

The cost effectiveness of dynamic and static interspinous spacer for lumbar spinal stenosis compared with laminectomy

Mohsen Yaghoubi¹, Maziar Moradi-Lakeh², Mohammad Moradi-Joo³
Vafa Rahimi-Movaghar⁴, Neda Zamani⁵, Ahmad Naghibzadeh-Tahami⁶

Received: 14 September 2015

Accepted: 16 November 2015

Published: 6 March 2016

Abstract

Background: The present study aims to evaluate the cost-effectiveness of Dynamic Interspinous Spacer (Coflex®) and Static Spacer (X-STOP ®) compared to Laminectomy (LAMI) in patients with lumbar spinal stenosis.

Methods: A decision-analysis model was developed to estimate the cost-effectiveness. The effectiveness parameters were obtained from a systematic literature review in relevant databases including PUBMED and EMBASE. A meta-analysis was performed using the STATA statistical package and a random model was used to collect measures of mean difference of visual analogue scale (VAS) pain score before and after intervention in X-stop, Coflex and LAMI (95% confidence intervals). Cost data were obtained from provider and associated literature based on health care provider prospective. We assumed that the probability of the success rate of surgery in each intervention from associated literature and calculated Incremental cost effectiveness ratio. A one-way sensitivity analysis was also carried out.

Results: Twenty-four out of 294 studies are included in the Meta-analysis. The overall pooled estimate of the mean difference of VAS pain score were 3.49 (95% CI 3.7-4.2) and 4.14 (95% CI 3.09-5.19) for X-stop and Coflex, respectively. In addition, we assumed the overall pooled estimate of 5.3 (95% CI 2.15-7.4) on the basis of literature for LAMI. The average cost per LAMI surgery, X-stop and Coflex was US\$ 3019, US\$ 2022 and US\$ 2566, respectively. Incremental cost effectiveness ratio of X-stop and Coflex versus LAMI was US\$ 665.9 and US\$ 780.7, respectively.

Conclusion: Static Interspinous Spacer (X-stop) appears to be the most cost-effective treatment strategy in base case scenario with success rate of LAMI (range between (55%-70%). A sensitivity analysis shows that the increase probability of success rate of LAMI was more than 70 % and less than 55% which lead to the cost effectiveness of the Coflex intervention.

Keywords: laminectomy, interspinous, spinal stenosis, cost-effectiveness, lumbar vertebrae.

Cite this article as: Yaghoubi M, Moradi-Lakeh M, Moradi-Joo M, Rahimi-Movaghar V, Zamani N, Naghibzadeh-Tahami A. The cost effectiveness of dynamic and static interspinous spacer for lumbar spinal stenosis compared with laminectomy. *Med J Islam Repub Iran* 2016 (6 March). Vol. 30:339.

Introduction

Spinal stenosis is one of the most common vertebral column disorders. Between the vertebrae, the intervertebral discs and

spinal facet joints are located. As one's age increases, the discs lose their spongy state which might lead to reduced height, protrusion or bulging of hard disc into the spinal

¹. (Corresponding author) MS, Health Economic, Department of Community Medicine, School of Medicine, Iran University of Medical Sciences, Tehran, Iran. mohsenyaq@yahoo.com

². MD, MPH, Associate Professor of Community Medicine, Department of Community Medicine, School of Medicine, Iran University of Medical Sciences, Tehran, Iran. mazmoradi@yahoo.com

³. MS, Health Technology Assessment, Cancer Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran. moradi2001@yahoo.com

⁴. MD, Professor of Neurosurgery, Sina Trauma and Surgery Research Center, Tehran University of Medical Sciences, Tehran, Iran. v_rahimi@sina.tums.ac.ir

⁵. MD, Community Medicine Specialist, Department of Community Medicine, School of Medicine, Isfahan University of Medical Sciences, Isfahan, Iran. nzamani@med.mui.ac.ir

⁶. MS, Epidemiology Physiology Research Center, Institute of Neuropharmacology, Kerman University of Medical Sciences, Kerman, Iran. naghibzadeh61@gmail.com

canal. The bones and ligaments of spinal facet joints become thicker and larger and add inward pressure on spinal canal. These changes lead to a narrowing in the lumbar spinal canal which is also called spinal stenosis (1). Spinal stenosis is among the important factors leading to the feeling of low back pain (2). Low back pain is the third leading cause of Disability Adjusted Life Years in Iranian population aged 15 to 69 years, without considering causes of injuries (3). Due to the fact that spinal stenosis leads to the constriction and narrowing of bone canal, the objective of this surgery was to open it to increase the existing space for nerves. Such a surgery is called “Decompression” or “Laminectomy” (4). The semi-invasive method was used as a substitution of surgery for the treatment of spinal stenosis which requires the application of a new generation of vertebral column implants.

Dynamic Interspinous Spacer is a new class of vertebral column system from which new designs have been developed. They could be easily distinguished from compressible and non-compressible metal spacers. Of course, just like other vertebral column systems they are made of similar materials such as allograft bone, titanium alloy and PEEK and manufactured through elastomer (5). It should be noted that in the previous generation, titanium was used instead of steel in vertebral column implants which disrupted MRI imaging. Although all of these systems are completely distinctive in their details but the mechanical objective of all of them is affected by the deviation between thorn-shaped appendages of vertebral column which blocks the intervertebral extension in the surface. It is applied in the treatment of degenerative vertebral column stenosis, low back pain, intervertebral disc herniation and non-traumatic instability (*ibid*). This stabilizing implant device is placed among the thorn-shaped appendages of the vertebral column which leads to the non-constriction of the lumbar nerves when the patient is standing (*ibid*). This device is divided into two types: static and dynamic.

Some of these static systems are X-stop and Wallis. The implant of these systems is made of non-compressive materials such as metal and bone (6). The dynamic implant devices have a degree of compression. These devices are manufactured by elastomeric compounds and metal materials such as dampener. An instance of dynamic model is Coflex system in which a u-shaped alloy is placed within the thorn-shaped appendages of vertebral column. Another instance of dynamic model is DIAM system which is made of elastomeric polymer that is placed as an inter-canal lastic buffer (5,6). Considering the high prevalence of the spinal disc herniation and back pain in Iran and other disabilities of vertebral column, especially spinal stenosis, as well as complexity and consequences of invasive interventions, the application of a new generation of dynamic implants of vertebral column could be a promising alternative for surgery. As a result, it is essential to review the cost-effectiveness of this device through evidence-based decision-making system to decide about the development of this method.

