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Incidence and Patterns of Major Complications Following Spinal Instrumentation- A Retrospective Descriptive Study from a Tertiary Care Center in Nepal

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Background: With the continuous uprise of spinal instrumentations within the global front, the complications they harbinger may have multispectral effects upon the patients as well as their caretakers. These are of prime significance in the context of low and middle-income nations. There is however drought of studies pertaining to the same in our subcontinent. **Materials and methods:** A retrospective descriptive study was undertaken to study the incidence and patterns of early and late major complications among 300 patients undergoing spinal instrumentation from the hospital database of the College of Medical Sciences (CMS), in Bharatpur, Chitwan, Nepal. **Results:** Trauma comprised 63.33% of cases in the study. 40% of the study cohorts were either in the American Spinal Injury Association (ASIA) 'A' or 'B' neurological status. The incidence of major complications in our study cohort was 20.33%. The posterior-only surgical approach was undertaken in 200 (66.67%). Surgical site infection was the most common type of complication observed (6.67%). Hardware-related complications were observed in 5.67%) of cases. The incidence of re-operation was 2.67%. The mortality rate observed in our study was 2%.**Conclusion:** Adequate preoperative planning, proper optimization of the patient, and adoption of procedure-specific, risk-adjusted predictive models may be pivotal for nullifying complications adherent to spinal instrumentation.

Key words: Complications, Instrumentation, Spine Surgery

There has been a continuous up rise in the trend for spinal fusion procedures on the global front.[1] Paradoxically, there is concurrent odds risk of 2.95 for life-threatening complications and 1.94 for readmissions.[2] This also increased the length of hospital stay (10.6 vs. 2.7 days without complications).[3] There is a fourfold increment in health expenditure owing to the same.[4] These have ripple effects on the patients as well as their care-providers especially in the context of low and middle-income nations like us. However, there is a drought of studies within our subcontinent pertaining to the same. We sought to determine the

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incidence and patterns of major complications observed among cohorts of patients undergoing spinal instrumentations in our institution. This would help frame preventive measures as well as formulate algorithmic strategies in their timely and effective management.

Methods and Materials:

The methodology for the research was focused to study the incidence and patterns of early and late major complications among patients undergoing spinal instrumentation from the hospital database of the College of Medical Sciences (CMS), in Bharatpur, Chitwan, Nepal. The complications cases requiring reoperation, causing the permanent deficit, or leading to significant morbidity and mortality were considered major.5

The results were compiled to study the patterns through frequency measures and analysis. The approval for the study was obtained by the Institutional Review Committee (COMSTH-IRC/2021-33). Written consent was obtained from all patients or their relatives.

Sample size calculation

Convenience sampling method was undertaken for calculating the minimal sample size required for the study using the formula as-

N= z2 X p X q/d2

Where Z = 1.96 at 95% confidence interval

p = prevalence of complications in spinal instrumentation, 56%1

q= 1-p, and

d= margin of error, 10%.

Minimal sample size was calculated to be 94.65.

The total patients included in our study were 300.

Inclusion criteria:All patients undergoing spinal instrumentation in our institution.

Exclusion criteria: Patients operated in other institutions. Patients lost to follow-up.

Results:

The mean age of the patients in our study was 35.8 years with a male: female ratio of 3:1. Trauma comprised 190 (63.33%) of cases in the study. The posterior surgical approach was undertaken in 200 cases while the anterior approach was taken in 100 cases. The level of instrumentation was lumbosacral in 120 cases followed by cervical and thoracic regions in 110 and 70 cases respectively.

Surgical site infection was the most common type of complication (6.67%) observed. All were managed conservatively and implant removal was not required in any of these cases. 40% of the study cohorts were either in the ASIA ‘A’ or ‘B’ neurological status. 90% of the surgical site infections occurred in these subsets of patients. The instability with progressive kyphosis was all observed in patients sustaining transitional zone injuries barring a case of cervical Pott’s spine in one case. Two cases of esophageal injury were observed. One patient, who also had cervical spondyloptosis, expired following sepsis. The other patient was managed conservatively with nasogastric tube feeding for a month and showed complete resolution. Two cases had transient recurrent laryngeal nerve palsy.

The incidence of re-operation was 2.67% (8 cases). Two cases had to be re-operated following surgical site hematoma and six cases underwent reoperation for wrong projections of the implants (one odontoid, three thoracic, and two lumbar pedicle screws).

The mortality rate observed in our study was 2% (6 cases). Four cases expired from sepsis and two cases expired due to pulmonary embolism. The indication for spinal instrumentation is listed in

Table 1.

Table1: Indications for spinal instrumentation in our study.

Indications	Frequency (%)
Traumatic fracture	130 (43.33%)
Traumatic subluxation	60 (20%)
Disc pathology	50 (16.67%)
Degenerative canal stenosis with instability	30 (10%)
Pott's spine	20 (6.67%)
Tumor	5 (1.67%)
OPLL	5 (1.67%)

The patterns of complications observed are listed in **Table 2**.

Table 2: Patterns of complications following spinal instrumentation in our study.

Complications (as per acuity from the time of operation)	Frequency (%) (Incidence-20.33%)
Surgical site hematoma	2 (0.66%)
Esophageal perforation	2 (0.66%)
Recurrent laryngeal nerve injury	2 (0.66%)
Wrong projection	6 (3%)
Surgical site infection	20 (6.67%)
Implant hardware loosening	7 (2.33%)
Screw pullout	4 (1.33%)
Screw fracture	6 (2%)
Progressive kyphotic deformity	6 (2%)
Metal allergy	4 (1.33%)
Mortality	6 (2%)

Some patterns of major complications observed in our patients have been demonstrated in **Figures 1 and 2**.

