Rehabilitation following lumbar fusion surgery: a systematic review and meta-analysis.

Introduction;

Lumbar fusion surgery (LFS) is undertaken to rigidly stabilise adjacent vertebral motion segments. LFS is commonly performed simultaneously with decompression of affected neural tissue, to relieve back and/or neurogenic leg pain [1-3]. Common surgical indications include spondylolisthesis, disc disease and stenosis [4-6].

In the UK the rate of LFS is increasing in 2009/10 4036 were performed increasing by over 60% to 6547 by 2012/13 [7]. A similar trend of escalating LFS is reported in the USA, particularly in patients over 60 years [8]. It is suggested that as 30% of the UK population is predicted to be over 60 by 2037 [9], rates of LFS will continue rising.

Following LFS, many patients have residual problems. Data from the Swedish National Spine Register reports that 25% of patients experience static/worsening pain, and 40% are unsure/dissatisfied with outcomes 12 months after LFS [10]. It is timely, therefore, to evaluate mechanisms to improve post-surgical clinical outcomes.

A recent Cochrane Back Review Group (CBRG) report suggests rehabilitation following laminectomy surgery for lumbar stenosis reduces pain and improves functional status [11]. It is not clear if this applies to LFS, with no clear consensus regarding the efficacy of rehabilitation following LFS [12].

A previous systematic review and meta-analysis found inconclusive, very low quality evidence for the effectiveness of physiotherapy following LFS and further research was an 'urgent consideration' [13].

Objectives

This review was undertaken to appraise the evidence evaluating rehabilitation in adults, having undergone LFS for degenerative conditions. Eligible trials included randomised design, suitable comparator (eg; usual care) and validated outcome measures related to pain and/or disability in the short and longer term (<6/>12 months respectively).

Materials and Methods

Protocol and registration

A protocol based on methods described by the CBRG and Cochrane Handbook [14, 15] was utilised. Reporting was in accordance with the PRISMA statement [16] and registered with the International Prospective Register of Systematic Reviews (POSPERO).

Eligibility criteria

Studies describing rehabilitation following LFS, fulfilling the criteria below, were included in the review.

Study inclusion criteria

- Design; Randomised Controlled Trial (RCT).

- Participants; >16 years, LFS for degenerative conditions.
- Intervention; Rehabilitation (physical, psychological or combined).
- Comparator; Suitable comparator, eg usual care.
- Date; 1974 onwards.
- Reporting; short and long-term (<6 months, >12 months).
- Outcome measures; One or more validated measure of pain/physical function.
- Language; any, necessary translation arranged.

Information sources

The following databases were utilised.

- CINAHL, EMBASE, MEDLINE, PEDro, PsycINFO, databases.
- Cochrane library; Health Technology Assessment Database, NHS Economic Evaluation database.
- National Research Register, Current Controlled Trial website (York).
- Cochrane Back Review Group.
- Grey literature.
- Hand searches key journals.

Search strategy

The search strategy employed a 3-phase approach. A scoping search of MEDLINE, AMED and CINAH utilising combinations of keywords, lumbar, fusion and rehabilitation was undertaken. Titles and abstracts of the results

identified specific keywords to develop a comprehensive search strategy, trialed and modified with librarian assistance (KB). The final phase included hand searching of key journals and 'grey literature'. See table 1.

Table 1; Example search strategy employed for MEDLINE

Study selection

Two review authors (JG, JM) independently searched the databases. Results were saved, pooled, duplicates removed, and combined with those from 'grey literature' and hand searches.

Titles were reviewed by one author (JG), rejecting those unrelated to the topic of interest. Abstracts of the remaining articles were obtained, reviewed by two authors (JG, JM) and graded; eligible, ineligible or potentially eligible according to the inclusion criteria.

Full text of eligible, and potentially eligible, articles were retrieved and evaluated independently by two authors (JG, JM) to determine eligibility for inclusion in the review. Inter-reviewer agreement was measured (Cohen's k). Disagreements between authors were addressed with a 3rd party mediator (AM, subject and methodological expert) to achieve consensus.

