Original Study

Interspinous process spacers versus traditional decompression for lumbar spinal stenosis: systematic review and meta-analysis

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Background: Interspinous spacers are used in selected patients for the treatment of lumbar spinal stenosis. The uses of interspinous devices are still debated, with reports of significantly higher reoperation rates and unfavourable cost-effectiveness compared to traditional decompression techniques.

Methods: Six electronic databases were searched from their date of inception to December 2015. Relevant studies were identified using specific eligibility criteria and data was extracted and analyzed based on predefined primary and secondary endpoints.

Results: Eleven comparative studies were obtained for qualitative and quantitative assessment, data extraction and analysis. There was no significant difference in VAS back pain, leg pain or ODI scores for standalone interspinous process device (IPD) *vs.* bony decompression. However, standalone IPD was associated with lower surgical complications (4% *vs.* 8.7%, P=0.03) but higher long-term reoperation rates (23.7% *vs.* 8.5%, P<0.00001). IPD as an adjunct to decompression had comparable patient-reported scores, complications and reoperation rates to decompression alone.

Conclusions: Current evidence indicates no superiority for mid- to long-term patient-reported outcomes for IPD compared with traditional bony decompression, with lesser surgical complications but at the risk of significantly higher reoperation rates and costs.

Keywords: Interspinous process; spacer; decompression; lumbar stenosis; systematic review

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Introduction

With the increasingly elderly patient population, the prevalence of degenerative spinal diseases is also rising steadily (1). In lumbar spinal stenosis, the dural sac and nerve roots are often compressed by one or a combination of bulging intervertebral discs, facet joint hypertrophy, and ligamentum flavum hypertrophy (2-5). Many individuals are symptomatic with pain and neurogenic claudication, and may present with muscular weakness, sensory changes and impeded mobility. In the case of lumbar spinal stenosis, for those refractory to conservative or medical therapy, the traditional surgical approach has been bony decompression, such as via a laminectomy using an open or minimally invasive access (6).

Since its introduction over 50 years ago by Knowles (7), interspinous process devices (IPD) or spacers have been designed and tested in various studies as an alternative or adjunct option to traditional decompression surgery (8-11). The rationale for using IPD is that it has been demonstrated that symptoms of lumbar spinal stenosis are often relieved on flexion and exacerbated on extension. IPD devices can limit extension of the spine, which may help relieve pain or neurogenic claudication. Other purported advantages of IPD include improved interlaminar space at the stenosed spinal level (12,13), distraction of interspinous space (14,15), reduced surgical trauma and complications, as well as minimized disruption to the structural integrity of the spine and paraspinal structures. Current IPD spacers on the market include X-Stop® (Medtronic Spine, LLC, CA, USA), Coflex® (Paradigm Spine, LLC, NY, USA), and Superion.

However, the use of interspinous devices is still debated, with recent reports demonstrating a significantly higher reoperation rate (16) with IPD as well as unfavorable cost-effectiveness (17) compared to traditional decompression techniques. Whether there are added benefits of using IPD spacers over the gold standard decompression surgical approach is still being debated. We aimed to conduct a systematic review and meta-analysis of the current literature to assess the relative benefits and risks of interspinous process spacers compared to traditional surgical decompression.

Methods

Literature search strategy

The present review was conducted according to PRISMA guidelines (18) and recommendations (19,20). Electronic searches were performed using Ovid Medline, PubMed, Cochrane Central Register of Controlled Trials (CCTR), Cochrane Database of Systematic Reviews (CDSR), ACP Journal Club and Database of Abstracts of Review of Effectiveness (DARE) from their dates of inception to December 2015. To achieve maximum sensitivity of the search strategy and identify all studies, we combined the terms: "lumbar spinal stenosis", "interspinous spacer", "IPD", "X-Stop", "Coflex", "DIAM", "Wallis", "Asperius", "decompression" or "laminectomy" as either keywords or MeSH terms. The reference lists of all retrieved articles were reviewed for further identification of potentially relevant studies. All identified articles were systematically assessed using the inclusion and exclusion criteria.

