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Article

Research on a Monitoring System for Catheter-Associated Urinary Tract Infection Warning

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Abstract: Catheter associated urinary tract infection (CAUTI) is one of the most common hospital acquired infections in hospitalized patients, and a large number of patients face prolonged hospitalization or even life-threatening every year. The current clinical monitoring methods mainly include urine test paper detection, spectral analysis, inflammatory markers detection and so on. Each monitoring method has its obvious advantages and limitations. This paper systematically reviews the biological logic of urinary tract infection, and proposes a conceptual framework of CAUTI monitoring system that integrates the detection of bacterial biomarkers and host inflammatory biomarkers. This study can provide support for the early warning of clinical urinary tract infection, help medical staff to make reasonable judgment based on the patient's symptoms, medical history and catheter indwelling time, select the appropriate antibiotics, and improve the efficiency of catheter care.

Keywords: Catheter-associated urinary tract infection (CAUTI); biomarker monitoring; asymptomatic bacteriuria; inflammation

1. Introduction

1.1. Research Background

Urinary tract infection (UTIs) is a serious challenge in the field of health care, affecting 150million people worldwide [1]. Among them, 80% of the infections are related to the use of urinary catheters, namely catheter-related urinary tract infections (CAUTIs) [2]. Most patients with long-term indwelling catheter are at risk of CAUTI. When using a catheter, bacteria adhere to the surface of the catheter and form a biofilm, which makes bacteria grow in a large number in a stable environment. At present, the common CAUTI detection method used by the hospital is urine sample analysis or test paper detection, but this detection is only carried out after the patients have clear clinical physical symptoms, and some groups' early symptoms do not appear, which will delay the bacterial reproduction and lead to the deterioration of the disease [3]. In addition, urinalysis takes a long time. If medical staff widely use broad-spectrum antibiotics, it will accelerate the drug resistance of antibiotics.

1.2. Research Significance

At present, hospitalized patients need a CAUTI monitoring system that can relieve their pain. However, current studies focus more on single microbial detection or judgment of the cause of inflammation. This paper proposes an ideal CAUTI monitoring system for hospitalized patients. The system uses immunosensors and capture probes and other tools to detect host inflammatory biomarkers (such as interleukin-8) and bacterial pathogens. It has the advantages of high accuracy, fast output and low cost. Theoretically, this study provides a theoretical basis for clinical monitoring of CAUTI. At the same time, the system uses biosensors to detect signals, which promotes the combination of bioengineering and information science. In practice, the monitoring system

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can reduce the pain of hospitalized patients using catheter, provide objective decision support for clinicians more quickly, and implement accurate treatment plan in time.

2. Development of CAUTI Monitoring System

2.1. Traditional Manual Urinalysis and Point-of-care Urine Dipstick

Urine is collected, usually via midstream clean-catch void. The clinician will complete a visual check on urine's color and clarity, cloudiness can indicate infection [4]. The dipstick test is then carried out by spotting the urine onto a dipstick. This allows comparison of color change to standard references to deduce levels of different substances, such as leukocyte esterase that indicates active immune response, nitrites produced by bacteria, pH, protein molecules, glucose, and hemoglobin. Urine is then also spun in a centrifuge and sediment viewed to confirm the presence of substances. This is often used for rapid screening to evaluate whether a follow-up diagnostic test needs to be implemented. Benefits and flaws to be improved are shown in Table 1.

Table 1. Advantage and Disadvantage of Traditional Method

Advantage	Disadvantage
Urine dipsticks are affordable	The color change of the test strip is judged subjectively by humans, which may lead to inaccurate results
The test strips and urine analysis results are obtained quickly	The false positive rate is relatively high

2.2. Bacterium Identification via Urine Culture

A sterile sample of urine is collected using a syringe from a sampling port to be put on an agar plate. This is put in an incubator with suitable conditions for 24–48 h. If bacteria are present, they will take in nutrients to form colonies. The data on the type of bacteria growing and colony-forming units per millimeter will be collected, and having a value of greater than or equal to 105 CFU/mL with no more than two unique species of bacteria present, alongside clinical symptoms, will help confirm infection [5]. This is often implemented after a temporal screening test that indicates positive results. Benefits and flaws to be improved are shown in Table 2.

