W5: Neurogenic detrusor overactivity: What to do after 15 years of Botulinum toxine?

Workshop Chair: Michele Spinelli, Italy
13 September 2016 11:00 - 12:30

Start	End	Topic	Speakers
11:00	11:20	Introduction	Michele Spinelli
11:20	11:35	On label Botox: revision of data and reinjection rate	Julien Renard
11:35	11:50	Role of posterior rizothomy and radiofrequency	Carlos D'Ancona
11:50	12:05	Neurostimulation and neuromodulation: are we waiting something new	Michele Spinelli
12:05	12:20	Back to augmentation surgery?	Julien Renard
12:20	12:30	Conclusion and discussion	All

Aims of course/workshop

Neurogenic bladder is a term applied to a malfunctioning urinary bladder due to neurologic dysfunction or insult emanating from internal or external trauma, disease, or injury. Symptoms of neurogenic bladder range from detrusor underactivity to overactivity (depending on the site of neurologic insult), sphincter underactivity or overactivity and loss of coordination with bladder function. Treatment options have evolved rapidly in the last 20 years. The aim of this workshop will be to give participants the most complete overview (features, diagnosis and management) of neurogenic bladder focusing especially on therapeutical options and their latest trends.

Learning Objectives

After this workshop participants should be able to:

1. Have an overview of the management of neurogenic bladder
2. Know what current treatment options are available
3. Learn about current research and potential new therapeutical approaches

Target Audience

Urologists, Neurourologists, Neurologists

Advanced/Basic

Advanced

Suggested Reading

- Mehnert T and Kessler. T. The management of urinary incontinence in the male neurologicla patient. Current opinion in urology, Vol : 24(6)-2014
- Jhang J-F and Kuo H-C: Botulinum Toxin A and Lower Urinary Tract Dysfunction: Patophysiology and Mechanisms of Action. Toxins 8 (120) -2016
- Mangera A., Apostolidis A., Andersson K.E et Al: An updated systematic review and statistical comparison of standardised mean outcomes for the use of botulinum toxin in the management of lower urinary tract disorders. Eur Urol 65(2014) 981-990
- Peyonnet B, Castel- Lacanal E, Rouniguie M et Al. Intradetrusor injections of onaboutlinum Toxin A (Botox®) 300 or 200 U versus Abobotulinum Toxin A (Dysport®) 750 U in the management of NEuorgenic Detrusor Overactivity : a case control study. Neurourology and Urodynamics ahead of print.
- European Association of Urology- Guidelines
- Textbook of the neurogenic bladder- J. Corcos; D. Ginsberg; G. Karsenty, Taylor and Franc

Michele Spinelli

In last 20 years urologists involved in study and treatment of neurogenic bladder had the occasion to assist at a revolution of care.

Starting from reflex voiding in neurogenic bladder by means of different triggers, introduction of larger use of intermittent catheterization has permitted to resolve voiding difficulties at low pressure and complete.

The concept of restoring micturition cycle in a "physiological approach", with conservation of anatomy became in last decades the goal. In the field of pharmacological and medical modulation we assisted to possibility of escape surgical approaches using less invasive and reversible approaches as second line treatment.

The era of Botulinum toxin injection and the era of electrical neurostimulation and modulation are today considered main revolutions in functional urology.

But what we are looking for future?

We have a population long term treated with botulinum toxin asking something different and in this population we have patients becoming less responder.

On the other hand in last ten years we assisted to nothing new in term of treatment, only to the on labelling of botulinum toxin with a low dosage.

Are we going back to necessity of augmentation surgery?

What is going on in neuromodulation?

Is precocious approach in neuromodulation one of the new target?

TBC

Julien Renard

One of the main complaints of neurological patients, whatever the main etiology might be (medullar lesion, Parkinson's disease, Multiple Sclerosis, Myelomeningocele…) is often linked to urological symptoms. In fact profound alterations of lower urinary tract control cause various symptoms. Among these, urinary incontinence is often the only apparent sign since urgency can be reduce or absent because of sensory deficits (1). Type of incontinence is in most of cases urge and due to neurogenic detrusor overactivity which requires a specific management. Antimuscarinic drugs often offer the first line of treatment but unfortunately can either be of insufficient effect for symptom management or cause side effects which are too much of a burden for patients (dryness of mouth, constipation). In this context, the advent of botulinum toxine has changed the game. Approved in 2011 by the Food and Drug Administration, the main indication for detrusor injection of botulinum toxin is the treatment of neurogenic detrusor overactivity in patients who have an inadequate response or intolerance to antimuscarinics. Recently the range of BoNT-A injections has increased, in some cases however in course of evaluation, to patients with painful bladder symptoms, idiopathic detrusor overactivity and voiding dysfunction.

Its mechanism of action involves the motor nervous system including the inhibition of neuromuscular jonctions by blocking acetylcholine release. However its action is not only limited to this aspect. Botulinum toxin injection, in fact, also regulated the sensory nerve function by blocking neurotransmitter release and reducing receptor expression in the urothelium. In addition recent studies revealed an anti-inflammatory effect and globally in an improvement of urothelium function helping restore bladder function (2)

From a technical point of view, injections require a cystoscopic (rigid or flexible) intervention that needs to be repeated every 6-9 months. The procedure can be performed in local anesthesia in most patients.

In terms of effect, intradetrusor injection determines in neurogenic detrusor overactivity patients, an improvement in daily incontinence and catherization episodes, in maximum cystometric capacity, reflex volume and maximum detrusor pressure. In overactive bladder patients, it leads to significant improvement in bladder diary (daily frequency and urgency) and daily incontinence. (3)

Today two types of toxins are available on the market:

- Onabotulinumtoxin A (Botox, Allergan Inc, Irvine, Ca)
- Abobotulinumtoxin A (Dysport , Ipsen bipharmaceuticals, Inc, BAsking Ridge, NJ)

Botox has been in the last years the main product used in larger studies. However some authors have challenged its superiority by comparative studies which concluded to similar effects between the two products but longer intervals between injections for Dysport (4)

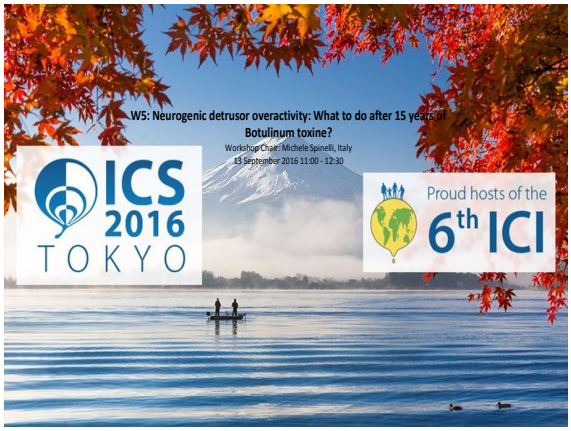
One other open debate lies in the required dose necessary for management of neurogenic detrusor overactivity which range in the literature form 50 U to 300 U. Nowadays guidelines however recommend doses of 200 U for correct management.

Michele Spinelli / Julien Renard

Surgical management of patients with neurogenic bladders represents the last line of treatment for neurological patients. In fact, usually these procedures represent a heavy surgery which is not facilitated by the general condition of patient. However, if followed regularly and correctly, if patient is compliant there is usually no need for this management. In fact Urinary diversions, although once frequently employed are only required in special circumstances (S. Herschorn) and that is in the case of failure of conservative management and medical management (intermittent catheterization, anticholinergic medications, beta3 agonist

therapy) which leads to complications of the upper urinary tract (hydronephrosis, uretreo-renal reflux bladder wall thickening and concomitant progressive renal deterioration, urosepsis) . Indications is found also in the case of unmanageable incontinence, inability to catheterize per urethra or in the cases of infectious complications linked to lower urinary tract (bladder diverticula).

After posing a correct indication, the main burden for physician and patient will be to choose a urinary diversion suitable. Two main types can be offered. Non continent diversion such as ileal conduit or colon conduit, or ileo vesicostomy. Continent diversions such as continent catheterizable pouch (Indiana, Koch, T pouch, Duke pouch, others) or catheterizable continent stoma with or without augmentation cystoplasty (Mitrofanoff, Hemi-Koch)
The main advantages of these diversions will be to restore low pressure urinary storage and protect the upper tract. Furthermore it should improve the quality of life providing a reliable state of continence.



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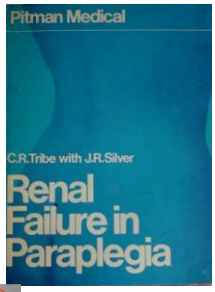
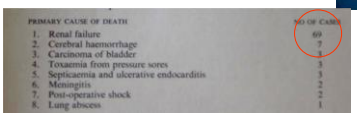
Stoke Mandeville
Retrospective study on 150 pts.
1945-1963





PRIMARY CAUSE OF DEATH	NO OF CASES
1. Renal failure	69
2. Cerebral haemorrhage	7
3. Carcinoma of bladder	7
4. Toxaemia from pressure sores	3
5. Septicaemia and ulcerative endocarditis	3
6. Meningitis	2
7. Post-operative shock	2
8. Lung abscess	1

Long-term survival in spinal cord injury: a fifty year investigation

HL Frankel[1], JR Coll[2], SW Charlifue[2], GG Whiteneck[2], BP Gardner[3], MA Jamous[1], KR Krishnan[3], I Nuseibeh[1], G Savic[1] and P Sett[1]

[1]*National Spinal Injuries Centre, Stoke Mandeville Hospital, Aylesbury, Buckinghamshire, UK;* [2]*Craig Hospital, Englewood, Colorado, USA;* [3]*Northwest Regional Spinal Injuries Centre, Southport, Merseyside, UK*

The aims of this study were to examine long-term survival in a population-based sample of spinal cord injury (SCI) survivors in Great Britain, identify risk factors contributing to deaths and explore trends in cause of death over the decades following SCI. Current survival status was successfully identified in 92.3% of the study sample. Standardised mortality ratios (SMRs) were calculated and compared with a similar USA study. Relative risk ratio analysis showed that higher mortality risk was associated with higher neurologic level and completeness of spinal cord injury, older age at injury and earlier year of injury. For the entire fifty year time period, the leading cause of death was related to the respiratory system; urinary deaths ranked second followed by heart disease related deaths, but patterns in causes of death changed over time. In the early decades of injury, urinary deaths ranked first, heart disease deaths second and respiratory deaths third. In the last two decades of injury, respiratory deaths ranked first, heart related deaths were second, injury related deaths ranked third and urinary deaths fourth. This study also raises the question of examining alternative neurological groupings for future mortality risk analysis.

Keywords: mortality; spinal cord injury; survival analysis

'60
treatment of complications

'70
Quantity of life
UUT safety

80

early treatment

90

Not only Plumbers

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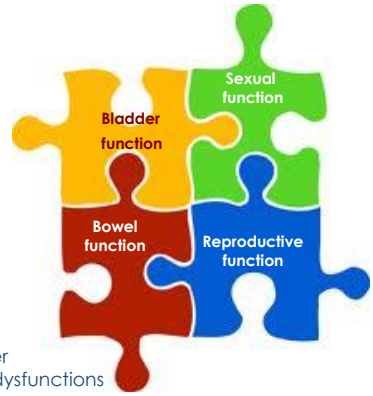
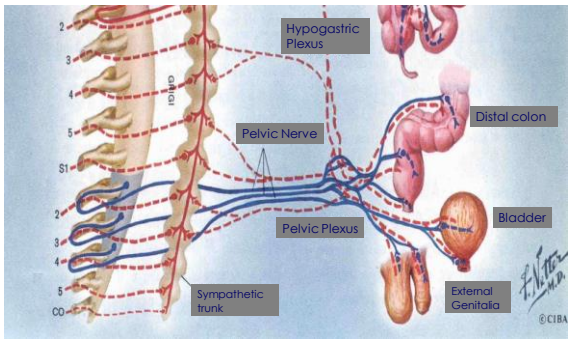
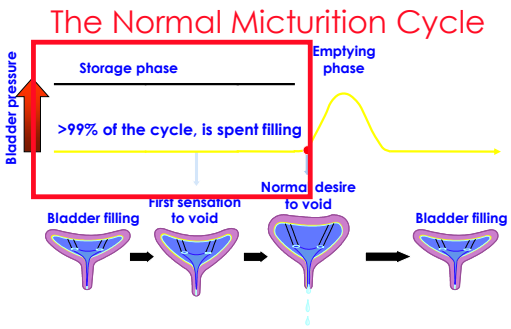


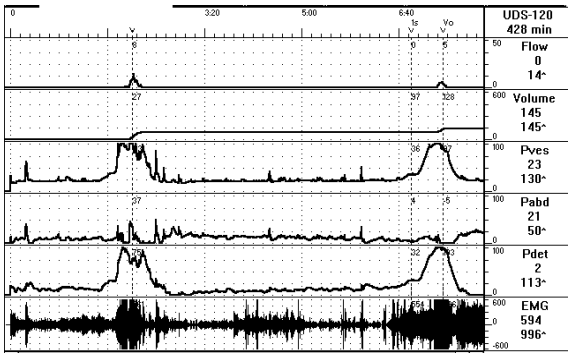
not only bladder
all sacral area dysfunctions

alberto zanollo center

for study and treatment of neurogenic bladder and sacral area dysfunctions







Goals

permit adequate storage at low intravesical pressure

realize emptying at low intravesical pressure

preservation of upper urinary tract

control of infections

continence control without catheter or stoma

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treatment modalities to facilitate bladder emptying

- external compression
- initiation of reflex contraction
- pharmacological manipulation
- bladder neck incision or resection
- external sphincterotomy
- alfa-sympaticolitic drugs
- relaxants of striated muscle

- intermittent catheterization

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Sir Ludwig Guttmann

Intermittent catheterization : history

- 1° February 1944 : opening of the National Spinal Injuries Centre in Stoke Mandeville

– *« From the author's personal observations it would appear that neither urethral catheterisation (indwelling) nor suprapubic cystostomy hat yet proved a safeguard against ascending urinary infection »*

- **Non touch intermittent catherization**
  - **Sterile, by MD, every 6 hours**
  - **First publication in 1947: decrease of UTI, no urethral stricture, no urethral fistulae**
  - **Earlier return to micturition**

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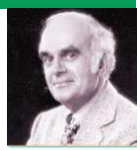
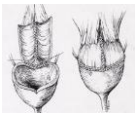


Lapides J, Diokno AC, Silber SJ, Lowe BS. Clean, intermittent self-catheterization in the treatment of urinary tract disease. J Urol. 1972 Mar;107(3):458-61.

