ORIGINAL RESEARCH PAPER

Volume - 11 | Issue - 06 | June - 2022 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr

INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

A PROSPECTIVE COMPARATIVE COHORT ANALYSIS OF ADVERSE EVENTS FOLLOWING SPINE SURGERY IN PATIENTS ABOVE 60 YEARS OF AGE IN COMPARISON WITH THOSE UNDER 60 YEARS OLD USING SPINAL ADVERSE EVENTS SEVERITY SYSTEM, VERSION 2 , SAVES V2 IN A TERTIARY CARE CENTRE IN INDIAN SCENARIO

Neurosurgery

Harish Kumar	Consultant Nerosurgeon, Vardhman Mahaveer Hospital, Urban Estate Phase II, Patiala,Punjab-147002
Dr Aditendraditya Singh Bhati	Consultant Neurosurgeon, Indraprastha Apollo Hospital, Neurosciences OPD Gate no 10,Room No 1023,Sarita Vihar, New Delhi-110076.
Dr Aarti Narula	Assistant Professor, Department of Obstetrics and Gynaecology, Government Medical College,Patiala,Punjab-147001

KEYWORDS

A prospective comparative cohort analysis of adverse events following spine surgery in patients above 60 years of age in comparison with those under 60 years old using Spinal Adverse Events Severity System, version 2 , SAVES V2 in a tertiary care centre in Indian scenario

AIMS AND OBJECTIVES

- To determine the incidence, severity and outcome of adverse events using Spinal Adverse Events Severity System, version 2 (SAVES V2) system undergoing spinal surgery of patients above 60 years of age and to compare it with those with age below 60 years

Primary Objective:

- There is a need to identify any age related factors leading to adverse events, so that they can be utilized for better patient counselling and management.

Secondary objective:

- To identify the premorbid conditions contributing towards the adverse events in a spine surgery

MATERIAL AND METHODS

Setting: Dept. of Neurosurgery and Spine Surgery, Indraprastha Apollo Hospital, New Delhi

Study design: Prospective Comparative Cohort Study
Time frame: May 2018 to December 2019

Population: All the consecutive cases undergoing spine surgery at Dept. of Neurosurgery and Spine Surgery, Indraprastha Apollo Hospital, New Delhi, from May 2018 to December 2019 of all age groups.

Sample Size: In the absence of similar previous study based on the web search with key words of adverse events, age, spine surgery and SAVES V2. Cohen's effect size is used to calculate sample size of two samples with a continuous outcome variable. To detect medium scale ES (.5), the minimum required sample size with 80% power of study and two sided alpha of 5% was 63 patients per group. So, minimum sample size taken is 130 (65 per group). Formula used where Z_α is value of Z at two sided alpha error of 5% and Z_β is value of Z at power of 80% and ES is effect size.

Inclusion criteria:
All the consecutive cases between 1st May, 2018 to 31st December 2019 undergoing spine surgery

Exclusion criteria: Nil

Methods:
This prospective study included all the patients undergoing spine surgery between May 2018 and December 2019 at Indraprastha Apollo Hospital, New Delhi with a minimum target of 130.

After taking due written consent patients were enrolled for the study.

Clinical characteristics included pre-operative history, associated co-morbidities, detailed neurological and systemic examination, pre-operative imaging and other related investigations were recorded. Patient was thoroughly evaluated pre operatively and physician clearance for surgery was done. Special investigation like 2D Echo, Dobutamine stress echo were done and cardiology clearance taken in certain individuals wherever it was indicated. Other investigation like DEXA scan was done in suspected osteoporotic patients, and if T Score was less, then endocrinology consultation taken and treatment modified as per their advice and surgery was postponed for 6 – 8 weeks. Pre anesthetic evaluation was done and then patient was posted for surgery. Complete details of the procedure, intra operative findings and AE if any were recorded.

Data was collected for operative and post-operative period using SAVES V2 system which was as follows

SAVES-V2 Intraoperative Adverse Event categories
Intra-op Adverse Events Category
1. Allergic reaction
2. Anesthesia related
3. Bone implant interface failure requiring revision
4. Cardiac
5. Cord injury
6. Dural tear
7. Hardware malposition requiring revision
8. Hypotension (systemic <85 mm Hg for 15 min)
9. Massive blood loss (>5 L in 24 hrs or >2 L in 3 hrs)
10. Nerve root injury
11. Pressure sores
12. Vascular injury
13. Airway/ventilation
14. Visceral injury
15. Other (specify)

SAVES-V2 postoperative Adverse Events categories
Postop Adverse Events Category
1. Cardiac arrest/failure/arrhythmia
2. Construct failure with loss of correction
3. Construct failure without loss of correction
4. CSF leak/meningocele
5. Deep vein thrombosis
6. Deep wound infection
7. Delirium
8. Dysphagia
9. Dysphonia
10. Gastrointestinal bleeding
11. Hematoma
12. Myocardial infarction
13. Neurologic deterioration ≥1 motor grade in ASIA motor scale
14. Nonunion
15. Pneumonia
16. Postop neuropathic pain
17. Pressure sores
18. Pulmonary embolism
19. Superficial wound infection
20. Systemic infection
21. Urinary tract infection
22. Wound dehiscence
23. Other (specify:)

 PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr

Estimated effect of AE on LOS:
□ None□ 1–2 days□ 3–7 days
□ 8–14 days□ 15–28 days□ More than 28 days

SAVE S-V2 severity grades

Severity of Adverse Events Clinical	Impact
1	AE does not require treatment & has no adverse effect
2	AE requires minor invasive (e.g.Foley catheter, nasogastric tube) or simple treatment but has no long-term effect
3	AE requires invasive (e.g., surgery) or complex treatment (e.g., monitored bed) & is most likely to have a temporary (<6 mos) adverse effect on outcome
4	AE requires invasive (e.g., surgery) or complex treatment (e.g., monitored bed) & is most likely to have a prolonged (>6 mos) adverse effect on outcome
5	Significant neural injury (i.e., 1 or more grade deterioration in ASIA grade) or serious life- or limb-threatening event or any sentinel event
6	AE resulting in death

OPD follow up
1. Fever
2. Wound discharge
3. Chest pain
4. Breathlessness
5. Persistent Cough
6. Persistent pain
7. Worsening of neurological deficit
8. Re-joining of duty after how many days
9.Re-exploration at same level

OPD follow up done after 1 week and at the end of 1 month. Patient was followed in between if he had any adverse event.

