered which constitutes 38.9% of patients. One of the screws was revised on the second day after surgery due to significant screw malposition. [25]

3. OBJECTIVES

3.1. General Objective

To assess early complications and short term neurologic outcome following thoracolumbar pedicle screw fixations.

3.2. Specific Objective

To assess common indications for thoracolumbar pedicle screw fixations.

To describe intra-op and early post-op complications following thoracolumbar pedicle screw fixations.

To assess the prevalence of post-op cortical breach rate, and to determine accuracy rate of screws inserted.

To identify factors associated with the development of early perioperative complications.

To assess the short term neurologic outcome following PSF for traumatic indications.

To assess factors associated with short term neurologic outcomes.

To evaluate the accessibility of physiotherapy services on early post-op periods

4. METHODOLOGY

4.1. Study Design and Setting

One year hospital-based prospective descriptive study on patients that underwent posterior thoracolumbar pedicle screw fixation and fusion was conducted at ALERT and MCM hospitals from September 2019 to August 2020 G.C.

ALERT hospital is one the largest governmental hospital in A.A, and since its trauma center was opened with a collaboration with Federal Ministry of Health (FMOH) in 2015, it is one of the neurosurgical training sites that gives general neurosurgical services including surgical management of spine traumas. Myungsung Christian Medical Center (MCM) is a private hospital at which a number of spine surgeries including spinal fixations are performed, and it is also one of the neurosurgical training sites.

4.2. Study Population

All patients that underwent posterior thoracolumbar pedicle screw fixation and fusion during the study period mentioned above, and that fulfills the inclusion criteria's listed below were included in the study.

4.3. Inclusion Criteria

All patients that underwent thoracolumbar pedicle screw fixations following traumatic spinal cord injury, following surgical management of degenerative disc diseases, spine tumors, spine infections and that have provided informed consent and willing to comply with study treatments were included.

4.4. Exclusion Criteria

Subject who does not consent for the study treatment, and subjects underwent screw fixation for correction of spine deformities and congenital abnormalities were excluded.

4.5. Sample Size Determination and Sampling Technique

The sample size for the study was determined using the formula described below was 77.

$$n = \frac{(Z\alpha/2)^2 P(1-p)}{d^2}$$

Where: n = required sample size, Z α/2= Critical value=1.961.
p= 50%: Since there is no similar study published in our country, P-value was taken as 50%.
d = precision (marginal error) = 0.05

$$\text{Therefore: } n = \frac{(1.96)^2 \text{ X } 0.5(1-0.5)}{(0.05)^2} = 384$$

$$nf = \frac{n}{[1 + n/N]} \quad \text{and} \quad nf = \frac{384}{[1 + 384/96]} = \mathbf{77}$$

Where: nf - Final sample size
N - Estimated average no. of patients undergo PSF within one year by looking the OR logbooks.

4.6. Study Variables

4.6.1. Independent Variables

In these study age, sex, the presence of comorbidity, indication for fixation, level of fixation, operative time, intra-op blood loss, time to operation, the presence of associated injury, pre-op motor status, sphincter function, and sensory status were considered as independent variables.

4.6.2. Dependent Variables

Early complications, total hospital stay and neurologic status at 3rd month were considered as dependent variables.

4.7. Operational Definitions

Operating time: time period in minutes starting from skin incision to skin closure.

Total hospital stay: the time lapse in days from admission to discharge of the specified patient.

Poly-trauma: two or more associated extra-spinal injuries more major organ systems.

Medical comorbidities: patients with a history of hypertension, diabetes, heart disease, chronic respiratory problems, and renal problems

Early post op complication: any events for which the patient required specific treatment from immediate post-op to 3rd month post-op.

Surgical site infection (SSI): any purulent discharge, abscess or spreading cellulitis at surgical site.

Urinary tract infection (UTI): positive urine culture (1 or 2 species) with at least 100,000 bacteria/ml with or without clinical symptoms.

Respiratory infections: respiratory symptoms with at least two of the following sign: cough, purulent sputum, new infiltrates on chest x-ray consistent with infection.

Reoperation: surgical intervention done after initial surgery during the same admission.

Postop neurologic deficit: a fall in neurologic status of the patient comparing to pre-op neurologic status.

Intra-op pedicle fracture: sudden give away was felt during gear shift probing and a breach confirmed on palpation/probing.

Intra-op CSF leak: any CSF leak seen and confirmed by the operating surgeon or confirmed using valsalva maneuvers intraoperatively.

Single-level fusion: fusion involving only one level.

Multi-level fusion: fusion more than one level.

Cortical breach: screws that pass beyond the confined cortex in any position confirmed on post op radiologic imaging.

Postop neurologic deficit: a fall in neurologic status of the patient comparing to pre-op neurologic status.

Significant neurologic improvement: in lower extremity muscles groups an increase in power from pre-op non-ambulatory status (motor grade 0 - 3 or ASIA A – C) to ambulatory status at 3rd month post-op (motor grade 4 – 5 or ASIA D – E).

Some neurologic improvement: any improvement in lower extremity muscle's motor grade or any increased in ASIA score that is not significant.

4.8. Data Collection and Analysis

4.8.1. Data Collection and Handling

Data was collected by the principal investigator and assigned neurosurgical residents at the respective centers using structured questioner in English. During patient presentation to emergency room demographic data's (age, sex, and addresses) was recorded from the chart, and mode of presentation to hospital (whether direct or referral) and the name of referring institution if referral was taken from the patients referral paper. After admission, working diagnosis, presenting symptom, preoperative neurologic status, sphincter function status, etc. and was documented based on the structured questionnaire.

Following each procedures, the most senior resident attending the specific procedures documented the intraoperative data's including duration of procedure, intra-op blood loss, levels fixed, if any additional procedure done and if any intraoperative complications (CSF leak, pedicle fracture or nerve root injury). All patients post-operatively control imaging's were collected by the principal investigator and imaging based data's for assessing the position of screws was filled by the principal investigator.

On the day of discharge, assigned neurosurgical residents recorded post-op data's regarding total hospital stay, if any revision surgery was done and if any post-op complications (DVT, UTI, HAI, pressure sore etc.) during post-op hospital stay (DVT, UTI, HAI pressure sore etc.).

For those patients that were able to come on the third post-op month, physical examination by assigned resident at outpatient clinic was done lower extremity power, sphincter function. Those patients were also asked about access to physiotherapy and if there was any post-op complication requiring treatment during this period, and data's was documented based on the structured questionnaire. And those patients who were un-able to come to OPD were asked about their reasons for not coming and whether they are getting physiotherapy or not.