- Antimuscarinic agents

- Surgery



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- Lifestile modifications
- Bladder retraining FES
- Antimuscarinic agents

- **Pharmacological "modulation"**
- Intravesical vanilloids

- **Electrical "modulation"**

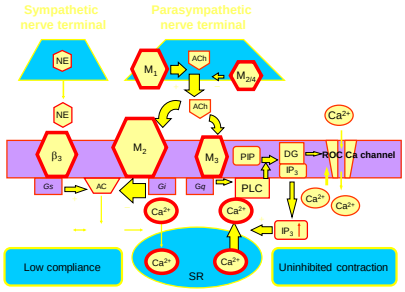
- Botulinum toxin
- Surgery

antimuscarinics

- antimuscarinic (anticholinergic) drugs have been the mainstay of oral medical therapy for NDO

- limited by the high incidence of side effects and lack of selectivity
  - dry mouth
  - constipation
  - blurry vision

Muscarinic Receptors



	tertiary*	quartanary #
Oxybutynin	x	
Tolterodin	x	
Propiverin	x	
Trospiumchlorid		x
Solifenacin	x	
Darifenacin	x	
Fesoterodin	x	

* CNS penetration, metabolisation via cystochrome system
\# no CNS penetration, renal elimination unchanged

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experience from Sept.2007

557

Spinelli M[1], Zanollo L[1], Citeri M[1], Rizzato L[1], Guerrer C[1]
1. Neurourology Alberto Zanollo Center Niguarda Hospital Milan Italy

TREATMENT OF NEUROGENIC DETRUSOR OVERACTIVITY (NDO) BY COMBINED LOW DOSED ANTIMUSCARINICS: FOUR YEARS EXPERIENCE

Hypothesis / aims of study
Primary aim in treatment of neurogenic lower urinary tract dysfunctions after spinal cord injury (SCI) is bladder emptying by intermittent catheterization (IC) avoiding bladder overdistension and treatment of neurogenic detrusor overactivity (NDO) to achieve a low pressure reservoir to protect upper urinary tract and bladder anatomy.
Anticholinergic agents are recommended as first line treatment - .
We report long term follow up in our experience in use combined low dosed antimuscarinics in NDO refractory to high dosage of a single drug.

Study design, materials and methods
Starting from September 2007 we introduced a protocol of treatment with antimuscarinics in patients with NDO with insufficient treatment outcome under monotherapy at high doses of oxybutynin (15 mg,a day) and trospium chloride (60 mg, a day) with introduction of a combined antimuscarinics treatment with the same drugs at low dosage.
All patients demonstrated NDO at Updater diary and urodynamic and started with oxybutynin 7,5 mg,(2,5 mg, every 8 hours) and trospium chloride 40 mg, (20 mg, every 12 hours)
Bladder diary was used as continuous control urodynamic was repeated at 3 and 6 months.
85 pts. were enrolled after sub-optimal results with monotherapy
All patients had a NDO due to upper motor neurolesion. All patients used IC 4-6 times a day avoiding overdistension.

Results
56 patients continue in the use of combined antimuscarinic treatment maintaining a significant decrease of incontinence from an average of 4 to 1 event per day. Mean bladder capacity at bladder diary increased with combined treatment of 160 mL from the value with monoterapy. In this population 13 patients stopped temporary reinjection of botulinum toxin in detrusor muscle and they don't require different treatment for NDO and are satisfied. No subjective increase of side effects related on antimuscarinics were noted.
29 patients stopped the treatment due to suboptimal results an were treated with second line options.

Interpretation of results
Looking at literature, other options of approach in NDO with antimuscarinics, in front at sub-optimal results, are reported: two main studies reported a doubling of the recommended dosage of a single drug (1) and a subsequent experience in combined high dosage (2).
In our experience we tried to start with a combined treatment but using a low dosage.
Our results are encouraging especially in a group of patients with a short time after SCI before to decide further treatment by botulinum toxin injection or neurostimulation. A combined treatment is actually proposed as an option before to decide second line treatments. Different combinations with different antimuscarinics drugs could be evaluated in the future.

Concluding message
A combination of antimuscarinic agents at low dosage is an effective treatment strategy in patients who have failed with high dosage monotherapy.

References
1. 1 — M2Horstmann e coll. Neurogenic bladder treatment by doubling the recommended antimuscarinic dosage Neurourol Urodyn 25: 2006 441-445
2. 2 — B. Amend e coll. Effective treatment of neurogenic detrusor dysfunction by combined high dosed antimuscarinics without increase side effects Eur. Urol. 53: 2008: 1021-1028

Disclosures
Funding: None **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** observation of results in approved treatments **Helsinki:** Yes **Informed Consent:** No

Neuro Urologia centroalbertozanollo

Treatment of neurogenic detrusor overactivity (NDO) by combined low dosed antimuscarinics

Spinelli M. Citeri M. Zanollo L. Guerrer C. Rizzato L.

EAU 2013

Ossibutinina 2,5 mg.
+
Cloruro di trospio 20 mg. 2/die

Results
56 patients continue in the use of combined antimuscarinic treatment maintaining a significant decrease of incontinence from an average of 4 to 1 event per day. Mean bladder capacity at bladder diary increased with combined treatment of 160 ml. from the value with monoterapy. In this population 13 patients stopped temporary reinjection of botulinum toxin in detrusor muscle and they don't require different treatment for NDO and are satisfied. No subjective increase of side effects related on antimuscarinics were noted.
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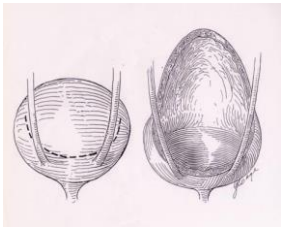
Augmentation Cystoplasty

- Enlargement of the bladder using an intestinal segment
  - Increase bladder capacity and compliance
  - Eliminate or decrease involuntary contractions
    - increase threshold volume at which involuntary contractions occur

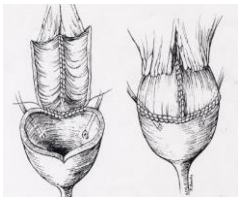
Augmentation Cystoplasty Technique

- Create a large opening in the bladder
  - Clam
  - Anterior flap (posterior incision)
  - Posterior flap (anterior incision)
- Addition of a bowel segment
  - Ileum
  - Cecum (ileo-cecal), sigmoid
  - Stomach
- Can be combined with a catheterizable stoma

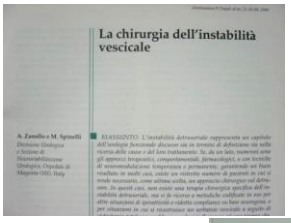


Augmentation Cystoplasty Technique

- Bowel segment must be detubularized
  - increase surface area
  - eliminate peristalsis
- Ileal cystoplasty
  - 25 - 30 cm. of ileum
  - detubularized into "U" or "S" shape
  - "W" for larger segments

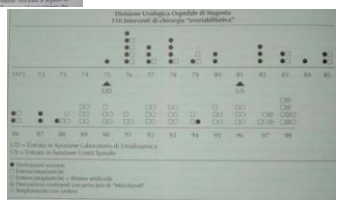


$V = \pi r^2 h$



110 pts.

81 EC
10 EC + AS
6 EC + MIT

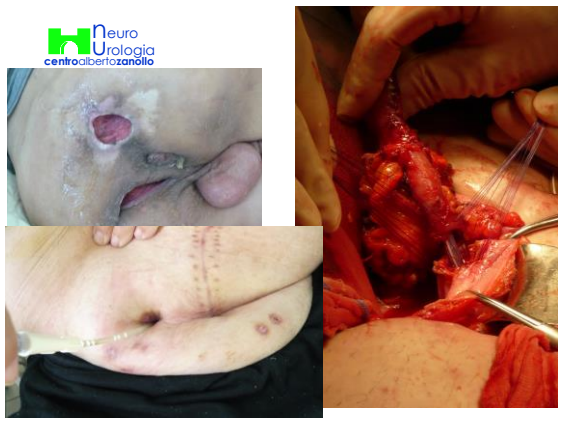


Augmentation Cystoplasty Complications

- Recurrent UTI
- Persistent mucus
- Stone formation
  - 35% for large and 13% for small intestine (Flood)
- Incomplete emptying
  - Requires intermittent catheterization
  - All patients should be willing to accept this

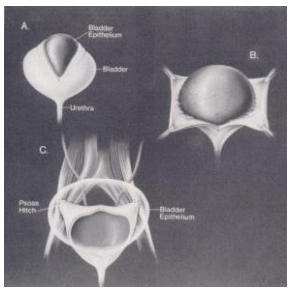
Augmentation Cystoplasty Complications

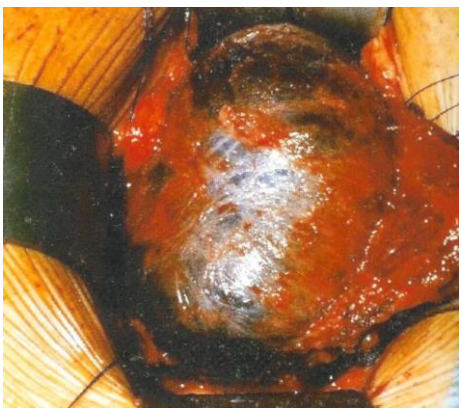
- Metabolic disturbances
  - Hyperchloremic metabolic acidosis with small and large intestine
- Perforation
  - 5% in long term
  - ? more common in patients who catheterize
- Tumor
  - Minimal risk in detubularized, effectively emptied, uninfected cystoplasty



Autoaugmentation

- Detrusor myotomy
  - No addition of bowel segment
  - Detrusor muscle dissected off of the anterior, superior and lateral surfaces of the bladder to create a large diverticulum
- Stohrer, et al.
  - 52 pts with NVD
  - Mean f/u 6.4 yrs (min 4 yrs)
  - MCC 132 to 320 ml
  - Compliance 9 to 25 ml/cmH2O
  - Pdetmax 95 to 48 cmH2O
  - PVR 45 to 163 ml
  - 6 failures, 9 LTFU
  - Level 4 evidence





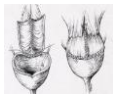
don't modify the antomy!

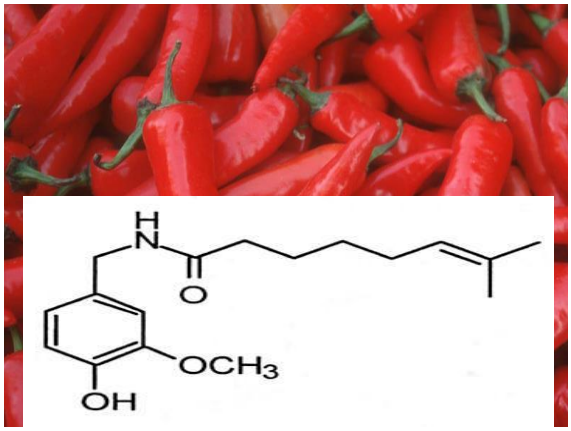
try to modulate neurogenic dysfunction

- Antimuscarinic agents

- **Pharmacological "modulation"**
  Intravesical vanilloids

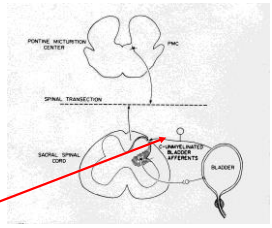
- Surgery





Vanilloids

- Capsaicin and Resiniferatoxin
- Activate nociceptive sensory nerve fibers via vanilloid receptor (VR1)
  - Transducer of painful thermal stimuli and acidity
- Activation of VR1 selectively excites and subsequently desensitizes C-fibers



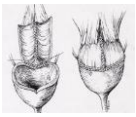
Vanilloids

- Interesting concept
- Many small series
- Best concentrations and delivery methods for each not established
- No interest by companies

- Antimuscarinic agents

- **Pharmacological "modulation"**
  Intravesical vanilloids

- Surgery

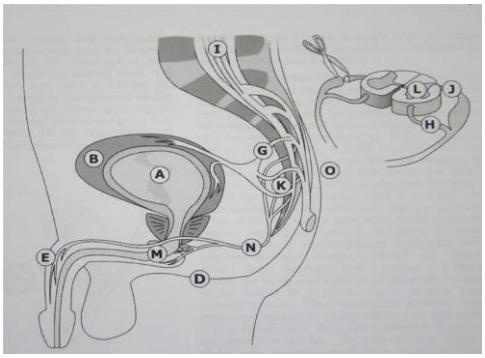


- Antimuscarinic agents

- **Pharmacological "modulation"**
  Intravesical vanilloids

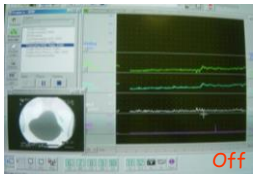
Electrical stimulation and modulation

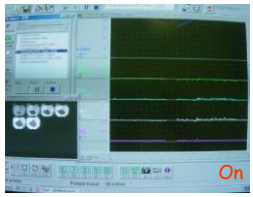
- Surgery



porte di ingresso e indicazioni

Sacral anterior roots stimulation
for bladder control in paraplegia
Paraplegia 20:365-381,1982





- Lifestile modifications
- Bladder retraining FES
- Antimuscarinic agents

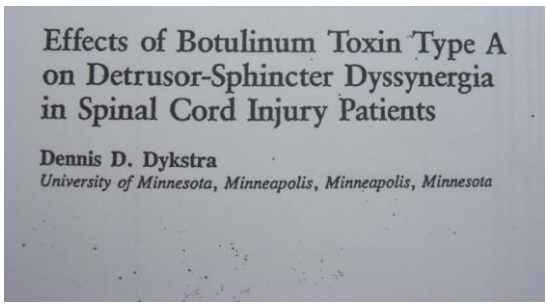
- **Pharmachological "modulation"**
- Intravesical vanilloids

- **Electrical "modulation"**

- Botulinum toxin
- Surgery

Botulinum toxine A

- Botox (Allergan)
  - Vacuum dried
  - 100U vials
- Dysport (Ipsen)
  - Freeze dried
    - More disruptive
  - 500 U vials
- Come from different bacterial strains
  - clostridium botulinum
- Dose comparison depending on indication
  - 1 Botox unit = 2-5 Dysport units !!!!

