Response to 2020-07-16 e-mail

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July 21, 2020 04:07 AM

Data version: The version of data we're using is from 2020-01-31 15:45.

Could you provide us with a demographics breakdown so we can do a table 1 with

- ***Age at enrollment***
- ***Gender***
- ***Ethnicity***
- ***Time since diagnosis***

	Overall (N=677)
Age at enrollment (years)	
Mean (SD)	14.2 (3.09)
Median [Min, Max]	15.0 [0, 20.0]
Sex	
Female	563 (83.2%)
Male	114 (16.8%)
Race	
White	205 (30.3%)
Black	178 (26.3%)
Asian	80 (11.8%)
Mixed	30 (4.4%)
Other race	26 (3.8%)
Missing	158 (23.3%)
Ethnicity	
Hispanic	172 (25.4%)
Non-hispanic	505 (74.6%)
Time since diagnosis (years)	
Mean (SD)	1.07 (1.62)
Median [Min, Max]	1.00 [0, 13.0]

The total number of LN cases were reported as 234 and 235 different places throughout the data. Could you help clarify this?

From the raw biopsy data we have the following table:

LN Status	n	percent

LN Status	n	percent
FALSE	440	65.2%
TRUE	235	34.8%
Total	675	•

In the table for Principle 4 you are seeing 234 patients with LN. This is because for that analysis we were looking at number of visits after LN diagnosis. The information available for subject 597 showed that diagnosis was at an unscheduled visit, and where that visit was temporally between baseline, 6 month and 12 month visit was not available. So this subject was removed from that analysis since the number of visits post diagnosis could not be computed for that subject.

This has now been noted in the original report

> ***For principle 2, the total of LN is 217 instead of 235. I think this wasn't updated when we added in the rest of the nephritis patients (class I and II) to principle 1***

This wasn't quite the problem. I had truncated the table to 2 or fewer years, and so several individuals were omitted from this table. It has now been fixed in the original report (summaries.html, attached)

> ***For principle 2, can we do a kaplan meyer curve for time to nephritis?***

Yes, I can, though it will be a bit choppy due to the fact that we only have years since diagnosis, and not more granular data. Added to summaries.html

UPC information

> ***For principle 3, can you please report the UPC by class both the numerical and categorical variable? I know the data is limited but we'd like to report what we have***

