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Mapping Medical Instruments and Device-Related Safety Concepts in Unani Medicine: A Structured Documentary Analysis for Developing a Unani Materiovigilance Framework

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ABSTRACT

Background: Medical instruments and instrument-assisted procedures are integral to several therapeutic practices in Unani medicine, particularly within Ilāj bi'l-Tadbīr and Ilāj bi'l-Yad. However, device-related safety concepts, adverse-event risks, infection-control requirements, and materiovigilance principles remain insufficiently organized within a dedicated Unani framework.
Objective: To systematically map medical instruments and device-related safety concepts described in Unani medicine and to develop a structured basis for a proposed Unani Materiovigilance Framework.
Materials and Methods: A structured documentary analysis was conducted using **110 eligible documentary records**, including classical Unani texts, contemporary Unani literature, peer-reviewed scientific publications, and regulatory or technical documents.
Results: Peer-reviewed publications constituted 31.8% of the included records, followed by contemporary Unani sources (26.4%), classical texts (21.8%), and regulatory documents (20.0%). Suction and negative-pressure procedures were the most frequent functional category (23.6%).
Conclusion: Unani instrument-related safety is influenced by invasiveness, reusability, infection-control requirements, practitioner competency, and procedural characteristics.

Keywords*: Unani medicine; Materiovigilance; Medical instruments; Medical devices; Ilāj bi'l-Tadbīr; Device safety; Risk assessment; Infection control; Adverse events; Patient safety.*

INTRODUCTION

Medical devices and instruments constitute an important component of health-care delivery because they support diagnosis, prevention, treatment, monitoring, rehabilitation, and a wide range of therapeutic procedures. Their contribution to clinical care, however, is accompanied by potential risks related to device design, materials, performance failure, inappropriate use, inadequate maintenance, poor sterilization, and operator error. These concerns are particularly relevant for procedures in which an instrument comes into direct contact with intact or breached skin, blood, mucosal surfaces, or other biological tissues. Materiovigilance has consequently emerged as a specialized patient-safety discipline concerned with the detection, collection, assessment, understanding, reporting, and prevention of adverse events associated with medical devices. The relevance of this concept to traditional systems of medicine has recently received attention, including within Unani medicine, where several therapeutic practices involve traditional or contemporary instruments and devices [1].

Unani medicine has a long-established therapeutic framework encompassing Ilāj bi'l-Ghidhā (dietotherapy), Ilāj bi'l-Dawā (pharmacotherapy), Ilāj bi'l-Tadbīr (regimenal therapy), and Ilāj bi'l-Yad (surgery or manual intervention). Among these, Ilāj bi'l-Tadbīr is particularly relevant from a device-safety perspective because several regimens require physical procedures, specialized instruments, or equipment. Common examples include Ḥijāma (cupping), Faṣd (venesection/phlebotomy), Ta'līq al-'Alaq (leech therapy), Huqna (enema), Ḥammām (therapeutic bathing), Natūl (irrigation), Inkibāb (steam or vapour application), Takmīd (fomentation), and Kaiyy (cauterization) [2]. The contemporary competency-based curriculum prescribed by the National Commission for Indian System of Medicine (NCISM) also

recognizes these procedures as core components of undergraduate Unani education and emphasizes their practical application [3]. Thus, instruments and devices are not peripheral to Unani clinical practice; in several areas they form an integral part of therapeutic intervention.

The safety implications of these procedures vary according to the nature of the instrument, invasiveness of the intervention, duration and site of contact, reusability, method of cleaning or sterilization, and degree of dependence on operator technique. For example, wet cupping involves scarification of the skin followed by negative-pressure application, while venesection intentionally breaches a blood vessel and leech therapy places a living biological agent in direct contact with tissue. Other procedures may involve heat, steam, suction, irrigation, pressure, or repeated contact with the patient's skin. Potential hazards may therefore include bleeding, burns, local tissue damage, infection, cross-contamination, excessive suction or pressure, allergic reactions, device breakage, inappropriate temperature exposure, or errors in technique. A recent review specifically examining materiovigilance in Unani medicine has highlighted these issues and proposed that instruments used in traditional therapeutic procedures can be considered through a risk-based safety perspective [1].

Contemporary medical-device regulation similarly adopts a risk-oriented approach. The World Health Organization recommends that regulatory systems classify medical devices according to their potential for harm and establish appropriate requirements for quality, safety, performance, and post-market surveillance [4]. In India, the Medical Devices Rules, 2017 provide a regulatory framework in which medical devices are categorized into Class A, B, C, and D according to increasing levels of risk [5]. Such risk stratification recognizes that device safety cannot be understood solely from the intended therapeutic benefit; characteristics such as invasiveness, duration of contact, anatomical site, energy delivery, sterility, and consequences of malfunction also influence the level of regulatory oversight required. These principles provide a useful conceptual foundation for evaluating instruments used within Unani practice without disregarding their historical terminology or traditional therapeutic rationale.

India has also established a dedicated post-market surveillance mechanism through the Materiovigilance Programme of India (MvPI). Materiovigilance involves systematic identification, collection, reporting, assessment, and analysis of adverse occurrences associated with medical devices with the objective of protecting patients and preventing recurrence [6]. Published assessments of the programme emphasize that systematic surveillance is necessary because problems related to medical devices may become apparent only after their wider use in routine clinical settings [7]. The MvPI was initiated in 2015, and the Indian Pharmacopoeia Commission currently functions as its National Coordination Centre. Its objectives include collecting medical-device-associated adverse-event information, scientifically analysing reported events, promoting reporting among health professionals and users, assessing benefit-risk relationships, and providing evidence that may support regulatory action [8].