Information other than included in SAVES criteria, which was also included in Study Performa

DELIP
AGE
SEX
Date of admission
Date of surgery
Date of discharge
Diagnosis/indication of surgery
Hypertension. Yes/No
Diabetes Mellitus type 2 Yes/No
CAD. Yes/No
Bronchial Asthma Yes/No
Previous Tuberculosis treatment. Yes/No
Any history of drug intake like aspirin/ methotrexate/ steroids. Yes/No
Previous spine surgery. Yes/No
Procedure performed
Instrumentation used Yes/No

RESULTS AND OBSERVATIONS

The present study was conducted in the Department of Neurosurgery and Spine Surgery, Indraprastha Apollo Hospital, New Delhi with the objective to determine the incidence, severity and outcome of adverse events using SAVES V2 system undergoing spinal surgery of patients above 60 years of age and to compare it with those with age below 60 years. A total of 357 patients were included in the study.

Table-1: Distribution of age among the study population

Age in years	No. (n=357)	%
<60	216	60.5
≥60	141	39.5
Mean±SD	51.29±18.42	

Table-1 show the distribution of age among the study population. More than half, 216 of 357 patients were <60 years of age (60.5%). The mean age of patients was 51.29±18.42 year

Fig. 1 show the distribution of gender among the study population. More than half of patients 214(59.9%) were males.

The percentage of male patients was also found to be among more than half of patients in both <60 years (56.5%) and ≥60 years (65.2%). There was no significant (p>0.05) difference in gender between the age groups.

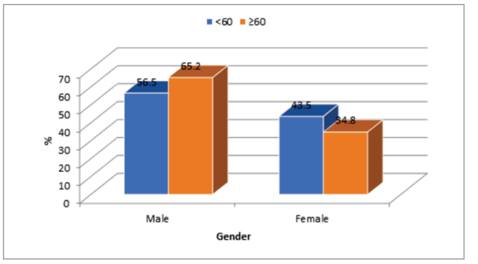

Fig 1: Distribution Of Gender Among The Study Population

Table-2: Comparison of type of surgery among the study population

Type of surgery	No. of cases (n=357)		Age in years				p-value[1]
			<60 (n=216)		≥60 (n=141)		
	No.	%	No.	%	No.	%	
Emergency surgery	7	2.0	3	1.4	4	2.8	0.33
Elective surgery	350	98.0	213	98.6	137	97.2	

[1]Chi-square test

Table-2 show the comparison of type of surgery among the study population. Elective surgery was performed among 350 patients (98%). The percentage of elective surgery was also found to be among majority of patients in both <60 years (98.6%) and ≥60 years (97.2%). There was no significant (p>0.05) difference in type of surgery between the age groups.

Fig.2 show the comparison of comorbidity among the study population. Hypertension was the most common comorbidity among the patients (30.5%). Diabetes mellitus was the second most common comorbidity among the patients (23.5%). Diabetes mellitus, Hypertension, Cardiac and Bronchial asthma were found to be significantly (p<0.05) higher among the patients of age ≥60 years than <60 years.

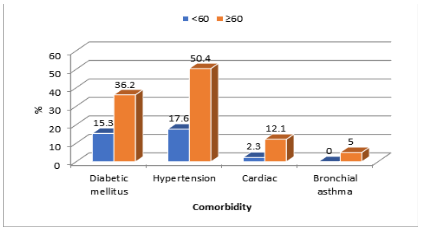

Fig. 2: Comparison of comorbidity among the study population

Table-3: Comparison of Drug history - aspirin/methotrexate among the study population

Drug history - aspirin/methotrexate	No. of cases (n=357)		Age in years				p-value1
			<60 (n=216)		≥60 (n=141)		
	No.	%	No.	%	No.	%	
Present	4	1.1	1	0.5	3	2.1	0.14
Absent	353	98.9	215	99.5	138	97.9	

[1]Chi-square test

Table-3 shows the comparison of drug history among the study population. The drug history was present in 4 (1.1%) patients. There was no significant (p>0.05) association of drug history of aspirin, methotrexate and steroids.

Fig.3 shows the comparison of previous spine surgery among the study population. The previous spine surgery was present in 12.6% patients.

 PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr

There was no significant (p>0.05) association of previous spine surgery with age among the study population.