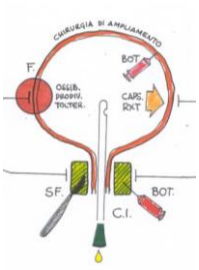


Effects of Botulinum Toxin Type A on Detrusor-Sphincter Dyssynergia in Spinal Cord Injury Patients

Dennis D. Dykstra

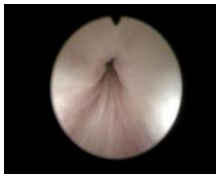
University of Minnesota, Minneapolis, Minneapolis, Minnesota

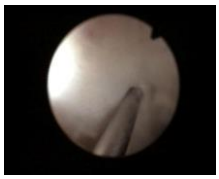
primi 5 pazienti **1988**



1994 BTA in the sphincter

M. Spinelli, a. Tagliabue, P. Politi, L. Zanollo, A. Zanollo
Treatment of detrusor-sphincter dyssynergia due to upper motor neurolesion using botulinum toxin
Urodinamica 7:140-141,1997
European Urology 1998



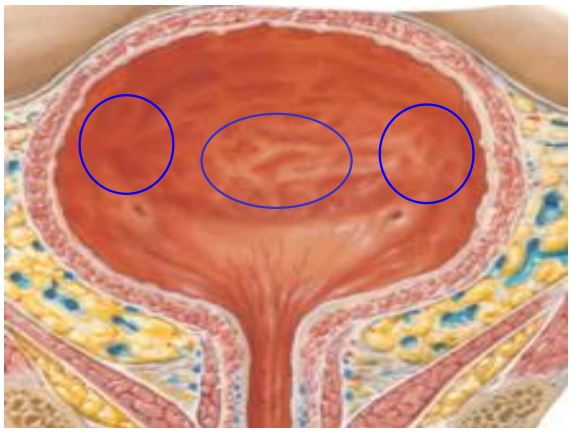


- Detrusor external sphincter dyssynergia
- **Neurogenic detrusor overactivity**
- Pelvic floor spasticity in women
- Non-neurogenic overactive bladder
- Benign prostatic hyperplasia
- Interstitial cystitis

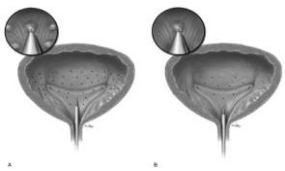
are there systemic side effects?

how many times to repeat?

where is the position in alghorithm?

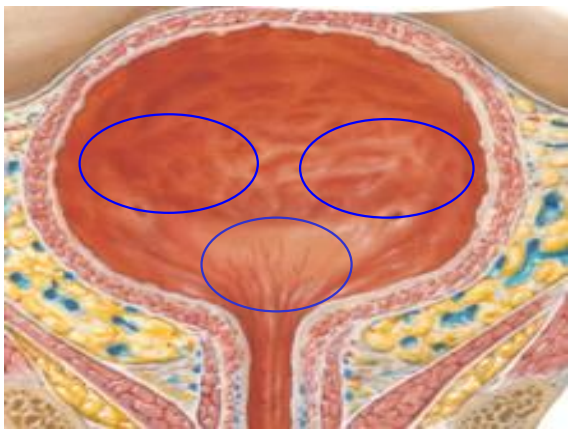


Injection technique

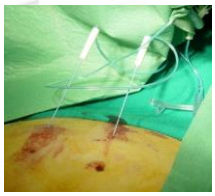


- Rigid or flexible scope
- Feasible under local anesthesia
  - Cohen BL et al. J Urol 2007
- Trigone sparing or including the trigone?

  - Karsenty G et al. J Urol 2007
  - Spinelli M et al. Eur Urol 2007
  - No induction of VUR at 6 weeks
  - No local or systemic side effects
  - Efficacy remains to be evaluated



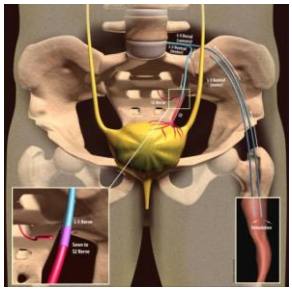
new technologies



Radiofrequency rizothomy

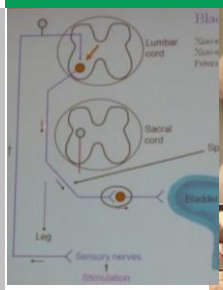
centro alberto zanollo u.s.u. niguarda milano

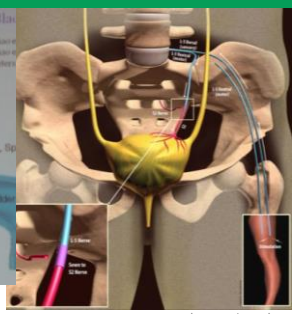
microanastomosi intradurale tra radici lombari sane e radici motorie sacrali



Consensus sept.2009, Beaumont Hosp.,Michigan

centro alberto zanollo u.s.u. niguarda milano





Consensus sept.2009, Beaumont Hosp.,Michigan

microanastomosi intradurale tra radici lombari sane e radici motorie sacrali

centro alberto zanollo u.s.u. niguarda milano

Xiao technique, nerve rerouting.....

Neuro Urologia
centroalbertozanollo

Sacral Rhizotomy

Carlos D'Ancona
Division of Urology, School of Medical Sciences
State University of Campinas – UNICAMP
Campinas, Sao Paulo, Brazil

Carlos D'Ancona

Affiliations to disclose†:

Astellas
Ache

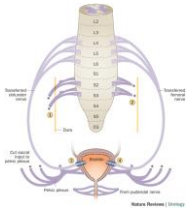
† All financial ties (over the last year) that you may have with any business organisation with respect to the subjects mentioned during your presentation

Funding for speaker to attend:

- ☐ Self-funded
- ☒ Institution (non-industry) funded
- ☐ Sponsored by:

Sacral Rhizotomy

• Background – open surgery



- Munro (1945) - anterior rhyzotomy with occasional improved vesical function
- Mierovisky (1950) - sacral rhyzotomy S2 to S5, detrusor arreflexia, sexual dysfunction, urethral and anal sphincter dysfunction
- Misak et al. (1962) – comparative study between rhyzotomy and alcohol injection in subarachnoid space with advantage of rhyzotomy

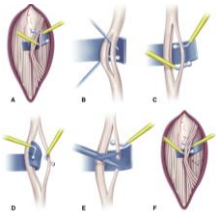
Sacral Rhizotomy

• Background – anesthetic block

- Heimburger et al. (1948) – improved vesical capacity after lydocaine injection in the sacral foramen
- Rockswold et al. (1974) – anesthetic unilateral S3 block decrease detrusor contraction

Sacral Rhizotomy

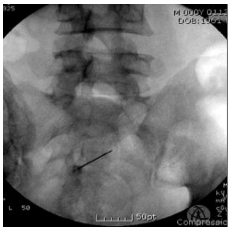
• Background – selectivity



- Tockzek et al. (1975) – identification of sacral roots by electrical stimulation and cystometry
- Törrens & Griffth (1976) – good results with selective sacral rhyzotomy
- Gasparini et al. (1992) -selective sacral rhyzotomy 94% increase vesical capacity

Sacral Rhizotomy

• Percutaneous Radiofrequency



- Mulcahy & Young (1978) – first study in percutaneous radiofrequency
- Ferreira & D'Ancona (2011)*
- Cho & Lee (2012)
- Kim JH et al. (2015)

*Ferreira RS, D'Ancona C. Actas Urol Esp, 35(6):325-330, 2011

Sacral Rhizotomy

- Percutaneous Radiofrequency


Actas Urológicas Españolas

ARTÍCULO ORIGINAL

Rizotomía sacra percutánea por radiofrecuencia en el tratamiento de la hiperactividad del detrusor neurogénico en pacientes con lesiones de la médula espinal

R. S. Ferreira[a,b], C.A. Levi d'Ancona[c], V.P. Dantas-Filho[c], N. Rodrigues Netto Jr.[c] y R. Miyaoka[a,c]

- Prospective study
- n = 12 SCI patients
- Percutaneous radiofrequency sacral rhizotomy is performed in 8 patients
- Follow-up: 12 months

*Ferreira RS, D'Ancona C. Actas Urol Esp, 35(6):325-330, 2011

Percutaneous Radiofrequency sacral rhizotomy Patients and Methods

Inclusion criteria

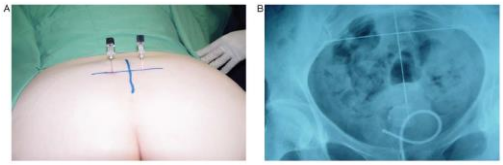
- SCI and NDO, refractory to antimuscarinic drug
- ASIA score A
- Age ≥18
- Positive S3 bilateral anesthetic blockage

Exclusion criteria

- Negative of S3 bilateral anesthetic blockage response
- Presence of ulcer pressure in sacral region

Ferreira RS, D'Ancona C. Actas Urol Esp, 35(6):325-330, 2011

Percutaneous Radiofrequency sacral rhizotomy S3 bilateral anesthetic blockade

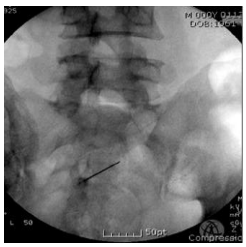


Urodynamic parameters at baseline and after S3 bilateral anesthetic blockade

	Baseline	30' after S3 bilateral anesthetic blockage	*p*
MCC (mL))	99.2 (± 57.9)	330.5 (± 139.3)	< 0.05
P_{det}MCC (cm H_2O)	90.0 (±25.0)	46.0 (± 21.0)	< 0.05

Ferreira RS, D'Ancona C. Actas Urol Esp, 35(6):325-330, 2011

Percutaneous Radiofrequency sacral rhizotomy RF Ablation Technique



- S3 stimulation: 0.1V / 30 Hz / 1.0 m.s
- S3 RF ablation: 70 °C

Ferreira RS, D'Ancona C. Actas Urol Esp, 35(6):325-330, 2011

Percutaneous Radiofrequency Sacral Rhizotomy

Demographic data.

Patient	Gender	Age	Neurological level of injury	ASIA score	Voiding method	Time since injury (mo)
1	F	27	T8	A	CIC	72
2	M	28	C6/C7	A	CIC	72
3	M	40	T9	A	CIC	60
4	F	41	C5/C6	A	CIC	24
5	M	22	C5/C6	A	CIC	60
6	F	37	T12	A	CIC	96
7	M	33	L1	A	CIC	20
8	F	23	C5	A	CIC	24

Ferreira, RS, D'Ancona C. Actas Urol Esp, 35(6):325-330, 2011

Percutaneous Radiofrequency sacral rhizotomy Results

Urodynamic parameters at baseline, 6 and 12 months after percutaneous radiofrequency sacral rhizotomy.

	Baseline (n = 8)	6 mo (n = 8)	12 mo (n = 8)
MCC (mL))	100.2 (± 57.1)	313.7 (± 103.1), p < 0.05	289.2 (± 133.4) p < 0.05
P_{det}MCC (cm H_2O)	82,4 (± 31.77)	64.5 (± 18.8) p < 0.01	69.9 (± 28.7) p < 0.02

- Increased bladder capacity
- Reduced maximum detrusor pressure
- Reduced autonomic dysreflexia
- Erectile dysfunction (1 patient)
- Detrusor overactivity after 12 months

Ferreira, RS, D'Ancona C. Actas Urol Esp, 35(6):325-330, 2011

Conclusion

Safe procedure

Low incidence of morbidity

Good results up to 12 months of follow-up

Decrease autonomic dysrreflexia

However, further studies are needed with greater number of patients

Ferreira, RS, D'Ancona C. Actas Urol Esp, 35(6):325-330, 2011


Original Article

Ann Rehabil Med 2012; 36: 213-219
pISSN: 2234-0645 • eISSN: 2234-0653
http://dx.doi.org/10.5535/arm.2012.36.2.213

arm
Annals of Rehabilitation Medicine

Radiofrequency Sacral Rhizotomy for the Management of Intolerable Neurogenic Bladder in Spinal Cord Injured Patients

Kang Hee Cho, M.D., Sang Sook Lee, M.D.

Department of Rehabilitation Medicine, Chungnam National University School of Medicine, Daejeon 301-172, Korea

- Prospective study
- n = 12 SCI patients
- Percutaneous radiofrequency sacral rhizotomy
- Follow-up: 4 weeks

Cho, KH and Lee, SS. Ann Rehabil Med, 36(2):213-9,2012

Results

Characteristics of the Patients with Spinal Cord Injury

Patient	Age/ Sex	Level (ASIA impairment scale)	Time since injury (months)	Voiding method
1	34/F	C4 (B)	60	CIC
2	46/M	C6 (D)	12	Self voiding
3	52/M	T10 (A)	7	CIC
4	53/M	T5 (A)	88	CIC
5	28/M	T4 (A)	28	CIC
6	69/M	L1 (A)	39	Diaper voiding
7	60/M	C4 (A)	76	CIC
8	49/M	T10 (A)	16	CIC
9	37/M	T4 (B)	120	Self voiding
10	51/M	T8 (A)	34	CIC
11	62/M	T3 (A)	142	CIC
12	55/M	C4 (A)	32	CIC

ASIA: American spinal injury association, CIC: Clean intermittent catheterization

Cho, KH and Lee, SS, Ann Rehabil Med, 36(2):213-9,2012

Results

Comparison of urinary volume and incontinence

Parameter	Before	After
Average CIC volume of each time (ml)	304±109	467±134*
Total amount of incontinence (ml)	255±68	65±91*

Values are mean±standard deviation
CIC: Clean intermittent catheterization
*p<0.05

Cho, KH and Lee, SS, Ann Rehabil Med, 36(2):213-9,2012

Results

Comparison of cystometrogram findings before and after RSDR

Patient	Before		After	
	Maximal bladder capacity (ml)	Trabeculation (Grade)	Maximal bladder capacity (ml)	Trabeculation (Grade)
1	100	0	270	0
2	300	1	500	1
3	540	1	600	1
4	300	1	750	1
5	550	0	300	0
6	200	3	250	3
7	300	1	480	1
8	180	3	250	3
9	300	1	380	1
10	160	1	240	1
11	330	3	200	3
12	250	3	130	3

