Identification and Description of Randomized Controlled Trials and Systematic Reviews on Patient Safety Published in Medical Journals.

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ABSTRACT

Objective

To identify and describe randomized controlled trials (RCTs) and systematic reviews (SRs) on patient safety published from 1973 onward.

Materials and Methods

We handsearched a total of 12 medical journals published in English with contents related to patient safety to identify RCTs and SRs published between 1973 and the end of 2010. The results obtained from this search were complemented with an additional search in MEDLINE. The documents were classified by area of specialty or service in which the intervention was applied, level of preventive action, and type of patient safety incident, the latter in accordance with the International Classification for Patient Safety proposed by the World Health Organization (WHO). The main features of the identified studies are also described.

Results

A total of 787 issues of 12 journals published between 1973 and 2010 were handsearched. This procedure yielded 10,162 references, of which, 131 corresponded to RCTs and 127 to SRs. A parallel MEDLINE search identified only about two-thirds of these articles. Of all the studies identified, 83 RCTs and 64 SRs addressed interventions related to patient safety. The types of incident related to patient safety that were included most often in RCTs involved the clinical process, and for SRs, those related to resources/organizational management. On average, only 3.5 RCTs and 3.4 SRs were published per year, many of which had significant deficiencies in the reported information, such as, for instance, a lack of details on the methodology used.

Conclusions

The number of RCTs and SRs on patient safety published in specialized journals is scarce. No studies on interventions to improve the safety of the handling of blood and derivatives, infections related to health care, nutrition, or infrastructure were identified as a result of our search. Handsearching plays a key role in the identification of all the clinical trials that could be included in SRs on patient safety interventions. Knowing the content of RCTs and SRs published on patient safety can better target future research.

Keywords

patient safety, randomized controlled trials, systematic reviews, meta-analysis

PATIENT SAFETY

Patient safety is the reduction of risk of unnecessary harm associated with health care to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available, and the context in which care was delivered weighed against the risk of nontreatment or other treatment. Health care-associated harm is a significant source of morbidity and mortality worldwide. (1,2) Studies suggest that between 4% and 17% of hospitalized patients experience an adverse event (AE). (3-13)

An AE is defined as an untoward incident, injury, or unnecessary harm that is caused by health-care delivery rather than by the underlying disease process and that can result in complications, prolonged hospitalization, disability on discharge, or death. (1,2,6,7) Moreover, it is estimated that approximately 50% of the AEs are preventable. (3) Given the world-wide necessity to improve health-care safety, the World Health Organization (WHO) announced in 2004 the launch of the World Alliance for Patient Safety, (14) which aims to make health-care safety a top priority in the health agendas of all countries.

Research in patient safety plays a key role in improving the quality of health care. However, despite the effort invested in this field during the last 20 years, the more effective interventions to prevent or minimize the damage associated with AEs, and the most appropriate strategy to implement them, remain relatively unknown. To address this issue, the World Alliance for Patient Safety created a working group to identify priorities for research in patient safety, which took into consideration the frequency of adverse events, the severity of damage generated on the patient, and their impact on the health system. Thanks to this work, 50 topics were identified for research, including adverse events related to medications, injuries caused by health products, health care-associated infections, and injuries from falls in hospitals. (2,15,16).

Evidence on the Effects of Interventions to Improve Patient Safety

Research on patient safety is a relatively recent practice. Scientific output in this field has increased dramatically in recent years and, as a result, evidence on practices to improve patient safety is increasing. (17) However, research on the efficacy of the interventions to decrease unnecessary risks associated with health care presents peculiarities. For instance, they are often "complex interventions" that target on groups of subjects in an equally complex environment, such as health organizations. (18,19)

In general, the best available research design to evaluate the efficacy of health interventions is the randomized controlled trial (RCT), which is the study design that provides the most robust evidence. (20-24) The term controlled clinical trial (CCT) was incorporated into the electronic bibliographic databases during the 1990s; thus, CCTs that had been published previously were classified in other categories, hindering their identification. Additionally, in many cases, the study authors do not clearly describe

the methodology used, which makes the classification of their studies more difficult. Despite efforts to improve documents indexation in databases, the sensitivity of electronic searches remains unsatisfactory. (23-28) Hence, if the purpose of an electronic search is to comprehensively identify all published RCTs, as is the case when conducting a systematic review (SR), handsearching is an indispensable complement to obtain the best available evidence. (27,29,30)

In recent years, there have been numerous studies aimed to identify all RCTs published on various health topics, (31-37) but none has identified clinical trials and systematic reviews on patient safety. Therefore, we conducted this study to identify and describe RCTs and SRs that have been published in the most relevant journals on patient safety.