Table 2. Advantage and Disadvantage of Urine Culture

Advantage	Disadvantage
It exhibits high specificity and can indicate the precise genus of bacteria	It takes a long time to obtain results
Antibiotic resistance can be avoided	It cannot distinguish between active, tissue-invasive infections and harmless colonization

2.3. Spectroscopic Method to Distinguish Infected and Healthy Urine

A non-invasive spectroscopic method has also been studied to determine the presence of infection. It utilizes measurements of fluorescence spectroscopy and transmittance to measure scattering due to bacteria. It indicates that results can be available in 60–120 s. Benefits and flaws to be improved are shown in Table 3.

Table 3. Advantage and Disadvantage of Spectroscopic Method

Advantage	Disadvantage
The detection speed is faster than that of strip tests, and the results are more objective	This method has not been used in an active clinical setting yet
The accuracy rate is as high as 90.2% [6]	Its cost is relatively high, and it can only detect infections

2.4. Inflammatory Biomarker Tests

A urine sample is collected from the patient using standard sterile techniques, and it's centrifuged to remove cellular debris. The concentration of the biomarker cytokine interleukin-8 (IL-8), associated with immune response, is then measured using an immunoassay, enzyme-linked immunosorbent assay (ELISA). The presence of IL-8 indicates an inflammatory response [7]. The biomarker present will bind to the coated antibodies and is combined with another antibody. At last, the solution is reacted with an enzyme to produce a colored product, where intensity correlates with the concentration of the substance. Benefits and flaws to be improved are shown in Table 4.

Table 4. Advantage and Disadvantage of Inflammatory Biomarker Tests

Advantage	Disadvantage
This test boasts extremely high sensitivity and is accurate in identifying infections	This biomarker is not specific to CAUTIs
It has the potential to yield quick results	The clinical data demonstrating its effectiveness is limited

2.5. Magneto-Agglutination Biosensor System for Detection of Bacteria

This is a system that consists of an instrument and a low-cost, multi-channeled disposable cartridge. The channels are pre-loaded with dried paramagnetic particles coated in antibodies specific to the target bacteria's cell walls. These antibodies are complementary to bacterial cell walls, including Proteus and Escherichia coli. When a urine sample with bacteria flows through the channel, the dried layer is dissolved. Then large paramagnetic particle (PMP) agglutinates are formed. These complexes are then pulled through a fluctuating magnetic field. They alter the electromagnetic field of a sensor coil and generate a voltage trace. Bacteria present give large, dipping voltage curves [8]. Benefits and flaws to be improved are shown in Table 5.

Table 5. Advantage and Disadvantage of Biosensor System

Advantage	Disadvantage
It is highly effective in detecting early CAUTIs	This biomarker is not specific to CAUTIs
It has the potential to yield quick results	It can identify specific bacteria in urine samples and output the results within 7 min [8]

3. Theory Basics and Logic

3.1. Biological Basis of CAUTI Development

Catheter related urinary tract infection is developed through a series of biological events, rather than immediately after catheter insertion. The bacteria in the patient's own flora may migrate along the outside of the catheter and form a protein coating on its surface, and the bacteria will adhere to the catheter. Subsequently, biofilm will form on the surface of the catheter, which is a protective layer that can protect bacteria from antibiotics, host immune cells and mechanical scouring of urine. Under these conditions, bacteria can reproduce and grow safely. When bacteria invade tissues and trigger immune response, it will lead to the release of cytokines such as interleukin-8 (IL-8) and the accumulation of neutrophils, leading to clinical symptoms such as fever [2]. However, bacterial colonization does not necessarily mean infection. Asymptomatic bacteriuria may occur. There are a large number of bacteria in the urethra and biofilm, but because they will not invade or cause a strong immune response, infection symptoms will not occur. Therefore, diagnosis may be delayed only by clinical symptoms, and harmless colonization and active infection cannot be distinguished only by bacterial detection.

