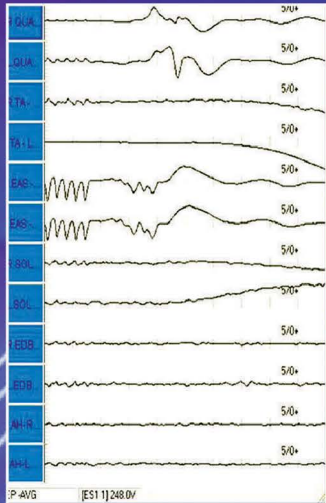




Monograph

Safe Spine Surgery

Avoiding Adverse Events and Improving Outcomes



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Safety in Complex Adult Spinal Deformity Surgery

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■ INTRODUCTION

Human life expectancy has improved significantly over the last few centuries. This improvement has been starker in the last 50–100 years. This has led to a burgeoning population of people who are living longer, both in developing and developed world. However, the disease-free proportion of life has stagnated and age-old morbidity period still hovers around 16–20%.¹ There will be a constant growth of adult population, which will be more in number and will be living longer over the coming years. Consequently, the incidence and prevalence of adult spinal deformity (ASD) will gradually increase over time. Symptomatic ASD causes significant disability which usually supersedes the disability caused by more prevalent chronic diseases.² The worst is reported in patients with lumbar scoliosis combined with sagittal malalignment [sagittal vertical axis (SVA) >10 cm], which causes extreme disability. Surgical management, despite demonstrating significant improvement in quality of life, as shown in various studies, has complication rates which are significantly higher than the “run of the mill” spine surgeries. Complex adult spinal deformity (CASD) patients have reported complications rates between 40 and 86% in various studies^{3,4} (**Table 1**). Despite this, complex adult spine deformity surgery (CASDS) is one of the newer and

rapidly evolving fields in spine surgery, where horizons have expanded and new strides have been taken in the last few decades with improved outcomes. This has been done by increased surgical skill development/experience along with a sharp focus on the patient, outcomes, and procedural safety. Significant efforts have been put into understanding the patient’s disability and treatment journey from multiple stand points, to identify sources of error, pain points, and creating awareness about the complexity of handling this problem. The recent endeavors have been aimed at reducing not just mortality but morbidity of the procedure, diagnostic and technical errors, miscommunication, and upholding the dignity of patients.

Patient safety literature is usually divided into clinical aspects and other factors. The clinical aspect usually relates to the procedure and surgery related such as management of osteoporosis, choosing the right procedure/plan, spinal cord monitoring minimally invasive spine surgery (MISS), strategies for mitigating blood loss, obesity, etc. The other factors include team communication, coordination strategies, safety checklist and culture, etc. The chapter looks at these aspects to give an overview to the readers regarding the salient issues to be kept in mind for complex adult spine deformity with keeping “*Primum non nocere*.” “First, do no harm” as the guiding principle.⁵

TABLE 1: List of complications in complex adult spine deformity surgery.

<i>Medical complications</i>	<i>Surgical complications</i>
Pulmonary complications (effusion/atelectasis/infiltrates)/ (collapse/edema/pneumothorax/hemothorax)	Surgical site infections (early/late)
Pneumonia (nosocomial) (aspiration)	Excessive bleeding
Acute respiratory distress syndrome (ARDS), acute lung injury (ALI), transfusion related acute lung injury (TRALI)	Instrumentation failure
Pulmonary embolism and deep vein thrombosis	Graft failure
Cardiac complications	Epidural hematoma
Renal failure	Vertebral compression fracture
Prolonged ileus	Vascular injury
SMA syndrome	Incision abdominal hernia
Pancreatitis	Pedicle or lamina fracture
Cholecystitis	Dural tears
GI hemorrhage	Transient neurological deficits
Urinary tract infection	Retroperitoneal hemorrhage
Pseudomembranous colitis	Complete paralysis
Delirium	Para/quadruplegia/paresis
DIC	Perioperative blindness
Decubitus ulcers	Junctional failures
Hyponatremia/SIADH	Revision surgery
Rhabdomyolysis	

