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THE EFFECT OF OBESITY ON THE EFFICACY AND COMPLICATION RATE OF SACRAL NEUROMODULATION

Hypothesis / aims of study

The impact of obesity on the success of sacral neuromodulation and the rate of complications is unknown. We theorized that implanted sacral neuromodulators would be less effective and fraught with more complications in obese patients. <u>Study design, materials and methods</u>

We retrospectively reviewed Interstim (Medtronic, Minneapolis, Minnesota) sacral neuromodulators implanted by two surgeons from 2000 to 2010. A BMI of \geq 30 was considered obese, or any patient whose weight was >100 kg whose height was unknown. A BMI of <30, or a weight of <70 kg in a patient with unknown height was considered not obese. Patients were excluded if no weight was known, if their weight was between 70 and 100 kg and no height was known, or if they had a previous Interstim. Outcomes measured at most recent follow-up (mean 38 months) were as follows: failure of stage 1 (no permanent implant placed), implant functioning (including those that required reimplantation), implant ineffective but not removed, implant removed. Complications measured included chronic urinary tract infections, wound infection, pain, and malfunctions (nonfunctioning leads or early battery failure). We compared our two groups using the chi-squared test.

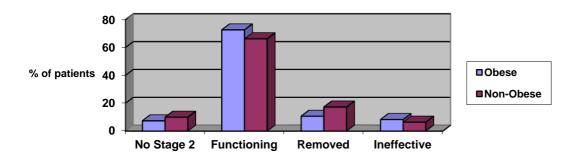
Devices were implanted in 281 patients ages 6-91 (mean 47), of which 50 were excluded for unknown height or weight (n=43) and for previous Interstim (n=7). No differences in age, gender (83% female), or race (96% white) were measured between the two groups. Of the 110 non-obese patients, 11 (10%) did not progress to stage 2, 73 (66.3%) had functioning implants, 19 (17.3%) were removed, and 7 (6.4%) were ineffective but had not yet been removed. Of the 121 obese patients 9 (7.4%) did not progress to stage 2, 88 (72.7%) had functioning implants, 13 (10.7%) were removed, and 10 (8.3%) were ineffective but had not yet been removed. None of these differences were statistically significant. Complications in non-obese/obese patients included chronic UTIs (4.5%/1.7%), wound infections (6.4%/6.6%), pain (10%/7.4%), and malfunctions (21.8%/9.1%), respectively. The only statistically significant difference was malfunctions (p=0.01).

Obese patients faired at least as well as non-obese patients after Interstim. In fact, they were less likely to experience a malfunction of their device perhaps due to increased adipose tissue acting as a buffer or fundamental neurologic differences in obese patients.

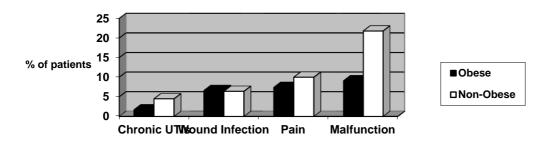
Concluding message

Interstim is a safe and effective procedure in the obese population.

Outcomes



Complications



Specify source of funding or grant	none
Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Internal Review Board of the University of Missouri - Columbia.
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	No