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META-ANALYSIS

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SF36 Is a Reliable Patient-Oriented Outcome Evaluation Tool in Surgically Treated Degenerative Cervical Myelopathy Cases: A Systematic Review and Meta-Analysis

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

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Background: Degenerative spinal disorders have adverse impacts on patients' quality of life. Because the main objectives of any surgical intervention are to improve health-related quality of life and to reduce disability, instruments capable of measuring patient-oriented outcomes are now increasingly used. The aim of this study was to evaluate the use of the Short Form 36 Health Survey Questionnaire (SF36) for assessing patient-oriented outcomes of degenerative cervical myelopathy surgery.

Material/Methods: A literature search was conducted in electronic databases (Google Scholar, Ovid SP, PubMed, Science Direct, and Springer). Studies were included if they reported SF36 scores by following patients for at least 12 months. Random effects meta-analyses were performed to estimate changes in SF36 physical/mental component summary (SF36-PCS/MCS), SF36 dimensional, Japanese Orthopedics Association (JOA)/modified JOA (mJOA), and Neck Disability Index (NDI) scores by latest follow-up.

Results: Fourteen studies (1966 patients; age 58.2 years [95% confidence interval (CI), 56.6 to 59.9]; 60% males [95% CI, 55 to 64]; follow-up 24.8 months [95% CI, 20.9 to 28.7]) were included in meta-analysis. SF36-PCS (6.60 [95% CI, 4.91 to 8.28]; p<0.00001), SF36-MCS (6.33 [95% CI, 4.31 to 8.35]; p<0.00001) and SF36 dimensional (p<0.05) scores improved significantly at latest follow-up. Surgery significantly improved JOA/mJOA (3.43 [95% CI, 2.80 to 4.06]; p<0.00001) and NDI (–13.70 [95% CI, –17.35 to –10.06]; p<0.00001) scores also. Change in SF36-PCS score were correlated (r=–0.554) with change in NDI score, whereas change in SF36-MCS score was correlated with change in JOA score (r=0.550).

Conclusions: Surgery for degenerative cervical myelopathy is associated with significantly improved SF36-measured patient-oriented outcomes.

MeSH Keywords: Meta-Analysis • Nerve Compression Syndromes • Neurodegenerative Diseases • Spinal Cord Compression

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Background

Degenerative cervical myelopathy causes altered motor and sensory functions due to spinal cord compression [1]. Neurological impairment due to nerve compression forms the basis for many symptoms, including weakness and numbness, pain in the neck and arm regions, gait instability, palpitations, facial flushing, and problems in walking, vision, digestion, excretion, memory, and hearing [1,2]. Degenerative cervical myelopathy may arise from static compression of the spinal cord, malalignment of the spinal cord that can alter its tensile strength and vascular supply, or segmental hypermobility due to repeated dynamic injury. Such changes can be either osteoarthritic (spondylotic) or non-osteoarthritic [3]. Osteoarthritic changes may involve osteophyte or chondro-osseous malformations and/or alterations in discs, facet joints, and ligaments, leading to canal stenosis and impaired sagittal alignment [4]. Nonosteoarthritic changes include hypertrophy or ossification of the spinal ligaments, disc herniation, and subluxation [3].

Incidence of degenerative cervical myelopathy-related hospitalization is estimated at 4.04 per 100 000 person-years [3,5]. Degenerative spinal disorders have adverse impacts on patients' quality of life. Because the main objectives of any surgical intervention are to improve health-related quality of life and to reduce disability, instruments capable of measuring patient-oriented outcomes are now increasingly used to evaluate the clinical and functional outcomes from the patients' perspectives [6].

Many instruments have been developed to assess surgical outcomes from clinical and esthetic perspectives. The Japanese Orthopedic Association (JOA) score is a frequently used tool to evaluate the functional status of cervical myelopathy patients. Initially, it was developed for Japanese and related Asian populations; later, its use became global, with some modifications. The JOA score and the modified JOA (mJOA) scores are found to correlate well (r=0.87) [7]. The Neck Disability Index (NDI) is a well-validated patient-filled questionnaire to assess functional status with 10 items (7 for functional activity, 2 for symptoms, and 1 for concentration) measuring disability due to neck pain [8]. A good correlation is reported between the JOA and the NDI scores in the surgical cervical myelopathy patient population (r=–0.6) [9]

The Short Form 36 Health Survey Questionnaire (SF36), a 36-item instrument, is widely used to assess the health-related quality of life [10]. It is a multidimensional generic instrument validated for several pathologies including diseases of the cervical spine [11]. The physical component summary (PCS) of the SF36 evaluates functional capacity, physical aspects, pain, and general health, whereas its mental component summary (MCS) assesses vitality, social functioning, emotional aspects, and mental health [10].

In the literature, many studies have reported the outcomes of surgical interventions in patients with degenerative cervical myelopathy, including SF36-measured patient-oriented outcomes. The aim of this study was to evaluate the patient-oriented outcomes of the surgical management of degenerative cervical myelopathy reported by relevant studies after using the SF36, and to examine its concordance with NDI and JOA/mJOA scores.

Material and Methods

The present study was carried out by following Cochrane Handbook guidelines for the conduction of systematic reviews and meta-analyses and is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement.

Eligibility criteria

Studies were included if: a) they reported the patient-oriented outcomes of the surgical management of degenerative cervical myelopathy, b) their follow-up period was at least 12 months, and c) they reported preoperative and latest follow-up SF36-PCS/MCS) and/or SF36 dimensional scale scores. Studies were excluded if they reported: a) the patient-oriented outcomes of the surgical management of cervical radiculopathy, radiculomyelopathy, or other related cervical surgeries other than degenerative cervical myelopathy, and b) the outcomes of related quality of life assessment tools other than the SF36.

