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Abstract Reproduction Form B-1

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| Title (type in CAPITAL LETTERS) | PERCUTANEOUS NERVE EVALUATION (PNE) IN LOWER URINARY TRACT DYSFUNCTION: NEW INSIGHTS ON A MULTICENTRE PROSPECTIVE STUDY ON 136 PATIENTS. |

Aim of Study: In current literature there are no data about the exact percentage of improvement in symptoms required to perform a permanent implant after PNE test although most authors consider the cut off value an improvement > 50%. The aim of our study is to evaluate which pathologies have the best response to neuromodulation, to evaluate the percentage of patient response and to find an objective value above which the patient is eligible for permanent implant.

Material and Methods: From May 1998 to March 1999 129 pts. affected by lower urinary tract dysfunction not responsive to conventional therapies (49M, 80F, mean age 53, range 20-79) underwent 199 PNE, pts suffering from: 48 retention, 38 detrusor instability, 17 iperreflexia, 12 pelvic pain, 4 uretral instability, 10 other. 70 pts performed only 1 PNE, 56 pts performed 2 PNE's (33.9% verify previous PNE, 32.2% lead displacement, 33.9% insufficient result of previous PNE), 11 pts performed 3 PNE's (18.2% verify previous PNE, 54.5% lead displacement, 27.3% insufficient result of previous PNE). All patients entered a prospective multicentric study and data were collected employing the same methodology, voiding diary and data collecting form .

Baseline evaluation of disorders was made through the urinary frequency, incontinence episodes and number of pads per day, mean voiding volume, mean post voiding residual urine and number of intermittent catheterism . Moreover all patients filled in a pain analogue scale (Scott) to evaluate pelvic pain .

Results: Data concerning respondents and percentage of improvement for each pathology are as follows:

| Retention | | | | % of Improvement | |
|-------------------------|----------|--------|---------------|------------------|---------------|
| | Baseline | 1° PNE | 2° PNE (N=10) | % 1° PNE | % 2° PNE |
| Implanted (N=17) | | | | | |
| Voided volume (cc) | 122,73 | 223 | 246,11 | 81,70% | 100,53% |
| Residual volume (cc) | 239,23 | 70,33 | 58,33 | 70,60% | 75,62% |
| Mean improvement | | | | 76.15% | 88.08% |

| Not implanted (N=18) | | | | % of Improvement | |
|-------------------------|----------|--------|-------------|------------------|---------------|
| | Baseline | 1° PNE | 2° PNE(N=9) | % 1° PNE | % 2° PNE |
| Voided volume (cc) | 134,44 | 149,5 | 183,33 | 11,20% | 36,37% |
| Residual volume (cc) | 292,65 | 265,29 | 330 | -9,35% | 12,76% |
| Mean improvement | | | | 10.28% | 24.56% |

Abstract Reproduction Form B-2

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| | | | | % of Improvement | | |
|-----------------------------|-------------------------|-----------------|---------------|---------------------|-----------------|-----------------|
| | <i>Implanted (N=21)</i> | <i>Baseline</i> | <i>1° PNE</i> | <i>2° PNE (N=9)</i> | <i>% 1° PNE</i> | <i>% 2° PNE</i> |
| Voiding episodes (num./die) | | 14,96 | 5,90 | 6,80 | 60,57% | 54,56% |
| Leaking episodes/day | | 6,00 | 0,61 | 1,40 | 89,88% | 76,67% |
| Pads (num./die) | | 4,32 | 0,88 | 2,25 | 79,56% | 47,87% |
| <i>Mean improvement</i> | | | | | 76.67% | 59.7% |

| | | | | % of Improvement | | |
|-----------------------------|-----------------------------|-----------------|---------------|---------------------|-----------------|-----------------|
| | <i>Not implanted (N=10)</i> | <i>Baseline</i> | <i>1° PNE</i> | <i>2° PNE (N=7)</i> | <i>% 1° PNE</i> | <i>% 2° PNE</i> |
| Voiding episodes (num./die) | | 18,06 | 11,00 | 9,00 | 39,08% | 50,16% |
| Leaking episodes/day | | 4,77 | 4,50 | 1,00 | 5,66% | 79,04% |
| Pads (num./die) | | 3,88 | 2,50 | | 35,57% | |
| <i>Mean improvement</i> | | | | | 26.77% | 64.6% |

| | | | | % of Improvement | | |
|-----------------------|------------------------|-----------------|---------------|---------------------|-----------------|-----------------|
| | <i>Implanted (N=3)</i> | <i>Baseline</i> | <i>1° PNE</i> | <i>2° PNE (N=3)</i> | <i>% 1° PNE</i> | <i>% 2° PNE</i> |
| Analogue scale (0-10) | | 9,00 | 2,5 | 3 | 72,22% | 66,67% |

| | | | | % of Improvement | | |
|-----------------------|----------------------------|-----------------|---------------|---------------------|-----------------|-----------------|
| | <i>Not implanted (N=6)</i> | <i>Baseline</i> | <i>1° PNE</i> | <i>2° PNE (N=3)</i> | <i>% 1° PNE</i> | <i>% 2° PNE</i> |
| Analogue scale (0-10) | | 7,60 | 5,5 | 7,8 | 27,63% | 2,63% |

When the first PNE fails we perform a contralateral PNE and if this also fails, a bilateral test is performed.

Conclusions: Data analysis shows that in retention is the mean improvement in main symptoms to be suitable for permanent implant is 82% (min 76%-max 97%), in detrusor instability 68% (min 59%-max 76%), in pelvic pain is 69% (min 66%-max 72%).

All the patients eligible for definitive implants were enrolled in a prospective register, which allow to verify the long term results of Sacral Neuromodulation (SNM) in patients selected for definitive implant on the basis of criteria cited above. From this we will be able to define what percentage of improvement at the PNE test can predict excellent long term results.

In the future, we foresee being able to define common guidelines for evaluation of patients selected for PNE and permanent implant with the aim of minimizing the procedure failures and improving patient quality of life.