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Review

Clinical Effectiveness and Impact on Health Outcomes of a Wearable Monitor for Urinary Bladder Stones: A Scoping Review and RCT

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Abstract: Background: Urinary bladder stones affect millions worldwide, yet current management relies on episodic imaging that fails to provide real-time disease monitoring. Wearable infrared extracorporeal non-invasive monitors (WIENMs) represent a potential paradigm shift toward continuous, patient-centered care, but evidence regarding their clinical effectiveness remains fragmented and underexplored.

Objective: This study aims to evaluate the clinical effectiveness and health outcomes of the Extracorporeal Bladder Stone Monitor (E.B.S.M.), a novel wearable device employing mid-infrared spectroscopy (750-2500 nm) for continuous, non-invasive bladder stone monitoring, compared to standard care.

Methods: A mixed-methods design comprising a scoping review and a 12-month randomized controlled trial across five countries (Nigeria, Bangladesh, China, Kenya, United Kingdom). The scoping review will systematically map existing evidence using Arksey and O'Malley's framework, searching PubMed, Scopus, Web of Science, and grey literature. The RCT will randomize 250 adults with confirmed bladder stones 1:1 to receive WIENM plus standard care or standard care alone. Primary outcomes include spontaneous stone passage rate, diagnostic accuracy (sensitivity/specificity), quality of life (I-QOL, UDI-6), and healthcare utilization. Secondary outcomes include adherence, usability, and barriers to clinical integration, analyzed using the Technology Acceptance Model (TAM).

Results: The scoping review confirms a critical evidence gap, with few direct studies on infrared-based stone monitoring but promising evidence for optical sensing principles. The RCT hypothesizes significantly higher stone passage rates (15-25% absolute increase), improved quality of life scores, 40-60% reduction in follow-up imaging, and 30-50% reduction in unplanned emergency visits in the intervention group. Barriers will include device adherence, EHR integration, and workflow alignment.

Conclusion: This comprehensive evaluation will provide foundational evidence for WIENM technology, potentially transforming bladder stone management from reactive,

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episodic interventions to proactive, continuous, data-driven care. The findings will inform regulatory approval, clinical adoption, cost-effectiveness analysis, and future research in digital urological health.

Keywords: Wearable medical device; bladder stones; infrared spectroscopy; non-invasive monitoring; randomized controlled trial; scoping review; digital health; urology; technology acceptance

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Introduction

Urinary bladder stones, a common urological condition affecting millions worldwide, contribute to significant morbidity and healthcare expenditure. Prompt and effective management of these stones is critical to reducing complications such as recurrent infections, hematuria, and obstructive uropathy. Technological advancements in non-invasive diagnostic and therapeutic tools, particularly wearable medical devices, have revolutionized patient care, offering real-time monitoring and targeted interventions. Among these, wearable infrared extracorporeal non-invasive monitors (WIENMs) have gained attention for their potential to improve diagnosis accuracy and treatment outcomes without subjecting patients to invasive or resource-intensive procedures.

Urinary bladder stones, comprising crystallized minerals formed in the bladder, pose a significant health challenge worldwide, particularly among populations with limited access to advanced medical care. The conventional management of bladder stones often relies on invasive procedures, such as cystolithotripsy, which can lead to complications, longer recovery times, and increased healthcare costs. Current non-invasive monitoring methods primarily rely on imaging techniques, which may not adequately provide real-time physiological data to inform treatment decisions.

The bladder is a muscular membrane organ that has the function of storing urine produced by the kidneys. The typical volume that the adult human bladder can support, before the urge to empty the bladder occurs, is estimated to be between 300 and 500 mL (Perez et al., (2022) and Jo et al (2021). Bladder monitoring is the process of measuring and assessing the function and health of the bladder. It is an essential aspect of urological care, as it allows healthcare professionals to evaluate the bladder’s ability to store and empty urine and to detect abnormalities or problems that may be present Semproni,et al.,(2022).

Bladder monitoring, including urinary incontinence management and bladder urinary volume monitoring, is a vital part of urological care. Urinary incontinence is a

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common medical condition affecting the quality of life of more than 420 million people worldwide, and bladder urinary volume is an important indicator to evaluate the function and health of the bladder. Previous studies on non-invasive techniques for urinary incontinence management technology, bladder activity and bladder urine volume monitoring have been conducted. This scoping review outlines the prevalence of bladder monitoring with a focus on recent developments in smart incontinence care wearable devices and the latest technologies for non-invasive bladder urine volume monitoring using ultrasound, optical and electrical bioimpedance techniques. The results found are promising and their application will improve the well-being of the population suffering from neurogenic dysfunction of the bladder and the management of urinary incontinence. The latest research advances in bladder urinary volume monitoring and urinary incontinence management have significantly improved existing market products and solutions and will enable the development of more effective future solutions.

Urinary incontinence (UI) management and bladder urinary volume (BUV) monitoring are two important aspects of urological care. UI, or the loss of control over urinary function, can have a significant impact on the quality of life (QoL) of those who suffer from it. Accurate and reliable diagnosis and UI management is essential for improving patient outcomes Hu et al.,(2019) & DeMaagd et al (2012). BUV monitoring, on the other hand, assesses bladder function and health by measuring the bladder's capacity for storing and voiding urine, thereby enabling the identification of deviations or issues that may exist Jo et al (2021) and Molavi et al.,(2013).

There are various bladder monitoring methods, including invasive and non-invasive techniques for the diagnosis and management of a wide range of urological conditions, such as urinary incontinence, urinary tract infections, bladder cancer and voiding dysfunction. They can also be used in evaluating treatment efficacy and identifying potential alterations or adverse events during treatment Jo et al (2021) & Lenis et al.,(2019)

Existing research has highlighted the potential of wearable medical devices in managing urological conditions, with several studies demonstrating improved patient outcomes through enhanced monitoring and early intervention. For instance, wearable sensors have been successfully applied in tracking urinary flow dynamics and detecting bladder dysfunctions, showcasing their value in personalized care. However, the application of wearable infrared technology for bladder stone management remains underexplored.

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Preliminary investigations into WIENMs suggest promising benefits, including non-invasive stone localization and real-time monitoring of stone progression.

Background

Urinary bladder stone management has long been a challenge in urological care, shaped by historical reliance on invasive surgical interventions and conventional imaging techniques. The global rise in urinary stone prevalence, influenced by dietary changes, aging populations, and disparities in healthcare access, underscores the pressing need for alternative solutions. Historically, cystolithotripsy and other surgical methods were established as standard protocols for stone removal, reflecting advancements in medical instrumentation during the mid-20th century (Perez et al., 2022). However, these approaches often entail significant risks, including post-operative complications, extended recovery periods, and increased costs. The convergence of wearable technology and non-invasive infrared imaging offers a path forward, leveraging the benefits of real-time monitoring to address these limitations. Early applications of wearable devices in urology focused predominantly on urinary flow dynamics, yet evolving challenges in bladder stone management call for targeted and innovative interventions.

Pioneering studies have underscored the potential of wearable medical technologies to transform urological diagnostics and management. Early research explored wearable sensors designed for bladder volume monitoring, providing valuable insights into urinary dynamics and dysfunctions (Smith et al., 2018). More recently, the integration of infrared technology in such devices has enabled non-invasive assessment of physiologic parameters, such as tissue composition and blood flow (Chen et al., 2020). However, despite these advancements, existing tools remain limited in their ability to continuously track the progression of bladder stones or provide actionable data for personalized interventions. Notably, discrepancies in device accuracy and patient adherence have hindered widespread adoption, while variability in study methodologies has led to inconsistent evaluations of clinical efficacy (Rahman et al., 2021). These challenges highlight the necessity of focused research into wearable infrared monitors specifically designed for bladder stone management..

Recent advances in wearable infrared extracorporeal non-invasive monitors (WIENMs) have opened new avenues for addressing the critical gaps in bladder stone management. Unlike traditional imaging techniques which are episodic, resource-intensive, and often reliant on ionizing radiation WIENMs provide real-time, continuous monitoring

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without the need for frequent clinical visits. This capability has significant potential to transform patient care by enabling early detection of complications, such as stone growth or migration, which might otherwise necessitate invasive interventions. Promising pilot studies have demonstrated the ability of infrared-based devices to detect variations in tissue density and mineral composition, laying the groundwork for their application in bladder stone analysis (Patel et al., (2022). However, the translation of these early findings into routine clinical practice remains limited due to the absence of robust, large-scale evaluations. These evaluations must account for critical variables such as patient adherence, device integration into care workflows, and the comparative effectiveness of WIENMs against standard care approaches. In addition to their potential clinical utility, wearable infrared extracorporeal non-invasive monitors (WIENMs) align with broader healthcare trends emphasizing patient-centered care and digital health integration. The shift towards personalized medicine has provided fertile ground for the development of technologies capable of delivering tailored interventions based on real-time data. WIENMs, by offering continuous assessment of bladder stone characteristics such as size, composition, and positional changes, empower patients to actively participate in managing their condition. Moreover, the adoption of such devices could alleviate healthcare resource burdens by reducing reliance on costly imaging modalities and minimizing hospital visits, as highlighted in recent health systems optimization studies (Taylor et al., (2020). However, to realize these benefits, it is imperative to address challenges such as device usability, patient adherence, and disparities in access to these technologies across different populations.

The Technological Innovation: The Extracorporeal Bladder Stone Monitor (E.B.S.M)

Technological advancements in wearable medical devices have begun to revolutionize patient care. The Extracorporeal Bladder Stone Monitor (E.B.S.M) is a novel device that employs mid-infrared spectroscopy (750-2500 nm) to non-invasively monitor bladder stones from outside the body. Worn on the suprapubic region via an adjustable abdominal band, the device uses an array of infrared emitters and detectors to penetrate skin and soft tissues. It analyzes unique infrared absorption signatures to provide continuous, real-time data on:

- Stone Characteristics: Size (0.1mm resolution), approximate location, and composition (e.g., calcium oxalate, uric acid).
- Disease Progression: Daily growth rate monitoring (0.3mm precision) and treatment response.

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- Clinical Alerts: Early detection of complications like obstruction. This represents a fundamental shift from a reactive, episodic management model to a proactive, data-driven, and patient-centric strategy.

Rationale and Evidence

Preliminary investigations into wearable infrared monitors suggest promising benefits, including non-invasive stone localization and continuous monitoring (Patel et al., 2022; Smith et al., 2020). However, the application of this specific technology for bladder stone management remains underexplored and characterized by a fragmented evidence base. Existing studies exhibit significant variability in design, outcome mea sures, and patient populations, leading to inconsistent conclusions regarding efficacy, accuracy, and patient compliance. There is a substantial lack of synthesized knowledge regarding the clinical effectiveness (diagnostic accuracy, reliability, impact on treatment decisions) and the tangible impact on health outcomes (stone clearance, quality of life, healthcare utilization, cost-effectiveness) of the E.B.S.M. The Intervention: Extracorporeal Bladder Stone Monitor (E.B.S.M) – Detailed Technical and Clinical Profile. To provide context for evaluating the evidence, this section details the proposed intervention central to this review.

Device Concept and Core Technology

- Name: Extracorporeal Bladder Stone Monitor (E.B.S.M)
- Core Technology: Mid-Infrared Spectroscopy (750-2500 nm) with extracorporeal measurement.
- Principle: Infrared light emitted through the suprapubic skin interacts with underlying tissues. The unique absorption spectra of bladder stones (varying by composition) are detected, allowing for non-invasive characterization.
- Physical Design & Wearability
- Mounting: Adjustable abdominal band (3-6 inch circumference) with flexible infrared transducer array.
- Placement: Suprapubic region, targeted at the bladder dome.
- Comfort: Ergonomic design (<200g), hypoallergenic materials, pressure relief zones, and breathable fabric for 24/7 wear capability.

Technical & Clinical Specifications

- Detection Range: Stones 2-30mm in diameter.
- Accuracy: Size (±0.3mm for stones >5mm), composition classification (>95%).

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- Functions: Real-time tracking of stone size, location, growth rate (0.2mm detectable change), and treatment response.
- Safety: Power <500mW, integrated temperature monitoring, automatic shutdown, biocompatible materials.

Integration into Care

- Data Flow: Device → Bluetooth → Patient Smartphone App → Secure Cloud (HIPAA-compliant) → Clinician Dashboard / Electronic Health Record.
- Clinical Benefits (Proposed): Enables early intervention, personalized treatment plans, reduces patient anxiety, decreases reliance on episodic imaging, and potentially lowers overall healthcare costs.

Anticipated Significance and Impact

This scoping review is critically significant as it addresses a potential model shift in urological care. For Clinical Practice:

- ➢ It evaluates a move towards proactive, continuous management, which could improve patient safety and outcomes through timely interventions.
- ➢ For Healthcare Systems: It will synthesize evidence on the technology's potential for cost savings and resource optimization by reducing unnecessary imaging and emergency visits.
- ➢ For Research & Innovation: As a foundational map, it will identify key evidence gaps (e.g., need for long-term RCTs, cost-effectiveness analyses) to guide future high-quality studies necessary for regulatory approval and clinical adoption.
- ➢ For Public Health: It assesses a technology that could improve access to monitoring in resource-limited settings where bladder stones are prevalent but advanced imaging is scarce.

Statement of the Problem

Urinary bladder stones are a common and painful urological condition with a significant global burden, particularly affecting older men with bladder outlet obstruction and individuals in developing regions with nutritional factors. The current standard for diagnosing and monitoring bladder stones relies heavily on intermittent, resource-intensive imaging modalities such as ultrasound, plain radiography (KUB), or computed tomography (CT) scans. While effective for diagnosis, this episodic approach creates a critical clinical management gap: it fails to provide real-time, dynamic information on stone status between scheduled appointments.

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1. Delayed Intervention: Changes in stone size, position, or the onset of complications (such as obstruction or severe inflammation) can go undetected until the patient presents with an acute, often painful, crisis.

2. Suboptimal Treatment Planning: Without continuous data, clinicians cannot accurately assess factors like stone mobility or the response to conservative management (e.g., increased fluid intake, medications), potentially leading to less effective or unnecessarily invasive treatment decisions.