4.8.2. Data Processing and Analysis

The collected data was cleaned, coded and entered into IBM/SPSS 26.0 statistics software for analysis. Participants' socio-demographic characteristics and relevant variables are presented by frequency tables and charts using descriptive statistics.

To determine the existence and level of association between independent and dependent variables bivariate correlation analysis was done, assuming normal distribution of variables (Pearson correlation) at 10% level of significance. The Pearson´s correlation coefficient (r) was used to conduct the correlation analysis to find the level and direction of the relationships between independent and dependent variables. The classification of the correlation efficient (r) is as follows: 0.1 – 0.29 is weak; 0.3 – 0.49 is moderate; and > 0.5 is strong (Field, 2005).

Multiple regression analysis was done to identify the existence of statistically significant association between independent variables and neurologic status at 3rd month. Adequacy was checked by the model summary table R-Square value, and significance of the final model was checked using ANOVA, in which is $p < 0.05$ proved the presence of a good degree of prediction.

4.9. Methods

4.9.1. Preoperative Neurologic and Radiologic Evaluation

For assessing the severity of pre-op neurologic injury, pre-op assessment of lower extremity muscles power, sensory examination, and PR examination (to assess perianal sensation, anal tone and voluntary contraction) was done. Power of the lower extremities muscle groups were grades and classified as Intact (power 5/5), Incomplete weakness (power 2/5-4/5), and complete weakness (power 0/5). Pre-op evaluations of the sphincter functions were classified as Continent, Bladder incontinence only, or Double incontinent. Sensation were classified as Intact (including patients with preserved perianal sensations), and as affected. Pre-op neurologic injury of all patients that came after trauma were classified according to ASIA scoring system.

Level of injury and pattern of fracture was assessed using pre-op CT-scan for all trauma patients. For non-traumatic patients (for which PSF was indicated for pathologies other than acute traumas), pre-op radiologic assessment was done using pre-op MRI. Level of injuries was classified into four (upper thoracic T1 to T4, lower thoracic T5 to T10, thoracolumbar junction T11 to L2, and lumbar L3 to L5), and patterns of fracture were also classified into four types using simplified McAfee classification (Type 1 - compression fracture, Type 2 - burst fracture, Type 3 - seatbelt injury, and Type 4 - fracture dislocation).

For deciding on surgical management these patients classification into three groups (non-operative candidates, grey zone, and surgical candidates) was done using both radiologic and clinical criteria's using TLICS scoring system.

4.9.2. Surgical Procedures

All procedures at MCM were attended by a spine surgeon, and three senior consultants of A.A University were involved on procedures at ALERT. GA was used for most patients, and spinal fixation using spinal anesthesia was done for 4 patients operated at MCM.

Prior to surgery antimicrobial prophylaxis (IV ceftriaxone) was given for all patients. Patient was positioned on prone position after preoperative planning done for selecting appropriate screw size and deciding on level of fixation. Entry point was identified intraoperatively and trajectories was planned. Once the entry point is identified, a sharp awl used to remove the posterior cortex. A blunt gearshift pedicle finder is then used to identify a trajectory through the pedicle. Probe through the pedicular cancellous cavity used.

As a general trend all procedures at both centers were assisted with intra-op fluoroscope, but for one patient operated at ALERT fluoroscopy was not functional at the time of operation and fixation for this patient was done using intraoperative anatomic landmarks. All patients screw was connected with connecting rods on both sides and additional crosslinks connecting the right and left was applied for 7 patients operated at MCM.

Only one screw system was used for all procedures at MCM, and most screws and screw system at ALERT were gained from donation different screw systems were used. Depending on indication and operative plan additional procedures (decompressive laminectomies for those having significant spinal canal stenosis, biopsy of spine tumors, wound debridement) were done.

Up on completion irrigation of the wound cavity using vancomycine powder with and without iodine was done at both centers Intra-op drains were left for procedures with excessive bleeding, or intra-op CSF leak, and due to surgeons preference intra-op drain left for all patients operated at MCM.

4.9.3. Postoperative Radiologic Evaluation

During postoperatively hospital stay patients will be evaluated for any postop complications. Control AP and lateral x-ray imaging was taken within 48 hours post-op period for assessing screw positions. AP X-ray's was used to see any lateral or medial breech, and lateral x-ray was used to see any anterior, superior or inferior breech.

Early complications related to thoracolumbar PSF were classified into intra-op complications, post-op complications before discharge, and post-op complications after patient discharge to 3rd month follow-up.

4.9.4. Follow-Up and Post-Op Neurologic Assessment

For assessing complications happened after patients discharge, short-term neurologic outcome at 3rd month, and access to physiotherapy all patients were followed for three months post-operatively. For assessing complications that happened after they were discharged and their access to physiotherapy, all absent patients or their relatives were contacted through the phone.

All patients were followed at outpatient clinic for three months post-operatively. On the third post-op month, physical examination was done by assigned resident at outpatient clinic for assessing the neurologic status and sphincter function. Patient will also be asked if there was any post-op complication requiring treatment during this period, and data's was documented based on the structured questionnaire.

For patients that are lost at 3rd month follow-up day, the principal investigator took the patient's phone number from the chart and patients was contacted and asked to come if possible through the phone. For those patients came after being called neurologic status and sphincter function was assessed during their visit to OPD. Those patients who are un-able to come to OPD was asked about the reasons for not coming and whether they are getting physiotherapy or not.

For assessing short-term neurologic outcome, assessment of lower extremity muscles power, sensory examination, and PR examination (to assess perianal sensation, resting anal tone and voluntary contraction) was done for only 48 patients who were able to come on regular follow-up.

4.10. Ethical Consideration

The research project was ethically cleared and approved by Research and Ethics Committee of Department of Surgery and Faculty Research Publications Committee. Communication to the medical directors of the respective hospitals was made through a formal letter obtained from the department of surgery and official permission were taken.

Informed consent was obtained from all the study participants willing to participate in the study prior to interviewing and operation by the assigned neurosurgical resident at the respective hospitals. The study participants were not subjected for unnecessary clinical investigations, intervention or follow up unless it is warranted for the benefit of the patient.

In order to keep confidentiality of any information provided by study subjects, the data collection procedure was anonymous, and the privacy of all perioperative results was maintained.

5. RESULTS

5.1. Socio-Demographic Data

A total of 68 patients were included in this study period. The majority 49 patients (72.1%) were from ALERT hospital and 19 patients (27.9%) were from MCM hospital.

The minimum and the maximum age of the study participants was 12 years and 66 years respectively, and the mean age was 31.79 (SD=13.241). Majority 86.7 % were age below 45, and there was male predominance with 52 patients (76.5%) being male and 16 patients (23.5%) being female.