Research Questions

Based on the Health Technology Assessment Protocol, the present study aims at answering the following questions:

Q.1- How effective and safe are semi-invasive methods of static and dynamic implants in treating spinal stenosis compared with laminectomy?

Q.2- How much do semi-invasive methods of static and dynamic implants cost in comparison with laminectomy in treating spinal stenosis?

Objectives

The objective of the present study was to examine the effectiveness of semi-invasive methods of static and dynamic implants in treatment of spinal stenosis compared with laminectomy

Methods

The present study is done through a sys-

tematic review of the evidences regarding effectiveness of the vertebral column implant systems (i.e. static and dynamic). This technology was compared with gold standard intervention for the removal of spinal stenosis, namely wide and large laminectomy and decompression. To determine the efficiency of implant systems, a systematic review and meta-analysis were conducted. In addition, the existing studies were used to determine the efficiency of the semi-invasive interventional laminectomy and decompression surgery. Regarding the economic evaluation, the decision-making tree in Excel Software was used (Fig. 1). Considering the costs, a quick review of cost-effectiveness studies and costs of these interventions was done. We used the estimated average cost determined through finding evidence. In addition, the mean cost of laminectomy in Iran was estimated from the prospective of a health-care provider.

Literature Review

The main review of the primary and secondary studies was done in 15th April 2014. At first, the sources containing these studies were selected for the collection of systematic reviews, meta-analysis, and evaluations of health technologies as well as the reports related to the economic evaluations. In regard to EBM reviews, CDSR, DARE, CENTRAL, NEED, HTA and ACP JC databases were comprehensively searched through an OVID SP interface. The Medline, EMBASE, Proquest, Science Direct, Wiley and Springer were searched for primary studies through OVID and PubMed. All studies in the associated databases and websites were investigated without imposing any temporal limitation. The title and abstract of all papers found through electronic searching or other methods were independently evaluated by two people (MY and MM) regarding the association of their subject with the research questions. Then, the full texts of these papers were obtained. Regarding quality assessment, we used "Critical Appraisal Skills Program" checklist (CASP). The majority of studies select-

ed for this review had been assessed to be of moderate quality but articles thought to be of lower quality were also included.

Inclusion and Exclusion Criteria

All studies that revolved around intended criteria of primary intervention, namely the treatment of degenerative vertebral column stenosis, and included a type of static or dynamic implants, were included. In addition, the laboratory studies and those studies conducted on animal models were excluded along with the studies on human corpses.

PICO Questions

In the present study, PICO is considered in the following manner.

Problem: The lumbar canal stenosis was regarded as the main problem in the present study.

Intervention: The placement of dynamic and static implants of vertebral columns was referred to as the main intervention.

Comparison: The gold standard intervention for the removal of spinal stenosis, namely wide and large laminectomy and decompression was intended for comparison.

Outcome: The mean reduction of visual analogue scale (VAS) pain score regarded as an indicator of one of the primary clinical consequences was analyzed in the present study.

Study design: The systematic reviews and meta-analysis, economic evaluation and clinical trials were added to the study in three phases.

Synthesizing method

The data analysis was done through STATA Software (version. 10). To estimate the pooled index, the weighted mean difference of intended index before and after intervention, the meta-analysis was used. In addition, the heterogeneity was verified by Q-test and $p < 0.1$ were considered as significance limit. To estimate the pooled index due to heterogeneity, a random model was used. In addition, the stud-

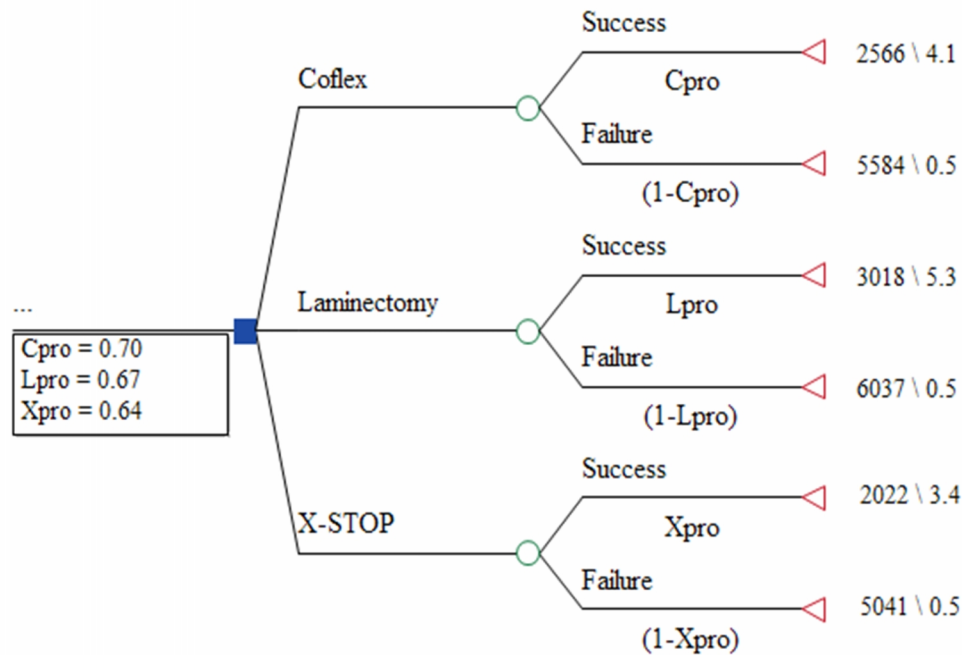


Fig. 1. An illustration of the decision-making tree for economic evaluation of vertebral column implants with alternative surgical method

ies were categorized into static and dynamic implants and the pooled index of mean difference values were calculated for each.

Costing method

To determine the costs of laminectomy, the mean cost of surgery based on the health care provider was calculated. To do this, the mean final cost for each patient was estimated through inclusion of costs of operation, hospital, hoteling, drug, and diagnostic tests, etc. Regarding the mean cost of application of static and dynamic vertebral columns implants, due to unavailability of these implants in the market of Iranian medical care and lack of such surgeries in Iran the cost information of economic evaluation concerning the cost of static and dynamic implants compared with laminectomy cost was used. Based on the mean cost of laminectomy in Iran, the mean cost of intervention was also estimated.

