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Minimum data set of mucormycosis

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A B S T R A C T

Introduction: Mucormycosis, the third most prevalent invasive fungal disease ranked, has a very high mortality rate .The timely diagnosis, coupled with the prompt administration of drug and surgical interventions, yields a substantial reduction in mortality rates. To accomplish these objectives, the acquisition of accurate data and information assumes paramount importance. A minimum data set serves as a crucial tool for data collection, offering healthcare managers a standardized information resource. Consequently, the aim of this study was to develop a MDS to mucormycosis in Iran.

Material and Methods: This research was conducted using a practical approach, employing a two-step Delphi method. An extensive literature review was conducted aimed at extracting relevant information specific to mucormycosis. two individual checklists were developed. Following these checklists underwent rigorous evaluation through the Delphi, involving the 20 experts, consisting of five specialists each in the fields of infectious diseases, dermatology, otolaryngology, and health information management.

Results: Experts thoroughly examined a total of 72 out of 86 items on the demographic information checklist throughout both the initial and second phases of the Delphi process. Furthermore, within the clinical information checklist, experts meticulously evaluated 303 out of 323 data elements during the first and second phases of the Delphi process. The demographic checklist was structured into four categories basic information, demographic information, insurance information, and referral information. The clinical checklist consisted of seven categories, encompassing risk factors, types of mucormycosis disease, clinical signs and symptoms, diagnosis, species, treatment, and outcomes.

Conclusion: In recent years, the prevalence of underlying diseases has witnessed an upward trend, resulting in a subsequent escalation in the number of mucormycosis patients. In light of the burgeoning incidence of mucormycosis cases in Iran, it becomes imperative to establish a standardized MDS for this disease.

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INTRODUCTION

Mucormycosis, commonly referred to as zygomycosis, is an infectious fungal disease attributed to the Mucorales family. The primary mode of transmission is through exposure to mold found in various environmental sources such as soil, manure, plants, and vegetables. This mold can be detected even within the mucus of individuals in a state of good health [1, 2]. The initial documentation of mucormycosis in humans' dates back to 1855 when a German pathologist named Paltauff reported the first known case [3]. Throughout the decades of the 1980s and 1990s, there was a notable escalation in the incidence rates of the disease within the immunocompromised population [4]. Studies have

indicated a global increase in the prevalence of mucormycosis [5]. A study conducted in India demonstrated that mucormycosis accounted for approximately 24% of all invasive fungal infections in multicenter intensive care units (ICUs) [6]. Moreover, a study carried out by Dolatabadi et al. in Iran unveiled a notable surge in the prevalence of mucormycosis. The findings exhibited a prevalence increase, from 9.7% in 2008 to 23.7% in 2014 [7].

In accordance with research findings, it is evident that in developed countries, an increased incidence of this condition is observed among individuals diagnosed with hematological malignancies and those who have undergone organ transplants. Conversely, in developing countries, with a specific focus on India, diabetes emerges as the predominant underlying disease among individuals affected by mucormycosis [8-10].

Mucormycosis presents itself in diverse forms, such as rhino-orbital-cerebral, pulmonary, gastrointestinal, cutaneous, renal, and disseminated, with each manifestation contingent upon the precise site of involvement. The disease is characterized by a rapid and progressive course, resulting in prompt vascular thrombosis and necrosis [5, 11]. Individuals with blood malignancies, bone marrow stem cell transplantation, neutropenia, organ transplantation, AIDS, diabetes, corticosteroid treatment, deferoxamine treatment for iron overload, chemotherapy, and skin injuries, including burns, exhibit a heightened susceptibility to mucormycosis [12, 13].

The disease is characterized by a range of common symptoms, including fever, rhinorrhea, headache, facial numbness, blurred vision, conjunctivitis, and vision loss [14, 15]. When compared to other invasive fungal infections such as Aspergillus or Candida, mucormycosis exhibits a significantly higher mortality rate and is often accompanied by more severe complications for patients. In contrast to surgical intervention and drug therapy, which generally yield more favorable prognoses, the mortality rate for mucormycosis remains notably elevated, spanning a wide range of 50 to 100 percent [11, 16].

Mucormycosis gives rise to a wide range of complications that are particularly relevant to this disease. These complications comprise cavernous sinus thrombosis, infection, palatine ulcers, periorbital destruction, nephrotoxicity, hypokalemia, prolonged hospitalization, and ultimately mortality [17]. The successful management of mucormycosis necessitates adherence to four critical factors: timely diagnosis, removal of the underlying precipitating factor, surgical intervention, and prompt initiation of pharmacotherapy. Swift and accurate diagnosis assumes paramount significance owing to the rapid progression of the infection, thereby mandating the immediate commencement of drug therapy.

Furthermore, the rectification of any deficiencies in the patient's immune system holds pivotal importance throughout the treatment process. The diagnostic challenges associated with this disease stem from the lack of specific diagnostic tools and the clinical resemblance it shares with invasive Aspergillus infections [18-20]. Moreover, as a result of the significant diagnostic challenges associated with this disease, more than fifty percent of mucormycosis cases are diagnosed following the patient's demise, typically during the postmortem examination [14].