(DIC: disseminated intravascular coagulation; GI: gastrointestinal; SIADH: syndrome of inappropriate antidiuretic hormone secretion; SMA: superior mesenteric artery)

DECISION-MAKING, CHECKLIST, AND WORKFLOW

An ideal decision is one which is tailor made and suited to give a favorable outcome to the patient with least possible complications, and arrived at with consensus. Decision-making in CASDS suffers from the “problem of many hands.” This term was first used in context of politics which illustrates the lack of responsibility in complex systems due to interaction of multiple parties. CASDS requires a multiple set of intensely specialized, yet discordant, actors who have different aims, priorities, and limitations. Most of the times, the decision-making process in CASDS

is haphazard and is heavily skewed toward surgeon’s/institution’s biases, along with the inability of the patient to fully grasp the scale of intervention and its implications.

These lead to systematic weaknesses that, when accumulated over time and left unnoticed, lead to poor outcomes. In order to avoid the above issues, it is required to stop making adult spine deformity decisions in a top-down manner with the surgeon being the sole expert and authority, and shift to a system of meritocracy and proper coordination, where the expertise and experience of every person in the team can be employed. The team should seek to expand

their perspectives, understand how patients think, understand and behave, and how to leverage strengths toward specific treatment goals. Moreover, there should be a feedback loop across the cycle aimed at refining and improving this approach to optimize the safety goals. Aviation and healthcare sectors have a lot of similarities. Military Crew Resource Management (CRM), in addition to civilian CRM (effective leadership, interpersonal communication, and decision-making amongst all crew members), emphasizes upon extensive briefing and debriefing after the procedure.^{6,7} This allows reflection and leads to continuous improvements in the care and outcomes even if a small amount of time is devoted to it. Military CRM has good lessons which can help in achieving these safety goals as surgeons are like fighter pilots.⁸

Avoidable errors in routine preoperative and planning steps can greatly enhance the safety in spine surgery. The utility of checklist has been proven beyond doubt to enhance safety in other complex fields, such as aviation. Application of World Health Organization (WHO) surgical checklist is one such successful example in medicine and one of the most impactful interventions in medicine in the last 30 years.⁹ Extension of these checklists to standardize the preoperative work-up, intraoperative steps, and postoperative protocol can have far-reaching effects in providing surgical decision-making and care consistently, correctly, and safely. Following a checklist helps everyone in the team navigate the complex world of adult spine deformity care where the volume and complexity of data can be overwhelming. The “time out” built in checklist allows the surgical team/medical team to address any communication issues or questions, before and during the procedure.

The various form of workflow algorithms from automobile manufacturing such as lean methodologies (Toyota system) or assembly line philosophy (Ford motors), which revolutionized and standardized the automobile manufacturing in USA, have some learning which can be applied to healthcare and CASDS. These techniques have been reported to reduce error rates, enhance productivity, reduce production times, and provide consistent quality improvements. These methodologies also form the basis of some deformity surgeon groups workflow recommendations, and one such example is the Seattle Spine Team Protocol (SSTP).¹⁰

PATIENT COUNSELING AND OPTIMIZATION

Another necessary part of safety is awareness of reasonable goals and complications by both the patient and the surgeon. A clear understanding and effective coordination between the patient and the surgeon helps in setting reasonable expectation out of the procedure. This process starts when the treatment options are first discussed; however, this information is often forgotten or not fully understood. This problem is addressed by ensuring that the surgeon has discussed and counseled the patient in the language best understood by him/her, ideally on two different days and sessions to improve retention and absorption of information. At the end of counseling session, both the patient and the surgeon should be in agreement on all steps of the medical/surgical procedure. There might be specific concerns which need to be addressed in the course of preliminary counseling itself and some might require further consultation. The patient should be encouraged to explain back to the treating team what he/she understood after the counseling session, in

order to address any misunderstanding and loss of information during the counseling session. The patient should also be encouraged to do his own research and collate his question and concerns, which arise out of primary counseling session. These need to be addressed, to the best of the treating team's ability, before the final detailed consent is obtained.

