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# Gender-gap in randomized clinical trials reporting mortality in the perioperative setting and critical care: 20 years behind the scenes

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#### ABSTRACT

*Background*: Women researchers might experience obstacles in academic environments and might be underrepresented in the authorship of articles published in peer-reviewed journals.

*Material and Methods*: This is a cross-sectional analysis of female-led RCTs describing all interventions reducing mortality in critically ill and perioperative patients from 1981 to December 31, 2020. We searched PubMed/ MEDLINE and EMBASE with the keywords RCTs and mortality. The gender of the first author was extracted and descriptive analysis was performed including the year of publication, impact factor, country of the first author, and methodological aspects.

*Results:* We analyzed 340 RCTs, of which 42 (12%) were led by female researchers. The presence of women increased from 8% (14/172) until 2010 up to 17% (28/168) in 2010 and beyond. The United States, the United Kingdom, and Brazil were the main countries of origin of female researchers. Women authors conducted mainly single-center and single-nation studies as compared to male authors. The median impact factor of the target journal was 6 (3-27) in women vs. 7 (3-28) in men, with a p-value of 0.67; *Critical Care Medicine, JAMA*, and *The New England Journal of Medicine* were the most frequent target journals for both women and men.

*Conclusion:* In the last 40 years, only one out of eight RCTs had a woman as the first author but the presence of women increased up to 17% by 2010 and beyond. The impact factor of publication target journals was high and not different between genders.

#### 1. Introduction

While the presence of females in the health field amounts to almost 75% [1], female physicians are poorly represented in scientific articles compared to their male peers. A reduced presence of women in the top positions as first or senior authors of scientific articles in high-impact journals has been reported [2]. There is also a documented reduced presence of women on the editorial boards of journals [3], in senior

university positions [4], and in leadership positions in medical societies [5]. Furthermore, articles with women in leading positions have lower diffusion [6] and a lower number of citations [7].

These discrepancies were documented in several settings including anesthesia and critical medicine [8,9], internal medicine [10], orthopedics [11], ophthalmology [12], plastic surgery [13], among others. Several causes have been suggested, such as the later incorporation of women into the labor market, family aspects, the work environment, or

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#### tradition.

Randomized clinical trials (RCTs), when they are well designed and conducted, are the highest level of scientific evidence to investigate the efficacy and safety of a given intervention. In addition, the methodology of RCTs is one of the most sophisticated and rigorous. For this reason, these studies are highly recognized by the academic body, are highly respected, and have the potential to transform clinical practice.

The number of major surgeries undertaken worldwide each year is 234 million [14]. Critically ill patients are usually admitted to intensive care units (ICUs) and have high mortality. Therefore, it is essential to conduct and analyze RCTs that lead to a decrease in mortality in perioperative and critically ill patients.

The aim of this study is to describe the contribution of women who have performed RCTs in the field of critically ill and perioperative patients with a statistically significant influence on mortality outcome over the last 40 years.

# 2. Methods

#### 2.1. Data

This cross-sectional study focused on RCTs published in peerreviewed journals and led by female researchers. We considered only Contemporary Clinical Trials Communications 33 (2023) 101117

RCTs with a statistically significant difference in mortality in critically ill and perioperative patients.

We identified all RCTs concerning every kind of nonsurgical intervention influencing mortality in critically ill and perioperative patients, without publication time limits. The search string included critically ill and perioperative trials which tested any non-surgical intervention (technique/drug/strategy) and showed a statistically significant effect on mortality. A filter for RCT was included and only studies published in peer-reviewed journals were included.

We defined patients as critically ill when presenting an acute failure of at least one organ and/or the need for intensive care and/or emergency treatment. The perioperative period was described from patient hospital admission before surgery to patient discharge after the operation. We contemplated the difference in mortality as being statistically significant when present at a specific time point (benchmark mortality) with simple statistical tests and without adjustment for baseline characteristics.

The exclusion criteria were non-randomized clinical trials and other types of studies such as systematic reviews, meta-analyses, and literature or narrative reviews. Also, RCTs without a statistically significant result were excluded.