Doctors bear a significant responsibility in making diagnostic and therapeutic choices, where the accuracy of the information they rely on serves as the bedrock for such decisions. Moreover, thorough research conducted within the clinical domain guarantees the presence of reliable and applicable data. The integration of information technologies in gathering and analyzing medical information plays a pivotal role in facilitating well-informed decision-making [21].

The minimum data set (MDS) serves as an essential data collection tool that facilitates access to health information systems. Its multifaceted role spans across several critical domains, encompassing planning, management, evaluation, monitoring, the enhancement of patient care quality, and cost reduction [22]. The design of a MDS constitutes the primary step in efficiently managing disease information, as well as facilitating the improvement of patient care quality and disease control [23]. MDS is a standard method used for gathering data [24, 25].

The MDS comprises two primary categories: patient demographic information and clinical data, providing secure access to precise and unequivocal insights into the disease [26]. The MDS encompasses crucial and standardized data that is systematically collected from medical centers. Its primary purpose is to enable the comprehensive comparison and analysis of disease-related information, along with the evaluation of innovative treatment approaches and their respective outcomes [27].

In light of the rising prevalence of diseases and the rapid spread of various ailments, including the recent surge in coronavirus cases, which have contributed to immunodeficiency and a significant upsurge in opportunistic infections like mucormycosis, accompanied by high mortality rates, there is an imperative need for precise and timely information to facilitate effective diagnosis and treatment of mucormycosis. Furthermore, given the limited existing research on this topic in Iran and the absence of comparable studies, the researcher has opted to undertake the present investigation.

MATERIAL AND METHODS

This study adopts applied research with the objective of determining the essential data set necessary for investigating mucormycosis disease. The research consists of three consecutive phases. In the initial phase, an extensive review of relevant studies was conducted to gather information regarding this disease. The search was executed utilizing a specific search strategy across external databases such as PubMed, Web of Science, Scopus, and ProQuest, without imposing any temporal limitations. In order to ascertain suitable keywords and construct a robust search strategy (Table 1), a comprehensive examination of pertinent literature in the realm of minimally invasive diseases and mucormycosis was conducted. Additionally, the application of Mesh vocabulary was employed to identify the most pertinent and effective keywords for the study. The search was subsequently carried out in the aforementioned databases. To explore the field of mucormycosis, thorough internet searches were conducted to review relevant texts and information from reputable sources such as the websites of the World Health Organization (WHO), Centers for Disease Control and Prevention (CDC), and Indian Medical Association (IMA).

TABLE 1: Search strategy in databases (29 January 2023)

Database	Search Strategies	Result
Web of Science	(((((((TS= ("minimum data set")) OR TS= ("minimal data set")) OR TS= ("core data set")) OR TS= ("common data elements")) OR TS=("dataset")) OR TS= ("essential data set")) OR TS=("registries")) OR TS=("registry")	565,529
	((((TS=("mucormycosis")) OR TS=("mucor")) OR TS= ("mucorales infection")) OR TS=("zygomycosis")) OR TS=("mucormycoses")	12,332
	(#1 & #2)	64
ProQuest	title ("minimum data set") OR title ("minimal data set") OR title ("core data set") OR title ("common data elements") OR title ("essential data set") OR title("dataset") OR title("registries") OR title("registry")	132,605
	title("mucormycosis") OR title("mucormycoses") OR title("mucor") OR title ("mucorales infection") OR title("zygomycosis")	7,023
	(Title ("minimum data set") OR title ("minimal data set") OR title ("core data set") OR title ("common data set") OR title ("essential data set") OR title("dataset") OR title("registries") OR title("registry")) AND (title("mucormycosis") OR title("mucormycoses") OR title("mucor") OR title ("mucorales infection") OR title("zygomycosis"))	11
PubMed	(("dataset"[All Fields]) OR ("common data elements"[MeSH Terms])) OR ("registries"[MeSH Terms])	227,462
	(((((((("minimum data set"[Title/Abstract]) OR ("minimal data set"[Title/Abstract])) OR ("core data set"[Title/Abstract])) OR ("dataset"[Title/Abstract])) OR ("essential data set"[Title/Abstract])) OR ("common data elements"[Title/Abstract])) OR ("registry"[Title/Abstract])) OR ("registries"[Title/Abstract])	282,675
	(("mucormycosis"[MeSH Terms]) OR ("zygomycosis"[MeSH Terms])) OR ("mucor"[MeSH Terms])	6,657
	("mucormycoses"[Title/Abstract]) OR ("Mucorales infection"[Title/Abstract])	110
	((("dataset"[All Fields]) OR ("common data elements"[MeSH Terms])) OR ("registries"[MeSH Terms])) OR (((((((("minimum data set"[Title/Abstract]) OR ("minimal data set"[Title/Abstract])) OR ("core data set"[Title/Abstract])) OR ("dataset"[Title/Abstract])) OR ("essential data set"[Title/Abstract])) OR ("common data elements"[Title/Abstract])) OR ("registry"[Title/Abstract])) OR ("registries"[Title/Abstract]))	334,226
	((((("mucormycosis"[MeSH Terms])) OR ("zygomycosis"[MeSH Terms])) OR ("mucor"[MeSH Terms])) OR (("mucormycoses"[Title/Abstract]) OR ("mucorales infection"[Title/Abstract]))	6,700
	(((((("dataset")) OR ("common data elements"[MeSH Terms])) OR ("registries"[MeSH Terms])) OR (((((((("minimum data set"[Title/Abstract]) OR ("minimal data set"[Title/Abstract])) OR ("core data set"[Title/Abstract])) OR ("dataset"[Title/Abstract])) OR ("essential data set"[Title/Abstract])) OR ("common data elements"[Title/Abstract])) OR ("registry"[Title/Abstract])) OR ("registries"[Title/Abstract])))) AND (((((("mucormycosis"[MeSH Terms])) OR ("zygomycosis"[MeSH Terms]))	30
	OR ("mucor"[MeSH Terms])) OR (("mucormycoses"[Title/Abstract]) OR ("mucorales infection"[Title/Abstract]))))	30
Scopus	title("minimum data set") OR title("minimal data set") OR title("core data set") OR title("common data elements") OR title("essential data set") OR title("dataset") OR title("registries") OR title("registry")	1,039,310
	title("mucormycosis") OR title("mucormycoses") OR title("mucor") OR title("mucorales infection") OR title("zygomycosis")	16,743
	(title("minimum data set") OR title("minimal data set") OR title("core data set") OR title("common data set") OR title("essential data set") OR title("dataset") OR title("registries") OR title("registry")) AND (title("mucormycosis") OR title("mucormycoses") OR title("mucor") OR title("mucorales infection") OR title("zygomycosis"))	73

