[PCN437]

Reconstruction of individual patient data from published survival curves: case of pralatrexate for peripheral T-cell lymphomas

Hyeonseok Cho[1], Seok-Jae Heo[2], Ah-Young Kim[3], Hye-Young Kang[1]

[1]College of Pharmacy, Yonsei Institute of Pharmaceutical Sciences, Yonsei University, Incheon, South Korea
[2]Department of Biostatistics and Computing, Yonsei University Graduate School, Seoul, South Korea
[3]Department of Pharmaceutical Medicine and Regulatory Sciences, Colleges of Medicine and Pharmacy, Yonsei University, Incheon, South Korea

INTRODUCTION

- Extrapolating survival data beyond the duration of a clinical trial is increasingly being used to provide long-term survival benefits in cost-effectiveness analysis of new cancer drugs.
- However, access to individual patient data (IPD) is rarely available, and thus researchers need to reconstruct IPD from published Kaplan-Meier survival curves, so that parametric survival analysis can be conducted.

OBJECTIVE

- This study aims to reconstruct IPD from a case match control study by O'Connor et al. (2018), which compared the overall survival outcome of pralatrexate (PDX) to historical controls in patients with peripheral T-cell lymphomas.

METHODS

- The Kaplan-Meier survival curves for both groups were digitized using DigitizeIt software.

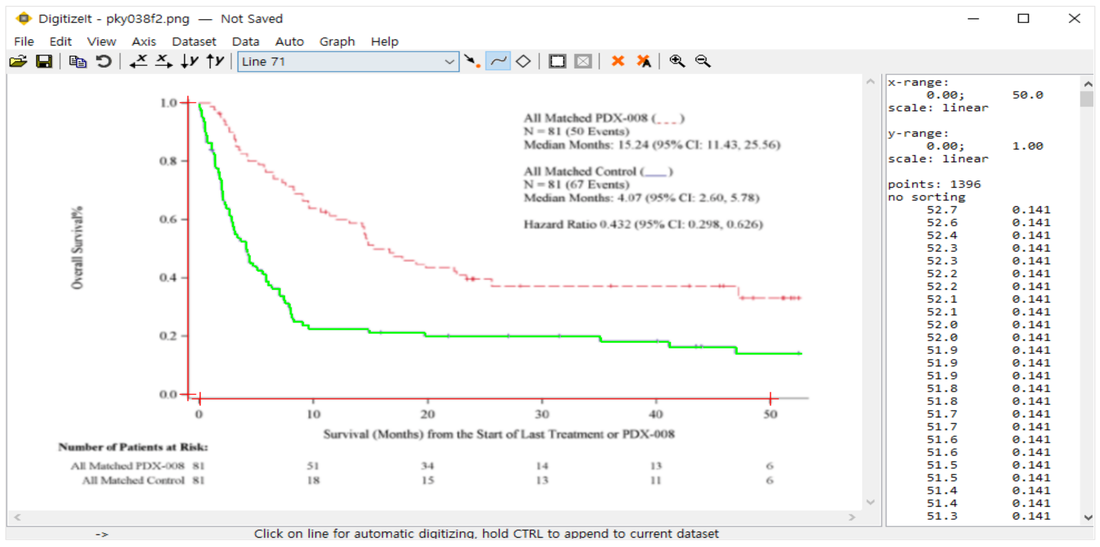

Figure 1. Extraction of coordinates from published survival curves

- The method developed by Guyot et al. (2012) was applied to reconstruct IPD from the extracted coordinates, using R software. Guyot's algorithm is the most commonly used method and closely approximates the original survival curves if numbers at risk and total number of events are reported.
- The estimated median overall survival and hazard ratio (HR) of the reconstructed data were compared to the original ones to assess the validity of results.

RESULTS

- Compared with the O'Connor publication, the reconstructed IPD showed a similar trend in estimated total number of events, overall survival, and HR for both pralatrexate and control groups.

