Predicting the Early Risk of Chronic Kidney Disease in People with Diabetes Using Real-World Data

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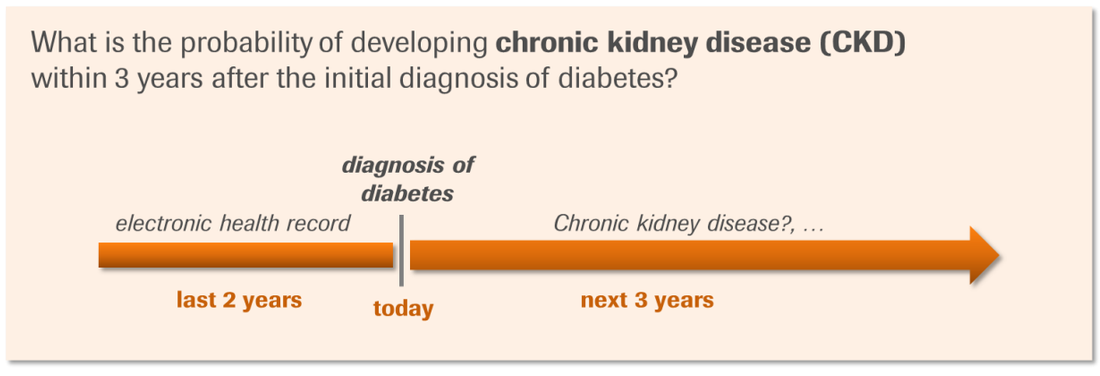
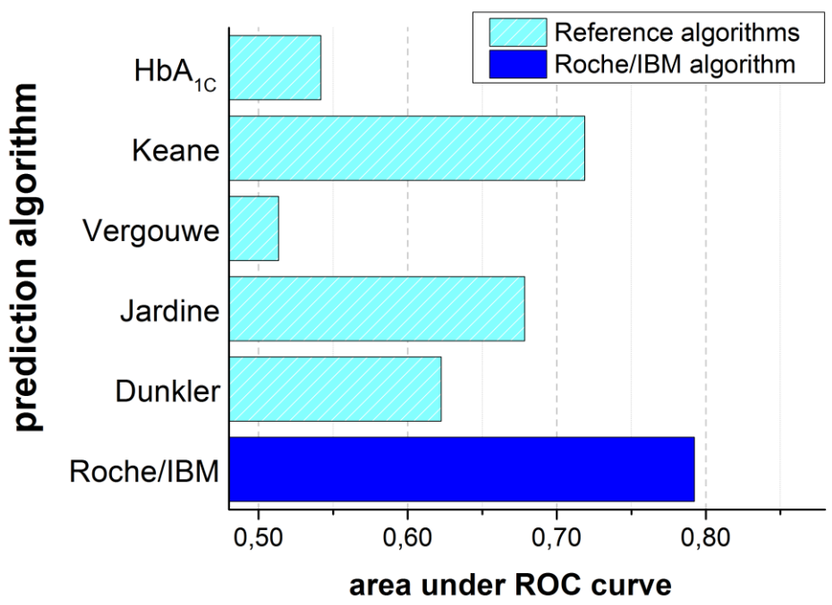
The volume of real-world medical data from clinics and medical doctors' offices greatly exceeds the information available in clinical trials. However, the increase in data volume comes at the expense of completeness, uniformity, and control when using such real-world data. We have explored **real world data** originating from more than **half a million people with diabetes** of the IBM Explorys database.