Selection criteria

Eligible randomized controlled trials (RCTs) or prospective observational studies (OS) for the present systematic review and meta-analysis included those in which patient cohorts underwent treatment for lumbar spinal stenosis using either an interspinous spacer or traditional decompression surgery. When institutions published duplicate studies with accumulating numbers of patients or increased lengths of follow-up, only the most complete reports were included for quantitative assessment at each time interval. All publications were limited to those involving human subjects and in the English language. Abstracts, case reports, conference presentations, editorials and expert opinions were excluded. Review articles were omitted because of potential publication bias and duplication of results.

Data extraction and critical appraisal

All data was extracted from article texts, tables and figures. Two investigators independently reviewed each retrieved article (K.P., P.J.R.). Discrepancies between the two reviewers were resolved by discussion and consensus with senior investigators. Collected data included the publication date, study design, sample size, follow-up duration, interventions, complications, incidence of reoperation, and clinical outcomes, including low back pain, leg pain, the Oswestry disability index (ODI), and the Roland disability questionnaire (RDQ).

Statistical analysis

The risk ratio (RR) and standardized mean difference (SMD) were used as summary statistics. In the present study, both fixed- and random-effects models were tested. In the fixed-effect model, it was assumed that treatment effect in each study was the same, whereas in a random-effects model, it was assumed that there were variations between studies. χ^2 tests were used to study heterogeneity between trials. I^2 statistic was used to estimate the percentage of total variation across studies, owing to heterogeneity rather than chance, with values greater than 50% considered as substantial heterogeneity. I^2 can be calculated as: $I^2 = 100\% \times (Q - df)/Q$, with Q defined as Cochrane's heterogeneity statistics and *df* defined as degree of freedom. If there was substantial heterogeneity, the possible clinical and methodological reasons for this were explored qualitatively. In the present meta-analysis, the results using the random-effects model were presented to take into account the possible clinical diversity and methodological variation between studies. Specific analyses considering confounding factors were not possible because raw data was not available. All P values were 2-sided. All statistical analyses were conducted with Review Manager Version 5.3.2 (Cochrane Collaboration, Software Update, Oxford, UK).

Results

Literature search

A total of 556 references were identified through electronic database searches. After exclusion of duplicate or irrelevant references, 538 potentially relevant articles were retrieved. After detailed evaluation of these articles, 33 articles remained for assessment. After applying selection criteria, 11 studies (16,21-30) were selected for analysis. The study

Table 1 Characteristics of included studies

First author	Year	Country	Study design	Type of device	Type of DP	N (IPD)	N (DP)	Follow-up	Comparison
Moojen	2015	The Netherlands	P, RCT	distraXion	Minimally invasive	80	79	2-years	Decompression *vs*. IPD
Lønne	2015	Norway	P, RCT	X-stop	Minimally invasive	41	40	2-years	Decompression *vs*. IPD
Richter	2014	Germany	P, OS	Coflex	Open	31	31	2-years	Decompression *vs*. decompression + IPD
Patil	2014	US Nationwide	R, registry	All types (medicare) 2007–2009	Open	174	174	2.1-years	Decompression *vs*. IPD
Marsh	2014	UK	P, RCT	Wallis	Open	30	30	40-months	Decompression *vs*. decompression + IPD
Galarza	2014	Spain	P, OS	Device for intertebral assisted motion, intraspine	Minimally invasive	47	45	1-year	Decompression *vs*. decompression + IPD
Strömqvist	2013	Sweden	P, RCT	X-stop	Open	50	50	2-years	Decompression *vs*. IPD
Brodke	2013	US	R, OS	Mixed	Open	21	24	5-years	Decompression *vs*. IPD
Beyer	2013	Germany	P, OS	Asperius	Open	12	33	2-years	Decompression *vs*. IPD
Postacchini	2011	Italy	P, OS	Asperius	Open	22	20	1-year	Decompression *vs*. IPD
Kim	2007	Australia	R, OS	DIAM	Open	31	31	1-year	Decompression *vs*. decompression + IPD

P, prospective; R, retrospective; RCT, randomized controlled trial; OS, observational study; DP, decompression; IPD, interspinous process device.

characteristics are summarized in *Table 1*.

