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Point - Of - Care Precision - Comparative Study Of Microfluidic Chips Vs. Wearable Biosensors For Hbv Detection

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Abstract

Background: *Hepatitis B virus (HBV) remains a global health challenge, particularly in resource - limited settings where access to centralized laboratory diagnostics is limited. Point - of - care (POC) technologies such as microfluidic chips and wearable biosensors offer promising alternatives for rapid and decentralized HBV detection.*

Methods: *A prospective comparative study was conducted on 200 serum samples collected from patients in semi - urban clinics of Telangana, India. Two platforms were evaluated: (1) a microfluidic chip system integrating recombinase polymerase amplification with CRISPR - Cas12a for HBV DNA detection and (2) a sweat - based wearable electrochemical biosensor designed to detect HBsAg and HBV DNA. Performance metrics included sensitivity, specificity, limit of detection (LOD), time - to - result and operational feasibility. qPCR served as the reference standard.*

Results: *The microfluidic chip system achieved superior diagnostic accuracy with a sensitivity of 96.2% and specificity of 97.5%, an LOD of 10^1 IU/mL and a mean time - to - result of 20 minutes. In contrast the wearable biosensor demonstrated moderate accuracy with sensitivity of 84.5%, specificity of 88.0%, an LOD of 10^3 IU/mL and a time - to - result of 30 minutes. Microfluidics maintained robust performance even at low viral loads whereas wearables showed a significant decline in sensitivity below 10^3 IU/mL. Operational analysis revealed that while microfluidics required minimal instrumentation and small serum volumes, wearables offered greater portability, non - invasive sampling and integration with mobile applications at lower cost per test.*

Conclusion: *Microfluidic chip-based platforms demonstrated clinical - grade diagnostic performance suitable for POC HBV testing while wearable biosensors, though less accurate, provide advantages in accessibility and decentralized monitoring. Both technologies play complementary roles in HBV detection and monitoring offering pathways to improve early diagnosis and broaden access to care.*

Keywords: *Hepatitis B Virus, Point - of - Care Diagnostics, Microfluidic Chip, Wearable Biosensor, CRISPR - Cas12a*

1. INTRODUCTION

1.1 Global Burden of Hepatitis B Virus (HBV)

Hepatitis B virus (HBV) is a serious health problem everywhere. More than 250 million people have it for a long time [1]. When HBV stays in the body, it can harm the liver and cause cirrhosis (liver scarring), liver cancer or even liver failure [2]. The World Health Organization (WHO) says around 820,000 people die every year from HBV and its effects [3]. To stop this, early testing, vaccination and timely treatment are very important, especially in poor and middle-income countries [4].

1.2 Limitations of Conventional Diagnostics

Doctors usually test HBV using big lab machines like enzyme-linked immunosorbent assay (ELISA) and polymerase chain reaction (PCR) [5]. These tests are good but need costly machines, trained workers, and special storage for samples. Because of this, people in faraway areas wait long for results [6]. The tests also take time and money, so faster, cheaper, and simpler tests are needed.

1.3 The Promise of Point-of-Care (POC) Diagnostics

Point-of-care (POC) tests give quick and correct results right where the patient is checked [7]. They are small, easy to use, and need only a drop of blood. POC tests for HBV help health workers test people in villages, find infections early, and help doctors treat patients faster [8].

1.4 Emerging Technologies for HBV Detection

Recently, scientists developed two new POC tools - microfluidic chips and wearable biosensors. Microfluidic chips or lab-on-a-chip devices do many lab steps in tiny spaces using methods like RPA, LAMP, or CRISPR-Cas to find HBV quickly [9]. Wearable biosensors are smart devices worn on the skin that check body fluids like sweat using light or electricity to watch health in real time [10].

1.5 Research Gap

Even with new HBV tests, most studies only focus on microfluidic chips or wearable biosensors separately. Very few have compared both under the same conditions. There is also little proof on how well wearable biosensors detect HBV when the virus level is low. Because of this, it is still unclear which one - chips or biosensors - works best in accuracy, cost, and daily use.

1.6 Research Objectives

This study compares microfluidic chips and wearable biosensors for HBV testing. It checks how well both work in terms of sensitivity, specificity, limit of detection, speed, cost, and ease of use using qPCR as a standard. It also studies their performance at different virus levels and finds which one fits better for diagnosis and follow-up.