MATERIALS AND METHODS

We selected the 12 journals published in English that, in our opinion, addressed more specifically topics related to patient safety and the health-care quality. These journals were reviewed through handsearch for the period between 1973 and 2010 (Table 1).

One author (L.B.-N.) handsearched the previously chosen journals to identify RCTs and SRs published in each volume. This process consisted of a careful review of every article in each issue, including letters to the editor, abstracts, and conference presentations. Studies that met the following criteria were eligible for inclusion: RCTs (with assignment of subjects to each arm of the study using a random method, where the unit of randomization could be individuals, groups, or body parts) or SRs (without restrictions by study designs) that compared 2 or more interventions, of which, at least one was on patient safety. A patient safety intervention was defined as any intervention designed to reduce the unnecessary risk of harm associated with health care to an acceptable minimum. (2,18,38) With this in mind, any intervention that sought to prevent or detect patient safety incidents or mitigate their consequences was considered as eligible. A patient safety incident was defined following the criteria of the conceptual framework for the International Classification for Patient Safety (v 1.1): "an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient. The use of the word 'unnecessary' in this definition recognizes that errors, violation, patient abuse and deliberately unsafe acts occur in healthcare.

These are considered incidents. Certain forms of harm, however, such as an incision for a laparotomy, are necessary. This is not considered an incident." According to this framework, a patient safety incident could be a reportable circumstance, near miss, no harm incident, or harmful incident (adverse event). (1) Interventions could be pharmacological, surgical, educational, organizational, or otherwise. When several reports that referred to the same RCT were found, only the original report was considered. In

Table 1. Handsearched Journals (1973-2010)

Journal	Review Period
Health Services Research	1973-2010
Journal of Safety Research	1982-2010
Quality and Safety in Health Care	1992-2010
Injury Control and Safety Promotion	1994-2005
The Joint Commission Journal on Quality Improvement	2000-2002
Joint Commission Journal on Quality and Safety	2003-2004
Joint Commission Journal on Quality and Patient Safety/Joint Commission Resources	2005-2010
Journal of Health Services Research & Policy	2001-2010
BMC Health Services Research	2001-2010
Quality Management in Health Care	2001-2007
International Journal of Injury Control and Safety Promotion	2005-2010
Journal of Patient Safety	2005-2010

addition, SRs with or without meta-analysis that evaluated the effects of an intervention on patient safety were eligible.

The search process consisted on an initial reading of the titles of the articles published in each issue. When this reading did not provide sufficient information regarding a particular article, keywords of its abstract were reviewed, such as randomization/randomized, quasi-random, controlled trial, blinding or masking, open clinical trial, prospective study, control group, placebo, systematic review, or meta-analysis. Afterward, the abstract was read in search of additional information, and if there were still doubts regarding the eligibility of an article, the full text was assessed.

Each journal was searched retrospectively, starting in December 2010 and going back until the beginning of its publication. If no RCTs or SRs were found in 5 consecutive years, handsearching was stopped. Two forms were used, one for recording the results of the handsearch and another for monitoring the reviewed journals. In addition, 2 data extraction forms were designed, one for entering the citation and the type of study (RCT, SR) for each article identified and another for registering the review process of the journals (years and volumes reviewed).

A trained researcher (I.S.) completed a parallel electronic search in the selected journals using MEDLINE (February 2011) through the PubMed search interface (www.pubmed.gov). The search terms "journal name" [Journal] AND (((((“Patient Safety”[Mesh])) AND “Safety Management”[Mesh]) OR “Quality Assurance, Health Care”[Mesh]) AND (“Medical Errors/adverse effects”[Mesh] OR “Medical Errors/prevention and control” [Mesh])) OR “Iatrogenic Disease/prevention and control”[Mesh] were used, limiting type of article to systematic reviews, review, meta-analysis, clinical trial, randomized controlled trial, studies in humans, indexed and with abstract.