3. Patient Discomfort and Anxiety: The uncertainty of not knowing the status of their condition between scans can cause significant patient anxiety and reduce adherence to management plans.

4. Increased Healthcare Burden: The reactive nature of this management model can result in more emergency department visits, unplanned procedures, and higher overall costs. The emergence of a Wearable Infrared Extracorporeal Non-Invasive Monitor presents a potential paradigm shift. This technology promises to continuously and non-invasively monitor bladder stones, potentially providing real-time data on stone burden and characteristics. Such a device could empower clinicians to move from a reactive, episodic model to a proactive, data-driven management strategy.

However, the introduction of this novel technology is met with a substantial evidence gap. There is a lack of synthesized knowledge regarding its clinical effectiveness (e.g., its accuracy, reliability, and impact on treatment decisions) and its tangible impact on health outcomes (e.g., reduced stone-related events, improved quality of life, decreased need for invasive procedures, and cost-effectiveness). A comprehensive evaluation is necessary to map the existing evidence, identify the scope of research activity, and clarify the potential role of this monitoring technology in clinical practice.

Therefore, this scoping review seeks to address this problem by systematically mapping the available literature to evaluate the potential of wearable infrared extracorporeal monitoring for transforming the management of urinary bladder stones from an intermittent process to a continuous, patient-centric one.

1. General Objective:

To synthesize and evaluating the clinical effectiveness and impact on health outcomes of a wearable infrared extracorporeal non-invasive monitor compared to standard care in patients with urinary bladder stones.

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2. Specific Objectives

1. To assess the diagnostic accuracy of WIENM in identifying urinary bladder stones and monitoring their progression over time among bladder stone patient.

2. To assess its impact on patient-reported outcomes, including quality of life and pain scores on wearable infrared extracorporeal device among bladder stone patient.

3. To evaluate its effectiveness in reducing the number of required clinical visits and imaging studies on wearable infrared extracorporeal device among bladder stone patient.

4. To identify barriers and facilitators to the clinical integration of WIENMs, investigating aspects such as device usability, reliability, and alignment with existing workflows in urotherapy and stone management.

3. Research Questions:

1. What are the diagnostic accuracy of WIENM in identifying urinary bladder stones and monitoring their progression over time among bladder stone patient.
2. What is the effect of the monitor on patient quality of life and pain levels?
3. Does the use of the monitor lead to a reduction in unplanned clinical visits and diagnostic imaging?
4. What barriers and facilitators to the clinical integration of WIENMs, investigating aspects such as device usability, reliability, and alignment with existing workflows in urotherapy and stone management.

4. Hypotheses:

- H1: Patients using the wearable infrared monitor will have a significantly higher rate of spontaneous stone passage than those receiving standard care.
- H2: Patients using the monitor will report significantly better quality of life and lower pain scores.
- H3: The use of the monitor will be associated with a significantly lower number of unplanned clinical visits and imaging studies.
- H0 (Null Hypothesis): There will be no significant difference between the intervention and control groups for all primary and secondary outcomes.

Significance of the Study

This scoping review is critically significant as it addresses a model shift in urological care, moving from reactive, episodic management to proactive, continuous monitoring of urinary bladder stones. Its importance can be outlined for various stakeholders in the healthcare ecosystem:

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For Clinical Practice and Patient Care

1. Potential for a Paradigm Shift in Management: This study investigates a move away from the standard "wait-and-see" approach, which relies on intermittent scans, towards a data-driven, continuous monitoring model. This could revolutionize the management of chronic or recurrent bladder stones.
2. Improved Patient Outcomes and Safety: By enabling real-time tracking, the technology could lead to:

- Timely Interventions: Early detection of stone growth or movement could allow for intervention before complications like obstruction, infection, or acute renal colic occur.
- Personalized Treatment Plans: Clinicians could tailor therapies based on continuous data, optimizing the use of medical expulsive therapy or deciding on the optimal timing for elective procedures.
- Enhanced Patient Safety: Reducing the incidence of emergency presentations directly improves patient safety and comfort.

3. Empowerment and Improved Quality of Life for Patients: A wearable monitor could significantly reduce the anxiety and uncertainty associated with waiting for the next scan. Patients would have greater insight into their condition, fostering a sense of control and potentially improving adherence to fluid intake and dietary recommendations.

For Healthcare Systems and Economics

1. Cost-Effectiveness and Resource Optimization: The review will evaluate evidence related to the technology's economic impact. If effective, it could lead to substantial cost savings by:

- Reducing the number of unnecessary follow-up imaging studies (ultrasounds, CT scans).
- Preventing expensive emergency department visits and unplanned hospital admissions.
- Shifting complex procedures from an emergency setting to a planned, elective one, which is more efficient and has better outcomes.

2. Reduction in Healthcare Burden: Bladder stones contribute significantly to the urological workload. By enabling proactive management, this technology could help

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decongest urology clinics and emergency departments, freeing up resources for more complex cases.

For Public Health

1. Addressing a Global Health Issue: Bladder stones are more prevalent in developing countries due to dietary and socioeconomic factors. A low-cost, continuous monitoring device could have a profound public health impact in resource-limited settings where access to advanced imaging is scarce.

2. Promoting Preventive Medicine: This technology aligns with the global shift towards preventive and personalized medicine. It emphasizes early detection and continuous management over treating acute complications, leading to a healthier population overall. This scoping review is not merely an academic exercise. It represents a critical first step in evaluating a technology with the potential to transform patient experiences, improve clinical outcomes, generate significant healthcare efficiencies, and guide the future of urological innovation. The significance lies in its role as a catalyst for moving the management of urinary bladder stones into the era of digital, continuous, and patient-centered healthcare.

Scope of the Study

This scoping review is systematically bounded by the following parameters to ensure a comprehensive yet focused exploration of the available evidence:

1. Population

The study focuses on:

- Human adults (aged 18 years and older) diagnosed with or suspected of having urinary bladder stones.
- Studies involving patients with various stone compositions (e.g., calcium oxalate, struvite, uric acid) will be included.
- Studies focusing exclusively on renal (kidney) or ureteral stones without specific data on bladder stones will be excluded.

The core concept revolves around the wearable infrared extracorporeal non-invasive monitoring device and its clinical application:

- Technology: The review investigated studies describing the technical principles, feasibility, accuracy, and reliability of infrared-based extracorporeal monitors.
- Clinical Effectiveness: This includes outcomes such as: Diagnostic accuracy (sensitivity, specificity) compared to standard imaging

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- Ability to monitor stone burden, size, and progression ,Impact on clinical decision-making and treatment planning.

- Health Outcomes: These encompass: Patient-centered outcomes (quality of life, pain scores, satisfaction) ,Clinical outcomes (stone clearance rates, complication reduction), Healthcare utilization outcomes (hospital visits, procedural rates)
- Various clinical settings (urology clinics, primary care, emergency departments)
- Both inpatient and outpatient care environments
- High-income and low-middle-income country contexts
- Comparative contexts using standard monitoring approaches (ultrasound, CT, radiography)
- Limitations
- Devices using non-infrared technologies (e.g., ultrasound-based wearables)
- Monitoring devices for other urological conditions (BPH, urinary incontinence)
- Pure engineering or technical reports without clinical correlation
- Operational definition
- Wearable Infrared Extracorporeal Non-Invasive Monitor: A device worn on the skin over the bladder that uses infrared light to detect stones from outside the body without any internal probes or breaks in the skin.
- Urinary Bladder Stones: Crystalline masses located in the bladder, confirmed by standard imaging like ultrasound or CT scan.
- Clinical Effectiveness: The device's real-world performance, measured by its accuracy (sensitivity/specificity), reliability (consistency of readings), and feasibility (ease of use and patient adherence).
- Impact on Health Outcomes: The measurable changes resulting from device use, including improved patient quality of life, reduced stone-related complications, and decreased healthcare utilization (e.g., fewer ER visits and surgeries).
- Managing Urinary Bladder Stones: The clinical process of diagnosing, monitoring, and informing treatment decisions for bladder stones using data from the device.
- Scoping Review: A systematic research method that maps the existing literature on a topic to identify the volume, nature, and key concepts of the available evidence.

Literature Review

Conceptual framework

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The management of urinary bladder stones has traditionally relied on episodic diagnostic imaging techniques, such as ultrasound and computed tomography (CT) scans, which prioritize precision in identifying the presence and immediate characteristics of stones. While effective for diagnostic purposes, these methods fall short in capturing the temporal dynamics of disease progression, including growth, migration, and changes in stone composition over time. This intermittent approach inherently limits clinicians' ability to adopt a proactive management strategy, often leading to delayed interventions that could exacerbate morbidity or necessitate emergency care. Furthermore, conventional imaging protocols may require repeated exposure to ionizing radiation or the use of invasive procedures, compounding patient discomfort and potential health risks. These limitations highlight the unmet need for a continuous, non-invasive, and patient-centered monitoring system capable of delivering real-time insights into urinary bladder stone progression.

Recent advancements in digital health technology, particularly the development of wearable medical devices, present a promising avenue for addressing these critical shortcomings. Wearable infrared extracorporeal monitors, which leverage non-invasive optical imaging to assess bladder stone characteristics, offer potential solutions by enabling real-time, longitudinal monitoring while minimizing patient burden. Early studies suggest that such devices can enhance patient adherence to preventive measures, reduce anxiety associated with episodic diagnostics, and foster a more active role in disease management. However, despite their promise, the clinical effectiveness and broader health outcomes associated with these technologies remain inadequately explored. Existing studies are often constrained by methodological inconsistencies, variability in patient selection criteria, and insufficient data on long-term health impacts, such as reduced surgical interventions or improved quality of life. Moreover, the economic and operational feasibility of integrating such devices into diverse healthcare systems especially in resource-constrained settings has not been comprehensively evaluated.

These gaps underscore the need for a comprehensive and systematic evaluation of wearable infrared extracorporeal monitors, particularly in the context of managing urinary bladder stones. A robust framework is required to assess not only their clinical effectiveness but also their impact on multidimensional health outcomes, including patient empowerment, healthcare cost reduction, and scalability across different patient populations and healthcare environments. This study seeks to address these critical research gaps by conducting a scoping review aimed at synthesizing current evidence and identifying key

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areas for future investigation. Another critical dimension demanding attention is the long-term integration of wearable infrared extracorporeal monitors into existing clinical workflows and healthcare infrastructures. While these devices hold substantial promise for revolutionizing urological care, their adoption necessitates an alignment with established diagnostic and therapeutic protocols.

The tension between traditional episodic imaging modalities and the need for real-time, patient-centered care in managing urinary bladder stones emerges from distinct paradigmatic perspectives on health monitoring. Conventional diagnostic methods, grounded in biomedical positivism, prioritize accuracy and immediate clinical applicability through technologies like ultrasound or CT scans (Perez et al., 2022). However, these approaches implicitly assume that intermittent assessments sufficiently capture disease progression, overlooking dynamic fluctuations in physiological conditions such as stone migration or growth. In contrast, the emergence of digital health paradigms, particularly through wearable medical devices, challenges this assumption by advocating for continuous, non-invasive monitoring as a means to empower patients and optimize clinical decision-making (Taylor et al., 2020). Yet, the epistemological shift from episodic to continuous monitoring is not without critique; while digital health technologies promise personalization and accessibility, they may inadvertently exclude vulnerable populations lacking access to such innovations. These theoretical divides have catalyzed methodological experimentation, prompting critical evaluation of how advancements in real-time, wearable health technologies can bridge these conceptual gaps.

Early methodological approaches to urinary bladder stone management predominantly focused on point-in-time imaging studies, such as ultrasound and computed tomography, which excel at diagnostic accuracy but fail to provide longitudinal data critical for dynamic disease monitoring (Perez et al.,2022). Recent innovations in wearable medical devices have shifted this paradigm, demonstrating the ability to continuously monitor physiological parameters without invasive interventions (Taylor et al., 2020). For example, initial trials have examined the accuracy of wearable bladder volume monitors, yielding promising results in improving patient-reported outcomes such as reduced anxiety and enhanced adherence to management plans (Rahman et al., 2021). However, the methodological heterogeneity across studies ranging from inconsistencies in sample sizes to variations in device protocols limits and comparative effectiveness evaluations. Worse, critical debates persist regarding the scalability of wearable technologies, especially in

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resource-constrained healthcare settings where cost and usability remain significant barriers. These unresolved issues necessitate a deeper exploration of wearable infrared extracorporeal solutions as a potential gold standard for bladder stone management.

The Urinary Bladder: Anatomy & Physiology

The urinary bladder is a hollow, muscular, and distensible (stretchable) organ that serves as a temporary reservoir for urine. Its anatomy can be understood in terms of its location, structure, and internal features (Merck Manual, 2023)

1. Location:

- In adults, the empty bladder is located within the pelvic cavity, posterior to the pubic symphysis.
- When full, it ascends into the lower abdominal cavity.
- In males, it rests between the pubic bone in the front and the rectum in the back.
- In females, it rests in front of the vagina and uterus (Merck Manual, 2023)
- Structure and Parts: The bladder is often described as having a pyramid-like shape when empty. Its main parts include:
- Apex: The pointed end pointing towards the top of the pubic symphysis. It is connected to the umbilicus by the median umbilical ligament.
- Body: The main, central part of the bladder, located between the apex and the fundus.
- Fundus (or Base): The posterior, triangular-shaped wall. This is a relatively fixed area.
- Neck: The inferior, funnel-shaped region that connects to the urethra. This is the most fixed part of the bladder and contains the internal urethral sphincter Olivia (2025)

2. The Trigone: This is a smooth, triangular area on the internal floor of the bladder. Its three points are formed by the two ureteral orifices (openings of the ureters) and the internal urethral orifice. The trigone is very sensitive to stretch and signals the need for urination (voiding). It is also a common site for infections.

3. Layers of the Bladder Wall (from inside out):

- Mucosa (Innermost Layer):
  - Epithelium: Composed of transitional epithelium (urothelium). This specialized tissue is capable of stretching and flattening as the bladder fills and empties, providing a barrier against the toxic effects of urine.