Fig. 1 shows the flowchart of the article selection and appendix 1 shows the literature search used to identify studies in PubMed/

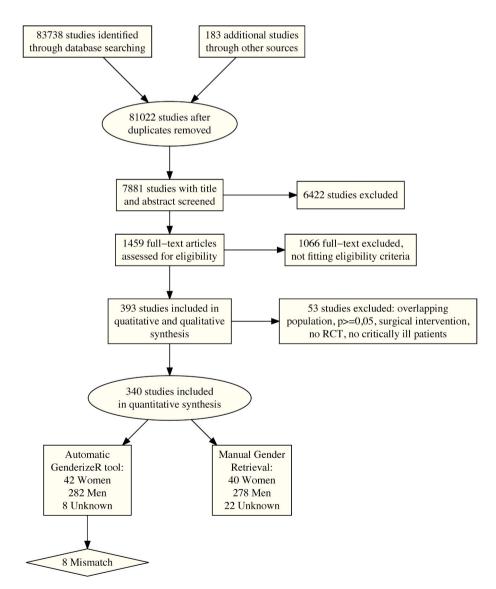


Fig. 1. Literature search strategy and gender assessment of the first author.

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### MEDLINE and in EMBASE.

The following general information was extracted: first author's name and surname, country, publication date, journal, impact factor of the journal, language, main area of research, funding, number of centers and nations involved, and gender of the first author. Gender was retrieved both manually using publicly available data and automatically with a prediction tool used before in previous works examining gender disparities in the authorship of articles [15].

The following RCT characteristics were extracted as well: trial design, length of follow-up, ad-interim analysis, and mortality.

## 3. Outcome: mortality, other relevant outcomes

The study was conducted in line with Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) [16].

# 3.1. Statistical analysis

Descriptive statistics were used to analyze the study variables, and variables were expressed as medians and interquartile range (IQR) in continuous variables or counts and percentages in categorical data. Data were analyzed using the statistical software R [17] and the *ggplot2* and *genderizeR* [18] packages. The *genderizerR package* uses name databases from different countries to predict the gender of the first name with a given probability.

# 4. Results

We identified 340 published RCTs (Fig. 1) reporting a statistically significant reduction of mortality in critically ill patients (Appendix 1); 40 (12%) of them had a female researcher as the first author. Overall,

the number of women who published an article in a peer-reviewed journal increased over time, from an almost non-existent presence before 2000 (Fig. 2) to a continuous upward presence after 2010. Table 1 shows the characteristics of RCTs conducted by female and male investigators. The presence of women increased from 8% (14/172) until 2010 and reached over 17% (28/168) after 2010. The number of patients treated in studies led by females (median 165, IQR 82-692) and males (median 175, IQR 81-420) were similar. However male investigators more frequently designed multicenter and multinational studies compared to female investigators. Regarding methodological characteristics, female and male researchers designed studies mainly with the intention-to-treat type (female 23, 60% and male 171, 58%). Similarly, for both genders, mortality was the primary outcome (female 19, 48% and male 143, 49%). We did not find any relevant difference in terms of settings and the rate of industry-supported studies (n = 10, 25%in women and n = 71, 26% in men). The journals which more frequently published these RCTs were Critical Care Medicine (CCMED), Journal of the American Medical Association (JAMA), and The New England Journal of Medicine (NEJM) for both genders with a median impact factor (IF) of 6 (3-27) for women and 7 (3-28) for men with a p value of 0.67. Adinterim analyses that led to premature interruption of the RCTs were observed twice as frequently in women (n = 10, 25%) as in men (n = 34, 10%)12%) and the number of studies documenting increased mortality was reduced in women (n = 4, 10%) as compared to men (n = 41, 15%). Fig. 3 shows the point cloud graphical distribution of the studies published according to the years and the impact factor of the journal ranked by gender. As for the countries of the first authors, the United States leads the ranking (Fig. 4) in the number of RCTs in both genders, followed in second place by the United Kingdom for women and by France for men.