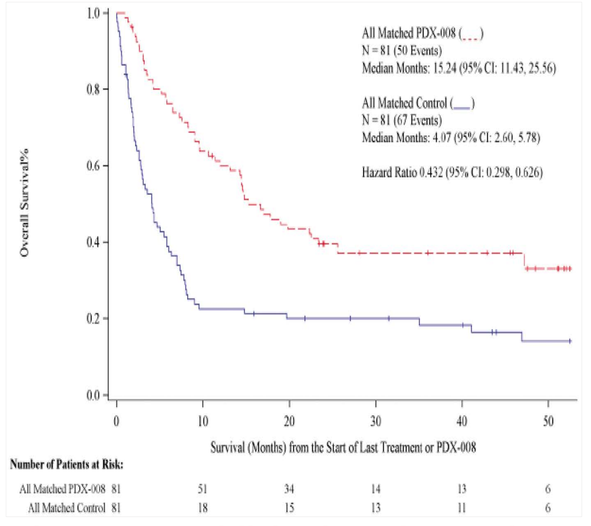

Figure 2a. Published Kaplan-Meier survival curves

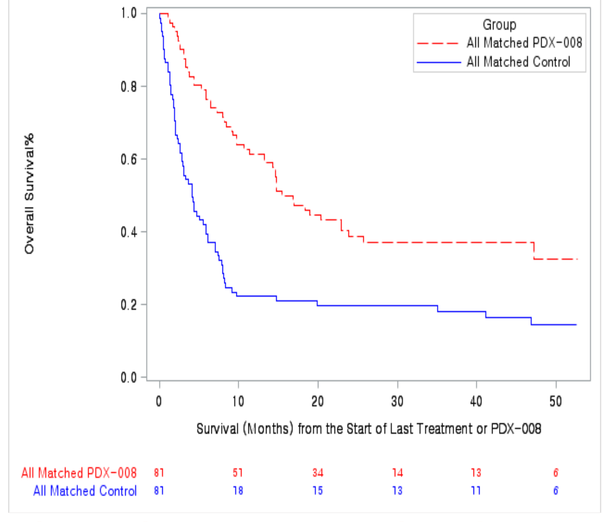

Figure 2b. Reconstructed Kaplan-Meier survival curves

Table 1. Comparison of overall survival outcome

Pralatrexate group		O'Connor publication	Reconstructed IPD
Total number of events		50	50
Median OS (95% CI)		15.24 (11.43-25.56)	15.40 (11.43-25.56)
OS rate	at 10 months	0.639	0.639
	at 20 months	0.446	0.447
	at 30 months	0.372	0.371
	at 40 months	0.372	0.371
	at 50 months	0.331	0.324
Control group		**O'Connor publication**	**Reconstructed IPD**
Total number of events		67	68
Median OS (95% CI)		4.07	4.10
OS rate	at 10 months	0.226	0.222
	at 20 months	0.201	0.197
	at 30 months	0.201	0.197
	at 40 months	0.183	0.180
	at 50 months	0.142	0.143
HR (95% CI)		0.432 (0.298-0.626)	0.431 (0.298-0.623)

IPD: individual patient data, CI: confidence interval, OS: overall survival, HR: hazard ratio

CONCLUSIONS

- Generating patient-level data from the published survival curves is feasible by adopting established methods.
- The reconstructed IPD can be utilized for fitting parametric survival models. This, in turn, can provide transition probabilities which are necessities for cost-effectiveness analysis of pralatrexate in patients with peripheral T-cell lymphomas.

REFERENCES

- O'Connor, O. A., Marchi, E., Volinn, W., Shi, J., Mehrling, T., & Kim, W. S.. Strategy for Assessing New Drug Value in Orphan Diseases: An International Case Match Control Analysis of the PROPEL Study. JNCI Cancer Spectrum, 2018:2(4):pky038.
- Guyot P, Ades AE, Ouwens MJ, Welton NJ. Enhanced secondary analysis of survival data: reconstructing the data from published Kaplan-Meier survival curves. BMC medical research methodology. 2012;12:9.

Financial support disclosure: The study was funded by Mundipharma Korea.