This treatment is being used for children with severe spasticity due to conditions such as cerebral palsy.

Intrathecal injection of baclofen (Lioresal) is clearly denoted as ?Not recommended' for use in children in the British National Formulary([1]).

Baclofen was approved by the United States FDA, in 1996 for the use in Medtronic pumps, to treat "cerebral spasticity". Previously trials of up to 41 months had been undertaken and reported efficacy and safety in adults with spinal spasticity ([2]).

However, more than one study noted frequent complications: Ordia et al ([3]) reporting catheter-related problems occurring 19 times in 15 patients (out of 59 in the study), whilst Levin and Sperling ([4]) cited an "overall incidence of total complications" of 62% (24% with Infusaid pumps, 167% in Medtronic pumps).

However, these studies were both in the mid 90s, and the pump techniques and technology have improved somewhat since then.

In 1996, Albright ([5]) reported complications in around 20% of patients and infection necessitating pump removal in 5%.

In 1997, Armstrong et al ([6]) studied 12 children with a follow-up of 1-5 years. There were "favourable" results, although some central side effects.

There were 10 mechanical complications, local infections in 3 children and meningitis in 2. The authors concluded:

"Results demonstrate the potential value of continuous intrathecal baclofen infusion for the treatment of severe spasticity of cerebral origin.

However, this treatment can result in significant complications and more experience is required before the long-term benefits can be determined."

Rawicki's ([7]) paper in 1999 suggested that

"Long-term continuous infusion of intrathecal baclofen delivered via an implantable pump offers an effective method for dealing with otherwise intractable spasticity."

This emphasizes the point that cases in which this treatment is used are at the most severe end of the spectrum.

More recent studies have reported that baclofen administered intrathecally is effective in managing the spasticity associated with cerebral palsy. In 2000, Gilmartin and colleagues ([8]) studied this in 44 patients who were followed up for up to 43 months.

Adverse events occurred in 42 patients, although procedural/system problems were also reported as 59 events occurring in 30 patients. Adverse effects included hypotonia, seizures, somnolence and nausea/vomiting.

A study published in February of 2001([9]) evaluated the baclofen pump in treating spasticity in adolescents and adults with cerebral palsy. After one year, all the patients had some improvement.

The authors noted that the side effects common after an oral dose (drowsiness and confusion) were reduced by the spinal delivery of the drug. A recent small study ([10]) found that whilst the Ashworth scale showed a substantial decrease in spasticity in the upper and lower extremities at 6 months, there was no evidence of functional change.

Most treatment goals were at least partly achieved and carers reported that there were

"improvements in comfort, function, and ease of care".

However,

"During 80 recipient-years of pump operation, 153 treatment-associated adverse events occurred: 27 of these were device-related."

This sort of result again suggests that much closer attention should be paid to the longer-term effects of this type of treatment.

The Cochrane review in 2000([11]), cited 2 studies that had demonstrated a significant effect of intrathecal baclofen(ITB) in reducing spasticity due to spinal cord injury, but concluded, having reviewed several studies on the various antispastic agents, that

"There is insufficient evidence to assist clinicians in a rational approach to antispastic treatment for SCI. Further research is urgently needed to improve the scientific basis of patient care."

[1] BNF 40 September 2000 p.473

[2] Nance P, Schryvers O, Schmidt B, Dubo H, Loveridge B, Fewer D *Can J Neurol Sci* 1995 Feb; 22(1):22-9 Intrathecal baclofen therapy for adults with spinal spasticity: therapeutic efficacy and effect on hospital admissions

[3] Ordia JI, Fischer E, Adamski E, Spatz EL *J Neurosurg* 1996 Sep; 85(3):452-7 Chronic intrathecal delivery of baclofen by a programmable pump for the treatment of severe spasticity.

[4] Levin AB Sperling KB, *Stereotact Funct Neurosurg* 1995; 65(1-4):147-51 Complications associated with infusion pumps implanted for spasticity.

[5] Albright AL *J Child Neurol* 1996 Mar; 11(2): 77-83 Baclofen in the treatment of cerebral palsy.

[6] Armstrong RW, Steinbok P, Cochrane DD, Kube SD, Fife SE, Farrell K *J Neurosurg* 1997 Sep; 87 (3) :409-14 Intrathecally administered baclofen for treatment of children with spasticity of cerebral origin.

[7] Rawicki B. *J Neurosurg* 1999 Nov; 91(5):733-6 Treatment of cerebral origin spasticity with continuous intrathecal baclofen delivered via an implantable pump: long-term follow-up review of 18 patients.

[8] Gilmartin R *J Child Neurol* 2000; 15:71-77 Westport Newsroom 203 319 2700

[9] Meythaler et al *Archives of Physical Medicine and Rehabilitation* 2001; 82:155-161

[10] Campbell WM, Ferrel A, McLaughlin JF, Grant GA, Loeser JD, Graubert C, Bjornson K. *D ev Med Child Neurol*
2002 Oct;44(10):660-5 Long-term safety and efficacy of continuous intrathecal baclofen.

[11] Taricco M, Adone R, Pagliacci C, Telaro E *Cochrane Database Syst Rev* 2000; (2): CD001131 Pharmacological interventions for spasticity following spinal cord injury.