Shazia Shaheen Mir et al., J Clin Exp Dermatol Res 2016, 7:6(Suppl)
http://dx.doi.org/10.4172/2155-9554.C1.042

Development and evaluation of loop mediated isothermal amplification (LAMP) for rapid detection of *Neisseria gonorrhoeae*

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Nucleic acid amplification tests (NAATs) have gradually taken over the conventional methods for detection of *N. gonorrhoeae*. However, all these NAATs have intrinsic disadvantages of requiring a specialized instrument for amplification or an elaborated and complicated method for detection of amplified products. Thus, for settings with minimal facilities, there is a need for a simple and cost-effective test that would permit rapid and reliable screening of *N. gonorrhoeae*. In the present study, potential of LAMP has been exploited to develop a technique that can be introduce as a "point-of-care" test in resource limited settings for the screening and identification of *N. gonorrhoeae*. Opa gene and porA pseudogene based LAMP assay were developed and clinically evaluated in a preselected patient population separately. A total of 388 samples were collected and evaluated, out of which 142 were male samples and 246 were female samples. Four of the 6 discrepant samples were sequenced and confirmed. Samples which were positive by culture or 2 gene PCRs or sequencing were considered as "True positives" (n=80). LAMP showed concordance (99.2%) with PCR and very high sensitivity, specificity and accuracy. With Cohan's Kappa statistics, LAMP and PCR showed substantial agreement (99.7%) and moderate chance agreement (67.4%) with each other. Detection of the end product with the naked eyes using SYBR Green I and Hydroxy Napthol Blue (HNB) dyes made LAMP feasible for field use also. This LAMP assay offers a highly sensitive and specific assay not only for detection but also confirmation of *N. gonorrhoeae* thereby saving cost and time.

Biography

Shazia Shaheen Mir is working as a PhD scholar in Jamia Millia Islamia, India. Her research work is on diagnostics related to disease gonorrhea, which is not only novel but also has an immediate application in the outpatient settings, if developed in the form of a kit. After her MSc in Biotechnology, she has worked as a Research Fellow in a Government funded project at All India Institute of Medical Science (AIIMS), India. She has more than 5 publications in reputed peer reviewed journals.

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