Dataset Integrity Check for the SISTEr Data Files

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Table of Contents

1 Standard Disclaimer

The intent of this DSIC is to provide confidence that the data distributed by the NIDDK repository is a true copy of the study data. Our intent is not to assess the integrity of the statistical analyses reported by study investigators. As with all statistical analyses of complex datasets, complete replication of a set of statistical results should not be expected in secondary analysis. This occurs for a number of reasons including differences in the handling of missing data, restrictions on cases included in samples for a particular analysis, software coding used to define complex variables, etc. Experience suggests that most discrepancies can ordinarily be resolved by consultation with the study data coordinating center (DCC), however this process is labor-intensive for both DCC and Repository staff. It is thus not our policy to resolve every discrepancy that is observed in an integrity check. Specifically, we do not attempt to resolve minor or inconsequential discrepancies with published results or discrepancies that involve complex analyses, unless NIDDK Repository staff suspect that the observed discrepancy suggests that the dataset may have been corrupted in storage, transmission, or processing by repository staff. We do, however, document in footnotes to the integrity check those instances in which our secondary analyses produced results that were not fully consistent with those reported in the target publication.

2 Study Background

Stress urinary incontinence (SUI) affects at least 12% of community dwelling women and causes leakage of urine when coughing, laughing, sneezing, running, and lifting. It is frequently treated with surgery to provide additional support to the bladder neck and urethra. The Stress Incontinence Surgical Treatment Efficacy Trial (SISTEr) conduced by the Urinary Incontinence Treatment Network (UITN), used urodynamic studies (UDS) in a randomized clinical trial to measure improved outcomes after surgery. UTIN is a network conducting research on the treatment of urinary incontinence, or accidental loss of urine. SISTEr compared two surgical procedures that use different mechanisms to treat SUI: the Burch colposuspension and the autologous fascia pubovaginal sling. The Burch procedure suspends the anterior vaginal vault with nonabsorbable sutures tied to the Coopers ligament. The autologous sling procedure provides suburethral support by transvaginal placement of a strip of autologous rectus fascia at the level of the bladder neck and proximal urethra. Overall treatment success required a negative pad test and no urinary incontinence on a 3-day diary. Stress specific success was defined as a negative stress test, no self reported SUI symptoms on MESA, and no retreatment for SUI. Two years after surgery, 66% of women with a sling and 49% with a Burch procedure were free of SUI, and 86% of women with a sling were satisfied, compared to 78% of the Burch group, although the sling procedure had a higher rate of side effects.

3 Archived Datasets

All SAS data files, as provided by the Data Coordinating Center (DCC), are located in the SISTEr data package. For this replication, variables were taken from the "baseline" and "final" datasets.

4 Statistical Methods

Analyses were performed to duplicate results for the data published by Albo et al [1] in The New England Journal of Medicine in May 2007. To verify the integrity of the dataset, descriptive statistics were computed, by surgery type (Tables B and D).

5 Results

Table 1 in the publication [1], Table 1 Selected Characteristics of the Patients. Table A lists the variables that were used in the replication and Table B compare the results calculated from the archived data file to the results published in Table 1. Variables that were not included in the data package are designated "N/A". The results of the replication are within expected results.

Table 2 in the publication [1] Table 2 Baseline Adverse Events. Adverse Event data were not provided in the data package.

6 Conclusions

The NIDDK repository is confident that the SISTEr data files to be distributed are within expected results.

7 References

1. Albo ME, Richter HE, Brubaker L, Norton P, Kraus SR, Zimmern PE, Chai TC, Zyczynski H, Diokno AC, Tennstedt S, Nager C, Lloyd LK, FitzGerald M, Lemack GE, Johnson HW, Leng W, Mallett V, Stoddard AM, Menefee S, Varner RE, Kenton K, Moalli P, Sirls L, Dandreo KJ, Kusek JW, Nyberg LM, Steers W, for the Urinary Incontinence Treatment Network. Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence. N Engl J Med. 2007 May 24;356(21):2143-55.

Table A: Variables used to replicate Table 1: Table 1 Selected Characteristics of the Patients

Table Variable	Variables Used in Replication from the "Table 1" Dataset
Study Procedure	SLING
Age	AGE
Race	RACE, HISP
Marital status	MARITAL
Education	EDUC
Household Income	H_INCOME
Body Mass Index	BMI
No. of Vaginal Deliveries	V_DEL
Previous Incontinence Surgery	UISURG
Smoking Status	SMKSTAT
Hormone Replacement Therapy	ANY_HRT
Total Score on Urogenital Distress Inventory	UDI_TOT
Total Score on Incontinence Impact Questionnaire	IIQ_TOT
Pad Test Weight	DIFFWT
Incontinence Episodes Per Day	N/A
Stress Score	STRESS_SCORE
Urge Score	URGE_SCORE
Prolapse Stage	STAGE
Q-tip Test Resting Angle	QTIP_RST
Q-tip Test Straining Angle	QTIP_STR
Q-tip Test difference Between Resting and Straining Angles	QTIP_RST, QTIP_STR
Stress Incontinence	N/A
Valsalva Leak Point Pressure	N/A
Detrusor Overactivity	DETRUSOR
Concomitant Surgery	CONCOM

Table B: Comparison of values computed in integrity check to reference article Table 1 values