The majority of patients were from Oromia - 35.3%, followed by A.A - 20.9%, Amhara - 14.7%, SNNP - 14.7%, the rest 13.3 % were from other regions of the country, and one patient was from neighboring country Eritrea – 1.5 %.

Among these majority of patients (64.7%) resides in the rural areas and the rest (35.3 %) resides in urban (see Table 01). During presentation to hospital, only 8 patients (11.8%) came directly without being seen in other institution, and 60 of them (88.2%) were referred from another institution.

Table 01. Patient and socio-demographic characteristics of the study participants

		Frequency	Percent (%)
Sex	Male	52	76.5
	Female	16	23.5
Age (years)	< 30	33	48.5
	30 - 45	26	38.2
	> 45	9	13.2
Address	A.A	14	20.6
	Oromia	24	35.3
	Amhara	10	14.7
	SNNP	10	14.7
	Tigray	4	5.9
	Somalia	3	4.4
	Afar	1	1.5
	Gambella	1	1.5
	Other*	1	1.5
Residence	Urban	24	35.3
	Rural	44	64.7
Total		68	100.00

*Other –from abroad country (Eritrea)

5.2. Etiology

Indications for hardware placement were trauma - 82.4 % (56 patients), degenerative and spondylolisthesis - 11.8% (8 patients), tumour - 2.9% (2 patients), infection - 1.5 % (1 patient), and one patient L2 screw fracture (previously PSF was done) (Table 02). Among these only three patients had medical comorbidity (two hypertension and one DM)

Table 02. Indications for fixation

Indications	Frequency	Percent (%)
Trauma	56	82.4
Degenerative and spondylolisthesis	8	11.8
Tumour	2	2.9
Infection (post-laminectomy)	1	1.5
Other*	1	1.5
Total	68	100.00

*Other –L2 screw fracture (post PSF).

5.3. Injury Characteristics (Trauma)

Among 56 patients with traumatic indication, the commonest cause injury was fall down accident 48.2%, followed by motor vehicle accident 35.7%, falling object 8.9%, bullet injury 3.6%, and the rest two patients 3.6% presented after machine injury and crush injury with a lift (Table 03). And the mean time between accidents to hospital presentation was 148.86 hours (ranges from 2 hours to 1008 hours, SD= 174.322).

About 11 trauma patients (19.6%) had other associated site of injury. Chest injury was the commonest associated site of injury (on 7 patients), abdominal injury (1 patient), long bone fracture (1 patient), and two patients had multi-trauma with more than one associated site of injury (Table 04).

Thoracolumbar junction from T11 to L2 was the commonest level injury (76.8%, 43 patients), followed by lumbar from L3 to L5 (16.1%, 9 patients), lower thoracic from T5 to T10 (5.4%, 3 patients), and upper thoracic from T1 to T4 (1.8%, 1 patients).

Fracture dislocation was the commonest pattern of fracture (48.2%, 27 patients), followed by burst fracture (35.7%, 20 patients), seat-belt injury (10.7%, 6 patients), compression fracture (2.9%, 2 patients), and one patient with bullet injury had no major type of fracture (1.8%).

The minimum TLICS score given was 3 and the maximum 8 (SD=1.358). And majority 82.1% had TLICS >= 5 (surgical candidate), 10.7 % had TLICS of 4 (grey zone), 7.1 % had TLICS of 3 (non-operative candidate).

5.4. Clinical Presentations (Non-Traumatic Indication)

Major presentations of patients operated for non-traumatic indications (excluding a patient with screw fracture) were LBP with radiculopathy (6 patients), LBP with myelopathy (4 patients). Duration of symptoms these patients generally ranges from 4 weeks to 48 weeks (mean 16.36, SD =12.42), with symptom durations of patients with radiculopathy ranging from 12 to 48 weeks, and those with myelopathy ranging between 4 to 12 weeks.

On pre-op radiologic evaluation using spinal MRI, seven patients had degenerative disc diseases with and without spondylolisthesis (5 were at the level of L4/5, 1 each at L2/3 and L3/4 levels), one patient had post-traumatic multiple disc herniation with vertebral collapse (at levels of T10/11/12), one patient had post-laminectomy abscess collection at L4/5 level, two patients had spine tumours (one spinal epidural mass located at L2/L3 and the other at T12 level). And one patient previously operated and PSF was done 4 years back, L2 screw fracture was diagnosed using control CT-scan.

Table 03. Injury characteristics of patients operated for traumatic indications

		Frequency	Percent (%)
Mechanism of injury	MVA	20	35.7
	Fall down accident	27	48.2
	Falling object	5	8.9
	Bullet injury	2	3.6
	Others[(a)]	2	3.6
Other site of injury	None	45	80.4
	Chest injury	7	12.5
	Abdominal injury	1	1.8
	Long bone fracture	1	1.8
	Multi-trauma[(b)]	2	3.6
Level of injury	Upper thoracic (T1-T4)	1	1.8
	Lower thoracic (T5-T8)	3	5.4
	T-L junction (T11-L2)	43	76.8
	Lumbar (L3-L5)	9	16.1
Pattern of fracture	Compression fracture	2	3.6
	Burst fracture	20	35.7
	Seat-belt injury	6	10.7
	Fracture dislocation	27	48.2
	Minor fracture	1	1.8
Total		56	100.0

a. Others: One patient presented after crushed with a lift, and the other after sustaining a machine injury.
b. Others: two patients with multi-trauma, one had both chest injury and long bone fracture, and the other had pelvic fracture and head injury

5.5. Preoperative Neurologic Status

Pre-op neurologic evaluation of lower extremity muscle group's power, sphincter functions, and sensory status was done for all patients, including those patients operated for non-traumatic indications. On lower extremity power 26 patients (38.2%) had complete weakness, 24 patients (35.3%) had no neurologic deficit and 18 patients (26.5%) had incomplete lower extremity weakness.

Most patients (31 patients-45.6%) were continent, and among patients that had pre-op sphincter dysfunction, only 8 patients (11.8%) had only bladder incontinence and 29 patients (42.6%) had double incontinence. Sensation (including perianal sensation) was intact for 44 patients (64.7%) and was affected for 24 patients (35.3%).

Pre-op classification using ASIA scoring system was done for 56 patients operated for traumatic indications. And 24 patients - 42.9% of traumas had complete SCI (ASIA-A), 18 patients - 32.1% had incomplete SCI (ASIA B - 8 patients, ASIA C - 6 patients, and ASIA D - 4 patients), and 14 patients - 25.0% were neurologically intact (ASIA-E).