Literature search

A literature search was conducted in Google Scholar, Ovid SP, PubMed, Science Direct, and Springer electronic databases. Several relevant key terms and medical subject headings (MeSH) were used in combinations or as phrases. These included: 'cervical myelopathy', 'patient-outcomes', 'patient-reported outcomes', 'surgery', 'anterior', 'posterior', 'corpectomy', 'discectomy', 'laminectomy', 'laminoplasty', 'fusion', 'decompression', 'Short Form 36 Health Survey Questionnaire', 'SF36', 'physical component summary', 'SF36-PCS', 'mental component summary', and 'SF36-MCS'. Reference lists of relevant research articles and database indicated articles were also screened.

During the database search, 2 reviewers screened for abstracts independently by pooling all abstracts obtained from a keyword/MeSH based literature search. After scrutinizing the abstracts, full-text articles were retrieved, and eligibility criteria were refined. Later, full-text articles were studied in detail for risk of bias for quality assessment and data extraction. This examination was also performed by 2 authors independently, who then unified their outputs after reaching agreement on

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eligibility issues. The help of a third reviewer was also sought whenever reviewers found difficulty in deciding.

Data and analyses

The demographic, clinical, and orthopedic characteristics of the patients; technical details of surgery and instrumentation; study-design characteristics; outcome measures; analytical details; and outcome data were obtained from respective research articles of the included studies and were organized in Microsoft Excel software spreadsheets. Data were extracted independently by 2 authors, and disagreements were resolved by mutual discussions. Inter-rater reliability was good (kappa=0.94).

A random effects model was used for meta-analyses, which estimated the changes in the SF36 score (last follow-up minus preoperative values). Meta-analysis endpoints were the changes in the SF36-PCS; SF36-MCS; SF36 dimensional; NDI and JOA/mJOA scores. For this purpose, the change from baseline through the last follow-up values of individual studies were either extracted raw from the research articles or calculated, if not found in study report, by using the preoperative and latest follow-up values. Respective standard deviation values of calculated changes were imputed using a standard procedure [12]. These data were then pooled to obtain the inverse variance-weighted overall and subgroup effect sizes of the change. Meta-analyses were performed with Stata software (version 12; Stata Corporation, College Station, TX).

Statistical heterogeneity was estimated with the I^2 index. To assess publication bias, Begg's funnel plot asymmetry test and Egger's precision plot test were performed using the change in the SF36-PCS score as an outcome measure. To assess the quality of the included studies, the New Castle-Ottawa Scale for Assessment of Cohort Studies was used.

In the Results section, Supplementary Figures and Tables refer to materials found in the Supplementary Materials file.

Results

Fourteen studies [13–26] reporting the SF36 outcomes of 1966 patients with degenerative cervical myelopathy were included, while excluding 181 studies during study selection stage (Appendix 1). Because many studies had more than 1 arm, 22 datasets were obtained. A flowchart of the abstract screening and study selection processes are given in Figure 1. No significant publication bias was detected by the Begg's test (adjusted Kendall's score –11±20 (SD); p=0.586; Supplementary Figure 1A) or the Egger's test (bias coefficient 2.22 [95% CI, –3.14, 7.57]; p=0.387; Supplementary Figure 1B).

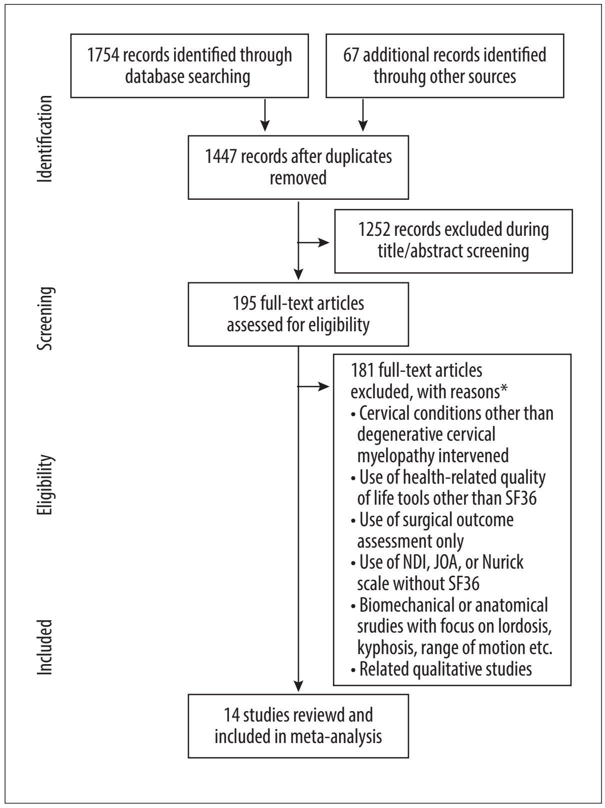

Figure 1. A flowchart of the study screening and selection processes.

Important characteristics of included studies are given in Supplementary Table 1. The age of the participants at the time of surgery was 58.2 years [95% CI, 56.6 to 59.9], of which 60% [95% CI, 55 to 64] were male. Symptom duration was 26.4 months [95% CI, 24.2 to 28.6]. Durations of the surgery, and the hospital stay were 177 minutes [95% CI, 146 to 207], and 8.3 days [95% CI, 5.7 to 10.6], respectively. The follow-up duration was 24.8 months [95% CI, 20.9 to 28.7].

The quality of the included studies was adequate with respect to representativeness and ascertainment of exposure, assessment of outcome, adequacy of the follow-up duration, and adequacy of follow-up completion criteria. However, 4 studies lacked comparability of cohorts based on the design or analysis and all studies lacked the selection of a non-exposed cohort (Supplementary Table 2).

Overall, there was significant improvement in the SF36-PCS score. The change in the SF36-PCS score was 6.60 [95% CI, 4.91 to 8.28] (p<0.00001; Figure 2). The improvement in the SF36-PCS score after the anterior surgical approach was 6.80 [95% CI, 3.41 to 10.19]) and that after the posterior approach was 4.58 [95% CI, 3.43 to 5.73] (Supplementary Figure 2A).

