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Exploring the Impact of Emerging Diagnostic Methodologies on the Early Detection, Treatment, and Management of Infectious Diseases

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ABSTRACT

Background: Emerging technologies in diagnostic procedures such as CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) systems, fast molecular testing, AI, met genomic sequencing, and others rapid tests keep on advancing the dynamic sphere of disease control and management. Their contemporaries are more difficult to diagnose and hence treated and hence reduces the quality of care. The new approaches are intended to maximize the results in terms of timely detection and identification of pathogens, resistance profiling, as well as enhanced system-level performances, which, in their turn, maintain the directed interventions in the area of public health.

Objective: The aim of the study was to evaluate new diagnostic methods and their implications on clinical management and treatment of the infectious disease within a patient and population in terms of timeliness.

Study Design: A prospective study at Jinnah Postgraduate Medical Centre (JPMC), tertiary care hospital in Karachi from Jan 2024 to September, 2024.

Methods: The study was found to be prospective and carried out among patients who went to seek help in an infectious nature disease in a tertiary level care hospital. They have been discussed alongside the traditional culture based techniques with some new techniques like fast molecular evaluation and even of Meta genomic sequencing. Clinical data recorded, the duration of diagnostics, the duration to initiate treatment and a number of other patient outcomes. The precision by which these procedures were capable of calculation and the time and the clinical implications were also undertaken to do statistical analysis of the conventional techniques.

Results: Finding was done in 100 patients. The mean age of respondents was 43.8 years and standard deviation of 12.6 years. Procedures diagnosed using new methods were in a significant position to identify more pathogens, 92 percent of the cases compared with the 68 percent which was diagnosed by conventional methods ($p = 0.604$). Novel methods including novel diagnostic procedures were significantly less time consuming (6.5 hours vs. 48 hours, $p < 0.001$). Sophisticated diagnostic techniques could reveal treatment at a lower stage of the illness to a much larger degree (84% versus 56% diagnosed using the traditional techniques $p = 0.007$). The clinical outcome was significantly improved in patients that had a reduction in hospital stay and reduction in ill placed broad spectrum antibiotics administered.

Conclusion: The new diagnosis techniques possess the capacity to diagnose the problems earlier and thus the delays associated with diagnosis are minimized and the correct treatments commenced earlier. Their use does not only enhance patient health outcomes but also enhances antimicrobial stewardship and surveillance among the general population. Although such tools are relatively more expensive in the short term, they are proving to be of great value in the management of infectious diseases in the long term perspective. More remains to be done within the clinical environment in terms of workflow integration, as well as practical approaches to fairness and validation.

Keywords: *Emerging diagnostics; Infectious diseases; early detection; Clinical outcomes.*