Table 04. Preoperative neurologic status of all patients

		Frequency	Percent (%)
LE motor power status	No deficit	24	35.3
	Incomplete weakness	18	26.5
	Complete weakness	26	38.2
Sphincter function	Continent	31	45.6
	Bladder incontinence only	8	11.8
	Both bladder and bowel incontinence	29	42.6
Sensory status	Intact	44	64.7
	Affected	24	35.3
	Total	**68**	**100.0**
ASIA score	ASIA A	24	42.9
	ASIA B	8	14.3
	ASIA C	6	10.7
	ASIA D	4	7.1
	ASIA E	14	25.0
	Total	**56**	**100.0**

5.6. Surgical Procedures

A total of 351 screws were inserted for 68 patients that underwent thoracolumbar pedicle screw fixation. The majority 250 screws (71.22% of screws) were used for 49 patients that were operated at ALERT hospital and the rest 101 screws (28.77% of screws) were used for 19 patients that were operated at MCM hospital.

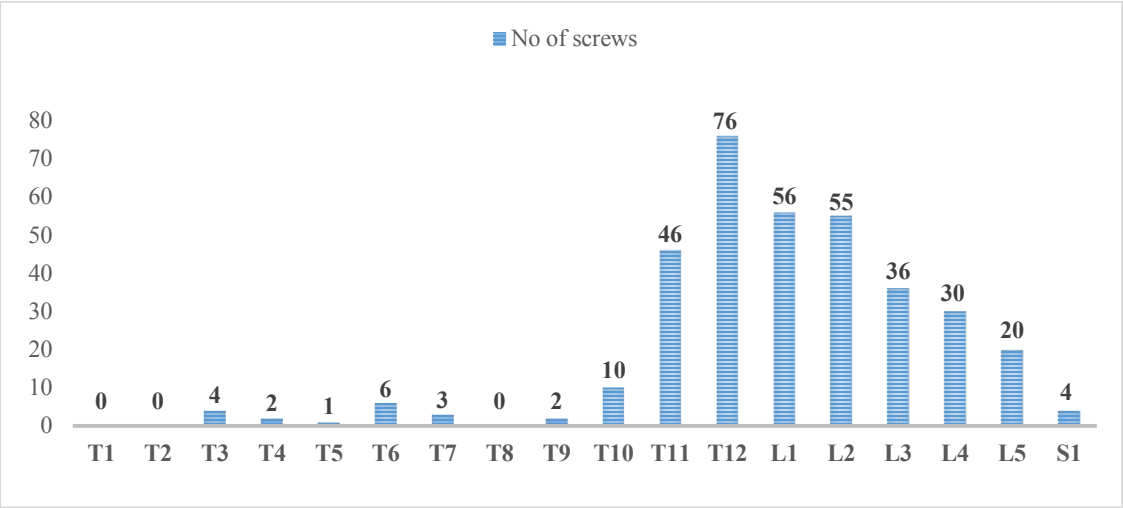
Single level fixation using four screws was done for 32 patients (47.1%), and multilevel fixation was performed for 36 patients (52.9%). Majority of screws, 197 screws (56.1% of total screws) were used for lumbar pedicles, 150 screws (42.7%) used for thoracic pedicles, and only 4 screws used for sacrum.

The maximum number of screws used for single patient was 12 screws. Most screws (76 screws - 21.7%) were inserted at the level of T12, followed by L1- 56 screws (15.9%), L2- 55 screws (15.6%), and T11- 46 (13.1%). And during the study period no screws were inserted for the level of T1, T2 and T8 (Figure 01 and Table 06).

Operative time in minutes ranges from minimum 120 to 360 minutes (mean 179.56 minutes, SD-44.502). The mean intra-operative bleeding measured in ml was 410.29 ml (SD=182.756). Intra-op drain was left for all 19 patients operated at MCM, and for only 6 patients operated at ALERT.

For 28 patients with traumatic SCI, simple or partial laminectomy, and decompressive laminectomy was done in addition to pedicle screw fixation, and laminectomy with bullet removal was also done for a patient with bullet injury. Decompressive laminectomy was done for all patients operated for an indication of DDD (laminectomy with discectomy for 4 patients that had significant disc prolapse, only decompressive laminectomy without discectomy for 3 patients with lumbar canal stenosis, and multilevel decompression for a patient with multilevel post-traumatic disc herniation). Spinal decompression with tumour biopsy was done for two patients with spinal tumour, wound debridement was done for a patient with post-laminectomy epidural abscess collection, and prior to PSF all previously inserted screws were removed for a patient with screw fracture.

Figure 01. Distribution of screws inserted over level of pedicle



5.7. In-Patient Complications and Post-op Radiologic Assessment

The overall hospital stay ranges from minimum 4 days to maximum of 30 days (mean 7.94 days, SD=5.444). Early complications following thoracolumbar PSF were classified into in-patient complications (including both intra-op complications, and post-op complications before discharge) and post-op complications after patient discharge to 3rd month follow-up.

Intra-op complications happened for 16 patients (23.5%), 8 were intra-op CSF leak, 7 - intra-op pedicle fracture, and one nerve root injury (Table 08). For patients that had intra-op CSF leak, it was possible to do primarily dural repair for only one patient, for the rest five patients crushed muscle patch with or without surgicel was applied. And intra-op drainage tube was left for all patients with intra-op CSF leak, and none of this patients had post-op CSF leak through the wound.

Before patient discharge one patient develop deep SSI (1.5%) that was diagnosed by both clinical and post-op MRI. Two patients developed UTI (2.9%), both treated with antibiotics. Three patients develop HAI (4.4%), focus of infection was chest for one patient, and not known for the rest two patients, all were treated with IV antibiotics. Five patients (7.4%) had bed sore on the day of discharge, all of these patients with bedsore were patients with traumatic SCI with complete lower extremity weakness (4 were ASIA A, and 1 was ASIA B).

For determining accuracy rate and prevalence of cortical breech all screws were evaluated using AP and lateral post-op x-ray. Out of 351 screws inserted, 309 screws (88.0 % of the screws) were accurately placed with no cortical breech, and the rest 42 screws (12.0%) had cortical breech.

Highest number of breech was found at the level of T12 - 9 breeches, followed by T11 – 8 breeches, L2 – 6 breeches, T10, L1, L3 – 4 breeches each, L5 - 3 breeches, and T9, S1 – 2 breeches each (Table 06). Among 42 screws with cortical breech medial breech was the commonest (47.6 % of breeches, 20 screws), followed by anterior breech (38.09 %, 16 screws), superior breech (9.5 %, 4 screws), lateral (4.7 %, 2 screws), and inferior (2.3 %, 1 screw) (Table 06 and Figure 02).

