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REVIEW ARTICLE

Loop-mediated isothermal amplification (LAMP): recent progress in research and development

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Abstract Loop-mediated isothermal amplification (LAMP) is an established technology that continues to attract the attention of researchers in many fields. Research and development efforts on LAMP technology in recent years have focused on two major areas; first, the study of its clinical application as an approved in vitro diagnostics tool in Japan and certain other countries; and second, research aimed at further simplifying the LAMP test process. This review provides an overview of the status of LAMP on these two topics by summarizing research work conducted, in the main, after our previous review article.

Keywords Loop-mediated isothermal amplification · LAMP · In vitro diagnostics · Point-of-care testing

Introduction

Loop-mediated isothermal amplification (LAMP) was first reported in 2000 [1] and has, since then, been the focus of extensive research efforts. The number of studies performed using LAMP is increasing every year; as of November 2012, PubMed database has listed more than 750 articles on this topic. The findings of reports published up to 2008 have been summarized in our previous review article published in this journal [2]; consequently, the aim of this article is to review research activities undertaken thereafter.

Research and development (R&D) efforts on LAMP technology in recent years have focused on two major areas. One is its practical application in clinical settings, including its role in the improvement of existing assays. Since the LAMP method was invented, LAMP reactions for detecting various pathogens were developed by many research groups and their performance observed by comparing to that of existing reagents [such as polymerase chain reaction (PCR)], as reviewed in the papers [3, 4]. These initial studies can be considered as a sort of validation study to evaluate the feasibility of LAMP technology. After these intensive validation studies, LAMP was actually applied for clinical practice. This review offers an overview of the status of LAMP in terms of its practical applications. The second area is basic research on further simplification of the LAMP assay. Current basic research efforts now focus on testing the distinct features of the LAMP technique owing to its simplicity and rapidity of use. Extensive improvement of LAMP technology is necessary to integrate this method into simple genetic tests to be used as point-of-care diagnostics. Thus, this article also reviews the basic techniques involved in improvement of LAMP technology.

Development and clinical application of LAMP reagents

Practical applications of LAMP reagents

The extensive basic research efforts on LAMP have facilitated the use of LAMP technology in actual clinical settings. Before 2008, the Severe Acute Respiratory Syndrome (SARS) coronavirus detection kit was the only LAMP reagent approved for in vitro diagnostics (IVD) in Japan. Currently, the number of approved LAMP reagents in Japan has increased to eight: SARS coronavirus, as

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mentioned, along with *Mycobacterium tuberculosis* (TB), *Mycoplasma pneumoniae*, *Legionella* species, influenza type A virus, H1 pdm 2009 influenza virus, H5 influenza virus, and human papilloma virus (HPV). In addition, one-step nucleic acid amplification (OSNA), an automated molecular detection system using a RT-LAMP method for detecting cancer cells that have metastasized to the lymph nodes, has also been approved as IVD in Japan [5]. Current status of the application of LAMP technology to IVD may be summarized as follows.

A LAMP reagent kit for detecting the *M. tuberculosis* complex (Loopamp MTBC detection kit, TB-LAMP; Eiken Chemical, Tokyo, Japan) was launched in April 2011. The new reagent features two improvements. First, the test process has been made faster and simpler; by using the kit named the Loopamp PURE DNA extraction kit (Eiken Chemical) for sputum processing, the NALC (*N*-acetyl-L-cysteine)-NaOH decontamination step is no longer necessary. Second, TB-LAMP is now provided as a dry reagent, allowing easier storage, that is, it can be stored at room temperature with satisfactory shelf life. Figure 1 shows the operation process of PURE and TB-LAMP. Mitarai et al. [6] reported the results of a clinical trial of PURE-TB-LAMP in Japan, concluding that it is a simple, effective, and rapid test for TB testing and that the sensitivity of TB-LAMP for smear-negative and culture-positive samples is about 55 %. Evaluation studies for the use of this system as a simple TB diagnostics tool suitable for use in resource-limited facilities are currently ongoing in some developing countries.

