

Quality control for laboratory diagnosis for hand, foot and mouth disease: a forgotten issue in epidemic

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ABSTRACT

Background: Hand, foot and mouth disease is a viral infection that is an important disease in paediatric population. The epidemic of this disease occurs each year and becomes the focused public health threat. The diagnosis of this disease is important for disease control. The laboratory investigation plays important role in such process. **Aim:** However, an important forgotten issue is on the quality control. This mini-review focuses on this specific issue. **Materials and Methods:** Literature review is done. **Result:** The available details on quality control of laboratory investigation in hand, food and mouth disease are summarized and presented. **Conclusion:** Quality control is an important issue that still requires more concern.

Key words: Hand, foot and mouth disease, viral, quality, control.

INTRODUCTION

Hand, foot and mouth disease (HFMD) is a viral infection that is an important disease in paediatric population. The epidemic of this disease occurs each year and becomes the focused public health threat. Within the present 2 - year period, there are several outbreaks causing thousands of infected cases. The big epidemics are reported in China, India and Thailand.^[1,2] Generally, the disease affects a larger group young school age children. In epidemics, thousands of infected cases were reported within a few week and the poor hygienic was believe to be the rooted cause.^[1,2] The disease control includes quarantine of the infected cases, school closing and promotion of sanitation.^[1,2]

In general, HFMD is a viral disease hitting the paediatric population. The infected cases usually present febrile illness and further develop exanthematous lesions at hands, feet and mouths.^[3] The main clinical features of the infected cases include sore throat, fever, loss of appetite and painful lesions will be observed at the mouth and oral cavity accompanied with rash at the hands and feet within 3 days.^[3] Since there is no specific antiviral drug, the general management is supportive and symptomatic treatments.^[3] Rarely, the severe complications as meningitis and encephalitis can be seen and result in fatality.^[3] The causative pathogens of this disease are many picornaviridae viruses, especially cox-sackie A virus and enterovirus 71

(EV-71).^[3] The route of transmissions are mainly faeco-oral and respiratory transmission.^[3] However, the disease is sometimes not classical. The skin lesion or fever might not completely manifest. For successful disease control, the diagnosis with use of laboratory investigation is an important step. However, the quality control is an important issue that is usually forgotten issue. This specific issue is focused in this mini-review.

THE USE OF LABORATORY DIAGNOSIS OF HFMD DURING EPIDEMICS

The laboratory diagnosis plays important role in managing of HFMD. Although, the classical clinical presentations might be the clue for simple diagnosis of HFMD. However, the diagnosis can be difficult in atypical case.^[4] The basic laboratory investigation such as complete blood count (CBC) is reported to be a basic useful clue for diagnosis of the infection.^[1,2,4] However, only basic investigation cannot provide definitive diagnosis. The use of virological study is required.^[5] According to the present clinical guideline, (http://www.chp.gov.hk/files/pdf/sceifd_management_of_hfmd_in_health_care_settings.pdf) the viral isolation by cell culture or reverse transcriptase – polymerase chain reaction (RT-PCR) test for viral nucleic particle on collected samples (cerebrospinal fluid, throat swab, nasopharyngeal aspirate, vesicle fluid or stool) are recommended. Roles of laboratory diagnosis for viral pathogen can also provide the epidemiological data which is needed for planning of population scale disease management.^[6] WHO recommends for international collaboration for the viral testing as a tool for fighting the HFMD.

However, there are many present problems. Lack of the laboratory testing is the basic problem seen in many resource-limited settings where the epidemic usually occurs.^[2] Although the use of simple test such as CBC is reported to be an effective tool but it cannot replace the standard virological test (viral culture or RT-PCR).^[2] Many diseases such as chicken pox can be misdiagnosed based on clinical signs and CBC.^[7]

Indeed, the more advanced tests such as immunological tests is also available at present.^[8-10] However, it is expensive and might not be affordable in poor countries. Also, the available immunological test still posed the diagnostic problems (such as cross reactivity).^[10] Last, the new gold standard virological test based on the

molecular biology technique (such as multiplex

RT-PCR) is still far from generalization due to its high cost.