Baseline characteristics

Similar baseline characteristics were observed in both comparison arms (*Table 2*). Median age for both IPD and decompression was 67 years (range, 38.5–75 years) and 67 years (range, 42.5–73 years), respectively. The proportion of males in the IPD group was 51.3% (range, 36.7–67%) compared to 48% (range, 27–58%) in the decompression group. The stenosis was localized in IPD patients to L2/3, L3/4, L4/5 at 3%, 17% and 69%, respectively. In the decompression group, the stenosis was localized to L2/3, L3/4, L4/5 in 4%, 18%, and 66% of patients, respectively. Median baseline Visual Analog Scale (VAS) low back pain score was similar between the IPD and decompression cohorts (median 6 each). VAS leg pain scores were also similar (6.1 *vs*. 6.45), as well as baseline ODI (48.9 *vs*. 51.8). Surgery time was reported in studies. Lønne *et al*. reported operating time of 47 minutes in the IPD group versus 113 minutes in the traditional decompression group. Galarza reported 22 minutes surgery time for IPD + decompression compared to 17 minutes for decompression alone, whilst Strömqvist *et al*. reported IPD surgery time of 62 minutes compared to 98 minutes for decompression.

Assessment of clinical outcomes

Clinical outcomes were assessed using VAS scores and ODI, assessed into subgroups: studies which compared IPD + decompression *vs*. decompression, or IPD alone *vs*. decompression. In terms of VAS scores for low back pain, significantly lower scores were obtained in the decompression group compared to IPD postoperatively (MD, 0.82; 95% CI, 0.61–1.03; I^2=3%; P<0.00001). However, IPD as an adjunct to decompression compared with decompression alone resulted in comparable follow-up VAS back pain scores (MD, –0.15; 95% CI, –0.97 to 0.67;

Table 2 Baseline characteristics of patients included in the present systematic review

First author	Age(years)		Males (%)		Stenosis L2/3 (%)		Stenosis L3/4 (%)		Stenosis L4/5 (%)		Baseline VAS back pain		Baseline VAS leg pain		Baseline ODI	
	IPD	D	IPD	D	IPD	D	IPD	D	IPD	D	IPD	D	IPD	D	IPD	D
Moojen	66	64	60	47	3	4	31	28	66	68	5	5.2	5.2	5.8	NR	NR
Lønne	67	67	42	56	0	2	8	10	73	59	NR	NR	NR	NR	32.9	33.8
Richter	68	68	52	58	3	16	23	48	87	84	6.5	6.2	NR	NR	48.9	40.1
Patil	73	73	47	43	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Marsh	59.6	56.4	36.7	46.7	NR	NR	NR	NR	NR	NR	7.9	8.2	6.7	6.7	50.6	58.3
Galarza	38.5	42.5	51	47	NR	NR	NR	NR	NR	NR	6.7	7.3	NR	NR	NR	NR
Strömqvist	67	71	60	52	2	4	6	18	54	38	5.9	6	5.9	5.4	NR	NR
Brodke	75	69	NR	NR	NR	NR	NR	NR	NR	NR	5.7	4.6	6.2	6.2	NR	NR
Beyer	64	71	67	27	NR	NR	NR	NR	NR	NR	6	5.9	6	7.9	45.7	51.8
Postacchini	68	65	44	49	6	2.8	17	14	69	66	NR	NR	NR	NR	68	69.0
Kim	51	50	51.6	51.6	NR	NR	NR	NR	NR	NR	6	6	6.9	6.7	NR	NR
Minimum	38.5	42.5	36.7	27	0	2	6	10	54	38	5	4.6	5.2	5.4	32.9	33.8
Maximum	75	73	67	58	6	16	31	48	87	84	7.9	8.2	6.9	7.9	68	69.0
Median	67	67	51.3	48	3	4	17	18	69	66	6	6	6.1	6.45	48.9	51.8

IPD, interspinous process device; D, decompression via traditional approach; NR, not reported; VAS, visual analogue scale; ODI, Oswestry disability index.