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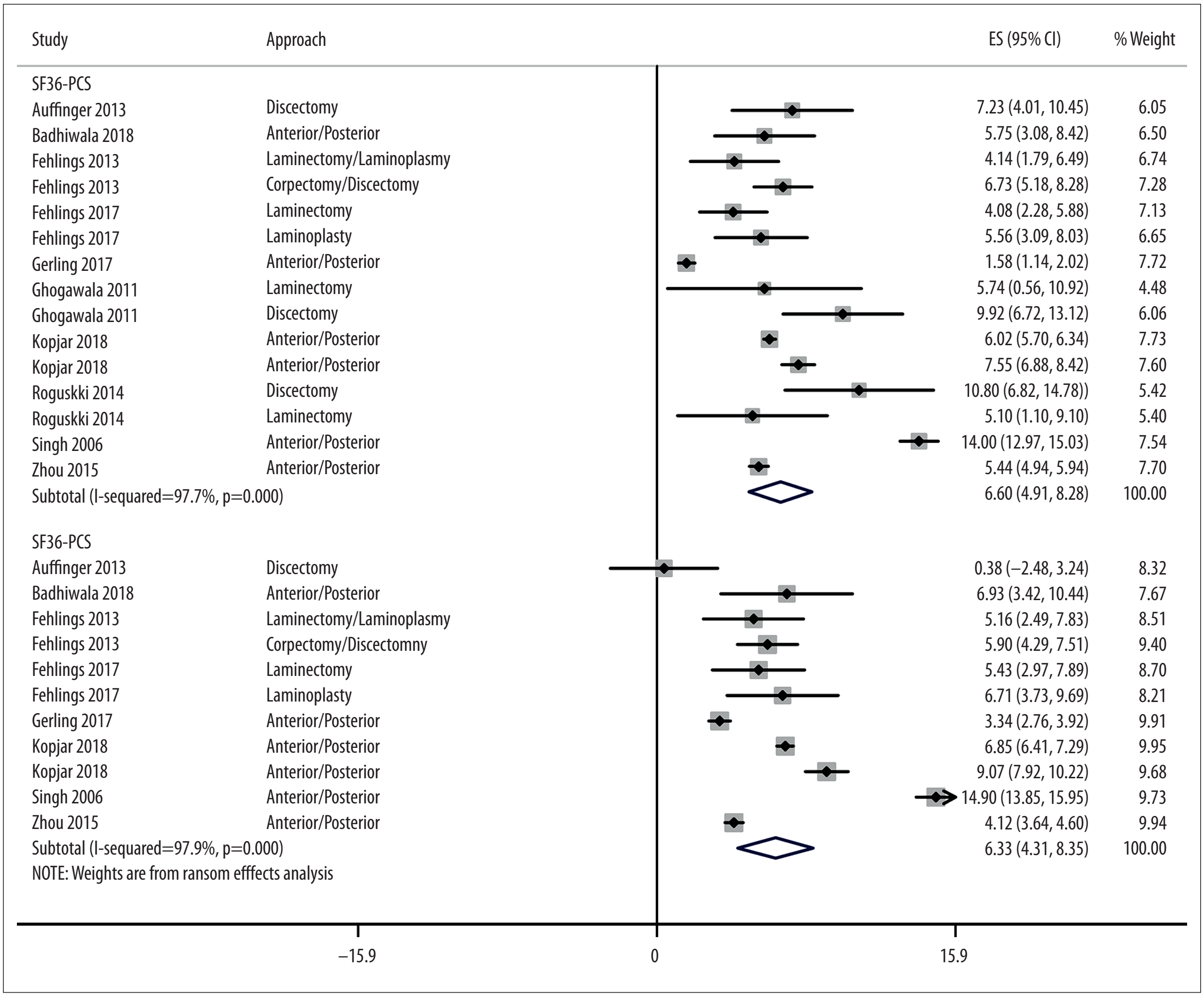

Figure 2. Forest graph showing the changes in the SF36-PCS and the SF36-MCS score by the latest follow-up.

The SF36-MCS score also improved significantly after surgery. The change in the SF36-MCS score was 6.33 [95% CI, 4.31 to 8.35] (p<0.00001; Figure 2). The improvement in the SF36-MCS score after the anterior surgical approach was 4.08 [95% CI, 1.94 to 6.21] and that after posterior approach was 5.68 [95% CI, 4.14 to 7.23] (Supplementary Figure 2B).

There were also significant improvements in all SF36 dimensional scores: Physical Function (25.4 [15.7 to 35.1]; p<0.00001), Role-Physical (26.4 [17.2 to 35.6]; p<0.00001), Bodily Pain (17.0 [5.6 to 28.5]; p=0.004), General Health (12.7 [3.1 to 21.6]; p=0.009), Vitality (11.4 [1.3 to 21.5]; p=0.027), Social Function (18.4 [11.7 to 25.1]; p<0.00001), Role-Emotional (20.5 [13.4 to 27.6]; p<0.00001), and Mental Health (11.7 [2.5 to 21.0]; p=0.013) (Supplementary Figure 3).

Surgical interventions for the treatment of degenerative cervical myelopathy were also associated with significant improvements in the JOA/mJOA score (3.43 [95% CI, 2.80 to 4.06]; p<0.00001) and the NDI (–13.70 [95% CI, –17.35 to –10.06]; p<0.00001) scores (Figure 3).

The correlation coefficient between the change in the SF36-PCS score and the change in the NDI score was –0.554 (p=0.049) and that between the change in the SF36-MCS and the change in the NDI score was –0.07 (p=0.945). The correlation coefficient between the baseline NDI score and the baseline SF36-PCS score was –0.647 (p=0.017) and that between the baseline NDI score and the baseline SF36-MCS score was –0.620 (p=0.075) (Table 1).

The correlation coefficient between the change in the SF36-PCS and the change in the JOA score was –0.027 (p=0.935) and that between the change in the SF36-MCS score and the change in the JOA score was 0.550 (p=0.158). The correlation coefficient between the baseline JOA score and the baseline SF36-PCS scores was 0.891 (p<0.00001) and that between the baseline JOA score and the baseline SF36-MCS score was 0.899 (p=0.0024) (Table 1).