Cost-effectiveness model

An economic evaluation model was used based on decision-making tree model (Fig. 1). In this model, for each intervention by static and dynamic implant and laminecto-

my surgery, the probability of success or failure of intervention, cost and effectiveness for each case were calculated. Ultimately, the final mean for each intervention (mean reduction of VAS pain score) was reported.

Results

Results of Literature Review

Data extraction was done by two project colleagues (MY and MM). In the cases of difference, the third person (VRM) evaluated the papers causing disagreement among the peers. The applied technological data and reviewed findings in each case were extracted. The data concerning the number of patients in each study, type of applied intervention, follow-up period, and mean VAS pain score before and after implanting in patients was extracted into a common index in all studies (Table 1). Thirty-five out of 294 papers found in the step of systematic and manual search were repetitive. After excluding them, 259 papers were verified in regard to title and abstract. In this regard, 79 papers were selected for complete text review. Fifty-three out of 79 papers lacked the inclusion criteria of present

Table 1. Characteristics of Studies on Systematic Review Procedure of Static and Dynamic Implants

N	Writer (s)	Year	No.	Type of Technology	System	Follow-up	VAS Pain Score	Percentile Progress (%)	Standard Deviation
1	Sobottke R, et al (9)	2009	129	Static	X-STOP	12M	6.65 (6.1-7.1) 95%CI	99.25	-0.26
2	Sobottke R, et al (9)	2009	129	Static	Wallis	12M	5.44 (7.2-3.6) 95%CI	95.44	0.92
3	Sobottke R, et al (9)	2009	129	Dynamic	DIAM	12M	5.64 (3.8-7.4) 95%CI	95.59	-0.92
4	Kim HJ, et al (10)	2012	40	Static	X-STOP	12-22M	5.86 (5.0-6.6) 95%CI	81.84	-0.41
5	Ploumis A, et al (11)	2012	22	Static	X-STOP	24-26 M	2.00 (2.3-1.7) 95%CI	44.44	0.15
6	Shabat Sh, et al (12)	2011	53	Static	X-STOP	6W-2Y	4.50 (3.1-5.9) 95%CI	52.94	-0.71
7	Bowers C, et al (13)	2010	13	Static	X-STOP	41-48M	5.20 (6.1-4.3) 95%CI	71.23	0.46
8	Miller E (14)	2012	86	Static	X-STOP	6M	4.20 (3.8-4.6) 95%CI	18.99	-0.20
9	Tuschel A, et al (15)	2009	46	Static	X-STOP	24-70M	1.60(1.4-1.8) 95%CI	33.33	-0.10
10	Zhou D, et al (16)	2013	23	Dynamic	Coflex	6-18 M	6.30 (7.7-4.9) 95%CI	80.77	0.71
11	Sun HL, et al (17)	2011	27	Dynamic	Coflex	30M	2.90 (3.2-2.6) 95%CI	52.73	0.15
12	Sun HL, et al (17)	2011	25	Static	Wallis	30M	2.80 (4.1-1.5) 95%CI	52.83	0.66
13	Zhao Y (18)	2010	8	Dynamic	DIAM	12-31M	4.94 (2.1-7.7) 95%CI	58.53	-1.43
14	Buric J, et al (26)	2011	47	Dynamic	DIAM	48M	3.20 (2.5-3.9) 95%CI	53.33	-0.36
15	Antonio P, et al (27)	2011	1315	Dynamic	DIAM	12M	5.13 (5.5-4.7) 95%CI	68.04	0.20
16	Ryu SJ, et al (28)	2011	16	Dynamic	DIAM	17-27M	5.70 (6.5-4.9) 95%CI	73.08	0.41
17	Richter A, et al (29)	2010	30	Dynamic	Coflex	12M	4.80 (5.6-4.0) 95%CI	69.57	0.41
18	Cabraja M et al (30)	2009	41	Dynamic	Coflex	24M	3.90 (2.1-5.7) 95%CI	52.70	-0.92
19	Kong DS, et al (31)	2007	18	Dynamic	Coflex	12M	4.60 (4.1-5.1) 95%CI	62.16	-0.26
20	Sénégas J, et al (32)	2009	107	Static	Wallis	156M	2.60 (2.7-2.5) 95%CI	41.97	0.05
21	Floman Y, et al (33)	2007	37	Static	Wallis	12-24M	5.20 (5.1-5.3) 95%CI	78.79	-0.05
22	Sénégas J (34)	2002	40	Static	Wallis	12-56M	6.00 (6.9-5.1) 95%CI	74.07	0.46
23	Beyer F, et al (35)	2013	12	Static	Aperius	12M	3.40 (3.3-3.5) 95%CI	56.67	-0.05
24	Kuchta J, et al (36)	2009	175	Static	X-STOP	24M	2.20 (2.3-2.1) 95%CI	36.07	0.05

VAS= visual analogue scale

study and the reasons of their exclusion are mentioned in the annex. Twenty-four out of 26 primary studies were also included in meta-analysis of which 10 studies were concerned with dynamic implants and the remaining 14 papers verified static implants. In Figure 2, the steps of systematic review of primary intervention are represented. To determine the mean difference

of VAS index in decompression and laminectomy surgeries considered as comparative interventions, systematic review and meta-analysis were considered as the basis of the data extraction (7).