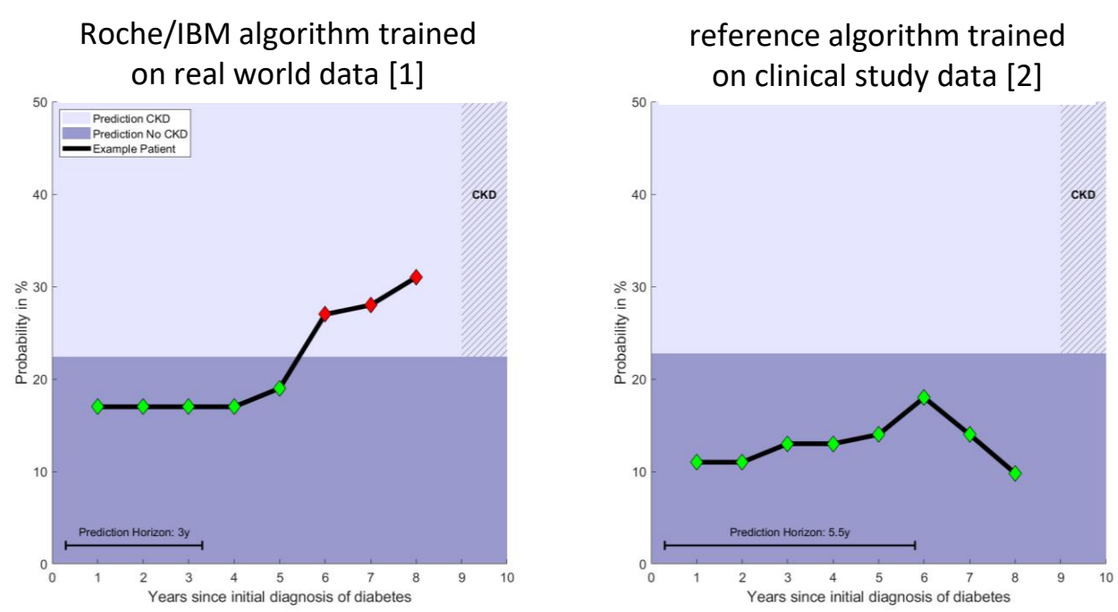
A predictive algorithm was developed [1] using data available for two years before and at least three years after the initial diagnosis of diabetes with the goal to identify those people with diabetes, who are at high **risk for developing chronic kidney disease (CKD)** in the near future.



Comparison of algorithm [1-5] performance and HbA_{1C} as predictors for chronic kidney disease (CKD). (independent validation using 187.416 patients' real-world data sets; ROC: receiver operator characteristics).

In a direct comparison between the real world data-based predictive Roche/IBM algorithm [1] and similar, prior algorithms [2-5] derived from clinical trial data, the **Roche/IBM algorithm outperforms all tested methods** in a one-to-one comparison and even in sub-cohorts selected *a posteriori*. Furthermore, the algorithms were applied to an **additional, independent real world dataset** originating from almost 100.000 people with diabetes of the Indiana Network for Patient Care (INPC) and the prior **findings were confirmed**.

Further analysis shows that differences in the veracity, definition, and/or severity of CKD outcome cannot sufficiently account for the differences in AUC. In order to analyze the impact of the actual **machine learning approach**, random forest models[23] for binary classification were trained but delivered no notable improvement when compared to a logistic regression model. Conceptually, an increase in sample size improves the teaching capabilities and delivers more representative results when applied to an independent validation data set. However, further investigations show that the large number of patients is not the main reason for the superiority of the Roche/IBM algorithm, which also also proved to be more tolerant to missing data.



Example patient data for predicting the risk for CKD as a function of time since the initial diagnosis of diabetes (actual CKD in year 9).

We could also demonstrate that the prediction algorithm for developing chronic kidney disease algorithm is also applicable to patients at up to 10 years after the initial diagnosis of diabetes.

These results may fuel the fundamental debate on the future of medical evidence in that costly, long-lasting clinical trials on a limited number of patients may one day be augmented by real world data-driven risk assessments.

Further information:

[1] Ravizza et al., *Nature Medicine*, 25:57-59, 2019.

[2] Dunkler et al., *Clin J Am Soc Nephrol* 10: 1371–1379, 2015.
[3] Jardine et al., *Am J Kidney Dis.* 60:770-778, 2012.
[4] Vergouwe et al., *Diabetologia* 53:254–262, 2010.
[5] Keane et al., *Clin J Am Soc Nephrol* 1: 761–767, 2006.