Cho, KH and Lee, SS, Ann Rehabil Med, 36(2):213-9,2012

Conclusion

It is safe

There are few complications

Decreases the incontinence

Increases bladder volume

Limitation – long term effects on the detrusor

Further studies are needed with greater number of patients and longer follow-up

Cho, KH and Lee, SS, Ann Rehabil Med, 36(2):213-9,2012

Original Article
Ann Rehabil Med 2015;39(5):718-725
pISSN: 2234-0645 • eISSN: 2234-0653
http://dx.doi.org/10.5535/arm.2015.39.5.718
arm Annals of Rehabilitation Medicine

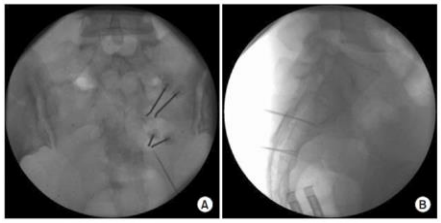
Short-Term Effect of Percutaneous Bipolar Continuous Radiofrequency on Sacral Nerves in Patients Treated for Neurogenic Detrusor Overactivity After Spinal Cord Injury: A Randomized Controlled Feasibility Study

Jin Hyun Kim, MD[1], Sang Ho Ahn, MD[1], Yun Woo Cho, MD[1], Sang Gyu Kwak, PhD[2], Hyo Sung Kim, MD[1]
[1]Department of Physical Medicine and Rehabilitation, Yeungnam University College of Medicine, Daegu;
[2]Department of Medical Statistics, Catholic University of Daegu School of Medicine, Daegu, Korea

- Prospective and randomized study
- n = 10 SCI patients
- Percutaneous bipolar continuous radiofrequency sacral rhizotomy
- Follow-up: 12 weeks

Kim, JH et al., Ann Rehabil Med, 39(5):718-725,2015

Percutaneous bipolar continuous radiofrequency on sacral nerves



A - The anteroposterior view of bipolar radiofrequency on right S2 and S3 nerve root.
B - Lateral view of bipolar radiofrequency on the right S2 and S3 nerve roots

Kim, JH et al., Ann Rehabil Med, 39(5):718-725,2015

Percutaneous bipolar continuous radiofrequency on sacral nerves

Theory :

- bipolar RF is more effective than monopolar
- bipolar RF generates current between two closely placed electrode tips
- generates a high RF electric field
- more rapid tissue heating
- ability to generate larger lesions than monopolar

Kim, JH et al., Ann Rehabil Med, 39(5):718-725,2015

Results

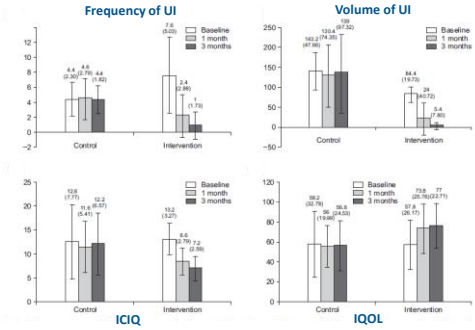
Patient's demographic and clinical data

Patient no.	Age/sex	NLI (AIS)	UDS parameter				ICIQ	IQOL	Incontinence	
			RDV	MDP	V at MDP	MCC			Frequency	Volume (mL)
Intervention										
1	M/53	C4 (A)	286	66	344	402	7	101	5	100
2	M/32	C5 (B)	179	67	595	600	10	85	2	70
3	F/48	C4 (B)	66	77	260	300	12	33	10	57
4	F/40	T6 (A)	209	112	230	500	11	44	15	100
5	M/37	T12 (A)	253	78	180	360	18	28	6	95
Control										
1	M/46	C4 (A)	162	153	189	315	7	100	7	221
2	M/36	C6 (A)	215	48	298	400	10	37	2	125
3	F/31	T8 (A)	232	41	277	320	12	71	5	150
4	M/52	T6 (B)	49	50	101	275	12	91	2	120
5	M/37	T11 (A)	250	31	171	345	17	30	6	90

NLI, neurological level of injury; AIS, American Spinal Injury Association impairment scale; UDS, urodynamic study; MCC, maximum cystometric capacity; MDP, maximum detrusor pressure during filling; RDV, reflex detrusor volume at first contraction; V, volume.

Kim, JH et al., Ann Rehabil Med, 39(5):718-725,2015

Results



Kim, JH et al., Ann Rehabil Med, 39(5):718-725,2015

Results

Values of UDS parameters at baseline and follow-up

Variable	Control group			Intervention group			Z (p-value)
	Baseline	3 mo	Post-Pre	Baseline	3 mo	Post-Pre	
RDV (mL)	181.60±81.09	205.80±42.33	9.75±13.65	198.60±84.67	285.00±70.15	85.75±92.59	-2.310 (0.029)*
MDP (cmH$_2$O)	64.60±49.97	77.00±23.82	-5.25±15.65	80.00±18.72	63.50±14.06	19.75±17.12	-1.440 (0.200)
Volume at MDP (mL)	207.20±163.90	222.80±48.01	13.25±16.38	321.80±163.92	373.30±63.89	-19.75±100.31	-2.310 (0.029)*
MCC (mL)	331.00±46.02	351.30±46.23	-2.50±8.89	432.40±118.67	472.80±39.63	-82.25±61.44	-1.443 (0.200)

Values are presented as mean±standard deviation.
UDS, urodynamic study; RDV, reflex detrusor volume at first contraction; MDP, maximum detrusor pressure during filling; MCC, maximum cystometric capacity.
*Statistically significant at the p<0.05.

Kim, JH et al., Ann Rehabil Med, 39(5):718-725,2015

Percutaneous is more cost-effective

Percutaneous RF & neuromodulation therapy:

- $1,800 test sacral nerve stimulation
- $23,000 sacral nerve stimulation implant
- $300 - $400 bipolar RF

Kim, JH et al., Ann Rehabil Med, 39(5):718-725,2015

Sacral Rhizotomy

Advantages

- Minimally invasive
- Outpatient procedure
- Low cost
- High success rate in short and mid-term follow-up

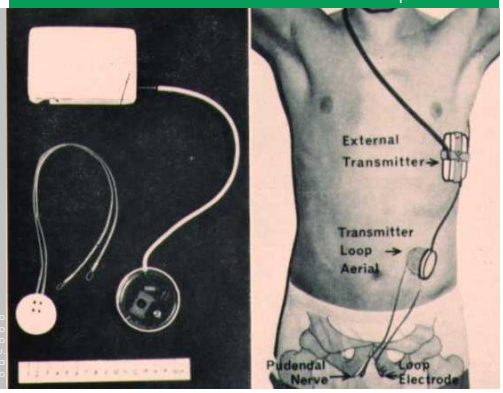
Disadvantages

- Erectile dysfunction
- Lower limb atrophy
- Urethral and anal sphincter dysfunction
- Recurrent NDO in long-term follow-up

Hers , D et al., Spine, 8:729-732,1983
Houle, AM et al, , J Urol,160:1088-1091,1998

Thank you
どうもありがとうございました

Caldwell: direct stimulation of the sphicter



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Direct stimulation of reservoir

Boyce e coll.

Research related to the development of an artificial electrical stimulator for the paralyzed human bladder

J Urol 91:41-51,1964

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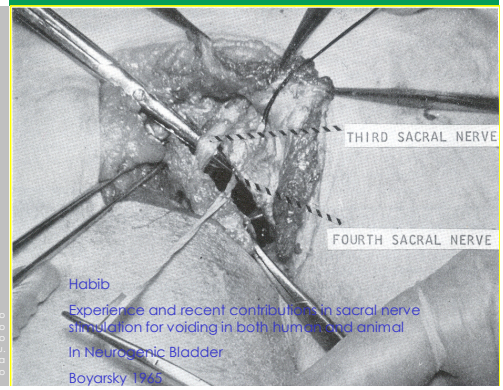
Sacral roots stimulation



Habib

Experience and recent contributions in sacral nerve stimulation for voiding in both human and animal

In Neurogenic Bladder

Boyarsky 1965

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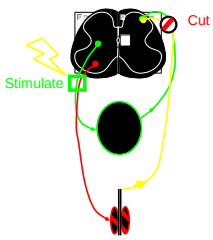
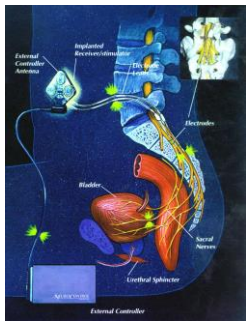
Sacral Root *Stimulation*: Brindley Approach

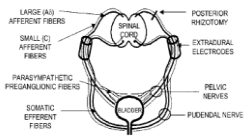




The Brindley era

the revolution!

DIRECT STIMULATION OF SACRAL ROOTS IN HUMANS



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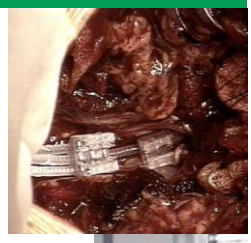
The Brindley era



SACRAL ANTERIOR ROOT STIMULATORS FOR BLADDER CONTROL IN PARAPLEGIA

By G. S. Brindley, M.D., F.R.C.P., C. E. Polkey, M. D., F.R.C.S. and D. N. Rushton, M.D., M.R.C.P.

M.R.C. Neurological Prostheses Unit and Neurosurgical Unit, The Maudsley Hospital, London, England.

Abstract. Nine men and 2 women with spinal injuries have received radiolimbed implants to stimulate the S2, S3 and S4 anterior roots. By activating these they can empty their bladders at will with greatly reduced residual volumes, and the majority of them can achieve continence. Follow-ups are from two months to 4 years.

Key words: Paraplegia; implant; stimulator; bladder; sacral roots.

Paraplegia **32** (1994) 795–805 © 1994 International Medical Society of Paraplegia

The first 500 patients with sacral anterior root stimulator implants: general description

G S Brindley MD FRCP FRS

Spinal Injuries Unit, Royal National Orthopaedic Hospital, Stanmore HA7 4LP, UK.

The first 500 patients to have sacral anterior root stimulators implanted for bladder control are described. Of 479 survivors, 424 were using their stimulators when last followed up between 3 months and 16.1 years (mean 4 years) after implantation.

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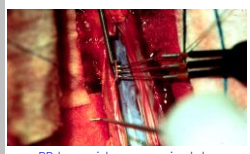
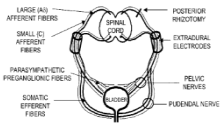
Sacral anterior root stimulation (SARS) with posterior sacral rhizotomy (PR)



PR to avoid neurogenic detrusor overactivity



SARS with intradural book electrode

SARS with extratradural cuff leads

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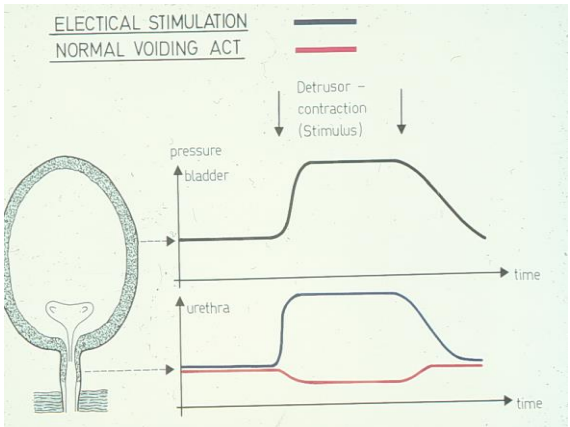

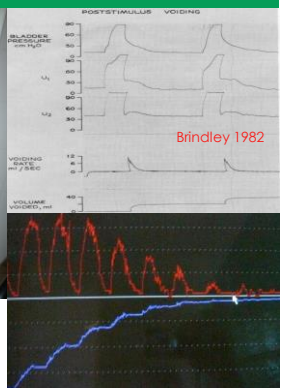

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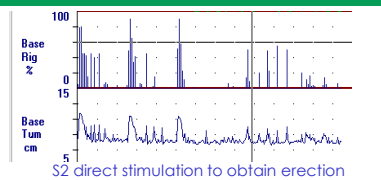
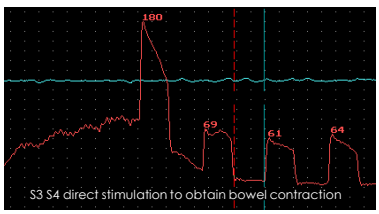


S2 direct stimulation to obtain erection



S3 S4 direct stimulation to obtain bowel contraction

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effect parameters related

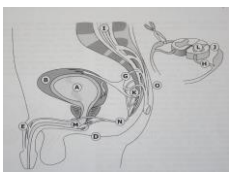
effects on all sacral area dysfunctions with 3 different programs

only SCI complete lesion

invasive

PR non accepted

long term wallerian degeneration



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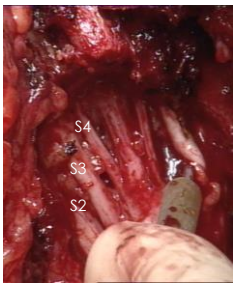
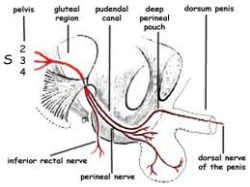


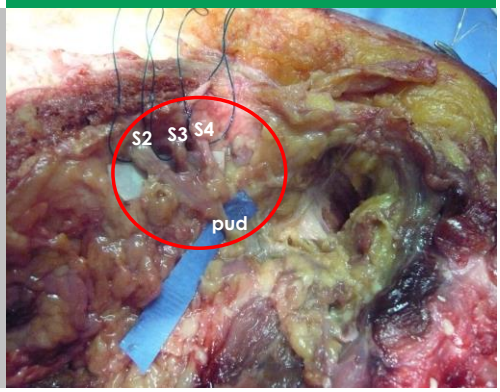
anatomical and functional knowledge of "sacral box"

The electrical box of "pelvic area"

S1
S2
S3
S4



anatomical studies



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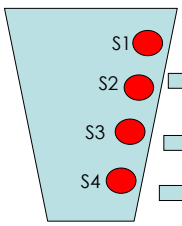
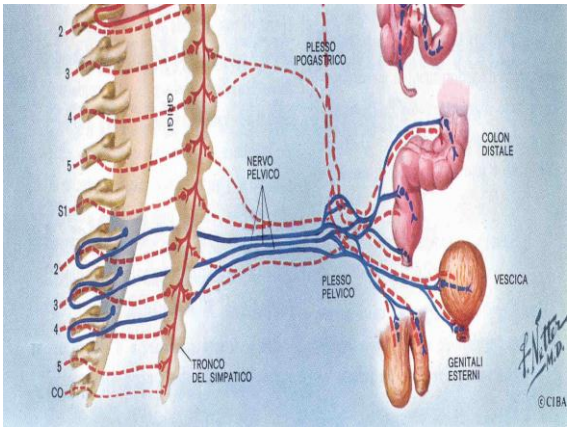


primary somatic contributor of pudendal nerve for external sphincter leg,foot

all pelvic autonomic functions and striated muscles

pelvic autonomic and somatic no leg or foot



from neurostimulation to neuromodulation

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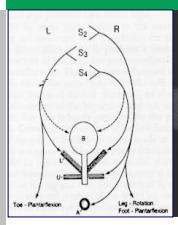

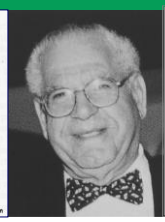

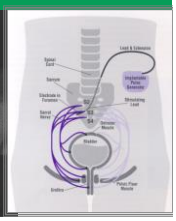

Tanagho, Schmidt
Bladder pacemaker: scientific basis and clinical future
Urology 1982;20:614-61

Tanagho, Schmidt
Electrical stimulation in the clinical managenment of the neurogenic bladder
J Urol 1988;140:331-339

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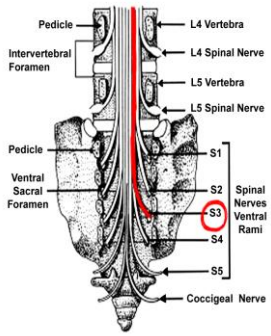
Neuro Urologia centroalbertozanollo

✓contraction of levator ani, external anal, sphincter muscle (Pudendal nerve)

✓sensation in labia majora, vagina, penis, scrotum (perineal branch of Pudendal nerve) and into rectum (inferior rectal nerve)

✓ flexion of the toes (tibial branch of sciatic nerve)



sacral neuromodulation indications

urge incontinence

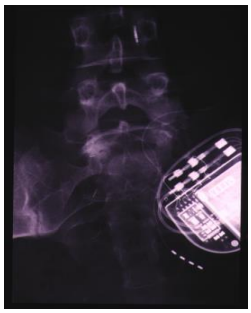
voiding difficulties

urgency frequency

faecal incontinece

pelvic pain

idiopathic ?