Meta-analysis

The data analysis was done through STATA Software (version.10). To estimate

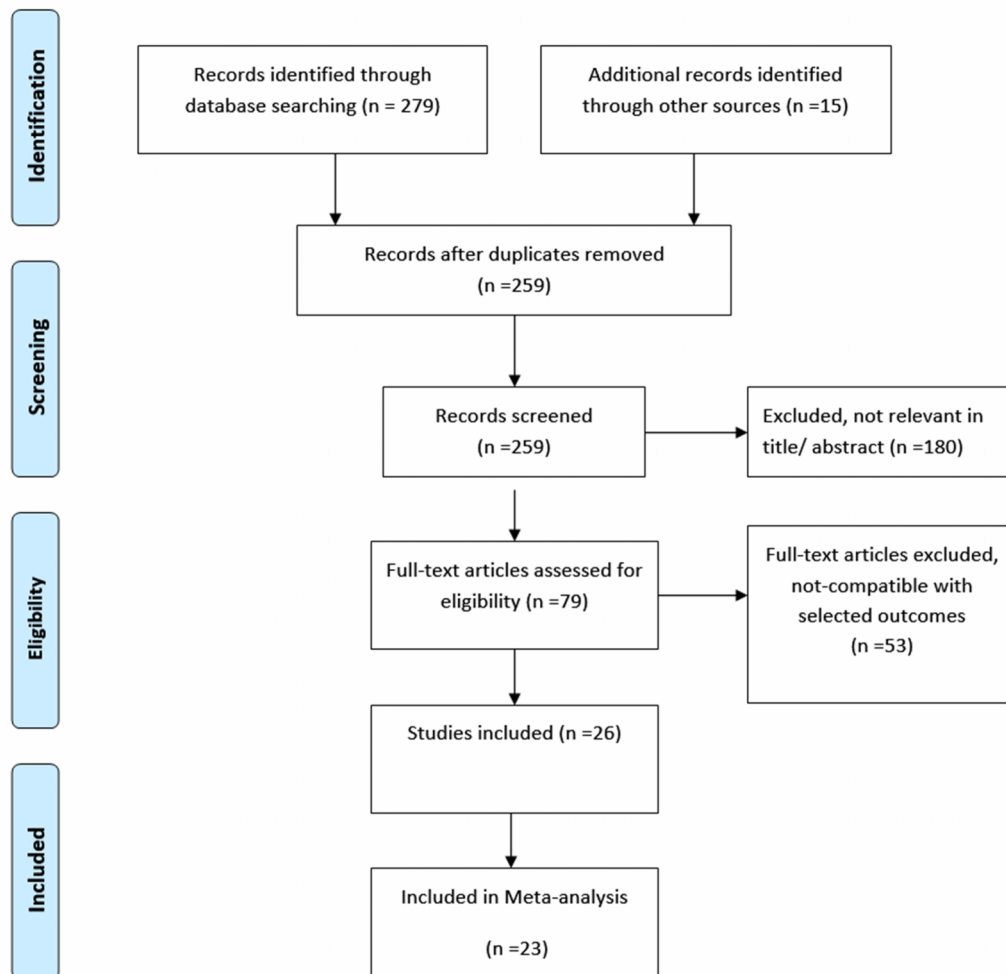


Fig. 2. Systematic literature review based on prisma statement

the pooled index, the weighted mean difference of intended index before and after intervention through the meta-analysis was used. In addition, the heterogeneity was verified by Q-test and $p < 0.1$ were considered as significance limit. To estimate the pooled index due to heterogeneity, a random model was used. In addition, the studies were categorized into static and dynamic implants and the pooled index of mean difference values were calculated for each.

Meta-analytical pooled estimation results of mean VAS difference in static implants: In this group, 14 studies were examined. In sum, concerning 785 patients the pooled index of mean difference of VAS paint score was equal with 95%CI (3.7-4.2) and 3.49 ($Q=324.8$, $p < 0.001$, and $I^2=96.2\%$). The results of meta-analysis are represented in Figure 3.

Meta-analytical pooled estimation results of mean VAS difference in dynamic implants: In this category, 10 studies were examined. In sum, concerning 785 patients the pooled index of mean VAS pain score difference was 95% CI (3.09-5.19) or 4.14 ($Q=299.2$, $p < 0.001$, and $I^2=97.0\%$). The results of meta-analysis are shown in Figure 4.

Based on the results of meta-analysis, the estimated value of the pooled mean difference of VAS pain score in regard to dynamic implants was equal to 4.14 which is higher than the value for static implants. Accordingly, it has a higher efficiency, and both tests have high heterogeneity.

Meta-analytical pooled estimation results of mean VAS difference in laminectomy: To estimate this consequence, the results of a meta-analysis by Dasenbrock et al (7) were