Patient engagement and education are key to ensuring that a surgical procedure goes smoothly. It is a good practice to go through the discussion involving the explanation of pathology, treatment options, alternatives along with risk and benefits, once again after the admission and before signing the consent form. Certain protocols such as SSTP call for extensive opportunity to ensure that the patient understands exactly what is going to happen and also mandates an education class for the patient and family.¹⁰ While this is a desired activity, the form of patient education, such as one-on-one versus a class-based session, should be left in the author's opinion to the treating team depending on what is best suited for their health system and its antecedent pressures.

After the decision is made to proceed with a surgery, a presurgical optimization process is begun and is aimed to identify and address modifiable risk factors such as medical comorbidities, anticoagulation, nutrition, and bone density. Preoperative optimization plays a significant part in ensuring that CASDS cases have a decreased risk of negative patient outcomes. This process starts usually with a preanesthetic evaluation which usually follows consultation from cardiologist, physician, pulmonologist, and any other specialty may be involved depending on comorbidities. The patient undergoes extensive blood work-up to identify any abnormality in major organ system and may also need a cardiac

stress echocardiography for evaluation of heart status. Depending on the feedback from various specialties, the patient is optimized before the surgery which may include iron supplementation for anemia, antiosteoporosis medications, altering anti-diabetic medication for glycemic control and stopping anticoagulants to minimize intraoperative bleeding. Preoperative optimization also allows for ordering any additional imaging which may be required and was not available at the time of initial decision-making. It usually includes a dual-energy X-ray absorptiometry (DEXA) scan, a magnetic resonance imaging (MRI) screening of whole spine in addition to a regional scan, whole spine X-rays, and local computed tomography (CT) scan with pedicular cuts, if required, for surgical planning. A special emphasis on patients with osteoporosis and patients with significantly low bone density is needed as there is a higher risk of a fracture related to the surgery or an instrumentation failure postsurgery. Additional steps such as risk stratification should be considered in form of multidisciplinary approach for treatment and modification of the surgical plan. Risk Stratification has been dealt extensively in a separate section in this monograph and can be referred by readers for further information.

MEDICAL COMPLICATIONS IN ADULT SPINAL DEFORMITY

The incidence of medical complications in CASDS has been reported to be 13.7% and 16.1% in two retrospective series.^{11,12} However, a recent large multicentric prospective series reported medical complication rates of 26% after CASDS. The same study reported smoking, hypertension, and duration of symptoms as independent risk factors for

development of medical complications. This can help in planning and gauging, individual risk for likelihood of medical complications after the surgery. The medical complications did not affect the final functional outcome as measured by Oswestry Disability Index (ODI), Short Form-36 (SF-36), and SRS 22r (Scoliosis Research Society Questionnaire) in both short term and long term. The functional results were comparable to patients who did not develop any medical complications.¹³

The most common medical complication after adult spinal surgery includes pulmonary complications which can occur in almost two-third of patients. The common radiographic abnormalities include pleural effusion, atelectasis, and infiltrates. If not managed and recognized early, it can lead to frank pneumonia. The risk factors for increased incidence of pneumonia include age >70 years, smoking history, chronic obstructive pulmonary disease, malnutrition, dental plaques, long duration of surgery, gastric tubes and enteral feeding, thoracic/anterior approaches, and prolonged immobilization.¹⁴ This can significantly prolong the length of stay in both intensive care unit (ICU) and hospital, which leads to additional costs. Hemothorax and pneumothorax are potentially lethal pulmonary complications whose incidence in adult deformity surgery is not well documented in literature unlike pediatric deformity where the reported incidence is between 1 and 2.2%.¹⁵ Preventive measures for pulmonary complications should be considered in the course of treatment which include adequate analgesia to prevent chest splinting and promote deep breathing along with incentive spirometry. Early mobilization helps in improvement of general well-being and prevents pulmonary complications. The other prominent medical ones include urinary tract infection (UTI) (9%) and deep

vein thrombosis (DVT)/embolism (0.3–14%). UTI also can increase the length of stay and costs. The urinary catheter is the main source of infection and should be removed as early as possible after the surgery. Washing hands before placing catheters and decompressing the tubing to facilitate continuous drainage prevents infection. The diagnosis is usually made by collecting and sending urine cultures and treated by appropriate antibiotics.

