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Are the Outcomes of Minimally Invasive Transforaminal/Posterior Lumbar Fusion Influenced by the Patient's Age or BMI?

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Study Design: A retrospective subgroup analysis of a prospective observational study was carried out.

Summary of Background Data: Patients' baseline characteristics may influence the clinical outcomes after minimally invasive lumbar interbody fusion (MILIF).

Objective: This study aimed to investigate the influence of patient's age and body mass index (BMI) on the clinical outcomes of MILIF for degenerative lumbar disorder.

Materials and Methods: A total of 252 patients underwent MILIF. The clinical outcomes, including time to first ambulation, time to postsurgical recovery, back/leg pain in visual analog scale, Oswestry

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Disability Index, and EuroQol-5 Dimension, were collected at baseline, 4 weeks, 6, and 12 months. Patients were subgrouped by age (50 y and below: N=102; 51–64 y: N=102; 65 y and above: N=48) and BMI (\leq 25.0: N=79; 25.1–29.9: N=104; \geq 30.0: N=69). Data from baseline to 12 months were compared for all clinical outcomes within age/BMI subgroups. Adverse events (AEs) and serious adverse events (SAEs) were summarized by age and BMI subgroups.

Results: All age and BMI subgroups showed significant improvements in clinical outcomes at 12 months compared with the baseline. The median time to first ambulation was similar for all subgroups (age groups: P = 0.8707; BMI: P = 0.1013); older people show a trend of having longer time to postsurgical recovery (age groups: P = 0.0662; BMI: P = 0.1591). Oswestry Disability Index, back, and leg pain visual analog scale, and EuroQol-5 Dimension were similar in all subgroups at every timepoint. A total of 50 AEs (N = 39) were reported, 9 of which were SAEs; 3 AEs and 1 SAE were considered to be related to surgical procedure. No differences were observed in safety by age groups and BMI groups.

Conclusion: MILIF appears to be safe and effective, independent of age or weight in the treatment of degenerative lumbar disorder.

Level of Evidence: Level II.

Key Words: minimally invasive spine surgery, minimally invasive lumbar interbody fusion, minimal access spinal technologies, degenerative lumbar disorder, BMI, age

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Inimally invasive spine surgery (MISS) is increasingly being used in the treatment of degenerative lumbar disorders (DLDs). The advantages of these techniques suggest that it is likely that they will continue to play an increasingly important long-term role in the treatment of these disorders. Surgical outcomes reported after MISS demonstrate a high degree of variability, which may be caused by various factors including surgeon experience, patient factors, study outcome measures, and small sample sizes. These factors should each be addressed separately to confirm the statistical and clinically significant effects of MISS techniques. ²⁻⁶

The MASTERS-D study (NCT01143324; https://clinicaltrials.gov/ct2/show/NCT01143324) was designed to

observe and document surgical practice and to evaluate clinical and radiologic patient outcomes up to 12 months after minimally invasive lumbar interbody fusion (MIL-IF). Posterior lumbar interbody fusion or transforaminal lumbar interbody fusion techniques that are used to treat DLD in a real-world patient population were used in the MASTERS-D study.^{7,8} MILIF demonstrated early benefits [short time to first ambulation (TFA) and time for postsurgical recovery (TPSR), high patient satisfaction, and improved patient-reported outcomes (PRO)] and low major perioperative morbidity at 4 weeks postoperatively. Early statistically significant results observed in all PRO measurements were maintained through 12 months postsurgery, with minimal complications.⁸ Patients achieved early mobility postoperatively, allowing them to return back to work at a faster rate.^{7,8}

The MASTERS-D study was set up to reflect a reallife setting with a diverse patient population. Also, it is important to determine whether subgroups of patients with different baseline characteristics may influence the clinical outcomes after MILIF. Obesity, for example, is one variable associated with more complex recovery and significantly related to inferior clinical outcomes after traditional open surgery. P-11 In addition, elderly patients, by virtue of their increased age, may be reluctant to undergo surgery due to the fear of perceived increased risks. L2,13 Elderly patients with associated comorbid factors, including osteoporosis, diabetes, hypertension, coronary artery disease (prior procedures), depression, and obesity, may experience higher postoperative complication rates.

