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ORIGINAL ARTICLE

Minimal invasive electrode implantation for conditional stimulation of the dorsal genital nerve in neurogenic detrusor overactivity

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Study design: Experimental.

Objectives: Electrical stimulation of the dorsal genital nerves (DGN) suppresses involuntary detrusor contractions (IDCs) in patients with neurogenic detrusor overactivity (DO). The feasibility of minimal invasive electrode implantation near the DGN and the effectiveness of conditional stimulation to suppress IDCs at different amplitudes in spinal cord injury (SCI) patients with DO were studied.

Setting: Radboud University Nijmegen MC, The Netherlands.

Methods: In eight healthy volunteers, a needle electrode was inserted from both a medial and lateral-to-midline site at the level of the pubic bone. Electrode insertion was guided by the genito-anal reflex (GAR) evoked by electrical stimulation and by sensation to this stimulation. In eight SCI patients with DO, the bladder was repeatedly filled and emptied partially in between. Conditional stimulation using a needle electrode was applied when an IDC was observed at urodynamics. Different amplitudes were used during each filling. Control cystometry was carried out before electrode insertion and after stimulation.

Results: The lateral implant approach was preferred, as it was easier to manoeuvre the needle along the pubic bone and fixate the needle. In SCI patients, the electrode was positioned successfully, and IDCs were suppressed (range 1–6 IDC suppressions) with conditional stimulation at maximum tolerable amplitude, except for one patient. Stimulation was less effective at lower amplitudes. Stimulation lowered the intensity of bladder sensations concomitant with IDC.

Conclusion: The lateral-to-midline implant approach, in combination with GAR and sensation to stimulation, is feasible for electrode implantation near the DGN in SCI patients. Conditional stimulation effectively suppresses IDCs.

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Keywords: electric stimulation; neurogenic urinary bladder; overactive urinary bladder; prosthesis and implants; spinal cord injuries.

Introduction

Detrusor overactivity (DO) with concomitant high intravesical pressures during involuntary detrusor contractions (IDCs), especially sustained high pressures, is not only a risk factor for upper urinary tract deterioration but also for urinary incontinence. Incontinence increases the risk of complications in patients with spinal cord injury (SCI), such as pressure ulcers and poor wound healing. DO and/or detrusor external sphincter dyssynergia occurs in the majority of patients with suprasacral SCI (95%), and with combined suprasacral and sacral SCI (70%).[1]

Continuous electrical stimulation of the dorsal nerve of the penis or clitoris (dorsal genital nerves (DGN)) using surface electrodes increases bladder capacity in SCI patients.[2,3] However, the same can be obtained with conditional stimulation. With conditional stimulation, stimuli are only given when an IDC occurs. Conditional stimulation of the DGN suppresses IDCs and increases bladder capacity.[2,4] Pilot studies using ambulatory continuous or conditional stimulation of DGN in male SCI patients showed the feasibility to improve bladder capacity and continence.[5,6]

Application of surface electrodes is a major limitation for DGN stimulation in daily practice, because of electrode fixation and hygienic problems. Therefore, implanted electrodes for stimulation seem to be more practical. Goldman *et al.*[7] reported the results of a percutaneous implanted electrode in patients with urge incontinence. However, acute

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effects of stimulation and the feasibility of implantation in neurogenic patients without sensation to stimulation were not described.

The current study was conducted to determine the feasibility of minimal invasive electrode implantation near the DGN guided by electrical burst stimulation to evoke the genito-anal reflex (GAR) and sensation to stimulation in SCI patients. Other objectives were to obtain reference data for sensation thresholds and maximal tolerable amplitudes in SCI patients, and to investigate the acute effect of conditional pulse train stimulation of the DGN to suppress IDCs at different amplitudes using a percutaneous implanted electrode.

Materials and methods

Cadaver study

The approach to the DGN was practised in a male and female cadaver. Needle electrodes were inserted at several positions close to the pubic bone in the direction of the DGN. The DGN is a branch of the pudendal nerve. It appears from underneath the pubic bone after it leaves Alcock's canal (Figure 1). The DGN continues bilaterally on the dorsal aspect of the penis. The electrode was directed in between the base of the penis and the pubic bone along the suspected course of the DGN. The position of the electrode in relation to the pubic bone and the DGN was determined by dissections of the perineum.