Venous thromboembolism (VTE) is another common preventable complication in adult spine deformity surgery (ASDS). The reported rate of VTE in meta-analysis by Kim et al. is 4.3% which is higher than other surgeries and can be attributed to extensive duration and length of surgery and can lead to delayed mobilization. Moreover, the authors feel that even this high incidence may be underreported. The rate of pulmonary embolism (PE) is around 2.4% compared to 1.9% for DVT. They also reported that patients with VTE have poor functional outcomes, stay longer in hospitals, and have higher mortality rates.¹⁶

Curiously, in the statistical model, Kim et al. found osteoporosis, SVA correction, and preoperative low mobility as independent predictors for higher risk of DVT in ASDS. Thus, prevention of VTE is paramount in complex adult spine surgery which includes use of pneumatic compression devices, early mobilization, and use of low molecular weight heparin and inferior vena cava filters in certain high-risk cases.

Obesity

Obesity is a worldwide epidemic which is common in both in developing and developed world. Studies have placed the incidence around 40% in US population and up to 35% in Indian population may be suffering from

abdominal obesity.¹⁷ More and more people with complex spinal deformity are coming with obesity as a comorbidity, as this problem has been increasing over the past decades. Role of obesity is still being investigated in detail in spinal surgery and the jury is still not out on the conclusive effects of obesity as conflicting results have been reported by various authors. Since complex ASD is a more extensive form of spine surgery, the effects may be more pronounced and obesity may be a factor which might negatively tilt the scale.

Obesity has been shown to be a risk factor which increases the complication rate in ASD in a multicentric study by Smith et al. with a minimum 2-year follow-up.¹³ In one study, obese patients have been reported to experience significantly more major complications and with higher trend toward overall complications rates with similar rates to minor complications compared to nonobese patients. Moreover, obesity is an independent risk factor for surgical site infection (SSI) as reported in meta-analysis by spine surgery patients by Jiang et al.¹⁸ Despite this the obese patients who underwent ASD surgery reported significant improvement in health-related quality of life (HRQoL) outcomes from preoperative levels though the extent was less for them. Hence, the obese patients do benefit from the procedure albeit at the risk of experiencing more adverse events in intraoperative and follow-up period. In fact, Class 1/2/3 obesity is associated with more than two times odds of extended ICU duration and length of stay. Obesity is also a risk factor for 30-day readmission.¹⁹ Overall, patients with body mass index (BMI) ≥ 35 are associated with significantly inferior perioperative outcomes and higher costs compared with those of nonobese patients undergoing complex adult spine surgery.²⁰ Despite this preoperative bariatric surgery

may not be of benefit to patients undergoing complex ASD surgery as prevalence of greater pre- and postoperative pain as well as higher ODI/Neck Disability Index (NDI) scores in patients with prior bariatric surgery undergoing lumbar spine surgery.²¹

Contrary to prevalent belief, the implant-related complication/failure rates do not correlate with BMI measurements which has been shown by Soroceanu and Fu et al. in their respective study.²² Instead of BMI, they have postulated absolute weight to be a determining factor in implant-related issues. This is likely due to absolute weight being the factor causing stress fatigue of implants leading to more complications.