Data extraction

A data extraction form, based on the 'characteristics of included studies' table from the Cochrane Handbook, [15] was utilised. This was piloted in parallel with the development of the search strategy and modified to match the needs of this review. Data extraction was undertaken independently by two reviewers (JG, JM). A third reviewer (MH) checked the form against selected studies for accuracy of data imputation. Authors of studies included in the review were contacted for raw data. This was received from one study [17].

Extracted data items

Study design, participants (including surgical indications), interventions, comparators, primary and secondary outcome measures (short/longer term time points) and results, including disability, pain, mental health and kinesiophobia. No simplifications or assumptions were made.

Risk of bias within individual studies

The Cochrane risk of bias assessment tool was used to assess internal validity and potential sources of systematic error.

Summary measures and synthesis of results

The meta-analysis protocol only allowed inclusion of studies with similar participants, interventions, comparators and outcomes. The review authors identified short and longer term outcomes for disability, pain, mental health and fear avoidance behaviour as suitable for pooled analyses across studies.

Meta-analysis using RevMan [18] software, utilising the inverse variance model for continuous data (change in mean values from baseline), was employed. The DerSimonian Laird [19] random effects model was utilised to accommodate the assumption that the studies were reporting different, yet related intervention effects. Confidence intervals (CI) were set at 95% and mean change from baseline scores analysed using the standardised mean difference [15].

The standard deviation (SD) for mean change from baseline was available for one study [20], raw data provided by the corresponding author utilised to calculate this for the other [17].

Risk of bias across studies

Formal risk of bias across studies was not indicated due to the paucity of studies. Funnel plots were not warranted. The quality of evidence using the GRADE criteria [21] was reported.

Additional analyses

The lack of studies precluded additional analysis.

Results

Study selection process (Figure 1)

Identified databases were searched (JG, JM, 13th/20th October, 2014 respectively). This yielded 1006 results, screened by title, (JG) to remove 972 irrelevant papers/duplicates. Abstracts for the 34 remaining articles were retrieved and reviewed (JG, JM) leaving 13 papers considered eligible/potentially eligible for full text review. Inter-reviewer reliability was good (Cohen's k 0.78).

Five papers, reporting data from 3 original studies, were selected for inclusion in the review with very good agreement between authors (Cohen's k 0.88).

Fig 1; Flow chart of study selection process with reasons for rejection

Study characteristics

Intro

Three papers met the eligibility criteria for inclusion in this review [12] [22] [17]. All three studies compared usual care with novel form(s) of

rehabilitation. Christensen et al compared 'usual care' with a 'back café' group and a physical training group [12], Abbott et al with 'psychomotor therapy' [22] and Monticone et al with exercise and cognitive behavioural therapy (CBT) [17].

Detail of studies (Table 2)

In the study by Christensen et al, [12] participants (n=90, mean age 45) were randomised to 3 intervention arms. They compared usual care (video demonstration and single physiotherapy session for explanation of exercises) with two novel intervention groups ('back café', physical training group). Rehabilitation commenced 3 months after LFS.

The physical training group was offered twice-weekly physiotherapy appointments (90 minutes each, for supervised exercises, over 8 weeks). The 'back café' group received usual care (video and advice) and, in addition, was invited to attend a 'back café'. This consisted of 3 meetings (90 minutes each) with other LFS patients and a physiotherapist modulator. The purpose was to exchange experiences related to pain, disability, concerns regarding rehabilitation, and coping strategies.

A primary outcome measure was not identified but evaluation with the low back pain rating (LBPR) [23] scale was reported at 3, 6, 12 and 24 months post LFS.

Abbott et al [22] randomised participants (n=107, mean age 51 years) to either usual care or 'psychomotor therapy'. The usual care group (n=54) received a single session of exercise advice (20 minutes) delivered in Hospital by a physiotherapist. The 'psychomotor therapy' group (n=53) received usual care, and also received three 90-minute Hospital outpatient appointments (post-operative weeks 3, 6 and 9) for physiotherapist-supervised, core stability exercises, education, training in cognitive coping strategies, relaxation, motivational goal setting and help managing blocks to recovery/relapses. This combined physical rehabilitation based on the work of Richardson et al [24] and CBT based on the work of Linton [25] was coined 'psychomotor therapy' by the authors. Rehabilitation was commenced within 3 weeks of discharge following LFS.