QUALITY CONTROL FOR LABORATORY TEST IN HFMD: A REQUIRED ISSUE

Any laboratory test can have pitfall. Therefore, it is necessary to perform laboratory quality control. The question is whether there is any problem in the system for laboratory diagnosis in HFMD. Despite using molecular based technique, some laboratories can still not possibly detect the pathogen.^[11] For sure, this can cause the problem in disease control during the outbreak. It is noted that using internal control help improve diagnostic property of laboratory test.^[12] According to a recent report from China, it is concluded that 'External quality assessment should be performed periodically to help laboratories monitor their ability to detect HFMD viruses and to improve the comparability of results from different laboratories'.^[11]

As a recommendation, to improve the laboratory diagnosis, these principles should be followed.^[13]

- Laboratory diagnosis must be a tool that is concomitantly used with good history taking and physical examination
- The quality control is required for all steps: pre-analytical, analytical and post-analytical step.^[13] For the pre-analytical step, the good specimen collection technique is required. The contamination of specimen, delayed transportation and incorrect patient identification are common problems. For analytical step, routine regular internal quality control and external quality assessment are required. For post-analytical step, the problem on incorrect validation and loss of laboratory result in reporting process are common problems. Only the standardized and certified laboratory should be allowed for diagnosis.
- The assessment and accreditation of laboratory serving the diagnostic test for HFMD is needed. There must be the regulation body to help certify and approve the service laboratory. National and international collaboration among practitioners for control of the laboratory analysis standards are also required.

CONCLUSION

The problem on diagnosis of HFMD is still in existence. The use of good laboratory investigation is required and the focus should be

on quality control.

REFERENCES

1. Kar B.R, Dwibedi B, Kar S.K. Outbreak of Hand, Foot and Mouth Disease in Bhubaneswar, Odisha: Epidemiology and Clinical Features. *Indian Pediatr* 2012;10:S097475591100618-1. [Epub ahead of print]
2. Li Y, Zhu R, Qian Y, Deng J. The characteristics of blood glucose and WBC counts in peripheral blood of cases of hand foot and mouth disease in China: a systematic review. *PLoS One* 2012;7:e29003.
3. Wong S.S, Yip C.C, Lau S.K, Yuen K.Y. Human enterovirus 71 and hand, foot and mouth disease. *Epidemiol Infect* 2010;138:1071-89.
4. Chong C.Y, Chan K.P, Shah V.A, Ng W.Y, Lau G, Teo T.E, Lai S.H, Ling A.E. Hand, foot and mouth disease in Singapore: a comparison of fatal and non-fatal cases. *Acta Paediatr* 2003;92:1163-9.
5. Shimizu H. Hand, foot and mouth disease. *Nihon Rinsho* 2007;28:65:339-42.
6. Shimizu H. Roles and functions of WHO Enterovirus Collaborating Center. *Uirusu*. 2009;59:43-52.
7. Muppa R, Bhupatiraju P, Duddu M, Dandempally A. Hand, foot and mouth disease. *J Indian Soc Pedod Prev Dent* 2011;29:165-7.
8. Hamblin C, Kitching R.P, Donaldson A.I, Crowther J.R, Barnett I.T. Enzyme-linked immunosorbent assay (ELISA) for the detection of antibodies against foot-and-mouth disease virus. III. Evaluation of antibodies after infection and vaccination. *Epidemiol Infect* 1987;99:733-44.
9. Lin Y, Wen K, Pan Y, Wang Y, Che X, Wang B. Cross-reactivity of anti-EV71 IgM and neutralizing antibody in series sera of patients infected with Enterovirus 71 and Coxsackievirus A 16. *J Immunoassay Immunochem* 2011;32:233-43.
10. Yu N, Guo M, He S.J, Pan Y.X, Chen X.X, Ding X.X, Hao W, Wang Y.D, Ge S.X, Xia N.S, Che X.Y. Evaluation of human enterovirus 71 and coxsackievirus A16 specific immunoglobulin M antibodies for diagnosis of hand-foot-and-mouth disease. *Virol J* 2012;9:12.
11. Song L, Sun S, Li B, Pan Y, Li W, Zhang K, Li J. External quality assessment for enterovirus 71 and coxsackievirus A16 detection by reverse transcription-PCR using armored RNA as a virus surrogate. *J Clin Microbiol* 2011;49:3591-5.
12. Xiao X, He Y, Yu Y, Yang H, Li H, Yang X, Zhang J, Chen G, Liu D, Li X, Wu H. Simultaneous detection of enterovirus 71 and coxsackievirus A16 by multiplex real-time PCR with an internal control. *Wei Sheng Wu Xue Bao* 2009;9:98-104.
13. Wiwanitkit V. *Focus for Excellence Laboratory Practice*. New York: Nova Publishers, 2008.

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