



Literature trends and hidden patterns in health literacy studies among individuals with type 1 diabetes: A scoping review protocol [☆]



Ilaria Milani ^{a,*}, Elisa Cipponeri ^{b,c}, Paola Ripa ^d, Arianna Magon ^e, Silvia Cilluffo ^b, Stefano Terzoni ^b, Maura Lusignani ^b, Rosario Caruso ^{b,e}

^a Department of Biomedicine and Prevention, University of Rome Tor Vergata, Rome, Italy

^b Department of Biomedical Sciences for Health, University of Milan, Milan, Italy

^c Department of Endocrinology, Nutrition and Metabolic Diseases, IRCCS MultiMedica, Sesto San Giovanni, Milan, Italy

^d Nursing School, Ospedale San Giuseppe - MultiMedica, Milan, Italy

^e Health Professions Research and Development Unit, IRCCS Policlinico San Donato, San Donato Milanese, Italy

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ABSTRACT

The rising prevalence and incidence of Type 1 Diabetes (T1D) highlights its impact on quality of life, long-term health complications, and the economic burden it poses across socio-economic strata. Effective management of T1D demands robust self-care skills, which are significantly influenced by health literacy (HL) levels; studies have shown that lower HL is associated with poorer health outcomes. This scoping review protocol is designed to identify literature trends and hidden patterns in research assessing HL among individuals with T1D. The review will consider studies that address HL in individuals with T1D across all age groups and settings. Studies published in English or those with an available HTML version will be included to allow automatic translation of the contents for non-English records. Guided by the Joanna Briggs Institute (JBI) guidelines and the PRISMA-ScR 2020 framework, this scoping review will systematically search electronic databases, including PubMed, Scopus, CINAHL, EMBASE, Google Scholar, and Web of Science (WoS) without time restrictions. Two independent reviewers will assess each study for eligibility and perform data extraction using a standardized form.

- The review aims to map out the existing research landscape on HL in T1D and highlight areas requiring further investigation.
- It seeks to establish connections between HL and self-care efficacy in T1D, contributing to improved patient education and management strategies.
- Findings will inform future research directions and potentially influence policy and clinical practices surrounding diabetes care management.

[☆] Related research article: None.

* Corresponding author.

E-mail address: ilaria.milani@students.uniroma2.eu (I. Milani).

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Specifications table

Subject area:	Medicine and Dentistry
More specific subject area:	Nursing
Name of your protocol:	Literature trends and hidden patterns in health literacy studies among individuals with type 1 diabetes: a scoping review protocol
Reagents/tools:	Not applicable
Experimental design:	Not applicable
Trial registration:	<i>Not applicable</i>
Ethics:	Since this protocol involves a scoping review of existing literature and does not directly engage human subjects, animals, or social media platforms for primary data collection, no ethical concerns are raised. Ethical Considerations for Scoping Review: Human Subjects: This work did not involve direct interaction with human subjects or the collection of primary data from individuals; therefore, informed consent was not required. The review strictly synthesizes information from previously published studies, which are assumed to have obtained necessary ethical approvals. Animal Experiments: No animal experiments were conducted as part of this scoping review. The study exclusively focuses on reviewing and synthesizing existing literature on human health literacy in individuals with Type 1 Diabetes. Data from Social Media Platforms: This review did not involve the collection of data from social media platforms. All analyzed data are derived from peer-reviewed academic publications and officially published reports that comply with ethical standards for research.
Value of the Protocol:	<ul style="list-style-type: none"> • This protocol provides a structured approach to identify and synthesize existing research on health literacy in Type 1 Diabetes, laying the groundwork for future studies by highlighting knowledge gaps and emerging trends that can inform targeted research questions and intervention strategies. • This protocol aims to deepen our understanding of the role health literacy plays in patient outcomes, which is crucial for developing more effective educational programs and healthcare policies. • Introducing the OCTIS framework for topic modeling within the scope of health literacy research offers a novel methodological approach that could provide more detailed insights and a comprehensive understanding of complex datasets, potentially setting a new standard for literature reviews in healthcare research

Background

Globally, there are 8.75 million people affected by Type 1 Diabetes (T1D), with one-fifth of these residing in low- and middle-income countries [9]. The literature indicates that the prevalence and incidence of the condition are rising, with adults comprising most of the affected population. T1D is associated with reduced quality of life, long-term complications, and substantial costs, even in high-income countries [8]. The condition is associated with significant management challenges, requiring adequate health literacy (HL) [1].

