



North East Treatment Advisory Group

Prosthetic intervertebral disc
replacement in the cervical spine:
Cost-effectiveness compared
with cervical discectomy
with or without vertebral fusion

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Summary

- Artificial cervical disc replacement using synthetic disc prostheses is a proven intervention which has been positively evaluated by NICE. It has demonstrated equivalence with established surgical interventions such as discectomy plus fusion.
- The hypothesised benefits of cervical disc replacement over fusion surgery are a reduced incidence of adjacent disc disease and increase spinal mobility arising from maintenance of joint flexibility. However these outcomes may only become apparent in the longer term and have yet to be demonstrated in clinical studies.
- Consequently, there are not yet any proven benefits for cervical disc replacement compared with other established surgical interventions for degenerative disc disease.
- Cervical disc replacement surgery is a costly intervention and is about £2,300 more costly than alternative fusion surgery.
- On the basis of that efficacy of the treatment options are equivalent, cervical disc replacement does not represent a cost-effective treatment option.
- Cervical disc replacement surgery is already undertaken within NHS North East and is estimated to be provided to about 70 patients per annum between two centres. Total treatment numbers and the ratio of disc replacement to fusion surgery demonstrate considerable variation between centres although this could be due to clinical cases and specialities.
- NHS North East appears to exhibit a greater rate of cervical disc replacement to fusion surgery compared with the English NHS as a whole.

Introduction

Prosthetic intervertebral cervical disc replacement has been positively appraised by NICE for degenerative cervical disc disease. ¹

NICE Interventional Procedure Guidance No. 314:

Prosthetic intervertebral disc replacement in the cervical spine

- Current evidence on the efficacy of prosthetic intervertebral disc replacement in the cervical spine shows that this procedure is as least as efficacious as fusion in the short term and may result in a reduced need for revision surgery in the long term. The evidence raises no particular safety issues that are not already known in relation to fusion procedures. Therefore this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.
- This procedure should only be carried out in specialist units where surgery of the cervical spine is undertaken regularly.
- NICE encourages further research into prosthetic intervertebral disc replacement in the cervical spine. Research outcomes should include longterm data on preservation of mobility, occurrence of adjacent segment disease and the avoidance of revision surgery.

Alternative treatment options include conservative and non-invasive treatments such as rest, physiotherapy, analgesic drugs (e.g. 'painkillers'), and local injections. ²

Surgical intervention is reserved for those patients in whom permanent neurological damage is thought likely, or when conservative management fails to resolve symptoms. The current standard treatment is surgical decompression of the nerve root or spinal cord by cervical discectomy with or without vertebral body fusion using iliac crest autograph or a variety of medical spacers devices ('cages'). ²

It has been suggested that following cervical discectomy with or without fusion, the lack of natural movement of the immobilised (fused) intervertebral joint may increase the mechanical load applied to adjacent joints and this could potentially accelerate their degeneration. On the basis of this hypothesis, artificial intervertebral discs have been developed with the aim of acting as a functional prosthetic replacement for the damaged disc. Replaced disc may help to reduce abnormal loading patterns on adjacent joints, and, consequently, the risk and speed of degeneration in adjacent levels. However there is uncertainty regarding the natural history of degenerative disease in adjacent discs. ²

Artificial intervertebral discs have been developed to act as a functional prosthetic replacement unit for intervertebral units in much the same way as prostheses have been developed for a variety of joints such as the hip or knee. The intention is to maintain movement at the spinal joint in the hope of reducing the need for subsequent operations. There are a number of different prosthetic discs available as approved medical devices. They share common design features and typically consist of two metal plates which are fixed to the upper and lower vertebrae either side of the affected disc. The two metal plates are commonly separated by a plastic insert.² More than one disc can be replaced during the same procedure.¹

The operation is carried out under general anaesthesia. The patient is placed in the supine (lying-down) position and the anterior (front) cervical spine is exposed. After standard decompression of the neural elements, an artificial disc prosthesis is placed between the vertebrae and anchored to them.²

Replacement of a failed intervertebral disc using a functional prosthesis aims to offer the same benefit as decompression while preserving motion at the operated segment thereby reducing abnormal stresses on adjacent disc levels associated with fusion procedures.²

The NHS North East Treatment Advisory Group has been requested to consider the cost effectiveness of cervical disc replacement (CDR) compared with other surgical treatment options for degenerative cervical disc disease. Spinal surgery and related interventions fall under the specialised services definition set³ although current commissioning arrangements within NHS North East may not reflect this (i.e. such services may still be commissioned by individual primary care organisation clusters as opposed to the North East Specialised Commissioning Team).

