



Lumbar infusion test for the investigation of normal pressure hydrocephalus

Interventional procedures guidance Published: 25 June 2008

www.nice.org.uk/guidance/ipg263

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

1 Guidance

1.1 Current evidence on use of the lumbar infusion test for the investigation of normal pressure hydrocephalus (NPH) raises no major safety concerns. In terms of efficacy, some clinicians find the procedure helpful in the investigation of NPH. Therefore, it may be used with normal arrangements for clinical governance, consent and audit.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Normal pressure hydrocephalus (NPH) is an accumulation of cerebrospinal fluid (CSF) in and around the brain and spinal cord, which can cause symptoms such as abnormal gait, urinary incontinence and impaired cognitive function. It usually occurs in the elderly, and is characterised by enlarged cerebral ventricles but with normal CSF pressure on lumbar puncture.
- 2.1.2 Conventionally, NPH is treated by the surgical insertion of a shunt that diverts CSF from the brain (or lumbar spinal sac) to the abdominal cavity, where it is then absorbed into the circulation. This may relieve gait disturbance, help prevent permanent loss of cognitive function and halt the progression of other symptoms.
- 2.1.3 It is important to diagnose NPH correctly as shunting may be unnecessary (and potentially harmful) when symptoms are caused by conditions other than NPH,

such as degenerative cerebral atrophy. Diagnosis of NPH based on clinical and radiological signs alone can be problematic, so additional testing may be required. Conventional tests include temporarily reducing the volume of CSF by a large-volume lumbar puncture test (also known as a spinal or CSF tap test) or a period of external CSF drainage, then assessing the effect on the patient's symptoms. Clinical improvement (which may be sustained for several days or weeks) indicates that the patient may benefit from shunting; however, the tests are not completely reliable.

2.2 Outline of the procedure

- The lumbar infusion test (also known as the intrathecal infusion test) aims to assess the adequacy of CSF absorptive capacity by the administration of a fluid challenge. An abnormal and sustained rise in CSF pressure in the face of the challenge is indicative of reduced absorptive capacity and, therefore, of NPH.
- 2.2.2 Under local anaesthesia, a needle connected to a pressure monitor is inserted through the skin of the lower back and into the lumbar spinal sac. CSF pressure is then recorded and monitored as fluid is infused. A common measure used to determine which patients are most likely to benefit from shunt surgery is the resistance to CSF outflow (measured in mmHg/ml/min), which is calculated from the pressure gradient (mmHg) during a constant infusion (ml/min). Alternatively, the plateau pressure (measured in mmHg), at which a balance between CSF absorption and infusion is reached, may be used. Various numerical cut-off points in the test have been used to assess the likelihood that a given patient may benefit from subsequent shunt surgery.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more details, see the <u>overview</u>.

2.3.1 A case series of 101 patients, which assessed the ability of CSF outflow

resistance (measured by the lumbar infusion test) to predict the response to shunting, reported that 92% (33 out of 36) of patients with a CSF outflow resistance above 18 mmHg/ml/min (n=36) had improved scores after shunting (measured on a neurological outcome scale incorporating measures of gait and dementia). However, two thirds of patients with CSF outflow resistance below 18 mmHg/ml/min (n=59) also showed some clinical improvement (absolute numbers not given).

- In a case series of 83 patients, 80% (66 out of 83) met the criteria for shunt surgery, using a threshold of 12 mmHg/ml/min or above for CSF outflow resistance. Clinical improvement (based on a consensus between the neurologist and the patient) was reported in 59% (39 out of 66) of these patients at a minimum follow-up of 1 year.
- In a second case series of 83 patients, 30 underwent lumbar infusion testing alone and 19 of these patients (63%) met the criteria for shunt surgery (using a threshold of 16 mmHg/ml/min or above for CSF outflow resistance). Of those who underwent shunt surgery, 90% (17 out of 19) improved clinically after surgery.
- In a case series of 68 patients who underwent both a lumbar infusion test and a CSF tap test, 69% (47 out of 68) had either a positive CSF tap test or a positive lumbar infusion test (plateau pressure 22 mmHg or above) and underwent shunt surgery. Clinical improvement was reported in 38 patients after surgery, of whom 84% (32 out of 38) had a positive lumbar infusion test and 42% (16 out of 38) had a positive CSF tap test.
- A case series of 200 patients, who underwent shunt surgery following a lumbar infusion test, reported on 155 patients who were followed up for 7 months. Patients with a CSF outflow resistance greater than 15 mmHg/ml/min had significantly more favourable clinical outcomes than patients with a lower CSF outflow resistance (p=0.01).
- 2.3.6 The Specialist Advisers considered key efficacy outcomes to include clinical or functional outcomes of CSF diversionary procedures.

2.4 Safety

- 2.4.1 Five of the six reports described no adverse events related to the lumbar infusion test. In another case series of 200 patients who underwent the lumbar infusion test, 19% of the 107 patients with a positive test result (pathologically increased CSF resistance) reported headache after the test (absolute number not reported) and 2% (2 out of 107) were reported to have developed meningism without signs of inflammation in the CSF.
- 2.4.2 The Specialist Advisers considered theoretical adverse events to include infection, postprocedure headache, bleeding, localised pain and nerve root damage.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the <u>overview</u>.

Information for patients

NICE has produced <u>information for the public on this procedure</u>. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

ISBN: 978-1-4731-6280-8

Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.