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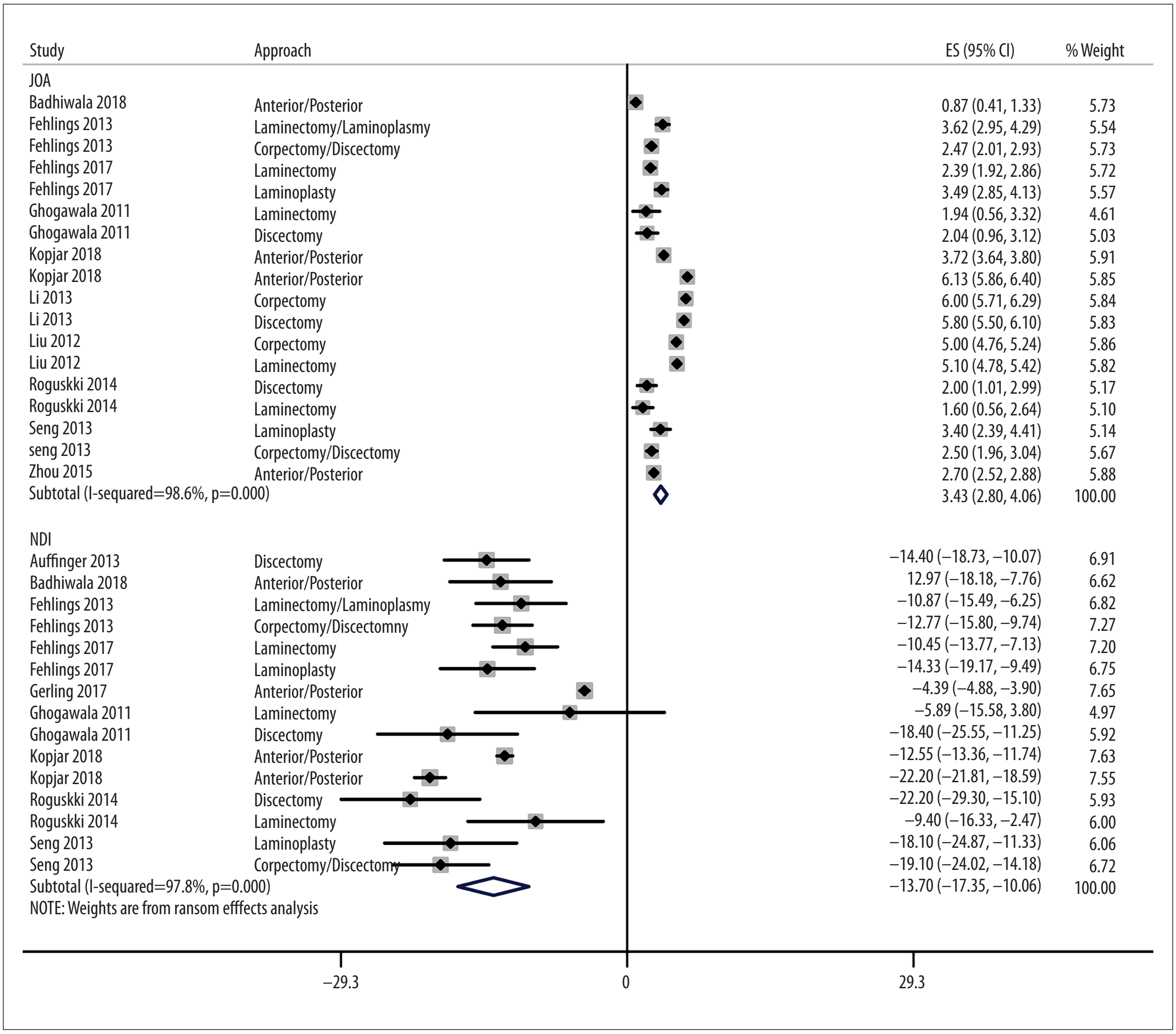

Figure 3. Forest graph showing the changes in the JOA/mJOA and NDI scores by the latest follow-up.

Table 1. Correlation between SF36 and NDI or JOA/mJOA scores.

	Change in JOA/mJOA score	Change in NDI score
Change in SF36-PCS score	−0.027 (p=0.935)	−0.554 (p=0.049)
Change in SF36-MCS score	0.550 (p=0.158)	−0.07 (p=0.945)
	Baseline JOA/mJOA score	**Baseline NDI score**
Baseline SF36-PCS score	0.891 (p<0.00001)	−0.647 (p=0.017)
Baseline SF36-MCS score	0.899 (p=0.0024)	−0.620 (p=0.075)

Discussion

This meta-analysis found that surgery for degenerative cervical myelopathy is associated with significantly improved SF36-measured patient-oriented outcomes. While the change in the SF36-PCS score were correlated with the NDI score, the change in the SF36-MCS score was correlated with the change in the JOA score. These observations show that the SF36 is a reliable tool for assessing patients with degenerative cervical myelopathy for surgical outcomes.

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The SF36 is a 36-item questionnaire for measuring responses in 8 health domains (physical functioning, physical role functioning, bodily pain, general health, vitality, social functioning, emotional role functioning, and mental health) that can be combined to produce summary health measures, i.e. the PCS score for physical and the MCS for mental components [27]. Use of the SF36 has shown that, in comparison with age-adjusted normal individuals, patients with degenerative cervical myelopathy experience a poor quality of life characterized by physical debility and impaired emotional and mental functioning [27].

Although the goal of a surgical intervention is to provide substantial clinical benefit, the minimum clinically important difference (MCID) is the minimal threshold of improvement considered beneficial by the patient. Recently, Badhiwala et al. [28] reported that the MCID of the SF36 PCS and MCS scores should be 4 points in evaluating patients with degenerative cervical myelopathy. They used the NDI score as an anchor to determine the MCID for the SF36-PCS or MCS scores. We have found improvements in the SF36 PCS, MCS, or dimensional scores above 4 points, indicating surgery can provide substantial benefit to patients with degenerative cervical myelopathy.