Revision surgery was done for two patients (2.9%). The first revision was done for a patient with deep wound site infection, wound debridement without removing the screws was done during the same admission. The second was for a patient with significant anterior cortical breech on post-op imaging, screw removal and correction done on immediate post-op day.

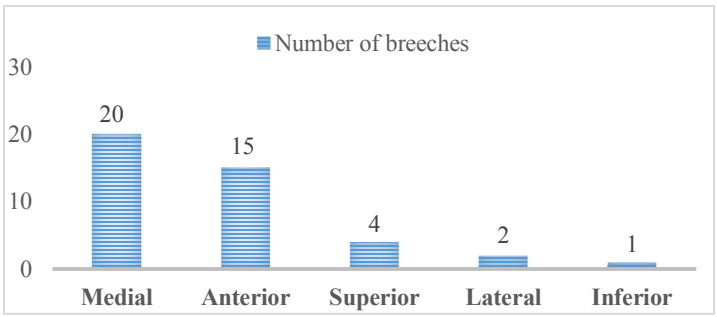
Table 05. Post-op complications before patient discharge

		Frequency	Percent (%)
Intra-op complications	Intra-op CSF leak	8	11.7
	Intra-op pedicle fracture	7	10.2
	Nerve root injury	1	1.47
	Total	**16**	**23.5**
Post-op complications (In-patient)	Deep wound site infection	1	1.5
	UTI	2	2.9
	HAI	3	4.4
	Bedsore	5	7.4
	Total	**11**	**16.2**
Revision surgery		2	2.9

Table 06. Distribution of screws inserted and direction breeches

Level	No. of screw inserted	No. of breeches	Direction of breech				
			Medial	Lateral	Anterior	Superior	Inferior
T1	0	0	0	0	0	0	0
T2	0	0	0	0	0	0	0
T3	4	0	0	0	0	0	0
T4	2	0	0	0	0	0	0
T5	1	0	0	0	0	0	0
T6	6	0	0	0	0	0	0
T7	3	0	0	0	0	0	0
T8	0	0	0	0	0	0	0
T9	2	2	2	0	0	0	0
T10	10	4	3	0	1	0	0
T11	46	8	2	0	6	0	0
T12	76	9	5	0	2	2	0
L1	56	4	4	0	0	0	0
L2	55	6	3	1	1	0	0
L3	36	4	1	1	1	1	1
L4	30	0	0	0	0	0	0
L5	20	3	0	0	2	1	0
S1	4	2	0	0	2	0	0
Total	**351**	**42**	**20**	**2**	**15**	**4**	**1**

Figure 02. Relative frequency of breeches in relation with direction



5.8. Follow-up and Short-term neurologic outcome

Post-operatively patients were followed up to 12 weeks, for assessing complications happened after patients discharge, and short-term neurologic outcome at 3rd month. 70.6% of patients (48 patients) were able to come on regular follow-up (most came after they were contacted through a phone and suggested to come) and the rest 29.4 % of patients (20 patients) were un-able to come on 3rd month regular follow-up. For these 20 absent patients, complications that happened after they were discharged and their access to physiotherapy were recorded through the phone

Only 15 patients (22.1%) had received post-op physiotherapy, and the majority of patients 87.9% did not receive physiotherapy during the 3rd month postoperative periods. Among the reason asked, lack of the service at their area of residence and fear of infection due to the rise of COVID infection in the country were mentioned by most patients that didn't receive post-op physiotherapy.

Assessment of short-term neurologic outcome was only done for those 48 patients who were able to come on on 3rd month post-op regular follow-up (38 patients were trauma, 6 - degenerative disc disease, 2 - tumor, 1 - infection, 1 - other). And on neurologic evaluation at third month, 72.9% of patient (35 patients) were neurologically the same, 14.6% (7 patients) had some improvement, 12.5% (6 patients) had significant improvement, and none of these patients had neurologic worsening comparing to pre-op neurologic status.

After patients were discharged two patients develop superficial wound site infection, both treated with po antibiotics and wound care, improved subsequently. Two patients developed UTI, which was also managed with po antibiotics. And seven patients developed pressure sore after they was discharged to home (Table 09).

Table 07. General neurologic outcome at 3rd month

Neurologic status at 3rd month	Frequency	Percent (%)
Same	35	72.9
Some improvement	7	14.6
Significant improvement	6	12.5
Total	48	100.0

Table 08. Early post-op complications after discharge

		Frequency	Percent (%)
Post-op complications (discharge-3rd month post-op)	Superficial wound site infection	2	2.9
	Recurrent UTI	2	2.9
	Bedsore	7	10.3
	Total	11	16.1

5.9. The Relationship between the Study Variables and In-patient complications

To determine the existence and level of association between independent and dependent variables bivariate correlation analysis was done.

With 95% CI, only the presence of associated other site of injury (P=0.02) and lower extremity power status (P=0.02) have moderate correlation with the development of in-patient complications with r value of .404 and .362 respectively. Patient factors (age, sex, and the presence of comorbidity), indication for fixation, surgical factors (level of fixation, operative time, intra-op blood loss, and the presence of intra-op drain) have no association with the development of in-patient complications.

For assessing factors associated with delayed hospital stay, the association and relations of all mentioned factors above and additional two separate factors (the presence of intra-op complications, and the presence of post-op complications) as independent variable were also studied using Pearson correlation. With 95% CI, the presence of In-patient complication and the presence of associated injury had moderate association with overall hospital stay with r value of .436 and .489 respectively.

Table 09. Factors with their level of association with In-patient complication

		In-patient complications
Age	**Pearson Correlation**	**-.179**
	Sig. (2-tailed)	**.145**
	N	**68**
Sex	**Pearson Correlation**	**-.026**
	Sig. (2-tailed)	**.833**
	N	**68**
Comorbidity	**Pearson Correlation**	**-.037**
	Sig. (2-tailed)	**.764**
	N	**68**
Indication for fixation	**Pearson Correlation**	**-.145**
	Sig. (2-tailed)	**.238**
	N	**68**
Level of fixation	**Pearson Correlation**	**.200**
	Sig. (2-tailed)	**.103**
	N	**68**
Associated other site of injury	**Pearson Correlation**	**.404****
	Sig. (2-tailed)	**.002**
	N	**56**
Lower extremity power status	**Pearson Correlation**	**.362****
	Sig. (2-tailed)	**.002**
	N	**68**
Operative time	**Pearson Correlation**	**-.023**
	Sig. (2-tailed)	**.855**
	N	**68**
Intra-op bleeding	**Pearson Correlation**	**.034**
	Sig. (2-tailed)	**.786**
	N	**68**
Intra-op drain	**Pearson Correlation**	**.046**
	Sig. (2-tailed)	**.710**
	N	**68**

5.10. Factors Associated With Neurologic Outcome At 3rd Month

Since neurologic outcome following post-surgical management non-traumatic conditions depends on the primarily surgical procedure (level of discectomy, extent of tumor resection), and disease factors rather than the posterior decompression and fixation, only 38 traumatic patients that came at follow-up were included for assessing factors associated with neurologic outcome at 3rd month.