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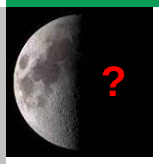

Paradox 1

How does sacral neuromodulation suppress voiding in patients with incontinence,but promote voiding in patients with "non-obstructive" urinary retention?

De Groat ISPIN 2003

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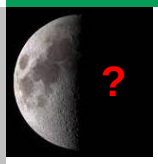


Paradoxe2

treatment for everything!

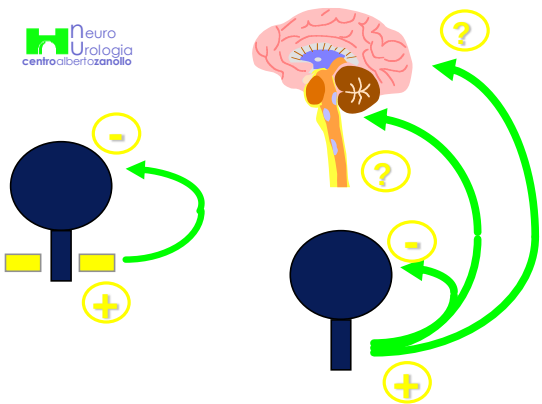
"If I enter in an "electrical system" and I have success with a modulation it means that I have an undisclosed neurogenic situation"

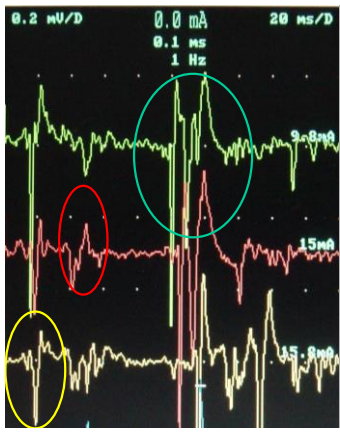
Spinelli 2003

neurourologia - ospedale niguarda "ca granda" milano

centro alberto zanollo U.S.U. niguarda milano

Experimental results on mechanisms of action of electrical neuromodulation in chronic urinary retention

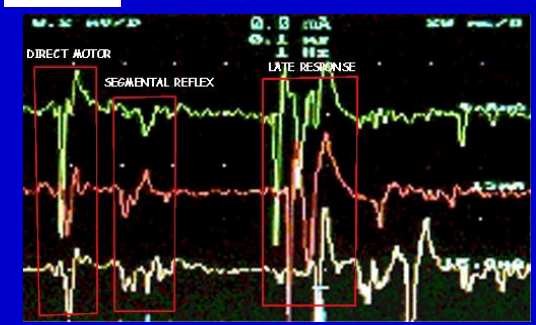




Fowler: 98 msec afferent response

Schurch: 33 msec spinal reflex

Spinelli: 8 msec afferent and efferent responses



Electrical stimulation of peripheral nerves

- to cause muscle contraction
- to produce sensation
- to activate reflexes
- to modulate some function of central nervous system (neuromodulation)

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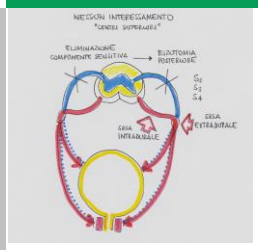
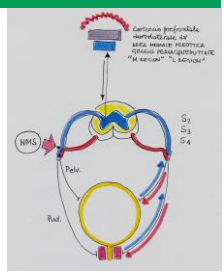


direct stimulation only
of the efferent pathway



stimulation of afferent and
efferent pathway with
modulation of CNS

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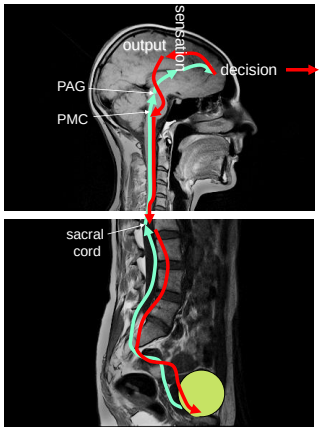
Spinelli 1995

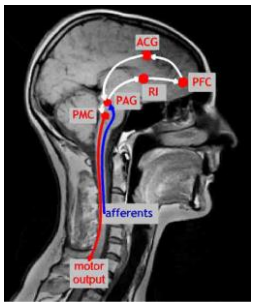
bladder control system



to void or not to void = voluntary control

Working model: normal function

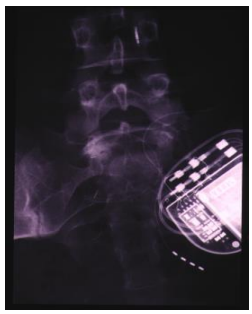
- Afferents synapse in PAG
- Sensation registered in RI
- Decision to void in PFC
- Motor output in ACG
- For voiding, motor output activates PMC (via PAG)
- PMC sends motor output to bladder and urethra



sacral neuromodulation indications

LUTS

motor and sensory



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Selection of patients — predictive factors
psychological evaluation
neurophysiological evaluation

Method — from PNE and one stage implant
to SPI two stage
tined lead
sacral and pudendal

Outcome — parameters?

method

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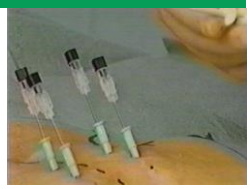
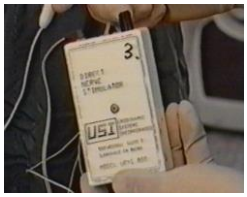
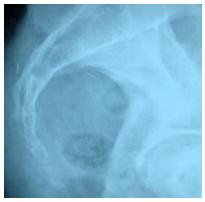
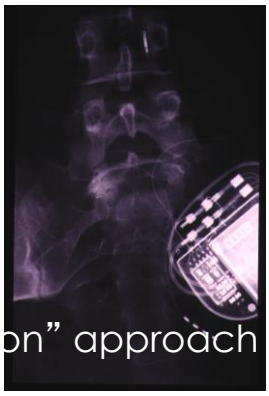
primi "tentativi"....

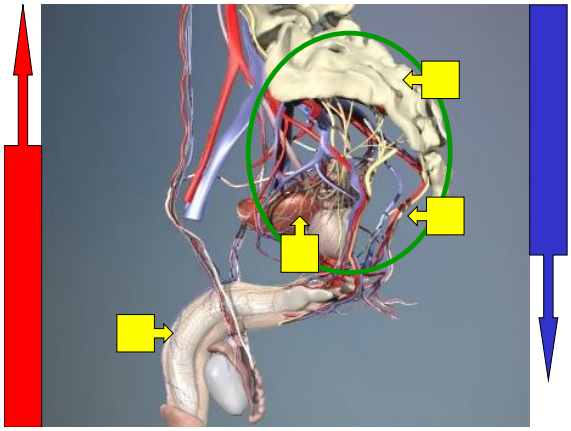








the "old fashion" approach



First desciption of the minimally invasive technique

European Urology

European Urology 43 (2003) 70–74

New Percutaneous Technique of Sacral Nerve Stimulation Has High Initial Success Rate: Preliminary Results

Michele Spinelli[a,*], Gianluca Giardiello[b], Andrea Arduini[b], Ubi van den Hombergh[c]

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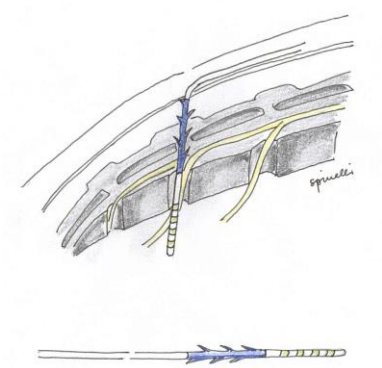
[b]Medtronic Italia, Viale Fulvio Testi 280, Milano, Italy
[c]Medtronic, Endopaludamein 5, P.O. Box 1220, 6201 MP Maastricht, The Netherlands

Accepted 17 September 2002



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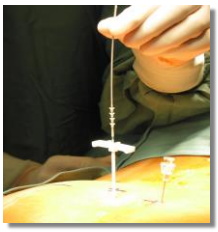
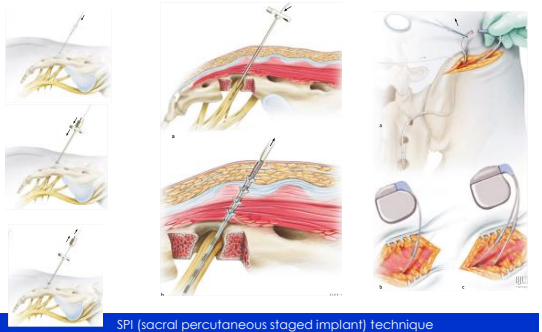
DOI: 10.1097/01.ju.0000092634.64580.9a

NEW SACRAL NEUROMODULATION LEAD FOR PERCUTANEOUS IMPLANTATION USING LOCAL ANESTHESIA: DESCRIPTION AND FIRST EXPERIENCE

MICHELE SPINELLI,*†‡ GIANLUCA GIARDIELLO,† MARTIN GERBER,† ANDREA ARDUINI,† UBI VAN DEN HOMBERGH† AND SILVIA MALAGUTI

From the Ospedale Fornaroli (MS, SM), Magenta (Milano) and Medtronic Italia (GG, AA), Milano, Italy, Medtronic, Inc. (MG), Minneapolis, Minnesota, and Medtronic Europe (UvdH), Tolochenaz (Lausanne), Suttzerland





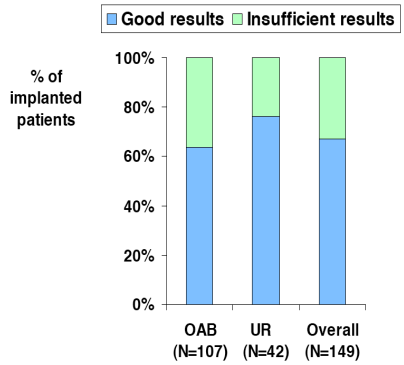
SPI (sacral percutaneous staged implant) technique
Spinelli e coll. JUrol. November 2003

Italian experience

Sacral Neuromodulation (Interstim®)

- Frequency / Urgency
  ≤ 50-80%
- Urinary Incontinence
  ≤ 50-80%
- Urinary Retention
  > 80%
- Chronic constipation
  > 70%
- Faecal incontinence
  > 90%

literature data thanks to Dr. Elneil



van Voskuilen AC,et al., Eur Urol 2006; 49:366-72

SNM Concerns

- Not approved for neurogenic LUTS
- ? of indications/studies
- ? of financial reimbursement if done
- ? about MRI safety

literature

Interstim for Neurogenic LUTS

- Review of neurogenic patients tested with SNS
- 33 patients tested, 28 implanted

Wallace et al, AJOG, 2007

SNM for Neurogenic LUTS Meta-analysis

- 26 studies (357 patients) as of April 15, 2010
- Pooled success rates
  - 68% for test phase
  - 92% for permanent SNS
- Mean follow-up of 26 months

Kessler, et al, Eur Urol, 2010

Reference	Year of publication	Level of evidence	Study type	No. of patients	No. of women (%)	Mean age, yr	Study includes data on
Hohenfellner et al [15]	1998	4	RCS	11	9 (82)	43	P
Ishigooka et al [16]	1998	4	RCS	4	1 (25)	44	P
Chartier-Kastler et al [7]	2000	2b	PCS	9	9 (100)	43	T + P
Spinelli et al [19]	2001						
Retrospective registry		4	RCS	18	11 (61)	NR	P
Prospective registry		2b	PCS	16	9 (56)	59	P
Hohenfellner et al [20]	2001	4	RCS	27	19 (70)	45	T + P
Scheepens et al [21]	2002	4	RCS	24	18 (75)	45	T
Braun et al [23]	2003	4	RCS	41	26 (63)	48	T
Bross et al [24]	2003	4	RCS	24	21 (88)	46	T
Everaert et al [25]	2003	2b	PCS	8	8 (100)	44	T + P
Ruffion et al [26]	2003	4	CR	2	2 (100)	45	T + P
Schurch et al [27]	2003	4	RCS	3	2 (67)	31	T
Spinelli et al [28]	2003	2b	PCS	5	NR	NR	T + P
Lavano et al [29]	2004	4	RCS	6	4 (67)	48	T + P
Minardi et al [30]	2005	4	RCS	5	3 (60)	49	P
Garg et al [32]	2007	4	CR	1	1 (100)	58*	T + P
Roth et al [33]	2007	4	CR	1	1 (100)	45*	T + P
Sutherland et al [34]	2007	4	RCS	10	9 (90)	60	P
Wallace et al [8]	2007	4	RCS	33	31 (94)	54	T + P
Lombardi et al [35]	2008	2b	PCS	17	17 (100)	37	P
Bertapelle et al [36]	2008	4	RCS	11	3 (27)	55	T + P
Lombardi et al [39]	2009	4	RCS	24	10 (42)	46	P
Wosnitzer et al [40]	2009	4	CR	1	1 (100)	20*	T + P
Sievert et al [41]	2010	2b	PCS	10	0 (0)	31	P
Marinkovic et al [42]	2010	4	RCS	14	14 (100)	46	T + P
Daniels et al [43]	2010	4	RCS	32	26 (81)	62	T + P

RCS = retrospective case series; P = permanent sacral neuromodulation; T = test phase; PCS = prospective cohort study; NR = not reported; CR = case report.
* Absolute value, not mean.

