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MIS

Cost-utility analysis of posterior minimally invasive fusion compared with conventional open fusion for lumbar spondylolisthesis

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Abstract

Background: The utility and cost of minimally invasive surgical (MIS) fusion remain controversial. The primary objective of this study was to compare the direct economic impact of 1- and 2-level fusion for grade I or II degenerative or isthmic spondylolisthesis via an MIS technique compared with conventional open posterior decompression and fusion.

Methods: A retrospective cohort study was performed by use of prospective data from 78 consecutive patients (37 with MIS technique by 1 surgeon and 41 with open technique by 3 surgeons). Independent review of demographic, intraoperative, and acute postoperative data was performed. Oswestry disability index (ODI) and Short Form 36 (SF-36) values were prospectively collected preoperatively and at 1 year postoperatively. Cost-utility analysis was performed by use of in-hospital micro-costing data (operating room, nursing, imaging, laboratories, pharmacy, and allied health cost) and change in health utility index (SF-6D) at 1 year.

Results: The groups were comparable in terms of age, sex, preoperative hemoglobin, comorbidities, and body mass index. Groups significantly differed ($P < .01$) regarding baseline ODI and SF-6D scores, as well as number of 2-level fusions (MIS, 12; open, 20) and number of interbody cages (MIS, 45; open, 14). Blood loss (200 mL vs 798 mL), transfusions (0% vs 17%), and length of stay (LOS) (6.1 days vs 8.4 days) were significantly ($P < .01$) lower in the MIS group. Complications were also fewer in the MIS group (4 vs 12, $P < .02$). The mean cost of an open fusion was 1.28 times greater than that of an MIS fusion ($P = .001$). Both groups had significant improvement in 1-year outcome. The changes in ODI and SF-6D scores were not statistically different between groups. Multivariate regression analysis showed that LOS and number of levels fused were independent predictors of cost. Age and MIS were the only predictors of LOS. Baseline outcomes and MIS were predictors of 1-year outcome.

Conclusion: MIS posterior fusion for spondylolisthesis does reduce blood loss, transfusion requirements, and LOS. Both techniques provided substantial clinical improvements at 1 year. The cost utility of the MIS technique was considered comparable to that of the open technique.

Level of Evidence: Level III.

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Minimally invasive surgical (MIS) techniques and technologies have been increasingly introduced in spine surgery over the last decade.^{1,2} In the scenario where a surgical technique may obtain comparable or superior clinical effi-

cacy while decreasing surgical morbidity, consideration for adoption is logical. However, many factors influence acceptance of novel techniques. Although clinical efficacy has to be first and foremost, factors such as complication rate, significant learning curve, and increased cost all have to be weighed against the reported benefits of less postoperative morbidity, faster recovery, less pain, and faster improvement of function. Furthermore, the relative consequences of the pros and cons of any given new technology will be perceived very differently from the patient, surgeon, payer, or societal perspective; hence adoption of newer techniques

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is never a simple matter. For example, techniques such as knee arthroscopy or laparoscopic cholecystectomy, despite dramatic differences in invasiveness and perioperative morbidity, took many years to become the standard of care.

As with most MIS techniques, posterior lumbar fusion is marketed with the premise of being better than current open interventions; however, comparative evidence of this is generally lacking.^{1–4} Most early studies have shown benefits of reduced pain, blood loss, and length of stay (LOS); however, these studies have been predominantly short term, and longer-term studies assessing validated clinical outcomes, complications, and revision rates have only recently started to surface.^{5–12} These more recent studies show short-term benefits of reduced surgical morbidity, but they do not show dramatic clinical benefit. Furthermore, these series typically mix a heterogeneous group of diagnoses with degenerative disc pathology predominating. Different diagnoses have been shown to have significant clinical impact on outcome, with degenerative discs causing back pain being the most variable.^{13–15} Therefore evidence to strongly support adoption of MIS spine fusion techniques is far from adequate. Although short-term benefits are desirable from the patient's perspective, the perceived increased cost and significant learning curve typically associated with MIS fusion are potential deterrents from the payer's and surgeon's perspective, particularly in the absence of a dramatic difference in outcomes.