The objective of this subgroup data analysis from the MASTERS-D study was to investigate whether the safety and clinical outcome of MILIF used in the treatment of DLD may be influenced by the patients' age or body mass index (BMI).

MATERIALS AND METHODS

The MASTERS-D study methodology has been described in detail in earlier publications.^{7,8} In this paper, we present a summary of the trial methodology and study aspects related to the subgroup analyses.

Study Design, Surgical Technique, and Patient Population

The MASTERS-D was a prospective, international, multicenter observational study with a 12-month follow-up that monitored patients with DLD causing back or leg pain and who received treatment from an experienced MILIF surgeon. All patients who fulfilled the study inclusion criteria and were willing to participate in the study were enrolled consecutively to reduce selection bias. Adult patients older than 18 years of age with an indication for a single-level or double-level instrumented lumbar fusion used for the treatment of DLD were selected. A total of 252 consecutive patients received minimally invasive surgery transforaminal lumbar interbody fusion (95%) or posterior lumbar interbody fusion (5%) (CD Horizon Spinal System; Medtronic Sofamor Danek Inc., Memphis, TN) through the minimal access spinal

technologies (MAST) approach (Medtronic Sofamor Danek Inc.). Patients who had previously undergone lumbar spine surgery other than microdiscectomy were excluded from the study, as were patients with pathologies other than DLD.

All patients received routine standard of care according to the hospital protocol to reflect real-life practice. All patients signed an informed consent or patient data release form. As per local regulations, written approval from the Ethics Committee/Institutional Review Board/Human Resource Ethics Committee (EC/IRB/HREC), with authority over the participating site, was obtained before the start of the study. The study, carried out in 19 centers across 14 countries (Europe, Canada, and the Middle East), was carried out by a group of experienced surgeons (an experienced surgeon is defined as someone who has performed at least 30 MILIF surgeries previously as this helps to minimize the learning curve effect).

Subgroups

Patient subgroups for this analysis were defined by age and BMI, where patients were categorized as follows: age: 50 years and below, 51–64 years, 65 years and above; and BMI: ≤ 25.0 , 25.1–29.9, ≥ 30.0 . The distinction between patients older or younger than 65 years is commonly reported in the literature. The choice of an additional, younger age group of patients was made in an effort to differentiate a population more likely to be in better health and more able to tolerate surgery. The age division created 2 groups (50 y and below and 51–64 y, respectively) of equal sample sizes (n=102) and a third group (65 y and above) with a sample size of 48. The BMI 3-group categories were based on widely accepted standards for normal, overweight, and obese patients 14 and as per the World Health Organization (WHO) guideline. 15

Endpoints and Statistical Analyses

Surgical outcomes, TFA and TPSR (both reported in days), PRO assessments to quantify back and leg pain using the visual analog scale (VAS), disability using the Oswestry Disability Index (ODI), and health status [EuroQol-5 Dimension (EQ-5D)] were calculated for age group (age: 50 y and below, 51–64 y, 65 y and above) and BMI group (BMI: \leq 25.0, 25.1–29.9, \geq 30.0). TFA was defined as the number of days after surgery before patients were able to get out of bed and ambulate with or without assistance. TPSR was defined as the number of days after surgery until patients no longer needed an intravenous infusion of analgesic drugs, had no surgery-related complications/adverse events (AEs) impeding discharge, and no longer needed nursing care. Timepoints for these assessments included baseline, 4 weeks, and 6 and 12 months.