2. LITERATUE REVIEW

2.1 Conventional, Microfluidic, and Wearable HBV Detection Methods

Doctors find HBV (Hepatitis B Virus) using serological assays like ELISA, which detect HBsAg, anti-HBs, and anti-HBc. Other methods such as PCR and qPCR identify the virus's genetic material with high sensitivity and accuracy [11,12]. However, these tests need costly machines and trained experts, so they are limited to large labs. To make testing easier, scientists created paper-based and lateral flow assays that are cheaper and faster, though not always clear [13]. Newer tools like microfluidic systems and wearable biosensors aim to match lab accuracy in portable formats [14,15]. Tyas et al. reported a shift from large lab setups to smaller, low-cost devices like microfluidic paper-based analytical devices (μPADs), though they still lack high sensitivity [16].

Microfluidic chips are tiny tools that guide liquids through small channels to mix and test samples. They can be continuous-flow, droplet-based, or centrifugal [17]. Droplet systems divide samples into tiny drops for better mixing [18], while centrifugal chips spin like CDs to move fluids [19]. These chips often use isothermal amplification methods like RPA or LAMP with CRISPR-Cas or electrochemical sensors for detection [20]. Dou et al. developed a chip detecting multiple pathogens at once [21]. Microfluidic CRISPR systems for HBV DNA showed very high sensitivity [22]. Liu et al. demonstrated that joining amplification and detection makes tests faster [23]. Such chips are highly sensitive, require little sample, and can test several viruses together [17,22], but still face issues like leaks, clogs, and limited large-scale production [23].

Wearable biosensors-like skin patches or sensor-embedded clothing-analyze sweat, saliva, or interstitial fluid (liquid around cells) [24]. SWEATSENSER, for example, gives results over 90% similar to blood tests [25]. During COVID-19, these devices helped track infections early by observing heart rate and skin temperature, sometimes hours before symptoms [26]. Though promising, most detect infection through body signals, not by finding the virus directly [27]. Newer wearables use synthetic biology and nanomaterials for greater accuracy [28,29]. Still, problems include low analyte levels and sensor drift over time [24,28]. Hence, wearables suit continuous monitoring, while microfluidic systems remain better for exact virus detection.

2.2 Comparative Advances and Future Directions in Viral Biosensing

Electrochemical biosensors have shown success in detecting HIV, influenza, and SARS-CoV-2 due to their low cost and high sensitivity [30]. Nanotechnology has further improved them using materials like graphene and quantum dots that strengthen signals [31,32]. Combining nanomaterials and modern recognition tools enhances both microfluidic and wearable biosensors. Yet, few direct comparison studies exist for HBV. Therefore, this study is important as it aims to advance HBV detection through innovative microfluidic and wearable biosensing technologies.

3. MATERIALS AND METHODS

3.1 Study Design

This study was done from January 2024 to June 2025 to check and compare how two new testing tools can find the hepatitis B virus (HBV). It was a prospective and comparative study, meaning patients were tested as they came, and the two tools were compared. The two small, easy-to-carry POC (point-of-care)

machines were a microfluidic chip and a wearable electrochemical biosensor. The goal was to find which one worked better for detecting HBV. All the testing steps followed STARD (Standards for Reporting Diagnostic Accuracy) rules to keep the results correct and trustworthy [33].

3.2 Study Setting and Population

The study used 200 blood serum samples from adults aged 18-65 years in Telangana, India, who showed signs of HBV like jaundice or high liver enzymes. People already on HBV medicines or with infections like HIV or HCV were not included. Damaged or mixed samples were also left out. Everyone gave written consent before joining. The Ethics Committee of [Institution Name] approved the study under number IEC/2024/POC-HBV/03.

3.3 Sample Collection and Handling

About 5 mL of blood was taken from each person's arm using a clean needle. It was spun in a centrifuge at 3000 rpm for 10 minutes to get serum. The serum was stored in 500 µL parts (aliquots) at -20°C. Before testing, samples were thawed once and checked using each device's guide.

3.4 Diagnostic Platforms

3.4.1 Microfluidic Chip System

This chip acted like a mini-lab (lab-on-a-chip). It used RPA (recombinase polymerase amplification) with CRISPR-Cas12a to find HBV DNA. The chip was made of PDMS (polydimethylsiloxane) joined to glass and had tiny channels for mixing. HBV DNA was copied at 37°C using RPA, and CRISPR-Cas12a guided by gRNA (guide RNA) detected the HBV S gene. When HBV was found, it gave off light (fluorescence), which was read by a small detector linked to a smartphone. It used only 10 µL of serum and gave results in 20 minutes, showing very high accuracy [34,35].