TABLE 2: New search strategy for PubMed (10 May 2023)

Search Strategies	Result
("risk factors"[MeSH Terms]) OR ("causality"[MeSH Terms])	970,392
(" Correlates"[Title/Abstract]) OR ("population at risk"[Title/Abstract])) OR ("risk scores"[Title/Abstract])	214,849
("risk factors"[MeSH Terms]) OR ("causality"[MeSH Terms])	970,392
(" Correlates"[Title/Abstract]) OR ("population at risk"[Title/Abstract])) OR ("risk scores"[Title/Abstract])	214,849
(("mucormycosis"[MeSH Terms]) OR ("zygomycosis"[MeSH Terms])) OR ("mucor"[MeSH Terms])	6,742
("mucormycoses"[Title/Abstract]) OR ("Mucorales infection"[Title/Abstract])	112
(((diagnosis[MeSH Terms]) OR (diagnose[Title/Abstract])) OR (diagnose[Title/Abstract] AND examinations[Title/Abstract])) OR (antemortem diagnosis[Title/Abstract])	9,461,654
(("therapeutics"[MeSH Terms]) OR ("therapy"[Title/Abstract])) OR ("treatment"[Title/Abstract])	9,645,544
(("risk factors"[MeSH Terms]) OR ("causality"[MeSH Terms])) OR ((" Correlates"[Title/Abstract]) OR ("population at risk"[Title/Abstract])) OR ("risk scores"[Title/Abstract]))	1,170,016
(("mucormycoses"[Title/Abstract]) OR ("Mucorales infection"[Title/Abstract])) OR ((("mucormycosis"[MeSH Terms]) OR ("zygomycosis"[MeSH Terms])) OR ("mucor"[MeSH Terms]))	6,807
(((((("therapeutics"[MeSH Terms]) OR ("therapy"[Title/Abstract])) OR ("treatment"[Title/Abstract])) AND (((therapeutics[MeSH Terms]) OR (therapy[Title/Abstract])) OR (treatment[Title/Abstract])))) AND (((("risk factors"[MeSH Terms]) OR ("causality"[MeSH Terms])) OR ((" Correlates"[Title/Abstract]) OR ("population at risk"[Title/Abstract])) OR ("risk scores"[Title/Abstract])))) AND ((("mucormycoses"[Title/Abstract])	88
((("Therapeutics"[MeSH Terms]) OR ("therapy")) OR ("treatment")) AND (((((("risk factors"[MeSH Terms]) OR ("causality"[MeSH Terms])) OR ((" Correlates"[Title/Abstract]) OR ("population at risk"[Title/Abstract])) OR ("risk scores"[Title/Abstract])))) AND ((("mucormycoses"[Title/Abstract]) OR ("Mucorales infection"[Title/Abstract])) OR ((("mucormycosis"[MeSH Terms]) OR ("zygomycosis"[MeSH Terms])) OR ("mucor"[MeSH Terms])))) AND (("diagnosis"[MeSH Terms]) OR ((("Diagnose") OR ("Diagnoses and Examinations")) OR ("Antemortem Diagnosis")))) AND (English[Filter])	78

Due to the inadequacy of data obtained from the initial search in the databases, a subsequent search was performed in the PubMed database using an adjusted strategy and novel keywords (Table 2).

Eligibility criteria

As part of the second phase, a comprehensive review was conducted on all the gathered studies, adhering to the guidelines outlined in the latest version of PRISMA [28].

Inclusion and exclusion criteria

For the purpose of this research, articles that were deemed relevant to the research objectives and specifically addressed the design of minimum data collection for mucormycosis disease or the mucormycosis disease registry, as well as those providing insights into the risk factors, diagnosis, and treatment of mucormycosis disease, were carefully selected for review. Moreover, articles available in either Farsi or English languages were included based on the selection criteria. Studies that did not provide adequate information regarding the MDS collection for mucormycosis disease or were not relevant to the topic were excluded from the research.

