Dataset Integrity Check for the APRON (Aprepitant for the Relief of Nausea) Trial (APRON)

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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

Aprepitant is an FDA-approved medication for the treatment of nausea following chemotherapy or surgery. Aprepitant is also used by some doctors to reduce nausea and vomiting in patients with gastroparesis, although the drug is not approved for this use. The Aprepitant for the Relief of Nausea in Patients with Chronic Nausea and Vomiting of Presumed Gastric Origin (*APRON*) study is a multicenter, randomized, placebo-controlled clinical trial designed to test the safety and efficacy of aprepitant in reducing symptoms among patients with gastroparesis.

3 Archived Datasets

All data files, as provided by the Data Coordinating Center (DCC), are located in the APRON study data package. For this replication, variables were taken from the derived datasets: “apron_table1.sas7bdat”.

4 Statistical Methods

Analyses were performed to duplicate results for the data published by Pasricha et al. [1] in the Gastroenterology, January 2018. To verify the integrity of the datasets, descriptive statistics were computed.

5 Results

For Table 1 in the publication [1], Table 1- Baseline Characteristics of the Study Population, Table A lists the variables that were used in the replication and Table B compares the results calculated from the archived data file to the results published in Table 1.

6 Conclusions

The results of the replication are almost an exact match to the published results.

7 References

[1] Pankaj J. Pasricha, Katherine P. Yates, Irene Sarosiek, Richard W. McCallum, Thomas L. Abell, Kenneth L. Koch, Linda Anh B. Nguyen, William J. Snape, William L. Hasler, John O. Clarke, Sameer Dhalla, Ellen M. Stein, Linda A. Lee, Laura A. Miriel, Mark L. Van Natta, Madhusudan Grover, Gianrico Farrugia, James Tonascia, Frank A. Hamilton, and Henry P. Parkman, for the NIDDK Gastroparesis Clinical Research Consortium (GpCRC). Aprepitant Has Mixed Effects on Nausea and Reduces Other Symptoms in Patients With Gastroparesis and Related Disorders. Gastroenterology 2018;154:65–76.

Table A: Variables used to replicate Table 1- Baseline Characteristics of the Study Population

Characteristic	**dataset.variable**
Treatment Group	apron_table1.TX
Women, no. (%)	apron_table1.FEMALE
Hispanic, no. (%)	apron_table1.HISPANIC
Race, no. (%)	apron_table1.RACE3
Diabetes type 1 or type 2, no. (%)	apron_table1.DM
Proton pump inhibitors	apron_table1.RX_PPI
Benzodiazepine or anxiolytic	apron_table1.ANXIOLYTIC
Prokinetic	apron_table1.PROKINETIC
Antiemetic	apron_table1.ANTIEMETIC
Narcotic	apron_table1.NARCOTIC
Neuropathic or pain modulator, anti-seizure, or other psychiatric medication	apron_table1.PAIN_MOD
Nausea/vomiting predominant symptom, no. (%)	apron_table1.PREDOMSX_CAT5
Delayed gastric emptying, no. (%)c	apron_table1.GEDELAY
Rapid gastric emptying, no. (%)c	apron_table1.GERAPID
Age (y)	apron_table1.AGERZC
Body mass index (BMI) (kg/m2)	apron_table1.BMI
Weight (kg)	apron_table1.WT
Waist circumference (cm)	apron_table1.WAIST
7-Day nausea VAS score, mm	apron_table1.VASB
Nausea (h)	apron_table1.NAUSHRB
GCSI total score	apron_table1.GCSIDDB
Nausea severity	apron_table1.NAUSB
Vomiting severity	apron_table1.VOMITB

Characteristic	dataset.variable
Early satiety severity	apron_table1.EARLYSATB
Excessive fullness severity	apron_table1.EXCFULLB
Bloating severity	apron_table1.BLOATB
Upper abdominal pain severity	apron_table1.UPABB
Vomiting (no. of episodes)	apron_table1.VOMITNB
Retching (no. of episodes)	apron_table1.RETCHNB
Overall symptom severity	apron_table1.OSXB
GCSI, total score	apron_table1.GCSI
Nausea/vomiting severity subscore	apron_table1.NAUSEA_SS
Nausea severity	apron_table1.NAUSEASX
Retching severity	apron_table1.RETCHINGSX
Vomiting severity	apron_table1.VOMITSX
Fullness/early satiety subscore	apron_table1.APPETITE_SS
Bloating subscore	apron_table1.BLOAT_SS
Upper abdominal pain/discomfort subscore	apron_table1.UPAB_SS
Lower abdominal pain	apron_table1.LOWABPAINSX
Lower abdominal discomfort	apron_table1.LOWABDISCOMFSX
GERD subscore	apron_table1.GERD_SS
Constipation severity	apron_table1.CONSTIPATESX
Diarrhea severity	apron_table1.DIARRHEASX
GSRS (items coded 0 to 7, no to very severe discomfort) Total score	apron_table1.GSRSTOT
GESb Percent gastric retention at: 1 hour (%)	apron_table1.RETAIN1
GESb Percent gastric retention at: 2 hours (%)	apron_table1.RETAIN2
GESb Percent gastric retention at: 4 hours (%)	apron_table1.RETAIN4