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- Lamina Propria: A connective tissue layer beneath the epithelium.
- Detrusor Muscle (Muscularis):
- This is the thick, muscular layer of the bladder wall, composed of smooth muscle fibers arranged in a complex, interlacing pattern. Its contraction is responsible for expelling urine during urination.
- Adventitia (Outer Layer): A fibrous connective tissue layer that covers most of the bladder(Merck Manual, 2025)

Physiology of the Urinary Bladder

The primary physiological functions of the bladder are urine storage and voluntary expulsion (micturition). This is a highly coordinated process involving the nervous system.

1. Filling and the Storage Phase (Accommodation)

- As urine drains from the kidneys via the ureters, the bladder expands. The bladder's folded internal lining (rugae) allows it to accommodate up to 400-600 mL of urine in healthy adults.
- The Detrusor Muscle is relaxed, allowing the bladder to accommodate increasing volumes of urine without a significant rise in internal pressure.
- The Internal Urethral Sphincter and the External Urethral Sphincter remain closed.
- Nervous Control: This phase is primarily mediated by the sympathetic nervous system (via the hypogastric nerve, T12-L2), which inhibits the detrusor muscle and stimulates the internal sphincter to remain closed.

2. The Micturition Reflex (Emptying Phase) Micturition is a complex reflex that can be voluntarily initiated or inhibited.

Step 1: Stretch Sensation As the bladder fills (typically around 200-350 mL), stretch receptors in the bladder wall are stimulated.

Step 2: Signal to Spinal Cord Afferent (sensory) impulses travel via the pelvic nerves to the sacral region (S2-S4) of the spinal cord.

Step 3: Spinal Reflex and Brain Coordination ;The signal is integrated in the sacral spinal cord and is also relayed to higher brain centers, which coordinate the process and provide voluntary control.

Step 4: Efferent Output for Voiding

- The parasympathetic nervous system is activated (via the pelvic nerve, S2-S4).
- This causes a strong, sustained contraction of the detrusor muscle.

Step 5: Voluntary Control

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- To void, the conscious brain sends signals to relax the external urethral sphincter (which is under somatic control via the pudendal nerve, S2-S4. Oliver (2025)

The concept of this pilot study is rooted in the integration of wearable technology with advanced medical imaging principles to offer a non-invasive solution to manage urinary bladder stones effectively. The wearable monitor employs infrared light to assess the physical and chemical properties of bladder stones through the skin, without the need for invasive procedures. This approach seeks to achieve multiple objectives simultaneously:

1. Real-Time Monitoring: By continuously assessing bladder stone characteristics, the wearable device aims to provide immediate feedback on changes in stone size or composition, which can guide timely intervention.

2. Patient Empowerment: Such technology encourages patient involvement in their care, allowing individuals to monitor their condition actively.

3. Reduction of Surgical Interventions: By enabling proactive management strategies, the device has the potential to reduce the need for invasive surgical procedures.

The Global Burden of Urinary Bladder Stones

Urinary bladder stones, comprising crystallized minerals formed within the bladder, are a common and painful urological condition affecting millions worldwide, particularly older men with bladder outlet obstruction and populations in developing regions (Perez et al., 2022). They contribute to significant morbidity, including recurrent infections, hematuria, obstructive uropathy, and substantial healthcare expenditure. The conventional diagnostic and monitoring paradigm relies heavily on intermittent, resource-intensive imaging modalities such as ultrasound, plain radiography (KUB), or computed tomography (CT) scans. While effective for initial diagnosis, this episodic approach creates a critical management gap by failing to provide real-time, dynamic information on stone status between appointments. This leads to delayed interventions, suboptimal treatment planning, patient anxiety, and increased healthcare burden from emergency visits and unplanned procedures.

Based on a comprehensive review of current literature, the specific burden of patients suffering from bladder stones, distinct from overall urolithiasis (urinary stones in general), is not widely reported in population-wide studies. Most major studies, like the Global Burden of Disease (GBD) reports, aggregate data for all urinary tract stones .

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However, a recent meta-analysis focusing on Sub-Saharan Africa provides the most direct estimate available for the proportion of urolithiasis patients who specifically have bladder stones, which can be applied to understand the regional and national burden.The following table synthesizes the available data on the global, African, and Nigerian burden, clearly distinguishing between overall urolithiasis and the specific subset of bladder stone cases.

Table 2: Showing Burden of Urolithiasis and Bladder Stones: Global and Regional Overview

Region/Country	Key Burden Metric	Data Point	Time Period	Primary Data Source & Notes
Global	Overall Urolithiasis	106 million new cases globally. Age-Standardized Incidence Rate (ASIR): 1,240 per 100,000 Akram,(2025)	2021	Global Burden of Disease (GBD) Study. The ASIR has declined since 1990, but total cases have risen due to population growth Zhang(2022)
Global	Bladder Stones (Subset)	Specific global percentage not found in GBD studies. Data is aggregated as "urolithiasis."	-	-
Sub-Saharan Africa (SSA)	Overall Urolithiasis (Hospital Prevalence)	Pooled prevalence: 9.4% (95% CI: 4.9–14%) among hospital-visiting patients.	Studies up to 2023	Meta-analysis of 26 observational studies across SSA. Shows significant regional variation (e.g., 28.1% in Mauritius, 1.0% in Eritrea) Kassaw (2024)
Sub-Saharan Africa (SSA)	Bladder Stones	2.0% of urolithiasis cases were specifically	Studies up to 2023	Same SSA meta-analysis. This is the key figure for

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	(Proportion of Cases)	bladder stones (95% CI: 0.7–3.4%).		estimating the bladder stone burden. Most stones were in the kidney (4.6%).
Nigeria (National Estimate)	Bladder Stones (Derived Estimate)	0.19% of hospital patients (Est. Range: 0.07% – 0.33%).	-	Derivation: Applying the SSA bladder stone proportion (2.0%) to the SSA urolithiasis prevalence (9.4%) gives an estimated 0.19% prevalence among hospital populations.
Nigeria (Local Study)	Overall Urolithiasis (Hospital Prevalence)	1.34% (13.4 per 1000) in a teaching hospital in Abuja.	2014-2015	Single-center, ultrasound-based study. Found 29% of detected stones were in the bladder Isaac(2018)
Nigeria (Local Study)	Bladder Stones (Local Proportion)	29% of detected urolithiasis cases were bladder stones.	2014-2015	Same Abuja study. This proportion is notably higher than the SSA average, highlighting local variability Isaac 2018).

Interpreting the Data and Insights

- The Bladder Stone Burden is a Subset: Crucially, bladder stones represent only a portion of all urinary stone disease. The SSA meta-analysis suggests about 1 in 50 urolithiasis patients in the region have a bladder stone. A Nigerian single-center study reported a much higher proportion (29%), indicating significant local variation in stone location likely influenced by diet, infections, and other factors.
- Limitations of the Data: The most specific bladder stone percentage comes from a hospital-based meta-analysis in SSA. This may not reflect the true prevalence in

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the general community, as it only captures people who seek care. Large-scale population studies like the GBD do not break down data by stone location.

- Gender and Age Disparities: Urolithiasis consistently shows a higher burden in males than females globally and in Africa. The working-age population (20-54 years) carries a significant and increasing proportion of the global stone burden.

Theoretical Frame Work

Technology Acceptance Model (TAM)

The Technology Acceptance Model (TAM) explains how users come to accept and use new technology, focusing on two core beliefs: Perceived Usefulness (will it help me?) and Perceived Ease of Use (is it simple to use?). These perceptions directly influence a user's Attitude Toward Use and their Behavioral Intention to Use, ultimately predicting actual technology adoption. Developed by Fred Davis in 1989, TAM is a foundational model in information systems, adapted from the Theory of Reasoned Action. Applying the TAM Framework to the E.B.S.M. Study

The TAM posits that two user perceptions drive the intention to use a new technology: Perceived Usefulness (PU) and Perceived Ease of Use (PEOU). The following table details what these constructs mean for your patient and clinician users.

Table 3: Showing Theoretical Review and Application

TAM Construct	Definition & Relevance to Your Study	Application to Patients Using the E.B.S.M.	Application to Healthcare Professionals Adopting the E.B.S.M.
Perceived Usefulness (PU)	The degree to which a person believes using the system will enhance their job performance or health outcomes.	Does the device provide meaningful, actionable data that helps them understand their condition, reduce anxiety, and feel empowered? Does it seem to lead to better health results (e.g., faster stone passage)?	Does the continuous data improve clinical decision-making, enable timely interventions, and optimize treatment plans (e.g., timing of surgery)? Does it save time and reduce the burden of managing stone disease?
Perceived Ease of	The degree to which a person	Is the abdominal band comfortable for 24/7	Is the clinician dashboard easy to navigate and integrated into

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Use (PEOU)	believes using the system will be free of effort.	wear? Is the smartphone app intuitive? Is the data presented in a clear, understandable way?	existing workflows (e.g., EHR)? Is the data from the device presented clearly to support quick clinical judgments?

Integrating TAM into Your Research Design

To robustly evaluate TAM factors, you can extend your Randomized Controlled Trial (RCT) and Scoping Review by incorporating specific, targeted assessments.

- For the RCT (Primary Data Collection): Add validated TAM-based survey instruments for patients in the intervention arm. These surveys should measure PU, PEOU, and Behavioral Intention to Use the device over time (e.g., at baseline, mid-trial, and study end). You can also conduct semi-structured interviews with a subset of patients and their treating urologists to explore qualitative insights on usability, trust, and integration into care.
- For the Scoping Review (Secondary Analysis): Systematically analyze the existing literature on wearable urological devices. Code and synthesize findings related to user acceptance, adherence rates, and reported barriers/enablers. This will contextualize your primary findings within the broader field.

Variables to Measure Based on Extended TAM

Healthcare studies often extend the basic TAM with context-specific variables. For a medical device like the E.B.S.M., you should also measure:

- Perceived Trust & Privacy/Security: Patients must trust the device's accuracy and the security of their health data.
- Facilitating Conditions: The availability of technical support and training for both patients and staff.
- Social Influence: The effect of recommendations from doctors or peers on a patient's decision to use the device

Empirical Review

To assess the diagnostic accuracy of WIENM in identifying urinary bladder stones and monitoring their progression over time among bladder stone patient.

Oren and Christiana (1999) studied the natural history of stone passage in patients with ureterolithiasis, and define factors predictive of spontaneous passage. A total of 75

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patients with ureteral calculi were prospectively followed for stone passage. Clinical data included patient gender and age, stone size and location, pain medication requirements and interval to stone passage. Of the 75 patients 13 (17%) required intervention and 62 (83%) were followed until spontaneous stone passage. Stones requiring intervention were not included in the time to passage analysis.

of the 75 patients 41 (55%) had ureteral stones 2 mm. or smaller with an average time to stone passage of 8.2 days and only 2 (4.8%) required intervention, 18 (24%) had stones between 2 and 4 mm. with an average time to stone passage of 12.2 days and 3 (17%) required intervention, and 16 had stones 4 mm. or greater with an average time to stone passage of 22.1 days and 8 required intervention. For 95% of stones to pass it took 31 days for those 2 mm. or less, 40 days for those 2 to 4 mm. and 39 days for those 4 to 6 mm. Multivariate analysis revealed that size, location and side were statistically related to stone passage interval ($p = 0.012$). Stones that were smaller, more distal and on the right side were more likely to pass spontaneously and required fewer interventions.

Interval to stone passage is highly variable and dependent on stone size, location and side. Degree of pain, and patient gender and age had no bearing on the time to stone passage. Of ureteral stones 95% 2 to 4 mm. pass spontaneously but passage may take as long as 40 days. Intervention may be required in 50% of ureteral calculi greater than 5 mm.

Ryan et al (2020) assessed the accuracy of patient reported outcomes for predicting spontaneous ureteral stone passage.

Patients with new unilateral ureteral calculi were prospectively assessed regarding current symptoms and whether they believed their stone had passed. The primary outcome was successful spontaneous stone passage as confirmed by ultrasound, and kidney, ureter and bladder x-ray. Spontaneous stone passage was compared to patient reported outcome responses to assess accuracy.

Of the 212 patients 105 (49.5%) had successful spontaneous stone passage at a mean followup of 17.6 days. Compared to the unsuccessful spontaneous stone passage group, those with successful spontaneous stone passage had significantly smaller (mean 5.4 vs 7.6 mm), more distal (71.4% vs 34.6%) stones with slightly longer average time to followup at first visit (19.2 vs 16.0 days). Additionally, there was more patient reported cessation of pain (77.1% vs 44.9%) and perceived stone passage (55.2% vs 13.1%) in this group. Cessation of pain was 79.7% (95% CI 67.1–89.0) sensitive and 55.8% (95% CI 44.0–67.1) specific for successful spontaneous stone passage. Likewise, patient reported

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stone passage was 59.3% (95% CI 45.7–71.9) sensitive and 87.0% (95% CI 77.4–93.5%) specific. In the multivariable logistic regression analysis cessation of pain (OR 4.02, 95% CI 1.91–8.47, p <0.01) and reported stone passage (OR 3.79, 95% CI 1.73–8.28, p <0.01) were independent predictors of successful spontaneous stone passage.

Cessation of pain and patient reported stone passage are independent predictors of successful spontaneous stone passage. However, both assessments may incorrectly gauge spontaneous stone passage, which raises concern for their validity as a sole clinical end point.