Study selection

During this stage, an extensive review was performed on the titles, abstracts, and keywords of all the selected articles. Relevant articles were selected, while irrelevant ones were excluded from consideration. The complete texts of the relevant articles, along with their corresponding data elements, were meticulously collected and recorded in the data extraction form. Additionally, a comprehensive search was conducted across various online resources, including the websites of esteemed organizations such as WHO, IMA, and CDC. Furthermore, other relevant sources identified through the Google search engine were explored to compile the necessary data elements for the study.

The data extraction form was meticulously created utilizing Excel 2020, incorporating three distinct columns for source name and data elements. Conversely, the initial checklist was thoughtfully devised in Word 2020. Within this comprehensive checklist, the demographic data was thoughtfully divided into four sections: basic data, demographic data, insurance data, and referral data. Furthermore, the clinical data within the checklist was meticulously organized into seven distinct sections, encompassing risk factor data, disease types data, disease signs and symptoms, diagnosis, pathogenic species, treatment, and disease outcomes. The designed checklist underwent a rigorous validation process for its data elements, employing the widely recognized Delphi method.

The checklists incorporated a two-column format. The first column encompassed the data elements, while the second column conveyed the corresponding importance of each data elements. A panel of esteemed experts, consisting of 5 infectious disease specialists, 5 dermatologists, 5 otolaryngologists, and 5 health information management specialists, was entrusted with the pivotal responsibility of meticulously evaluating the carefully designed checklist. To gauge their assessment, experts utilized a five-point Likert scale, which ranged from one (indicating "very low" importance) to five (representing "very high" importance). At the conclusion of the checklist, two sections were included: explanations and suggested elements.

These sections afforded experts an opportunity to provide explanatory notes regarding specific data elements and propose additional elements that were deemed important, but were not initially included in the checklist. The inclusion of data elements was determined based on the level of agreement among the experts. As a result, data elements that attained a median score of one or two were excluded, while data elements with a median score of three were retained for further consideration in the second phase of the Delphi method. Similarly, data elements that attained a median score of four or five were confirmed during the initial phase of the Delphi process. During the first phase of the Delphi method, no new data elements were suggested by the experts. Those data elements that achieved a median score of three in this phase progressed to the second phase of the Delphi method. The checklist utilized in the second phase adhered to the same format as the first phase, with the exception of the suggested data elements section being omitted.

In order to perform a comprehensive analysis of the data and present the status of each data elements to the experts, the SPSS V26 was meticulously employed throughout each phase of the Delphi process. The statistical measures employed included the calculation of mean, standard deviation, median, and interquartile range.

RESULTS

All sources obtained from the database search were thoroughly checked using PRISMA guideline [28]. Upon conducting an extensive search across databases and search engines, a comprehensive total of 256 articles was retrieved with the objective of identifying the fundamental components of the mucormycosis data elements. Additionally, an additional 8 articles specifically related to mucormycosis disease were extracted from Google. Subsequent to meticulous scrutiny and the elimination of duplicated entries (135 articles), a final corpus of 121 articles remained, warranting meticulous assessment of their titles and abstracts. Among these, 71 articles were deemed incongruous with the objectives of the current study and, consequently, were excluded from inclusion within the minimum data set for mucormycosis. Subsequently, a refined selection of 50 articles was designated for an in-depth analysis. It should be noted, however, that limitations in accessibility hindered the retrieval of the full text for 3 articles, while an additional 5 articles lacked the requisite level of detail concerning mucormycosis. Subsequently, a total of 42 articles were acquired for meticulous scrutiny, thus culminating in a comprehensive corpus of 50 articles when combined with the additional 8 articles extracted through Google. The insights and perspectives of relevant experts were duly incorporated in this context (Fig 1).

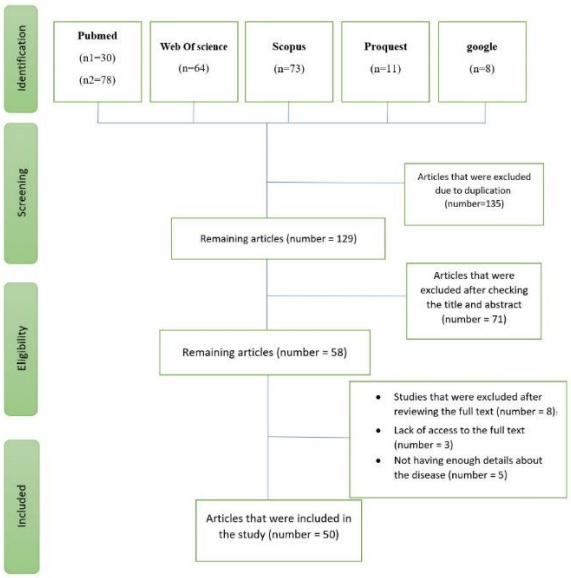

Fig 1: Workflow of the paper selection.

The extracted data elements were meticulously organized into two distinctive sections: demographic information and clinical information. Within the demographic information section, a comprehensive total of 86 data elements were retrieved from the scrutinized articles. These data elements were further categorized into four specific classifications, namely subject information, demographic information, insurance information, and referral information. In the context of the clinical information section, an exhaustive review of 50 articles yielded a sum of 451 extracted data elements. A stringent validation process was then employed to ensure the precision of the final checklist. Consequently, any data elements that were solely sourced from a single reference were excluded, resulting in the removal of 128 data elements instances. Conversely, data elements that were substantiated through two or more references were duly integrated into the checklist.