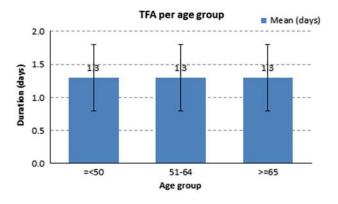
AEs and serious adverse events (SAEs) were collected and reported in this paper by age and BMI subgroups. An AE was defined as "any untoward medical occurrence in a subject" and a SAE was defined as "an AE that led to death; led to serious deterioration in the health of a subject; or congenital abnormality." All investigators classified the AEs by severity and whether it was related to the surgery, MAST approach, or device (unrelated, unlikely, possibly, probably, or definitely). For reporting, all

AEs were classified into their lowest level terms following the medical dictionary for regulatory activities terminology (MedDRA) version 15.1.¹⁶

Assessed variables (TFA, TPSR, ODI, VAS leg and back pain, EQ-5D) within the defined subgroups were not normally distributed; therefore, nonparametric testing was applied using the Shapiro-Wilks test for normality. The Kruskal-Wallis test analyses of variance tests were performed for the primary endpoints TFA and TPSR to look for differences between the age and BMI subgroups, respectively. The Kruskal-Wallis test was also used to determine whether there were differences between the age or weight subgroups for the PRO assessments at each timepoint (baseline, 4 wk, 6 mo, and 12 mo). Change from baseline to 12 months for the PROs within each subgroup was analyzed using the Wilcoxon signed-rank test. Differences between each subgroup were statistically significant if *P*-value <0.05.

RESULTS

Results from the MASTERS-D study have been recently published and reveal that clinically significant improvements were observed in all endpoints. Short-term postsurgery improvements at 4 weeks were maintained up to the 12-month endpoint, with minimal complications.^{7,8} In this paper, we report the primary outcome measures on patient subgroups stratified by age and BMI.



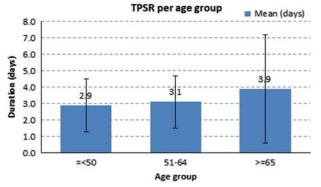


FIGURE 1. Mean (\pm SD) time to first ambulation and TPSR by age subgroups. BMI indicates body mass index; TFA, time to first ambulation; TPSR, time for postsurgical recovery.

Study Population

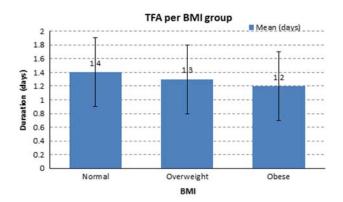
A total of 252 patients with DLD underwent a MILIF procedure, of whom 233 (91.4%) patients remained in the study up till the 12 months after surgery. For the purpose of the current subgroup analyses, patients were stratified into the following age and BMI groups: Age 50 years and below (N = 102), 51–64 years (N = 102) and 65 years and above (N = 48) and normal BMI (BMI \leq 25.0; N = 79), overweight (BMI of 25.1–29.9; N = 104), and obese (BMI of \geq 30.0; N = 69).

Primary Endpoints: TFA and TPSR Effect of Age

The mean TFA was 1.3 days and remained the same in each age subgroup (Kruskal-Wallis test; P = 0.8707); we observed a different trend for TPSR, in which the mean increased proportional to the age of the patient (Kruskal-Wallis test; P = 0.0662). However, the differences in TFA and TPSR were not statistically significant (Fig. 1).

Effect of Weight

The mean TFA has a decreasing trend with increasing BMI, whereas the mean TPSR has an increasing trend with increasing BMI, although none reach statistical significance. Specifically, for the respective Kruskal-Wallis test of the effect of: BMI on TFA, P = 0.1013; and for the effect of BMI on TPSR, P = 0.1591 (Fig. 2).



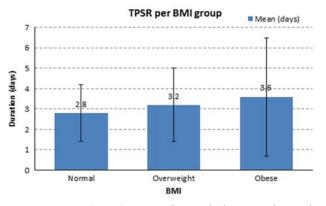


FIGURE 2. Mean (\pm SD) time to first ambulation and TPSR by BMI subgroups. BMI indicates body mass index; TFA, time to first ambulation; TPSR, time for postsurgical recovery.