I^2=66%; P=0.73) (*Figure 1*).

For VAS leg pain scores, no difference was found between IPD alone versus decompression approaches (MD, 0.18; 95% CI, –1.04 to 1.39; I^2=95%; P=0.78). Similarly, there was no difference in postoperative VAS leg pain scores between patients who received both IPD and decompression compared with decompression alone (MD 0.38; 95% CI, –0.12 to 0.88; I^2=NA; P=NA) (*Figure 1*).

There were 2 studies which reported ODI scores for IPD versus decompression. No significant difference was found (MD, –0.32; 95% CI, –2.72 to 2.07; I^2=97%; P=0.79). There were also two studies which reported ODI outcomes for IPD+decompression compared with decompression alone. Similarly, there was no significant difference in ODI outcomes at follow-up (MD, 0.28; 95% CI, –0.08 to 0.64; I^2=0%; P=0.12) (*Figure 1*).

Assessment of surgical complications

A significantly lower rate of surgical complications was found in the IPD alone group compared to decompression surgery (4.0% *vs.* 8.7%; RR, 0.54; 95% CI, 0.31–0.95; I^2=0%; P=0.03). However, IPD as an adjunct to decompression had significantly higher surgical complications compared to decompression surgery alone (8.6% *vs.* 2.2%; RR, 3.90; 95% CI, 1.15–13.26; I^2=0%; P=0.03) (*Figure 2*).

Assessment of reoperation rates

IPD was associated with significantly higher reoperation rates compared to decompression (23.7% *vs.* 8.5%; RR, 3.00; 95% CI, 1.76–5.13; I^2=41%; P<0.0001). No significant difference in reoperation rates was found between IPD + decompression cohort versus decompression alone (6.6% *vs.* 8.3%; RR, 0.80; 95% CI, 0.30–2.08; I^2=0%; P=0.64) (*Figure 3*).

Literature review of costs associated with IPD and decompression

Five studies compared costs associated with IPD versus decompression procedures for lumbar spinal stenosis. Parker *et al.* developed a Markov model to compare IPD versus decompression *vs.* conservative care. The authors used data from the Superion FDA clinical trial, a prospective spinal registry, to populate the model, and concluded that IPD device had similar costs to standard decompression. Both were more cost-effective compared