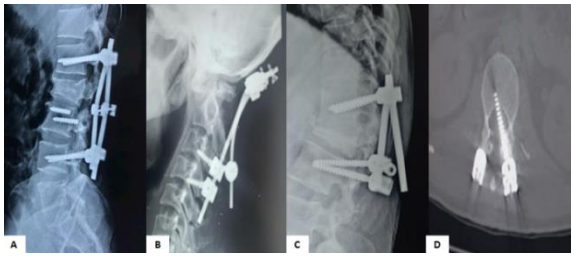

Figure 1: Images showing a) fracture, b) screw pull out, c) implant loosening, and d) medial projection of the screw.

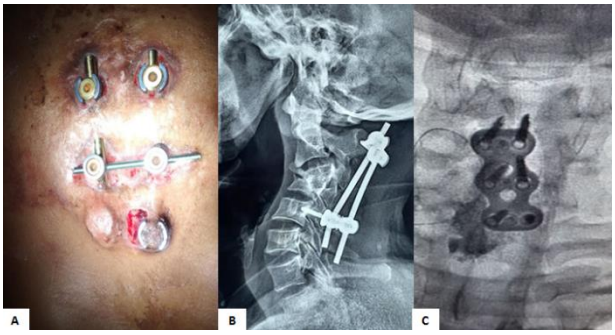

Figure 2: Images showing a) metal allergy, b) instability with kyphotic deformity, and c) esophageal perforation in barium shallow study.

Discussion:

A systematic review showed an incidence of complications in spinal surgery of 16.4%.6 Nationwide Inpatient Sample database reported complication rates of 9.02% to 10.5% following fusion procedures.[7] Study pertaining to the Medicare database showed a twofold risk of complications in fusion surgeries.[8] There is an almost threefold increase in life-threatening complications following complex fusions procedures.[9] Spine Patient Outcomes Research Trials (SPORT) study showed a 30.8% incidence of early and late complications.10 One prospective study showed that 56.4% of their patients had at least one complication following instrumented fusions.[1] The overall incidence of major complications in our cohort was 20.33%. This may be accountable for the fact that the previous study comprised more of the complex fusion procedures requiring combined anterior and posterior approaches.

The same study had degenerative pathology accounting for almost 65.3% of cases followed by traumatic pathology observed in 19.3% of them.[1] Posterior only approach was undertaken in 41.1% and a combined approach was undertaken in 35.6% of cases in their study.[1] Comparatively, trauma comprised 190 (63.33%) of cases in our study. The posterior-only surgical approach was undertaken in 200 (66.67%).

Surgical site infection was the most common type of complication (6.67%) observed. This is similar to rates of 0.7 to 16% observed in the literature.[1, 11].

Biofilm within the implants can provide a milieu for protection as well as a phenotypic alteration for the growth and genetic transcription of the bacteria.[12]

Hardware-related complications (fracture, pullout, and loosening) were observed in 17 cases (5.67%) in our study. One study showed a risk rate of 2.4% per screw placement.[13] The most common complication has been shown to result from pedicle violation following medial angulation.[14] Screw loosening is more common in non-augmented screws (22.5% vs. 2.2%).There are twofold risks for reoperations on non-augmented compared to augmented screws.[15]

7.3% of patients in a study underwent revision surgery; mostly secondary to infections.[16] Another study showed revision rates of 24.3%.[1] The incidence of re-operation was 2.67% in our study but none of them were secondary to infections.

The mortality rate in our study was 2%. One study showed a mortality rate of 3.1% due to sepsis.[17]Another study pertaining to lumbar spine surgeries showed a mortality rate of 0.13% with the highest mortality resulting from shock and pulmonary embolism.[18] All of the mortalities observed in our study from the same consequences.

Relatively higher rates of complications observed in our study may be attributable to various factors. Firstly, being a tertiary level care centre, relatively higher proportions of patients sustaining severe injuries and presenting with low neurological status are being managed in our center. Secondly, almost 90% of the cases of surgical site infections are observed in patients with ASIA 'A' or 'B' neurological status. Thirdly, due to financial constraints, most of the patients have to be managed with short-segment fixation with low-cost implants; with the aim of providing anatomical stabilization for early rehabilitative strategies.

There are few limitations to our study. This is a single center study with relatively low patient inclusions. Further prospective multicentric studies or provision of nationwide database study would certainly help to provide the real-world incidence and patterns of complications of spinal instrumentations. Furthermore, being a retrospective study, recall bias is a limiting factor. Loss to follow-up is also an important confounding bias in our study.

Preoperative optimization of the patients, adoption of lean methodology, and implementation of procedure-specific, risk-adjusted predictive models may be pivotal for nullifying complications adherent to spinal instrumentation.[1, 19, 20]

Conclusion:

There are high risks of major complications associated with spinal instrumentations. These encompass multispectral and continuum short and long-term effects upon the patient and their caretakers. A thorough understanding of the incidence and patterns of such complications therefore can provide insights on forming preventive strategies, diagnostic algorithms as well as therapeutic ladders targeted against the same.

Conflict of interests- None

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