Table B-1: Comparison of values computed in integrity check to reference article Table 1 values. Aprepitant (n, %)

		Aprepitant					
		N			**%**		
	Demographic/ anthropometric	**Manscript**	**DSIC**	**Diff**	**Manuscript**	**DSIC**	**Diff**
	Women, no. (%)	49	49	0	78	78	0
	Hispanic, no. (%)	14	14	0	22	22	0
Race, no. (%)	White	53	53	0	84	84	0
	Black	8	8	0	13	13	0
	Otherb	2	2	0	3	3	0
	Diabetes type 1 or type 2, no. (%)	24	24	0	38	38	0
Medications taken in past month, no. (%)	Proton pump inhibitors	42	42	0	67	67	0
	Benzodiazepine or anxiolytic	13	13	0	21	21	0
	Prokinetic	25	25	0	40	40	0
	Antiemetic	44	44	0	70	70	0
	Narcotic	6	6	0	10	10	0
	Neuropathic or pain modulator, anti-seizure, or other psychiatric medication	27	27	0	43	43	0
	Nausea/vomiting predominant symptom, no. (%)	38	38	0	61	60	1
	Delayed gastric emptying, no. (%)c	29	29	0	46	46	0
	Rapid gastric emptying, no. (%)c	2	2	0	3	3	0

Table B-2: Comparison of values computed in integrity check to reference article Table 1 values. Placebo (N, %)

		Placebo					
		N			**%**		
	Demographic/anthropometric	**Manscript**	**DSIC**	**Diff**	**Manuscript**	**DSIC**	**Diff**
	Women, no. (%)	52	52	0	83	83	0
	Hispanic, no. (%)	14	14	0	22	22	0
Race, no. (%)	White	59	59	0	94	94	0
	Black	2	2	0	3	3	0
	Otherb	2	2	0	3	3	0
	Diabetes type 1 or type 2, no. (%)	13	13	0	21	21	0
Medications taken in past month, no. (%)	Proton pump inhibitors	51	51	0	81	81	0
	Benzodiazepine or anxiolytic	27	27	0	43	43	0
	Prokinetic	18	18	0	29	29	0
	Antiemetic	49	49	0	78	78	0
	Narcotic	4	4	0	6	6	0
	Neuropathic or pain modulator, anti-seizure, or other psychiatric medication	29	29	0	46	46	0
	Nausea/vomiting predominant symptom, no. (%)	39	39	0	64	62	2
	Delayed gastric emptying, no. (%)c	43	43	0	68	68	0
	Rapid gastric emptying, no. (%)c	2	2	0	3	3	0

Table B-3: Comparison of values computed in integrity check to reference article Table 1 values. Total (N, %)

		Total					
		N			%		
	Demographic/anthropometric	**Manscript**	**DSIC**	**Diff**	**Manuscript**	**DSIC**	**Diff**
	Women, no. (%)	101	101	0	80	80	0
	Hispanic, no. (%)	28	28	0	22	22	0
Race, no. (%)	White	112	112	0	89	89	0
	Black	10	10	0	8	8	0
	Otherb	4	4	0	3	3	0
	Diabetes type 1 or type 2, no. (%)	37	37	0	29	29	0
Medications taken in past month, no. (%)	Proton pump inhibitors	93	93	0	74	74	0
	Benzodiazepine or anxiolytic	40	40	0	32	32	0
	Prokinetic	43	43	0	34	34	0
	Antiemetic	93	93	0	74	74	0
	Narcotic	10	10	0	8	8	0
	Neuropathic or pain modulator, anti-seizure, or other psychiatric medication	56	56	0	44	44	0
	Nausea/vomiting predominant symptom, no. (%)	77	77	0	63	61	2
	Delayed gastric emptying, no. (%)c	72	72	0	57	57	0
	Rapid gastric emptying, no. (%)c	4	4	0	3	3	0

Table B-4: Comparison of values computed in integrity check to reference article Table 1 values. Aprepitant (Mean, SD)