To our knowledge, no study has assessed the economic impact of minimally invasive posterior lumbar fusion on direct institutional cost (ie, health system perspective). The primary objective of this study was to compare the direct economic impact of a single- or 2-level primary decompression and fusion for degenerative or isthmic spondylolisthesis by use of an MIS technique compared with conventional open posterior decompression and fusion.

Methods

This is a retrospective cohort study performed at a tertiary care academic center of patients of 4 dedicated, fellowship-trained spinal surgeons, all with at least 5 years of experience in their respective surgical techniques for posterior lumbar fusion. Inclusion (grade I–II spondylolisthesis [degenerative or isthmic]) and exclusion (other causes of spondylolisthesis [eg, iatrogenic], high-grade spondylolisthesis, and revision surgery) criteria were applied to a prospective surgical registry for patients undergoing single- and 2-level lumbar fusions from August 2005 to August 2008. MIS fusion involved a paramedian muscle-splitting approach with a transforaminal lumbar interbody fusion by use of a fixed, 22- to 26-mm tubular retractor and percutaneous pedicle screws (Sextant; Medtronic, Memphis, Tennessee), whereas the open technique was a traditional midline muscle-stripping approach (lateral to the facets), with instrumented posterolateral fusion with or without interbody fusion. All patients were independently reviewed.

Data on baseline demographics, diagnosis, comorbidities, body mass index, and surgical procedure were collected. Operative data included number of levels fused, use of interbody cages, estimated blood loss, intraoperative complications, and total and anesthetic time (ie, total operating room time). Postsurgical data included postoperative complications and total hospital LOS. Clinical outcome measures included preoperative Oswestry disability index (ODI) and Short Form 36 postoperatively at 1 year. Furthermore, micro-case costing per individual patient was collected retrospectively from our institution's finance department. These costs included operative costs, nursing (including postanesthetic care, step-down unit, intensive care unit, and ward), medical imaging, laboratories, pharmacy, and allied health. Also included was any additional cost associated with the management of any inpatient adverse events. Costs of preoperative or postoperative rehabilitation or other outpatient health system costs were not collected. Institutional, patient, or societal indirect costs were also not collected. Because the groups were the same with regard to diagnosis, institution, and health care system, costs of preoperative and postoperative physician visits and imaging were assumed to be the same.

Univariate analysis of cohorts was conducted by *t* tests for normally distributed data or Whitney-Mann and χ^2 tests for categorical variables. Multivariate regression modeling was performed to assess predictor variables on total direct cost, LOS, and clinical outcome. Given the small sample size, only limited modeling was possible (4 variables per model). The primary outcome measure for the study was the total direct cost. The secondary measures were cost-utility analysis by use of the short-form 6D (SF-6D) health utility index (derived from the Short Form 36 at the 1-year time point and the surgical direct cost) and patient-reported clinical outcome (ODI) at 1 year.

Results

There were 37 patients in the MIS group and 41 in the open group (Table 1). Degenerative spondylolisthesis was present in 49% of patients in the MIS group versus 58% in the open group, with the remaining patients having isthmic spondylolisthesis ($P = .4$). The groups are comparable in terms of age, sex, preoperative hemoglobin, American Society of Anesthesiologists status, Charlson comorbidity index, and body mass index ($P > .05$). Outcomes are presented in Table 2. There were significantly fewer complications in the MIS group (12 vs 4, $P < .02$). The MIS group had an 11% adverse event rate, with 1 intraoperative incidental durotomy and 3 postoperative urinary tract infections. The open group had a 29% adverse event rate, with 3 incidental cases of durotomy, 8 urinary tract infections, and 1 patient with a minor neurologic deficit postoperatively. Postoperatively, none of the MIS patients required transfusion, as compared with 17% in the open group ($P < .0001$).

