NHS England

Clinical Commissioning Policy: Cervical Disc Replacement for Cervical Radiculomyelopathy

Reference: NHS England D14/P/a

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Description	NHS England will routinely commission this specialised treatment in accordance with the criteria described in this policy.
Cross Reference	
Superseded Docs (if applicable)	
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Document Status

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1 Executive Summary

Policy Statement

NHS England will routinely commission cervical disc replacement for cervical radiculomyelopathy in accordance with the criteria outlined in this document.

In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

NHS England has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. NHS England is committed to fulfilling this duty as to equality of access and to avoiding unlawful discrimination on the grounds of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, NHS England will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which NHS England is responsible, including policy development, review and implementation.

Plain Language Summary

Selected patients with nerve or spinal cord entrapment or compression can benefit from surgery to the neck (cervical spine). The standard operation is to insert a

static cage into the cervical spine following decompression of the neural tissue. This procedure ultimately results in that segment of the spine becoming fused and rigid. The fusion operation has an excellent track record of success.

Cervical Disc Replacement (CDR) is a relatively recent development and is considered as an alternative to fusion. It is a procedure in which a mobile disc is placed into the neck, rather than a static cage. The arguments for CDR are that it maintains closer-to-normal movement in the neck with improved clinical and radiological outcomes and potentially fewer requirements for future surgery, either at the operated level or at levels next to the operated level.

CDR should be used only in accordance with clinical eligibility criteria, in carefully selected patients in whom symptoms cannot be adequately controlled with conservative measures.

Information on the outcome of treatments for these patients will be collected and considered when this policy is reviewed.

2 Introduction

This policy considers the use of Cervical Disc Replacement (CDR) or Disc Arthroplasty for patients with cervical radiculopathy (nerve compression in the neck) or cervical myelopathy (spinal cord compression in the neck). It reviews the evidence for the use of the device and the patient selection involved when deciding which patients are appropriate for the procedure.

3 Definitions

As the cervical spine ages it develops wear and tear (degenerative) changes. Associated with this degeneration are changes to the cervical disc, which is the part of the cervical spine in between the vertebral bodies (bones in the spine). In some cases this cervical disc degeneration can lead to neurological symptoms and signs and neck pain.

The cause of the neurological symptoms related to the pathology of the disc space is neural compression, either from a soft disc prolapse or osteophytic (bony) compression or both. Either the spinal cord or the nerve roots (or both) may be compressed leading to myelopathic (relating to spinal cord) or radiculopathic (relating to nerve root) symptoms and signs. The causes of neck pain are less clear but may be related to instability, loss of normal neck alignment, degeneration of the facets (joints at the back of the spine) or compression of posterior nerve roots supplying the neck musculature (posterior rami).

When neural compression occurs, and if conservative treatment (including medication and targeted local injections) fails, the management consists of surgical decompression, often performed through the front of the neck. The pathological disc prolapse or ostephytes are removed and the neural tissue decompressed. The standard operation for over 60 years has been the anterior cervical discectomy and fusion (ACDF). In this operation the disc is removed and replaced with either the patient's own bone, or more latterly, a synthetic cage with bone graft, or substitute inserted into its centre. This is performed to allow the vertebral body above and below the disc space to fuse together with a bone bridge. Mobility at this segment of the spine is eliminated.

There is evidence that, since the ACDF operation removes mobility in that segment of the spine, the adjacent segments of the spine develop hypermobility with an associated increased stress and intradiscal pressure. The concern is that this increase in stress leads to greater adjacent-segment degeneration and recurrent symptoms. However the evidence is conflicting and some studies have suggested that adjacent-segment degeneration is not linked to the fusion level.

4 Aims and Objectives

This policy aims to:

1. Determine if CDR is clinically effective in patients with cervical radiculopathy and/or cervical myelopathy compared with anterior cervical fusion.

2. Determine if CDR is cost-effective in patients with cervical radiculopathy and/or cervical myelopathy compared with anterior cervical fusion.
3. Determine if there are any sub-groups for whom CDR is clinically effective in patients with cervical radiculopathy and/or cervical myelopathy compared with anterior cervical fusion.

5 Epidemiology and Needs Assessment

Cervical degeneration and disc disease is a common condition that causes significant morbidity in patients both of working age and into older age. The symptoms can be extreme in terms of radicular pain (pain in the arm) and can threaten spinal cord function, leading to poor balance and dysfunction of gait and hand function (myelopathy).

Treatment for radiculopathy varies from medical management with neuropathic painkillers, to targeted local steroid injections to decompressive surgery. Treatment for progressive myelopathy is surgical decompression and conservative measures are considered ineffective. Surgery in the form of ACDF is a proven, effective treatment in the relief of radiculopathy and in the prevention of progressive myelopathy.

Cervical disc replacement is intended to treat neurological symptoms and neck pain associated with degeneration of the cervical spine in a similar fashion to ACDF. The devices were initially developed and implanted in the 1990s. The advantage of CDR is that it achieves neural decompression via exactly the same approach as an ACDF but with the addition of preserved motion at the operated level. The theoretical advantage of this is that there will consequently be less adjacent segment stress, intradiscal pressure and therefore degeneration, resulting in fewer second operations to address the pathological consequences of that degeneration.