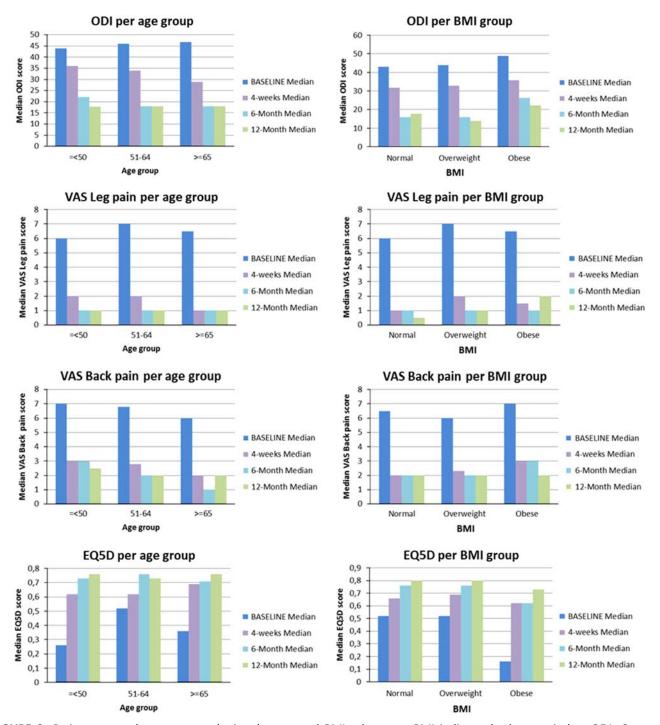


FIGURE 3. Patient-reported outcomes endpoints by age and BMI subgroups. BMI indicates body mass index; ODI, Oswestry Disability Index; VAS, visual analog scale.

PRO Measurements

Patients in all age and weight subgroups showed statistically significant improvements in ODI, VAS leg and back pain scores and quality-of-life scores as assessed by the EQ-5D (P < 0.0001 in all cases) immediately at 1 month and then the benefit gained is maintained (Fig. 3). Furthermore, the Kruskal-Wallis test between the subgroups was not statistically

significant or different at any of the timepoints before and after surgery for these PRO endpoints.

Safety

The distribution of AEs and SAEs by age groups is shown in Table 1. A total of 50 AEs in 39 patients were reported. These 50 AEs were considered by the investigator to

TABLE 1. Distribution of AEs and SAEs Related to General Surgery, MAST, or Device by Age Group, MAST Population (n = 252)

Age Group Lowest Level Term	≤50 y		51–64 y		≥ 65 y	
	Related to MAST	Related to General Surgery, MAST or Device	Related to MAST	Related to General Surgery, MAST or Device	Related to MAST	Related to General Surgery, MAST or Device
AEs (n)						
Acute allergic reaction	0	1	0	0	0	0
Back pain	0	2	0	4	0	1
Confusion postoperative	0	0	0	0	0	1
Dural tear	0	1	0	1	0	2
Fever	0	1	0	0	0	1
Hypoesthesia	0	1	0	2	0	0
Implant site seroma	0	1	0	1	0	0
Incision site abscess	0	0	0	1	0	0
Leg pain	1	6	1	2	1	2
Lumbar disk herniation	0	1	0	0	0	0
Lumbar radiculopathy	0	1	0	1	0	1
Nausea	0	3	0	1	0	0
Sacroiliac pain	0	3	0	0	0	1
Spinal hematoma	0	0	0	0	0	1
Urinary tract infection	0	0	0	0	0	3
Urosepsis	0	0	0	0	0	1
Vertigo	0	1	0	0	0	0
Vomiting	0	0	0	1	0	0
Total SAEs (n)	1	22	1	14	1	14
Acute allergic reaction	0	1	0	0	0	0
Back pain	0	1	0	0	0	0
Confusion postoperative	0	0	0	0	0	1
Leg pain	0	1	0	1	1	1
Lumbar disk herniation	0	1	0	0	0	0
Spinal hematoma	0	0	0	0	0	1
Urosepsis	0	0	0	0	0	1
Total	0	4	0	1	1	4

AE indicates adverse event; MAST, minimal access spinal technologies; SAE, serious adverse event.

be related to surgery, MAST, or device, 9 of which were SAEs (acute allergic reaction, postoperative confusion, leg pain, back pain, lumbar disk herniation, spinal hematoma, and urosepsis). Of 50 AEs, 3 AEs and 1 SAE were considered to be related to MAST.