Osteoporosis

One of the most common occurrences with symptomatic CASD is osteoporosis.²³ The deformities have been reported to progress at a higher rate in patients with pre-existing osteoporosis.²⁴ Osteoporosis is known to cause higher incidence of implant-related complications due to lower pull out strength and reduced insertional torque.²⁵ This leads to higher rates of implant failure, proximal junctional kyphosis, pseudarthrosis, and vertebral fractures.²⁶⁻²⁹ It has been shown in various studies that patient with osteoporosis require higher reoperations (41% vs. 28%) in ASD patients.

Hence, it is important to mitigate the effect of osteoporosis. However, the rate of detection is low in patients with ASD, and even in diagnosed cases, only a third of patients are on any medical treatment.³⁰ To diagnose osteoporosis, all patients should undergo a preoperative DEXA scan of at least two sites other than spine to determine the degree of osteoporosis/osteopenia as per WHO criteria [bone mineral density (BMD) -1 to -2.5 osteopenia; less than -2.5

osteoporosis]. This is done to remove the confounding by erroneously reported high bone density from spine in some patients with ASD. The preoperative diagnosis, where the BMD is less than -2.5 , helps us in optimizing the patients by building up bone density using medical therapy such as teriparatide, bisphosphonates, and calcitonin, unless the patient has neurological deficit.³¹ In some studies, teriparatide has been shown to have a positive impact on fusion rates in osteoporotic perimenopausal women.³² Moreover, it also prepares the surgical team to modify and stipulate surgical procedure and technique more suited to osteoporotic bone. The various strategies employed by the surgeons in setting of osteoporotic spine include extension of instrumentation in pelvis for better stability and level arm,³³ under tapping of pedicle screws, vertebral cement augmentation,³⁴ and soft tissue and joint preservation techniques, especially in area proximal to the construct.²⁵ Thus, osteoporosis has been shown to be a strong predictive factor for reoperation rates within 2 years in patients undergoing complex adult spine deformity correction and fusion surgery.³⁵ The excess morbidity arising out of reoperation should prompt the surgical team to place protocols to readily identify osteoporosis and aggressively treat it.

Blood Loss

Blood loss during the CASD is one of the challenging aspects of management as it involves extensive surgery with larger incision, exposure, extensive bone resection, and instrumentation which leads to operative duration extending over many hours.³⁶ Its effective management has implications for both intraoperative, postoperative, and ultimate outcome of spine surgery. The

management starts in the preoperative work up period to reveal any patient specific factor such as coagulopathies, anti-coagulant, and antiplatelet use along with starting hemoglobin levels. The latter is an important consideration in developing and underdeveloped world where the patients especially females are prone to chronic anemia. Diagnosing and correcting these factors go a long way in reducing blood loss during the surgery. This can also lead to alteration in surgical plan in extreme cases. The patient should be made aware of the anticipated amount of blood loss and antecedent transfusion requirements. Various strategies are employed by surgeons depending on center and resources available, which may include use of cell savers, hemostatic agents, rapid infusers, and especially tranexamic acid (TXA). Recent meta-analysis by Huang et al. has shown that TXA infusion is safe and effective, which significantly reduces the volume of blood loss and transfusion volume in patients undergoing eight or more levels of correction surgery, without any increased incidence of thromboembolic episode.³⁷

The workflow/checklist should have a mechanism to explicitly discuss the aspect of blood loss by the team, anesthetist, and if required the blood bank. There should be a predetermined work flow and hourly tracking system for blood loss, blood products, and coagulation parameters in the operating room which should lead to an informed and cooperative decision by the anesthetist and the operating team.

Spinal Cord Monitoring

One of the most devastating complications of complex adult spine deformity is paralysis and nerve injury. The reported rate for