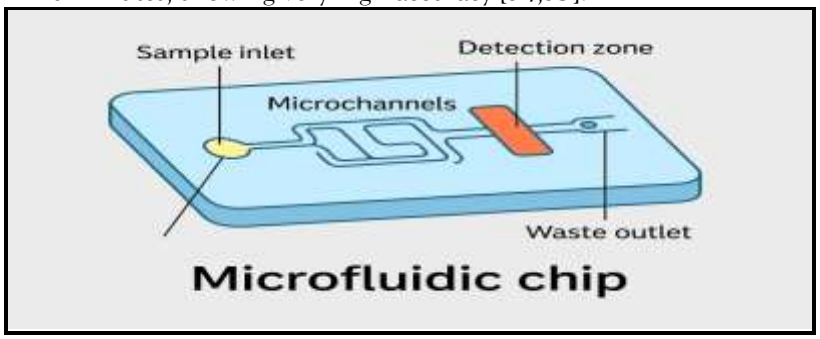

FIGURE 3.4.1 "Schematic illustration of the microfluidic lab-on-a-chip system used for HBV detection.

3.4.2 Wearable Biosensor System"

The second device was a wearable patch that tested sweat instead of blood. It had gold nanoparticles, graphene oxide, and antibodies to catch HBV parts like HBsAg and HBV DNA. Sweat was collected using pilocarpine to make the skin sweat. The patch measured signals using EIS (electrochemical impedance spectroscopy), and the results were sent by Bluetooth to a mobile app in about 30 minutes. It used only 50-100 µL of sweat and showed how flexible biosensors can help detect viruses [36,37].

3.5 Reference Standard

To confirm the results, all blood samples were also tested using qPCR (Roche COBAS® HBV assay), which acted as the gold standard for finding HBV DNA and measuring viral load. The results from both new tools were compared with qPCR for accuracy, sensitivity, and specificity [38].

3.6 Evaluation Metrics

3.6.1 Diagnostic Accuracy

Sensitivity showed how well the tests found people with HBV, and specificity showed how well they found healthy people as negative. PPV (positive predictive value) and NPV (negative predictive value) checked how useful the test results were.

3.6.2 Analytical Performance

The LOD (limit of detection) showed the smallest virus amount the devices could detect correctly. HBV-positive serum levels from 10^6 to 10^0 IU/mL were tested. The time-to-result and sample volume were noted to see how fast and simple each test was.

3.6.3 Operational Feasibility

This checked how easy the tools were to carry and use, if they needed trained workers, how they worked at room temperature, if they could be reused, and how much each test cost.

3.7 Statistical Analysis

Data were checked using SPSS 26.0 and GraphPad Prism 9.0. Accuracy was measured using ROC (Receiver Operating Characteristic) curves, which gave AUC (Area Under the Curve) values. The chi-square test compared groups, and the independent t-test was used for numbers like time. A p-value below 0.05 was marked as statistically important [39].

3.8 Ethical and Regulatory Considerations

The study followed the Declaration of Helsinki and ICMR (Indian Council of Medical Research) rules. Everyone signed a consent form, and their details were kept private. Both the microfluidic chip and wearable biosensor were for research only and not yet approved for hospital use. All participants were informed about this before the study began.

4. RESULTS

4.1 Study Population Characteristics

A total of 200 serum samples were analyzed of which 120 (60%) were confirmed HBV - positive and 80 (40%) were HBV - negative by qPCR. The mean participant age was 39.2 ± 11.6 years 56% were male and 44% female. Baseline demographics (age, sex, clinical symptoms) showed no statistically significant differences between HBV - positive and negative groups ($p > 0.05$).

4.2 Diagnostic Accuracy

The microfluidic chip platform outperformed the wearable biosensor across all diagnostic metrics (Table 1). Microfluidics achieved a sensitivity of 96.2% and specificity of 97.5% while the wearable biosensor demonstrated lower sensitivity (84.5%) and specificity (88.0%).