		Aprepitant					
		Mean			**SD**		
	Demographic/anthropometric	**Manscript**	**DSIC**	**Diff**	**Manuscript**	**DSIC**	**Diff**
	Age (y)	42.9	42.9	0	14.8	14.8	0
	Body mass index (BMI) (kg/m2)	27.8	27.8	0	8.3	8.3	0
	Weight (kg)	75.4	75.3	0.1	22.8	22.8	0
	Waist circumference (cm)	90.9	90.9	0	17.2	17.2	0
Daily diary symptoms evaluation	7-Day nausea VAS score, mm	63	63	0	21.5	21.5	0
GCSI-DD (all items scored 0 to 4, none to very severe)	Nausea (h)	9	9	0	7	7.1	-0.1
	GCSI total score	2.2	2.2	0	0.9	0.9	0
	Nausea severity	2.6	2.6	0	0.8	0.8	0
	Vomiting severity	1	1	0	1	1	0
	Early satiety severity	2.6	2.6	0	1.1	1.1	0
	Excessive fullness severity	2.7	2.7	0	1.1	1.1	0
	Bloating severity	2.2	2.2	0	1.4	1.4	0
	Upper abdominal pain severity	2.3	2.3	0	1.2	1.2	0
	Vomiting (no. of episodes)	1.3	1.3	0	1.6	1.5	0.1
	Retching (no. of episodes)	2	2	0	2.5	2.5	0
	Overall symptom severity	2.5	2.5	0	0.8	0.8	0
Gastroparesis symptoms inventories PAGI-SYM Severity index (symptoms each scored 0 to 5, none to very severe)	GCSI, total score	3.4	3.4	0	0.9	0.8	0.1
	Nausea/vomiting severity subscore	3.3	3.3	0	1.1	1.1	0
	Nausea severity	4.2	4.2	0	0.8	0.8	0
	Retching severity	3	3	0	1.6	1.6	0
	Vomiting severity	2.6	2.6	0	1.8	1.8	0
	Fullness/early satiety subscore	3.7	3.7	0	1	1	0
	Bloating subscore	3.3	3.3	0	1.4	1.4	0

Table B-4 (continued): Comparison of values computed in integrity check to reference article Table 1 values. Aprepitant (Mean, SD)

		Aprepitant				
		Mean			SD	
	Demographic/anthropometric	**Manscript**	**DSIC**	**Diff**	**Manuscript**	**DSIC**
	Upper abdominal pain/discomfort subscore	3.4	3.4	0	1.3	1.3
	Lower abdominal pain	2.4	2.4	0	1.6	1.6
	Lower abdominal discomfort	2.5	2.5	0	1.6	1.6
	GERD subscore	2.4	2.4	0	1.4	1.4
	Constipation severity	2.9	2.9	0	1.7	1.7
	Diarrhea severity	1.6	1.6	0	1.7	1.7
GSRS (items coded 0 to 7, no to very severe discomfort)	Total score	3.6	3.6	0	1.1	1.1
GESb Percent gastric retention at:	1 hour (%)	69.7	69.7	0	20	20
	2 hours (%)	45.6	45.6	0	24.9	24.9
	4 hours (%)	17.8	17.8	0	21.8	21.8

Table B-5: Comparison of values computed in integrity check to reference article Table 1 values. Placebo (Mean, SD)

		Placebo					
		Mean			SD		
	Demographic/anthropometric	Manscript	DSIC	Diff	Manuscript	DSIC	Diff
	Age (y)	46.8	46.7	0.1	13.5	13.5	0
	Body mass index (BMI) (kg/m2)	28	28	0	7.5	7.5	0
	Weight (kg)	75.1	75	0.1	20.6	20.6	0
	Waist circumference (cm)	91.3	91.3	0	18	18	0
Daily diary symptoms evaluation	7-Day nausea VAS score, mm	64.1	64.1	0	20.2	20.2	0
GCSI-DD (all items scored 0 to 4, none to very severe)	Nausea (h)	9.3	9.3	0	7.1	7.1	0
	GCSI total score	2.3	2.3	0	0.7	0.7	0
	Nausea severity	2.6	2.6	0	0.8	0.8	0
	Vomiting severity	0.9	0.9	0	1	1	0
	Early satiety severity	2.7	2.7	0	0.9	0.9	0
	Excessive fullness severity	2.8	2.8	0	0.9	0.9	0
	Bloating severity	2.6	2.5	0.1	1.1	1.1	0
	Upper abdominal pain severity	2.3	2.3	0	1	1	0
	Vomiting (no. of episodes)	1.1	1.1	0	1.5	1.5	0
	Retching (no. of episodes)	2.3	2.2	0.1	2.8	2.8	0
	Overall symptom severity	2.6	2.6	0	0.7	0.7	0
Gastroparesis symptoms inventories PAGI-SYM Severity index (symptoms each scored 0 to 5, none to very severe)	GCSI, total score	3.3	3.3	0	0.7	0.7	0
	Nausea/vomiting severity subscore	2.8	2.8	0	0.9	0.9	0
	Nausea severity	4	4	0	0.9	0.9	0
	Retching severity	2.6	2.6	0	1.3	1.3	0
	Vomiting severity	1.9	1.9	0	1.6	1.6	0
	Fullness/early satiety subscore	3.7	3.7	0	0.8	0.8	0
	Bloating subscore	3.4	3.4	0	1.4	1.4	0