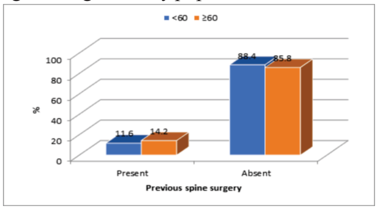

Fig. 3: Comparison of Previous spine surgery among the study population

Table-4: Comparison Of Diagnosis Among The Study Population

Diagnosis#	No. of cases (n=357)		Age in years				p-value[1]
			<60 (n=216)		≥60 (n=141)		
	No.	%	No.	%	No.	%	
TB Infection	13	3.6	10	4.6	3	2.1	0.21
Trauma	26	7.3	18	8.3	8	5.7	0.34
Spinal Tumor	53	14.8	38	17.6	15	10.6	0.07
Degenerative	254	71.1	139	64.4	115	81.6	0.0001*
Congenital	11	3.1	11	5.1	0	0.0	0.006*

[1]Chi-square test, #Multiple response, *Significant

Table-4 show the comparison of diagnosis among the study population. Degenerative diseases (ligamentum hypertrophy, disc herniation, bony spur) was the most common diagnosis among the 254 (71.1%) patients with 139 (64.4%) < 60 years and 115 (81.6%) > 60 years of age with a significant association (p = .0001). Spinal Tumor and trauma were the second(14.8%) and third most common diagnosis(7.3%) respectively.

Fig.4 show the comparison of intra-operative adverse events among the study population. Dural tear was the most common intra-operative adverse event among the patients (3.1%). Hypotension (systemic <85 mm Hg for 15 min) was the second most common intra-operative adverse event among the patients (2%) with no significant (p>0.05) difference in intra-operative adverse events between the two age groups.

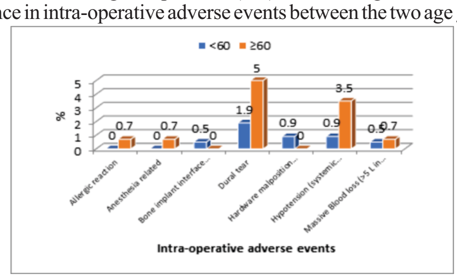

Fig. 4: Comparison Of Intra-operative Adverse Events Among The Study Population

Table-5: Comparison Of Post-operative Adverse Events Among The Study Population

Post-operative adverse events #	No. of cases (n=357)		Age in years				p-value[1]
			<60 (n=216)		≥60 (n=141)		
	No.	%	No.	%	No.	%	
Cardiac Arrest/failure/arrhythmia	3	0.8	2	0.9	1	0.7	0.82
Construct failure with loss of correction	3	0.8	1	0.5	2	1.4	0.33
Construct failure without loss of correction	1	0.3	1	0.5	0	0.0	0.41
Deep wound infection	1	0.3	1	0.5	0	0.0	0.41
Dysphagia	1	0.3	0	0.0	1	0.7	0.21
Neurologic deterioration >=1 motor grade in ASIA motor scale	8	2.2	2	0.9	6	4.3	0.06
Pneumonia	2	0.6	2	0.9	0	0.0	0.25
Postoperative neuropathic pain	10	2.8	8	3.7	2	1.4	0.20
Superficial wound infection	9	2.5	3	1.4	6	4.3	0.09
Systemic infection	4	1.1	2	0.9	2	1.4	0.66
Urinary tract infection	3	0.8	1	0.5	2	1.4	0.33
Others	10	2.8	5	2.3	5	3.5	0.49

[1]Chi-square test, #Multiple response

Table-5 & fig.5 show the comparison of post-operative adverse events among the study population. Postoperative neuropathic pain was the most common post-operative adverse event among the patients (2.8%). Superficial wound infection was the second most common post-operative adverse event among the patients (2.5%). There was no significant (p>0.05) difference in post-operative adverse events between the two age groups.

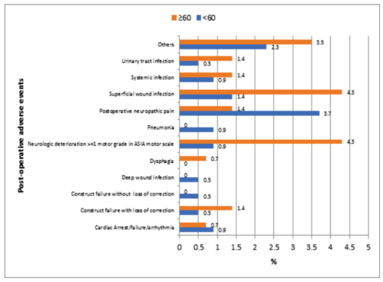

Fig. 5: Comparison of post-operative adverse events among the study population

Table-6: Comparison of length of hospital stay among the study population

Length of hospital stay In days	No. of cases (n=357)		Age in years				p-value[1]
			<60 (n=216)		≥60 (n=141)		
	No.	%	No.	%	No.	%	
1-2 days	76	21.3	52	24.1	24	17.0	0.51
3-7 days	240	67.2	141	65.3	99	70.2	
8-14 days	27	7.6	16	7.4	11	7.8	
15-28 days	9	2.5	4	1.9	5	3.5	
>28 days	5	1.4	3	1.4	2	1.4	
Mean±SD	4.96± 5.61	4.85± 6.20	5.12±4 .59				

[1]Chi-square test

Table-6 show the comparison of length of hospital stay among the study population. The length of hospital stay was 3-7 days among more than half of patients (67.2%) and 1-2 days in 21.3% patients. The mean length of hospital stay was 4.85±6.20 days and 5.12±4.59 among the patients of age <60 and ≥60 years respectively. There was no significant (p>0.05) difference in length of hospital stay between the two age groups.

Table-7: Comparison Of Grades Of AE As Per SAVES V2 Among The Study Population

Grades	No. of cases (n=68)		Age in years				p-value[1]
			<60 (n=33)		≥60 (n=35)		
	No.	%	No.	%	No.	%	
Grade 1	34	50.0	18	54.5	16	45.7	NA
Grade 2	16	23.5	5	15.2	11	31.4	
Grade 3	13	19.1	6	18.2	7	20.0	
Grade 4	0	0.0	0	0.0	0	0.0	
Grade 5	0	0.0	0	0.0	0	0.0	
Grade 6	5	7.4	4	12.1	1	2.9	

[1]Chi-square test, NA-Not applicable as >1 0s in a column

Table-7 show the Comparison of Grades of AE as per SAVES V2 among the study population with 34(50.0%) patients had grade 1 severity of AE with 18 (54.5%) < 60 years and 16(45.7%) > 60 years of age group with no significant association. 16 (23.5%) and 13 (19.1%) patients had a grade 2 and grade 3 severity respectively.