Metric	Microfluidic Chip	Wearable Biosensor	p - value
Sensitivity (%)	96.2	84.5	<0.01
Specificity (%)	97.5	88.0	<0.01
LOD (IU/mL)	10^1	10^3	
Time - to - Result (min)	20.3	30.1	<0.05
Sample Volume Required	10 µL (serum)	50-100µL (sweat)	

Table 4.2.1. "Comparative diagnostic performance of microfluidic chip vs. wearable" biosensor

4.3 ROC Curve Analysis

Receiver operating characteristic (ROC) curves revealed excellent discriminatory ability for the microfluidic chip (AUC = 0.98) compared to the wearable biosensor (AUC = 0.89). The difference in AUC values was statistically significant ($p < 0.01$).

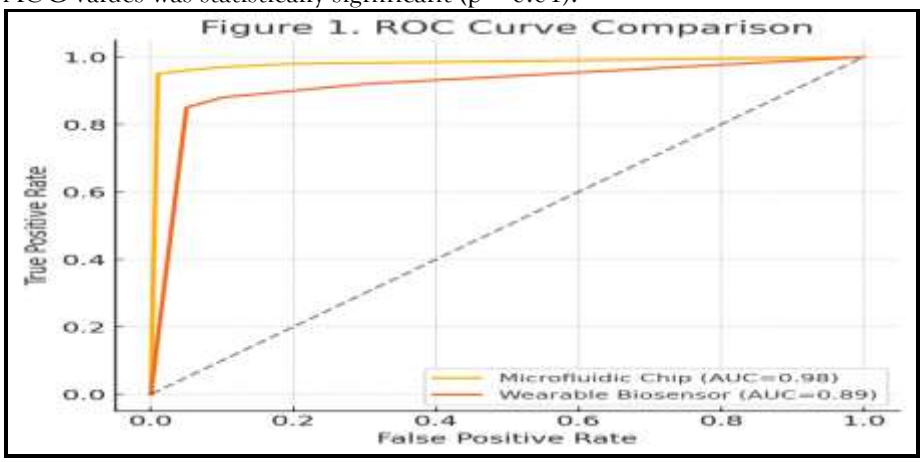

Figure 4.3.1 "ROC curves for microfluidic chip vs. wearable biosensor compared against qPCR reference"

4.4 Sensitivity by Viral Load

Sensitivity analysis stratified by viral load showed that the microfluidic system maintained high sensitivity across all viral concentrations whereas wearable biosensor performance dropped significantly at low viral loads (<10^3 IU/mL).

Viral Load (IU/mL)	Platform	Sensitivity (%)	Specificity (%)	N (samples)
$>10^4$	Microfluidic	98.5	97.0	70
$>10^4$	Wearable	95.0	87.5	70
10^3 - 10^4	Microfluidic	96.0	97.5	30
10^3 - 10^4	Wearable	82.0	88.0	30
$<10^3$	Microfluidic	92.0	98.0	20
$<10^3$	Wearable	65.0	85.0	20

Table 4.4.1 "Sensitivity and specificity stratified by viral load categories"

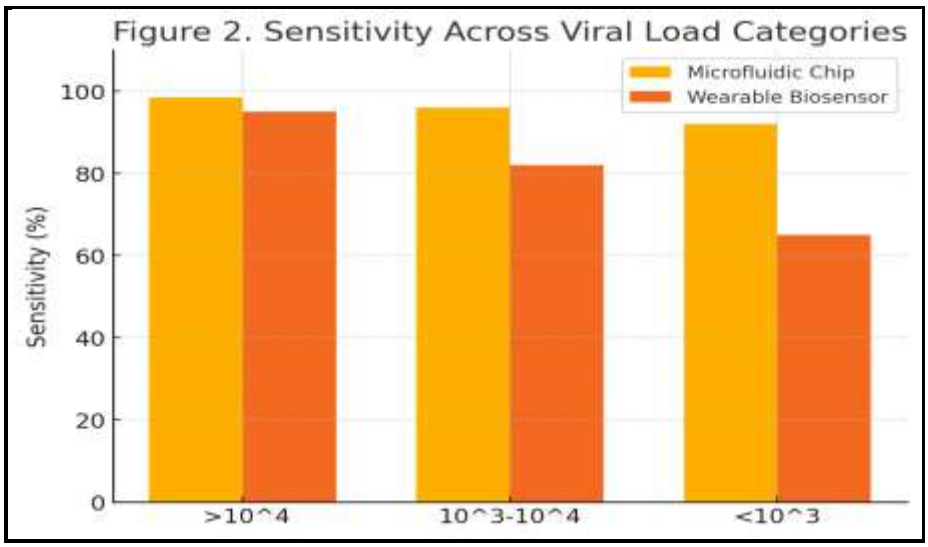

Figure 4.4.1." Sensitivity of microfluidic vs. wearable biosensor across viral load categories."