The majority (44%; 22/50) of general surgery-related, MAST-related, or device-related AEs were in the 50 years and below age group, with the remaining split between the 51–64 years and 65 years and above age group (28% each; 14/50). There were fewer general surgery-related, MAST-related, or device-related SAEs in the 51–64 years age group (11.1%; 1/9), whereas the majority (88.8%) were in the groups older than 65 years and 50 years and below (44.4% each; 4/9). Only 1 SAE (11.1%; 1/9) was MAST related and was found in patients aged 65 years and above (Table 1).

The distribution of 50 AEs across all BMI groups is shown in Table 2. Of 50 AEs across all BMI subgroups, the majority of general surgery-related, MAST-related, or device-related AEs were in the BMI 25.1–29.9 group (44%; 22/50), followed by BMI $\geq 30 (34\%; 17/50)$ and 22%

(11/50) in the BMI \leq 25 group. The majority of general surgery-related, device-related, or MAST-related SAEs were in the BMI 25.1–29.9 group (55.5%; 5/9), followed by the BMI \geq 30 group (44.4%; 4/9), of which only 1 MAST-related SAE was reported in the BMI 25.1–29.9 group.

DISCUSSION

The MASTERS-D study is the first study to evaluate MILIF for the treatment of DLD in daily clinical practice. The study outcomes at 4 weeks and 12 months from the MASTERS-D study have been published elsewhere. ^{7,8} In this paper, we have presented the results of a subgroup analysis of the influence of age group or BMI on surgical outcomes such as TFA and TPSR, clinical endpoints such as VAS back and leg pain, ODI and EQ-5D, and safety results. Overall, surgical outcomes were good, without an increased risk of complications in all patients irrespective of age or BMI. The findings from our subgroup analysis are in line with previously reported studies in the

TABLE 2. Distribution of AEs and SAEs Related to General Surgery, MAST or Device Per BMI Group, MAST Population (n = 252)

BMI Group Related to MAST	Normal (≤25.0)		Overweight (25.1–29.9)		Obese (≥30.0)	
	Related to MAST	Related to General Surgery, MAST or Device	Related to MAST	Related to General Surgery, MAST or Device	Related to MAST	Related to General Surgery, MAST or Device
AEs (n)						
Acute allergic reaction	0	0	0	0	0	1
Back pain	0	4	0	1	0	2
Confusion postoperative	0	0	0	0	0	1
Dural tear	0	0	0	0	0	4
Fever	0	1	0	0	0	1
Hypoesthesia	0	2	0	1	0	0
Implant site seroma	0	1	0	0	0	1
Incision site abscess	0	0	0	1	0	0
Leg pain	1	3	2	6	0	1
Lumbar disk herniation	0	0	0	1	0	0
Lumbar radiculopathy	0	0	0	1	0	2
Nausea	0	0	0	4	0	0
Sacroiliac pain	0	0	0	4	0	0
Spinal hematoma	0	0	0	1	0	0
Urinary tract infection	0	0	0	0	0	3
Urosepsis	0	0	0	0	0	1
Vertigo	0	0	0	1	0	0
Vomiting	0	0	0	1	0	0
Total	1	11	2	22	0	17
SAEs (n)						
Acute allergic reaction	0	0	0	0	0	1
Back pain	0	0	0	1	0	0
Confusion postoperative	0	0	0	0	0	1
Leg pain	0	0	1	2	0	1
Lumbar disk herniation	0	0	0	1	0	0
Spinal hematoma	0	0	0	1	0	0
Urosepsis	0	0	0	0	0	1
Total	0	0	i	5	0	4