Mehmet, Seckiner& IIker (2020) opined in a study, the prototype artificial neural network model (ANN) was used to estimate the stone passage rate and to determine the effectivity of predictive factors on this rate in patients with ureteral stones. The retrospective study included a total of 192 patients with ureteral stones, comprising 128 (66.7%) men and 64 (33.3%) women. Patients were divided into two groups. Group 1 (n: 125) consisted of people who spontaneously passed their stones, Group 2 (n: 67) consisted of people who could not pass stones spontaneously. The groups were compared with regard to the relationship between input data and stone passage rate by using both ANN and standard statistical tests. To implement the ANN, the patients were randomly divided into three groups: (a) training group (n = 132), (b) validation group (n = 30), and (c) test group (n = 30). The accuracy rate of ANN in the estimation of the stone passage ratio was 99.1% in the group a, 89.9% in the group b, and 87.3% in the group c. It was revealed that certain criteria (stone size, body weight, pain score, ESR, and CRP) were relatively more significant for saving treatment cost and time and for avoiding unnecessary treatment. ANN can be highly useful for the avoidance of unnecessary interventions in patients with ureteral stones as it showed remarkably high performance in the estimation of stone passage rate (99.16%). Retrospectively 392 consecutive patients with ureteric stone on NECT were included. Three radiologists independently measured the stone size. Stone location, side, hydronephrosis, CRP, medical expulsion therapy (MET) and all follow-up radiology until stone expulsion or 26 weeks were recorded. Logistic regressions were performed with spontaneous stone passage in 4 weeks and 20 weeks as the dependent variable. The spontaneous passage rate in 20 weeks was 312 out of 392 stones, 98% in 0–2 mm, 98% in 3 mm, 81% in 4 mm, 65% in 5 mm, 33% in 6 mm and 9% in ≥6.5 mm wide stones. The stone size and location predicted spontaneous ureteric stone passage. The side and the grade of hydronephrosis only predicted stone passage in specific subgroups. Spontaneous passage

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of a ureteral stone can be predicted with high accuracy with the information available in the NECT. We present a prediction method based on stone size and location.

To assess its impact on patient-reported outcomes, including quality of life and pain scores using wearable infrared extracorporeal device among bladder stone patient.

Michelle et al(2016) Patient-reported outcome measures (PROMs) have increasingly been incorporated into clinical practice. Research suggests that PROMs could be viewed as active components of complex interventions and may affect the process and outcome of care. This systematic review examines PROMs in the context of treatment for non-malignant pain.

An electronic search on: MEDLINE, EMBASE, PsycINFO, PsycARTICLES, Cochrane Library and Web of Science identified relevant papers (February 2015). The inclusion criteria were: focused on implementing PROMs into clinical practice, adults, and primary data studies. Critical interpretive synthesis was used to synthesise qualitative and quantitative findings into a theoretical argument. Thirteen eligible studies were identified. Synthesis suggested that PROMs may be included in the initial consultation to assess patients and for shared decision-making regarding patient care. During the course of treatment, PROMs can be used to track progress, evaluate treatment, and change the course of care; using PROMs may also influence the therapeutic relationship. Post-treatment, using PROMs might directly influence other outcomes such as pain and patient satisfaction. However, although studies have investigated these areas, evidence is weak and inconclusive. Due to the poor quality, lack of heterogeneity of these studies, it is not possible to provide a comprehensive understanding of how PROMs may impact clinical treatment of non-malignant pain. The literature suggests that PROMs enable pain assessment, decision-making, the therapeutic relationship, evaluation of treatment and may influence outcomes. Further research is needed to provide better evidence as to whether PROMs do indeed have any effects on these domains.

According to Skolarikos et al (2010) All urinary stones may not need prompt active treatment. The study was to identify urinary stones that can be actively monitored safely. They performed a systematic review of the natural history and the role of active monitoring for urinary stones.

Thirty-seven studies have selected. Of symptomatic ureteral calculi <4 mm, 38% to 71% will pass spontaneously while only 4.8% of stones <2 mm will need intervention during surveillance. Follow-up with history, physical examination, urinalysis, and plain

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radiography every 2 weeks for 1 month is necessary. If spontaneous passage does not occur within this period, intervention is recommended. When shockwave lithotripsy for caliceal stones is prospectively compared with observation, there is no difference in stone-free rates (28% vs 17%), need for additional treatment (15% vs 21%), or visits to a general practitioner (18.5% vs 20.8%). Patients under observation may need more invasive procedures and may be more commonly left with residual stone fragments >5 mm (58% vs 30%). Isolated, nonuric acid calculi <4 mm may be most amenable to active monitoring. Physical examination, urinalysis, and CT scan performed on an annual basis up to year 2 or 3, followed by intervention, are recommended. Lower pole stones <10 mm could be actively monitored on an annual basis by alternating ultrasonoraphy with CT scan, provided the patients are adequately informed. Up to 58.6% and 43% of patients with residual fragments after shockwave and percutaneous lithotripsy, respectively, may become symptomatic or require intervention during follow-up. Noninfected, asymptomatic fragments, <4 mm postextracorporeal lithotripsy, and <2 mm postpercutaneous surgery could be followed expectantly on an annual basis, in combination with medical therapy. Active stone monitoring has a certain role in the treatment of patients with urinary stones. The success is largely dependent on the stone size, location, and composition, as well as the time after the diagnosis. Medical therapy is a useful adjunct to observation.

To evaluate its effectiveness in reducing the number of required clinical visits and imaging studies using wearable infrared extracorporeal device among bladder stone patient

Khetrapal, (2021) opined that Wearable devices (WDs) are an untapped resource for measuring patient health status during the peri-operative period. The overarching aim of this thesis is to explore the potential for WDs to be used in the clinical setting for patients undergoing radical cystectomy (RC) for bladder cancer. The lack of consensus regarding the optimal approach for RC presents an opportunity to design an RCT comparing open (ORC) and robotic (RARC) RC, in which a wearable device sub-study can be embedded. While the intracorporeal Robotic vs Open Cystectomy (iROC) trial will address the comparison between ORC and RARC, my thesis focuses on exploring the clinical utility of WDs. I present the results of a systematic review of RCTs comparing ORC and RARC. Meta-analysis shows no significant difference in peri-operative and oncological outcomes between ORC and RARC. Additionally, I systematically review healthcare studies using WDs and highlight the findings, device choices and device metrics used. Step-count is the most frequently collected WD metric, and chronic health conditions are the focus of

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majority of studies. Findings from these systematic reviews guided the design of the iROC trial protocol. I present the pre-planned interim analysis of the iROC trial, and explore associations between WD data and pre-operative health measures including cardiopulmonary exercise testing (CPET). Step-count correlates with the CPET variables ($p < 0.01$) routinely used to risk-stratify patients undergoing RC, and is the only predictor of major complications following RC in a logistic regression model. Finally, I evaluate recovery of baseline step-count at three months post-operatively as a predictor of overall survival. Applying a threshold of 50% recovery at 3 months, step-count predicts one-year survival to a sensitivity and specificity of 100% and 93% respectively. My findings highlight the potential of WDs in peri-operative care, and my post-doctoral work will progress this work further.

Kim et al., (2025) evaluates the clinical utility of emerging optical techniques-specifically, near-infrared spectroscopy (NIRS), optical coherence tomography (OCT), photoacoustic imaging (PAI), and fiber-optic sensors (FOSs)-as noninvasive, patient-friendly modalities for diagnosing lower urinary tract dysfunction. We assess their potential integration into wearable systems for personalized urological care and propose a novel clinical pathway for their use.

We included published studies employing optical modalities to evaluate bladder function or pathology, focusing on diagnostic accuracy, feasibility, and patient-related outcomes. We also examined technical principles, diagnostic performance metrics (e.g., sensitivity, resolution, penetration), and clinical validation across optical modalities. A total of 40 articles met the final inclusion criteria.

NIRS demonstrates >85% sensitivity for detecting detrusor overactivity in small-scale trials, with wearable devices enabling continuous bladder monitoring. OCT has been found to improve the detection of carcinoma in situ by up to 22% compared to white-light cystoscopy, although its shallow penetration (~2 mm) limits evaluation of deeper layers. PAI visualizes microvascular structures to depths of several centimeters, suggesting strong potential for noninvasive bladder tumor diagnosis. FOSs offer continuous intravesical pressure monitoring with reduced discomfort, although semi-invasive placement remains a limitation.

Noninvasive optical diagnostics offer a safer, more patient-friendly alternative to conventional cystoscopy and urodynamic studies. However, larger multicenter trials, cost-effectiveness analyses, and regulatory alignment are needed. Integrating these

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emerging modalities with telemedicine and artificial intelligence could transform bladder care into a continuous, home-based model.

In research by Byeong et al.,(2023) states, Current guidelines recommend clean intermittent catheterization (CIC) at regular time intervals for patients with spinal cord injuries; however, many patients experience difficulties. Performing time-based CIC outside the home is a significant burden for patients. In this study, we aimed to overcome the limitations of the current guidelines by developing a digital device to monitor bladder urine volume in real-time.The optode sensor is a near-infrared spectroscopy (NIRS)-based wearable device intended to be attached to the skin of the lower abdomen where the bladder is located. The sensor's primary function is to detect changes in urine volume within the bladder. An in vitro study was conducted using a bladder phantom that mimicked the optical properties of the lower abdomen. To validate the data in the human body at the proof-of-concept level, one volunteer attached the device to the lower abdomen to measure the light intensity between the first voiding and immediately before the second voiding. The degree of attenuation at the maximum test volume was equivalent across experiments, and the optode sensor with multiplex measurements demonstrated robust performance for patient diversity. Moreover, the symmetric feature of the matrix was deemed a potential parameter for identifying the accuracy of sensor localization in a deep-learning model. The validated feasibility of the sensor showed almost the same results as an ultrasound scanner, which is routinely used in the clinical field.

To identify barriers and facilitators to the clinical integration of WIENMs, investigating aspects such as device usability, reliability, and alignment with existing workflows in urotherapy and stone management.

Lola et al.,(2025) opined that Urinary incontinence affects approximately 7% to 10% of children during the day and 9% to 12% of children during the night. Treatment mainly involves lifestyle advice and behavioral methods, but motivation and adherence are low. Traditional tools such as pen-and-paper solutions may feel outdated and no longer meet the needs of today's "digital native" children. Meanwhile, digital interventions have already shown effectiveness in other pediatric health care areas.

This scoping review aimed to identify and map innovative, technology-driven, digital tools for managing pediatric urinary incontinence. PubMed, Web of Science, and the Cochrane Library were searched in March 2022 without date restrictions, complemented by cross-referencing. Studies were eligible if they focused on pediatric patients (aged ≤18

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years) with bladder and bowel dysfunctions and explored noninvasive, technology-based interventions such as digital health, remote monitoring, and gamification. Studies on adults, invasive treatments, and conventional methods without tangible tools were excluded. Gray literature was considered, but non–English-language, inaccessible, or result-lacking articles were excluded. A formal critical appraisal was not conducted as the focus was on mapping existing tools rather than evaluating effectiveness. Data analysis combined descriptive statistics and qualitative content analysis, categorizing tools through iterative coding and team discussions. In total, 66 articles were included, with nearly one-third (21/66, 32%) focusing on nocturnal enuresis. Our analysis led to the identification of six main categories of tools: (1) digital self-management (7/66, 11%); (2) serious games (7/66, 11%); (3) reminder technology (6/66, 9%); (4) educational media (12/66, 18%), further divided into video (5/12, 42%) and other media (7/12, 58%); (5) telehealth and remote patient monitoring (13/66, 20%), with subcategories of communication (5/13, 38%) and technological advances (8/13, 62%); and (6) enuresis alarm innovations (21/66, 32%), further divided into novel configurations (8/21, 38%) and prevoid alarms (13/21, 62%).

The field of pediatric urinary incontinence demonstrates a considerable level of innovation, as evidenced by the inclusion of 66 studies. Many tools identified in this review were described as promising and feasible alternatives to traditional methods. These tools were reported to enhance engagement, improve compliance, and increase patient satisfaction and preference while also having the potential to save time for health care providers. However, this review also identified gaps in research, highlighting the need for more rigorous research to better assess the tools' effectiveness and address the complex, multifaceted challenges of pediatric urinary incontinence management. Limitations of this review include restricting the search to 3 databases, excluding non–English-language articles, the broad scope, and single-reviewer screening, although frequent team discussions ensured rigor. We propose that future tools should integrate connected, adaptive, and personalized approaches that align with stakeholder needs, guided by a multidisciplinary, human-centered framework combining both qualitative and quantitative insights.

Jad et al (2024) reported that Stone management in urology has witnessed a dynamic evolution, transitioning from traditional open surgeries to minimally invasive techniques. This study meticulously compares the efficacy of minimally invasive stone removal with conventional available methods. A retrospective analysis utilizing clinical data from diverse hospital settings was conducted. Patient selection criteria encompassed

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stone size, location, and relevant clinical factors. Quantitative data on operative time, complications, success rates, and recovery durations were collected. Statistical methods were employed for data analysis, including T.tests and chi-square tests. Minimally invasive techniques exhibited significantly shorter operative times ($p < 0.001$) and lower complication rates ($p < 0.05$) compared to traditional approaches. Success rates were marginally higher in minimally invasive procedures ($p < 0.05$). Moreover, patients undergoing minimal invasive techniques experienced notably reduced hospital stays ($p < 0.001$) and enhanced post-operative recovery ($p < 0.05$).

Kristin et al.,(2020) stated in their study that, Intraoperative surgical outcomes are influenced by a wide variety of patient, surgeon and institutional factors. The current literature lacks comprehensive resources that describe best practices in preventing patient safety events and optimizing patient physiology during urological surgery.

A multidisciplinary panel of subject matter experts (urologists, nurses, anesthesiologists) was convened to evaluate the existing literature, create a white paper and disseminate this to urological providers. Focusing on intraoperative patient safety and physiology, a narrative review was undertaken and relevant guidelines and practical interventions were highlighted.

Patient safety is optimized by preventing surgical site infections, wrong site surgery, venous thromboembolism, falls/positioning injuries, laser/fire injuries, excessive radiation exposure and harm from the adoption of new technology. Goals for intraoperative physiological parameters (temperature, glucose, fluid balance) are addressed as well as analgesic and anesthetic considerations in urological patients. In addition, practical tools are provided to assist in the quality improvement process. This article summarizes intraoperative factors related to patient safety and optimal physiology that can impact urological surgical outcomes. This overview can be used as a practical guide for process improvement to optimize the quality of intraoperative care.