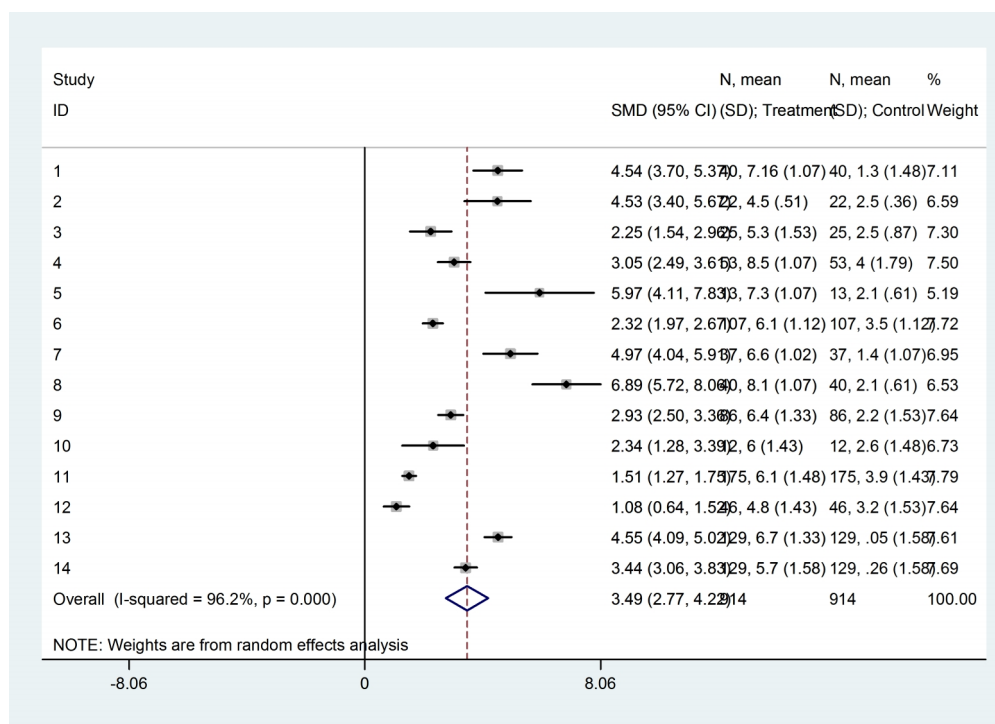


Fig. 3. Forest plot of pooled index of mean difference in static implants

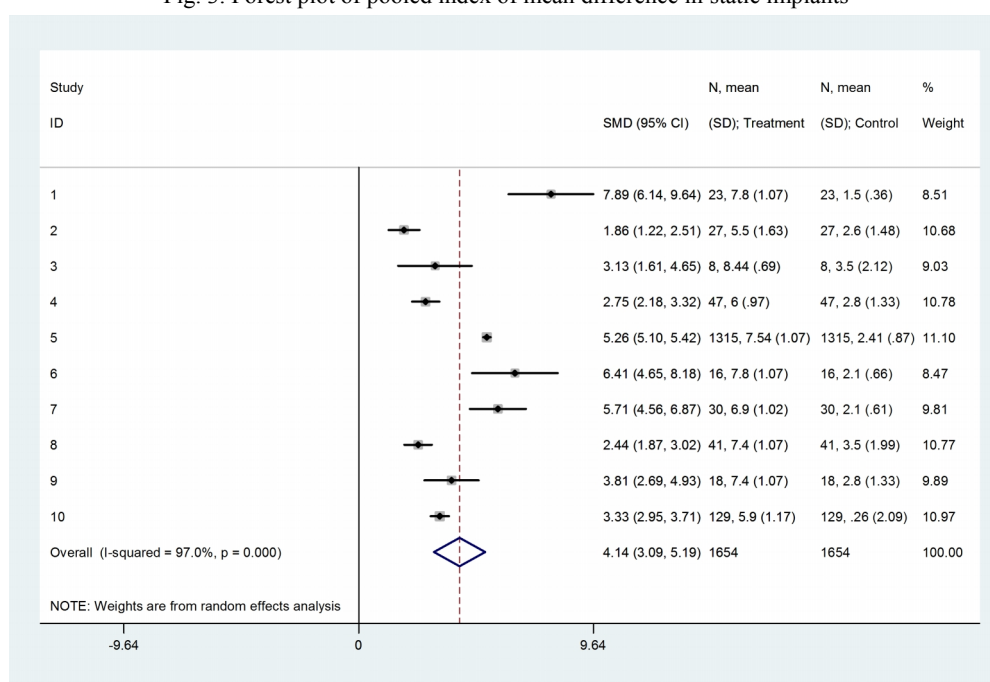


Fig. 4. Forest plot of pooled index of mean difference in dynamic implants

used. Considering the results of present study, the mean pooled difference of VAS pain score for leg and back pain in patients treated by semi-invasive laminectomy was estimated. Among the 6 studies, the clinical efficiency was equal with 95% CL (2.15-7.4) and 5.3 ($Q=28.6$, $p \leq 0.01$, $I^2=83\%$).

Model parameter

Regarding the fact that the meta-analytical results of estimating mean difference of VAS pain score in static, dynamic and laminectomy implants were respectively estimated to be 3-3.4, 3-4 and 5. This score as the expected consequence in the case of success of surgical operation was

added to the decision-making model. To examine the existing probabilities in the model regarding the extent of success of laminectomy as well as static and dynamic implants of vertebral column, the review of existing trials was done. In addition, to highlight the probability of operation failure, the first equation regarding the rate of success in surgical operation was used. The results of a systematic review on clinical trials show that the mean rate of success in laminectomy was equal to 67% (47-80) (8). The mean rate of success in application of static implants of vertebral column in 7 clinical trials (9-15) was equal with 64% (42-79) while for dynamic implants, the five random clinical trials in the present study (1,2), (16-18) showed that the mean success rate was equal with 70% (59-83%). In addition, the clinical tests showed that the mean value of difference in VAS pain score in the case of surgical failure for the 3 cases was considered to be 0.5 (6). In addition, it was hypothesized that in the case of failure, each intervention of a laminectomy will be done after a certain period of time from the date of initial operation (19).

Costing results

To verify the cost of laminectomy, the mean cost of surgery for treatment of first- and second-degree spinal stenosis while considering the perspective of health care provider for each patient was calculated as 3019 U.S dollars (i.e. 1 U.S dollar= 26500 Rials). In this regard, the costs of paying for the surgeon, hoteling in hospital, drug, diagnostic tests and other costs are also calculated and included (the costs of missed efficiency and tariffs are calculated). The mean cost was extracted based on the mean values in the bill of laminectomy of 30 patients in a private hospital located in Tehran. Based on the existing perspective, the calculation of costs was done based on determination of total cost while excluding the insurance-covered costs. To calculate the cost of statistic implant and laminectomy of vertebral column, three cost-effectiveness studies were reviewed (20-

Table 2. Mean Price of Vertebral Column Implements in European Union

Type of Implement	Mean Price in EU	Standard Deviation
X-STOP	2375 Euro	219 Euro
WALLIS	1016 Euro	435 Euro
DIAM	1500 Euro	591 Euro
COFLEX	2380 Euro	666 Euro

Source: Manufacturers (i.e. Zimmer and Medtronic)

22). The cost of static implanting in proportion to laminectomy was estimated. The results show that the mean cost of static implant as represented in studies on economic evaluation was equal with 67% of laminectomy cost. In addition, the review of two cost-effectiveness studies concerning dynamic implant compared with laminectomy (19,23) shows that the cost of dynamic surgery of vertebral column is equal with 85% of laminectomy. As a result, the mean costs of laminectomy, static and dynamic implant of vertebral column were respectively 3019, 2022, and 2566 U.S dollars. This signifies that laminectomy, dynamic implant and static implant have respectively highest costs. In addition, the mean price of vertebral column implants in European Union as shown in Table 2 shows higher cost of dynamic implants compared with static ones (5).

Cost-effectiveness results

To do the cost-effectiveness study, the decision-making tree model as shown in Figure 1 was used. To develop this model, Tree-age Pro Software (version 2011) was used. To do this, for each case of laminectomy, static implant and dynamic implant surgeries, the probability of success and failure scenarios in surgery as well as cost and consequence in both scenarios was added. In this regard, the mean cost for each unit of progress in outcome in laminectomy was estimated to be 1080 US dollars. These values for static and dynamic implant were calculated as 1319 and 1149 U.S dollars, respectively. In addition, the proportion of incremental cost-effectiveness of using static implant instead of laminectomy was equal with 665.9 U.S dollars while for dynamic implant it was

780.7 US dollars. As shown in Table 3, the incremental cost of static and dynamic implant compared with laminectomy were respectively 665.9 and 780.7 U.S dollars per each unit of reduction in VAS pain score. This signifies the potential cost-effectiveness of this intervention considering the gross domestic product threshold of Iran. As shown in Figure 5, the static implant intervention was more cost-effective due to lower incremental cost-effectiveness compared with dynamic implant.

