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THE USE OF NATIONAL DATASETS TO PREDICT OUTCOMES OF SACRAL NEUROMODULATION

Hypothesis / aims of study

Numerous studies have documented a relationship between provider variables, including surgeon volume and specialty, and outcomes for surgical procedures. In this study we analyzed claims data from two databases, Medicare and Ingenix, with the aim of determining which provider and patient factors impact the outcomes of sacral neuromodulation. We compared outcomes by provider volume and specialty. We also analyzed patient variables, including age, gender, race, and chief diagnosis for which sacral neuromodulation was performed.

Study design, materials and methods

For Medicare claims, we used a 5% random sample of Medicare(CMS) beneficiaries from 1997 to 2007 and for privately insured patients, the Ingenix (I3) database was used to determine demographic, diagnosis, and procedure success information for years 2002-2007. CPT codes were used to identify relevant procedures performed on each individual with separate codes for percutaneous (64561) and surgically implanted permanent lead (two stage) (64581), insertion of battery (64590) or removal (64585/64595). ICD-9 diagnosis codes linked to the procedure identified the indication and patients were divided into five separate mutually exclusive groups: neurogenic bladder, interstitial cystitis, urinary retention, overactive bladder with no urgency incontinence (OAB dry) and overactive bladder with urgency incontinence (OAB wet). Success was defined as a patient proceeding to battery implantation. Multivariate analysis was performed to identify predictors of outcome. High volume providers were defined at those who performed in the upper 25th percentile of procedures performed.

Results

In Medicare, there were 358 percutaneous tests and 1132 two stage (permanent) lead placements performed from 1997 to 2007. There were 266 percutaneous and 794 two-staged procedures in the Ingenix database. The overall success rate in the Medicare population was 39.9% and 49.1% in the Ingenix database.
Urologists had better outcomes after 2-stage procedure than gynecologists in both datasets (I3: 54% vs. 47%, CMS: 49% vs. 43%, $p < 0.0001$). Gynecologists had better outcomes of percutaneous testing in Medicare only (63% vs.44%, $p = 0.005$).
In multivariate analysis high volume providers in the top 25th percentile had significantly better outcomes after permanent lead implantation and overall compared to low volume providers, but only in the Medicare data.
Among the patient variables analyzed, female gender had better outcomes in both I3 and Medicare overall (OR 1.99 and 1.87 respectively). Among Medicare beneficiaries, patient with OAB-dry has worse overall outcomes than those with OAB-wet, whereas in the Ingenix dataset those with neurogenic voiding dysfunction had worse outcomes than OAB-wet. The impact of patient age on outcomes varied by dataset with no specific trend and there were no differences in success based on race.

Interpretation of results

Success of sacral neuromodulation, as defined by implantation of a permanent battery, was overall inferior than published in the literature [1]. Success was greater among high volume providers compared to lower volume surgeons in CMS. This suggests that technical factors, including the use of the 2-staged approach, play a role in improving outcomes. That outcomes were better among urologists may be due to that fact that there are more high volume providers among urologists than gynaecologists. These differences in outcomes between specialties will likely diminish as sacral neuromodulation spreads throughout the gynaecologic community. Women had consistently better outcomes than men, which is a trend that has previously not been reported in the published literature [2,3]. There were no consistent trends in outcomes by patient age or diagnosis in these datasets. Further research may better define the relationship between outcomes of sacral neuromodulation and specific aetiology of voiding dysfunction.

Concluding message

Sacral neuromodulation success in national datasets is less successful than expected based on case series. Female patients consistently fared much better than males and those who had procedures performed by higher volume providers had more success in one dataset.

Medicare 5% Sample									
	Successful percutaneous			**Successful 2-staged no percutaneous**			**Overall Success**		
	Odds ratio	**95% CI**		**Odds Ratio**	**95% CI**		**Odds ratio**	**95% CI**	
High volume (vs. low)	0.768	0.476	1.241	5.019	3.573	7.050	2.743	2.123	3.543
Urologist (vs. gynecologist)	0.749	0.387	1.451	1.470	0.999	2.162	1.575	1.149	2.160
White (vs. non-white) patient	1.842	0.667	5.090	0.705	0.399	1.246	0.820	0.511	1.316

Female (vs. male)	2.882	1.566	5.305	1.620	1.108	2.368	1.861	1.379	2.512
Age 65-75 (v >75) years	0.108	0.054	0.215	2.036	1.488	2.786	1.042	0.805	1.347
Diagnosis									
Wet OAB (comparison group)	1.000			1.000			1.000		
NGB	0.836	0.267	2.619	1.497	0.685	3.273	1.342	0.722	2.496
IC	1.913	0.435	8.414	0.416	0.173	1.002	0.829	0.412	1.670
Retention	0.807	0.401	1.624	0.925	0.565	1.514	0.967	0.656	1.427
Dry OAB	0.615	0.348	1.089	0.786	0.552	1.119	0.731	0.551	0.971
Ingenix dataset									
	Successful percutaneous			**Successful 2-staged no percutaneous**			**Overall Success**		
	Odds ratio	95% CI		Odds Ratio	95% CI		Odds ratio	95% CI	
High volume (vs. low)	0.918	0.471	1.788	1.086	0.776	1.520	1.061	0.791	1.423
Urologist (vs. gynecologist)	0.882	0.449	1.731	2.790	1.981	3.929	2.311	1.713	3.117
White (vs. non-white) patient	0.647	0.355	1.180	1.073	0.793	1.453	1.159	0.891	1.508
Female (vs. male)	1.498	0.718	3.125	1.632	1.077	2.474	1.986	1.404	2.808
Age <= 55 years (v > 55)	1.732	0.889	3.376	0.842	0.619	1.147	0.960	0.731	1.260
Diagnosis									
Wet OAB (comparison group)	1.000			1.000			1.000		
NGB	0.221	0.027	1.818	0.497	0.237	1.043	0.383	0.200	0.731
IC	1.510	0.536	4.250	1.092	0.599	1.990	1.142	0.686	1.900
Retention	1.199	0.460	3.130	0.923	0.589	1.447	1.079	0.726	1.603
Dry OAB	2.159	1.029	4.532	1.010	0.716	1.425	1.027	0.759	1.389

References

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**It utilised only de-identified claims based data**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**No**