

Dataset Integrity Check for The Study of  
Tamsulosin for Urolithiasis in the  
Emergency Department (STONE)  
Diabetes Krischer

**Prepared by Sabrina Chen**

**IMS Inc.**

3901 Calverton Blvd, Suite 200 Calverton, MD 20705

**January 9, 2018**

## Contents

1 Standard Disclaimer .....	2
2 Study Background .....	2
3 Archived Datasets .....	2
4 Statistical Methods .....	2
5 Results .....	2
6 Conclusions .....	3
7 References .....	3
Variables used to replicate Table 1: Characteristics of the Enrolled Participants at Study Entry by Treatment Group .....	4
Table B: Comparison of values computed in integrity check to Table 1 values .....	5
Attachment A: SAS Code .....	7

## 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

The Study of Tamsulosin for Urolithiasis in the Emergency Department (STONE) was initiated at a single site with 109 participants who were randomized from 2008 to 2009. This first phase allowed an assessment of the feasibility of recruitment and provided the opportunity to determine the rate of stone passage in the placebo group. The primary outcome was not analyzed at the end of phase 1. The second phase of the study was conducted from 2013 to 2016 at 6 emergency department recruiting sites, including the original site in phase 1. The data from participants enrolled in both phases were analyzed together.

## 3 Archived Datasets

All the SAS data files, as provided by the Data Coordinating Center (DCC), are located in the Data folder in the data package. For this replication, variables were taken from the sas7bdat datasets cl, pilot, mc, st01, st02, st03, and st11.

## 4 Statistical Methods

Analyses were performed to duplicate results for the data published by Meltzer et al [1] in the journal JAMA Intern Med in 2018. To verify the integrity of the dataset, descriptive statistics were computed.

## 5 Results

For Table 1 in the publication [1], Characteristics of the Enrolled Participants at Study Entry by Treatment Group, Table A lists the variables that were used in the replication and Table B compares the results calculated from the archived data files to the results published in Table 1.

## 6 Conclusions

The NIDDK repository is confident that the STONE data files to be distributed are a true copy of the study data.

## 7 References

[1] Meltzer et al. Effect of Tamsulosin on Passage of Symptomatic Ureteral Stones: A Randomized Clinical Trial. *JAMA Intern Med.* 2018 Aug 1;178(8):1051-1057. doi: 10.1001/jamainternmed.2018.2259.

**Table A:** Variables used to replicate Table 1: Characteristics of the Enrolled Participants at Study Entry by Treatment Group

<b>Table Variable</b>	<b>dataset.variable</b>
Treatment Group	pilot.group and mc.group
Age at screening, mean (SD), y	not replicable
Female sex	pilot.ssex and st01.ssex
Nonwhite race	pilot.race_cat and st01.race_cat
Hispanic	pilot.ethn_cat and st01.lethnic
Personal history of kidney stones	pilot.shxkstn and st02.shxkstn
Family history of kidney stones	pilot.sfamhx and st02.sfamhx
Presence of flank pain at screening	pilot.ssidep and st02.ssidep
Symptomatic stone location on CT	pilot.rlocasym and st03.rlocasym
Symptomatic stone size on CT, mean (SD), mm	pilot.rsizesym and st03.rsizesym
Symptomatic stone size distribution on CT, mm	pilot.rsizesym and st03.rsizesym
Hydronephrosis on CT	pilot.rhydron and st03.rhydron
Evidence of multiple stones on CT	pilot.rctstone and st03.rctstone