Of the 340 RCTs analyzed, the gender was identified manually in 318

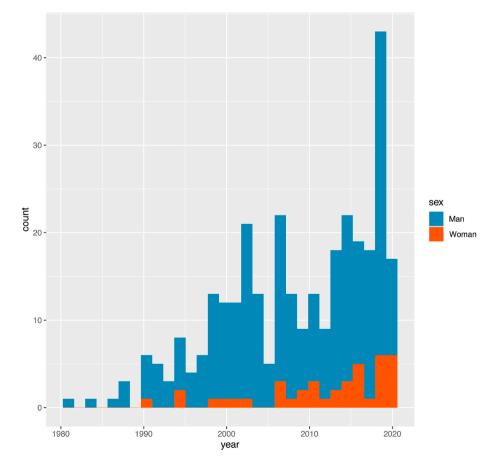


Fig. 2. Histogram showing the proportion of women and men as first authors in RCTs reporting mortaility in critical care and in the perioperative setting.

#### Table 1

Descriptive analysis of Randomized clinical trials in critically ill and perioper-
ative patients led by a female or male researcher as first author.

First author	Female n (%)	Male n (%)
Studies	42 (12)	278 (82)
Main Journals	CCMED 6 (15)	NEJM 48 (17)
	JAMA 4 (10)	JAMA 25 (9)
	NEJM 4 (10)	CCMED 22 (8)
	The Lancet 3 (8)	The Lancet 20 (7)
	Shock 2 (5)	Intensive care med 11
		(4)
		Am J Respir Crit Care
		Med 11 (4)
First nation	United States 12 (30)	United States 66 (24)
	United Kingdom 5 (13)	France 23 (8)
	Brazil 4 (10)	United Kingdom 19 (7)
	Iran 3 (8)	Italy 18 (7)
	Belgium, China, Greece, Italy,	Spain 18 (7)
	Netherlands 2 (5)	
Study characteristics		
Multicentric	17 (43)	161 (58)
Multinational	5 (12)	62 (22)
Intention to treat	23 (60)	171 (62)
ICU Setting	19 (50)	184 (65)
Industry sponsored	10 (25)	71 (26)
Mortality primary	19 (48)	143 (49)
outcome		
Interrupted by interim	10 (25)	34 (12)
analysis Harm	4 (10)	<i>4</i> 1 (1E)
	4 (10) 5 (12)	41 (15)
Quality of life assessment	5 (12)	17 (6)
Cardiac surgery	6 (17)	27 (10)
Trauma	13 (30)	19 (7)
Sepsis	12 (27)	60 (27)
Neurology	10 (22)	43 (15)
Median (IQR)	10 (22)	45 (15)
Year	2014 (2008–2018)	2009 (2002–2016)
Impact Factor	6 (3–27)	7 (3–28)
Number of centers	23 (58)	117 (42)
1	3 (7)	19 (7)
2	1 (3)	10 (4)
3	1 (3)	8 (3)
4	1 (3)	9 (3)
5	1 (0)	
Total treated patients	165 (82–692)	175 (81–420)
Longest follow up	28-days 8 (21)	28-days 38 (14)
ocor 1011011 up	ROSC 6 (16)	48-h 29 (11)
	24-h 5 (13)	Hospital stay 25 (9)
	90-days 4 (11)	30-days 21 (8)
	1 year (8)	ICU discharge 20 (7)
	J (=)	

Abbreviations: *Critical Care Medicine (CCMED)*; the *New England Journal of Medicine (NEJM)*; Intensive care unit (ICU); return of spontaneous ventilation (ROSC).

(94%) and then automatically in 332 (98%). In 16 (4.7%), the gender of the first author could not be identified manually because the data were not found on the institutional or research Web sites. A total of 6 (1.8%) had only the first initial of the name of the first author, so the gender could not be determined with any method. The degree of concordance obtained between the gender obtained in the manual comparison with the gender assigned by the prediction tool was 98%. Therefore, the mismatch accounted for 8 articles, in 6 of which the gender prediction was in the range of 0.56–0.9.

#### 5. Discussion

In this cross-sectional study, we presented a descriptive analysis of 340 RCTs carried out by female and male researchers as the first author in critically ill and perioperative patients. We confirmed that the presence of women as first authors of scientific articles published in peer-reviewed scientific journals is still very low compared to men, only 12% from our current review.