3.2. Dual Biomarkers Working Mechanism

The fundamental limitation of current CAUTI monitoring methods lies in their focus on either bacterial detection or host inflammatory responses independently. Yet, the combination of bacterial and inflammatory biomarkers provides complementary diagnostic information. One confirms microbial colonization by detecting bacterial enzymes or cell wall; the presence of bacteria can be confirmed. Another confirms the active response. Both positive results give stronger evidence of active infection than either indicator alone. This approach enables differentiation between asymptomatic bacteriuria and CAUTI. This prevents over-prescription of antibiotics, avoiding the development of resistance to be developed and over-testing, avoiding the waste of medical resources. The workflow diagram of dual biomarker is shown in Figure 1.

3.3. Clinical Decision Logic

To meet NHSN/CDC Catheter-Associated Urinary Tract Infection surveillance criteria, a patient must meet strict clinical thresholds. This is utilized when a patient develops a UTI while an indwelling urinary catheter is in place or has been removed within the past two calendar days. During the 7-day infection window period, cases must meet all of the following criteria, as shown in Table 6.

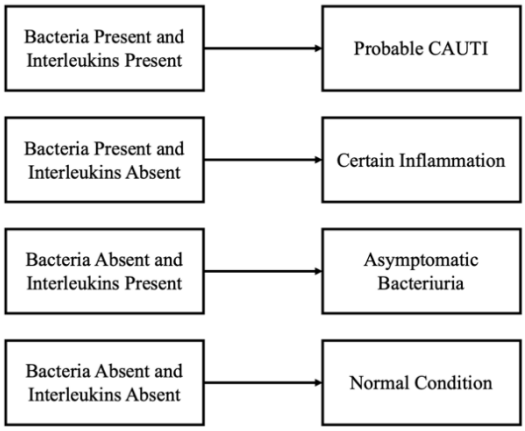


Figure 1. Dual Biomarker Working Logic Flowchart.

Table 6. Clinical criteria.

Catheter Presence	An indwelling urinary catheter was in place for more than 2 consecutive days on the date of event, or the day before
Clinical Symptoms	Adults: Fever > 100.4 °F (>38 °C), suprapubic tenderness, urinary urgency, frequency, or dysuria (the last three not to be used if a catheter is still in place) Children: Fever, lethargy, or vomiting
Laboratory Criteria	A positive urine culture yielding not more than 2 species of organisms, where at least one bacterium is present in high quantities (≥105 CFU/mL)

It can be deduced that symptoms are key to differentiating actual catheter-associated urinary tract infections and asymptomatic bacteriuria (ASB) [9]. Therefore, although dual-biomarker monitoring provides more comprehensive biological information than existing approaches, biomarker detection alone shouldn't replace clinical judgement. Instead, the monitoring system should function as an early warning tool that continuously evaluates urinary biomarkers and notifies healthcare professionals when standards are exceeded. After an alert, clinicians should integrate the results with patient symptoms, medical history, catheter duration, urine culture findings, and establish a final judgement.

4. Design Framework for an Ideal Monitoring System

A comprehensive and efficient system should be able to distinguish between asymptomatic bacteriuria and actual inflammatory responses, identify and quantify pathogens, produce results in a short timeframe, while being cost-effective, and ultimately support clinical decision-making.

4.1. Multi-Biomarker Dual-Sensing for Differentiating ASB and Inflammation

The main obstacle to prevent over diagnosis of CAUTI is to distinguish between asymptomatic bacteriuria (ASB), that is, bacteria colonize the catheter surface without causing tissue damage, and immune response of active host. A single parameter cannot make this distinction. The ideal monitoring system should adopt the strategy of multiple biomarkers and dual sensors, and simultaneously collect the signals of pathogen and host on the same platform. Host and pathogen detection results are shown in Table 7.

Table 7. Host and pathogen detection.