HL is a multidimensional concept of a complex and dynamic nature, defined by Parnell as a collaborative competence that integrates previous health knowledge and experiences, personal traits, health conditions, cultural and linguistic preferences, and cognitive capacities [17]. These elements collectively enhance the ability of organizations, caregivers, and healthcare recipients to obtain, comprehend, and apply health information and services. This interplay, in turn, enables informed, actionable decisions that enhance health outcomes [17].

Conner defines health behaviors as “activities undertaken to prevent or detect disease or to enhance health and well-being,” while literature indicates that HL may be a significant factor influencing these behaviors [6]. Low levels of HL are associated with negative health outcomes [20]. In this context, the nurse’s role is crucial in assessing HL levels in patients with T1D. This evaluation allows for the design of highly personalized educational interventions aimed at ensuring the acquisition of the knowledge and skills necessary for the autonomous management of the disease [17].

The literature addressing HL in individuals with T1D is diverse and heterogeneous. An overview of this topic provides a comprehensive perspective useful for guiding future research and improving intervention strategies. While HL has been well-summarized in individuals with Type 2 Diabetes mellitus (T2D), it has not been thoroughly synthesized in

T1D [5]. For this reason, a scoping review could be useful to elucidate key concepts and definitions within the literature, identify and define knowledge gaps, offer a comprehensive and current overview for practitioners, researchers, and educators, and support future research and development [2,11,19]. This protocol aims to outline the rationale and methodology for conducting a scoping review to map literature trends and potentially hidden patterns in studies that have measured HL in individuals with T1D.

Description of protocol

Design

The scoping review will be performed in accordance with JBI guidelines [10,12], employing the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) 2020 framework to guide the research process [22]. Authorships follow a score-based strategy to determine the individual contribution of the involved researchers [13].

Consistently with the aim, the primary question for the proposed scoping review is: “What are the emerging trends in the literature that have measured HL among individuals with T1D?”

The sub-research questions (RQs) to guide the study are:

RQ1: How are HL levels measured?

RQ2: Which dimensions of HL are assessed?

RQ3: What are the sociodemographic characteristics of the analyzed samples?

RQ4: In which geographical and clinical contexts are the instruments used for measuring HL?

RQ5: What are the relationships between HL and clinical outcomes in T1D?

RQ6: How does HL influence the management and control of T1D?

RQ7: Are there identifiable associations between HL and patient-reported outcomes in T1D?

RQ8: What impact does HL have on healthcare utilization and costs among T1D patients?

Eligibility criteria

Eligibility criteria for the scoping review are rigorously defined using the Populations, Concepts, and Context (PCC) framework, adhering to the standards set forth by the Joanna Briggs Institute [10].

- **Population:** The investigation is centered on individuals diagnosed with T1D without age restrictions. This population has been selected to specifically understand the HL challenges and outcomes associated with this chronic condition.
- **Concept:** The cornerstone of the search strategy is HL. The review aims to explore how HL is measured, the dimensions that are evaluated, and the overall impact of HL on the management and clinical outcomes of T1D.
- **Context:** The scope of this review encompasses studies performed in diverse settings that involve T1D patients (any clinical setting). There will be no exclusions based on cultural, subcultural, racial, or gender considerations, ensuring a comprehensive analysis. Moreover, the review intends to incorporate research from all geographical areas to discern any regional differences in HL implementation and its effects.

The inclusion and exclusion criteria are established based on the PCC framework, ensuring a comprehensive and academically rigorous approach. The inclusion criteria encompass all records that adhere to the specified PCC framework, which includes studies focusing on individuals diagnosed with T1D. The conceptual focus of the investigation mandates that the primary or significant secondary inquiry of each study pertains to HL, examining its measurement, the dimensions assessed, and the impact on management and clinical outcomes in T1D. Additionally, the context of the research has to involve any clinical or healthcare-related setting that addresses HL among patients with T1D. The scope of eligible literature is expansive, accommodating various study designs from both primary and secondary sources. This includes empirical research—quantitative, qualitative, and mixed-methods—as well as reviews, opinion pieces, editorials, discussion papers, and published theses. The exclusion criteria are singularly focused on language and accessibility constraints. Studies not available in English or lacking an HTML version are excluded. The absence of an HTML version limits the feasibility of translating non-English texts, which is crucial for evaluating the content's relevance and accuracy concerning the scoping review's objectives.