Recently, LAMP reagents for detecting certain parasites using the same platform as that used in PURE-TB-LAMP have been commercialized. The malaria LAMP kit (Loopamp MALARIA Pan/Pf detection kit) has been launched as a CE-approved IVD. It consists of two LAMP reagents, one for the detection of *Plasmodium falciparum* and another that reacts with all four types of human malarial parasites. The sensitivity of these reagents is enhanced by targeting of mitochondrial DNA, as demonstrated by Polley et al. [7]. The clinical performance of the kit has been evaluated by the same author and his colleagues [8]. They have demonstrated that the clinical sensitivity and specificity compared with a nested PCR method are 97.0 % and 99.2 % for pan-malaria detection and 98.4 % and 98.1 % for *P. falciparum*-specific detection, respectively, and concluded that the diagnostic accuracy of the kit is similar to that of nested PCR with greatly reduced time to availability of results. The Loopamp *Trypanosoma brucei* detection kit has also been developed, acting as a highly sensitive tool for the diagnosis of human African trypanosomiasis (HAT), in which sensitivity is enhanced by targeting of the multicopy gene named RIME (repetitive insertion mobile element) [9]. This reagent kit is currently being clinically evaluated in the HAT endemic countries of Democratic Republic of the Congo and the Republic of Uganda, in collaboration with the Foundation for Innovative New Diagnostics (FIND) [10]. Furthermore, the application of this kit as an animal test reagent for the diagnosis of surra disease and covering

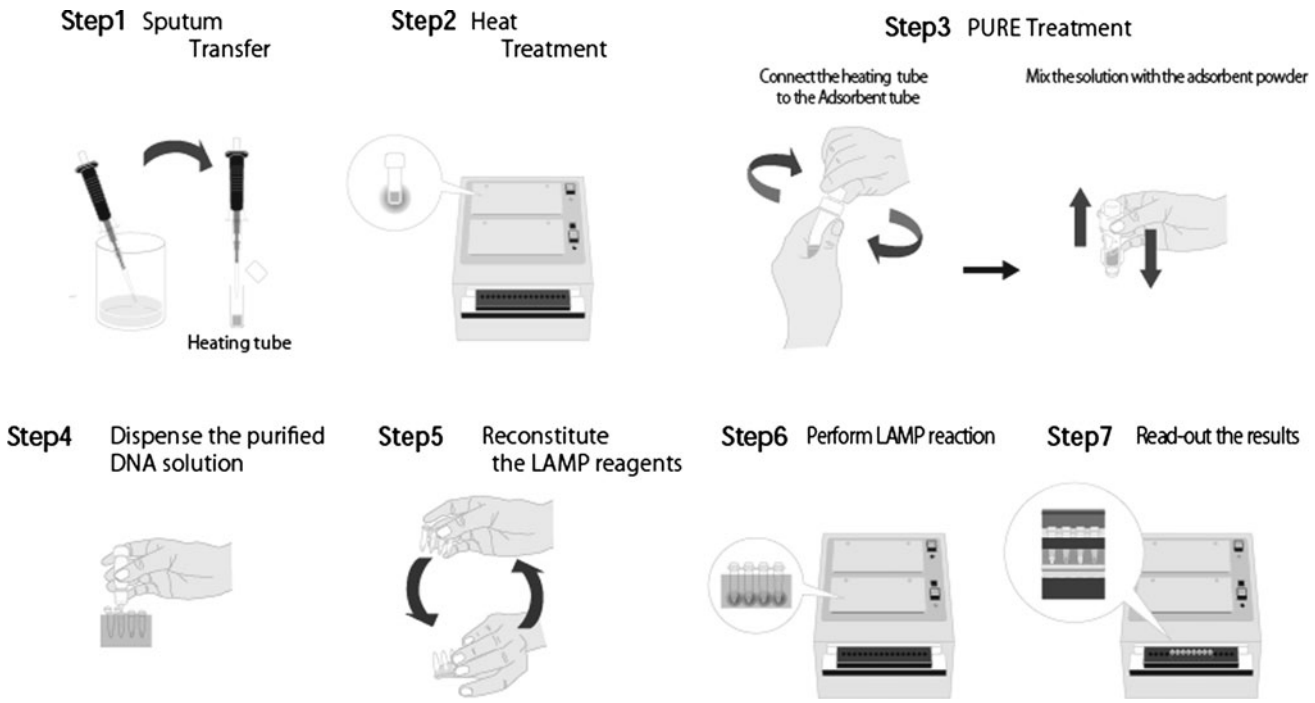

Fig. 1 Diagrams of the process for the PURE-TB-LAMP assay

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