Fig.6 show the comparison of procedure done among the study population. Lumbosacral procedure was done among more than half of patients (61.1%) and cervical procedure was done in 26.3% patients. There was no significant (p>0.05) difference in procedure done between the two age groups.

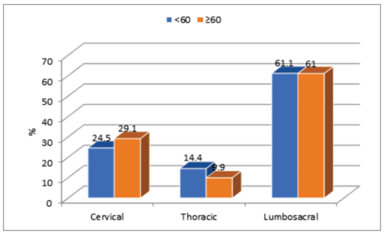

Fig. 6: Comparison of procedure done among the study population

Fig.7 show the comparison of OPD follow-ups among the study population. Persistent pain and Re exploration at same level each constituted in 1.4% patients at OPD follow-up. There was no significant (p>0.05) difference in OPD follow-ups between the two age groups.

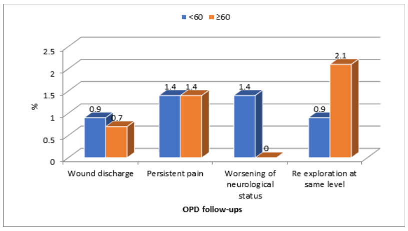

Fig. 7: Comparison of OPD follow-ups of patients among the study population

Table-8: Comparison Of Any Intra-operative AEs Among The Study Population

Any intra-operative AEs	No. of cases (n=357)		Age in years				p-value[1]
			<60 (n=216)		≥60 (n=141)		
	No.	%	No.	%	No.	%	
Present	23	6.4	8	3.7	15	10.6	0.009*
Absent	334	93.6	208	96.3	126	89.4	

[1]Chi-square test

Table-8 & Fig.8 show the comparison of any intra-operative AEs among the study population. Any intra operative AEs was present in 6.4% patients. Any intra-operative AEs was lower among the patients of age <60 years (3.7%) than ≥60 years (10.6%).

There was significant (p=0.009) association of any intra-operative AEs between the two age groups.

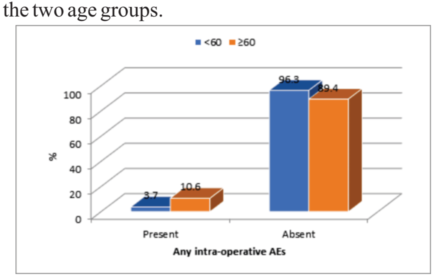

Fig. 8: Comparison of any intra-operative AEs among the study population

Table-9: Comparison Of Any Post-operative AEs Among The Study Population

Any post-operative AEs	No. of cases (n=357)		Age in years				p-value[1]
			<60 (n=216)		≥60 (n=141)		
	No.	%	No.	%	No.	%	
Present	49	13.7	25	11.6	24	17.0	0.14
Absent	308	86.3	191	88.4	117	83.0	

[1]Chi-square test

Table-9 show the comparison of any post-operative AEs among the study population. Any post-operative AEs was present in 49 (13.7%) patients. Incidence of any post-operative AEs was lower among the patients of age <60 years 25 (11.6%) than ≥60 years 24 (17%) patients with no significant (p>0.05) difference in any post-operative AEs between the two age groups.

Table-10: Comparison of any intra-operative AEs among the study population with duration of hospital stay

Duration of hospital stay	No. of patients	Any intra-operative AEs				p-value1
		Present	Absent			
		No.	%	No.	%	
1-2 days	76	4	5.3	72	94.7	NA
3-7 days	240	17	7.1	223	92.9	
8-14 days	27	0	00	27	100.0	
15-28 days	9	2	22.2	7	77.8	
>28 days	5	0	0.0	5	100.0	
Mean±SD		5.65±1.18		4.90±0.30		

1Chi-square test, NA-Not applicable as >10s in a column

Table-10 show the comparison of any intra-operative AEs among the study population with duration of hospital stay. Any intra-operative AEs was highest among whom who stayed for 15-28 days (22.2%) and lowest in 1-2 days (5.3%).

Table-11: Comparison of any intra-operative AEs among the study population with duration of hospital stay

Any intra-operative AEs/ Duration of hospital stay	Age in years				p-value[1]
	<60 (n=216)		≥60 (n=141)		
	No.	%	No.	%	
Present	(n=8)		(n=15)		
1-2 days	2	50.0	2	50.0	0.66
3-7 days	5	29.4	12	70.6	
15-28 days	1	50.0	1	50.0	
Absent	(n=208)		(n=126)		
1-2 days	50	69.4	22	30.6	0.56
3-7 days	136	61.0	87	39.0	
8-14 days	16	59.3	11	40.7	
15-28 days	3	42.9	4	57.1	
>28 days	3	60.0	2	40.0	

1Chi-square test

Table-11 show the comparison of any intra-operative AEs among the study population with duration of hospital stay with no significant (p>0.05) association.

Table-12: Comparison of any post-operative AEs among the study population with duration of hospital stay

Duration of hospital stay	No. of patients	Any post-operative AEs				p-value[1]
		Present	Absent			
		No.	%	No.	%	
1-2 days	76	7	9.2	69	90.8	0.0001*
3-7 days	240	30	12.5	210	87.5	
8-14 days	27	4	14.8	23	85.2	
15-28 days	9	6	66.7	3	33.3	
>28 days	5	2	40.0	3	60.0	
Mean±SD		7.35±1.05		5.17±0.29		

[1]Chi-square test, *Significant

Table-12 show the comparison of any post-operative AEs among the study population with duration of hospital stay. Any post-operative AEs was highest among whom who stayed for 15-28 days (66.7%) and lowest in 1-2 days (9.2). There was significant (p=0.0001) association of any post-operative AEs among the study population with duration of hospital stay.