Table 1
Demographics

Variable	Open group			MIS group			P value
	N	Mean	SD	N	Mean	SD	
Age (years)	41	57.05	13.38	37	55.11	14.98	.7826*
Sex (female)	20	—	—	19	—	—	.7263†
Body mass index (kg/m ²)	39	30.65	5.72	36	29.84	6.50	
No. of levels fused‡	41	1.49	0.51	37	1.22	0.42	.0133†
Estimated blood loss (mls)	40	797.75	564.27	37	200.41	165.12	< .0001*
LOS (days)	41	8.41	5.45	37	6.08	1.86	.0525*
Adverse events	12	—	—	4	—	—	< .02†
Operating room time (hours)	41	3.79	1.04	37	3.70	0.90	.6794§

* Whitney-Mann test.

† χ^2 test.

‡ Two-level fusions were performed in 20 patients in the open cohort and 12 in the MIS cohort.

§ *t* Test.

The mean LOS was 2.3 days shorter for the MIS group ($P = .01$).

ODI, as well as health utility index, was significantly improved in both groups at 1 year (Tables 2 and 3). Differences between groups were significant at baseline and 1 year ($P < .01$) (Table 2). The preoperative to postoperative reduction in ODI was 19.7 (SD, 15.4) and 16.6 (SD, 18.3) for the MIS and open groups, respectively. The change was significant for both the MIS group ($P = .0002$) and open group ($P = .0006$) but was not significant between groups ($P = .55$).

The mean total direct cost was Can \$14,183 for the MIS group compared with Can \$18,633 for the open group ($P = .0009$). The preoperative and postoperative change in health utility was significant for both groups ($P < .0001$ for MIS and $P < .003$ for open) at the 1-year mark, with a gain of 0.113 (SD, 0.10) and 0.079 (SD, 0.08) quality-adjusted life-years (QALYs) for the MIS and open groups, respectively. The change between groups neared statistical significance ($P = .08$). The cost-utility analysis using mean cost per QALY for both groups is shown in Table 4. Table 4 also shows projected cost utility at 2 years and 4 years with 5% annual discounting of the mean gain in QALYs at the 1-year time point.

Predictors of cost and clinical outcomes

Multivariate regression analysis shows that LOS was the dominant predictor of cost (coefficient, Can \$896.8 [95% confidence interval (CI), 701.5 to 1,092.2]; $P < .0001$). For

every 1-day increase in LOS, the patient's cost is likely to be higher by Can \$896. Complications, operative time, and type of surgery (MIS vs open) were not independent predictors of cost ($P > .05$). Independent of the MIS or open technique, the number of levels of fusion was also a predictor of cost (coefficient, Can \$2,777 [95% CI, 1,094.1 to 4,459.9]; $P = .001$). Comparison of only 1-level cases resulted in the same findings as above (except for number of levels), with LOS being the sole predictor of cost ($P < .0001$, data not shown).

Age (coefficient, 0.13 [95% CI, 0.07 to 0.19]; $P < .0001$) and MIS technique (coefficient, -2.1 [95% CI, -3.8 to -0.3]; $P = .02$) were the only independent predictors of LOS. For every 1-year increase in age, the patient's LOS is likely to be higher by 0.13. An MIS patient is likely to have a lower LOS by 2.1 days than an open patient. The number of levels of fusion was not a predictor of LOS.

MIS technique (coefficient, -10.5 [95% CI, -20.8 to -0.2]; $P = .04$) and baseline ODI (coefficient, 0.48 [95% CI, 0.13 to 0.83]; $P = .009$) were predictors of postoperative ODI at 1 year. MIS technique (coefficient, 0.10 [95% CI, 0.03 to 0.18]; $P = .007$) and baseline utility score (coefficient, 0.46 [95% CI, 0.06 to 0.86]; $P = .03$) were predictors of postoperative utility score at 1 year. Patient age ($P > .5$) and type of spondylolisthesis (isthmic or degenerative) ($P > .1$) did not predict outcome.