And these patients was also classified according to ASIA scoring system at third month and scores were compared with pre-op ASIA (Table 10). Neurologic improvement at 3rd month was found for 11 patients who had incomplete SCI pre-operatively (3 out of 4 pre-op ASIA D patients were intact ASIA E at 3rd month, 2 out of 4 pre-op ASIA B and 2 out of 3 pre-op ASIA C patients were ASIA D on 3rd month).

All patients who had complete SCI preoperatively (ASIA-A) had no neurologic improvement at 3rd month (all were ASIA-A at 3rd month, and all patients who were neurologically intact preoperatively (ASIA E) were also neurologically the same at 3rd month (ASIA E) and had no neurological worsening.

Table 10. ASIA score at 3rd month comparing to pre-op ASIA score

		ASIA score (at 3rd month)					
		ASIA A	ASIA B	ASIA C	ASIA D	ASIA E	**Total**
ASIA score (pre-op)	ASIA A	15	0	0	0	0	15
	ASIA B	0	2	0	2	0	4
	ASIA C	0	0	1	2	0	3
	ASIA D	0	0	0	1	3	4
	ASIA E	0	0	0	0	12	12
Total		15	2	1	5	15	38

Multiple regression analysis was done to identify the existence of statistically significant association between independent variables and neurologic status at 3rd month. Adequacy was checked by the model summary table R-Square value (Table 11), and R-Square value was found to be .734 (means that 73.4 % of the patient's neurologic outcome was explained by the variations of predictors mentioned on table 13. The significance of the final model was also checked using ANOVA, and the regression analysis proved the presence of a good degree of prediction with significance result on the ANOVA table being 0.000 which is $p< 0.05$ (Table 12).

Among the independent factors pre-op sensory status, pre-op ASIA score and time to operation had significant association with ($P<0.05$) neurologic outcome at third month. The contribution of each factor as seen on the results of multiple regressions in the coefficient table (Table 13) revealed, at 95% confidence level ($p < 0.05$) pre-op sensory level has a negative and significant effect on neurologic outcome at third month (standardized beta = . -1.690) than pre-op ASIA score and time to operation.

Table 11: R square level of the study

Model	R	R Square	Adjusted R square	Std.Error of the Estimate
	.856[a]	.734	.606	.451

a. Predictors: (Constant), Time between trauma to presentation (In hours), Sex, TLICS Score, Additional procedure done, Age, Time between presentation to operation (in hour), Level of injury, Sphincter function (Pre-operative), Pattern of fracture, LE motor power status (Pre-operative), Sensory status (Pre-operative), ASIA Score

Table 12: Significance of the model

ANOVA[a]

Model	Sum of Squares	df	Mean Square	F	**Sig.**
Regression Residual Total	13.995 5.084 19.079	12 25 37	1.166 .203	5.735	.000[b]

a. Dependent Variable: Neurologic outcome at 3rd month
b. Predictors: (Constant), Time between trauma to presentation (In hours), Sex, TLICS Score, Additional procedure done, Age, Time between presentation to operation (in hour), Level of injury, Sphincter function (Pre-operative), Pattern of fracture, LE motor power status (Pre-operative), Sensory status (Pre-operative), ASIA Score

Table 13: coefficients of the variables

Model	**Unstandardized Coefficients**		**Standardized Coefficients**			**95.0% Confidence Interval for B**	
	B	Std. Error	Beta	**t**	**Sig.**	Lower Bound	Upper Bound
(Constant)	7.082	1.835		3.858	.001	3.301	10.862
Age	.003	.009	.040	.322	.750	-.015	.021
Sex	-.194	.199	-.121	-.976	.339	-.605	.216
TLICS Score	.063	.116	.125	.549	.588	-.175	.301
Pattern of fracture	-.128	.145	-.182	-.880	.387	-.426	.171
Level of injury	-.071	.171	-.056	-.419	.679	-.423	.280
Pre-op LE motor status	-.086	.201	-.107	-.427	.673	-.499	.327
Pre-op sphincter function	.133	.161	.260	.826	.417	-.198	.463
Pre-op Sensory status	-2.450	.448	-1.690	-5.475	.000	-3.372	-1.529
Time to operation	-.005	.002	-.287	-2.430	.023	-.009	-.001
Additional procedure done	-.114	.126	-.114	-.906	.373	-.374	.145
ASIA Score	-.521	.196	-1.280	-2.661	.013	-.925	-.118

a. Dependent Variable: Neurologic outcome at 3rd month

6. DISCUSSION

Since the establishment of neurosurgical training program in Ethiopia on 2006, spine procedures including pedicle screw fixations were performed for varieties of indications.[9] Even though there are few retrospective studies related to outcome of spine traumas and outcome following spine surgeries[10, 11, 12], there are no studies done specific to thoracolumbar pedicle screw fixation. With the primarily objective to assess and describe early complications and short term neurologic outcome related to thoracolumbar pedicle screw fixation, our study is the first study of its own kind done in these set-ups.

PSF is the preferred and well known technique to achieve fixation and fusion, indicated commonly for traumatic SCI. Even though there was a controversies for using instrumentations for degenerative disc disease, currently pedicle screw fixations are also indicated for degenerative disc diseases, deformities, neoplastic, and also infectious spine pathologies that have associated spine instabilities.[1, 28]

In our study 68 patients operated at two different study areas with different pathologies were included, and trauma was the commonest indication for fixation (Table 02). This was similar to a reports of a Turkish and an Indian study, [23, 24] but there are also studies on pedicle screw fixation that reported non-traumatic conditions as there commonest indication for fixation among multiple etiologies included in there study.[28] Also on literature review of 35, 630 pedicle screws, degenerative disc disease was commonest reported indication among papers that included multiple indications for fixation.[28] Trauma was the commonest indication for fixation due to the fact that majority of patients included in this study were from ALERT trauma center (72.1 % patients) whereby only patient with acute trauma or those having a trauma history will be operated.