Female first authorship was also studied by Filardo et al., who found an increasing number of publications in high-impact journals during the last 20 years [19] as confirmed by our findings and by other authors [20, 21]. Among the leader countries in terms of publication of RCTs led by women, we identified Anglo-Saxon countries (the United States and the United Kingdom). However, Brazil in South America and Iran in Asia are in the spotlight, with 4 and 3 RCTs, respectively. The other nations with at least one published RCT are mainly in Western countries. No RCT published by a female researcher from the African continent was recovered. It can be speculated that, in addition to the lower presence of women scientists at the leadership of RCTs, there might also be an ethnic cleavage in the publication of research articles that contributes to the promotion and improvement of personal and professional development [22]. Other circumstance that can enhance this disparity is related to other indicators, such as the Gross domestic product (GDP) and the percentage of the GDP allocated to research and development (R&G) called GERD [23].

Women are also less represented in higher academic positions [24], on editorial boards [25], and in medical societies [26]. Furthermore, some studies have pointed out a difference in the language used by male and female researchers, stating that male researchers tend to be more optimistic in the title expressing the results of the study [27].

According to Fridner et al., there is no relationship between pregnancy breaks and the number of papers published between women and men [28], though it has also been argued that one of the causes preventing women researchers from reaching higher levels of professional development is pregnancy and maternity leave [29], as well as the upbringing of their children [30]. Thus, male career-orientated researchers showed less stress and anxiety regarding parental duties. Men with children spent, per week, a median of 56 h on activities such as teaching, patient care, and research, while women reported 49 h for the same duties [31].

Paradoxically, after the higher level of constraint for female researchers in terms of reaching the same level as their male colleagues, institutional support is lower [32].

In addition to this, other studies argue that the lack of mentorship, sponsorship, protected time, and experience might play a role in running for leadership positions [5].

Gender-heterogenous teams produce higher quality science [33]. Diversifying the academic workforce represents one of the fundamental stages in supporting the formal career development of female researchers through leadership training initiatives.

There are several measures proposed to level gender-related leadership gaps, such as women networking forums, leadership skill programs, and even on-site child-care facilities to promote conference attendance [34].

Gender was identified manually in 318 (94%) and automatically in 332 (98%) and the degree of concordance between them was high. In this increasingly globalized world, the adoption of automated tools might help in the context of gender-gap-related challenges by encouraging and promoting studies that endorse equal access and equal opportunities for women and men. In this study, where we have manually collected the genders of the researchers, the use of the predictive tool has proven to be time-saving and accurate. The discordance between the manual process of retrieving gender and the predictive tool went down to eight articles (2%) but those articles showed an interval in the prediction's probability of 0.56-0.9, which is lower than the recommended threshold. Most of the mismatches asserted with the genderizer. io API were related to names of Asian origin. Therefore, in the future, this tool could be of use in characterizing barriers in science in relation to the gender gap as well as ethnic identity for purposes of fostering fairness and balance [2,15,27,35].

Organizations must move toward dynamic measures to immediately establish effective interventions that reduce gender disparities inn research, such as increasing local funding collaboration to support practices in implementing new ways of working, providing free training

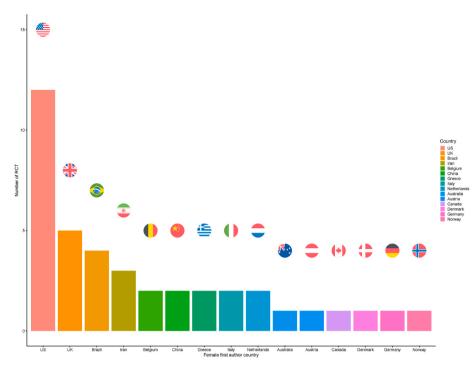
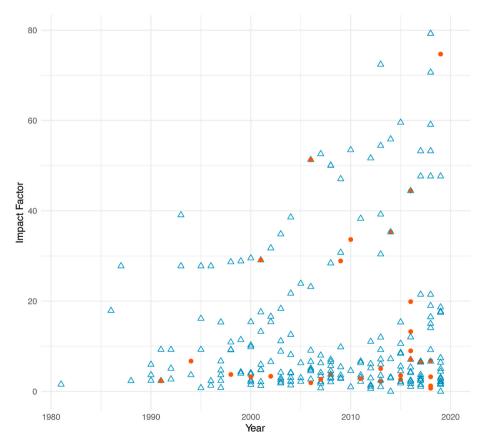


Fig. 3. Histogram with the number of women as first authors in RCTs reporting mortality in critical care and in the perioperative setting.