Sensitivity analysis

To verify the uncertainty of estimating the ratio of total cost-effectiveness, the variable of laminectomy success probability changed from 0.47 to 0.80. The cost-effectiveness value of static and dynamic implants in proportion to laminectomy was estimated. As shown in Figure 6, the mean cost-effectiveness ratio of static implants ranged from 258.6 to 3773 US Dollars. In addition, this range for dynamic implements was negative and from 8805 to 7547. The noteworthy point in this analysis is ab-

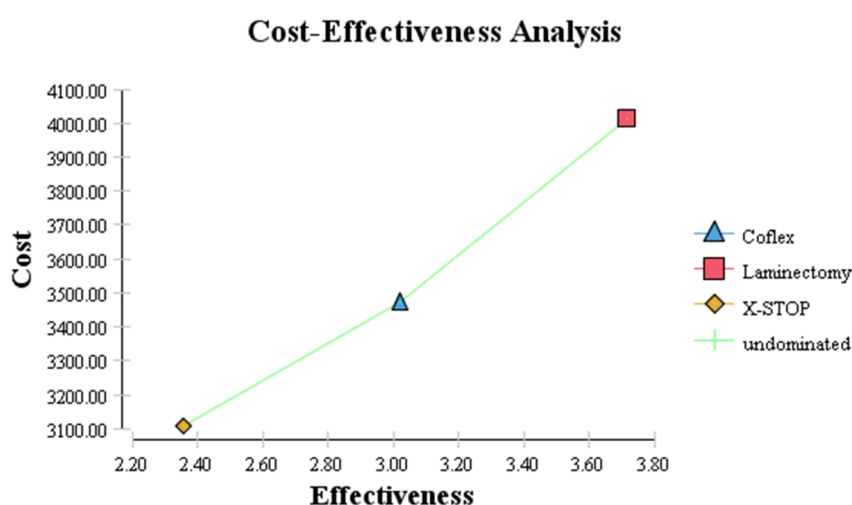


Fig. 5. Cost-effectiveness ratio of laminectomy, static implant and dynamic implant

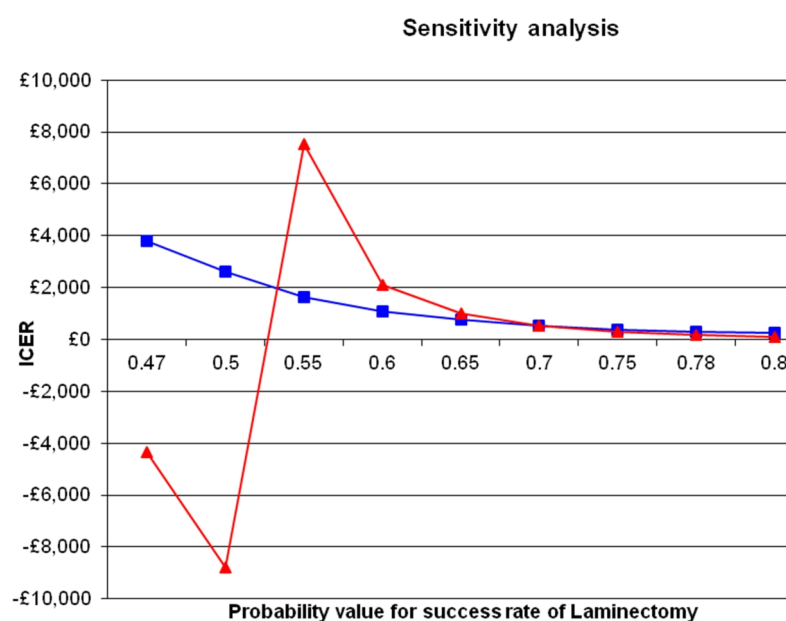


Fig. 6. Ratio variance of incremental cost-effectiveness of static and dynamic implants compared with laminectomy in single-way sensitivity analysis (success probability variance of laminectomy; red line: dynamic implant, blue line: static implant)

Table 3. Determination of Incremental Cost-effectiveness Ratio of Static and Dynamic Implements Against Laminectomy

	Expected cost	Expected outcome	Incremental cost	Incremental effect	ICER
Laminectomy	£ 4,015.1	3.716	-	-	-
Static Implant	£ 3,109.4	2.356	-£ 905.66	- 1.360	£ 665.93
Dynamic Implant	£ 3,471.7	3.02	-£543.40	- 0.696	£ 780.74

Table 4. Sensitivity Analysis (Single-Way)

Success rate of Laminectomy	Base case	0.47	0.50	0.55	0.6	0.65	0.7	0.75	0.78	0.8
ICER	665.9	3773.6	2608.2	1617.3	1090.8	764.3	542.0	380.8	303.8	258.7
Static Implant										
ICER	780.7	Dominant	Dominant	7547.2	2096.4	1006.3	539.1	279.5	172.6	114.4
Dynamic Implant										

solute cost-effectiveness of dynamic implants compared with laminectomy (less cost and higher effectiveness) considering 47-50% probability of success for laminectomy which makes the incremental cost-effectiveness of dynamic implants negative. In addition, regarding the range of 55-69% that covers the first hypothesis of present study the static implants have higher cost-effectiveness compared with dynamic ones. But within 70-80%, dynamic implants have higher cost-effectiveness compared with static ones.