Within the designated section focusing on demographic information, data elements were further categorized into four specific classifications, namely subject information, demographic information, insurance information, and referral information.in initial phase of delphi, the experts deemed 58 out of the total 86 data elements as acceptable. Furthermore, 23 data elements successfully advanced to the second phase of the Delphi method. However, subsequent expert evaluation led to the removal of five data elements. During the second phase of the Delphi process, out of the 23 data elements that entered this phase, nine data were eliminated based on expert evaluation, while the remaining elements attained a consensus among the experts (Table 3).

Table 3: Demographic Data Elements for The Mucormycosis minimum data set

Main Data	Approved Data Elements	Deleted Data Elements
Basic Information	Name of the hospital, number of health record, date of visit, number of visits	Weight, height, BMI, address of the hospital
Demographic Information	Name, surname, father's name, gender (male, female), date of birth, place of birth, age, marital status (single, married, divorced, unknown), seniority/passport number, level of education (illiterate, under diploma, diploma), bachelor's degree, master's degree, doctorate, unknown)، Nationality (Iranian, foreign, unspecified), ethnicity (Kurdish, Ler, Arab, Baloch, Persian, unspecified) Occupation (unemployed, employee, free, other), place of residence (city, village, unknown), mobile phone, landline, email, address	Race, Workplace address, language
Insurance Information	Insurance status, insurance type (social security, Iranians, armed forces, unknown, insurance serial number, insurance validity date)	-
Referral Information	Referral type (referred by the patient himself, referred to the emergency room, referred by prisoners, referred from the addiction treatment institute, referred from other cities (name of the city),), referring doctor (specialty type)، Date of admission, time of admission, admitting doctor (doctor's specialist، Place of hospitalization (emergency, infectious, ENT, other)	Acceptor's name referred from other cities(unknown)

Within the clinical information section, a comprehensive total of 323 data elements were meticulously extracted from the articles. Subsequently, 22 data progressed to the advanced stage of evaluation. It is noteworthy that five data elements were subsequently excluded from further consideration, while the remaining data garnered validation and approval from the experts. During the second phase, consisting of the initially identified 22 data elements, a consensus was reached among the experts for six specific data elements, while the remaining data were deemed unsuitable and thus discarded (Table 4).