	No. of patients with success/total no. of permanently implanted patients	Success rate, %
LUTD resulting from:*		
MS	46/50	92
Parkinson's disease	6/6	100
Myelomeningocele	1/2	50
CVA	6/10	60
CP	2/2	100
Pelvic surgery	14/23	61
Disk disease	10/18	56
Spinal cord injury:	47/61	77
Complete	10/12	83
Incomplete	30/37	81
Unknown	7/12	58
Other neurologic disease or injury	38/52	73
Type of LUTD:**		
Chronic urinary retention	65/89	73
Urgency–frequency syndrome	12/14	86
Urgency incontinence	62/84	74
Combination†	31/37	84

LUTD = lower urinary tract dysfunction; MS = multiple sclerosis; CVA = cerebrovascular accident; CP = cerebral palsy.

Interstim for Neurogenic LUTS

- N = 62 trialed
  - DO = 34
  - Retention = 28
  - DSD = 9
- 41/62 had > 50% improvement, 37 implanted
- Follow up avg 4.3 years

- 76% of those implanted maintained outcomes
- 8% results partially altered
- 16% loss of efficacy

Chaabane, et al, Neurourol Urod, 2011

Neurological pathology	n = 62
Multiple sclerosis	13
Incomplete spinal cord injury	13
Peripheral neuropathy	8
Parkinson's disease	4
Myelitis/encephalitis	4
Stroke	4
Acquired brain injuries	3
Cerebral palsy	2
Central nervous system tumor	2
Friedreich ataxia	1
Subarachnoid hemorrhage	1
Primitive dysautonomia	1
Williams–Beuren syndrome	1
Adrenoleukodystrophy	1
Multiple system atrophy	1
Spinocerebellar atrophy	1
Operated cerebral angioma	1
Familial hereditary degeneration	1

Patients with Retention

TABLE III. Comparison of the Urodynamic Results Before and During the Sacral Neuromodulation Test Stimulation in Patients With Chronic Urinary Retention

	Before the test	During the test	P
Mean maximum flow rate (ml/sec)	7.6 ± 3.3	14.6 ± 4.9	0.03
Mean post-void residual volume (ml)	550.0 ± 124.5	34.0 ± 16.3	<0.0001
Mean maximum cystometric capacity (ml)	341.4 ± 224.3	331.5 ± 221.1	n.s.
Mean compliance	44.9 ± 43.5	39.3 ± 23.2	n.s.
Mean maximum urethral closure pressure (cm H_2O)	68.8 ± 42.7	57.0 ± 18.1	n.s.

Patients with NDO

TABLE IV. Comparison of the Bladder Diary and the Urodynamic Evaluation Before and During the Sacral Neuromodulation Test Stimulation in Patients With Detrusor Overactivity

	Before the test	During the test	P
Voiding diary (/24 hr)			
Mean number of micturitions	10.90 ± 3.18	6.07 ± 2.05	0.0002
Mean number of incontinence episodes	3.08 ± 0.53	0.34 ± 0.15	<0.0001
Mean number of urgency episodes	7.57 ± 0.48	1.53 ± 0.83	<0.0001
Mean number of nocturia	2.63 ± 0.41	0.15 ± 0.10	<0.0001
Urodynamic evaluation			
Mean maximum flow rate (ml/sec)	18.8 ± 3.5	18.9 ± 3.25	n.s.
Mean post-void residual volume (ml)	35.3 ± 4.5	11.7 ± 10.0	n.s.
Mean volume of first uninhibited detrusor contraction (ml)	83.3 ± 22.7	161.0 ± 34.3	0.0022
Mean maximum cystometric capacity (ml)	199.7 ± 12.5	285.0 ± 31.38	0.0022
Detrusor-sphincter dyssynergia			
Yes	9	1	0.0167
No	53	61	
Mean maximum intravesical pressure (cm H_2O)	46.0 ± 16.56	20.0 ± 8.9	0.026
Mean compliance (ml/cm H_2O)	35.83 ± 10.2	32.2 ± 6.0	n.s.
Mean maximum urethral closure pressure (cm H_2O)	64.7 ± 25.4	55.3 ± 26.1	n.s.

ORIGINAL ARTICLE

Clinical outcome of sacral neuromodulation in incomplete spinal cord injured patients suffering from neurogenic lower urinary tract symptoms

G Lombardi and G Del Popolo

Neurourology and Urodynamics Department, Careggi, University Hospital, Florence, Italy

Objective: To determine the efficacy and safety of sacral neuromodulation (SNM) in incomplete spinal cord injured (SCI) subjects affected by neurogenic lower urinary tract symptoms (NLUTS).

Methods: Twenty-four SCI patients were enrolled. The individuals were divided into two groups: 13 individuals in the urinary retention subgroup and 11 suffering from overactive bladder syndrome. All subjects underwent definitive SNM implantation (Medtronic, Inc.). Voiding symptoms were assessed using patient bladder diaries, which recorded leaks per-SNM and further each follow-up (1, 3 and 6 months, and then every 6 months). Urodynamic measures were per 24 h: number of micturitions and voided volume per void for both groups; number of urinary leakages, pad use and sockets for patients with overactive bladder symptoms; and volume per catheterization and number of catheterizations for urinary retention subjects only. Final check-up was completed by June 2005.

Results: Median follow-up was 61 months. Up to the final visit, all subjects maintained a clinical improvement of more than 50% compared with baseline. Twenty-two side effects were recorded. Four subjects with urinary retention needed a new implant in the contralateral S3 sacral root because of loss of efficacy. One patient with urinary retention developed a wound infection at the implanted pulse generator site.

Conclusions: Our study contains the largest series of implanted SCI patients ever published. SNM is a therapy to consider in the treatment of NLUTS in spinal SCI patients, even if the loss of clinical benefits for patients with retention NLUTS must be taken into account. All adverse events were treated effectively.

Spinal Cord (2006) 47, 488–492; doi:10.1038/sj.sc.3101972; published online 24 February 2009

Keywords: neurogenic bladder; SNM; spinal cord lesion; urinary retention; voiding diaries

Results: Median follow-up was 61 months. Up to the final visit, all subjects maintained a clinical improvement of more than 50% compared with baseline. Twenty-two side effects were recorded. Four subjects with urinary retention needed a new implant in the contralateral S3 sacral root because of loss of efficacy. One patient with urinary retention developed a wound infection at the implanted pulse generator site.

Issues with SNM for Neurogenic LUTS

- Potential loss of efficacy in patients with progressive disease
- MRI issues: *"MRI is not recommended for a patient who has any implanted component of a neurostimulation system. Exposing a patient with an implanted neurostimulation system or component to MRI may potentially injure the patient or damage the neurostimulator…"*

Medtronic website, 2006

Chronic Pudendal Nerve Stimulation

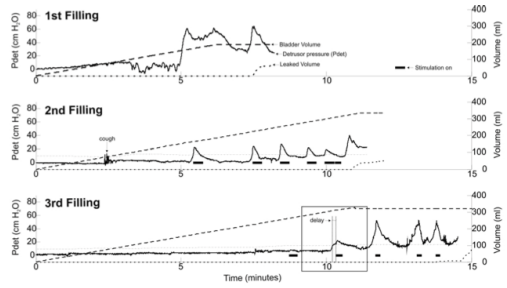
- N = 15 with neurogenic DO (8M, 7F)
- Tined leak placed near pudendal nerve
- 12/15 had successful trial stage and implanted
  - 8 became continent
  - Remainder had significant improvement
- Many had improvement in bowel function
- At 6 mo follow-up improvements maintained

Spinelli et al, Neurourol Urod, 2005

Genital Nerve Stimulation

- N = 67 (41 M, 26 F; 56 SCI)
  - 17 had sensation and completed all 3 cycles
- Clitoral or Penile stimulation
- Automatic or Patient controlled stimulation
- 3 cystometrograms
  - 1 - no stim
  - 2 - automatic stim
  - 3 - patient controlled stim

Opissio et al, J Urol, 2008



Neuromodulation for Neurogenic LUTS

- Large number of studies on commercially available neuromodulation devices
- SNM – studied on a plethora of neurogenic etiologies
  - OAB and Retention
  - Results similar to idiopathic?

Early Sacral Neuromodulation Prevents Urinary Incontinence After Complete Spinal Cord Injury

- Placement of bilateral S3 leads soon after SCI
  - during flaccid stage
- At 2 years fu prevented progression to high pressure overactive bladder

KD Sievert, et al, Ann Neuro, 2010

The "dark side": what efforts for future

What's the real aim of our efforts in the future?

- to find out an answer for non-responder patients
- to improve the clinical outcome in therapeutic options
- to open new fields in modulation and direct stimulation of sacral area

Neuro Urologia centroalbertozanollo

method

monitoring

Objective responses

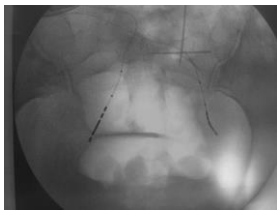
size
recharge

sacral and pud

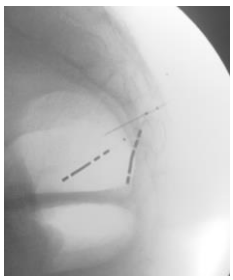
monolateral
bilateral

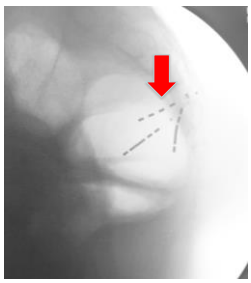
easy for pts and ph

Neuro Urologia centroalbertozanollo

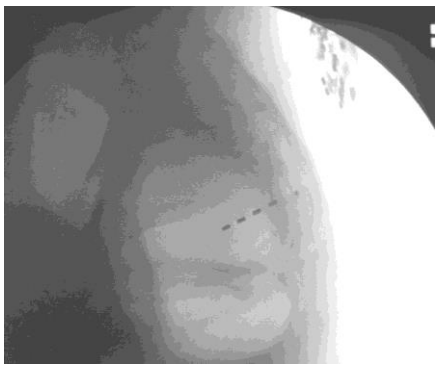


Neuro Urologia centroalbertozanollo



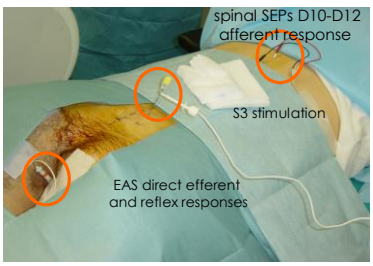


Neuro Urologia centroalbertozanollo

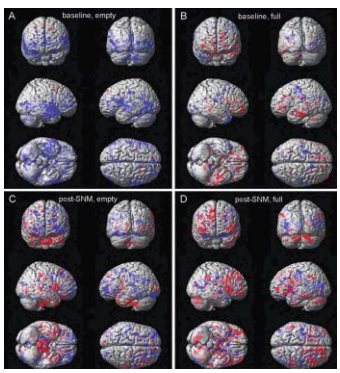


Neuro Urologia centroalbertozanollo

Neurophysiological Assessment During Implant Of Sacral Neuromodulation Lead (SPI technique)



Neuro Urologia centroalbertozanollo



method

monitoring

objective responses

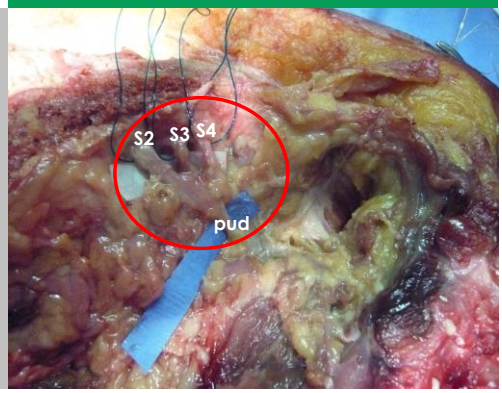
size
recharge

easy for pts and ph

sacral vs pud

monolateral
bilateral

anatomical studies



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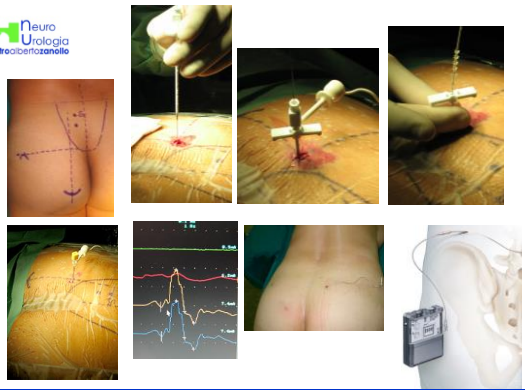
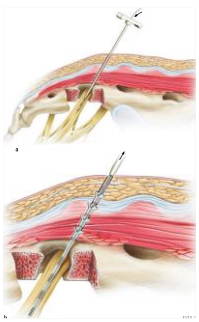
Activation of afferent innervation over up to three sacral segments

Efferent stimulation also provides direct activation of the external urethral sphincter, the external anal sphincter, and levator ani muscles,
which may be of some benefit in sacral area control