neurological deficit in ASD is around 1.8% as reported by Sansur et al. from the Scoliosis Research Society (SRS) morbidity and mortality database of 4,980 patients. The majority of injury is root injuries with complete paralysis, an uncommon complication.³⁸ The reported rate of complete paralysis ranges from 0.51 to 0.65% in various series, whereas the incomplete paralysis rate can be as high as 1.25%. In a recent meta-analysis by Sciubba et al. on complications in adult spine surgery, the incidence of neurological complications has been reported as high as 3.1% out of total cases of total 11,692 included cases in study.³⁹ This is due to the surgical procedure involving a significant work around the neural structures along with prolonged surgery time and excessive blood loss. The common modes of neural injury include mechanical causes or ischemic. The mechanical injury can be due to direct trauma by instruments or misplaced implants, bone grafts, and sometimes due to hematoma. Ischemic injury can be due to cord ischemia/hypoperfusion, compression, or abnormal stretching during correction maneuvers. The incidence of spinal cord/neural injury increases with deformity correction of large curves and instrumentation levels, short kyphosis, patients with pre-existing neurological deficit, and congenital malformations.⁴⁰ Among the many strategies to mitigate this complication, intraoperative neural monitoring remains the most essential and critical. It can be in the form of transcranial motor evoked potential (Tc-MEP), somatosensory evoked potential (SSEP), electromyography (EMG), and triggered EMG for checking screw placement or combination of either. Both mechanical and ischemic injuries to the cord can be reliably detected by intraoperative spinal cord monitoring. It allows the surgeon to do more correction maneuvers/osteotomy and

instrumentation with reasonable confidence and in some cases can allow guided correction of deformity. In one study, intraoperative multimodal monitoring has been shown to be having a sensitivity of 100%, specificity of 99.3%, and more importantly negative predictive value of 100%. Similar rates of sensitivity were noted for motor evoked potential (MEP) monitoring.⁴¹ The SRS data also shows high level of intraoperative spinal cord monitoring changes in patient with postoperative neurological deficit. Intraoperative spinal monitoring, by alarming the team, prevents further injury to the cord and reduces response time between the insult and action which can help avert permanent deficit and add a robust safety layer in CASDS.

Proximal Junctional Kyphosis

One of the most commonly encountered complications after CASDS in the follow-up period is that of proximal junction kyphosis/failure (PJK) with reported incidence between 20 and 40%.^{42,43} However, not all cases are symptomatic, but up to 47% of severe cases of proximal junctional failure (PJF) may require operative intervention in form of revision surgery in one study.⁴⁴ The common reasons attributed to PJK are intraoperative factors such as facet violation, indiscriminate soft tissue dissection, injury to posterior tension band and vertebral fracture, degenerative disk disease and natural progression of deformity due to aging, and instrumentation failure in the follow-up period. The accepted definition of PJK varies from 5 to 20° of kyphosis more than the normal angulation at one or two level of proximal instrumented vertebrae.⁴⁵ However, in the authors' opinion, >10° of angle is an acceptable working cut-off for diagnosing a case of PJK, based on available

studies and experience. Up to two-third of PJK is diagnosed within 3 months of index surgery and after 18 months, the incidence comes down drastically.⁴⁶ The various strategies for preventing PJK are categorized mainly into amendable and nonamendable. The amendable ones include decreased stiffness of construct, preservation on soft tissue around upper instrumented vertebra (UIV), inclusion of segments with $>5^\circ$ of kyphosis proximally, using less implants, performing osteotomies distally, transition rods, hooks, avoiding thoracoplasty procedures, fusion to the lower lumbar vertebra and sacrum, and most important achieving optimal sagittal alignment. The nonamenable ones include older age (>55 years), high pelvic incidence, BMI, and large abnormal preoperative sagittal parameters. Position of UIV in upper thoracic and lower thoracic spine has been shown to be independent risk factor for PJK. It is interesting to note that both sites of UIV have different modes of failure where the more proximal thoracic one is usually due to posterior tension band failure and subluxation and the distal thoracic PJK is commonly attributed to fracture of the vertebrae.^{47,48} Cement augmentation of UIV or vertebrae above it has been used as a strategy by many surgeons to reduce the incidence of PJK and PJF based on limited clinical data⁴⁹ and few biomechanical studies.^{50,51} However, its long-term effect is controversial, as cementing leads to altered load transfer causing fractures and collapse of adjacent vertebrae.^{52,53} Further, cement being nonbiological in nature reduces the disk nutrition and enhances the disk degeneration cascade which promotes the environment for PJK.⁵⁴ Recently, two classifications have been proposed to describe the various grades of PJK based on meta-analysis of published data. These include Modified Boachie-Adjei