Table-13: Comparison Of Any Post-operative AEs Among The

PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr

Study Group With Duration Of Hospital Stay

Any post-operative AEs/Duration of hospital stay	Age in years				p-value[1]
	<60 (n=216)		≥60 (n=141)		
	No.	%	No.	%	
Present	(n=25)		(n=24)		
1-2 days	4	16.0	3	12.5	0.86
3-7 days	14	56.0	16	66.7	
8-14 days	3	12.0	1	4.2	
15-28 days	3	12.0	3	12.5	
>28 days	1	4.0	1	4.2	
Absent	(n=191)		(n=117)		
1-2 days	48	25.1	21	17.9	0.51
3-7 days	127	66.5	83	70.9	
8-14 days	13	6.8	10	8.5	
15-28 days	1	0.5	2	1.7	
>28 days	2	1.0	1	0.9	

[1]Chi-square test

Table-13 show the comparison of any post-operative AEs among the study group with duration of hospital stay with no significant (p>0.05) association.

Fig.9 show the comparison of instrumentation of patients among the study population. Instrumentation of patients was done among 45.4% patients.

The instrumentation was required lower among patients of age <60 years (36.1%) than ≥60 years (59.6%) with significant (p=0.001) difference between the two age groups.

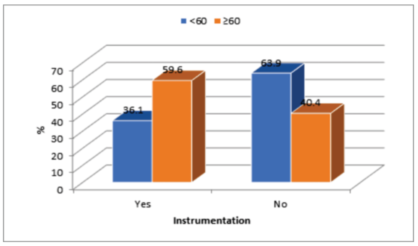

Fig. 9: Comparison of instrumentation of patients among the study population

Fig.10 show the comparison of comorbidities of patients among the study population with hypertension has a significant association with any intra op AEs (p=.001) . diabetes mellitus, cardiac and bronchial asthma has no significant (p>0.05) association with any intra-operative AE.

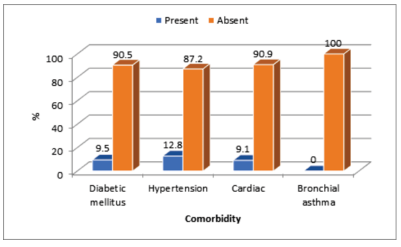

Fig 10:Comparison of comorbidity of among the study population with any intra-op AE

Table-14: Comparison Of Comorbidity Of Among The Study Population With Any Post -Op AEs

Comorbidity	No. of patients	Any Post-op AEs				p-value[1]
		Present		Absent		
		No.	%	No.	%	
Diabetic mellitus	84	16	19.0	68	81.0	0.10
Hypertension	109	20	18.3	89	81.7	0.09
Cardiac	22	6	27.3	16	72.7	0.06
Bronchial asthma	7	1	14.3	6	85.7	0.96

[1]Chi-square test

Table-14 show the comparison of comorbidities of patients among the study population with any post op AEs. There was no significant (p>0.05) association of comorbidities among the study population with any post op AEs.

Table-15: Comparison of comorbidity with complications at follow-up

Comorbidity#	No. of patients	OPD follow-up#											
		Wound discharge			Persistent pain			Worsening of neurological status			Re exploration at same level		
		No.	%	p-value[1]	No.	%	p-value[1]	No.	%	p-value[1]	No.	%	p-value[1]
Diabetic mellitus	84	1	1.2	0.69	2	2.4	0.39	0	0.0	0.42	0	0.0	0.20
Hypertension	108	0	0.0	0.24	3	2.8	0.15	0	0.0	0.34	3	2.8	0.15
Cardiac	22	1	4.5	0.06	1	4.5	0.20	0	0.0	0.71	0	0.0	0.56
Bronchial asthma	7	0	0.0	0.80	0	0.0	0.74	0	0.0	0.84	0	0.0	0.74

[1]Chi-square test, #Multiple response

Table-15 shows the comparison of comorbidity with complications at follow-up. There was no significant (p>0.05) association of comorbidity with complications at follow-up.

DISCUSSION

Adverse events during any surgical procedure are becoming increasingly relevant given that the population is aging and postoperative complications increase with age (Fang et al, 2015; Ogura et al, 2014).[1,2]

Unfortunately, poor adverse-event reporting by physicians is well-documented in the literature. Spinal Adverse Events Severity System, version 2 (SAVES V2) may help tackle this issue as the list of adverse events serves as a prompt while also improving convenience of reporting (Milch et al, 2006; Rowin et al, 2008).[3,4]

The present study was conducted with the objective to determine the incidence, severity and outcome of adverse events using SAVES V2 system undergoing spinal surgery of patients above 60 years of age and to compare it with those with age below 60 years. A total of 357 patients were included in the study. In the best knowledge of the researcher, most of the studies done have not evaluated those parameters as in this study, hence, many parameters could not be compared with earlier studies.

More than half of patients, 216 patients were <60 years of age (60.5%) in this study. The mean age of patients was 51.29±18.42 years. In the present study, 214 (59.9 %) and 143 (40.1%) were males and females respectively. In present study 122(56.5%) male patients was below 60 and 94 (65.2%) were above 60 years with no significant (p>0.05) difference in gender between the age groups. Shillingford et al (2019)[46] reported that the mean age of patients with undergoing spinal surgery was 38.5±25.5 years with a female predominance (67.5%). Amit Kumar et al (2020) majority of the patients were male 57 (81.43%) with mean age of 74.19 years.[5]

In this study, elective surgery was performed among 350 (98%) patients with 213 (98.6 %) <60 years and 137 (97.2 %) ≥60 years. There was no significant (p>0.05) difference in type of surgery between the age groups. Emergency surgery was done in 7 (2%) patients.