Table B-5 (continued): Comparison of values computed in integrity check to reference article Table 1 values. Placebo (Mean, SD)

		Placebo					
		Mean			SD		
	Demographic/anthropometric	**Manscript**	**DSIC**	**Diff**	**Manuscript**	**DSIC**	**Diff**
	Upper abdominal pain/discomfort subscore	3.3	3.3	0	1.3	1.3	0
	Lower abdominal pain	2.5	2.5	0	1.4	1.4	0
	Lower abdominal discomfort	2.6	2.6	0	1.4	1.4	0
	GERD subscore	2.3	2.3	0	1.4	1.4	0
	Constipation severity	2.6	2.6	0	1.8	1.8	0
	Diarrhea severity	1.8	1.7	0.1	1.7	1.7	0
GSRS (items coded 0 to 7, no to very severe discomfort)	Total score	3.7	3.7	0	1	1	0
GESb Percent gastric retention at:	1 hour (%)	73	73	0	19.3	19.3	0
	2 hours (%)	53.1	53.1	0	23.4	23.4	0
	4 hours (%)	20.4	20.4	0	17.5	17.5	0

Table B-6: Comparison of values computed in integrity check to reference article Table 1 values. Total (Mean, SD)

		Total					
		Mean			SD		
	Demographic/anthropometric	**Manscript**	**DSIC**	**Diff**	**Manuscript**	**DSIC**	**Diff**
	Age (y)	44.8	44.8	0	14.3	14.2	0.1
	Body mass index (BMI) (kg/m2)	27.9	27.9	0	7.9	7.9	0
	Weight (kg)	75.2	75.2	0	21.7	21.7	0
	Waist circumference (cm)	91.1	91.1	0	17.5	17.5	0
Daily diary symptoms evaluation	7-Day nausea VAS score, mm	63.6	63.6	0	20.8	20.8	0
GCSI-DD (all items scored 0 to 4, none to very severe)	Nausea (h)	9.2	9.2	0	7.1	7.1	0
	GCSI total score	2.3	2.3	0	0.8	0.8	0
	Nausea severity	2.6	2.6	0	0.8	0.8	0
	Vomiting severity	1	1	0	1	1	0
	Early satiety severity	2.6	2.6	0	1	1	0
	Excessive fullness severity	2.7	2.7	0	1	1	0
	Bloating severity	2.4	2.4	0	1.2	1.2	0
	Upper abdominal pain severity	2.3	2.3	0	1.1	1.1	0
	Vomiting (no. of episodes)	1.2	1.2	0	1.5	1.5	0
	Retching (no. of episodes)	2.1	2.1	0	2.6	2.6	0
	Overall symptom severity	2.6	2.6	0	0.8	0.8	0
Gastroparesis symptoms inventories PAGI-SYM Severity index (symptoms each scored 0 to 5, none to very severe)	GCSI, total score	3.4	3.4	0	0.8	0.8	0
	Nausea/vomiting severity subscore	3	3	0	1.1	1.1	0
	Nausea severity	4.1	4.1	0	0.9	0.9	0
	Retching severity	2.8	2.8	0	1.5	1.5	0
	Vomiting severity	2.2	2.2	0	1.7	1.7	0
	Fullness/early satiety subscore	3.7	3.7	0	0.9	0.9	0
	Bloating subscore	3.4	3.3	0.1	1.4	1.4	0

Table B-6 (continued): Comparison of values computed in integrity check to reference article Table 1 values. Total (Mean, SD)

		Total					
		Mean			SD		
	Demographic/anthropometric	**Manscript**	**DSIC**	**Diff**	**Manuscript**	**DSIC**	**Diff**
	Upper abdominal pain/discomfort subscore	3.4	3.4	0	1.3	1.3	0
	Lower abdominal pain	2.5	2.5	0	1.5	1.5	0
	Lower abdominal discomfort	2.6	2.6	0	1.5	1.5	0
	GERD subscore	2.3	2.3	0	1.4	1.4	0
	Constipation severity	2.8	2.8	0	1.8	1.8	0
	Diarrhea severity	1.7	1.7	0	1.7	1.7	0
GSRS (items coded 0 to 7, no to very severe discomfort)	Total score	3.7	3.7	0	1.1	1.1	0
GESb Percent gastric retention at:	1 hour (%)	71.3	71.3	0	19.6	19.6	0
	2 hours (%)	49.4	49.4	0	24.4	24.4	0
	4 hours (%)	19.1	19.1	0	19.7	19.7	0