Types of sources

This scoping review will include all studies identified through the literature search that meet the inclusion and exclusion criteria. If the comprehensive search yields a limited number of eligible studies, grey literature will be reviewed to capture hard-to-find or unpublished sources

Search strategy

Potentially relevant records will be identified by searching the following electronic databases without any time restrictions: PubMed, Scopus, CINAHL, EMBASE, and Web of Science (WoS). In addition to the primary databases, Google Scholar will also be searched to capture additional relevant studies, including grey literature and less accessible sources that may not be indexed in traditional academic databases. The search strategies were initially designed for PubMed and then modified for the other databases. The complete search strategy for all databases is provided in [Table 1](#). The databases will be re-searched once the protocol will be published.

Source of evidence selection

Following the systematic search, all identified citations will be collated and uploaded into Rayyan software [14], and duplicates will be removed. Titles and abstracts will be independently screened by two reviewers (IM and EC) to evaluate their eligibility based on the inclusion criteria for the review. Both reviewers will thoroughly assess the full texts of the selected studies against the same criteria. The final scoping review will document and report reasons for excluding studies at the full-text stage that do not meet the inclusion criteria. Any disagreements between the reviewers during the selection process will be resolved through discussion or by involving an additional reviewer if necessary. The complete results of the search and study selection process will be included in the final review and illustrated using a PRISMA flow diagram [15].

Table 1
Search strategy.