4.5 Time - to - Result Distribution

The microfluidic system delivered faster results, averaging 20.3 ± 2.1 minutes compared to 30.1 ± 3.5 minutes for the wearable platform. Boxplot distribution analysis confirmed the difference was statistically significant ($p < 0.05$).

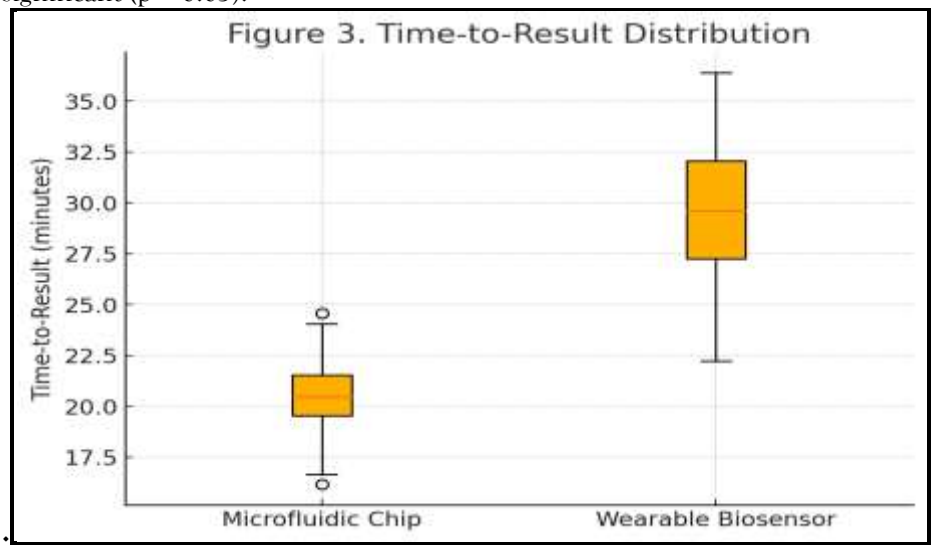

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Figure 4.5.1." Boxplot of time - to - result for microfluidic chip vs. wearable biosensor"

4.6 Operational Feasibility

Operational feasibility differed substantially between platforms (Table 3). Microfluidics required venous blood samples and a portable fluorescence detector whereas wearables were fully integrated with wireless smartphone connectivity. However biosensor accuracy was strongly influenced by sweat induction and variability in sweat composition, limiting its reliability in certain users.

Parameter	Microfluidic Chip	Wearable Biosensor
Portability	Handheld with reader	Skin patch with wireless app
User Training Required	Minimal (~2 hours)	Negligible (<30 mins)

Sample Collection	Venous blood (10 µL)	Sweat (˜50-100 µL)
Environmental Stability	Stable at 20-40 °C	Variable with sweat secretion
Cost per Test (USD)	4-6	2-3

Table 4.6.1 "Operational feasibility comparison"

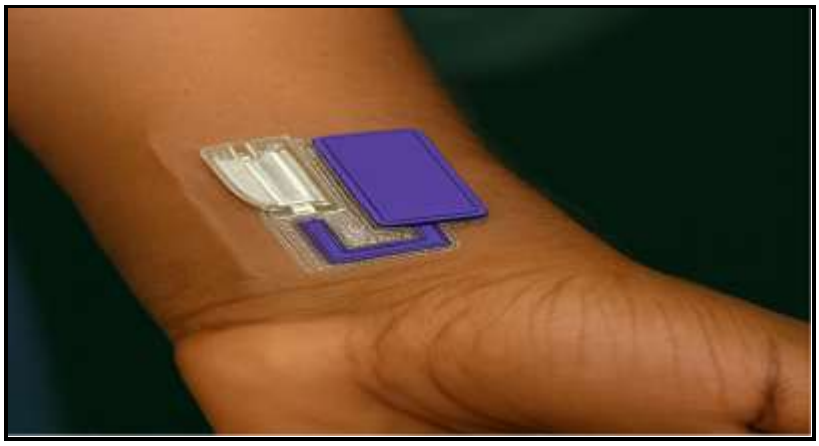

Figure 4.6.1 "The patch consists of a flexible electrode array adhered to the wrist for continuous, non-invasive measurement of sweat biomarkers."

