# Childhood Acute Lymphoblastic Leukemia (ALL): Four Years Evaluation of Protocols 2013 and 2016 in a Single Center in Indonesia, a Low-Middle Income Country

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#### Abstract

Background: As in LMICs, the prognosis of childhood ALL in Indonesia was lower than in HICs. Indonesian-ALL2013 protocol resulted in more toxicities and abandonments than expected. Therefore, it was modified into a pilot ALL2016 protocol. Changes to the ALL2013 protocol: no anthracyclines in SR, dexamethasone replaced prednisone in reinduction for HR and some drugs were rescheduled. Procedure: We compare the outcome of ALL2013 and ALL2016. Results: A total of 383 children with ALL were diagnosed, 21 were excluded. ALL2013 included 174 patients (106 SR and 68 HR) and ALL2016 188 (91 SR and 97 HR). The outcome of the ALL2016 was better than the ALL2013 (pOS 67.0% vs 60.3%; p=0.087 and pEFS 50.0% vs 37.9%; p=0.012) even when the number of HR patients was significantly higher in ALL2016 (51.6% vs 39.1%). The ALL2016 showed an early advantage for SR patients (pEFS 56.7% vs 47.2%; p=0.114 and pOS 74.4% vs 69.8%; p=0.298) due to the decrease of toxic deaths (10.4% vs 5.5%; p=0.211) however the number of late relapses were still high (19.5% vs 13.2%; p=0.282). In the HR group, both pEFS and pOS were significantly better in ALL2016 (pEFS 43.3% vs 23.5%; p=0.010 and pOS 59.8% vs 45.6%; p=0.036) due to less relapses (14.4% vs 29.4%; p=0.019). Both SR and HR showed a smaller number of abandonments in ALL2016. Conclusions: After small changes in protocol, initial toxicity and abandonments were reduced and the pOS and pEFS were improved. However, relapses still need to be lessened in the next protocol.

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Table 1. baseline characteristics.docx available at https://authorea.com/users/447047/articles/546142-childhood-acute-lymphoblastic-leukemia-all-four-years-evaluation-of-protocols-2013-and-2016-in-a-single-center-in-indonesia-a-low-middle-income-country

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 $\label{thm:composed} \begin{tabular}{ll} Table 2. clinical response.docx available at https://authorea.com/users/447047/articles/546142-childhood-acute-lymphoblastic-leukemia-all-four-years-evaluation-of-protocols-2013-and-2016-in-a-single-center-in-indonesia-a-low-middle-income-country available at https://authorea.com/users/447047/articles/546142-childhood-acute-lymphoblastic-leukemia-all-four-years-evaluation-of-protocols-2013-and-2016-in-a-single-center-in-indonesia-a-low-middle-income-country.$ 

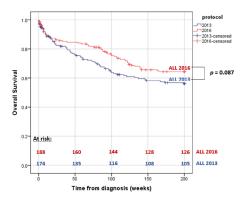
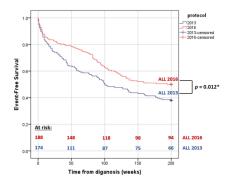
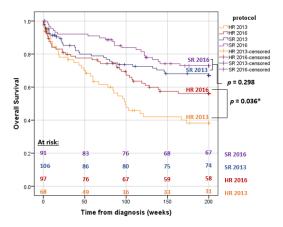


Figure 1. Probable Overall Survival (pOS) ALL2013 vs ALL2016



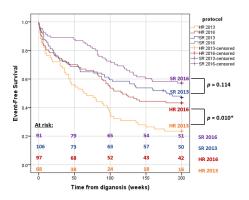
\*statistically significant (p<0.05)

Figure 2. Probable Event-Free Survival (pEFS) ALL2013 vs ALL2016



\*statistically significant (p<0.05)

Figure 3. Probable Overall Survival (pOS) based on stratification ALL2013 vs ALL2016



\*statistically significant (p<0.05)

Figure 4. Probable Event-Free Survival (pEFS) based on stratification ALL2013 vs ALL2016