Database	Query	Records
Pubmed	((("Diabetes Mellitus, Type 1"[Mesh]) OR (((((((((((((((IDDM[Title/Abstract]) OR T1DM[Title/Abstract]) OR "Type 1 Diabetes"[Title/Abstract]) OR "Autoimmune Diabetes"[Title/Abstract]) OR "Juvenile Onset Diabetes"[Title/Abstract]) OR "Juvenile-Onset Diabetes"[Title/Abstract]) OR "Brittle Diabetes Mellitus"[Title/Abstract]) OR "brittle diabetes"[Title/Abstract]) OR "diabetes mellitus type 1"[Title/Abstract]) OR "diabetes mellitus type I"[Title/Abstract]) OR "diabetes type 1"[Title/Abstract]) OR "diabetes type I"[Title/Abstract]) OR "early onset diabetes mellitus"[Title/Abstract]) OR "insulin dependent diabetes"[Title/Abstract]) OR "juvenile diabetes"[Title/Abstract]) OR "juvenile diabetes mellitus"[Title/Abstract]) OR "type 1 diabetes"[Title/Abstract]) OR "type I diabetes mellitus"[Title/Abstract]) OR "Insulin-Dependent Diabetes Mellitus"[Title/Abstract]))) AND (health literacy[mesh] OR (health[ti] AND literacy[ti]) OR ("health literacy" OR "health literate" OR "medical literacy") OR (functional[tw] AND health[tw] AND literacy[tw]) OR numeracy OR ((low literate[ti] OR low literacy[ti] OR literacy[ti] OR illiteracy[ti] OR literate[ti] OR illiterate[ti] OR reading[mh] OR comprehension[mh] OR "information literacy"[mesh]) AND (health promotion[major] OR health education[major] OR patient education[major] OR Communication Barriers[major] OR communication[major:noexp] OR health knowledge,attitudes OR attitude to health[major])) OR (comprehension[major] AND educational status[major]) OR (family[ti] AND literacy[ti]) OR ("drug labeling" OR Prescriptions [mh]) AND ("comprehension" OR "numeracy")) OR "low health literacy"[tw] OR "ehealth literacy"[tw] OR "limited health literacy"[tw] OR "low numeracy"[tw] OR ((cancer[ti] OR diabetes[ti]) AND (literacy[ti] OR comprehension[ti])) OR "adult literacy" OR "limited literacy" OR "patient understanding"[ti] OR "disease knowledge"[tw] OR ((self care [major] "self care"[tw] OR "self-care"[tw]) AND perception[mh]) OR (comprehension AND food labeling[mh]) OR (comprehension AND informed consent) OR (comprehension AND insurance, health))	N = 231 (07–31–2024)
Embase	('diabetes mellitus, type 1'/exp OR iddm:ti,ab OR t1dm:ti,ab OR 'type 1 diabetes':ti,ab OR 'autoimmune diabetes':ti,ab OR 'juvenile onset diabetes':ti,ab OR 'juvenile-onset diabetes':ti,ab OR 'brittle diabetes mellitus':ti,ab OR 'brittle diabetes':ti,ab OR 'diabetes mellitus type 1':ti,ab OR 'diabetes mellitus type i':ti,ab OR 'diabetes type 1':ti,ab OR 'diabetes type i':ti,ab OR 'early onset diabetes mellitus':ti,ab OR 'insulin dependent diabetes':ti,ab OR 'juvenile diabetes mellitus':ti,ab OR 'type i diabetes mellitus':ti,ab OR 'insulin dependent diabetes mellitus':ti,ab OR 'insulin-dependent diabetes mellitus':ti,ab) AND ('health literacy'/exp OR (health:ti AND literacy:ti) OR 'health literacy' OR 'health literate' OR 'medical literacy' OR (functional AND health AND literacy) OR numeracy OR 'low literate':ti OR 'low literacy':ti OR literacy:ti OR illiteracy:ti OR literate:ti OR illiterate:ti OR 'reading'/exp OR 'comprehension'/exp OR 'information literacy'/exp)	N = 717 (07–31–2024)
Cinahl	ALL (((('diabetes AND mellitus, AND type AND 1') OR ("t1dm :ti,ab") OR ("type 1 diabetes:ti,ab") OR ('autoimmune AND diabetes:ti,ab) OR ('juvenile AND onset AND diabetes:ti,ab) OR ('juvenile-onset AND diabetes:ti,ab) OR ('brittle AND diabetes AND mellitus:ti,ab) OR ('brittle AND diabetes:ti,ab) OR ('diabetes AND mellitus AND type AND 1':ti,ab) OR ('diabetes AND type AND 1':ti,ab) OR ('diabetes AND type AND i':ti,ab) OR ('early AND onset AND diabetes AND mellitus:ti,ab) OR ('insulin AND dependent AND diabetes:ti,ab) OR ('juvenile AND diabetes:ti,ab) OR ('juvenile AND diabetes AND mellitus:ti,ab) OR ('type AND i AND diabetes:ti,ab) OR ('type AND i AND diabetes AND mellitus:ti,ab) OR ('insulin AND dependent AND diabetes AND mellitus:ti,ab) OR ('insulin-dependent AND diabetes AND mellitus:ti,ab)) AND ('health AND literacy'))type 1 diabetes mellitus"[ti] AND "health literacy"[ti])	N = 17 (07–31–2024)
Scopus	ALL (((('diabetes AND mellitus, AND type AND 1') OR ("t1dm" :ti,ab) OR ('type 1 diabetes:ti,ab) OR ('autoimmune AND diabetes:ti,ab) OR ('juvenile AND onset AND diabetes:ti,ab) OR ('juvenile-onset AND diabetes:ti,ab) OR ('brittle AND diabetes AND mellitus:ti,ab) OR ('brittle AND diabetes:ti,ab) OR ('diabetes AND mellitus AND type AND 1':ti,ab) OR ('diabetes AND type AND 1':ti,ab) OR ('diabetes AND type AND i':ti,ab) OR ('early AND onset AND diabetes AND mellitus:ti,ab) OR ('insulin AND dependent AND diabetes:ti,ab) OR ('juvenile AND diabetes:ti,ab) OR ('juvenile AND diabetes AND mellitus:ti,ab) OR ('type AND i AND diabetes:ti,ab) OR ('type AND i AND diabetes AND mellitus:ti,ab) OR ('insulin AND dependent AND diabetes AND mellitus:ti,ab) OR ('insulin-dependent AND diabetes AND mellitus:ti,ab)) AND ('health literacy':ti,ab))	N = 10 (07–31–2024)
WoS	ALL= (((('diabetes mellitus, type 1') OR ('diabetes AND type AND 1':ti,ab) OR ('diabetes AND type AND i':ti,ab) OR ('early AND onset AND diabetes AND mellitus:ti,ab) OR ('insulin AND dependent AND diabetes:ti,ab) OR ('juvenile AND diabetes:ti,ab) OR ('juvenile AND diabetes AND mellitus:ti,ab) OR ('type AND i AND diabetes:ti,ab) OR ('type AND i AND diabetes AND mellitus:ti,ab) OR ('insulin AND dependent AND diabetes AND mellitus:ti,ab) OR ('insulin-dependent AND diabetes AND mellitus:ti,ab)) AND ('health AND literacy'))	N = 274 (07–31–2024)

Data extraction

Data will be extracted from the selected papers for the scoping review by two independent reviewers, IM and EC, employing a data extraction tool, specifically a Microsoft Excel table, that has been designed by another reviewer, RC. The data to be extracted encompasses detailed information about the participants, the conceptual focus, context, study methodologies, and key findings that are pertinent to the review questions. A preliminary version of the extraction form is provided (Table 2).