Discussion

The results of this limited cohort study of patients with lumbar spondylolisthesis undergoing 1- or 2-level fusion with posterior MIS compared with conventional open posterior fusion show short-term benefits of reduced blood loss, transfusion rate, adverse events rate (all minor), and hospital LOS within the same institution. The clinical (ODI and SF-6D) improvement was substantial for both groups at the 1-year mark, and the relative changes from the preoperative to postoperative period were clinically comparable. The mean direct cost was 28% lower in the MIS group.

Table 2
Clinical outcomes

Variable	Open			MIS			P value
	N	Mean	SD	N	Mean	SD	
ODI at baseline	30	51.33	15.85	28	36.90	15.04	.0011*
ODI at 1 y	29	33.68	18.84	28	18.91	17.85	.0028*

* Whitney-Mann test.

Table 3
Cost-utility data

Variable	Open			MIS			P value
	N	Mean	SD	N	Mean	SD	
Direct cost (Can \$)	40	\$18,632.91	6,197.32	36	\$14,171.93	3,269.73	.0009*
Utility score at baseline	29	0.49	0.08	28	0.60	0.09	< .0001†
Utility score at 1 y	29	0.57	0.10	28	0.72	0.09	< .0001†

* Whitney-Mann test.

† *t* Test.

Outcomes

In general terms, patient-reported clinical outcomes at 1 year are consistent with the respective literature for both MIS posterior interbody fusion and conventional open decompression and fusion for low-grade spondylolisthesis.^{5–7,11,16–18} More specific to posterior MIS fusion, the results of our study regarding the impact of the MIS technique (transforaminal lumbar interbody fusion) on acute short-term outcomes, such as blood loss, transfusion rates, and shorter hospital stay, are consistent with the results of 8 recently published studies comparing MIS posterior fusion with open fusion.^{5–12} Data from these studies (with total of 296 MIS patients vs 408 controls undergoing open technique) showed that MIS patients had fewer postoperative complications than open controls (7.6% vs 16.6%), less blood loss (192 mL vs 455 mL), shorter operating room time (167 minutes vs 184 minutes), and shorter LOS (3.4 days vs 5.2 days). Several articles reported no significant between-group differences in clinical outcomes at 6, 12, and 24 months' follow-up.^{5,6,11} With regard to patient-reported clinical outcome, our study is also consistent with those comparative studies reporting clinical outcomes at or beyond 1 year.^{5,6,11}

Cost factors

The mean and median difference in direct cost (public health care system perspective) between the MIS and open groups were Can \$4,461 and Can \$3,333, respectively. Given the heterogeneity (Table 1) within these 2 small cohorts, the relatively small (statistically significant) difference in cost could be easily affected by several factors. Multivariate regression analysis showed that the majority of cost savings was achieved through reduction in LOS, with the only independent factors affecting LOS being MIS technique and age. As expected, the number of levels also

affected cost, with a 2-level fusion patient's cost averaging Can \$2,777 greater than a single-level patient's cost. This was independent of the MIS or open technique (ie, the cost is higher for a 2-level fusion regardless of technique). In addition, the number of levels fused did not affect LOS. In our health care system, it would appear that LOS is a modifiable but dominant factor that influences direct cost for lumbar fusion in this population. The 2-day reduction in LOS in this study is consistent with the available comparative literature.^{5–12} It should be noted that reported LOS for the same diagnoses is variable from one health care system/country/region to another and typically depends on whether there is a direct cost disadvantage to the patient. Thus comparisons must always be made using the relative change in LOS within the same health care system and not the absolute mean LOS for a given study. Although age was also shown to be an independent predictor of LOS, the mean age was essentially equal between groups. Given the small sample size, our multivariate models were limited to 4 predictor variables and therefore confounding effects cannot be ruled out. Several areas of heterogeneity in our cohorts could have affected cost and are worthy of discussion. First, there were more 2-level fusions performed in the open group ($P = .01$); although this was not a predictor of LOS, it is likely associated with a greater LOS because of greater morbidity. The mean LOS was 8.0 days for 1-level open fusions and 8.9 days for 2-level open fusions ($P = .584$). Comparison of the mean cost for the 2-level MIS technique (Can \$15,410; SD, 2,279) and 2-level open technique (Can \$20,370; SD, 6,897) showed a statistically significant difference ($P = .045$). Second, the MIS cohort used 45 interbody cages, whereas the open cohort used only 14 ($P < .01$). At our institution, each cage is approximately Can \$1,000 to Can \$1,250, and hence this would add greater cost to the MIS group. Although this favors the cost utility of the