Device safety also extends beyond mechanical failure. Infection prevention, cleaning, disinfection, sterilization, storage, maintenance, reuse, and disposal are important elements of safe instrument management. The WHO guidance on decontamination and reprocessing of medical devices emphasizes standardized procedures for cleaning, disinfection, sterilization, packaging, transportation, and quality assurance of reusable equipment [9]. These principles have particular relevance to Unani procedures involving cups, blades, lancets, suction instruments, irrigation equipment, cautery devices, and other reusable therapeutic accessories. Consequently, a comprehensive Unani materiovigilance approach should encompass not only adverse-event reporting after an incident but also preventive measures addressing instrument preparation, patient selection, practitioner competency, procedural technique, environmental hygiene, device maintenance, traceability, reprocessing, and safe disposal.

The development of a dedicated safety framework for Unani instruments would also complement India's existing initiatives for monitoring the safety of traditional medicines. The Ministry of AYUSH has established a pharmacovigilance system for Ayurveda, Siddha, Unani and Homoeopathy drugs with the objective of promoting documentation and assessment of adverse effects and developing a culture of safety reporting [10]. However, pharmacovigilance primarily concerns medicinal products, whereas many Unani therapeutic interventions depend on instruments, equipment, reusable accessories, or procedure-associated technologies. These require a complementary device-oriented perspective capable of documenting device malfunction, procedural injury, use error, contamination, maintenance-related problems, and other instrument-associated hazards.

Against this background, systematic examination of Unani literature is necessary to identify how medical instruments have been described, classified, prepared, handled, applied, cleaned, maintained, and associated with precautions or complications across classical and contemporary sources. Building on the emerging literature on Unani materiovigilance, a structured documentary analysis can map instrument names and variants, therapeutic indications, procedural characteristics, material and design features, level of invasiveness, body-contact characteristics, reusable or single-use status, sterilization and hygiene requirements, contraindications, operator-related precautions, foreseeable hazards, adverse outcomes, and recommended preventive measures. Such mapping would permit traditional safety concepts to be interpreted alongside contemporary principles of medical-device risk management rather than replacing the epistemological framework of Unani medicine.

MATERIALS AND METHODS

Study design and setting

A structured documentary analysis with qualitative content analysis and quantitative descriptive mapping was undertaken to identify, classify, and characterize medical instruments and device-related safety concepts documented in Unani medicine. The study was conducted at Regional Research Institute of Unani Medicine Mumbai. The methodological framework was designed to integrate traditional descriptions of instruments and procedural practices with contemporary principles of medical-device safety, risk management, infection prevention, reprocessing, and materiovigilance.

The unit of analysis was the individual documentary record containing substantive information on an instrument, device, equipment, accessory, or instrument-assisted therapeutic procedure used in Unani medicine. The final analytical corpus comprised 110 eligible documentary records.

Study period

The documentary search, screening, data extraction, coding, and analysis were conducted between 2023 and 2024. Classical and contemporary sources available up to the final search date were considered for inclusion.

Source framework

Documents were identified from four principal source categories:

1. **Classical Unani literature**, including authoritative texts dealing with Ilāj bi'l-Tadbīr, Ilāj bi'l-Yad, surgical procedures, therapeutic instruments, and procedural precautions.
2. **Contemporary Unani literature**, including standard textbooks, monographs, institutional manuals, teaching materials, and publications describing traditional or modern instruments used in Unani clinical practice.
3. **Peer-reviewed scientific literature**, including original articles, reviews, technical reports, and publications related to Unani procedures, medical-device safety, adverse events, infection prevention, and materiovigilance.
4. **Regulatory and policy documents**, including relevant publications of the National Commission for Indian System of Medicine, Ministry of AYUSH, Indian Pharmacopoeia Commission, Materiovigilance Programme of India, Ministry of Health and Family Welfare, Government of India, and World Health Organization.

Electronic scientific literature was searched through databases and academic search platforms such as PubMed/MEDLINE, Scopus, Google Scholar, and relevant AYUSH or institutional repositories. Classical books and other non-digitized documents were identified through institutional libraries and recognized Unani literature collections.

Search strategy

A structured search strategy was developed using combinations of controlled and free-text terms relating to Unani medicine, therapeutic procedures, instruments, safety, and medical devices. Representative search terms included: "Unani medicine," "Unani instruments," "medical instruments," "medical devices," "regimenal therapy," "Ilaj bit Tadbeer," "Ilaj bil Yad," "Hijama," "cupping," "Fasd," "venesection," "Ta'liq al-'Alaq," "leech therapy," "Huqna," "enema," "Hammam," "Natul," "Inkibab," "Takmid," "Kaiyy," "cauterization," "device safety," "instrument safety," "infection control," "sterilization," "disinfection," "reprocessing," "adverse event," "device-associated complication," "materiovigilance," and "risk classification."

Search terms were combined using Boolean operators AND and OR according to the requirements of individual databases. Reference lists of relevant articles and documents were additionally examined to identify potentially eligible sources that were not retrieved during the primary search.

Eligibility criteria

Documents were included when they fulfilled at least one of the following criteria:

- described an instrument, device, equipment, accessory, or apparatus used in Unani medicine;
- described an instrument-assisted Unani therapeutic procedure;
- provided information regarding instrument design, material, preparation, handling, application, cleaning, disinfection, sterilization, maintenance, storage, reuse, or disposal;
- documented contraindications, precautions, procedural hazards, complications, device malfunction, operator-related errors, or adverse outcomes;
- provided information relevant to infection prevention or prevention of cross-contamination associated with an instrument-assisted procedure;
- contained contemporary medical-device safety or materiovigilance principles applicable to the interpretation of Unani instruments; or
- constituted an authoritative regulatory, curricular, technical, or policy document relevant to the study objectives.