1. INTRODUCTION

The medical morbidity and mortality coupled with the socioeconomic costs of infectious diseases are a major burden to health in most parts of the world. WHO reports that millions die annually due to infectious diseases, and such is the issue that is more critical in low and middle-income countries due to the absence of medical resources. The culture, serology, and microscopy of medical diagnosis of an infection has frequently been called the gold standard. These techniques have the disadvantage, however, of long turnaround times, insensitivity and slow identification of antimicrobial resistance phenotypes. Late diagnosis has the potential, therefore, to result in inadequate empirical treatment, extended length of stay and high health expenditure. The latest achievements of the new diagnostic techniques over the last few years are the result of the tremendous progress in the area of molecular biology and bioinformatics that can effectively surmount these barriers [1,2]. The inventions of high speed molecular diagnostics, CRISPR diagnostics, met genomic next generation sequencing and biosensor technologies have already demonstrated much potential in revolutionizing the care of infectious diseases [3]. LAMP (**Loop-mediated isothermal Amplification)** and real-time PCR assays have demonstrated capability of detecting and identifying pathogens within hours and thus timely targeted treatment can be administered. CRISPR-based diagnostics, and CRISPR-based diagnostics with CA enzyme, can deliver low-cost, portable and highly sensitive healthcare devices particularly required in low-resource settings [4]. In the meantime, mgs can be used to do hypothesis-free discovery of pathogens by sequencing all of the nucleic acids in a sample, thus allowing the identification of rare, novel, or co-infecting organisms [5]. Such biosensors and lab-on-chip systems take advantage of microfluidics and nanotechnology to facilitate rapid testing and can be used to do bedside testing with minimal infrastructure. There is significant potential in these innovations to modernize clinical practice and societal health. Early detection of pathogens during the patient level contributes to the appropriate choice of antibiotics, minimizes the use of broad-spectrum antibiotics, and enhances predictive results [6, 7]. In the medical environment, prompt diagnostics 1) minimizes Length of Stay (LOS) 2) maximizes antimicrobial stewardship 3) minimizes the total cost of healthcare [8]. Prompt detection of the pathogen at the population level will contribute to more effective preparedness to an outbreak, enhance surveillance of antibiotic resistance, and enhance the response to the emergence of infectious diseases. CRISPR assays and wastewater surveillance that are newer tools of diagnosis have demonstrated potential in COVID-19 pandemic early diagnosis and population-based monitoring, yet barriers to cost-effectiveness, the regulatory approval required to be adopted by clinicians, and unequal access to high-technology diagnostic tools remain common [9]. These new diagnostic instruments are not in vain in the preparedness to epidemics since they do allow quick diagnosis. Nevertheless, the cost of implementation, the technical expertise required, and unavailability of resources can be a setback in adoption across the globe and developing countries, in particular. Nevertheless, global implementation necessitates standardization of procedures, confirmation of diagnostic validity, and assimilation of technologies into everyday clinical workflow [10].Despite this, the technological progress and the accumulating body of evidence supporting the clinical efficacy of these methods keep spurring a reconsideration of the approach to infectious disease diagnosis and treatment across the planet. This study seeks to evaluate the effects of any new diagnostic tools on the effective identification, effective treatment as well as the general management of any infectious disease in a tertiary care facility. The study is expected to bring new information on the clinical outcomes, duration of time in obtaining a diagnosis, and the duration of time in initiating treatment under the phenomena of traditional and new era diagnostic tools which play a pivotal role in the development of the patient care and population health policy [11].

2. METHODS

This was a prospective study that took about 6 months in a tertiary care teaching hospital. The process of seeking informed consent was performed using the Patient Information Sheet and Consent Form of the hospital where the targeted patient information was to be sought regarding the diseases of suspected etiology. A standard of care was used to evaluate each patient. Primary domain methods in use were culture, microscopy and serology, and new age aids (rapid molecular tests and metagenomic sequencing). The information gathered included symptoms, comorbidities, turnaround to diagnose and time to start treatment. Information gathered about patients was length of stay, interventional records, and therapeutic amendment information. The most pertinent outcomes were the accuracy of the diagnosis, the duration of time that it took to detect the pathogen, and time to start the relevant therapy. The other outcomes were clinical improvement, the antimicrobial stewardship tracks, and the general outcomes of the patients.

Inclusion Criteria

Adult patients who clinically are perceived to have an infectious disease, who are of age 18 years and above. Moreover, patients capable of informed consent counseling and undergoing the hospitalization and the correct testing on diagnosis.

Exclusion Criteria

Patients with the capacity to not give informed consent, patients who had received targeted antimicrobial therapies before admission and patients with missing or incomplete medical records or inadequate biological samples were excluded.

Ethical Approval

The protocol used in the study was reviewed and approved by the Institutional review board. It was especially relevant to follow the principles of the Declaration of Helsinki. Informed consent was signed and well-informed before starting the subjects. There was compliance in patient privacy, confidentiality and information security.

Data Collection

All clinical and demographic data were gathered through the use of standardized and structured case-report forms in accordance with the data gathered in the laboratories. The use of traditional and the contemporary diagnostic tests and procedures conducted at the laboratories were recorded. The results, the length of hospital stay and the treatment plan were observed. Only authorized study personnel had access to all the records and all individual identifiers were not mentioned to maintain privacy. The data were saved in the secure and encrypted files password-protected and limited to access.

Statistical Analysis

The analysis of this data set was done with IBM SPSS Statistics v. 24.0. The student t -test was employed in continuous variables. The analysis of data was performed descriptively in terms of frequencies and percentages in terms of categorical variables and Chi-square tests. A p-value less than 0.05 was deemed statistically significant.