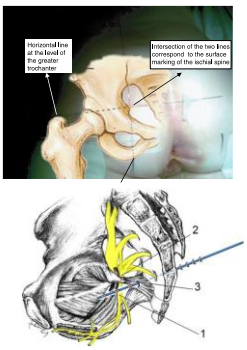


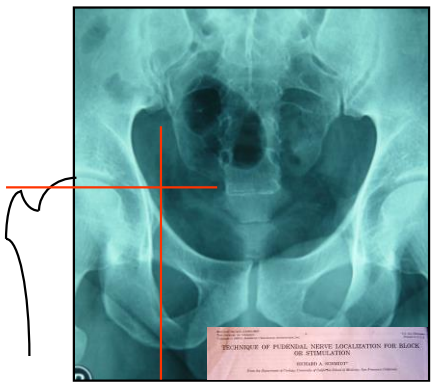
Spinelli M., e coll A new minimally invasive procedure for pudendal nerve stimulation to treat neurogenic bladder: description of the method and preliminary data . Neurourol Urodyn 2005;24:305-9

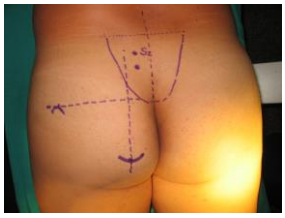
from sacral to pudendal nerve

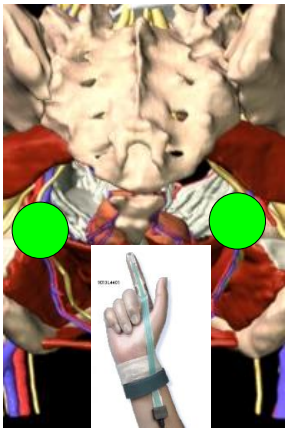


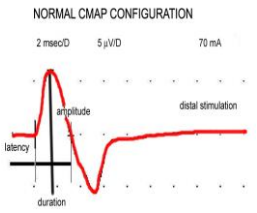
Spinelli e coll. Neurourol Urodyn 2005;24:305-9











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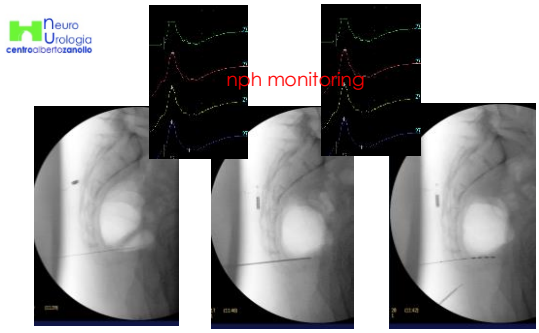

needle and stylet | introduction system | tined lead

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Spinelli e coll
A new minimally invasive procedure for pudendal nerve stimulation to treat neurogenic bladder description of the method and preliminary data
. Neurourol Urodyn 2005;24:305-9

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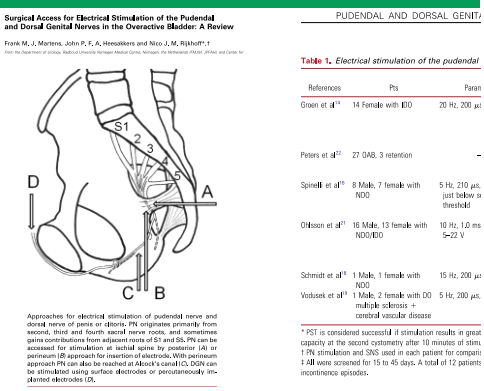

Surgical Access for Electrical Stimulation of the Pudendal and Dorsal Genital Nerves in the Overactive Bladder: A Review

Frank M. J. Martens, John P. F. A. Heesakkers and Nico J. M. Rijkhoff*,†

Approaches for electrical stimulation of pudendal nerve and dorsal nerve of penis or clitoris. PN originates primarily from second, third and fourth sacral nerve roots, and sometimes gains contributions from adjacent roots of S1 and S5. PN can be accessed for stimulation at ischial spine by posterior (A) or perineum (B) approach for insertion of electrode. With perineum approach PN can also be reached at Alcock's canal (C). DGN can be stimulated using surface electrodes or percutaneously implanted electrodes (D).

PUDENDAL AND DORSAL GENITA

Table 1. *Electrical stimulation of the pudendal*

References	Pts	Param
Groen et al[14]	14 Female with IDO	20 Hz, 200 μs
Peters et al[22]	27 OAB, 3 retention	–
Spinelli et al[15]	8 Male, 7 female with NDO	5 Hz, 210 μs, just below s threshold
Ohlsson et al[17]	16 Male, 13 female with NDO/IDO	10 Hz, 1.0 ms 5–22 V
Schmidt et al[18]	1 Male, 1 female with NDO	15 Hz, 200 μs
Vodusek et al[19]	1 Male, 2 female with DO multiple sclerosis + cerebral vascular disease	5 Hz, 200 μs,

* PST is considered successful if stimulation results in great capacity at the second cystometry after 10 minutes of stim PN stimulation and SNS used in each patient for compari All were screened for 15 to 45 days. A total of 12 patients incontinence episodes.

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CPNS personal experience

2002-2007

39 first stage
27 second stage
(published)

2007-2011 "clinical sevice"

37 first stage
26 second stage

Janaury 2013 revision data base

91 pts first stage
65 pts second stage

more than one lead?

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method

monitoring

objective responses

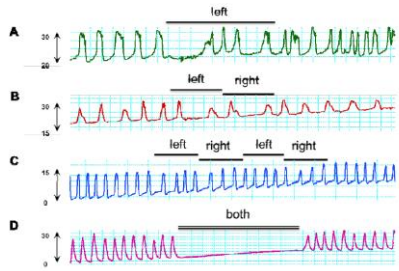
size
recharge

monolateral
bilateral

sacral and pud

easy for pts and ph

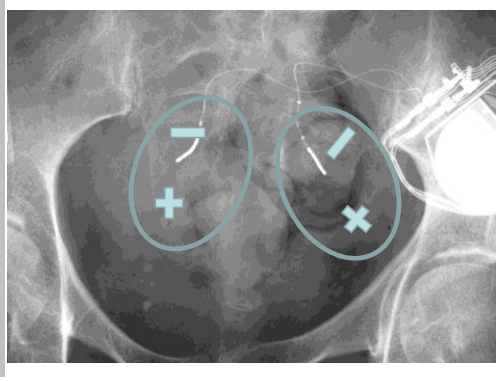
Unilateral versus bilateral neuromodulation in a rat rhythmic bladder contraction model



Bilateral stimulation abolished bladder contractions.

Xin Su, Neurostimulation I

BILATERAL IMPLANT BIPOLAR EACH SIDE



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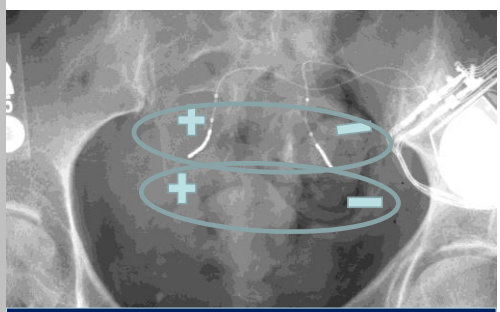
BILATERAL IMPLANT CROSS OVER STIMULATION



The stimulation is not trans-foramen rather anterior to sacrum

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method

monitoring

objective responses

IPG size
recharge

sacral and pud

monolateral
bilateral

easy for pts and ph

bifurcated extension lead

Restore Prime
Two octapolar lines

Weight 67 g
H:65mm
L:49mm
Thickness 15 mm

Socket A: 0-7

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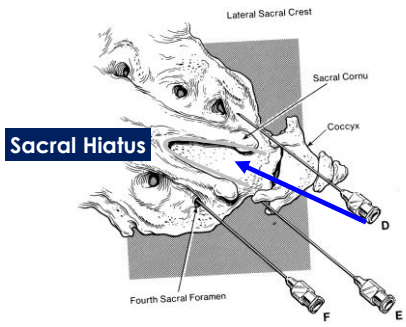
sacral epidural approach

thank to Prof. Raz



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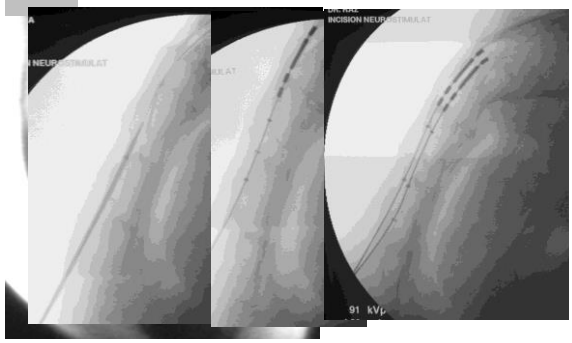
bilateral caudal epidural

thank to Prof. Raz



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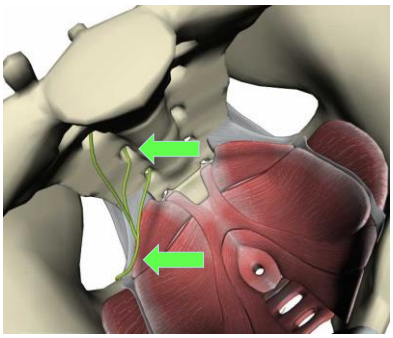
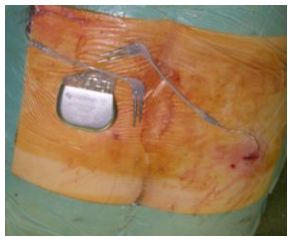
sacral and pudendal





simultaneous pudendal and sacral stimulation

bilateral pudendal nerve stimulation

sacral bilateral

sacral and pudendal

pudendal bilateral

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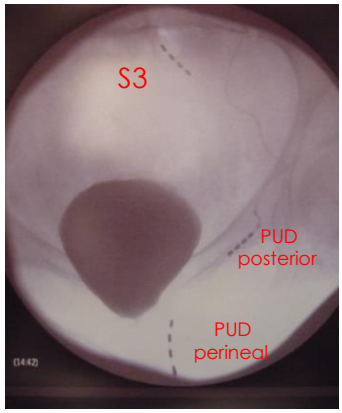

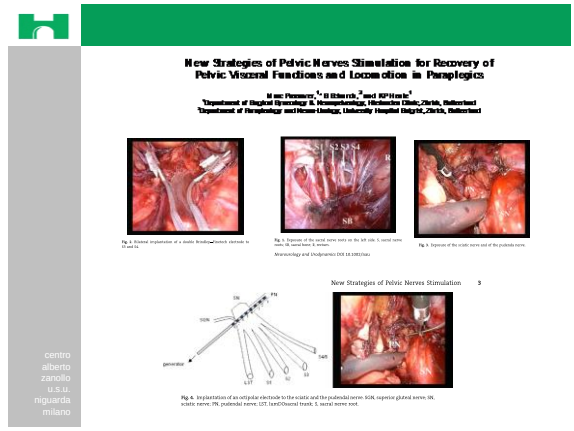
New Strategies of Pelvic Nerves Stimulation for Recovery of Pelvic Visceral Functions and Locomotion in Paraplegics

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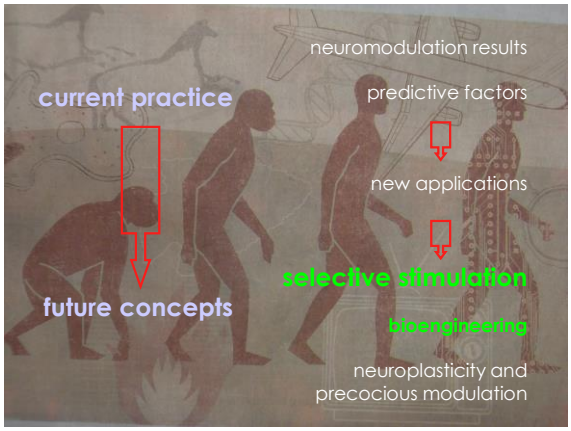
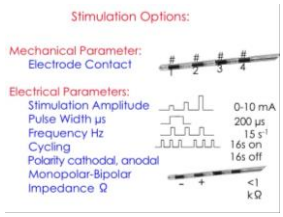


device and leads



different parameters related on symtoms?

cycling to avoid nerve abitude?

Tai C.
voiding reflex in chronic spinal cord injured cats induced by stimulating and blocking pudendal nerves
Neurourol Urodyn 2008

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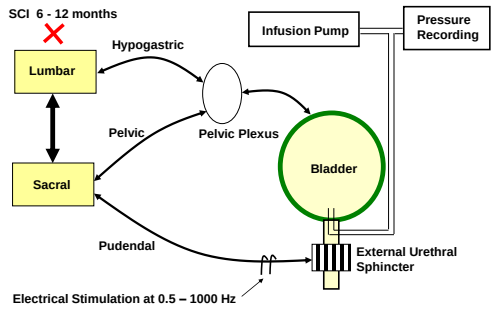
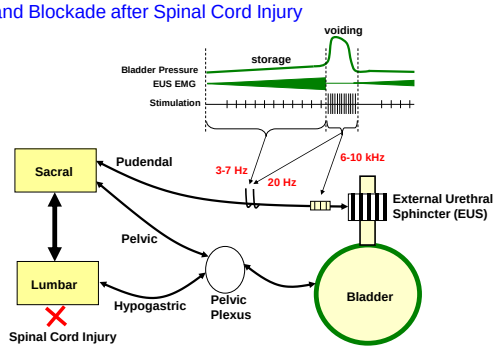
Pudendal Nerve Neuromodulation of Bladder Activity



with permission Dr. Tai - Pittsbugh Univ.

Control Bladder and EUS by Pudendal Nerve Stimulation and Blockade after Spinal Cord Injury



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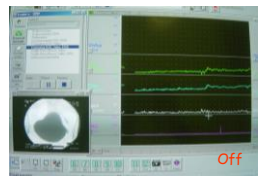

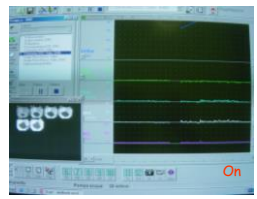

What to choose?

- Constant voltage vs constant current
- High frequency tonic stimulation
- Burst stimulation
- Current fractionalization
- Khz tonic stimulation with complete current conduction blockage
- Different waveforms
- Indipendent power sources

Round the corner?