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

Group value	Characteristic	Manuscript	DSIC	Diff
Tamsulosin	-	n = 267	n = 267	0
Tamsulosin	Age at screening, mean (SD), y	41.8 (13.6)		N/A
Tamsulosin	Female sex	70 (26.2)	70 (26.2)	0 (0)
Tamsulosin	Nonwhite race	56 of 254 (22.0)	56 of 254 (22.0)	0 (0)
Tamsulosin	Hispanic	19 of 266 (7.1)	19 of 266 (7.1)	0 (0)
Tamsulosin	Personal history of kidney stones	76 (28.5)	76 (28.5)	0 (0)
Tamsulosin	Family history of kidney stones	64 (24.0)	64 (24.0)	0 (0)
Tamsulosin	Presence of flank pain at screening	224 (83.9)	224 (83.9)	0 (0)
Tamsulosin	Symptomatic stone location on CT			
Tamsulosin	Ureteropelvic junction/renal pelvis	4(1.5)	4(1.5)	0 (0)
Tamsulosin	Proximalureter	46 (17.2)	46 (17.2)	0 (0)
Tamsulosin	Mid-ureter	32 (12.0)	32 (12.0)	0 (0)
Tamsulosin	Distalureter	71 (26.6)	71 (26.6)	0 (0)
Tamsulosin	Ureterovesical junction	114 (42.7)	114 (42.7)	0 (0)
Tamsulosin	Bladder	0 (0.0)	0 (0.0)	0 (0)
Tamsulosin	Symptomatic stone size on CT, mean (SD), mm	3.8 (1.4)	3.8 (1.4)	0 (0)
Tamsulosin	Symptomatic stone size distribution on CT, mm			
Tamsulosin	1--2	47 (17.6)	47 (17.6)	0 (0)
Tamsulosin	3--4	148 (55.4)	148 (55.4)	0 (0)
Tamsulosin	5--6	60 (22.5)	60 (22.5)	0 (0)
Tamsulosin	7--8	12 (4.5)	12 (4.5)	0 (0)
Tamsulosin	Hydronephrosis on CT	202 (75.7)	202 (75.7)	0 (0)
Tamsulosin	Evidence of multiple stones on CT	92 (34.5)	92 (34.5)	0 (0)
-	-	-	-	-
Placebo	-	n = 245	n = 245	0
Placebo	Age at screening, mean (SD), y	39.3 (12.9)		N/A
Placebo	Female sex	69 (28.2)	69 (28.2)	0 (0)
Placebo	Nonwhite race	54 of 228 (23.7)	54 of 228 (23.7)	0 (0)
Placebo	Hispanic	16 of 243 (6.6)		0 (0)
Placebo	Personal history of kidney stones	76 (31.0)	76 (31.0)	0 (0)
Placebo	Family history of kidney stones	66 (27.0)	66 (27.0)	0 (0)
Placebo	Presence of flank pain at screening	206 (84.1)	224 (83.9)	0 (0)
Placebo	Symptomatic stone location on CT			
Placebo	Ureteropelvic junction/renal pelvis	10 (4.1)	9 (3.67)	1 (0.43)
Placebo	Proximalureter	43 (17.6)	44 (17.96)	1 (0.36)
Placebo	Mid-ureter	19 (7.8)	19 (7.8)	0 (0)
Placebo	Distalureter	55 (22.4)	55 (22.4)	0 (0)
Placebo	Ureterovesical junction	115 (46.9)	115 (46.9)	0 (0)
Placebo	Bladder	3(1.2)	3(1.2)	0 (0)
Placebo	Symptomatic stone size on CT, mean (SD), mm	3.7 (1.4)	3.7 (1.4)	0 (0)
Placebo	Symptomatic stone size distribution on CT, mm			
Placebo	1--2	47 (19.2)	47 (19.2)	0 (0)

<b>Group value</b>	<b>Characteristic</b>	<b>Manuscript</b>	<b>DSIC</b>	<b>Diff</b>
Placebo	3--4	137 (55.9)	137 (55.9)	0 (0)
Placebo	5--6	50 (20.4)	50 (20.4)	0 (0)
Placebo	7--8	11 (4.5)	11 (4.5)	0 (0)
Placebo	Hydronephrosis on CT	181 (73.9)	181 (73.9)	0 (0)
Placebo	Evidence of multiple stones on CT	104 (42.4)	104 (42.4)	0 (0)

