

Dataset Integrity Check for the
Biomarker Collection and Analysis in the
Prevention of Serious Adverse Events
Following Angiography (PRESERVE) Trial
Cohort

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
Table A: Variables used to replicate Table S1 – Demographic, Clinical, and Procedural Characteristics of the PRESERVE Trial and Sub-Study.....	4
Table B: Comparison of values computed in integrity check to reference article Table S1	5
Attachment A: SAS Code.....	6

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

This sub-study collected, banked, and analyzed blood and urine specimens for biomarkers from participants from the VA-funded PRESERVE trial. Blood and urine proteins and other markers may predict the development of contrast-induced acute kidney injury and diagnose the very early stages of this condition following angiography. In addition, these biomarkers may predict which patients that develop acute kidney injury following angiography are likely to experience serious longer-term complications such as death, need for dialysis, and/or progressive loss of kidney function.

3 Archived Datasets

All data files, as provided by the Data Coordinating Center (DCC), are located in the PRESERVE folder in the data package. For this replication, variables were taken from the “f07_demographics.sas7bdat”, “f05_biometrics.sas7bdat”, “f06_preproclabs.diabetic”, “f11_procedure.sas7bdat”, and “csp578_itt.sas7bdat” datasets.

4 Statistical Methods

Analyses were performed to replicate results for the data in the publication by Parikh et al. [1]. To verify the integrity of the data, only descriptive statistics were computed.

5 Results

For Table S1 in the publication [1], Demographic, Clinical, and Procedural Characteristics of the PRESERVE Trial and Sub-Study, 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 in Table S1. The results of the replication are within expected variation to the published results.

6 Conclusions

The NIDDK Central Repository is confident that the PRESERVE data files to be distributed are a true copy of the study data.

7 References

[1] Parikh CR, Liu C, Mor MK, Palevsky PM, Kaufman JS, Philbrook HT, Weisbord SD. Kidney Biomarkers of Injury and Repair as Predictors of Contrast-Associated AKI: A Substudy of the PRESERVE Trial. *American Journal of Kidney Diseases*, 75(2), 187-194, February 2020. doi: <https://doi.org/10.1053/j.ajkd.2019.06.011>

Table A: Variables used to replicate Table S1 – Demographic, Clinical, and Procedural Characteristics of the PRESERVE Trial and Sub-Study

Table Variable	dataset.variable
Age	f07_demographics.angiodate f07_demographics.birth_month_year
Male sex	f07_demographics.sex
Race/Ethnicity	f07_demographics.racew f07_demographics.raceaa f07_demographics.raceai f07_demographics.raceas f07_demographics.raceab f07_demographics.racepi f07_demographics.raceot f07_demographics.ethnic
Weight	f05_biometrics.weight
Diabetes	f06_preproclabs.diabetic
Coronary procedure	f11_procedure.angiotype
Percutaneous intervention	f11_procedure.pci
Left ventricular end diastolic pressure	f11_procedure.leftventmeasure
Trial arm	csp578_itt.txallocation

Table B: Comparison of values computed in integrity check to reference article Table S1

Characteristics	Pub: Sub-Study Participants (n=922)	DSIC: Sub-Study Participants (n=924)	Diff. (n=2)
Demographic			
Age-years, mean \pm sd	70 \pm 8	70.1 \pm 9.4	0.1 \pm 1.4
Male sex, no. (%)	896 (97%)	898 (97.2%)	2 (0.2%)
Race/Ethnicity, no. (%)			
White	718 (78%)	749 (81.1%)	31 (3.1%)
Black	144 (16%)	140 (15.2%)	4 (0.8%)
Other	26 (3%)	34 (3.7%)	8 (0.7%)
Hispanic	32 (3%)	32 (3.5%)	0 (0.5%)
Clinical			
Weight - kg, mean \pm sd	100 \pm 22	100.5 \pm 22.1	0.5 \pm 0.1
Diabetes, no. (%)	760 (82%)	763 (82.6%)	3 (0.6%)
Procedural			
Coronary procedure, no. (%)	812 (88%)	808 (88%)	4 (0%)
Percutaneous intervention, no. (%)	255 (28%)	257 (28%)	2 (0%)
Left ventricular end diastolic pressure - mmHg, mean \pm sd	19 \pm 8	19.3 \pm 8.4	0.3 \pm 0.4
Trial arm, no. (%)			
Saline + Placebo	211 (23%)	211 (23%)	0 (0)
Saline + Acetylcysteine	236 (26%)	237 (26%)	1 (0)
Sodium Bicarbonate + Placebo	242 (26%)	240 (26%)	2 (0)
Sodium Bicarbonate + Acetylcysteine	233 (25%)	236 (26%)	3 (1%)

Attachment A: SAS Code

```
libname dsic "X:\NIDDK\niddk-dr_studies6\PRESERVE\private_created_data\Redacted Data";
```

```
/******  
/* PRESERVE DSIC */  
/******
```

```
proc contents data=dsic.f07_demographics;  
run;
```

```
proc freq data=dsic.f07_demographics;  
tables SubjectNo;  
run;
```

```
proc contents data=dsic.csp578_itt;  
run;
```

```
proc freq data=dsic.csp578_itt;  
tables SiteNo tx TxAllocation;  
run;
```

```
/******  
/* Demographic */  
/******
```

```
*age;  
data demo; set dsic.f07_demographics;  
run;
```

```
data proc; set dsic.f11_procedure;  
run;
```

```
proc sort data=demo;  
by SubjectNo;  
run;
```

```
proc sort data=proc;  
by SubjectNo;  
run;
```

```
data age; merge  
demo (in=a)  
proc (in=b);  
by subjectno;  
if a = b;  
run;
```

```

data age_1; set age;
age = (angiodate-birth_month_year)/365.25;
run;

proc means data=age_1 n mean std;
var age;
run;

*sex;
proc freq data=dsic.f07_demographics;
tables sex;
run;

*race;
proc freq data=dsic.f07_demographics;
tables racew;
run;

data race; set dsic.f07_demographics;
race = . ;
if racew = 1 then race = 1;
if raceaa = 1 then race = 2;
if raceai = 1 OR raceas = 1 OR raceab = 1 OR racepi = 1 OR raceot = 1 then race = 3;
eth = .;
if ethnic = 1 OR ethnic = 6 then eth = 0; else eth = 2;
run;

proc freq data=race;
tables race eth;
run;

/*****/
/* Clinical */
/*****/

*weight;
proc means data=dsic.f05_biometrics n mean std;
var weight;
run;

*diabetic;
proc freq data=dsic.f06_preproclabs;
tables diabetic;
run;

/*****/
/* Procedural */

```

```
/******
```

```
*Coronary and Percutaneous intervention;
```

```
proc freq data=dsic.f11_procedure;
```

```
tables angiotype pci;
```

```
run;
```

```
*Left ventricular end diastolic pressure;
```

```
proc means data=dsic.f11_procedure n mean std;
```

```
var LeftVentMeasure;
```

```
run;
```

```
*trial arm;
```

```
proc freq data=dsic.csp578_itt;
```

```
tables TxAllocation;
```

```
run;
```