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REVIEW

Portable Technologies in Clinical Biochemistry, from the laboratory to the point of care

Tecnologías Portátiles en Bioquímica Clínica, del laboratorio al punto de cuidado

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ABSTRACT

Constant advances in science, technology, and innovation have favored the development of biomedical sciences, providing them with tools such as computer science and artificial intelligence. In the field of clinical biochemistry, advances are needed to optimize and accelerate timely diagnosis. This article aims to describe the advantages and usefulness of POCT devices for diagnosis in clinical biochemistry. Portable technologies in clinical biochemistry applied to laboratory diagnosis promise to overcome the barriers of conventional techniques (time, infrastructure, cost, sensitivity, and specificity). Their usefulness varies, being applicable in response to pandemics, for the management of chronic diseases, promoting accessibility and equity in health, and improving the efficiency of the system while empowering the patient. Similarly, the possibility of integration into wearable devices and smartphones makes it an accessible and attractive medium. Use cases were identified that demonstrate not only its theoretical usefulness but also its actual capacity for use in practice.

Keywords: Clinical Biochemistry; Clinical Laboratory; Point-of-Care Testing; Nanoparticles; Wearable Devices.

RESUMEN

Los constantes avances en materia de Ciencia, Tecnología e Innovación han favorecido el desarrollo de las Ciencias Biomédicas, dotándolas de herramientas como la informática y la inteligencia artificial. En el campo de la bioquímica clínica, se hacen necesarios avances que optimicen y aceleren el diagnóstico oportuno. Este artículo tiene como objetivo describir las ventajas y utilidad de los dispositivos POCT para el diagnóstico en bioquímica clínica. Las tecnologías portátiles en Bioquímica Clínica aplicadas al diagnóstico de laboratorio prometen superar las barreras de las técnicas convencionales (tiempo, infraestructura, coste, sensibilidad y especificidad). Su utilidad varía, siendo aplicable en respuesta a pandemias, para la gestión de enfermedades crónicas, favorece la accesibilidad y equidad en salud y mejora la eficiencia del sistema a la par que empodera al paciente. De igual forma, la posibilidad de integración en dispositivos Wearables y Smartphones lo hacen un medio accesible y atractivo. Se identificaron casos de uso, que mueran no solo su utilidad teórica, sino la capacidad real de utilización en la práctica.

Palabras clave: Bioquímica Clínica; Laboratorio Clínico; Pruebas en el Punto de Atención; Nanopartículas; Dispositivos Wearables.

INTRODUCTION

Today advances in information and communication technologies have led to the modernization of every sector of society.[1] The use of more powerful computers, such as the Internet of Things (IoT)[2] and artificial intelligence, has been or is being integrated into the everyday life of society.[3]

This has been no different in the Biomedical Sciences, integrated into teaching, diagnosis, and decision-making processes in evidence-based clinical practice. These new technologies have favored the development and optimization of processes and treatments.[4]

The practice of modern medicine is at a crossroads: on the one hand, the capacity of clinical laboratories to analyze biomarkers with high accuracy has never been greater; on the other hand, the operating model that underpins this power - centralized, reactive and dependent on massive infrastructure - has become a bottleneck that limits the agility, accessibility, and equity of healthcare globally.[4]

The response to the limitations of the centralized model is the decentralization of diagnosis through Point-of-Care Testing (POCT). POCT represents a fundamental transformation in health care delivery, moving diagnostic capacity from the laboratory to the patient's bedside or home.[5]

This article describes the advantages and utility of POCT devices for clinical biochemistry diagnostics.

DEVELOPMENT

Limitations of traditional methods

Conventional diagnostic methods, such as enzyme-linked immunosorbent assay (ELISA), quantitative polymerase chain reaction (qPCR)[6], and microbiological cultures[7], are considered the 'Gold Standard' for their robustness and reliability. However, their efficient and effective development requires a laboratory infrastructure that imposes operational constraints.

One of the main limitations is the time to results. Microbiological cultures for pathogen identification are lengthy processes, which can take up to days; in circumstances such as sepsis, the time is equivalent to a reduced chance of survival.[4] This latency also affects the management of diseases where the integration of several serological tests is required, as in the case of syphilis, lengthening response times.[8] Even tests such as qPCR, which is a faster test, involve time-consuming processes and are not practical at the point of care.[9]

Second, infrastructure and cost represent a value barrier. Centralized laboratories rely on bulky, expensive, and complex instrumentation - such as thermal cyclers, plate readers, and electrophoresis systems - that require controlled environments and highly skilled personnel for operation and maintenance.[10] These high capital requirements and the ongoing operational costs of reagents drastically limit their implementation in low- and middle-income countries and in rural or resource-limited areas.[4] Methods such as ELISA, while conceptually more straightforward, can be costly and suffer from poor thermal stability, which increases expenses.[9]

Similarly, traditional methods are not foolproof and may have shortcomings in sensitivity and specificity. They may lack the sensitivity needed for early detection of disease, at which stage biomarkers are expressed at low or minimal concentrations.[10] Cultures of difficult-to-grow pathogens may fail or may be affected in samples from patients who have already received antibiotics, resulting in false negatives.[4] Immunoassays may be susceptible to high false favorable rates and cross-reactivity, compromising diagnostic specificity.[9]

The Demand for Point-of-Care and Decentralised Diagnostics (POCT)

Several critical factors drive demand for this transition:

