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Original Research Article

Evaluation of the safety, efficacy and technical advantages of spinal anesthesia in patients undergoing single lower lumbar level minimally invasive transforaminal lumbar interbody fusion, as an alternative to general anesthesia: a prospective study

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ABSTRACT

Background: In spinal anesthesia, patients experience shorter OT, quicker recovery and ambulation, better post-operative analgesia and fewer complications than general anesthesia. Minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) shows fewer complications and early ambulation than open TLIF. Our study aims to assess spinal anesthesia's safety, efficacy and technical benefits in MIS-TLIF.
Methods: Patients unresponsive to conservative treatment for 6-8 weeks underwent MIS TLIF for lower lumbar degenerative pathologies. The demographic data, OT entry to incision time, blood loss, bandaging to exit from OT time, post anesthesia care unit (PACU) time, post-op complications, requirement of analgesia, visual analogue scale (VAS) and Oswestry disability index (ODI) scores, hospital stay, fusion rates and satisfaction scores were noted and assessed.
Results: The study included a total of 200 patients undergoing MIS-TLIF with mean age being 54.32±10.36 years; mean surgery time being 165.23±21.41 minutes; and mean blood loss being 123.56±65.14 ml. The mean OT entry to incision time was 28.91±9.63 minutes, while the mean bandaging to exit time was 7.43±4.12 minutes. The mean PACU stay was 41.35±5.78 minutes. The mean hospital stay was 3.28±1.23 days, with 97% patients showing solid radiographic fusion while 92.5% patients were fully satisfied with the surgery. VAS and ODI scores were significantly improved as compared to the pre operative status.
Conclusions: Spinal anesthesia for lower lumbar MIS-TLIF is cost effective and safe alternative to general anesthesia with lesser post operative pain and other side effects; taking into consideration proper patient selection for the same.

Keywords: MIS-TLIF, PACU, VAS, ODI, Radiographic fusion

INTRODUCTION

The total numbers of the spine fusion surgeries being performed per year are on an increasing trend in recent few years, due to increase in the life expectancy and increase in the incidence and prevalence of the degenerative spine pathology in the elderly.[1] Cloward was the first one to introduce the technique of spine fusion surgery via posterior lumbar interbody fusion (PLIF); where the spinous process harvested during the decompression was used as an autograft for the fusion. However, there were large numbers of cases showing pseudoarthrosis using this PLIF technique, owing to stand alone grafts. Thus, the technique was modified and augmented with instrumented fixation using Harrington rod system in 1950s, which was later replaced with Hartshill rectangle; and finally in

today's era we have been using the pedicle screws for the same purpose.[2]

TLIF, using a posterolateral approach was first described in 1982 by Harms and Rollinger, which after the work by Harms and Jeszenszky in 1992 gained its popularity,[3,4] The main advantage of TLIF over PLIF is minimal chance of any injury to the neural structures owing to its posterolateral approach. However, at the same time open TLIF requires extensive soft tissue and muscle retraction leading to iatrogenic injury. In order to avoid this iatrogenic injury, Foley et al introduced a novel modification of performing TLIF in MIS-TLIF, using serial tubular dilators so as to retract the muscles; and has now gained a lot of popularity.[5] MIS-TLIF can be done in general as well under spinal (regional) anesthesia.[6] General anesthesia is most commonly used to perform these fusion surgeries with advantage of having secured airway in prone position.[7,8] Spinal anesthesia on other side has many advantages like: repositioning the patient intra operatively so as to avoid compression injuries, better neurocognitive function, less pulmonary complications, better post operative analgesic and antiemetic effect, and no side effects of reversal medications associated with general anesthesia.[9-11]

There have been few studies in the literature comparing spinal and general anesthesia in spine fusion surgeries. These studies have found spinal anesthesia to have better outcomes with respect to shorter duration of surgery, less time in the recovery room, lesser incidence of post operative pain, urinary retention and nausea-vomiting.[12,13] On the other hand, MIS TLIF has revolutionized the field of spine fusion surgery, with advantage of quicker rehabilitation and shorter hospital stay, thus turned out to not only cosmetically as well as financially better option when compared to open TLIF.[14] However, very few studies have been done to evaluate the safety, efficacy and technical advantages of spinal anesthesia in patients undergoing single lower lumbar level MIS TLIF (awake fusion); as an alternative to general anesthesia.