Attachment A: SAS Code

```
options nocenter validvarname=upcase fmtsearch=(formats) nofmterr;

title '/prj/niddk/ims_analysis/APRON/prog_initial_analysis/apron.dsic.2020.sas';
run;

/* APRON_Gastroenterology.pdf Table 1 check */

**********;
* INPUT   ;
**********;
libname orig '/prj/niddk/ims_analysis/APRON/private_orig_data/GpCRC_Data_Sharing_APRON/1. SAS Datasets/';


************;
* MACROS    ;
************;
%macro readin(ds);
  data &ds;
    set orig.&ds;
  run;

  proc contents data=&ds;
  title3 "&ds";
  run;
%mend;


* produce n and %;
%macro npercent(rownum, var, varf, subset, subsetname);
  proc freq data=analy noprint;
    where &subset = 1;
    tables &var/list missing out=tbl1&subsetname;
  run;

  data tbl1&subsetname;
    length covar covarf $100;
    set tbl1&subsetname;
    covar = "&var";
    covarf = put(&var,&varf..);
    rownum = &rownum;
  run;

  data prnt&subsetname;
    set prnt&subsetname tbl1&subsetname;
  run;

%mend;


%macro univ(rownum, var, subset, subsetname);

  proc univariate data=analy outtable= univ&subsetname noprint;
```

```
    where &subset=1;
    var &var
       ;
  run;

  data univ&subsetname;
    length covarf $100 _var_ $25;
    set univ&subsetname;
        covarf = "&subset";
        rownum = &rownum;
  run;

  data prntuniv&subsetname;
    set prntuniv&subsetname univ&subsetname;
  run;

%mend;



*************;
* FORMATS    ;
*************;
proc format;
  value novalue
      . = "No Value"
  other = "   Value"
  ;

  value racegf
  1='White'
  2='Black'
  3='Other'
  ;

  value sexf
  0='Male'
  1='Female'
  ;

  value ynf
  1 = 'yes'
  0 = 'no'
  ;

run;


%readin(tx );
proc freq data=tx;
  tables tx*txname/list missing;
run;

%readin(apron_table1 );
```

```
proc sort data=tx;
  by id tx txname;
run;

proc sort data=apron_table1;
  by id tx txname;
run;

data analy;
  merge tx           (in=in1 keep=id tx txname)
        apron_table1 (in=in2)
       ;
  by id tx txname;
  if not (in1 and in2) then abort;
  if in1 and in2;

  * create subset flags;
  total=1;
  if tx = 1 then Aprepitant=1;
  else if tx = 0 then placebo=1;

  *Nausea/vomiting predominant symptom;
  if PREDOMSX_CAT5 = 0 then predomsx_nv = 1;
  else predomsx_nv = 0;

run;

proc freq data=analy;
  tables total*tx*Aprepitant*placebo/list missing;
  tables PREDOMSX_CAT5*predomsx_nv/list missing;
  title3 "checking";
run;



** TOTAL;
data prnttot;
 * length _VAR_ $100;
  set _null_;
run;

%npercent(1 ,FEMALE       , SEXF  , total, tot);
%npercent(2 ,HISPANIC    , ynf   , total, tot);
%npercent(3 ,RACE3       , racegf, total, tot);
%npercent(4 ,DM           , ynf   , total, tot);    /*  1. 1=dx with diabetes type 1 or type 2                                  */
%npercent(5 ,RX_PPI       , ynf   , total, tot);    /*  1=current use proton pump or gi rx (past month)                         */
%npercent(6 ,ANXIOLYTIC   , ynf   , total, tot);    /*  1=current use of benzodiazepines/anxiolytic rx (past mo)                */
%npercent(7 ,PROKINETIC   , ynf   , total, tot);    /*  1=current use prokinetic rx (past month)                                */
%npercent(8 ,ANTIEMETIC   , ynf   , total, tot);    /*  (STOP) 1=current use antiemetic rx (past month)                         */
%npercent(9 ,NARCOTIC     , ynf   , total, tot);    /*  (Caution) 1=current use narcotic > 3X/wk (past month)                   */
%npercent(10,PAIN_MOD     , ynf   , total, tot);    /*  1=used neuropathic/pain modulator/anti-seizure, anti-psych, mood modulator*/
%npercent(11,predomsx_nv  , ynf   , total, tot);
%npercent(12,GEDELAY      , ynf   , total, tot);    /*    delayed emptying at either 2 or 4 hr    */
%npercent(13,GERAPID      , ynf   , total, tot);    /*    rapid emptying: < 30% at 1 hr           */

data prnttot;
```

```
  set prnttot;
  percent = round(percent);
run;

proc print data=prnttot;
  where covarf not in('no', 'Male');
  var rownum covar covarf count percent;
  title3 "Total - N(%)";
run;


* med, q1, q3;