Previously, Carreon et al. [29] suggested an MCID of 4.1 points for the change in the SF36-PCS scores and MCID of 7.5 for the change in the NDI score. In their study, the calculated substantial clinical benefit (SCB) was 6.5 for the change in the SF36-PCS score and 9.5 for the change in the NDI score. Their analysis was based on over 500 patients who underwent a cervical fusion for a degenerative spine and were followed for at least 1 year. Tetreault et al. [30] found the MCID of mJOA to be between 1 and 2 points, depending on myelopathy severity. They identified younger age, shorter disease duration, abstinence from smoking, and normal gait as the predictors of achieving an MCID on the mJOA scale [31].

Zhang et al. [25] found SF36 to be reliable for evaluating patients with cervical spondylotic myelopathy, and suggested MCIDs of 5.52 for the SF36-PCS score and 3.43 for the SF36-MCS score. They found that earlier improvements in the mJOA scores had good correlation with the physical functioning section of the SF36 scale, but with extended recovery, both physical and mental functions were correlated with the improvements in the mJOA scores. Moreover, they found that improvements in neurological function were correlated mainly with the mental function section. The changes in the SF36-MCS scores were correlated with the changes in JOA scores in the present study as well.

In a study evaluating the reliability of the SF36 tool in patients with neck pain, the correlation between the SF36 and the NDI was –0.45 to –0.74, and all 8 SF36 domains were at least moderately correlated with the NDI [32]. In the present study, the baseline NDI score correlated well with the baseline SF36-PCS score (r=–0.65) and with the SF36-MCS score (r=–0.62). On the other hand, at the latest follow-up, the change in the NDI score was strongly correlated with the change in the SF36-PCS (r=–0.55), but the change in the SF36-MCS score correlated well with the change in the JOA score (r=0.88). Ricciardi et al. [33], who used esthetic satisfaction as the primary outcome measure to evaluate lumbar spine surgery, have suggested that a functional outcome evaluation, if considered parallel to an esthetic evaluation, can be more useful for the assessment of any possible bias in outcome assessment.

In this meta-analysis, the outcomes were associated with high statistical heterogeneity, which should be considered an important limitation of the present study. However, this limitation could be due to the methodological heterogeneity attributable to differing surgical approaches and instrumentation. The outcomes are based mostly on cohort studies with follow-up durations of 12 to 80 months. Both these factors could have some impact on overall outcomes. Because the changes in the outcomes by the latest follow-up were not reported by many studies, these values were calculated from baseline and final values and respective standard deviations were imputed. This might also have had a slight impact on the outcomes. Many of the included studies were not comparative in design, which necessitated the pooling of outcome data; therefore, a comparative account could not be performed.

Conclusions

In a population of degenerative cervical myelopathy patients with a mean age of 58 years (95% CI, 56 to 60) who were followed for 25 months (95% CI, 21 to 29), surgical interventions are found to be associated with significant improvements in patient-oriented outcomes when measured with the SF36. The change in the SF36-PCS score was correlated with the change in the NDI score, but the change in the SF36-MCS score was correlated with the change in the JOA score. These observations support the use of the SF36 as a tool for assessing degenerative cervical myelopathy patients for surgical outcomes.

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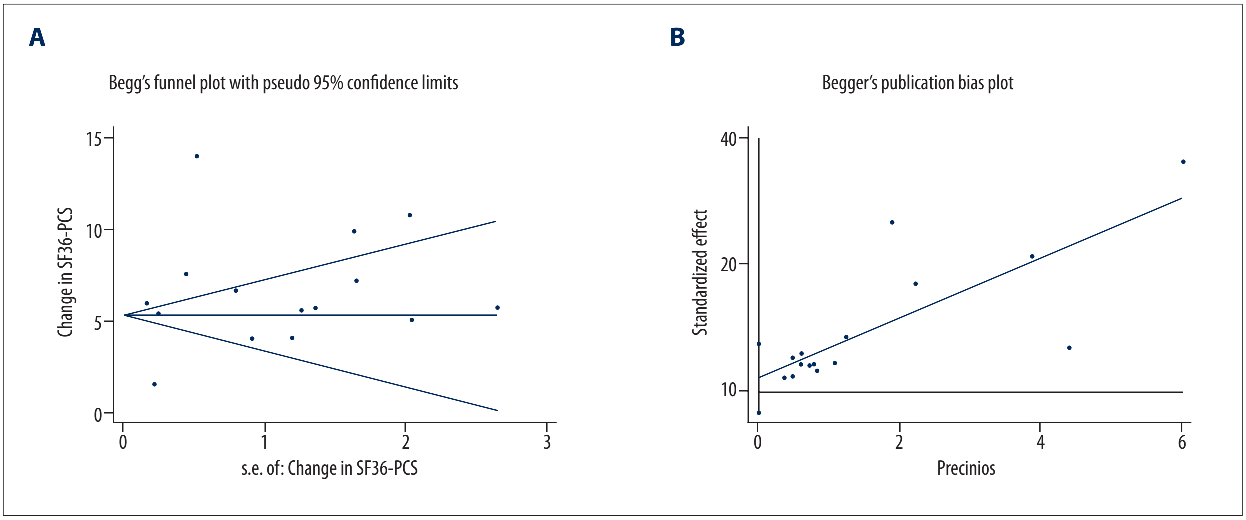
Supplementary Data



Supplementary Figure 1. Plots showing the outcomes of publication bias assessment of the change in SF36-PCS with (**A**) Begg's test of funnel plot symmetry and (**B**) Eggers's test of precision.

Supplementary Table 1. Important characteristics of the included studies.