Hypertension was most common comorbidity among the 109 (30.5 %) patients. Diabetes mellitus was second most common comorbidity among 84 (23.5 %) patients. The patients with CAD and Bronchial asthma were 22 (6.2 %) and 7 (2 %) respectively. Diabetes mellitus, Hypertension, Cardiac and Bronchial asthma were found to be significantly (p<0.05) higher among the patients of age ≥60 years than <60 years. Shillingford et al (2019)[6] found that there were 73 patients with hypertension (23.5%), 42 with pulmonary disease (13.5%), 33 with diabetes (10.6%), 22 with vascular disease (7.1%), and 12 with coronary artery disease (3.9%). In other studies, Carreon LY et al (2003) and Choi JM et al (2017) hypertension was the most common co-morbidity.[7]

The present study showed that previous history of treatment for

Tuberculosis was present in 7 (2%) patients. History of drug intake like aspirin, methotrexate and steroids was present in 4 (1.1%) patients **.** Aspirin is commonly taken by cardiac patients and with more incidence of bleeding, while methotrexate and steroids are taken by rheumatoid arthritis patient. These patients has high incidence of delayed bone and wound healing. These are usually more common in older papulation. History of previous spine surgery was present in 45 (12.6%) patients with 25 (11.6%) < 60 years and 20 (14.2%) > 60 years of age with no significant association (p> 0.05).

In the present study, degenerative disease (ligamentum hypertrophy, disc herniation, bony spur) was the most common diagnosis among 254 (71.1%) patients. Spinal Tumor was the second most common diagnosis among 53 (14.8 %) patients and Trauma was the third most common diagnosis among 26 (7.3%) patients. Degenerative disease was found to be significantly (p=0.0001) higher among the patients of age ≥60 years (81.6% than <60 years (64.4%). Ishimoto y et al , shown that the prevalence of degenerative spinal conditions was much more common with increase in age and is expected to increase further with the increase in papulation and life expectancy all over the world.[8]

In this study, Dural tear was the most common intra-operative adverse event among 11 (3.1 %) patients. Hypotension (systemic <85 mm Hg for 15 min) was the second most common intra-operative adverse event among 7 (2%) patients. There was no significant (p>0.05) difference in intra-operative adverse events between the two age groups. Street et al (2012) in their study Morbidity and mortality of major adult spinal surgery. A prospective cohort analysis of 942 consecutive patients, reported that the rate of intraoperative surgical complication was 10.5% (4.5% incidental durotomy and 1.9% hardware malposition requiring revision and 2.2% blood loss >2 L).[9]
This study found that postoperative neuropathic pain was the most common post-operative adverse event among 10 (2.8 %) patients. Superficial wound infection was the second most common post-operative adverse event among 9 (2.5 %) patients. There was no significant (p>0.05) difference in post-operative adverse events between the two age groups**.** Street et al (2012)reported the incidence of postoperative complication of 73.5% (wound complications, 13.5%; delerium, 8%; pneumonia, 7%; neuropathic pain, 5%; dysphagia, 4.5%; and neurological deterioration, 3%).[9]

This study observed that the length of hospital stay was 3-7 days among 240 (67.2 %) and 1-2 days in 76 (21.3%) patients. The mean length of hospital stay was 4.85±6.20 days and 5.12±4.59 among the patients of age <60 and ≥60 years respectively. There was no significant (p>0.05) difference in length of hospital stay between the two age groups. Jetan H. Badhiwala et al in their study shows the length of hospital stay as 3.5+/- 3.1 and 3.7 +/- 2.6 in a patients below and above 70 years with no clinical significance.[10]

In our study 68 patients(19.05%) had either intraoperative or postoperative AE. Out of this 34 patients (50 %) with 18 (54.5%) and 16 (45.7%) are < 60 years and > 60 years respectively had a Grade I AE that does not require any intervention. 16 patients(23.5%) with 5 (15.2%) < 60 years and 11(31.4%) > 60 years had a Grade 2 AE where minor invasive procedure or monitoring done but has no long term effect. Total 13 patients (19.1%) with 6 (18.2%) patients < 60 years and 7 (20.0%) patients had a Grade 3 AE who underwent major surgical procedure and most likely to have a temporary (< 6 months) adverse effect on outcome. Out of these 13 patients, 3 patients had a construct failure with loss of correction, 5 patients had a neurologic deterioration > 1 grade in ASIA motor scale and 5 patients had a persistent neuropathic pain. 5 (7.4%) patients with 4 (12.1%) < 60 years and 1 patient (2.9%) had a Grade 6 AE . One patient > 60 years developed systemic infection and had a cardiac arrest on 7th post-operative day. Another patient who underwent dorsal deformity correction had a bone implant interface failure requiring revision and dural tear intraoperatively. Post-operatively he had a neurologic worsening in postoperative period and develop pneumonia which aggravates to systemic infection and expired on 28th postoperative day. Another patient with polytrauma who underwent emergency spine surgery for fracture L1 vertebrae with acute paraplegia had a cardiac arrest on 10th day of surgery secondary to associated multiple co-morbid conditions. One patient operated in emergency for trauma develop pneumonia and died on 30th day after surgery. Another patient operated for trauma but after stabilizing operated but develop pneumonia and later succumb to systemic infection on 10th postoperative day. Carreon et al followed 98 elderly patients above 65 years of age who underwent lumbar decompression and arthrodesis the incidence of total perioperative complication rate was 80 %. Incidence of major complication in patient aged group 65 – 69 and 70 – 74 years was 14.3 5 and 13.3 % respectively. The incidence of minor complication rate was 82.7% and 76.5 % respectively.[11] Street et al (2012) found that of the 942 patients, there were 14 mortalities during the study period.[9] Drazin et al summarized the complication of spinal deformity surgery in elderly patients. A total of 311 complications were reported in 14 studies involving 815 patients, with a total complication rate of 38 %. Among them, 13 studies reported an average mortality of 0.85 %.[12]