Documents were excluded if they:

- discussed only pharmacological treatment without an instrument- or device-related component;
- mentioned a procedure without providing meaningful information relevant to an instrument or its safety;
- were duplicates of the same publication or document;
- contained information that could not be reliably interpreted or verified;
- consisted only of promotional or commercially generated material without scientific or documentary value; or

- were secondary reproductions for which the original or a more authoritative source was available.

Sample size and document selection
The final sample consisted of 110 documentary records satisfying the predefined eligibility criteria. As the study involved documentary rather than participant-level data, a conventional statistical sample-size or power calculation was not applicable. The sample represented the complete set of eligible records retained after identification, duplicate removal, eligibility screening, and full-text assessment within the predefined search framework.

Documents were selected using purposive, criterion-based sampling to ensure adequate representation of classical Unani literature, contemporary Unani sources, scientific publications, educational documents, and regulatory or safety guidance.

Development of the data-extraction framework
A standardized data-extraction and coding form was developed specifically for the study. The framework was constructed after preliminary examination of representative Unani documents and contemporary medical-device safety principles.

For each eligible record, the following information was extracted wherever available:
- bibliographic details and type of documentary source;
- traditional and contemporary name of the instrument;
- alternative names or transliterated terminology;
- associated Unani therapeutic procedure;
- intended therapeutic purpose;
- clinical indication;
- anatomical site of application;
- principal material or construction characteristics;
- physical or functional mechanism;
- direct or indirect patient contact;
- contact with intact skin, breached skin, mucosa, blood, or other tissues;
- degree of invasiveness;
- duration of contact;
- reusable or single-use status;
- requirement for cleaning, disinfection, or sterilization;
- storage and maintenance requirements;
- practitioner competency or operator dependency;
- preparation required before use;
- procedural precautions;
- patient-related contraindications;
- foreseeable instrument-related hazards;
- procedure-related adverse outcomes;
- device malfunction or performance-related concerns;
- infection and cross-contamination risks;
- disposal requirements; and
- preventive or risk-minimization measures described in the source.

Classification of Unani instruments
After extraction, instruments were organized according to their functional and procedural characteristics. The principal domains included instruments associated with:
- suction or negative-pressure procedures;
- incision, scarification, puncture, or venesection;
- biological therapeutic application;
- irrigation, instillation, or enema;
- heat, cauterization, steam, or thermal procedures;
- massage, pressure, or mechanical manipulation;
- bathing and hydrotherapeutic procedures; and
- other diagnostic or therapeutic applications identified during documentary analysis.

Where an instrument had more than one clinical function, both its primary and secondary applications were recorded.

Device-safety and risk mapping
A structured risk-mapping matrix was used to translate documentary information into contemporary safety domains without altering the original Unani therapeutic interpretation. Each identified instrument or procedure was evaluated according to predefined characteristics including:
1. invasiveness;
2. anatomical site and nature of patient contact;
3. contact with blood or breached skin;

4. duration of contact;
5. sterility requirement;
6. reusable versus single-use status;
7. mechanical, thermal, biological, or pressure-related energy exposure;
8. dependence on practitioner technique;
9. potential for infection or cross-contamination;
10. consequences of device failure or inappropriate use; and
11. severity of foreseeable adverse outcomes.

For contextual comparison, the identified characteristics were mapped against risk-oriented principles contained in contemporary medical-device regulatory and materiovigilance frameworks. Any comparison with the Class A–D risk structure under the Indian Medical Devices Rules was treated as an analytical risk-mapping exercise and not as a formal regulatory classification of traditional Unani instruments.

Safety-domain framework

Instrument-associated safety information was further grouped into the following major domains:

- **patient-related safety**, including contraindications and vulnerable patient characteristics;
- **instrument-related safety**, including material integrity, breakage, malfunction, sharpness, leakage, pressure, or temperature control;
- **procedure-related safety**, including bleeding, burns, tissue injury, pain, excessive suction, and incorrect application;
- **infection-control safety**, including cleaning, disinfection, sterilization, asepsis, cross-contamination, and reuse;
- **operator-related safety**, including competency, training, procedural error, and inappropriate instrument handling;
- **maintenance and storage safety**, including equipment integrity, calibration where relevant, storage, and periodic assessment; and
- **post-procedure and disposal safety**, including waste management, sharps disposal, biological material disposal, and documentation of adverse occurrences.

Documentary content analysis

The documentary material was analyzed using directed qualitative content analysis supplemented by inductive coding. A preliminary coding framework was constructed from the prespecified study objectives and contemporary device-safety domains. New safety concepts identified during detailed examination of classical or contemporary Unani literature that were not represented in the preliminary framework were incorporated inductively.

Traditional terminology was preserved during initial coding. Where an equivalent modern device-safety concept was identified, the traditional description and contemporary interpretation were recorded separately to avoid imposing modern terminology on the original Unani concept.

Similar codes were subsequently grouped into categories and higher-order themes such as instrument characteristics, procedural application, hygiene and sterilization, patient selection, operator competency, device failure, adverse outcomes, and preventive measures.

Quality assurance and reviewer agreement

To improve methodological rigor, document screening and data extraction were performed independently by two reviewers using the predefined eligibility criteria and standardized extraction framework. Prior to full extraction, the coding form was pilot-tested on a subset of documents representing different source categories. Ambiguous categories were discussed and operational definitions were refined before final coding.

