Sacral Anterior Roots Stimulation
In spinal cord injured patients

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Disclosures:

- Medtronic
- Finetech
Neurogenic Bladder Management

Are you giving to your SCI patient a treatment based on what he needs?

Neurogenic Bladder and SCI

- SCI incidence lies between 10.3 -83 per million
- One third tetraplegic
- 50% complete lesions
- 3.8 male / 1 female
- Mean age 33 y/o
- Neurogenic bladder is the leading cause of morbidity in spinal cord injury

Neurogenic Bladder and SCI

Complications secondary to Neurogenic bladder

- Recurrent infections
- Urinary calculus
- Fistulae and diverticula
- Urinary incontinence
- Ureteric hydroureteronephrosis
- Vesicoureteral reflux
- Kidney failure

All of them preventable complications with timely management

Treatment must meet:

- Storing urine at low pressure
- Emptying of bladder periodically
- Avoid the use of a permanent catheter or stoma
- Protect the upper urinary tract
- Reduce the frequency of urinary tract infections
- Avoid urinary tract lesions
- Provide continence
- To provide independence
- Allow patient’s social engagement
Neurogenic bladder and spinal cord injury

Neurogenic Bladder and SCI

• Supra-sacral spinal lesions:

  • Detrusor Overactivity
  • Detrusor sphincter Dyssynergia
  • Low compliance
  • High pressure storage functional obstruction
  • Renal deterioration
Current treatments

- Clean Intermittent Catheterization
  - Risk of urinary infection
  - Urethral trauma
  - Poor adherence when complications arise
  - Difficult in patients with cervical lesions
  - High cost long term

Current Therapies

Anticholinergics
- High rate of adverse effects
- Poor adherence
- Effectiveness no greater than 50%
- Long term costs

Botulinum Toxin
- Excellent results in storing
- No role in voiding
Current Treatments

• Palliative
  • External collectors and pouches
  • Diapers
  • Indwelling Catheter
  • NONE OF THEM MEET UROLOGIC MANAGEMENT GOALS

Prof. Giles Brindley

Electrodes for Stimulation 1972
Experiments in baboons
First human Intradural implants

SARS (sacral anterior roots estimulation)

- Principle
  - Roots S2-S4
  - Deafferentation
  - Elimination of a reflex arc

- Motor Preservation
- Functional Electrical Stimulation

Solving storage disorder
Solving voiding disorder
S.A.R.S (candidates)

- Complete or incomplete spinal cord injury.
- Complications associated with the malfunction of the sphincters
- Failure of conservative therapy type
- Lesions deemed to be of spastic behavior
- Bladder and rectum, these must retain its spontaneous or induced muscle contraction, or show responsive to contractile electrical stimulation tests

SARS Techniques

<table>
<thead>
<tr>
<th>T12 – L1, L2</th>
<th>Extradural</th>
</tr>
</thead>
<tbody>
<tr>
<td>L2 – L4, L5</td>
<td>Intradural</td>
</tr>
<tr>
<td>S1 – S4</td>
<td>Extradural</td>
</tr>
</tbody>
</table>
SARS Techniques

<table>
<thead>
<tr>
<th>“Pros”</th>
<th>“Cons”</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EXTRA</strong></td>
<td><strong>Cons</strong></td>
</tr>
<tr>
<td>Less time consuming</td>
<td>Roots more difficult to separate</td>
</tr>
<tr>
<td>Easier approach for Urol</td>
<td>Risk of motor damage</td>
</tr>
<tr>
<td>No fistulae risk</td>
<td></td>
</tr>
<tr>
<td>Faster recovering</td>
<td></td>
</tr>
<tr>
<td><strong>INTRA</strong></td>
<td></td>
</tr>
<tr>
<td>Roots easier to separate</td>
<td>More time consuming</td>
</tr>
<tr>
<td>Less risk of motor damage</td>
<td>Risk of fistulae</td>
</tr>
<tr>
<td>If fails extradural option left</td>
<td>Osteosynthesis material</td>
</tr>
<tr>
<td></td>
<td>Arachnoiditis</td>
</tr>
</tbody>
</table>

S.A.R.S – Extradural implantation


- First non-American extradural SARS
  - 1986, Bad Wildungen
  - Previous myelography with oily contrast medium
Extradural Surgical Technique – Laminectomy