Classification and Description of the Studies

Identified studies were entered into a database created in ProCite for Windows, Version 5.0, and were labeled taking into consideration the criteria proposed by the WHO (International Classification for Patient Safety [ICPS]) (1) according to type of incident on patient safety, level of preventive action, (39) specialty and/or service area where the intervention was implemented (Table 2). Level of prevention was defined as follows: (1) primary: measures to prevent the occurrence of a disease or health problem through the control of the causative agents and risk factors; (2) secondary: measures to stop or slow the progression of a disease or of health problems already present in an individual at any point during its course; and (3) tertiary: measures to prevent, delay, or reduce the occurrence of long-term effects from a disease or health problem. Once the studies had been identified and classified according to these criteria, the outcomes evaluated for each study were recorded (Table 2).

Data Collection and Analysis

We entered all the extracted information into an Excel spreadsheet and performed descriptive and comparative analysis for the different outcomes of interest using SPSS for Windows Version 15.0. We established 5-year intervals to study the evolution of the number of studies published. We built 2 x 2 contingency tables to determine the sensibility (percentage of studies identified through MEDLINE) and specificity (percentage of studies not identified through MEDLINE) of the MEDLINE search.

RESULTS

Identification of Publications

A total of 10,162 articles from 787 issues of the 12 selected journals were handsearched, which resulted in the identification of 131 RCTs (1.28%; 131/10,162) and 127 SRs (1.24%; 127/10,162). The parallel electronic search allowed the identification of only 89 of the 131 RCTs and 87 of the 127 SRs retrieved through the handsearch. Thus, the sensitivity of the search in MEDLINE (proportion of studies (RCTs or SRs) retrieved through the MEDLINE search over those identified by handsearching) was 67.9% for RCTs and 68.5% for SRs (Table 3).

Of all the studies identified, 83 RCTs (63.4%, 83/131) and 64 SRs (50.3%, 64/127) assessed the effects of interventions on patient safety. The remaining 48 RCTs (36.6%) and 63 SRs (49.7%) evaluated interventions on road safety, accessibility to health care, health-care management, or economic evaluations, among others. During the period from 1973 to 1992, no RCTs or SRs regarding interventions on patient safety were published in the journals reviewed. The period from 2003 to 2007 had the highest number

Table 2. Incident on Patient Safety and Data Extracted From Studies

Incident on Patient Safety
Clinical administration
Clinical process/procedure
Documentation
Health care-associated infection
Medication/IV fluids (application process, problem)
Blood/blood products
Nutrition
Oxygen/gas/vapor
Medical device/equipment
Behavior
Patient accidents/falls
Infrastructure/building/fixtures
Resources/organizational management
Data extracted from identified studies
Randomized controlled trials
- Year of publication
- Country where the study was conducted
- Scope: primary care, hospital care, other
- Level of prevention: primary, secondary, tertiary
- Type of incident on patient safety
- Specialty and/or service area in which the intervention was implemented
- Number of participants included
- Number of centers: single-center, multicenter h Arms of comparison
- Inclusion criteria
- Setting
- Assigned intervention
- Blinding
- Application of the intervention
- Outcomes assessed
- Methods to assess outcomes
- Sample size calculation
- Cointerventions
Systematic reviews
- Year of publication
- Country where the review was conducted
- Scope: primary care, hospital care, other
- Level of prevention: primary, secondary, tertiary h Type of incident on patient safety
- Specialty and/or service area in which the intervention was implemented
- No. studies included
- Literature search: yes, no, not specified
- Quality assessment of included studies: yes, no, not specified
- Meta-analysis: yes, no

of RCTs published (40 RCTs), the same being true for the period from 2008 to 2010 with respect to SRs (27 in total). The studies were conducted in different countries, the UK being the most productive (23 of the 83 RCTs [27.7%] and 31 of the 64 SRs [48.4%]), followed by the United States (18 of the 83 RCTs [21.7%] and 12 of the 64 SRs [18.7%]), and the Netherlands (13 of the 83 RCTs [15.6%] and 8 of the 64 SRs [12.5%]) (Fig. 1).