Cost analysis

This cost analysis is conducted from the perspective of NHS commissioning bodies and not from a cross-sector NHS or societal perspective.

Costs include VAT at 20% where applicable unless otherwise indicated.

This analysis also uses an underlying assumption that CDR is a homogenous treatment and therefore does not distinguish between the specific devices available. This assumption is generally supported by the evidence described in an evidence overview published by NICE in 2009² and a more recent systematic review.⁴

This analysis will also assume that all equipment and devices required for the respective procedures are included in the payment-by-results tariff for the intervention. This is supported by the latest version of the tariff⁵, which does not list any spinal devices or associated equipment as tariff excluded, and by information published on the website of the British Association of Spine Surgeons (BASS) regarding the costing of tariff-based spinal surgeries.⁶

Table 1 highlights the cost of substitute treatments based on information provided by BASS.⁶ The most common alternative treatments to CDR would most likely be anterior cervical discectomy with fusion.² Discectomy plus fusion is less costly than CDR by about £2,300 regardless whether treating a single intervertebral joint or multiple joints. Cervical laminoplasty may only be appropriate in a small number of cases but is still less costly than CDR. Instrumented fusion is also likely to be less commonly used. This intervention is more costly than CDR by £700 at one level (single joint) and £4,200 for more than one level (multiple joints). Revision of cervical fusion is the same cost as CDR. There is no cost specified for revision of CDR and it is assumed therefore that CDR revision would cost the same as the initial treatment if the disc prosthesis was to be replaced with another disc prosthesis, or the patient would receive a different treatment, for example cervical discectomy with fusion.

The NICE evidence overview utilised evidence from three randomised study populations of CDR vs. fusion surgery, two non-randomised controlled studies (both comparing single vs. multiple level CDR), one case series and one safety case report. The three randomised studies included in the NICE evidence overview originate from four publications and are all included in a recent systematic review of seven studies. Two of the studies in the systematic review appear to relate to the same population with results reported separately for efficacy and safety outcomes. Therefore the systematic review actually utilises the results from six study populations (total n = 1,835, range per study 49 to 625).

Key outcomes from the systematic review are summarised in table 2. The review did not contain a meta-analysis of any outcome. The review authors concluded:

‘Evidence from randomised controlled clinical studies has shown that after two years CDR is equal to fusion surgery in terms of outcomes and complications. In the context of limited resources, we recommend to additionally analyse the costs of the two technologies and to propose the technology that shows lower net costs until new research data is available.’

No relevant published cost analyses of CDR were identified.

It is not clear what the annual NHS North East patient population would be for CDR or indeed the alternative procedures. NHS Hospital Episode Statistics (HES) data ⁷ indicates that in all English NHS hospitals in 2009-10 there were about 3,300 interventions relating to ‘primary decompression operations on cervical spine’ and just over 100 for ‘revisional decompression operations on cervical spine’ indicating a revision rate of about 3%, broadly in-line with that observed in the fusion treatment arms of the systematic review. The former description also includes 1,112 episodes of ‘primary anterior decompression of cervical spinal cord and fusion of joint of cervical spine’ (i.e. discectomy plus fusion). This compares with 377 episodes of ‘prosthetic replacement of cervical intervertebral disc’ representing a ratio of discectomy plus fusion to CDR of about 3:1. Data from the North East Specialised Commissioning Team for the year 2010-11 indicates 101 episodes for discectomy plus fusion and 70 for CDR, a ratio of about 3:2. ⁸ However the NESCT data set may not be complete as some activity is probably charged directly to primary care organisations and will therefore not appear on the NESCT data set. At a price difference of £2,300 for CDR compared with discectomy plus fusion, the 70 cases of CDR represent an incremental cost of £161,000. The number of 70 cases over 12 months represents about six patients per NHS North East PCT per annum, or six per month from the NHS North East region. Again it should be noted that these figures may not represent the total patient population for the region. Based on a per capita calculation of the NHS North East population relative to the whole of England population, the expected number of episodes would be 56 episodes of discectomy plus fusion and 19 episodes of CDR. Again, caution should be expressed in making direct comparisons as differences may exist in the nature of coding for the same activity. Analysis of the NESCT data for 2010-11 reveals that the majority of procedures are performed at one centre with a ratio of fusion to CDR of almost 1:1, with the other centre performing only about one-quarter of all procedures at a ratio of 5:1. These differences may reflect underlying levels of expertise or specialism within each centre. ⁸

