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URGENT-SQ IMPLANT IN TREATMENT OF OVERACTIVE BLADDER SYNDROME: NINE-YEAR FOLLOW-UP STUDY

Hypothesis / aims of study

Percutaneous Tibial Nerve Stimulation (PTNS) is an established therapy for Overactive Bladder Syndrome (OAB). Although effective, the treatment has drawbacks such as frequent clinical visits and discomfort at the site of needle insertion. The Urgent SQ™ implant was developed to reduce the amount of clinical visits and to make 'on demand' stimulation possible. The Urgent SQ™ consists of an electromagnetic pulse receiver with two platinum electrodes. The device is implanted close to the posterior tibial nerve near the ankle during a minimally invasive surgical procedure (fig 1). The receiver is activated by an external radiofrequency pulse generator. In 2003, eight patients with OAB received an Urgent SQ™ implant. All patients were PTNS responders and were followed up for one year after having received the implant [1]. Four out of eight patients had significant improvement of voiding parameters on voiding diary and quality of life (I-QoL) at one year. The aim of the current study was to assess safety and durability of the Urgent SQ™ implant and to evaluate how many patients were still actively using the treatment.

Study design, materials and methods

Of the eight patients (6 female, 2 male), one patient had the implant removed within the first year. Of the remaining seven patients, ankle X-ray images were taken at t=0, t=1 and t=9 year. At baseline, 1 and 9 years, patients filled in a voiding diary and questionnaires (incl. I-QoL) concerning treatment efficacy, durability and discomfort of the implant. During a clinical visit at 9 years, the patients were evaluated with a physical examination and a trial stimulation. If patients could not visit the department, X-rays were performed at a local hospital and patients were interviewed by phone during which a trial stimulation was performed.

Results

Six out of seven patients still had a sensory-motor response during a trial stimulation at 9 years (table 1). Three patients still used the Urgent SQ™ on a regular basis with I-QoL scores and voiding diary parameters that were comparable to one year follow up. The patients who weren't using the device, had various motives. The device was easy to handle. Little discomfort at the implant site was reported in one patient and one patient reported sporadic sensory reactions in the foot (table 2). There were no displacements or defects of the implants on X-ray. No local abnormalities were detected on physical examination or X-ray images.

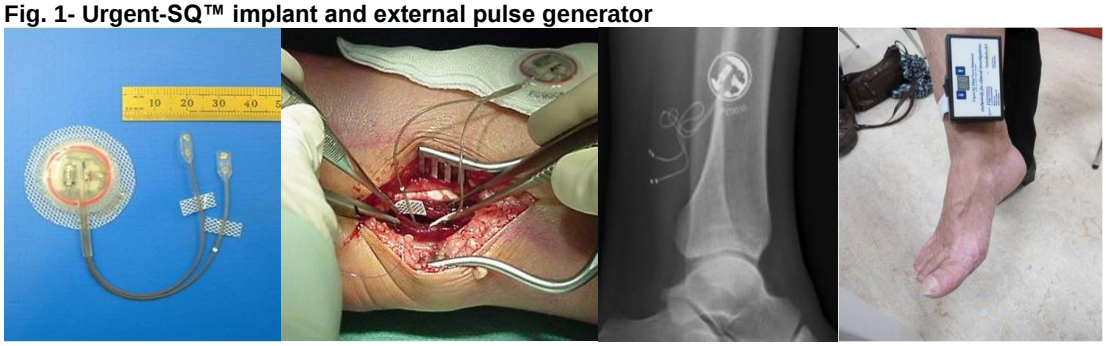
Interpretation of results

The implant has a long lifespan and is well tolerated by patients. There were remarkably few problems and discomfort reported by the patients.

Concluding message

After nine years of clinical experience, we demonstrated that the Urgent SQ™ is a safe therapy for OAB.

Fig. 1- Urgent-SQ™ implant and external pulse generator



The electrodes were placed adjacent to the PTN and connected to a subcutaneous receiver plate that was placed in at a higher position of the ankle, antero-medially.
Patients were instructed how to use the device and were systematically followed-up for 1 yr to evaluate efficacy and safety of the implant.

Table 1- Technical performance and efficacy of Urgent-SQ™ in 9-yr follow-up

Aspect	P1	P2	P3	P4	P5	P6[$]	P7	P8
Age (yr) on 2012	58	74	75	55	59	57	71	73
Sex	M	F	F	F	M	F	F	F
Duration in use (yr)	0	9	3	9	4	<1	9	<1

Motor response	+	+	-	+	-	?	+	$
Sensory response	+	+	-	+	+	+	+	$
Satisfaction handling Urgent-SQ™	+	+	+	+	+	+	+	$
Recommend treatment to close friend?	-	+	-	-	+	-	+	$

P = patient number, M = male, F = female; $ P8 was explanted during after 1-yr follow-up; $$ P6 dropped out of study < 1-yr follow-up

Table 2- Adverse events and radiological findings in 9-yr follow-up

Adverse event	P1	P2	P3	P4	P5	P6$$	P7	P8$
Sporadic spontaneous sensory response	-	-	-	-	-	+	-	na
Tenderness at implant site	-	-	-	+*	-	-	-	na
Pain at implant site	-	-	-	-	-	-	-	na
Inflammation/infection at implant site	-	-	-	-	-	-	-	na
Abnormal scarring / pigmentation**	-	-	-	-	-	-	-	na
Walking/mobility difficulties	-	-	-	-	-	-	-	na
Bone deformation/abnormalities	-	-	-	-	-	-	-	na
Implant displacement	-	-	-	-	-	-	-	na
Defects of implant integrity	-	-	-	-	-	-	-	na

P = patient number, na = not applicable; $ P8 was explanted after 1-yr follow-up;
$$ P6 dropped out of study < 1-yr follow-up; *P4 feels the implant on walking; ** A visible dermal scar was present in all patients (see Figures 3A-9A)

References

1. Implant-Driven Tibial Nerve Stimulation in the Treatment of Refractory Overactive Bladder Syndrome: 12-Month Follow-up. Neuromodulation. 2006 Apr;9(2):163-71.

Disclosures

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