Sex AMan • Woman

Fig. 4. Dotplot showing the number of women and men as first authors in RCTs reporting mortaility in critical care and in the perioperative setting according to the impact factor of the journal.

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for clinicians and managers to promote practice redesign, and offering programs to help with routine updates to everyday practice. Raising awareness of gender bias, can improve equity in science [36] and might encourage the implementation of a broad range of programs that facilitate the academic environment to evolve toward gender equity. Nonetheless, we urge for an international effort to study and characterize the trends in gender distribution in Anesthesia and Critical Care during the last decades.

To the best of our knowledge, this is the first time that a comprehensive analysis of differences in RCT-related topics based on the gender of the researcher has been described. However, we would like to address some limitations in this cross-sectional analysis. First, during the bibliographic search process, the literature search strategy might not have captured some articles. Second, the gender of the first authors could not be recorded in 1% of manuscripts. Third, these results cannot be extrapolated to other medical domains and refer only to RCTs that statistically affected mortality in critically ill and perioperative patients. Forth, this study does not allow to draw definitive conclusions about the reasons for the observed gender-gap, and these differences might be always due to gender discrimination. Last but not least, this database only covers RCTs with statistical significance result in mortality but do not reflect what happens in observational studies or other type of research. Nevertheless, these limitations are unlikely to have an impact on the core findings of this work due to the disproportionate lack of female first authors of RCTs published in peer-reviewed journals.

# 6. Conclusion

RCTs involving female first authors in Anesthesia and Critical Care currently represent a small minority. Over 40 years, one in eight RCTs published on critical and perioperative patients have been developed by women, mainly from the United States, the United Kingdom, and Brazil. The presence of women as first authors has been increasing in the last decades and there are no differences based on the gender of the first author in terms of the impact factor; *CCMED, JAMA*, and *NEJM* were the journals where these studies were most frequently published, for both women and men.

# Declaration of transparency

CR and GL affirm that this manuscript is an honest, accurate, and transparent account of the study being reported, that not important aspects of the study have been omitted, and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

This work has been partially presented in a Critical Care conference in Bologna (Italy) called #AreaCritica in November 1–2, 2022. This work won the poster award and was presented during the Rising Star session by Alessandra Bonaccorso.

#### Funding

None.

#### Availability of data and materials

The data and R code created to carry out this study is available upon request from the authors.

#### Ethics approval and consent to participate

This study outlines a mapping review of secondary data and, hence, does not require ethical approval or consent to participate.

#### **Consent for publication**

Not applicable.

#### Author contributions

Concept and design: Romero, Maimeri, Bonaccorso, Baiardo-Redaelli, Lombardi, Iwuchukwu, Ortalda, Schmid, Fleming, Landoni. Acquisition, analysis, or interpretation of data: Romero, Maimeri, Baiardo-Redaelli, Lombardi, Iwuchukwu, Ortalda, Schmid, Fleming, Landoni. Drafting of the manuscript: Romero, Maimeri, Baiardo-Redaelli, Bonaccorso, Lombardi, Iwuchukwu, Ortalda, Schmid, Fleming, Landoni. Critical revision of the manuscript for important intellectual content: Romero, Maimeri, Baiardo-Redaelli, Lombardi, Bonaccorso, Iwuchukwu, Ortalda, Schmid, Fleming, Landoni. Statistical analysis: Romero, Maimeri, Baiardo-Redaelli, Lombardi, Iwuchukwu, Ortalda, Schmid, Fleming, Bonaccorso, Landoni. Administrative, technical, or material support: Romero and MaimeriSupervision: Romero, Maimeri, Baiardo-Redaelli, Lombardi, Iwuchukwu, Ortalda, Schmid, Fleming, Landoni.

## 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.

# Appendix 1

Literature Search Strategy - Gender-Gap in Randomized Clinical Trials Reporting Mortality in the Perioperative Setting and Critical Care: 20 years behind the scenes.