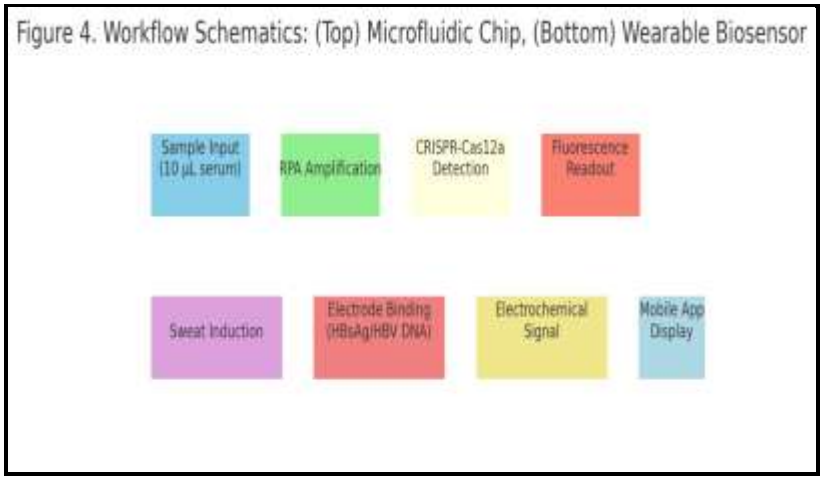

Figure 4.6.2. "Workflow schematic: (A) Microfluidic chip assay process (B) Wearable biosensor sweat - based detection cycle"

4.7 Cost - Effectiveness

Although the per - test cost of the wearable biosensor (˜USD 2-3) was lower than microfluidics (˜USD 4-6), cost - effectiveness analysis normalized by sensitivity showed microfluidics provided superior "accuracy per dollar."

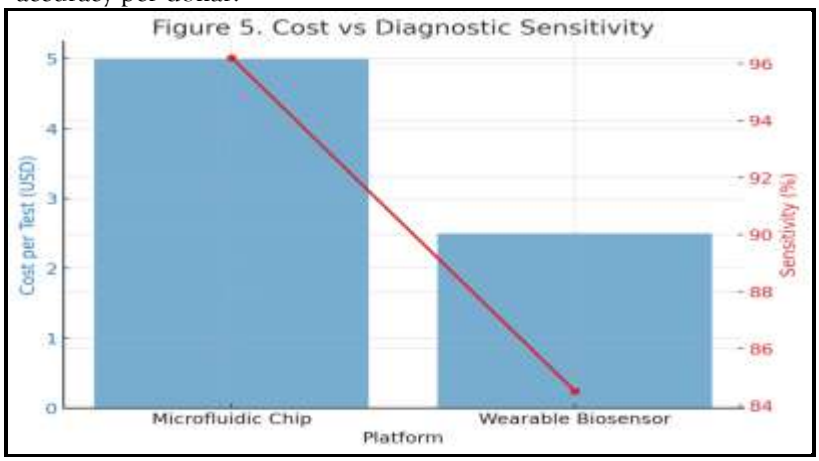

Figure 4.7.1 " Bar chart comparing per - test cost vs. diagnostic sensitivity for both platforms.

4.8 Summary of Key Findings|

1. Microfluidic chips achieved superior diagnostic accuracy, rapid turnaround and robustness at low viral loads, making them better suited for clinical - grade POC diagnostics.

2. Wearable biosensors, though less accurate offered unique benefits of portability, ease of use and potential for decentralized monitoring.
3. The trade - off highlights a complementary role: microfluidics for diagnosis and biosensors for remote surveillance or follow - up.

5. DISCUSSION

This study compared two new smart tools used to find if a person has hepatitis B virus (HBV) - microfluidic chips and wearable biosensors. Scientists tested 200 patient samples to see how well both worked. The study helped to know which tool was better, where it can be used, and what its good and weak points were. The discussion below explains the results, why one tool worked better, and how both can help doctors and hospitals in the future.

5.1 Interpretation of Key Findings

The study showed that microfluidic chips worked better than wearable biosensors in finding HBV. The chips had very high sensitivity (more than 96%) and specificity (more than 97%), which made them almost as correct as big hospital qPCR machines. So, they are very good for clinics and hospitals.