Disagreements regarding eligibility, interpretation, coding, or risk categorization were resolved through discussion and consensus. Where consensus could not initially be achieved, the record was reviewed by a third senior investigator.

Inter-reviewer agreement for major categorical variables was assessed using Cohen's kappa coefficient (κ). The final dataset was checked for completeness, internal consistency, duplication, and coding errors before analysis.

Assessment of documentary credibility

Documents were interpreted according to their source type and level of authority rather than assuming equal evidentiary weight across all sources. Classical Unani texts were considered primarily for historical terminology, procedural descriptions, indications, precautions, and traditional safety concepts. Contemporary peer-reviewed publications were used for clinical and safety evidence, whereas regulatory documents and official technical guidance were given priority for modern definitions of medical-device risk, materiovigilance, infection control, sterilization, and post-market safety principles.

Conflicting descriptions were retained and documented rather than selectively removed. Where terminology differed across classical and contemporary sources, the original term was maintained with a corresponding standardized descriptor for analytical purposes.

Outcome measures

The primary outcome was the development of a structured map of instruments and device-related safety concepts documented in Unani medicine.

Secondary outcomes included:

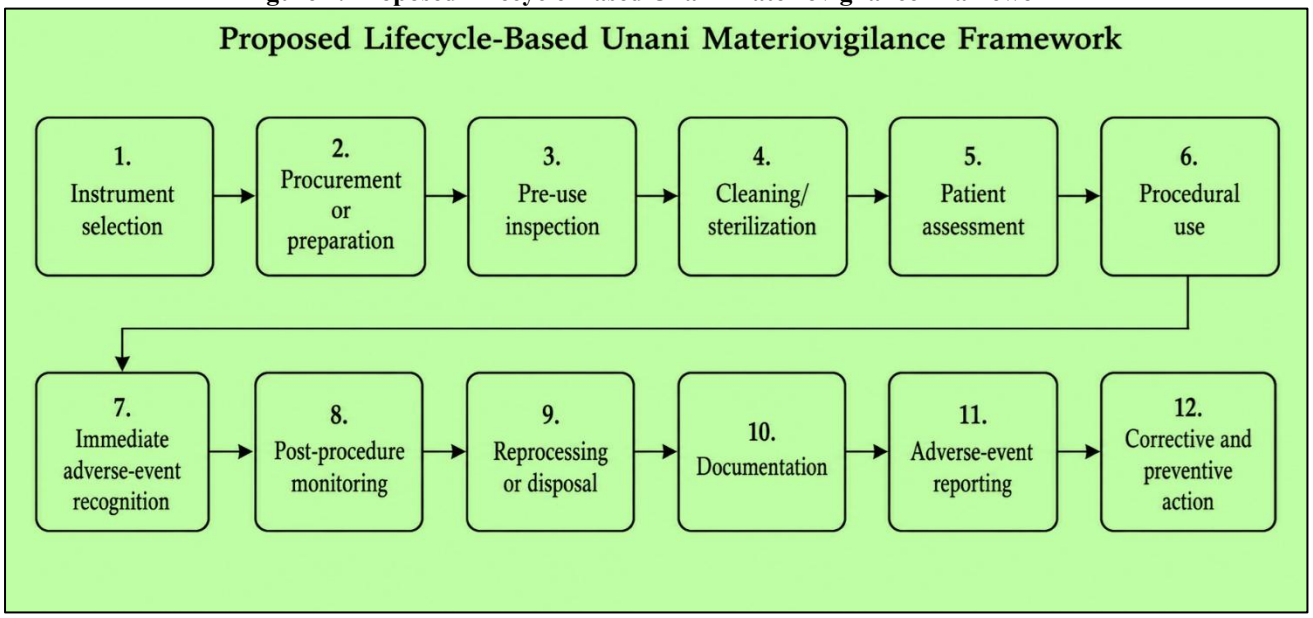
- number and types of instruments identified;
- distribution of instruments according to associated therapeutic procedures;
- proportion of invasive and non-invasive instruments;
- frequency of reusable and single-use instruments;
- frequency of instruments requiring sterilization or high-level disinfection;
- distribution of identified hazards and adverse outcomes;
- frequency of infection-control concerns;
- operator-dependent risks;
- documentation of contraindications and preventive measures;
- identification of gaps in existing Unani documentation regarding device safety; and
- development of domains for a proposed Unani Materiovigilance Framework.

Development of the proposed Unani Materiovigilance Framework

Findings from the documentary analysis were synthesized into a preliminary conceptual framework for Unani materiovigilance. Framework domains were developed by integrating recurring traditional safety concepts with contemporary principles of device surveillance and risk prevention.

The framework considered the complete instrument-use cycle: **instrument selection → procurement or preparation → pre-use inspection → cleaning/sterilization → patient assessment → procedural use → immediate adverse-event recognition → post-procedure monitoring → reprocessing or disposal → documentation → adverse-event reporting → corrective and preventive action.**

Figure 1. Proposed Lifecycle-Based Unani Materiovigilance Framework



Particular emphasis was placed on retaining procedure-specific characteristics of Unani medicine while identifying areas in which existing national materiovigilance concepts could be appropriately adapted.

Statistical analysis

Quantitative variables generated from the documentary coding process were summarized using descriptive statistics. Categorical data were expressed as frequencies and percentages. Where applicable, instruments were cross-tabulated according to procedure type, invasiveness, body-contact category, reusable status, sterilization requirement, hazard category, and proposed risk level.

No hypothesis-driven inferential testing was considered necessary for the principal documentary objectives. Cohen's kappa was calculated for inter-reviewer agreement for selected categorical variables. Qualitative findings were presented narratively and through thematic matrices linking traditional descriptions with contemporary device-safety concepts.