Healthy volunteers

A study in four male and four female healthy volunteers was conducted to determine the feasibility of needle electrode insertion for stimulation. Volunteers were in the supine position. The skin was disinfected and sterile covered. Local anaesthetics were applied to the skin at the electrode suprapubic insertion site. A surface electrode was attached to the lower abdomen to serve as anode. A needle electrode (041828, Medtronic, Minneapolis, MN, USA) was connected as cathode. Both a midline insertion and lateral-to-midline insertion of the electrode were tried (Figure 1).

Sensation to stimulation and the GAR, monitored by anal palpation or anal pressure measurements using a pressure balloon catheter, were used to position the electrode near the DGN. Electrical stimulation (Medelec Synergy, Oxford Instruments Medical, UK) with pulse train stimulation (biphasic, rectangular, 20 Hz, pulse width 200 μs, 0–25 mA) was used in all eight volunteers, and burst stimulation (1 Hz, five pulses per burst, interpulse interval 4 ms, biphasic, rectangular, pulse width 200 μs, 0–10 mA) in four out of eight volunteers in additional sessions. Burst stimulation was used in these four patients, as GAR activation is more effective with burst stimulation compared with pulse train stimulation.[8]

SCI patients

Two complete and six incomplete SCI patients with IDCs at a bladder volume below 400 ml were included to verify the feasibility of electrode insertion and effect of conditional stimulation on IDCs. IDC was defined as an involuntary detrusor contraction not related to desired and voluntary voiding. Patients stopped anticholinergic treatment 5 days before the study date.

A comparable study setting and method for electrode insertion as in healthy volunteers were used (Figure 1). Detrusor and abdominal pressures were measured using water-filled catheters. An additional pressure balloon catheter was positioned anally to monitor anal contractions.

The bladder was emptied before needle electrode insertion. The skin of the insertion site was disinfected, sterile covered and locally anaesthetized. The electrode was inserted craniolaterally to the os pubis and directed inferiomedially over the pubic bone towards the base of the penis or clitoris, according to the lateral-to-midline approach in healthy volunteers (Figure 1).

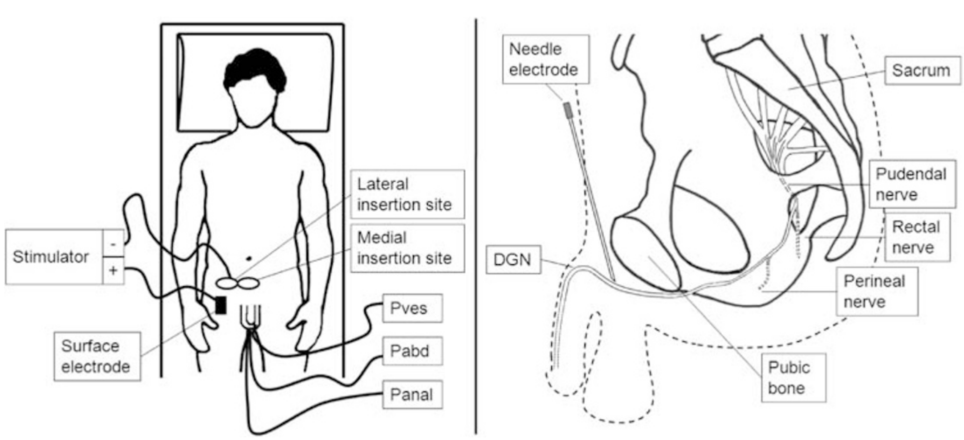

Figure 1 Study setting and electrode insertion. Healthy volunteers: lateral insertion site and medial insertion site of the needle electrode. SCI patients: a two-lumen catheter was used for bladder filling and recording of vesical pressure (Pves). Abdominal pressure (Pabd) and anal contractions (Panal) were recorded with a rectal and anal pressure catheter, respectively. The needle electrode (cathode) for stimulation of the DGN was inserted by the lateral approach suprapubically approximately 5–7 cm out of the midline and directed over the pubic bone towards the genital nerve for 7–9 cm. A surface electrode was used as anode.