Table 4
Cost-utility analysis, with projections for 2 and 4 years (all cost in Can \$)

	Cost	QALY gained (5% annual discounting of QALY)			Cost/QALY		
		1 y	2 y	4 y	1 y	2 y	4 y
MIS group	\$14,183	0.11	0.2	0.38	\$128,936	\$ 70,915	\$37,720
Open group	\$18,633	0.08	0.15	0.28	\$232,912	\$122,585	\$67,510

open group, we believed that the variations in surgical technique of the 3 open surgeons were reflective of current clinical practice and hence the cost was more generalizable. A third issue is the use of recombinant human bone morphogenetic protein 2. Given the lack of evidence of superior clinical outcomes in non-high-risk patients, the cost of bone morphogenetic protein (BMP) is not paid for at our institution and hence represents an out-of-pocket expense to the patient.¹⁹ Patients may purchase BMP from the manufacturer at a significantly discounted price if they choose. In the MIS group, 65% of patients chose to use BMP for their fusion. Because this is an out-of-pocket expense, it is not counted in the direct institution cost or the cost-utility analysis (see below). Obviously, if the institution (public health care system) was to cover the routine use of BMP, then the total cost for the MIS group would increase. For this cohort, if every patient in the MIS cohort used BMP and none in the open group did so, the mean cost difference would essentially become neutral. However, as evident in the United States, if BMP was readily available and paid for, the use of BMP would be increased in both groups.²⁰ One final issue that may have increased cost for the open group is the fact these patients were generally more disabled than those in the MIS group, a fact that may have increased the mean LOS. However, adjusted analysis did show that in addition to baseline ODI, MIS technique also significantly impacted the final ODI scores. Recently, Carreon et al.,²¹ confirming the findings of other authors, showed that a worse preoperative ODI (as in the open cohort) predicts a greater improvement in ODI after lumbar fusion. This was also shown in our study; however, the MIS group had a comparable improvement, which is consistent with the results of the regression model showing a positive effect on final outcome by the baseline score and the MIS technique. Clearly, any or all of these factors could influence the LOS and cost in favor of either technique. Given the standard deviations, a much larger sample size would have been necessary to truly determine a cost advantage of either technique. Though not studied, a 2-day difference in LOS could also be impacted in either group by institution of a more aggressive postoperative care pathway. Although all patients were cared for on the same spinal ward, caregiver biases and/or patient placebo effect of the MIS technique may have also influenced LOS.

Cost-utility factors

From a cost-effectiveness perspective, the cost utility (cost per QALY gained) of both procedures at the 1-year mark is over the \$100,000 per QALY, and hence these procedures would be considered costly (Table 4). For the reasons stated previously, the cost utilities in this study should not be considered significantly different in that the variability of the numerator (cost) is likely not reflected in this limited cohort. Similar utility outcomes (denominator) and cost utility at 2 years were noted from the degenerative spondylolisthesis SPORT (Spine Patient Outcomes Re-