This analysis has been added to Principle 3 in summary.html

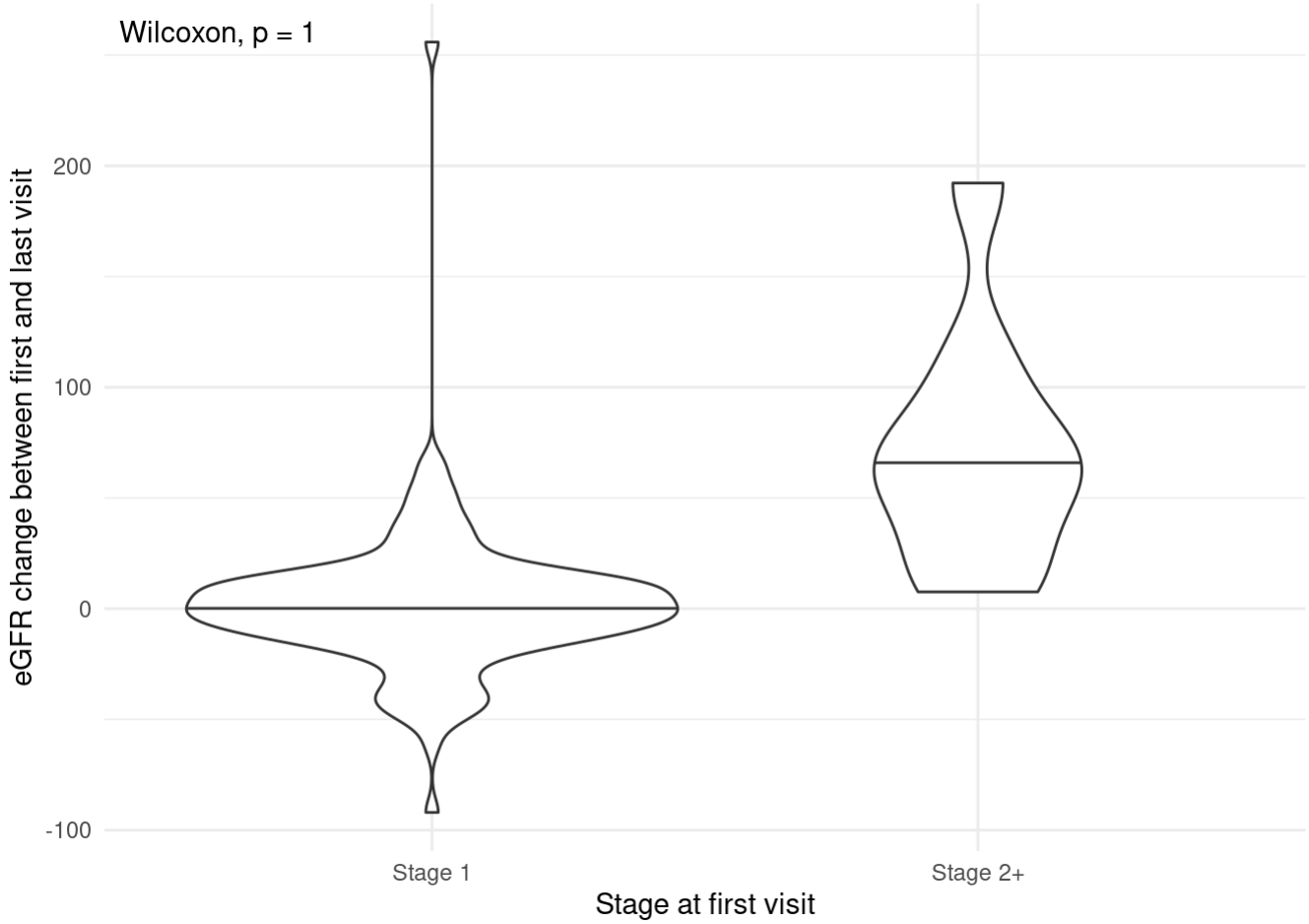
> ***For principle 4, the GFR table total is 234 not 235 including NA. Where did the one patient go?***

This has been answered above

> ***For principle 5, what is the p-value for the change in GFR? Can we do this by collapsing state 2 and state 3 into one group and compare GFR >60 vs <60?***

This is an ill-posed problem. What is the hypothesis test you're asking for? If you're testing H_0: *No difference between Stage 1 and Stage 2+3 in what proportion get worse* vs H_1: *Stage 2+3 gets worse more often than Stage 1*, which is how I interpret the principle, then you have a problem. People starting in Stage 2+3 cannot get worse.

You could consider if eGFR values worsen on average for non-Stage 1 patients compared to Stage 1 patients.



This plot clearly shows that individuals who start at Stage 2+ (eGFR <= 60) have strong **improvement** by their last visit.

> The violin plots have the medians marked. Hypothesis testing to test if the change in eGFR was the same in the two groups was performed using a Wilcoxon rank-sum test, with the alternative hypothesis being that median eGFR among Stage 2 subjects is **less than** median eGFR among Stage 1 subjects.

> ***For principle 6, for the top medications- which patients are being compared? What is the denominator?***

Thanks for bringing this up. It looks like I didn't quite do the right thing before (hence your confusion). I've updated the tables in summary.html. Denominators for each entity is the number of Ritux users or non-Ritux subjects as the case might be for each column. This is what makes sense to me. So the interpretation of the *With Ritux* entries is the proportion of Ritux users who also took the drug in quesiton.