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Dandolu V[1], Pathak P[1]
1. *UNSOM OB/GYN Dept.*

SNM EFFICACY BY DIAGNOSTIC CATEGORY AND BY AGE IN A NATIONAL DATABASE IN US

Hypothesis / aims of study

Evaluate the real world experience subsequent to insertion of SNM device in a national database by age and by diagnostic category

To analyse the efficiency of staged procedure vs. PNE as a test procedure for SNM

Study design, materials and methods

Truven Medstat Commercial Claims and Encounters (CCAE) and Medicare Supplemental and Coordination of Benefits (MDCR) datasets 2002-2013 were used for the analysis. The CCAE datasets contained information on 140 million unique patients and is representative of privately insured population in USA <65 yrs age encompassing >100 employer-sponsored plans. The MDCR datasets contained information on 11 million unique patients and consists of claims for Medicare-eligible retirees with employer-sponsored supplemental plans and comprised of subjects >65 yrs. The database has established validity and reliability. Various SNM related procedures (PNE, stage 1, stage 2, generator removal, lead revision) were identified by CPT procedure codes while ICD-9 codes were used to determine the underlying diagnoses. Patients were required to be continuously enrolled during 60-days post index. Patients with successful battery insertion during 60 days post-index were further required be to continuously enrolled during 360 days post battery insertion, during which subsequent explants and re-implants were observed. Statistical analyses were performed using SAS 9.3.

Results

There were 11,789 CCAE and 8,418 MDCR patients who were tested for SNM. The proportion of patients in CCAE and MDCR datasets by diagnosis group was 71.2% vs. 81.8% for OAB/UI, 13.4% vs. 10.9% for urinary retention, 6.7% vs. 0.9% for IC, 5.1% vs. 3.7% for neurogenic bladder and 2.9% vs. 2.1% for fecal incontinence, respectively. For CCAE, mean age was 50.4 +/- 11.4 yrs with 86.2% female patients. For MDCR, mean age was 75.8 +/- 6.9 yrs with 73.6% female patients. For both CCAE and MDCR, SNM was more commonly done in South (46.4% and 36.2%) followed by North Central US (27.5% and 34.3%). Of those who were continuously enrolled, 32.7% (n=2,608) CCAE and 26.7% (n=1,711) MDCR patients started with staged procedure of which 76.3% and 72.5% received generator implantation, respectively. Remaining 67.3% (n=5,369) CCAE and 73.3% (n=4,703) MDCR patients started with PNE, of which only 6.7% and 4.7% progressed to generator implantation, 39.5% and 46.4% abandoned further attempts while 53.8% and 48.9% progressed to staged procedure, respectively. Among those that went from PNE to staged procedure 85.6% and 86.1% of CCAE and MDCR patients received the generator, respectively. Mean total cost (provider & pharmacy) was highest among patients that started with PNE followed by Stage 1 and generator implantation ($27,485 and $26,185 for CCAE and MDCR, respectively) compared to those who underwent staged procedure ($24,354 and $19,581). Of the 4,822 CCAE and 3,443 MDCR patients who received the generator, 11.4% (549) and 7.6% (261) encountered explants, while 6.5% (519) and 3.6% (231) had a second generator, respectively. 15.2% (731) CCAE and 10.6% (366) MDCR patients had some sort of lead revision procedure during the 360d f/u. The most common diagnosis groups for generator removal were IC (19.0%) and urinary retention (13.7%) for CCAE and fecal incontinence (11.6%) and urinary retention (10.2%) for MDCR. Among OAB/UI subjects with continuous enrolment data for 360 days, 10.9% CCAE and 20.5% MDCR patients restarted anticholinergic meds.

Interpretation of results

PNE seems to be a sub-optimal test procedure compared to staged procedure and significantly adds to the overall cost. Patients with IC and urinary retention have higher rate of generator removal than OAB/UI patients. Even if the generator is still in place substantial number of subjects restart anti-cholinergic meds particularly those over 65 yrs age. Within 3yrs after generator insertion, over one fourth of patients need additional procedures including explant, replant and lead revision.

Concluding message:

Staged procedure should be the preferred approach as test procedure for evaluation of therapeutic efficacy of SNM. There are differences in the generator removal rates by diagnosis and IC and urinary retention patients tend to have higher rates of removals. Failure rate for OAB/UI is high as indicated by rate of restarting anticholinergic medications in these groups. Patients need to be counselled on the need for additional procedures subsequent to insertion of SNM device.

References

1. Results of a prospective, multicenter study evaluating quality of life, safety, and efficacy of sacral neuromodulation at twelve months in subjects with symptoms of overactive bladder.
2. Long term safety of sacral nerve modulation in medicare beneficiaries.
3. The Refractory Overactive Bladder: Sacral NEuromodulation vs. BoTulinum Toxin Assessment: ROSETTA trial.

Disclosures

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