Characteristics of the Studies Identified Assessing the Effects of Patient Safety Interventions

Randomized Controlled Trials

Among the 83 RCTs identified, 58 (69.9%) were articles that reported trial results, whereas 25 (30.1%) were protocols. The settings where the studies took place were hospitals (44 RCTs, 53%), primary care centers (38 RCTs, 45.7%), and nursing homes (1 RCT, 1.2%). Most RCTs assessed secondary prevention interventions (59 RCTs, 71%). The types of incidents on patient safety addressed most often were those related to the clinical process/procedure (26 RCTs, 31.3%), documentation (20 RCTs, 24%), resources/organizational management (16 RCTs, 19.3%), medical device/equipment (8 RCTs, 9.6%), and medication/IV fluids (7 RCTs, 8.4%). No RCT assessed incidents on health care-associated infections, blood and derivatives, nutrition, behavior, or infrastructure. A large number of studies were implemented in the area of internal medicine (13 RCTs, 15.6%) and family medicine (12 RCTs, 14.4%). Although 44 RCTs (53%) were performed in one center, 39 RCTs (47%) were multicenter, of which, 17 (20.4%) were performed in more than 10 centers. The studies included a median of 200 participants (range, 29-33,000). Allocation to interventions at the group level (randomization performed by clusters) was reported in 28 RCTs (33.7%). The assigned intervention was described in detail in 80 RCTs (96.4%), whereas the application of the intervention was presented in the 83 studies identified (100%). Most studies (75 RCTs, 90.3%) included 2 arms of comparison. Blinding was used in 25 RCTs, of which, 10 (12%) were double blind, and 15 (18%) were single-blind. In 69 RCTs (83%), the outcomes assessed were specified, and in 79 (91.6%), the method to assess outcomes was provided. Table 4 provides a summary of the main aspects of the RCTs identified.

Systematic Reviews

Of the 64 SRs identified, 47 (73.4%) involved the hospital setting. Thirty (46.8%) assessed secondary prevention interventions, another 30 (46.8%) assessed primary prevention interventions, and only 4 (6.2%) assessed tertiary prevention interventions. The types of incidents on patient safety that were most often included were those related to resource/organizational management (21 SRs, 32.8%), clinical process/procedure (14 SRs, 21.8%), medication/IV fluids (11 SRs, 17.1%), clinical administration (6 SRs, 9.3%), and documentation (6 SRs, 9.3%). No SR assessed incidents on health care-associated

infections, blood and derivatives, nutrition, oxygen, or infrastructure. Most SRs focused on health services research (18 SRs, 28.1%), hospital administration (7 SRs, 10.9%), and public health and preventive medicine (7 SRs, 10.9%). Systematic reviews included a median of 18 studies (range, 3-156). Forty-six SRs (71.8%) reported a literature search, but only 28 (43.7%) described the search period and the databases where the literature search was conducted. Only 16 SRs (25%) reported methodological quality assessments of the included studies. Meta-analysis was performed in 11 SRs (17.1%). Table 4 provides a summary of the main aspects of the RCTs identified.

Table 3. Studies Identified by Handsearching and Electronic Searches in MEDLINE

	Electronic Search (MEDLINE)		
	Yes	**No**	**Total**
Randomized controlled trials			
Handsearch			
Yes	89	42	131
No	0	0	0
Total	89	42	131
Sensitivity: 67.9% (89 RCTs identified through MEDLINE/131 RCTs in total) RCTs not retrieved by MEDLINE search: 32%			
Systematic reviews			
Handsearch			
Yes	87	40	127
No	0	0	0
Total	87	40	127
Sensitivity: 68.5% (87 SRs identified through MEDLINE/127 SRs in total) SRs not retrieved by MEDLINE search: 31.4%			

DISCUSSION

The main objective of our study was to identify and describe RCTs and SRs on the efficacy of interventions in patient safety published in journals that focus on this topic. This allows us to contribute to assess of the current status of the production and publication of these study designs, so common in other areas of healthcare and, therefore, to facilitate the planning of future actions. One of the main strengths of this study is the wide-ranging review conducted, covering 37 years (787 volumes). The handsearch was systematic and exhaustive for all issues and supplements, including letters to the editor, abstracts, and conference presentations, which allowed the identification of all the RCTs and SRs of interventions on patient safety published in specialized journals. This work, however, did not intend to assess the quality of the identified studies, which should be the scope of a future study.