Table 4: Clinical Data Elements for Mucormycosis minimum data set

Main Data	Approved Data Elements	Deleted Data Elements
Risk Factor	Diabetes Mellitus (Type I or II,With or Without Ketoacidosis), Hyperglycemia, Hematological Malignancy(Hematopoietic Stem Cell Transplantation (HSCT), Graft Versus Host Disease (GVHD), Acute Or Chronic Myeloid Leukemia, Acute Or Chronic Lymphoblastic Leukemia, Hodgkin Lymphoma, Non-Hodgkin Lymphoma, Myelodysplastic Syndrome, allo-sct (Allogeneic Hematopoietic Stem Cell Transplantation), Multiple Myeloma, Lymphoma), Malignancy, Steroid(Dexamethasone, Methylrednisone, Prednisolone, Hydrocortisone, Budesonide), Immunocompromised, Chemotherapy, Solid Organ Transplantation, Trauma, Burns, Prematurity, HIV, Neutropenia, Iron Overload, Use Of Deferoxamine, , Cancer, Obesity, Lymphocytopenia, Dialysis, Chronic Pulmonary Disease (Asthma, COPD), Thyroid Dysfunction ,Improper Use of Oxygen, Heart Disease, Covid19 (Hospitalization, Intubated, Antiviral Therapy, Remdesivir, Favipravir, Tacilizumab, Covid19 Vaccine), Autoimmune Disease, Aplastic Anaemia, Systemic Lupus Erythematodes, Car Accident, Tuberculosis, Cirrhosis, Hepatitis, Loosening Of Teeth, Toothache, Major Surgery, Bronchopneumonia, Alcoholic Chronic Liver Disease, Bowel Perforation, Renal Failure, Low Birth Weight Infants, Injecting Drug Users (IDU)/Drug Abuse, Immunosuppressive Therapy, Concomitant Infection (Bacterial Infection), Malnutrition, Hypertension, Rhinorrhea, Chronic Antibiotic Use	Pearson's Syndrome
Type of Mucormycosis	Rhino-Orbito-Cerebral (Rhino-orbital, Rhino-cerebral), Gastrointestinal, Cutaneous\soft tissue\skin, Pulmonary\lung, Brain\ Central nervous system, Sinus (sino-orbital), Bone/Joints, Jawbone, Eye/Orbital, Vessels, Kidney, Liver, Spleen, Oral, Peritoneum, Intestine, Renal, Nose, Mediastinum, Disseminated	Heart
Clinical Sign & Symptom	Fever\Pyrexia, Cough, Fatigue, Nasal Obstruction, Nasal Discharge, Nasal Crusting, Foul Smell/ Halitosis, Epistaxis, Swelling (Facial Swelling, Lid Swelling, Soft Tissue Swelling, Preorbital Swelling), Necrosis (Necrotic Cutaneous, Necrotic Eschar, Necrotic Ulcer, Necrotic Palate, Necrotic Tissue), Edema, Pain (Orbital Pain, Facial Pain, Chest Pain, Abdominal Pain), Erythematous, Headache, Proptosis/ Exophthalmus, Ptosis, Vision Loss\Diminution/Blindness, Vision Disturbances, Blurred Vision, Diplopia, Ophthalmoplegia, Dyspnea, Paresthesia, Paralysis/Palsy, Facial Palsy,, Hemiplegia, Hemiparesis, Ulcers\Wound, Sinusitis, Nausea, Vomiting, Hematemesis, Mental Status, Facial Numbness, Anosmia, Anaesthesia, Chemosis, Seizures, Dysarthria, Warmth, Pleural Effusion, Discoloration Of Skin, Discoloration Of Palate, Consciousness, Endophthalmitis, Hemoptysis, Black Lesion, Red Eye, Redness, Thrombosis, Diarrhea, Melena, Peritonitis, Abdominal Distension, Hospitalization, Periorbital Cellulitis, Hypoxemia, Sepsis, Gastrointestinal Hemorrhage, Asymptomatic, Altered Sensorium, Conjunctival Suffusion, Black Escher, Palatal Eschar, Cranial Nerve Dysfunction, Tenderness, Tachypnea, SpO2, Auscultation of Lung (Stridor, Ronchi, Wheeze, Rales), Arthralgia/Arthritis	Anaesthesia Warmth
Diagnosed by	Imaging/Radiology (CT Scan, MRI, Tomography (Sinus Thickening, Mucosal Thicking, Internal Cranial Artery Involvement, Cavernous Sinus Involvement, Boney Erosion, Orbital Invasion, Nodular Lesion, Enhancement Of Vessels, Lung Consolidation, CNS Lesion (Cerebritis, Cerebral Edema, Focal Lesion), Infiltrate, Mass Radiology, Caviation, Brain, Paranasal Sinus, Abdomen, Lung, Maxillary Sinus, Ethmoid Sinus, Sphenoid Sinus, Frontal Sinus, Orbit)), Endoscopy (Edema, Crusting, Discharge, Ulcer, Necrosis, Nodules, Polyps, Destruction), Biopsy, Laboratory Value (Hba1c, FBS PBS), Culture, Histopathology (Direct Microscopy, Sample, Nasal Mucosa, Paranasal Sinus Mucosa, Orbital Tissue, Tissue, Sputum, Appropriate Lesion, Blood, Bone Marrow), Polymerase Chain Reaction (PCR), Broncho-Alveolar Lavage/ Bronchoscopy, Transthoracic Needle Aspiration,	-
Species	Rhizopus Spp. Lichtheimia Spp. Mucor Spp. Cunninghamella Spp. Rhizomucor Spp. Saksenaea Spp. Apophysomyces Spp. Mucorales Spp. Absidia Spp. Syncephalastrum Spp.	Rhizopus Homothallicus, Rhizopus Microsporus, Rhizopus Oryzae, Rhizopus Microsporus Var. Rhizopodiformis, Rhizopus Pusillus, L. Corymbifera, L. Ramosa, Mucor Circillenoides, Cunninghamella Bertholletiae, Rhizomucor Pusillus, Rhizomucor Variabilis

Main Data	Approved Data Elements	Deleted Data Elements
Treatment	Combination Therapy, Antifungal Drug/Therapy (Amphotericin B (Liposomal Amphotericin B, Amphotericin B Deoxycholate, Amphotericin B Lipid, Amb Colloidal Dispersion), Triazoles (Posaconazole, Itraconazole, Isavuconazole, Fluconazole, Ketoconazole), Echinocandin (Caspofungin, Micafungin, Anidulafungin), Deferasirox, Flucytosine), Prophylaxis, Surgery (Sinus Surgery (FESS), Orbital Exenteration (Wedge Resection), Debridemant (Turbinectomy, Maxillectomy, Lobectomy, Palatectomy, Carniotomy, Partial Pneumonectomy, Zygoma Debridement,,Debridement Of Orbital Floor , Debridement Of Osteomyelitis Skull Bone, Debridement Of Paranasal Sinusis, Debridement Of a Necrotic Lesion)), Adjuvant Therapy (GM-CSF, Interferon- γ),,Combination Therapy, Antifungal Drug/Therapy (Amphotericin B (Liposomal Amphotericin B, Amphotericin B Deoxycholate, Amphotericin B Lipid, Amb Colloidal Dispersion), Triazoles (Posaconazole, Voriconazole, Itraconazole, Isavuconazole, Fluconazole, Ketoconazole), Echinocandin (Caspofungin, Micafungin, Anidulafungin), Deferasirox, Flucytosine), Prophylaxis, Hyperbaric Oxygen Therapy, Surgery (Sinus Surgery (FESS), Orbital Exenteration (Wedge Resection), Debridemant (Turbinectomy, Maxillectomy, Lobectomy, Carniotomy, Partial Pneumonectomy, Zygoma Debridement, Debridement Of Orbital Floor, Anterior Table Debridement, Posterior Table Cranialisation, Debridement Of Osteomyelitis Skull Bone, Debridement Of Paranasal Sinusis, Debridement Of a Necrotic Lesion)), Adjuvant Therapy (GM-CSF, Interferon- γ),	Voriconazole, Hyperbaric Oxygen Therapy, Anterior Table Debridement, Posterior Table Cranialisation, Palatectomy,
Outcome	Recovery and Discharge, Death, Type of IM (probable, proven), Follow-up (Time since Discharge (3month, 6month, other), Sequelae)	