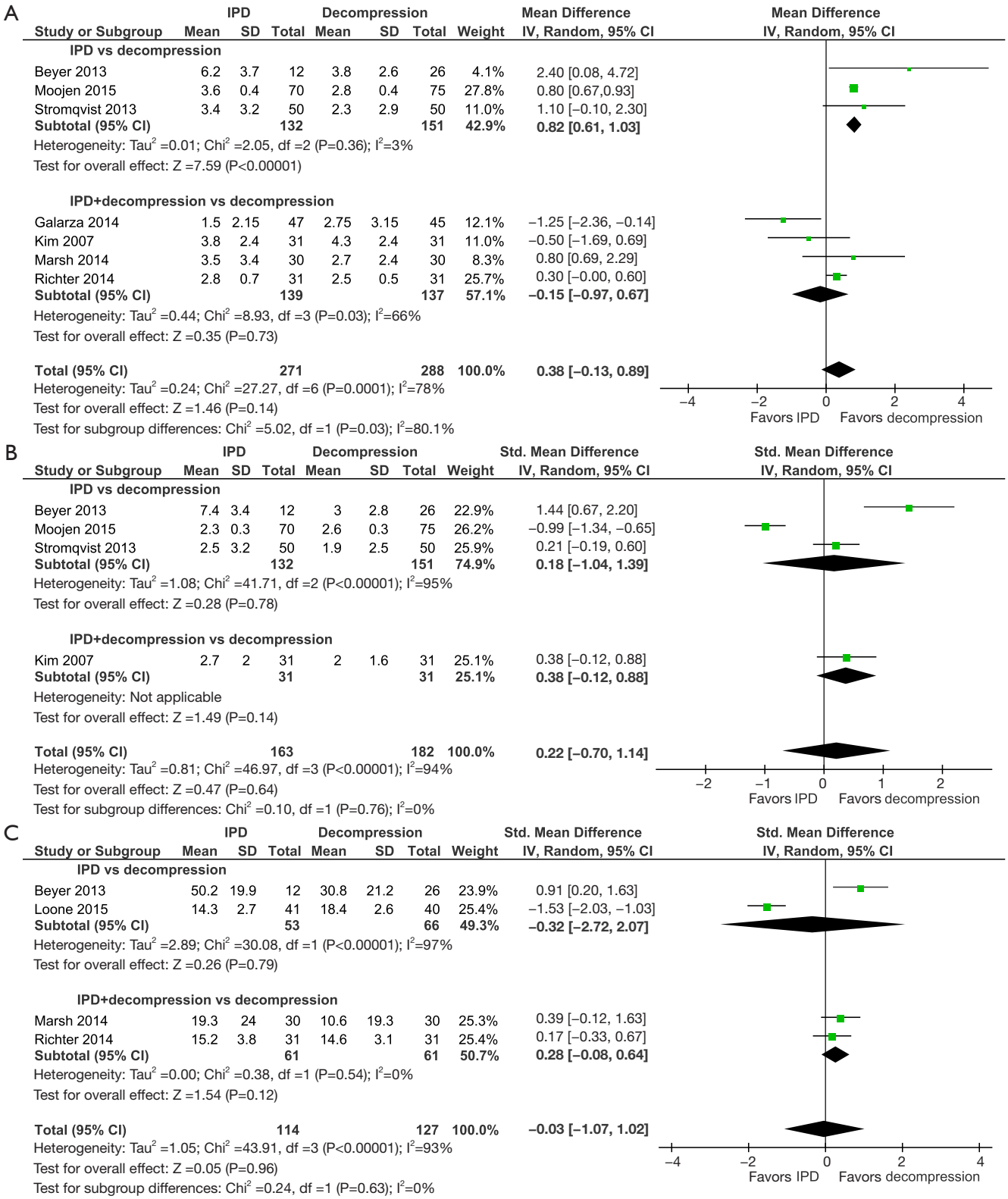

Figure 1 Forest plot of patient-rated outcomes. (A) VAS low back pain; (B) VAS leg pain; (C) ODI scores. IPD, interspinous process device; VAS, visual analogue scale; ODI, Oswestry disability index.