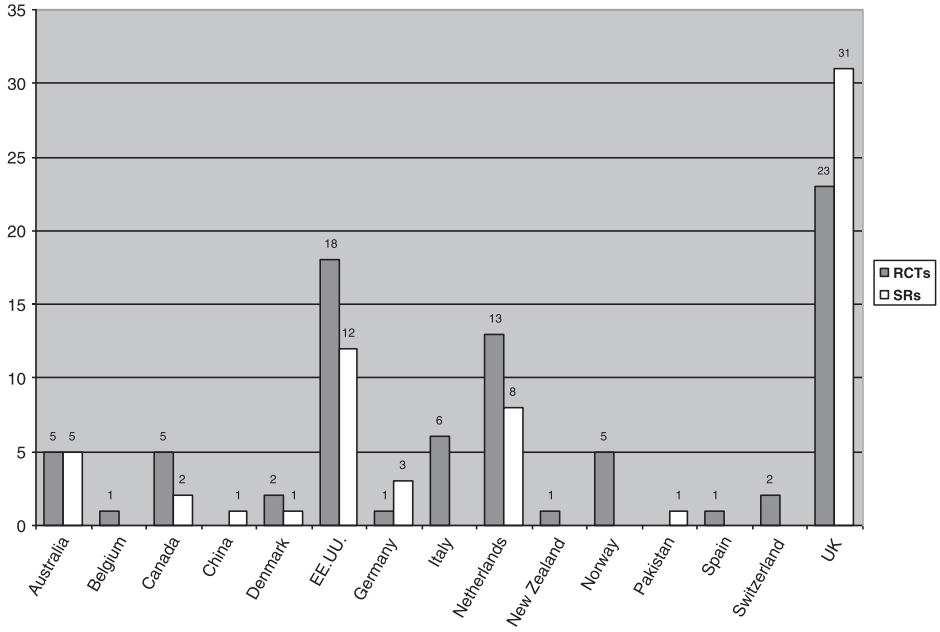

Figure 1. Number of publications on patient safety, per country.

Table 4. Descriptive Characteristics of the Studies Identified on Patient Safety

Randomized Controlled Trials (n=83)		
Setting:	**n**	**%**
- Primary care	38	45.7
- Hospital setting	44	53
- Others(nursing home)	1	1.2
Level of prevention:	**n**	**%**
- Primary	23	27.7
- Secondary	59	71
- Tertiary	1	1.2
Type of patient safety incident:	**n**	**%**
- Clinical administration	3	3.6
- Clinical process/procedure	26	31.3
- Documentation	20	24
- Health care-associated infection	0	0
- Medication/IV fluids	7	8.4
- Blood/blood products	0	0
- Nutrition	0	0
- Oxygen/gas/vapor	1	1.2
- Medical device/equipment	8	9.6

Table 4. Descriptive Characteristics of the Studies Identified on Patient Safety (continued)

- Behavior	0	0
- Patient accidents/falls	2	2.4
- Infrastructure/building/fixtures	0	0
- Resources/organizational management	16	19.3
Specialty and/or service area where the intervention was implemented:	**n**	**%**
- Hospital administration	3	3.6
- Cardiology	8	9.6
- Endocrinology and nutrition	6	7.2
- Gastroenterology	2	2.4
- Geriatrics	8	9.6
- Gynecology	1	1.2
- Research on health services	3	3.6
- Family and community medicine	12	14.4
- Internal medicine	13	15.6
- Preventive medicine and public health	2	2.4
- Pulmonology	6	7.2
- Oncology	5	6
- Orthopedics and traumatology	3	3.6
- Otolaryngology	2	2.4
- Pediatrics	2	2.4
- Psychiatry	6	7.2
- Emergency department	1	1.2
No. participants included in the studies	**Median**	**Range**
	200	29 to 33.000
Number of centers:	**n**	**%**
- One center	44	53
- Multicentric < 10 centers	22	26.5
- Multicentric > 10 centers	17	20.5
Comparison arms:	**n**	**%**
- 2 arms	75	90.3
- 3 arms	7	8.4
- 4 arms	1	1.2
Systematic reviews (n=64)		
Setting:	**n**	**%**
- Primary care	12	18.7
- Hospital setting	48	75
- Others (nursing home, community medicine)	4	6.2
Level of prevention:	**n**	**%**
- Primary	30	46
- Secondary	30	46