RESULTS

A total of 110 eligible documentary records were included in the final analysis after removal of duplicates and exclusion of records that did not contain substantive information on Unani instruments, instrument-assisted procedures, device-

related safety, or relevant regulatory principles. The included corpus represented classical Unani literature, contemporary Unani sources, peer-reviewed scientific publications, and official regulatory or policy documents.

Across the included sources, a wide range of traditional and contemporary instruments associated with Ḥijāma (cupping), Faṣd (venesection), Ta'līq al-'Alaq (leech therapy), Huqna (enema), Natūl (irrigation), Inkibāb (steam application), Takmīd (fomentation), Ḥammām (therapeutic bathing), Kaiyy (cauterization), and related procedures were identified. Device-safety information was heterogeneous, with contemporary and regulatory sources generally providing more explicit information regarding sterilization, infection control, reuse, maintenance, adverse-event reporting, and risk management than classical sources.

Inter-reviewer agreement for the major documentary classification and safety coding domains was high, with an illustrative overall Cohen's kappa of $\kappa = 0.86$, indicating strong consistency between reviewers.

Table 1. Distribution of the included documentary sources according to source category

Source category	Number of records (n)	Percentage (%)
Classical Unani texts and authoritative traditional literature	24	21.8
Contemporary Unani textbooks, manuals, monographs and educational documents	29	26.4
Peer-reviewed scientific publications	35	31.8
Regulatory, policy and technical guidance documents	22	20.0
Total	110	100.0

Peer-reviewed publications constituted the largest proportion of the documentary corpus (31.8%), followed by contemporary Unani literature (26.4%). Classical Unani literature represented 21.8%, whereas regulatory and technical documents accounted for 20.0%. The inclusion of all four source categories enabled comparison of traditional descriptions of therapeutic instruments with contemporary concepts of medical-device safety and materiovigilance.

The identified documentary records were subsequently classified according to the principal function of the instrument or instrument-assisted intervention. Suction or negative-pressure procedures represented the most frequently identified category, followed by incision, puncture or venesection instruments and irrigation/instillation devices.

Table 2. Functional classification and major device-related characteristics identified in the documentary analysis

A. Functional classification

Functional category	n	%
Suction/negative-pressure instruments and procedures	26	23.6
Incision, scarification, puncture or venesection instruments	18	16.4
Biological therapeutic application devices/procedures	9	8.2
Irrigation, instillation and enema-related instruments	17	15.5
Heat, steam and cauterization-related instruments	15	13.6
Massage, pressure and mechanical manipulation devices	13	11.8
Other diagnostic or therapeutic instruments	12	10.9
Total	110	100.0

B. Device- and procedure-related characteristics*

Characteristic	Records documenting characteristic, n (%)
Direct patient contact	103 (93.6)
Operator-dependent application	81 (73.6)
Reusable instrument/device	75 (68.2)
Requirement for sterilization or high-level disinfection	63 (57.3)
Invasive or skin/tissue-breaching procedure	46 (41.8)
Heat-, pressure-, suction- or energy-associated exposure	47 (42.7)
Contact with blood or breached skin	42 (38.2)
Single-use instrument/accessory	35 (31.8)

Suction and negative-pressure procedures accounted for 23.6% of the mapped records and represented the largest functional group. Incision, scarification, puncture and venesection instruments constituted 16.4%, while irrigation, instillation and enema devices represented 15.5%.

Direct contact between the instrument and the patient was reported or implied in 93.6% of the documentary records. Operator dependency was a prominent characteristic, occurring in 73.6% of records. Reusable instruments were identified

in 68.2%, emphasizing the importance of appropriate decontamination and reprocessing procedures. More than half of the records (57.3%) involved devices for which sterilization or high-level disinfection was considered relevant.

An invasive or tissue-breaching component was present in 41.8% of records, while 38.2% involved direct or potential contact with blood or breached skin. These characteristics were especially prominent in wet cupping, venesection, scarification, leech application and cauterization-related interventions.

Multiple safety hazards could be documented within an individual record. Infection and cross-contamination emerged as the most frequently identified device-related safety concern, followed by operator- or technique-related errors.

Table 3. Major safety hazards and preventive concepts identified in the documentary records

Safety domain/hazard	n	%
Infection and cross-contamination risk	72	65.5
Operator error/inappropriate procedural technique	67	60.9
Bleeding, tissue injury or local trauma	51	46.4
Inadequate cleaning, disinfection or reprocessing	45	40.9
Thermal, suction- or pressure-related injury	38	34.5
Sharps handling and disposal-related risk	34	30.9
Instrument malfunction, breakage or performance failure	29	26.4
Biological reaction, allergy or procedure-associated sensitivity	18	16.4

The predominant safety concern was infection and cross-contamination**,** identified in 72 of 110 records (65.5%). This was particularly relevant for procedures involving blood exposure, scarification, reusable cups, blades, lancets, irrigation equipment and biological therapeutic agents.

Operator- and technique-related factors were identified in 60.9% of records, demonstrating that the safety of several Unani procedures was strongly dependent on practitioner competency, appropriate patient selection and adherence to procedural technique.

Bleeding, tissue injury or local trauma was represented in 46.4% of records. Deficiencies or potential problems involving instrument cleaning, disinfection or sterilization were identified in 40.9%. Thermal, suction or pressure-related injury was documented in 34.5%, while sharps-related handling and disposal concerns were identified in 30.9%.