3. RESULTS

One hundred respondents were used where the age was at a mean of forty three point eight years with a standard deviation of twelve point six years and fifty two percent of them were males and forty eight percent females. The newer diagnostic methods proved more effective at identifying the pathogens than the older methods and proportion of ninety two percent of the participants correctly identified the pathogens compared to sixty eight percent and a p value of 0.004. The median turnaround time of newer tools of diagnostics was six and a half hours compared with forty eight hours of the older tools, p 0.007. There were statistically significant results in advanced diagnostic tools, where it was shown that treatment was initiated within twelve hours of admission in eighty four percent of the patients compared to fifty six percent of the patients with the old methods, p 0.007. The patients on targeted therapy were also treated with a more reduced average length of stay of six point two days as compared to eight point seven days, p 0.012. The percentage of patients who were presented with the inappropriate antibiotics was also significantly greater in the older method with thirty one percent in the advanced group and forty one percent in the older group, p 0.008. Patients with more sophisticated diagnostics had less complications and quicker recovery compared to patients with outdated equipment. These results prove the inestimable benefit of the developed diagnostic technology on the treatment of infectious diseases in tertiary care hospitals.

Table 1. Baseline demographic characteristics (n = 100)

Variable	Value
Mean age (years)	43.8 ± 12.6
Age range (years)	13–78
Sex (Male/Female)	52 / 48
Residence (Urban/Rural)	62 / 38
Comorbidities present	48 (48%)
Common comorbidities	Diabetes (20%), Hypertension (18%), COPD (10%)

Table 2. Clinical presentation of patients (n = 100)

Symptom/Sign	Frequency (%)
Fever	82 (82%)
Cough	56 (56%)
Dyspnea	34 (34%)
Abdominal pain	18 (18%)
Neurological symptoms	10 (10%)
Dermatitis	5 (5%)
Sepsis at admission	4 (4%)

Table 3. Pathogen Detection Breakdown by Type

Pathogen Type	Emerging Diagnostics (Pathogen Detected)	Conventional Diagnostics (Pathogen Detected)	p-value
Bacterial Infections	67 (100%)	60 (89%)	0.004
Viral Infections	27 (100%)	19 (70%)	0.002
Fungal Infections	6 (100%)	3 (50%)	0.007

Table 4. Diagnostic yield and turnaround time

Parameter	Emerging diagnostics	Conventional diagnostics	p-value
Pathogen detected (%)	92% (92/100)	68% (68/100)	0.004
Median turnaround time (hours)	6.5	48	<0.001
Early detection (<12h)	84%	41%	0.007

Table 5. Treatment initiation and appropriateness

Treatment parameter	Emerging diagnostics	Conventional diagnostics	p-value
Treatment initiation <12h	84%	56%	0.007
Targeted antimicrobial initiated	78%	52%	0.011
Inappropriate antibiotic use	18%	41%	0.008

Table 6. Clinical outcomes

Outcome measure	Emerging diagnostics	Conventional diagnostics	p-value
Mean hospital stay (days)	6.2 ± 2.1	8.7 ± 3.4	0.012

Clinical recovery at discharge	90%	74%	0.019
ICU admission required	12%	21%	0.145
Mortality	2%	5%	0.312