The search was divided into three sections. In section A, we used the MeSH terms and keywords to identify critically ill patients. In section B, we applied keywords to search for articles reporting mortality. In section C, we searched for RCT. The results of these three sections were combined using the Boolean operator "AND" to retrieve the relevant articles. The first search was performed in January 1, 2020 and a second search was updated to December 31, 2020. The target population included human adults (>18 years old) admitted to the intensive care unit (ICU) or an equivalent unit without a restriction for the diagnosis or exposure at admission, and perioperative patients who underwent emergence or elective surgery. The literature search in PUBMED/MEDLINE is included below:

((((dead[tiab] or death[tiab] or die[tiab] or died[tiab] or mortality [tiab] or fatalit\*[tiab] or exitus[tiab] or surviv\*[tiab]) AND("anesthesia"[tiab] OR "cardiac arrest"[tiab] or "critical care"[tiab] or sepsis [tiab] or "critical illness"[tiab] or "critically ill" [tiab] or "ARDS"[TIAB] or "acute respiratory distress syndrome"[tiab] OR "ecmo"[tiab] OR "intensive care"[tiab] or emergen\*[tiab]) AND ("randomized controlled trial"[tiab] OR "controlled clinical trial"[tiab] OR "randomized controlled trials"[tiab] OR blind\*[tiab] OR "clinical trial"[tiab] OR "clinical trials" [tiab] OR placebo\* [tiab] OR random\* [tiab]) NOT (animal[mh] NOT human[mh]) NOT (comment[pt] OR editorial[pt] OR meta-analysis[pt] OR practice-guideline[pt] OR review[pt] OR pediatrics[mh]))) OR ((dead[tiab] or death[tiab] or die[tiab] or died[tiab] or mortality[tiab] or fatalit\*[tiab] or exitus[tiab] or surviv\*[tiab]) AND ("anesthesia" [tiab] OR "cardiac arrest" [tiab] or "critical care" [tiab] or sepsis[tiab] or "critical illness"[tiab] or "critically ill" [tiab] or "ARD-S"[TIAB] or "acute respiratory distress syndrome"[tiab] OR "ecmo"[tiab] OR "intensive care"[tiab] or emergen[tiab]) AND ((randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized controlled trials[mh] OR random allocation[mh] OR double-blind method[mh] OR single-blind method[mh] OR clinical trial[pt] OR clinical trials[mh] OR (clinical trial[tw] OR ((singl\*[tw] OR doubl\*[tw] OR trebl\*[tw] OR tripl\*[tw]) AND (mask\*[tw] OR blind[tw])) OR (latin square[tw]) OR placebos[mh] OR placebo\*[tw] OR random\*[tw] OR research design[mh:noexp] OR comparative study[tw] OR follow-up studies[mh] OR prospective studies[mh] OR cross-over studies[mh] OR control\*[tw] OR prospectiv\*[tw] OR volunteer\*[tw]) NOT (animal

[mh] NOT human[mh])))) OR ((surgery[tiab] OR surgic\*[tiab] OR operation\*[tiab]) AND ((death\* OR survival OR mortality)) AND (prevent\* OR reducti\* OR reduci\*) AND (significat\* OR significan\*) AND (randomised controlled trial[pt] OR controlled clinical trial[pt] OR randomised controlled trials[mh] OR random allocation[mh] OR double-blind method[mh] OR single-blind method[mh] OR clinical trial [pt] OR clinical trials[mh] OR (clinical trial[tw] OR ((singl\*[tw] OR doubl\*[tw] OR trebl\*[tw] OR tripl\*[tw]) AND (mask\*[tw] OR blind [tw])) OR (latin square[tw]) OR placebos[mh] OR placebo\*[tw] OR random\*[tw] OR research design[mh:noexp] OR comparative study[tw] OR follow-up studies[mh] OR prospective studies[mh] OR cross-over studies[mh] OR control\*[tw] OR prospectiv\*[tw] OR volunteer\*[tw]) NOT (animal[mh] NOT human[mh]) NOT (comment[pt] OR editorial [pt] OR meta-analysis[pt] OR practice-guideline[pt] OR review[pt])))

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