The primary outcome measure was the Oswestry Disability Index (ODI) [26] (3, 6, 12 and 24-36 months post-LFS). Secondary outcomes included measures of pain, visual analogue scale, (VAS), quality of life (QoL), European Quality of Life Questionnaire (EQ-5D), mental health, the mental health sub-scale of the Short Form Health Survey (SF-36) and fear avoidance behaviour, Tampa Scale of Kinesiophobia (TSK).

Monticone et al [17] randomised participants (n=130, mean age 57) to UC or the 'experimental group'. UC consisted of supervised exercise sessions, (90 minutes) 5 times per week, for 4 weeks. The 'experimental group' received UC and additionally CBT twice-weekly for 4 weeks (60 minutes). Rehabilitation commenced after LFS, but the exact time is not well described.

The primary outcome was post-rehabilitation change in ODI score [17]. Secondary outcomes included TSK, pain, Numerical Rating Scale (NRS) and QoL, including mental health (SF-36). Outcomes were recorded pre-treatment, immediately post rehabilitation and at 12 months following LFS.

All three studies described usual care based on physical exercise and an experimental, 'complex rehabilitation' arm involving exercise and CBT.

Risk of bias (Figure 2)

The paper by Christensen et al [12] had a mixture of high and unclear risk of bias. Subsequent publications describing the long term primary health care demands [27] and economic analysis [28], did not change the overall risk of bias. Papers by Abbott et al [22] and Moticone et al [17] had a lower overall risk of bias with one unclear and one high risk domain, the remaining domains being low risk. Agreement between study authors was good (Cohen's k 0.72).

The nature of the interventions made blinding participants problematic to adequately achieve, all three studies had this high-risk domain in common. This is however, unlikely to have significantly affected results.

Fig 2; Risk of Bias Summary Table

Results of individual studies

Table 2; for summary data.

Table 2; Summary data from included studies evaluating rehabilitation following LFS.

Synthesis of results

The reporting of median and range (non-parametric) data in the study by Christensen et al [12] precludes its inclusion in the meta-analysis. Abbot et al [22] and Monticone et al [17] describe several comparable outcomes, and the consensus amongst review authors was to pool data for disability (ODI), back pain (VAS and NRS), mental health (SF-36, mental health sub-scale) and fear avoidance behaviour (TSK).

The results of 2 individual studies with an unclear risk of bias were pooled, (n=237, females=62%, mean age=55) to compare change from baseline in mean value, at short and longer term, for participants undergoing usual care versus 'complex rehabilitation' [17, 22].

In the short term one study showed evidence of significant improvements in disability, back pain and fear avoidance behaviour [22]. The other study reported significant improvements in disability, pain (low back and leg), fear avoidance behaviour, and mental health [17].

Pooled analysis of the two studies suggests a significant short term effect for disability (effect size, -0.85, 95% CI -1.41, -0.29, Fig 3a) and fear avoidance behaviour, (-1.07, 95% CI -1.33, -0.80, Fig 3b) favouring 'complex rehabilitation'. Pooled analysis for low back pain (LBP) narrowly failed to reach levels of significance (-0.71, 95% CI -1.44, 0.01, Fig 3c).

Fig 3a; meta-analysis results, short term disability

Fig 3b; meta-analysis results, short term fear avoidance behaviour

Fig 3c; meta-analysis results, short term low back pain

Heterogeneity (I^2) was high in the pooled analysis for LBP (87%, Fig 3c) and disability (77%, Fig 3a) perhaps contributing to the lack of effect. However heterogeneity for fear of movement behaviour was lower (0%, Fig 3b).