Aims and objectives

Our prospective study aimed at evaluating the safety, efficacy and technical advantages of spinal anesthesia in patients undergoing single lower lumbar level MIS-TLIF (awake fusion); as an alternative to general anesthesia.

METHODS

The present study was a prospective one conducted in the department of orthopaedics at government medical college, Nagpur from August 2017 to July 2021, with prior approval taken from the institutional ethical committee. The study population consisted of 200 patients undergoing single lower lumbar level MIS TLIF under spinal anesthesia (awake fusion) after abiding the inclusion and exclusion criteria, with the surgery done by the same team of spine surgeons and anesthesia given by the same team of anesthesiologists; following the same anesthesia, pre operative, post operative and rehabilitation techniques and protocols for all the study patients. All the patients were initially given the trial of conservative treatment for 6-8 weeks, which included standard protocol of muscle relaxants, physiotherapy and hot fomentation. It was only after failure of this conservative protocols; patients were advised surgery.

Inclusion criteria

All the patients with symptomatic lumbar spine pathology (mechanical low back pain with radiculopathy with/without claudication and with/without neuro-deficits), with involvement of the lower lumbar spine (below L3 levels); due to any one of the etiology: degenerative/dysplastic/isthmic type of spondylolisthesis, degenerative lumbar canal stenosis (LCS) with instability, and/or prolapsed intervertebral disc with instability; needing spine fusion surgery in the form of MIS TLIF.

Exclusion criteria

Patients with pathological spine diseases such as tumors (primary or secondary), inflammatory or infective conditions; multilevel surgery; or having a previous history of spine interventions including surgery or injections (transforaminal, epidural, facetal) for pain relief; or extra spinal cause of back pain or radiculopathy; or requiring surgery at higher lumbar levels i.e. L1-L2 or L2-L3 levels, were excluded from the study.

All the patients were operated by the standard technique and protocols of MIS-TLIF, using 2-3 cm paramedian incision taken on the most affected side, and then microscopic tubular decompression done with unilateral laminotomy and inferior facetectomy. This was followed by disectomy, end plate preparation and then cage preparation and insertion under c arm guidance. Pedicle screws were then inserted on the same side followed by the insertion of the rod, through the same incision. Contralateral side screws were then inserted using 0.5-1 cm stab incisions followed with the rod insertion. Compression and the final tightening of the screws was then done. In case of any dural tear encountered, it was managed intra operatively with fat pad patch and surgicel with water tight closure.

Patients were then shifted to the PACU. After confirming the hemodynamic stability, patients were then shifted to the ward. Post operatively any requirement of analgesia or antiemetic if any was recorded. All the demographic variables, indication, duration and level of surgery were noted down. Pain was assessed using VAS and ODI scores pre operatively and then at immediate post operative, 3rd, 6th, 12th, 18th and 24th month of follow up and compared. Peri-operative parameters such as total duration of surgery, total blood loss during the surgery, time from entering into the ot to incision, any intra operative dural tears and need to convert the procedure into open for the same, time from

bandaging to exit, any requirement of analgesic or antiemetic in the post operative period (within 4 hours), any episode of post operative nausea, vomiting or urinary retention, time of stay in PACU and total hospital stay; were recorded. Post operative complications were all noted down and divided into two categories: general and neurological. General complications included: fever, wound infection, cardiac/pulmonary complications. Neurological complications included: any persistent CSF leak needing either re exploration or any neurological deficits if nay. Fusion was documented at the final follow up (24th month) with Bridwell criteria.[15]

Statistical analysis

All the data was collected in a Microsoft excel spreadsheet. The nominal data was expressed as a number and percentage. The continuous data was expressed as mean, standard deviation, and range. Comparison for significance for nominal data (comparison of proportion) was done using Chi square test and for continuous data (VAS and ODI scores) (comparison of mean) was done by paired student t test. A $p<0.05$ was considered statistically significant.