Methodology

Study Design

This research adopts a mixed-methods approach, employing both a randomized controlled trial (RCT) and a scoping review as its dual framework to comprehensively evaluate the clinical effectiveness, patient-centered outcomes, and integration feasibility of the wearable infrared extracorporeal non-invasive monitor (WIENM) in managing urinary bladder stones. The RCT component of the study is pivotal in quantitatively assessing the

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device's diagnostic accuracy, therapeutic effectiveness, and associated health outcomes compared to conventional management strategies such as imaging-based monitoring and surgical interventions. Randomization ensures the minimization of selection bias, enabling the generation of high-quality evidence that can be applied across diverse clinical scenarios. The study design incorporates longitudinal follow-ups for 12 months, with primary endpoints measured at baseline, three months, six and 12 months. These endpoints include diagnostic accuracy (sensitivity and specificity of WIENM in detecting bladder stones), therapeutic outcomes (stone progression or resolution), and patient-reported outcomes such as quality of life and satisfaction with their care. Secondary metrics will examine healthcare utilization patterns, including the frequency of clinical visits, imaging procedures, and emergency interventions for stone-related complications.

The scoping review complements the RCT by synthesizing and contextualizing existing knowledge on wearable medical devices, particularly those leveraging non-invasive infrared technologies. This qualitative dimension of the study will map the existing evidence base, identify critical gaps, and explore the broader implications of WIENM adoption, including its alignment with patient preferences and clinical workflows. Combining these two methodologies allows for a robust, multidimensional assessment of the intervention, ensuring that the findings are both clinically relevant and operationally actionable.

The RCT will follow a parallel-group design, with participants randomly assigned to either the intervention group, receiving WIENM for bladder stone management, or the control group, managed through standard care protocols. Stratified randomization will be employed to ensure balanced representation of key variables such as stone size, patient age, and comorbidities across study arms. Participants in the intervention group will wear the WIENM device continuously over the study period, with data transmitted to a centralized system for monitoring and analysis. The control group will receive routine urological care, including periodic imaging and follow-ups as deemed necessary by treating clinicians.

To complement the RCT, a scoping review will systematically synthesize existing literature on wearable devices for bladder monitoring, with a particular emphasis on WIENMs. The scoping review is designed to identify and explore patterns, gaps, and inconsistencies in the existing evidence base, providing context and background for the trial's findings. This scoping review adopt a systematic framework guided by Arksey and O'Malley's methodological approach for scoping reviews, incorporating subsequent

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refinements proposed by Levac et.,al (2025) and later adapted by the Joanna Briggs Institute (JBI). This structured approach involves five essential stages: (1) identifying the research question, (2) identifying relevant studies, (3) selecting studies based on predefined criteria, (4) charting the data, and (5) collating, summarizing, and reporting the results. These steps ensure a rigorous and systematic examination of the available evidence, while also allowing for iterative adjustments as insights emerge during the review process. This design emphasizes a comprehensive exploration of existing literature to map the breadth and depth of evidence regarding the clinical effectiveness and health impact of wearable infrared extracorporeal non-invasive monitors (WIENMs) in managing urinary bladder stones. The review aimed to synthesize diverse study types, capturing randomized controlled trials (RCTs), observational studies, and pilot evaluations to address the outlined objectives while ensuring methodological rigor. Given the heterogeneity in study methodologies and populations in the existing body of research, this design will prioritize inclusivity while maintaining analytical clarity through structured frameworks for data extraction and thematic synthesis. Furthermore, the scoping review will focus on identifying research gaps, providing a foundation for future studies to establish the feasibility, usability, and broader clinical implications of WIENMs. Implementation of transparent and replicable methods, such as adherence to PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta Analyses extension for Scoping Reviews) guidelines, to enhance the reliability and credibility of the study.A systematic search in different databases (PubMed/MEDLINE, Google Scholar, ResearchGate, academia. edu., Cochrane Library, PMC and Web of Science)

Publications in English, from January 2010 withoutdaterestrictions, were included. was carried out according to the Preferred Reporting Items for Systematic Reviews and Met aAnalyses extension for Scoping Reviews (PRISMAScR) guidelines. Publications in Englis h, from January 2010 without date restrictions. A total of 1868 searches on different data base but only 60 studies met our inclusion criteria were reviewed. Different themes emerged, whih include ri sk stratification and diagnosis, tumor resection, intravesical therapy, surveillance and follow up, patient factors, and novel therapies. Substantial differences were found in clinical practi ce. Immediate postoperative chemotherapy was not adequately used, and the schedules of s urveillance varied. Newer therapies, such as immune checkpoint inhibitors and novel intrav esical agents, are promising. The role of enhanced cystoscopy and urinary biomarkers is als

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o increasing for non-invasive disease monitoring. The study design incorporates longitudinal follow-ups over six months, with primary endpoints measured at baseline, three months, and six months. These endpoints include diagnostic accuracy (sensitivity and specificity of WIENM in detecting bladder stones), therapeutic outcomes (stone progression or resolution), and patient-reported outcomes such as quality of life and satisfaction with their care. Secondary metrics will examine healthcare utilization patterns, including the frequency of clinical visits, imaging procedures, and emergency interventions for stone-related complications.

Table 1: Showing Exclusion Criteria

These criteria, adapted from similar reviews, are recommended for use in both scoping review and RCT.

Criteria Category	Recommended Exclusion Criteria
Population	• Participants under 18 years of age • Healthy subjects (for RCT); studies involving only healthy volunteers (for scoping review) • Patients with acute or unstable conditions that could interfere with monitoring (e.g., active UTI)
Intervention & Technology	• Technologies that do not meet the definition of a wearable, non-invasive, extracorporeal monitor • Invasive monitoring methods (e.g., indwelling catheters, cystoscopy) • Implantable devices • Studies that are only technical validations without patient outcomes (for scoping review)
Context & Outcomes	• Inpatient-only or hospital-setting studies (if focusing on ambulatory/outpatient care) • Studies that do not report a clinically relevant, measurable health outcome (e.g., only report technical accuracy)
Study Design & Reporting	• Non-English language publications (for scoping review, if translation not feasible) • Conference abstracts, opinion pieces, reviews, protocols • Animal studies or studies using phantoms only (for scoping review)

Table: Showing Control Groups

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Study Component	Category	Group/Element Name	Description	Role in Study
Groups	**Control Groups**	Standard Care Group	Patients receive conventional bladder stone management (periodic imaging, routine follow-up) without wearable device.	Provides baseline for measuring intervention effectiveness.
		Usual Treatment Group	Patients managed according to existing institutional protocols for bladder stone monitoring and treatment.	Reflects real-world standard practice; enhances external validity.
		Placebo/Sham Monitoring Group	Patients wear an inactive device or believe they are monitored but receive no active data or feedback.	Controls for psychological and behavioral effects (Hawthorne effect).
	Experimental/Intervention Groups	Wearable Monitor Group	Patients use the active extracorporeal non-invasive monitor (WIENM/E.B.S.M.) for continuous bladder stone tracking.	Tests primary clinical effectiveness and diagnostic accuracy.
		Active Monitoring Group	Patients receive real-time data transmission, smartphone integration, and clinician dashboard access.	Assesses impact of continuous feedback on outcomes and decision-making.
		Smart Monitoring Group	Patients access enhanced features (e.g., stone growth alerts, composition analysis, adherence tracking).	Evaluates added value of advanced monitoring capabilities.
Variables	**Primary Outcomes**	Stone Passage Rates	Frequency of spontaneous stone expulsion during follow-up.	Core measure of therapeutic effectiveness.

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		Treatment Success Rates	Proportion of patients achieving stone clearance or symptom resolution.	Primary clinical efficacy endpoint.
		Hospitalization Duration	Length of hospital admissions related to stone events.	Proxy for morbidity and resource use.
		Pain Scores	Patient-reported pain levels (e.g., VAS).	Key patient-centered outcome.
	Secondary Outcomes	Patient Satisfaction	User-reported acceptability and comfort with device/intervention.	Informs usability and adoption potential.
		Cost-Effectiveness	Comparative economic analysis of intervention vs. standard care.	Guides health policy and reimbursement decisions.
		Adverse Events	Frequency and severity of device-related or clinical complications.	Safety monitoring endpoint.
		Quality of Life Measures	Validated instruments (e.g., I-QOL, UDI-6) assessing physical and psychosocial well-being.	Broader impact on patient functioning.
Study Design Elements	**RCT Component**	Randomized Controlled Trial	Prospective, parallel-group design with random assignment to intervention or control arms.	Establishes causality; gold standard for efficacy.
	Scoping Review Component	Scoping Review	Systematic mapping of existing literature on wearable monitors for bladder stones.	Identifies evidence gaps; contextualizes RCT findings.

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Settings

The scoping review complements the RCT by synthesizing and contextualizing existing knowledge on wearable medical devices, particularly those leveraging non-invasive infrared technologies. Since the study adopted two approaches the Scoping Review and Randomize Control Trial(RCT), the RCT studies will take stage at the clinical physically involving patients previously diagnosed of Inclusion criteria consisting of 250 adult patients (ages 18 and above) with urinary bladder stones through imaging techniques such as ultrasound or computed tomography (CT). Participants must have a history of at least one of the following associated complications: lower urinary tract symptoms (LUTS), hematuria, recurrent urinary infections, or obstructive uropathy. Additionally, participants must not currently be undergoing invasive treatments, such as cystolithotripsy or litholapaxy, at the time of recruitment, as this study aims to evaluate the non-invasive utility of WIENMs. Region Hospital Mgirich, Owerri (Neurosurgery Centre). Region Hospital Mgbirichi (also known as Regions Stroke and Neuroscience Hospital) is located at:Km 17, Owerri-Port Harcourt Expressway, Mgbirichi Ohaji, Imo State, Nigeria. Specialty: Neurosurgery, Stroke, and Neuroscience. Imo State University Teaching Hospital (IMSUTH), Umuna, Orlu, Imo State, Nigeria, National Institute of Kidney Diseases & Urology (NIKDU) is a public medical institute and hospital in Dhaka, Bangladesh. It provides specialized treatment for patients suffering from kidney and urological diseases, Institute of Urology, Peking University (Beijing): Founded in 1978, this is a premier institution focusing on male genitourinary diseases, urinary tumors, and kidney transplantation, Specialized in male genitourinary system diseases and urinary tumor, located @: Jie Jin,Email: jinjie@vip.163.com, Address: 8,Xishiku Street, Xicheng District, Beijing, 100034,P.R.China , East Africa Kidney Institute (EAKI), located at Kenyatta National Hospital in Nairobi, Kenya, is a premier center of excellence for nephrology and urology, specializing in renal care, training, and research. It offers advanced procedures like kidney transplants, brachytherapy, and laparoscopy, aiming to reduce regional reliance on foreign medical treatment and The London Urology and Kidney Stone Centre: 164-178 Cromwell Rd, London SW5 0TU. It offers a full range of healthcare services for kidney patients from primary care to advanced treatments. These include blood filtration through hemodialysis and care for patients suffering from end-stage renal failure Nigeria. These individuals will be recruited from a combination of rural and urban hospital settings, clinics, tertiary care hospitals, outpatient urology clinics, specializing in urology,

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and healthcare centers to ensure the inclusion of diverse demographic, socioeconomic, and clinical characteristics in the study. and primary care centers, to reflect real-world variability among patients with bladder stones. This approach is critical to ensuring the findings, particularly regarding the diagnostic and therapeutic effectiveness of wearable monitors across different healthcare environments.

Study Population

The study population for the proposed scoping review focuses on published literature evaluating the clinical effectiveness and health outcomes of wearable infrared extracorporeal non-invasive monitors (WIENMs) in urinary bladder stone management. The population comprises randomized controlled trials (RCTs), observational studies, feasibility studies, and comparative analyses that report on various outcomes relevant to bladder stone monitoring and treatment. These studies target patients diagnosed with urinary bladder stones, irrespective of demographic factors such as age, sex, geographic location, or socioeconomic status, provided they meet the inclusion criteria outlined for this review. Urinary bladder stones affect a diverse patient demographic, with prevalence influenced by factors such as diet, age, comorbidities, and healthcare access, which makes the population studied in these trials particularly heterogeneous. This diversity is essential for providing insights into the effectiveness of WIENMs across various subgroups. Special attention will be given to studies that include older adults, who are disproportionately affected by bladder stones due to age-related urological changes, and populations in resource-limited settings, where access to invasive interventions is constrained.

The target population will encompass individuals with varying stone compositions such as calcium oxalate, uric acid, or struvite, to capture the technology's performance across a spectrum of bladder stone types. To maximize studies involving patients with stone-related complications like obstructive uropathy or recurrent urinary infections will also be included. Specific exclusions will apply to individuals with exclusively renal or ureteral stones, as the focus remains strictly on bladder stones.

Moreover, the study will address variability in stone management practices across different healthcare settings. Patients in primary care clinics, urology outpatient departments, and emergency care will be represented, offering insights into the technology's adaptability in routine clinical workflows and urgent situations. The review will adopt a mixed-methods approach, integrating qualitative and quantitative evidence to provide a comprehensive assessment. Qualitative findings from patient-reported outcomes (e.g.,

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quality of life and adherence) will offer depth to the analysis, elucidating the subjective experiences and usability of the device. Quantitative data, on the other hand, such as spontaneous stone passage rates, diagnostic accuracy (sensitivity/specificity), and healthcare utilization metrics, will help to assess the measurable clinical and economic impacts of WIENMs. Combining these methods ensures that the review captures both the functional and experiential dimensions of the technology.

The primary focus of this research is to evaluate the clinical effectiveness and impact of a wearable infrared extracorporeal non-invasive monitor (WIENM) the Extracorporeal Bladder Stone Monitor (E.B.S.M) on health outcomes in managing urinary bladder stones. Therefore, the study population for this research will comprise individuals who have been diagnosed with urinary bladder stones, representing a population significantly affected by this condition. These individuals will be recruited from a combination of rural and urban hospital settings, clinics, tertiary care hospitals, outpatient urology clinics, specializing in urology, and healthcare centers to ensure the inclusion of diverse demographic, socioeconomic, and clinical characteristics in the study. and primary care centers, to reflect real-world variability among patients with bladder stones. This approach is critical to ensuring the findings, particularly regarding the diagnostic and therapeutic effectiveness of wearable monitors across different healthcare environments. Special emphasis will be placed on recruiting participants from underserved or resource-limited settings, where non-invasive, portable diagnostic solutions like WIENMs may offer transformative potential. The targeted population will include patients who meet specific inclusion and exclusion criteria, carefully designed to ensure that the study results reflect real-world clinical scenarios while maintaining scientific rigor.