In the longer term, (12 months) one study reported significant improvements in disability and fear avoidance behaviour [22], the other reported significant improvements in disability, pain (back and leg), fear avoidance behaviour and mental health [17]. In all cases this favoured 'complex rehabilitation' where CBT and physical rehabilitation were combined.

Pooled analysis revealed levels of statistical significance for disability (effect size -0.84, 95% CI, -1.11, -0.58, Fig 4a), and fear avoidance behaviour (-1.40, 95% CI -1.69, -1.12, Fig 4b) in favour of 'complex rehabilitation'.

Fig 4a; meta-analysis results, long term disability

Fig 4b; meta-analysis results long term fear avoidance behaviour

Heterogeneity was acceptable in both meta-analyses.

The long term meta-analysis for LBP (Fig 5) did not support any positive effect of 'complex rehabilitation' over usual care.

Figure 5; meta-analysis results, long term low back pain

Risk of bias across studies

Two studies were included in the meta-analysis. Both studies had one high risk domain (blinding participants), and one also had an unclear risk of bias (blinding outcome assessment) [22]. The summary risk of bias assessment has the majority of information coming from studies with a low/unclear risk of bias and the overall risk of bias across studies is therefore unclear (Fig 2).

Discussion

Summary of evidence

Results from this systematic review and meta-analysis suggests patients undergoing 'complex rehabilitation' have better physical function and reduced fear avoidance behavior compared to patients receiving usual care for up to 12 months following LFS. Therefore usual care may contribute to the reported dissatisfaction amongst some patients [10].

The results from this review contrast with a previous review which showed no effect of physiotherapy following LFS [13]. This is most likely due to the exclusion of the Christensen study [12], and the inclusion of the recent study by Monticone et al [17]. That enabled a wider comparison between studies and increased the number of participants in the pooled analyses.

As 12.4% has been suggested as the minimally important clinical difference in the Oswestry Disability Index [29] the studies of Abbott et al [22] and Monticone et al [17] showed that 'complex rehabilitation' could produce a clinically meaningful reduction in disability in the short and longer term.

Monticone et al [17] showed the largest reduction in disability (ODI). This is possibly related to the greater content of the 'experimental group' intervention, however dose response relationships in pain rehabilitation programs for chronic low back pain are contentious [30] . The setting, a specialised, multi-professional, rehabilitation centre, may also have contributed to the greater effect size.

Limitations

The main factor limiting this review is the lack of available studies for inclusion in the meta-analyses. The strength of evidence, using the GRADE assessment [21], was low, so further research is very likely to have an important impact on the estimated effect sizes.

The meta-analysis should be interpreted within the context of potential risks of bias (unclear) across the two included studies. Service users/providers and commissioners alike should be mindful of this.

There are limitations related to the varied composition of both usual care and 'complex rehabilitation' groups in each study. Both provide a CBT component as an adjunct to exercise therapy however the volume of the intervention is markedly different between studies. This will have contributed to the heterogeneity observed and contributed to the overall lack of effect in some comparisons.

Conclusions

'Complex rehabilitation', comprising exercise and CBT offers long term functional benefits to patients following LFS. There remains a lack of high quality research in this area. If commissioners and surgical teams are to continue providing LFS, more research needs to be undertaken to better understand the post-operative requirements of patients, and the optimal rehabilitation regimens that are best designed to meet these needs.

Further research needs to be of a higher methodological quality, with clearer reporting, including compliance, which has been shown to be problematic in comparable works [31]. Mixed methods of evaluation, proposed as the new gold standard' of clinical research [32], should be employed with robust economic evaluation to assess affordability. Recent guidelines on the process evaluation of complex interventions should be considered [33].

Studies will need to consider the possible mechanistic underpinning of interventions and highlight the 'active' components of rehabilitation strategies. The current review demonstrates a significant and meaningful improvement in physical function and kinesiophobia, independent of pain. It is difficult to currently discern whether reported gains are due to improvements in physical conditioning, psychological functioning, or both. Further work in this area is needed and there is at least one protocol [34] and one registered study [35] expanding the evidence base.