Study	n	Follow-up		Design	Surgery	Age (years)	% males	Disease duration (months)	Hospital stay (days)	Baseline scores			
		Duration (months)	Rate (%)							JOA	NDI	SF36-PCS	SF36-MCS
Auffinger 2013 [13]	30	12	100%	RETRO	ACDF	57.5 ±13	48		1.7 ±1.3		29.3 ±13.9	37 ±7.1	47.8 ±7.9
Badhiwala 2018 [14]	193	24	93%	PROSP	Ant/Post	52.4 ±10	65	27 ±36		15.8 ±1.7	31.3 ±18.8	39.7 ±9.8	42.7 ±12.8
Fehlings 2013 [15]	95	12	87%	PROSP	LMN/LAMP	62.8 ±11	62	27 ±42.8		11.8 ±2.9	43.1 ±19.3	35.7 ±9.6	39.9 ±10.8
Fehlings 2013 [15]	95	12	87%	PROSP	CORP/DISC	52.5 ±11	57	26 ±48		13.7 ±2.5	41 ±21.9	36.6 ±9.8	40.2 ±11
Fehlings 2017 [16]	166	24	79%	PROSP	LMN-fusion	61.4 ±11	68	32 ±40	7.8 ±7.2	12.3 ±2.9	39.2 ±21	33.1 ±9.3	41 ±14.6
Fehlings 2017 [16]	100	24	79%	PROSP	LAMP	60.7 ±11	67	23 ±33	11.6 ±8.9	11.5 ±2.8	41.8 ±21	35.1 ±10	38.9 ±12.5
Gerling 2017 [17]	203	24		RETRO	Ant/Post	57.7 ±9.3	57				20.8 ±10.8	35.5 ±8.4	40 ±13.3
Ghogawala 2011 [18]	28	12	92%	PROSP	ACDF	60 ±9.3	57		4 ±1.7	11.6 ±2.3	36.2 ±23.5	32.7 ±10.3	
Ghogawala 2011 [18]	22	12	92%	PROSP	LMN-midline	64 ±9.3	73		2.6 ±1.4	13.4 ±2.3	36.2 ±23.2	35.3 ±11.8	
Kopjar 2018 [19]	60	24	93%	PROSP	Ant/Post	59.4 ±12	61	24.5 ±28	9.7 ±9.5	10.2 ±0.5	44.6 ±12.7	30.8 ±4.6	37 ±8.1
Kopjar 2018 [19]	60	24	93%	PROSP	Ant/Post	62.5 ±12	35	21.6 ±37	14.4 ±13	6.83 ±1	54.5 ±22.7	29 ±8.5	37 ±15
Li 2013 [20]	42	80	21%	RETRO	ACCF	51.3 ±6.5	65			8.1 ±2			

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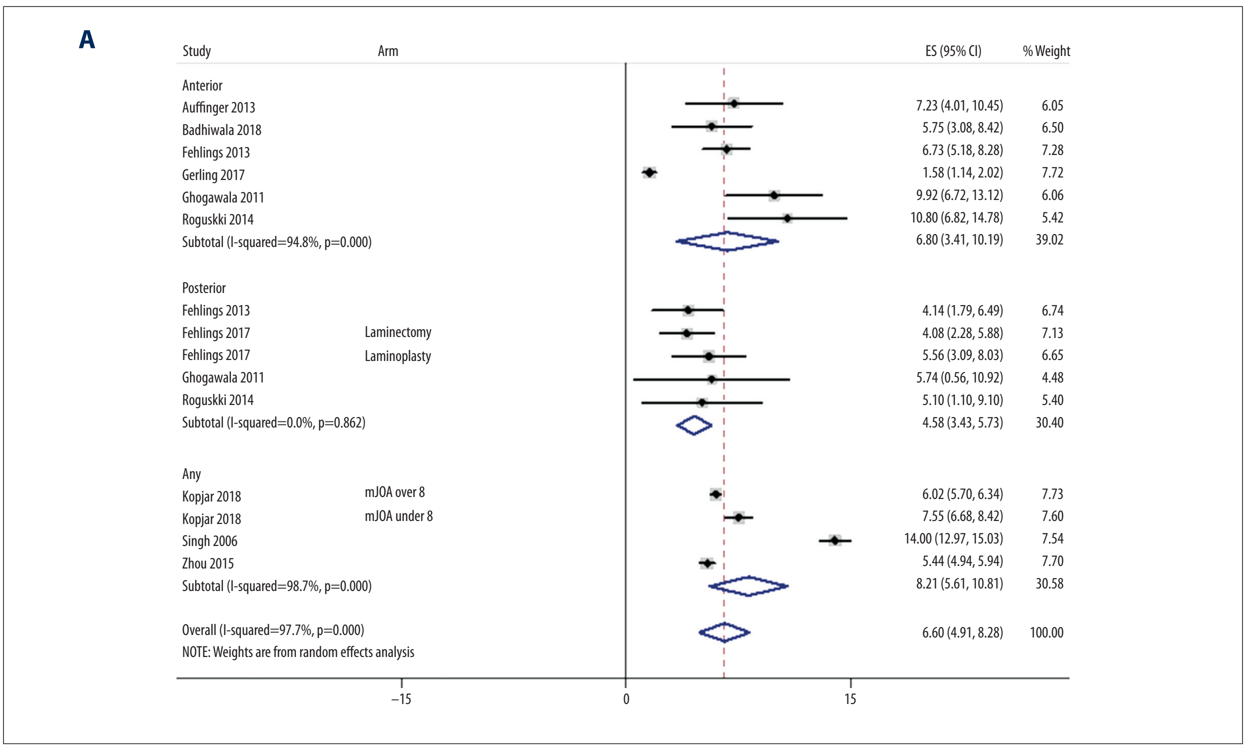
Study	n	Follow-up		Design	Surgery	Age (years)	% males	Disease duration (months)	Hospital stay (days)	Baseline scores			
		Duration (months)	Rate (%)							JOA	NDI	SF36-PCS	SF36-MCS
Li 2013 [20]	47	80	21%	RETRO	ACDF	51.3 ±6.5	65			8.2 ±1.9			
Liu 2012 [21]	71	31	90%	RETRO	ACCF	53.9 ±1	62	27.6 ±46.4	14.9 ±5.3	10.5 ±2.5			
Liu 2012 [21]	45	31	90%	RETRO	LMN-fusion	57.1 ±10	67	33.5 ±34.6	16.6 ±3	9.5 ±2.7			
Roguskki 2014 [22]	21	12		PROSP	ACDF	62.4 ±9.5	43			13.2 ±2.5	37.4 ±24.8	37.5 ±9.8	
Roguskki 2014 [22]	28	12		PROSP	LMN-Midline	62.2 ±10	75			13.1 ±2.2	30.7 ±20.4	36.7 ±12.5	
Seng 2013 [23]	52	24	81%	PROSP	LAMP	60.6 ±11	77		5.4 ±1.4	11 ±3	32.1 ±22.5		
Seng 2013 [23]	64	24	81%	PROSP	CORP/DISC	58.6 ±11	62		3.7 ±1.5	11 ±3	35.9 ±21		
Singh 2006 [24]	105	12		PROSP	Ant/Post	58 ±9.3	65					39.7 ±20.5	47.8 ±20.5
Zhang 2015 [25]	142	24	99%	PROSP	Ant/Post	60	40						
Zhou 2015 [26]	113	12	100%	PROSP	Ant/Post	57.6 ±10	40			12.5 ±2.5		37.9 ±6.6	39.5 ±5.54