data prntunivtot;
 * length _VAR_ $100;
  set _null_;
run;

* Age continuous is NOT provided, skip;
%univ(14   , AGERZC    , total , tot);
%univ(15   , BMI       , total , tot);
%univ(16   , WT        , total , tot);
%univ(17   , WAIST     , total , tot);
%univ(18   , VASB      , total , tot);
%univ(19   , NAUSHRB   , total , tot);
%univ(20   , GCSIDDB     , total , tot);       /*  Mean total GCSI-DD score over 7-day BL                    */
%univ(21   , NAUSB       , total , tot);       /*  Mean GCSI-DD nauseas severity over 7-day BL               */
%univ(22   , VOMITB      , total , tot);       /*  Mean GCSI-DD vomiting severity over 7-day BL              */
%univ(23   , EARLYSATB   , total , tot);       /*  Mean GCSI-DD early satiety severity over 7-day BL             */
%univ(24   , EXCFULLB    , total , tot);       /*  Mean GCSI-DD excessive fullness severity over 7-day BL        */
%univ(25   , BLOATB      , total , tot);       /*  Mean GCSI-DD Bloating severity over 7-day BL              */
%univ(26   , UPABB       , total , tot);       /*  Mean GCSI-DD Upper absominal pain severity over 7-day BL      */
%univ(27   , VOMITNB     , total , tot);       /*        Mean daily episodes of vomiting over 7-day BL           */
%univ(28   , RETCHNB     , total , tot);       /*      Mean daily episodes of retching over 7-day BL             */
%univ(29   , OSXB        , total , tot);       /* Mean overall severity of gp symptoms over 7-day BL             */

%univ(30   , GCSI      , total , tot);
%univ(31   , NAUSEA_SS   , total , tot);
%univ(32   , NAUSEASX    , total , tot);
%univ(33   , RETCHINGSX  , total , tot);
%univ(34   , VOMITSX   , total , tot);
%univ(35   , APPETITE_SS , total , tot);
%univ(36   , BLOAT_SS    , total , tot);
%univ(37   , UPAB_SS   , total , tot);
%univ(38   , LOWABPAINSX , total , tot);
%univ(39   , LOWABDISCOMFSX , total , tot);
%univ(40   , GERD_SS      , total , tot);
%univ(41   , CONSTIPATESX   , total , tot);
%univ(42   , DIARRHEASX     , total , tot);

%univ(43   , GSRSTOT      , total , tot);
%univ(44   , RETAIN1        , total , tot);       /*    % gastric retention at 1 hr            */
%univ(45   , RETAIN2        , total , tot);       /*    % gastric retention at 2 hr            */
%univ(46   , RETAIN4        , total , tot);       /*    % gastric retention at 4 hr            */

data prntunivtot;
  set prntunivtot;
```

```
   _median_  = round(_median_ , 0.1);
   _q1_      = round(_q1_     , 0.1);
   _q3_      = round(_q3_     , 0.1);
   _mean_    = round(_mean_   , 0.1);
   _std_     = round(_std_    , 0.1);
run;

proc print data=prntunivtot;
 var rownum _var_ covarf _nobs_/* _median_ _q1_ _q3_ _min_ _max_*/ _mean_ _std_;
  title3 "Total - Mean(SD)";
run;




** Aprepitant;
data prntapr;
 * length _VAR_ $100;
  set _null_;
run;

%npercent(1 ,FEMALE       , SEXF  , Aprepitant, apr);
%npercent(2 ,HISPANIC    , ynf   , Aprepitant, apr);
%npercent(3 ,RACE3       , racegf, Aprepitant, apr);
%npercent(4 ,DM           , ynf   , Aprepitant, apr);    /*  1. 1=dx with diabetes type 1 or type 2                                  */
%npercent(5 ,RX_PPI       , ynf   , Aprepitant, apr);    /*  1=current use proton pump or gi rx (past month)                         */
%npercent(6 ,ANXIOLYTIC   , ynf   , Aprepitant, apr);    /*  1=current use of benzodiazepines/anxiolytic rx (past mo)                */
%npercent(7 ,PROKINETIC   , ynf   , Aprepitant, apr);    /*  1=current use prokinetic rx (past month)                                */
%npercent(8 ,ANTIEMETIC   , ynf   , Aprepitant, apr);    /*  (STOP) 1=current use antiemetic rx (past month)                         */
%npercent(9 ,NARCOTIC     , ynf   , Aprepitant, apr);    /*  (Caution) 1=current use narcotic > 3X/wk (past month)                   */
%npercent(10,PAIN_MOD     , ynf   , Aprepitant, apr);    /*  1=used neuropathic/pain modulator/anti-seizure, anti-psych, mood modulator*/
%npercent(11,predomsx_nv  , ynf   , Aprepitant, apr);