Classification and Hart-International Spine Study Group (ISSG) PJK Severity Scale. The Modified Boachie-Adjei Classification is simpler, easily communicable and descriptive, with limited actionable management information and includes types of failure, angle of kyphosis, and presence of spondylolisthesis.⁵⁵ This is in contrast to Hart-ISSG PJK severity scale which helps in identifying cases requiring revision surgery based on the point score assigned based on six parameters which include neurological deficit, focal pain, instrumentation problem, change in kyphosis/posterior ligament complex integrity, fracture location, and level of UIV.⁴⁵ This system has been shown to have good reliability and reproducibility, with revision surgery usually required for a score of ≥ 7 .⁵⁶

Surgical Site Infection

Infection is the second most common complication (2.4%) after dural tears (2.9%) in ASDS as reported in SRS morbidity and mortality of adult scoliosis surgery data. The deep infection (1.5%) was nearly twice as more common than superficial infection (0.9%) cases. The infection was more common in osteotomy group as compared to the group of patients who did not undergo osteotomies (3.3% vs. 2.1%).³⁸ Nearly similar rates of infection (2.4%) were reported by Lee et al. in their study but within 30 days of the adult deformity spine surgery, which included 5,803 patients. The independent risk factors which predispose for early wound infection include preoperative blood transfusion, obesity grade 2 and 3, American Society of Anesthesiologists (ASA) grade ≥ 3 , posterior approach, and operative time >4 hours.⁵⁷ Thus, reducing incidence of infection in complex spine surgery is important as

SSI increases length of stay, morbidity, cost, and affects outcomes. There are many strategies to be employed in combination to achieve this goal. This includes identifying and aggressively acting on modifiable factors which predispose for infection in preoperative period such as stopping to smoke, tight glycemic control, and managing obesity. This is followed by appropriate use of standardized antibiotic prophylaxis, aseptic precautions, and antibiotic dressings in operation theater (OT). Some people have reported decreased rates of infection by using frequent wound wash with copious amount of saline or diluted betadine during the surgery.^{58,59}

ROLE OF MINIMALLY INVASIVE SPINE SURGERY

Minimally invasive spine surgery for complex adult spine deformity helps in reducing the morbidity associated with the procedure. It also allows feasibility of surgical options in patient with comorbidities and advance age, where open techniques may not be suitable. It improves safety by reducing blood loss, surgical exposure, preservation of spinal musculature, and early mobilization, but with some limitations.⁶⁰ Hence, identifying patients who are most suitable for this approach is paramount for getting optimal results. There are various techniques and combinations applied in order to get the desired result, which includes minimally invasive-transforaminal lumbar interbody fusion (Mi-TLIF), Mi-lateral approach for interbody fusion [lateral lumbar interbody fusion (LLIF)], and a combination of anterior [mini open anterior lumbar interbody fusion (ALIF)] and posterior surgery in the form of circumferential MISS involving percutaneous pedicle screw and cages.⁶¹

The first-generation minimally invasive deformity (MISDEF) algorithm incorporated initially available techniques which primarily included percutaneous screw fixation along with lateral interbody cages or Mi-TLIF for anterior reconstruction.⁶² These techniques produced only modest changes in sagittal alignment and limited the use of MISS. Since the advent of anterior longitudinal ligament release (ALLR) and anterior column realignment (ACR), the ability of surgeons to deal with these complex deformities has significantly increased. This technique allows not only coronal but sagittal plane deformity correction simultaneously. The use of ACR resulted in significant improvements in lumbar lordosis, physical therapy (PT), and pelvic incidence–lumbar lordosis (LL-PI) mismatch. A multicentric study done by Turner et al. shows significant segmental lordosis improved at ACR levels from mean of -2.2° preoperative to -16.0° postoperative; this is in contrast to the patient who underwent LLIF without ALLR had modest improvement in segmental lordosis from preoperative (-2.4°) to postoperative (-7.1°). The addition of osteotomy along with ACR increases the segmental lordosis by 72.7%.⁶³

