Diagnostic Study of *Rapid Test Chlamydia Ag* in Patients with Genitalia Infection of *Chlamydia trachomatis*

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Abstract

Genitalia infection of *Chlamydia trachomatis* is a sexual transmitted disease in 10-40% women causing *pelvic inflamatory disease* (PID) with infertility and ectopic pregnancy complications. This infection is very difficult to diagnose due to clinical asymptomatic manifestations. Some of diagnostic methods were developed but still giving unsatisfied results. One of promising method for detecting *C. trachomatis* infection is *rapid test Chlamydia* or *point of care test.* Gold standard of identification *C. trachomatis* was culture or detecting nucleic acid by *polymerase chain reaction* (PCR). This was a diagnostic study conducted in Klinik Graha Sriwijaya Palembang and Departemen Mikrobiologi Klinik RSUP Dr. Moh.Hoesin Palembang from Februari - Mei 2012. Endoservic specimen were collected for Gram staining, *rapid test* QuickStripe™ *Chlamydia Ag* (Savyon® Diagnostic Israel), DNA extraction and PCR. The 108 subjects with 26.82 years old in average were recruited. Result of QuickStripe™ *Chlamydia Ag* were 23 (21,3%) positive and 85 (78,7%) negative. Result of PCR detection were 21 (19,4%) positive and 87 (80,6%) negative. Value of Kappa test between 2 examiners of *rapid test* QuickStripe™ *Chlamydia Ag* was 0.893 indicating the examination was reliable. Analysis of *rapid test Chlamydia* result was compared with PCR result showed sensitivity and spesificity 90,4% dan 95,4% respectively (PPV 82,6%; NPV 97,6%; PLR 19,65%; NLR 0,100). The result was indicated that *QuickStripe™ Chlamydia Ag* was good for screening of the disease. Conclusion: *Rapid Test Chlamydia Ag* showed diagnostic significant value and can implementate as a alternative diagnostic method for detecting *C. trachomatis* infection especially in high risk population.

Key Words: *Rapid Test Chlamydia Ag*, PCR, Diagnostic Study

Introduction

The sexual transmitted disease due to *Chlamydia trachomatis* infection is found in 10-40% high risk women.[1] *C. trachomatis* is a intracellular pathogen which destruction of genital mucous layer.[2] Study by Jazan *et al*. (2003) with subjects women sexual workers in 7 cities in Indonesia showed prevalence 14% - 55% .[7] Margareth *et al.* (2004) showed that recurrency of the disease up to 40% in 9 months.[3] Ascending infection to pelvic area caused *pelvic inflamatory disease* (PID) with infertility and ectopic pregnancy complications.[2,3,8,9] Some factors contribute to the disease such as age, sexual habit and accuracy of clinical screening. *Centers for Disease Control and Prevention* (CDC) USA recomended screening for women that rare use condom in sexual relation and women with more than 1 partners.[6]

Genital infection of *C. trachomatis* was difficult to diagnose because more than 70% infection was asymptomatic.[3] Routin laboratory examination can not different this condition.[2,12] Some of diagnosis approach have developed but no one satisfaction. Gold standard of diagnosis was culture but it was difficult so identification of nucleic acid by polymerase chain reaction (PCR) can replace the gold standard. PCR is needed a high grade of laboratory. In Indonesia where the laboratory facilities was minial, need another method for diagnosig the infection. A promising method is detection of antibody against lipopolysaccharides of *C. thracomatis* by *rapid test Chlamydia* or *point of care test.* The method was based on chromatography that can give false positive because of cross reaction with other bacteria's lipopolysaccharrides..[1,15-18] *C. trachomatis* rapid test produced by S*avyon*®*Diagnostic* (Israel) has 88,5% sensitivity and 96,7% specificity.[18] Tapay *et al*. (2007) got 83,5% and 98,8% in sensitivity and specificity respectively.[19].[1,21] This research is aimed to count diagnostic value of rapid test for detection *C. trachomatis* infection in women sexual worker. It is very important to find promptly diagnosis of asymptomatic manifestation of the disease.

Method

This is an obseravtional study with diagnostic test design. The study conducted in Klinik Graha Sriwijaya Palembang (a clinic in localization of women sexual worker) and Clinical Microbiology Departement Moh. Hoesin General Hospital Palembang from Februari until July 2012. The subjects were all women sexual workers in Klinik Graha Sriwijaya Palembang with clinical sign endoservic mucopurulen *discharge*. All the subjects were given informed consent, taking endoservic mucopurulen *discharge* specimen, Gram staining examination, *rapid test Chlamydia* and PCR. Rapid test QuickStripe™ *Chlamydia Ag* S*avyon*®*Diagnostic* (Israel) was done according to manufactured guidance. DNA extraction and isolation by *Chelex-100* reaction. PCR using pairs of primer:[34,53]

Sense: 5'GCCGCTTTGAGTTCTGCTTCC 3' and antisense: 5' GTC GAA AAC AAAGTCACCATA GTA3'. Positive result showed 180 bp in 2% agarose.