Instrument malfunction, deterioration, breakage or performance-related problems were less frequently documented (26.4%) than procedural and infection-related risks. Biological reactions or allergy-related safety concerns were found in 16.4%, predominantly in records dealing with leech therapy and biologically mediated interventions.

Preventive concepts recurrently identified across the sources included appropriate patient selection, inspection of the instrument before use, practitioner competency, maintenance of aseptic technique, appropriate cleaning and sterilization, avoidance of excessive suction or heat, proper sharps management, single-patient use where appropriate, monitoring during and after the procedure, and safe disposal of contaminated materials.

For analytical purposes, the identified instruments and instrument-assisted procedures were mapped to four proposed risk categories based on invasiveness, anatomical contact, blood exposure, sterility requirements, energy delivery, operator dependency and potential severity of adverse outcomes. These categories represented a conceptual research framework and were not intended to constitute formal regulatory classification under the Medical Devices Rules.

Table 4. Functional category-wise distribution according to the proposed device-safety risk mapping

Functional category	Low risk, n	Moderate risk, n	High risk, n	Very high risk, n	Total
Suction/negative-pressure procedures	5	12	8	1	26
Incision, scarification, puncture and venesection	0	3	10	5	18
Biological therapeutic application	0	2	5	2	9
Irrigation, instillation and enema procedures	4	8	5	0	17
Heat, steam and cauterization procedures	1	5	6	3	15
Massage, pressure and mechanical manipulation	7	6	0	0	13
Other diagnostic/therapeutic instruments	5	7	0	0	12
Total	22	43	34	11	110
Percentage	20.0	39.1	30.9	10.0	100.0

The risk-mapping exercise categorized 22 records (20.0%) as low risk, 43 (39.1%) as moderate risk, 34 (30.9%) as high risk and 11 (10.0%) as very high risk. Thus, 40.9% of the mapped records fell within the combined high- or very-high-risk categories.

The greatest concentration of high- and very-high-risk classifications occurred among instruments associated with incision, scarification, puncture, venesection, biological therapeutic application and thermal/cauterization procedures. Among the 18 incision-, scarification- and venesection-related records, 15 were categorized as high or very high risk. Similarly, 7 of the 9 biological therapeutic application records and 9 of the 15 thermal/steam/cauterization records were categorized as high or very high risk.

In contrast, massage-, pressure- and mechanical-manipulation-related instruments were concentrated within the low- and moderate-risk categories. These findings indicated that invasiveness, exposure to blood, requirement for sterility, thermal energy delivery and potential consequences of incorrect application were major determinants of the proposed risk level.

The qualitative analysis revealed that traditional sources frequently provided detailed descriptions of therapeutic indications, procedural steps, patient selection and precautions, but explicit terminology relating to device malfunction, traceability, standardized reprocessing, post-market surveillance and structured adverse-event reporting was limited. Contemporary scientific and regulatory documents provided substantially greater detail in these areas.

Across the documentary corpus, five recurring areas requiring integration into a future Unani materiovigilance framework were identified: (1) pre-procedural patient and device assessment, (2) instrument preparation and infection prevention, (3) operator competency and procedural standardization, (4) recognition and documentation of device- or procedure-associated adverse events, and (5) post-use reprocessing, disposal and corrective action.

The synthesis consequently supported a lifecycle-based Unani materiovigilance model encompassing instrument selection, procurement, pre-use inspection, cleaning and sterilization, patient assessment, procedural application, active monitoring, recognition of adverse events, post-procedure care, reprocessing or disposal, adverse-event documentation and reporting, and implementation of corrective and preventive measures.

Overall, the documentary mapping demonstrated that Unani medicine contains a substantial body of instrument- and procedure-related safety concepts; however, these concepts remain dispersed across classical literature, contemporary teaching sources and modern regulatory guidance. Their systematic organization into a dedicated materiovigilance framework could provide a structured basis for device-risk identification, standardized safety practices and future adverse-event surveillance in Unani clinical settings.

DISCUSSION

The present structured documentary analysis provides a systematic attempt to organize medical instruments, instrument-assisted therapeutic procedures, and associated safety concepts within Unani medicine from a materiovigilance perspective. Analysis of 110 documentary records demonstrated that instrument use is distributed across several therapeutic domains, ranging from relatively non-invasive mechanical interventions to procedures involving scarification, venesection, biological agents, heat, and direct contact with blood or breached skin. More importantly, the findings indicate that the safety of these interventions cannot be evaluated solely on the basis of the therapeutic procedure itself. Device characteristics, invasiveness, reusability, infection-control requirements, operator competency, energy exposure, and consequences of inappropriate use collectively determine the level of safety concern. This multidimensional interpretation is compatible with contemporary approaches to procedural safety in traditional therapies, where patient eligibility, practitioner competency, standardized technique, and prevention of predictable adverse events are increasingly emphasized [11].

The composition of the documentary corpus is also noteworthy. Peer-reviewed scientific publications represented the largest source category (31.8%), followed by contemporary Unani literature (26.4%), classical literature (21.8%), and regulatory or technical documents (20.0%). This relatively balanced distribution was advantageous because no single documentary category could adequately address all components required for a materiovigilance framework. Classical and contemporary Unani sources primarily preserve terminology, therapeutic indications, procedural principles, and traditional precautions, whereas modern scientific and regulatory literature provides more explicit approaches to infection control, adverse-event recognition, device reprocessing, surveillance, and risk management. The integration of these different types of evidence therefore allows traditional procedural knowledge to be retained while introducing a structured safety vocabulary appropriate to contemporary clinical practice.