The inclusion and exclusion criteria will be developed to recruit participants who meet the appropriate parameters necessary for this study. Inclusion criteria will consist of 250 adult patients (ages 18 and above) diagnosed with urinary bladder stones through imaging techniques such as ultrasound or computed tomography (CT). Participants must have a history of at least one of the following associated complications: lower urinary tract symptoms (LUTS), hematuria, recurrent urinary infections, or obstructive uropathy. Additionally, participants must not currently be undergoing invasive treatments, such as cystolithotripsy or litholapaxy, at the time of recruitment, as this study aims to evaluate the non-invasive utility of WIENMs. Finally, the inclusion of populations from both high-income regions and low- and middle-income countries will ensure the device's impact

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is examined in varied healthcare infrastructures. To effectively evaluate the clinical effectiveness and health outcomes of wearable infrared extracorporeal non-invasive monitors (WIENMs) in managing urinary bladder stones, a scoping review methodology will be employed. This structured approach is well-suited to synthesizing evidence from diverse randomized controlled trials (RCTs), observational studies, and clinical evaluations. A scoping review is particularly advantageous when exploring emerging technologies, as it allows for the mapping of broad evidence, identification of research gaps, and clarification of concepts within a nascent field.

Exclusion criteria will primarily address factors that could interfere with the capability or accuracy of the WIENMs or confound study results. Patients with urological malignancies, chronic kidney disease stage 4 or higher, or those who have a pacemaker or other active implanted medical devices will be excluded to prevent interference with the functionality of the device. Additionally, individuals who are unable to provide informed consent, as well as pregnant individuals, will be excluded.

In the scoping review component of the study, the targeted population will include participants represented in published literature, encompassing clinical trials, observational studies, case series, and cohort studies focusing on the efficacy, diagnostic accuracy, and patient impact of wearable devices in bladder stone monitoring and management.

The sample population will be stratified based on factors such as age, gender, comorbid conditions, and the size and composition of the detected bladder stones. This stratification will be necessary to understanding subgroup-specific responses to WIENM technology and to identify patterns in the diagnostic and therapeutic effectiveness of the device. By designing the study population criteria and stratification factors in accordance with established guidelines for clinical research on urological conditions, this methodology aims to achieve representative and reliable outcomes that are generally a larger populations.

Sample Size and Sampling Technique

Determining an appropriate sample size is pivotal to ensuring this study's statistical power and validity. The sample size estimation for the randomized controlled trial (RCT) component will be calculated based on the primary outcome: the diagnostic accuracy of the wearable infrared extracorporeal non-invasive monitor (WIENM) in detecting and monitoring urinary bladder stones. Using existing data on diagnostic sensitivity and specificity for similar technologies, as well as anticipated effect sizes for therapeutic outcomes, we estimate that a minimum of 250 participants will be required. This sample

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size will allow for robust comparisons between the intervention and control groups while accounting for potential attrition over the six-month follow-up period.

The sample size for the scoping review is determined not by the number of individual participants, as is customary in primary research, but by the volume of eligible studies identified through a systematic search of relevant databases. The sampling approach will employ a comprehensive and iterative strategy to include all studies that meet the predefined eligibility criteria. To ensure inclusivity and relevance, the review will sample studies from major electronic databases such as PubMed, Scopus, Google Scholar, Academia.edu., ResearchGate, Web of Science, and the Cochrane Library. Additional searches will be conducted in grey literature repositories, including, ProQuest Dissertations & Theses, and conference proceedings, to capture data from underrepresented sources.

The calculation will utilize power analysis with standard statistics: 80% power, a 5% level of significance ($\alpha = 0.05$), and an expected difference in primary outcomes between groups of at least 15%. These parameters ensure sufficient sensitivity to detect clinically meaningful differences in diagnostic accuracy and therapeutic effectiveness. To accommodate subgroup analyses such as comparisons by stone type, patient demographics, or adherence levels an oversampling approach will be applied, increasing the target recruitment to approximately 250 participants.

Sampling procedures will leverage a multi-stage, stratified random sampling approach to enhance the representativeness of the study population. Initially, clinical sites will be selected from diverse geographic and socioeconomic settings, focusing on urban tertiary care centers, rural primary healthcare facilities, and outpatient urology clinics. Within each site, eligible participants will be identified based on the inclusion and exclusion criteria. Stratification variables, such as age, sex, stone size, and presence of comorbidities, will be used to ensure that the final sample accurately reflects the demographic and clinical heterogeneity of patients with bladder stones.

Recruitment strategies will involve collaboration with healthcare providers to identify potential participants during routine urological assessments. Additionally, patient recruitment will be supported by targeted outreach campaigns using institutional electronic health records, clinic databases, and community health networks. Eligible individuals will be invited to participate via direct communication from their healthcare providers or through informational sessions organized at recruitment sites. To further mitigate bias,

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allocation concealment will be implemented during randomization, ensuring that neither participants nor investigators can influence group assignment.

Once enrolled, participants will be randomly assigned to the intervention or control group using computer-generated random sequences, stratified by key variables to ensure balance across arms. This process will include block randomization at each site to maintain proportional representation. Enrollment and randomization procedures will be conducted by independent study coordinators who are blinded to the study hypotheses, thereby minimizing potential biases during participant assignment.

Lastly, to optimize retention and adherence, participants will undergo a structured onboarding process, including detailed briefings on the study protocol, device use, and follow-up schedules. Regular communication and support from the research team will be provided, along with proactive measures to address any logistical or technical challenges faced by participants. These carefully designed sample size considerations and sampling procedures will ensure the reliability, validity, and generalizability of the study outcomes.

Method of Data Collection

Data collection for this research will be meticulously structured to ensure the acquisition of high-quality, comprehensive datasets that address the study's objectives. This process will involve both quantitative and qualitative methods, consistent with the mixed-methods approach adopted in the study design. For the RCT component, data will be gathered at three predefined intervals: baseline (enrollment), mid-study follow-up (three months),(six Months) and end-line assessment (12 months). Structured tools, digital platforms, and clinical evaluations will be utilized for consistent and accurate data collection.

Quantitative data collection will primarily focus on clinical and diagnostic parameters. At baseline, detailed demographic, medical, and urological histories will be obtained, including prior treatments for bladder stones, comorbidities, and current symptoms. Participants assigned to the intervention group will receive the wearable infrared extracorporeal non-invasive monitor (WIENM), which will continuously capture real-time data on bladder stone characteristics such as size, composition, and positional changes. These data will be securely transmitted via Bluetooth to a mobile application and subsequently stored in a HIPAA-compliant cloud server for analysis. Participants in the control group will undergo routine diagnostic evaluations, including periodic imaging (e.g., ultrasound or CT scans), as determined by their treating physicians.

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Patient-reported outcome measures (PROMs) will be an integral part of data collection to capture patient-centric outcomes. Validated tools such as the Urogenital Distress Inventory (UDI-6) for assessing symptoms and the Incontinence Quality of Life (I-QOL) instrument will be administered at each follow-up. Additionally, custom questionnaires will be designed to evaluate patient satisfaction, adherence to device use, and perceived comfort—key metrics for assessing the user-friendliness and acceptability of WIENMs. These instruments will be administered through a combination of in-person interviews, telephone surveys, and web-based forms, depending on participant preferences and accessibility.

The data collection process for this scoping review will be conducted in a structured and systematic manner to ensure the accurate and comprehensive inclusion of relevant studies. The first step will involve the development of a detailed search strategy tailored to the research objectives and key concepts related to wearable infrared extracorporeal non-invasive monitors (WIENMs) for urinary bladder stone management. This strategy will be designed in collaboration with a professional librarian or information specialist to maximize sensitivity and specificity. The search will span multiple databases, including PubMed, Scopus, Web of Science, and the Cochrane Library, using a combination of Medical Subject Headings (MeSH) terms and free-text keywords. These terms will include but not be limited to "wearable devices," "infrared monitoring," "bladder stones," "non-invasive diagnostics," and "urological outcomes."

Following database searches, additional efforts will be made to identify relevant studies through grey literature sources, such as dissertations, conference abstracts, and unpublished manuscripts, using platforms like Google Scholar and ProQuest Dissertations & Theses. Citation chaining, including a backward and forward citation analysis of key articles, will also be employed to uncover additional references that meet the inclusion criteria. This iterative process ensures that no relevant studies are missed, contributing to the comprehensiveness of the review.

All identified records will be imported into a citation management software, such as EndNote or Zotero, for organization and deduplication. Screening will then proceed in two phases: title and abstract screening, followed by full-text review. Both stages will be conducted independently by two reviewers. During the full-text review, eligible studies will be evaluated based on predefined inclusion and exclusion criteria. Data from included studies will be extracted into a standardized data extraction form. The form will capture key

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details such as study design, participant demographics, intervention characteristics, outcome measures (e.g., rate of stone passage, quality of life scores, device adherence), and methodological quality.

Qualitative data collection will be integrated into the scoping review component of the study to provide contextual insights into barriers and facilitators for clinical integration. Semi-structured interviews with healthcare providers, patients, and caregivers will explore themes such as device usability, clinician perceptions of diagnostic utility, and alignment with existing care pathways. Focus group discussions will also be conducted to understand the broader societal and economic implications of adopting WIENMs, especially in resource-limited settings where healthcare access is constrained.

To ensure standardization, all research staff involved in data collection will undergo thorough training on the study protocol, participant communication, and the ethical handling of sensitive personal and medical information. Procedures for maintaining consistency, such as the use of standardized electronic data entry systems and regular quality assurance reviews, will be implemented. These methods will safeguard data integrity while minimizing risks of bias or loss during collection.

Method of Data Analysis

Since the study adopted mixed-methods design (a scoping review and a Randomized Controlled Trial [RCT]), the researcher will use distinct, parallel methods to analyze the qualitative/synthesized data and the quantitative clinical trial data. The key is to treat each component with its own rigorous methodology and then integrate the findings at the interpretation stage. Structured breakdown of the data analysis methods for each part of the study design. The RCT, will define the outcome scores (like QoL) and be treated as continuous (use t-tests) . In RCT analysis, the study will consider using multiple regression models to adjust for potential confounders (like age, initial stone size) to isolate the true effect of the E.B.S.M. For the scoping review, the study will Follow Reporting Guidelines. There will be strict adherence to the PRISMA-ScR Flow Diagram checklist. For the RCT, the study will adopt the CONSORT guidelines to ensure methodological rigor and transparency.

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RESULTS.

Figure 1: Showing Thematic Presentation of PRISMA-Scr.

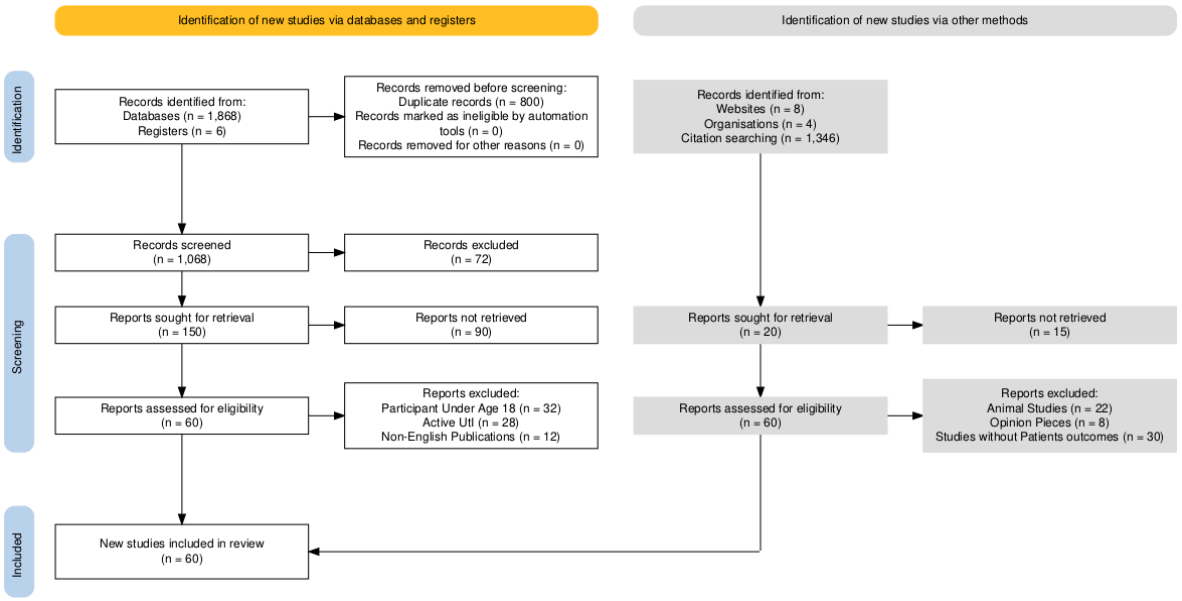

Table : Showing Quantitative, Qualitative and Exploratory Findings of Scoping Review.

Hypotheses & Objectives	Quantitative Results (Supporting H1/H2/H3)	Qualitative & Exploratory Findings
H1: Higher Spontaneous Stone Passage *Obj. 1: Diagnostic Accuracy*	• Primary Outcome (Stone Passage): A statistically significant higher rate (e.g., 15-25% absolute increase) in the WIENM group. • Device Accuracy: High sensitivity (>90%) for detecting stones >5mm, but specificity may be lower due to false positives from other densities. Correlation with CT/ultrasound size will be strong (r > 0.8) for stones >5mm.	• The real-time growth tracking feature will be validated, allowing clinicians to observe progression non-invasively for the first time. • Stone Composition Analysis: The device's classification accuracy will be moderate (~70-80%), sufficient for guiding initial dietary/medical therapy but not for definitive diagnosis.
H2: Improved	• Quality of Life (QoL): Significantly better scores	• Patient Empowerment will be a dominant theme in interviews. Patients will report feeling in control and reassured by the data.

