

COMPLICATIONS OF INTERSTIM® THERAPY: COMPARISON OF STAGED VERSUS TRADITIONAL IMPLANTATION

Hypothesis / aims of study

Although InterStim® (Medtronic Inc., Min. Minnesota) therapy was initially introduced as two staged procedure using percutaneous test stimulation, staged implantation is being performed more frequently after the introduction of a Tined® lead (a percutaneous implantable quadripolar lead). We compared staged implantation of Tined® leads versus the traditional implantation method utilizing percutaneous test stimulation to determine which method may be best at reducing complications.

Study design, materials and methods

All 31 patients with permanent InterStim® therapy at our facility between October 1999 and July 2003 were divided into a traditional implant versus a staged implant group based on their operative records. All patients in the traditional implant group had implantation of both a lead and a neurostimulator under general anaesthesia following the prior successful test stimulation. All patients in the staged implant group underwent implantation of a quadripolar lead to a sacral foramen under MAC (monitored anaesthesia care) for test stimulation, and then after a successful response, they underwent implantation of a neurostimulator on a later day for a chronic use. We compare the incidence of complications in these two groups retrospectively.

Results

There were 26 females and 5 males (averages age 47, range 17-83) who underwent permanent InterStim® implantation with an average follow up of 20 months (range 2-48). A total of 14 staged implantation were performed and 27 traditional implantation to the above 31 patients. The incidence of complications in each group is:

Complications	Staged (n=14)	Traditional (n=27)
Painful stimulation	1 (7 %)	4 (15 %)
Loss of efficacy	0	4 (15 %)
Infection	1 (7 %)	1 (4 %)
Pain at IPG site	0	1 (4 %)
Total	2 (14 %)	10 (38 %)

Interpretation of results

Staged implantation resulted in lower complication, especially related to painful stimulation and reproducible efficacy of symptoms resolution same as the test stimulation. In addition, a Tined lead made the implant procedure less invasive and better tolerated by patients.

Concluding message

Staged implantation demonstrated an overall lower complications rate compared to traditional implantation, especially related to painful stimulation. Staged implantation done under MAC with patient feedback appears to reduce the incidence of painful stimulation that can occur with InterStim® therapy.