Discussion

The results of present study show that the incremental cost-effectiveness values of static and dynamic implant compared with laminectomy were respectively 665.9 and 780.7 US dollars per one unit of reduction in VAS pain score that are potentially regarded as cost-effectiveness intervention. In addition, in basic case static implants have higher cost-effectiveness than dynamic ones. In sensitivity analysis and with reduced percentage of success probability in laminectomy operation, dynamic implant intervention was completely more cost-effective in both scenarios compared with laminectomy (i.e. less cost and higher effectiveness). The results of reviewing the outcome of mean VAS pain score reduction show that laminectomy, dynamic and static implant respectively have the highest reduction of VAS pain score. In addition, regarding the verification of costs the application of static and dynamic implants com-

pared with laminectomy was less because these interventions in health-care provision system of other countries is an outpatient one. As a result, the cost of anesthesia and accommodation in hospital was much lesser than laminectomy. The reason of higher cost of dynamic implants compared with static ones was higher expenses of purchasing them as shown in Table 4.

The results of safety and complication analysis in vertebral column implant interventions are categorized into two mild and severe groups. The severe complications include admission in hospital as reported in limited number of studies. Zucherman et al (24) suggested that in a case, severe damage led to post-surgery death after static implant in a patient with cardiovascular diseases record. The studies show that mild complications include infections, respiratory problems, open wounds and swelling at the incision site that are observed in more than 70% of patients. After a short duration, these complications were eliminated without need for admission for the second time in hospital (25). Regarding dynamic implants, the results of analyzing the complications in a study by Zang Lei et al (19) show that the prevalence of certain complications such as pain, infection, protrusion, and rejection of vertebral column implant among the patients was equal to 9.8%. In addition, in some studies the number of further surgeries in patients with record of vertebral column implant was more than those with laminectomy operation (19,23). Although in basic mode, static and dynamic

implants are potentially more cost-effective than laminectomy (less complication and cost). But in the case of reduced probability of laminectomy from 67 to 50%, dynamic implant intervention has more absolute cost-effectiveness compared with laminectomy (higher complication and less cost). Other studies also suggest wide distribution of results in economic evaluation of these interventions. In addition, Skidmore et al (21) suggest that application of static implant compared with conservative interventions such as medication and epidural administration to the spine was cost-effective which was followed by incremental cost of US\$ 17,894 per each operation. In addition, compared with laminectomy this type of implant intervention is totally cost-effective. Another study by Burnett et al (20) suggests that laminectomy with less cost and higher complications are more cost-effective than static implants. On the other hand, Schmier et al (23) suggested that dynamic implant surgery compared with fusion surgery is completely cost-effective. It seems that due to lack of sufficient evidence, more precise clinical tests could offer verified results.

Conclusion

Due to the lack of cases of static and dynamic implant surgery of vertebral column in Iran, the estimation of cost ratio of these surgeries compared with laminectomy was done based on international studies. In this regard, cost-effectiveness study was done and it is suggested to act more carefully in generalization of results, this issue could be consider as limitation of this study. Finally, in the case of precise simulation of health care provision system in regard to this surgical operation in Iran the application of implants is recommended due to their higher cost-effectiveness compared with laminectomy while considering precise indications (e.g. width of spinal canal, etc.) and sufficient expertise of surgeons, precise trainings and purchase of suitable implants. Considering the study of cost-effectiveness and review of complications, dynamic im-

plants have higher efficiency and safety compared with static ones.

References

1. Battié MC, Ortega-Alonso A, Niemelainen R, Gill K, Levalahti E, Videman T, et al. Lumbar spinal stenosis is a highly genetic condition partly mediated by disc degeneration *Arthritis Rheumatol* 2014 Dec; 66(12):3505-10.
2. Xu ZW, Lun DX. Surgical management of multilevel cervical spinal stenosis and spinal cord injury complicated by cervical spine fracture. *J Orthop Surg Res* 2014 Aug 22;9:77.
3. Mousavi SJ, Akbari ME, Mehdian H, Mobini B, Montazeri A, Akbarnia B, et al. Low back pain in Iran: a growing need to adapt and implement evidence-based practice in developing countries. *Spine (Phila Pa 1976)* 2011 May 1;36(10):E638-46.
4. Chang X, Chen B, Li HY, Han XB, Zhou Y, Li CQ. The safety and efficacy of minimally invasive discectomy: a meta-analysis of prospective randomized controlled trials. *Int Orthop* 2014 Jun; 38(6):1225-34.
5. Stordeur S, Gerkens S, Roberfroid D. Interspinous implants and pedicle screws for dynamic stabilization of lumbar spine: Rapid assessment. *Federaal Kenniscentrum voor de Gezondheidszorg Centre fédéral d'expertise des soins de santé Belgian Health Care Knowledge Centre* 2009.
6. Gazzeri R, Galarza M, Alfieri A. Controversies about Interspinous Process Devices in the Treatment of Degenerative Lumbar Spine Diseases: Past, Present, and Future. *BioMed Research International*, 2014;2014.
7. Dasenbrock HH, Juraschek SP, Schultz LR, Witham TF, Sciubba DM, Wolinsky JP, et al. The efficacy of minimally invasive discectomy compared with open discectomy: a meta-analysis of prospective randomized controlled trials. *J Neurosurg Spine* 2012 May;16(5):452-462.
8. Javid MJ, Hadar EJ. Long-term follow-up review of patients who underwent laminectomy for lumbar stenosis: a prospective study. *J Neurosurg* 1998 Jul;89(1):1-7.
9. Sobottke R, Schlüter-Brust K, Kaulhausen T, Rölinghoff M, Joswig B, Stützer H, et al. Interspinous implants (X Stop, Wallis, Diam) for the treatment of LSS: is there a correlation between radiological parameters and clinical outcome? *Eur Spine J* 2009 Oct;18(10):1494-503.
10. Kim HJ, Bak KH, Chun HJ, Oh SJ, Kang TH, Yang MS. Posterior Interspinous Fusion Device for One-Level Fusion in Degenerative Lumbar Spine Disease: Comparison with Pedicle Screw Fixation - Preliminary Report of at Least One Year Follow Up. *J Korean Neurosurg Soc* 2012 Oct;52(4):359-364.
11. Ploumis A, Christodoulou P, Kapoutsis D, Gelalis I, Vraggalas V, Beris A. Surgical treatment

of lumbar spinal stenosis with microdecompression and interspinous distraction device insertion. A case series. *J Orthop Surg Res* 2012;7:35.

12. Shabat Sh, Miller LE, Block JE, Gepstein R. Minimally invasive treatment of lumbar spinal stenosis with a novel interspinous spacer. *Clin Interv Aging* 2011;6:227-233.