ACCF – anterior cervical corpectomy and fusion; ACDF – anterior cervical discectomy and fusion; Ant/Post – anterior/posterior approach; CORP/DISC – corpectomy/discectomy; JOA – Japanese Orthopedic Association; LAMP – laminoplasty; LMN – laminectomy; NDI – neck disability index; PDF – posterior decompression and fusion; PROSP – prospective; RETRO – retrospective; RCT – randomized controlled trial; SF36-PCS/MCS – short form 36 – physical/mental component score. Values with ± represent standard deviation.



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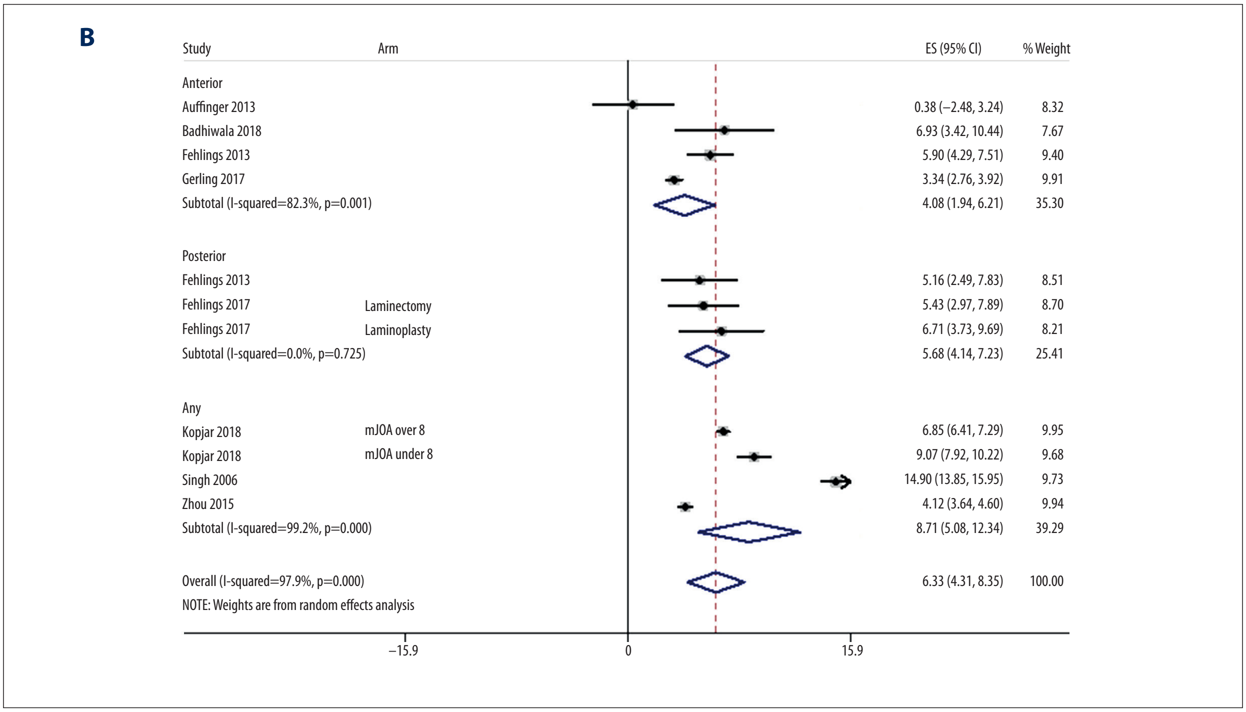

Supplementary Figure 2. (**A**) Forest graph showing the surgery-wise effect size of the change in SF36-PCS score. (**B**) Forest graph showing the surgery-wise effect size of the change in SF36-MCS score

Supplementary Table 2. Quality assessment of the included study with New Castle-Ottawa Quality Assessment Scale.