In this study, lumbosacral procedure was done among more than half of patients 218 (61.1%) and cervical procedure was done in 94 (26.3%) patients. There was no significant (p>0.05) difference in procedure done between the two age groups. Amitkumar et al shows in the degenerative only group, Lumbar pathology was the most common 30 (55.56 %) whereas, in traumatic group, cervical injury was the most common 13 (81.25 %).[5]

In this study, persistent pain and Re exploration at same level each constituted in 5 (1.4%) patients at OPD follow-up. There was no significant (p>0.05) difference in OPD follow-ups between the two age groups. Using Medicare data in a cohort of elderly (65 – 84 year) patients who underwent lumbar fusion for degenerative pathology, Puvanesarajah et al found re admission rates to be 2.9 % at 30 day and 5.3 % at 90 day.[13]

In the present study, any intra-operative AEs was present in 23(6.4%) patients. Any intra-operative AEs was lower among the patients of age <60 years 8 (3.7%) than ≥60 years 15 (10.6%). There was significant (p=0.009) association of any intra-operative AEs between the two age groups.

In this study, any post-operative AEs was present in 49 (13.7%) patients. Any post-operative AEs was lower among the patients of age <60 years 25 (11.6%) than ≥60 years 24 (17%) patients. There was no significant (p>0.05) difference in any post-operative AEs between the two age groups. Daubs et al observed a complication rate of 37 % in patients aged above 60 years in surgeries for spinal deformity.[14] Naseer et al in 2010 observed 16.4 % complication rate, that include 79417 patients who received surgery for degenerative spondylosis.[15] Among patients having spine surgery, Chen et al (2017)[16] reported an overall complication rate of 44% using reviewer-collected adverse-event data which was lower than the complication rate of 87% among patients having spine procedures reported by Street et al (2012).[9]

In this study, 17 patients who had any kind of intra-operative complication had a stay of 3-7 days and 4 patients had a stay of 1-2 days with mean duration of stay is 5.65+/- 1.18 days which corresponds to overall stay in hospital suggesting majority of intra operative complication does not alter the duration of stay in hospital. In our study group also, there is no significant association between any intra operative complication and duration of stay in hospital.

In our study, 30 patients who had any kind of post-operative complication has a stay of 3- 7 days, while 7 patients had a stay of 1- 2 days however, 2 patients had a prolonged post-operative stay more than 4 weeks due to associated multiple co-morbid conditions.

In our present study, 6 out of 9 (66.7%) patients had post-operative AEs who has prolonged hospital stay lasting 15 – 28 days and lowest of 7 out of 76 (9.2%) patients among those with 1-2 days of hospital stay suggestive of significant (p=0.0001) association of any post-operative AEs among the study population with duration of hospital stay. Vitaz et al have reported postoperative complications as a reason for a longer hospital stay.[17] Instrumented fusion were also reported to have a longer hospital stay by choi et al[7] however, in our study population, there is no association of any postoperative complication with duration of stay in hospital.

Over all Instrumentation was done during surgery in 162(45.4%) patients with 78(36.1%) patients of age <60 years and 84 (59.6%) patients ≥60 years with significant (p=0.001) difference between the two age groups. Intra-op AE were higher among patients who required instrumentation but with insignificant association. There was significant (p=0.007) association of instrumentation among the study population with any post op AEs. Spinal laminectomy vs instrumented pedicle screw (SLIP)[18] and Swedish Spinal Stenosis Study (SSSS)[19] are the largest randomized trials examining the safety and efficacy of fusion surgery for lumbar degenerative spondylolisthesis, neither study specifically examined outcomes with in subset of elderly patients. In a cohort of 98 patients (age > 65 years) who underwent lumbar decompression and fusion, Carreon et al reported a 70 % rate of minor complications and 21 % rate of major complications.[11]

In this study, there was no significant (p>0.05) association of comorbidities among the study population with any intra op AEs except hypertension. There was no significant (p>0.05) association of comorbidities among the study population with any post op AEs in this study, Raffo et al, Acosta et al , showed that preoperative comorbidity is a risk factor for perioperative complications.[20,21] However, Carrreon et al, Ragab et al reported that comorbidities are not associated with postoperative complications.[11,22]

CONCLUSIONS

1. Most common intra operative adverse events were Dural tear and postoperative adverse events was persistent neuropathic pain. Incidence of intraoperative and postoperative adverse events were higher among patients above 60 years of age and was statistically insignificant.

2. Majority of the adverse events were of grade 1 as per SAVES V2 which doesn't require any intervention. The incidence of lower grades was higher among patients >60 years of age but was statistically insignificant.

3. The length of stay in hospital was increased with presence of any intraoperative or postoperative adverse events. Length of stay in hospital has a statistically significant association with postoperative adverse events but not with age.

4. There was a higher incidence of instrumentation among patients > 60 years of age with statistically significant association. There is a higher incidence of intraoperative adverse events with use of instrumentation during surgery but with no significant association. Postoperative adverse events have a significant association with use of instrumentation.

5. There is a statistically significant association of any intra-operative adverse events with hypertension. There is statistically insignificant association between co-morbidities with any postoperative adverse events.