13. Bowers C, Amini A, Dailey AT, Schmidt MH. Dynamic interspinous process stabilization: review of complications associated with the X-Stop device. *Neurosurg Focus* 2010 Jun;28(6):E8.

14. Miller LE, Miller VM. Safety and effectiveness of microvascular decompression for treatment of hemifacial spasm: a systematic review. *Br J Neurosurg* 2012 Aug; 26(4):438-44.

15. Tuschel A, Chavanne A, Eder C, Meissl M, Becker P, Ogon M. Implant survival analysis and failure modes of the X STOP interspinous distraction device. *Spine (Phila Pa 1976)* 2013 Oct 1; 38(21):1826-31.

16. Zhou D, Nong LM, Du R, Gao GM, Jiang YQ, Xu NW. Effects of interspinous spacers on lumbar degenerative disease. *Exp Ther Med* 2013 Mar; 5(3):952-956.

17. Sun HL, Li CD, Liu XY, Lin JR, Yi XD, Liu H, et al. Mid-term follow-up and analysis of failure cases of interspinous implant for degenerative lumbar diseases. *Beijing Da Xue Xue Bao* 2011 Oct 18;43(5):690-5.

18. Zhao Y, Wang YP, Qiu GX, Zhao H, Zhang JG, Zhou X. Efficacy of the Dynamic Interspinous Assisted Motion system in clinical treatment of degenerative lumbar disease. *Chin Med J (Engl)* 2010 Nov;123(21):2974-7.

19. Zang L, DU P, Hai Y, Su QJ, Lu SB, Liu T. Device related complications of the Coflex interspinous process implant for the lumbar spine, *Chin Med J (Engl)* 2013 Jul;126(13):2517-22.

20. Burnett MG, Stein SC, Bartels RH. Cost-effectiveness of current treatment strategies for lumbar spinal stenosis: nonsurgical care, laminectomy, and X-STOP. *J Neurosurg Spine* 2010 Jul; 13(1):39-46

21. Skidmore G, Ackerman SJ, Bergin C, Ross D, Butler J, Suthar M, et al. Cost-effectiveness of the X-STOP® Interspinous Spacer for Lumbar Spinal Stenosis. *Spine (Phila Pa 1976)* 2011 Mar 1;36(5):E345-56.

22. Kondrashov D, Hannibal M, Hsu K, Zucherman J. Stop versus decompression for neurogenic claudication: economic and clinical analysis. *The Internet Journal of Minimally Invasive Spinal Technology* 2007;1(2).

23. Schmier JK, Halevi M, Maislin G, Ong K. Comparative cost effectiveness of Coflex interlaminar stabilization versus instrumented posterolateral lumbar fusion for the treatment of lumbar spinal stenosis and spondylolisthesis. *Clinicoecon Outcomes Res* 2014 Mar 18;6:125-31.

24. Zucherman JF, Hsu KY, Hartjen CA, Mehalic

TF, Implicito DA, Martin MJ, et al. A multicenter, prospective, randomized trial evaluating the X STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication: two-year follow-up results. *Spine (Phila Pa 1976)* 2005 Jun 15;30(12):1351-8.

25. Lee J, Hida K, Seki T, Iwasaki Y, Minoru A. An interspinous process distractor (X STOP) for lumbar spinal stenosis in elderly patients: preliminary experiences in 10 consecutive cases, *J Spinal Disord Tech* 2004 Feb;17(1):72-7.

26. Buric J, Pulidori M. Long-term reduction in pain and disability after surgery with the interspinous device for intervertebral assisted motion (DIAM) spinal stabilization system in patients with low back pain: 4-year follow-up from a longitudinal prospective case series. *Eur Spine J* 2011;20:1304-1311.

27. Fabrizio AP, Maina R, Schiabello L. Interspinous spacers in the treatment of degenerative lumbar spinal disease: our experience with DIAM and Aperius devices. *Eur Spine J* 2011 May; 20(Suppl 1):20-26.

28. Ryu SJ, Kim IS. Interspinous Implant with Unilateral Laminotomy for Bilateral Decompression of Degenerative Lumbar Spinal Stenosis in Elderly Patients. *J Korean Neurosurg Soc* 2010 May; 47(5):338-44.

29. Richter A, Schütz C, Hauck M, Halm H. Does an interspinous device (Coflex TM) improve the outcome of decompressive surgery in lumbar spinal stenosis? One-year follow up of a prospective case control study of 60 patients. *Eur Spine J* 2010 Feb;19(2):283-9.

30. Cabraja M, Abbushi A, Woiciechowsky C, Kroppenstedt S. The short- and mid-term effect of dynamic interspinous distraction in the treatment of recurrent lumbar facet joint pain. *Eur Spine J* 2009 Nov;18(11):1686-94.

31. Kong DS, Kim ES, Eoh W. One-year outcome evaluation after interspinous implantation for degenerative spinal stenosis with segmental instability. *J Korean Med Sci* 2007 Apr;22(2):330-5.

32. Sénégas J, Vital JM, Pointillart V, Mangione P. Clinical evaluation of a lumbar interspinous dynamic stabilization device (the Wallis system) with a 13-year mean follow-up. *Neurosurg Rev* 2009 Jul;32(3):335-41.

33. Floman Y, Millgram MA, Smorgick Y, Rand N, Ashkenazi E. Failure of the Wallis Interspinous Implant to Lower the Incidence of Recurrent Lumbar Disc Herniations in Patients Undergoing Primary Disc Excision. *J Spinal Disord Tech* 2007 Jul;20(5):337-41.

34. Sénégas J. Mechanical supplementation by non-rigid fixation in degenerative intervertebral lumbar segments: the Wallis system. *Eur Spine J* 2002 Oct;11 Suppl 2:S164-9.

35. Beyer F, Yagdiran A, Neu P, Kaulhausen T, Eysel P, Sobottke R. Percutaneous interspinous

spacer versus open decompression: a 2-year follow-up of clinical outcome and quality of life. *Eur Spine J* 2013 Sep;22(9):2015-21.

36. Kuchta J, Sobottke R, Eysel P, Simons P.

Two-year results of interspinous spacer (X-Stop) implantation in 175 patients with neurologic intermittent claudication due to lumbar spinal stenosis. *Eur Spine J* 2009 Jun;18(6):823-9.