Despite technical advances in screw fixations, complications can happen either intraoperatively or postoperatively.[7] In our series intra-op complication happened on 16 patients (23.5% of patients). Including both incidental dural tears and leaks that may be related to significant trauma, intra-op CSF leaks happened on 8 patients (11.7% of patients), which was similar to Di Silvestre et al report (dural lesion happened in 14 patients 12.2% of patients.[29]

Intra-op complications are not commonly reported by literatures, and due to medico legal issues of the author underreporting of these complications is also common.[28] we reported these complications for the sake of completeness, otherwise all complications were not clinically significant; all intra-op CSF leaks were managed successfully and none of this patients had post-op CSF leak through the wound, trajectory corrected for all patents that had intra-op pedicle fracture, a patient who had nerve root injury also didn't have post-op no neurologic deficit.

Instrument related post PSF complications include SSI, post-op neurologic deficit or instrument failures like screw malpositions, screw loosening, screw-rod disconnections due to techniqual errors[14], and one of our study objective was to find out the prevalence of these complications. Despite the use prophylaxis antibiotics high rate of post-op deep SSI with a prevalence rate of 4.7% was reported on one study.[13] Prophylactic antibiotics and intra-op infection prevention methods (using iodine and vancomycine powder) were used in these study and despite that we found one patient that developed deep SSI (1.5%) requiring revision surgery, also two patients developed superficial SSI which was managed with po antibiotics for 7 days.

The prevalence of pressure ulcers – the proportion of persons with pressure ulcers at a specific point in time – in general acute care setting is 10–18%, long-term facilities 2.3–28%, and home care from 0–29%.[30, 31]In these study

17.6 % of patients developed bedsore during 3 month follow-up (5 - 7.4 % were before discharge and 7 - 10.2% after discharge). This was lower than previous study in our set-up with incidence of 22.7%, a study in Zimbabwe with 33% incidence,[11, 32] but these studies were retrospective with longer follow-up periods.

In a studies done on degenerative lumbar scoliosis with complication rate of 68 %, excessive blood lose, age more than 65 years and fusion more than five levels were associated with the development perioperative complications related to fusion and instrumentation.[15] And in our study we only found those who had associated other site of injury (P=0.02) and complete lower extremity weakness (P=0.02) to have an association with the development of in-patient complications with r value of .404 and .362 respectively.

Since there was no study on accuracy of screw fixations in our setups, one of the aim of these study was also to determine the accuracy of screws inserted in these resource limited areas. Determined accuracy rate of this study is 88.0% (299 screws acurately placed), which is similar to the median accuracy rate 89.2% found on a meta-analyis of literatures.[19] Literatures with their accuracy rate are described on table 16, but as described by many meta-analyses the definition of breeches, and assessment of screw accuracy varies significantly which makes difficult to compare our result side by side.[18, 19, 20]

Due to anatomical structure of pedicles breeches are more common on the level of mid-thoracic, and more frequently in the medial or lateral wall.[7] In our study most of the breeches were at the level of thoracolumbar area, this may be due to higher number of thoracolumbar fractures and fixations included in this study. Although medial breech was still the commonest breech in our study (20 screws-5.7%), comparing to other literatures with a lower rate of anterior breech[21,22,23,24,25] we found a significant higher number of anterior breech (15 screws-4.2%).

Table 14. Summary of literatures on screw accuracy

Study	Most common pathology	Screw location	No. of patients	No. of screws	**Accuracy**	Revision rate
Halm *et al*[33], 2000	Scoliosis	T10-L4	12	104	81.7	8.3
Belmont *et al*[34], 2001	Scoliosis	T1-T12	40	279	57.0	5.0
Carbone *et al*[35], 2003	Trauma	T1-T12	22	126	86.5	N/A
Kuntz *et al*[36], 2004	Trauma	T1-T12	28	199	27.6	N/A
Vougioukas *et al*[37], 2005	Degenerative	T1-T12	41	328	78.0	0.0
Amato *et al*[38], 2010	Degenerative	L1-S1	102	424	92.2	8.8

A significant number of patients (87.9%) did not receive physiotherapy during the 3rd month postoperative periods. Both of our study areas had physiotherapy services, but access to these hospitals services was limited since the majority of patients resides in rural areas. In these study in addition to lack of access, fear related to the rise of COVID infection in the country was also mentioned by patients as factor limiting access to physiotherapy. Comparing to previous pre-COVID outcome studies on similar setups[11] (with 46.4% of patients getting the access), only 22.1% of patients in these study had received post-op physiotherapy.

Taking all patients generally that were able to come at 3rd month follow-up, 29.1% of patients had some or significant improvement at 3rd month and majority 72.9% were neurologically the same. Since neurologic outcome of patients with non-traumatic indications mainly depends on the primarily pathology, we excluded this patient for determine factors associated with outcome. We found pre-op sensory level to be the most predictive factor for neurologic outcome at 3rd month, also none of patients that had pre-op sensory level or absent per-anal sensation had neurologic improvement at 3rd month. Considering the limitation of instrumentations in these resource limited areas, this paper strengthened the suggestions made by previous studies for not operating ASIA-A patients.[10, 12]

7. CONCLUSIONS AND RECOMMENDATIONS

Trauma was the commonest indication for fixation. Intra-op complications and post-op complications were comparable to other studies, and all of intra-op complications happened were not clinically significant. Patients that had associated other site of injury and complete lower extremity weakness are most likely to develop of in-patient complications.

Determined accuracy rate of 351 screws inserted was 88.0%, with screw malposition rate of 12%. And even though we found medial breeches to be the commonest, rate of anterior breeches were significantly higher. And a significant number of patients didn't receive post-op physiotherapy.

Based on our result finding posterior thoracolumbar pedicle screw fixations and fusions with can be done with acceptable complication rate and good recovery considering the limited resources.

Since our follow-up period was only 3 month, we recommend further follow-up study on these patients for assessing late instrument related complications (like adjacent segment disease, psedoarthrosis, loosening of screws), to assess final radiologic outcome.

8. LIMITATIONS

Limitation of this study includes lack lack of local studies with similar subject to compare the results made from this study.

Using plain x-rays for assessment of screw malposition in this study is also another limitation of this study, since comparing to thin-cut CT scans this may lead to false-positive and false-negative evaluations **(27).**.