- Pandemic response: the crisis caused by COVID-19 unequivocally demonstrated the vital need for rapid, mass, and accessible testing to control the transmission of infectious diseases. This urgency acted as a catalyst, accelerating innovation and regulatory pathways for POCT devices on an unprecedented scale.[11]
- Chronic disease management: diabetes, cardiovascular disease, or inflammatory bowel disease (IBD) requires frequent and continuous monitoring. POCT empowers patients by enabling home monitoring, improving quality of life, promoting treatment adherence, and allowing for proactive medical interventions before severe complications occur.[12]
- Accessibility and health equity: POCT is a critical tool for extending diagnostic outreach to remote, rural, or underserved communities that lack the infrastructure of a centralized laboratory. By overcoming geographic and economic barriers, POCT can potentially reduce disparities and promote greater equity in access to health care.[13]

System efficiency and patient empowerment: By facilitating out-of-hospital diagnosis, POCT can alleviate the workload of central laboratories, reduce overall health system costs by reducing hospitalizations, and optimize the use of resources. It also actively involves patients in managing their health. This paradigm shift has strong public support, as evidenced by surveys where most patients are willing to perform self-diagnostics.[14]

Wearable biosensors for continuous and non-invasive monitoring

Wearable biosensors represent a paradigm shift towards continuous, non-invasive monitoring of a person's physiology. These devices, which come in skin patches, wristbands, or even smart textiles, are designed to analyze biomarkers in readily accessible biological fluids, primarily sweat.[15]

Sweat, far from being just water, is an information-rich biofluid that contains a wide range of analytes, including electrolytes (Na^+, Cl^-), metabolites (glucose, lactate, uric acid), hormones (cortisol), and drugs.[15,16] Real-time analysis of these biomarkers can provide valuable information on hydration status, muscle fatigue, stress levels, and dietary response and even serve as a diagnostic tool for diseases such as cystic fibrosis (through chloride levels) or inflammatory bowel disease (by measuring cytokines such as TNF-α).[17]

The technology for these wearables typically combines a soft, flexible microfluidic platform for collecting and controlling sweat transport with an array of electrochemical sensors for detection. Microfluidics is crucial for guiding the sweat to the detection zones, preventing evaporation and contamination, and allowing sequential sampling.[15,18]

Electrochemical sensors, in turn, use electrodes modified with nanomaterials (such as graphene, carbon nanotubes, or metal nanoparticles) and specific enzymes to achieve highly sensitive and selective detection of target analytes.[17] A commercial precursor to this technology was the GlucoWatch, one of the first FDA-approved devices for non-invasive glucose monitoring through the skin.[19]

Smartphone integration

The smartphone has become the democratizing nexus linking these various hardware platforms. Its ubiquity, coupled with its intrinsic technological capabilities - high-resolution cameras, processing power, wireless connectivity, and a plethora of integrated sensors - makes it a near-universal readout and analysis platform for POCT.[20]

This integration manifests itself in several ways:

- Image Analysis: The smartphone camera, often supplemented with a simple 3D printed fixture to standardize lighting and positioning, captures and quantifies test results. Image processing and artificial intelligence algorithms can analyze the intensity of colorimetric or fluorescent signals to provide a quantitative, objective result.[20] Companies, such as Healthy.io, have demonstrated the feasibility of this approach, transforming a smartphone camera into a clinical-grade device for urine analysis.[21,22]
- External Connected Readers: A wide range of diagnostic devices are now designed to connect directly to a smartphone, which acts as a display, processing, and communication unit. Notable examples include AliveCor 's electrocardiogram (EKG) monitor[23] and Butterfly iQ's portable single-probe ultrasound scanner.[24,25]
- Data management and telehealth ecosystem: mobile apps go beyond simply reading results. They guide the user through the test procedure, record data over time, securely connect it to electronic health records (EHRs), and facilitate sharing with healthcare professionals. This creates a complete telehealth ecosystem, enabling remote monitoring and more connected care.[25,26]

Real-world success stories: from research to impact

The feasibility of these technologies is not merely theoretical; several products and projects have demonstrated their real-world impact.

Abbott BinaxNOW™ COVID-19 Ag Card

This device epitomizes POCT's success in a public health crisis. It is a simple and ingenious lateral flow test strip for qualitative detection of SARS-CoV-2 antigen. Its design, which requires no instrumentation and provides a visual result within 15 minutes, allowed for its mass distribution and use by both professionals and the general public under an FDA Emergency Use Authorisation (EUA).[27]

Its mass deployment, often accompanied by mobile applications such as NAVICA™ for recording results, was central to public health strategies during the pandemic, demonstrating the power of decentralized diagnosis.[27]

HIV testing in resource-poor settings

Combating HIV in resource-limited settings has been a powerful driver of innovation in POCT. The chip, developed by researchers at Columbia University, is a microfluidic device that performs a complete ELISA assay on a low-cost (less than $1 per test) chip.[28]

Using only 1 µL of unprocessed whole blood, it can simultaneously diagnose HIV and syphilis in less than 20 minutes with sensitivity and specificity, rivaling that of reference laboratory tests.[28] In parallel, paper-based technologies such as µPADs (paper-based microfluidic analytical devices) are extremely promising.[29] They harness capillary flow to move fluids, eliminating the need for pumps or external power sources and making them ideal for diagnosis in the most remote and underserved communities.[30]

CONCLUSIONS

Portable technologies in clinical biochemistry applied to laboratory diagnostics promise to overcome the barriers of conventional techniques (time, infrastructure, cost, sensitivity, and specificity). Their usefulness varies, being applicable in response to pandemics for the management of chronic diseases, favoring accessibility and equity in health, and improving the efficiency of the system while empowering the patient. Similarly, the possibility of integration into wearable devices and smartphones makes it an accessible and attractive medium. Use cases were identified, which demonstrate not only its theoretical usefulness but also its real capacity for use in practice.

FINANCING

None.

CONFLICT OF INTEREST

No conflict of interest.

AUTHORSHIP CONTRIBUTION

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