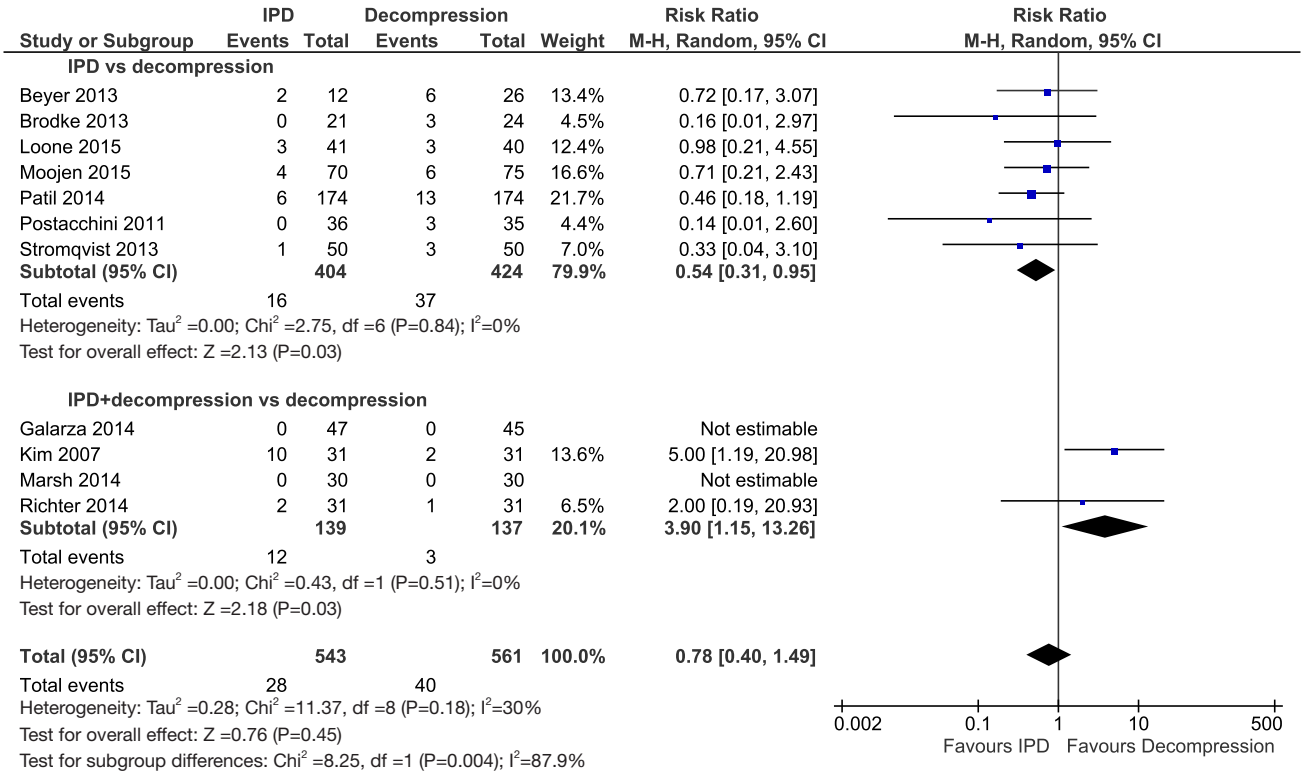

Figure 2 Surgical complications. IPD, interspinous process device.

to conservative care. Lønne *et al.* enrolled 96 patients and calculated the cost-effectiveness of X-Stop with minimally invasive decompression for lumbar spinal stenosis. The authors concluded that there is a 50% likelihood that X-stop is cost-effective at the extra cost of €25,700 (incremental cost-effectiveness ratio) for a quality-adjusted life-year. The significantly higher cost of X-stop is mainly due to implant cost and the significantly higher reoperation rate. Van den Akker-van Marle *et al.*, Patil *et al.*, and Burnett *et al.* made similarly conclusions, with higher costs associated with IPD compared to decompression surgery (*Table 3*).

Discussion

Pooled results in the present meta-analysis demonstrate no significant difference in patient-rated clinical outcomes (VAS and ODI scores) between those who receive decompression alone versus standalone IPD or IPD as an adjunct to decompression. There were significantly lower surgical complications associated with implanting a standalone IPD compared to bony decompressive surgery. However, the reoperation rates for standalone IPD were significantly higher than that compared to traditional decompression. These results support prior prospective studies and the conventional belief interspinous spacers may have fewer surgical complications compared to traditional laminectomy, at higher risk of reoperations.