We conclude that in spite of higher incidence of comorbidities and presence of degenerative diseases among patients above 60 years of age group, incidence of intra operative and postoperative adverse events was higher among older patients but with no significant statistical significance. The peri operative adverse events are also of lower SAVES-2 grades only.

Surgery can be performed, after complete pre anesthetic checkup, physician and cardiology clearance in older patients above 60 years of age with no significant higher morbidity and mortality compared to patients under 60 years of age. These findings need to be validated with further multi-centered randomized control trials.

Limitations of the study

1. No categorization of the procedures involving single, 2 levels or multiple levels was done.
2. Long term follow up was not done.

8. REFERENCES

1. Fang M, Noiseux N, Linson E, Cram P. The effect of advancing age on total joint replacement outcomes. Geriatr Orthop Surg Rehabil. 2015;6:173–179.
2. Ogura K, Yasunaga H, Horiguchi H, Fushimi K, Kawano H. What is the effect of advanced age and comorbidity on postoperative morbidity and mortality after musculoskeletal tumor surgery? Clin Orthop Relat Res. 2014;472:3971–3978.
3. Milch CE, Salem DN, Pauker SG, Lundquist TG, Kumar S, Chen J. Voluntary electronic reporting of medical errors and adverse events: an analysis of 92,547 reports from 26 acute care hospitals. J Gen Intern Med. 2006;21:165–170.
4. Rowin EJ, Lucier D, Pauker SG, Kumar S, Chen J, Salem DN. Does error and adverse event reporting by physicians and nurses differ? Jt Comm J Qual Patient Saf. 2008;34:537–545.
5. Amitkumar M, Singh PK, Singh KJ, Khumukcham T, Sawarkar DP, Chandra SP, Kale SS. Surgical outcome in spinal operation in patients aged 70 years and above. Neurol India 2020;68:45-51
6. Shillingford JN., Laratta JL., Sarpong NO., Alrabaa RG et al. Instrumentation complication rates following spine surgery: a report from the Scoliosis Research Society (SRS) morbidity and mortality database. J Spine Surg 2019;5(1):110-115
7. Choi JM, Choi MK, Kim SB. Perioperative results and complication after posterior lumbar interbody fusion for spinal stenosis in geriatric patients over 70 years old .J Korean Neurosurg Soc 2017;60:684-90
8. Ishimoto Y, Yoshimura N, Muraki S, Yamada H, Nagata K et al. prevalence of symptomatic lumbar spinal stenosis and its association with physical performance in a papulation based cohort in Japan : The Wakayama spine study, Osteoarthritis Cartilage 2012;20:1103-08
9. Street JT, Lenehan BJ, DiPaola CP, Boyd MD, Kwon BK, Paquette SJ, et al: Morbidity and mortality of major adult spinal surgery. A prospective cohort analysis of 942 consecutive patients. Spine 2012; J 12:22–34
10. Jetan H. Badhiwala et al. The effect of older age on the perioperative outcome of spinal fusion surgery in patients with lumbar degenerative disc disease with spondylolisthesis: A propensity score-matched analysis. Neurosurgery 2019; 0:1-7
11. Carreon LY, Puno RM, Dimar JR II et al. Perioperative complications of posterior lumbar decompression and arthrodesis in older adults. J Bone Joint Surg Am 2003;85-A:2089–2092
12. Drazin D, Shirzadi A, Rosner J et al. Complication and outcomes after spinal deformity surgery in the elderly: review of the existing literature and future directions. Neurosurg Focus. 2011 ;31(4): E3.doi:10.3171/2011.7.FOCUS11145
13. Puvanesarajah V, Nourbakhsh A, Hassanzadeh H, Shimer AL et al. Readmission rates, reasons and risk factors in elderly patients with lumbar fusion for degenerative pathology. Spine (Phila Pa 1976), 2016;41(24):1933-1938.
14. Daubs MD, Lenke LG, Cheh G et al. Adult spinal deformity surgery: Complications and outcomes in patients over age 60. Spine 2007;32:2238–2244
15. Naseer R, Yadla S, Maltenfort MG, Harrop JS et al: Complication in spine surgery. J Neurosurg spine 2010;13 :144-157
16. Chen BP., Garland K et al. Can Surgeons Adequately Capture Adverse Events Using the Spinal Adverse Events Severity System (SAVES) and OrthoSAVES? Clin Orthop Relat Res 2017; 475:253–260
17. Vitaz TW, Raque GH, Shields CB, Glassman SD. Surgical treatment of lumbar spinal stenosis in patients older than 75 years of age. J Neurosurg 1999; 91 :181-5
18. Ghogawala Z, Dziura J, Butler WE et al. Laminectomy plus fusion versus laminectomy alone for lumbar spondylolisthesis. N Engl J Med. 2016; 374 (15): 1424-1434
19. Forsth P, Olafsson G, Carlsson T et al. A randomized, controlled trial of fusion surgery for lumbar spinal stenosis. N Engl J Med. 2016; 374 (15): 1413-23
20. Raffo CS, Lauerman WC. Predicting morbidity and mortality of lumbar spine arthrodesis in patients in their ninth decade. Spine 2006;31:99–103.
21. Acosta FL Jr., McClendon J Jr., et al. Morbidity and mortality after spinal deformity surgeryin patients 75 years and older: Complications and predictive factors. J Neurosurg Spine. 2011;15 (6):667-674
22. Ragab AA, Fye MA, Bohlman HH. Surgery of the lumbar spine for spinal stenosis in 118 patients, 70 years of age and older. Spine (Phila Pa 1976) 2003;28 (4): 348-353