

## THE BRINDLEY BLADDER STIMULATOR IMPROVES QUALITY OF LIFE AND CLINICAL OUTCOMES IN SPINAL CORD INJURED PATIENTS AS COMPARED TO A MATCHED CONTROL GROUP

### Hypothesis / aims of study

One of the contributing innovations to improve long-term urological management in spinal cord injury (SCI) patients is the introduction of the Brindley bladder stimulator. The Brindley procedure combines sacral anterior root stimulation (SARS) with rhizotomy of the dorsal sacral roots. It enables controlled voiding of the urinary bladder and abolishes neurogenic detrusor overactivity (NDO). This study documents the long-term effects regarding Quality of Life (QoL), urinary tract infections (UTI's) and urinary continence in SCI patients who underwent the Brindley procedure for bladder control.

### Study design, materials and methods

The validated disease specific questionnaire Qualiveen and generic SF-36 questionnaire were sent to 92 patients who underwent a Brindley procedure in The Netherlands between 1987 and 2007. Specific questions regarding urinary continence and UTI's were added to these questionnaires. A control group of 71 patients with complete SCI and NDO using other methods of micturition also obtained the questionnaires. In order to apply SF-36 in complete SCI patients, the "physical functioning" dimension was omitted. Groups were compared.

### Results

72 patients (78%) with an implant completed the questionnaire. In 46 patients (Brindley group) the stimulator was actual used for micturition. In 26 patients, the stimulator was not used for micturition anymore. This group, labeled as rhizotomy group, benefited rhizotomy only. At time of investigation, mean postoperative time of Brindley and rhizotomy group were respectively 13 (1-19) and 14 (3-21) years. In the control group, 30 patients (42%) returned their questionnaires. In rhizotomy and control group intermittent catheterization was applied in respectively 77% and 70%.

	Brindley (n=46)	Group	Rhizotomy (n=26)	Group	Control Group (n=30)
<b>Qualiveen (Median Scores)</b>					
Limitations	0.33		0.67		0.88
Constraints	1.56		2.19		2.63
Fears	0.50		1.00		0.95
Feelings	0.20		0.40		0.68
Mean SIUP index*	0.68***		1.08		1.28
QoL index**	0.89***		0.70		0.56
<b>SF-36 (Median Scores)</b>					
Role Physical limitations	100		62.5		50.0
Bodily Pain	79.6		67.3		69.4
General Health	70.0***		50.0		57.5
Vitality	70.0		65.0		65.0
Social Functioning	87.5***		75.0		75.0
Role Emotional Limitations	100		100		100
Mental Health	84.0		78.0		82.0
<b>Urinary Continence (n)</b>					
Yes	24 (52.2%)***		9 (34.6%)***		1 (3.3%)
No	21 (45.7%)***		15 (57.7%)***		25 (83.3%)
Missing Data	1 (2.2%)		2 (7.7%)		1 (8.3%)
<b>UTI's / yr (n)</b>					
None	23 (50%)***		4 (15.4%)		10 (33.3%)
1-2	17 (37%)***		7 (26.9%)		7 (23.3%)
3-4	3 (6.5%)***		4 (15.4%)		5 (16.7%)
> 5	3 (6.5%)***		11 (42.3%)		8 (26.7%)

\* Specific Impact of Urinary Problems; the lower the better

\*\* QoL; the higher the better

\*\*\* Significant vs. control

### Interpretation of results

As shown in the table, median scores of the Qualiveen SIUP and QoL-index were significant better in the Brindley group compared to control, indicating less impact of urinary problems and better QoL. The rhizotomy group had better SIUP and QoL scores compared to control. In most SF-36 dimensions the Brindley group scored higher compared to controls. "General health" and "social functioning" were significantly better in the Brindley group. The Brindley and rhizotomy group achieved significant

improvement of continence compared to controls. Infection rates decreased significant in the Brindley group compared to rhizotomy and control group. Most patients using a stimulator did not suffer from UTI's at all.

#### Concluding message

This study shows that a Brindley procedure significantly improves quality of life regarding both disease specific QoL and general QoL aspects in complete spinal cord injured patients as compared to a matched control group. Also significant improvement of urinary continence is achieved in SCI patients using the bladder stimulator and suffer less from frequent UTI's as compared to controls. Also rhizotomy alone compares favourably to controls. These findings support the idea that, in terms of QoL, UTI's and Urinary Continence, the Brindley procedure is an effective treatment option in a selected group of SCI patients.

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<b><i>Is this a clinical trial?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>No</b>
<b><i>This study did not require eithics committee approval because</i></b>	<b>A cross-sectional descriptive study with informed consent</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>