MISDEF-2 algorithm has been published by Mummaneni et al. which is an advancement over MISDEF algorithm for a guide to patient selection for MISS using the current available techniques including ACR.⁶⁴ The flexible deformities (Classes 1 and 2) and some limited cases of fixed deformities (Class 3) are available for MISS deformity surgery. It appears to be an effective tool in mild-to-moderate cases of deformity with minimal-to-modest sagittal plane deformity (SVA: 5–9 mm).⁶⁵ The Class 3 deformity correction where (LL-PI mismatch $>30^\circ$, thoracic kyphosis $>30^\circ$, thoracolumbar kyphosis $>10^\circ$) is to be attempted only by

surgeons with significant experience in adult MISS surgery and may involve combination of various technique such as mini-open pedicle subtraction osteotomy (PSO), circumferential minimally invasive surgery (MIS), use of expandable cage, and hybrid approaches. MISS is clearly not suited for patients with Class 4 deformities which include rigid deformities requiring >5 levels of fusion including L5-S1, >10 segments needing treatment, pre-existing multilevel instrumentation with severe derangement of pelvic parameters, and significant SVA >10 mm, are best treated with open surgery.

The outcome of meta-analysis reported by Dangelmajer et al. found no significant difference between the complication rates of MIS and open approaches.⁶⁶ This was further reinforced in another recent meta-analysis by Zanirato et al. on complications between open (10.9%), hybrid (14.7%), and MISS (9%) surgery for adult deformity also demonstrated comparable results.⁶⁷ Nevertheless, choosing the correct technique and the right patient is vital for acceptable outcome. This has to be done with extreme care and on case-to-case basis taking into account the skill and experience of surgeons as MISS techniques have notoriously high learning curve.

■ CONCLUSION

CASDS is a very complex problem which has a lot of variables which need to be taken care of to optimize the outcome. The intention is to reduce the incidence of complications by taking steps to anticipate and mitigate them, as much as humanly possible, in a given setting. The preoperative counseling, protocols, checklist, work flow, and CRM approach help in standardization of the care process and making it efficient, with active participation and understanding of the patient. It is also important to note that most

of the data/research has originated from the developed world. This may not be applicable in current avatar to the developing and underdeveloped parts of world. Therefore, it is advisable that the spirit of the above should be taken and improvisation and modification to be done as per the local conditions/healthcare systems. There can be significant differences in the patient's preoperative profile in developing and least developed worlds, which can be in the form of more advanced/neglected disease, pre-existing poor nutritional status, anemia, osteoporosis, and vitamin D deficiency. Moreover, both financial and logistical resources may also be constrained significantly depending on the healthcare delivery model. Most of the times, the healthcare cost is borne out-of-pocket expenditure unlike insurance or state support as available in the developed world. Hence, the decision to safely operate may have to be taken more carefully and should integrate the social aspect of healthcare in addition to clinical. Last but not the least, MISS has rapidly gained strides which has enhanced the safety profile of these complex procedures in carefully selected patients.

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ASSI Monograph Safe Spine Surgery

Avoiding Adverse Events and Improving Outcomes

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- Awareness about the preventable adverse events with detailed description of preventing them by following checklists, safety protocols, risk stratification and postoperative protocols for early rehabilitation in complex spine surgeries
- Value and use of modern technologies (Functional MRI, EOS, O-arm, Navigation and Robotics) for safe spine surgery during the course of decision-making and performing the spine surgery
- Use of comprehensive safety protocols in management of complex spinal deformity in adults and pediatrics
- Understanding and learning of nontechnical skills from nonmedical fields to increase the safety of the patients undergoing spine surgery
- Incorporating medicolegal aspects for safety in the protocols and methods to approach if safety is breached.

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