RESULTS

The study included a total of 200 patients undergoing MIS-TLIF under spinal anesthesia (awake fusion), due lower lumbar pathology as described. The mean age of the study patients was 54.32±10.36 years, with around 80% of the patients being more than 40 years of age. The study had female preponderance with around 69% of the patients being female. The mean BMI of the study patients was 28.96±2.65 kg/m^2. The mean duration of the symptoms were 8.12±6.56 months, with the mean follow up post operatively being 26.19±6.81 months. Around 48.5% of the patients were diabetic, while 51% of the patients being hypertensive, and around 31% of the patients suffering from both diabetes as well as hypertension. Demographic data of the study patients is enlisted in Table 1.

Table 1: Depicts the demographic data of the study patients.

Variables		N (%)
Age (In years)		54.32±10.36
Gender	Male	62 (31)
	Female	138 (69)
BMI (kg/m^2)		28.96±2.65
Co morbidities	Diabetes	97 (48.5)
	Hypertension	102 (51)
	Both	62 (31)
Duration of symptoms (months)		8.12±6.56
Mean duration of follow up (months)		26.19±6.81

The most common indication for surgery in our study was degenerative spine leading to instability with radiculopathy (55%), followed by LCS with instability (20.5%). The most common level of surgery was L4-L5 level (62%), followed by L5-S1 level (25.5%). The mean duration of surgery was 165.23±21.41 minutes, with the mean blood loss during the surgery being 123.56±65.14 ml. The extent of spinal anesthesia achieved in majority of our case was up to D8 level. The mean time from entering into the OT to incision was 28.91±9.63 minutes, while the mean time from bandaging to exit from OT was 7.43±4.12 minutes. The mean time of stay in the PACU was 41.35±5.78 minutes. Around 31 patients (15.5%) needed added analgesia within 4 hours after surgery. The mean hospital stay was 3.28±1.23 days. Solid radiographic fusion (Bridwell 1 and 2) was achieved at the last follow up (24th month) in around 97% of the patients. Patients who had no pain, no nausea, no vomiting, and no headache were labeled to be fully satisfied; while patients with >1 symptoms were labeled to be partially satisfied; while the patients with all the symptoms were considered to be unsatisfied.[16] Around 92.5% of the patients in the study were fully satisfied, while 6.5% of the patients were partially satisfied and only 1% of the patients were reported to be unsatisfied after the surgery. All the clinical parameters of the study patients are enlisted in Table 2.

Table 2: Depicts the distribution of the study patients on the basis of clinical parameters.

Clinical parameters		N (%)
Level of Surgery	L3-L4	25 (12.5)
	L4-L5	124 (62)
	L5-S1	51 (25.5)
Indication of surgery	Degenerative	110 (55)
	Isthmic	34 (17)
	LCS with instability	41 (20.5)
	PIVD	15 (7.5)
Duration of surgery (minutes)		165.23±21.41
Mean blood loss (ml)		123.56±65.14
Time from entering into OT to incision (minutes)		28.91±9.63
Time from bandaging to exit (minutes)		7.43±4.12
Stay in PACU (minutes)		41.35±5.78
Requirement of immediate post operative analgesic or antiemetic (within 4 hours)		31 (15.5)
Mean hospital stay (days)		3.28±1.23
Solid radiographic fusion		194 (97)
Satisfaction score	Fully satisfied	185 (92.5)
	Partially satisfied	13 (6.5)
	Unsatisfied	2 (1)

There was significant statistical, clinical and functional improvement in the VAS and ODI scores when compared between the pre operative status and the final follow up at 24th month post surgery as depicted in Table 3. Also, the improvement in the VAS and ODI scores at different time frames of follow ups (3rd, 6th, 12th and 18th month) with

respect to the pre operative status was statistically significant.