The nearer the tip of the electrode to the DGN, the lower the threshold amplitude to elicit the GAR with burst stimulation. In addition, patients were asked to describe the site where they sensed stimulation. Two surface electrodes were used in patient 3 on the dorsal site of the penis, as the GAR could not be evoked using the needle electrode. In the last four patients, surface electrodes on the dorsum of the penis or the clitoris were used to test the presence of the GAR, and the resulting anal pressure responses before needle electrode insertion.

The needle electrode was repositioned until the minimum amplitude to elicit the GAR was comparable to the results in the study with healthy volunteers and sensation to stimulation was described in the glans penis or clitoris, and until repositioning of the electrode did not further improve these results. The inserted electrode was kept in this final position manually. The lowest pulse train stimulation that resulted in sensation to stimulation (sensation threshold) and maximum tolerable amplitude were determined in this final position by stepwise amplitude changes (0.05–2 mA). The sensation threshold was checked in between fillings with conditional stimulation, and the electrode was repositioned accordingly if there was a change in sensation to stimulation.

After needle insertion, the bladder was filled with water at room temperature at a filling rate of 20 ml min^{-1}. Pulse train stimulation at maximum tolerable amplitude was started manually at an IDC when bladder pressure increased with 10 cmH_2O. Stimulation was switched off after an IDC was suppressed. IDC was defined as suppressed when detrusor and vesical pressure returned back to or decreased to near baseline pressure owing to conditional stimulation. After the bladder had been emptied partially, filling was started again with conditional stimulation at a lower amplitude. These stimulation sessions were repeated 2–5 times in each patient. A control cystometry was carried out before needle insertion and after the cystometries with conditional stimulation. Cystometry was stopped at maximum cystometric capacity or at a bladder volume of 500 ml or at a sustained IDC.

Studies on both healthy volunteers and SCI patients were approved by the local ethical committee. We certify that all applicable institutional and governmental regulations regarding the ethical use of human volunteers were followed during the course of this research.

Results

Healthy volunteers

The volunteers' median age was 26 years (range 20–61). GAR was elicited by electrical stimulation and was detected by anal palpation or anal pressure measurements in four out of eight volunteers with pulse train stimulation and in four out of four volunteers with burst stimulation. The median minimum threshold to elicit a GAR with burst stimulation was 2.0 mA (range 0.75–12.0). The lateral implant approach was preferred as it was easier to manoeuvre the needle along the pubic bone and to insert the needle over a longer tract for stability. Stability is important as the needle is kept in place manually during stimulation in both healthy volunteers and SCI patients.

Sensation thresholds using pulse trains varied between 0.75 and 2.25 mA, and with burst stimulation between 0.25 and 2.00 mA. Mean maximum tolerated pulse train amplitude was 10 mA (range 4–25). Overall, stimulation was well tolerated and described in the majority as tingling or pulsing depending on the stimulation settings. Most male volunteers described sensation to stimulation at the penile base along the left or the right site of the penile shaft and eventually in the glans penis when the electrode was directed towards the DGN. Female volunteers located stimulation successively at the left or the right labia and at the clitoris.

SCI patients

All eight SCI patients who were included (Table 1) were incontinent. Four patients were on anticholinergics and one used posterior tibial nerve stimulation, which were all stopped before the investigation. Five patients used clean intermittent catheterization and three used reflex voiding. All SCI patients had DO at baseline cystometry with specific or nonspecific bladder sensations concomitant with IDC, similar to abdominal fullness and autonomic dysfunction symptoms (for example, flushes, perspiration and piloerections). The waveform of IDC was comparable between baseline and control cystometry.

