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UPPER BUTTOCK PLACEMENT OF SACRAL NEUROSTIMULATOR RESULTS IN DECREASED ADVERSE EVENTS AND REOPERATION RATES

Aims of Study

Large multicenter clinical trials have established the therapeutic efficacy of sacral neuromodulation (SNS) for the treatment of refractory voiding dysfunction. In these trials, the sacral lead was placed in the prone position. The patient was then placed in the supine position, reprepped and redraped, and the neurostimulator was then placed in the lower abdomen. Noted in these trials was a moderately high rate of complications including a 33% surgical revision rate. 16% of the surgical revisions were performed due to pain at the site of the neurostimulator (IPG) in the abdomen and 6% of the devices were explanted due to infection. Over the last three years, upper buttock placement of the neurostimulator has become common. This study examines if upper buttock placement (UBP) of the IPG results in a decrease in complications related to infection and pain at IPG site.

Methods

Patient data from the Medtronic MDT- 103 post market study was analyzed and 31 patients from five North American sites who underwent UBP of IPG were compared to 225 patients who underwent abdominal placement of IPG. The rates and types of adverse events and percentage of patients requiring surgical intervention were compared. Specifically analyzed were the infection rates requiring device removal and pain at the IPG site. Follow up ranged from 15 to 46 months with an average follow up of 26 months.

Results

The demographics were similar with 4/31 (12.9%) male patients in the UBP group and 28/225 (12.4%) males in the abdominal group. Similarly the mean ages were 45.0 +/- 10.3 and 47.1 +/- 11.3. The efficacy rates for both groups were similar. The table below details the adverse events. The probability at 12 months of UBP patient requiring revision surgery is 7.9% compared to 19.8% for abdominal placement.

Adverse event	# total events	#surgical intervention	#total events	#surgical intervention	p (total events)	p (surgical intervention)
	UPB	UPB	Abdominal	Abdominal		
Pain at IPG site or infection	5/31	1/31	95/225	62/225	0.005	0.003
All adverse events	32/31	8/31	378/225	174/225	NS	NS

Conclusions

UBP results in statistically significant decreased rate of complications related to infection and pain at IPG site. This may be partly because the device does not become wedged between the anterior superior iliac spine and the costal margin and possibly because the upper buttock area is less sensitive. Also, because there is no change in patient position and the operative time is also shorter, the rate of infection is probably lower. UBP should be considered the standard for IPG placement. Only patients who are extremely thin and would have difficulty obtaining adequate soft tissue coverage over the neurostimulator should have abdominal placement.