This extraction tool will be dynamically refined throughout the data extraction phase based on the insights gained from each analyzed source. Any alterations to the tool will be meticulously recorded in the scoping review documentation. If discrepancies arise between the reviewers, these will be resolved through discussion or consulting an additional reviewer when necessary. Furthermore, authors of the studies may be approached to supply missing or additional data as deemed relevant.

Table 2
Data extraction instrument.

First author, year and country	Knowledge synthesis method/Study design	Aim	Research focus	Sample characteristics	Context	Instruments	Dimensions of HL	Key findings
[article n]	[concise extraction]	[concise extraction]	[concise extraction]	[concise extraction]	[concise extraction]	[concise extraction]	[concise extraction]	[no limits to the extracted words to produce a textual corpus]

Additionally, the data extraction tool is designed to facilitate the creation of a textual corpus derived from the key findings of each study. This corpus will then serve as the dataset for applying advanced analytics based on a Bayesian Optimization approach to identify topics from a textual corpus [21]. Two authors (IM and RC) will independently evaluate each study and proceed with data extraction. A consensus discussion will be used to merge and compare the extractions and views of the involved authors.

Data analysis

This review will summarize the study findings, employing both tabular summaries and visual data representations to effectively present the complex information extracted. These may include, but are not limited to, flow diagrams of study selection, tables summarizing study characteristics, and figures illustrating key outcomes.

To rigorously analyze the textual corpus formed from the key findings of the included studies, we will employ the Optimizing and Comparing Topic Models Is Simple (OCTIS) framework [21]. This innovative tool facilitates the training, analysis, and comparison of various topic models, including the well-established Latent Dirichlet Allocation (LDA), as used in previous reviews [4].

The primary advantage of using OCTIS lies in its integration of Bayesian Optimization, a strategy that optimizes the hyperparameters of topic models [21]. This optimization is crucial as it allows us to adjust the parameters of models like LDA to enhance their performance specifically for our dataset, which consists of diverse texts concerning health literacy in T1D extracted from the included literature. In other words, Bayesian Optimization is an advanced statistical method designed to fine-tune model hyperparameters for optimal performance [21]. Hyperparameters, which control aspects like the number of topics in LDA models, significantly impact the quality of the results in topic modeling analyses [21]. Therefore, Bayesian Optimization improves LDA modeling by iteratively testing various parameter combinations and evaluating each one against a predefined performance metric. Instead of exhaustively testing all possibilities, Bayesian Optimization uses a probability-based approach to guide each new iteration toward promising configurations, leading to a more efficient and targeted search for the optimal model settings [21]. Overall, OCTIS ensures that the topic models generate more coherent and relevant topics by determining the optimal configuration of these parameters, providing clearer insights into the underlying themes of the data [4]. Bayesian Optimization will guide these metrics and aim to ensure that the resulting topics will be statistically significant, meaningful, and interpretable in relation to the research questions posed by our scoping review (i.e., to map literature trends and potentially hidden patterns in studies that have measured HL in individuals with T1D). This methodology will enhance the scoping review, extending it beyond a descriptive synthesis to serve as an exploratory and analytical approach.

Quality assessment

The quality assessment in the context of this scoping review will adhere to the guidelines and principles outlined by the JBI and the PRISMA-ScR framework [10,16]. However, it is crucial to note that conducting a quality assessment in scoping reviews is not a mandatory component, as the primary aim is not to grade the quality of the evidence or establish analytic associations between concepts as typically seen in systematic reviews or meta-analyses [7,10]. Instead, the focus of a scoping review is to map the available literature on a given topic, identifying key concepts, types of evidence, and gaps in research, irrespective of the quality of the evidence [18].

Given the exploratory nature of scoping reviews, the inclusion of a quality assessment phase depends significantly on the specific objectives of the review and the nature of the questions being addressed. For this scoping review, the diversity in study designs and methodologies is anticipated to be broad, ranging from empirical research to opinion pieces and grey literature. This heterogeneity presents a considerable challenge in applying a uniform quality assessment tool or criteria across all included studies.