Video

Extradural Surgical Technique-Rhizotomy

- Posterior Rhizotomy (deafferentation)
- Capability
- Compliance
- Continence

Video
Extradural Surgical Technique-Rhizotomy

- Posterior Rhizotomy (deafferentation)
- Capability
- Compliance
- Continence

Surgical Technique Electrodes

- Tripolar
- Bifurcated S2 - Bilateral S3 and S4 Mutually
- Electrostimulation of Anterior roots
- Emptying of bladder
- Intestinal
- Erection
Components

Mechanism of action

- Micturition with SARS
Mechanism of action

- Micturition with SARS

How we measure surgery success?

- Valuing parameters related to bladder function
  - Continence
  - Bladder capacity
  - Emptying of bladder
  - QoL

- Intestinal and erection evaluation are not the primary objectives of the surgery, but are important
Results:

**Extradural Implantation of Sacral Anterior Root Stimulator in Spinal Cord Injury Patients**

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2Department of Urology, Hospital Universitario 12 de Octubre, Madrid, Spain
3Department of Urology, Hospital del Trabajador, Santiago de Chile, Chile

**TABLE I. Baseline Demographic and Clinical Characteristics in the Overall Population**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Overall study population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>154</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td>Male 95 (61.5)</td>
</tr>
<tr>
<td>Female 5 (3.3)</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>30 (10.0)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>34 (12.2)</td>
</tr>
<tr>
<td>Thoracic</td>
<td>66 (43.4)</td>
</tr>
<tr>
<td>Lumbosacral</td>
<td>2 (1.9)</td>
</tr>
<tr>
<td>ASIA grade, n (%)</td>
<td>Grade A 96 (62.3)</td>
</tr>
<tr>
<td>Grade B 10 (6.5)</td>
<td></td>
</tr>
<tr>
<td>Grade C 0 (0.0)</td>
<td></td>
</tr>
<tr>
<td>Grade D 0 (0.0)</td>
<td></td>
</tr>
</tbody>
</table>

* Number, SD, standard deviation; ASIA, American Spinal Injury Association.


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Results:

**TABLE II. Comparison of Clinical Variables at Baseline and After Extradural Sacral Anterior Root Stimulation (SARS) Implantation**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline</th>
<th>SARS</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>U incontinence, n (%)</td>
<td>104 (100.0)</td>
<td>15 (14.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>U infection, n (%)</td>
<td>95 (91.3)</td>
<td>16 (15.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>A dysreflexia, n (%)</td>
<td>69 (63.3)</td>
<td>6 (5.8)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**RESULTS (SARS + POSTERIOR RHIZOTOMY)**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bladder capacity ≥400ml</td>
<td>97%</td>
</tr>
<tr>
<td>Post void residual ≤50ml</td>
<td>91%</td>
</tr>
<tr>
<td>Erectile function</td>
<td>56%</td>
</tr>
<tr>
<td>Bowel function</td>
<td>87%</td>
</tr>
</tbody>
</table>

Complications:

- **Infection**: 5.1%
- **Explantation**: 3%
- **Non functioning device**: 9.1%
- **Stress urinary incontinence**: 10.9%
  - 5 Slings
  - 1 bladder augmentation

Does SARS succeed in meeting goals?

- To store urine at low pressure ✔
- Emptying of the bladder periodically ✔
- To protect the upper urinary tract ✔
- To reduce the frequency of urinary tract infections ✔
- Avoid the use of permanent catheters or stoma ✔
- Avoid Urinary tract lesions ✔
- To provide independence ✔
- To provide continence ✔
- Enabling the patient in social engagement ✔
Looks great! But...

- One of the main issues are those related to rizothomy consequences:
  - Lost of reflex erections
  - Lost of sensations en genital area /incomplete
  - Promised cure based on stem cells therapies

Next SARS generation

- Electrical nerve block
- Kilohertz frequency stimulation
- Non destructive alternative to neurotomy
- Avoid undesirable effects of rizothomy

Closing Message:

• SARS is an adequate alternative for managing Neurogenic bladder in well selected patients when conservative treatment fails.
• It has shown good clinical results of QoL and cost-effectiveness*
• Extradural approach can equiparate the good results of the ID technique with some advantages making this a feasible procedure for the urologist