Post operative urinary retention was reported in 23 patients (11.5%), while 14 patients (7%) had post operative nausea/vomiting. Dural tears were encountered in 12 patients; however, none of these patients progressed to have persistent CSF leak post operatively. Wound infection was seen in 10 patients, which was managed conservatively and none needed re surgery. The other complications encountered are enlisted in Table 4. None of the patients in the study had newly developed post operative neurological deficits (iatrogenic).

Table 3: Depicts the VAS and ODI scores of the study patients at pre operative and final follow up post-surgery (24th month).

Parameters	Pre operative	Final follow up	P value
VAS	82.65±4.18	16.81±3.39	<0.001
ODI	8.56±1.69	2.13±1.02	<0.001

Table 4: Depicts the peri operative and post operative complications.

Variables	N (%)
Dural tear	12 (6)
Screw malposition	2 (1)
Cage slippage	2 (1)
Screw loosening	4 (2)
Implant failure	1 (0.5)
Urinary retention	23 (11.5)
Nausea/vomiting	14 (7)
Fever	17 (8.5)
Wound infection	10 (5)
Cardiopulmonary complications	0
Post operative CSF leak	0
Post operative neurological deficits	0

DISCUSSIONS

There have been few studies in the literature comparing spinal and general anesthesia in spine fusion surgeries and have found spinal anesthesia to have better outcomes with respect to shorter duration of surgery, less time in the recovery room, lesser incidence of post operative pain, urinary retention and nausea-vomiting.[12,13] Also spinal anesthesia has an advantage of less neuro cognitive dysfunction associated with general anesthesia medications.[17] When compared to conventional open TLIF; MIS TLIF has an advantage of early ambulation and early discharge due to less pain and less peri operative complications.[18] However, very few studies have been done to evaluate the safety, efficacy and technical advantages of spinal anesthesia in patients undergoing single lower lumbar level MIS TLIF (awake fusion); as an alternative to general anesthesia. Thus, we decided to conduct one such study combining the two to evaluate the safety, efficacy and technical advantages of spinal anesthesia in patients undergoing single lower lumbar level MIS-TLIF (awake fusion), with bupivacine for longer duration surgeries.[19]

The mean blood loss in our study was 123.56±65.14 ml. In study conducted by Habib et al the mean blood loss in patients operated by MIS TLIF was 163 ml, while that in open TLF was 366.8ml.[20] Schwender et al in his study done under general anesthesia recorded blood loss of around 140 ml.[21] It was thus concluded that MIS TLIF under spinal anesthesia leads to relatively lesser blood loss than under general anesthesia. The exact cause of this has not been found in the literature; however, the relative hypotension achieved under spinal anesthesia could be one of the reasons of this lesser blood loss. The total duration of surgery in our study was 165.23±21.41 minutes; which is comparable with the studies by Jhala et al and Patel et al where the procedure was done under general anesthesia.[18,22] This concludes that the type of anesthesia does not influence the total duration of surgery. However, we taking into consideration two other parameters with respect to the total duration of operation theatre: time from entry into OT to incision and time from bandaging to exit from OT; it was found that these two-time landmarks were significantly lower in our study as compared to the other studies done in general anesthesia. This finding is in accordance with the study done by Pierce et al.[23] This is because less time taken for the patient induction in spinal anesthesia as compared to that in general anesthesia, which involves peri operative events like preparation of pre anesthetic medications and time taken to give these medications before tube insertion, intubation as well as post operative anesthesia medications for reversal. This reflects quicker efficacy and OT turn over time of spinal anesthesia, thus proving to be cost effective alternative to general anesthesia.

The mean time of stay in the PACU in our study was 41.35±5.78 minutes, which was relatively less as compared to the patients in the study done by Jellish et al.[14] The total duration of hospital stay in our study was 3.28±1.23 days, which was similar to the study done by Garg et al.[24] Our study was done including the patients with lower lumbar spine involvement (below L3); thus, the chance of any neuro-deficits was very less. Also, we did not experience any iatrogenic neuro-deficits in any of the patients. Although general anesthesia allows us to have quick neurological assessment after the reversal of anesthesia, but the exact sensible assessment cannot be done as the patient is in drowsy state. On the other hands spinal anesthesia allows having good post operative analgesia, early neuro-cognitive function, and early shifting to the ward. Also, spinal anesthesia allows having early ambulation, early start to oral feeds, less irritation to the throat, early return of bowel functions and thus favoring early discharge.