In five out of eight patients, it was possible to insert the needle successfully using the electrically elicited GAR in combination with sensation to stimulation. In two patients, only sensation to stimulation could be used. In patient 3, it was not possible to insert the needle electrode properly. This patient could not give feedback of electrode position owing to the absence of sensation to stimulation, and the GAR could not be elicited, neither using a needle electrode nor surface electrodes.

Conditional stimulation at maximum tolerable stimulation amplitude suppressed at least one IDC (Table 1). With lower stimulation amplitudes, it was still possible to suppress some IDCs in five patients. Two examples of stimulation effects are shown in Figure 2.

Stimulation did not cause autonomic dysfunction during the test for the sensation threshold and maximum tolerable amplitude. Patients who had autonomic dysfunction symptoms reported a decrease or relief in symptoms at IDC when stimulation was able to suppress that IDC. However, patients 2, 6 and 7 had leg spasms at the start of stimulation, which resolved in a few seconds during stimulation. Spasms were amplitude dependent. For example, spasms were almost absent in patient 7 if the amplitude was decreased to 9.0 mA, which still suppressed two IDCs.

Mean stimulation time for all patients was 28 s, and varied between patients from a mean of 19–38 s. Patients reported that the intensity of specific and nonspecific bladder sensations at IDC was lower during stimulation.

No adverse events related to the needle electrode insertion and electrical stimulation occurred.

Table 1 Results of conditional stimulation of the DGN using a needle electrode

Patient	*Age*	*Level of spinal cord injury*	*Genito-anal reflex/sensation to stimulation*	*Sensation threshold—maximum tolerable amplitude of stimulation (mA)*	*Amplitude pulse train stimulation (mA)*	*Number of suppressed undesired detrusor contractions*
1 ♂	45	C5 incomplete	Yes/yes	1.0–9.0	9.0	2 (Figure 2a; stimulation stopped at the third suppression)
					5.0	1
					3.0	0
2 ♂	41	C5 complete	Yes/no	NA	16.0	4 (stimulation stopped after four suppressions)
					8.0	1
3 ♂	67	T5 complete	No/no	NA	—[a]	—[a]
4 ♂	56	T12 incomplete	No/yes	4.0–10.0	8.0	3 (Figure 2b)
					6.0	0
					7.0	1
5 ♂	58	C5 incomplete	—/Yes[b]	0.8–8.3	8.0	2
					8.0	2 (stimulation stopped at the third suppression)[c]
6 ♂	33	C6 incomplete	Yes/yes	0.95–18.6	18.6	0
					18.6	5[d]
					10.0	0[e]
7 ♀	59	C5 incomplete	Yes/yes	3.0–15.5	15.5	6 (stimulation stopped after six suppressions)
					9.0	2
8 ♂	54	T10 incomplete	Yes/yes	1.5–15.0	15.0	4
					10.0	0
					10.0	2[d]

Abbreviation: NA, not applicable.
[a]The needle electrode was not successfully inserted in patient 3 due to absence of sensation to stimulation, and the GAR could not be elicited using surface and needle electrodes.
[b]Not clear due to failure of equipment.
[c]Stimulation was repeated at the same stimulation amplitude, because stimulation had been started during the first stimulation cystometry at vesical pressure increase combined with bladder sensation in the absence of clear detrusor pressure increase. During the second stimulation cystometry, stimulation was stopped during the third stimulation, which resulted in an immediate and clear detrusor pressure increase.
[d]Compliance $<10\,ml\,cm^{-1}\,H_2O^{-1}$. Stimulation at maximum tolerable stimulation amplitude was repeated, because during the first stimulation cystometry stimulation was started too late at first IDC.
[e]Stimulation at 10 mA did not suppress an IDC to baseline pressures. When stimulation was started, detrusor pressure did not increase as fast as before and pressure increased strongly after stimulation was switched off.

Discussion

Urinary incontinence is not only a social and hygienic burden for patients but is also a risk factor for pressure ulcers and interferes with wound healing, especially in neurogenic patients with decreased mobility. It would be beneficial when incontinence caused by IDC could be prevented by conditional stimulation of the DGN. Patients will have extra time to find a suitable place to empty the bladder. In addition, when IDCs can be suppressed, this will theoretically result in lower peak detrusor pressures during bladder filling and an increase in bladder capacity. Lower detrusor pressures will reduce the risk of renal deterioration. As this study did not assess bladder capacity, the exact influence on capacity could not be determined and can better be studied in clinical trials.