- Axonics
- Bioness
- Biowave
- Bluewind
- Stimguard

Sacral
Tibial
Pudendal
Cavernous

Implantable
Wireless
cutaneous

Multiple channel indipendent programming IPG

Low and high frequency

More flexible leads

Selective stimulation settings

Close loop

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Neuro-urology

Safety of MRI at 1.5 Tesla in Patients with Implanted Sacral Nerve Neurostimulator

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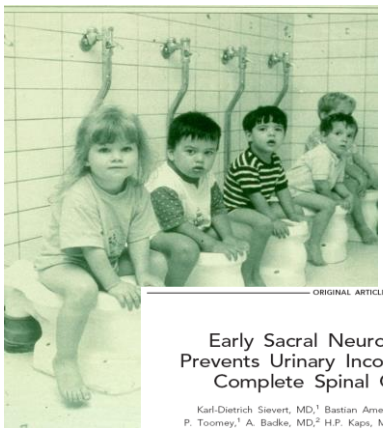
Magnetic resonance imaging
Safety
Implantable devices

Abstract
Objective: Sacral neuromodulation has become an established method to treat voiding dysfunction. Currently the use of implanted sacral nerve stimulators is becoming more popular worldwide. Magnetic resonance imaging (MRI) is an important diagnostic tool for many medical and neurological disorders. Many radiology centers do not perform MRI examinations on patients with implanted sacral nerve stimulator. The basis for this policy is that potential hazards such as motion, dislocation or torquing of the implanted pulse generator (IPG), heating of the leads, and damage to the IPG may occur, resulting in painful stimulation. In contrast, many studies conducted on MRI at 1.5 Tesla in patients with implantable devices have found the examination to be safe if the area to be imaged is out of the isocenter of the MRI scanner and other precautions are taken.
Methods: Eight MRI examinations at 1.5 Tesla were conducted in areas outside the pelvis on six patients with implanted sacral nerve stimulator (InterStim® neurostimulator; Medtronic, Inc. Minneapolis, MN, USA). Implanted pulse generators were



ANN NEUROL 2010;67:74–84

precocious modulation

ORIGINAL ARTICLE

Early Sacral Neuromodulation Prevents Urinary Incontinence After Complete Spinal Cord Injury

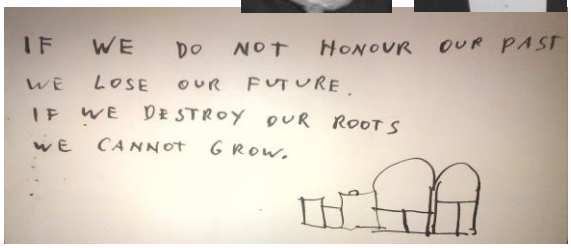
Karl-Dietrich Sievert, MD,[1] Bastian Amend, MD,[1] G. Gakis, MD,[1] P. Toomey,[1] A. Badke, MD,[2] H.P. Kaps, MD,[2] and Arnulf Stenzl, MD[1]

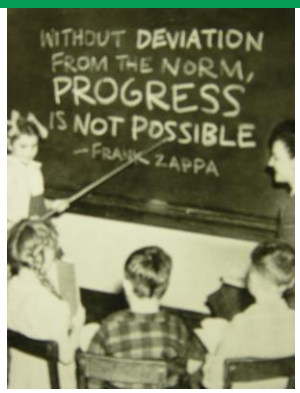
precocious modulation!

CARE

CURE

Neuro Urologia
centroalbertozanollo





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Thanks for your attention

IS THERE STILL A PLACE FOR AUGMENTATION CYSTOPLASTY

Julien Renard MD

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Geneva University Hospital, Geneva Switzerland

Augmentation Cystoplasty

Remains an option

➔ in neurogenic

➔ non-neurogenic bladder dysfunction

when conservative management, pharmacological methods and minimally invasive treatments have been unsuccessful and exhausted

Augmentation Cystoplasty

- used for the small capacity, high-pressure, poorly compliant or overactive bladder

- The technique aims to
➔ provide urinary storage
➔ protect the upper urinary tract and preserve renal function
➔ provide continence
➔ resistance to infection
➔ offer a convenient method of voluntary and complete emptying.

History

➔ first described in the canine model by Tizzoni and Foggi in 1888

➔ first described in humans by von Mikulicz in 1889

➔ The technique was popularised by Couvelaire in the 1950s, as a treatment for small contracted tuberculous bladders

➔ The introduction of clean intermittent self-catheterisation (CISC) contributed to the wider use of AC,

Techniques

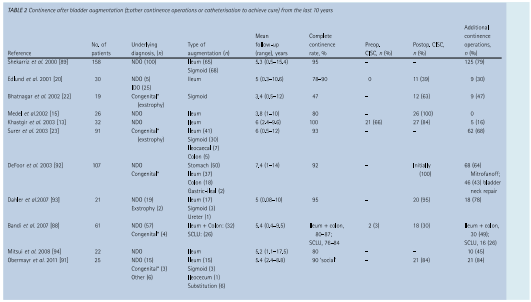


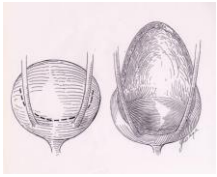
TABLE 2 Continence after bladder augmentation (Either continence operations or catheterisation to achieve cure) from the last 10 years

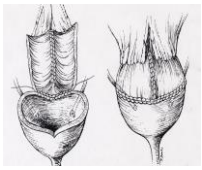
Reference	No. of patients	Underlying diagnosis, (n)	Type of augmentation (n)	Mean follow-up (range), years	Complete continence rate, %	Preop. CIDC, n (%)	Postop. CIDC, n (%)	Additional continence operations, n (%)
Simsiriwong et al. 2000 [89]	158	NDO (100)	Ileum (65) Sigmoid (68)	5,1 (0,2–15,4)	95	–	–	125 (79)
Edlund et al. 2001 [20]	30	NDO (5) IDO (25)	Ileum	5 (0,5–10,0)	75–90	0	11 (39)	9 (30)
Bhatnagar et al. 2002 [22]	19	Congenital (exstrophy)	Sigmoid	3,4 (0,5–12)	47	–	12 (63)	9 (47)
Medel et al.2002 [15]	26	NDO	Ileum	3,4 (1–10)	80	–	26 (100)	0
Khastgir et al. 2003 [13]	32	NDO	Ileum	6 (0,4–16)	100	21 (66)	27 (84)	5 (16)
Surer et al. 2003 [23]	91	Congenital (exstrophy)	Ileum (41) Sigmoid (30) Ileocaecal (7) Colon (6)	6 (0,5–12)	93	–	–	62 (68)
Defoor et al. 2003 [92]	107	NDO Congenital	Stomach (60) Ileum (37) Colon (10) Gastric bud (2)	2,4 (1–14)	92	–	Initially (100)	68 (64) Mitrofanoff: 46 (43) bladder neck repair 18 (19)
Duffer et al.2007 [93]	21	NDO (19) Exstrophy (2)	Ileum (17) Sigmoid (3) Ureter (1)	5 (0,08–10)	95	–	20 (95)	18 (78)
Banoli et al. 2007 [88]	61	NDO (57) Congenital (4)	Ileum + Colon: (32) SCLI: (26)	5,4 (0,4–6,5)	Ileum + colon, 86–87, SCLI, 73–84	2 (3)	18 (30)	Ileum + colon, 30 (46); SCLI, 16 (26)
Mitsui et al. 2008 [94]	22	NDO	Ileum	5,1 (1,1–12,1)	80	–	–	10 (45)
Obermayr et al. 2011 [91]	25	NDO (15) Congenital* (3) Other (6)	Ileum (15) Sigmoid (1) Ileocecum (1) Substitution (8)	5,4 (0,4–6,0)	90 "social"	–	21 (84)	21 (84)

Techniques

Ileum

- most widely used bowel segment
- Ideally 25–40 cm from the ileocaecal
- detubularized into “U” or “S” shape
- “W” for larger segments





Techniques

Sigmoid

- is generally detubularised as a straight patch or a cup patch
- most common alternative to ileum

➔ Advantages: Its thick muscular wall, large lumen and abundant mesentery guarantee adequate bladder capacity and manoeuvrability

➔ Potential disadvantages:
- the higher risk of UTI (secondary to colonic commensal bacteria)
- larger amounts of mucus production
- theoretically higher long-term risk of malignancy

Indications

Caecum

- can be used in its original tubular shape more
- as a detubularised patch to prevent spontaneous colonic contractions and avoid associated rises in bladder pressure

- most commonly used in conjunction with the terminal ileum as an ileo-caecocystoplasty

➔ It has great mobility, which permits tension-free ureteric anastomosis;
➔ however, the diarrhoea and malabsorption associated with resection of the ileo-caecal valve is often

Indications

GASTROCYSTOPLASTY

Where bowel is unavailable or unsuitable, and in patients with metabolic acidosis, stomach is an alternative to bowel.

Advantages

➔ reduced secretion of mucus
➔ reduced infection risk
➔ reduced absorption of electrolytes.

Disadvantages
➔ include the haematuria-dysuria syndrome in particular, are less commonly used

Complications

EARLY COMPLICATIONS

➔wound infection (5–6.4%)

➔ small bowel obstruction (3–5.7%)

➔bleeding requiring re-operation (0–3%)

➔infection of ventriculo-peritoneal shunt where present (0–20%)

➔Regular CISC is needed in 6–39%

➔The mortality rate from AC is reported to be 0–2.7%

Complications

Thromboembolism, cardiovascular and gastrointestinal complications

Reflux and renal function

ISC, UTI AND URINARY TRACT CALCULI

TABLE 1 Complications after bladder augmentation from the last 10 years

Reference	No. of patients	Recurrent UTI, n (%)	VUR, n (%)	Bladder stones, n (%)	Residual NDO, n (%)	Delayed bladder rupture, n (%)	Bowel obstruction, n (%)	Minor bowel dysfunction, n (%)	Revision, n (%)	Renal deterioration, n (%)	Fistula, n (%)
Shekarriz et al. 2000 [89]	150	–	6 (4.2)	14 (10.1)	–	17 (12.8)	6 (4.5)	–	18 (11)	4 (3)	–
Stölzel et al. 2001 [20]	30	1 (3.2)	–	1 (3.2)	2 (6.7)	–	1 (3.3)	6 (25)	2 (6.7)	–	–
Bhatnagar et al. 2002 [22]	19	2 (10.5)	1 (5.2)	3 (15.8)	–	–	–	–	–	0	2 (10.5)
Medd et al. 2002 [15]	28	–	2 (7.2)	–	–	–	–	–	–	–	–
Khastgir et al. 2003 [13]	32	2 (6.2)	64 (20)	2 (6.2)	1 (3.1)	1 (3.1)	1 (3.1)	6 (18.7)	27 (84.4)	–	3 (9.4)
Surer et al. 2003 [23]	91	3 (3.2)	–	24 (26)	13 (14.2)	–	3 (3.3)	–	–	–	3 (3.3)
DeFoor et al. 2003 [92]	107	–	–	–	–	4 (5)	–	–	–	–	–
DeFoor et al. 2004 [90]	105	–	–	12 (11)	–	–	–	–	–	–	–
Metcalfe et al. 2006 [87]	500	–	–	75 (15)	–	43 (8.6)	16 (3.2)	–	47 (9.4)	–	–
Danko et al. 2007 [93]	21	–	0	1 (4.8)	–	0	–	–	–	0	–
Bandi et al. 2007 [88]	61	–	4 (6.6)	10 (16.4)	–	6 (9.8)	6 (9.8)	–	7 (11.5)	–	–
Mitsui et al. 2008 [94]	22	–	–	1 (5)	–	0	2 (9)	(40–60)	–	–	–
Oberman et al. 2011 [91]	25	–	–	10 (38)	–	–	2 (8)	–	–	1 (5)	–

Bladder perforation and carcinoma

Urinary and bowel function

Metabolic acidosis, calcium balance and hypokalemia in ileo-and colo-cystoplasty

Stone Formation

formation of urinary tract stones common complication of cystoplasty' 3-40%

- ➔ 2% of patients who void spontaneously and efficiently
- ➔ 5-times as common in augmented patients who need to perform CISC when the bladder is catheterised urethrally
- ➔ up to 10-times as common in patients with Mitrofanoff-type channels when the bladder is emptied from above,

stasis as an important factor in stone formation

Stone Formation

- usually triple phosphate

➔ implying that bacteriuria with urease-producing bacteria (Proteus, Providencia and Klebsiella) may be a causative factor

- Other risk factors are the presence of intravesic al foreign bodies

➔ staples
➔ mesh
➔ mucus
➔ hypocitraturia.

Carcinoma

- ➔ risk of bladder cancer is higher for patients with congenital bladder dysfunction over the normal population
- ➔ controversy as to whether enterocystoplasty is an independent risk factor for carcinogenesis
- ➔ Approximate risk of 1.2%
- ➔ Many associated with urogenital TB or with other risk factors tobacco use
- ➔ long latency period between augmentation and the occurrence (mean of 19–22 years in some series)

Carcinoma

Risk factors
➔urinary stasis
➔Nitrosamines
➔ infection
➔ bladder calculi
➔ chronic patch inflammation
➔ immunosuppression

Tumours are generally adenocarcinomas of the bladder or bowel,
➔ most commonly located in the region of the anastomosis

Incontinence

Nocturnal enuresis

- ➔ attributed to a reduction in urethral closing pressure
- ➔ relaxation of the pelvic floor muscles,
- ➔ increased urine output
- ➔ failure of the sphincter to increase in tone in response to contractions from the bowel patch during sleep

combination of anticholinergic medication, CISC and bladder neck surgery

Incontinence

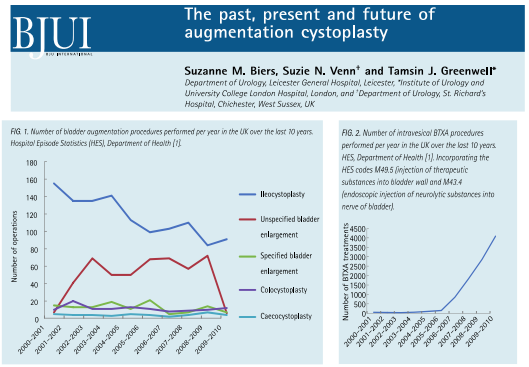
Surgical correction usually required only for selected patients with either congenital sphincter deficiency or neuropathy.

Incontinence

➔ AUS is the outlet procedure that offers the maximum chance of spontaneous voiding.

➔performed concomitantly with AC without any increased morbidity, infection rate or change to success rates of either procedure

➔ theoretical concern that urethral trauma due to CISC in patients with both an AC and an AUS may introduce bacteria into the urine and risk infective complications: not been a concern identified in published studies



Conclusions

There remains a role for AC in the 21st century, greater competition from less invasive procedures

It remains an essential component of the full armamentarium of 1 interventions required to treat bladder overactivity,

Excellent and sustained continence rates, and acceptable morbidity.