%npercent(12,GEDELAY      , ynf   , Aprepitant, apr);    /*    delayed emptying at either 2 or 4 hr    */
%npercent(13,GERAPID      , ynf   , Aprepitant, apr);    /*    rapid emptying: < 30% at 1 hr           */

data prntapr;
  set prntapr;
  percent = round(percent);
run;

proc print data=prntapr;
  where covarf not in('no', 'Male');
  var rownum covar covarf count percent;
  title3 "Aprepitant - N(%)";
run;


* med, q1, q3;
data prntunivapr;
 * length _VAR_ $100;
  set _null_;
run;

* Age continuous is NOT provided, skip;
%univ(14   , AGERZC       , Aprepitant , apr);
%univ(15   , BMI          , Aprepitant , apr);
```

```
%univ(16   , WT           , Aprepitant , apr);
%univ(17   , WAIST        , Aprepitant , apr);
%univ(18   , VASB         , Aprepitant , apr);
%univ(19   , NAUSHRB      , Aprepitant , apr);
%univ(20   , GCSIDDB        , Aprepitant , apr);       /*  Mean total GCSI-DD score over 7-day BL                    */
%univ(21   , NAUSB          , Aprepitant , apr);       /*  Mean GCSI-DD nauseas severity over 7-day BL               */
%univ(22   , VOMITB         , Aprepitant , apr);       /*  Mean GCSI-DD vomiting severity over 7-day BL              */
%univ(23   , EARLYSATB      , Aprepitant , apr);       /*  Mean GCSI-DD early satiety severity over 7-day BL              */
%univ(24   , EXCFULLB       , Aprepitant , apr);       /*  Mean GCSI-DD excessive fullness severity over 7-day BL         */
%univ(25   , BLOATB         , Aprepitant , apr);       /*  Mean GCSI-DD Bloating severity over 7-day BL                     */
%univ(26   , UPABB          , Aprepitant , apr);       /*  Mean GCSI-DD Upper absominal pain severity over 7-day BL       */
%univ(27   , VOMITNB        , Aprepitant , apr);       /*        Mean daily episodes of vomiting over 7-day BL            */
%univ(28   , RETCHNB        , Aprepitant , apr);       /*      Mean daily episodes of retching over 7-day BL              */
%univ(29   , OSXB           , Aprepitant , apr);       /* Mean overall severity of gp symptoms over 7-day BL             */
%univ(30   , GCSI         , Aprepitant , apr);
%univ(31   , NAUSEA_SS      , Aprepitant , apr);
%univ(32   , NAUSEASX       , Aprepitant , apr);
%univ(33   , RETCHINGSX     , Aprepitant , apr);
%univ(34   , VOMITSX      , Aprepitant , apr);
%univ(35   , APPETITE_SS    , Aprepitant , apr);
%univ(36   , BLOAT_SS       , Aprepitant , apr);
%univ(37   , UPAB_SS      , Aprepitant , apr);
%univ(38   , LOWABPAINSX    , Aprepitant , apr);
%univ(39   , LOWABDISCOMFSX , Aprepitant , apr);
%univ(40   , GERD_SS      , Aprepitant , apr);
%univ(41   , CONSTIPATESX   , Aprepitant , apr);
%univ(42   , DIARRHEASX     , Aprepitant , apr);
%univ(43   , GSRSTOT      , Aprepitant , apr);
%univ(44   , RETAIN1        , Aprepitant , apr);       /*    % gastric retention at 1 hr            */
%univ(45   , RETAIN2        , Aprepitant , apr);       /*    % gastric retention at 2 hr            */
%univ(46   , RETAIN4        , Aprepitant , apr);       /*    % gastric retention at 4 hr            */

data prntunivapr;
  set prntunivapr;
   _median_  = round(_median_ , 0.1);
   _q1_      = round(_q1_     , 0.1);
   _q3_      = round(_q3_     , 0.1);
   _mean_    = round(_mean_   , 0.1);
   _std_     = round(_std_    , 0.1);
run;

proc print data=prntunivapr;
 var rownum _var_ covarf _nobs_/* _median_ _q1_ _q3_ _min_ _max_*/ _mean_ _std_;
  title3 "Aprepitant - Mean(SD)";
run;



** Placebo;
data prntplb;
 * length _VAR_ $100;
  set _null_;
run;

%npercent(1 ,FEMALE       , SEXF  , Placebo, plb);
%npercent(2 ,HISPANIC    , ynf   , Placebo, plb);
```

```
%npercent(3 ,RACE3       , racegf, Placebo, plb);
%npercent(4 ,DM           , ynf   , Placebo, plb);    /*  1. 1=dx with diabetes type 1 or type 2                                  */
%npercent(5 ,RX_PPI       , ynf   , Placebo, plb);    /*  1=current use proton pump or gi rx (past month)                         */