In our study there was statistically, clinically and functionally significant improvement in the mean VAS

and ODI scores when the pre operative scores were compared with the final follow up score at 24th month post operatively. Also, the improvement in the VAS and ODI scores at different time frames of follow ups (3rd, 6th, 12th and 18th month) with respect to the pre operative status was statistically significant. This is in accordance with the studies by Patel et al and Wang et al which also showed statistically significant improvements in the VAS and ODI scores when pre operative scores were compared with the post operative scores in MIS TLIF done under general anesthesia. This shows that the pain improvement in MIS TLIF is independent of the type of anesthesia given.[22,25]

In our study we had 11.5% incidence of post operative urinary retention while the incidence of nausea/vomiting was 7%. McLain et al had higher incidence of nausea in general anesthesia group and lower incidence of urinary retention in spinal anesthesia group.[9] Prolonged sensory loss post spinal anesthesia (due to bupivacaine) could be the reason of higher incidence of urinary retention in our study. All the patients with urinary retention were managed conservatively with Foley's catheter and hot fomentation, followed with clamping the catheter the next day and then removal. We had 6% incidence of dural tear intra operatively. All the patients were managed with fat pad and surgical placement over the tear, with water tight closure. None of the patients needed conversion of the surgery to open for the dural tear repair, and also none of the patients had post operatively persistent CSF leak. None of the patients had post operative iatrogenic neurological deficits.

In our study we had solid radiographic fusion (Bridwell 1 and 2) in around 97% of the patients, which is comparable with the study by Schwender et al who had100% fusion. We tried to quantify the satisfaction of the patients undergoing MIS-TLIF under spinal anesthesia; and found 92.5% to be fully satisfied, 6.5% of the patients partially satisfied and only 1% of the patients to be unsatisfied.[21] In all our cases we made sure to have soft music being played in the background to calm down the pre-existing apprehension amongst the patients and also to make them comfortable against the loud sounds during the procedure of instrumentation; so as to have better hemodynamic fluctuations.[26]

Our study as well as previous ones in the literature has though shown spinal anesthesia to have upper hand over general anesthesia for the lower lumbar spine fusion surgeries; but this cannot be followed for all the patients. Loss of spinal anesthesia effect can happen if the duration of the surgery extends due to any unprecedented intra operative events; however, we did not experience any such event in our study. Other disadvantages being contraindications in morbid obesity, obstructive sleep apnoea and cardiopulmonary dysfunction. Thus, proper patient selection is utmost important to have favorable results and to make utmost use of multiple efficacies of spinal anesthesia over general anesthesia in lower lumbar spine fusion surgeries (awake fusion).

Our study however had few limitations. Firstly, intra operative hemodynamic variations were not considered. Secondly, there was no comparison of theses hemodynamic fluctuations and the final results with the patients undergoing same procedure under general anesthesia. However, our study did have little strength. Firstly, all the surgeries being performed by the same team of spine surgeons and anesthesiologists, chance of procedure bias was eliminated. Secondly, we included the radiological fusion and patient satisfaction scores in our study; which very few previous studies in the literature have done.

CONCLUSION

MIS TLIF done under spinal anesthesia (awake spinal fusion) has number of advantages such as prolonged post operative analgesia, early ambulation with early hospital discharge and early return to work; thus, reducing the overall cost. In addition to these, it also offers shorter duration of OT time with respect to shorter entry in OT to incision time and bandaging to exit from OT time, lesser stay in PACU; thus, offering better operating room efficiency and thus being cost effective alternative to general anesthesia. Hence, spinal anesthesia for lower lumbar level spinal fusion surgeries in minimally invasive fashion (MIS-TLIF) is not only cost effective but also safe alternative to general anesthesia with lesser post operative pain and other side effects; taking into consideration proper patient selection for the same.

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