DISCUSSION

Mucormycosis is recognized as the third most prevalent fungal infection, distinguished by a significant mortality rate. The increase in underlying diseases has given rise to a concurrent elevation in the global prevalence of this disease, particularly notable in the context of Iran [7, 29]. The expeditious diagnosis, eradication of predisposing factors, prompt initiation of drug therapy, and surgical intervention have the potential to mitigate mortality [20]. Accurate and practical data form the cornerstone for making informed decisions regarding diagnostic and therapeutic interventions [21]. The design of the minimum data collection holds paramount significance in the comprehensive gathering and utilization of mucormycosis data.

The minimum data set for mucormycosis is composed of two separate checklists, one for clinical data and the other for demographic data. The collection of demographic data serves the purpose of patient identification and the establishment of the healthcare provider-patient relationship. Alongside this, the collection of clinical data during patient treatment by healthcare providers plays a pivotal role in enabling medical education, research endeavors, and effective planning.

This study involved the extraction of 286 articles utilizing a specific search strategy with the Google search engine. From this initial pool, 50 articles were identified as relevant to the research objectives. A meticulous examination of these selected articles ensued to extract pertinent data elements.

Subsequently, two distinct checklists were developed to capture demographic and clinical data elements. These checklists underwent rigorous evaluation through a two-phase Delphi process, which engaged the insights of 20 experts representing various specialties including infectious disease specialists, dermatologists, otolaryngologists, and health information management specialists. Notably, out of the initial 86 data elements included in the demographic information checklist, the experts' consensus resulted in the acceptance of 72 data elements during both the first and second phases of the Delphi process. With regard to the clinical information checklist, 303 out of 323 data elements received consensus and approval from the panel of experts during the successive phase of the rigorous Delphi process.

Subsequent to an extensive review of diverse articles, the requisite data elements for the demographic information checklist were acquired [30, 31]. The aforementioned data elements were categorized into four distinct categories: basic information, demographic information, insurance information, and referral information.

The data elements within the clinical information checklist were meticulously categorized into seven distinct categories: risk factors, types of mucormycosis disease, clinical signs and symptoms, disease diagnosis, species, treatment, and outcomes. The risk factors category encompassed a total of 80 data elements.

The findings of a study conducted by CDC unveiled that individual with underlying conditions, including diabetes, hematological malignancies, cancer, organ transplantation, and stem cell transplantation, heightened levels of iron in their bodies, as well as skin injuries stemming from surgical procedures or burns, along with premature or underweight infants, exhibit an augmented susceptibility to the development of mucormycosis [32]. The study

conducted by Chakrabarti et al. revealed a significant correlation between the escalation of mucormycosis cases and the rising prevalence of uncontrolled diabetes mellitus among individuals residing in developing countries and tropical regions. As a result, it becomes imperative to conduct thorough screenings for mucormycosis in patients with uncontrolled diabetes mellitus within these geographical areas [13]. In India, diabetes has been identified as a prominent [33] risk factor for mucormycosis, accounting for 73.5% of disease cases. Similarly, in Iran and Mexico, diabetes is associated with mucormycosis in 75% and 72% of cases, respectively [7, 34, 35].

Multiple studies have documented hematological malignancy as a significant risk factor for mucormycosis [35-39]. According to Prakash et al.'s study, diabetes emerges as the predominant risk factor for mucormycosis in India, whereas blood malignancy and organ transplantation exhibit higher prevalence as risk factors in America and European countries [5]. Research studies have provided evidence of a notable increase in the incidence of mucormycosis among patients diagnosed with acute lymphoblastic leukemia, acute myeloid leukemia, and those who have undergone bone marrow transplantation. This surge in cases can largely be attributed to the administration of steroids and chemotherapy [4, 40, 41]. These data elements were deemed acceptable by experts during the initial phase of the Delphi methodology.

In the study conducted by Patrikos et al., risk factors such as burns, trauma, and vehicular accidents were identified as significant factors [42]. These findings are consistent with the outcomes of the current research and received approval from experts during the preliminary phase of Delphi. It is worth highlighting those individuals who develop mucormycosis because of burn wounds frequently experience severe complications and face heightened mortality rates [43]. In a study conducted by Duashel et al., it was demonstrated that the mortality rate of mucormycosis among patients with burn injuries ranges from 29% to 100% [44]. Similarly, in a separate investigation by Kyriopoulos et al., six cases of mucormycosis were examined, with three cases associated with burn injuries and the remaining three cases resulting from vehicular accidents [45].

In the classification of risk factors, experts in the initial phase acknowledged the inclusion of premature infants and infants with low birth weights as noteworthy data elements. Furthermore, a multitude of studies has consistently recognized these elements as prominent risk factors [33, 46-49]. Based on the research findings from CDC in the United States, there is a higher prevalence of gastrointestinal mucormycosis among premature and underweight infants, as well as individuals afflicted with malnutrition [32].