Several randomized trials have compared X-Stop IPD versus standard decompression. In 2013, Strömqvist *et al.* (16) compared 100 patients with symptomatic one- or two-level lumbar spinal stenosis and neurogenic claudication that was relieved on flexion. Intention-to-treat analysis at 6, 12, 24 months demonstrated no significant differences between X-Stop versus decompression in terms of VAS back pain, VAS leg pain, SF-36 and Zurich Claudication Questionnaire (ZCQ) scores. Reoperation rate for IPD was 26% compared to 6% in the decompression group, which is similar to the pooled results of the present study. There was also an apparent decrease in surgical operation duration (62 *vs.* 98 minutes) and blood loss (54 *vs.* 262 mL) for the X-Stop group compared to decompression surgery. A randomized comparison between X-Stop and decompression was also reported by Lønne *et al.* (22) in 2015. Whilst no differences in patient-reported scores and ZCQ was reported, reoperation rates were significantly higher for IPD versus decompression (25% *vs.* 5%).

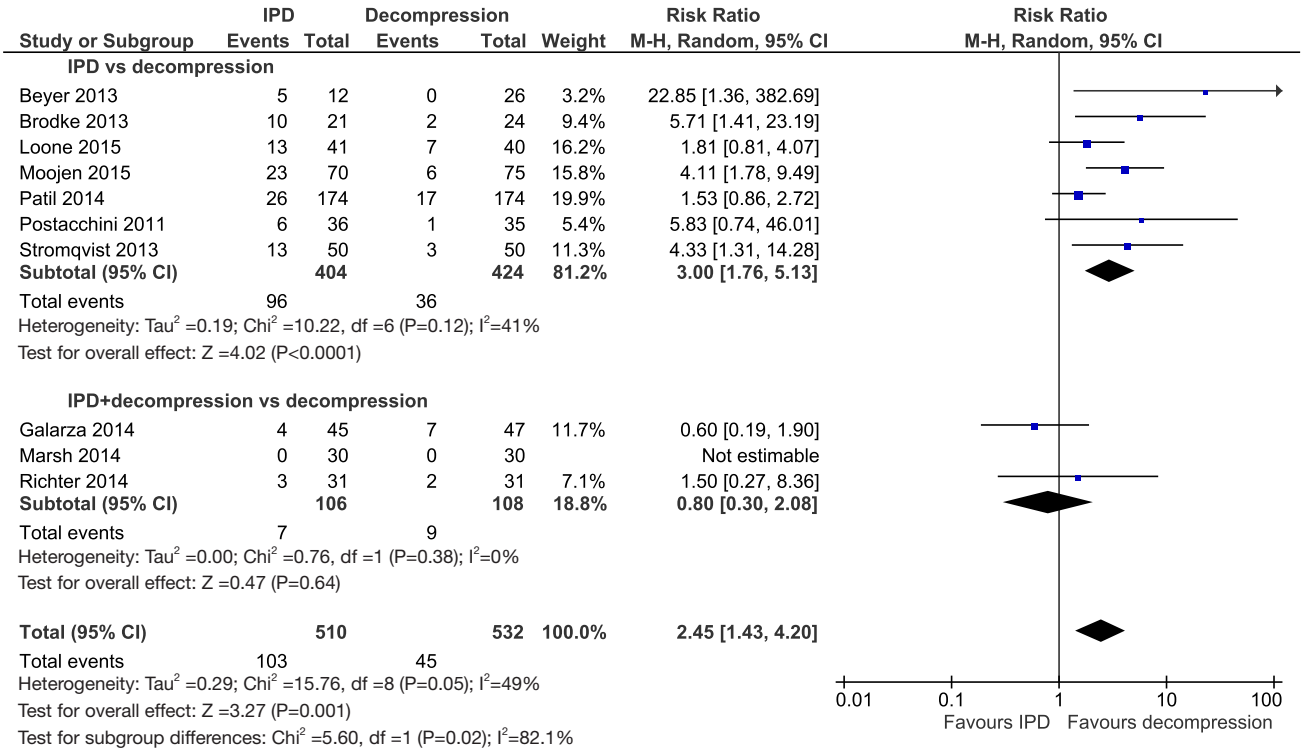

Figure 3 Reoperations. IPD, interspinous process device.