Table 1. Cost of substitute procedures for degenerative cervical disc disease ^{5,6}

Intervention	PbR tariff value		Difference with CDR	
	One level	> 1 level	One level	> 1 level
'Basic' discectomy (e.g. laser)	£4,534	£4,534	£3,430	£5,779
Cervical laminoplasty	£5,701	£5,701	£2,263	£4,612
Anterior cervical discectomy with fusion	£5,701	£7,964	£2,263	£2,349
Instrumented fusion *	£8,696	£14,553	- £732	- £4,240
Revision of cervical fusion	£7,964	£10,313	Not applicable	
Cervical disc replacement	£7,964	£10,313		

PbR tariff value includes 32% increase for specialised services with further 2.9% market forces factor increase ⁵

*: One level value based on posterior fusion only; > 1 level value based on anterior plus posterior fusion

Table 2. Summary outcomes of systematic review of randomised studies of CDR vs. cervical fusion ⁴

Outcome	CDR	Fusion	Comment
Consistently statistically significant difference			
Overall success* at 24 months	68 to 73%	63 to 83%	About 10% greater with CDR. Three studies
Number of days until return to work	61 days	About 45 days	Difference of about 15 days in favour of CDR, data from two studies
Differences where significance is variable, consistently non-significant or inconsistently reported			
Neurological success **	About 92%	84 to 90%	Three studies
Neck disability index (range 0 to 50); > 15 point improvement at 24 months	80 to 86%	About 79%	Two studies
Neck pain on 100 point visual scale, 24 months	Reduced by about 55 points	Reduced by about 45 points	
Arm pain on 100 point visual scale, 24 months		Reduced by about 48 points	
Overall quality-of-life (any improvement from baseline using short form 36), 24 months	79%	70%	One study (p = 0.09)
Employment rate at 24 months	75 to 83%	74 to 80%	Typically, about 2% greater with CDR. Three studies
Serious adverse events	2 to 13%	3 to 21%	Two studies
Implant-related serious adverse events	About 3%	5 to 7%	
Operation-related events	15%	15%	Only one study reported
Symptomatic adjacent disc disease	0 to 1%	1 to 15%	Three studies reported, all greater with fusion
Secondary surgical procedure	2 to 5%	3 to 9%	Four studies reported, all greater with fusion

* Overall success defined as ≥ 15 point gain in neck disability index, no serious adverse events or additional procedures, and maintenance or improvement of neurological features.

** Neurological success defined as maintenance or improvement in sensory, motor and reflex functions.

Points to consider

Cervical disc replacement therapy for degenerative cervical disc disease has been robustly evaluated compared with cervical discectomy plus fusion surgery in a number of randomised studies with follow-up of up to three years. It has demonstrated non-inferiority with respect to numerous outcomes and provides an acceptable risk:benefit ratio. Consequently, CDR has been positively appraised by NICE. It is to be considered principally as an alternative to, or substitute for, cervical discectomy plus fusion.

CDR is a costly procedure and based on tariff coding guidelines is about £2,300 more costly than an alternative discectomy plus fusion procedure.

CDR has only consistently demonstrated significantly superior efficacy compared with discectomy plus fusion in two outcomes: the first being also the primary outcome for many of the studies; a composite outcome of uncertain clinical value. The second relates to the length of time patients wait to return to work, which is of unknown relevance to a UK setting and, across two large studies, demonstrated a benefit of about 15 days. All of the randomised comparative studies were designed as non-inferiority studies and had not been designed to demonstrate superior efficacy. Most other outcomes for the two interventions demonstrated little if any difference between treatment groups.

The expected benefits of CDR over discectomy plus fusion may not be apparent until many years post-treatment, if they exist at all, and currently represent only a clinical hypothesis. There is an absence of data which demonstrates, for example, reduced incidence of adjacent disc disease and the associated consequences (e.g. need for additional surgery, pain, immobility, etc).

The volume of NHS North East patients treated with CDR in the past few years is relatively low. However the relative volume of patients receiving CDR compared with other surgical interventions for degenerative disc disease appears to be greater within NHS North East compared with data for the whole of England. Substantial differences in patient volumes and ratios of discectomy plus fusion to CDR appear to exist within NHS North East treatment centres.

On an assumption that CDR is clinically equivalent to discectomy plus fusion, CDR does not represent a cost-effective intervention on the basis of the current clinical evidence (i.e. there are no important proven clinical benefits of CDR over discectomy plus fusion, yet the cost of CDR is greater).

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