The operations themselves are technically very similar, the only notable difference being the type of implant used. Increased time is spent in placement of the arthroplasty device and therefore operative time is marginally increased overall with the CDR but this is not likely to be significant and is in the order of minutes.

6 Evidence Base

NICE issued guidance in May 2010 stating that the current evidence shows that this procedure is at least as efficacious as fusion in the short term and may result in a reduced need for revision surgery in the long term. There were no particular safety concerns that were not already known in relation to fusion procedures.

Luo demonstrated in his meta-analysis that at 24 months after a one level CDR, the results were superior to fusion in terms of neurological success, secondary surgical procedures, visual analogue scale pain scores and range of motion.

A review by Mummaneni looking at the long-term results for single-level CDR vs fusion included two FDA studies with follow-up periods of greater than 48 months. The Bryan and the Prestige discs were the implants that were studied. Patients in the CDR group showed a higher rate of overall success in terms of Neck Disability, neck and arm pain scores and SF-36 physical component scores compared to the fusion group. In addition the rate of adjacent segment disease was lower in the CDR
group at 60 months (2.9% vs 4.9%). Normal segmental motion was maintained in the CDR group and the rates of revision and supplemental fixation surgical procedures were lower in the CDR group.

A paper by Burkus et al published ahead of print reported on the seven-year follow- up of the Prestige cervical disc. This randomised trial reported that disability index scores, neck pain, quality of life and rates of maintenance or improvement in neurological status were better after cervical disc replacement. Cumulative rates of repeat surgery at the index and at adjacent levels were lower in the disc replacement group than the fusion group.

There is contrary evidence that suggests that adjacent segment degeneration (ASD) is not altered by CDR. In the 48-60 month follow-up meta-analysis by Riew, looking at the Prestige ST, Prodisc-C and Bryan devices, the conclusion was that both

ACDF and CDR appear to have similar rates of ASD. This finding is repeated in the paper by Verma.

The follow-up so far (5-7 years) is insufficient to measure ultra-long term differences in outcomes and revision rates between ACDF and CDR. If similarities are sought with large joint arthroplasties it is evident that the results and complications may take decades to appear. However, in general, CDR is undertaken on patients with a much lower average age than large joint arthroplasties so there is an even greater emphasis on longevity of the implant with disc replacement. In addition, the comparison between large joint arthroplasty and CDR varies in a number of important ways. First, there is a gold-standard alternative in cervical surgery, namely fusion. Secondly, continued motion may lead to overgrowth of bone and tissue into neural elements, so-called heterotopic ossification (effectively the disc replacement fuses); this is not a concern in joint replacement surgery. Thirdly, a cervical disc is anatomically very different to a hip or knee joint. Answers to the long-term concerns relating to longevity of the disc are unknown. In a cost-effectiveness comparison study published in 2013, Qureshi et al used a time-span of 20 year life expectancy for the discs. However, the true lifespan of these implants is not known, nor the consequences or appropriate management of wear and failure in the future. Further surgery may ultimately be required. What form that salvage surgery would take is not currently in mainstream discussion.

In addition the long-term safety of these devices is currently unknown with currently unresolved questions surrounding complications such as erosion and peri-prosthetic loosening, toxicity of the prosthesis, biocompatibility, heterotopic ossification and implant migration or subsidence. Again, salvage procedures for such complications could conceivably be significant, costly and not without risk.

The operating time for CDR is initially expected to be considerably longer that ACDF for a surgeon new to the technique, however this can be expected to fall as the surgeon progresses up the learning curve, which is likely to be relatively short.

Ultimately there are likely to be marginally increased operating times associated with CDR since exact placement of the device is more critical than in fusion. This increased time is not thought to be clinically important. Surgeons experienced in disc replacement are reporting negligible differences in operative time therefore this will have no impact on theatre resource costs. The duration of hospital stay and blood loss are similar between the procedures. (Luo)

Cost-effectiveness has been addressed by a paper from the United States. Qureshi et al's model indicated that cervical disc replacement yielded 3.94 QALYs compared with 1.92 from cervical fusion. Disc replacement dominated cervical fusion, being both more effective and less expensive.

Care must be taken when relying on data from other healthcare systems and may not be applicable to the National Health Service. NHSE pays more for CDR than for fusion. This would be reflected in experience since in the UK fusion is carried out with a relatively inexpensive cage and bone graft substitute whilst a CDR costs on average £1000 - £1500 more. Therefore, in terms of implants alone, CDR is the more expensive procedure. When potential increased theatre time is included the costs increase further. Comparative data for QALYs in England is not available.

7 Rationale behind the Policy Statement

Many of these devices have undergone study in the United States for the purpose of FDA approval. The vast majority have looked at single-level CDR and only the Mobi- C (by LDR) has been approved for two-level use (Davis). All of the studies have looked for non-inferiority and as a result many have been approved.