Table 3 Summary of conclusions regarding the costs and cost-effectiveness of IPD versus laminectomy for lumbar spinal stenosis

First author	Year	Cost of treatment strategies ($)			Author's conclusions
		IPD	Decompression	Conservative therapy	
Parker	2015	13,947	13,958	10,540	The IPD device has similar costs to standard decompression, both being cost-effective compared to conservative care
Lønne	2015	8,247	5,415	NR	The significantly higher cost of X-stop is mainly due to implant cost and higher reoperation rates
van den Akker-van Marle	2014	13,858	11,096	NR	IPD is highly unlikely to be cost effective compared with bony decompression
Patil	2014	17,674	12,670	NR	Index hospitalization costs were significantly higher for IPD compared to laminectomy
Burnett (1-level)	2010	7,900.79	9,291.18	3,478.79	Laminectomy appears to be the most cost-effective treatment strategy
Burnett (2-level)	2010	13,429.07	9,329.66	3,435.25	

IPD, interspinous process device; NR, not reported.

The purported advantages of interspinous or interlaminar stabilization devices are that they distract the spinous processes (14,15) or laminar space and restrict extension. In doing so, these spacers may assist in unloading facet joints, restoration of foraminal height (12,13), and lowering intradiscal pressures (31-33). Initial IPD spacers were designed with the aim of limiting spinal extension, thereby limiting pain and neurogenic claudication (34,35). Devices

were also designed with increased rigidity (36) to increase longer-lasting effect. Theoretically, these devices may enlarge neural foramen and decompress nerve roots in patients with spinal stenosis and neurogenic claudication. Depending on the type of interspinous implant used, the procedure is considered minimally invasive. Biomechanically, IPD spacers have been reported to demonstrate non-rigid fixation and can return a destabilized specimen back to the intact state in terms of flexion and extension (37,38). As such, IPD is conventionally thought to be a suitable operation for frail, elderly patients who are at high risk of medical complications compared to open laminectomy.

There are several reported disadvantages associated with IPD devices. In contrast to laminectomy, implantation of interspinous or interlaminar spacers converts the spinous processes from naturally tension-bearing structures to compression-loading structures. This can induce spinous process fractures, an uncommon but recognized complication following IPD implantation. Osteopenic or osteoporotic patients may be particularly susceptible to spinous process fractures. Other studies have reported heterotopic bone formation as a long-term complication following IPD implantation (39). Formation of large osteophytes may intrude into the spinal canal, leading to recurrence of lumbar spinal stenosis symptoms. Tian *et al*. (40) reported an 81.2% incidence of heterotopic bone formation in 32 patients at 24–57 months follow-up after IPD implantation. Other early complications following IPD implantation include device dislocation and malposition, spinous process erosion, infection, hematoma, and neurological sequelae. A further disadvantage of IPD devices is the poor cost-effectiveness compared to traditional decompression surgery based on current literature reports (17,24,41-43) (*Table 3*). Based on the current data, the role of IPD spacers remains questionable, given that they do not produce better clinical outcomes, have higher reoperation rates and are more costly compared to traditional decompression surgery.

Limitations

The present systematic review and meta-analysis is constrained by several limitations. It is not valid to extrapolate results to all cases of lumbar spinal stenosis patients. Current evidence has been attained from different brands and types of IPD devices, as such it is difficult to compare efficacy and complication rates between different devices. IPD devices also vary by their mechanism, static versus dynamic, and vary in material composition including titanium, PEEK, and elastomeric substances. The question of which patient subgroup benefits the most from an IPD compared to laminectomy or traditional decompression remains unclear. Future trials should stratify patients according to age groups and comorbidities.

Conclusions

Current evidence indicates no superiority for mid- to long- term patient-reported outcomes for IPD compared with traditional bony decompression, with lesser surgical complications but at the risk of significantly higher reoperation rates and costs. The role of IPD as standalone or adjunct devices for lumbar spinal stenosis surgery needs to be scrutinized, with careful consideration of the risks, benefits and costs before implantation.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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