AE indicates adverse event; BMI, body mass index; MAST, minimal access spinal technologies; SAE, serious adverse event.

literature. $^{3,5,17-19}$ TPSR was not significantly different among age groups (P=0.0662). Similar effects akin to these have also been reported in Senker et al, 20 but these observations might be due to the fact that elderly patients' spinal pathology frequently show more degenerative variations and present with more severe spinal stenosis. In terms of BMI, the Kruskal-Wallis test was not statistically significant for TFA and TPSR.

Our analysis revealed that age and BMI did not influence the mean and the median outcome scores for all subgroups over the 4 timepoints (baseline, 4 wk, 6, and 12 mo) with respect to the clinical primary endpoints studied [VAS (back and leg pain), ODI, and EQ-5D]. The 12-month data compared with the baseline showed statistically significant improvements (P < 0.0001) for all variables (ODI, VAS leg pain, VAS back pain, and EQ-5D) and within all subgroups (age groups and BMI classes). These observations reveal that MILIF outcomes

for older and heavier patients are expected to be as good as those for patients in other age and BMI groups.

Elevated BMI and older age are major risk factors for perioperation complications for spine surgery. ^{13,21} In this study, no meaningful differences were observed in safety by age and BMI groups. This finding indicates that the use of minimally invasive surgery techniques may decrease the complication risks caused by elevated age and/ or BMI. Therefore, we corroborate that minimally invasive approaches are safe when utilized in patients irrespective of age or BMI.

This study has a few limitations. As this is a subgroup analysis from a larger data set, subgroups tend to be smaller, which did not allow for parametric testing. Where the Kruskal-Wallis test for difference is borderline significant, this could have been deemed significant with larger sample sizes and normally distributed data. TFA and TPSR were collected as days after the surgery was

performed. Particularly for TFA, this could be less meaningful because patients are usually encouraged to ambulate very soon after surgery and, in some cases, even the next day if possible. However, this can also be influenced by the time of day at which the surgery took place, that is, morning versus evening. Given these limitations and the fact that these analyses were carried out post hoc, care needs to be taken, especially when these findings are extrapolated to the general population.

In addition to these limitations, surgeon selection bias may have influenced the study results. As noted previously by Manson et al,²¹ surgeon perceptions influence the conscious and unconscious clinical decision-making process when selecting the suitability of obese or elderly patients for surgery. This study may simply include a subset of obese or elderly patients who present the lowest risk for surgical complications. Furthermore, this study is also limited by the relatively short duration of follow-up. A longer-term follow-up will help determine the durability of the MILIF surgery and the risk of adjacent disk degeneration. Finally, the use of the Patient Activation Measure²² to measure the patients' skills, knowledge, and confidence in managing their postoperative rehabilitation may further determine whether there is an influence of BMI and age on clinical outcomes. Although BMI represents the most widely used and easily obtained measure of obesity, other measures such as subcutaneous fat thickness over the lumbar spine or percent body fat may be more accurate in correlating obesity and surgical complications.²¹ No correlation has been found between these measures and BMI in the literature.

The study could not quantify the surgical challenges associated with treating obese or very elderly patients. Obesity may increase the difficulty of certain technical aspects of the surgery such as exposure and visualization. Elderly tissue quality may affect implant fixation, stability, and the quality of bony healing. Increased efforts required to achieve successful surgical outcomes are often absorbed by the individual surgical team and the health care system in general and thus are more difficult to identify.

CONCLUSIONS

The MILIF approach for spine surgery revealed surprisingly good results for patients of all age groups and weight classes. Clinical endpoints demonstrated a similar improvement in all groups from baseline to the 12-month timepoint. These results corroborate the fact that MILIF is an effective and safe treatment for DLD independent of age or weight in a broad patient population under typical clinical conditions.

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