Therefore, while this protocol recognizes the potential value of assessing the methodological rigor and quality of the included records, it does not obligate the reviewers to perform such an assessment. The review authors will determine the feasibility of conducting a quality assessment once the selection process has been completed. If a quality assessment is deemed appropriate and feasible, it will evaluate the clarity of reporting, the appropriateness of the study's design to the research question, and the risk of bias within individual studies. This evaluation will be tailored to the types of literature included in the review. It will be conducted in a manner that respects the diverse forms of evidence that scoping reviews typically encompass.

Ultimately, any decisions regarding the quality assessment will be documented and justified in the final scoping review report to ensure transparency and adherence to the highest standards of research integrity.

Novelty of this study

This scoping review introduces a comprehensive approach to synthesizing the literature on HL in individuals with T1D. While HL has been extensively studied in T2D populations, its implications in T1D remain underexplored, despite T1D's unique management challenges and significant impact on quality of life [3]. For this reason, this review aims to bridge an essential gap, providing insights into how HL influences disease management, health outcomes, and healthcare utilization specifically for this population.

The review's innovative methodology also sets it apart. Utilizing the OCTIS framework and LDA analytics, along with Bayesian Optimization for tuning model parameters, brings advanced precision and interpretability to the topic modeling process [21]. Unlike traditional reviews that provide a descriptive synthesis, this review will identify and analyze key themes and patterns within the HL literature on T1D, leveraging topic modeling capabilities to generate coherent, data-driven insights into the state of the field. This approach will yield a nuanced understanding of HL dimensions in T1D and their relationships with sociodemographic and clinical outcomes, supporting the formulation of targeted interventions and educational strategies. For this reason, this scoping review stands out for its exploratory and analytical framework, extending beyond mere literature mapping to present an in-depth analysis of the relationship between HL and T1D management. This level of analysis provides a valuable foundation for researchers seeking to address unmet needs in T1D care, particularly regarding HL's role in patient outcomes and healthcare resource optimization. The insights derived will thus be instrumental in driving evidence-based, patient-centered strategies to improve health literacy and, ultimately, the quality of life for individuals with T1D.

Protocol validation

Anticipated results of this scoping review are expected to provide a comprehensive overview of the current state of research on HL among individuals with T1D. Through the rigorous synthesis and mapping of literature, the review is likely to highlight various measurement tools and dimensions of HL currently in use, revealing how these methodologies correlate with patient outcomes. The review should identify predominant themes and trends within the scope of HL, including detailed insights into the sociodemographic profiles of studied populations and the clinical contexts in which HL assessments are conducted. Notably, the utilization of the OCTIS framework to analyze the textual corpus is anticipated to uncover subtle, hidden patterns and emergent topics within the literature, potentially revealing gaps in current research and areas ripe for future inquiry [4,21]. This innovative analytical approach, therefore, not only enriches the narrative synthesis but also adds a layer of quantitative rigor, offering a comprehensive view of the landscape of health literacy research in T1D.

Limitations

This scoping review protocol acknowledges certain limitations. One key limitation is the exclusion of non-English language records that do not have an HTML version available. This specific restriction could potentially omit significant studies, limiting the scope of findings to primarily English-speaking contexts and affecting the generalizability across diverse cultural backgrounds. Furthermore, this review does not include a quantitative synthesis of results, which aligns with the methodology of scoping reviews but limits the ability to perform numerical data aggregation and trend analysis.

Credit author statement

Ilaria Milani: Conceptualization, Data curation, Investigation, Methodology, Project administration, Resources, Writing - original draft. **Elisa Cipponeri:** Data curation, Investigation, Methodology, Writing - review & editing. **Paola Ripa:** Data curation, Investigation, Methodology, Writing - review & editing. **Arianna Magon:** Data curation, Investigation, Methodology, Writing - review & editing. **Silvia Cilluffo:** Data curation, Investigation, Methodology, Writing - review & editing. **Stefano Terzoni:** Data curation, Investigation, Methodology, Writing - review & editing. **Maura Lusignani:** Data curation, Investigation, Methodology, Writing - review & editing. **Rosario Caruso:** Conceptualization, Formal analysis, Funding acquisition, Investigation, - Methodology, Supervision, Validation, Writing - review & editing.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

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