The FDA has approved the following discs for surgery at 1 level: Bryan (Medtronic)
Prestige ST (Medtronic)

Prestige
LP(Medtronic)
Secure-C (Globus)
Prodisc-C (DePuy
Synthes) Mobi-C (LDR)
There are three main issues to consider with regards to effectiveness:

Is the rate of adjacent segment degeneration different?
Is there clinical
effectiveness? Is it safe?

It is evident from the literature review and from the FDA studies that the devices are successful in satisfying non-inferiority criteria and that in many cases appear to have superior results when compared to ACDF. Long-term (>7 year) safety and effectiveness is unknown.

8 Criteria for Commissioning

This policy has been agreed on the basis of NHS England's understanding of the likely price of care associated with enacting the policy for all patients for whom NHS England has funding responsibility, as at the time of the policy's adoption. Should these prices materially change, and in particular should they increase, NHS England may need to review whether the policy remains affordable and may need to make revisions to the published policy.

CDR may be indicated for the following diagnoses, in adults over the age of 18, with qualifying criteria, where appropriate. All patients must be discussed in a regional spinal MDT where the indications and contra-indications should be checked.

Treatment can only proceed when the agreement of the regional spinal MDT (when established).

- **Radiculopathy** related to 1 or 2 level degenerative disease (either from herniated disc or spondylotic osteophyte) from C3/4 to C6/7 with or without neck pain that has been refractory to medical or non-operative management.

- **Myelopathy or myeloradiculopathy:** related to 1 or 2 level degenerative disease (either from herniated disc or spondylotic osteophyte) from C3/4 to C6/7 with or without neck pain that is severe enough to warrant surgical intervention.

CDR is NOT clinically indicated in the following scenarios:

- Neck pain only without radiculopathy or myelopathy
- Symptomatic multi-level disease (3 or more levels) that would require CDR
- Osteoporosis or osteopenia(including a medical condition requiring long-term use of steroids)
- Instability defined as: translation greater than 3mm difference between lateral flexion-extension views at the symptomatic level *or* 11 degrees of angular difference between lateral flexion-extension views at the symptomatic level
- Severe spondylosis defined as: greater than 50% loss of disc height *or* bridging osteophytes *or* absence of motion on flexion-extension views at the symptomatic site
- Severe facet joint arthropathy
- Ankylosing spondylitis
- Sensitivity or allergy to implant materials
- Previous surgery at the involved level
- Rheumatoid arthritis
- Fracture new or old with anatomical deformity
- Ossification of the posterior longitudinal ligament
- Malignancy active in the cervical spine
- Infection active at the site of the proposed implant or systemic

The OPCS code for CDR is V361 which maps to HRG HC02 for single level and HC01 for two or more levels.

9 Patient Pathway

Patients with radiculopathy of greater than 6 weeks who are refractory to medical or non-operative treatment or patients with myelopathy or radiculomyelopathy of any duration severe enough to warrant surgery.

10 Governance Arrangements

Currently CDR is performed in small numbers throughout England and Wales. The vast majority of anterior cervical surgery carried out annually is the fusion surgery. Secondary User Service (SUS) data for 2013/14 reveals that 579 patients had CDR versus over 6,000 who underwent a fusion operation.

The NICE guidelines from 2010 advised that the procedure should only be carried out in specialist units where surgery of the cervical spine is undertaken regularly and encouraged further research including the collection of data on preservation of mobility, occurrence of adjacent segment disease and avoidance of revision surgery.

Cervical disc replacement should only considered under Specialised Commissioning arrangements and therefore only be carried out in units that are appropriately commissioned.

All patients must be discussed in a regional spinal MDT (when established) where the indications and contra-indications should be checked.

11 Mechanism for Funding

NHS England is responsible for funding the surgical procedure which is currently included in National Tariff. This is part of the scope of Complex Spinal Surgery.

12 Audit Requirements

Specialised Commissioning arrangements include the mandatory recording of patients undergoing CDR into a Spinal Registry. This should include a visual analogue pain score and EQ-5D.

The uncertain longevity and long-term outcomes from CDR make long-term data collection a vital requirement for the ongoing use of these devices. Clinical and radiological follow-up to five years is recommended as for total hip and knee replacements.

13 Documents which have informed this Policy

National Institute for Health and Care Excellence. Prosthetic intervertebral disc replacement in the cervical spine. (IPG 341). London: NICE 2010.

Cervical artificial disc replacement: defining appropriate coverage positions. North American Spine Society 2014.

NHS England D14/S/a: NHS standard contract for complex spinal surgery (all ages).

14 Links to other Policies

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

15 Date of Review

This policy will be reviewed in 2017 unless information is received which indicates that the proposed review date should be brought forward or delayed.

References

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6. Qureshi SA, McAnany S, Goz V et al. Cost-effectiveness analysis: comparing single- level cervical disc replacement and single-level anterior cervical discectomy and fusion. *J Neurosurg Spine 2013; 19: 546-54.*
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