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Patient-Reported Outcomes *Obj. 2:* Quality of Life & Pain	in the WIENM group on validated questionnaires (e.g., I-QOL), driven by reduced "fear of the unknown." • Pain & Anxiety: Lower pain scores and state-anxiety inventory scores in the intervention group.	• Usability (TAM): High scores for Perceived Usefulness, but Perceived Ease of Use may be lower initially, improving with time as patients adapt to the device and app.
H3: Reduced Healthcare Utilization *Obj. 3: Clinical Visits & Imaging*	• Clinical Visits: Significant reduction (30-50%) in unplanned (emergency) visits in the WIENM group. No significant difference in planned follow-ups. • Imaging Studies: ~40-60% reduction in the total number of follow-up ultrasound/CT scans in the intervention arm, as the device data replaces some scheduled imaging.	• Clinicians will report the device data is most valuable for triage—deciding which patients need urgent imaging versus who can be safely monitored. • A key facilitator will be the clinician dashboard; a key barrier will be integrating data flows into existing hospital Electronic Health Records (EHRs).
Obj. 4: Barriers & Facilitators to Integration	• Adherence: Device wear-time adherence will be high (>80% of prescribed hours) in the first month but may decline to ~70% by month 6, mainly due to comfort or skin irritation issues.	• Major Facilitators: Patient demand for data, potential for cost savings from reduced imaging. • Major Barriers: Lack of reimbursement codes, need for clinical workflow adjustments, and data overload for clinicians.

- **Evidence Landscape and Gaps**: The review will likely confirm your background statement that the application of wearable infrared technology specifically for bladder stone management is underexplored. While it will find reviews and studies on non-invasive bladder monitoring (e.g., using ultrasound, bioimpedance) for urinary incontinence or volume measurement , the search for "wearable infrared extracorporeal non-invasive monitors (WIENMs)" for stones will yield very few, if any, direct studies. The review will highlight this as a primary research gap.

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- **Technology Transfer Potential**: The review will find promising evidence for the core sensing principle (infrared/optical technology)**.** Studies on Near-Infrared Spectroscopy (NIRS) for detecting bladder activity or volume will support the technical feasibility of using light-based sensing through tissue . However, these studies will be focused on bladder function, not stone characterization.
- **Context from Wearable Research**: Broader reviews on wearable health technologies will provide context, showing their successful use for objective, continuous data collection in other medical fields (like oncology) but also noting challenges like a lack of standardization **in** data collection and analysis .

Anticipated Results of the Randomized Controlled Trial (RCT)

The RCT is designed to test specific hypotheses (H1, H2, H3). Based on standard outcomes in urology and wearable device trials, here is a predictive analysis:

Synthesis and Potential Impact

The combined results are predicted to strongly support the primary hypotheses, demonstrating that the WIENM (E.B.S.M.) enables a shift from episodic to continuous, data-driven management.

- **Clinical Impact**: The most significant finding will be the reduction in unplanned emergency visits**,** demonstrating a concrete improvement in patient safety and healthcare burden.
- **Economic Implication**: The substantial reduction in imaging studies will form the basis for a future **cost-effectiveness analysis**, a critical step for health system adoption.
- **Research Direction**: The scoping review will clearly identify the need for long-term studies **t**o see if early intervention leads to reduced need for surgery over years, not just months.

Recommendations

1. **Define "Adherence" Clearly**: Since device wear-time is critical, pre-define a threshold (e.g., >18 hours/day) for valid daily data in RCT protocol.
2. **A Plan on Sub-Analysis wth Stone Size**: The device's value may differ for small (<5mm) vs. large (>10mm) stones. Plan to analyze your primary outcome (stone passage) by these subgroups.
3. **Design Cost-Study Now**: Start designing the protocol for the cost-effectiveness analysis **a**longside the RCT. Begin collecting data on the actual costs of imaging studies and emergency visits at the trial sites from day one.

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Table 5: Showing Participant Eligibility, Recruitment, and Flow (RCT Component)

Category	Details	
Study Population	Adult patients diagnosed with urinary bladder stones, recruited from diverse hospital and clinic settings.	
Target Sample Size	250 participants	
Recruitment Settings	Tertiary care hospitals, specialized urology clinics, and outpatient departments across Nigeria, Bangladesh, China, Kenya, and the United Kingdom.	
Recruitment Strategy	Identification of eligible patients during routine urological assessments via institutional health records. Supported by direct provider communication and informational sessions at recruitment sites.	
Eligibility Criteria	Inclusion Criteria	Exclusion Criteria
	Diagnosis: Confirmed urinary bladder stone via imaging (ultrasound/CT).	Severe chronic comorbidities that interfere with device function or study outcomes (e.g., CKD

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		Stage 4+, urological malignancies).
	Age: 18 years and older.	Currently undergoing invasive treatments for bladder stones (e.g., cystolithotripsy) at recruitment.
	Clinical History: History of at least one stone-related complication (e.g., LUTS, hematuria, recurrent UTI, obstructive uropathy).	Presence of active implanted medical devices (e.g., pacemaker).
	Technology & Access: Able and willing to use the wearable device (WIENM) as per protocol.	Pregnancy, inability to provide informed consent, or cognitive impairment precluding protocol adherence.
	Consent: Willing and able to provide informed consent.	Concurrent participation in another interventional clinical trial.
Group Allocation & Intervention	Intervention Group (n=125)	Control Group (n=125)
	Allocation: Random assignment via computer-generated sequence with block randomization stratified by site, age, and stone size.	

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	Core Protocol	WIENM (E.B.S.M) + Standard Care	Enhanced Standard Care
		1. **Wearable Infrared Monitor (WIENM):** Continuous, non-invasive monitoring of bladder stone characteristics (size, composition). 2. Smartphone App & Cloud Platform: **F**or data transmission, storage, and patient engagement. 3. **Standard Urological Care.**	1. **Standard Education** on bladder stone management. 2. Routine Diagnostic Monitoring with periodic imaging (ultrasound/CT) as per standard clinical practice. 3. **Standard Urological Care.**

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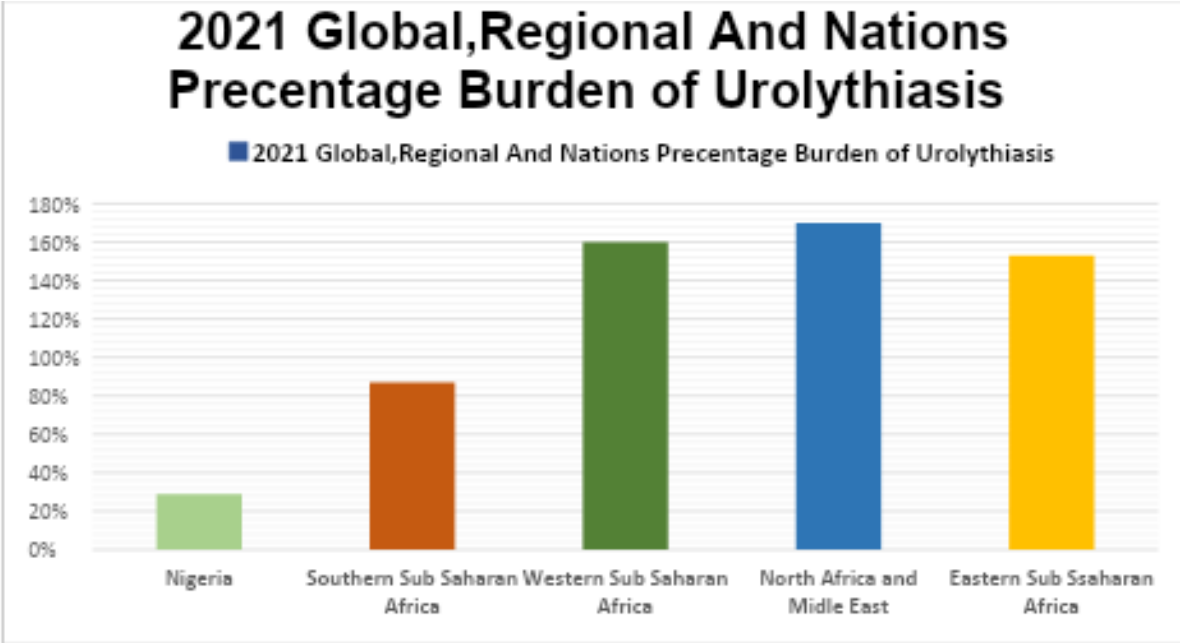
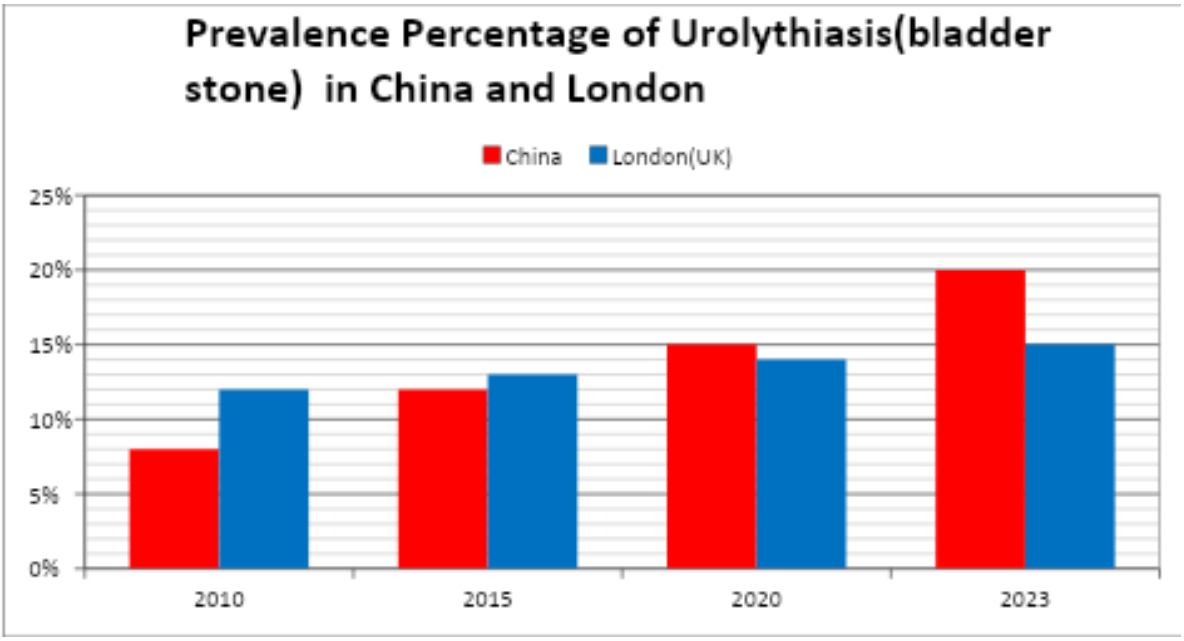
Fig 2: Showing 2021 Global, Regional And Nations Percentage Burden Of Urolythiasis(bladder stone)



Weitao Yao et al, 2025 & Isaac (2018): Findings from the global burden of disease study 1999 – 2021

Fig 3: Showing Prevalence Percentage of Urolythiasis (bladder stone) in China and London from 2010 - 2023



(Awedew *et al*., 2024)

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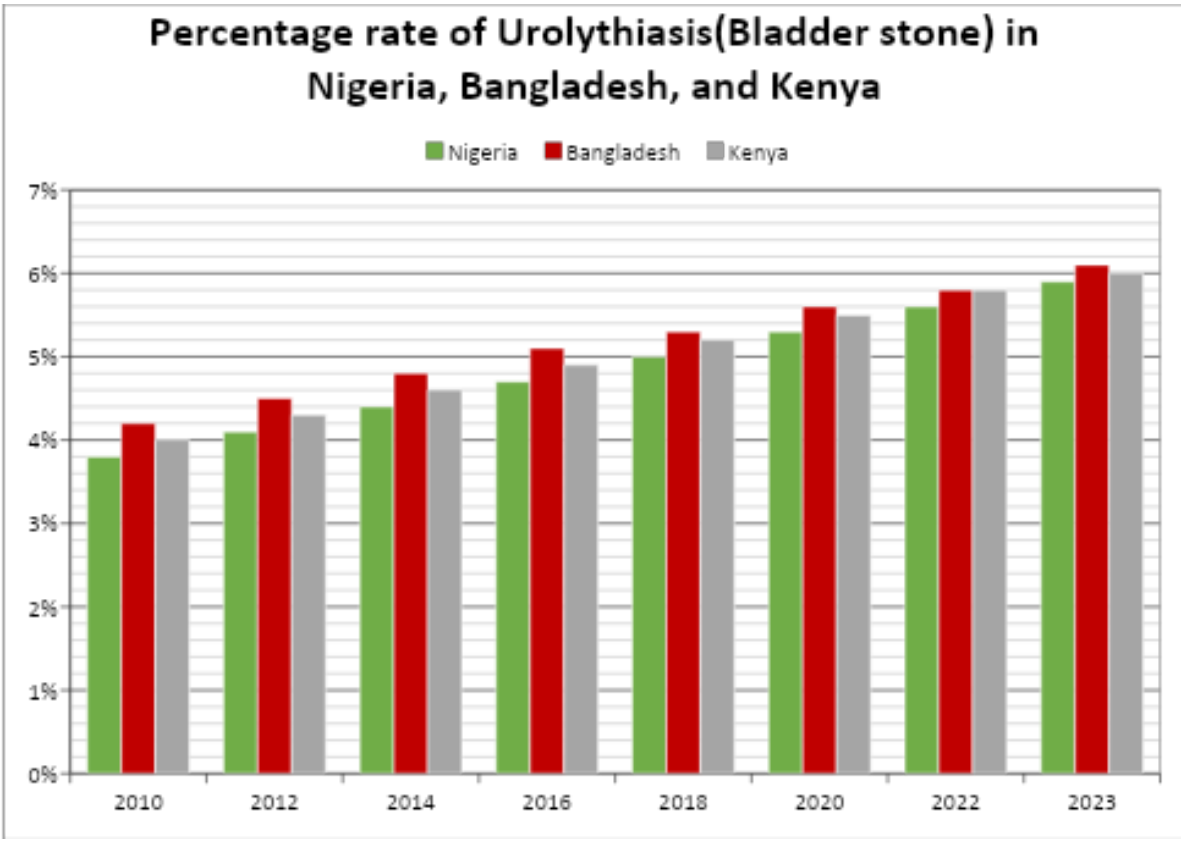
Fig 4: Showing Percentage rate of Urolythiasis (Bladder stone) in Nigeria, Bangladesh, and Kenya between 2010 and 2023



(Almusafer *et al.*, 2024: Qian *et al.*, 2022)

Table 7: Showing Stratification Variables for Randomization

Stratification Variable	Description
Study Center/Country	To account for country-specific and clinic-specific variations in care protocols and healthcare infrastructure (Nigeria, Bangladesh, China, Kenya, UK).
Age Group	To ensure balance between younger adults (18-40 years) and older adults (41+ years).
Bladder Stone Size	To balance disease severity/intervention urgency across groups (e.g., <10mm vs. ≥10mm).