Several studies investigating electrical stimulation of the DGN have been carried out in patients with neurogenic DO, non-neurogenic DO or overactive bladder syndrome (Table 2).[2–7,9–11] These studies show that stimulation suppresses IDC and increases bladder capacity using surface or wire electrodes for continuous and conditional stimulation.

Regarding this literature, the present results, which met the study objectives, are important for two reasons. First, a suitable site and a combination test, consisting of the electrical elicitation of the GAR and sensation to stimulation, enabled minimal invasive implantation of electrodes near the DGN in neurogenic patients and in non-neurogenic volunteers. Second, an implanted electrode near the DGN enabled acute suppression of IDC in SCI patients by conditional stimulation. The effectiveness of conditional stimulation to suppress IDC is amplitude dependent.

Lee *et al*.[9] implanted wire electrodes in the midline dorsal penile shaft. Electrodes in the penile shaft have to endure penile erectile mobility and external mechanical stress, especially in sexually active people. To decrease the risks for electrode fracture and displacement, it was decided to test positioning of the needle near the DGN between the pubic bone and base of the penis or clitoris.

An implanted electrode can make DGN stimulation a feasible treatment for neurogenic and non-neurogenic DO in daily life. Goldman *et al*.[7] inserted a wire electrode in the midline of the mid-pubis in patients with intact sensation, who located sensation to stimulation at the clitoris with a mean sensation threshold of 4.3 mA (range 2–10 mA). In the current study with neurogenic patients who had absent or decreased sensations, the combination of sensation to stimulation and elicitation of the GAR by DGN stimulation were successfully used in seven out of eight patients to insert the electrode with only a mean sensation threshold of 1.9 mA (range 0.8–3.0 mA). In patient 3 without a sensation to stimulation and the inability to evoke a GAR, the latter might be due to his complete SCI, preventing the reflex to occur. On the other hand, it is not possible to evoke a GAR in all people.[8]