search Trial) study.²² As noted by Tosteson et al.,²² the cost utility of a procedure will improve assuming that the clinical impact is maintained over time. Furthermore, the longer the positive impact on health utility, the better the cost utility. Recently, the authors of the degenerative spondylolisthesis SPORT trial have demonstrated sustained outcomes of surgery compared with nonsurgical treatment at the 4-year mark.¹⁶ Sustained outcome is also expected for the isthmic spondylolisthesis group.¹⁷ On the basis of current evidence, it is reasonable to assume that the outcomes in our cohorts will remain relatively stable for 4 years (by use of a 5% per annum discount on the health utility score), and thus the cost utility for these 2 cohorts should significantly improve at 2 and 4 years (Table 4). This, however, does not account for any revision cost that may occur in that time period. The projected 2-year cost utility for both MIS and open fusion is favorable compared with that reported by Tosteson et al. at 2 years. This is because of the greater estimated direct cost (numerator) in the US health care system (US \$31,938 per patient). This cost is essentially double that of our study and highlights the challenges of interpreting and comparing cost-utility analyses.^{23–31} In addition, when interpreting cost-utility analyses, the reader must also consider the utility measure that was used. For example, the interval change of the EuroQol (ED-5Q) and SF-6D may differ within the same population, and hence these measures are not interchangeable.^{32–39} The SF-6D tends to be associated with a smaller effect and hence would result in an increased cost utility than if the ED-5Q was used instead. This effect was shown in the study by Tosteson et al., where the increase in the cost utility for surgical intervention was significantly greater (approximately US \$30,000) with the SF-6D than with the ED-5Q. For our study, another specific issue to consider in interpretation of the cost-utility value is the denominator. As noted previously for ODI, the utility score was also independently affected by the MIS technique and the baseline outcome score; thus the true effect of MIS on the change in utility score versus other confounders is unknown.

Despite the limited 1-year time horizon, this study does allow a relative comparison of the cost-effectiveness of the MIS technique compared with the conventional open technique. A cost-effectiveness analysis would typically be calculated by use of an incremental cost-effectiveness ratio (ICER); in brief, ICER equals the cost of a new strategy less the cost of current practice, divided by the change in outcome of the new strategy, minus that of the current practice.²⁶ The ICER analysis typically makes the assumption that the new strategy is likely to cost more but have a clinically greater effect and hence typically is used to determine the cost per the differences in outcome. In this case because the new strategy cost less or is at least equivalent and has a greater yet statistically insignificant difference in effect on the outcome, the MIS technique would be at least cost neutral. Consequently, an ICER analysis was not performed.²⁶

Limitations

The major limitation of this study is the baseline differences in outcome measures, which reflects a more disabled open fusion cohort. Because this is a retrospective analysis of a prospectively collected database documenting outcomes in different practices, these differences in baseline factors are not surprising. Although selection bias may account for the more disabled open cohort, the MIS cases are consecutive, and all 1- and 2-level fusions performed by the MIS surgeon are performed using the aforementioned technique. Despite efforts to control for various factors with regression modeling, given the limited models and small sample size, there are differences in the patient populations that may have impacted key outcomes. The inherent biases of retrospective study are also shown by the fact that patient-reported outcomes data (pain, ODI, SF-6D) were only available for 75.7% of the MIS group and 70.7% of the open group.

As with many health economic studies, other assumptions and limitations must be considered when one is interpreting the results. The costs in this study represent only those from an institutional perspective and hence do not reflect indirect societal or direct out-of-pocket patient costs. The micro-case costing data presented in this study are comprehensive and from a single payer system. Given the congruency of diagnosis and overall treatment, as well as similar preoperative and postoperative protocols (physician visits, imaging), no patient in either cohort underwent inpatient rehabilitation, and there were no revisions in either group at the 1-year mark. We assumed that all other direct costs would be equal between groups. Several studies have noted that the majority of cost associated with a surgical procedure typically reflects the majority of the direct cost.^{22,29} Thus we believe that we have adequately represented the direct cost from a Canadian hospital perspective associated with fusion for low-grade spondylolisthesis. However, the relative rate of revision surgery or sustained change in utility scores (ie, QALYs gained) over time between groups will significantly impact the cost-utility analysis, and thus longer-term follow-up is paramount.

In conclusion, this observational cohort study confirms that MIS fusion for the treatment of spondylolisthesis reduces blood loss, transfusion requirements, and hospital LOS by 2 days on average. Both groups were associated with substantial clinical improvements at 1 year. Furthermore, contrary to popular belief, MIS fusion did not increase operative time or direct cost. Because of group heterogeneity and small sample size, the cost utility of the MIS technique was considered comparable to the open technique. Longer-term follow-up is required to determine the impact of revision rates and utility scores on the relative cost utility of both techniques.

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