Result

The 108 specimen was taken from patients at Klinik Graha Sriwijaya Palembang. Characteristic of subjects were 26.82 years old in average, the youngest 17 years old and the oldest 41 years old. Status of subject's education 60 (55.6 %) elementary school, 32 (29,6%) junior high school and 16 (14.8%) senior high school. Marital status 75 (69,4%) widows, 22 (20,4%) unmarried and 11 (10,2 %) married. Income per month in average Rp.7.330.000 with range Rp.1.000.000,- until Rp. 25.000.000,-. The first sexuall intercourse were the youngest 2 (1,9%) in 14 years old and the oldest 2 (1,9%) in 29 years old. Duration of working as women sexuall worker were 40 subjects (37,0%) 1 year, 48 subjects (44,4%) 2 years and the rest were 3 – 6 years. Number of customer in last month were 3 persons for 14 subjects (13,0%), 4 persons for 17 subjects (15,7 %), 8 persons for 7 subjects (6,5%), 10 persons for 13 subjects (12,0%) and 15 persons for 12 subjects (11,1%). Complient using condom during intercourse 83 subjects (76,9%) were rarely, 22 subjects

(20,4.%) routine and 3 subjects (2,8%) never using condom. Clinical complain 62 subjects (57,4 %) symptomatic and 46 subjects (42,5 %) unsymptomatic. Leukorrhae found in 57 subjects (52,8%) and 5 subjects (4,6 %) disuria.

The result of *rapid test Chlamydia* (QuickStripe™*Chlamydia* Ag) was shown on table 1.

Table 1. Result of *rapid test Chlamydia*

Rapid test Chlamydia	N	%
Positive	23	21,3
Negative	85	78,7
Total	108	100

Proportion of *C. trachomatis* infection from QuickStripe™ *Chlamydia* Ag was 21,3%.

The result of PCR test was shown in tabel 2

Table 2. Result of PCR test

PCR	N	%
Positive	21	19,4
Negative	87	80,6
Total	108	100

Proportion of *C. trachomatis* infection from PCR test was 19,4%.

Kappa testing from 2 examiners QuickStripe™ *Chlamydia Ag* showed kappa 0.893.

Diagnostic test result were showed in table 3.

Table 3. Diagnostic test results

		PCR		
		Positive	Negative	Total
QuickStripe™	Positive	19 (90,4%)	4 (4,5%)	23(21,2%)
Chlamydia Ag	Negative	2 (9,5%)	83 (95,4%)	85(78,7%)
	Total	21(19,4%)	87(80,5%)	108 (100%)

Table 4. Analysis of diagnostic test result

Pemeriksaan	Sn	Sp	PPV	NPV	PLR	NLR
QuickStripe™ *Chlamydia Ag*	90,48	95,40	82,6	97,6	19,68	0,100

Sensitivity	= Sn	Spesificity	= Sp
Positive predictive value	= PPV	*Negative predictive value*	= NPV
Positive likelihood ratio	= PLR	*Negative likelihood ratio*	= NLR

Discussion

Age average of subject was 26,82 years old with range 17 - 41 years old. Previous research by Krishnaputri in 2011 in the same place age average 25,91 with range 17 - 47 years old.[54] These data are mostly similar, all subjects in high risk age to get Chlamydia infection. Screening is needed.[55]

Proportion of *C. trachomatis* infection in Palembang by Sedyaningsih et al. (2005) showed 34% higher than this result 19,4%. Although decreasing but still high and need to early diagnostic.[56] Philips (2006) showed that highly prevalence of *C.*

trachomatis influenced by low grade of socioeconomic and number of costumer as well as in this research.[55]

The first sexuall intercourse lower than 20 years old in this research was a risk factor for *C. trachomatis* infection.[6] Only 22 subjects (20,4%) routine using condom before intercourse is very low complient as well as study by Sedyaningsih et al. (2005) [56] and Krishnaputri (2011).[54] It is also a risk factor for *C. trachomatis* infection.

Most of patients are asymptomatic as well as in more previous research and other research from abroad[3,54,56.] The data were consistent that Chlamydial infection was asymptomatic and need promptly diagnosis.

Kappa result 0.893 indicate that the *rapid test Chlamydia* is reliable. Analysis from diagnostic test result *rapid test Chlamydia* compare to gold standard PCR showed that number of sensitivity in this result better than result by Saison et al. (2007) in Philippines.[20] This high sensitivity suggest that *QuickStripe™ Chlamydia Ag* can be a usefull for screening. Also the specificity result around 96% as well as result by Saison et al. (2007) [20]. PPV and NPV also support the specificity result. Probability false positive and false negative were also support the specificity as seen in positive and negative *likelihood* ratios. Overall the result from this research showed diagnostic value good compare to gold standard. Thus the rapid test can be used as an alternative method for detecting *C. trachomatis* in high risk population.

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