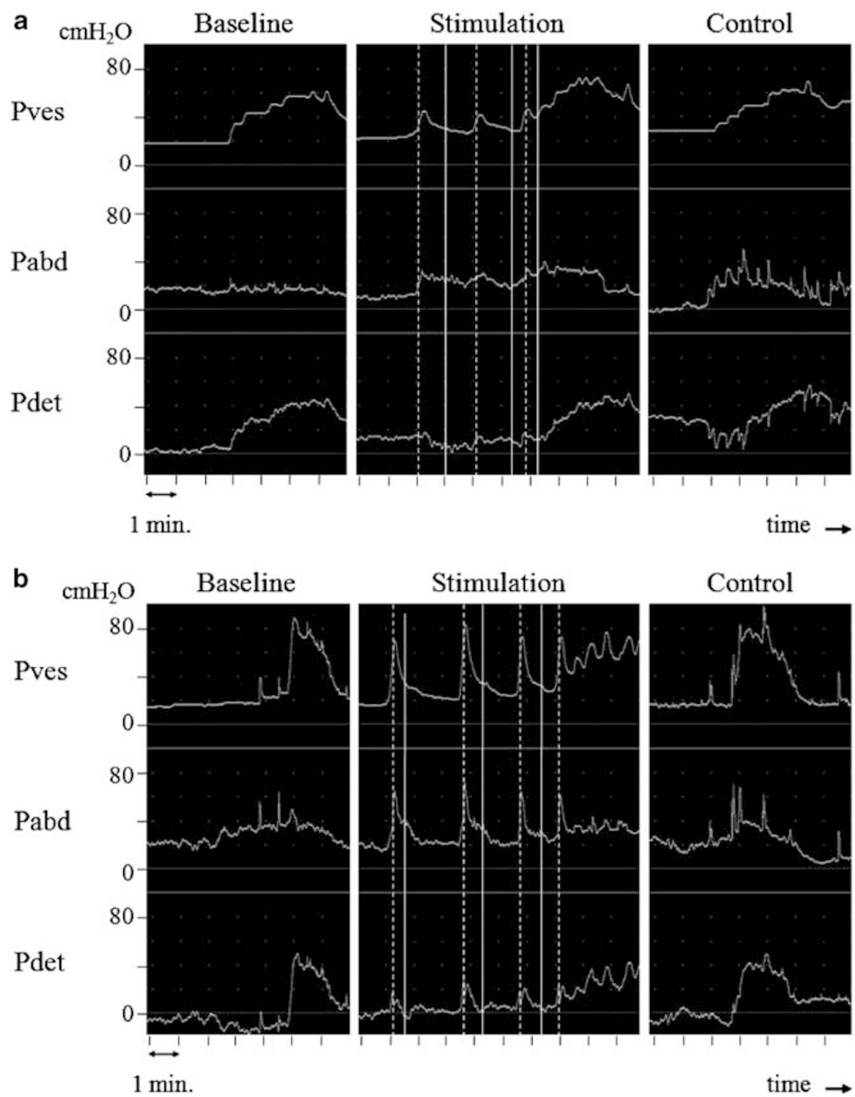

Figure 2 Examples of stimulation effect. Two examples of cystometry at baseline without stimulation, cystometry with DGN stimulation and control cystometry without stimulation in (**a**) patient 1 and (**b**) patient 4. The start and end of stimulation were marked manually at the urodynamic recordings during the study. To be perfectly clear, these manually placed markers have been interchanged with other markers in the figure. (**a**) Patient 1: Conditional pulse train stimulation at 9.0 mA suppressed two IDCs. Because of rectal pressure increases, stimulation was started when a Pves increase concomitant with a bladder sensation occurred instead of Pdet increase. These rectal pressure increases were also recorded during the control cystometry. Stimulation was stopped during the third suppression of an IDC, which resulted in an increase in Pdet and urgency feeling. (**b**) Patient 4: Conditional pulse stimulation at 8.0 mA suppressed three IDCs. Stimulation failed to suppress the fourth involuntary detrusor contraction completely. -----, stimulation on; ——, stimulation off; Pabd, abdominal pressure; Pdet, detrusor pressure; Pves, vesical pressure.

Suppression of IDC with conditional stimulation was most effective at maximum tolerable amplitude (mean 12.9 mA, range 8.0–18.6 mA) and less effective at lower amplitudes. The stimulation amplitude of the pulse train stimulation during bladder filling was not related to the threshold for the GAR, as the GAR could not effectively be evoked with pulse train stimulation in the majority of patients. Previnaire *et al.*[12] showed that continuous stimulation (bipolar surface electrodes, rectangular pulse, 5 Hz, pulse width 500 μs) at twice the GAR threshold increases bladder capacity more than does a stimulus at one times the threshold (mean 24.2 mA, range 14.0–40.0 mA). Although our study did not assess capacity, and stimulation parameters were different, it also demonstrated the importance of amplitude on IDC suppression.

As the positioning of the electrode was controlled manually and only checked in between bladder filling with conditional stimulation in case of suspicion of dislocation, confounding or failure by movements of the electrode cannot be ruled out. As the stimulation surface of the needle electrode tip was small (Figure 3), small movements of the electrode could have influenced stimulation effect. In addition, the timing of application of stimulation was controlled manually, resulting in a variation in timing across repeated fillings and patients.

