Uji Diagnosis Pemeriksaan hrHPV DNA Urine dan hrHPV DNA Serviks dengan Cobas® 4800 di RSUPN dr. Cipto Mangunkusumo Jakarta = Comparison of Urine and Cervical Samples for Detecting High Risk Human Papillomavirus (HPV) with the CobasÂ® 4800 HPV test at dr. Cipto Mangunkusumo National Central General Hospital Jakarta

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Abstrak

Latar Belakang: Infeksi Human Papillomavirus risiko tinggi(hrHPV) dianggap sebagai etiologi utama terjadinya kanker serviks. Target WHO pada tahun 2030 skrining kanker serviks diharapkan mencapai 70%. Keengganan masyarakat untuk melakukan pemeriksaan hrHPV DNA serviks salah satunya karena rasa malu karena harus dilakukan pemeriksaan dalam. Pemeriksaan hrHPV DNA pada urine diharapkan akan meningkatkan cakupan skrining kanker serviks. Objektif: Penelitian ini dilakukan untuk membandingkan keakuratan, sensitivitas, spesifisitas, nilai prediksi positif, nilai prediksi negatif, serta faktor yang mempengaruhi hasil pemeriksaan hrHPV DNA urine dan serviks dengan Cobas® 4800 di RSUPN dr. Cipto Mangunkusumo Jakarta. Metode: Penelitian ini merupakan penelitian potong lintang. Sebanyak 72 sampel diambil dari data rekam medis hasil pemeriksaan hrHPV DNA serviks sebelumnya dengan hasil positif atau negatif pada pemeriksaan tahun 2017-2020. Subyek diperiksakan kembali sampel urine dan swab serviksnya dengan PCR Cobas® 4800 pada satu waktu. Selanjutnya pada sampel dengan hasil pemeriksaan hrHPV DNA positif pada serviks, urine maupun keduanya kemudian diperiksakan sitologi serviksnya(LBC). Analisis data menggunakan chi square. Hasil: Akurasi deteksi hrHPV DNA dalam sampel urine dibandingkan serviks adalah 84,72%. Tingkat kesesuaian substansial dari deteksi hrHPV DNA pada kedua sampel (ka = 0,62; 95% IC: 39-84). Dalam populasi ini sensitivitas, spesifisitas, NPP dan NPN untuk deteksi hrHPV DNA dari sampel urine versus serviks masing-masing adalah 87,5% (95% IC: 64–97%), 84%(95% IC: 72–91%), 60,9% (95% IC: 40,8–77,8) dan 96%(95% IC: 86,3–98,9). Analisis lebih lanjut didapatkan bahwa usia, tingkat pendidikan, dan paritas tidak berpengaruh terhadap kesesuaian hasil hrHPV DNA urine terhadap serviks. Pada pemeriksaan lanjut sitologi pada hrHPV DNA positif baik di serviks, urine maupun keduanya, ditemukan 68% sitologi normal, 20% LSIL, 8% ASCH dan 4% ASCUS. Kesimpulan: Deteksi hrHPV DNA dengan urine cukup akurat untuk menilai adanya infeksi hrHPV di serviks. Hasil ini menunjukkan bahwa sampel urine yang diproses dengan uji Cobas® 4800 HPV berguna untuk manajemen klinis infeksi hrHPV.

.....Backgound: High risk Human Papillomavirus(hrHPV) infection is the main cause of cervical cancer. WHO target in 2030 cervical cancer screening is expected to reach 70%. One of the reasons for the reluctance of the to carry out cervical hrHPV DNA examination is because of the shame that gynecological examinations have to be carried out. The development of non-invasive self-sample collection methods would have the potential advantage of increasing the acceptance of the screening procedures. High risk HPV DNA examination in urine is expected to increase the coverage of cervical cancer screening. Objectives: To compare accuracy, sensitivity, specificity, positive predictive value, negative predictive value, and factors that influence high risk human papillomavirus (hrHPV) DNA detection and genotyping with the Cobas®

4800 HPV test on paired cervical and urine at dr. Cipto Mangunkusumo National General Hospital Jakarta. Methods: This research is a cross sectional study. The number of subjects was 72 samples with result were positive or negative on medical record data from previous any hrHPV DNA tests in year 2017-2020. Subjects were re-collected and re-examine for urine samples and cervical swabs with Cobas® 4800 at one time. On the results of positive hrHPV DNA examination on the cervix, urine or both then examined for cytology(LBC). Data analysis using chi square. Results: The overall percent agreement between hrHPV DNA detection in urine and cervical samples was 84.72%. A Substantial concordance rate of hrHPV DNA detection in both samples was observed (ka = 0.62; 95% IC: 39-84). In this population, the sensitivity, specificity, PPV and NPV for detection of hrHPV DNA from urine versus cervical samples were 87.5% (95% IC: 64–97%), 84%(95% IC: 72–91%), 60.9% (95% IC: 40.8–77.8) and 96% (95% IC: 86.3–98.9) respectively. Further analysis found that age, education level, and parity had no effect on the concordance of the hrHPV DNA between cervix and urine results. On cytological follow-up examination of positive hrHPV DNA either in the cervix, urine or both found 68% normal cytology, 20% LSIL, 8% ASCH and 4% ASCUS. Conclusions: Detection of hrHPV DNA with urine is accurate to assess the presence of hrHPV infection in the cervix. These results suggest that urine samples processed with Cobas® 4800 HPV test may be useful for clinical management of hrHPV infection.