COVID-19 stands as a significant risk factor for mucormycosis, garnering unanimous acceptance by experts in the initial phase of the Delphi process. The findings of studies have revealed a rapid escalation in the incidence of mucormycosis globally during the second wave of the COVID-19 pandemic. Although the initial reported case of mucormycosis in connection with COVID-19 emerged in Chile, a significant majority of cases, accounting for approximately 70%, have been reported from India [1, 50, 51].

Within the risk factors classification, Pearson's syndrome garnered a median score of less than three during the second phase of the Delphi process, leading to its exclusion from the roster of data elements. It is worth noting that the rarity of this disease potentially influenced participants' perception of the element as being irrelevant or nonessential.

mucormycosis manifests in a range of prevalent forms, such as Rhino-orbital-cerebral, pulmonary, cutaneous, diffuse, and gastrointestinal presentations [8]. Patients with diabetes bear a heightened vulnerability to the Rhino-orbital-cerebral form, while those with cancer or organ transplants exhibit a greater susceptibility to the pulmonary variety. Moreover, the cutaneous form predominantly affects individuals afflicted by traumatic conditions, including burn injuries, accidents, war-related injuries, and chemical burns [52]. The aforementioned data received validation from experts during the initial phase of the Delphi process.

Nevertheless, the cardiac form of the disease failed to achieve consensus among the experts and was subsequently deemed ineligible for inclusion in the study. The decision to exclude this form was primarily based on its notable rarity and infrequency of occurrence [53].

A study published by CDC examined the clinical presentation of mucormycosis and identified several associated symptoms. Rhino-Orbital-Cerebral mucormycosis is characterized by facial swelling, headache, fever, and nasal congestion. Pulmonary mucormycosis is manifested through symptoms such as black lesions, cough, and chest pain, while cutaneous pulmonary mucormycosis is distinguished by redness, pain, and swelling in the vicinity of the wound. Gastrointestinal mucormycosis presents with clinical symptoms including abdominal pain, nausea, vomiting, and gastrointestinal bleeding [32]. These data elements were collectively established and agreed upon by experts during the initial phase of the Delphi process.

The study conducted by Arian et al. examined the prevailing clinical symptoms associated with

mucormycosis, with a particular focus on symptoms concerning the ear, throat, and nose, which accounted for 69.6% of cases. Otolaryngology-related symptoms included palate and nose necrosis, nasal discharge, nasal congestion, and Epistaxis. Furthermore, vision-related manifestations comprised vision loss, eye paralysis, Proptosis, pain around the eye, Ptosis, eye cellulitis, swelling around the eye, and Chemosis [54]. All data elements mentioned above received unanimous endorsement from experts during the initial phase of the Delphi process.

Antifungal medications, including Amphotericin B, Posaconazole, and Isaconazole, are frequently prescribed in the management of this disease. Furthermore, surgical intervention is often imperative to excise the affected tissue [32]. A range of surgical procedures, including turbinectomy, maxillectomy, enucleation, and other appropriate interventions, are utilized for the treatment of this particular condition [38].

During the initial phase of the Delphi process, experts reached a unanimous decision to exclude the inclusion of voriconazole as an informative element. Voriconazole, an antifungal medication prescribed for treatment purposes, was eliminated based on expert assessment of its limited effectiveness in addressing the disease and its potential to worsen the patient's condition. Empirical evidence from diverse studies has consistently demonstrated the resistance of Mucorales to voriconazole [55, 56].

The data element "hyperbaric oxygen therapy" obtained an average score of one and did not achieve consensus among the experts. The decision to exclude this element was grounded in the unavailability of this treatment modality within the context of Iran.

The conducted studies shed light on a notable deficiency in Iran's mucormycosis data collection, emphasizing the absence of a standardized dataset addressing essential data elements pertinent to the disease. As a result, the findings derived from this study served as the impetus for the development of a framework aimed at establishing a minimum data set for mucormycosis. The creation of this minimum data set holds significant significance as an initial and pivotal step towards the establishment of a comprehensive mucormycosis disease registry. Such a registry will facilitate the systematic compilation of provincial-level data within this realm, empowering specialists to utilize the gathered information for advanced research endeavors and expedited patient treatment.

Limitations

One of the limitations of this study was the inadequate involvement of mycology experts, which can be considered a weakness. To enhance the validity and comprehensiveness of future studies, it is highly recommended to include the valuable insights and expertise of mycology specialists during the Delphi phase.

It is recommended to leverage the collected data in order to develop artificial intelligence-based models aimed at predicting the risk of mucormycosis among patients with underlying factors.

CONCLUSION

In recent years, the prevalence of underlying diseases has witnessed an upward trend, resulting in a subsequent escalation in the number of mucormycosis patients. In light of the burgeoning incidence of mucormycosis cases in Iran, it becomes imperative to establish a standardized MDS for this disease.

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AUTHOR'S CONTRIBUTION

All authors contributed to the literature review, design, data collection and analysis, drafting the manuscript, read and approved the final manuscript.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest regarding the publication of this study.

FINANCIAL DISCLOSURE

No financial interests related to the material of this manuscript have been declared.

ETHICS APPROVAL

This study is approved by the ethics committee of Kerman University of Medical Sciences with approval code: IR.KMU.REC.1401.413

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