Table 4. Descriptive Characteristics of the Studies Identified on Patient Safety (continued)

- Tertiary	4	6
Type of patient safety incident:	**n**	**%**
- Clinical administration	6	9.3
- Clinical process/procedure	14	21.8
- Documentation	6	9.3
- Health care-associated infection	0	0
- Medication/IV fluids	11	17.1
- Blood/blood products	0	0
- Nutrition	0	0
- Oxygen/gas/vapor	0	0
- Medical device/equipment	2	3.1
- Behavior	3	4.6
- Patient accidents/falls	2	3.1
- Infrastructure/building/fixtures	0	0
- Resources/organizational management	21	32.8
Specialty and/or service area where the intervention was implemented:		
- Hospital administration	7	10.9
- Angiology and vascular surgery Cardiology	1	1.5
- General surgery	2	3.1
- Endocrinology and nutrition	2	3.1
- Geriatrics	3	4.6
- Gynecology	1	1.5
- Research on health services	18	28.1
- Family and community medicine	2	3.1
- Internal medicine	2	3.1
- Preventive medicine and public health	7	10.9
- Pulmonology	1	1.5
- Neurology	1	1.5
- Obstetrics	2	3.1
- Ophthalmology	1	1.5
- Oncology	4	6.2
- Orthopedics and traumatology	1	1.5
- Pediatrics	2	3.1
- Psychiatry	3	4.6
- Urology	1	1.5
No. studies included	**Median**	**Range**
	18	3 to 156
Literature search:	**n**	**%**
- Yes	46	71.8
- No	18	28.2

Table 4. Descriptive Characteristics of the Studies Identified on Patient Safety (continued)

Evaluation of the quality of the studies included:	**n**	**%**
- Yes	16	25
- No	48	75
Meta-analysis:	**n**	**%**
- Yes	11	17.1
- No	53	82.8
Main aspects assessed in each RTC:	No. Articles That Fulfill Requirement	
	Yes (%)	**No (%)**
- Inclusion criteria	78 (94)	5 (6)
- Setting	68 (82)	15 (18)
- Assigned intervention	80 (96.4)	3 (3.6)
- Double-blind	10 (12)	58 (70)
- Single-blind	15 (18)	0 (0)
- Application of the intervention	83 (100)	0 (0)
- Primary and secondary outcomes	69 (83)	14 (17)
- Methods to assess outcomes	76 (91.6)	7 (8.4)
- Sample size calculation	61 (73.5)	22 (26.5)
- Groups comparable at baseline	59 (71)	24 (29)
- Detailed demographic characteristics	60 (72.3)	23 (27.7)
- Lack of cointervention	46 (55.4)	37 (44.6)

Despite the observed increase in the number of publications on patient safety, (17) the number of RCTs and SRs that end up being published in journals that focus on this topic is still scarce. In the 37-year period analyzed (1973-2010) (38 years in total), we identified only 131 RCTs and 127 SRs, which amounts to about 3.5 RCTs and 3.4 SRs per year.

It was confirmed that there is a significant number of RCTs and SRs identified only by handsearching and that were not detected by searching through MEDLINE (42 RCTs, 32%, and 40 SRs, 31.4%). This proves, again, the limitations of documental searches carried out exclusively by electronic means, (25-30,34,40) given that it entails the loss of at least one- third of the RCTs and SRs published on patient safety journals. Despite the fact that many journals have been indexed in databases and that, consequently, many RCTs and SRs can be identified through electronic searches, there are still serious problems related to the incorrect indexation of bibliographic databases, even for RCTs and SRs. This limitation must be taken into consideration when conducting electronic searches.