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APPENDIX

QUESTIONNAIRE

I. Demographic data - (at ER)

Patient name: _____ Card number: _____ Phone no: _____

1. Hospital: ☐MCM ☐ ALERT
2. Age (in year):_____
3. Sex: ☐Male ☐Female
4. Patient address: ☐ A.A ☐Tigray
   ☐ Oromia ☐SNNP
   ☐ Amhara ☐Other:_____
5. Residence: ☐Urban ☐Rural
6. Mode of admission to ER: ☐ Direct ☐ Referral
7. If referral: Name of the referring institution: _____
   Location (in km from current center): ☐ <100km
   ☐ 100-500km
   ☐ >500km

II. Preoperative evaluation – (during admission)

1. Mode of admission: ☐Emergency ☐ Elective
2. Place of admission: ☐ Ward ☐ ICU
   If ICU admission: Reason for ICU admission: _____
   Duration of ICU stay (in days): _____
3. Any comorbidity (more than one choice possible):
   ☐None ☐Cardiac illness
   ☐Hypertension ☐Chronic respiratory problems
   ☐DM Other (specify) _____
4. History of smoking: ☐Yes ☐No
5. Indication for hardware placement: ☐ Trauma
   ☐ Degenerative and deformity
   ☐ Tumor
   ☐ Infection
   Other (Specify): _____

For traumatic indications only:

1. Time between accident to hospital presentation (in hours): _____
2. Mechanism of injury: ☐ MVA: pedestrian, driver, passenger (specify)_____
   ☐ Fall: height (specify) _____
   ☐ Falling object: height (specify) _____
   ☐ Assault: type (specify) _____
   ☐ Unknown
   Other (Specify): _____
3. Other site of associated injury: ☐ None ☐ Maxillofacial
   (more than one possible) ☐ Head injury ☐ Long bone
   ☐ Chest injury Other (Specify): _____
   ☐ Abdominopelvic injury
4. Level of fracture: ☐ Upper thoracic (T1-T4)
   ☐ Lower thoracic (T5-T10)
   ☐ T-L junction (T11-L2)
   ☐ Lumbar (L2-L5)
5. Pattern of fracture: ☐ Simple compression
   ☐ Burst
   ☐ Seat-belt
   ☐ Fracture dislocation
6. TLICS score: _____
7. ASIA score (ASIA A to E): _____

For non-traumatic indications only:

1. Major presenting symptom: ☐ Mechanical LBP
   ☐ Radiculopathy
   ☐ Myelopathy
   ☐ Incontinence
2. Duration of symptoms (in weeks): _____
3. Major pre-op imaging finding(CT or MRI): ☐ HLD with canal stenosis
   ☐ Canal stenosis only
   ☐ Tumor
   Other (Specify): _____
4. Level of pathology: ☐ Upper thoracic ☐ L1/L2
   ☐ Middle thoracic ☐ L2/L3
   ☐ Lower thoracic ☐ L3/L4
   ☐ L4/L5
   ☐ L5/S1

Pre-op neurologic status:

1. ASIA score *(for traumatic indication only):* Specify ASIA A, B, C,D, or E: _____
2. Pre-op motor status: ☐ Not affected (power 5/5)
   (For non-traumatic only) ☐ Incomplete weakness (power 2/5-4/5): specify power: ____
   ☐ Complete weakness (power 0/5)
3. Preoperative sphincter function: ☐ Continent
   ☐ Bladder Incontinence only
   ☐ Bowel Incontinence only
   ☐ Double incontinence
4. Pre-op sensory status: ☐ Intact
   ☐ Affected (specify the sensory level): _____

III. Intraoperative finding

1. Time between admission to operation (in hours): _____
2. Operating time (in minutes): _____
3. Intraoperative bleeding (in ml): _____
4. Level of fixation: ☐ Single level ☐ Multilevel
5. Intraoperative techniques used: ☐ Free hand ☐ Using fluoroscopy
6. Intra-op drain left: ☐ Yes ☐ No
7. Additional procedure done (more than one possible):
   ☐ None
   ☐ Simple laminectomy only
   ☐ Decompressive laminectomy
   ☐ Discectomy only
   ☐ Discectomy with foraminotomy
   ☐ Tumour removal: Extent: _____
   ☐ Debridement
   ☐ Graft inserted: Level and type of graft used: _____
   Other (specify): _____
8. Any Intraoperative complications:
   8.1 Intra-op CSF leak: ☐ Yes ☐ No
   If yes: specify measures taken: _____
   8.2 Intra-op pedicle fracture: ☐ Yes ☐ No
   If yes: specify the level _____
   Specify alternative method of fixation used_____
   8.3 Nerve root injury: ☐ Yes ☐ No
   If yes: specify the root affected: _____
   8.4 Other: _____

IV. Postoperative evaluation

Post-op evaluation (before discharge)

1. Total hospital stay (in days): _____
2. Any post-op complication during hospital stay: (more than one possible)
   - ☐ Wound site infection Culture result if sent: _____
   - ☐ Post op severe pain- neurapraxia
   - ☐ Postop neurologic deficit
   - ☐ HAI
   - ☐ UTI
   - ☐ DVT or Pulmonary embolism
   - ☐ Bed sore

   Other complications (specify):_____
3. Revision surgery done: ☐ Yes ☐ No
   - If yes specify the indication, the day of revision, procedure done during revision_____

Post-op neurologic status (at 3rd month follow-up)

1. ASIA score at 3rd month postop (specify ASIA A, B, C, D, or E): _____
   (For traumatic indication only)
2. Post-op motor status: ***(For non-traumatic only)***
   - ☐ Not affected (power 5/5)
   - ☐ Incomplete weakness (power 2/5-4/5):
   - ☐ Complete weakness (power 0/5)
3. Sphincter function 3rd month postop:
   - ☐ Continent
   - ☐ Bladder Incontinence only
   - ☐ Bowel Incontinence only
   - ☐ Both bladder and bowel incontinence
4. Post-op sensory status:
   - ☐ Intact
   - ☐ Affected
5. Postop neurologic status:
   - ☐ Same
   - ☐ Some improvement
   - ☐ Significant improvement
   - ☐ Worsened

Postoperative access to rehabilitation (at 3rd month follow-up)

1. Access to physiotherapy:
   - ☐ Not required
   - ☐ Required and access gained: how frequent_____
   - ☐ Required but couldn't get the access: reason _____

V. Post-op radiologic evaluation

Level of the screw inserted	Position of screw (In or Breeched)		Direction of breech (Medial, Lateral, Anterior, Superior, or Inferior)		Grading of the position (Grade 0-3)		Other Comments
	Right	Left	Right	Left	Right	Left	
T1							
T2							
T3							
T4							
T5							
T6							
T7							
T8							
T9							
T10							
T11							
T12							
L1							
L2							
L3							
L4							
L5							
S1							