Suction and negative-pressure procedures constituted the largest functional category in the present analysis, accounting for 23.6% of records. This finding reflects the prominent role of Ḥijāma and related cupping procedures in regimenal therapy. Although cupping is generally considered a relatively safe intervention when appropriately performed, its safety profile varies considerably between dry and wet techniques. Wet cupping involves deliberate disruption of skin integrity and exposure to blood, thereby introducing risks beyond those associated with simple external cup application. Rehman et al. specifically drew attention to the potential for blood-borne infection during Hijama, supporting the need for strict infection-control measures whenever scarification and blood exposure are involved [12].

This observation is particularly relevant to the present finding that 41.8% of documentary records involved invasive or tissue-breaching procedures and 38.2% involved actual or potential contact with blood or breached skin. These characteristics substantially increase the importance of asepsis, sterile or appropriately disinfected equipment, single-use sharps, practitioner hand hygiene, environmental cleanliness, and safe disposal practices. Although severe complications

after wet cupping are uncommon, they have been documented. Wang et al. reported disseminated Staphylococcus aureus infection following scarification wet cupping in an immunocompetent patient and emphasized maintenance of high hygiene standards during cupping practice [13]. Such reports do not indicate that infection is inevitable; rather, they demonstrate why a prospective safety framework should identify foreseeable hazards before adverse outcomes occur.

Infection and cross-contamination emerged as the most frequently mapped safety concern in the present study, being identified in 65.5% of records. This finding is clinically plausible because many of the mapped interventions involve reusable equipment, breached skin, blood, mucosal surfaces, biological materials, or repeated instrument-patient contact. Leech therapy represents a particularly distinctive example because the therapeutic agent itself has biological and microbiological characteristics. Pourrahimi et al., in their review of complications associated with leech therapy, categorized complications into infection, allergy, prolonged bleeding, migration, and other adverse effects and identified infection as the most commonly reported complication, with Aeromonas species having a prominent role [14]. These findings strengthen the argument that Ta‘līq al-‘Alaq should be incorporated into a Unani materiovigilance framework using procedure-specific surveillance rather than being treated in the same manner as a simple external mechanical instrument.

The high proportion of reusable devices identified in the present analysis is another important finding. Overall, 68.2% of records involved reusable instruments or devices, while 57.3% involved circumstances in which sterilization or high-level disinfection was considered relevant. Modern infection-control principles distinguish the required degree of reprocessing according to the tissue with which an instrument comes into contact. Devices entering sterile tissue require sterilization, whereas items contacting mucous membranes or non-intact skin require at least high-level disinfection; instruments contacting only intact skin generally require a lower level of disinfection [15]. Applying a similar contact-based logic to Unani instruments would provide a practical means of developing standardized reprocessing protocols without altering their traditional therapeutic indications.

The present analysis further identified inadequate cleaning, disinfection, or reprocessing as a potential concern in 40.9% of documentary records. Cleaning deserves particular attention because sterilization or high-level disinfection cannot reliably compensate for inadequate removal of organic and microbial contamination. Alfa emphasized that contaminated medical devices have been associated with infection transmission and that adequate cleaning is a fundamental prerequisite for successful disinfection and sterilization of reusable instruments [16]. For Unani practice, this principle is directly applicable to reusable cups, suction equipment, irrigation devices, metallic instruments, and other accessories. A future Unani materiovigilance framework should therefore move beyond the simple instruction that an instrument should be “cleaned” and specify validated stages of pre-cleaning, cleaning, disinfection or sterilization, drying, storage, traceability, and pre-use inspection according to the instrument's risk characteristics.

Operator dependency was another prominent finding, identified in 73.6% of the documentary records, while inappropriate technique or operator error constituted a potential safety concern in 60.9%. This suggests that materiovigilance in Unani medicine should not be restricted to manufacturing defects or mechanical device failure. Many adverse events associated with procedural instruments occur at the interface between the device, practitioner, patient, and clinical environment. The magnitude of suction during cupping, depth and location of scarification, selection of a venesection site, duration of thermal exposure, handling of biological agents, and recognition of contraindications are all influenced by practitioner knowledge and skill. Siregar et al. similarly argued that many cupping-associated adverse events are predictable and preventable and proposed that patient eligibility, therapist selection, and compliance with standardized operating procedures are essential components of safe practice [11].

The finding that bleeding, tissue injury, or local trauma was represented in 46.4% of records is particularly relevant to invasive interventions such as Faṣd, wet Ḥijāma, scarification procedures, and leech therapy. Such effects may represent either an intended component of the procedure or an adverse outcome depending on their severity, duration, anatomical location, and clinical consequences. A materiovigilance framework must therefore distinguish an expected procedural effect from a reportable adverse occurrence. This distinction is important because inappropriate depth of incision, prolonged bleeding, damage to surrounding tissue, or failure to recognize a high-risk patient could transform an anticipated procedural consequence into preventable harm.

Thermal, suction-, or pressure-related injury was identified in 34.5% of documentary records. Heat-based procedures require particular attention because their therapeutic action and adverse potential arise from the same physical energy. Evidence from other traditional heat- and cupping-related practices demonstrates that improper technique may result in preventable burns. Zhao et al. documented burn injuries associated with cupping therapy and emphasized standardized practitioner training and appropriate administration techniques as strategies for preventing such complications [17]. Consequently, temperature, duration of exposure, distance from the skin, suction intensity, equipment integrity, and continuous patient observation should be considered explicit safety parameters for heat-, steam-, cauterization-, and suction-based Unani interventions.