Host inflammatory biomarker detection	The system will integrate local electrochemical or optical immunosensors targeting host immune indicators, especially interleukin-8 (IL-8), prostaglandin E2 (PGE2) and leukocyte esterase [10]. Elevated levels of these markers indicate host tissue damage and neutrophil recruitment within the bladder epithelium. These are typical manifestations of immune response.
Bacterial pathogen detection	The system will use immobilized capture probes for surface antigens (such as lipopolysaccharide (LPS) of Gram-negative bacteria), nitrites produced by bacteria or universal bacterial cell surface proteins to measure the total bacterial load, so as to confirm the existence and quantity of microorganisms.

Finally, electrochemical impedance spectroscopy (EIS) or surface plasmon resonance (SPR) technology is used to comprehensively analyze the signal, so as to calculate the infection index [11]. The presence of high bacteria is accompanied by low host inflammatory markers to produce ASB alarm, and immediate use of antibiotics is not required. On the contrary, the simultaneous rise of biomarkers of host and pathogen triggers CAUTI warning. This allows reporting of bacterial related infections to healthcare professionals to distinguish between bacteriuria and possible infections.

4.2. Identify and Quantify Pathogens

The identification and quantification of pathogens are the key steps for achieving precise early warning of CAUTI. Traditional urine culture takes at least 24 to 72 h to obtain results. Some bacteria cannot grow due to the limitations of culture conditions, which will lead to missed detection. In an ideal monitoring system, microfluidic "lab on chip" channels will be used to process low volume urine, which can replace the traditional quantitative threshold (≥103 cfu/mL or ≥105 cfu/mL). In order to measure the impedance change proportional to the total microbial load, the detection system is equipped with a microfluidic channel with a gold-plated microelectrode array. This impedance change is concentration dependent. In addition, in order to identify and distinguish strains, the system will use different functional sub reactors of the sensor, which contain DNA probes or specific monoclonal antibodies against common urinary tract pathogens (such as Escherichia coli). Therefore, the system can detect the number and species of bacteria, and provide the basis for clinical judgment of infection type and selection of corresponding antibiotics.

4.3. Rapid Signal Processing for Fast Output and Low-Cost Manufacturing

The ideal monitoring system ultimately needs to produce test results quickly and can be widely used in clinic. Fast signal processing can achieve the timeliness of the result output. When bacteria or inflammatory markers specifically bind to the capture probe on the sensing interface, it will immediately cause changes in electrical parameters such as surface potential, charge transfer resistance or impedance, which can be captured by the transducer and converted into a readable signal at the moment of binding. Through EIS biosensor, the impedance spectrum is fitted, de-noising and feature extraction by using fast signal processing algorithm, and the system can output quantitative detection results in about 5 min [12]. At the same time, in order to make the system widely used in clinic, the whole system must maintain cost-effectiveness and prevent financial pressure on the health care system. Medical staff should use lower cost materials to build such a system to maximize efficiency and minimize costs.

5. Conclusions

In conclusion, catheter-related urinary tract infection is an important challenge for hospitalized patients. Bacterial colonization in the catheter can gradually develop into infection, which is difficult to distinguish from asymptomatic bacteriuria. The current detection methods of urinary tract infection mainly include artificial urine analysis, instant urine test paper, spectral method and inflammatory biomarker detection, and each method has its advantages and disadvantages. Based on the biological logic, this paper proposes an ideal CAUTI monitoring system. The system uses microfluidic sensing, electrochemical impedance spectroscopy, immunosensor and capture probe technology and equipment to detect bacterial biomarkers and host inflammatory biomarkers, and judge urinary tract infection by bacterial number, pathogen identity and inflammatory biomarker level. This system can be used as a CAUTI early warning and clinical decision support tool to quickly and accurately detect urinary tract infection, and urge health care professionals to consider patients' symptoms and make reasonable clinical decisions.

However, due to the limited experimental conditions, the system has not yet been developed. In the future, a monitoring system can be established to verify the sensor performance in a diversified large-scale patient population, and determine the reliability of detecting combined biomarker signals to distinguish CAUTI from asymptomatic bacteriuria.

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Conflicts of Interest

The author declares no conflict of interest.

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