Study	Representa-tiveness of exposed cohort	Selection of non-exposed cohort	Ascertainment of exposure	Demonstration that outcome of interest was not present at start of study	Comparability of cohorts based on design or analysis	Assessment of outcome	Was follow-up long enough for outcomes to occur	Adequacy of follow up completion of cohorts
Auffinger 2013 [13]	*		*	*		*	*	*
Badhiwala 2018 [14]	*		*	*		*	*	*
Fehlings 2013 [15]	*		*	*	**	*	*	*
Fehlings 2017 [16]	*		*	*	**	*	*	*
Gerling 2017 [17]	*		*	*		*	*	*
Ghogawala 2011 [18]	*		*	*	**	*	*	*
Kopjar 2018 [19]	*		*	*	**	*	*	*
Latimer 2002 [20]	*		*	*	**	*	*	*
Li 2013 [21]	*		*	*	**	*	*	*
Liu 2012 [22]	*		*	*	**	*	*	*
Roguskki 2014 [23]	*		*	*	**	*	*	*
Seng 2013 [24]	*		*	*	**	*	*	*
Zhang 2015 [25]	*		*	*		*	*	*
Zhou 2015 [26]	*		*	*		*	*	*

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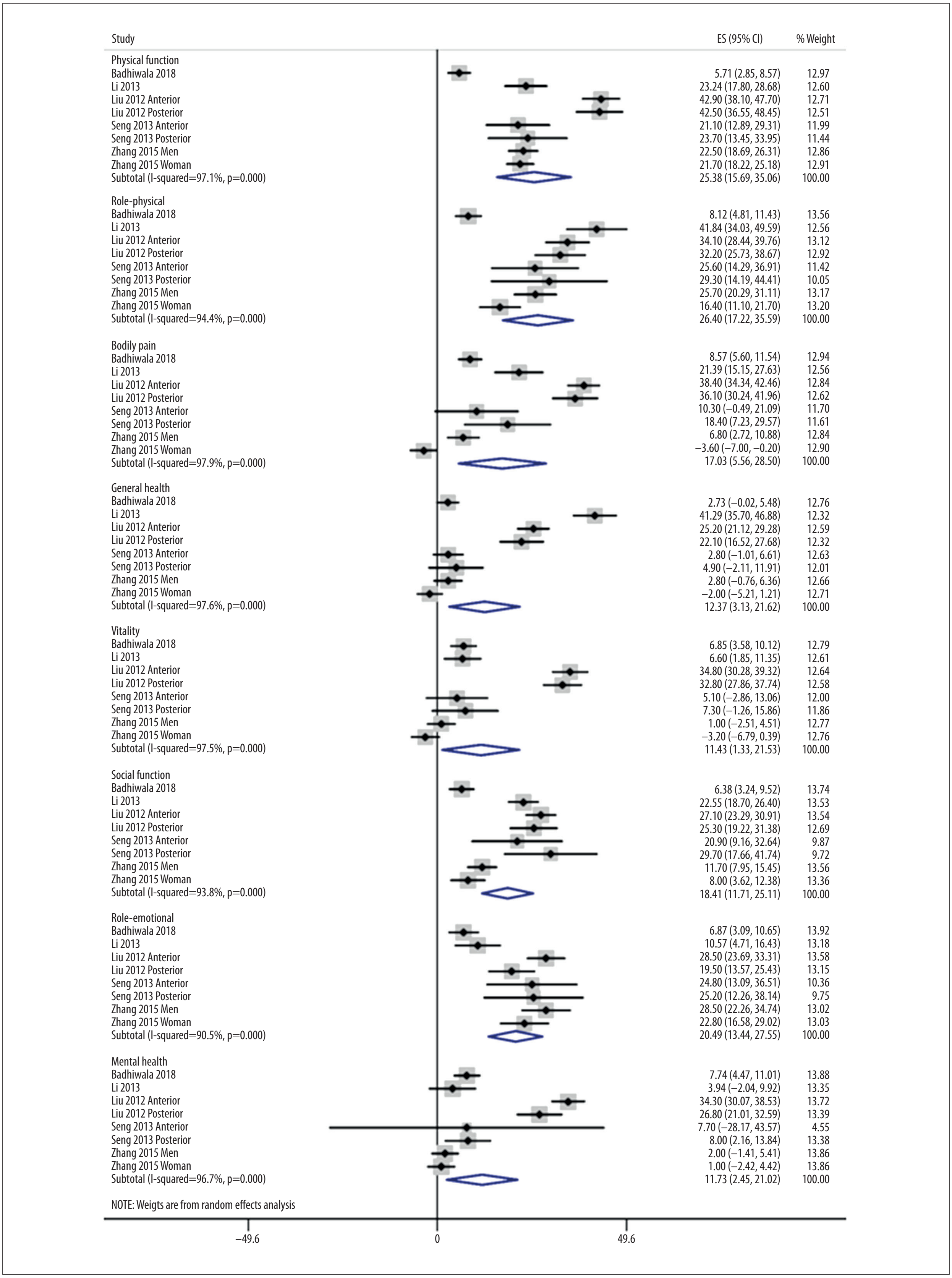

Supplementary Figure 3. Forest graph showing the change in SF36 dimensional score by the latest follow-up.

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NEWCASTLE-OTTAWA QUALITY ASSESSMENT SCALE FOR COHORT STUDIES

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

Selection

1) Representativeness of the exposed cohort
   a) truly representative of the average _______________ (describe) in the community *
   b) somewhat representative of the average ______________ in the community *
   c) selected group of users e.g. nurses, volunteers
   d) no description of the derivation of the cohort
2) Selection of the non-exposed cohort
   a) drawn from the same community as the exposed cohort *
   b) drawn from a different source
   c) no description of the derivation of the non-exposed cohort
3) Ascertainment of exposure
   a) secure record (e.g. surgical records) *
   b) structured interview *
   c) written self-report
   d) no description
4) Demonstration that outcome of interest was not present at start of study

a) yes *
b) no

Comparability

1) Comparability of cohorts on the basis of the design or analysis
   a) study controls for _____________ (select the most important factor) *
   b) study controls for any additional factor * (This criterion could be modified to indicate specific control for a second important factor.)

Outcome

1) Assessment of outcome
   a) independent blind assessment *
   b) record linkage *
   c) self-report
   d) no description
2) Was follow-up long enough for outcomes to occur
   a) yes (select an adequate follow up period for outcome of interest) *
   b) no
3) Adequacy of follow up of cohorts
   a) complete follow up - all subjects accounted for *
   b) subjects lost to follow up unlikely to introduce bias - small number lost - > ____% (select an adequate%) follow up, or description provided of those lost) *
   c) follow up rate < ____% (select an adequate%) and no description of those lost
   d) no statement

Appendix 1

References to the excluded studies (This data available from the corresponding author on request).

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