## Attachment A: SAS Code

```
options nocenter validvarname=uppercase;

title '/prj/niddk/ims_analysis/STONE/ims_analysis/prog_initial_analysis/stone_check_v3.sas';
run;

/*
*/

*****;
* INPUT ;
*****;
libname sasdir '/prj/niddk/ims_analysis/STONE/ims_analysis/private_orig_data/sasfile/';

*****;
* FORMATS ;
*****;
proc format;
  value groupf
    0 = "2 - Placebo"
    1 = "1 - Tamsulosin"
  ;

  value oneplus
    0 = '0'
    1-high = '1+'
  ;

  value stonesz
    1-2.9 = '1-2'
    3-4.9 = '3-4'
    5-6.9 = '5-6'
    7-8.9 = '7-8'
  ;

run;

data cl;
  set sasdir.cl;
run;

data pilot;
  set sasdir.pilot;
run;

data scrn;
  set sasdir.scrn;
run;

data mc;
  set sasdir.mc;
run;

data st01;
  set sasdir.st01;
run;

data st02;
  set sasdir.st02;
run;

data st03;
  set sasdir.st03;
run;

data st11;
  set sasdir.st11;
```



```

run;

* pilot;
proc contents data=cl;
run;

proc contents data=pilot;
run;

proc contents data=scrn;
run;

* phase 2;
proc contents data=mc;
run;

proc contents data=st01;
run;

proc contents data=st02;
run;

proc contents data=st03;
run;

proc contents data=st11;
run;

* Combine phase 2 subjects and pilot;
data univ (keep=id_no group group_label);
  set mc pilot;
run;

proc freq data=univ;
  table group*group_label/list missing;
run;

* pick up vars for pilot;
proc sort data=cl out=pilot (keep=id_no race_cat ssex shxkstn ssidep sfamhx rlrenpel rlproxur
rlmidur rldistur rluvj rlblad rhydron rsizesym ETHN_CAT RLOCASYM RCTSTONE );
  by id_no;
run;

proc freq data=pilot;
  tables race_cat ssex rsizesym/missing;
run;

data pilot (keep=id_no race_cat ssex shxkstn ssidep sfamhx rlrenpel rlproxur rlmidur rldistur
rluvj rlblad rhydron rsizesym xrsizesym ETHN_CAT RLOCASYM RCTSTONE );
  set pilot (rename=(rsizesym=xrsizesym));

  rsizesym = input(xrsizesym,best.);
run;

proc freq data=pilot;
  tables rsizesym*xrsizesym/list missing;
run;

* pick up vars for phase 2;
proc sort data=st03;
  by id_no;
run;

proc freq data=st01;
  tables race_cat lgen/missing list;

```

```

run;

proc sort data=st01 (rename=(lgen=ssex));
  by id_no;
run;

proc sort data=st02;
  by id_no;
run;

proc sort data=st11;
  by id_no;
run;

data phase2;
  merge st01 (in=in1 keep=id_no race_cat ssex LETHNIC )
        st02 (in=in2 keep=id_no shxkstn ssidep sfamhx)
        st03 (in=in3 keep=id_no rlrenpel rlproxur rlmidur rldistur rluvj /*rlblad*/ rhydron
rsizesym rnumstn RLOCASYM RCTSTONE )
        st11 (in=in4 keep=id_no dhydron dkidney dldistur dlmidur dlproxur dlrenpel dluvj
dnumstn );

  by id_no;

  if in1 then in_st01=1;
  if in2 then in_st02=1;
  if in3 then in_st03=1;
  if in4 then in_st11=1;
run;

proc freq data=phase2;
  tables in_st01*in_st02*in_st03*in_st11/list missing;
run;

** combine;
data combine (keep=id_no race_cat ssex shxkstn ssidep sfamhx rlrenpel rlproxur rlmidur rldistur
rluvj rlblad rhydron rsizesym rnumstn
             dhydron dkidney dldistur dlmidur dlproxur dlrenpel dluvj dnumstn
             in_phase2 in_pilot LETHNIC RLOCASYM RCTSTONE );
  set phase2 (in=in1) pilot (in=in2 rename = (ETHN_CAT = LETHNIC));
  if in1 then in_phase2=1;
  if in2 then in_pilot=1;
run;

* add group;
proc sort data=combine;
  by id_no;
run;

proc sort data=univ;
  by id_no;
run;

data combine (keep=id_no race_cat ssex shxkstn ssidep sfamhx rlrenpel rlproxur rlmidur rldistur
rluvj rlblad rhydron rsizesym rnumstn
             dhydron dkidney dldistur dlmidur dlproxur dlrenpel dluvj dnumstn
             in_phase2 in_pilot group LETHNIC RLOCASYM RCTSTONE );
  merge combine (in=in1) univ (in=in2);
  by id_no;

  if in1 or in2 then output combine;

run;

proc freq data=combine;
  table in_phase2*in_pilot/list missing;
run;

* Table 1;

```

```

proc freq data=combine order = formatted;
  tables ( ssex race_cat LETHNIC shxkstn sfamhx ssidep RLOCASYM rsizesym rhydron
RCTSTONE)*group/missing;
  /*tables (dhydron dkidney dldistur dlmidur dlproxur dlrenpel dluvj
dnumstn )*group/missing; */
  format ssidep oneplus. rsizesym stonesz. group groupf.;
run;

proc sort data=combine;
  by descending group;
run;

proc means data=combine MEAN STD;
  var rsizesym;
  by descending group;
  format group groupf.;
run;

```