Handsearching plays an important role in the identification of RCTs reports that may be included in SRs on interventions in health care, especially in the identification of RCTs reported as abstracts and letters to the editor, and that are published in languages other than English. The Cochrane Central Register of Controlled Trials (CENTRAL) remains in good standing, thanks to the handsearch of medical literature, given that the Cochrane Review Groups (CRGs) in each country are responsible for coordinating the search of specialized medical literature in their areas of interest. Until now, more than 3000 journals have been or are currently being reviewed through handsearching. Theoretically, handsearching allows the identification of all the literature available. Therefore, combining it with an electronic search is the most comprehensive approach to identify RCTs reports, (25-29,40) which is the best strategy to reduce publication bias. (40)

Although many of the studies identified did not describe in detail the methodology that was used or that some reports were incomplete, we were able to determine their main features. Most RCTs and SRs are centered on the hospital setting. Approximately 71% of RCTs and 47% of SRs assessed secondary prevention interventions, which shows that emphasis has not been placed on preventing patient safety incidents (which are primary prevention interventions, i.e., education on potential risks of accidents in hospitals or control of risk factors for infectious diseases) but rather on hindering or delaying the progression of an incident to causing harm. The types of incidents on patient safety that were more often studied in RCTs and SRs were those related to the clinical process/procedure, documentation, and resources/organizational management. The studies (RCTs, SRs) that evaluated incidents on medication, medical devices, clinical administration, and patient accidents were scarce. No RCTs or SRs evaluated incidents on health care-associated infections, blood and derivatives, nutrition, or infrastructure. The studies were related to different medical specialties or service areas, especially with internal medicine, family and community medicine, and research on health services.

We detected a low or null number of RCTs and SRs published on the effect of interventions to improve medication safety, the handling of blood and derivatives, nosocomial infections, and accidents in patients. This contradicts the recommendations of the WHO on the need to prioritize and encourage research on these topics, which are crucial to patient safety. (2) The above evidence may reflect an insufficient development of investigation in this area or that an undetermined number of RCTs and SRs on patient safety interventions were published in journals of other medical specialties or of general medicine. They could also have been available in journals not published in English. We consider this possibility should be explored in future studies that cover the entire medical literature using handsearching. On the other hand, it should also be noted that studies that evaluate the effects of interventions on patient safety often have methodological peculiarities and that, generally, these interventions are complex. (19,41) Such is the case of the identified studies. Most RCTs were not blinded (58%) or

were single blind (18%), which is due to the fact that many of the interventions assessed did not allowed blinding. Despite the fact that there are other designs that are valid for the evaluation of interventions in patient safety, the RCT remains the study of choice because of the thoroughness with which it must be conducted and the low risk of bias associated to its results. (2,16-19) It was also observed that there is a significant need to increase the production of SRs on the efficacy of interventions on patient safety, given that SRs provide an exhaustive overview of the best available evidence. However, the complexity of patient safety interventions and of the designs used to assess their effects makes it difficult to complete these SRs. The traditional guidelines to perform SRs, such as the Cochrane Handbook, (42) usually focus on the assessment of the effects of pharmacological interventions. (41) These and other factors call for the adaptation of the traditional methods used in clinical research to generate evidence on patient safety. (2,18,19,38)

One of the limitations of this study is that eligibility of the included studies was not evaluated by peer independent reviewers, which could diminish the reliability of the results and increase the risk of subjective bias. Another limitation is that it is restricted to journals published in English, which prevents us from evaluating the efficacy of the searches in non-English journals and the identification of studies published in them. Moreover, we did not evaluate the quality of the studies identified, which we expected to do in the future.

For future research, it would be interesting to identify RCTs and SRs published in non-English journals. Similar works that explore the publication of studies on the efficacy of interventions in patient safety in journals of other medical specialties and in journals of general medicine should also be carried out. In addition, it would be important to take into consideration study designs different from RCTs, which would give us a broader perspective of the current status of research on patient safety.

CONCLUSIONS

The number of RCTs and SRs on interventions to improve patient safety published in journals related to this topic remains limited. Handsearching is indispensable for the identification of all RCTs and SRs available. Having this information promotes a reduction of publication bias, which is essential for conducting systematic reviews, while facilitating the planning process of future research. Further investigation is required to identify all published studies on patient safety interventions, including more journals published in major languages, whether they focus on this or other medical fields.

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