Characteristic	Burch Procedure [Manuscript] (N = 329)	Burch Procedure [DSIC] (N = 329)	Sling Procedure [Manuscript] (N = 326)	Sling Procedure [DSIC] (N = 326
Age	52.2±10.5	52.2±10.5	51.6±10.1	51.6±10.1
Race or Ethnic Group (%)				
Hispanic	9	9	13	13
Non-Hispanic white	75	75	71	71
Non-Hispanic black	5	5	9	9
Non-Hispanic other	11	11	7	7
Marital status (%)				
Married or living with	69	69	67	67
Not married	31	31	33	33
Education (%)				
High school or less	33	33	36	36
Some training after high	40	40	39	39
College degree or more	27	26.4	25	25
Household Income (%)				
<$20,000	21	21	17	17
$20,000-49,000	29	29	31	31
$50,000-79,999	21	21	21	21
>=$80,000	29	29	31	31
Body Mass Index	29.7±6.1	29.7±6.1	30.3±6.1	30.3±6.1
No. of Vaginal Deliveries (%)				
0	8	8	10	10
1–2	46	46	39	39
>=3	46	46	51	51
Previous Incontinence Surgery (%)	15	15	13	13
Smoking Status				
Never smoked	59	59	49	49
Former smoker	29	29	34	34
Current smoker	12	12	17	17
HRT (%)				
Yes	35	35.56	32	32
No	36	36	36	36
No, premenopausal	29	29	32	32

Characteristic	Burch Procedure [Manuscript] (N = 329)	Burch Procedure [DSIC] (N = 329)	Sling Procedure [Manuscript] (N = 326)	Sling Procedure [DSIC] (N = 326
Quality of Life (%)				
Total Score on Urogenital Distress Inventory	150.3±49.9	150.3±49.9	151.6±47.4	151.6±47.4
Total Score on Incontinence Impact Questionnaire	173.2±99.2	173.2±99.2	169.7±103.4	169.7±103.4
Pad Test Weight (g)	42.4±61.2	42.4±61.2	44.7±94.3	44.7±94.3
Incontinence Episodes Per Day (no.)	3.3±3.1	N/A	3.1±2.9	N/A
Urinary-Incontinence Symptom Scores				
Stress Score	19.5±4.5	19.5±4.5	19.2±4.7	19.2±4.7
Urge Score	6.6±3.9	6.6±3.9	6.3±3.9	6.3±3.9
Prolapse Stage (%)				
0 or 1	26	26	24	24
2	59	59	59	59
3 or 4	15	15	17	17
Q-tip Test (degree)				
Resting Angle	15.6±17.1	15.6±17.1	15.2±18.3	15.2±18.3
Straining Angle	61.1±19.3	61.1±19.3	59.3±17.3	59.3±17.3
Difference Between Resting and Straining Angles	45.5±19.1	45.5±19.1	44.1±17.3	44.1±17.3
Urodynamic Studies (%)				
Stress Incontinence				
Yes	89	N/A	89	N/A
No	9	N/A	10	N/A
Invalid Study	2	N/A	1	N/A
Valsalva Leak Point Pressure				
<=60 cm of H20	4	N/A	3	N/A
Change of <=60 cm of H20	22	N/A	20	N/A
Detrusor Overactivity	11	11	7	7

Characteristic	Burch Procedure [Manuscript] (N = 329)	Burch Procedure [DSIC] (N = 329)	Sling Procedure [Manuscript] (N = 326)	Sling Procedure [DSIC] (N = 326
Surgical Characteristics				
None	44	44	40	40
Prolapse surgery with repair of anterior vaginal wall (with or without other repair)	17	17	23	23
Prolapse surgery without repair of anterior vaginal (including posterior wall and apex)	31	31	32	32
Other nonprolapse surgery	8	8	6	6

```
/*************************************************************************************************************************
***Program: /prj/niddk/ims_analysis/SISTEr/prog_initial_analysis/dsic.sas;
***Programmer: campbeld
***Date Created: jul14
*************************************************************************************************************************/;

title1 "%sysfunc(getoption(sysin))";

options nofmterr nocenter;

libname sasdata '/prj/niddk/ims_analysis/SISTEr/private_orig_data/Repository14_0404/';
libname forms '/prj/niddk/public_orig_data/SISTEr_V1/Data/';

proc format;
        value slingf 0="Burch"
                     1="Sling";

data f05;
        set forms.f05;
        format _all_;

data baseline;
        set sasdata.baseline;
  format _all_;

data final;
        set sasdata.final;
  format _all_;

proc sort data=baseline;
        by AID;
proc sort data=final;
        by AID;
proc sort data=f05;
        by AID;

data f05;
        merge f05 (in=inf)
              baseline (in=inb keep=AID sling);
        by aid;

proc sort data=f05;
        by sling;

data merged;
        merge baseline (in=inb)
              final (in=inf);
        by AID;

        qtip_diff=qtip_str-qtip_rst;

proc freq data=merged;
  table sling/missing list;

proc sort data=merged;
        by sling;
```

```
 *****table 1*****;
proc freq data=merged;
  by sling;
  by sling;
  tables hisp*Race marital educ h_income  v_del uisurg smkstat any_hrt stage  concom
         /list;
  title2 'table 1';
  format sling slingf.;

proc freq data=merged;
  by sling;
  by sling;
  tables hisp*Race marital educ h_income  v_del uisurg smkstat any_hrt stage  concom
         /missing list;
  title2 'table 1';
  format sling slingf.;

proc means data=merged;
  by sling;
  var age bmi STRESS_SCORE urge_SCORE udi_tot iiq_tot diffwt  qtip_rst qtip_str  qtip_diff;
  format sling slingf.;

proc freq data=f05;
        by sling;
        table sling*detrusor /missing list;
        format sling slingf.;

endsas;
```