Table 2 Electrical stimulation of the dorsal genital nerves

Author	*Patients*	*Electrodes*	*Stimulation*	*Outcome*
Goldman *et al.*[7]	21♀ Urge incontinence	Percutaneous wire	Continuous	11/20 increase in cystometric capacity
Hansen *et al.*[4]	14♂, 2♀ DO (SCI)	Surface	Conditional	53% increase in cystometric capacity 13/15 ⩾1 suppressed IDC
Kirkham *et al.*[2]	14♂ DO (SCI)	Surface	Continuous, 6/14 Conditional, 6/14	110% increase in cystometric capacity 144% increase in cystometric capacity IDC suppression
Lee *et al.*[5]	1♂ DO (SCI)	Surface	Conditional	Catheterization volume increase from 205 ml to 353 ml Catheterization interval increase from 242 to 284 min
Lee *et al.*[9]	7♂ DO (SCI)	Surface Percutaneous wires penile shaft	Conditional Conditional	IDC suppression IDC suppression
Nakamura *et al.*[10]	22♂, 10♀ OAB, 13/32 DO	Surface	Continuous	8/13 UDC suppression
Opisso *et al.*[11]	41♂, 26♀ Neurogenic, 42/67 DO < 400 ml	Surface	Conditional (33/42 automatic conditional stimulation, 17/33 patient-controlled stimulation)	16/17 automatic stimulation ⩾1 IDC suppression, 14/17 patient-controlled stimulation, ⩾1 IDC suppression, cystometric capacity increase from 186 to 254 ml
Wheeler *et al.*[3]	6♂ DO (SCI)	Surface	Continuous	76% increase in cystometric capacity

Abbreviations: DO, detrusor overactivity; IDC, involuntary detrusor contraction; SCI, spinal cord injury.

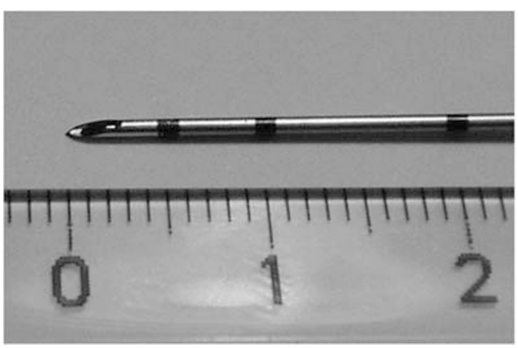

Figure 3 Tip of the needle electrode (Medtronic 041828, 20 G, 9 cm). The needle is insulated along the shaft and the electrode is only exposed at the end.

Conditional stimulation can reduce power consumption compared with continuous stimulation, owing to a reduction in stimulation duration. Goldman *et al.*[7] used maximum tolerable amplitudes (mean 9.6 mA, range 5–25 mA) at the start of their study with continuous stimulation in female patients with overactive bladder symptoms, which were comparable to the current study amplitudes, although the exact stimulation parameters and wire electrode characteristics were not described. The most effective stimulation amplitudes at maximum tolerable level in our study using needle electrodes near the DGN were lower than the amplitudes at two times the GAR threshold required for the optimal effect in the study of Previnaire *et al.*[12] using surface electrodes.

The healthy male volunteers and male SCI patients described a clear distinction of feeling the stimulation in the penile shaft or glans penis. This specific localization might be due to the penile innervation.[13] At the base of the penile shaft, the DGN consists of a single trunk on either side of the shaft. Each trunk consists of two populations of axons: one to innervate the penile shaft and urethra, and one to innervate the glans penis. It is unknown from our current study what the clinical implications for the effectiveness of stimulation of these different axons are. In accordance with the bilateral innervations, patients sensed stimulation more to either the left or the right site of the penile shaft. This suggests that unilateral conditional DGN stimulation may be sufficient to suppress IDC.

Stimulation was started manually when an IDC was observed from pressure recordings using indwelling catheters, which is not a viable method for application in daily life. Patient-controlled suppression of IDC provides additional time for patients to empty their bladder and therefore a possibility to stay continent.[11] Patient-controlled conditional stimulation seems not to be satisfactory in daily life in SCI patients, as the detection rate of IDC by bladder sensations is too low.[14] Bladder activity monitoring methods in animals and humans have been reported, such as external urethral or anal sphincter electromyography, sacral root electroneurography and bladder pressure monitoring by sensor implantation.[15–18] At present, no suitable device is available for clinical application. Further studies for reliable IDC sensors are required to make a fully implanted closed loop conditional stimulator possible.

Conflict of interest

The authors declare no conflict of interest.

Acknowledgements

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