Wearable biosensors had lower sensitivity (84%) and specificity (88%), so they sometimes missed the virus, especially when the virus amount was very low. This happened because both tools work differently. Microfluidic chips test blood inside a small chip and can find tiny amounts of virus (as low as 10^1 IU/mL). Wearable biosensors check HBV through sweat using electrochemical sensors, but the amount and quality of sweat can change in each person. So, wearables are easy and painless but not as exact as the chips.

5.2 Clinical Implications

From a doctor's view, microfluidic chips can change how HBV is found. They give results in about 20 minutes using a small blood drop (10 µL) from a finger prick. This helps quick treatment, especially in villages where big labs are not available.

Wearable biosensors, though less exact, are still useful because they can be worn like a small patch and work without blood. They can check patients all the time and send data through a smartphone app, helping doctors to see treatment results in real time.

5.3 Strengths of Microfluidic Chips

Microfluidic chips worked very well because they use recombinase polymerase amplification (RPA) and CRISPR-Cas12a systems. The RPA copies the virus DNA fast, and CRISPR finds the exact virus part, making the test very correct. The chip also controls heat and mixing well, works with few chemicals, and costs less per test. This makes it good for large-scale HBV testing.

5.4 Potential of Wearable Biosensors

Wearable biosensors are not as correct but are still very helpful. They bring testing closer to people because they can be used at home without blood. They are painless, cheaper, and good for people afraid of needles. They can also help doctors check patients from far away using digital health systems. Scientists are improving them using nanomaterials and better electrodes, so they may become as good as chips in the future.

5.5 Complementary Roles of the Two Platforms

This study showed that microfluidic chips and wearable biosensors can work together. Chips are perfect for correct testing in hospitals, and wearables are good for home checks or village areas. Together they can make HBV testing easier and faster, helping doctors and health workers reach more people.

5.6 Operational Considerations

Both tools have practical points. Microfluidic chips need a small blood sample and a trained person to read results, which can be hard in small areas. Wearable biosensors are easy to use but depend on how much a person sweats. Cost also matters - wearables cost 2-3 USD and chips cost 4-6 USD per test. Even though chips cost more, they give fewer wrong results, so they save money in the long run.

5.7 Study Strengths and Limitations

This study is one of the first to compare both tools using real patient samples. It followed clear methods and checked real-life use, not just lab accuracy. But it also had limits - only 200 samples were tested in one place, and the wearable biosensor used was a prototype. Since chips test blood and wearables test sweat, the fluids differ a bit. Also, the study did not check how long wearables last or if people like wearing them for a long time.

5.8 Future Directions

Future studies should test these tools in more areas with more people. Scientists can try to make hybrid devices combining both systems and add AI (artificial intelligence) to improve speed and reduce errors. They should also study cost and use in poor countries. Microfluidic chips can be used in clinics for exact diagnosis, and wearables for regular checking in villages. Together, they can help reach global goals for early HBV detection and lower liver disease.

5.9 Conclusion of Discussion

In short, microfluidic chips are very correct and good for clinics, while wearable biosensors are simpler, cheaper, and useful for daily checking. When both are used together, doctors can give better and faster care. This teamwork helps make HBV testing safer, easier, and available for everyone.

6. CONCLUSION

This study compares two new point-of-care tools - microfluidic chip systems and wearable biosensors - used to find the hepatitis B virus (HBV). The study found that microfluidic chips work very well and give very correct results. Their sensitivity and specificity are almost the same as big lab machines. These chips can find very tiny virus amounts quickly using only a small drop of blood, making them useful for hospitals and clinics. Wearable biosensors were not as perfect as chips but had other strong points. They are easy to carry, do not need needles or big machines, and can connect with mobile apps to check the body for a long time. This helps people in villages or faraway areas where hospitals are few. However, some problems like sweat changes, low sensitivity at small virus levels, and electrochemical part issues still need fixing. The study says both tools can work together. Microfluidic chips are better for first tests and early doctor action, while wearable biosensors are good for later check-ups and large testing. Together, they help from early testing to easy home follow-up. In real use, microfluidic chips may need small machines and trained people but give steady results in hospitals. Wearable biosensors are cheaper and simpler for home or school use, but their limits should be handled carefully.

In the end, microfluidic chip systems look very promising for better HBV testing, and wearable biosensors can make testing easier and faster. Using both together can help doctors act early and support the world's goal to end hepatitis B forever..

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