

Pengaruh talasemia minor terhadap pengukuran HbA1C metode high performance liquid chromatography HPLC dan afinitas boronat point of care testing poct = The effects of thalassemia minor on HbA1C results by high performance liquid chromatography hplc and boronate affinity point of care testing poct analyzers

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Abstrak

ABSTRAK

HbA1c dapat diukur dengan berbagai metode. Talasemia dapat memengaruhi akurasi hasil HbA1c. Peneliti ingin mendapatkan proporsi pasien yang dicurigai talasemia beta menggunakan parameter HbF >1 dengan metode ion-exchange HPLC program HbA1c pada populasi pasien yang melakukan pemeriksaan HbA1c di RSCM dan mengetahui pengaruh talasemia minor pada pengukuran HbA1c dengan ion-exchange HPLC dan afinitas boronat POCT. Subjek penelitian proporsi didapatkan dari pasien yang melakukan pemeriksaan HbA1c di RSCM selama Bulan Maret 2017. Subjek penelitian rerata/median nilai HbA1c antar metode HbA1c dibagi menjadi kelompok subjek fraksi hemoglobin normal dan talasemia minor. HbA1c diukur dengan metode ion-exchange extended HPLC sebagai metode rujukan pengganti, ion-exchange HPLC, dan afinitas boronat POCT. Pada hasil uji ketelitian dan ketepatan, hanya metode afinitas boronat POCT yang belum memenuhi ketentuan ADA, NGSP, dan IFCC. Proporsi pasien yang dicurigai talasemia beta menggunakan parameter HbF >1 dengan metode ion-exchange HPLC program HbA1c pada populasi pasien yang melakukan pemeriksaan HbA1c di RSCM pada Bulan Maret 2017 sebesar 0,8, belum angka yang sebenarnya karena keterbatasan alat tidak mendeteksi HbA2. Nilai HbA1c antar metode pada kelompok subjek fraksi hemoglobin normal tidak berbeda bermakna. Pada kelompok talasemia minor, didapatkan nilai HbA1c afinitas boronat POCT lebih rendah bermakna secara statistik dan klinis dibandingkan metode rujukan. Nilai HbA1c ion-exchange HPLC lebih rendah bermakna secara statistik tetapi tidak bermakna secara klinis dibandingkan metode rujukan. Hasil uji regresi dengan y adalah HbA1c metode rujukan dan x metode yang diuji metode ion-exchange HPLC dan afinitas boronat POCT pada subjek talasemia minor untuk HPLC yaitu $y = 0,959x + 0,86$, sedangkan untuk boronat POCT $y = 1,012x + 0,815$. Sebagai kesimpulan, proporsi pasien yang dicurigai talasemia beta menggunakan parameter HbF >1 dengan metode ion-exchange HPLC program HbA1c pada populasi pasien yang melakukan pemeriksaan HbA1c di RSCM sebesar 0,8, serta pada kelompok talasemia minor, nilai HbA1c afinitas boronat POCT lebih rendah bermakna secara statistik dan klinis dibandingkan metode rujukan. Nilai HbA1c ion-exchange HPLC lebih rendah bermakna secara statistik tetapi tidak bermakna secara klinis dibandingkan metode rujukan. Rumus dari uji regresi dapat digunakan pada laboratorium yang tidak menggunakan metode rujukan.

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ABSTRACT

HbA1c can be measured by many methods. Thalassemia will affect HbA1c test accuracy. The purpose of this study is to get the proportion of suspected thalassemia with HbF >1 by ion exchange HPLC HbA1c program in RSCM patients who did the HbA1c analysis and to know the effect of thalassemia minor on

HbA1c results by ion exchange HPLC and boronate affinity POCT. The subjects of thalassemia proportion study were selected from RSCM patients who did the HbA1c analysis in March, 2017. The subjects of the comparison study were divided to subjects with normal hemoglobin fraction and subjects with thalassemia minor. HbA1c analysis from each patient was measured by ion exchange extended HPLC as surrogate gold standard method, ion exchange HPLC, and boronate affinity POCT. Based on the precision and accuracy test, only the CV of boronate affinity POCT method didn't reach the ADA, NGSP, and IFCC requirement. The proportion of suspected thalassemia with HbF 1 by ion exchange HPLC HbA1c program in RSCM patients who did the HbA1c analysis was 0,8 , but this number was not the correct number yet because the device's limitation which could not detect HbA2. The HbA1c value between methods were not different in normal subjects. The HbA1c value by boronate affinity POCT method was significantly lower than the value by ion exchange extended HPLC in subjects with thalassemia minor statistically and clinically . The HbA1c value by ion exchange HPLC method was statistically lower than the value by ion exchange extended HPLC in subjects with thalassemia minor, but it was not clinically different. The regression analysis between y HbA1c value by gold standard and x HbA1c value by tested analyzers resulted formulas $y = 0,959x - 0,86$ x HbA1c by HPLC and $y = 1,012x - 0,815$ x HbA1c by boronate affinity POCT . As conclusion, the proportion of suspected thalassemia with HbF 1 by ion exchange HPLC HbA1c program in RSCM patients who did the HbA1c analysis was 0,8 , and in subjects with thalassemia minor, the HbA1c value by boronate affinity POCT was statistically and clinically lower than gold standard, while the HbA1c value by ion exchange HPLC was statistically lower than gold standard. The formulas from regression analysis can be used in the laboratory which do not use gold standard method.