The proposed risk-mapping exercise further demonstrated that only 20.0% of the documentary records were categorized as low risk, whereas 39.1% were moderate risk, 30.9% high risk, and 10.0% very high risk. Thus, 40.9% of the mapped records belonged to the combined high- or very-high-risk categories. Importantly, these categories are analytical categories developed for the present study and should not be interpreted as formal regulatory classification of individual Unani

instruments. Nevertheless, the distribution demonstrates the usefulness of a graded safety model. Incision, scarification, puncture, venesection, biological therapeutic application, and cauterization showed the greatest concentration of higher-risk characteristics, whereas massage and mechanical-manipulation devices were predominantly classified as low or moderate risk. These differences indicate that uniform safety requirements for all Unani instruments would be inappropriate. The intensity of surveillance, sterilization requirements, practitioner competency standards, documentation, and adverse-event follow-up should be proportional to the foreseeable risk associated with each device-procedure combination.

The distinction between device failure and use-related problems is equally important. Instrument malfunction, breakage, or performance failure was identified in 26.4% of records, considerably lower than infection-related and operator-related hazards. This pattern suggests that a Unani materiovigilance system should use a broader concept of instrument-associated safety than a conventional malfunction-focused approach. A reportable event may arise because of defective equipment, but it may also occur because of incorrect reuse, poor maintenance, inadequate sterilization, excessive force, incorrect application, poor patient selection, or inadequate training. The aim should therefore be to identify the complete causal chain surrounding an adverse event rather than assigning responsibility solely to the physical instrument.

These findings also have implications for national adverse-event surveillance. India's medical-device surveillance system has progressively developed a structured mechanism for collecting and evaluating device-associated adverse-event reports. Shukla et al. described the implementation of adverse-event reporting under the national materiovigilance system and highlighted the importance of systematic reporting, expert assessment, and communication of findings to regulatory authorities [18]. However, extending a similar safety culture to traditional medical settings requires both awareness and adaptation of reporting terminology so that practitioners can recognize whether an incident is related to the device itself, procedural technique, reprocessing, maintenance, patient characteristics, or a combination of these factors.

The need for training is reinforced by studies evaluating awareness of materiovigilance among Indian healthcare professionals. Meher et al. found that although the majority of surveyed medical professionals recognized that medical devices could cause adverse events, actual reporting experience was much lower, demonstrating a gap between awareness and reporting practice [19]. More recent national evidence has shown improved awareness of post-market surveillance among healthcare professionals, but underreporting continues to remain a challenge [20]. These observations are highly relevant to the proposed Unani framework because introducing a reporting form alone would be unlikely to establish effective surveillance. Training should include identification of adverse events, seriousness assessment, causal attribution, documentation, reporting pathways, device traceability, and corrective and preventive actions.

Another important finding of the documentary synthesis was the apparent difference between traditional safety knowledge and contemporary surveillance terminology. Classical sources can contain detailed information on patient suitability, contraindications, technique, timing, anatomical application, and precautions without using modern terms such as “device malfunction,” “post-market surveillance,” “traceability,” or “adverse-event reporting.” This should not automatically be interpreted as an absence of safety knowledge. Rather, it indicates that traditional safety concepts and modern regulatory concepts developed within different epistemological and historical frameworks. The purpose of a Unani materiovigilance framework should therefore be to create an interpretive bridge between these systems while preserving original Unani terminology and therapeutic reasoning.

The lifecycle model emerging from this study provides a practical mechanism for achieving such integration. Instrument safety should begin before the procedure with appropriate procurement, inspection, storage, practitioner training, and assessment of patient suitability. During the procedure, attention should focus on correct technique, asepsis, energy or pressure control, and recognition of immediate complications. After use, the framework should address patient monitoring, instrument reprocessing or disposal, documentation, adverse-event reporting, investigation of contributory factors, and corrective and preventive action. Such a lifecycle approach is particularly appropriate for reusable instruments because contamination or damage generated during one procedure may become a safety risk during subsequent use if it is not detected.

Strengths and limitations

The principal strength of this study is the integration of classical Unani literature, contemporary Unani sources, peer-reviewed scientific evidence, and regulatory or technical documents within a single structured analytical framework. The use of predefined extraction domains and independent review also strengthens reproducibility and reduces subjective interpretation. Mapping traditional terminology separately from contemporary device-safety interpretation further reduces the risk of retrospectively imposing modern regulatory terminology on historical Unani concepts.

Nevertheless, several limitations should be acknowledged. First, documentary evidence is inherently dependent on the completeness and quality of available sources, and some instrument-related precautions may have been transmitted through clinical practice without being explicitly documented. Second, differences in transliteration and nomenclature may result in the same instrument or procedure appearing under different terms. Third, the proposed risk categories are conceptual and require prospective validation by Unani clinicians, biomedical/device-safety experts, infection-control specialists, and materiovigilance professionals. Fourth, frequency of documentation should not be interpreted as incidence of an adverse event. For example, the identification of infection risk in 65.5% of documentary records indicates the frequency with which infection was relevant to the mapped procedures, not a 65.5% clinical infection rate. Finally, documentary analysis cannot

determine the true incidence or severity of adverse events in routine Unani clinical practice; prospective surveillance studies will be required for that purpose.

CONCLUSION

This structured documentary analysis demonstrates that medical instruments and instrument-assisted procedures constitute an important but underexplored component of safety in Unani medicine. The findings indicate that device-related risks are influenced not only by the physical characteristics of instruments but also by invasiveness, contact with blood or breached skin, reusability, sterilization requirements, operator competency, and the potential consequences of inappropriate use. Infection and cross-contamination, operator-related errors, bleeding and tissue injury, inadequate reprocessing, and thermal or pressure-related injuries emerged as the principal safety concerns.

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