%npercent(6 ,ANXIOLYTIC   , ynf   , Placebo, plb);    /*  1=current use of benzodiazepines/anxiolytic rx (past mo)                */
%npercent(7 ,PROKINETIC   , ynf   , Placebo, plb);    /*  1=current use prokinetic rx (past month)                                */
%npercent(8 ,ANTIEMETIC   , ynf   , Placebo, plb);    /*  (STOP) 1=current use antiemetic rx (past month)                         */
%npercent(9 ,NARCOTIC     , ynf   , Placebo, plb);    /*  (Caution) 1=current use narcotic > 3X/wk (past month)                   */
%npercent(10,PAIN_MOD     , ynf   , Placebo, plb);    /*  1=used neuropathic/pain modulator/anti-seizure, anti-psych, mood modulator*/
%npercent(11,predomsx_nv  , ynf   , Placebo, plb);
%npercent(12,GEDELAY      , ynf   , Placebo, plb);    /*    delayed emptying at either 2 or 4 hr    */
%npercent(13,GERAPID      , ynf   , Placebo, plb);    /*    rapid emptying: < 30% at 1 hr           */

data prntplb;
  set prntplb;
  percent = round(percent);
run;

proc print data=prntplb;
  where covarf not in('no', 'Male');
  var rownum covar covarf count percent;
  title3 "Placebo - N(%)";
run;


* med, q1, q3;
data prntunivplb;
 * length _VAR_ $100;
  set _null_;
run;

* Age continuous is NOT provided, skip;
%univ(14   , AGERZC       , Placebo , plb);
%univ(15   , BMI          , Placebo , plb);
%univ(16   , WT           , Placebo , plb);
%univ(17   , WAIST        , Placebo , plb);
%univ(18   , VASB         , Placebo , plb);
%univ(19   , NAUSHRB      , Placebo , plb);
%univ(20   , GCSIDDB       , Placebo , plb);       /*  Mean total GCSI-DD score over 7-day BL                    */
%univ(21   , NAUSB         , Placebo , plb);       /*  Mean GCSI-DD nauseas severity over 7-day BL                 */
%univ(22   , VOMITB        , Placebo , plb);       /*  Mean GCSI-DD vomiting severity over 7-day BL                */
%univ(23   , EARLYSATB     , Placebo , plb);       /*  Mean GCSI-DD early satiety severity over 7-day BL             */
%univ(24   , EXCFULLB      , Placebo , plb);       /*  Mean GCSI-DD excessive fullness severity over 7-day BL        */
%univ(25   , BLOATB        , Placebo , plb);       /*  Mean GCSI-DD Bloating severity over 7-day BL                */
%univ(26   , UPABB         , Placebo , plb);       /*  Mean GCSI-DD Upper absominal pain severity over 7-day BL      */
%univ(27   , VOMITNB       , Placebo , plb);       /*        Mean daily episodes of vomiting over 7-day BL           */
%univ(28   , RETCHNB       , Placebo , plb);       /*     Mean daily episodes of retching over 7-day BL              */
%univ(29   , OSXB          , Placebo , plb);       /* Mean overall severity of gp symptoms over 7-day BL             */
%univ(30   , GCSI         , Placebo , plb);
%univ(31   , NAUSEA_SS     , Placebo , plb);
%univ(32   , NAUSEASX      , Placebo , plb);
%univ(33   , RETCHINGSX    , Placebo , plb);
%univ(34   , VOMITSX      , Placebo , plb);
%univ(35   , APPETITE_SS   , Placebo , plb);
%univ(36   , BLOAT_SS      , Placebo , plb);
%univ(37   , UPAB_SS      , Placebo , plb);
%univ(38   , LOWABPAINSX   , Placebo , plb);
```

```
%univ(39   , LOWABDISCOMFSX , Placebo , plb);
%univ(40   , GERD_SS       , Placebo , plb);
%univ(41   , CONSTIPATESX   , Placebo , plb);
%univ(42   , DIARRHEASX     , Placebo , plb);
%univ(43   , GSRSTOT       , Placebo , plb);
%univ(44   , RETAIN1        , Placebo , plb);       /*    % gastric retention at 1 hr            */
%univ(45   , RETAIN2        , Placebo , plb);       /*    % gastric retention at 2 hr            */
%univ(46   , RETAIN4        , Placebo , plb);       /*    % gastric retention at 4 hr            */

data prntunivplb;
  set prntunivplb;
   _median_  = round(_median_ , 0.1);
   _q1_      = round(_q1_     , 0.1);
   _q3_      = round(_q3_     , 0.1);
   _mean_    = round(_mean_   , 0.1);
   _std_     = round(_std_    , 0.1);
run;

proc print data=prntunivplb;
 var rownum _var_ covarf _nobs_/* _median_ _q1_ _q3_ _min_ _max_*/ _mean_ _std_;
  title3 "Placebo - Mean(SD)";
run;
```