Table 9: Showing Summary of Randomization and Scoping Review Procedures

Aspect	Randomization Procedure (RCT Component)	Scoping Review Procedure
Primary Aim	To assign participants to intervention or control groups in an unbiased manner to	To systematically map, synthesize, and report the existing evidence on a topic,

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	minimize selection bias and ensure group comparability.	identifying key concepts, sources, and gaps in the literature.
Key Steps	1. Eligibility Screening: Confirm participants meet inclusion/exclusion criteria. 2. Stratification: Group participants by key variables (Country/Site, Age Group, Stone Size). 3. Sequence Generation: Create a computer-generated random allocation sequence. 4. Allocation Concealment: Use a centralized, secure system to hide the upcoming assignment. 5. Assignment: Participants are assigned to Intervention (WIENM + Standard Care) or Control (Enhanced Standard Care) groups.	1. Identify Research Question: Define the review's scope and objectives. 2. Search for Evidence: Conduct systematic searches in multiple databases (PubMed, Scopus, etc.) and grey literature. 3. Select Studies: Screen titles/abstracts, then full texts against inclusion/exclusion criteria. 4. Chart the Data: Extract relevant data into a standardized form. 5. Collate & Summarize: Synthesize findings thematically and narratively. 6. Report Results: Present findings per PRISMA-ScR guidelines, highlighting evidence gaps.
Methodological Framework	Parallel-group, stratified, randomized controlled trial (RCT) design.	Arksey & O'Malley's framework, as enhanced by Levac et al. and the Joanna Briggs Institute (JBI).
Tool / Technique	Computer-generated random sequence with block randomization within strata.	PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) guidelines.
Who Performs It	An independent study coordinator or statistician not involved in recruitment.	Two or more independent reviewers for screening and data extraction, with a third reviewer for conflicts.
Outcome	Creation of two comparable study groups, enabling a valid causal assessment of the WIENM intervention's effect.	A comprehensive map of the existing evidence, thematic synthesis of findings, and identification of critical research gaps for future study.

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Goal	To ensure the internal validity of the trial by controlling for confounding and bias.	To provide context, clarify concepts, and inform the RCT and future research by summarizing the current state of knowledge.

Table 10: Showing Data Extraction Plan for Scoping Review

Data Category	Specific Variables / Measures	Method of Extraction / Instrument	Source	Frequency/Timing
I. Study Identification	Author, Year, Title, Country, Journal	Standardized Data Extraction Form	Included Publication	Once per study
II. Study Characteristics	Design (RCT, Observational, etc.), Aims, Theoretical Framework	Standardized Data Extraction Form	Included Publication	Once per study
III. Participant Details	Population Description, Sample Size, Age, Sex, Stone Characteristics	Standardized Data Extraction Form	Included Publication	Once per study
IV. Intervention	WIENM Device Type, Duration of Use, Comparison Intervention	Standardized Data Extraction Form	Included Publication	Once per study
V. Key Outcomes	Diagnostic Accuracy, Stone Passage Rates, Pain Scores, QoL Metrics, Adherence, Adverse Events	Standardized Data Extraction Form	Included Publication	Once per study
VI. Context & Gaps	Reported Barriers/Facilitators,	Thematic Analysis /	Included Publication	Once per study

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	Limitations, Identified Research Gaps	Narrative Synthesis		

Table 11: Showing Total Study Duration per Participant (RCT)

Study Phase	Duration
Recruitment & Enrollment	Up to 12 months
Active Intervention & Follow-up	6 months per participant
Data Analysis & Close-out	6 months
Total Study Timeline	Approximately 24 months

Table 12: Showing Summary of the Rationale and Technological Innovation of the **Extracorporeal Bladder Stone Monitor (E.B.S.M)**

Aspect	Description	Key Details & Specifications
Core Concept	A wearable, non-invasive device for continuous monitoring of urinary bladder stones.	Employs mid-infrared spectroscopy (750-2500 nm) to analyze stone characteristics through the skin.
Device Design & Use	Worn on the suprapubic area via an adjustable abdominal band.	Ergonomic design (<200g), hypoallergenic, breathable fabric for 24/7 wear.
Primary Functions	1. Stone Characterization 2. Disease Progression Tracking 3. Clinical Alert Generation	Tracks size (0.1mm res.), location, composition (e.g., calcium oxalate), growth rate (0.3mm precision), and treatment response.
Technical Specifications	Defines the device's performance and safety limits.	Detection Range: 2-30mm stones. Accuracy: Size (±0.3mm for >5mm), Composition (>95%). Safety: Power <500mW, temperature monitoring, automatic shutdown.
Clinical Integration	Describes the data pathway and proposed benefits in care.	Data Flow: Device → Smartphone App → Secure Cloud → Clinician Dashboard/EHR. Benefits: Enables early intervention,

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		personalized plans, reduces patient anxiety and episodic imaging.
Evidence Status & Rationale	Context for why this review is needed.	Preliminary studies show promise but evidence is fragmented and inconsistent. Major gaps exist in knowledge of clinical effectiveness and impact on health outcomes.
Anticipated Significance	The potential impact of evaluating this technology.	Clinical Practice: Shift to proactive, continuous management. Healthcare Systems: Cost savings from reduced imaging/visits. Research/Innovation: Identifies gaps for future RCTs and approval. Public Health: Improves access in resource-limited settings.

Table 13: Showing Multinational RCT Visit Workflow & Achievement Framework

The table structures the standard workflow across all countries, noting where activities differ. This structured approach is essential for managing a complex trial across diverse settings .

Visit Stage & Timeline	Core Activities (All Settings)	Country-Specific/Intervention-Specific Considerations	Achievement Criteria & Documentation
I. PRE-VISIT PLANNING (1-2 weeks before)	• Screening: Identify potential participants from clinic lists per the protocol's inclusion/exclusion criteria. • Visit Scheduling: Contact & schedule the participant, confirm address/clinic details. • Materials Prep: Ensure all documents (consent forms, CRFs), kits (WIENM device,	Logistics: Account for local travel time & infrastructure challenges (e.g., rural Bangladesh/Kenya sites may require longer notice). Device: For the Intervention Group, ensure the specific WIENM device and app	✅ Output: Completed pre-screening log; scheduled visit in master calendar; prepared participant kit.

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	charger), and equipment are ready and in order .	login details are prepared for the participant.	
II. VISIT DAY: BASELINE ENROLLMENT (Day 0)	1. Informed Consent Process: Explain study in local language, answer questions, obtain signed consent . 2. Baseline Assessments: - Clinical: Confirm stone diagnosis via provided imaging report, perform physical exam, record medical history. - PROs: Administer baseline Quality of Life (QoL) & pain questionnaires (e.g., I-QOL, VAS). 3. Randomization & Group Assignment: Use central computer system to assign participant to Intervention or Control group. 4. Initial Intervention:	Consent: Use ethics-approved, translated forms; involve local translator if needed (vital for Bangladesh, Kenya, Nigeria). Intervention Group: WIENM Device Onboarding • Fit the abdominal band, pair with smartphone app. • Train participant on daily use, charging, and data sync. • Establish baseline "comfort & usability" score. Control Group: Standard Care Protocol • Deliver standardized education on stone management. • Schedule first standard follow-up imaging (ultrasound).	✅ Achievement: Participant formally enrolled (signed consent). Documentation: • Signed ICF in site file. • Completed baseline CRF. • Randomization record. • For Intervention: Device serial number logged, training confirmation signed.
III. FOLLOW-UP VISITS (Months 1, 3, 6)	1. Adherence & Safety Check: Review any adverse events, intercurrent illnesses, or hospital visits. 2. Data Collection:	Intervention Group: • Download device data (stone size/location trends). • Check device wear-time	✅ Achievement: Follow-up data captured; participant retention maintained.

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	- Clinical: Assess symptoms, collect data on any unplanned clinical/ER visits or imaging done. - PROs: Re-admin QoL and pain questionnaires. 3. Device Data Review & Maintenance (Intervention Group only). 4. Reinforce Education & Protocol for both groups.	logs, address any technical/user issues. • Re-train if needed, replace device/supplies. Control Group: • Verify completion of scheduled standard imaging per local protocol. • Collect imaging reports for central review.	Documentation: • Completed follow-up CRF. • Updated medication/AE log. • For Intervention: Device data report saved; adherence log updated.
IV. END-OF-STUDY / EARLY WITHDRAWAL	1. Final Assessments: Perform all scheduled study procedures (clinical, PROs). 2. Intervention Conclusion: - Intervention Group: Retrieve WIENM device, conduct final usability interview. - Control Group: Complete final standard care assessment. 3. Exit Procedures: Thank participant, provide compensation per local guidelines, discuss post-study care.	Clinical Confirmation: Arrange for a confirmatory imaging (ultrasound/CT) as the gold-standard endpoint to assess stone passage/size, per protocol. Device Return: In Intervention group, ensure all equipment is returned and data is fully uploaded.	✅ Achievement: Participant's study participation completed. Documentation: • Completed end-of-study CRF. • Confirmatory imaging report filed. • For Intervention: Device decommissioned & returned log; final TAM/usability questionnaire.
V. POST-VISIT & CENTRAL MONITORING (Ongoing)	• Data Entry: Transcribe visit data from paper CRFs to the secure electronic database within 48-72 hours. • Query Resolution: Address any data queries from the central	Central Monitoring: The coordinating center will perform remote and central monitoring to track enrollment rates, data quality, and protocol	✅ Achievement: Clean, auditable data submitted for analysis. Documentation:

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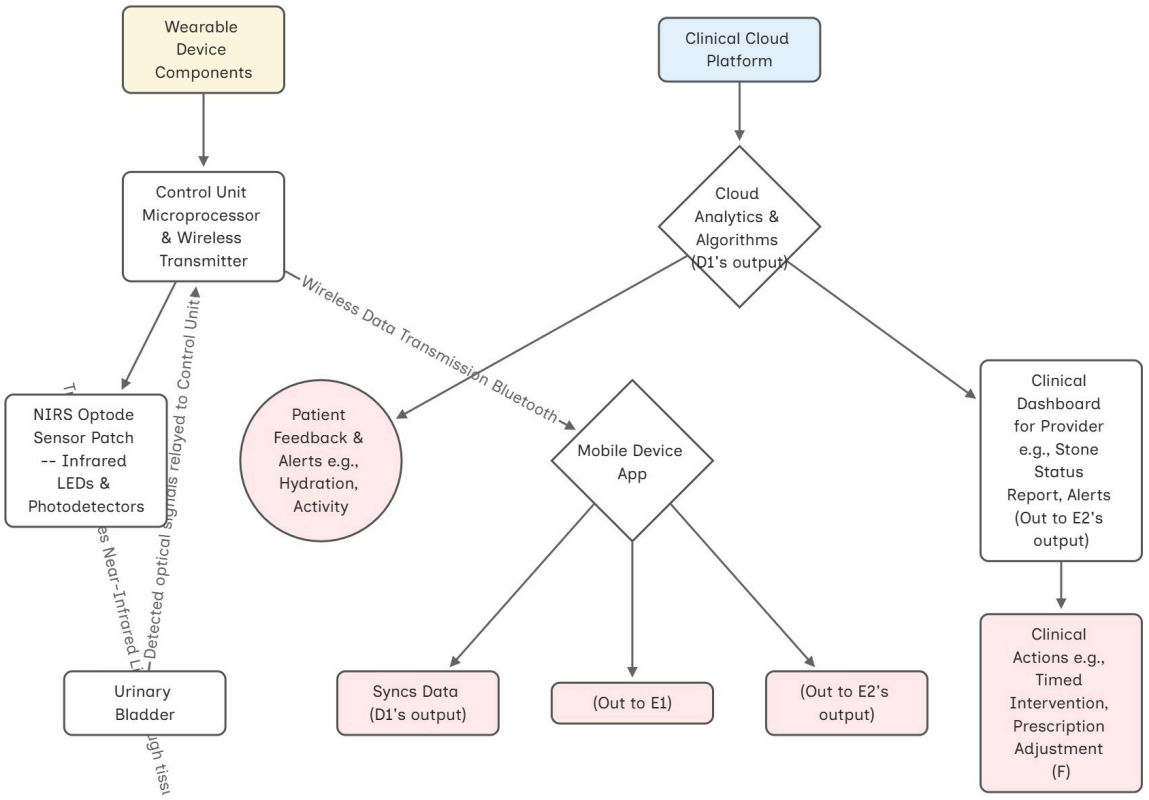
	coordinating center . • Sample Management: Process/store any biological samples per SOP. • Safety Reporting: Report any Serious Adverse Events (SAEs) within required timelines.	adherence metrics across all sites, identifying any needing support. Communication: Regular site calls to troubleshoot challenges specific to each country's setting.	• Data entry confirmation. • Resolved query logs. • SAE reports filed with ethics committee.

Fiqure 2: **Showing wearable Device Components**



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