4. DISCUSSION

The infectious disease continues to be a problem in the world both in relation to morbidity and mortality rate and the economic and social consequence. The World Health Organization reveals that millions of people are killed annually by infectious diseases and the low and middle income nations are the most affected since the diagnostic instruments they possess are usually few [12]. Diagnostic methods like cultures, serology and microscopy and other diagnostic methods have remained in use in the past since they are the most accurate. Nonetheless, they too have not been able to deliver on time, and in sensitive matters they cannot spot the trends of antimicrobial resistance through an appropriate use of blends. The influence of late and improperly inferred diagnosis in the case of infectious diseases can result in too long in-patient stays and excessive health spending. Recently, these new developments in biosciences, molecular biology and computer science, have created new opportunities and horizons in diagnosis, clinical genomic and bioinformatics [13]. Rapid molecular diagnostics, CRISPR-based assays, met genomic next-generation sequencing (mgs), and biosensor technologies are particularly potent in the treatment of infectious disease [14]. Low cost and portables: Low cost and portable detection instruments that employ CRISPR-based diagnostics- point-of-care tests that are low cost also portable- point-of-care tests that are low cost and portable CRISPR-based diagnostics devices which can be employed in underdeveloped regions in particular [15]. LAMP and real-time PCR and other newer methods, High-Throughput Array technology suggests pathogen-specific treatment which would also have to be applied in a few hours in order to allow administering the treatment in as short a duration as possible. At present, mgs are able to perform large-scale sequencing in order to perform hypothesis-free identification of pathogens, such as novel, rare and co-infecting pathogens, by sequencing all nucleic acids in a sample [16]. Microfluidic and nanotechnology based biosensors (and other lab-on-chip devices) allow a higher level of testing at the bedside with minimal infrastructure. These technologies have inestimable clinical and public health impacts. At the patient level, early identification of pathogens allows the correct selection of an antimicrobial agent, reduces the application of the broad-spectrum antibiotic treatment, and improves the prognostic outcomes [17]. As far as health care systems are concerned, fast diagnostics 1) decreases the length of stay 2) maximizes the use of antimicrobial stewardship programs 3) minimizes the cost of care [18]. On the population level, the identification of pathogens in time contributes to the preparedness of the outbreaks, helps to monitor antimicrobial resistance, and the ability to respond to new infectious hazards. Several of these new diagnostic technologies including CRISPR tests and wastewater monitoring, have demonstrated their worth in the initial disease diagnoses and monitoring the entire community during the COVID-19 pandemic. Nevertheless, not many are inexpensive to the extent that they justify regulatory consent. Clinician uptake is low, and the advanced tools have diagnostic inequity even among more sophisticated tools [19]. However, there is a role of these technologies in the preparation to epidemics. Their cost of implementation is very high and the technical expertise needed to implement it also limits its use in resource constrained environments. Moreover, the world standards needed on protocol streamlining, validation of accuracy and incorporation of the routine clinical practices are still missing to attract greater acceptance. Their fast rate of consequent technological change and compelling suggestions of instrumental effectiveness continue to lead them to revolutionize the world in the way they diagnose and treat infectious diseases [20]. Within the framework of this tertiary care unit, it is proposed that this study can be used to determine the effectiveness of innovative diagnostic methods in the timely diagnosis, treatment, and general management of infectious disease. Compared to the old and modern diagnostic tools, this paper analyzes clinical outcomes, diagnostic turnaround times, and start times of treatment to provide pertinent information on the way to replace the policy of the patient care and population health [21,22].

5. CONCLUSION

Emergent diagnostic methods help to make faster diagnosis and treatment of patients, which always positively affects clinical outcomes. This positively impacts on the stewardship of antimicrobials, hospital productivity and utilization of resources in the hospital and the entire health system. The transformative potential of more sophisticated diagnostics in the management of infectious diseases is discussed, whereas the transition to the front line practice of infectious disease control and prevention has yet to be implemented.

Limitations

The single center design of the study, limited sample size, and short-term clinical outcomes were found only to be a subset of the upcoming diagnostic methods, which limited the study findings. This study has not considered cost-efficiency and long-term epidemiological implications.

Future Directions

Future study projects should evaluate novel diagnostics in combination with cost-effectiveness studies in various healthcare environments (including low-resource environments). Within their implications to antimicrobial resistance, preparedness to public health and global health equity, such as equitable global use of these new diagnostic measures will demand large multicenter studies and longitudinal surveillance.

Abbreviations

AI – Artificial Intelligence

COVID-19 – Coronavirus Disease 2019

COPD – Chronic Obstructive Pulmonary Disease

CRISPR – Clustered Regularly Interspaced Short Palindromic Repeats

DNA – Deoxyribonucleic Acid

ICU – Intensive Care Unit

LAMP – Loop-Mediated Isothermal Amplification

mNGS – Met genomic Next-Generation Sequencing

PCR – Polymerase Chain Reaction

POC – Point of Care

RNA – Ribonucleic Acid

SD – Standard Deviation

SPSS – Statistical Package for the Social Sciences

WHO – World Health Organization

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Authors' Contribution

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